Developing Evidence- based User Centered Design and Implementation Guidelines to Improve Health Information

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Structured Abstract

Purpose: The purpose of this grant is to improve health information technology (health IT) usability, specifically electronic health records (EHRs), given the pervasive use of EHRs and potential impact on safety.

Scope: The research focus of this grant is on (Aim 1) developing computational algorithms to facilitate the identification of health IT usability and safety issues from patient safety event (PSE) reports, (Aim 2) identifying specific usability issues that impact patient safety, and (Aim 3) developing tools to improve health IT usability and safety.

Methods: Clinical and human factors experts qualitatively analyzed PSE reports to identify health IT usability and safety related reports. Coded reports were used to develop computational algorithms to facilitate identification of patterns and trends in large databases of reports. Based on these results an EHR usability and safety evaluation tool was developed and tested with ten participants at two healthcare facilities.

Results: Aim 1: From a database of over one million PSE reports, a subset was sampled, and 5,287 reports were manually coded as likely or unlikely related to health IT. A unigram predictive approach showed the best performance. Aim 2: Analysis of PSE reports showed an association between EHR usability and patient safety in both adults and children. Data entry and alerting usability issues were prominent for adults and system feedback and alerting were prominent for children. Aim 3: The EHR usability and safety evaluation tool identified eight usability issues at one site and seven at another showing promise for use of such a tool.

Keywords: health information technology, electronic health records, patient safety, human factors, usability

Section I: Purpose

Objectives of the study

Our objective was to pinpoint health information technology (IT) related patient safety gaps in current health IT systems, based on retrospective analysis of tens of thousands of safety event reports, and use this knowledge to inform the development of materials to improve health IT systems. These materials may include design and implementation guidelines, test case scenarios, and risk assessment tools.

This project included three aims:

Specific Aim 1. Identify health IT-related patient safety events from large patient safety event databases using natural language processing and machine learning techniques in combination with manual review.

Specific Aim 2. Systematically categorize the health IT patient safety events into usability design or implementation related and identify the specific user-centered design or implementation process that would have prevented the patient safety event.

Specific Aim 3. Develop, test, and disseminate materials to improve the safety of health IT systems. We originally proposed to develop design and implementation guides. However, through the course of the grant we determined that these would not be useful to health IT vendors or healthcare facilities. Instead, we developed an EHR usability and safety evaluation tool that can be self-administered by healthcare facilities.

Section II: Scope

Background

For health IT to reach its full potential of dramatically improving healthcare quality and safety, the technology must be deliberately designed, developed, and implemented with a focus on usability and safe use. To achieve health IT usability and safety vendors must employ a rigorous user centered design (UCD) process when developing their product and, when the product is purchased, it must be implemented appropriately. There is general dissatisfaction with health IT and these technologies present patient safety risks. Health IT improvements will require identification of specific usability and safety issues, development of methods to improve the technology, and adoption of these methods by vendors and healthcare facilities.

Context

To address challenges with health IT usability and safety the MedStar Health National Center for Human Factors in Healthcare partnered with computer scientists from Georgetown University and clinical experts from the Institute for Safe Medication Practices. We analyzed a large dataset of patient safety event reports to identify health IT related usability and safety issues, developed computational algorithms to assist with characterizing the impact of health IT on patient safety, identified critical health IT usability and safety issues through usability testing, and created a usability and safety assessment tool for use by healthcare facilities.

Settings

The health IT usability and safety evaluation tool was developed for inpatient settings and was tested at two large healthcare systems on the East coast of the United States.

Participants

The participants in this study were five resident and attending internal medicine physicians and five resident and attending emergency medicine specialists.

Section III: Methods

Given the numerous analyses performed under this multi-year grant we have segmented the methods by aim.

