MEDINFO 2021: One World, One Health – Global Partnership for Digital Innovation
P. Otero et al. (Eds.)
© 2022 International Medical Informatics Association (IMIA) and IOS Press.
This article is published online with Open Access by IOS Press and distributed under the terms of the Creative Commons Attribution Non-Commercial License 4.0 (CC BY-NC 4.0).
doi:10.3233/SHTI220108

SHACL-Based Report Quality Evaluation for Health IT-Induced Medication Errors

Daniel Keuchel[a], Nicolai Spicher[b], Ju Wang[b,1], Michael Völcker[b], Yang Gong[c], Thomas M. Deserno[b]

[a]Department of Computer Science, University of Applied Sciences and Arts Dortmund, Dortmund, North Rhine-Westphalia, Germany
[b]Peter L. Reichertz Institute for Medical Informatics of TU Braunschweig and Hannover Medical School, Braunschweig, Lower Saxony, Germany
[c]School of Biomedical Informatics, University of Texas Health Science Center, Houston, Texas, United States

Abstract

Patient safety event (PSE) reports are an important source of information for analyzing risks in healthcare processes. However, the reports' quality is often low due to missing or imprecise information. We work towards an automatic analysis of reports and quality evaluation. To leverage a suitable data representation of health IT-induced medication error reports, we apply the Shapes Constraint Language (SHACL). We define an ontology representing these reports and construct a corresponding SHACL graph. Three authors manually annotate and transform 20 textual reports to the SHACL representation. Furthermore, we use this representation to compute a quality score for each report. The results indicate the suitability of SHACL as a representation of health IT-induced medication error reports, which paves a path of automatically extracting information from PSE reports using text mining and transform them to SHACL for quality evaluation.

Keywords:

Patient safety, health IT, information representation

Introduction

Patient safety is a global challenge [1], in which medication error is a leading cause of avoidable harm in healthcare systems across the world [2]. Health IT systems, including electronic health records (EHR), computerized provider order entry (CPOE), and electronic medication administration records (e-MARs), can improve medication safety by, for instance, improving communication, assisting in calculations, real-time checking, and providing decision support [3]. However, health IT may also potentially introduce new paths to medication errors [4]. This includes lack of interoperability among hospital information systems [5], unexpected software design [6], inappropriate use of health IT products [7], poorly designed user interfaces [8], or malfunction of data transmission [9] [10].

Learning from patient safety events (PSE) leads to better awareness of unsafe healthcare environments and a better understanding of causes. The concept of incident reporting was introduced by high-risk industries such as aviation [11]. More than two decades ago, the Institue of Medicine (IOM) recommended establishing a nationwide, mandatory public reporting system to learn about medical care issues associated with severe injury or death and to prevent future occurrences [12][13]. To this end, both national and local patient safety reporting systems have been implemented, which makes it possible to analyze the events, identify underlying factors, and take actions to mitigate risks [14]. Among others, Stavicki et al. consider reporting a cornerstone for safety and quality improvement as it provides a powerful source of information [15]. In many countries, mandatory public reporting systems have already been used in practice.

However, underreporting and low-quality reporting issues impede the use of the event reports for signal detection, root cause analysis (RCA), and learning [16]. Conceptual frameworks, such as the World Health Organization (WHO) International Classification for Patient Safety (ICPS) and the WHO Minimal Information Model [17] [18], serve as the foundation of a comprehensive understanding of patient safety events. Besides, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) analytical framework of patient safety [19] and the Generic Reference Model [20] are prevailing in PSE analysis. More specifically, for measuring and analyzing health IT-related safety hazards, the sociotechnical model laid the groundwork [21]. To facilitate the quality assessment of narrative medication error reports, Yao et al. developed the Necessary Data Elements Model [22]. The model demonstrates the effectiveness of ontological approaches in evaluating reports. However, a formal ontology representation is still in demand to automate the evaluation process. Therefore, we intend to advance the ontology representation by applying SHACL to health IT-induced medication error reports and use it for quality evaluation.

