# Design Effective Voluntary Medical Incident Reporting Systems: A Literature Review

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**Abstract.** Voluntary medical incident reporting systems (VMIR) are an application of information technology to support medical errors reporting for health professionals and thus ultimately improve healthcare quality and patient safety. The overall goal of this paper was to investigate the usage and effective design of VMIR by literature review. We expected to uncover design potentials from prior studies by examining on both incident reports analysis and system design, by which to establish a user-centered design framework that integrates identified factors for advancing VMIR effectiveness and efficiency. All papers regarding voluntary reporting system were identified through systematic electronic database searches. Three eligibility criteria were applied: 1) voluntary programs; 2) information system; 3) medical incident/error reporting. Of 8 eligible articles identified, the main themes are about current systems' shortcomings on underreporting, report quality, standardized nomenclature/ taxonomy, communication, usability as well as reporting culture and environment. Eventually, all of identified concerns in the study will be addressed in a VMIR system prototyping process to attack the shortcomings aforementioned.

**Keywords:** Medical Incident Reporting, User-centered Design, Information System.

## 1 Introduction

With the suggestion of the Institute of Medicine (IOM)[1], an increasing number of US hospitals have implemented voluntary reporting systems to learn from error and prevent its reoccurring in the future. Since 2000, a growing number of quantitative and qualitative researches have been published regarding voluntary medical incident reporting system usage and design.

As many other clinical information systems, the VMIR is struggling of effective design to overcome barriers on system acceptance and usage. Legislation, leadership support, blame culture and punitive environment, clinician involvement, and system usability are influential factors to the data quantity and quality of medical incident reporting systems. In this study, we investigated the usage and design concerns of

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previous VMIR systems to identify technical contributing factors, with which the researchers can coordinate in a user-centered VMIR framework for removing barriers of voluntary medical incident reporting systems in a technical manner.

## 2 Method

### 2.1 Data Source

Databases selected for literature searching were (1) Medline (1950-2010); (2) Compendex (1969-2010); (3) PsycINFO (1987-2010). Terms and keywords fell in three categories (voluntary participation, computer system, medical errors) for searching:

- Voluntary programs (MeSH & "explode"), voluntary (Ei controlled vocabulary);
- Information system (MeSH & "explode", Ei controlled vocabulary), system analysis (MeSH & "explode"), system design, reporting system;
- Medical errors (MeSH & "explode"), medical incident;

The "explode" box of searching tool was ticked. It included all narrower terms under the MeSH terms listed above. The authors are also searching the reference lists to ensure all relevant articles to be properly reviewed.

### 2.2 Inclusion and Exclusion Criteria

The article inclusion criteria were composed of:

- Voluntary system
- Medical incident/error reporting pertinent
- Computer-based system
- Practical studies regarding VMIR use and design
- Studies detailed with reported data statistics and system design discussions

Medical incident/error reporting is not a brand new territory. Many reporting systems were designed in paper forms, call center supported forms and computerized applications. Usage and design concerns on varied type of forms could manifest differently. Thus, the authors excluded literature regarding mandatory medical incident reporting system and non-electronic systems, as focusing on computer-based platform and voluntary use, Different from the comprehensive review of Holden & Karsh[2], we are more interested in potentials of system design improvement on a basis of analyzed reports. Therefore, the authors further excluded the papers that merely talked about pure data analysis than both of them.

