Triggers and Targeted Injury Detection Systems (TIDS) Expert Panel Meeting: Conference Summary

Conference Summary

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Conference Summary Report

Triggers and Targeted Injury Detection Systems (TIDS) Expert Panel Meeting: Conference Summary

June 30 - July 1, 2008
Rockville, MD

U. S. Department of Health and Human Services
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850

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I. Meeting Summary

Purpose of the Meeting

The Agency for Healthcare Research and Quality (AHRQ) is developing and supporting the implementation of clinical triggers and targeted injury detection systems (TIDS) to identify patient safety risks and hazards. Clinical triggers are data flags identifying patients who may be at risk of harm or clinical situations that have the potential for harm. Prospective trigger tools provide rapid, real-time identification of adverse events and enable timely intervention that can prevent or mitigate an adverse event. In contrast, retrospective trigger tools allow identification of risky situations after the clinical episodes have terminated and are most suitable for measurement of event rates.

With many of AHRQ's initial research projects relating to triggers and TIDS coming to a close, AHRQ decided to convene a meeting of trigger and TIDS researchers and Federal and private stakeholders to (1) review progress on trigger/TIDS development and (2) identify (or explore) options for future work in this area.

Meeting Structure and Contents of This Publication

On June 30 and July 1, 2008, AHRQ convened a meeting to achieve the above-named goals. Forty-three researchers and key stakeholders participated in this meeting. In order to provide focus to the discussion, two panel presentations were held: one panel examined the methodological issues arising during triggers/TIDS development; the second panel explored issues surrounding the implementation of triggers/TIDS systems. These panel presentations were followed by extensive small-group discussion of issues raised during the presentations, as well as discussion of action options for assuring successful implementation and sustainable outcomes for future triggers/TIDS work.

This publication summarizes the key points raised at this meeting and contains:

- A literature review, prepared for this meeting, summarizing published work to date in the trigger/TIDS research domain.
- Seven brief articles submitted by the panelists, summarizing their research and implementation work to date.
- A glossary, also prepared specifically for this meeting, to ensure a common understanding of trigger-related terms.

Key aspects of each of these items are briefly summarized below.

Literature Review

The literature review (Section IIA) notes that the majority of work published to date on triggers is related to adverse drug events. These publications on triggers for adverse drug events display a wide variety in the amount of detail and type of data used to detect the adverse event. A less common type of trigger, with significant presence in the literature, relates to surgical adverse events. In this review, Mull and colleagues note that adverse events related to operations are both prevalent and costly. Another significant category of triggers identified in the review consists of triggers linked to causes of adverse events. The review notes a gap in the literature of work surrounding triggers in the ambulatory setting (including outpatient surgery), triggers for diagnostic errors, and circumstances of failure to follow up.

Panel Presentations

Methodological Issues

The methods panel noted that positive predictive value (PPV) is a commonly used measure for determining the value of a trigger system, but PPV is limited because it is dependent on prevalence. Other methods such as sensitivity can be used, but this requires large numbers of patients to be reviewed; therefore, the panelists felt that the field would benefit from the development of new methods.

The importance of developing triggers/TIDS that are appropriate for their intended purpose was also emphasized. It was specifically noted that trigger methods for diagnostic events and ambulatory adverse events are underdeveloped.

Panelists noted that it is critical to develop triggers/TIDS that are integrated into workflow; often this will require an integrated, advanced electronic health record. Paper-based trigger systems can be very informative in identifying adverse events, but generally, paper-based systems require significant staff training and labor-intensive, manual chart review.

Development of real-time, concurrent trigger/TIDS systems for both inpatient and ambulatory care would significantly advance the field.

Focus group work presented during the methods panel revealed clinicians are most interested in triggers that are associated with frequently occurring, critical, and preventable adverse events. The clinicians represented in the research focus group assigned the most value to actionable triggers.

Implementation Issues

Themes surrounding the implementation of triggers/TIDS were identified by the second group of panelists. In AHRQ-funded contracts, inpatient adverse drug event and pressure ulcer algorithms have proved useful for identifying adverse events and hold potential value for mitigating harm. The panelists noted that generally, clinicians perceived an incremental benefit from the triggers/TIDS systems when the systems filled a gap in clinical knowledge. Additionally, implementation of triggers/TIDS tended to be more successful when a multidisciplinary team approach was used.

Like the methods panel, the implementation panel noted that implementation of paper-based systems is often cumbersome due to the large number of charts needing to be reviewed. Some participants in paper-based systems found it difficult to find significant clinical value when weighed against the efforts of implementation. Therefore, automated systems were identified as critical to long-term successful implementation across many health care organizations.

Although automated systems may be costly to develop, one panelist demonstrated methods to develop a clear business case for preventing adverse events based upon hospital discharge cost data and the institution's harm prevalence rates. The panelists noted that harm sustained because of adverse events during hospitalizations results in significant costs to the organization, with impact on reimbursement and opportunity costs. A second approach identified to aid with the business case development for triggers/TIDS was integration of trigger tools into existing quality processes within organizations.

Glossary of Terms

Both earlier researchers and attendees at the expert meeting identified a need for definitional alignment of trigger/TIDS elements. This publication contains a glossary of trigger/TIDS terms (Section III) that both clinicians and researchers will find valuable. The glossary was provided to the attendees for the purpose of advancing the discussions.

Contributing Experts

AHRQ would like to acknowledge the contributing experts who have provided this framework, who are listed in Section IV.

Action Options

A number of future options for AHRQ to consider emerged during the small-group discussions. These included:

- Continued development of triggers/TIDS systems that match the intended purpose of use (in terms of logic, method of evaluation, etc.). Systems intended for ranking or rate estimation functions must be evaluated very stringently.
- Continued research to explore methods of integrating trigger/TIDS harm identification and mitigation into existing health information technology and into existing workflow. Implementation of the trigger tools is not easy and may require guidance and support from entities external to the implementing organization.
- Support of development and spread of the business case for triggers/TIDS and for systems that mitigate harm.
- Continued dialog among Federal agencies likely to be interested in triggers/TIDS and patient safety monitoring.
- New grant or contract funding for triggers/TIDS development on outpatient surgery, care transitions, long-term care, and ambulatory settings.

- Development of standards for definitions of triggers/TIDS variables to facilitate easier adoption and promotion of uniformity.
- Support for collaborative organizations seeking to apply triggers/TIDS.
- Support for demonstrations and research on trigger/TIDS implementation, with distribution of lessons learned to systems interested in implementation.
- Development of a standardized implementation tool for triggers/TIDS.

A final observation is perhaps in order regarding further work on trigger/TIDS development. No clear definition of triggers/TIDS emerged that clearly delineated a mechanism or mechanisms substantially different from current approaches found in either (1) real-time alerts and reminders embedded in electronic health records or (2) retrospective chart review conducted using either explicit "triggers" (measures) or subjective analysis. Further work may be needed to be define a unique and cost-effective role for new triggers/TIDS mechanisms.

II. Articles Submitted for Meeting

A. A Review of the Trigger Literature: Adverse Events Targeted and Gaps in Detection

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Stephanie Shimada, Ph.D.[a]
Jonathan Nebeker, M.D., M.S.[b]
Amy Rosen, Ph.D.[a]

Background

An important development in adverse event (AE) detection is the use of triggers, algorithms that use patient data to look for patterns consistent with a possible AE.[A1–A4] In a trigger system, when a trigger flags a record, there is a method to further determine whether an AE occurred. In the case of action-oriented trigger systems, triggers are designed to support clinical interventions that prevent or mitigate iatrogenic harm. Trigger systems have been used in inpatient settings for rate detection and to signal providers to investigate a possible AE in real time.[A5–A7] Recently, trigger systems have been used to detect AEs that occur in particular settings, such as emergency departments[A8] or neonatal intensive care units,[A7] or among specific patient groups, such as pediatric populations.[A7,A9,A10]

This paper reviews the literature on triggers developed as part of an outpatient trigger development project funded by the Agency for Healthcare Research and Quality (AHRQ).[A11]

Methods

This review summarizes the trigger literature published prior to January 1, 2008. In addition to literature from the project team, we conducted searches of information databases using standardized keywords. Forty-five references contained information on triggers or trigger systems. We also reviewed articles for background information on the leading causes and types of AEs.

Summary of Literature on Accounting Trigger Systems

Some triggers are designed to be used together as a trigger system, typically for the purpose of AE rate estimation or accounting.[A3,A6,A12–A17] Most accounting trigger systems were developed by the Institute for Healthcare Improvement (IHI) and include information on implementation as well as guidelines on classifying the harm and/or preventability of AEs detected.[A16] The objective of accounting trigger systems is not to test and improve the positive predictive value (PPV) of any individual trigger, but to estimate rates of AEs within the system.

Summary of Triggers Linked to Specific AEs

For this paper, our primary focus is on triggers and trigger systems that were linked to specific AEs or specific AE causes. (Therefore, we do not include triggers that were part of accounting trigger systems in this section.) The majority of the triggers linked to AEs were drug related (n = 364). Figure 1 shows the most frequent adverse drug events (ADEs) targeted by triggers or trigger systems in the literature. (Only ADEs with ≥ 5 triggers are shown.) In addition to the 23 ADEs shown in Figure 1, there were 88 other ADEs targeted by specific triggers. Triggers varied in the amount of detail or in the type of data used to detect a specific AE. For example, one of the triggers that targeted bleeding was "Vitamin K given," while another trigger that also targeted bleeding included information on the type of bleeding by specifying "International Normalized Ratio (INR) elevated or increasing."[A18]

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Note: The views in this article are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs.