Methods

HIT-ME Ontology

An ontology representation of information facilitates sharable and transferrable frameworks. When the elements described in a PSE are rebuilt with ontology frameworks, their analysis can be automated, and further, it may lead to automated case-based reasoning. Based on the existing general and specific frameworks of patient safety analysis, we propose an ontological model, namely the health IT-induced medication error (HIT-ME) ontology (Figure 1).

The highest level follows the Generic Reference Model [3][20], namely the c*ontributing factors and hazards* causing incidents, which have outcomes and consequences to either patients or health care organizations. Within this category, we adopted the sociotechnical model to exclusively reflect the impact of health IT in causing an incident. Due to the overlap of the sociotechnical model and the existing aspects in the Generic Reference Model, we merge them to organization factors, environmental factors, and human factors. Within the *incident*, we adopted the elements summarized in the Necessary Data Elements Model with the error type referring to the National

[1] Correspondence.

Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) [23]. We categorized the *outcomes and consequences* on patients into miss and patient reach. Furthermore, the latter is classifed as reach to the patient either with harm or without observed consequences.

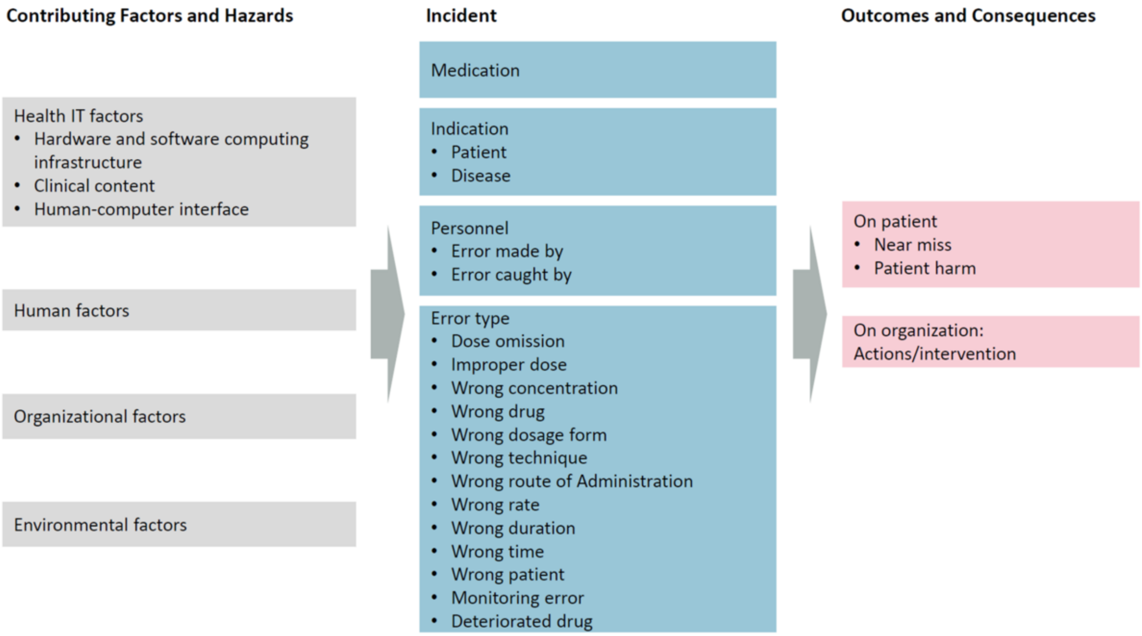

Figure 1 – HIT-ME ontology

SHACL shape graph representation of ontology

The World Wide Web Consortium (W3C) published the recommendation of SHACL as a web standard in 2017. It is a language for validating Resource Description Framework (RDF) graphs against various possible conditions. SHACL graphs consist of two different graphs: a *data graph* containing the actual data and a *shapes graph* containing the conditions the data in the data graph has to fulfill. The validation is performed using algorithms validating the data in the data graph against each condition. Based on the HIT-ME ontology (Figure 1), we define a shapes graph representing this information.

