Improving the Safety of Primary Care by Measuring Adverse Events and Improvement

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STRUCTURED ABSTRACT

Purpose: The proposal centers on a diverse set of objectives related to characterizing the utility of and potential generalization of a method to evaluate the rate of adverse events (AEs) in ambulatory primary care.

Scope: The five aims address care provided in primary care practices of a physician practice organization in North Texas and explore the new use of this method in two geographically distinct primary care environments in a different health system.

Methods: A variety of analytic methods were used to evaluate the consistency of this method as applied in other health systems, the economic impact of AEs on patients, and the capacity of this method to be used to evaluate the impact of ambulatory EHR deployment.

Results: A dissemination package for this method was developed and tested and was found to be fairly effective, given the complexity of the method. Although there was a modest trend of additional medical care cost for patients with an AE, the difference did not approach statistical significance. This methodology has been sufficiently characterized for use by other organizations committed to better understanding the nature and frequency of AEs that arise during ambulatory primary care.

Key Words: adverse events, patient safety, primary care, trigger tool

I. PURPOSE (OBJECTIVES OF STUDY).

Previous work by the research team has indicated that the burden of adverse events (AEs) in the delivery of ambulatory primary care is substantial. In 2005, Baylor Health Care System (BHCS) initiated a major local deployment of a structured audit approach for detecting AEs in its HealthTexas Provider Network (HTPN) ambulatory care practices. We developed a modified version of the Institute for Healthcare Improvement's (IHI) Outpatient Trigger Tool, a methodology for identifying AEs and tracking AE rates over time through the retrospective review of a random sample of patient records. The deployment of the modified BHCS/IHI Outpatient Trigger Tool (BI-OTT) has allowed for the efficient detection of a large fraction of AEs taking place during routine primary care within HTPN practices, as the BI-OTT features a standardized, structured audit process to detect and describe AEs as opposed to relying on voluntary reporting systems.

The overall objective of this study was to enhance the safety of care received in ambulatory primary care by testing the utility of the BI-OTT measurement methodology as an intervention itself, evaluating the impact of a specific patient safety intervention upon the rate of AEs, and conducting an economic analysis of the impact of AEs taking place in ambulatory primary care to help inform policy pertaining to source of economic support for AE measurement and improvement.

The specific aims of the study were:

1. To develop a dissemination package of training materials and implementation tools for adoption by a large number of organizations that would enable them to effectively use the BI-OTT to measure the rate of AEs in their own organizations.

2. To test the effectiveness of the dissemination package in terms of its ability to provide a reliable and valid measurement system for AEs outside of its development environment within the Baylor Health Care System (BHCS).

3. To evaluate the economic impact of identified ambulatory AEs from a variety of perspectives, including patient, primary care provider, payer (including health plans), employer, and society. This information will provide important input to payment policy debate related to evaluating cost and benefit of AE reduction when the cost of measurement and improvement is likely incurred by providers, but the benefit is anticipated to accrue to payers and employers.

4. To 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 emergency department (ED) use. Because there is no current "gold standard" against which to compare the BI-OTT, we propose to estimate the sensitivity of the BI-OTT by evaluating whether it detects AEs for patients who have had an ambulatory AE (prior to admission) identified as part of routine use of the modified IHI Global Trigger Tool (GTT) applied to hospital inpatients.

5. Early work using the BI-OTT indicated that adverse drug events (ADEs) are the most common type of AE in ambulatory primary care. In order to both demonstrate, as a proof of concept, that the BI-OTT can be used productively in a research setting and evaluate the effectiveness of a specific patient safety intervention, we propose to use the BI-OTT to quantify the patient safety effects of implementing an ambulatory electronic health record (AEHR) by measuring the pre- and post-implementation AEHR frequency of adverse drug events (ADEs), as detected by the BI-OTT.

II. SCOPE (BACKGROUND, CONTEXT, SETTINGS, PARTICIPANTS, INCIDENCE, PREVALENCE).

Background

Patient Safety Measurement

A vital factor in generating a strong commitment to improving the safety of care is credible data indicating the existence of a problem. A standardized, reliable, objective way to determine both an accurate AE rate and provide sufficient AE characterization to identify the underlying risk factors and system failures has not been available for ambulatory care. 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.[1]

Development of the BI-OTT

Consistent with the "no preventable injuries" vision for BHCS, the BHCS Office of Patient Safety in 2005 piloted the IHI Outpatient Trigger Tool (I-OTT) developed by Resar and his colleagues in an HTPN primary care practice to test the ability of an ambulatory care patient safety program to improve patient safety culture and reduce AEs. Our pilot work suggested that several revisions to the tool were needed to adapt it for large-scale use in a resource-limited setting. Thus, we developed the BHCS/IHI Outpatient Trigger Tool (BI-OTT).

The original version of the BI-OTT deviated from the I-OTT by having only one nurse review each chart, versus two nurses and one physician. To enhance specificity, however, we had two physicians independently review each nurse-identified report of an AE. Some triggers in the I-OTT were not productive in the HTPN environment and were omitted, while two new triggers were added. These triggers included an "Urgent Care" trigger category for patient visits to physician offices outside normal office hours and an "Other" category to capture potential AEs unrelated to existing trigger categories. For each positive trigger identified in a chart, the nurse auditors searched for evidence of an AE involving patient harm. If an AE was identified, information was collected about the severity of the AE, and judgments were made related to several new variables:

- *Attribution* – Whether the identified AE was believed to relate to 1) care provided by the primary care physician (PCP), 2) care provided outside of the scope of the PCP's office, and/or 3) processes controlled by the patient.
- *Nature of care leading to the AE* – Whether the AE was felt to relate to 1) care provided or 2) care not provided. There was a purposeful effort made to avoid the notion of error and the secondary issue associated with omission/commission definitions.
- *Preventability* – Whether the AE was felt to be 1) preventable, 2) probably preventable, 3) possibly preventable, or 4) not preventable.
- *Severity* – The severity of patient harm was assessed using the National Coordinating Council Medication Error Reporting and Prevention (NCC MERP) index.[2] The audit tool targets AEs linked with patient harm, so only levels E (an error occurred that contributed to or resulted in temporary harm [or risk] to the patient and required intervention) through I (death) are used.

An electronic data acquisition module was also built in Microsoft Access. The final major revision was to have nurse chart auditors summarize in a comment box the clinical information that led them to conclude that an AE had taken place. This narrative information resulted in an "AE report" for each identified AE, which served as the starting point for confirmatory physician review. Nurse-identified AEs are reviewed by physicians to evaluate agreement regarding preventability, attribution, nature, and severity of the AE as well as their confidence that an AE had occurred. Each physician judges whether or not identified AEs might have been mitigated through more timely and/or more robust intervention, as described by Forster et al.[3]

Applying of the BI-OTT to Ambulatory Care Patient Safety Research

We used the BI-OTT within the primary care practices of the BHCS ambulatory care physician network, HTPN, to identify AEs from the years 2005 to 2010. This implementation combined with the implementation of our GTT to detect present-on-admission (POA) and inpatient AEs and the timely implementation of an AEHR by HTPN in 2006 provided an opportunity to examine a number of important topics related to the rate of AEs, the nature of unintended harm that patients incur as a result of primary care, the costs associated with AEs, and the effect of an AEHR on AEs.

