Adverse Event-Directed Analysis in Ambulatory Primary Care Final Report

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STRUCTURED ABSTRACT

Purpose: The purpose of this research was to better understand the magnitude, nature, and causation of adverse events (AEs) in ambulatory primary care and to design risk mitigation strategies that would yield demonstrable improvements in patient outcomes.

Scope: The need to reduce risk for persons interacting with the healthcare system is well recognized as a public health issue. AEs and risk factors for AEs have not been extensively investigated or characterized in the ambulatory care setting.

Methods: A general outpatient trigger tool method (BI-OTT) was refined and deployed within a large primary care group practice to estimate the magnitude and nature of AEs that take place in ambulatory primary care.

Results: A review of > 10,000 charts revealed that > 12% of patients aged ≥ 50 years with ≥ 3 primary care visits in 1 year had an AE. Many AEs appeared to be preventable, indicating that efforts to improve the reliability of primary care may yield important improvements in patient outcomes. Continued testing and refinement of the BI-OTT should produce an effective tool that can be implemented in other healthcare systems to improve healthcare delivery and patient outcomes.

Key Words: trigger tool, adverse event, patient safety, ambulatory care

PURPOSE

The purpose of this research was to gain a better understanding of the specific processes of patient care in primary care practices that result untoward outcomes (adverse events or AEs) for patients and to design risk mitigation strategies that would yield demonstrable improvements in patient outcomes. The overall goals of the project were to 1) generate a mature audit instrument/process (including electronic data collection tools and training manuals) that could be used to quantify and characterize AEs in ambulatory primary care environments; 2) provide a large scale estimate of the extent, nature, and source of AEs with sufficient generalizability to begin to estimate this burden upon adult patients in the United States; 3) establish the underlying high-risk care processes that contribute to the development of AEs that do NOT depend upon more biased ways to identify them; and 4) estimate the burden of AEs that are amenable to prevention or amelioration as a result of risk mitigation.

To achieve the objectives of this research, the following specific aims were proposed.

Aim 1: Refine the Baylor version of the IHI Outpatient Trigger Tool (BI-OTT) audit process to generate a BI-OTT2.

Aim 2: Characterize the performance characteristics of the BI-OTT2 process pertaining to reliability and its capabilities and limitations related to more general application of the study findings and BI-OTT process.

Aim 3: Characterize the nature of AEs experienced by patients receiving ambulatory primary care in HTPN practices and evaluate the input of patient, practice, and physician characteristics on them.

Aim 4: Apply standard risk evaluation techniques and taxonomies to 3-4 AE themes amenable to prevention and or mitigation.

Aim 5: Develop specific "off-the-shelf" training tools so that other organizations can test and/or utilize the BI-OTT methods.

SCOPE

Background and Context

The need to reduce risk for persons interacting with the healthcare system is well recognized worldwide as a public health issue.[1, 2] In 1999, the Institute of Medicine (IOM) report "To Err Is Human" illuminated the high rate of medical errors and adverse events (AEs) occurring in hospitals and the morbidity and mortality associated with these errors, catapulting this issue to national and international attention and prompting initiatives to improve patient safety and quality of care.[3-5] A telephone survey of 6700 US households in 2001 found that 22% of respondents said that they or a family member had experienced a medical error. This translates into an estimated 22.8 million people or 8% of the US population, with an estimated 8 million (3% of the US population) saying that the medical error had caused serious problems. In ambulatory care, adverse drug events alone are estimated to be 8.8 million yearly, with 3 million of them categorized as preventable.[6]

Current knowledge about safety in the ambulatory care setting

AEs and factors increasing the risk of patients experiencing AEs have not been as extensively investigated or characterized in the ambulatory (and particularly primary) care setting as they have in inpatient care. This is in part due to the difficulties in such investigations posed by the nature of primary care: care takes place in multiple locations, involves multiple visits, may be provided by a variety of healthcare providers, may involve in-person, phone, mail, or electronic interaction between patients and providers, and involves multiple interactions between providers caring for the same patient.[7] Working within these limitations, however, synthesis of primary care safety research to date has identified three main categories of preventable adverse events in primary care - those related to diagnosis, treatment, and preventive services – and four categories of process errors associated with such events – clinician (judgment, decision making, skill), communication (clinician-patient, and clinician-clinician), administration (office and personnel issues), and "blunt end" (insurance and government regulations).[7] Dividing these into more specific categories, errors relating to communication problems, diagnostic tests, and medications are most frequently reported.[8] Studies by the American Academy of Family Physicians (AAFP) Policy Center found that, though half the reported errors in primary care did not appear to affect patients, 20% led to delayed patient care, 10% to worsening illness, and 5% to hospitalization.[9-12]

Tools and Methods used to Determine or Track Adverse Events in Primary Care

A wide variety of methods and data sources has been used to investigate prevalence of AEs in primary care. These include chart review (paper or electronic),[13-15] patient surveys,[15-21] voluntary reporting systems,[8,22] and malpractice claims/risk management data review.[23-25] All these methods have their respective strengths and weaknesses. Comprehensive chart reviews are expensive and time consuming and may substantially underestimate the true rate of events, as only those resulting in a provider visit or consultation will be included in the chart.[16] Computerized searches of electronic records are quicker and less expensive but, depending on the sophistication of the search strategy, may miss documented events that have been described without using the selected search terms (i.e., variable sensitivity).[14] Studies relying on patient surveys, though more likely to detect events that do not result in a provider visit, are subject to response bias and all the limitations inherent in self-report[16] and make strict definitions of what constitutes an AE more difficult. Voluntary reporting systems have been found to substantially underestimate the true rate of AEs[26, 27] and to predominantly capture "near-miss" reports, as opposed to AEs,[22] which may lead to inaccurate estimates of the proportion of such cases that are caught and corrected before an AE occurs. Voluntary reporting systems have been used effectively in combination with systems analysis to identify underlying causes of errors and design and implement interventions to address these.[22] Malpractice claims data have proved a useful source of information regarding AEs related to delayed or missed diagnoses, which can be hard to detect through medical record review alone but are typically biased toward severe injuries and younger patients.[23, 25] In addition, because extensive review of legal and medical records is required, this data source suffers from the same time and cost constraints as medical chart review.

Given the high priority of improving patient safety as part of overall healthcare quality improvement and the importance of monitoring performance both to provide feedback and to identify areas, systems, and processes to be targeted for improvement, a tool/process that can provide a reasonably accurate and unbiased estimate of the prevalence and nature of AEs in primary care and that can be widely applied at a reasonable cost is urgently needed. The investigator's refinement and formal testing of Institute for Healthcare Improvement (IHI) Outpatient Trigger Tool represents a significant step in this direction.