Aim 1: A diverse team of subject matter experts including a physician, nurse, pharmacist, and human factors engineer reviewed thousands of patient safety event reports to identify those that are both health IT usability and safety related. From these coded data machine learning and other statistical algorithms were developed to semi-automatically categorize a patient safety event as being health IT and/or usability related. The algorithms were applied to a larger uncoded dataset of patient safety event reports to determine if the algorithms could identify EHR usability and safety reports. The same diverse team of experts reviewed these reports to determine algorithm accuracy.

Aim 2: A team of human factors and usability experts, with physicians, pharmacists, and nurses, reviewed the health IT patient safety event reports that were identified as usability related and identified specific usability challenges from the reports. This was done with reports related to adults and pediatric populations. For the reports related to adults, we used a filtering process to distill a large dataset of over 1.7 million reports to those most relevant by focusing on reports that explicitly mentioned an EHR vendor and resulted in patient harm. For the pediatric reports we applied the algorithm developed as part of Aim 1 and focused on medication related reports to identify EHR usability issues. These reports were sourced from three large healthcare systems.

Aim 3: A diverse team of subject matter experts including a physician, nurse, pharmacist, and human factors engineer developed an EHR usability and safety evaluation tool to identify specific risks and to provide guidance on how to address those risks. This tool was tested at two sites with five participants from each site. During this testing the participant completed the self-assessment tool by recording their responses and the interaction with the EHR was screen recorded.

Section IV: Results

Results are described by aim and pointers to specific publications that provide greater detail on both the methods and results are provided.

Principal Findings and Outcomes

Aim 1. From a database of over one million reports, a subset was sampled, and 5,287 patient safety event reports (PSEs) were manually coded as likely or unlikely related to health IT and were used to train unigram, bigram, and combined unigram-bigram logistic regression and support vector machine models using five-fold cross validation. A difference-based scoring approach was used to prioritize and select unigram and bigram features by their relative importance to likely and unlikely health IT reports. A held-out set of 2000 manually coded reports were used for testing. Unigram models tended to perform better than bigram and combined models. A 300-unigram logistic regression model had comparable classification performance to a 4030-unigram SVM model but with a faster relative run-time. The 300-unigram logistic regression model evaluated with the testing data had an AUC of 0.931 and a F1-score of 0.765. A more detailed description of the results can be found in publication number eight in the journal publication list.

We also examined the use of active learning as an approach to reduce the burden of manually coding reports to develop different algorithms. We found that an active learning approach can be used in certain contexts. A more detailed description of this work can be found in publication number one in the journal publication list.

Focusing specifically on medication related patient safety events we also explored having natural language processing expertise as part of the patient safety event review committee. This work demonstrated that having this expertise can expedite review and discussion of some medication errors.

The outcomes from Aim 1 are a set of algorithms that can be applied to any database of patient safety event reports to identify health IT related reports from the free-text description in each report.

Aim 2. The analysis of EHR usability related patient safety reports with adult populations showed that the most common usability issues were related to data entry (27% of reports), alerting (22%), interoperability (18%), visual display (9%), availability of information (9%), system automation and defaults (8%), and finally workflow support (7%). A more detailed description of this work can be found in publication number six in the journal publication list.

The analysis of EHR usability and medication related patient safety reports with pediatric populations showed the most common usability issues were system feedback (82.4%), followed by visual display (9.7%), data entry (6.2%), and workflow support (1.7%). A more detailed description of this work can be found in publication number nine in the journal publication list.

The outcomes from Aim 2 are an understanding of specific health IT usability and safety issues that impacted both adult and pediatric patient populations.