The BI-OTT might help other primary healthcare practices identify the rate, nature, and cause of AEs and design and test quality improvement strategies designed to reduce and mitigate the effects of AEs. Although this method of AE detection was successfully deployed in HTPN, the external validity of the tool remains

untested. To derive the full research and operational benefits of the work to develop the refined BI-OTT instrument/ process, it is necessary to demonstrate that it can be effectively used in other settings. Accordingly, we proposed to develop and test a dissemination package for use by other professionals (in both research and operational roles) interested in improving primary care patient safety.

The extant HTPN BI-OTT AE data also provide an opportunity to examine the utility of the BI-OTT in testing the effectiveness of primary care interventions with the goal of improving patient safety. The AEHR implemented by HTPN also provides clinical decision support related to prescriptions expected to reduce the incidence of ADEs. Given that the BI-OTT process allows ADEs to be isolated from the general AEs identified and that we have used the BI-OTT to collect data on AEs prior to and following AEHR implementation, we have data that allow us to examine the impact of the AEHR on rates of ADEs.

Setting

The majority of this research was conducted within HTPN, the solely owned large physician group practice within the BHCS, a large, not-for-profit, integrated healthcare delivery system in North Texas. Two ambulatory care practices in Oregon, Providence Medical Group Northeast in Portland and Providence Medical Group Milwaukie, participated as testing sites for the BI-OTT training tools and BI-OTT implementation. Both of these practices are part of Providence Health & Services (PHS), a large, not-for-profit, integrated healthcare system that serves Alaska, Washington, Oregon, Montana, and California.

III. METHODS (STUDY DESIGN, DATA SOURCES/COLLECTION, INTERVENTIONS, MEASURES, LIMITATIONS).

Overall Objective: As introduced in Section I, the research conducted sought to develop and test the effectiveness of a dissemination practice that might be used by other organizations seeking to implement this method to evaluate the frequency and nature of AEs in ambulatory patient care.

Specific Aim 1: To develop a dissemination package of training materials and implementation tools for adoption by a large number of organizations that would enable them to effectively use the BI-OTT to measure the rate of AEs in their own organizations.

We developed a BI-OTT training manual and website as a means to disseminate the BI-OTT to other organizations and provide instruction on how to use the BI-OTT process and tools. The manual and website were based on materials used to train the nurse auditors who performed the HTPN BI-OTT audits, including formal classroom learning curriculum, written instructions, sample patient charts, and software training sessions. The manual and website were designed with the goals of: 1) generating necessary knowledge/understanding on the part of the trainee; 2) generating relevant professional skill; 3) deploying necessary standard tools; and 4) providing a support resource to address unanticipated situations. We collected information from nurses through surveys to inform the development and dissemination of training materials. We conducted an alpha testing of the materials with a group of nurses and revised the training tools based on their feedback.

First Survey: Identifying Nurses' Training Preferences

To inform the development of training materials and tools designed to enable effective use of the BI-OTT to detect adverse events relative to ambulatory care, Research Triangle Institute International (RTI) conducted a survey via telephone with six nurses employed by PHS. Potential participants were contacted by RTI using a screening questionnaire to determine a candidate's eligibility to participate in the interview. If the candidate was eligible to be a participant, a time for the phone interview was scheduled. RTI recruited nurses with an RN, BSN, or graduate-level training who had at least 5 years of experience in a clinical setting and some experience with chart review. Each of the qualifying participants used computers at least "most days" for work and were at least "somewhat proficient" with using a computer. The phone interviews focused on assessing

nurses' training preferences, facilitators to training, and barriers and lasted approximately 30-45 minutes. Interviews were conducted using an interview guide designed in collaboration with BHCS. Oral consent was obtained at the start of the interview. Interviews were audio taped. No identifying information was connected with the audiotapes. RTI's Institutional Review Board reviewed and approved the interview guide and procedures. Qualitative data from the interviews were analyzed to identify recurring themes based on topic domains identified in collaboration with BHCS.

Alpha Testing – Phase 1

Alpha testing of the web-based BI-OTT training materials involved five nurse chart reviewers representing BHCS (two nurses experienced in BI-OTT chart review, three nurses inexperienced in BI-OTT chart review). These five nurses were contractors with KDJ Consulting, an agency that has provided nurse chart reviewers to BHCS/HTPN to conduct BI-OTT chart reviews since 2006. The first phase of the alpha test was an abbreviated, yet thorough test of the efficacy of the training materials. The five nurses were asked to study the web-based training materials for 4-6 hours over the span of a few days. A questionnaire was provided the nurses at the onset of the review of the training materials and each was asked to rate the level of clarity of the concepts presented and to estimate her level of competency performing BI-OTT chart reviews based on information gleaned from studying the web-based BI-OTT training materials. The nurses' feedback was used to refine the web-based training materials and the database data collection tool.

Following review of the OTT educational materials and completion of the evaluation instrument, KDJ nurses reviewed 10 BHCS/HTPN patient charts using BI-OTT methodology. Four of the five KDJ nurses that took part in the first phase of the alpha testing reviewed 10 patient charts each. Consistent with the BI-OTT protocol, a 15-minute time limit was placed on the total time a nurse was permitted to review the chart and enter the data in the database. Nurses could refer to the web-based training materials if they needed to review how to document information contained in the chart or if they needed guidance on making decisions on how to determine the presence of a trigger, the presence of an AE, the harm score of an AE, the preventability of an AE, attribution, treatment effectiveness, etc. Nurses were not permitted to ask each other about questions they had regarding execution of the chart review. However, they were permitted to contact the developer of the training materials who could then direct them to the section or sections of the website that would be most helpful in answering their questions.

Second Survey: Informing Healthcare Organizations about the Use and Methodology of the BI-OTT

To inform the development of a plan to disseminate information about the BI-OTT to nursing staff and decisionmakers within healthcare organizations, RTI conducted a telephone survey with nine PHS nurses employed at the two test sites: Providence Medical Group Northeast in Portland and Providence Medical Group Milwaukie. Potential participants were identified by PHS and asked of their interest in participating in the interview. A screener questionnaire was used to determine the candidate's eligibility to participate in the interview. RTI recruited nurses with a RN, BSN, or graduate-level training who had at least 5 years of experience in the clinical setting and some experience with chart review.

Specific Aim 2: Test the effectiveness of the dissemination package in terms of its ability to provide a reliable and valid measurement system for AEs outside of its development environment within BHCS.

We deployed the website and training manual developed as part of Aim 1 and the BI-OTT data collection tool as a dissemination package to two PHS test sites (Portland and Milwaukie) to evaluate the degree to which reviewers trained exclusively by this "off-the-shelf" dissemination package could produce reliable estimates of AE rates. We planned to include test sites from two other healthcare systems that served different areas of the country and different patient populations to determine the effectiveness of the training materials across a variety of settings and generalizability of findings. However, the two other systems that initially committed to participate in the research withdrew due to IRB concerns and other logistical issues, and we were unable to recruit other healthcare systems to participate.

A project manager and three nurse auditors/chart reviewers from each PHS site were selected based on the qualifications for these roles outlined in the training materials. The dissemination package, consisting of the website, manual, and data collection tool (MS Access database), were delivered to the project manager and nurse auditors via email. The nurses were asked to study the web-based training materials for a period of 4

to 6 hours. This 4- to 6-hour study period occurred the week just prior to the chart reviews were to begin. A sample of 472 patient charts was created through random selection of 236 charts from the two PHS sites that met the inclusion criteria. Charts belonging to patients who had at least three face-to-face visits with a physician during the review period, were at least 50 years of age by the third visit, and were unknown to the chart reviewer were eligible for review. Each site performed a review of the entire sample of 472 charts (approximately 157 charts per nurse) to enable a comparison of AE detection rates between the two PHS sites. Four nurse auditors employed by KDJ Consulting, the agency responsible for conducting the BI-OTT audits within BHCS/HTPN, also reviewed the sample of 472 charts as the "gold standard" auditors via remote access. Data obtained from the chart reviews regarding AEs were entered into the BI-OTT database.