Use of Trigger Tools in Outpatient Care

Although the concept of a trigger has existed in the literature for over 30 years, it became best known through Classen's application to automated adverse drug event (ADE) monitoring in hospital information systems.[28, 29] The original trigger tool described by Classen[28, 29] was fully automated and was found to be "effective but expensive and required customized software linkages to pharmacy databases".[30] It thus was impractical in many healthcare settings, so a relatively low-cost and "low-tech" version was developed by a group of experts convened by IHI and Premier in 2000.[30] Classen's fully automated trigger tool was designed to detect in-hospital ADEs.[29] A positive signal, such as an INR > 6, 'triggered' review of that chart. If the review showed that an ADE (preventable or not) had occurred, the ADE was classified and assigned a severity score using the E-I (actual patient harm) levels of the NCC MERP Index.[31] The modified IHI/Premier trigger tool replaced the computerized detection of triggers with manual chart review and expanded the number of triggers from 12 to 24.[31] The IHI/Premier trigger tool has been used by > 200 organizations and has been shown to be consistent, reliable, and low cost.[30] It appears to increase the rate of ADE detection ~50-fold.[31]

The manual trigger tool methodology has been extended to the ambulatory care setting and looks beyond ADEs to other types of AEs that might occur in the course of patient care.[32,33] The tool structures chart review, through the use of triggers, to evaluate whether an AE occurred or not. For example, 'life events,' such as a new diagnosis of cancer or emergency department visit, are used as indicators to attract chart review to possible adverse events. It is important to make the distinction between a positive trigger and evidence that an AE occurred. A positive trigger is the signal for situations in which the likelihood that an adverse event has occurred is higher; as a result, the patient chart warrants more detailed evaluation for the presence of an AE. A preliminary test of a tool (IHI Outpatient Trigger Tool [I-OTT]) incorporating 12 'life event' triggers using charts of patients age ≥ 60 years with at least two ambulatory care visits during the 24-month study period showed an AE rate of 17% per year of care.[30] The outpatient trigger tool has undergone some additional testing at selected Kaiser-Permanente and Ascension Health Care facilities. A great value of such trigger tools is that, by providing a structured process for identifying AEs through review of a random sample of patient charts, they provide real-world estimates of AE incidence rates – in contrast to mechanisms that rely on voluntary reporting, which vastly underestimate the true rates of AEs.[26, 27]

Nature of AEs taking place in patients receiving ambulatory primary care.

Three characteristics of AEs identified in primary care are of particular interest: 1) attribution (to primary care processes, patient responsibilities, economic barriers, and care processes outside the purview of the primary care physician); 2) preventability and/or ameliorability of AEs; and 3) the level of patient burden associated with AEs. Previous researchers have examined aspects of these factors in a variety of ways. Brown et al[34] used structured interviews with 22 patients and root cause analysis to examine underlying causes of ADEs in ambulatory care. Patients identified 164 causes that were categorized into eight major pathways: medication nonadherence, prescriber-patient miscommunication, patient medication error, failure to read medication label/ insert, polypharmacy, patient characteristics, pharmacist-patient miscommunication, and self medication. The AAFP Policy Center studies found that, among errors reported by family physicians, 66% are caused by process and charting problems (misfiled lab results, failure to schedule follow-up), 15% by noncompliance, 13% by medication errors, and 3% each by clinical judgment and interdisciplinary communication problems.[9, 10, 12] Examination of AEs due to missed and delayed diagnoses through malpractice claims data identified the most common breakdowns in the process as failure to order an appropriate test, to create a proper follow-up plan, or to obtain an adequate history or perform an adequate physical examination. Leading factors contributing to errors were failure in judgment, vigilance or memory, or knowledge, patient-related factors (including nonadherence), and provider handoffs.[25]

The burden of harm associated with errors or AEs varies substantially between studies. AAFP Policy Center studies found half the errors reported by family physicians did not affect patients, but 5% led to hospitalizations.[11] In contrast, the evaluation of AEs using malpractice claims data – which the authors acknowledged were biased toward more severe events – found that 59% of the identified errors were associated with serious harm, and 30% resulted in death.[25] For events identified through a voluntary reporting system in two practice-based research networks, approximately 10% were found to be associated with clinical harm, and an additional 9% were associated with increased risk of clinical harm.[8] With respect to ADEs, a prospective cohort in four primary care practices identified 13% as serious and the remaining 87% as "significant."[16] The variation demonstrated by data source emphasizes the need for a less biased tool, such as the outpatient trigger tool central to this proposal.

Moving from Adverse Events to Underlying Risks

Methods initiated in safety science for the petro-chemical industry and translated and adapted for use in healthcare emphasize the need to look at patterns of AE characteristics, application of prioritization schemes based on risk assessment, and design of improvement strategies based on the types of associated antecedent care process risks and hazards identified as contributing to the event. This process also involves 'stopping rules' to ensure that investigations, root cause analyses, and process improvement activities focus on the types of AEs the organization has some level of control over,[35-37] a strategy to avoid the natural tendency to react only to single, dramatic AEs.

Retrospective in nature, the data generated from the BI-OTT is an important addition to the ambulatory healthcare AE detection toolkit. AE data, combined with information from data collection approaches such as medical event reporting and focus groups, triangulates information about AEs to achieve as complete an understanding as possible of both the types of events occurring and how a process or system is actually operating.[38] Information from these diverse sources informs the sense-making process. Triangulation involving discussions by those involved at all levels of the event can help negate what Westrum describes as passive social intelligence – understanding of hidden events is slowed due to barriers to the reporting of this information.[39]

Tools for Sense-making.

Sense-making is the process by which individuals reduce ambiguity in their environment. Existing information is used to frame the conversation to explain what happened, why it happened, and what action, if any, should taken.[40, 41] There are a variety of tools that can be used in sense-making of patient safety events and processes. Rather than selecting one method as the most appropriate method for an organization, the methods should be used in combination. When embarking on the shift from retrospective reaction to an event to prospective risk modeling, the logical tool for initial use is sociotechnical probabilistic risk assessment (ST-PRA).[42, 43] This assessment provides a macro-level view of the system with the undesired outcome as the subject of discussion. A focus-group methodology is essential so that all actors in the process share their insights. The various ways in which the undesired outcome can occur are diagrammed sequentially and the probability for failure at each step is estimated to the best of the knowledge of those involved.

This process is necessary, as most knowledge of risk is undocumented. Perfection is not the goal, as the ST-PRA becomes a living document, added to and revised as more knowledge comes forth. The process(es) with the highest probabilities for failure are prioritized for more study and targeted improvement initiatives.

Importance of the Research

Our approach to AE detection provides a more complete and accurate assessment of the incidence rate of AEs than is currently available, because it does NOT rely upon processes, such as voluntary reporting and threatened litigation, that are fraught with bias and underestimation. The approach also specifies the collection of information about contributing factors, such as suboptimal performance of people, systems, and the issues related to the natural uncertainties of medical care. Therefore, the yield of this work is a rich substrate of AE data that has generated the ability to develop specific risk reduction methods that would address a broader spectrum of AEs that occur in ambulatory primary care.

Setting

This research was conducted within HealthTexas Provider Network (HTPN), the solely owned, large, physician group practice within the Baylor Health Care System (BHCS). At the time of the study, HTPN included 36 primary care practices located throughout the greater Dallas area, staffed by 190 family practice and internal medicine physicians and caring for approximately 200,000 patients annually.

METHODS

This study focused on improving patient care, improving detection of adverse events, identifying the underlying causes of the adverse events, and improving processes of care to prevent future adverse events by building on knowledge gained.

SPECIFIC AIM 1 – *Develop Enhanced Version of the BI-OTT (BI-OTT2)*

We conducted an audit of the BI-OTT and identified areas for improvement in the creation of the BI-OTT2. We specified a list of proposed changes for the BI-OTT2 and obtained input about the proposed changes from others; based on the feedback, we finalized the BI-OTT2.

SPECIFIC AIM 2 – *Determine Performance Characteristics of the BI-OTT2*

When applied to 2005 patient visits, the BI-OTT1 tool/process focused upon a limited population of patients (age ≥ 50 with ≥ 3 physician visits during 2005), which extended the age range used by Resar (age ≥ 60). A focus upon an older segment of the population by Resar and ourselves related to selecting a population with more frequent care and for whom the occurrence of suboptimal care might be more likely to result in an observable AE. This selection bias (toward enhanced sensitivity) is practical but significantly limits generalizing these finding to the broader US adult population. In an effort to attenuate (though clearly not to eliminate) these generalizability issues, additional chart audit components were added to the BI-OTT2 deployment to test the impact of changing the age requirement or change the visit requirement.