Aim 3. Based on the prominent usability and safety issues identified in Aim 2 we developed an EHR usability and safety evaluation tool that can be self-administered by a healthcare facility. The tool is currently focused on computerized provider order entry (CPOE)

because of the patient safety risks associated with the ordering of medications, diagnostic tests, and laboratory tests. The tool consists of 104 questions that focus on medication, laboratory, and radiology ordering. The tool serves to identify specific EHR usability challenges that may pose patient safety risks such as issues with visual display, data entry, system automation and defaults, availability of information, and alerting. These usability issues were identified as posing safety concerns from the analysis of over 1.7 million patient safety event reports as part of Aims 1 and 2 and were prominent issues. For each of the usability issues identified by the evaluation tool in the context of medication, diagnostic test, and laboratory ordering specific guidance for improving usability is provided. The guidance is based on research and literature from the National Institute of Standards and Technology (NIST), Office of National Coordinator for Health Information Technology (ONC), The Joint Commission, and the Institute for Safe Medication Practices (ISMP) as well as from the usability and safety literature. Each of the questions were reviewed by two physicians and one nurse for face validity.

Validation of the evaluation tool is currently underway and we have pilot tested use of the evaluation tool at two hospitals with five participants at each hospital. One hospital used Epic and one used Cerner. The evaluation tool identified eight usability issues at one site and seven at the other site. The complete results are currently being submitted to a journal for publication. Further validation of the questions is ongoing with additional planned testing across different healthcare facilities.

The outcome from Aim 3 is a usability and safety evaluation tool that can be used by any healthcare facility to identify EHR risks and to understand how these risks can be mitigated through usability improvements. The evaluation tool includes a guide for how to perform the assessment so that it can be self-administered. Once validation testing and optimization is complete the tool will be made available on an open-source site.

Conclusion

Our research shows the association between EHR usability and patient safety through the analysis of patient safety event reports. We have also demonstrated how computational algorithms can be used to identify health IT related patient safety event reports and how this methodology can be expanded to other types of safety hazards and integrated with current patient safety processes. The EHR usability and safety assessment tool that was developed shows promise as a tool that can be used by any healthcare facility to identify specific issues in their EHR and to identify potential solutions to those issues.

Limitations

There are limitations to this research. One limitation is that the identification of health IT related usability and safety issues in Aims 1 and 2 are based on patient safety event reports which are limited in the amount of information provided about the safety issue. The study team was not able to follow-up with the reporter to seek clarification and accuracy of the report text. In Aim 2 a limitation of the models is that accuracy may be reduced if the model is applied to report text that differs significantly from the report text used to create the models. For example, if the model is applied to an institution's reports where a proper name is used for their EHR (e.g. MedConnect) and this name was not in the reports used to generate the model the model may underperform. A limitation of the usability and safety assessment tool is that different physicians within the same institution may have different workflows and the usability and safety issues identified will be specific to the workflows completed during the assessment.

Significance

There are several significant aspects to the body of research conducted under this grant in the broader context of understanding the impact of health IT usability on patient safety, the ability to identify these types of issues, and current methods and tools to improve health IT safety. The research showing the association of EHR usability on patient harm, in both adults and children, was the first of its kind and brought much needed attention to these issues from policymakers and mainstream media. The computational algorithms that were developed make it easier for healthcare facilities, patient safety organizations, and other stakeholders to identify health IT related safety issues which are otherwise difficult to detect. These algorithms have already been used by other healthcare facilities and patient safety organizations to advance their understanding of health IT related patient safety hazards. Finally, the EHR usability and safety assessment tool enables healthcare facilities to identify usability and safety issues that have been otherwise difficult and expensive to identify. This tool is especially useful given the extensive EHR customization and configuration that typically occurs at each healthcare facility which prevents a “one size fits all” solution to EHR usability and safety challenges.

Implications

There are several implications from the body of research conducted under this grant. First, the identification of the association between health IT usability and safety has several policy implications. Policies around health IT vendor usability testing from the Office of the National Coordinator for Health Information Technology (ONC) should be optimized to address the health IT usability shortcomings. Since the time some of the work from this grant was published in 2018 there have already been policy changes, including the requirement for real-world testing, that may begin to address the types health IT usability and safety challenges identified under this grant.