Report transformation to SHACL data graph

We randomly selected 20 health IT-induced medication error reports from the dataset of 155 PSE reports we collected in our previous work [10], which were retrieved from the Food and Drug Administartion (FDA) Manufacturer and User Facility Device Experience (MAUDE) database [24]. The main content of the reports is in free text. An instance is shown (Figure 2) with colored text representing the mapping of the text to the information in the HIT-ME ontology. For each of the 20 reports, a data graph was generated by three of the authors ("annotators") using a freely available software TopBraid Composer (TopQuadrant Inc, North Carolina, USA).

Report quality assessment based on SHACL data graph

We defined a simple metric for expressing the quality of a report based on its SHACL data graph. We introduced weights for the existence of a shape instance: 30% for contributing factors and hazards, 40% for incidents, and 30% for outcomes and consequences. The 40% for incidents are split 10% for each of the second-layer shapes: medication, indication, personnel, error type. Thereby, we assign a high percentage value to a report containing much of the information covered by the HIT-ME ontology, i.e., the SHACL data graph, A report with missing information has a correspondingly lower value.

with the work flow controlled by the electronic care record system, vital sign data is out of sight, tucked away is a silo that requires multiple clicks and time to access. consequently, the key data of vital signs is out of sight, and thus, out of mind. no one knows the pt data, yet medications are administered resulting in complications because of the inappropriate (for the pt's vital signs) administration of therapies. in this particular case, the pt was hypotensive and received add'l blood pressure lowering medication resulting in critical condition.

Figure 2 – Health IT-induced medication error report with annotations by a single annotator shown as colored text. Gray: contributing factors and hazards; blue: incident; red: outcomes and consequences

Experimental evaluation

For each of the 20 reports, three annotators generated a data graph. However, we excluded two reports as they were not health IT-caused medication errors. Therefore, we used a total number of 54 data graphs.

We compared the graphs and analyzed inter-annotator variation. In each graph, there are 29 terminal vertices (leaves) that can be set. Hence, we compared the three corresponding data graphs for each report and checked for each of the 29 terminal vertices if an instance is defined. If all three annotators made the same decision, i.e., all annotators defined or did not define this instance, we counted that as *agreement*. In every other case, we counted as *disagreement*.

Furthermore, we computed the quality score of each report for each annotator. Additionally, we calculated the consensus quality for each report by averaging.

Results

We developed a SHACL data graph with 38 shape vertices (Figure 3) to describe the structure of the HIT-ME ontology. On the highest level, there are three shapes contributing factors and hazards, incidents, and outcomes and consequences which are similar to the categories of the HIT-ME ontology (Figure 1). The second layer represents the colored boxes (Figure 1) as ten vertices. On the third layer, 25 vertices reflect the individual items in the enumerations. Vertices are connected using the subclass relationship.

