

University of Wollongong - Research Online

Thesis Collection

Title: The application of the FMEA risk assessment technique to electronic health record systems

Author: Khin Than Win

Year: 2005

Repository DOI:

Copyright Warning

You may print or download ONE copy of this document for the purpose of your own research or study. The University does not authorise you to copy, communicate or otherwise make available electronically to any other person any copyright material contained on this site.

You are reminded of the following: This work is copyright. Apart from any use permitted under the Copyright Act 1968, no part of this work may be reproduced by any process, nor may any other exclusive right be exercised, without the permission of the author. Copyright owners are entitled to take legal action against persons who infringe their copyright. A reproduction of material that is protected by copyright may be a copyright infringement. A court may impose penalties and award damages in relation to offences and infringements relating to copyright material.

Higher penalties may apply, and higher damages may be awarded, for offences and infringements involving the conversion of material into digital or electronic form.

Unless otherwise indicated, the views expressed in this thesis are those of the author and do not necessarily represent the views of the University of Wollongong.

Research Online is the open access repository for the University of Wollongong. For further information contact the UOW Library: research-pubs@uow.edu.au

2005

The application of the FMEA risk assessment technique to electronic health record systems

Khin Than Win
University of Wollongong

Follow this and additional works at: <https://ro.uow.edu.au/theses>

University of Wollongong

Copyright Warning

You may print or download ONE copy of this document for the purpose of your own research or study. The University does not authorise you to copy, communicate or otherwise make available electronically to any other person any copyright material contained on this site.

You are reminded of the following: This work is copyright. Apart from any use permitted under the Copyright Act 1968, no part of this work may be reproduced by any process, nor may any other exclusive right be exercised, without the permission of the author. Copyright owners are entitled to take legal action against persons who infringe their copyright. A reproduction of material that is protected by copyright may be a copyright infringement. A court may impose penalties and award damages in relation to offences and infringements relating to copyright material.

Higher penalties may apply, and higher damages may be awarded, for offences and infringements involving the conversion of material into digital or electronic form.

Unless otherwise indicated, the views expressed in this thesis are those of the author and do not necessarily represent the views of the University of Wollongong.

Recommended Citation

Win, Khin Than, The application of the FMEA risk assessment technique to electronic health record systems, PhD thesis, School of Information Technology and Computer Science, University of Wollongong, 2005. <http://ro.uow.edu.au/theses/710>

NOTE

This online version of the thesis may have different page formatting and pagination from the paper copy held in the University of Wollongong Library.

UNIVERSITY OF WOLLONGONG

COPYRIGHT WARNING

You may print or download ONE copy of this document for the purpose of your own research or study. The University does not authorise you to copy, communicate or otherwise make available electronically to any other person any copyright material contained on this site. You are reminded of the following:

Copyright owners are entitled to take legal action against persons who infringe their copyright. A reproduction of material that is protected by copyright may be a copyright infringement. A court may impose penalties and award damages in relation to offences and infringements relating to copyright material. Higher penalties may apply, and higher damages may be awarded, for offences and infringements involving the conversion of material into digital or electronic form.

The Application of the FMEA Risk Assessment Technique to Electronic Health Record Systems

A thesis submitted in partial fulfilment of the
requirements for the award of the degree

Doctor of Philosophy

from

University of Wollongong

by

Khin Than Win
M.B.B.S, DCS, IDCS, MS-CIS

School of Information Technology and Computer Science
2005

Declaration

I, Khin Than Win, declare that this thesis, submitted in partial fulfilment of the requirements for the award of Doctor of Philosophy, in the School of Information Technology and Computer Science, University of Wollongong, is wholly my own work unless otherwise referenced or acknowledged. The document has not been submitted for qualifications at any other academic institution.

Khin Than Win
May 2005

ABSTRACT

Patient safety and Medical errors are of growing concern in the health care industry. Some errors are caused by preventable adverse events; identifying potential errors and preventing them would mitigate risk and hence enhance the safety. Electronic health records (EHRs) are an inherent part of the healthcare systems and thus it is imperative that errors do not originate from EHRs.

A thorough literature review indicated that *no* risk assessment methods currently exist for EHR systems. Project management risk and system security risk assessments do exist but not risk assessment of threats to safety. Accordingly, this research aims to develop a framework for the safety and dependability of EHRs, in order to analyse the risks associated with electronic health record systems.

This research has identified a relationship of dependability and data quality of EHRs and attributes for the safety assessment of EHRs. The research involved (i) developing a theoretical basis of safety, based on dependability and data quality, (ii) defining the safety attributes of EHRs, (iii) identifying the risk assessment method applicable to EHRs, and (iv) conducting case studies of EHRs in different healthcare settings.

