Toward safer health care: a review strategy of FDA medical device adverse event database to identify and categorize health information technology related events

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ABSTRACT

Introduction: Health information technology (HIT) is intended to provide safer and better care to patients. However, poorly designed or implemented HIT poses a key risk to patient safety. It is essential for healthcare providers and researchers to investigate the HIT-related events. Unfortunately, the lack of HIT-related event databases in the community hinders the analysis and management of HIT-related events.

Objectives: Develop a standardized process for identifying HIT-related events from a Federal Drug Administration (FDA) database in order to create an HIT exclusive database for analysis and learning.

Methods: The FDA Manufacturer and User Facility Device Experience (MAUDE) database, containing over 7-million reports about medical device malfunctions and problems leading to serious injury or death, was considered as a potential resource to identify HIT-related events. We developed a strategy of identifying and categorizing HIT-related events from the FDA reports through the application of a keyword filter and standardized expert review. Ten percent identified reports were reviewed to measure the consistency among experts and to initialize a database for HIT-related events.

Results: With the proposed strategy, we initialized an HIT-related event database with over 3500 reports, and updated the estimation of the HIT-related event proportion in the FDA MAUDE database to 0.46–0.69%, up to 50,000 HIT-related events.

Conclusion: The proposed strategy for HIT-related event identification holds promise in aiding the understanding, characterization, discovery, and reporting of HIT-related events toward improved patient safety. The analysis of contributing factors under the 8-dimensional sociotechnical model shows that hardware and software, clinical content, and human–computer interface were identified more frequently than the other dimensions.

Key words: health information technology, patient safety, database

INTRODUCTION

The Agency for Healthcare Research and Quality (AHRQ) defines health information technology (HIT) as the use of information and communication technology in healthcare to support the delivery of patient or population care or to support patient self-management. In practice, HIT is often considered a synonym of electronic health records (EHR) and EHR components such as computerized provider order entry (CPOE) or clinical decision support system (CDSS). Generalized HIT also includes administrative or practice management systems, automated dispensing systems, laboratory information systems, and diagnostic imaging systems. Nowadays, HIT has become an integral part of healthcare and has been widely applied to collect, transmit, process, display, and store patient data. The Institute of Medicine (IOM) and recent literature suggest
that HIT plays an imperative role in saving healthcare cost, improving patient outcomes, decreasing occurrence of medication errors, and refining healthcare process measures across diverse settings.

However, HIT was listed in the top 10 technology-related hazards because it may lead to new uncertainties and risks for patient safety through disrupting established work patterns, creating new risks in practice, and encouraging workarounds. For instance, the increasing adoption of EHR has revealed potential safety implications related to EHR design, implementation, and use. These risks are not solely related to the technological features of EHR but may involve EHR users and their workflows, aspects of the organizations where they function, and the rules and regulations that govern or oversee their activities. To understand and manage these risks in a sociotechnical context, Sittig and Singh developed an 8-dimensional sociotechnical model that includes (1) hardware and software, (2) clinical content, (3) human-computer interface, (4) people, (5) workflow and communication, (6) organizational policies and procedures, (7) external rules, regulations and pressures, and (8) system measurement and monitoring. The model accounts for the complexities of technology, its users, the involved workflow, and the larger external or organizational policies and context in assessment of EHR-related safety concerns. The sociotechnical model has been applied as a practical tool in patient safety studies regarding the safety and effectiveness of HIT at all levels of design, development, implementation, use, and evaluation.

