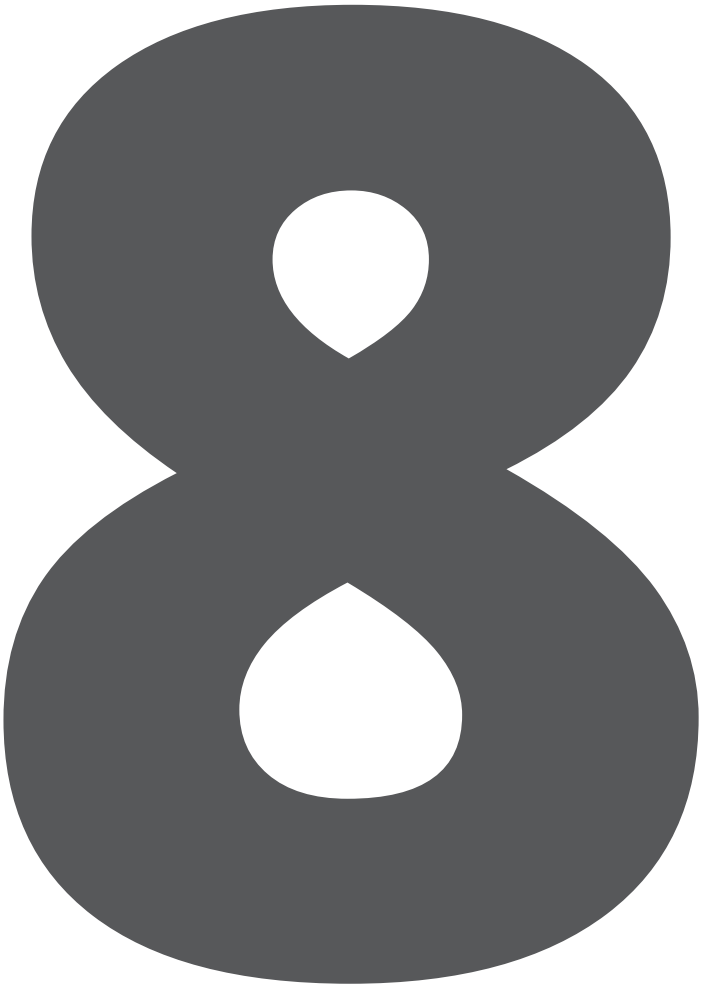
Information technology and medication safety

van der Veen, Willem



SUMMARY AND GENERAL DISCUSSION

SUMMARY

This thesis focuses on increasing our understanding of the use of Information Technology (IT) based interventions to enhance medication safety, such as Computerized Physician Order Entry (CPOE) and Bar-Code-assisted Medication Administration (BCMA). In this chapter, the main findings of our research are summarized and discussed.

In Chapter 2, we provide an overview of interventions to contribute to the safe administration of medication in hospitals and conclude that there is only limited scientific evidence on their effectiveness. IT-based medication safety interventions are most likely to improve medication safety. IT has the potential to contribute to standardization, transparency, proper documentation and structure of a process. Therefore, the use of IT-based interventions should eliminate most medication errors. However, despite this promising potential, various medication errors were reported while using IT-based interventions. Thus, technology-based interventions still need to be improved to prevent medication errors.

In chapter 3, we report the results of our study aimed to investigate the nature and consequences of IT-related medication incidents. We have analyzed a significant sample of medication errors, voluntarily reported by healthcare professionals in both hospitals and community pharmacies in the Netherlands. One out of six of these reported incidents were IT-related. The interaction between human and machine (IT-systems) played a critical role in these reports. The pharmacy information system (Apotheek Informatie Systeem, [AIS]) was most frequently involved in community pharmacies, while in hospitals the CPOE was most frequently involved. IT-systems need to match the user's standard workflow. IT-based systems in healthcare ask for skilled end-users to use these systems as intended. Our research shows that in almost four out of five reported IT-related errors the human end-user miscommunicated with the IT-system. Healthcare workers did not know how to respond to system output or computer jamming, and poor design caused input problems. System designers and software programmers should learn from error reports because the same errors are reported for different brands of software, each intended for the same purpose. Our results are in line with earlier research carried out by Magrabi et al. [1-3] and by Warm and Edwards [4], but we discovered more human-machine interaction related IT-errors and less general technical errors. These differences were possibly due to the improved classification we applied. Our study shows that organizations should be aware of imperfections in both system design and workflow. Healthcare providers should be attentive to design, software and hardware imperfections and unintended effects, potentially leading to errors, when using IT in healthcare. Our study emphasizes the importance to train health care workers in the use of IT-based interventions and to increase awareness of potential IT-system imperfections which could harm patients.