Figure 1. Frequency of triggers linked to specific adverse drug events

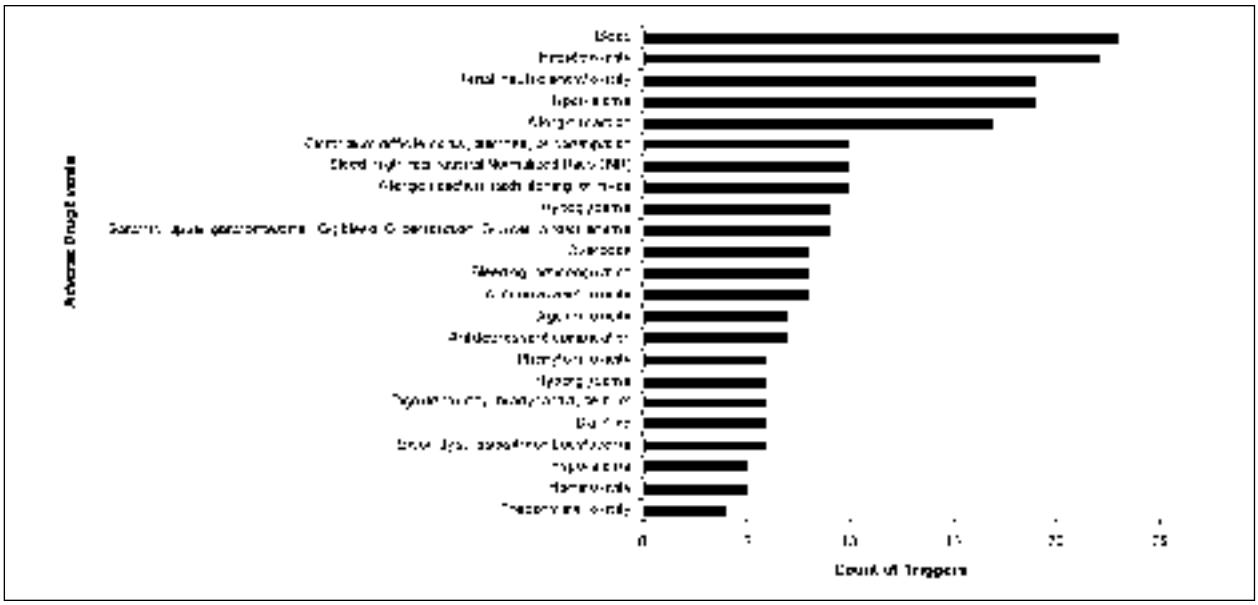


Figure 2 presents the frequency of triggers designed to detect specific AEs that occurred because of medical mismanagement and progression of underlying disease. (Only AEs with ≥ 2 triggers are shown.) In addition to the 18 "medical management failure" events shown, there were 34 other AEs targeted by one trigger. AEs classified as medical mismanagement tend to be rare but harmful, and trigger development in this area is focused primarily on expanding the number of AEs detected, rather than refining the detection process.

Figure 3 shows the distribution of surgical AEs targeted by triggers in the literature. AEs resulting from inpatient and same-day surgeries are prevalent and costly;[A19–A21] however, we found only 31 surgical triggers. Several of these triggers were not part of trigger systems and therefore did not have any mechanism for confirming that an AE occurred.

Figure 2. Frequency of triggers linked to specific medical management adverse events

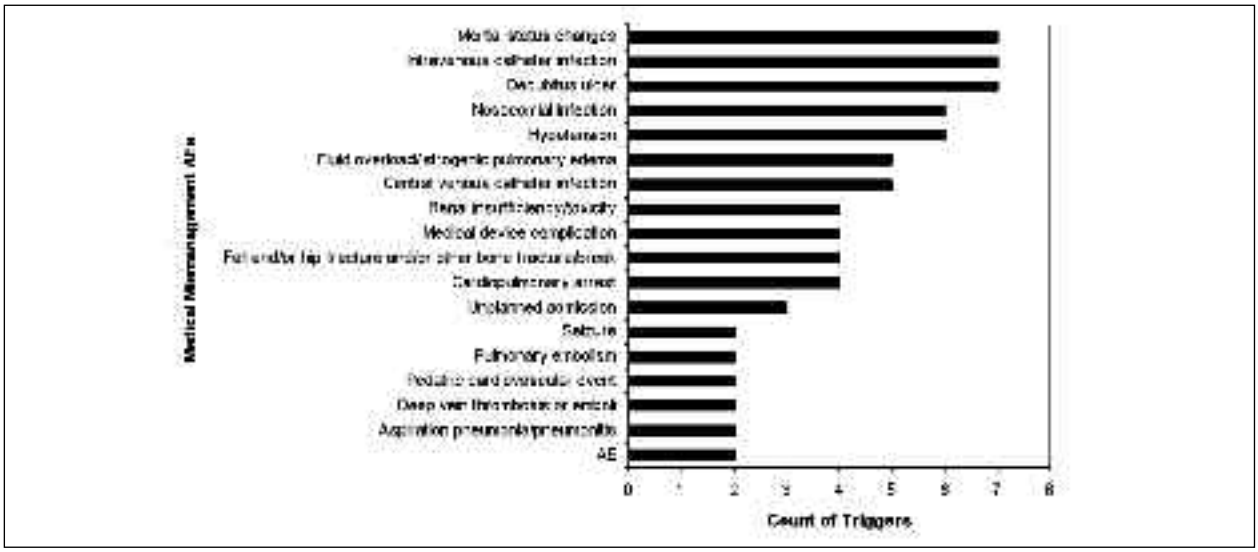
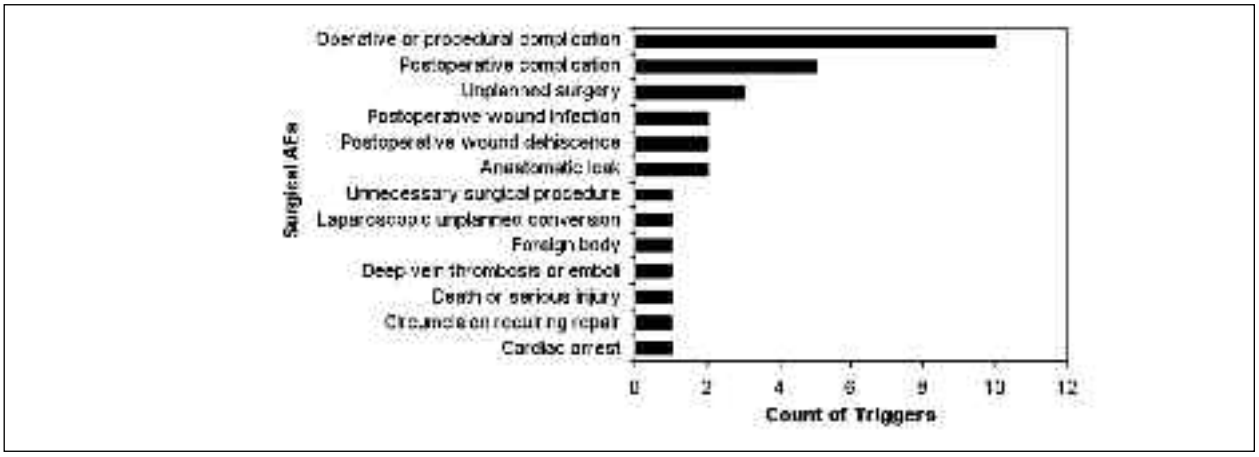


Figure 3. Frequency of triggers linked to surgical adverse events

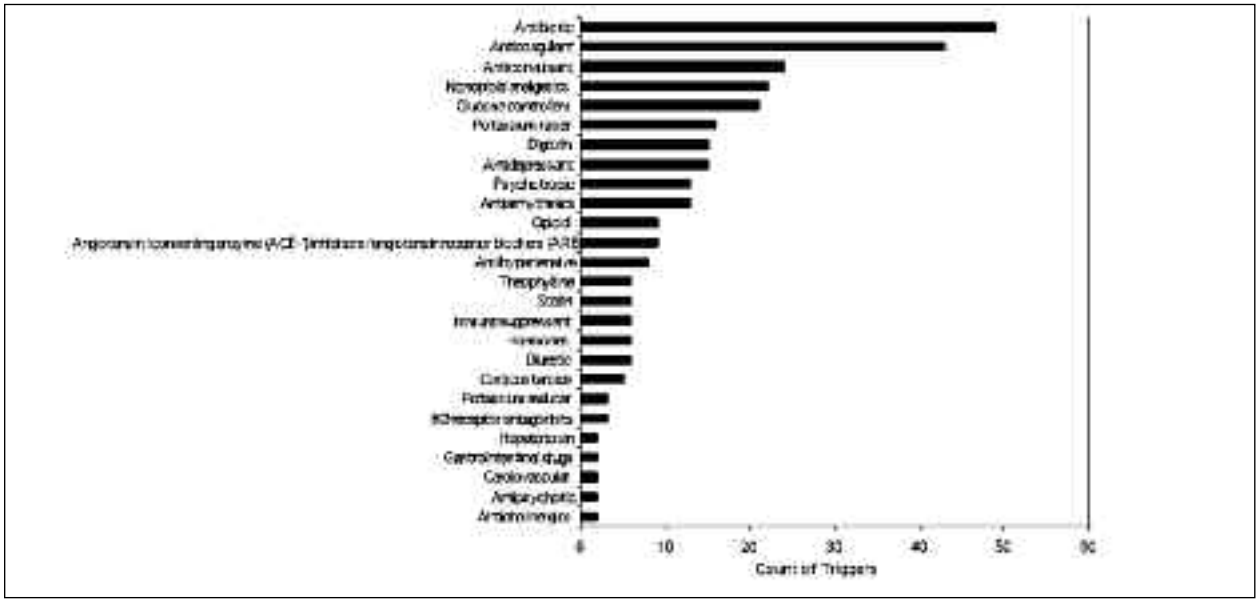


We found 27 triggers that could not be easily categorized. These triggers concerned global AEs (e.g., a natural language processing discharge summary review that used trigger words like "error"[A22]); crimes (e.g., infant abduction[A23]); or death/serious injury with an unspecified cause.[A23]

Summary of Literature on Triggers Linked to AE Causes

We also reviewed triggers and trigger systems linked to the cause of an event. In some cases, particularly with respect to medical mismanagement and surgical triggers, the event was specified and is therefore included in the previous section. There were 314 drug-related triggers that specified the drug that caused the ADE; types of causal drugs are shown in Figure 4. (Only causal agents with ≥ 2 triggers are shown.) One hundred drug-related triggers specify the targeted ADE but do not include the drug or drug class that may have been the causal agent.

