Drug changes and shortages: A patient safety perspective

Background

Drug changes (DCs) and drug shortages (DSs) are common challenges in Danish hospitals. They affect the work of hospital personnel, are time consuming and have potentially serious patient safety consequences, such as medication errors and adverse patient outcomes. With an increasing focus on medication safety in healthcare, there is a need for identifying DCs´ and DSs' challenges, potential risks of failure and possible measures to improve the overall patient safety in the medication process in hospitals. In addition, DSs affects and involves many actors in hospitals, but little is known about the management, decision-making, collaboration and communication around DSs in Danish hospitals. Thus, the overall aim of the present PhD study was to contribute to the improvement of patient safety in the medication process in hospitals when challenged by DCs and DSs in secondary healthcare in Denmark.

Methods and results

Sub-study 1 combined two qualitative methods to obtain a detailed understanding of the medication process when challenged by DCs in Danish hospitals and to identify potential facilitators and barriers in this process. Data were obtained from the Danish Patient Safety Database (DPSD) and from five focus group interviews with hospital and pharmacy personnel (doctors, nurses, pharmacists and pharmacy technicians) from the five regions of Denmark. From the DPSD, 88 incidents related to DCs due to tender or DSs were identified, and the incidents were linked to prescribing errors, incorrect dose being dispensed/administered, and delayed/ omitted treatment. From the focus group interviews, four themes 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. DCs, particularly due to DSs, are a complex challenge in hospitals. Pharmacy personnel were identified as facilitators to ensure patient safe DCs implementation.

Sub-study 2 used direct observation combined with time-registration tools, such as eye-tracking, video recording and manual time tracking to study and analyze the time spend by hospital personnel in a DC situation following tendering while dispensing medicine to in- and outpatients in a hospital setting in the Capital Region of Denmark. Hospital personnel at the cardiology inpatient ward spent 20.5 seconds on dispensing one drug, which DCs increased up to 28.4 seconds. At the rheumatology outpatient clinic, DCs due to tender increased the time spent on handing out one drug from 8 minutes and 6 seconds to 15 minutes and 36 seconds. In addition, DCs due to DSs increased handout time to 16 minutes and 54 seconds. Statistical analysis revealed that DCs due to tender and DSs significantly increased the time spent on this function in both hospital settings.

Sub-study 3 used individual interviews to explore the communication, decision-making and collaboration around DSs and critical DSs management in Denmark by secondary healthcare actor representatives from Amgros, the procurement department of the hospital pharmacy in the Capital Region of Denmark (RAP-MLV), medicine suppliers, pharmaceutical wholesaler and distributors and the Danish Medicines Agency (DMA). Data were analyzed using a social constructivist approach, revealing that no common definition of a DS exists among the actors, but referential definitions related to "contract" and delivered "as expected" were identified. This leads to different initiation of DS procedures among actors and with a minimal coordination of efforts, work procedures overlap. Further, discrepancies in available DS information arise, as information is distributed through different electronic systems, unavailable to all actors. A joint decision in choosing an alternative drug exists between Amgros and RAP-MLV. However, diverse collaborative relationships between actors were found in the study, especially around the collaboration with the DMA, which were limited to medicine regulations and unlicensed medicine.

Sub-study 4 uses prospective risk assessments to identify potential patient safety risks associated with the management of DSs at three actor levels in Denmark, and based on a prioritization of risks, potential solutions are proposed to prevent failure. The Healthcare Failure Mode and Effect Analysis (HFMEA) was employed, and at national level, 71 failure modes were identified to the process of DS management, of which nine of them were rated as high risk. At regional level, 33 failure modes were identified, of which 9 were rated as high risk, and at local level, 63 failure modes were identified, of which 32 were rated as high risk. The high-risk failures were related to a lack of electronic IT support in the modules of the medication process, underestimation of patient safety aspects, and insufficient personnel training and patient information, and solutions were proposed to address these issues.

Conclusion

The four sub-studies in this PhD thesis have contributed new and valuable knowledge about the numerous patient safety challenges associated with drug changes and drug shortages in Denmark's secondary healthcare. These sub-studies provide holistic insights into the drug changes and drug shortages related management procedures, practices and processes that the many, highly diverse actors use at different actor levels. In addition, detailed knowledge has been garnered about the challenges, issues and potential failures associated with drug changes and drug shortages at the hospital ward level, including the implementation of drug changes due to tender. To meet the four sub-study objectives, the methodological approaches varied, using several methods in each sub-study to capture the many nuances respectively revealed. The PhD thesis is based on in-depth, extensive and detailed data about patient safety challenges due to drug changes and shortages.