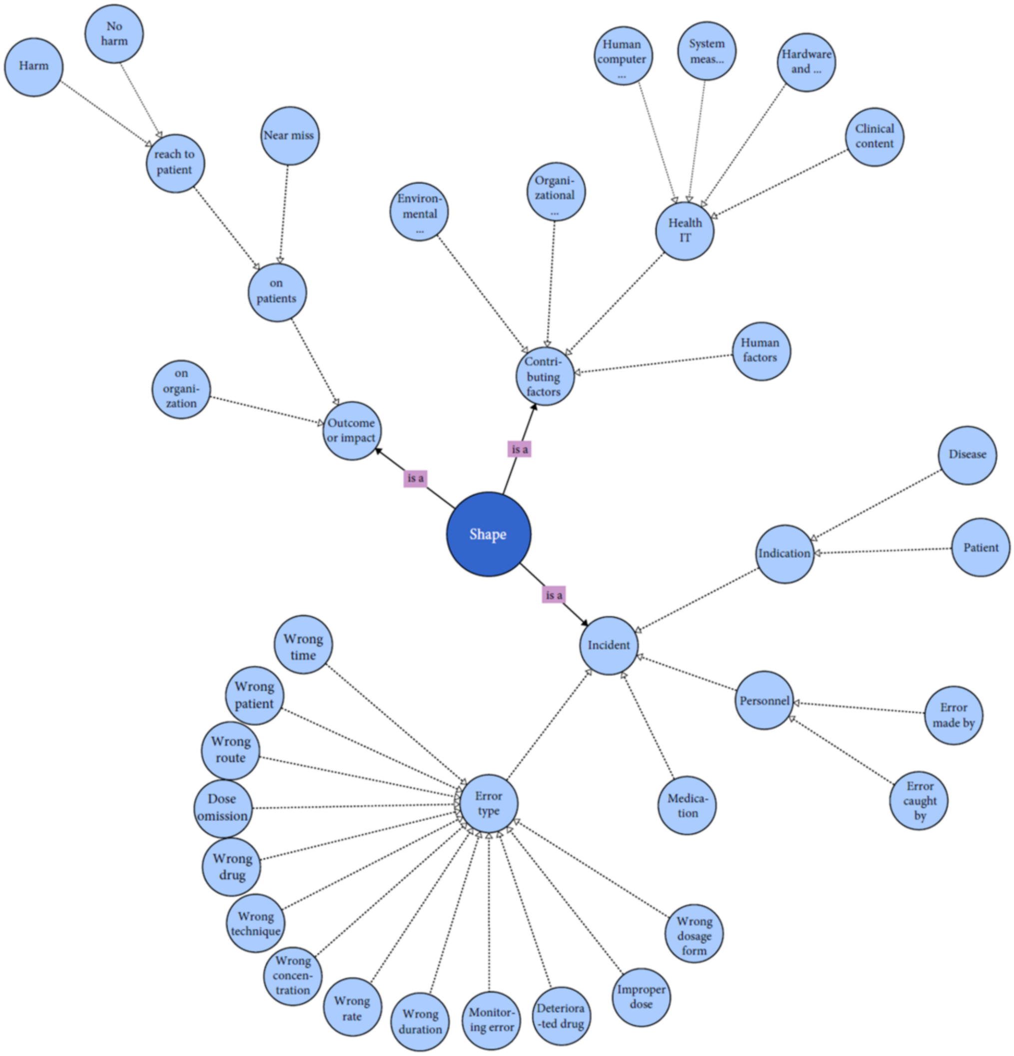

Figure 3 – SHACL graph representing the HIT-ME ontology

Conditions are not shown in the figure but were defined using cardinality constraints. For example, each report should contain a contributing factor or hazard using the *minCount* constraint (Figure 4).

The average level of agreement for all reports was 85.3%, with a standard deviation of 7.5% (min: 72.4%, max: 100%). For example, all three annotators defined an instance of patient harm for the report shown in Figure 2.

Disagreement was most frequently observed in contributing factors and hazards (50.0%), followed by incidents (40.3%), and outcomes and consequences (9.7%). Reading a report and converting it to the SHACL graph took approximately 5-10 minutes, depending on complexity and length.

```
# Shape graph: Patient Safety Report Incident
Patient_Safety_Report:Patient_Safety_Report_Incident
  rdf:type rdfs:Class ;
  rdf:type sh:NodeShape ;
  rdfs:label "Patient Safety Report Data" ;
  rdfs:subClassOf rdfs:Resource ;
  # SHACL properties
  sh:property [
      rdf:type sh:PropertyShape ;
      sh:path Patient_Safety_Report:at_least_one_Outcome_or_Impact ;
      sh:class Patient_Safety_Report:Outcome_or_Impact ;
      sh:minCount 1 ;
      sh:name "at least one Outcome or Impact" ;
      sh:nodeKind sh:IRI ;
    ] ;
```

Figure 4 – SHACL shape condition

The consensus quality of the reports ranged from 60% to 100%, with an average of 87.6%. For example, the report shown in Figure 2 was assigned a consensus quality of 90%, with the quality based on the annotators was 80%, 90%, and 100%, respectively.

The deviation between consensus and individual scores ranged from -20.0% to 26.6%, with 0% mean of and standard deviation of 8.0%

Discussion

In previous work, we demonstrated how SHACL can be used to detect errors in metadata of clinical studies [25] and Business Process Model and Notation (BPMN) models of medical processes [26]. In this work, we demonstrated the potential of using SHACL as a representation for patient safety reports. As a use-case, we limited our analysis to health IT-induced medication error reports.