We compared the level of agreement among the two PHS sites and KDJ reviews for each chart to determine the effectiveness of the BI-OTT training tools in terms of their ability to provide a reliable and valid measurement system for adverse events outside of the BHCS development environment. The presence or absence of AEs was the primary variable of interest. For charts with agreed-upon AEs, we examined severity and preventability variables as secondary variables of interest. Kappa coefficients of inter-rater reliability were used to examine agreement between the "gold standard" reference point findings of the KDJ nurses and the findings of the nurse chart reviews at each of the two PHS test sites independently. Cohen's kappa coefficient test was used to measure the inter-rater agreement between the KDJ review and Milwaukie review and between the KDJ and Portland reviews.

Specific Aim 3: To evaluate the economic impact of identified ambulatory AEs from a variety of perspectives, including patient, primary care provider, payer (including health plans), employer, and society.
Using the patient population that was randomly selected for inclusion in the 2010 BI-OTT process, we created a sample consisting of patients with identified AEs and matched controls of patients with identified triggers but no evidence of AEs to evaluate the economic impact of identified ambulatory AEs. We compared healthcare costs and patient-reported outcomes between the two groups using data obtained from a patient survey and HTPN and BHCS billing records.

Sample Creation: A one-to-two match of AE-positive cases to AE-negative cases was created using propensity score approach. In this approach, a multivariable logistic regression model was fitted to model AE status as a function of patient characteristics (age and gender), primary care practice type, and healthcare utilization (total number of ambulatory visits, inpatient admissions) observed for each patient over a period of 12 months preceding and following the date of the positive AE or positive trigger. The AE-positive cases were matched to AE-negative cases using the predicted probabilities from the logistic regression model.

Patient Surveys: We developed a patient survey to estimate the economic impact of AEs and patients' experiences related to AEs including monetary value of time lost from work and/or leisure activity as well as diminution of quality of life. The survey included questions related to patient characteristics, overall health, medications, satisfaction with clinical care, healthcare utilization, healthcare costs, and employment during calendar year 2010. The survey was delivered via phone interviews lasting 30-45 minutes. Participant responses were recorded in a database during the interviews. We used chi-squared and Fisher's exact tests to test for differences in response between AE-positive and AE-negative patients for categorical variables. For ordinal categorical items, we used a Cochran-Armitage trend tests to account for the ordinal nature of the data. Independent sample t tests were used to test for differences in continuous measurements.

Financial Analysis: We performed a financial analysis to compare healthcare costs between AE-positive and AE-negative cases. We examined the total cumulative costs for patients for a period of 12 months from date of first AE (for AE-positive cases) or date of first positive trigger (for AE-negative cases). Costs associated with ambulatory care visits, ED, and inpatient admission were analyzed separately and then combined for analysis of total cost. A Bootstrap method was used to estimate the average cost and for assessment of statistical significance difference between groups. A pre- and post- AE cost analysis was also conducted. Pre-cost was determined by considering the total cumulative cost incurred 12 months prior to the date of first AE (for AE-positive cases) or date of first positive trigger (for AE-negative cases).

Specific Aim 4: To test the sensitivity 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.
There is no "gold standard" to compare the BI-OTT's sensitivity to detect AEs that are known to be present for hospitalized/ED patients that arise out of ambulatory care. Our hospital-based work using the GTT provided an unexpected and important nexus related to AE detection. This pool of GTT-identified AEs offered an opportunity to cross-walk AEs that were deemed to be present on admission (POA) back to the primary care setting.

Using data obtained from GTT chart audits of patients who had been discharged from a BHCS hospital between July 2007 and June 2009, we identified patients who had AEs that were determined to be POA. Of the patients with POA AEs, we determined how many were HTPN patients and how many had a primary care visit with a HTPN physician in the 12 months prior to the index hospital admission. We planned to have KDJ auditors conduct a blinded review using the BI-OTT of these patient charts combined with a sample of ambulatory care charts of patients who were discharged from a BHCS hospital between July 2007 and June 2009, had a HTPN primary care visit during the prior 12 months, and did not have a POA AE to evaluate the sensitivity of the BI-OTT in regard to its ability to identify ambulatory AEs that have been independently confirmed to exist as a result of the separate GTT audit.

Specific Aim 5: Use the BI-OTT to quantify the patient safety effects of implementing an AEHR by measuring the pre- and post-implementation AEHR frequency of ADEs, as detected by the BI-OTT.

We investigated the effect of AEHR implementation on:

- The probability of a patient experiencing at least one ADE of any type in the year of interest;
- The number of ADEs per patient (rate) in the year of interest;
- The probability of a patient experiencing a level harm greater than E on the NCC MERP index, given that harm was experienced;
- The probability that the ADE could have been prevented, given that harm was experienced;
- The probability that the ADE occurred as a result of primary care physician care, given that harm was experienced

Data collection: Patient charts were randomly selected for each physician who had seen at least 30 patients in a given year in the 34 primary care practices with no previous AEHR exposure (totaling 189 physicians) annually from 2006 through 2009. 'Eligible' patients were those with ≥3 physician visits during a calendar year and who were age ≥50 years on the date of their last visit. Charts were reviewed for AEs by external nurse auditors using the BI-OTT. Data related specifically to ADEs were available within the BI-OTT dataset, as auditors are prompted by the electronic data collection tool to evaluate if each identified AE was related to medication. In addition to the ADE data collected through the BI-OTT, for each patient, we collected age, sex, and number of primary care visits to include as independent variables in the analytic models.

Outcomes: Our primary outcomes were 1) at least one AE (per patient-year); and 2) at least one ADE (per patient-year). Our secondary outcomes were the proportion of AEs and ADEs that were 3) preventable (yes/probable); 4) preventable (yes/probable); 5) attributable to the primary care physician; and 6) had harm at the F through I levels, given that harm occurred.

Statistical Analysis: We summarized patient characteristics according to whether the AEHR was or was not implemented prior to the year of assessment. We compared characteristics between groups using χ^2 tests adjusted for clustering by practice-year. To test the hypotheses that the AEHR impacted each of the AE-related outcomes, we estimated a series of hierarchical logistic regression models (HGLMs). For the primary outcome of the patient experiencing the AE, we specified an HGLM as follows: let π_{jkl} be the probability of AE-related outcome for the j^{th} patient, seen by the k^{th} physician at the l^{th} practice; and let Y_{jkl} be a binary variable indicating whether there was an AE for this patient. Then, we estimated the following model

$$Y_{jkl} \sim \text{Binomial}(\pi_{jkl}, 1)$$

$$\text{logit}(\pi_{jkl}) = \beta_0 + \beta_X X + \beta_{EHR} * EHR + \beta_T * T_{jk}l + u_{kl} + \eta_l$$

in which u_{kl} and η_l are error terms reflecting the random effects at physician and practice level, respectively; T_{jkl} represents calendar time; and β_T is the secular effect. X is a vector of patient characteristics (age, sex, number of visits, and year of visits). The term EHR indicates whether the AEHR has been implemented at the practice; β_{EHR} is thus the log(OR) of a patient having an AE-related event after the AEHR was implemented as compared to a patient with a visit before AEHR implementation. Testing the hypothesis H_0: $\beta_{EHR} = 0$ provides evidence as to whether the AEHR had an effect on the probability a patient experienced of an AE-related outcome. Analogous models were estimated for each outcome. To account for missing patient characteristics we used multiple imputation, with 30 imputations.