Figure 1 illustrates the populations not evaluated by the BI-OTT1 process due to having too few visits or being too young (yellow/light shading) vs. the target population (dark shading).

Figure 1. Populations not evaluated by the BI-OTT1 process

Age → / Visits ↓	20-49	50+	Supplementary Review
1-2	***Lower age and lower visit rate*** *(20 physicians /600 charts)*	***Lower visit rate only*** *(20 physicians / 600 Charts)*	***Lower visit rate*** *40 physicians (~20% of HTPN) /1,200 Charts*
3+	***Lower age only*** *(20 physicians/600 Charts)*	***Standard BI OTT1 and BI OTT2*** *180 physicians (100% of HTPN) / 5,400 Charts*	***NA***
Supplementary Review	***Lower age*** *40 physicians (~20% of HTPN) / 1,200 charts*	***NA***	***Either / Both Categories*** *60 physicians (30% of HTPN) /1,800 charts*

For each of the three populations not previously evaluated, 600 charts each were identified for review (20 eligible physicians, 30 charts per physician), and the total number of patients, visits, and AEs were determined for each of the three shaded quadrants representing patient populations not previously evaluated. We explored whether the frequency and/or pattern of adverse events for the primary population (3+ visits and 50+ years of age) differed for patients having fewer visits during the target year (1 or 2 visits) and/or for younger adults (20-49 years). Thus, the estimated impact of each patient population selection criterion (age, annual visit volume) was separately and jointly evaluated to enhance the capacity to better estimate the degree to which the research findings using the BI-OTT2 might be generalized for all adults receiving ambulatory primary care.

SPECIFIC AIM 3 – *Characterize AEs in primary care practices detected during 2006 using the BI-OTT2*
The data generated by the BI-OTT2 audit of CY2006 patient visits were analyzed to better understand the extent, nature, and source of AEs for care received by patients in the practices of ~180 HTPN primary care physicians. The BI-OTT2 had different triggers than the I-OTT and the BI-OTT1. The list of triggers for the BI-OTT2 is shown below (Figure 2):

Figure 2. Trigger Categories for the BI-OTT2

• Hospital Admission	• ED Visit
• Medication Adverse Event (ADE)	• Abnormal Lab Value
• Surgery	• New Diagnosis of Cancer
• Calls to 'nurse' (revised criteria)	• Other *(no trigger identified)*

Analysis of AEs - For each trigger category (and for the aggregation of all AEs), the AEs were analyzed with regard to a series of characteristics as shown in Figure 3.

Figure 3. Endogenous Characteristics of AEs

Characteristic	Detail
Severity	NCC MERP class: E (requiring additional care/monitoring but not requiring hospitalization)→→ I (death)
Preventability	Not preventable; Possibly Preventable; Probably Preventable; Preventable
Ameliorability	Ability of more robust or more timely care to reduce the burden of the observed AE
Nature of AE	AE related to care provided vs. care not provided
Attribution	To patient and/or to PCP practice and/or to care by an provider outside the PCP practice and/or to financial/access issues

Exploratory model development - In addition to standard descriptive analysis, we explored the impact upon the frequency of AEs (AEs per patient-year and AEs per physician visit) of patient, physician, and practice characteristics (exogenous variables). Specifically, each of the endogenous variables was regressed on the exogenous variables to formulate a log-linear model (used due to the presence of both scale and categorical variables). The interaction of endogenous variables was evaluated both by two-way and multi-way correlational analyses. Accordingly, work will be undertaken to develop models that characterize meaningful relationships that contribute to "sense-making" of these AEs.

Figure 4. Exogenous variables of interest in analyzing AEs

Physician Characteristics	Practice Characteristics	Patient Characteristics
Age	Number of physicians	Age
Years in Practice with HTPN	Use of Physician Assistants or nurse practitioners	Gender
Gender	Productivity (RVUs per physician)	Race / Ethnicity
Specialty *(Internist vs. Family Practice)*	Mean age of physicians (may influence culture of the practice)	Payer Type
	Mean PS climate score of staff (Fall 2005; and Fall, 2006)	Utilization intensity (including number of ambulatory care visits to the PCP)
	Mean PS climate score of physicians (Fall 2005; and Fall 2006)	

Preliminary results have indicated that patients ≥ 65 years of age have a significantly higher probability (27.7%) of incurring an AE than those < 65 years of age (19.5%) [p<0.001]. Similarly, more female patients (23.5%) than male patients (21.5%) experience an AE, a difference that is not significant (p=0.11). Because the number of visits per patient was not collected for the BI-OTT1 data, we cannot yet approach the impact of the extent of exposure to primary care as a protective vs. risk-generating factor.

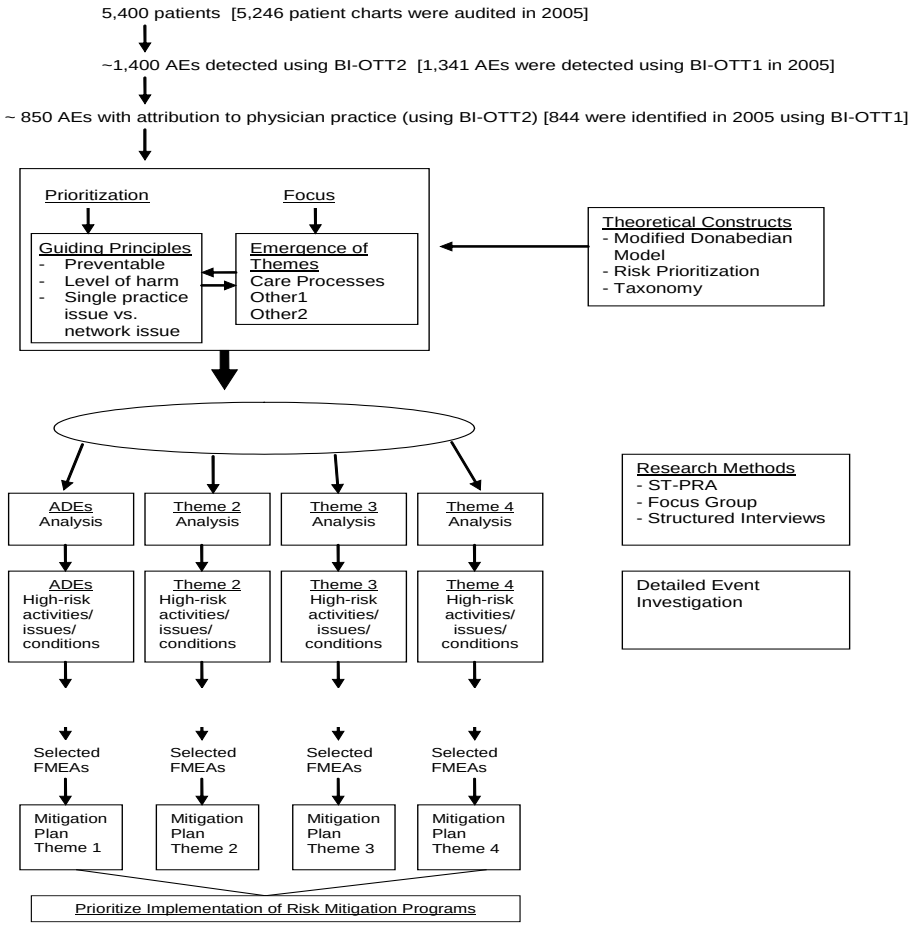
Patient information can be acquired from the HTPN billing system ICD-9 codes and CPT-4 codes and related relative value units (RVUs) associated with patient visits. This information can be used to classify patients according to their services utilization and resulting propensity to have an AE overall, as well as many of the different categories.