Figure 4. Frequency of triggers linked to adverse drug event causal agent



Gaps and Future Directions for Trigger Development

Our review of the literature found that the majority of triggers and trigger systems were drug related. Based on the ADE prevalence literature, the most frequent drug-related triggers detect the most common ADEs in the population.[A24] However, several drugs that cause high rates of ADEs in the outpatient setting are not in the trigger literature: contraceptives, and drugs used for skin, eye, and dental problems.[A24] Future drug-related trigger system development should consider ADE detection in ambulatory settings, including primary and specialty care.

We found a wide variety of triggers designed to detect specific medical mismanagement AEs. Most of these triggers were designed as accounting triggers; however, there is also an opportunity to use the trigger language to develop action-oriented trigger systems. Only two articles specified a cause of medical mismanagement AEs.[A25–A26] Diagnostic errors and failure to follow up are common causes of AEs, and more work needs to be done in developing action-oriented trigger systems that detect these types of events.

With the exception of the IHI,[A14] surgical trigger systems have not yet been developed. While we found two articles with triggers that could be used in an inpatient action-oriented trigger system,[A22–A23] there were no surgical triggers designed for outpatient surgery. Given the severity and nature of surgical AEs, future research should target the development of action-oriented surgical trigger systems for inpatient and outpatient care.

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B. Considering Sensitivity and Positive Predictive Value in Comparing the Performance of Triggers Systems for Iatrogenic Adverse Events

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Background

Trigger systems are typically evaluated for their accuracy in identifying iatrogenic adverse events by examining their positive predictive value (PPV). PPV is an important metric for the performance of a trigger system, since it provides the adverse-event yield of triggered alerts. Hence, it is a measure of efficiency. PPV is also relatively easy to estimate. It requires review of a small sample of patients relative to what would be required for other important performance characteristics. Many authors compare the performance of triggers solely on the basis of PPV. They make comparisons between PPV of triggers targeting different events or similar events in different settings. However, comparison of trigger accuracy based on PPV alone is highly problematic. This brief paper addresses three issues in measuring the performance of a trigger system: the limitations of PPV alone, the need for estimating sensitivity, and the difficulty in assessing sensitivity.

To facilitate discussion, some relevant test characteristics for a binary trigger to detect a binary event, or disease state, are shown in Table 1.

Table 1. Classification table of trigger results by event status

		Trigger		
		Yes (1)	No (1)	
Event	Yes (1)	a	b	a+b
	No (0)	c	d	c+d
		a+c	b+d	a+b+c+d

Sensitivity = true positive fraction = TPF = P[Trigger = 1 | Event = 1] = a/(a+b)

False Negative Fraction = FNF = 1 – Sensitivity = P[Trigger = 0 | Event = 1] = b/(a+b)

Positive Predictive Value = PPV = P[Event = 1 | Trigger = 1] = a/(a+c)

Prevalence = P[Event = 1] = (a+b)/(a+b+c+d)

The Limitations of PPV

There are two limitations in using PPV. First, although PPV provides information on the likelihood of a positive trigger flagging a true event, it does not provide any information on how many events the trigger succeeds in flagging or fails to flag. Second, PPV is largely a function of event prevalence.[B1] Low PPV may be due to poor trigger performance, low event prevalence, or a combination of the two. The correlation of PPV with prevalence may generate problematic comparisons among triggers or across different times and settings. Figure 1 illustrates how prevalence affects PPV. The figure shows curves for three possible values of sensitivity given high specificity, which is typical of trigger applications. As sensitivity and specificity remain fixed for a given line, PPV increases solely as a result of increasing prevalence. Also note the large change in PPV over just a small change in prevalence. The variability in PPV is highest at low prevalence; low prevalence is typical of many types of iatrogenic adverse events.[B2]

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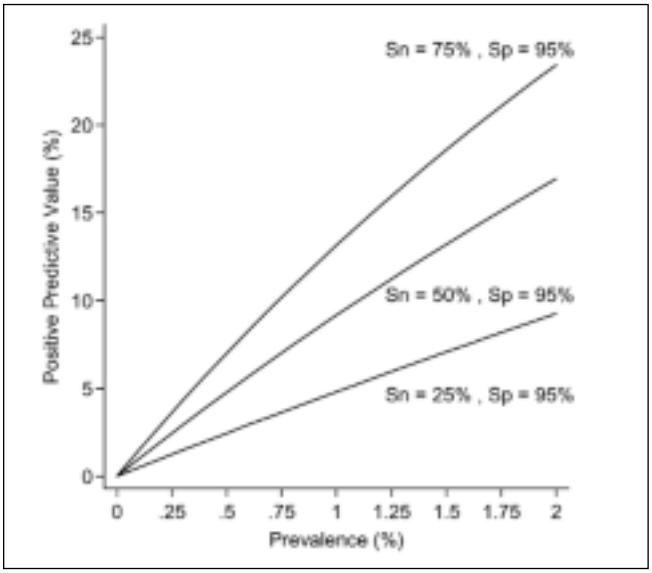
[b] VA Salt Lake City Informatics, Decision Enhancement, and Surveillance (IDEAS) Center; Department of Medicine, University of Utah.
[c] VA Center for Health Quality Outcomes and Economic Research (CHQOER) and School of Public Health, Boston University.
Note: The views in this article are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs.

Figure 1. Relationship of positive predictive value (PPV) and prevalence shown for three combinations of sensitivity (Sn) and specificity (Sp)



The Need for Estimating Sensitivity

There are three advantages to using sensitivity as a performance characteristic of trigger systems. First, sensitivity is independent of prevalence and thus provides a consistent measure of performance in different settings and times. This metric may be used to compare the accuracy of trigger systems.

Second, sensitivity provides clinically significant information about the fraction of targeted events hit (true positive fraction) and missed (1 – sensitivity, false negative fraction). For triggers intended to guide interventions related to individual patients, sensitivity is useful in describing any events that the trigger picks up.

Finally, sensitivity provides important information about the suitability of a trigger system for rate estimation. In a dichotomous system (e.g., events happen or do not), overall accuracy is the average of sensitivity and specificity. The more accurate a system is, the better it can estimate the true rate of an event.[B3] Conversely, trigger systems without sensitivity or accuracy estimates cannot be relied on for rate estimation.

The Difficulty in Assessing Sensitivity

For estimates of sensitivity, a reasonably narrow confidence interval (CI) is desired, which is considered to be "informative." A very wide CI suggests uninformative estimates. Figure 2 shows how confidence levels vary with varying prevalence. It was derived by populating all cells of the 2 by 2 table (Table 1) using random sampling. Note that CIs for sensitivity are unacceptably wide at low prevalence—even for large sample sizes. For sample sizes of at least n = 500, somewhat informative CIs can be obtained if prevalence is as low as 2 percent. However, for a sample size of n = 250, prevalence needs to be 10 percent to achieve the same level of precision. Note that, at low prevalence, confidence intervals for PPV do not widen as dramatically as they do for sensitivity. Of course, much narrower CIs will result if the sample selection is restricted to only trigger-positive cases.

Overall Conclusions

PPV is an important performance metric of trigger systems, but it alone cannot be used to compare performance of triggers unless the underlying prevalence of events is known. Sensitivity provides more clinically relevant information than PPV and can be used to estimate the accuracy of a trigger system. However, when using a random sample of subjects from the population, a arge sample of patients must be reviewed to achieve a moderately precise estimate of sensitivity.

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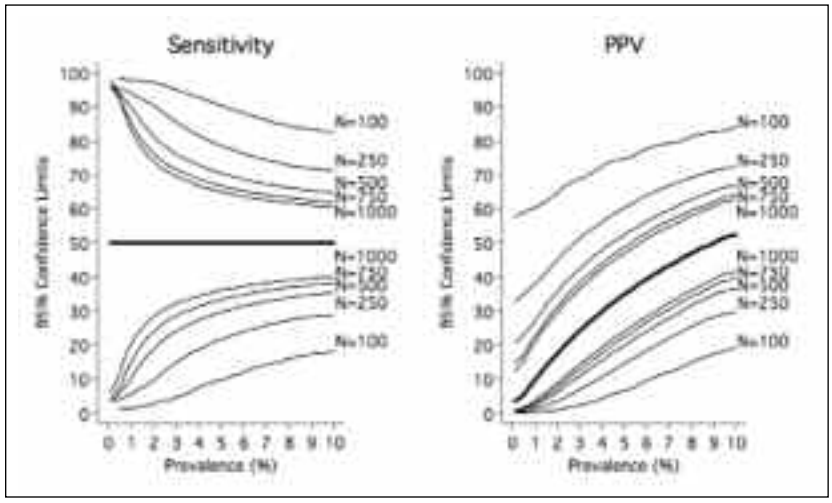
Figure 2. 95-percent confidence limits around sensitivity and positive predictive value (PPV) for various levels of prevalence and sample sizes



Note: Sensitivity and specificity were set at 50 percent and 95 percent, respectively. Waves in lines are caused by rounding values to integers for computation of confidence intervals. Thick lines are the point estimates of each characteristic

C. Triggers and Targeted Injury Detection Systems: Aiming for the Right Target With the Appropriate Tool

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Background

Despite significant attention to detecting inpatient adverse events, very little research has focused on the ambulatory setting.[C1-C3] As described in our task order (The Development and Use of Ambulatory Adverse Event Trigger Tools, AHRQ Task Order No. 3, HHSA 2902006000012), we aim to (1) generate a set of triggers to detect adverse events in the ambulatory setting through an iterative approach involving a literature review of existing triggers and input from a clinical advisory panel, focus groups, and a Delphi panel of experts in trigger tools and related methodologies; (2) conduct an indepth baseline assessment of ambulatory adverse events in the Veterans Health Administration, Intermountain Healthcare, and Boston Medical Center using these triggers; (3) revise and improve the triggers based on results obtained in (2); and (4) evaluate which triggers are most useful, actionable, and amenable to targeted injury detection system (TIDS) development through feedback to quality managers, patient safety officers, clinicians, and managers in each of the three systems.