**Table 1.** Eligible VMIR Studies

| Year | Clinical Fields | Reporting No. and Ratio | Report Statistics | Terms in Use (TIU)<br>System Acceptance Factors (SAF) |
|---|---|---|---|---|
| 2004 | Pediatric chemotherapy field in a Hospital[3] | 97 (Feb. 8, 2002 - Mar. 9, 2003) | **Severity:** 13% reached patients, 1% increased patient monitoring, 2% temporary harm<br>**Reporters:** chemotherapy pharmacists (69%), floor nurses (31%)<br>**Others:** no significant different on age, gender, race and residence between hospitalized incident and non-incident patient populations | **TIU:** National Coordinating Council for Medication Error Reporting and Prevention<br>**SAF:** leadership; project ownership; standard data definition; human factors; team dynamics; data and performance feedback; security and privacy |
| 2004 | Academic and general field, Ohio State University Health System[4] | 676 (28 weeks started from Oct. 22, 2001); **Ratio:** 14.6 - 16.2 events/week (122 beds); 15.1/week (207 beds) | **Reporters:** physicians (10%), nurses (>50%)<br>**Average time expense:** 7 minutes 40 seconds<br>**Others:** statistically significant reduction both in event open time and management complete time proves efficiency improvement | **TIU:** already-familiar house language<br>**SAF:** Usability enhancement; user classification and centered; access and security control; facilitate event follow-up |
| 2004 | Neonatal intensive care field, Vermont Oxford Network[5] | 1,230 (Oct. 4, 2000 - Mar. 7, 2002, 17 months) | **Severity:** 25% minor harm, 1.9% serious harm, 0.15% death (673 reported harm)<br>**Others:** contributory factors were failure to follow policy or protocol (47%), inattention (27%), communications problem (22%), error in charting or documentation (13%), distraction (12%), inexperience (10%), labeling error (10%), and poor teamwork (9%); 581 (47%) reports related to medications, nutritional agents (breast milk, formula, and parenteral nutrition), or blood products | **TIU:** Leape[6], Nadzam[7] and Kaushal[8]<br>**SAF:** specialty-based system; anonymous reporting |
| 2005 | Intensive care field, in Johns Hopkins Hospital[9] | 854 (July 1, 2002 - June 30, 2003) | **Severity:** 21% led to physical injury, 14% increase ICU length of stay, the most are no harm<br>**Average time expense:** 12 minutes 45 seconds | **TIU:** home-made taxonomy for coding<br>**SAF:** usability e.g. reduce free text entry and print option; feedbacks to individual and organization |

**Table 1.** (*continued*)

| Year | Clinical Fields | Reporting No. and Ratio | Report Statistics | Terms in Use (TIU)<br>System Acceptance Factors (SAF) |
|---|---|---|---|---|
| 2005 | General field, Osaka University Hospital[10] | 6,041 (June 1, 2001 - Mar. 31, 2004); **Ratio:**177 reports/month (1076 beds) | **Reporters:** nurses(84.7%), physicians (10.2%), pharmacist(2.3%)<br>**Others:** uncovered problems on computer prescription, intravenous administration of a high risk drug, and the manipulation of syringe pumps and blood transfusion according to reports analysis | **TIU:** N/A<br>**SAF:** anonymous and blame free; new organizational structure; education, system improvement and feedback; |
| 2005 | Cardiothoracic Intensive care and post anesthesia care in Barnes-Jewish Hospital[11] | 157 in total, 112 from ICU (Jan. 6, 2003 - Dec. 31, 2003) ; **Ratio:** 25.3 reported events/1000 patient-days(ICU) | **Severity:** 54% patient reached without harm, test/treatment/procedure-related and medication were the 2 most frequently types of events contributing to patient harm<br>**Reporters:** nurses (69%), physicians (19%), other staff (6%), anonymous (4%)<br>**Others:** 20 patients (19%) have more than 1 event; the median number of days from hospital admission to the first event was 3 days; 3-fold increase in reporting ratio; identified cause and classification of event | **TIU:** home-made taxonomy via coding<br>**SAF:** voluntary, accessible, anonymous, and non-punitive; time tense and unsure what to report; classification and coding of events |
| 2006 | Anesthetic field (via mobile devices), Geelong Hospital[12] | 156 (Aug. 2001 - Feb. 2004); **Ratio:** 35 reports/1000 anesthetic procedures | **Severity:** 46.2% near misses, 53.8% serious outcome anesthetic trainee<br>**Average time expense:** 5 seconds<br>**Others:** summarized categories and sub-classification for incident reporting with numbers of incidents and outcomes | **TIU:** 8 anesthetic incident categories from literatures by 1999; Patient Safety International terms [13]<br>**SAF:** nomenclature for critical incidents in health care; supportive and blame-free environment; timely and efficient feedback |
| 2009 | General field, Brigham and Women's Hospital[14] | 14,179 (May 2004 - Nov. 2006, 31 months); **Ratio:** 20 reports/1000 inpatient days | **Severity:** 24% near misses, 61% adverse events but no harm, 14% temporary harm, 0.4% permanent harm, 0.1% death<br>**Reporters:** Physicians submitted only 2.9% of the reports; most reports were submitted by nurses, pharmacists, and technicians<br>**Average time expense:** 14 minutes, varies from incident type to type | **TIU:** home-made category of incident types<br>**SAF:** immediate response and reassurance; lack of time; ease of use |

