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Prospective risk assessments of patient safety events related to drug shortages in hospitals: Three actor-level perspectives

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ABSTRACT

Background: The increasing number of drug shortages (DSs) worldwide calls for more proactive solutions to prevent the negative impacts of DSs on patient care. Such solutions require in-depth knowledge about potential patient safety risks related to DSs, the processes of recognizing and managing DSs, the contextual setting in which DSs occur, and the actors involved.
Objective: The aim of the study is to use prospective risk assessment to identify patient safety risks in hospitals associated with the management of DSs among actors at national, regional and local level in Denmark.
Methods: Healthcare Failure Mode and Effect Analysis (HFMEA) was employed in composition with elements from the Systematic Human Error Reduction and Prediction Approach (SHERPA) and the Systems-Theoretic Accident Model and Processes (STAMP). Potential risks related to DS management across three actor levels (national, regional and local) in the Danish healthcare system were described. Each actor level consisted of six participants that were identified using a purposive sampling strategy. Processes and sub-processes related to managing critical DSs were outlined and the actors identified, prioritized and rated potential failure modes, causes and consequences related to the processes. Recommendations to mitigate failures were proposed for high risk failures modes.
Results: Overall, a total of 167 failure modes were identified across the three actor levels. At the national level, the process of DS management consisted of 17 sub-processes, from which 71 failure modes were identified. Nine of them were rated as high risk. At regional level, 7 sub-processes and 33 failure modes were identified, of which 9 were rated as high risk. At local level, 14 sub-processes and 63 failure modes were identified, of which 32 were rated as high risk. The high-risk failures were related to a lack of IT support in the medication modules, underestimation of patient safety aspects, and insufficient personnel training and patient information.
Conclusion: Exploring DS management failure modes across actor levels provided an overview of interrelated failures. Potential solutions related to high risk failures were developed to ensure that actors ensure patient safety related to DS in healthcare.

1. Introduction

Over the past two decades, the number of drug shortages (DSs) has increased worldwide and has become a well-known healthcare problem.[1–3] Numerous papers have discussed various aspects of DSs, such as the underlying causes, consequences, management and mitigating strategies.[2–6] Among the most frequently mentioned reasons for the increase in DSs are changing market conditions (e.g. increased sales, cessation of marketing, parallel imports, price-related aspects), supply chain management (e.g. missing raw material and excipients), manufacturing process (e.g. quality concerns), and regulatory issues (e.g. non-compliance with quality regulations, recalls owing to errors on the leaflet/package).[2,3,7,8] Some DSs can be solved relatively easily owing to the availability of generic medicines that can replace the missing drug, but severe consequences are also

Abbreviations: DS, drug shortage; EAHP, European Association of Hospital Pharmacists; HFMEA, Healthcare Failure Mode and Effect Analysis; RAP-MLV, the procurement department of the Hospital Pharmacy in the Capital Region of Denmark; SHERPA, Systematic Human Error Reduction and Prediction Approach; SPW, Single Point Weakness; STAMP, Systems-Theoretic Accident Model and Processes.

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described in the literature, such as delayed, omitted, and/or suboptimal treatment.[1,4,5,9]

DSs often present themselves as emergency situations posing a variety of challenges such as the duration of the shortage, the availability of alternatives and the frequency of shortages.[1,5,9] Healthcare practices, hospitals and professional organizations should integrate contingency plans into their practice to ensure that DS management procedures are implemented immediately and consistently.[5,6,9,10] Such plans could, for example, comprise monitoring for potential shortages, allocation procedures, and an assessment of the overall impact of shortages and plans on patient care if drugs need to be replaced.[6,11] However, a US survey of different health system institutions showed that approximately 35% of those surveyed had no process for managing DSs.[9] Additionally, a European survey from 2019 showed that 61% of hospitals pharmacists described a lack of protocol or contingency plans for managing DSs, suggesting that the adoption of in-hospital DSs contingency plans has not yet been achieved.[5]

The increasing number of DSs has led to calls for more proactive solutions to prevent the negative impacts of DSs on patient care.[2,9] Such solutions require in-depth knowledge about potential patient safety risks related to DSs, the processes of recognizing and managing DSs, the contextual setting in which DSs occur, and the actors involved. This knowledge can be obtained through the use of risk assessments.[9,12,13] Risk assessment is a term used to describe the overall process of identifying, analyzing and evaluating risks or events related to DSs that have the potential to cause harm.[13,14] This typically involves an estimation of the likelihood of certain – unwanted – outcomes and their effects for the respective parts of the system, for example the patient.[14] Risk assessment can be accomplished both retrospectively and prospectively. In a retrospective analysis, known events or outcomes, e.g. patient harm, are reconstructed for analysis to back-trace the chain of events to the time at which something went wrong or someone made an error.[15] Prospective approaches focus on process evaluation – the identification of risks before they occur and their potential causes – in order to understand the potential actions underlying all shortage-related risks.[12,13,15–17] An example of a widely used prospective risk assessment is the Healthcare Failure Mode and Effect Analysis (HFMEA), a proactive, multidisciplinary method designed to reveal potential failure modes in high-risk processes.[14] Generally, the prospective approach is assumed to stimulate learning and to prevent the blaming of individuals.[15] In addition, different prospective approaches have been used individually or in combination to supplement the identification, understanding and prioritization of risks during treatment and care in various healthcare settings. The approaches involve methods such as brainstorming,[9,14,16,18] focus groups,[19] direct observations,[19] literature review,[19] incident reporting[17] and/or simulation.[20]

Risk assessment has been described in the literature as a useful DSs mitigation strategy.[12,13] However, a study among members of the European Association of Hospital Pharmacists (EAHP) and a European DS research network found that risk assessment was integrated in less than a third of the daily DS procedures surveyed across 23 European countries and Israel.[12] Conversely, 85% of respondents considered risk assessments a useful strategy to mitigate DSs, a finding that is in line with another study exploring user feedback and the meaningfulness of the prospective approach to ensure safer healthcare processes.[16,18] Further, the European cross-country study reported a variety of DS-related risks including, for example, insufficient single-dose barcode packs, medicine available in non-uniform concentrations, look-alike/sound-alike medicines, and unknown preparations.[12] Similar risks are reported from proactive risk assessment studies of healthcare personnel and investigating different aspects of the medication process,[9,16,18] surgical care[19] and radiotherapy.[21] Thus, proactive risk assessments have been used successfully in a variety of studies in hospital settings.

This study applies a prospective risk assessment to identify patient safety risks related to the management of DSs across organizations, with a specific focus on critical DSs in the secondary healthcare sector. In the current study, the following Danish DS definition from the Hospital Pharmacy in the Capital Region of Denmark is used in an English translation: *"When the customer does not receive the drug on time. It may be shorter or longer drug shortages. For contractual drugs an order becomes a drug shortage when the delivery date is exceeded by more than three days"* [22]. In this case, prolonged DSs are defined as when the delivery date exceeds three weeks.[22] Additionally, criticality implies drug changes in treatment, such as analogue changes, use of unlicensed medicine or, in worst case, no available drug substitutions. Thus, critical DSs emerge when an uncertain or unknown time perspective for the delivery of a certain drug critically affects the treatment options and patient safety.[22] These critical DSs force hospitals and healthcare personnel to change their working procedures and routines, which increases the risk of errors in the medication process and compromises patient safety.[3,23] Ensuring the safety of patients in connection with DSs is thus of utmost importance.[9,13,14,17]

2. Aim

The aim of the current study is to use prospective risk assessment to identify patient safety risks associated with the management of critical drug shortages in Denmark. More specifically, potential failures related to the process will be identified across actor levels, prioritized on the basis of risk ratings. This will be followed by proposed solutions for preventing failures.

3. Methods

Examining the interplay between actors at the various levels of the healthcare system is one means of determining how to improve safety when drugs are in shortage. In the current study, the term "actors" will be used rather than "stakeholders". This is because the more "pinned down" stakeholder position is affiliated with an organization or a society with responsibilities towards a company and an interest in its success, whereas the term actor focuses on shared meanings across organizational affiliations.[24] This is of interest in the current study, since prospective risk assessment is employed to identify patient safety risks related to the management of DSs across actors, with a specific focus on critical DSs.

3.1. Prospective risk analysis

Designed by the United States Department of Veterans Affairs' National Center for Patient Safety, the HFMEA is a proactive, multidisciplinary method for revealing potential failure modes in healthcare processes.[14] HFMEA consists of five steps, the first four being: 1) identification of topic of interest; 2) establishment of a multidisciplinary analysis team; 3) graphical mapping out of the process of DS management, which is further broken down into sub-processes; and 4) identification of potential failure modes by the team, based on the sub-processes in step 3. The patient safety consequences and probability of each failure mode occurrence are determined. Four categories are used to express the severity of the patient safety consequences (minor, moderate, major, catastrophic) along with the probability rating (remote, uncommon, occasional, frequent). From these ratings, a hazard score is calculated, followed by the use of a decision tree to identify the criticality, presence of control measures and detectability of a failure. Step 5 entails outlining recommendations aimed at preventing or mitigating failures as well as establishing proposed potential improvement measures and the person responsible for implementing them.[14]

The five HFMEA steps usually require four or five meetings each lasting two hours, an approach described in the literature as a method limitation.[13,16,18,21,25] HFMEA has also been criticized in the literature for its high costs, the complexity of its analytical steps and its subjectivity.[16,18,21,25] Additionally, HFMEA does not take into account human factors such as perception, cognition, emotions, nor does it consider preventive measures and controls in a process.[16,18,21,25] Thus, an extended version of the HFMEA was introduced in 2017,[25] combining two supplementary risk assessment tools to address specific HFMEA limitations – namely the Systematic Human Error Reduction and Prediction Approach (SHERPA)[26] and the Systems-Theoretic Accident Model and Processes (STAMP).[27]

SHERPA aims to analyze system performance through the prediction of potential failure of an activity caused by "typical" types of human error, for example, slips, neglect, misunderstandings. These errors can be due to failure/lack of attention, lack of control or an inability to understand a work activity, and the error conditions are then identified through various analytical steps.[26] Conversely, STAMP is an accident causality model, focusing on failure in a system due to insufficient control or safety in that system.[27] The combination of HFMEA, SHERPA and STAMP – termed the HFMEA hybrid – should compensate for the shortcomings critiqued in the literature, although conducting an HFMEA hybrid further increases analytical costs. The HFMEA hybrid elements are illustrated by Parand et al. (2017), and the HFMEA hybrid will be shown later in that the current study uses analytical elements taken from it.[16]