The three sites assembled for this project combine the presence of strong local expertise and interest in trigger tool development and diversity of patient populations, ambulatory care settings, and information systems. The VA is the largest integrated health care system in the Nation, designed to address the health care needs of the Nation's veterans through a variety of ambulatory settings. Boston Medical Center is an urban academic medical center with a racially and socioeconomically diverse mix of ambulatory patients due to its presence in an underserved and working class neighborhood. Intermountain Healthcare is a not-for-profit integrated health care delivery system located in Utah and Idaho that provides more than 50 percent of all care delivered in the region through providers in both urban and rural settings.

Where Current Triggers/TIDS Work Can Contribute Most

Determining High-Priority Areas to Target

The decision was made a priori to focus our work on developing triggers to identify preventable adverse events related to diagnosis (loss to followup) and treatment (medication, surgery) in outpatient settings. The Delphi panel of clinical experts was therefore asked to rate all ambulatory adverse events they felt were most important to target in these areas. Table 1 lists the ambulatory adverse events that had a median priority rating of 3 or lower. The panelists rated missed or delayed diagnoses as the highest priority area for targeting with triggers, followed by surgical adverse events and adverse drug events.

Determining How to Focus Adverse Drug Event Triggers

In ambulatory care, adverse drug events are common[C4] and represent a large portion of total adverse events.[C5] A systematic review of the literature revealed that

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Note: The views in this article are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs.

Table 1. Highest priority adverse events for trigger development

Adverse event	Priority rating (1=highest priority, 9=lowest priority)
Missed/delayed diagnoses/loss to followup	
Missed/delayed cancer diagnosis	1
Missed/delayed myocardial infarction diagnosis	1
Missed/delayed infection diagnosis	2
Surgical adverse events	
Pulmonary embolism/deep vein thrombosis	2
Postoperative respiratory failure	2.5
Postoperative wound infection	3
Postoperative cardiac event	3
Adverse drug events	
Cardiovascular problems	2
Hemorrhagic event	2
Syncope/dizziness	3
Respiratory problem	3
Infection	3
Hepatic damage	3
Hematologic problem	3
Falls (without injury)	3
Electrolyte imbalance/decreased renal function	3

cardiovascular drugs, analgesics, and hypoglycemic agents accounted for 86.5 percent of preventable adverse drug events in ambulatory care.[C4] However, the most frequently involved agents appear to vary by patient population[C6–C8] and detection setting.[C7,C9] Thus, to determine which drugs were most important to target for trigger development, the Delphi panel was asked to rate the relative importance of the drugs specific to the ambulatory setting. The panel determined the following drug classes to be highest priority for trigger development: analgesics, cardiovascular drugs, hematologic and oncologic agents, antibiotics, neuropsychological drugs, and glucose controllers.

Conclusions

More research is needed to characterize the causes and incidence of adverse events in outpatient settings. The variation observed in studies to date suggests that there is significant variation across settings and patient populations in the prevalence and causes of adverse events. Although adverse drug events are the best characterized to date, there is still much to gain from developing and improving triggers to detect and prevent them. Adverse events resulting from loss to followup and ambulatory surgery are critical areas for trigger development, as very little has been done in these areas thus far.

Relative Advantages of Various Trigger Types

Choosing the Appropriate Trigger System

The type of trigger system that is most appropriate depends on its intended purpose. An **interventionist system** is one that provides actionable notifications that can be used at the patient level to prevent or intervene in an adverse event. Other trigger systems might provide nonactionable notifications useful at the system level to generate feedback to clinicians or to design system change. The clinical specificity and timing of trigger systems should also be compatible with their intended purpose. For example, **general or global trigger systems** are helpful for identifying the types of adverse events that occur, and they can be used for surveillance and for guiding system-level interventions. However, they would not be useful for targeting specific adverse events or for patient-level intervention. Compared to general systems, **specific trigger systems** can be readily translated into patient- and system-level interventions because they are clinically specific regarding the cause of the adverse event. However, specific systems cannot identify all iatrogenic events, just those for which triggers are in place. **Concurrent trigger systems** can identify patients at high risk during the clinical episode in which the adverse event occurred to guide clinical intervention. **Retrospective trigger systems** are useful only for raising awareness, event rate measurement, and evaluating system-level interventions. The ability to run a trigger concurrently or retrospectively depends on data availability and ability to incorporate trigger response into workflow.

Evaluating Trigger Characteristics

Physicians, nurses, pharmacists, quality managers, and informaticists participated in focus groups to evaluate a number of specific triggers for clinical relevance, utility, and ease of implementation. Some consistent general themes emerged.

Trigger systems should target adverse events that are both prevalent and preventable. "Prevalence" included the size of the population at risk, how frequently the cases occurred within that population, and the frequency of cases that would benefit from the trigger. "Preventability" included whether the trigger was likely to be able to prevent harm that was avoidable (e.g., not address side effects that were a conscious tradeoff as part of treatment).

Trigger systems should fill a need and add value. Triggers should not duplicate existing quality, safety, or performance measures or information already being captured to meet internal or external requirements.

Trigger notifications should be actionable. Concurrent triggers should be implemented so that the data are received by individuals who can act on the information within the appropriate timeframe to prevent or mitigate harm.

Trigger systems should have a good "signal-to-noise" ratio and cost-benefit ratios. The degree and cost of harm to the patient that the trigger is designed to prevent should be weighed against the cost of implementing the trigger. Trigger systems should have good sensitivity and positive predictive value.

Trigger systems should be easy to implement. The data needed to run the trigger should be readily available in the necessary format. Ideally, the trigger should be integrated with existing computer systems and/or processes of care.

Conclusions

The type of trigger system that is most appropriate depends on its intended use. The perceived importance of trigger types and characteristics may depend also on the individual doing the evaluating. Our focus groups, which were heavily composed of front-line clinicians, placed a greater value on specific, concurrent, interventionist trigger systems that would allow for patient-level intervention. Test characteristics such as positive predictive value or sensitivity were not the only important criteria for evaluating trigger systems for potential implementation.

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D. Reflections on the Institute for Healthcare Improvement Global Trigger Tool

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Experience With the IHI Global Trigger Tool

Discussion

The Institute for Healthcare Improvement (IHI) Global Trigger Tool (GTT) is based on 10 years of trigger tool component testing and experience in the acute inpatient setting,[D1–D3] resulting in a clearly articulated and described methodology.[D4] The current use of the GTT is to establish a baseline level of harm (adverse events) in an organization and then, using statistical process control rules, collect data points over time to determine improvement. In some organizations, an evaluation of actual adverse events allows targeting of improvement strategies at a fairly high level (postoperative infections, anticoagulant-related events, etc.). The GTT is the only method available to quantify harm at a system level in a reproducible fashion in any hospital system, whether paper based or electronically endowed. The combining of triggers to a robust, tested, and clearly articulated methodology is crucial to creating the reproducible findings. A two-step process, using primary reviewers whose consensus is validated by a physician reviewer, is required initially on prepared training records. Measured kappa scores for testing and training demonstrate high inter-rater agreement.[D4]

Without a believable acknowledgment of the level of harm created by health care, there is a lack of incentive to change and there is no way to determine whether the resources being devoted to safety are having any sustained effect. The harm surfaced (revealed) by the GTT, by definition, removes from consideration preventability (very subjective and would result in an ever-changing denominator), omissions (data almost always missing from the single chart review and very accusatory), error (harm looked at from the patient perspective, regardless of whether an error can be documented), and, for the most part, any considerations of cause. The harm identified is carefully tied to commission and represents a majority subset, but not all, of the totality of institutional harm. (Ninety percent or more of adverse events identified in retrospective traditional chart review are surfaced by the GTT.)[D5]

Evidence from hundreds of organizations using the GTT, as well as coordinated implementation directed by IHI faculty, have established baseline "ballpark" expectations of harm for organizations. As a caveat, these are treated as a general evaluation of the review process rather than as a benchmark. After some initial variability (we usually discount the first four to six data points as learning opportunities), most organizations report about 90 adverse events per 1,000 patient days, 40 adverse events per 100 admissions; about 30 percent of all admissions (using GTT criteria for definition of an admission) experience an adverse event.

Conclusion

The IHI GTT generates reproducible results due to a highly structured methodology of training, testing, and reviewing of charts and is utilized by organizations worldwide. The results have unfortunately provided evidence of even more harm than previously reported.

Triggers are built to surface harm. Harm can be identified in the construct of the GTT in multiple ways. These include, of course, the triggers themselves (some are, by definition, adverse events); triggers that require further chart investigation to determine if harm has occurred (glucose of 50 is harm only if symptoms of hypoglycemia are present); harm identified using the methodology of GTT chart review (reviewing the discharge codes and diagnoses without any use of triggers); and just plain luck while paging through the chart.

The harm surfaced with the GTT commonly is associated with a trigger but does not necessarily require a trigger. (Eighty percent of harm surfaced has an associated trigger; 20 percent does not.) A given harm may well have multiple triggers, and reviewers commonly will have identified different triggers to surface the same harm.

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Although it is tempting to be overly academic about the triggers chosen to review charts, at least in the retrospective view and with the methodology established by the IHI GTT, the specificity and sensitivity of the triggers are secondary.