### 2.3 Study Selection and Information Extraction

The authors reviewed the titles and abstracts of the identified citations and applied a screening algorithm based on the inclusion and exclusion criteria described above. The two investigators rated each paper as "potentially relevant" or "potentially not relevant." The authors collected the following information from each "potentially relevant" article: year of publication, clinical field, reporting amount and ratio, reported data statistics, controlled vocabulary/terminology/taxonomy in use, discussed contributory factors to system acceptance.

## 3 Results

Comprehensive literature searches identified 80 articles: 69 in Medline, 6 in Compendex and 5 in PsycINFO. After reading the fully papers, 72 articles were excluded. Eight articles met the eligibility criteria as shown in Table 1[3-5, 9-12, 14].

These studies took place in the United States[3-5, 9, 11, 14], Australia[12] and Japan[10]. The studies on VMIR were not limited to a particular local or regional area but an international topic. Most of them shared a similar writing style to elaborate importance and difficulty at the beginning, followed by statistics on amount and ratio of reporting, and the distribution of reporters and event severities, and ended by discussion on VMIR design trends. It partially represented the homogenization and limitation of current VMIR researches.

Moreover, all qualified articles were published after 1999, at the year when the IOM report released. They illustrated following facts across investigated studies:

- VMIR still encounters underreporting but performs better than paper-based reporting systems. The ratio ranges from 0.5% to 3.5%, with comparing to the prevalence of adverse events in a range from 2.9% to 16.6% [15]. Seemingly, specialty-based systems received high rates than comprehensive systems.
- Five specialty-based systems including three ICU based reporting systems, and the other three are hospital-wide comprehensive incident reporting systems.
- The pyramids of severity of harm across the studies are similar. The majority of reported incidents caused no harm and severity increases along when rates decrease.
- Except for a few studies [3, 12] that are designed for specialists, the majority of users are nurses.
- The reduction on reporting time expense is unclear. A comprehensive report with multiple sections combing coded fields and free text entries often requires around 10 minutes [4, 9, 14], which largely vary from incident type to type. Comparatively, a single paper form or call center for incident reporting might even save a few minutes [16].
- The seven of eight studies explain their preference in choosing terminology or taxonomy. Three of them employ established works, and the rest produce their own coding system of incident categories and terms.
- All articles make discussions on design concerns of VMIR, which suggested a design of given blame-free, usability enhancement and feedback, etc.

## 4 Discussion

Overall, all eight articles exhibited a variety of difficulties in designing and adopting VMIR for high-quality incident reports. It includes voluntariness, terminology/taxonomy/nomenclature[12, 17, 18], blame-free environment and reporting culture[19], usability and utility concerns[20-22], feedback[23] and administrative issues.

Voluntariness shared a controversial point of view in medical incident reporting system design. In several technology acceptance researches [21, 22, 24], it was identified as a negative factor to decline system use. In the case of low perceived voluntariness, where user felt that use of the system is mandatory, the system use will be more often[21]. However, voluntary systems are still dominant and more acceptable in incident reporting area than mandatory ones. The mandatory systems are often adopted in military area, and typically designed to identify "bad" practitioners and facilities with an emphasis on individuals and on the error itself, but not its correction[25].