We performed a number of secondary analyses. First, we estimated a second series of models similar to the above model but with AEHR implementation included as number of years elapsed since implementation. Then, to assess whether the AEHR effect was independent of secular trends, we estimated a final series of models similar to that above but including an interaction between AEHR exposure and calendar year.

IV. RESULTS (PRINCIPAL FINDINGS, OUTCOMES, DISCUSSION, CONCLUSIONS, SIGNIFICANCE, IMPLICATIONS).

Principal Findings

Specific Aim 1: To develop a dissemination package of training materials and implementation tools for adoption by a large number of organizations that would enable them to effectively use the BI-OTT to measure the rate of AEs in their own organizations.

First Survey: Identifying Nurses' Training Preferences

To inform the development of training materials and tools designed to enable effective use of the BI-OTT to detect adverse events relative to ambulatory care, RTI conducted a telephone survey with six PHS nurses.

Respondent Characteristics

One of the six respondents was a man, and five were women. Five of the respondents reported themselves as being White. One respondent reported being of mixed race. All were over the age of 35. Four of the six respondents had experience working in an outpatient setting. All respondents reported using a computer every day. Two categorized themselves as being very proficient with a computer, three indicated that they were moderately proficient, and one reported being somewhat proficient.

Experiences With Previous Training

Respondents' training experiences varied; however, most reported that they had participated in a recent training session via a software program or computer application. Recent training formats included web-based training, in-facility training by an IT staff member, and classroom training provided by an external instructor. When asked what was especially helpful to them when learning a new skill for which they were being trained, participants reported the importance of the relevance of the topic to their job and the use of practice examples.

Training Preferences

Most respondents preferred in-person training sessions or webinars, because these formats enable an opportunity to ask questions. Most respondents reported that they did not find hard-copy manuals sufficient, because hard-copy manuals alone were not particularly helpful to the nurses when attempting to apply the needed skills. Preferences for the use of CD-ROMs/DVDs ranked somewhere between use of a webinar and a hard-copy manual, because respondents liked the interactivity associated with CD-ROMs/DVDs but still preferred to engage a live person in order to have any questions answered. Most respondents did not recall having encountered a video-based training session. Several of the nurses reported having taken advantage of the opportunity to get additional help via email and/or by phone after their recent training session was complete. Others found it useful to request help from colleagues who were using the same tool.

Most Important Features of Training

In terms of the most important features of training in general, relevance to the job was rated highest. Cost was also important. Some respondents reported that training would not be approved by their managers if it was too expensive. Inclusion of hands-on practice and skills was also important; several nurses said that repetition was the best way for them to learn. The length of time required to complete training was also important. Several mentioned that their attention can be held for only so long. In general, nurses thought having to rely on the computer was slightly less important. There was not much agreement about the importance of dedicated training time. Some said that it depends on the flexibility of nurses' schedules. We also asked nurses about the most important features of several specific types of training, including web-based or self-led training with a manual, face-to-face training in a conference setting, and on-the-job training by a supervisor.

For web-based or self-led training that used a manual, two nurses mentioned clarity of the training materials as being most important. Others felt that flexibility in where/when the training session was held was more important. Two said that they liked being able to start a training session and then come back to it later in the day. For face-to-face training in a conference setting, two nurses mentioned that the knowledge of the presenter was most important. Two nurses thought that having dedicated time for the training experience would be essential to achieving participation. With regard to on-the-job training by a supervisor, several nurses thought that fitting this into their current work day could be difficult. Two emphasized that the ability to ask specific questions and get immediate feedback was very important.

Additional Help After Training

Respondents were asked to identify the kinds of support that would be most helpful to them after they completed their training and had begun to apply the new tool. They were specifically asked about the following options: a help tab, a list of FAQs, an email address to write to with questions, live online support, an 800 number, example case studies or scenarios, follow-up training, and written materials. Of these, the preferred method was live online support because of the immediacy with which they could obtain a response to a very specific question. Respondents also like the idea of an 800 number or an email address but commented on the potential for a long wait for a response or that staff answering the phone would not be knowledgeable enough to answer their questions. They liked case studies for training but thought they would be less useful once they started implementing the tool. Most respondents liked FAQs, but several pointed out that sometimes their question is not on the list and they would need to seek additional help elsewhere. Respondents liked the idea of a help tab. They did not have much to say about web links or follow-up training.

Alpha Testing

Nurses who participated in phase 1 of the alpha testing of the BI-OTT training materials completed a questionnaire, Evaluation of OTT Training Materials, designed to assess the efficacy of the materials. They generally reported that the concepts presented in the web-based training materials were clear. In addition, nurses reported an overall feeling of competency to perform BI-OTT audits after studying the web-based training materials. As might be expected, nurses who were experienced in BI-OTT chart review methodology reported a greater sense of clarity concerning the training materials and a greater feeling of competency to perform the tasks associated with the BI-OTT chart review than the inexperienced nurses. In answering the question regarding their rating of the overall effectiveness of the BI-OTT educational materials presented, the three inexperienced nurses answered with "somewhat effective," "effective," and "very effective." The two experienced nurses answered with "effective" and "very effective."

After performing a review of 10 charts using BI-OTT methodology, the nurses again completed the Evaluation of OTT Training Materials questionnaire. One inexperienced nurse reported a noticeably increased feeling of competency to perform BI-OTT chart reviews based on review of the web-based training materials. For the remaining two inexperienced nurses, the feeling of competency remained generally high. For the one experienced nurse chart reviewer, the feeling of competency to perform BI-OTT chart reviews based on information gleaned from the web-based training materials remained high.

In rating the overall effectiveness of the BI-OTT educational materials presented, the three inexperienced nurses rated the materials as "effective" (reflecting a change from phase 1, when the responses were reported

as “somewhat effective,” “effective,” and “very effective”). The experienced nurse answered the same question with “very effective.”

After each of the four KDJ nurses individually reviewed the 10 BHCS/HTPN patient charts, they provided feedback to us concerning the web-based training materials and associated chart reviews. All four nurses reported that the 15-minute time limit was not enough time to document within the database all the names of medication and supplements a patient had been taking during the review period. Documenting the medication/supplement table is required when a patient has experienced a medication-related adverse event. In response to the nurses’ feedback, the web-based instructions concerning the documentation of medication and supplement names in the database were changed to emphasize that the names of medication and supplements should be listed only as time permits. This instruction was originally included in the web-based training materials, although it was not stressed. Now, it is set apart and bolded so that chart reviewers know in advance to reserve listing the names of medication and supplements for last and to complete only as time permits.

The KDJ nurse reviewers also recommended the addition of patient sample scenarios to the web-based training materials. In using patient sample scenarios, a nurse would review the descriptive information about each scenario and then use his or her judgment to identify the presence or absence of a trigger or an adverse event, the conditions surrounding an adverse event, the conditions surrounding any treatment for the adverse event, and the outcome of the treatment for each scenario. After the nurse arrived at what seemed to be an accurate description of what the patient had encountered, he or she could check those answers against the hidden correct answers by clicking on a link. Based on the recommendation by the four KDJ nurse reviewers, five patient scenarios were added to the website.