Physician characteristics and practice characteristics can be used to determine their impact on patient safety as reflected by AE frequency and pattern. Relationships between physician characteristics and harm may highlight groups of practitioners that might be productively engaged for specific types of interventions that we expect will emerge from the risk analysis activities (Specific Aim 4). Similarly, the level of productivity (RVU per physician FTE) at the practice level may also influence the occurrence of AEs.

SPECIFIC AIM 4 - *Risk Analysis Based Upon Identified AEs*

The goal of Aim 4 was to use the rich "harvest" of AEs generated by the BI-OTT2-enabled review of primary care of patient records during 2006 as a basis for an enlightened risk analysis to develop a set of candidate clinical processes worth of improvement. The strategy for the risk assessment is illustrated in Figure 5.

Figure 5. Risk Assessment Strategy



The HTPN Patient Safety Committee (PSC), with guidance and validation from the investigators, proposed to begin the sense-making process by using the AEs "harvested" by the BI-OTT2 to look into identifiable event clusters. The initial outcome of these discussions will be a set of AE "themes," process of care areas best suited for proactive patient risk reduction activities.

A case-study approach, as described by Yin, will be incorporated into the proactive risk assessment strategies such as Root Cause Analysis (RCA) and Sociotechnical Risk Assessment (ST-PRA). [44] For some types of events, the sense-making may result in the understanding that action should not be taken or that a better understanding of the event or situation is needed."[45]

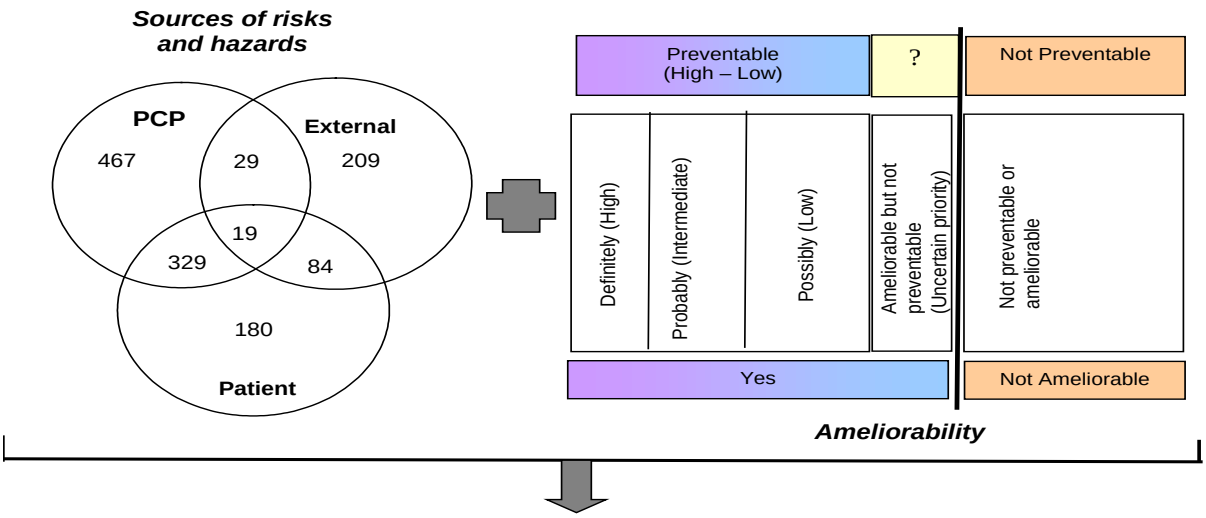
The BI-OTT methodology results in the detection of a large number of AEs from which to learn. After describing the overall characteristics of the identified AEs in Aim 3, the next stage involves the creation of a more manageable subset of the higher-priority events (perhaps 75-250) felt to be more informative to the risk analysis. Although this process should be directed by physician-confirmed AEs, the methodology can be illustrated using the nurse-identified AE information from the BI-OTT1 with regard to analysis of events and the classification, identification, and prioritization of those event types best suited for improvement opportunities.

Rather than retaining the association each AE has with the trigger category that led to its discovery, we propose to use a more generalizable patient safety taxonomy. To reiterate, the triggers are only a means to detect AEs. The patient safety taxonomy outlined by Chang and colleagues utilizes a set of primary classifications - *impact, type, domain, cause,* and *prevention and mitigation*.[46] *Impact* is defined as the "outcome of effects of medical error and systems failure, commonly referred to as harm to the patient." *Type* is the "implied or visible processes that were faulty or failed," *domain* is "the characteristics of the setting in which an incident occurred and the type of individuals involved," and *cause* is "the factors and agents that led to an incident"; *prevention and mitigation* are "the measures taken or proposed to reduce incidence and effects of adverse occurrences." This proposal will focus on the first four of these classifications. The prevention and mitigation classifications will emerge as the proactive risk assessments take place and understanding of the events is achieved. The *impact* domain represents an expansion beyond the NCC MERP index for scoring patient harm to include a categorization of preventability and ameliorability. Using this framework, a prioritization algorithm will be applied to identify the desired subset of 75-250 AEs. Though the approach retains flexibility, it provides a consistent *a priori* strategy for creating a high-priority AE subset. Figure 6 outlines the strategy for generating this subset.

The subset of AEs is created by including only those events that are attributed at least in part to the primary care practice, since the focus of our proposed risk assessment is provider centric. In the future, patient issues, external caregivers and financial/access barriers may be of sufficient interest to direct similar analysis. This is not to negate the importance of the role of patients or external providers in the observed AEs, but administrative "traction" in HTPN is likely to exist for derivative process improvements related to physician practice issues. This group of AEs will be stratified based on impact (harm and preventability) and other attribution characteristics. Events that are determined to be neither preventable nor ameliorable will be excluded from further consideration. Without the additional benefit of information on ameliorability (since has not yet been done for the BI-OTT1 process), 15 clusters are created as outlined in Figure 6. Event clusters that are determined to have higher levels of preventability/ameliorability and higher levels of adverse impact upon patients are viewed as having higher priority for further analysis. Inclusion of AEs in the upper right quadrant is obvious but including some clusters in the lower left area may be challenging and require segmentation of high volume clusters. Moreover, the characteristic of ameliorability will add three new clusters that will inform this prioritization scheme. Finally, the shear volume of ADEs warrants focus upon ADEs as a theme, but this might well deserve segmentation using this paradigm.

Patterns of events within the prioritized clusters will be described more, including whether they are limited to a small group of practices or generalized issues across the practice network as well as specification of type of AE (patient management, communication, clinical performance), subtype themes (adverse drug events, care coordination, patient education, patient-provider communication, provider-staff communication), and domain (patient and other characteristics). The HTPN PSC, which has nursing and physician representation and is charged with patient safety improvements across HTPN, will work with the project team to determine the AE themes (ADEs plus other topics that derive from the initial prioritization/focus exercise [Figure 6] to reduce the number of AEs to study in more depth). Themes might include care coordination, patient education, patient-provider communication, or provider-staff communication. The HTPN PSC decisions will be guided by and validated by the SAB. This process should be applied to physician-confirmed AEs, but the methodology and taxonomy can be illustrated using the nurse-identified AE information from the BI-OTT1 with regard to detecting, classifying, and prioritizing those AE types that may be best suited for investigation and improvement focus.