A thorough understanding of EHRs is important to identify safety attributes of EHRs. Therefore, different EHRs, EHR systems around the world - their purposes, functionalities and information management - are all explored.

This study investigated different available risk assessment methods and analysed them against different case scenarios to determine the appropriate risk assessment method for EHRs. After careful consideration, Failure Mode Effect Analysis (FMEA) was identified as an appropriate method for EHRs risk assessment.

The idea and concept of risk assessment of EHRs were investigated by empirical studies on (i) the Community Health Information Management Enterprise (CHIME), Illawarra Area Health Service, and (ii) Maternal and Infant Network (MINET) database, South Western Sydney Area Health Service.

Results from the case studies indicated that safety attributes identified from this research are appropriate for EHRs and that FMEA is indeed a suitable risk assessment method for EHRs. This study has verified by case studies that data availability, reliability and security are all important for safety. Potential systems risks- such as patient misidentification, security breaches due to initial password, and incorrect linkage of data were identified from this research and notified to the appropriate personnel such as system administrators and health care providers. Improvements to the systems in question have been achieved through modifications based on the results uncovered from these case studies. It can be concluded that the safety attributes identified from this research are essential for the safety of EHRs. It was also discovered that system quality is just as important, and therefore should be included in any safety assessment of electronic health record systems. It was further found that the safety cultures of

organisations and healthcare providers are important in conducting risk assessment of EHRs.

Publications from this Thesis

1. **Win K.T.**, Croll P. (2005), Engineering Dependable Health Information Systems, In: Creating knowledge based healthcare organization, editors: Wickramasinghe N., Gupta J.N.D., Sharma S. K. Idea Group Publishing, pp 91-109
2. **Win K.T.**(2004), Identifying the risk assessment method applicable to the electronic health record systems, Proceedings of HIC2004, Brisbane, July 25-27
3. **Win K.T.**, Cooper J., Alcock C. (2004), Risk assessment of electronic health record system, Proceedings of COLLECTeR2004 Workshop, Adelaide, May 7-8
4. **Win K.T.**, Croll P., Cooper J. (2002), Introducing Risk Assessments to Electronic Medical Record Systems, Proceedings of Second International Conference on the Management of Healthcare and Medical Technology on: The Hospital of the Future, Chicago, Illinois, USA, July 28-30, 2002
5. **Win K.T.**, Croll P., Cooper J. (2002), Setting a Safety standards for electronic medical records, Proceedings of HIC2002, The Tenth Annual Health Informatics Conference, Melbourne, Australia, August 4- 6.
6. **Win K.T.**, Phung H, Young L, Tran M, Alcock C, Hillman K. (2004), Electronic Health Record System risk assessment: a case study from the MINET, Health Information Management Journal, vol.33, is. 2, 43-48

II. Other Related Publications by this author

7. **Win K.T.**, Croll P., Cooper J., Alcock C. (2002), Issues of Privacy, Confidentiality and Access in Electronic Health Record, Journal of Law and Information Science, vol.12, is.1, pp 24-45
8. Phung H, Young L, Tran M, **Win K.T.** (2004), Alcock C, Hillman K., Health informatics and health information management in maternal and child health services, Health Information Management Journal, vol.33, is. 2, pp 36-42
9. **Win K.T.**, Cooper J. (2004), Information Age, Electronic Health Record and Australia Healthcare, International Journal of Computer Internet and Management, Special Issue on Managing Healthcare Science And Technology For Effective Delivery (in press)
10. **Win. K.T** (2005), Web based personal health record systems evaluation, accepted for the Special Issue on "The application of Internet-based information and communication technologies to healthcare", International Journal of Healthcare technology Management” (in press)
11. Alcock C., Burgess L., Cooper J., **Win K. T.**(2004), Electronic Health Systems: Integration of Inconsistent Information in Heterogeneous Multidatabase Health Systems, Proceedings of COLLECTeR LatAm 2004, Santiago, Chile
12. **Win K.T.**, Cooper J., Croll P., (2003), Engineering Pragmatic Patient Consent in Electronic Health Record Systems, Proceedings of World

Congress on Medical Physics and Biomedical Engineering 2003,
Sydney, Australia August 24-29