Furthermore, the sociotechnical model may be applicable for educating healthcare providers toward safer use of HIT, yet the lack of resources for HIT-related event reports hinders the progress toward this goal. There is no single reporting system exclusively designed for HIT-related events. Instead, HIT is often cited as one of the contributing factor categories in most patient safety reporting systems (eg the AHRQ Common Formats for Event Reporting Hospital Version 2.0 released in 2017). Although The Informatics Patient Safety Office of the Veterans Health Administration (VA) maintains a non-punitive, voluntary reporting system to collect, and investigate EHR-related safety concerns, the VA system does not cover other types of HIT-related events. Establishing an HIT-related event database could provide an integrated view of HIT-related events toward effective learning. Each year, the U.S. Food and Drug Administration (FDA) receives approximately 2 million reports about adverse events, use errors, and product complaints from consumers, healthcare professionals, manufacturers, and others, within which the reports involving medical device malfunctions and problems leading to serious injury and death have been archived in the FDA Manufacturer and User Facility Device Experience (MAUDE) database since 1991. Updated weekly, the FDA MAUDE database is searchable online. As of July 2018, MAUDE has archived more than 7 million reports, which makes it a rich and publicly accessible resource for the extraction of HIT-related events. Magrabi et al estimated that the proportion of HIT-related event reports in the FDA MAUDE database is 0.1% based on the data between 2008 and 2010. Magrabi’s research was not guided by the sociotechnical model, and the estimation has been out of date due to a sharp increase (4.6 million) in the MAUDE reports received after 2010 and the wide adoption of HIT in healthcare settings. Recently, Castro et al identified 77 contributing factors in the 8 sociotechnical dimensions and applied the factors to analyze HIT-related sentinel events. Castro’s research conducted on a small dataset that is publicly inaccessible constrains the reproducibility of the results by other researchers. Therefore, it is necessary to update the estimation of HIT-related event proportion in the FDA MAUDE database that is publicly accessible and to develop a practical and reproducible strategy for extracting and categorizing HIT-related events toward shared learning.

Identifying HIT-related events from the FDA MAUDE database is challenging due to its unique data structure. Most structured fields in MAUDE reports are not specific for identifying HIT-related events since MAUDE was not originally designed for HIT-related event reporting. Additionally, applying machine-learning approaches such as directly training classifiers based on the unstructured fields is challenging because of the fractional proportion of HIT-related events in the MAUDE database. Moreover, manual review of unstructured fields is labor intensive and requires consistent criteria. To meet the challenges, our objectives were to: (1) improve the HIT filter proposed in our preliminary study based on the structured fields of MAUDE; (2) develop a strategy based on the sociotechnical model to identify and categorize HIT-related events from MAUDE; (3) initialize an HIT-related event database by identifying and categorizing HIT-related events from the 2008 to 2016 MAUDE reports toward shared learning; and (4) update the estimated proportion of HIT-related events in MAUDE.

METHODS

Improve the filter for HIT-related event reports
Each report in the FDA MAUDE database consists of 45 structured fields regarding the device involved in an event. Most of the fields, unfortunately, are of little use for the purpose of identifying and synchronizing HIT-related events and are often left blank. In our preliminary study, we successfully identified that the structured fields of MAUDE, including generic name and manufacturer name fields, have the greatest potential in identifying HIT-related events. Further, we utilized the 2 fields in the creation of a keyword-based filter. In this study, we integrated Magrabi’s and Castro’s work to further improve the inclusion and exclusion keyword list of the filter to apply the filter on the 2008–2016 MAUDE data. The variations of keywords, such as “electronic health record” in addition to “EHR”, were added to help ensure the maximum inclusion of HIT-related events.

Data curation and sampling
Multiple narrative entries from duplicate filtered reports were merged into a single report. Then, all reports were categorized according to one of the following numbers: Health Care Facility Association (HCFA) number, distributor report number, or manufacturer report number. All numbers were in the format NNNNNNNNNN-YYYY-XXXXX, where Ns represent either the 10-character HCFA number or the 7-digit registration number of manufacturer/distributor; YYYY is the year of the report and XXXXX represents the 4- or 5-digit sequence number in the reporting year.

To reduce the review burden for expert review, 10% of the filtered reports were randomly sampled according to the distribution of HCFA/distributor/manufacturer number. When fewer than 10 reports were available within a given HCFA/distributor/manufacturer number, we randomly selected one report to represent the group. The sample reports were grouped per year for expert review.

Expert review
The review criteria were determined according to the HIT definition by AHRQ and the sociotechnical model proposed by Sittig and Singh. Reports involving electronic processing (eg to create,
collect, transmit, analyze, store, or display) of data or information were identified as an HIT-related events. We discussed with a research group of Patient Safety Organization institute and classified all the reports into 3 categories:

1. HIT-related event: an event that involves at least one issue of electronically processing data or information;
2. Non-HIT event: an event that does not involve any issue of electronically processing data or information;
3. Unsure event: an event that involves any device applied to generate analysis results but has limited information about whether electronically processing data or information is involved.