In chapter 4, we describe our study aimed to investigate whether performing risk analysis (prospective, retrospective, or a combination) contributes to the satisfaction of end-users with CPOE-implementation in 40 hospitals in the Netherlands. Risk analysis may disclose the possibilities and the risks of new IT-systems, and this may help end-users to become familiar with the new CPOE. For medical doctors, a statistically significant association between performing prospective and / or retrospective risk analysis and end-user satisfaction was shown. No such association could be demonstrated for either nurses or hospital pharmacists. Performing prospective risk analysis can be an excellent opportunity to involve end-users expectations and knowledge of IT-based interventions [5-7]. Unfortunately, performing a prospective risk analysis such as (Health) Failure Mode and Effects Analysis [H(FMEA)] is costly and time-consuming, requiring a balanced team [8], representing each group of stakeholders. The method focuses on only one healthcare process per risk analysis.

Moreover, the outcome of the analysis sometimes demands a firm decision by the hospital management. These (perceived) disadvantages may hamper broad implementation of prospective risk analysis when introducing new IT systems. However, failure to apply prospective risk-analysis may result in non-involved end-users which may, in turn, reduce their satisfaction with the IT system [9-11].

Chapters 5, 6 and 7 contain the design and results of our workaround study in four hospitals in the Netherlands, in which nurses used BCMA to administer medication. We identified workarounds in more than two-thirds of medication administrations, and these were significantly associated with medication administration errors. Workarounds appear to be the result of patient-ID and medication barcode scanning failures, technological difficulties, and nurses not following protocols.

Factors associated with workarounds were the administration of non-oral medication, medication from ATC classes which were infrequently given, the patient-nurse ratio, the day of the week, and the medication round shift. These findings are in line with studies of Debono et al. [12,13] which found nurses' performing workarounds as a response to operational failures, time pressure, workflow restraints, ward-rules, guidelines, and regulations.

GENERAL DISCUSSION

Considerations about the use of different data sources in our research

In this thesis, a range of different data sources was used. All of them have their advantages and disadvantages. Reporting systems that focus on safety improvement are generally 'voluntary reporting systems.' Voluntary reporting systems usually focussed on errors that resulted in no harm (sometimes referred to as "near misses") or very minimal patient harm [14]. These reports aimed to identify vulnerabilities in healthcare systems before they could harm patients, while mandatory reporting systems are focussed on serious patient harm and deaths. Nevertheless, voluntary error reports as we use in the IT-related incidents study may be hampered by underreporting, selective reporting and the influence of process changes on reporting. However, voluntary incident reporting and subsequent analysis of these reports could be an important strategy to enhance safety. Voluntary error reports provide more information about errors and their causes than mandatory reports do [15,16]. Moreover, healthcare professionals do realize themselves that other professionals can learn from the reported errors [17].

In our CPOE-risk analysis study, we performed a survey using questionnaires. The main advantage of using questionnaires is that the researcher can reach a large number of people collecting quantitative data. Some disadvantages may be respondents misinterpreting the questions or giving socially desirable answers [18]. The response rate in our research was over 88%. Therefore another known limitations of this method, the low response rate, was not applicable in our case. On the other hand, questionnaires have proven to be an excellent method to obtain data about opinions, attitudes, values, experiences, and behavior in scientific research with satisfactory quality [19].

In the workaround studies, we used disguised observation of nurses as the method of data collection. Observation is considered to be the best method for data collection in medication administration error studies [20-22]. However, bias may occur: the observations may influence the nurse but, from the literature, we know that this effect (known as the Hawthorne effect) is small [23]. Also, the observer may also become tired and thus less accurate. Bias may also occur when the same assessor is responsible for identifying both workarounds and medication errors from the observations. In retrospect, to avoid bias, it would have been better to have two independent assessors: one to identify the medication errors and one to identify the workarounds from the observations.

In Australia, researchers developed an elegant observation system called 'Work Observation Method By Activity Timing' (WOMBAT) [24-27]. This well-designed paperless method of activity registration is used for time- and activity-based observations of nurses working

with patients on the wards. Redesigning this software for more than only observing activity but also with a focus on the effects of activities may render it suitable for observing and, afterward, documenting workarounds and Medication Administration Errors (MAEs) as well. Researchers may also consider making video recordings during the actual process of medication administration to inpatients and assess them concerning workarounds and medication errors afterward as was used by Sitterding [28] and colleagues to research nurse awareness and interruptions during medication administration. However, video recordings may be hampered by privacy constraints.