The most important factor appears to be the ability to evaluate the trigger (is it easy to find in the record and easy to make a determination of harm?) and the total number of triggers (the greater the number, the more time it will take to review the chart). The IHI has by definition limited the time to retrospectively review a chart to 20 minutes, which forces a limitation on the number of triggers and the way in which the chart is reviewed. Starting from page one and continuing to page zed is not an option, particularly with very thick (long stay) charts. The primary concern with the IHI GTT triggers is to accomplish a quick review of key inpatient modules within an appropriate timeframe to allow the sampling methodology to be robust.

Conclusions

Triggers for the IHI GTT are not based on an evaluation grounded in specificity and sensitivity, but rather on an empiric model. Since there are multiple ways to surface harms in this retrospective methodology, the sensitivity and specificity of the triggers are actually secondary both to the sampling and to the robustly structured methodology.

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E. Diagnostic Event Triggers: Current State of Science and Future Directions

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Background

The spectrum of patient safety events in ambulatory care is quite different from the inpatient setting. For instance, in addition to medication events, diagnostic and other types of care management events are more likely to be common and harmful in ambulatory care.[E1] Errors in diagnosis are expensive[E2,E3] and are the leading basis for ambulatory malpractice claims.[E2,E4,E5] Despite their importance, diagnostic errors are, in general, an underemphasized and understudied area of patient safety research.[E6] Considered as errors of omission, they bring about complex questions of causation and appropriateness and are at times difficult to identify.[E4] Tracking a patient's diagnostic process over time is also not easy in a fragmented outpatient environment, especially when clear standards defining "delays" are lacking.

In our preliminary work, carried out in the Nation's largest electronic health record (EHR) system (the Veterans Affairs [VA] health care system), we developed and tested two computerized triggers to identify patient records that may contain evidence of diagnostic errors.[E7] Triggers are signals that can alert providers to review the medical record to determine if an actual or potential patient safety event occurred.[E8] Our triggers were based on primary care visit patterns in an internal medicine trainee clinic of a tertiary care VA facility. Although their performance was comparable with that of electronic trigger tools used to identify ambulatory medication errors, the positive predictive value (PPV) was only modest: 16.1 percent for one trigger and 9.7 percent for the other.

In work funded by the Agency for Healthcare Research and Quality (AHRQ), we are now refining these trigger tools by integrating them with additional clinical variables (predictive variables) and by reducing false positive triggers. Our efforts focus on increasing the signal-to-noise ratio of positive triggers and could lead to a higher PPV. We have expanded our research beyond the VA to a large primary care network in Texas that has an EHR comparable in many aspects to that of the VA. Hence, our settings will now include internal medicine and family medicine; academic and nonacademic practices; urban and rural patients; and significant racial, gender, ethnic, age, and socioeconomic diversity. Since diagnostic errors due to a lack of followup of abnormal test results are also a significant concern in ambulatory care,[E9] we are now testing a computerized method that potentially can be used as a new trigger tool to detect these problems. Such triggers may be useful to detect and learn about diagnostic errors in ambulatory health care systems that use an advanced EHR.

Development of Methods To Trigger Ambulatory Diagnostic Events

Based on our preliminary research and experience, we believe that the trigger methodology may be useful to advance the study of diagnostic events in ambulatory care. Many opportunities as well as challenges exist. For instance, many diagnostic events, including loss of followup of patients and test results, occur in the outpatient setting,[E10] and triggers to address them have not been well developed.

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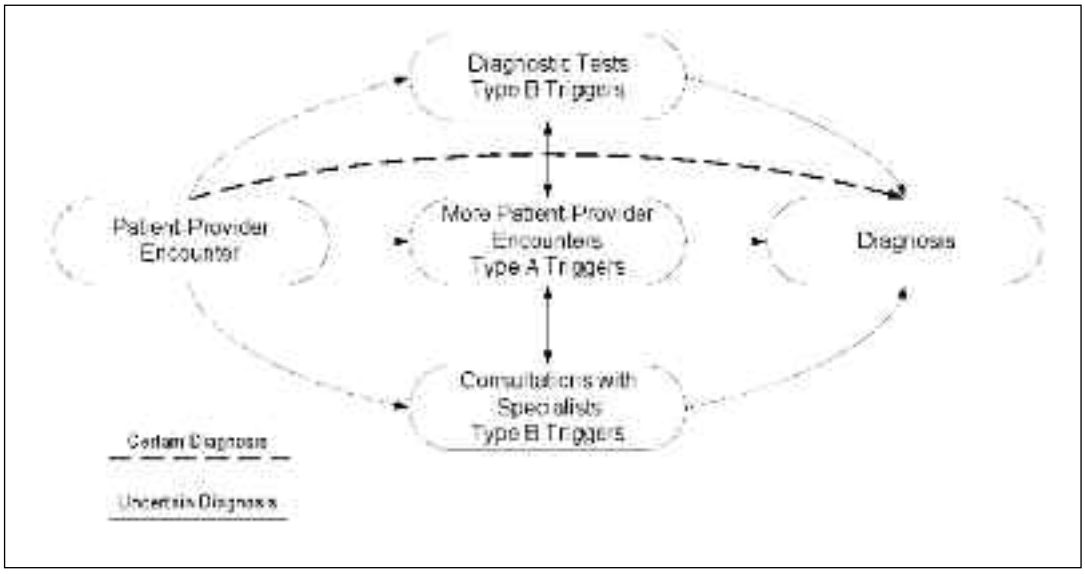
Note: The views expressed in this article are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs.

Figure 1. A proposed conceptual model to apply triggers to detect diagnostic events in ambulatory care



We propose a conceptual model (Figure 1) to illustrate how the use of two types of triggers (henceforth called Type A and B) may be useful to advance the detection of diagnostic events in ambulatory care. Type A triggers target patterns of visits (such as a primary care visit followed by a hospitalization in the next 14 days) that may be able to identify patients whose diagnosis was missed at the initial visit and who returned to seek care. Electronic medical record review of available progress notes, laboratory and imaging tests, consultations, and other subsequent appointments could confirm or refute the presence of a diagnostic error at the primary care visit. Our current work focuses on developing the next generation of Type A triggers by enriching these trigger tools with additional clinical data from the primary care visit, such as information about abnormal vital sign data, laboratory values, and imaging studies. It may result in higher PPV and the subsequent detection of more diagnostic errors. Due to the nature of this methodology, it also holds promise in identifying other care management problems that occur in ambulatory care in addition to diagnosis. For instance, patients may return to seek care not just because of diagnosis problems but also due to some treatment or monitoring errors.

Type B triggers address events related to loss of followup, either of patients or their abnormal diagnostic test results. These triggers are still in the developmental stages. Currently, we are in the process of testing actionable, concurrent triggers to prevent loss of followup of certain abnormal diagnostic test results in the outpatient setting. If validated, this type of trigger can be used in advanced EHR systems that use a computerized test result notification system to "alert" providers about abnormal results.

Key Considerations in Applying Proposed Diagnostic Event Triggers

Our proposed Type A triggers are global and retrospective. Even though they are considered "nonactionable," they provide useful information for system-level interventions. For instance, once practices detect errors using our triggers, a review of these cases could be conducted by multidisciplinary teams to ensure that all contributing factors are identified. Multidisciplinary interventions can be designed in the future to prevent these errors. This is similar to the goal of voluntary incident reporting systems, except it does not depend upon providers identifying and then taking the time to report the events.

Conversely, Type B triggers are more specific, actionable, and concurrent, and they offer potential for putting into place novel monitoring and surveillance tools that can significantly reduce diagnostic errors in ambulatory care.[E11] For instance, once abnormal diagnostic results that have not received any diagnostic followup within a certain time

interval are triggered positive, several actions could be put in place to ensure that they receive prompt attention. Similarly, a missed consultation with a subspecialist could be an indication of a delayed diagnostic evaluation. We would caution, though, that much of this work is untested and is still undergoing development.

The key considerations in defining relative advantage over other methods to detect similar adverse events are PPV, feasibility of use, and limitations imposed by the trigger itself. Methodological constraints do not allow calculation of the true sensitivity and specificity of our triggers; however, PPV provides a reliable indication of trigger effectiveness. PPV must be higher than for some other comparable methods to identify these types of events. (PPVs of our two triggers, although modest, were much higher than those for random chart reviews.) The types of diagnostic triggers we propose may not be feasible in clinical settings where the information management system does not integrate the EHR with the inpatient setting and with other ancillary systems (such as with consultants and with radiology and laboratory information systems). They also will underestimate the error rate for Type A triggers if any patients sought medical care outside the study setting after the initial visit. Other limitations that would affect usability and implementation of such triggers are issues such as hindsight bias and disagreements among reviewers about the presence or absence of a diagnostic error. Hence, rigorous reviewer training is critical.[E12] Lastly, these triggers will inevitably miss some errors (as seen by the presence of errors even in controls in our previous work) and should not be used to determine rates of diagnostic error or compare performance across practices.

Conclusions

We believe it is possible to identify diagnostic events and advance the science of their prevention through the application of trigger methods. Current methodology has encouraging prospects but is relatively underdeveloped compared with triggers for other types of medical errors. The available preliminary triggers are most apt to be used in systems that have an integrated, advanced EHR. A significant investment in further development and refinement of current methods is needed prior to large-scale implementation.

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F. Challenges in Implementation of Trigger and TIDS Tools for Detection of Adverse Events in Health Care Settings

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Introduction

This conference on targeted injury detection system (TIDS) and trigger tools sponsored by the Agency for Healthcare Research and Quality (AHRQ) outlines the critical need to develop practical and effective systems to measure the safety of care in the health care system. If the goal of patient safety efforts is to reduce the harm to patients while providing them with the care they need, then recognizing the true nature and sources of harm is critical to this endeavor.[F1] This goal requires some form of surveillance for detection of harm to patients and is indispensable to modern patient safety practices: it allows us to overcome the serious defects associated with dependence on spontaneous reporting as a method for detecting adverse events. While such reporting can play an important role in supporting a culture of safety—for example, encouraging the candid discussion of errors—it is by its nature anecdotal and superficial.[F2] In addition to the obvious barriers to reporting (time constraints, fear of retribution, liability concerns), we know that most events causing harm to patients are not even recognized as such by clinicians at the time they occur. Thus, voluntary reporting describes a small—and by no means representative—minority of the universe of harm to our patients. It is useless for the quantitative study of adverse events, and it is not reliable either as an indicator of the principal sources of harm or as a measure by which to assess improvement.