Figure 6. AE Prioritization Framework



	Ameliorability	NCC MERP Severity of Harm			Total
Preventability		E	F	G-I	
Definitely	Yes	9	7	1	17
Probably	Yes	43	17	2	62
Possibly	Yes	266	77	10	353
No	Yes	394*	12*	2*	408*
No	No				
Total	-	712	113	15	840
* Ameliorable 'Yes' and 'No' combined as this determination will be based on physician review of nurse-identified AEs, which is still pending					

Figure 7 illustrates that 63% of the 1341 AEs observed during the 2005 BI-OTT1 audit were attributed to the primary care practice. Of these 844 events, 51% had preventability levels of 'definitely,' 'probably,' or 'possibly.' Obviously, propensity for amelioration has not yet been addressed and will likely increase AEs under consideration substantially. Figure 7 illustrates two extreme positions that form boundary situations for the prioritization/focus process and that point to its importance. In the first scenario, the severity of the AE and its preventability are not valued; in doing so, a total of 613 events would need to be considered. In the second scenario, all low-severity and "low-preventability" AEs are eliminated, and only 27 events remain for investigation and risk analysis. Clearly, subset 1 is too large and subset 2 is too small. The AEs meeting the criteria that emerge from this process would be placed into an event "type" vis à vis patient management, communication, clinical performance, and subtype theme (adverse drug events, care coordination, patient education, patient-provider communication, provider-staff communication) taxonomy, and a similar table would be created. Simple descriptive analyses, such as those below, and narrative summaries of the AE comments would be presented to the HPTN PSC, investigators, and SAB for consideration, discussion, and identification related to the AE themes meeting the criteria for the proactive risk methodologies. Included in the criteria for the proactive risk assessment process are practical contextual issues, such as the leadership necessary to implement changes, financial feasibility, and consideration of other initiatives occurring in the environment. It is recognized, that, as these issues are discussed, additional types of events, not detected through the BI-OTT audit, may come to light and be added into the proactive risk assessment process, because the goal is to be as inclusive as is feasible related to informative data.

Figure 7. Boundary Situations for Prevention of AEs

Trigger Category	Subsets of Adverse Events *(Number of AEs)*		
	All AEs	**Subset 1**	**Subset 2**
Attribution →	All	PCP Provider	PCP Provider
Severity (NCC MERP) →	E,F,G,H,I	E,F,G,H,I	F,G,H,I
Preventability →	All Levels	Possible, Probable, or Definite	Probable or Definite
Patient Admitted to Hospital	155	96	13
ED Visits	81	49	4
New Cancer Diagnosis	35	21	1
Nursing Home Placement	4	2	0
Abnormal Lab Values	205	96	4
>2 Consultants for the Same Problem	9	4	0
Urgent Care Clinic Visit	7	3	0
Patient Taking >5 Medications	258	102	3
>6 Calls to RN	3	1	0
Surgeries	98	31	2
MD Change	1	0	0
Other	485	208	0
Total	**1,341**	**613**	**27**

After AE themes are determined, proactive risk assessment methodologies will be initiated. The HTPN PSC and project team will create a subcommittee to address each of several themes. The subcommittees will be multidisciplinary teams of physicians, physician extenders, nurses, and office staff from across the HTPN network. The members of the subcommittee will discuss the theme and its associated constructs as they understand them, document information about the theme, and, with facilitation from the project team, create the first pass of a graphical, sequential display of the process analogous to the causal diagram included in the Sociotechnical Probabilistic Risk Assessment (ST-PRA) methodology. Theoretically, the process of assigning probabilities of occurrence to the antecedent hazards and risks leading to the AE cluster reasonably can occur at this stage.

Each subcommittee will then select a small group of HTPN practices that they feel will collectively give the broadest view of the targeted AE theme. The subcommittee and project team will work with this group of practices and create practice level graphical displays (ST-PRA) of the AE theme using the same method as described previously for hazards, risks, failures, and recoveries. Probabilities will be assigned to the contributing hazards and risks identified and well as categorizations of the root hazards/risks (causes) using the Eindhoven Classification Matrix – Medical Version. In addition to the group discussions, the project team will arrange to speak with a cross-section of the practice about the AE theme using a structured interview technique. Each practice-level diagram will be completed and shared with the practice to confirm the accuracy of the information as they perceive it. This process will be completed for each targeted practice. Opportunity will be provided for the practice members to share other AE themes that they feel are important for future proactive assessments.

The process diagrams from each practice will merge into the HTPN-level diagram. This will be shared with the practices that had input into the process. A second small group of practices will be selected. The project team and subcommittee will visit these practices and obtain group input on the HTPN-level diagram. These practices will have the opportunity to input additional information into the diagram. The final product will be a ST-PRA diagram with probabilities assigned as well as root cause categorizations and recovery mechanisms.

Information about the probabilities will inform future HTPN process improvement initiatives. The root causes and recovery information will guide the content and priority of PS initiatives. For instance, some AE risks and hazards will be latent in nature, and improvements focusing on training of the ‘sharp end’ providers will not be successful. Success of these initiatives will be determined by changes to the HPTN and/or practice ‘fingerprint’ of AE information from future audit activities.

The AE themes for this project will be identified from 2006 patient care data resulting from the BI-OTT2 audit scheduled for early summer 2007. Though the audit process and creation of the identification of AE themes will occupy the majority of the funding period, the data will be used to frame the discussions around the prioritization of initiatives and enhancement of implementation of improvements.

SPECIFIC AIM 5 – *Development of Dissemination Materials for Broader Use of the BI-OTT2*

The experience our group has gained as part of this large-scale implementation of this technique has pointed to the value of having strong educational materials to provide direction and structure to the effective use of the BI-OTT. The BI-OTT might well have broader use by others: 1) identification of AEs that serve as a starting point for an outcome-based risk analysis; 2) quantifying and characterizing AEs that permit the BI-OTT to be used as a measurement tool to compare performance across different healthcare organizations; 3) use in longitudinal studies to explore performance improvement; and 4) broader use that might permit more realistic national estimates of the frequency, burden, and nature of AEs in ambulatory primary care. We will refine the educational materials and data collection tools we developed for the BI-OTT1 implementation so that they can be used for the BI-OTT2 and will prepare them for more rigorous testing and dissemination in future work.

RESULTS

Outcomes

SPECIFIC AIM 1 – *Develop Enhanced Version of the BI-OTT (BI-OTT2)*

The following modifications were made to the BI-OTT to generate the BI-OTT2.

a) Enhanced detection of triggers/AEs. The nursing Inter-rater Reliability from the BI-OTT was expanded from 5% to 10% of charts. The sources of differences between detected triggers and AEs informed modifications to the chart review tool and protocol.

b) Enhanced identification of AEs associated with medications. A new variable was added to each trigger/AE category that allowed nurse auditors to indicate if an AE was associated with medication. In this manner, medication AEs were characterized in a cross-cutting approach throughout the different areas of potential AEs.

c) Elimination of trigger categories with a low yield of AEs. The initial chart review instrument was developed outside BHCS. Some trigger categories were not applicable to the BHCS environment.

d) Consider addition of new trigger categories. The BHCS version of the OTT used in the 2005 chart review included an 'Other' category to enable nurse auditors to record information about AEs not fitting existing trigger categories. Information from this AE subset will inform the addition of BHCS-specific trigger categories. Initial work showed that 60% of the AEs documented in this category were medication related but did not meet the criteria to be documented under the ‘polypharmacy’ trigger initially used by Resar et al.

e) Revision of existing definitions for categorization of identified AEs.

f) Addition of other AE descriptor variables. The following variables were added to the chart review tool within each trigger category: 1) nurse judgment as to whether the AE could have been mitigated or prevented by the provider or patient and 2) an option to indicate if financial issues or healthcare access limitations were contributing factors to the AE.

g) Addition of patient descriptors: The following variables were added to the chart review tool to describe the patient: 1) number of office visits in the audit period (validation of administrative data incidence rates per visit) and 2) physician-described race/ethnicity of the patient.

