

# Drug change: 'a hassle like no other'. An in-depth investigation using the Danish patient safety database and focus group interviews with Danish hospital personnel

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## Abstract

**Background:** Drug change (DC) is a common challenge in Danish hospitals. It affects the work of hospital personnel and has potentially serious patient safety consequences. Focus on medication safety is becoming increasingly important in the prevention of adverse events. The aim of this study is to identify and describe patient safety challenges related to DCs, and to explore potential facilitators to improve patient safety in the medication process in Danish hospital setting.

**Method:** Two qualitative methods were combined. Data were obtained from the Danish Patient Safety Database (DPSD) containing incidents reports of adverse events related to DCs. Additionally, five semi-structured focus group interviews with hospital personnel (doctors, nurses, pharmacists and pharmacy technicians) from the five regions of Denmark were held.

**Results:** The DPSD search identified 88 incidents related to DCs due to tender or drug shortage. The incidents were linked to prescribing errors, incorrect dose being dispensed/administered, and delayed/omitted treatment. Four themes from the interviews emerged: (1) challenges related to the drug itself; (2) situational challenges; (3) challenges related to the organization/IT systems/personnel; (4) facilitators/measures to ensure patient safety.

**Conclusion:** DC is as a complex challenge, especially related to drug shortage. The results allow for a deeper understanding of the challenges and possible facilitators of DCs on the individual and organizational level. Pharmacy personnel were identified to play a key role in ensuring patient safety of DCs in hospitals. Indeed, this emphasizes that pharmacy personnel should be engaged in developing patient safety strategies and support hospital personnel around drug changes.

**Keywords:** drug change, drug shortage, facilitators and measures, hospital, patient safety challenges, tender

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## Introduction

Implementing drug change (DC) is a common challenge in hospitals. Causes are many and include drug shortages, tendering programs, and implementing new clinical guidelines.<sup>1</sup> Implementation may cause generic or biosimilar substitution, a more complex process of analog

substitution, or alterations in the preparation or administration of the drug.<sup>1-6</sup>

DC implementation is a field of growing scientific interest owing to patient safety issues as well as emerging evidence of the many resources consumed in the process.<sup>1-6</sup> In both Europe and the

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US, DCs affect the work of hospital personnel, doctors, nurses, pharmacists and pharmacy technicians, thus consuming a considerable amount of time.<sup>3,4,7</sup> A European survey described how nearly 90% of hospital pharmacists spend a minimum of 5 h a week managing drug shortages, with one third reporting spending more than 10 h.<sup>7</sup> In the US, drug shortages were estimated to result in an annual labor cost as high as US\$216 million.<sup>5</sup> Consequently, it is evident that drug shortages are a frequent, persistent and globally increasing problem across healthcare sector.<sup>3,6-9</sup>

Focus on medication safety is growing in importance. Ensuring patient safety in the medication process is a highly important and critical step given that drug-related adverse events have been reported as one of the most common type of errors experienced in hospital systems.<sup>10-12</sup> Further, patient safety must be ensured throughout the entire drug supply chain. Pharmaceutical companies must provide a stable delivery of drugs to avoid DCs caused by shortages. Drug shortage is reported to cause 1–5% error rates in hospitals in a survey with hospital pharmacy directors.<sup>13</sup> Several studies have shown that DCs induce a variety of medication errors with different causes and outcomes. Reported consequences include delayed or omitted drug treatment and the wrong dose or drug being administered/dispensed etc.<sup>1,4,10</sup> A Norwegian study reported that 42 of 100 nurses had experienced medication errors related to generic substitution, because doctors had failed to prescribe from revised drug lists owing to DCs caused by tender.<sup>1</sup> Recognition of and treatment with a new drug unfamiliar to hospital personnel are two of the challenges described in relation to DCs.<sup>1,6,14,15</sup> Although reports vary on patient harm owing to errors related to DCs, the literature describes how some errors reach patients and result in serious or even fatal outcomes.<sup>10,15,16</sup> Thus, DC challenges an otherwise safe and rational medication process.<sup>7,10,16,17</sup>

Since 2004 Danish healthcare professionals have been legally obligated to report any incidents of adverse events to the Danish Patient Safety Database (DPSD).<sup>18,19</sup> An adverse event is defined as ‘an event related to the health care practice for example, from treatment at or stay in a hospital, and which is not caused by the patient’s illness, but is concomitantly either harmful or could have been harmful.’<sup>19</sup> Adverse events

include ‘both previously known and unknown events and errors.’<sup>19</sup> The DPSD is designed solely to identify risk situations and is generally not a statistically applicable system.<sup>20</sup> The DPSD has received approximately 45,000–50,000 incident reports from public hospitals annually since 2011.<sup>21</sup> The incidents are subsequently used for learning and training purposes at both the local and national level in the Danish healthcare system.<sup>22,23</sup>

