

Educational Brief

Al/algorithm-related Issues in the NPSD

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Overview

Executive Order 14110 - "Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence (AI)" outlines the Biden administration's vision for ensuring the safe, responsible deployment and use of AI, particularly in healthcare. This vision calls for a partnership with Patient Safety Organizations (PSOs) to establish a common framework for capturing and analyzing clinical errors resulting from AI deployed in healthcare settings that cause harm. In response to this landmark Executive Order, this brief summarizes exploratory analysis of potential AI-related patient safety events within the Network of Patient Safety Databases (NPSD). Specifically, this brief focuses on Health Information Technology (HIT)-related events to shed light on potential AI-related issues, including improper algorithm design, algorithm malfunctions, or unplanned human-algorithm interactions.

The Common Formats for Event Reporting – Hospital (CFER-H) provides a framework for capturing potential AI-related errors. The CFER-H considers HIT devices, which involve hardware and/or software that algorithmically handle data to aid in the diagnosis, treatment or prevention of disease. Data submitted to the NPSD from June 26, 2014 through December 31, 2023 were explored to determine the extent of such errors reported within the NPSD. Among a total of 4,523,459 reported events using both CFER-H versions 1.2 and 2.0, 101,912 (2.3%) cases were associated with HIT: either directly as Device or HIT events, or indirectly as having data or HIT as contributing factors.

Data Submission on Device and HIT Events

Figure 1 shows HIT-related events detected through both direct and indirect approaches. It should be noted that CFER-H V1.2 data were examined using both the direct and indirect approach whereas CFER-H V2.0 data were examined using only the indirect approach as HIT is not included in the Device module, but is a contributing factor in CFER-H V2.0.



Figure 1: Hierarchy of HIT-related event identification

Among the 85,576 Device/HIT events reported in CFER-H V1.2, 43,200 events reported valid *Type of Device* (DE141). Within specified types of devices, *medical equipment* (e.g., walker, hearing aid) was the most commonly reported (86.9%), while *HIT device* was the least commonly specified type of device, only specified in 1,132 (2.6%) events.

Of these 1,132 Device/HIT events that involve HIT device, 438 events (38.7%) included the *Device Event Description* (DE156). Among the reported event description categories, 32.2% were reported as device defect or failure, 21.9% cases reported use error, and 20.1% cases reported a combination or interaction of the two categories above (Figure 2). The remaining 25.8% of cases were reported as unknown in the event description.







Within the 1,132 Device/HIT events that involved HIT device, 597 events (52.7%) included the specific type of HIT device (DE534). Figure 3 shows the most common types of HIT device: *electronic health record (EHR) (41.3%)* and *human interface device* (e.g., keyboard, mouse, touchscreen, speech recognition system, monitor/display, printer) (20.6%), respectively. *Radiology/diagnostic imaging system*, including picture archiving and communications system (PACS) (8.5%), *administrative/billing or practice management system* (7.5%), and *automated dispensing system* (4.8%) were less frequent. The remaining 17.2% of events involved *Other* types of HIT device.

Of the events where EHR was the reported HIT device type, 220 cases specified the EHR component involved (DE540) in the event. *Computerized provider order entry (CPOE)*, *Electronic medication administration record (e-MAR)*, and *Clinical documentation system* were the top three most commonly reported EHR components, making up 31.8%, 26.8% and 13.6% of cases respectively.

Figure 3. HIT Device in Device/HIT Events



Free-Text Reports for Device or HIT Events

While the structured data offer a promising mode for capturing AI-related patient safety errors, a more comprehensive understanding requires additional context from free-text narratives for nuance. Among Device or HIT events within CFER-H V1.2 data, there were 1,470 narratives related to HIT, device, or data issues and 7,466 narratives concerning software-related problems. For CFER-H V2.0, 6,683 narratives noted HIT as a contributing factor.



Text mining and natural language processing (NLP) approaches that identify word importance (Term Frequency-Inverse Document Frequency, "TF-IDF"), common themes shared by texts (Latent Dirichlet Allocation, "LDA"), and text similarities (text clustering) were used to explore the HIT-related narratives (see Figure 4) and identify keywords. HIT/algorithm-related keywords yielded from each NLP approach were used to select text examples for experts' manual review.



Figure 4. NLP Workflow to Explore Free Narratives in Device/HIT Events

Examination of these narratives yielded from the NLP workflow, revealed several potential AI/HIT-related issues. Table 1 highlights select issues detected from free-text narratives.

Table 1. HIT/AI Issues Identified using NLP

Potential HIT/AI issues	HIT related paraphrases
Improper algorithm design in EHR	Patient had hysterectomy. Epic didn't route the report to the doctor as the patient is inpatient. This is concerning as pathology reports should always be routed regardless of if the patient is inpatient or outpatient.
Improper algorithm design in EHR	Current insulin gtt order in Epic does NOT have a safeguard for a quickly decreasing blood glucose. Nurse recognized a potential for future hypoglycemia and consulted pharm and intensivist for a decreased rate that is outside of the order.
Malfunction of medication dispensing system	Nurse removing medication from Pyxis, however, Pyxis count is incorrect.
Malfunction of Image Guided planning and navigation system	Both the computer assisted Image Guided planning system and Navigation system froze during neurosurgical procedure causing delay of 40 60 minutes
Improper use of medication dispensing system	Pharmacist discovered no TPA stored in Pyxis. The medication should never be empty.

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Conclusion

Current data elements in the Common Formats can already accommodate reporting of some potential Albased safety issues. The analysis of past and current Al-related events provides valuable insights into Al-related issues from both algorithmic and human-algorithm interaction perspectives. These insights can shape approaches to identifying and quantifying future issues as Al is increasingly incorporated into healthcare settings. Beyond providing valuable lessons learned in the implementation of past and current technology, the comprehensiveness and completeness of Al-related issue submissions from PSOs can enhance the ability of the Common Formats to capture future AI issues, advance analyses and learning at the national level, promote awareness, and inform training opportunities for healthcare workforce as the integration of AI and range of AI technologies in healthcare settings continues to grow.

Technical Assistance

Contact the PSOPPC Help Desk for additional technical assistance via email at support@psoppc.org, or via phone at (866) 571-7712, Mon-Fri, 9am – 5:30pm, ET. You can also submit an inquiry via our contact Us page on the PSOPPC website.