Background

Initially developed trigger tools for adverse event detection were computerized, such as the automated surveillance for adverse drug events, which was first demonstrated on a large scale in the early 1990s by Classen et al. at LDS Hospital.[F3] This methodology was refined and extended by investigators at Harvard[F4] and Duke.[F5] These groups used rules-based computer systems to identify combinations of clinical data (antidotes, toxic drug levels, drug-laboratory combinations, etc.) that suggest that a patient has suffered or is suffering an adverse drug event. In recent years, others have applied the principles of automated surveillance to events beyond adverse drug events—for example, using various technologies to search text documents such as discharge summaries for key words suggestive of adverse events.[F6,F7]

However, automated surveillance systems have significant difficulties that have limited their usefulness and broad adoption. Many hospitals lack the technical knowledge and resources to build the sophisticated, rules-based computer systems needed to operate comprehensive surveillance; as yet, these capabilities are not available in most commercial systems. Automated surveillance depends upon the availability in electronic form of data suggestive of an adverse event. The general availability of inpatient pharmacy and laboratory data in electronic form made possible the early work in surveillance of adverse drug events in hospitalized patients. While these systems detect certain types of adverse events very effectively, other event types for which electronic trigger data do not exist are not detected. Finally, perhaps the greatest limitation of comprehensive surveillance is the significant investment in resources required to evaluate the computer alerts.

Recognizing these limitations, a number of investigators have in recent years developed modified manual "trigger" methodologies based on the data types and methods used in automated surveillance.[F8-F10] These tools permit any hospital to conduct a focused explicit chart-review-based evaluation of safety in a small sample of their patient population. Investigators with the Institute for Healthcare Improvement (IHI) have built a series of chart-review-based trigger tools for detection of adverse events in various care settings, including the intensive care unit, labor and delivery, emergency room, and surgical environments.[F8-F10] This work has culminated in the development of a more comprehensive method for detecting adverse events called the global trigger tool.[F11]

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AHRQ Panel Lessons Learned

Whether it is a manual trigger or an automated trigger system, we have learned a lot about the challenges of implementing and sustaining trigger-based surveillance systems. Many organizations have begun trigger work as a research or pilot project and then struggled to disseminate this approach throughout the organization. Kaiser has learned valuable lessons with the global trigger tool, which include the importance of creating credible and actionable information.[F12] With small sample sizes and few adverse events detected, the credibility of the information gathered from the Global Trigger Tool can be variable and not revealing of any new findings, which can prevent spread throughout the organization. As well, if the information is not felt to be actionable or timely, it is also less likely to be helpful. Baylor may have demonstrated the best initial approach with the Global Trigger Tool: rather than use a small monthly sample, as has been the usual case, Baylor has used a much larger sample to understand the epidemiology of the adverse events in the organization and to help develop organizational awareness, attention, and leadership support to address the problems identified.[F13] Indeed, Baylor has built the use of trigger tools into its ongoing management processes and even into its management incentives. The RTI experience with TIDS reveals how important organizational leadership support for trigger tools is; RTI has experienced challenges getting adoption of the TIDS tools in several health care systems around the country. This only underscores the importance of the organizational self-discovery journey outlined by Baylor and also noted by many other organizations that have successfully implemented trigger tools.

Kaiser has successfully used focused trigger tool modules in problem areas identified, as demonstrated by the intravenous heparin focal study or the oncology trigger tool projects at Kaiser. Indeed, focal trigger tools can support specific quality improvement initiatives, as IHI has demonstrated in numerous collaboratives. This may be a major success factor. It outlines a major issue for all trigger work: its overlap with existing quality monitoring programs, which both makes the trigger work duplicative and requires more resources without clear justification. This requires organizations to decide if trigger-based adverse event detection programs can replace existing programs; indeed, this happened with a surgical trigger tool program that was adopted by one organization to replace its surgical peer review program. A related problem is workflow. If the same person is doing triggers in addition to usual quality monitoring, it requires adjudication. If it creates more work and resource requirements, it is not likely to be sustainable. Direct linkage of trigger tools to quality improvement initiatives may be a critical success factor based on the work at several organizations.

Conclusions

As hospitals learn more about the costs and risks associated with adverse events, and as regulators and other groups demand greater accountability for patient safety, we may see an increased willingness on the part of hospitals to invest in the resources needed to take full advantage of our increasingly sophisticated clinical information systems. Indeed, in the end, implementing and maintaining adverse event surveillance systems are useful only if there exists an interested and motivated executive audience for the data. Many in health care delivery organizations are not interested in knowing their rates of adverse events, at least unless they are immediately able to offer a definitive strategy for adverse event reduction. While this may be understandable, it is only by studying the nature and frequency of these events that effective improvement strategies can be formulated, implemented, and evaluated. Otherwise, hospitals will continue to be limited to the implementation of various generic improvement strategies to focus on what we can only guess are the most pressing problems, and with no hope of ever really knowing whether the time and resources committed have made a difference to patient safety.

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G. Challenges and Incremental Benefits in Implementing Targeted Injury Detection Systems for Adverse Drug Events and Pressure Ulcers in Inpatient Settings

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Background

RTI and its health system partners developed and deployed a concurrent targeted injury detection system (TIDS) for two classes of highly prevalent inpatient iatrogenic adverse events: pressure ulcers (PUs) and adverse drug events (ADEs). TIDS was implemented in three alpha sites (Baylor Health System, Intermountain Healthcare, and UNC Health Care) and planned in three beta sites (Emory University, Providence Health System, and the Salt Lake City VA). Triggers that were established for the events included a combination of indicators taken from administrative data, medical records information, and patient assessments. UNC Health Care led the development and implementation of the PU trigger. Simple ADE triggers were developed and implemented by Intermountain Healthcare 15 years prior to the study start. The Salt Lake City VA led the development of more clinically specific triggers.

Implementation Challenges

Discussion

Each beta site was charged with the implementation of two trigger sets, one focusing on ADEs and the second focusing on PUs. The implementation challenges were unique to each trigger.

The ADE TIDS implementation encountered a number of technical and operational challenges. All sites had difficulty implementing the relatively complex logic of the triggers. Through two to three teleconferences with each site, project leadership and local teams of information technology (IT) and project staff resolved most coding problems. An alpha site with more ADE TIDS experience made a significant modification to its rule engine to accommodate the more complex rules. Two of the three alpha sites were not able to implement triggers based on vital signs because that information was not available electronically.

None of the beta sites implemented all of the sets of rules for the ADE trigger set. Challenges associated with the ADE trigger implementation included limited perceived utility and impact on patient management, a perceived lack of new and timely information provided by the triggers, and time and staff resources required for data collection. One of the beta sites had recently purchased a commercial system and used stock ADE triggers instead of programming the more complex, clinically specific ADE triggers implemented at the alpha sites. Another beta site lacked an electronic solution and attempted a paper-based implementation. This site was not able to collect and process laboratory results within a timeframe that allowed the TIDS to prompt interventions that would prevent or mitigate ADEs.

The variety of operational challenges to ADE TIDS implementation was met with varying success. The ADE TIDS included a data collection tool that could help guide evaluation of the triggers and aggregated analysis of the

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Note: The views in this article are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs or the Agency for Healthcare Research and Quality.

ADEs. Except at one site, the pharmacists who reviewed triggers focused on using the TIDS for clinical interventions only. All sites found the classification tool to be excessively burdensome. They tracked only whether a trigger was associated with an ADE and whether it led to a change in patient care. Another barrier was a duplication of systems. Pharmacists did not want to implement the ADE TIDS at several sites because they perceived that the system duplicated the work they did routinely when making rounds as clinical pharmacists. At two institutions, protocols for anticoagulation rendered two of the related triggers useless. One beta site was not able to implement the ADE TIDS because of a congressionally mandated reorganization of its IT processes.

One beta site committed to implement the PU trigger but experienced difficulties obtaining Institutional Review Board (IRB) approval. Implementation challenges cited by staff at the other two beta sites were related to data collection systems. Manual calculation of Braden score and age was perceived as burdensome and time consuming. Floor nurses at this site perceived the PU trigger as outside the scope of usual care and viewed it as another requirement for documentation with no obvious value. Variation in determining the Braden score was another challenge in PU trigger implementation and use. Across the sites, nurses without specialized training in wound care had difficulty accurately assessing the Braden score, suggesting that successful adoption of this trigger should be accompanied by ongoing educational efforts in wound assessment.

Conclusions

Many of the challenges encountered were related to the local organizational structures and investigational aspects of the study (e.g., IRB issues, the need for consistency in measurement, and difficulty programming into existing IT systems). These challenges are not likely to be generalizable to process-improvement implementation. The lack of perceived utility of the ADE trigger may be more problematic for diffusion and adoption; this may be related partly to the presence of a clinical pharmacist who monitors patients on high-risk drugs or partly to the lag in the availability of laboratory data in the manual systems, resulting in trigger information that is somewhat dated and not as relevant to clinical decisions.

A perceived duplication of some ADE triggers with selected protocols and the activity of rounding clinical pharmacists was a major barrier. Of course, the appropriate response was to inactivate triggers that did not add value. The largest barrier to TIDS implementation for system-level changes was the increased burden of data collection for both PU and ADE TIDS.