Coping strategies for DC and its consequences depend on several factors, including the cause of the DC, the organization of the hospital, and the educational level, knowledge, and experience of the hospital personnel involved.<sup>4,6,7</sup> At present, few studies have addressed this issue, and most of the available knowledge comes from general surveys, reviews, or case reports, which mainly provide knowledge at a general level.<sup>3,5,10,13,24</sup> Conversely, qualitative methods provide in-depth knowledge of the topic of interest through interpretation and understanding of contextual data.<sup>25</sup> In the present study, we analyze adverse events associated with DCs and the results combined with focus group interviews provide a detailed understanding of the challenges associated with DCs. This is a crucial step in the process of alleviating problems and ensuring patient safety in the medication process.

### **Aim**

The aim of this study is to identify and describe medication errors and patient safety challenges related to DCs, and to explore potential facilitators to improve patient safety in the medication process in the Danish hospital setting.

### **Methods**

Two qualitative methods were combined in the study, allowing complementary data collection on the same topic for data triangulation purposes.<sup>25</sup> Data were obtained from DPSD containing incident reports of adverse events, as well as from five qualitative focus group interviews.

### *The DPSD*

In this study, a qualitative analysis of incidents reported to DPSD was made between January 2011 and March 2014, representing approximately

150,000 incidents. DPSD was searched for incidents that were associated with DCs to elucidate the types of adverse events that occurs when DCs are implemented insufficiently in Danish hospitals. Incidents were included if DC (shortage, tender, etc.) was specifically mentioned or if they included drugs known to have undergone a DC at the time of the incident. Thus, search items included the names of all drugs changed due to tender or drug shortage lasting more than 30 days, as well as specific drugs identified by hospital risk managers. The time limit (30 days) was set to ensure that a possible DC had reached the clinic due to exhaustion of stocks in the hospital pharmacies. In addition, the following general search terms, and synonyms for tender and drug shortage were used in their Danish version: ‘contracts for tender,’ ‘licita,’ ‘lisita,’ and ‘drug shortage.’ Identified incidents were reviewed in detail by one author to ensure that the incident was relevant in relation to DC and the incidents were subsequently categorized into types of errors, using inductive coding.<sup>26</sup>

#### *Focus group interviews*

Five focus group interviews were held from January–July 2014 in the five regions of Denmark, with one focus group in each region. In order to acquire a thorough understanding of the DC experience of different hospital personnel, each focus group consisted of a doctor, a nurse, a pharmacist and a pharmacy technician. The participants were recruited through the hospital pharmacies in each of the five regions. However, one group was conducted without a nurse and another without a doctor ( $n = 18$ ). The participants were primarily recruited by purposive sampling. It allowed the researchers to select individuals who represented the demographics of practicing hospital personnel in Denmark in terms of practice area, age, gender, and years of experience.<sup>26</sup> Conversely, to ensure recruitment of participants in all five regions, convenience sampling was used to meet some practical challenges such as geographic proximity, availability at given time, and willingness to participate.<sup>27</sup> The doctors and nurses in the focus group interviews were specialized in geriatrics, nephrology, anesthesiology, neurology, cardiology, pulmonary medicine, and orthopedic surgery. In all the wards, pharmacy technicians and pharmacists provided pharmacy services, such as drug supply and implementation of DCs.