3.2. Design

The current study design was based on the HFMEA hybrid proposed by Faiella et al. (2017),[25] and elements of the hybrid approach were used to understand the DS-related processes and associated patient safety risks. The analysis was conducted on three actor levels consisting of actors involved in managing DSs in Denmark on national, regional and local levels, respectively. The categorization was based on the actors' DS management practices and the information flow from the national level, down to the regional level and ending at the local level, as identified from guidelines and a previous study, see Fig. 1.[28] However, some adjustments were made to the execution of the hybrid approach in order to take the Danish context into account, with the largest being the number of team meetings. The literature

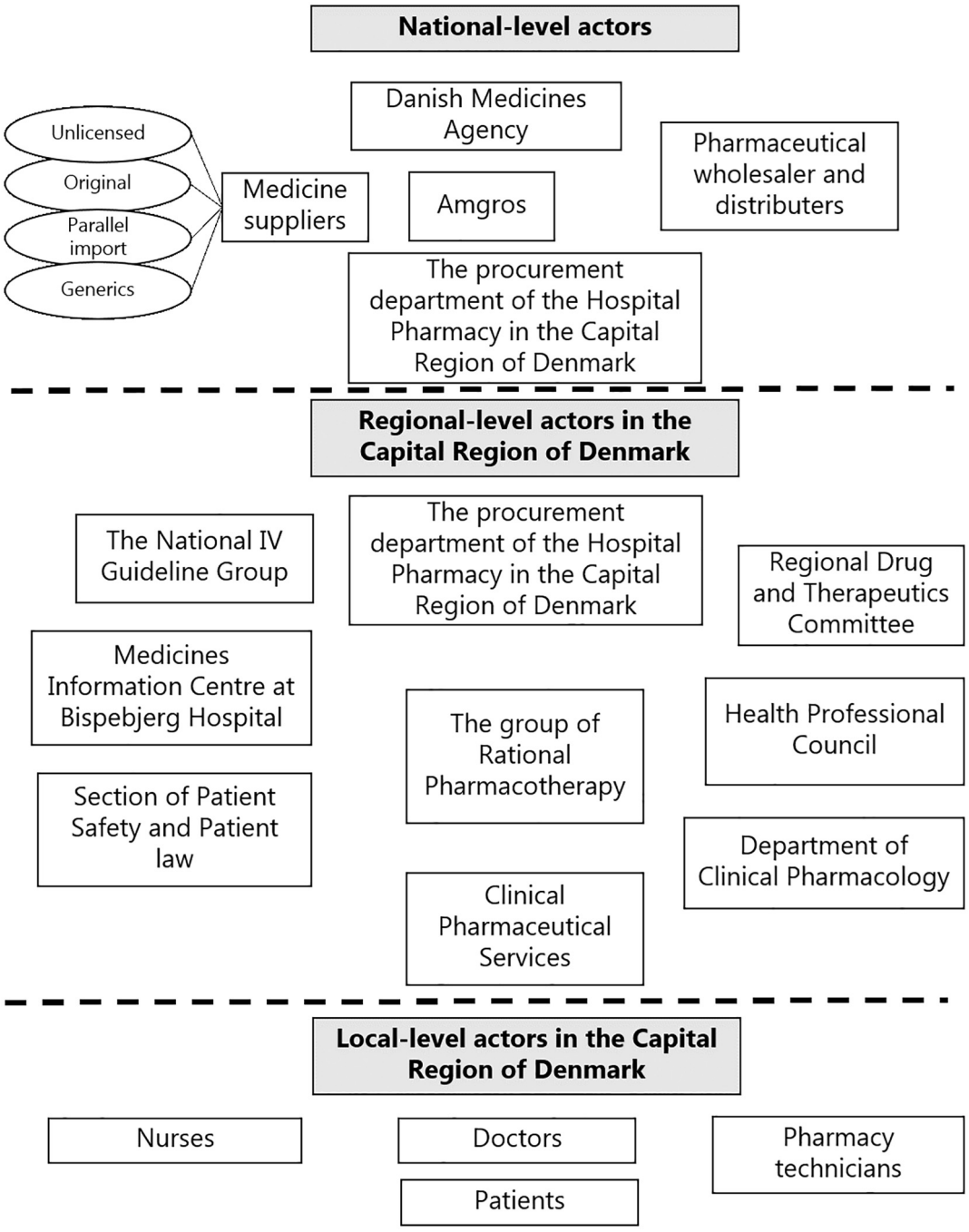

Fig. 1. Three actor levels consisting of actors involved in managing DSs in Denmark divided into national, regional and local levels.

recommends a minimum of four team meetings.[14,18,25] However, in the current study, only one meeting with each actor level was held. This was primarily due to the limited resources of the participating actors. A secondary reason for holding only one meeting was that the current study sought to include all the different levels of the Danish healthcare system involved in DS management and their mutual interplay. So, rather than probing a specific actor group, the current study aimed to gain an overview of all actors and three different levels. This approach is justified by the scarce knowledge about the patient safety challenges posed by DSs and the fact that in complex systems the challenges often lie in the interaction between the system elements or actors.[29,30] Further, from the literature, the multidisciplinary team can be made up by 6–14 individuals,[14,18,25,31] but to ensure that each participant had the opportunity to speak at the team meeting, a small group of maximum 8 participants was preferred in this study.

3.3. Team composition

A key focus of the current study was to investigate potential risks related to DS management across different actor levels in the Danish healthcare system. Three actor levels were identified for inclusion in the current study, with one team representing each level; see Table 1.

A purposive sampling strategy was used to identify the team members of each group, identifying and selecting information-rich individuals related to the phenomenon of interest – in this case actors who play a current active role in the different stages of managing DSs in secondary healthcare.[32] Combined with the purposive sampling, the principle of "follow the actors" was also applied.[24,32] The idea is to start at a certain point in the process, e.g. for the regional level, we read the DS guideline and selected actors and their described DS management role on this basis. Thus, these actors were invited to participate.[22] The process of reading guidelines and other written materials to identify actors was followed until no new actors were identified.

A total of 23 actor representatives were invited by email to participate in the study: eight actors on the national and local level, respectively, and seven actors on the regional level. Some of the regional actor representatives were involved in various organizational affiliations, and one actor might represent, e.g. both "The National IV Guideline Group" and "Medicines Information Centre". In this way, both perspectives were included in the risk assessment; see Table 1. As the medication process involves patients, two patient representatives were invited to the study, of which one was able to attend and was included in the HFMEA team on the local level. Further, in Denmark, drug dispensing and implementation of potential drug changes in the medication inventory room at hospital wards are primarily maintained by pharmacy technicians. The pharmacists are primarily involved in supporting the technicians and conducting clinical pharmacy at the patient level (medication reconciliation and medication review).[33] Thus, with the primary focus being DS management in the medication process, a pharmacy technician was invited to the study, as this is the role connected to the task. The HFMEA team meetings lasted about two hours each and took place during September and October 2019. The first and last authors facilitated the HFMEA meetings and wrote data on flipcharts as they were identified at the meetings. The last author was an experienced facilitator in HFMEA procedures and functioned as the main facilitator, which meant keeping participants focused on the data collection, managing the time, and guiding the participants through the different

Table 1
The invited actor representatives in the three risk assessments and their background.

Actor level	Actor representatives	N	Background
National	Amgros	1	A non-profit organization owned by the five Danish Regions responsible for tendering and the procurement of medicine to Danish public hospitals.
	RAP-MLV	1	The procurement department at the Hospital Pharmacy in the Capital Region of Denmark, which purchases and delivers medicines to all public regional hospitals and to Greenland.
	Tjellesen Max Jenne and Nomeco	2	Pharmaceutical wholesaler and distributors for pharmacies. Provide outsourced services for the pharmaceutical industry, such as medicine stockpiling, and distribute medicine to hospitals. Tjellesen Max Jenne and Nomeco are Denmark's two largest pharmaceutical distributors and wholesalers.
	Medicine suppliers	3	Representing original, generic, parallel import and unlicensed medicine suppliers
	Danish Medicines Agency	1	*Declined participation*
Regional	RAP-MLV	1	The procurement department at the Hospital Pharmacy in the Capital Region of Denmark, which purchases and delivers medicines to all public regional hospitals and to Greenland.
	The National IV Guideline Group	1	The National IV Guideline Group is a working group developing IV guidelines (instructions for mixture of infusions) used in Danish hospitals. The group consists of pharmacists from most hospital pharmacies in Denmark.
	Medicines Information Centre		The Medicines Information Centre provides advice on medicines to doctors, nurses and other health personnel from the secondary sectors in the Capital Region of Denmark. The Medicine Information Centre is run by the Hospital Pharmacy in collaboration with the Department of Clinical Pharmacology at Bispebjerg Hospital.
	Department of Clinical Pharmacology	1	*Declined participation*
	Section of Patient Safety and Patient law	1	The section has the overall responsibility for interpreting legislation in the field of health law, including the preparation of regional guidelines for ensuring patient rights in the clinical setting and handling service complaint cases in the practice area.
	Regional Drug and Therapeutics Committee	1	The Regional Drug and Therapeutics Committee ensures rational use of medicines by determining what medicines will be available and how they will be used at the regional level.
	Health Professional Council of Anesthesiology	1	Member of the health professional council of anesthesiology, the function of which is to provide unambiguous health professional advice in the Capital Region. There are 38 medical specific Health Professional Councils in the Capital Region of Denmark.
	The group of Rational Pharmacotherapy	1	A hospital pharmacy group that coordinates activities at the level of procurement, logistic and clinical pharmacy to support rational and patient safe drug use at the hospitals.
	Clinical Pharmaceutical Services		Hospital pharmacy personnel who provide top-up services, drug dispensing, and clinical pharmacy activities at the patient level (medication reconciliation and medication review) and support rational and patient-safe medicine use at the department level.
Local	Doctor	1[a]	Department of respiratory medicine
	Nurses	3	Nurse-led patient consultations including handing out medicine at the rheumatology outpatient clinic Nurse-led tasks, e.g. medicine dispensing, administration and monitoring at the cardiology ward and in the emergency department
	Pharmacy technician	1	Pharmacy technician employed in Clinical Pharmaceutical Services who undertakes clinical pharmacy activities, including top-up services and drug dispensing.
	Patient	1[a]	Parkinson Association representative

[a] Two participants were invited, but only one participant accepted to participate.

sub-processes. The first author was familiar with the investigated healthcare process and DS management at all actor levels and was thus able to answer participants' questions.