BHCS’s Finalized BI-OTT Training Toolkit

The finalized, web-based package of the BI-OTT Training Toolkit was developed for the purpose of enabling healthcare organizations to identify and document adverse events relative to ambulatory care. The BI-OTT training materials contain detailed instructions for implementing BI-OTT methodology, detailed instructions on how to use the BI-OTT MS Access database data collection tool, and a stand-alone PDF manual that provides all BI-OTT instructions and graphics conveniently in one document. The BI-OTT training materials are intended for project managers, nurse chart reviewers, physician reviewers, data managers and analysts, organizational leadership, stakeholders, and ancillary members of the Trigger Tool project team. Trigger Tool implementation is most successful when a multidisciplinary team approach is utilized. For this reason, the materials have been developed to meet the needs of a variety of individuals on the project team. The training materials are organized in such a way that individuals have access to a broad range of implementation information while allowing for a more focused review of content specific to their own roles and responsibilities.

The web-based training materials employ the use of clear, detailed instructions for every phase of BI-OTT methodology. Flowcharts and screenshots help to highlight the processes involved in identifying and documenting relevant items surrounding an adverse event. Also included in the BI-OTT training materials are sample chart scenarios enabling a student of the materials to test his or her knowledge level and skill in properly identifying and documenting the presence or absence of an adverse event along with any associated triggers. A section on FAQs is included in the web-based training materials along with an email address and phone number of a BI-OTT representative who is well-versed in the use of BI-OTT methodology. This individual is available to provide assistance and additional clarification concerning use of the materials.

Second Survey: Informing Healthcare Organization About the Use and Methodology of the BI-OTT

RTI conducted a telephone survey with nine PHS nurses to examine nurses’ preferred information sources for accessing professional tools and resources. This information was collected to inform the dissemination of the BI-OTT to nursing staff and decisionmakers within healthcare organizations. The information sources provided by the nurses are described in Figure 1. Nurses’ verbatim responses to the interview are documented in the RTI report, titled *Risk Informed Intervention Development and Implementation of Safe Practices Relative to Ambulatory Care: Nurses’ Communication Preference*s. RTI’s plan for disseminating information about widespread use of BI-OTT methodology is detailed in an RTI report, titled *Communication-Dissemination Plan for BHCS IHCRI BI-OTT*.

Figure 1. Nurses' Preferred Information Sources for Accessing Professional Tools and Resources

General sources of information:

- Peers, staff meetings;
- Healthcare administration & resources
  - E-mails and related communication from the hospital system with which they are affiliated
  - Facility libraries
  - Websites subscribed to by the healthcare system
- Articles in professional organization's magazines, journals, newsletters
- Nursing/Healthcare organization and association websites
- Conferences and meetings on patient safety topics
- Professional and public websites (e.g., Medscape, Cochrane Collaborative, WebMD)
- Continuing Medical Education opportunities (e.g., Webinars)
- Case studies citing best practices

Secondary audiences for BI-OTT communication:

- Practice/hospital/organization leadership/administration
- Patient safety organizations (e.g., private practice physician groups, community-based clinics)
- Employers

Strategies to promote the BI-OTT website:

- Paid and in-kind advertisement such as online Banners and/or Print Ads in Professional Journals, Facebook Ads, Twitter Feeds, Podcasts, and Posters
- Presentation within Nursing & Healthcare Quality Organizations
- Presentation of BI-OTT application and findings at professional conferences, annual meetings, newsletters, and listservs
- Press Releases, Media Interviews with BHCS BI-OTT Development Team
- Social Networking Sites such as Facebook, Twitter Feeds, Linked-In, Online Professional Nursing Forums
- Presentations via Web/Mobile devices

Specific Aim 2: Test the effectiveness of the dissemination package in terms of its ability to provide a reliable and valid measurement system for AEs outside of its development environment within BHCS.

We compared the level of agreement of AE detection between Milwaukie and KDJ and between Portland and KDJ to determine whether use of the web-based training materials resulted in reliable and valid identification of AEs outside the BHCS/HTPN development environment. We found fair agreement between the KDJ and Milwaukie reviewers and between the KDJ and Portland reviewers concerning the number of identified positive triggers, number of identified positive AEs, identified AE trigger type, AE harm score level, number of medication/supplements a patient was taking, and degree of AE preventability. The degree of agreement regarding harm score appeared to be stronger between the KDJ and Portland reviews than between the KDJ and Milwaukie reviews; for identified AE trigger type, agreement appeared to be stronger between the KDJ and Milwaukie reviews.

Table 1. Measure of Agreement between KDJ and Providence Nurse Reviewers (Milwaukee, Portland)

	Milwaukie vs. KDJ	Portland vs. KDJ
Outcome	Kappa(95%CI)	Kappa(95%CI)
AE Count	0.21(0.11;0.30)	0.20(0.12;0.29)
AE Trigger Type	0.41(0.22;0.61)	0.17(0.02;0.32)
Harm Score Level	0.32(0.06;0.58)	0.51(0.30;0.71)
Number of Medications/Supplements	0.24(0.19;0.28)	0.28(0.24;0.33)
AE Preventability	0.26(0.05;0.48)	0.28(0.11;0.45)
Positive Trigger Count	0.36(0.30;0.42)	0.34(0.28;0.40)

Specific Aim 3: To evaluate the economic impact of identified ambulatory AEs from a variety of perspectives, including patient, primary care provider, payer (including health plans), employer, and society.

In total, 586 patient charts were reviewed as part of the 2010 BI-OTT chart audits. Positive triggers were identified in 548 of these charts. Sixty-one (12%) of the patient charts with positive triggers had positive AEs. A sample of 183 patients consisting of the 61 patients with identified AEs and 122 matched controls of patients with identified triggers but no evidence of AEs was created to evaluate the economic impact of identified ambulatory AEs.

Patient Telephone Surveys Examining Economic Impact of AEs

We administered a phone survey to the sample of 183 patients. A 27% survey response rate was observed. Of the 50 patients with positive triggers who participated, 17 (34%) had experienced at least one AE. A comparison of responses to survey items for AE-positive and AE-negative patients is summarized in Table 2. There were no significant differences in terms of age and gender between patients who had and had not experienced an AE. For most survey items, no statistically significant differences between the two groups were observed at the $\alpha<=0.05$ level of statistical significance. A significant difference in responses to survey items included the following: The AE-positive patients had a significantly higher likelihood of having diabetes (41% vs. 14%, P=0.04) and asthma/COPD (35% vs. 3%, P<0.01) than did AE-negative patients. The level of difficulty in "walking a mile," "sitting for 2 hours," and "lifting or carrying 10 pounds" also appeared to be significantly higher ($\alpha<=0.05$) or approached significance for AE-positive patients versus for AE-negative patients. There were no significant differences observed between AE-positive and AE-negative patients in terms of reported medical expenditures, employment status, or work days missed due to illness or injury.