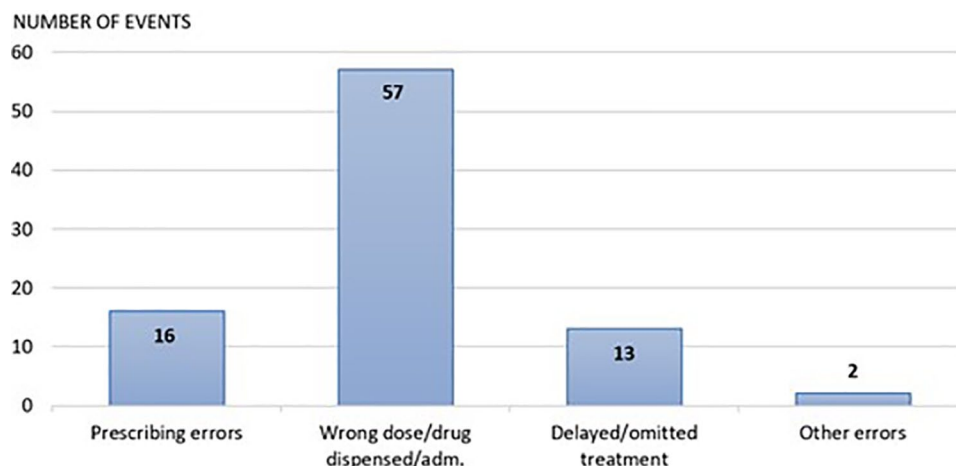
Prior to the focus groups, participants filled in a questionnaire concerning their experience with patient safety challenges associated with DCs in the different steps of the medication process.<sup>28</sup> Patient safety challenges included any situation that could potentially lead to an adverse event. The questionnaire also included experiences with the time required to manage drugs in such situations. A semi-structured interview guide was developed based on the questionnaires and included references to specific cases reported in the questionnaires. The interview guide contained the following topics: (1) an introduction, purpose, and consent; (2) patient safety challenges related to DCs; and (3) overcoming DC challenges. The interview lasted approximately 60 min, and the first focus group interview functioned as a pilot interview. As no changes were made in the interview guide after the pilot interview, data were included in the final analysis. One of the authors was the primary focus group facilitator, and one or two co-authors were present as observers. All interviews were tape recorded and subsequently transcribed verbatim.

Two authors analyzed the transcripts using inductive thematic coding, which is a subjective interpretation of qualitative data through the process of systematic identification and classification of meanings into codes and themes.<sup>26</sup> The transcripts were printed on paper, read twice to increase the general understanding and independently marked with different colors, where each color represented different patient safety challenges and facilitating strategies related to DCs. Any discrepancies were discussed and, if necessary, a third author assessed the analysis in order to determine the final themes. Within each color, cluster codes, summarizing the units of meaning, were assigned and subsequently grouped into subcategories.

#### **Ethics**

The Danish Patient Safety Authority granted approval to obtain data from the DPSD. Informed consent was obtained from each focus group participant. Consent indicated agreement to participate or withdraw from the study, to be audio recorded and for further use of the material.

All data were subsequently depersonalized. Thus, according to Danish legislation, no further ethical approval was needed, as Danish law exempts studies from a formal review, if no patients are involved.<sup>29</sup>



**Figure 1.** Type of error from the Danish Patient Safety Database (DPSD). Prescribing errors: prescription of wrong drug, prescription of the same drug twice, lack of prescription due to errors in the electronic medication system. Wrong dose dispensed/administered: situations where a wrong drug or dose is dispensed/administered due to for example, look-alikes, sound-alikes, changes in drug concentrations, situations where generic substitution is impossible. Delayed/omitted treatment: Situations where a drug/dose is delayed/omitted owing to, for example, unavailability of the prescribed drug in the medication inventory room, lack of knowledge of a unlicensed drug in terms of dispensing/administration. Other: error related to the administration rate of a drug, dispensing/administration of a drug past the expiration date.



**Figure 2.** Drug confusion (look-alikes) between saline and metronidazole provided by the same pharmaceutical company.

## Results

### *Incidents of adverse events reported to the DPSD*

From January 2011 to March 2014, a total of 2621 incidents with adverse events were identified in the DPSD using search terms as described. Of these, 88 incidents were associated with DCs. The identified incidents were categorized into

‘type of error’ revealing four overall categories, see Figure 1.

The categories show that errors occur in all steps of the medication process, from drug prescription to administration. The category ‘prescribing errors’ includes incidents where DCs result in prescription of the wrong drug or prescription of the same drug twice (active substance with different names). In two incidents, the electronic medication system did not allow for correct prescription of the alternative drug. Incidents related to the category ‘wrong dose/drug dispensed/administered’ covers situations related to dispensing the wrong drug owing to look-alike (37 events) and sound-alike (5 events) confusions. Interestingly, 19 out of 37 look-alike incidents are linked directly to drug confusion between saline and metronidazole, see Figure 2. In this case, the same pharmaceutical company provided both drugs because of tendering. This emphasizes how challenging a single DC can be. The remaining incidents in the category ‘wrong dose/drug dispensed/administered’ includes changes in drug concentrations or situations where generic substitution is impossible, resulting in dispensing or administering the wrong dose.