The HIT contributing factors associated with the 8 dimensions of the sociotechnical model were applied to help the reviewers make final decisions. A report was labeled as HIT-related if any contributing factor was identified in the report. More specific inclusion and exclusion criteria are described as follows. Please note that although EHR events are more expected, the inclusion criteria were developed to cover all HIT-related events.

### 1. Inclusion criteria
- A. Any software malfunction in EHR or a component of EHR (e.g., CPOE system, pharmacy system, e-MAR, clinical documentation system) that causes failure in retrieving, transmitting, or storing information;
- B. Any human–machine interaction issue (e.g., user interface design, information display) that causes or may cause failure or error in information collection (e.g., entering data) or information representation;
- C. Any hardware malfunction of an HIT device (e.g., monitor malfunction, printer malfunction, keyboard malfunction, network cable connection, problem of power supply such as an integrated battery module or circuit board issue);
- D. Any picture archiving and communication system (PACS) issue (e.g., transmission, retrieving, displaying, storage and measuring images);
- E. Any automated dispensing system malfunction (e.g., malfunction in drawer which may affect workflow);
- F. Any laboratory information system (LIS) issue (e.g., transmission, retrieving, displaying, storage and measuring analysis results).

### 2. Exclusion criteria
- A. Any event that involved an HIT device but was not a data or information issue (e.g., a device falls down);
- B. Any event that involved an image device but was not related to information issue (e.g., a patient’s skin is burned by a probe of an image device or a patient is physically injured by an image device);
- C. Any event that involved a laboratory device (e.g., an analyzer) but was not related to information issue (e.g., data transmission, displaying);
- D. Any event that involved a surgical device that failed to work due to mechanical problems or control system glitches.

Three experts who are familiar with patient safety data reviewed and further identified HIT-related events from the pre-identified reports. Each reviewer was assigned non-redundant 3-year sample reports from the 9 years (see data curation and sampling section). The review procedure for a report can be summarized as 2 steps: (1) identifying the medical device involved in an event through generic name, manufacturer name, and brand name; (2) identifying the type of event (HIT, non-HIT, or unsure) through event description and manufacture narrative. The review procedure is illustrated in Figure 1.

### Improve exclusion keyword list
We further improved the keyword filter to reduce review burden. Based on the hypothesis that a non-HIT product in MAUDE rarely leads to an HIT-related event, we extended the keyword filter by developing an additional exclusion list of non-HIT generic names through expert review. The generic names of the sample reports extracted from 2008 to 2016 were reviewed and annotated by 2 expert reviewers. To improve generalizability of the exclusion list, generic names that appeared in at least 2 years from 2008 to 2016 were selected for review. Additionally, if more than 25% of the reports related to a given generic name were labeled as non-HIT, this generic name would be added to the exclusion list.

### Assess the consistency among reviewers
To evaluate biases from manual review, we randomly chose 1-year data (2011) and asked all reviewers to review individually. A Fleiss’ kappa, a statistical measure for assessing the reliability of agreement among multiple raters, was calculated to the review results from the 3 reviewers. We also created a gold standard by applying the majority decision as a final decision to each report.

### Assign contributing factors
Toward exploring the overview of HIT-related events in MAUDE, we further annotated the MAUDE reports collected in the year 2016 with Castro’s contributing factors organized by the 8 dimensions of the sociotechnical model. Group discussions were applied to fix divergences.

### Update the estimated proportion of HIT-related events in MAUDE
We updated the estimation based on the manual review of the latest 9-year MAUDE data (2008–2016) sampled from the pre-identified reports. Our updated estimation was proposed as a range whereby the minimum value was estimated assuming all reports labeled as “unsure” were non-HIT, and the maximum value was estimated assuming all “unsure” reports were HIT-related.

### RESULTS
An improved filter for identifying HIT-related events
A full list of keywords was created by combining our preliminary study with Magrabi’s and Castro’s studies, as shown in Table 1 (for generic names) and Table 2 (for manufacturer names). The filter was applied on the recent 9-year MAUDE data (2008–2016) to extract potential HIT-related events.