4. Procedure

The flowchart of the HFMEA hybrid method used in the current study is shown in Fig. 2, together with the flowchart of HFMEA hybrid by Parand et al. (2017).

4.1. Prior to the team meetings

To optimize the team meetings with the participants, written materials were sent to them before the meeting, including a basic explanation of the method, a description of the HFMEA principles, and an outline of their role as an actor representative. Additionally, a graphical process description of the DS management and its sub-processes was created and sent to the participants prior to the meeting. The DS processes followed by national level actors were identified on the basis of the available literature and an unpublished Danish study by Poulsen et al. (2020), which explores DS management practices, decision-making and collaboration among national-level actors in the secondary healthcare sector.[28] Further, a list of potential failure modes in each sub-process was prepared upfront for national actors. This procedure is recommended in the literature to accelerate the brainstorming session and to reduce subjectivity.[19] The process descriptions for the regional- and local-level actors were based on available literature and guidelines. All three process descriptions were presented to two pharmacists and two pharmacy technicians from a hospital pharmacy for examination, changes and validation.

Additionally, given the complexity of the DS management processes on and across the three actor levels, the research group chose the focus for the work on each actor level on the basis of a subset of the process steps involved.[14,16] Further, each sub-step analyzed generates considerable amounts of data. Thus, the group focused on the DS management processes or sub-processes of highest relevance for the research question, and a narrower focus promoted a deeper analysis.[14] Otherwise, the workload would have exceeded the overall project resources.[14]

4.2. Team meetings

The first HFMEA team meeting was held with the national-level actors. At this meeting, the graphical description of the DS management process, its sub-processes and the focus of analysis were displayed on posters, and the participants were invited to suggest amendments to the posters. Once consensus on the processes was reached, the participants were asked to identify potential failure modes and asked: “what could go wrong here”? The pre-prepared list of failure modes was shown to the participants for potential validation and to stimulate brainstorming to find new failure modes

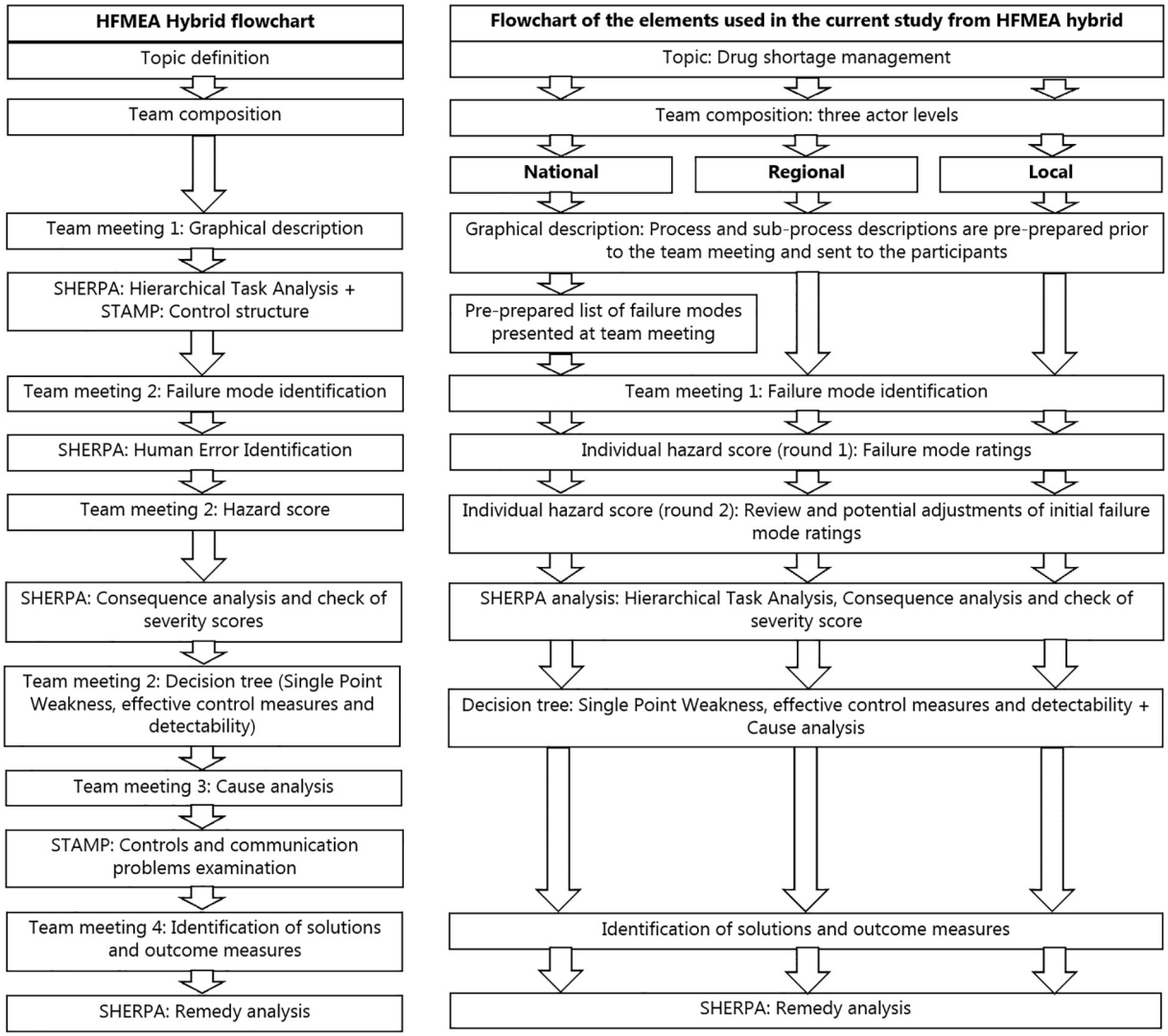

Fig. 2. Flowchart of HFMEA hybrid and flowchart of elements used in the study.[16]

for further inclusion. Although the pre-prepared failure mode list included additional failure modes, it also prevented the team from thinking "outside" the list. Thus, this approach was changed accordingly, and at the regional and local level meetings, the participants identified failure modes without a pre-prepared failure mode list. All suggested failure modes were discussed at the team meeting and displayed on posters once the participants had reached consensus about a failure mode. Potential causes of the failure modes were also established from responses to the question: "what can cause such a failure mode"?

A supplement to the brainstorming session with the regional actors was introduced, consisting of an exercise focusing on the redistribution of DS information between team members. During the exercise, pieces of paper represented pieces of information to share. One actor started by passing on a piece of the paper to another actor, who would be given a specific piece of information, e.g. the notice about delivery problems with a given drug. The paper was divided so that information could be distributed to more than one actor. In this way, the flow of information became visually tangible and allowed a discussion of challenges during the information flow. The reason for introducing this supplementary element was that the available guideline for the regional actors' DS management contained vague instructions about sharing DS information.[22] Generally, RAP-MLV, the procurement department at the hospital pharmacy, initiated the regional-level actors' DS management, as RAP-MLV was the first to become aware of a DS and subsequently initiated different information gathering and sharing activities among the other regional actors. However, the guideline did not state how and when each team member and his or her organization would potentially receive DS information from RAP-MLV. Thus, identifying potential failure modes related to the current DS management process would be challenging if the process of interest were unclear. Therefore, the exercise helped to generate an understanding of the actual interplay among actors regarding DS management and to identify the dynamics behind safety challenges that go beyond a mere discussion of the process.

The next HFMEA step was for the team to determine the severity of patient safety consequences and the probability of each failure mode occurring. A hazard score was calculated on this basis.[14] Although it stimulates brainstorming sessions, the group dynamic is not found reliable for determining an individual's point of view.[19] Some participants may dominate the discussion, thereby silencing other voices of dissent.[19,34] Thus, in this study, the team members scored the hazard individually. The identified failure modes and the causes mentioned during team meetings were written in a survey form, and the participants were asked individually to score the severity and probability of each failure mode occurring after the team meeting; see Fig. 3. A clear description of the different categories for rating the severity and probability was provided on the basis of the HFMEA procedure,[14] with categories adapted to the Danish contextual setting[35,36]; see Fig. 4. The participants were encouraged to substantiate their scoring in a comment field. The first author compiled all the incoming individual ratings in one document in an anonymized form.

The anonymized form with all ratings was resent to the participants for review, with a particular request to review "don't know" ratings within one week. Once the participants had returned their reviewed ratings, the first author calculated the hazard score for each failure mode; see Fig. 5. "Don't know" ratings were not included in the calculation of the individual failure mode's hazard score. Because of the small number of participants, a minimum response rate per failure mode was set at 50%.[19] Otherwise, the ratings were deemed unreliable. From the individual scorings, the final hazard scoring for each failure mode was determined using the median.

Next, a decision tree was used to determine whether a failure mode warrants further action. A decision tree is a triaging procedure to determine a failure mode's criticality, absence of effective control measures, and lack of detectability[14]; see Fig. 6. All failure modes with median hazard scores of 8 or higher automatically warrants further actions. For failure modes with median hazard scores <8, it was determined whether the occurrence of the failure mode was a "Single Point Weakness" (SPW), meaning that if the failure mode occurred, the entire process of DS management would fail.[14] Being an SPW or having a median hazard score of at least 8 led to the identification of effective control measures to detect the failure mode. If effective control measures could be identified, the processing of the failure mode would be discontinued. On the other hand, if no effective control measures were in place, the detectability of the failure mode was determined. If the failure mode was deemed undetectable, the failure mode processing proceeded to the identification of solutions proposed by the research group.

The first and second authors used the decision tree to triage the failure modes and to decide how to process them. In this process the authors also considered potential failure mode causes that might not have been mentioned during the team meetings. The findings were presented to the third and last authors, and potential disagreements were discussed until agreement was reached.