13. **Win K.T.**, Croll P., Cooper J., (2003), Dependability: Important factor for the success of electronic health record systems, Proceedings of The eleventh Annual Health Informatics Conference, Darling Harbour, Sydney, Australia, 10 –12 August
14. **Win K.T.**, Croll P., Cooper J., (2003), Privacy, confidentiality and consent of electronic health record systems, Proceedings of The eleventh Annual Health Informatics Conference, Darling Harbour, Sydney, Australia, 10 –12 August
15. **Win K.T.**, Song H., Croll P., Cooper J. (2002), Implementing patient's consent in electronic health record systems, Proceedings of COLLECTeR 2002, Melbourne, Australia., December 1, 2,2002
16. **Win K.T.**, Croll P., Cooper J., Alcock C. (2001), Issues of Privacy, Confidentiality and Access in Electronic Health Record, In: Proceedings of Information Technology and Emerging Law, Wollongong, September 28.
17. **Win K.T.**, Selakovic G. (2004), Evaluative study of Web Based Personal Health Record Systems, Proceedings of COLLECTeR2004 Workshop, Adelaide, May 7-8
18. Song H., Croll P., **Win K.T.** (2003), A Prototype of Patient e-Consent in Access Control to Electronic Medical Records, Proceedings of Asia-Pacific Association of Medical Informatics (APAMI) conference, Korea

19. Song H., **Win K.T.**, Croll P.(2002), Patient e-consent mechanism: Models and Technologies, Proceedings of COLLECTeR 2002, Melbourne, Australia., December 1, 2,2002
20. Fuller A., **Win K.T.**, Di L. (2002), Experiences using case studies to teach risk, Proceedings of 32nd ASEE/IEEE Frontiers in Education Conference, Boston, November 6-9
21. Alcock C., Burgess L., Cooper J., **Win K.T.** (2001), The Rise of E-health in Australia: Electronic Health Records and Privacy Legislation. In; Proceedings of the Fourth International Conference on Electronic Commerce Research (ICECR -4). Dallas, Texas, USA. November 8-11, vol.2, pp 466-474

Acknowledgement

I would like to extend my heartfelt gratitude and appreciation to my Supervisor Professor Joan Cooper for her invaluable guidance and support throughout the course of this research for my Ph.D. degree. My sincere thanks and appreciation go to Professor John Fulcher for assisting me and guiding me through the thesis in the final stage. I am also indebted to Associate Professor Carole Alcock for her assistance in the final stages of preparation of this thesis.

I highly value the assistance of Dr. Hai Phung and the staff of Simpson Center for Health Services Innovative Research for helping me in collecting information for the Risk Assessment of the Maternal and Infant Network (MINET). I also wish to convey my thanks to Mr. Shane Simpson and the staff involved in Community Health Information Management Enterprise (CHIME), Illawarra Area Health Service for their time and for providing information for the risk assessment study of CHIME.

My deep gratitude goes to my parents and brothers for their encouragement and inspiration in all my undertakings. I would also like to express my love and gratitude to my husband Liming Qiang for his support and patience during this study. Finally, I would like to dedicate this thesis to my son Vincent, my pride and joy, who was born during the course of this work.

Table of Contents

Abstract	iii
Publications from this thesis	vi
Other related publications by this author	vii
Acknowledgement	x
 CHAPTER ONE	
FRAMING THE RESEARCH PROBLEMS.....	1
1.1. Statement of the research problem.....	1
1.2. Research questions.....	1
1.3. Research approach.....	2
1.4. Significance of the research.....	2
1.5. Aims of the Research.....	4
1.6. Chapter Summary	4
 CHAPTER TWO	
ELECTRONIC HEALTH RECORD SYSTEMS.....	7
2.1. Medical informatics defined:.....	7
2.2. Health Information Systems.....	8
2.3. Electronic Health Records – EHRs.....	9
2.4. Chapter Summary.....	22
 CHAPTER THREE	
FAILURES OF COMPUTER SYSTEMS IN HEALTH CARE.....	26
3.1. London Ambulance Service System.....	26
3.2. US Cedars Sinai Medical Centre.....	27
3.3. Therac 25.....	28
3.4. North Staffordshire <i>under</i> doses.....	30
3.5. Chapter Summary.....	30
 CHAPTER FOUR	
DEPENDABILITY OF ELECTRONIC HEALTH RECORD SYSTEMS.....	33
4.1. Dependability.....	33
4.2. Data quality.....	36