The category of ‘delayed/omitted treatment’ includes incidents where the underlying causes is

**Table 1.** Themes and subcategories from the focus group interviews (details and quotations in the text).

Theme 1: challenges related to the drug itself	Theme 2: situational challenges	Theme 3: challenges related to the organization/ IT systems/personnel	Theme 4: facilitators/measures to ensure patient safety
Change in drug names, labels and packaging	Analog changes/ substitution	Several therapeutic treatment regimens available in the same ward	Use of generic names
Change in drug strength	Difference in unit terms (e.g. units to mg)	Lack of updated electronic systems	Healthcare authorities should ensure that generics are registered with the same dose units, independent of the marketing authorization holder
Change in drug formulation or carrier or shelf life	Frequent DCs	Lack of electronic prescribing support	The role of the pharmacy: <ul style="list-style-type: none"> <li>• pharmacy services support DCs in inventory rooms</li> <li>• ensure timely communication and education related to DC</li> <li>• ensure timely update of guidelines and instructions for use</li> </ul>
Change in drug preparation	DC to unlicensed drugs (requires a compassionate use permit from the Danish Medicines Agency)	Lack of timely or inefficient communication about DCs	Centralize applications to the Danish Medicines Agency for compassionate use permits for unlicensed drugs
Change in clinical guidelines	Patient involvement in the medication process (e.g. self-medication)	Lack of trade name knowledge	Pharmacy and hospitals ensure timely update of and support to the electronic medication system
Change in devices (inhalation)	Change to extemporaneous drugs		Hospitals allocates extra time for drug information to patients who self-administer
Change in storage requirements	Acute situations		The role of Amgros <sup>1</sup> : <ul style="list-style-type: none"> <li>• include all financial aspects during tender</li> <li>• focus on look-alike risks and ensure availability of barcodes on drugs during tender</li> <li>• reduce risk of drug shortages through obligations in contracts or minimize DCs through longer tender periods</li> </ul>

<sup>1</sup>Amgros I/S, Copenhagen, Denmark is a company owned by Danish Regions that carry out tendering procedures for all Danish hospitals.<sup>30</sup>

lack of knowledge of the new drug in terms of availability, dispensing, preparation, and administration of the new drug. In addition, time used to acquire a drug from another ward/another hospital is also an underlying cause in this category. Treatment with unlicensed drugs challenged patient safety, as personnel has no knowledge of the new drug. Further, drug information may be given in a language unknown to hospital personnel. The category 'other errors' covers one incident

of a drug being infused too rapidly and one incident of a drug used after its expiration date.

#### *Focus group interviews: thematic analysis*

The thematic analysis revealed four major themes: (1) challenges related to the drug itself; (2) situational challenges; (3) challenges related to the organization/IT systems/personnel; (4) facilitators/measures to ensure patient safety. The

themes and subcategories are displayed in Table 1. In the following, selected subcategories will be represented by quotes from participants. Quotes were included in the results independent of the number of participants mentioning them. To ensure transparency we find it relevant to mention if a statement is based on one participant, several participants, or all participants. The participants are classified (numbered) according to their focus group affiliations, for example, FG1 doctor, FG1 nurse, etc.

### Assessment of the relevance of the problem

In general, participants had mixed feelings about DCs and shared different experiences with them:

*I spoke with one doctor today... He said that if there weren't so many drug changes, there wouldn't be so many related mistakes' (FG5 nurse)*

*It's a hassle like no other' (FG4 doctor)*

All participants agreed that DCs take a heavy toll on the hospital personnel involved. One-third of the participants expressed doubts about the actual financial savings related to DCs owing to tender, *versus* the extra time and resources required to safely implement the new drug into clinical practice.

*I think you have to consider what kind of drugs yield a financial benefit... If you try to calculate the extra time spent from everyone involved – Amgros [the pharmaceutical procurement organization], pharmacy, pharmacy technician and everyone in the clinic – I don't think there are any savings to be made' (FG5 pharmacist)*

*I asked my colleagues and they said to make sure to tell them [the research team] that it's more than just saving a few pennies compared to the errors and insecurity it may mean for patients' (FG3 nurse)*

### Theme 1: challenges related to the drug itself

All participants agreed that the greatest challenges related to DC were changes in drug names, labels, and packaging. The risk of dispensing or administering the wrong drug owing to look-alike and sound-alike errors was mentioned several times during all focus group interviews. Primarily

pharmacy personnel and risk managers were those who discovered errors related to these risks:

*The reason for the mistake was that the container size was completely identical for both 50ml and 100ml [saline]' (FG2 pharmacy technician)*

*It means something when you have five different Cephalosporines, right? Where you can't see the name difference, whether it's Cefotrix or Ceftriaxone, or another one. And it's five different drugs... It's a hassle and problematic' (FG3 pharmacist)*

*At the moment I find that Metronidazole and Natriumchloride from the same company are very much look-alike due to the nearly identical packaging' (FG1 pharmacy technician)*

Over half of the participants mentioned challenges related to changing inhalation devices, which prompt insecurity among both patients and hospital personnel. Further, the majority of participants also mentioned the risk of prescribing the same drug twice due to name confusion.