Table 2. Results of Patient Telephone Survey Examining Economic Impact of Adverse Events (AEs)

	AE Positive (n=17)	AE Negative (n=33)	P value
Patient Characteristics			
Female	12(70.6)	23(67.6)	0.94
Age (Mean)	65.2	68.4	0.28
According to our records, you visited Dr.X for your primary care during 2010. Is that correct?	16(94.1)	33(97.1)	0.99**
Is that 2010 primary care physician still your doctor?	11(64.7)	28(82.4)	0.18**
At any time during or before 2010, did a doctor or other health professional tell you that you had			
a. Diabetes?	7(41.2)	5(14.7)	0.04**
b. Chronic or long-term liver condition?	1(5.9)	1(2.9)	0.61**
c. High blood pressure (hypertension)?	11(64.7)	23(67.6)	0.83**
d. High cholesterol (hyperlipidemia)?	9(52.9)	23(67.6)	0.36**
e. Osteoporosis?	3(17.6)	6(17.6)	0.99**
f. Asthma or COPD?	6(35.3)	1(2.9)	<0.01*
On a scale of 0-10, with 10 being the highest, how satisfied were you with your primary care physician medical treatment in 2010?	10(10-10)	10(8-10)	10(10-10)
Did all of your prescribed medications work well?	17(100)	32(94.1)	0.31**
During 2010, did any issues or problems arise related to the clinical care that you received?	1(5.9)	1(2.9)	0.99**

I'd like you to think about your overall health during 2010. Would you say that your health in general was excellent, very good, good, fair, or poor?	AE Positive (n=17)	AE Negative (n=33)	P-value
Poor	0(0)	2(5.9)	0.14##
Fair	3(17.6)	0(0)	
Good	6(35.3)	9(26.5)	
Very good	6(35.3)	13(38.2)	
Excellent	2(11.8)	10(29.4)	
To help get an idea of how good or bad your overall health was in 2010, please rate your health was on a scale of 0 to 10. – median (Q1-Q3)	8(7-9)	9(7.5-10)	0.28###
During 2010, how many times did you go to an emergency room about your own health? Please include emergency room visits that resulted in admission to the hospital. – median (Q1-Q3)	0(0-1)	0(0-1)	0.47###
How many different Times did you stay in any hospital overnight or longer during 2010? – median (Q1-Q3)	0(0-2)	0(0-0)	0.04###
During 2010, how many times did you see a doctor or other health care professional about your health at a doctor's office? – median (Q1-Q3)	3(2-5)	2(0-3)	0.09###
During 2010, how many times did you see your primary care physician, Dr.X about your own health? – median (Q1-Q3)	3(2-4)	3(2-4)	0.75###
During 2010 did you have any difficulty with			
a. Walking a quarter mile	8(47.1)	8(23.5)	0.08*
b. Walking up 10 steps without resting	6(35.3)	6(17.6)	0.18*
c. Standing or being on your feet for about 2 hours	8(47.1)	8(23.5)	0.10*
d. Sitting for about 2 hours	4(23.5)	1(2.9)	0.04*
e. Stooping, bending, or kneeling	6(35.3)	11(32.4)	0.99*
f. Reaching up over your head	4(23.5)	3(8.8)	0.19**
g. Using fingers to grasp or handle small objects	3(17.6)	2(5.9)	0.32**
h. Lifting or carrying 10 pounds	7(41.2)	5(14.7)	0.07**
i. Pushing or pulling large objects	7(41.2)	9(26.5)	0.28*
j. Going out for things, such as shopping or a movie	3(17.6)	2(5.9)	0.31**
k. Participating in social activities	3(17.6)	4(11.8)	0.67**
l. Relaxing at home, such as reading or sewing	1(5.9)	2(5.9)	0.99**
During 2010, about how much did you spend for medical/dental care (exclude insurance premiums, over-the-counter drugs, or reimbursable expenses)			
0	1(5.9)	2(6.3)	0.52
1-499	4(23.5)	7(21.9)	
500-999	3(17.6)	3(9.4)	
1,000-1,999	2(11.8)	5(15.6)	
2,000-3,999	4(23.5)	2(6.3)	
4,000-30,000	1(5.9)	5(15.6)	

	AE Positive (n=17)	AE Negative (n=33)	P-value
During 2010, did you receive income from work?	7(41.2)	15(46.9)	0.65
How many hours were you at this job in a typical week in 2010?			
1	0(0)	1(3.1)	0.96
20	0(0)	2(6.3)	
30	0(0)	1(3.1)	
35	1(5.9)	1(3.1)	
40	3(17.6)	5(15.6)	
> 40	5(29.4)	6(18.8)	
During 2010 about how many days did you miss work at a job or business because of illness or injury? Exclude maternity leave			
0	4(23.5)	8(25.0)	0.98
2	0(0)	2(6.3)	
3	1(5.9)	1(3.1)	
5	1(5.9)	2(6.3)	
7+	3(17.6)	3(9.4)	
* = Fisher's Exact test , ** = Chi-Square test, ## = Cochran-Armitage Trend test, ### = Kruskal-Wallis test			

Financial Analysis of Costs Associated with AEs

In general, a higher average cost for ambulatory visits, ED, and inpatient (IP) care was observed among AE-positive cases than AE-negative cases, but the difference was not statistically significant at the $\alpha <= .05$ level (Table 3). For the pre-post analysis, no significant differences were observed in pre- and post-AE costs. The average pre ambulatory cost was very similar for both AE-positive and AE-negative cases, which indicates that the matching algorithm was effective in balancing the AE-positive and AE-negative groups. However, the average post ambulatory cost in the AE-positive cases increased by almost $100; for AE-negative cases, there was an increase of $75.

Table 3. Comparison of pre ambulatory, emergency department, inpatient admission, and total cost for AE-positive and AE-negative patients in the 12 months pre- and post-AE or positive trigger.

	AE-Positive (N = 61)				AE-Negative (N=122)			
	Pre	Post	Total (Pre + Post)	Difference (Post - Pre)	Pre	Post	Total (Pre + Post)	Difference (Post - Pre)
Ambulatory Cost	528 (445;618)	625 (520;728)	1152 (918;1427)	97 (-1;193)	521 (461;589)	597 (534;661)	1063 (961;1174)	75 (3;145)
ED Cost	688 (171;1371)	244 (91;430)	819 (359;1393)	-444 (-1140;111)	518 (69;1304)	139 (85;198)	603 (185,1296)	-379 (-1166;80)
IP Cost	4129 (1448;7636)	3768 (1085;7464)	7158 (2894;12581)	-362 (-3835;3430)	3888 (1661;6486)	2523 (1181;4122)	5999 (3483;8831)	-1365 (-4305;1353)
Total Cost	5346 (2373;9154)	4637 (1892;8455)	9128 (4691;14784)	-709 (-4356;3321)	4927 (2636;7698)	3259 (1909;4864)	7664 (4948;10557)	-1669 (-4814;1129)

Little difference was observed in the pre- and post periods between the AE-positive and AE-negative groups for ambulatory care and ED costs. However, results from Table 3 indicate that the decrease in inpatient and total expenses over the two observation periods was much greater in the AE-negative group than in the AE-positive group. The slight decrease in inpatient costs for the AE-positive group was $362 versus $1,365 for the AE-negative group – exhibiting an approximate $1,000 increase in relative IP costs for the former group. Similarly, there was a decrease in total costs for the AE-positive group of $709 versus a decrease of $1,669 – consistent with the $1,000 increase in relative IP costs for the former group. These results are not statistically significant at the P<=.05 level. Given the small sample sizes, it might be suggested that those who experienced at least one AE had approximately $1,000 in additional costs in the year following the AE.