### Manual identification on sample reports
The filter identified 45 624 (0.92% of 4 947 220) potential HIT-related event reports from the latest 9-year MAUDE database. As shown in Table 3, 6994 (15.3% of 45 624) reports were sampled for manual review, among which 3521 reports were labeled as HIT-related, 1760 were labeled as non-HIT, and 1713 were labeled as unsure. Based on the sample rates, the minimum percentage of HIT-related events in the overall 4 947 220 reports was 0.46% (assuming all unsure reports were non-HIT), while the maximum percentage...
was 0.69% (assuming all unsure reports were HIT-related). The Fleiss’ kappa of the 3 reviewers’ decisions on a sample year’s data (2011) was 0.85 ($P < 0.01$), which indicates a high consistency among different reviewers guided by the same review criteria.

Distributions of the contributing factors and the 8 dimensions of the sociotechnical model
To assess the variety and to explore the learning values of the HIT-related events in the MAUDE database, the expert reviewers further labeled the 268 HIT-related event reports from the MAUDE database of year 2016 with the 8 dimensions of the sociotechnical model and successfully assigned at least one contributing factor to each report (Figure 2). The results showed that the 268 reports cover 41 contributing factors in 7 out of the 8 sociotechnical dimensions, among which 3 dimensions (ie hardware and software, clinical content, and human–computer interface) were assigned to more reports than the others.

A narrative section of MAUDE reports usually consists of 2 subsections: (1) event description and (2) manufacture narrative. The event description is written based on healthcare provider’s observation and patient’s narration, whereas manufacture narrative describes how the manufacture responds to the event, what kind of investigation was conducted and the findings of the investigation. According to our annotating experience, the information matching machine-related contributing factors (hardware and software, clinical content, human–computer interface) can usually be found in both sections, while the information matching non-machine-related contributing factors (people, organization and system) can only be reflected by manufacture narrative.

Improvement of keyword filter
The final exclusion list of keyword filter comprised of 38 generic names were determined to be non-HIT generic names. The average precision of filtering non-HIT reports by this exclusion list was 0.99. About 6% reports with high probability of non-HIT will be removed before manual review to reduce future review burden.

DISCUSSION
A standardized process for identifying HIT-related events from FDA database
The FDA MAUDE database is the richest, publicly accessible HIT-related event resource, yet the low proportion of HIT-related events hinders the application of machine learning algorithms to train and assess classifiers. The keyword-based filter proposed in this study can pre-identify potential HIT-related events from millions of raw reports in MAUDE and generate a dataset with only 0.5% amount of the raw reports. More importantly, at least 50% reports in the dataset are HIT-related, which provides a more balanced dataset to apply machine learning methods for further HIT-related event identification. To initialize a gold standard for HIT-related event
The lack of specific databases. In this study, we initialized the first larger problems. Learning from these events is challenging due to Some HIT-related events may seem trivial but could represent much Initialization of an HIT-related event database and categorize HIT-related events over time. On the other hand, event identification and provides a standardized process to identify This novel strategy overcomes the main challenges of HIT-related proposed a strict review strategy to standardize the manual review. Exclusion keywords (21) Automated chest compressor, Automated external defib, Blood glucose monitoring system, Blood pressure module, Bone paste, Contact lens, Defib, Defibrillator, Fecal management system, Glucose monitor, ICT calibrator, Implantable, Implanted, Pacemaker, Paste, PE SLIT, Pump, Thermometer, Toothette oral care suction swab, Ventilator, Warmer

Table 2. HIT-related keywords for manufacture names in alphabetical order

Inclusion keywords (38)
Allscripts, Aprima, AthenaClinicals, Athenahealth, Centricity, Cerner, CureMD, DocApp, DocPatient Network, Doctations, eClinicalWorks, Epic, EpicCare, GE Healthcare, Greenway, Hass, Healthtrons, Henry Schein, Homer, Horizon Ambulatory, Intergy, iPatientCare, Isite, iSOFT, Kestral, McKesson, Medical Director, Medisoft Clinical, Meditech, MedPro, Medsphere, MyChart, NextGen, Oasis, OpenVista, Practice fusion, Prime Suite, Sage

Identification and to grow an HIT-related event database, we applied the contributing factors from the sociotechnical model and proposed a strict review strategy to standardize the manual review. This novel strategy overcomes the main challenges of HIT-related event identification and provides a standardized process to identify and categorize HIT-related events over time. On the other hand, HIT might be designed as a contributing factor in some patient safety reporting systems, this contributing factor, however, have been often overshadowed by other major factors of specific types and thus ignored by clinicians. The HIT exclusive system may raise the clinician’s awareness of the HIT-related events.