*I've seen it go really bad with Panodil/Pamol/ Paracetamol – you name it – where they've been prescribed twice.... because the doctor thought "I'll prescribe it [paracetamol] for the patient", but it turns out that the patient was getting the drug already' (FG4 doctor)*

*From what we've seen... We experienced a drug change from Ibuprofen to Burana and the latter doesn't make you think it's an NSAID [Non Steroidal Anti-Inflammatory Drug]. So, when you look at a patient's medicine status and the patient is in pain, you would suggest/prescribe Ibuprofen [generic] with the brand name Ibuprofen... You just don't connect them as being the same generics' (FG3 pharmacist)*

Changes in drug formulation or drug preparation also pose a risk of error, which could potentially lead to a risk of omission/delayed drug administration due to challenges such as identifying the new drug. A few of the participants acknowledged this consequence:

*Of course you spend more time dealing with shifts regarding a transition from a ready-to-use solution to a powder that needs to be mixed before use' (FG3 doctor)*

*'You're feeling insecure about whether it's the same [drug] and if you're allowed to administer it and then you'll wait until ward rounds and you've missed a dose... or displaced it' (FG1 doctor)*

## Theme 2: situational challenges

The participants identified specific situations where they felt challenged by DCs. For instance, situations where analog changes/substitution were required, for example, changing specific anticoagulants, caused a risk of calculating a wrong dose when changing to a drug with a different potency.

*'The changes in low molecular heparins... They don't have the same units [concentrations] and therefore it's a different dosage... It's just not that simple... It requires new instructions on departmental level...'* (FG1 doctor)

*'About Heparin, Innohep and Fragmin... There are so many variations within capped vial and volume that it's difficult to understand... There is also a variation in how many units you should be given, which is highly individual from one patient to another... So, it's a very difficult situation'* (FG4 doctor)

Further, several focus group interviewees also thought that insecurity concerning DC from one unit term to another poses a substantial risk of calculating and/or dispensing the wrong dose to patients:

*'All of a sudden they're changing [containers] and it's impossible to dispense the prescribed dosage... I don't care what it's called – I know how to handle it with other names, but all of a sudden it comes in other ampoules and then you aren't able to dispense the prescribed milligrams'* (FG3 nurse)

*'There is also an example with Penicillin where the unit went from millions to milligrams...it racked your brains in the beginning'* (FG1 doctor)

Similarly, all participants identified situations with unlicensed drugs as being highly resource demanding, even though pharmacy personnel played a major role in the application process. This was due to a combination of the time spent to apply for permission to prescribe the drug and the time spent to prescribe the drug in the electronic system, as well as to lack of knowledge or package insert written in a foreign language. This

often leads to omission/delayed drug administration or treatments.

*'...insecurity about what to do and what things you have to be careful about... side-effects... you're very insecure about these drugs not marketed in Denmark'* (FG2 pharmacist)

*'Of course, there's a difference with drug shortages... there's something about the information... I mean the material [package insert] that comes with it [unlicensed drugs]... If it's in German... I think personnel aren't competent to handle it and therefore it must affect the patients, because they [the personnel] don't get the right information about dissolving the drug'* (FG5 pharmacist)

Another patient safety challenge was patient insecurity about DCs, especially in situations where patients self-administer drugs. Several participants mentioned the risk of noncompliance if a new drug looks different, has different side-effects, or requires a change in administration method:

*'They can't figure it out [drug change] and then we have the hassle of their not wanting to take their medicine at all'* (FG4 doctor)

*'Patients feel insecure [about drug change]... Don't forget that their feeling of safety means everything in this context'* (FG3 nurse)

*'I remember a situation involving growth hormones for children. There was a drug change, which meant that parents had to have X times [X represents a fictive amount of time] instruction beforehand. It required many resources – parents felt insecure and the wards had to inform them about all these changes... And they [parents] had to be trained all over again'* (FG5 pharmacists)

## Theme 3: challenges related to organization, IT systems, and/or personnel

All participants mentioned challenges related to the organization, IT systems, and personnel. In particular, patient safety issues arose in situations where there was a risk of confusion between drugs, especially if the same therapeutically equal but generically different drug was available on the same ward in different formulations, for example oxycodone tablet/capsule/sustained-release tablet:

*'It's called Oxycodonehydrochloride... Regardless of whether it's a sustained-release tablet or capsule... you might prescribe capsules for daily administration instead of sustained-release and the other way around... Or as a nurse, you might dispense the wrong one or have doubts about which one you were actually supposed to dispense' (FG1 pharmacist)*

Two participants explicitly mentioned having experienced challenges with the electronic system, because it did not support the generic substitution of the drugs available in the inventory room.