Incremental Benefits

Discussion

The ADE TIDS produced incremental benefits of treating new ADEs at sites that undertook electronic implementation. The triggers were designed to be more clinically specific than most previously published trigger logic. When the triggers did not overlap with existing protocols and systems, they resulted in dramatic increases in detection of some types of ADEs. Because of the perceived utility for clinical interventions, three alpha sites continued to use selected triggers after the implementation period. A beta site that implemented only part of the ADE trigger continues to develop a system through its existing commercial vendors. A beta site that implemented a paper-based ADE trigger discontinued its use; however, this site plans to implement an electronic ADE trigger system through a commercial vendor in the future.

The addition of age to the Braden score for the PU trigger was viewed as an added benefit, particularly for borderline patients who are elderly. Wound ostomy nurses emphasized that using the PU trigger resulted in better care plans, consultations for appropriate wound treatment (i.e., use of proper dressings), and face validity of the instrument itself, but that it did not improve identification of PUs. Incremental benefit was associated with alignment of the PU trigger with local and national priorities, the ability to engage clinical champions, and the low technical complexity of the trigger tool.

Conclusions

Incremental benefit is perceived when the trigger fills a gap in clinical knowledge and awareness. The most benefit provided by the ADE trigger was with high-risk drugs such as warfarin. The inclusion of age with the Braden score in the PU trigger highlighted the increased risk to older patients and the need to address the incremental risk through clinical care plans. In this case,

the trigger served as intended: it identified patients at elevated risk for an adverse event and the subsequent need for modification of the care plan. Age adjustment to the Braden score was especially appreciated by the wound ostomy nurses, who felt that age added more face validity.

Overall Conclusions

The TIDS beta sites implemented the PU and ADE triggers differently, which is not surprising given that patient safety efforts are unique and specific to local settings. Factors important to successful implementation included the similarity of the trigger tool to existing workflow, the availability of personnel, the IT resources and infrastructure, and the commitment of relevant clinical champions (e.g., pharmacy, medicine, and nursing).

At all but one site, there was a strong focus on the ability of the ADE TIDS to prompt interventions that prevented impending ADEs or mitigated ongoing ADEs. Only triggers containing logic that gave providers new information were appreciated. This barrier to adoption highlights a need for the design of more intervention-oriented trigger systems to satisfy frontline providers. The focus on ADE TIDS to prompt intervention also demonstrates the need for effective integration of frontline pharmacists into quality improvement efforts that require more diligent collection of information to guide and evaluate system-level interventions.

The perceived benefits of the ADE trigger system were few, and the amount of effort associated with data collection and trigger identification was viewed as substantial. Therefore, the perceived benefits of the ADE trigger did not exceed the effort required to use the system. However, users acknowledged that prospective ADE prevention was limited by current systems. The idea of a prospective ADE trigger system was viewed as important, and two sites are in the process of pursuing commercial vendors for prospective identification of ADEs.

Efforts to reduce pressure ulcers at all sites preceded the PU trigger implementation. Multiple PU reduction efforts already were underway through local, regional, and national initiatives. Organizations had a heightened awareness and motivation to prevent and eliminate hospital-acquired PUs in light of the Joint Commission accreditation requirements and the upcoming Centers for Medicare & Medicaid Services (CMS) reimbursement policy that, by fall 2008, would stop reimbursing costs associated with hospital-acquired PUs. These initiatives contributed to the organizations' interest and motivation to implement the PU trigger and integrate local clinical champions. However, the visibility of the PU trigger benefits was mostly limited to the specialty nurses; staff nurses at beta sites viewed it as a burden with no added value, suggesting that additional training may be needed for successful adoption of this trigger by nonspecialty nursing staff. Low technical complexity of this trigger and its alignment with existing organizational processes, as well as national priorities, contribute to the likelihood of adoption of this trigger.

H. Trigger Tool Implementation Experiences in Kaiser Permanente

Dot Snow, M.P.H.[a]

Background

Kaiser Permanente is the Nation's largest not-for-profit health plan, serving almost 9 million people. It is noted for being an integrated system with a focus on prevention: medical services are integrated with wellness activities, and care delivery processes are integrated with health plan operations. Kaiser Permanente has local markets in 8 geographical areas of the United States and operates with 32 hospitals, over 400 medical office buildings, approximately 13,000 physicians, and over 159,000 employees.[H1] Representing the world's largest civilian deployment, Kaiser Permanente's electronic medical record is called KP HealthConnect™. It provides a complete health care system by integrating clinical care, practice management, ancillary service systems, and online access to a personal health record.

Trigger Tools

For this panel discussion, three experiences with trigger tools within Kaiser Permanente will be addressed: an initial pilot of the IHI (Institute for Healthcare Improvement) Global Trigger Tool (GTT) in 2006; a focal trigger tool pilot of IV (intravenous) heparin therapy in 2007; and our current Automated Adverse Event Monitoring Program (AAEMP) project, which seeks to automate the IHI Global Trigger Tool.

Initial pilot of IHI GTT: The methodology was pilot tested at six medical centers across Northern and Southern California regions in 2006. Reported data representing 2,363 patient days across 400 patients came from 2 medical centers, 1 from each region, where data were collected during the same time period (January-October 2006). Consistent with previous studies, harm was detected by the trigger tool in over 30 percent of the charts reviewed.[H2] Approximately 20 percent of the patients experienced more than one harm event. Fifty-three percent of the adverse events fell in four categories:

- Medication events, 22 percent.
- Infection, 15 percent.
- Surgical complications, 8 percent.
- Blood pressure management (primarily associated with treatment of hypertension that resulted in hypotension and volume resuscitation or other complications), 8 percent.

Focal trigger tool pilot of IV heparin therapy: The methodology was piloted at one medical center. Twenty patient charts representing 50 days of treatment were reviewed by a multidisciplinary team comprised of an inpatient pharmacist, risk director, quality director, and nurse. Fifty percent of patients had positive triggers, including a drop in platelets, unplanned readmissions within 30 days, red cell transfusions, antifactor Xa > 1.4, and administration of Narcan. Twenty-five percent experienced harm, with 35 percent of patients experienced thrombocytopenia. While the pilot confirmed a high rate of compliance with the double-check policy, several improvement opportunities were identified.[H2]

Automated Adverse Event Monitoring Program (AAEMP): This foundation-funded project represents a collaborative effort between Kaiser Permanente and Computer Sciences Corporation to automate the IHI GTT methodology utilizing data from the electronic medical record (EMR). The project involves both the development of an application that searches the EMR of hospitalized patients for positive triggers and a pilot test to integrate the AAEMP into operations. The project is currently in the process of developing the application and preparing the first pilot site for implementation.

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Challenges and Benefits

What have been the one or two most significant challenges your team/organization has faced when implementing triggers/TIDS at the initial development site? Beyond the initial site?

Paper-based methodology: Resourcing and a perceived lack of actionability of the findings from trigger tool reviews have been the two main challenges. Implementing paper-based trigger tools does not replace carrying out existing surveillance processes, so additional time and personnel to undertake the activity must be identified. More importantly, a basic value proposition must emerge from the trigger tool review activity—-what new information is it telling us? Some medical centers discontinued the trigger tool activity because sampling across several categories led to small numbers of adverse events associated with individual triggers, and improvement activity based on one or two cases was not compelling.

Automated methodology: The project is still in the application development phase. It is anticipated that the automation of the trigger search across a hospitalized population will identify greater numbers of positive triggers to be evaluated for harm. Larger numbers may yield consistent patterns that direct improvement efforts. It is expected that the AAEMP will be more effective at detecting harm than existing surveillance efforts; hence, it may replace instead of augment current efforts at detection and measurement, thus reducing the challenge associated with resourcing the activity.

Discussion: With the paper-based trigger tool methodology, implementation beyond the initial site can be colored by the experience of the initial site. If the results were perceived to be inactionable or too resource intensive to integrate into operations, some centers may elect to forgo further trigger tool review. With the automated trigger tool methodology, it is expected that implementation challenges will be greatest at the initial site as the operational workflow processes are worked out. Subsequent site implementations should be able to benefit from the experience of the initial site. An automated trigger tool approach will yield more reliable measures of harm and shine the light on areas of improvement opportunity.

One region has incentivized medical center leadership to put trigger tool reviews of high-alert medications in place by the end of 2008. In order to receive full bonuses, the medical center must demonstrate that a high-alert medication trigger tool process is in place and that learnings from the activity are put to use in performance improvement processes.

What are the incremental benefits of TIDS compared with current systems for drug management and surgical quality initiatives? What have been your experiences using TIDS-like systems as a separate surveillance system vs. alerts going directly to the patient care team?

Kaiser Permanente saw several benefits emerge from the focal review of IV heparin therapy. The approach of bringing in a multidisciplinary team to review the patient charts and focus on that particular therapy led to the establishment of new relationships among the clinicians, risk manager, and quality director. There was also problem-solving and learning about both the trigger tool review as well as the clinical care processes. The improvement opportunities that were identified led to clearer logic for the regional heparin algorithm, improved documentation of double-checks in the emergency department, and improved training of nurses in the overall heparin protocol.

There is value derived from focusing on one category of harm at a time. Medical center leadership can use shortcuts and a strategic approach to utilizing trigger tools in the measurement of harm experienced in their medical center. Certain categories in the GTT can be eliminated, either by the absence of that service within their medical center or by known competent performance. Remaining categories can be prioritized for focal review based on known significant events and/or vulnerabilities.

Conclusions

Perhaps it is not an "either/or" proposition but rather "and/both" for targeted injury detection systems (TIDS) and quality-of-care initiatives. Compliance with evidence-based clinical processes is the heart of the Surgical Care Improvement Program (SCIP), and a focal trigger tool study of surgical care could yield information about outcomes.

The initial GTT activity identified the areas where harm is occurring in the Kaiser Permanente delivery system, and it appears to be consistent with the areas of harm reported in a recent Medicare study on medical errors, particularly infections and postoperative complications.[H3] Focal trigger tool studies of the individual categories

would generate larger samples, reveal consistent patterns, and provide understanding of that terrain. The data would be taken to the appropriate committees to decide if performance is acceptable or whether improvement work is needed.