Initialization of an HIT-related event database
Some HIT-related events may seem trivial but could represent much larger problems. Learning from these events is challenging due to the lack of specific databases. In this study, we initialized the first HIT-related event database with 3521 high-quality event reports identified and cross-validated by domain experts from the latest 9-year MAUDE data. The database holds promise in organizing the events by connecting and synchronizing them with large databases, which would help reporters and reviewers describe, understand, and integrate the events connecting to the content of a fuller spectrum of HIT. Moreover, an HIT-related event classifier based on unstructured field could be further improved by applying advanced machine learning methods. The initialized database also offers a gold standard for classifier training and assessment.

Applying the sociotechnical model and contributing factors for healthcare provider education
The HIT contributing factors and the 8 dimensions of the sociotechnical model were applied to identify HIT-related events. Labeling the identified HIT-related events from the 2016 MAUDE data indicates that the events identified from MAUDE cover most of the sociotechnical dimensions and more events are associated with the dimensions of hardware and software, clinical content, and human-computer interface. The contributing factors are very useful profiles for report archiving and learning. Moreover, the contributing factors have potential to be extended to an HIT knowledge base to measure the similarity between HIT-related events.

These findings, in contrast to Castro’s study of 120 HIT-related events from the Joint Commission, indicate that contributing factors associated with the human–computer interface are the most frequent, followed by contributing factors related to workflow and communication and clinical-content. The differences of factor frequencies between the 2 studies may be due to the scope and purpose of the patient safety databases and the people who have reported the events. The differences also suggest that the design of a patient safety event reporting system may influence the characterization of the reported events, because the event details provided by reporters may vary when different reporting systems are applied.

Benefits of shared learning and reporting systems
While all technologies are fallible, technology-induced errors in healthcare may have far more serious repercussions than those in other fields. Even with extensive testing, HIT may be especially vulnerable to failure due to the fast pace and complexity of healthcare systems. As an example, many EHR systems perform well in testing when used by only one user of each user category in an office setting. However, when released to the public, the EHR systems may malfunction as a group of clinicians from all areas of medicine may use them in a variety of settings. Manufacturers of technology often do not have the resources to test their products on such a large scale and must instead rely on user generated reports to inform them of possible defects with their products. Implementation of a similar system for HIT-related events could yield tremendous benefits and serve as a system for post-marketing surveillance and risk assessment. In our previous study, the Kirkpatrick model, a cognitive model frequently used for training and performance evaluation in various areas, was applied to prototype an integrated reporting and shared learning system for patient safety events, which connects knowledge collection, reorganization, and sharing. With the knowledge gleaned from a shared learning system, patient safety experts could analyze the distribution of HIT-related events and identify common underlying factors among the reports. Safety experts could then prioritize their efforts to generate actionable solutions for the most important and pressing patient safety events.
Though patient safety event reporting systems have been utilized over the last decade to increase awareness of patient safety issues, several barriers still impede the fulfillment of their potential. Many reporting systems are still paper based, which hinders data sharing. Ambiguity of wording and phrasing makes the reports hard to understand and analyze. It is also challenging to aggregate and integrate data scattered across multiple reporting systems.

FDA MAUDE may contain even more HIT-related events than estimated

Before this study, the only estimated proportion of HIT-related events in the FDA MAUDE database was 0.1%. However, the estimation is no longer able to reflect the up-to-date situation since it was proposed in 2012 based on 3-year MAUDE data. In our preliminary study, we proposed a dataset with 97% HIT-related event reports from the raw database of the 2015 FDA MAUDE, and roughly estimated that 0.4–0.9% reports in the 2015 MAUDE database are HIT-related. To explore the potential learning value of the whole MAUDE database toward HIT enhanced healthcare settings, we updated the estimation in this study to 0.46–0.69% through a well-designed review strategy. The decrease of the estimation from our preliminary study may be due to the peak in the HIT-related report ratio that appeared in year 2015 that was caused by a large number of follow-up reports to the events attributed to one a specific vital sign monitor rather than an EHR. If we exclude the outlier (data of 2015) from the list, the estimation of HIT ratio will drop to 0.25–0.48%. However, the real proportion of HIT-related reports in the whole MAUDE should be much larger, because the filter favored precision over recall to ensure the high ratio of HIT-related events in the filtered reports. Even so, the new estimation indicates a considerable amount of HIT-related events (up to 50,000) in MAUDE database, which makes MAUDE a valuable, and to our knowledge, the only publicly accessible resource so far for the identification of HIT-related events.