While the scope of this proposal initially covered the development and testing of the BI-OTT2, AHRQ’s granting of a no-cost extension allowed us to make additional refinements to the tool (BI-OTT3 and BI-OTT4) and to use the tool to review patient charts to collect data on AEs occurring in 2007 and 2008.

SPECIFIC AIM 2 – *Determine Performance Characteristics of the BI-OTT2*

The data collected in our preliminary studies had been limited with regard to generalizability to some degree based upon two entry criteria for chart review – age $\geq$ 50 and $\geq$ 3 MD office visits during year of review. To be able to better extrapolate population burden of AEs, the BI-OTT2 was applied to populations for which entry criteria were relaxed.

The BI-OTT2 was thus applied to HTPN 2006 data for patient cohorts representing three distinct populations:

- Standard Population: Age >5 0 years with ≥ 3 outpatient visits to the PCP (N=5172). Research Population 1 (R1): Age > 50 years with 1-2 outpatient PCP visits (N=564). Research Population 2 (R2): Ages 20-49 years with ≥ 3 outpatient PCP visits (N=563).

Figure 8. AEs by Trigger Category for each population in the BI-OTT2 HTPN audit for 2006

	Standard (50+ yrs, ≥ 3 visits) (n=5,172)		**R1 (50+ yrs, 1-2 visits) (n=564)**		**R2 (20-49 yrs, 3 or > visits) (n=563)**	
	Positive Triggers	RN Identified AEs	Positive Triggers	RN Identified AEs	Positive Triggers	RN Identified AEs
Total	8077	698	560	26	600	45
AE S PER 100 PATIENT-YEARS	**13.5**		**4.1**		**7.6**	

From these results, it appears that the AE rate more strongly related to the volume of care than to the age of the patient. These findings underscore the focus of the original exclusion criteria and provide a way to generate better estimates across these different patient populations.

A relatively high level of false-positive AEs (as defined by MD review) was identified for visits during CY2005, so attention was focused upon enhancing the quality of nursing review for office visits during CY2006. The improved process utilized in CY2006 greatly reduced the number of false positives.

Analysis of the physician confirmatory reviews for visits occurring during CY2006 revealed good inter-rater reliability between the two physician reviewers who reviewed RN-identified AEs to determine if it was an AE from their perspective (panel of five physician reviewers with random allocation of RN-identified AEs). Based on this finding, we have refined the BI-OTT process to only include one physician review of each RN-identified AE.

SPECIFIC AIM 3 – *Characterize AEs in primary care practices detected during 2006 using the BI-OTT2*
The analysis of the CY2006 data gathered from the BI-OTT2 focused upon:

a) Contribution to the development of AEs by primary care processes within the control of the practice, patient responsibilities, economic barriers, and care processes outside the purview of HTPN primary care;

b) Scoring of the detected AEs as to feasibility of the ambulatory care providers to prevent and/or mitigate the AEs;

c) Scoring of detected AEs related to impact to the patient (temporary or permanent physical harm);

d) Identification of physician, patient, and HTPN practice characteristics that impact AE rate.

The prevalence of positive triggers (not AEs) and AE yield of each trigger in BI-OTT2 audit of a random sample of patients > 50 years of age with ≥3 primary care physician visits during the audit year are shown in Figure 9. In the 2005 BI-OTT1 audit, there were 9322 positive triggers plus 485 AEs in the 'Other AE not associated with a trigger' category detected in 5246 charts. Not surprisingly, the presence of abnormal laboratory values was found to be nearly universal (90.4% of charts audited). Other high-volume triggers were taking ≥ 6 medications concurrently (26.3%) and surgery (25.0%). Only 6% of charts were not positive for one or more triggers. Four BI-OTT1 triggers were omitted from the BI-OTT2 instrument (nursing home placement, > 2 consultants, physician change, and urgent care clinic visit) after observation of low AE yields in the BI-OTT1 2005 audit.

Other changes made to the BI-OTT1 tool and audit process included having nurse auditors record their judgment of the potential for mitigation for each identified AE and having to record for all AEs – regardless of which positive trigger initiated the review for AEs – whether or not the event was medication related. 'Mitigation' was defined as any action the provider or healthcare team could have taken to substantially reduce the harm experienced by the patient. These data were collected for all AEs, regardless of the judgments related to preventability, as mitigation is more closely related to rapid detection of AEs and recovery actions. In the 2006 BI-OTT2 audit, there were 8077 positive triggers and 698 nurse-identified AEs in the 5172 charts audited.

Figure 9. Positive triggers and AE yields (% of positive triggers yielding AEs) for the HTPN 2006 BI-OTT2 audit (N=5172)

Trigger Category	Triggers Present	% All (+) triggers	Number of AEs	AE Yield [% (+) Triggers yielding AEs]	% of all detected AEs
New Cancer Diagnosis	103	1.3	11	10.7	1.6
ED Visit	580	7.2	13	2.2	1.9
Hospitalization	567	7.0	30	5.3	4.3
Surgery	1143	14.2	47	4.1	6.7
Medication-related	1362	16.9	533	39.1	76.4
> 6 Calls to PCP Office	51	0.6	1	2.0	0.1
Abnormal Lab Values	4244	52.5	36	0.8	5.2
Other	27	0.3	27	n/a	3.9
Total	**8,077**	n/a	**698**	**8.6**	n/a
Events per 100 patient-years	**156**	**n/a**	**13.5**	**n/a**	**n/a**

The percentage of patients experiencing a nurse-identified AE of any type was 23.2% during 2005. The majority of patients experiencing AEs had one detected AE (91% of patients with at least one detected AE). In the 2006 audit, 13.5% of patients had at least one nurse-identified AE. Again, the majority of these patients (97%) experienced only one AE. Discrepancies between results of the BI-OTT1 and BI-OTT2 audits are discussed in detail in Figure 13 and the associated text.

Medication-related Adverse Events – An interesting finding of the BI-OTT1 work was that many adverse drug events (ADEs) were identified by nurse auditors in patients not positive for the polypharmacy trigger (i.e., taking ≥ 6 medications): 60% of the AEs in the "other AE not associated with a trigger" category were, in fact, ADEs. This was investigated in detail using a text-mining approach to identify the specific nature of the symptoms generated by the administered medications that grouped "classes" of medications. The BI-OTT2 process used a substantively revised approach to identify ADEs, because the total burden of ADEs (those identified both by the polypharmacy trigger and independently by nurses in the "other AE" category) represented 40.6% of all identified AEs in the 2005 audit. Specifically, nurse auditors recorded their judgment as to whether or not an AE was medication related for all AEs identified in the BI-OTT2 audit – regardless of which trigger focused attention on the clinical circumstances that revealed the AE.

Figure 10 illustrates the level of harm/risk that patients experienced by AE type and the source of the AEs for the 2006 BI-OTT2 audit. Of the 698 AEs, 602 (86%) were categorized at the lowest level of patient harm category E (requiring specific care but not hospital or ED services). Due to lower frequencies, the most severe NCC-MERP categories of harm (G, H, and I) were grouped together and represent 2.4% of the AEs. The majority of nurse-identified AEs (88%) were judged to have derived from 'care provided' (as opposed to 'care not provided').The original I-OTT purposely directed auditors NOT to include AEs stemming from care not provided, a decision that underestimates the total we observed by approximately one eighth.