*'Most of our problems are that the electronic system doesn't meet expectations because it can't make generic substitutions... If it could there wouldn't be any problems at all' (FG1 doctor)*

*'It happens daily... It can be while dispensing whatever the drug is called, the system reports "prescribed drug unavailable in the ward". And it's due to a brand/generic name other than the one prescribed being available in the inventory room' (FG4 pharmacist)*

Timely and appropriate information about a DC (from pharmacy to ward personnel) was considered highly important but also challenging. The pharmacy personnel acknowledge the risk of nurses and doctors being unaware of a potential DC due to differences in the stock at each hospital ward:

*'The biggest challenge is to ensure that everyone gets the information without drowning in it...' (FG2 pharmacy technician)*

*'We [hospital pharmacy] try to send out the information [about an upcoming drug change] when a stock is empty; however, that is difficult as it varies from ward to ward' (FG4 pharmacist)*

#### **Theme 4: facilitators/measures to ensure patient safety**

The participants identified different facilitators and measures supporting patient safety with regard to DCs on a general level. For instance, participants in all focus groups identified a patient safety facilitator related to using generic drug names instead of trade names in instructions and guidelines:

*'We're actually trying to use generic drug names in our guidelines' (FG2 doctor)*

*'I encourage the wards to use generic drug names... But then again, you'll have all the generics names, but what specific drug is it referring to... I mean, they may not know that either' (FG5 pharmacist)*

Barcode scanning is implemented as a patient safety measure in one of the five regions. However, participants from that specific region found barcode scanning time consuming and problematic, because not every drug has a barcode:

*'In every hospital in this region, the drugs are barcode scanned during dispensing. Therefore it's simple – you can't have drugs here [in the medication room in hospitals] unless they have a barcode' (FG1 doctor)*

*'We've been bad at barcode scanning in general, because a lot of the drugs haven't had barcodes' (FG1 nurse)*

In general, pharmacy personnel were regarded as a primary source in relation to facilitating safety measures, hence playing a major role in improving patient safety with regard to DC. All participants found pharmacy services readily accessible regardless of types of enquiries:

*'I often call on you [pharmacy]... Asking for help in general' (FG4 doctor)*

*'We use the pharmacy a lot. They've helped us dispense medicine during a very busy period and we learned a lot about how to handle medicine and so on' (FG5 nurse)*

Pharmacy personnel used post-it notes and a clear division of look-alike drugs in the inventory room as two ways to improve patient safety regarding DCs:

*'First of all we made notes stating that the sustained-release tablet was equal to Oxycontin [original brand name for oxycodone] and capsules were equal to Oxynorm [original brand name for oxycodone]... And we separated them on the medication shelves' (FG1 pharmacist)*

*'It works really well with the notes in the dispensing room... For example, Pantoloc and Lanzoprazole... They've changed and they come in identical packaging... So they're placed opposite each other for a while until we've gotten used to the change' (FG1 nurse)*



Pharmacy newsletters were used as a facilitator for ensuring timely communication and extra information about critical DCs.

*'The hospital pharmacy prepares these really good newsletters... I often bring them to morning conferences. We have like five minutes and I often present them there' (FG2 doctor)*

Similarly, regarding unlicensed drugs, a few doctors believed that pharmacy personnel played an important role in helping them apply for a 'compassionate use permit' from the Danish Medicines Agency. According to one pharmacist, ensuring Danish information about an unlicensed drug, for example information on package inserts, should be handled at a national level:

*'It's not rational that we're physically located in the different regions and all doing the same work translating into Danish [drug information insert for drugs not marketed in Denmark]. This should be handled at national level instead' (FG2 pharmacist)*

The majority of participants also mentioned Amgros' role as a potential facilitator to ensure a safe DC:

*'Drug shortages shouldn't be allowed when they [Amgros] have your back [as responsible for the tendering procedures]. It could be part of the tender process, because they [shortages] generate more work for others' (FG1 doctor)*

*'If it's legal in terms of tender, longer contracts could be made' (FG5 pharmacist)*

## Discussion

The analysis of incident reports and focus group interviews helped in identifying types of medicine related errors, the estimated severity of the problem, challenges for drug safety, and potential measures to improve safety. This study provides in-depth details of challenges experienced by Danish healthcare professionals in the hospital setting when DCs occur. To the best of the authors' knowledge, this is the first study to combine incident reporting with focus group interviews to explore the challenges and underlying problems related to DCs.