Recommendations for daily practice

The findings of the studies compiled in this thesis, come with several suggestions for improving the effective use of IT-based interventions.

- More needs to be done to raise awareness for the classification of IT-based medication errors as this can give healthcare professionals insight into the various types of unintended consequences of the use of IT-based interventions. This may enable them to design specific interventions to prevent those incidents in the future use of IT. Also, system designers and software programmers of IT-based interventions may use the results of error reporting and classification to improve the design and especially the user interface of IT systems.
- Medical doctors and nursing teams also need to be better trained in technological skills aimed to help them with the proper use of IT-based interventions. Concerning CPOE and BCMA, the pharmacist could help in periodically analyzing errors and workarounds in the daily use of IT-based interventions. Because humans are pivotal in using IT-based interventions [29] in healthcare, IT should be lean in both programming and use, and involvement of future end-users, e.g., by performing prospective risk analyses by these users in the implementation of the intervention can improve its use.
- Based on our finding that nurses' frequently practiced workarounds, we urge for more post-implementation evaluation of IT-based interventions to prevent these workarounds. Furthermore, after the implementation of IT-based interventions, ward managers have to listen to comments and complaints from their staff to identify and prevent workarounds. Managers must also ensure enough nurses to be employed for the number of patients or activities. Additional training of nurses in procedures that they do not perform very often (such as infrequently used drugs administered to patients) can be useful [30].

Suggestions for future research

Given the association of workload with workarounds, it is recommended to study interventions aimed to reduce workload for nurses. An example of a workload reducing intervention may be the appointment of dedicated personnel - such as pharmacy techni-

cians – who are solely responsible for medication administration. Pharmacy technicians are trained to handle medication as the main part of their daily work, in contrast to nurses for whom medication administration is only a part of their daily routine. Besides that, most hospital pharmacies in the Netherlands are well equipped with state of the art technology, and pharmacy technicians are well trained to use that technology as intended. Although pharmacy technicians are not legally authorized to administer parenteral drugs to patients, this obstacle may be overcome by additional training.

Medication self-administration by patients may be another practical solution to reduce workload. Fundamentally, no one should be more dedicated to the proper administering of medication than the patient himself. Research by Vanwesemael et al. [31] showed that competent patients acknowledged benefits such as an increase in autonomy, independence, and knowledge of their medication. Patients did not expect self-administration would cause important safety issues [32]. More research is needed on the effects of self-administration on medication errors and patient compliance [33-35].

In hospitals, there is a need for strategies to promote error recovery; that is, people's ability to intercept errors and prevent patient harm [36]. Broader application of the Healthcare Failure Mode and Effect Analysis (HFMEA) technique is desirable. Performing such an HFMEA analysis in hospitals is often a struggle, demanding both limited available workforce and money. On the other hand, modified HFMEA procedures such as 'm-HFMEA' [37], and 'HFMEA light' [38] give opportunities for a more efficient and effective realization of prospective risk analysis in hospitals. Still, further research on the effect of prospective risk analysis on the successful implementation of new IT systems is needed, as our research is only hypothesis-generating because of the retrospective design.

Last but not least, new IT interventions are needed. Bedside identification of medication by using Radio-Frequency IDentification (RFID) of a pill and identification system such as MedEye [39], instead of barcoding could be very promising [40-42]. Application of blockchain technology could contribute to medication safety as well. The blockchain technology is at this moment mostly associated with Bitcoin, Ethereum, and other cryptocurrencies. However, blockchain is at its heart a digital ledger that is designed to track any transaction in the system securely and transparently. Because every system transaction is trusted, inalienable and present in the system of each of the participants, blockchain based technologies possibly can be used to enhance medication safety. Until now little research [43,44] has been done to examine whether or not these techniques are of use in daily practice. However, as is demonstrated by our research, we must remain alert to mistakes and shortcomings when introducing new information technology. The dangerous decade has not finished yet [45].

CONCLUSIONS

The studies combined in this thesis extend our understanding of the use of IT-based interventions in healthcare to prevent medication errors. Risks associated with the use of these IT-systems may arise from the systems themselves, the way they are implemented and how healthcare professionals in daily practice use them. Performing risk analyses, using results of voluntary error reporting, preventing workarounds by paying more attention to infrequent nursing procedures, and optimizing the nurse-patient ratio on nursing wards, may all result in the more optimal use of IT. Thus, our thesis contributes to what IT-based interventions in healthcare are designed for: the improvement of medication safety.