Specific Aim 4: To test the sensitivity 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.

The review of ED records by our inpatient chart reviewers identified relatively few AEs that were POA; because the fraction of these patients who were also HTPN patients was low, the proposed evaluation had to be terminated as being unproductive.

Specific Aim 5: Use the BI-OTT to quantify the patient safety effects of implementing an ambulatory electronic health record (AEHR) by measuring the pre- and post-implementation AEHR frequency of ADEs, as detected by the BI-OTT.

For the 4 years examined, there were 20,399 patients with at least three visits during a calendar year who otherwise met the inclusion criteria. Of these, 6,158 were seen at practices that had implemented the AEHR during a prior year. The characteristics of these patients are described in Table 5.

Table 4. Characteristics of 20,399 Patients Included in the Analysis for Specific Aim 5.

	no EHR n(%)	EHR n(%)	P value
N	14241 (100.0)	6158 (100.0)	
Age			0.079
<=50	1195 (8.4)	245 (4.0)	
51-60	5945 (41.7)	2483 (40.3)	
61-70	4060 (28.5)	1821 (29.6)	
71-80	2047 (14.4)	1061 (17.2)	
81+	994 (7.0)	548 (8.9)	
Sex			0.196
Male	5547 (39.0)	2288 (37.2)	
Female	8694 (61.0)	3870 (62.8)	
PCP visits			0.202
1-3	5704 (40.1)	2325 (37.8)	
4	3059 (21.5)	1555 (25.3)	
5	1811 (12.7)	857 (13.9)	
6-8	1903 (13.4)	1055 (17.1)	
9+	518 (3.6)	275 (4.5)	
Missing	1246 (8.7)	91 (1.5)	
Adverse Events			0.982
None	12697 (89.2)	5482 (89.0)	
Cancer Dx	21 (0.1)	3 (0.0)	
ED visit	24 (0.2)	4 (0.1)	
Admit	44 (0.3)	29 (0.5)	
Surgery	93 (0.7)	51 (0.8)	
ADE	1262 (8.9)	560 (9.1)	
Lab	41 (0.3)	11 (0.2)	
Misc	59 (0.4)	18 (0.3)	

There were no significant differences in patient characteristics between study groups; in unadjusted analysis, there was also no difference in probability of adverse events (P = 0.982). The results of the models for the primary outcomes are shown in Table 5.

Table 5. Effect of AEHR Implementation on the Probability of AEs and ADEs.

Outcome:	EHR as Dichotomous			
	Any AE		ADE	
	OR (SE)	P	OR (SE)	P
Intercept	0.06 (0.01)	0.000	0.04 (0.01)	0.000
EHR	**1.12 (0.10)**	**0.214**	**1.01 (0.10)**	**0.891**
EHR (yrs exposed)				
Year				
2006	ref		ref	
2007	0.77 (0.05)	0.000	0.90 (0.06)	0.141
2008	0.83 (0.07)	0.028	0.98 (0.09)	0.855
2009	0.85 (0.08)	0.098	1.04 (0.11)	0.696
Year (elapsed)				
Age				
50	ref		ref	
51-60	0.97 (0.10)	0.731	0.90 (0.10)	0.330
61-70	1.19 (0.12)	0.096	1.10 (0.12)	0.390
71-80	1.33 (0.15)	0.010	1.20 (0.14)	0.115
81+	1.47 (0.18)	0.002	1.23 (0.16)	0.111
Sex				
Male	ref		ref	
Female	1.30 (0.07)	0.000	1.37 (0.08)	0.000
PCP visits				
1-3	ref		ref	
4	1.46 (0.10)	0.000	1.53 (0.11)	0.000
5	2.00 (0.15)	0.000	1.90 (0.15)	0.000
6-8	2.61 (0.18)	0.000	2.47 (0.18)	0.000
9+	3.14 (0.32)	0.000	2.91 (0.33)	0.000
var(doctor)	1.862		1.959	
var(practice)	2.457		2.386	

As indicated, after adjusting for patient characteristics and calendar time, there was a not a significant increase in the rate of AEs and ADEs with the implementation of the AEHR. Results for the secondary outcomes of preventability are shown in Table 6. There were large, significant decreases in the proportion of AEs and ADEs that were preventable or probably preventable. An 11% (95% CI: 4%, 20%) and 19% (95% CI: 11%, 30%) reduction in the likelihood (odds) of incurring AEs and ADEs, respectively, were estimated on average annually for the impact of the AEHR. The models for physician attribution and level of harm (results not shown) found no effect of EHR implementation on either outcome for either AEs or ADEs.

Table 6. Effect of AEHR Implementation on Rates of Preventable AEs and ADEs.

	Preventable AEs		Preventable ADEs	
	OR (SE)	**P**	**OR (SE)**	**P**
Intercept	0.11 (0.04)	0.000	0.05 (0.02)	0.000
EHR	**0.63 (0.11)**	**0.008**	**0.43 (0.10)**	**0.000**
Year				
2006	ref		ref	
2007	1.12 (0.19)	0.503	1.28 (0.27)	0.249
2008	1.94 (0.38)	0.001	2.66 (0.66)	0.000
2009	1.57 (0.49)	0.151	3.43 (1.43)	0.003
Age				
50	ref		ref	
51-60	1.26 (0.36)	0.408	1.40 (0.50)	0.346
61-70	1.26 (0.36)	0.419	1.44 (0.52)	0.313
71-80	0.94 (0.28)	0.836	1.09 (0.41)	0.814
81+	0.66 (0.22)	0.222	0.76 (0.33)	0.526
Sex				
Male	ref		ref	
Female	1.06 (0.14)	0.641	1.09 (0.18)	0.622
PCP visits				
1-3	ref		ref	
4	1.03 (0.18)	0.867	1.11 (0.23)	0.606
5	1.09 (0.21)	0.664	1.05 (0.26)	0.842
6-8	1.15 (0.20)	0.420	0.92 (0.21)	0.730
9+	0.97 (0.26)	0.915	1.03 (0.36)	0.938
var(doctor)	4.637		0.895	
var(practice)	4.691		1.336	

Discussion

The purpose of this study was to develop tools that could contribute to enhancing the safety of ambulatory primary care by testing the utility of the BI-OTT measurement methodology as a measurement tactic to evaluate the impact of a specific patient safety intervention upon the rate of AEs and by conducting an economic analysis of the impact of AEs taking place in ambulatory primary care to help inform policy pertaining to source of economic support for AE measurement and improvement. Through the achievement of these aims, we have developed and tested a newly standardized methodology and toolkit (BI-OTT) for the detection of adverse events in primary care that can be easily disseminated to other healthcare systems. Most systems do not know the true incidence rate of AEs or the nature of these events, as they do not have a systematic, reliable method to capture AEs. Many organizations rely on voluntary reporting systems, patient surveys, or malpractice claims/risk management data for the reporting of AEs. These methods have many biases and typically lead to the underestimating the rate of AEs. By deploying the BI-OTT, these systems can better capture the rate and nature of AEs related to the delivery of primary care. Developing an understanding of the frequency and type of AEs will allow healthcare systems to design interventions to prevent AEs and improve the safety and quality of primary care as well as patient outcomes.