4.3. SHERPA procedure

SHERPA began with a "Hierarchical Task Analysis" where a hierarchy of action goals was described, followed by sequences of tasks performed to achieve these goals.[26] Each task identified was then classified according to the error taxonomy used in SHERPA, which includes the following error types: actions, retrieval, checking, selection and information communication. Within each of these five error types, the tasks are evaluated for potential human errors by means of an error taxonomy of "credible errors" associated with the activities.[26] Next, the consequences of each error were considered, and critical consequences, such as unacceptable losses, were noted and evaluated to determine the points of weakness, i.e., if the activity fails, the entire process will fail. A recovery analysis determined any point at which the activity can recover from failure, and this was followed by an ordinal probability and severity analysis. Finally, a mitigation and reduction strategy – "Remedy analysis" – was proposed with the categorizations equipment, training, procedures and organizational.[26]

4.4. STAMP procedure

STAMP examines the controls and communication problems in a process through the identification of potential causes and control measures already in place in a system.[27] According to the HFMEA hybrid, the potential causes of failure modes can be classified into three overall adapted STAMP

Process 1. ***Headline***											
Sub-process step 1.1. *Headline*											
Failure Mode	Severity					Probability					Comments
	Minor	Moderate	Major	Catastrophic	Don't know	Remote	Uncommon	Occasional	Frequent	Don't know	
1.1.a) failure mode name to sub-process 1.1											

Fig. 3. An example of the written survey form for the individual risk rating of process 1, sub-process step 1.1., with the name of the failure mode indicated as number 1.1. a).

SEVERITY (patient safety consequence)			
MINOR: No or minimal patient consequence			
MODERATE: Simple treatment or examination of one patient or an increased period of hospitalization for 1-2 patients			
MAJOR: One or more of the following: • Permanent lessening of bodily functioning/ disability for at least one patient with a degree of disability of <15% • Significantly increased diagnostic or treatment intensity of one patient • Increased length of stay for a minimum of 3 patients			
CATASTROPHIC: One or more of the following: • Death • Major permanent loss of bodily functioning/ disability for one patient with a degree of disability of ≥ 15%			
PROBABILITY (likelihood of occurrence)			
REMOTE: every second year	UNCOMMON: yearly	OCCASIONAL: every third month	FREQUENT: every month

Fig. 4. Description of the severity and probability categories.

categories: 1) inadequate control measures; 2) inadequate use of control measures; and 3) inadequate or missing information about the process.[27] The STAMP procedure means a causal analysis of the most common causes can be used to improve the safety design of DS management.[27]

The first and last authors performed the SHERPA and STAMP analysis. Cohen's kappa coefficient was used to measure the inter-rater reliabilities between the two authors regarding SHERPA's task classification according to error types, human errors and the remedy analysis, and regarding STAMP's cause classification.[37] All data were presented to the second and third authors for further discussion and validation.

5. Results

Twenty actor representatives agreed to participate in the risk analyses at a national (7), regional (6) and local level (7). One team member from the national level did not answer the individual risk rating and was characterized as leaving the study after the team meeting. Thus, six team members performed the risk ratings. Additionally, one member of the local-level team was unable to participate on the day of the meeting, so six participants represented the local level. Therefore, a total of 18 actor representatives, six in each team, were included in the study.

Overall, a total of 167 failure modes were identified across the three actor levels. In the following, the results will be presented for each actor level separately. The first and last authors assessed the use of SHERPA and STAMP in the current study, and the included elements will be covered at each actor level; see Fig. 1.

The illustration of the complete processes and sub-processes of DS management was inspired by the studies of Faiella et al. (2017)[25] and Parand et al. (2017)[16] and is shown in Figs. 7-9. The subparts not included in the analytical focus are shown in grey text and frames, while those included are shown in black text and frames. This graphical illustration of the DS management process also covers the SHERPA task classification.[27]

	HFMEA: Severity (patient safety consequence)				
HFMEA: Probability (likelihood of occurrence)		Catastrophic: rating 4 SHERPA rating: High	Major: rating 3 SHERPA rating: Medium	Moderate: rating 2 SHERPA rating: Medium	Minor: rating 1 SHERPA rating: Low
	Frequent: rating 4 SHERPA rating: High	(4 x 4) = 16	(4 x 3) = 12	(4 x 2) = 8	(4 x 1) = 4
	Occasional: rating 3 SHERPA rating: Medium	(3 x 4) = 12	(3 x 3) = 9	(3 x 2) = 6	(3 x 1) = 3
	Uncommon: rating 2 SHERPA rating: Medium	(2 x 4) = 8	(2 x 3) = 6	(2 x 2) = 4	(2 x 1) = 2
	Remote: rating 1 SHERPA rating: Low	(1 x 4) = 4	(1 x 3) = 3	(1 x 2) = 2	(1 x 1) = 1

Fig. 5. HFMEA hazard scoring matrix with SHERPA ratings. [14,16,25,26]

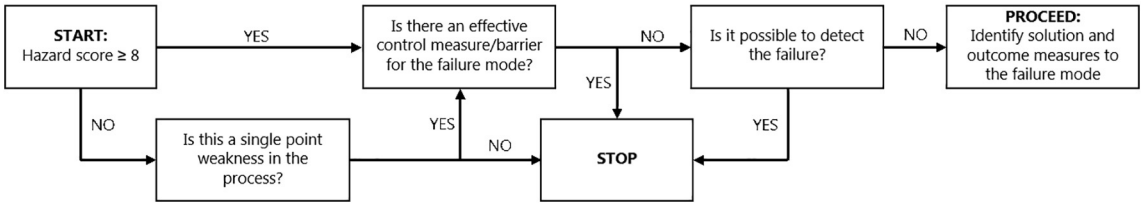

Fig. 6. Decision tree used as a triaging procedure to determine failure mode criticality.[14]

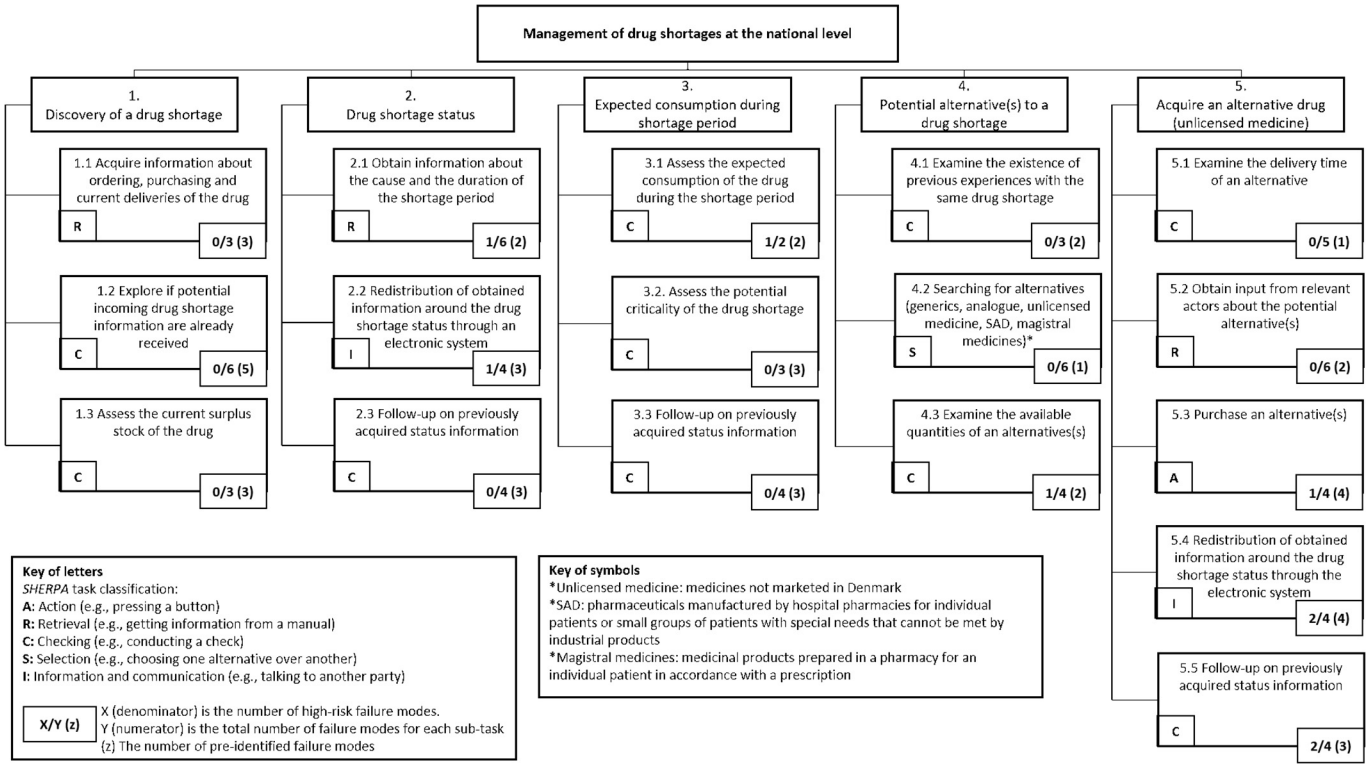

Fig. 7. Management of drug shortages at the national level.