4.3. Data quality and dependability.....	38
4.4. Data entry methods.....	40
4.5. Data linkage and integration.....	45
4.6. Unique Patient Identifier.....	49
4.7. Data Standards.....	51
4.8. System Security.....	55
4.9. Safety.....	67
4.10. Mapping adverse medical events.....	71
4.11. Reliability.....	72
4.12. Cause and effect relationship of impaired quality data.....	72
4.13. Chapter Summary.....	76
 CHAPTER FIVE	
RISK ASSESSMENT OF ELECTRONIC HEALTH RECORD	
SYSTEMS.....	78
5.1. Introduction.....	78
5.2. Safety Systems.....	80
5.3. Levels of risk.....	82
5.4. Risk analysis.....	87
5.5. Chapter Summary.....	104
 CHAPTER SIX	
METHODOLOGY	106
6.1. Research Plan	106
6.2. Case Study Design	109
6.3. Data Collection	110
6.4. Case Studies Approach	112
6.5. Case Studies and their significance	114
6.6. Analytic Generalizing from Case Studies	116
6.7. Validity and Reliability	116
6.8. Chapter Summary.....	117
 CHAPTER SEVEN	
CASE STUDIES.....	118
7.1. Introduction.....	118
7.2. Risk Assessment Case Study of CHIME (Illawarra Area Health Service).....	119
7.3. Risk Assessment Case Study- MINET (Simpson Centre for Health Services Innovative Research).....	140
7.4. Chapter Summary.....	153

CHAPTER EIGHT	
CONCLUSION and RECOMMENDATION	162
8.1. Summary of Research Findings	162
8.2. Recommendations for Future Research	166
BIBLIOGRAPHY	170
Appendix	206
IBIS Baseline and follow up data forms	

Tables

Table 2.1	
Levels of electronic patient record identified by NHS, UK.....	15
Table 3.1	
Accidents of Therac25	29
Table 4.1	
Attributes of data quality.....	38
Table 4.2	
Relationship of data quality and dependability.....	39
Table 4.3	
List of error prone abbreviation.....	42
Table 4.4	
Criteria and characteristics of universal health care identifier	50
Table 4.5	
Medication errors.....	69
Table 4.6	
Medication prescribing errors in a teaching hospital.....	70
Table 4.7	
Medication errors in the HIV- infected population.....	70
Table 4.8	
Examples of Cause and Effect.....	72
Table 4.9	
Safety attributes of electronic health record systems.....	75
Table 5.1	
Example acceptability levels of electronic health records.....	84
Table 5.2	
Relationships between Risk assessment methods and the Framework	104
Table 7.1	
Probability and severity of risks.....	121
Table 7.2	
Hazard Score.....	121

Table 7.3	
Possible failure modes for login.....	123
Table 7.4	
Possible failure modes for client search.....	123
Table 7.5	
Possible failure of search in Patient Medical Index.....	123
Table 7.6	
Confidentiality of the system.....	132
Table 7.7	
Possible failure modes of CHIME.....	133
Table 7.8	
Problems encountered during using the system.....	136
Table 7.9	
Comments regarding the system.....	137
Table 7.10	
Possible failure modes for MINET.....	151
Table 7.11	
What 99.9% means.....	156
Table 7.12	
Relationship of identified safety attributes and case study results	159
Table 8.1	
Original contributions made by this thesis dissertation.....	165

Figures

Figure 2.1	
Information capture/data entry methods of EHR.....	21
Figure 4.1	
Dependability.....	35
Figure 4.2	
Dependability and its attributes.....	35
Figure 4.3	
Security and its attributes.....	56
Figure 4.4	
Venn diagram: User, Technology, Legislation.....	58
Figure 4.5	
Directive graph of medical errors.....	71
Figure 4.6	
Data and decision making.....	74
Figure 5.1	
Acceptability levels.....	84
Figure 5.2	
Fault tree analysis of hypersensitivity to drug.....	90
Figure 5.3	
Fault tree: wrong dose of medication.....	91
Figure 5.4	
Event tree analysis for failure of access to health records.....	93
Figure 5.5	
Processes involved in the laboratory test.....	96
Figure 5.6	
Subprocesses of process 1a. “Enter order”.....	97
Figure 5.7	
Failure mode of “Enter order”.....	97
Figure 5.8	
Failure mode for process 2 (Draw sample).....	97

Figure 5.9	
Failure mode for process 3(Process sample).....	98
Figure 5.10	
Failure mode for processes 4(Report) and 5 (Result filed).....	98
Figure 5.11	
Processes involved in giving medication.....	99
Figure 5.12	
Decision tree for FMEA.....	100
Figure 5.13	
Erroneous record.....	101
Figure 5.14	
Misidentification.....	102
Figure 5.15	
Wrong treatment.....	102
Figure 6.1	
Research Plan.....	107
Figure 6.2	
Approaches used in the risk assessment case studies.....	114
Figure 6.3	
Convergence of multiple sources of evidence: Single study.....	115
Figure 7.1	
Integrated clinical information program.....	119
Figure 7.2	
Processes involved in CHIME.....	122
Figure 7.3	
Processes involved in MINET database.....	142
Figure 7.4	
Possible failure modes from processes.....	142