Drug shortages have become progressively common over the past decade and increasing

attention to their consequences has been reported in the literature worldwide.<sup>5-8,31,32</sup> Understanding the challenges and risk of errors associated with DC related to drug shortage is crucial in the process of improving patient safety in the medication process.<sup>6,8,11,32</sup> Regardless of origin, the risks that DCs pose to patient safety fall into two areas: increased risk of medication errors and adverse patient outcomes.<sup>6</sup> Our study supports this proposition, as data from DPSD revealed actual adverse events directly associated with DCs. The focus groups showed how DCs may indeed have potentially seriously impact on patient safety. Importantly, data from both DPSD and focus group interviews revealed that DCs do challenge all steps of the medication process from prescription to administration of the drug. It is clear from the focus group interviews that changing to an unfamiliar drug can have a significant negative impact on patient safety in the medication process. Other studies have also identified changing to an unfamiliar drug as a high risk situation related to drug shortage.<sup>6,14,15</sup> In addition, insecurity among hospital personnel may lead to medication errors or omitted or delayed treatment. This is in keeping with the most common patient outcomes caused by drug shortages identified by McLaughlin *et al.*<sup>10</sup>

Data presented in the current study were collected in 2014. The healthcare system is constantly developing, however, the DC situations from 2014 is still assessed to be of high relevance today. A released report from EAHP in 2018 displayed the impact of drug shortages on patient care.<sup>33</sup> The report is based on survey data from hospital pharmacists from 38 European countries. The main findings as a direct consequence of drug shortages include a delay of care/therapy, medication error, and adverse events. Facilitators and measures includes more timely and accurate information from manufacturers and suppliers, increased communication/collaboration, and the need for a central lead/agency to work on the problem to reduce duplication of efforts. Hence, the data obtained from this study in 2014 is still considered relevant.<sup>33,34</sup>

Both DPSD events and interviewees identified dispensing as a highly vulnerable process, in which look-alike and sound-alike challenges pose a great risk of error. These challenges have also been recognized in the literature.<sup>6,16</sup> Fox *et al.*<sup>6</sup>

specifically mention adverse events caused by a mix-up of containers due to look-alikes, similar to the metronidazole/saline cases found in the current study.<sup>6</sup> Barcode scanning could be a possible facilitator for preventing errors related to look-alikes; international studies have shown that barcode scanning is one viable way to reduce the number of drug dispensing and administration errors.<sup>35–37</sup> At the time of this study, only one Danish region had implemented barcode scanning in the medication process. However, a few participants found the existing barcode scanning system insufficient, because the scanner was unable to handle generic substitutions. In addition, some of the drugs did not even have barcodes or had unreadable barcodes, which was time consuming for hospital personnel. In response, these barriers are also identified in the literature to point out vulnerable situations for potential medication errors.<sup>6,38</sup>

Another patient safety facilitator was the use of generic names, which some of the focus groups' participants acknowledged. One main advantage of using generic names is that healthcare professionals do not have to remember all the different trade names. Similarly, using generic names would prevent the risk of double prescribing. However, not all drugs are suitable for generic prescribing, as described by Berman.<sup>37</sup> He found that drugs with the same generic names but different formulations (tablet *versus* sustained-release tablet) posed a risk of error in the medication process. The focus group interviewees also identified these findings. In addition, another study showed that drugs with the same generic names or complex trade names caused adverse events related to DC.<sup>1</sup>

In this study, one recurrent facilitator for ensuring safe DC was pharmacy personnel. Patient safety measures such as ensuring applications for unlicensed drugs, making a clear division of drugs in the inventory room, ensuring notification, and providing visible notes to hospital personnel were acknowledged by all the interviewees. These measures are in line with suggested strategies from the literature, especially in terms of reducing medication errors.<sup>4,15,37</sup> Indeed, pharmacy personnel showed an engagement and understanding of the patient safety issues created by DCs supporting that they play a key role in alleviating these challenges. Another important facilitator was timely

communication of DCs. Efficient management of drug shortages calls for communication between the implicated stakeholders,<sup>4,39</sup> and pharmacy personnel were regarded as an important stakeholder in terms of managing communication, and updating guidelines and instructions. Other studies have also identified information flow as an essential focus area in managing DCs owing to drug shortage.<sup>3,4,14,17</sup> However, timely communication and ensuring that messages about DCs reach everyone is difficult and can be extremely time consuming.<sup>4,17</sup> The pharmacy personnel in the focus group interviews acknowledged this.