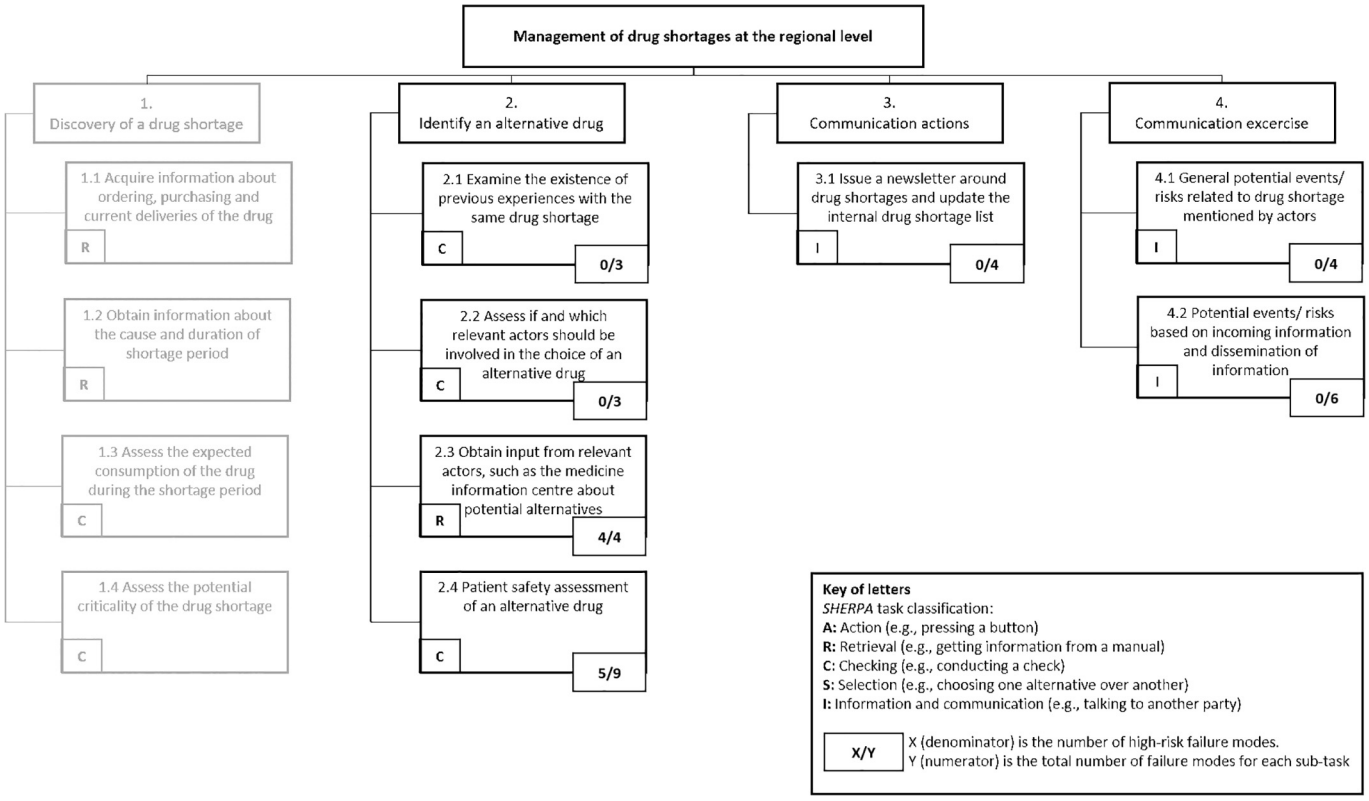

Fig. 8. Management of drug shortages at the regional-level (the grey elements are shown here for the purpose of completeness, but were not included in the brainstorming session).

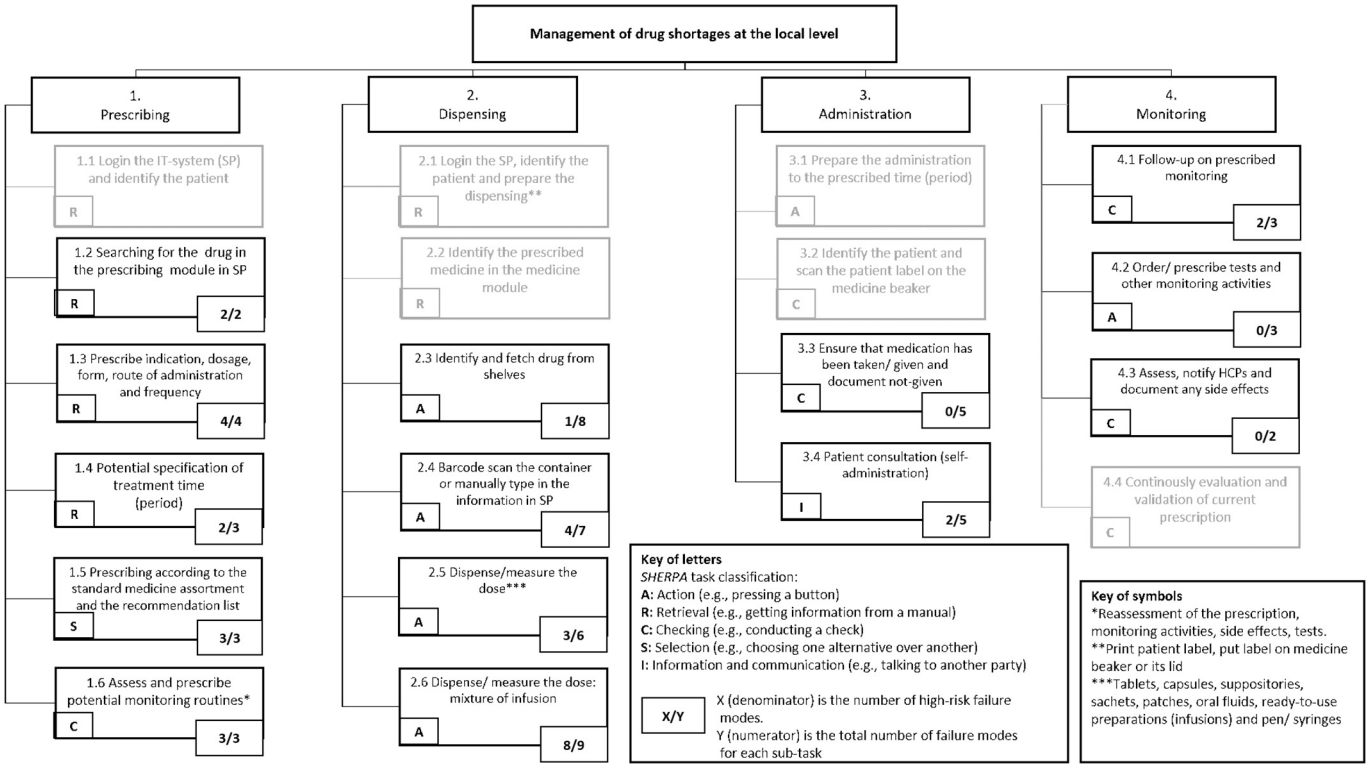

Fig. 9. Management of drug shortages at the local-level (the grey elements areshown here for the purpose of completeness, but were not included in the brainstorming session).

5.1. National actors

Five processes, 17 sub-processes and 71 failure modes related to DS management among national actors were identified; see Fig. 7. Forty-six failure modes were identified by the first and second authors and subsequently validated at the team meeting. Twenty-five additional failure modes were identified by the team members. Twenty-nine failure modes were discarded due to response rates from the risk ratings below 50%; 27 failure modes with a mean hazard score below 8 were not considered an SPW and were therefore excluded. As a result, 15 failure modes were examined for existing control measures and detectability by means of the decision tree. Of these, four failure modes were discarded due to existing control measures and two because of their detectability. The nine failure modes thus left for further analysis can be seen in appendix 1 together with the determined hazard scores, consequences from the SHERPA analysis, and existing controls identified by the HFMEA decision tree.

Given the nature of the empirical data, the first and last authors decided that rating both the error types with SHERPA and the control mechanisms with STAMP was not feasible. Both taxonomies offered many different options, and with the available empirical material it was impossible to decide which category to apply since too many were plausible. For example, the selected error taxonomy of "credible errors" in the SHERPA analysis covers errors such as "operation mistimed", "operation in wrong direction", "operation to little/much" and "operation incomplete".[27] These errors appear to be very similar, and these credible errors could all be applied to the failure modes, which made choosing one option over the other seemingly impossible without the team's input. We therefore decided to pursue the SHERPA and STAMP ratings no further than pointing out possible examples of these ratings. In addition, a strong Cohen's Kappa inter-rater reliability score for SHERPA hierarchical task analysis classifications for national-level actors (κ = 0,815) and regional-level actors (κ = 0,863) was found, whereas the reliability score was moderate for local-level actors (κ = 0,584).

5.2. Regional actors

Four processes were identified, but owing to process 1 "Discovery of a DS" being a repetition from the DS management process of national actors, it was not of high relevance for the regional actor. Thus, three of the processes were included in the research. Seven sub-processes and 33 failure modes related to DS management among regional actors were described; see Fig. 8. The team members identified 23 failure modes during brainstorming and 10 during the exercise. Twenty-four failure modes with a mean hazard score below 8 were not considered an SPW and were therefore excluded. As a result, nine failure modes were examined for existing control measures and detectability in the decision tree. No effective control mechanisms were present or detectable for any of them, and all were therefore included in the further analysis. They can be seen in appendix 2 together with the determined hazard scores, consequences from the SHERPA analysis, and existing controls identified by the HFMEA decision tree.

5.3. Local actors

Four processes, 14 sub-processes and 63 failure modes related to DS management among local actors were described; see Fig. 9. Ten failure modes were discarded due to response rates from the risk ratings below 50%. Two failure modes with a mean hazard score below 8 were not considered an SPW and were therefore excluded. As a result, 51 failure modes were examined for existing control measures and detectability in the decision tree. Of these, seven failure modes were discarded due to existing control measures, and since no failure mode was detected, this left 44 for further analysis. Of these, however, four failure modes emerged as direct consequences of failure modes from earlier sub-processes and were thus discarded. Two failure modes were a repetition of another failure mode, and six of those remaining were unrelated to DSs and thus outside the scope of the study. As a result, 32 failure modes were left for further analysis and can be seen in appendix 3 together with the determined hazard

Table 2
Proposed solutions to the critical failure modes at regional and local level.