Figure 10. NCC MERP Severity Score and Source of AEs in the BI-OTT2 HTPN audit for 2006

Trigger	AEs*,† (N)	NCC MERP Scores			AE the result of Care Provided (row%)
		E (%in E, % all AEs)	F (%in F, % all AEs)	G-I (%in G-I, % all AEs)	
New Cancer Diagnosis	11	n=6 0.9% Es 0.9% AEs	n=1 1.5% Fs 0.1% AEs	n=3 18.8% G-I 0.4% AEs	45.5%
ED Visit	13	n=8 1.3% 1.1%	n=3 4.6% 0.4%	n=1 6.3% 0.1%	53.8%
Hospitalization	30	n=4 0.7% 0.6%	n=21 32.3% 3.0%	n=1 6.3% 0.1%	70.0%
Surgery	47	n=29 4.8% 4.2%	n=13 20.0% 1.9%	n=2 12.5% 0.3%	89.4%
Medication-related	533	n=508 84.4% 72.8%	n=21 32.3% 3.01%	n=2 12.5% 0.29%	95.9%
> 6 Calls to PCP Office	1	n=1 0.2% 0.1%	n=0 0.0% 0.0%	n=0 0.0% 0.0%	100.0%
Abnormal Lab Values	36	n=29 4.8% 4.2%	n=3 4.6% 0.4%	n=0 0.0% 0.0%	36.1%
Other	27	n=17 2.8% 2.4%	n=3 4.6% 0.4%	n=7 43.8% 1.0%	51.9%
Totals	**698**	**N=602**	**N=65**	**N=17**	**88.0%**

** total AEs (including those for which a harm score was not recorded) used to calculate harm score percentages*
† AE = Nurse Identified Adverse Event

The preventability of the nurse-identified AEs was characterized in the BI-OTT2 audit, as illustrated in Figure 11. The distribution of "preventability" varied considerably across triggers. These results show that a relatively small fraction (4%) of the AEs was considered definitely preventable.

Figure 11. Trigger Category and Preventability of AEs based on the BI-OTT2 HTPN 2006 audit

Trigger	AEs (N=698)	Preventable				Mitigate (row %, % all AEs)
		Yes (row %, % all AEs)	Probable (row %, % all AEs)	Possible (row %, % all AEs)	No (row %, % all AEs)	
New Cancer Diagnosis	11	0%	27.3% 0.4%	54.5% 0.9%	9.1% 0.1%	27.3% 0.4%
ED Visit	13	15.4% 0.3%	15.4% 0.3%	53.8% 1.0%	7.7% 0.1%	23.1% 0.4%
Hospitalization	30	10.0% 0.4%	16.7% 0.7%	56.7% 2.4%	10.0% 0.4%	23.3% 1.0%
Surgery	47	12.8% 0.9%	21.3% 1.4%	53.2% 3.6%	10.6% 0.7%	10.6% 0.7%
Medication-related	533	1.9% 1.1%	12.9% 9.3%	84.8% 59.5%	8.3% 5.9%	3.9% 3.0%
> 6 Calls to PCP Office	1	0.0%	100.0% 0.1%	0.0%	0.0%	0.0%
Abnormal Lab Values	36	8.3% 0.4%	16.7% 0.9%	52.8% 2.7%	8.3% 0.4%	22.2% 1.1%
Other	27	11.1% 0.4%	22.2% 0.9%	48.1% 1.9%	11.1% 0.4%	22.2% 0.9%
Total – N (%)	698	25 (3.6%)	98 (14.0%)	502 (71.9%)	57 (8.2%)	53 (7.6%)

The distribution of AE attribution for the 2006 BI-OTT2 audit is shown in Figure 12. These sources included the patient, the primary care provider (PCP) being audited, care provided by an external provider or institution, and/or poor access to healthcare/financial barriers.

Figure 12. Source of AEs for the HTPN 2006 BI-OTT audit

Trigger	**AEs (N)**	**Source of AE†**			
		Patient (row %, % all AEs)	**Provider (row %, % all AEs)**	**External provider (row %, %all AEs)**	**Health Care Access or Financial Barrier (row %, % all AEs)**
New Cancer Diagnosis	11	45.5% 0.7%	45.5% 0.7%	36.4% 0.6%	0.0%
ED Visit	13	38.5% 0.7%	30.8% 0.6%	46.2% 0.9%	0.0%
Hospitalization	30	33.3% 1.4%	53.3% 2.3%	23.3% 1.0%	0.0%
Surgery	47	36.2% 2.4%	38.3% 2.6%	53.2% 3.6%	0.0%
Medication-related	533	22.7% 17.3%	89.5% 68.3%	6.6% 4.9%	1.3% 1.0%
>6 Calls to PCP Office	1	100.0%	100.0%	0.0%	0.0%
Abnormal Lab Values	36	50.0% 2.6%	41.7% 2.1%	5.6% 0.3%	8.3%
Other	27	55.6% 2.1%	25.9% 1.0%	44.4% 1.7%	0.0%
Total	**698**	**27.5%**	**77.8%**	**12.9%**	**1.4%**

A critical observation was made when the findings of the overall AE rates were compared between the first and second major audits of HTPN patients (BIOTT1 in 2005 and BIOTT2 in 2006). A summary of these findings is shown in Figure 13.

Figure 13: Comparison of AE Rates for Two Audit Years

Variable Description	Variable Units	Finding in BI-OTT1	Finding in BI-OTT2
Audit Year	NA	**2005**	**2006**
Charts Audited	Number	**5,246**	**5,172**
Overall rate of (+) AEs *(standard population)*	AEs/100 pt-yrs	**25.6**	**13.5**
Not preventable	AEs/100 pt-yrs	**11.3**	**1.1**
Possibly, probably, definitely preventable	AEs/100 pt-yrs	**14.0**	**12.1**
Overall rate of (+) triggers *(standard population)*	(+) triggers/100 pt-yrs	**172**	**153**
Percent of (+) triggers with a (+) AE that has some preventability *(yes + probable + possible)*	Percent	**7.9%**	**7.7%**

Clearly, the overall rate of AEs was markedly reduced for the 2006 audit using the BI-OTT2 (13.5 AEs/100 pt-yrs) compared to the 2005 audit using the BI-OTT1 (25.6 AEs/100 pt-yrs). Fractional distribution between components of most variables (severity, attribution, trigger type, etc.) were not substantively different between the two years. The exception is a major difference with regard to that of the distribution of ratings related to preventability. As Figure 13 shows, there was a 90% reduction in the rate of auditor-identified AEs that were judged to be not preventable (11.3 AEs/100 pt-yrs vs. 1.1 AEs/100 pt-yrs). The shift in proportions of 'not preventable AEs' observed between the two audits may have been at least partially related to modest changes in wording in the definitions provided for "possibly preventable" and "not preventable" during pre-audit refresher training for KDJ audit staff: In the BI-OTT1, these were described as "The patient harm might have been prevented" and "The patient harm was definitely not preventable," respectively; in the BI-OTT2, they were described as "There is a slight chance the AE was preventable" and "The AE was definitely not preventable." There may be a different perception relating to the use of the term 'AE' vs. 'patient harm' in the BI-OTT2 definitions – 'not preventable' might be subconsciously more acceptable for 'patient harm,' which is a somewhat amorphous quantity that could be related to multiple factors, than for an 'AE,' which might be considered a more discrete entity resulting from specific steps taken or not taken and so, by nature, having an implicit degree of preventability. In retrospect, it seems likely that part of the refresher training prior to the 2006 audit de-emphasized the identification of less preventable AEs. Additionally, it is possible that a clear understanding of what represents a lower threshold boundary may exist. Specifically, when modest symptoms that need treatment evolve in a patient and appear to have no clear link to a change in treatment, reviewers appeared in the BI-OTT1 work to label them as severity E/not preventable. Physician review identified most of these clinical situations as simply progression of the underlying illness. Accordingly, this class of RN-identified AEs diminished greatly for use of the BI-OTT2 as part of enhanced training.