We developed a SHACL shapes graph representing the key information elements of patient safety reports. Its hierarchical structure with three layers (Figure 2) represents the HIT-ME ontology (Figure 1) efficiently. Using freely available software, textual reports from the MAUDE databases were converted to SHACL data graphs. Comparing the agreement of the graphs showed that the intra-annotator variability was relatively low, reaching a minimum agreement of approximately 70% and an average of 85.3%. In 22% of reports, the agreement was higher than 90%. Disagreement was in most cases due to a different selection of contributing factors and hazards responsible for half of the cases. This was often the case in complex or inaccurate reports, e.g., if it was not clear whether the incident occurred due to an inadequately designed human-computer interface or due to a human error.

The defined quality score allowed for assignment of an intuitive percentage value to patient safety reports based on the SHACL data graph and could be calculated automatically. Evidently, it is only a first proposal with the weights being chosen using a rule of thumb and our experience in this field. This is underlined by the fact that the quality ranged between 60-100% in the randomly chosen set of reports, thereby not covering the range 0-100%. Therefore, this quality measure needs further work and in-depth evaluation on a more extensive and more representative set of reports.

We used a sample of PSE reports for a portable demonstration purpose of the technical feasibility in this work. In our experience, the selected reports are representative. In future work, we can apply a comprehensive report quality analysis to a scaled-up dataset.

The SHACL enables an information representation and quality evaluation approach that facilitates sharable and transferrable quality evaluation PSE reports across organizations and systems as an open standard. Further, an ontological PSE information representation may lead to the implementation of case-based reasoning.

We will work towards an automatic conversion of textual reports to SHACL graphs using natural language processing in future work. Eventually, this could allow integrating real-time quality feedback during creating a report that may lead to improved quality of PSE reports and thus enhanced medication safety.

Conclusions

SHACL is suitable to represent patient safety reports formally. Our explicit representation of contributing factors allows identifying the root cause and developing strategies for building up safer conditions. With the SHACL representation, we can partly automate the report quality evaluation.

Acknowledgments

This work was partially funded by the Lower Saxony Ministry of Science and Culture under grant number ZN3491 within the Lower Saxony "Vorab" of the Volkswagen Foundation and supported by the Center for Digital Innovations (ZDIN).

References

[1] Patient Safety [Internet]. World Health Organization. [cited 2021 May 12]. Available from: https://www.who.int/news-room/fact-sheets/detail/patient-safety

[2] WHO. Medication without harm [Internet]. World Health Organization. 2017 [cited 2021 Apr 26]. p. 16. Available from: https://www.who.int/initiatives/medication-without-harm

[3] Bates DW, Gawande AA. Improving safety with information technology. N Engl J Med. 2003 Jun 19;348(25):2526–34.

[4] Koppel R, Metlay JP, Cohen A, Abaluck B, Localio AR, Kimmel SE, et al. Role of computerized physician order entry systems in facilitating medication errors. J Am Med Assoc. 2005 Mar 9;293(10):1197–203.

[5] Falling between the cracks in the software [Internet]. PSNet. [cited 2021 Apr 26]. Available from: https://psnet.ahrq.gov/web-mm/falling-between-cracks-software

[6] Adams KT, Howe JL, Fong A, Puthumana JS, Kellogg KM, Gaunt M, et al. An analysis of patient safety incident reports associated with electronic health record interoperability. Appl Clin Inform. 2017 Feb 1;8(2):593–602.

[7] Situational (un)awareness [Internet]. PSNet. [cited 2021 Apr 26]. Available from: https://psnet.ahrq.gov/web-mm/situational-unawareness

[8] Slow down: right drug, wrong formulation [Internet]. PSNet. [cited 2021 Apr 26]. Available from: https://psnet.ahrq.gov/web-mm/slow-down-right-drug-wrong-formulation

[9] E-prescribing: E for error? [Internet]. PSNet. [cited 2021 Apr 26]. Available from: https://psnet.ahrq.gov/web-mm/e-prescribing-e-error

[10] Wang J, Liang H, Kang H, Gong Y. Understanding health information technology induced medication safety events by two conceptual frameworks. Appl Clin Inform. 2019 Jan;10(1):158–67.