In addition, this study allowed us to compare the characteristics and costs of BHCS/HTPN patients with and without AEs. We found that certain patient characteristics were associated with greater likelihood of experiencing an AE and that AEs may be associated with a slight increase in cost of care. The BI-OTT training toolkit is an important contribution to the advancement of AE detection and research that this method enables. We relied on the input of nurses and experienced nurse auditors to develop and refine the toolkit. Although we surveyed a small, nonrandom sample of nurses who were not representative of the population of nurses across the United States to determine training preferences, we feel that these nurses gave insightful feedback that allowed us to develop a ready-to-use toolkit that could be easily disseminated. In general, nurses preferred a training format that was interactive and included repetition and practice. After training, nurses prefer to receive help in a timely way through via email, phone, or live chat. Although the majority of nurses surveyed indicated that they preferred in-person training sessions or webinars for learning about new tools, we chose to provide a web-based platform for the BI-OTT toolkit due to logistical constraints and resource needs and the desire to have an "off- the-shelf-ready" BI-OTT training and database package that could be easily disseminated to a wide audience. The sample of experienced and inexperienced nurses who completed the alpha testing found that the web-based platform was a clear and effective means of conducting BI-OTT training and provided the researchers with suggestions for improving the BI-OTT training materials, which were incorporated into the final toolkit.

The findings from the beta testing of the BI-OTT toolkit indicate that there was moderate agreement between the highly experienced KDJ reviewers and the reviewers at the Providence sites. Providence reviewers tended to find a greater number of AEs than KDJ reviewers, who served as the "gold standard." We believe that KDJ reviewers may have been conditioned over time (through their experience with the BI-OTT) to find one AE and stop, while the Providence reviewers who had no previous experience with the BI-OTT may have been more motivated to identify all AEs that might have occurred.

In our survey of BHCS/HTPN patients, comparing those who had and had not experienced AEs, we found evidence that indicates that patients who are more frail are at greater risk for AEs. AE-positive patients were at a significantly higher likelihood of having diabetes, asthma, or COPD and were more likely to report difficulty in "walking a mile," "sitting for 2 hours," and "lifting or carrying 10 pounds" than AE-negative patients. This finding is not surprising, as frail patients are likely to have more encounters with the healthcare system and to be on more medications, which may well increase their likelihood of an AE. Interestingly, there were no significant differences observed between AE-positive and AE-negative patients in terms of reported medical expenditures, employment status, or days missed due to illness or injury. However, only 47% of AE-positive patients and 34% of AE-negative patients reported working 40 or more hours per week. There are several limitations related to the telephone survey, including a low sample size (n=183) and a low response rate (27%). Recall bias likely influenced the results, as the survey was administered in 2012 and patients were asked about their health and healthcare utilization in 2010.

The financial analysis (to compare healthcare costs between AE-positive and AE-negative cases) indicated that AEs may increase the costs the of care; however, these findings were not statistically significant. This analysis was limited to costs incurred from visits to BHCS/HTPN facilities, as we did not have data from other healthcare providers in the area. Thus, the observed healthcare costs likely underestimate the true costs of care for patients with and without AEs. We could argue that patients with AEs would be more likely to need additional care and to seek this care outside BHCS/HTPN if they felt that their AE could be attributed to the care (or lack thereof) that they received from their BHCS/HTPN provider, but this is entirely speculative.

Last, we examined the impact of the implementation of the HTPN AEHR on the rate of AEs in an attempt to quantify the patient safety effects of this technology. The fact that the AEHR (based on months of exposure) had no statistically significant effect indicates that the AEHR technology was not negatively disruptive from a patient safety standpoint. New innovations, including health IT, should be evaluated in order to quantify potential risk and benefits. Our finding also indicates that no positive effects (i.e., no benefits) have yet emerged. As was found in previous work, the AEHR had a negative impact on HTPN workflow and financial measures during the first year of implementation, but recovery to baseline was observed after this initial period.[4] Although we did not find that implementation of the AEHR reduced the number of AEs, when preventability of AEs and ADEs was considered (i.e., events that could be better impacted by this

technology), we observed a strong decrease in the level of preventable or probably preventable AEs and ADEs. Our results regarding the identification of AEs and the preventability of those AEs are consistent with the construct (predictive) validation of the tool. Specifically, the implementation of the EHR was associated with the reduced preventability of AEs during the course of the study, as would be expected according to the hypothesized safety benefit of health IT. One interpretation of this finding is that health IT can be impactful in those situations in which the opportunity exists to be impactful. These results are encouraging, as they demonstrate that we could surface no evidence that the AEHR technology increases the risk of AEs and that it could potentially provide some prevention. Related research for this same population found a positive increase in the likelihood to receive optimal care for diabetic patients.[5] Future research should examine the longer-term effects of the health IT related to AEs and ADEs, as some of the practices in our study had only 1 year of observation after AEHR implementation.

Conclusion

There are many gaps in knowledge related to the frequency and type of AEs and the effects of these AEs on patient outcomes and costs of care. This grant has enabled us to create a toolkit with a standardized method for AE detection that can easily be disseminated to ambulatory healthcare providers throughout the nation. The BI-OTT toolkit allows other systems to collect data on the AEs that are occurring in their system. These data can then be used to improve patient safety and delivery of patient care and to inform future research on AEs and AE prevention. We found that patients with AEs had slightly higher health costs and that health IT may reduce the occurrence of preventable AEs. However, more research is needed to examine these relationships. Widespread efforts to measure frequency and types of AEs should focus attention on improvement work that would ultimately lead to better and safer care for patients and yield methods that can be effectively implemented in other healthcare systems to reduce AEs and improve healthcare delivery and patient safety nationally.

List of Publications and Products

1. Kelly B, Scales M, Treiman K. Risk Informed Intervention Development and Implementation of Safe Practices in Ambulatory Care: Nurses' Training Preferences. RTI International. January 2012. RTI Project Number 0212143.
2. Kelly B, Scales M, Treiman K. Risk Informed Intervention Development and Implementation of Safe Practices in Ambulatory Care: Nurses' Communication Preferences. RTI International. September 2012. RTI Project Number 0212143.
3. Stevens T, Kelly B, Treiman K. Communication—Dissemination Plan for Baylor Health Care System Institute for Health Care Research and Improvement's Outpatient Trigger Tool (BI-OTT) RTI International. September 2012. RTI Project Number 0212143.
4. Baylor Health Care System Office of Patient Safety. Outpatient Trigger Tool: Implementation and Training Toolkit Manual.
5. Baylor Health Care System Office of Patient Safety. Outpatient Trigger Tool: Implementation and Training. Web-based Toolkit. September 2012.

References

1. Fernald DH, Pace WD, Harris DM, West DR, Main DS, Westfall JM. Event reporting to a primary care patient safety reporting system: a report from the ASIPS collaborative. Annals of family medicine 2004;2:327-32.
2. Anderson JG, Ramanujam R, Hensel D, Anderson MM, Sirio CA. The need for organizational change in patient safety initiatives. Int J Med Inform 2006;75:809-17.
3. Forster AJ, Murff HJ, Peterson JF, Gandhi TK, Bates DW. Adverse drug events occurring following hospital discharge. J Gen Intern Med 2005;20:317-23.
4. Fleming NS, Culler SD, McCorkle R, Becker ER, Ballard DJ. The financial and nonfinancial costs of implementing electronic health records in primary care practices. Health Aff (Millwood) 2011;30:481-9.
5. Herrin J, da Graca B, Nicewander D, et al. The effectiveness of implementing an electronic health record on diabetes care and outcomes. Health services research 2012;47:1522-40.