Understanding patient safety challenges is the first step in alleviating them.<sup>8,15,32</sup> Little is known about specific measures and facilitators that may improve patient safety in relation to DCs, and they may depend on the specific situation and institution. In 2009, the American Society of Health-System Pharmacists (ASHP) published a guideline on managing drug shortages in hospitals and health systems.<sup>40</sup> This guideline provides an overview of vital measures needed to manage a shortage situation: from identifying a drug shortage to establishing a plan with communication and implementation of new procedures including potential DCs.<sup>40</sup> Other organizations such as the World Health Organization (WHO) and the European Association of Hospital Pharmacists (EAHP) have suggested similar measures for managing drug shortage. Their focus is also on regulatory authorities and their role in legislative strategies to minimize the impact of shortages.<sup>7,8</sup> The interviewees also recognized these issues by stating that national authorities or Amgros should support drug shortage management by ensuring that information is available about, for example, unlicensed drugs. Further research in this area is highly relevant to ensure clear distribution of roles, responsibility, and communication between hospital pharmacies and ward personnel, healthcare professionals, organizations, and regulatory authorities in Denmark.

### Strengths and limitations

Several studies explore different aspects of drug shortages, but they are based on quantitative survey data.<sup>3,5,10,13,24</sup> One strength of this study is the qualitative insight provided by four Danish healthcare professions combined with incident reporting to the DPSD. Conducting five focus

group interviews provided in-depth cross-organizational insight and detailed description into patient safety challenges related to DCs experienced by hospital personnel. The focus groups were very effective for collecting data allowing participants to discuss and interact with each other, just as the interviews provided an understanding of the different experiences and attitudes about DCs.<sup>26,41,42</sup> This resulting rich description constituted an important element in meeting different trustworthiness criteria (such as transferability).<sup>43</sup> Another strength is the study design, which provided complementary data on the same topic, as well as allowed for mixing data during the interpretation phase and thus use for triangulation purposes.<sup>25</sup>

We also estimate the credibility of the study to be high, as two researchers independently performed the coding of the focus group interviews and subsequently discussed potential discrepancies prior to determining final themes. Another credibility-enhancing strategy was the composition of the research team, which represented different experiences such as junior and senior expertise and experiences with both qualitative and quantitative research in the clinical pharmaceutical field.<sup>43</sup> The study also met with the fairness criteria, because the focus group interviews were based on the same interview guide, and the same thematic analysis was applied.

There are a few limitations to the study. For instance, the findings might not be fully representative of every single healthcare professional in the hospital sector. However, with this study we aimed to identify relevant phenomena, not to investigate how widespread they are. Other findings might have appeared if the study had included nurses and doctors with no or limited experience with pharmacy personnel and services. In Denmark, pharmacy services are purchased at departmental level and not every hospital department have chosen this. Thus, the management of DCs are handled by a staff nurse.

Another limitation that might challenge the credibility of the study is that only one researcher performed the identification and categorization of the adverse events from DPSD. Further, the focus group participants did not validate the thematic analysis. In terms of reported adverse events from the DPSD, it is important to emphasize that

these findings do not uncover the entire problem, because incident reporting systems only reveal 'the tip of the iceberg'.<sup>44-46</sup> Similarly, healthcare professionals do not always recognize incidents of adverse events, which are then not reported.<sup>44-46</sup> In the present study, we analyzed incidents of adverse events associated with DCs to elucidate the types of adverse events that occur when DCs are implemented insufficiently. Each relevant incident was assessed thoroughly in terms of understanding the DC challenges associated with it. An editorial by Charles Vincent in 2007 supported this way of treating data from reporting systems.<sup>47</sup> He stated that reporting systems can point to important problems and provide some understanding of causes. In addition, they serve an important function in raising awareness, in this case patient safety around DCs.<sup>47</sup> Thus, DPSD provides good qualitative information on the type of adverse events with detailed descriptions of the incidents, including cause, potential patient consequence, and preventive actions.<sup>22,48</sup>

### Conclusion

This study has identified DCs as a complex challenge, especially related to drug shortage situations. The results allow for a deeper understanding of the challenges and possible facilitators and measures of DCs on the individual and organizational level. Pharmacy personnel were identified to play a key role in ensuring patient safety of DCs in hospitals. Indeed, this emphasizes that pharmacy personnel should be engaged in developing patient safety strategies and support hospital personnel around DCs.

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### Conflict of interest statement

The authors declare that there is no conflict of interest.

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