Level	Regional level: proposed solution	Local level: proposed solution to process 1 "prescribing"	Local level: proposed solution to process 2 "dispensing"
Proposed solutions	• A DS checklist to ensure patient-safe identification of an alternative drug	• IT support in the electronic prescribing module	• IT support in the electronic dispensing module • Implementation of hospital pharmacy services at wards
Failure modes [FM]	• Identification error around an alternative [FM 2.3.a-d] • The patient safety of an alternative is underestimated [FM 2.4.a-d + i]	• Searching for a "wrong" drug [FM 1.2.a-b] • Prescribing errors [FM 1.3.a-d] • The duration of the treatment does not match the new alternative drug (too short or too long) [FM 1.4.a-b] • The drug is not re-assigned to a drug available in the medication inventory room [FM 1.5.a] • Incorrect *prescription* of monitoring [FM 1.6.a-c]	• The drug cannot be located and the dispensing is omitted/ delayed [FM 2.3.g] • Barcode challenges [FM 2.4.a-c + f] • The medication is prepared/measured incorrectly [FM 2.6.h]
Causes	• Lack of attention to look-alikes, sound-alikes, the conversion of strength, another management procedure • Patient safety not assessed at all	• Lack of IT support • Lack of knowledge or attention because drug shortage information about a specific drug is not received or is overlooked • Following incorrect routines/assumptions for the alternative • Error generalization between two drugs • No end-date is prescribed owing to lack of knowledge or attention	• Lack of IT support • Change in trade name or physical appearance • Prescribed drug is not included in the standard assortment • Lack of knowledge or attention because drug shortage information about a specific drug is not received or is overlooked • Preparation guideline for a new drug is unavailable • Unawareness of the need for a new preparation guideline
Actions	Develop a checklist based on patient safety aspects to support the decision to use a suitable alternative drug in DS. After its use, the checklist is signed for documentation purposes.[9] SHERPA remedy analysis: *Procedures* Distribution of the checklist among the regional actors setting out usage in practice SHERPA remedy analysis: *Procedures*	Explore the possibilities for pop-up alerts in the electronic IT system to support doctors when prescribing drugs unavailable in the standard assortment or medication room. SHERPA remedy analysis: *Equipment*	Explore the possibilities for pop-up alerts and targeted drug information in the electronic IT system to support personnel while dispensing, i.e. a missed dose or lack of barcode scanning activate an alert. SHERPA remedy analysis: *Equipment* The pharmacy service involves having a pharmacy technician dispensing alongside and supporting the nurses SHERPA remedy analysis: *Organizational*
Respon-sible	• RAP-MLV • Hospital pharmacists	• RAP-MLV • Clinical Pharmaceutical Services (hospital pharmacy)	• RAP-MLV • Clinical Pharmaceutical Services (hospital pharmacy) • The ward management
Outcome measure	Regular checks of whether the checklist has been used and documented following a DS	Regular checks for incoming enquiries from dispensing personnel regarding unavailable medicine (owing to DS)	Regular checks for incoming enquiries from dispensing personnel regarding unavailable medicine (owing to DS)

Level	Local-level: proposed solution to process 2 "dispensing"	Local-level: proposed solution to process 3 "administration"	Local-level: proposed solution to process 4 "monitoring"
Proposed solutions	• Training and teaching dispensing personnel • IT support (see local - solution 2)	• Information and training	• IT support in the electronic monitoring module
Failure mode [FM]	• Barcode challenges [FM 2.4.a-c + f] • Incorrect dosing due to calculation challenges [FM 2.5.a] • The drug is managed incorrectly [FM 2.5.e-f] • The drug is prepared/mixture/measured incorrectly [FM 2.6.a-g]	• The patient incorrectly takes the medication at home due to procedural changes in administration [FM 3.4.c] • The [self-administering] patient does not want to take the medicine at home [FM 3.4.d]	• The monitoring does not take place at all [FM 4.1 .b]
Causes	• The barcode is not working, unavailable on the drug or not used in dispensing routine • Lack of IT support in barcode scanning • Lack of knowledge or information about an alternative • Unawareness of or inattention to the DS information • Calculation error • Wrong dissolvent used due to drug changes, look--alikes, prescribing error, changed management procedures	• Uncertainty about the drug change (new procedures) • Insecurity about the drug itself	• Inattention to prescribed monitoring activities • Unfamiliar with new/extra/changed monitoring activity related to an alternative drug
Actions	The dispensing personnel (nurses) are: 1) trained to always use the barcode as a double control and 2) trained in different medication scenarios where calculations related to dosage and strength (concentration) are included in courses held by the hospital pharmacy Sherpa remedy analysis: *Training* As local - solution 2: pop-up alerts in the electronic IT system if no barcode scanning has happened Sherpa remedy analysis: *Equipment*	Training and thoroughly informing the patients if their usual treatment is changed due to DS, e.g. having demo-devices and/or patients' leaflets available to demonstrate their new device/drug Sherpa remedy analysis: *Training*	Explore the possibilities for pop-up alerts in the electronic IT system to support the nurses' and the doctors' monitoring activities when an alternative drug is prescribed Sherpa remedy analysis: *Equipment* Integrate the check of potential monitoring activities while dispensing Sherpa remedy analysis: *Procedures*
Respon-sible	• Ward nurse • Dispensing personnel (nurses) • Hospital pharmacists	• Ward nurse • Dispensing personnel (nurses) • Hospital pharmacists	• RAP-MLV • The Medicines Information Centre • Clinical Pharmaceutical Services (hospital pharmacy)

Table 2 (*continued*)

Level	Local-level: proposed solution to process 2 "dispensing"	Local-level: proposed solution to process 3 "administration"	Local-level: proposed solution to process 4 "monitoring"
Outcome measure	The percentage of drugs scanned, and the percentage of drugs that are not scanned.	Number of patients showing adherence. This can be ascertained by systematically asking patients about their medicine habits.	Incident reports or observation of routines (none of which is simple to implement)

Proposed solutions to the critical failure modes at regional and local level, including potential causes, and a description of the actions related to the proposed solutions, together with the SHERPA remedy analysis containing SHERPA actions: *equipment (*redesign or modification of existing equipment), *training* (changes in training provided), *procedures* (provision of new or redesign of old procedures), and *organizational* (changes in organizational policies or culture). Those responsible for completing or ensuring completion of the actions and outcome measures for the actions are also mentioned. FM = failure mode.

scores, consequences from the SHERPA analysis and existing controls identified by the HFMEA decision tree.

5.4. Recommendations for critical failure modes

The proposed solutions and potential causes to the critical failure modes at regional and local level are related to a DS checklist to ensure patient-safe identification of an alternative drug; IT support in the electronic prescribing, dispensing and monitoring modules; implementation of hospital pharmacy services at wards; and training and teaching dispensing personnel, see Table 2. The proposed solutions assume that the IT system and any available equipment are functioning. The causes identified in Table 2 are not prioritized, and the proposed solutions in Table 2 are examples. The actions related to the solutions are described together with the SHERPA remedy analysis containing the following SHERPA actions: *equipment (*redesign or modification of existing equipment), *training* (changes in training provided), *procedures* (provision of new or redesign of old procedures), and *organizational* (changes in organizational policies or culture). Finally, those responsible for completing or ensuring completion of the actions and the outcome measures for the actions are also set out in Table 2.

Table 2 consists of six columns, where the first grey column relates to regional-level solutions and the following five to local-level solutions. The national-level actors represent different organizations with different roles, functions and responsibilities towards other actors. As the recommendations would not meet the needs of any individual organization, no recommendations are proposed, as they would not be applicable in practice across the organizations.

6. Discussion

A considerable number of failure modes and causes were identified at all three actor levels. At the national level, nine critical failure modes were identified. "Untimely communication actions" and "inaccurate DS information shared amongst actors" posed the biggest patient safety risk. No recommendations for the failure modes were proposed. At the regional level, the failure modes "identification errors" and "underestimation of the patient safety associated with an alternative" included the nine most critical failure modes. At this level, lack of knowledge, insufficient insight into the alternative, and clinical setting were identified as failure mode causes. The development of a DS checklist containing these patient safety aspects for an alternative was a proposed solution. At the local level, 32 failure modes were identified, with the majority of the causes being related to lack of knowledge of or inattention to DS information. Identified solutions were specific electronic IT support in the prescribing, dispensing and monitoring modules, together with the implementation of hospital pharmacy services and training for dispensing personnel.

The number of failure modes with hazard scores ≥ 8 was not overwhelming: two failure modes at the national level, none at the regional level, and 11 at the local level were identified. A substantial number of failure modes identified by the criteria applied here might not be sufficiently relevant to warrant further investigation. The differences between the failure modes identified at the different levels might be related to the more concrete nature of the sub-processes on the local level – making it easier to identify possible failure modes. This was also reflected in the level of causes, the risk ratings, SPW identification, and the control or detectability. Scrutinizing each step in the decision tree shows that the failure modes would depend on humans as failure preventers, controllers or detectors. Even though humans may discover several potential failures in time and thus prevent failure, humans cannot be considered 100% effective in controlling failure modes.

6.1. Contextual influences

The failure mode "the duration of the treatment does not match the new alternative (too short/long)" illustrates the complexity of rating a failure mode according to the different criteria. Whether a failure mode with a mean hazard score below 8 received an SPW rating would depend on the context. In a situation where an antibiotic whose treatment duration is too short is prescribed, for example, the answer would be yes, and the patient might need yet another round of treatment for the drug to be effective. However, for other drugs, this failure mode would not have such a central role. The situation gets even further complicated when the many potential sources of error during the other process steps are considered. These considerations emphasize that the effects of a failure mode depend highly on context.

Implementing a proposed solution in a specific setting would require reviewing and potentially adjusting the solution to ensure that the key cause(s) of a failure mode in the contextual setting are addressed. Moreover, further research would be necessary to verify the validity of the conclusions and recommendations in other healthcare settings before such a solution could be implemented.[18] Some of the proposed solutions are also difficult to implement in reality, as they require resources for such initiatives as healthcare personnel training, the implementation of hospital pharmacy services or IT support development. This is also acknowledged in the literature, where the associated financial burden of proposed recommendations was cited as an issue that implementers need to consider.[16] Additionally, the actors would have to be convinced or persuaded about the solution to be actively involved in its implementation, which makes the implementation in practice more challenging.

In summary, our study shows that it is possible to identify failure modes and causes that have value beyond the setting in which they were collected. As the study aimed to identify patient safety risks across the different actor levels of the Danish healthcare system, it seems acceptable that the current study remains on a general level and does not provide complete, implementation-ready solutions. Such solutions would also be context-dependent, and providing them here would be far too time-consuming. The findings and their interpretation can help readers to develop local solutions.

6.2. Comparing the current findings the with international literature

Another discussion relates to the actors' different interpretations of the failure modes. An recent Danish study by Poulsen et al. (2020) shows that different definitions of DSs exist among national-level actors in secondary sector healthcare.[28] Thus, the understandings of a DS and its interpretation may vary among participants. Generally, the different interpretations are

difficult to capture at a team meeting unless the different terms are directly discussed. Further, the variations in the individual ratings of the severity and probability of failure modes at all levels also suggest that actors perceive or understand failure modes differently. The lack of opportunity to explore these different perceptions and ensure a common understanding in the risk ratings is a limitation in our choice of method, which will be discussed under methodological considerations.

The risk assessments from regional- and local-level actors showed that critical failure modes were related to ensuring patient safety in connection with use of an alternative drug, together with changed drug preparation and the management and dosing of an alternative drug. In line with the current study, a risk assessment from the US involving representatives from a hospital pharmacy, drug information specialists and nurses showed that situations including look-alike/sound-alike medicines, administration and dosing differences, and "preparing the drug differently" were the highest-ranked patient safety concerns in connection with DSs.[9] A cross-country study mentioned similar DS-related risks: medication errors caused by substitution, the different usage of alternative drugs and the challenges caused by look-alike/sound-alike medicines.[12] Other studies using HFMEA procedures to explore different aspects in the general medication process identify similar failure modes to those found by the current study in the dispensing, administering and monitoring processes.[16,31,38] Thus, these studies support our findings, indicating that similar patient safety concerns are recurrent challenges related to the medication process.