[11] Sevdalis N, Hull L, Birnbach DJ. Improving patient safety in the operating theatre and perioperative care: obstacles, interventions, and priorities for accelerating progress. Br

J Anaesth [Internet]. 2012 Dec 1 [cited 2021 May 17];109(SUPPL1):i3–16. Available from: www.nrls.npsa
[12] Mitchell I, Schuster A, Smith K, Pronovost P, Wu A. Patient safety incident reporting: a qualitative study of thoughts and perceptions of experts 15 years after "To Err is Human." BMJ Qual Saf. 2016 Feb 1;25(2):92–9.
[13] Institute of Medicine (US) Committee on Quality of Health Care in America, Kohn L, Corrigan J, Donaldson M, editors. To Err Is Human: building a safer health system. Washington, D.C.: National Academies Press; 2000.
[14] Gong Y, Kang H, Wu X, Hua L. Enhancing patient safety event reporting: a systematic review of system design features. Appl Clin Inform. 2017 Aug 30;8(3):893–909.
[15] Stawicki SP, Green AM, Lu GG, Domer G, Oskin T, Firstenberg MS. Introductory chapter: patient safety is the cornerstone of modern health-care delivery systems. In: Vignettes in Patient Safety. IntechOpen; 2019.
[16] Gong Y, Song H-Y, Wu X, Hua L. Identifying barriers and benefits of patient safety event reporting toward user-centered design. Saf Heal. 2015 Aug 27;1(7):1.
[17] The conceptual framework for the International Classification for Patient Safety (ICPS) [Internet]. World Health Organization. [cited 2021 Mar 14]. Available from: https://www.who.int/patientsafety/implementation/taxonomy/ICPS-report/en/
[18] Minimal Information Model for Patient Safety [Internet]. World Health Organization. [cited 2021 May 13]. Available from: https://www.who.int/patientsafety/implementation/information_model/en/
[19] Chang A, Schyve PM, Croteau RJ, O'Leary DS, Loeb JM. The JCAHO patient safety event taxonomy: a standardized terminology and classification schema for near misses and adverse events. Int J Qual Heal Care. 2005 Apr;17(2):95–105.
[20] Runciman WB, Williamson JAH, Deakin A, Benveniste KA, Bannon K, Hibbert PD. An integrated framework for safety, quality and risk management: an information and incident management system based on a universal patient safety classification. Qual Saf Heal Care. 2006 Dec;15(Suppl. 1):i82-90.
[21] Sittig DF, Singh H. A new sociotechnical model for studying health information technology in complex adaptive healthcare systems. Qual Saf Health Care. 2010;19 Suppl 3(Suppl 3):i68-74.
[22] Yao B, Kang H, Wang J, Zhou S, Gong Y. Toward reporting support and quality assessment for learning from reporting: a necessary data elements model for narrative medication error reports. In: AMIA Annu Symp Proc. 2018. p. 1581–90.
[23] Taxonomy of medication errors now available [Internet]. NCC MERP. [cited 2021 Mar 25]. Available from: https://www.nccmerp.org/taxonomy-medication-errors-now-available
[24] MAUDE - Manufacturer and User Facility Device Experience [Internet]. The U.S. Food and Drug Administration (FDA). [cited 2021 Mar 10]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm
[25] Keuchel D, Spicher N. Automatic detection of metadata errors in a registry of clinical studies using Shapes Constraint Language (SHACL) graphs. In: Proceedings of the 31st Medical Informatics Europe Conference. 2021. p. (Accepted).
[26] Keuchel D, Böckmann B, Spicher N. Semantic verification during BPMN modeling of healthcare processes by integrating Shapes Constraint Language (SHACL) graphs. In: 64 Jahrestagung der Deutschen Gesellschaft für Medizinische Informatik, Biometrie und Epidemiologie e V (GMDS). 2019. p. 227.

Address for correspondence

Ju Wang, PhD, Peter L. Reichertz Institute for Medical Informatics of TU Braunschweig and Hannover Medical School, Muehlenpfordtstr. 23, D-38106 Braunschweig, Germany; Tel.: +49 531 391 9511; E-Mail: ju.wang@plri.de.