| Year | Raw reports | Filtered reports | Review results | HIT proportion |
|------|-------------|------------------|----------------|----------------|
|      | Unique HCFA/ | Unique HCFA/ | HIT-related | Non-HIT | Unsure | Min (%) | Max (%) |
|      | manufacturer/ | manufacturer/ |          |         |        |          |          |
|      | distributor | distributor | for review |          |        |          |          |
| 2008 | 145 598      | 9148            | 1817         | 146     | 373    | 123      | 82       | 168     | 0.41 | 0.97 |
| 2009 | 201 996      | 9906            | 2640         | 214     | 459    | 165      | 114      | 180     | 0.47 | 0.98 |
| 2010 | 327 961      | 10 792          | 3434         | 316     | 654    | 220      | 169      | 265     | 0.35 | 0.78 |
| 2011 | 414 083      | 12 597          | 2371         | 307     | 490    | 252      | 122      | 116     | 0.29 | 0.43 |
| 2012 | 520 043      | 12 952          | 4825         | 308     | 732    | 217      | 203      | 312     | 0.28 | 0.67 |
| 2013 | 636 145      | 12 516          | 3551         | 313     | 614    | 193      | 178      | 243     | 0.18 | 0.40 |
| 2014 | 867 451      | 12 927          | 4338         | 380     | 751    | 313      | 314      | 124     | 0.21 | 0.29 |
| 2015 | 965 240      | 15 762          | 17 963       | 384     | 2111   | 1770     | 216      | 125     | 1.56 | 1.67 |
| 2016 | 868 703      | 15 023          | 4685         | 408     | 810    | 268      | 362      | 180     | 0.18 | 0.30 |
| Sum  | 4 947 220    | 45 624          | 6994         |          |        | 3521     | 1760     | 1713    | 0.46 | 0.69 |

Table 3. Statistics of raw, filtered, sampled, and reviewed reports for the 2008–2016 FDA MAUDE database.
Future work
To reduce review burden and further identify HIT-related events after using the filter, machine-learning algorithms will be applied on the unstructured fields to train and assess a specific classifier. We are also developing an HIT taxonomy to sub-classify and explore the connection of HIT-related events. The improved review strategy, HIT taxonomy, as well as the machine-learning classifier will grow the database of HIT-related events, which holds promise in integrating scattered event reports and exploring the potential connections among events toward an overall understanding and analysis of the characteristics, occurrence, observation, and description of HIT-related events.

Limitations
This study did not cover the entire FDA MAUDE database; however, we believe the potential missing HIT-related events are limited because the reports from the recent 9 years cover nearly 80% of the whole MAUDE database. In addition, the HIT-related events should be more intensive in this 9-year period than in prior years since HIT has just become widely used in healthcare in the last decade. The insignificant discrepancies among reviewers during the review could be another limitation because a small percentage of the identified reports (~5%) might be improperly labeled and imported to the HIT-related event database.

CONCLUSION
We proposed a review strategy to identify and categorize HIT-related events from the FDA MAUDE database based on a keyword filter and sociotechnical model for HIT. The outcomes initialized an HIT-related event database with 3521 event reports, updated the estimated proportion of the HIT-related events in MAUDE to 0.46–0.69%, and demonstrated MAUDE, with up to 50,000 HIT-related event reports, is the most abundant resource of its kind thus far. The strategy and the database hold promise in growing a resource exclusive for HIT-related events, which integrates the scattered knowledge of HIT-related events and serves as an effective educational tool to improve the HIT environment in healthcare settings.

CONTRIBUTORS
H.K. and Y.G. designed the project, organized the expert review, and drafted the manuscript. H.K. performed the data filtering. The expert review was conducted by J.W., B.Y., and S.Z. J.W. performed the assessments of the identified reports. All authors discussed the results and contributed to the final manuscript.

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Conflict of interest statement. None declared.

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