The long-term view would be to systematically conduct focal reviews for all relevant harm categories and work the improvement opportunities as identified. Automating the process should lead to more reliable triggers to capture harm. Once a cycle of all categories is completed, the delivery system could use the GTT to keep a finger on the pulse, maintaining the level of performance achieved from the improvement efforts. While it is undeniable that the category-by-category approach for reducing harm involves lots of time and lots of work, people are willing to participate as long as they feel the work is actionable and leads to real improvements in the quality of care delivered to patients.

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III. Glossary: Definitions for Triggers Terminology

III. Glossary: Definitions for Triggers Terminology

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Term	General definition	Clinical specificity	Timing of trigger system firing and investigation	Potential use of trigger system	Evaluating trigger system performance
			Overall Definitions		
Trigger	A trigger is a surveillance rule or algorithm that can be applied to a patient's clinical and/or administrative data to identify a time of high risk of one or more iatrogenic adverse events. A positive result of the surveillance rule "triggers" further review of the patient record to confirm the occurrence of iatrogenic adverse events.	Triggers may be designed at varying levels of specificity (i.e., to address specific and nonspecific causes and events).	Triggers may contain logic that is time dependent. Time-dependent logic may determine whether the trigger can be investigated within a clinically relevant time period.	Discussions of potential uses most appropriately focus on trigger systems, not on triggers alone. See potential uses of trigger systems in next entry.	It is essential to evaluate the performance of trigger systems and not triggers alone because (1) by definition, it is impossible to implement a trigger without the rest of the investigation system and (2) the implementation of the trigger may have a large effect on the type and amount of information that is available for investigation in practice.
Trigger System	A trigger system is the combination of the surveillance rule, the method of processing patient data according to trigger logic (firing), and the method of investigating a positive trigger to determine whether it is a true positive.	Clinical specificity is largely a function of the trigger logic. However, a trigger system may increase the specificity of a trigger if the system applies the trigger only in a specific population.	The method of applying the logic to patient data and investigating a positive (fired) trigger usually determines the investigation timing and the extent to which a positive trigger may be clinically relevant.	Trigger systems can be useful (1) at the system level for surveillance of iatrogenic adverse events to guide improvement in systematic care processes and (2) at the patient level with subsequent primary prevention of a particular adverse event or secondary prevention (or mitigation) of its resultant harm in the particular patient. The implementation of the trigger system is usually more important than the logic in determining whether it can inform decision at the patient or system level.	The most important performance characteristics of trigger systems are sensitivity and positive predictive value. The evaluation cohort (also known as the denominator) should be drawn from the union of two populations: that in which the trigger is desired to fire *and* that in which it can theoretically fire. The reference standard should be applicable iatrogenic adverse events identified through a suitably sensitive and specific method. The trigger should be counted as a true positive only if it fires within a prespecified time span around the occurrence of the adverse event.

III. Glossary: Definitions for Triggers Terminology (continued)

Term	General definition	Clinical specificity	Timing of trigger system firing and investigation	Potential use of trigger system	Evaluating trigger system performance
			Clinical Specificity		
General Trigger System	A *general*, or *global*, trigger system identifies a time of high risk for a broad variety of iatrogenic adverse events. The term "general" is preferred to "global," which misleadingly connotes a comprehensive capture of causes or effects. Examples of general triggers include readmission 30 days after a hospital discharge, filing a tort claim, and changing one's primary care physician.	General triggers are designed to identify a spectrum of iatrogenic adverse events that is *not* specific in terms of either a set of manifestations or a set of causes of the events. Most general triggers or sets of triggers address a broad but not comprehensive set of causes and effects.	The general category does not have inherent criteria for trigger timing.	General triggers can be helpful for identification and surveillance of adverse events, interventions at the system level, and subsequent monitoring of the effects of these interventions on outcomes, patient safety, and quality of care. Since general triggers are not associated with specific treatments or specific outcomes, they are often less helpful for interventions at the patient level than are clinically specific trigger systems.	For the evaluation of a *single* general trigger, an attempt should be made to identify the types of events, the cohort, and the time window that are most pertinent to the general trigger. For a *set* of general triggers, it is reasonable to evaluate the performance of the system in terms of *all* iatrogenic adverse events for the entire population of interest.
Specific Trigger	A specific trigger system identifies an event occurring during a time of high risk for a specific type of iatrogenic adverse event or for a definable range of adverse events caused by a specific type of medical intervention. Examples of specific triggers include a positive C. difficile toxin assay and myocardial infarction within a week after surgery.	Specific triggers are clinically specific regarding the cause of the adverse event, the manifestations of the event, or both.	The specific category does not have inherent criteria for trigger timing.	Specific triggers can be translated into both patient- and system-level interventions because they are clinically specific regarding the cause of the adverse event and/or the nature of the iatrogenic adverse event itself.	Cause-specific triggers should be evaluated only in a cohort drawn from a population In the evaluation of event-specific, triggers, the denominator population should exclude subjects who are ineligible to experience both the effect *and* a positive trigger.

III. Glossary: Definitions for Triggers Terminology (continued)

Term	General definition	Clinical specificity	Timing of trigger system firing and investigation	Potential use of trigger system	Evaluating trigger system performance
			Trigger System Timing		
Concurrent Trigger System	A concurrent trigger system allows identification of the time of high risk *during the clinical episode* in which the adverse event originates. Usually this will occur within minutes or days of the beginning of the period of heightened risk, but it can take longer. How quickly this occurs depends on how long the underlying episode lasts.	The concurrent category does not have inherent criteria for clinical specificity.	Concurrency relates to the timing of trigger investigation. A concurrent trigger system provides the ability to identify a problem during the clinical episode in which the problem originates. For example, a concurrent trigger system would alert a provider to hyperkalemia 1 to 3 weeks after starting an angiotensin receptor blocker.	Some concurrent trigger systems allow productive intervention at the patient level to prevent or mitigate an iatrogenic adverse event. Other concurrent trigger systems identify events for which appropriate treatment is either underway or not possible.	To evaluate a concurrent trigger system, it is essential to use criteria that define the clinical episode of interest.
Real-Time Trigger System	A real-time trigger system is a type of concurrent system in which the trigger investigation is substantially completed within hours of the trigger firing.	The real-time category does not have inherent criteria for clinical specificity.	The trigger investigation is substantially completed within hours of the trigger firing.	Uses are the same as for concurrent trigger systems.	Real-time triggers should be investigated within hours of the time the adverse events are about to happen or become manifest. The window of interest should be measured in hours.
Retrospective Trigger System	A retrospective trigger system allows identification of the risky situation only *after the clinical episode* has occurred.	The retrospective category does not have inherent criteria for clinical specificity.	A retrospective trigger system allows identification of the risky situation *after* the clinical episode has terminated.	Retrospective trigger systems are most suitable for event rate measurement and for designing and evaluating system-level interventions.	The requirements for trigger-system evaluation (see definition for trigger systems) apply to retrospective trigger systems.

III. Glossary: Definitions for Triggers Terminology (continued)

Term	General definition	Clinical specificity	Timing of trigger system firing and investigation	Potential use of trigger system	Evaluating trigger system performance
			Designed Purpose of Trigger System		
Interventionist Trigger System	An interventionist trigger system reliably provides information necessary to guide new action on a specific iatrogenic adverse event in a specific patient. An actionable notification allows identification of unrecognized iatrogenic adverse events that are *imminent* for the purpose of primary prevention, *evolving* for the purpose of mitigation, or *mature* for the purpose of treatment and prevention of an imminent recurrence.	Although both specific and general trigger systems can provide actionable notifications, medical providers may find it easier to take action on notifications from clinically specific triggers. It is easier for them to intervene when the trigger gives them direction about the cause, the iatrogenic adverse event, or both.	Interventionist trigger systems are almost always concurrent. Real-time systems are more likely to provide notifications about events that have not already been treated. In some cases an actionable notification may not be concurrent; for example, trigger systems may target delayed adverse events such as osteoporosis from prior drug therapy.	Interventionist trigger systems are used for primary prevention, mitigation, and secondary prevention of adverse events. Because these systems are designed to identify a fraction of all iatrogenic adverse events, they will not accurately reflect rates of all iatrogenic adverse events.	There are two alternative metrics of an actionable notification: (1) whether the notification resulted in an event-relevant change in the care plan and (2) whether the notification could have resulted in actions to prevent or mitigate a relevant iatrogenic adverse event. Positive predictive value is possible to assess for the first metric. A counterfactual approach is necessary to estimate sensitivity for either metric and positive predictive value for the second metric.
Rate-Estimation Trigger Systems	Rate-estimation trigger systems are designed primarily to gather information to estimate the burden or rate of iatrogenic adverse events.	Both clinically specific and nonspecific trigger systems can be used to collect information on counts of iatrogenic adverse events.	Rate-estimation trigger systems may be retrospective or concurrent. Retrospective investigation has the advantage of being able to more definitively characterize the nature of detected events.	Rate-estimation trigger systems may provide instructional feedback to clinicians and help managers design system changes. High-performance systems may be used for benchmarking.	High sensitivity and specificity are essential performance characteristics of rate-estimation trigger systems and are necessary for accurately estimating changes in rates across time or across settings.
Awareness-Raising Trigger System	Awareness-raising trigger systems are designed to increase the salience of certain types of iatrogenic adverse events.	The need for clinical specificity is a function of the clinical specificity of the intended effect of the system.	The timing may vary to match the intended data presentation and behavior changes.	Salience of events may be increased to increase likelihood of patient-level action (learning) or system redesign.	Positive predictive value as a measure of efficiency is relevant. To accurately measure reductions of all targeted events, a rate-estimation trigger system must be used.
Other Purposes	Trigger systems may have many other uses.	Clinical specificity must match the system.	Timing should match the purpose of the system.	There may be many other purposes.	The requirements vary according to the purpose.

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