The algorithms developed under this grant have several implications for organizations that have numerous patient safety event reports to be analyzed. The algorithms provide a method to identify potential health IT related reports without extensive manual review which can reduce the cost of analysis and enable the identification of trends and patterns that may otherwise go unnoticed.

Finally, the EHR usability and safety assessment tool may provide a new, lower cost, method for assessing EHR usability and safety. With specific recommendations for how the EHR can be optimized at a specific healthcare facility the tool can be used to make much needed improvements that can have an immediate impact on patient safety.

Section V: List of Publications and Products

Peer-reviewed Journal Publications

1. Fong, A., Adams, K.T., Howe, J. & Ratwani, R. M. (2017). Using Active Learning to Identify Health Information Technology Related Patient Safety Events. *Applied Clinical Informatics*. 8(1), 35-46. PMID: 28097287 PMCID: PMC5373751 DOI: 10.4338/ACI-2016-09-CR-0148 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5373751/

2. Savage, E., Fairbanks, R.J., & Ratwani, R.M. (2017). Are informed policies in place to promote safe and usable EHRs? A cross industry comparison. *Journal of the American Medical Informatics Association*. PMID: 28339697, PMCID: PMC7651960, DOI: 10.1093/jamia/ocw185 https://pubmed.ncbi.nlm.nih.gov/28339697/

3. Adams, K. T., Howe, J. L., Fong, A., Puthumana, J. S., Kellogg, K. M., Gaunt, M., & Ratwani, R. M. (2017). An Analysis of Patient Safety Incident Reports Associated with Electronic Health Record Interoperability. *Applied Clinical Informatics*, 8(2), 593-602. PMID: 29388756, PMCID: PMC6241757, DOI: 10.4338/ACI-2017-01-RA-0014 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6241757/

4. Fong, A., Harriott, N., Walters, D. M., Foley, H., Morrissey, R., & Ratwani, R. M. (2017). Integrating natural language processing expertise with patient safety event review committees to improve the analysis of medication events. *International Journal of Medical Informatics*, 104, 120-125. PMID: 28529113, DOI: 10.1016/j.ijmedinf.2017.05.005 https://www.sciencedirect.com/science/article/pii/S1386505617301120?via%3Dihub

5. Ratwani, R. M. (2017). Electronic health records and improved patient care: opportunities for applied psychology. Current directions in psychological science, 26(4), 359-365. PMID: 28808359, PMCID: PMC5553914, DOI: 10.1177/0963721417700691 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5553914/

6. Howe, J., Adams, K., Hettinger, A.Z., & Ratwani, R.M. (2018) Electronic Health Record Usability Issues and Potential Contribution to Patient Harm. *JAMA* PMID: 29584833, PMCID: PMC5885839, DOI: 10.1001/jama.2018.1171 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5885839/

7. Sittig, D.F., Wright, A., Coiera, E., Magrabi, F., Ratwani, R.M., Bates, D.W. & Singh, H. (2018). Current Challenges in Health Information Technology-related Patient Safety. *Health Informatics Journal*. PMID: 30537881, PMCID: PMC7510167, DOI: 10.1177/1460458218814893 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7510167/

8. Fong, A., Adams, K.T., Gaunt, M.J., Howe, J.L., Kellogg, K. & Ratwani, R.M. (2018). Identifying Health Information Technology Related Safety Event Reports from Patient Safety Event Report Databases. *Journal of Biomedical Informatics*. PMID: 30213556, DOI: 10.1016/j.jbi.2018.09.007 https://www.sciencedirect.com/science/article/pii/S1532046418301813

9. Ratwani, R.M., Savage, E., Will, A., Fong, A., Karavite, D., Muthu, N., River, A. J., Gibson, C., Asmonga, D., Moscovitch, B., Grundmeier, R., & Rising, J. P. (2018) Identifying Electronic Health Record Usability and Safety Challenges in Pediatric Settings. *Health Affairs.* PMID: 30395517, DOI: 10.1377/hlthaff.2018.0699 https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.0699?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