Controlled vocabulary/terminology/taxonomy is a prevalent challenge, due to computerization in all domains requires semantic interoperability among human and computer systems. In fact, there are a number of medical incident taxonomies or concept frameworks available as candidates for the development of medical incident reporting systems. E.g. NCC MERP Taxonomy of Medication Errors (NCCMERP), JCAHO Patient Safety Event Taxonomy (PSET), JCAHO Sentinel Events Reporting (JSER), Taxonomy of Nursing Errors (TNE), a Preliminary Taxonomy of medical errors in Family Practice (PTFP), Cognitive Taxonomy of Medical Errors (COG), Taxonomy of Medical Errors for Neonatal Intensive Care (NIC), MedWatch Index (MEDWATCH), and the International Classification for Patient Safety (ICPS). These taxonomies or conceptual frameworks do not only guide what to report but can also provide an agreed-upon structure to error report data. Unfortunately, they are lacking of consistency in practice. It may impede the interoperability among different medical incident systems at a larger scope.

Utility and usability are major technical issues influencing system acceptance. They refers to not only VMIR systems but also aviation error reporting[20], building management [24], knowledge management [21] and the other health information technology area[22]. and are even highlighted in Davis' Technology Acceptance Model (TAM)[26] and Neilson's System Acceptability Model[27]. For example to VMIR, users might ask for better data entry tools which are ease of use and the reported data are re-usable at the usefulness level. On the contrary, if the system design failed to deliver a periodical progress or achievement to satisfy users' evolving requirements and expectations on system performance in a timely manner, the users might feel frustration and even stay away from current usage to seek any alternatives.

Feedback between reporters and expert reviewers is expected to encourage reporting, educate clinicians and notify corrective actions taken[2]. Discussed in all investigated articles, it was initially proved in support of reducing report open and complete time [4]. In view of communication science, feedbacks that meet users' expectation or provide an perceived benefits will bridge sense-making or sense-giving gaps to encourage incident reporting activities of target users.

By considering the above concerns, a computer-based prototype of VMIR has been under development since 2009 [28]. The authors reviewed the latest design

suggestions in medical incident reporting area which are based upon and beyond Holden & Karsh's work in 2007[2]. As a result, only three additional papers were identified and organized with the prior in Table 2 to complement system prototyping based on our previous studies [28-30]. By synthesizing the above works, we set up several objectives on design of our target VMIR system, by which the two major barriers of underreporting and low quality reports could be properly addressed.

- Consider specialty-based incident reporting design to VMIR
- Feedback at the various levels to a variety of stakeholders, especially to report submitters as encouragement
- Increase the usage of mobile devices in incident reporting
- Incorporate data sharing functions
- Encourage reporting more details in aspect of incident process than outcome
- Check value validity of data fields that easily encountered typos
- Add functional aids (e.g. shortcut buttons) for data field entry if it is statistically possible
- Set up prompts in reminding incident details that are important but were often overlooked in previous reports

However, the order of dealing with above issues has not been determined in that we still know little about information behavior model in medical incident reporting and whether they will be sense-making to real user in the practice. Nevertheless, we believe an iterative process of system prototyping is able to figure this problem out step by step.

**Table 2.** Recent design suggestions of VMIR

| Design suggestions for VMIR | Literatures |
|---|---|
| Specialty-based; Feedback to encourage reporting, educate clinicians and notify corrective actions taken | Holden & Karsh, 2007[2] |
| Handheld computer application narrowing down participation biases | Dollarhide, Rutledge, Weinger, & Dresselhaus, 2008[31] |
| Reinforce process-oriented than outcome-oriented in reporting | Nuckols, Bell, Paddock, & Hilborne, 2009[32] |
| The group level data sharing might prompt error reporting rate significantly | Anderson, Ramanujam, Hensel, & Sirio, 2010[33] |

## 5 Current Efforts

The computer-based prototype of VMIR has gone through its initial usability inspection[28] and testing on system interface. The usability violations identified by heuristic evaluation were partially fixed according to the severity. The latest prototype is undergoing a think aloud user testing by five human subjects who are target and

real users to identify cognitive difficulties in using the prototype of reporting patient fall incident. Simultaneously, an unobtrusive data analysis on historical reports is in process, which selects patient fall as a demonstrative incident category to extract reprehensive features and indexing vocabulary for (semi-)structuring free text entries in reports. The initial work of this process has been accepted and in press since 2010 summer[30]. Furthermore, we are transplanting a few theories in Information Science and Communication Science to collaborate with technical solutions for bridging sense-making gaps of organization and stakeholder individuals.

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