REFERENCES

1. Magrabi F, McDonnell G, Westbrook JI, Coiera E. Using an accident model to design safe electronic medication management systems. *Stud Health Technol Inform*. 2007;129(Pt 2):948-952.
2. Magrabi F, Ong MS, Runciman W, Coiera E. An analysis of computer-related patient safety incidents to inform the development of a classification. *J Am Med Inform Assoc*. 2010;17(6):663-670.
3. Magrabi F, Ong MS, Runciman W, Coiera E. Using FDA reports to inform a classification for health information technology safety problems. *J Am Med Inform Assoc*. 2012;19(1):45-53.
4. Warm D, Edwards P. Classifying health information technology patient safety related incidents - an approach used in wales. *Appl Clin Inform*. 2012;3(2):248-257.
5. Habraken MM, Van der Schaaf TW, Leistikow IP, Reijnders-Thijssen PM. Prospective risk analysis of health care processes: A systematic evaluation of the use of HFMEA in dutch health care. *Ergonomics*. 2009;52(7):809-819.
6. Ashley L, Armitage G. Failure mode and effects analysis: An empirical comparison of failure mode scoring procedures. *J Patient Saf*. 2010;6(4):210-215.
7. Stojkovic T, Marinkovic V, Manser T. Using prospective risk analysis tools to improve safety in pharmacy settings: A systematic review and critical appraisal. *J Patient Saf*. 2017.
8. Ashley L, Armitage G, Neary M, Hollingsworth G. A practical guide to failure mode and effects analysis in health care: Making the most of the team and its meetings. *Jt Comm J Qual Patient Saf*. 2010;36(8):351-358.
9. Wierenga PC, Lie-A-Huen L, de Rooij SE, Klazinga NS, Guchelaar HJ, Smorenburg SM. Application of the bow-tie model in medication safety risk analysis: Consecutive experience in two hospitals in the netherlands. *Drug Saf*. 2009;32(8):663-673.
10. Hoonakker PL, Carayon P, Walker JM. Measurement of CPOE end-user satisfaction among ICU physicians and nurses. *Appl Clin Inform*. 2010;1(3):268-285.
11. Khajouei R, Wierenga PC, Hasman A, Jaspers MW. Clinicians satisfaction with CPOE ease of use and effect on clinicians' workflow, efficiency and medication safety. *Int J Med Inform*. 2011;80(5):297-309.
12. Debono DS, Greenfield D, Travaglia JF, et al. Nurses' workarounds in acute healthcare settings: A scoping review. *BMC Health Serv Res*. 2013;13:175-6963-13-175.
13. Debono D, Taylor N, Lipworth W, et al. Applying the theoretical domains framework to identify barriers and targeted interventions to enhance nurses' use of electronic medication management systems in two australian hospitals. *Implement Sci*. 2017;12(1):42-017-0572-1.
14. Kohn LT, Corrigan JM, Donaldson MS. *To err is human: Building a safer health system.* Washington, DC: National Academy Press; 2000:287.
15. Reason J. *Managing the risks of organizational accidents.* Taylor & Francis Ltd; 1997.
16. Cohen MR. Why error reporting systems should be voluntary. *BMJ*. 2000;320(7237):728-729.
17. Huynh C, Wong ICK, Correa-West J, Terry D, McCarthy S. Paediatric patient safety and the need for aviation black box thinking to learn from and prevent medication errors. *Paediatr Drugs*. 2017;19(2):99-105.
18. Kader P. Questionnaires: Use, value and limitations. *Nurse Res*. 1994;1(2):4-15.
19. McColl E, Jacoby A, Thomas L, et al. Design and use of questionnaires: A review of best practice applicable to surveys of health service staff and patients. *Health Technol Assess*. 2001;5(31):1-256.
20. Barker KN, Allan EL. Research on drug-use-system errors. *Am J Health Syst Pharm*. 1995;52(4):400-403.
21. Barker KN, Flynn EA, Pepper GA. Observation method of detecting medication errors. *Am J Health Syst Pharm*. 2002;59(23):2314-2316.
22. Flynn EA, Barker KN, Pepper GA, Bates DW, Mikeal RL. Comparison of methods for detecting medication errors in 36 hospitals and skilled-nursing facilities. *Am J Health Syst Pharm*. 2002;59(5):436-446.