As mentioned earlier, failure modes related to communication and information were identified at the national level. This is in line with a cross-country study by Miljkovic et al. (2019), where the risk of miscommunication among stakeholders was detected while conducting risk assessment in medicine shortages.[12] Conversely, a US study ranked DS communication as the lowest patient safety concern in situations where an alternative drug was required.[9] This is somewhat similar to the results from the regional- and local-level actors in the current study, who did not consider communication and information as critical failure modes. Further, by conducting surveys sent to pharmacy organizations, a healthcare consortium and safety officers, the US study identified the areas where DSs had the greatest impact on patient safety.[9] From here, a shortage assessment checklist was developed, and the current study took inspiration from this list to develop a similar checklist that included the patient safety aspects identified by the regional-level actors.

6.3. Methodological considerations

A strength of the current study is its approach to identifying and studying risks across various actor levels. Thus, the current study operates holistically and captures cross-actor level aspects. This has value, since patient safety issues often evolve at interfaces and in connections.[29] The patient involvement provided contextual insight into the perspectives and outcomes that matter to patients. These inputs from patient involvement in risk assessments have been described as both useful and valuable to research.[18]

Furthermore, following a standard HFMEA procedure would be extremely complex in terms of the level of detail obtained from each actor level. Traditional HFMEA procedures recommend a minimum of four meetings, meaning a total of 12 meetings for the current study – which was beyond the scope of the study. We did not attempt to re-develop or test the hybrid method; we merely used different aspects from the hybrid approach to capture potential failures in DS management across actor levels. Another interesting finding in that regard was the process of gathering participants together for the first time and encouraging them to think systematically about potential failures of relevance to the entire team of participants from different organizations or professional standpoints. The setting triggered a form of process alignment among actors, which can be challenging and places an important responsibility on the facilitator(s). The facilitator's role has been pointed out as being crucial for the successful application of HFMEA.[18] In the current study, the main facilitator (the last author) at the team meetings had prior experience with HFMEA, whereas the first author supported the team, answered questions, and provided contextual examples where necessary.

During the information-sharing exercise among regional-level actors, the focus of attention and communication shifted from the facilitators to the fellow team members. Besides identifying additional failure modes, the exercise made the participants interact, explain and reflect upon the different action-oriented practices used when DS information is shared. Thus, the exercise was a successful supplement, revealing failure modes not identified by standard brainstorming. HFMEA has been successfully combined with classic simulation methods as an approach to explore the details of smaller elements of the scenario of interest.[20,39] The use of simulation has proved particularly effective in identifying additional failure modes, causes and effects in multidisciplinary settings.[20] Thus, simulation could be used for method triangulation purposes in future HFMEA analysis.

It should be noted that the different actor levels were introduced by the authors. While this analytical distinction proved helpful for conceptualizing the interactions between the different actors, we cannot rule out that this distinction is less relevant in the actors' daily practice. However, the actor representatives were introduced to the distinction between actor levels in the introduction mail and at the team meeting where Fig. 1 was shown to illustrate the overall aim of the study.

The aforementioned preparatory interviews about DS management with national-level actors revealed several potential failure modes, which it made sense for the team brainstorming to take into consideration.[28] Further, to optimize time and accelerate the brainstorming session with national-level actors, we prepared an initial list with failure modes identified from the interviews and relevant literature. In accordance with this approach, a study by Nagpal et al. (2010) proposed a triangulation of failure mode identification through original identification (brainstorming), the literature and observations of the process of interest.[19] The list of pre-prepared failure modes was distributed to the participants at the team meeting. Despite validating 46 failure modes from the list and identifying another 25, the list seemed to deadlock the participants' brainstorming of additional failure modes. However, it is difficult to anticipate whether the brainstorming would have yielded the same level of failure modes without the list. On the basis of this experience, we decided not to pre-prepare a list of failure modes for the team meetings with regional- and local-level actors.

It is difficult to estimate the honesty of the different participant statements and we cannot rule out that some topics have (un)deliberately been ignored, just as there may be underlying power structures between the participants. However, an experienced facilitator tried to ensure that all participants were involved in the brainstorming session, and by implementing individual risk ratings, we created an opportunity to determine an individual's point of views, just as we avoided dominant participants silencing others.[19] However, other challenges arose. First, despite encouraging participants to review their "don't know" scores in the second risk rating, we found that many of the scores remained unchanged. The proportion of "don't know" scorings suggests that participants had difficulty estimating, understanding or relating to the severity and/or probability of the failure modes. The patient representing the local level found estimating the probability of failure modes particularly difficult, and deliberately used the "don't know" ratings. This is fully understandable, since a patient representative has no detailed knowledge of the failures occurring in all sub-processes. The general risk rating challenge would have to be tackled through greater contextualization in more meetings, discussion of participants' individual risk ratings, and agreement on one final risk rate per failure mode. This was also concluded in a couple of studies that compared the variability in risk scorings from a traditional team meeting with variabilities in individual risk scoring.[40,41] Both studies found that the traditional team consensus procedure was most appropriate owing to the subjective variabilities in individual ratings.[40,41] However, different evaluations of the original HFMEA reported that participants generally found it difficult to determine the hazard score.[16,18,21] This suggests that, regardless of risk rating procedure, deciding on these risks is generally difficult. The current study provides an overview that would allow the reader to decide where to probe analytically deeper in each context.

The current study has several methodological limitations. Because there was only one team meeting per actor level, the authors independently performed several analytical steps, i.e. decision tree, proposed solutions,

SHERPA and STAMP. Hence, methodological challenges arose on several occasions, particularly regarding SHERPA's human error identification and STAMP's classification of causes. Choosing one taxonomy over the others without the participants' clarifying and validating these classifications seemed impossible. A range of possible underlying error mechanisms was plausible for any of the failure modes.

Further, scrutinizing the failure modes after the incoming risk ratings, the research team identified interconnected failure modes, where the consequence of one failure mode resulted in another failure mode. In these cases, the authors decided to include the initial, "original" failure mode and discard consequential failures. For example, consider a doctor prescribing a drug that is not available at the ward. This has different consequences. Whether or not the nurse discovers this failure, it could be a consequence of the medical doctor's error or a newly occurring failure unconnected with previous failures. However, making good decisions and defining criteria for distinguishing between the consequence of one failure mode and another new failure mode are challenging with this method.

Further, some failure modes were worded differently, but were repetitions of each other. Thus, all the different formulations of failure modes were collated into one. Ideally, the participants should have validated this new version, but this was beyond the scope of the project. Furthermore, the use of the decision tree and its analytical steps was based on the researcher's understandings without input from the contextual setting. This relates particularly to evaluating a failure mode as an SPW and determining the existence of effective control measures. Two researchers with some contextual insight into the three settings performed this analysis. However, without the team members' validations, it cannot be ruled out that judgement errors have occurred. On the other hand, studies report that participants found the decision tree difficult to use in practice, just as the many aspects of HFMEA were causing "useless discussions" among team members.[16,18,21] Despite the critique of the decision tree, we used it as a tool to identify areas where vulnerabilities needed to be mitigated and areas requiring no further attention.

As already mentioned, having at least four team meetings required time and resources unavailable in the current study, and only having one team meeting made it easier for participants to agree on a meeting date. The meetings were held in the afternoon and lasted two hours. Considering our findings and the methodological challenges, one more team meeting after the individual risk ratings would have been ideal. At such a meeting, the participants would present their initial ratings, discuss them in plenum and agree on a final risk rating. Failure modes with hazards scores >8 would then be subjected to decision tree analysis.[18] This would enable contextual insight into existing control measures or detectors in order to prevent failure. Additionally, the human error identification from SHERPA and the classification of causes from STAMP could have been integrated parts of the decision tree. In our overview-oriented approach to HFMEA, SHERPA and STAMP had limited value.

7. Conclusion

The management of drug shortages (DSs) is complex and involves different actors in a healthcare system. Prospective risk assessments with actors from three actor levels allowed a total of 167 failure modes to be identified, of which 9 were critical to national- and regional-level actors respectively and 32 were critical to local-level actors. This study demonstrated that the methodological approach based on one team meeting and individual risk ratings identified potential failures associated with DS management across different actor levels. The study also provided an overview of interrelated failures across the different layers of the Danish secondary healthcare sector, an overview that can form a basis for developing patient-safe solutions to prevent future risks. The findings can guide follow-up studies that explore individual aspects in more detail.

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Declaration of Competing Interest

None.

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Appendix 1. National level

Table containing critical failure modes left for further analysis, including the determined hazard scores, consequence analysis from SHERPA and the elements of HFMEA decision tree.

Sub-task	National-level	Potential consequences (SHERPA analysis)	Risk ratings					Decision tree			
	Failure mode (including potential cause)		Median hazard score	Minimum	Maximum	Standard deviation	Response rate (in %)	Single Point Weakness?	Existing Control Measure?	Detectability	Proceed?
2.1.b	Incorrect DS information about the re-availability date is obtained/received	The criticality of the DS is considered to be low/high; delay in/-initiation of wasteful DS procedures	7,5	4	12	3,5	67	Y	N	N	Y
2.2.c	DS information is disseminated too late	Delay in DS procedures	6	6	6	0	50	Y	N	N	Y
3.1.a	Wrongly assessment of the drug consumption in a DS period (too small owing to incorrectly estimates of expected consumption of the drug)	Lack of an alternative as small quantities are purchased	4	3	6	1,5	50	Y	N	N	Y

(continued on next page)

(*continued*)

Sub-task	National-level	Potential consequences (SHERPA analysis)	Risk ratings					Decision tree			
	Failure mode (including potential cause)		Median hazard score	Minimum	Maximum	Standard deviation	Response rate (in %)	Single Point Weakness?	Existing Control Measure?	Detectability	Proceed?
4.3.a	Incorrect information about available quantities of an alternative(s) are received (too little)	Lack of alternatives; extra purchase of (new and costly) alternatives	4,5	2	8	2,8	67	y	N	N	y
5.3.a	Too little of the alternative is ordered (based on incorrect estimates of expected consumption of the drug)	Lack of alternatives; extra purchase of new and costly alternatives; sub-optimal alternatives	6	1	8	3,6	50	Y	N	N	Y
5.4.b	Information about an alternative is redistributed too late	Delaying DS management at regional- and local-level actors; hoarding once the DS is discovered	4	2	12	5,3	50	Y	N	N	Y
5.4.c	Incorrect information about an alternative is redistributed	Purchase of the wrong drug; redistribution of incorrect information internally; risk of errors in the medication process	2	1	8	3,8	50	Y	N	N	Y
5.5.a	The follow-up of a drug in shortage happens too late	Changed DS information may lead to increased criticality or wasteful initiation of DS procedures; ordering of the wrong alternative; redistribution of incorrect information internally	3	3	8	2,9	50	Y	N	N	Y
5.5.b	Follow-up concerning of a drug in shortage is not assessed at all	Changed DS information may lead to increased criticality or wasteful initiation of DS procedures; ordering of the wrong alternative; redistribution of incorrect information internally	2	2	6	2,3	50	Y	N	N	Y

Appendix 2. Regional level

Table containing critical failure modes left for further analysis, including the determined hazard scores, consequence analysis from SHERPA and the elements of HFMEA decision tree.