10. Adams K.T., Kim T.C., Fong A., Howe J.L., Kellogg K.M., Ratwani R.M. (2019) Responding to health IT reported safety events: Insights from patient safety event reports. *Journal of Patient Safety and Risk Management.* https://doi.org/10.1177/2516043519847330 https://journals.sagepub.com/doi/abs/10.1177/2516043519847330

11. Fong, A., Komolafe, T., Adams, K.T., Cohen, A., Howe, J.L., & Ratwani, R.M. (2019) Exploration and Initial Development of Text Classification Models to Identify Health Information Technology Usability Related Patient Safety Event Reports. *Applied Clinical Informatics.* PMID: 31315139, PMCID: PMC6637025, DOI: 10.1055/s-0039-1693427 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6637025/

12. Pacheco, T., Hettinger, A.Z., & Ratwani, R.M. (2019). Identifying Potential Patient Safety Issues from the Federal Electronic Health Record Surveillance Program. *Journal of American Medical Association (JAMA).* PMID: 31846009, PMCID: PMC6990822 DOI: 10.1001/jama.2019.17242 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6990822/

13. Fong, A, Behzad, S., Pruitt, Z., & Ratwani, R.M. (2020). A Machine Learning Approach to Reclassifying Miscellaneous Patient Safety Reports. *Journal of Patient Safety*. PMID: 32555052, DOI: 10.1097/PTS.0000000000000731 https://journals.lww.com/journalpatientsafety/Abstract/9000/A_Machine_Learning_Approach_to_Reclassifying.99134.aspx

Peer-Reviewed Conference Proceeding Papers

Cohan, A., Fong, A., Goharian, N., & Ratwani, R. (2017, April). A neural attention model for categorizing patient safety events. In *European Conference on Information Retrieval* (pp. 720-726). Springer, Cham. https://link.springer.com/chapter/10.1007/978-3-319-56608-5_71

Cohan, A., Fong, A., Ratwani, R. M., & Goharian, N. (2017, August). Identifying harm events in clinical care through medical narratives. In *Proceedings of the 8th ACM international conference on bioinformatics, computational biology, and health informatics* (pp. 52-59). https://dl.acm.org/doi/abs/10.1145/3107411.3107485

Adams, K. T., Howe, J. L., Gaunt, M. J., Ratwani, R. M., & Fong, A. (2019, November). Where are health IT patient safety event reports hiding? Identifying health IT patient safety events in self-reported databases. In *Proceedings of the Human Factors and Ergonomics Society Annual Meeting* (Vol. 63, No. 1, pp. 703-707). Sage CA: Los Angeles, CA: SAGE Publications. https://journals.sagepub.com/doi/abs/10.1177/1071181319631410

Poster Presentations

Bonk, C. W., Pruitt, Z. M., Howe, J., & Ratwani, R. M. (2020, March). *#EHR: Analyzing the Discussion of Electronic Health Records in Social Media.* Poster session presented at the 2020 International Symposium on Human Factors and Ergonomics in Health Care, Toronto, Canada.

Howe, J., Adams, K., Hettinger, A. Z., & Ratwani, R. (2018, April). *Electronic Health Record Usability as a Contributing Factor to Patient Harm.* Poster session presented at the 2018 MedStar Health Research Institute Research Symposium, Bethesda, MD.

Adams, K., Fong, A., Howe, J., Kellogg, K., Puthumana, J., & Ratwani, R. (2017, May). *An Analysis of Patient Safety Incident Reports Associated with Electronic Health Record Interoperability.* Poster session presented at the 2017 MedStar Health Research Institute Research Symposium, Bethesda, MD.

Non-Peer Reviewed Articles

Howe, J. L., Hettinger, A. Z., & Ratwani, R. M. (2020). Electronic Health Record Usability and Patient Safety: Risks and Mitigation Strategies. *Inside Medical Liability.*