23. Gale EA. The hawthorne studies-a fable for our times? *QJM*. 2004;97(7):439-449.
24. Westbrook JI. Development and testing of an observational method for detecting medication administration errors using information technology. *Stud Health Technol Inform*. 2009;146:429-433.
25. Westbrook JI, Ampt A. Design, application and testing of the work observation method by activity timing (WOMBAT) to measure clinicians' patterns of work and communication. *Int J Med Inform*. 2009;78 Suppl 1:S25-33.
26. Westbrook JI, Duffield C, Li L, Creswick NJ. How much time do nurses have for patients? A longitudinal study quantifying hospital nurses' patterns of task time distribution and interactions with health professionals. *BMC Health Serv Res*. 2011;11:319-6963-11-319.
27. Westbrook JI, Creswick NJ, Duffield C, Li L, Dunsmuir WT. Changes in nurses' work associated with computerised information systems: Opportunities for international comparative studies using the revised work observation method by activity timing (WOMBAT). *NI 2012 (2012)*. 2012;2012:448.
28. Sitterding MC, Ebright P, Broome M, Patterson ES, Wuchner S. Situation awareness and interruption handling during medication administration. *West J Nurs Res*. 2014;36(7):891-916.
29. Turner P, Kushniruk A, Nohr C. Are we there yet? human factors knowledge and health information technology - the challenges of implementation and impact. *Yearb Med Inform*. 2017;26(1):84-91.
30. Aggarwal R, Mytton OT, Derbrew M, et al. Training and simulation for patient safety. *Qual Saf Health Care*. 2010;19 Suppl 2:i34-43.
31. Vanwesemael T, Van Rompaey B, Petrovic M, Boussery K, Dilles T. SelfMED: Self-administration of medication in hospital: A prevalence study in flanders, belgium. *J Nurs Scholarsh*. 2017;49(3):277-285.
32. Vanwesemael T, Boussery K, van den Bemt P, Dilles T. The willingness and attitude of patients towards self-administration of medication in hospital. *Ther Adv Drug Saf*. 2018;9(6):309-321.
33. Tran T, Elliott RA, Taylor SE, Woodward MC. A self-administration of medications program to identify and address potential barriers to adherence in elderly patients. *Ann Pharmacother*. 2011;45(2):201-206.
34. Richardson SJ, Brooks HL, Bramley G, Coleman JJ. Evaluating the effectiveness of self-administration of medication (SAM) schemes in the hospital setting: A systematic review of the literature. *PLoS One*. 2014;9(12):e113912.
35. Barrett AM, Galletta EE, Zhang J, Masmela JR, Adler US. Stroke survivors over-estimate their medication self-administration (MSA) ability, predicting memory loss. *Brain Inj*. 2014;28(10):1328-1333.
36. Kessels-Habraken M, Van der Schaaf T, De Jonge J, Rutte C. Defining near misses: Towards a sharpened definition based on empirical data about error handling processes. *Soc Sci Med*. 2010;70(9):1301-1308.
37. Rah JE, Manger RP, Yock AD, Kim GY. A comparison of two prospective risk analysis methods: Traditional FMEA and a modified healthcare FMEA. *Med Phys*. 2016;43(12):6347.
38. Anonymous. Q-consult zorg ontwikkelt slimme tool voor de PRI. https://www.qconsultzorg.nl/actueel/q-consult-zorg-ontwikkelt-slimme-tool-voor-de-pri. Updated 2018. Accessed 07/01, 2018.
39. Anonymous. A complete closed loop, medication safety suite for hospitals and healthcare institutions. https://medeye.com/medeye-landing-en#medeye. Updated 2018. Accessed 07/01, 2018.
40. Wu S, Chen K, Zhu Y. A secure lightweight RFID binding proof protocol for medication errors and patient safety. *J Med Syst*. 2012;36(5):2743-2749.
41. Hwang Y, Yoon D, Ahn EK, Hwang H, Park RW. Provider risk factors for medication administration error alerts: Analyses of a large-scale closed-loop medication administration system using RFID and barcode. *Pharmacoepidemiol Drug Saf*. 2016;25(12):1387-1396.
42. Martinez Perez M, Vazquez Gonzalez G, Dafonte C. Evaluation of a tracking system for patients and mixed intravenous medication based on RFID technology. *Sensors (Basel)*. 2016;16(12):10.3390/s16122031.
43. Hwang Y, Yoon D, Ahn EK, Hwang H, Park RW. Provider risk factors for medication administration error alerts: Analyses of a large-scale closed-loop medication administration system using RFID and barcode. *Pharmacoepidemiol Drug Saf*. 2016;25(12):1387-1396.

44. Mackey TK, Nayyar G. A review of existing and emerging digital technologies to combat the global trade in fake medicines. *Expert Opin Drug Saf*. 2017;16(5):587-602.
45. Coiera E, Aarts J, Kulikowski C. The dangerous decade. *J Am Med Inform Assoc*. 2012;19(1):2-5.