Sub-task	Regional-level	Potential consequences (SHERPA analysis)	Risk ratings					Decision tree			
	Failure mode (including potential cause)		Median hazard score	Minimum	Maximum	Standard deviation	Response rate (in %)	Single Point Weakness?	Existing Control Measure?	Detectability	Proceed?
2.3.a	Identification error around an alternative owing to a wrongful assumption that drug A can replace drug B	Medication errors	3,5	2	6	1,7	100	Y	N	N	Y
2.3.b	Identification error around an alternative owing to a lack of knowledge around the clinical use	Improper treatment	3	1	6	1,9	83	Y	N	N	Y
2.3.c	Identification error around an alternative due to changes or unknown factors related to the clinical equipment, making the alternative useless in practice	Delayed treatment	4	3	6	1,2	83	Y	N	N	Y
2.3.d	Identification error around an alternative owing to difficulties in seeing through all (specification) details about an alternative	Unexpected challenges for hospital personnel in the medication process (missing equipment, device etc.); delayed/omitted treatment	4	2	9	2,8	83	Y	N	N	Y
2.4.a	The patient safety around an alternative is underestimated owing to lack of attention to look-alikes	Errors in the medication process (incorrect dosage, strength, wrong drug dispensed)	7	3	9	2,4	100	Y	N	N	Y
2.4.b	The patient safety around an alternative is underestimated owing to lack of attention to sound-alikes	Errors in the medication process (incorrect dosage, strength, wrong drug dispensed)	7	3	9	2,2	100	Y	N	N	Y
2.4.c	The patient safety around an alternative is underestimated owing to lack of attention to the conversion of strength	Errors in the medication process (incorrect dosage, wrong drug dispensed); improper treatment	6	3	9	2,3	100	Y	N	N	Y

(*continued*)

Sub-task	Regional-level	Potential consequences (SHERPA analysis)	Risk ratings					Decision tree			
	Failure mode (including potential cause)		Median hazard score	Minimum	Maximum	Standard deviation	Response rate (in %)	Single Point Weakness?	Existing Control Measure?	Detectability	Proceed?
2.4.d	The patient safety around an alternative is underestimated owing to lack of attention to another management procedure	Errors in the medication process (incorrect dosage, strength, wrong drug dispensed); improper treatment	6	3	9	3,7	100	Y	N	N	Y
2.4.i	Patient safety not assessed at all	Errors in the medication process (incorrect dosage, strength, wrong drug dispensed)	6	4	9	1,9	83	Y	N	N	Y

Appendix 3. Local level

Table containing critical failure modes left for further analysis, including the determined hazard scores, consequence analysis from SHERPA and the elements of HFMEA decision tree.

Sub-task	Local-level	Potential consequences (SHERPA analysis)	Risk ratings					Decision tree			
	Failure mode (including potential cause)		Median hazard score	Minimum	Maximum	Standard deviation	Response rate (in %)	Single Point Weakness?	Existing Control Measure?	Detectability	Proceed?
1.2.a	Searching for a “wrong” drug owing to lack of knowledge of a DS	Wrong prescription; The drug is unavailable at dispensing in the medication room, followed by the wrong drug administered to the patient	6	1	8	3,6	50	Y	N	N	Y
1.2.b	Searching for a “wrong” drug owing to lack of attention to a DS (forgotten knowledge)	The drug is unavailable at dispensing in the medication room; delay in patient treatment	4	1	8	3,3	66	Y	N	N	Y
1.3.a	Prescribing the wrong dose - information about the new dosage is missing	Medication errors; Improper patient treatment	8	8	12	2,2	83		N	N	Y
1.3.b	Prescribing of incorrect strength - the “usual” amount and/or type of solvent is prescribed	Medication errors; Improper patient treatment	10	4	12	3,8	66		N	N	Y
1.3.c	Prescribing the wrong route or form of administration	Medication errors; Improper patient treatment	8	1	9	3,6	83		N	N	Y
1.3.d	Prescribing the wrong frequency of a drug	Medication errors; Improper patient treatment	8	1	9	3,8	83		N	N	Y
1.4.a	The duration of the treatment does not match the new alternative drug (too short)	Improper treatment period (too short) with the risk of an additional treatment	6	4	6	1,2	50	Y	N	N	Y
1.4.b	The duration of the treatment does not match the new alternative drug (too long)	Improper treatment period (too long); adverse patient outcome (side effect, overdose etc.)	6	4	6	1,2	50	Y	N	N	Y
1.5.a	The drug is not re-assigned to a drug available in the medication inventory room	time spent searching for the drug; delay in treatment owing to ordering the drug at hospital pharmacy	11	3	16	5,5	66		N	N	Y
1.6.a	The monitoring may occur too late, as one is unfamiliar of another monitoring routine owing to a drug change	Improper treatment (too long/short, no follow-up, assessing effect, changes etc.)	6	6	12	3,5	50	Y	N	N	Y
1.6.b	The monitoring may occur too soon, as one is unfamiliar of another monitoring routine owing to a drug change	Improper treatment (too long/short, no follow-up, assessing effect, changes etc.)	6	6	6	0	50	Y	N	N	Y
1.6.c	The monitoring of a drug change is not prescribed	Improper treatment (too long/short, no follow-up, assessing effect, changes etc.)	4	3	4	0,6	50	Y	N	N	Y

(continued on next page)

(*continued*)

Sub-task	Local-level	Potential consequences (SHERPA analysis)	Risk ratings					Decision tree			
	Failure mode (including potential cause)		Median hazard score	Minimum	Maximum	Standard deviation	Response rate (in %)	Single Point Weakness?	Existing Control Measure?	Detectability	Proceed?
2.3.g	The drug cannot be located and the dispensing is omitted/ delayed	Delayed or omitted patient treatment	9	1	12	4,6	83		N	N	Y
2.4.a	The electronic IT system does not accept or register the barcode scanning	The wrong drug is dispensed (medication error)	4	3	9	2,7	66	Y	N	N	Y
2.4.b	The barcode is not working	The wrong drug is dispensed (medication error)	4	4	6	1	66	Y	N	N	Y
2.4.c	A barcode is unavailable on the packaging of the drug	The wrong drug is dispensed (medication error)	4	3	6	1,5	50	Y	N	N	Y
2.4.f	Lack of knowledge of the barcode message “wrong drug “, as the barcode is generally not working and the routine is automatically to mark that “the barcode is not working” in the system	The wrong drug is dispensed (medication error)	3	2	12	5,5	50	Y	N	N	Y
2.5.a	Incorrect dosing owing to calculation challenges	Medication error (wrong strength); adverse patient outcome	6,5	3	12	4,2	66	Y	N	N	Y
2.5.e	Incorrect management of the alternative drug, as one follow routines and manage in accordance to the drug it replaces	Improper patient treatment; medication error; adverse patient outcome	3	2	8	2,8	66	Y	N	N	Y
2.5.f	Incorrect management owing to a lack of knowledge/information about the alternative drug	Improper patient treatment; medication error; adverse patient outcome	5	1	8	3	66	Y	N	N	Y
2.6.a	The drug is prepared incorrectly	Improper patient treatment; medication error; adverse patient outcome	5	4	8	1,9	66	Y	N	N	Y
2.6.b	The drug is prepared incorrectly owing to calculation error	Improper patient treatment; medication error; adverse patient outcome	4	4	6	1	66	Y	N	N	Y
2.6.c	Wrong dissolvent used owing to drug changes (drug prepared incorrectly)	Improper patient treatment; medication error; adverse patient outcome	3	2	6	2,1	50	Y	N	N	Y
2.6.d	Wrong dissolvent used owing to look-alikes (drug prepared incorrectly)	Improper patient treatment; medication error; adverse patient outcome	3	2	3	0,6	50	Y	N	N	Y
2.6.e	Wrong dissolvent used owing prescribing error of dissolvent (drug prepared incorrectly)	Improper patient treatment; medication error; adverse patient outcome	2	2	4	1,2	50	Y	N	N	Y
2.6.f	Incorrect management as the alternative drug's management procedure is changed, e.g. reduced volume per ampule requires more ampules to administer (takes more time)	Improper patient treatment; medication error; adverse patient outcome	4	4	8	2,3	50	Y	N	N	Y
2.6.g	Incorrect management of the alternative drug, as routines and management are followed in accordance to the drug in shortage	Improper patient treatment; medication error; adverse patient outcome	4	2	12	5,3	50	Y	N	N	Y
2.6.h	Incorrect management, as the preparation guideline for a new drug is unavailable	Improper patient treatment; medication error; adverse patient outcome	8	3	12	4,5	50		N	N	Y
3.4.c	The patient takes the medication at home wrongful owing to procedural changes in administration	Improper patient treatment; medication error; adverse patient outcome	6	5	6	1,2	50	Y	N	N	Y
3.4.d	The [self-administering] patient does not want to take the medicine at home	Impairment of condition	9	2	9	4	50		N	N	Y
4.1.a	The monitoring of a treatment are delayed compared the prescribed monitoring time	Improper patient treatment; adverse patient outcome	9	6	12	3	50		N	N	Y
4.1.b	The monitoring does not take place at all	Improper patient treatment; adverse patient outcome	9	6	12	3	50		N	N	Y

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