SPECIFIC AIM 4 - ***Risk Analysis Based Upon Identified AEs***

This aim has not been completed due to the unexpected departure of a key member of the research team with expertise in the ST-PRA. We will complete work on this aim with operational funding over the course of the next 12-18 months. The delay in this aim (the reason for which is described below) will allow use of more recent AE data (CY2007 vs. CY2006) as a starting point for ST-PRA.

NURSE SPECIFIC AIM 5 – ***Development of Dissemination Materials for Broader Use of the BI-OTT2***

Auditor selection/training program – A formal training curriculum was developed for the nurse auditors in the original BI-OTT1 work. Training involved didactic sessions with materials, discussion sections, and review of training charts for class discussion and homework assignments. The materials developed for the BI-OTT1 were modified for use with the substantially revised BI-OTT2, and additional overview/administrative materials are being developed with the goal of enabling others not familiar with this methodology to reproducibly use the BI-OTT2. An under-appreciated competence for the chart reviewer is a strong understanding of the concept that the trigger serves only as a structure to elicit the question, "Did an adverse event take place"? – a topic that receives a great deal of attention in the training program we have developed.

Data collection / integrity – Of great importance to the effectiveness of the current audit work was the capacity to have a user-friendly electronic audit support tool. We built a tool in MS Access for the BI-OTT1 work. This tool serves as an easy way not only to enter data by audit nurses but also to cue the reviewer related to important fields that have not yet been completed.

The resultant electronic data is needed for the more sophisticated analysis focusing upon patterns and of associations/causes of AEs. We refined the data collection tool to accommodate changes to the BI-OTT. A second tool was developed that presents each RN-identified AE to a physician for his/her secondary review.

Physician reviewer training – We developed a 1-hour module to generate consistency and efficiency on the part of physician reviewers. Included were 1) the process and definitions of characteristics of AEs; 2) the electronic review of nurse-identified AE reports; and 3) a review of the consolidated reports that summarize the two independent physician reviews and the nurse audit report that highlights the characteristics in which physicians differed in their assessment.

Effective audit deployment - Engagement with practices to be audited – Planning, logistic, and communication tools have been developed to facilitate the success of planned audits. Consistent approaches to practical issues (random selection of an audit patient population, dealing with missing charts, communicating with staff, communicating with physicians, etc.) had to be developed.

A more robust training program for auditor and project manager training will be developed as part of the scope of work of a related proposal (1 R18 HS017908-01) that includes two major aims seeking to develop more sophisticated dissemination methodologies for the BI-OTT methodology and to test their effectiveness.

Discussion

These data represent the findings of the first large-scale deployment (more than 10,000 patient records over 2 years) of a general outpatient trigger tool method to estimate the magnitude and nature of adverse events that take place in ambulatory primary care. That more than 12% of patients who are older than 50 years old and have three or more primary care visits during a 1-year period have an adverse event points to this being a common and important public health issue. Extrapolation to estimate a national burden of primary care-based adverse events is difficult, but there clearly are millions of adverse events each year. Somewhat reassuring is that a relatively small fraction of those adverse events require more serious intervention, such as emergency or hospital-based care (12% of total for the BI-OTT2 review). That a large fraction of these adverse events appear to be amenable to either prevention or amelioration indicates that efforts to improve the reliability of primary care, coupled with greater vigilance to the development of complications that are not preventable, may yield important improvements in patient outcomes.

These data likely underestimate the incidence of adverse events that result from ambulatory primary care inasmuch as chart documentation in ambulatory primary care is typically less robust than for inpatient care. Efforts to estimate the sensitivity of the BI-OTT3 process are underway based on patients who are admitted with adverse events that are present on hospital admission (part of subsequently funded work).

The use of the evolved BI-OTT2 method (BI-OTT3 for more recent work from our group) has involved stepwise improvement of a challenging technique. The differentiation by review nurses of what represent symptoms stemming from the natural progression of chronic illnesses was not fully appreciated until the BI-OTT1 data were reviewed by physicians. We recognize that judgments of preventability and/or ameliorability are not easy to make and that data related to these dimensions must be viewed with some caution. Nevertheless, the method provides important first-level estimates that have been helpful to physician committees charged with the safety of ambulatory primary care for a large group practice.

A major evolution of the initial method derived from our commitment to use the BI-OTT method not only as a measurement system but as a learning system. To do so, the nurses who review charts provide a formal description in a structured format (Situation, Background, Assessment) of what the adverse event is and why they think it is an adverse event. This not only provides information that helps with quality assurance of reviews by project staff and by physician reviewers but also provides information that is rich with regard to identifying process targets for quality improvement. Unfortunately, the potential of this aim of the proposed work was not realized during the term of AHRQ's funding. The importance of this part of our project, however, mandates that we complete the ST-PRA work using operational funding.

More recent R18 funding of research that builds on the work described here and primarily focuses on developing and testing the more mature BI-OTT technique is both appreciated and will leverage the progress made in the complex method. With data now for 4 years (2005-2008) involving more than 20,000 randomly chosen ambulatory records, we are in a position to share a method that not only may be of value to others but also estimates of the burden of adverse events that take place in ambulatory primary care that might help to inform national priorities related to patient safety.

Administrative Note

The progress of this project was slowed initially because a key member of our research team had to utilize FMLA. We were granted two no-cost extensions, each lasting 5 months, to complete the proposed scope of work. When the researcher unexpectantly abandoned her position, work on this project was further delayed while we searched for a replacement with similar expertise to assume the same role on the project. As a result of this personnel issue, we were unable to achieve all of the aims of this proposal, particularly the risk analysis associated with Aim 4, and our total expenditures for the project were less than the amount allocated by AHRQ for completion of the work. We plan to achieve all the aims of the project and will continue this work with operational funding. The additional time we received to work on this grant through the no-cost extensions allowed us to collect and analyze more data that lead to the refinement of the BI-OTT2 and to production of the BI-OTT3. The delays we encountered have prevented us from submitting publications pertaining to the refinement of the trigger tool while the grant was active. However, the additional data we were able to collect for 2008 during these delays have provided us with a greater understanding of the tool, and we are now producing manuscripts that provide a more robust description of the evolution of the tool and detail the results of OTT deployment through 2008. We believe this additional data greatly enhances the manuscripts and the working body of knowledge concerning the use of trigger tools. BHCS operational funds were used to support the further refinement of the BI-OTT2 and the testing of the BI-OTT3 and are being used to support the development of manuscripts related to this work.

Conclusion

Through the refinement and testing of the Baylor version of the IHI Outpatient Trigger Tool audit process, we have been able to better quantify and characterize AEs that are occurring in ambulatory primary care. Applying this technique has provided both a greater understanding of the magnitude of the harm associated with such events. Further analysis of data we have collected will improve our understanding of the specific processes of patient care in primary care practices that contribute to the development of AEs and help us improve these processes to prevent or mitigate the severity of these events. The refined BI-OTT forms the basis of a subsequent grant that will enable us to test the usability and effectiveness of the BI-OTT in other healthcare organizations, evaluate the economic impact of identified AEs, test the ability of the BI-OTT to detect AEs that take place as a result of ambulatory primary care and result in hospitalization and/or ED use, and examine the impact of an ambulatory electronic health record on the frequency of ADEs. Our continued efforts to test and refine the BI-OTT ultimately will lead to better and safer care for patients within the Baylor Health Care System and yield methods that can be effectively implemented in other healthcare systems to improve healthcare delivery and patient safety nationally.

LIST OF PUBLICATIONS AND PRODUCTS

1. RN Auditor Training Manual
2. MS Access data entry program (RN & MD Auditors)
3. MD Secondary Auditor Training program

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