GLIDES

GuideLines Into DEcision Support

EVALUATION PLAN
July 2012

GLIDES PROJECT

GuideLines Into Decision Support

sponsored by

The Agency for Healthcare Research and Quality

Yale New Haven Health

Yale School of Medicine

Nemours.

The Children's Hospital of Philadelphia

GEISINGER

American Academy of Otolaryngology–Head and Neck Surgery

ECRI Institute

American Academy of Pediatrics
Dedicated to the Health of All Children

American Urological Association

Alliance of Chicago
Community Health Services, L3C

ASCO
American Society of Clinical Oncology

1. Introduction

GLIDES Option Year 3 (OY3) Goals

The objective of the GLIDES project is the development, implementation and evaluation of demonstration sub-projects that advance understanding of how best to incorporate clinical decision support (CDS) into the delivery of healthcare. The project is exploring how the translation of clinical knowledge into CDS can be routinized in practice, and taken to scale, to improve the quality of healthcare delivery in the U.S. GLIDES has completed its first four years of contracted work for AHRQ. During this period, GLIDES has delivered agreed work products on schedule and within budget. This Evaluation Plan covers what is expected to be GLIDES' fifth and final year of operation – Option Year Three (OY3). GLIDES goals for OY3 are as follows:

1. **Using systematic and replicable processes, we will complete our work to design, develop, implement, and demonstrate guideline-based clinical decision support:**
   - Complete implementation and evaluation activity currently in progress at Yale, CHOP, Geisinger and Alliance of Chicago.
   - Complete consolidation of successful tools, implementation practices and lessons learned into a web-based "Tool-Kit" of tools and methods that are systematic, replicable, and documented.
   - Deploy these tools and methods, using the Internet, such that they can provide benefits to guideline implementers beyond the expected completion of AHRQ-funded GLIDES activities following OY3.

2. **Recognizing the critical importance of transparently developed and clearly stated guideline recommendations for effective implementation, work closely with guideline developers to provide tools and guidance to improve guideline development and reporting processes.**
   - Complete work with ECRI, AAP, AAO-HNS, AUA, ASCO and other developer partners to integrate BridgeWiz and GLIA tools into their guideline development processes.
   - Complete consolidation of successful development practices and lessons learned into a set of tools and methods that are systematic, replicable, and documented.
   - Deploy these tools and methods, using the Internet, such that they can provide benefits to guideline developers beyond the expected completion of AHRQ-funded GLIDES activities following OY3.

3. **Update the Guideline Elements Model and increase GEM adoption nationally and internationally.**
   - Focus on completion, standardization and promotion of the new GEM III release.
   - Perform a collaborative pilot (ECRI and AUA to process the AUA clinical practice guidelines through GEM-cutting, and the use of eGLIA).
   - Integrate BridgeWiz and GEM.

4. **Continue evaluation of both existing and newly developed CDS implementations.**
   - Complete evaluation activities across each of the implementation partners, through a series of site visits facilitated by ECRI.

5. **Disseminate the findings and lessons learned via a variety of modalities.**
   - Complete our program of dissemination, including presentations and papers.
   - Design and implement a web-based system for accessing GLIDES artifacts (tools, lessons learned, design documents, templates, project plans, methodologies, techniques, papers, etc).

Overview of Evaluation Plan

In OY2, evaluation work for earlier years of GLIDES (at Nemours and Yale) neared completion, while evaluation of new implementation activities ramped-up (at CHOP, Geisinger and Alliance of Chicago). In OY3, GLIDES will bring to a close its program of evaluation. Two streams of work will be performed:

- Evaluation work currently in progress at Yale, CHOP, and Geisinger will be completed, and Alliance of Chicago will perform preliminary evaluation work on CDS applications to be delivered in OY3. These evaluation activities, which were first documented in the GLIDES' OY2 Evaluation Plan, will form the basis for completing the evaluation work in OY3. A revised version of the OY2 Evaluation Plan, including updates on current status, is included in section 2.

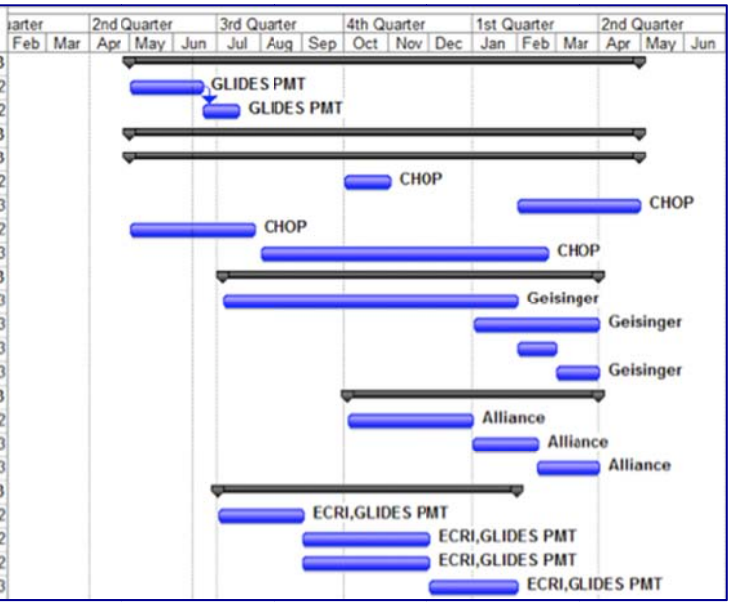
- ECRI will assist GLIDES in concluding the evaluation program with a series of structured site visits and teleconferences with each of our major collaborators (both implementers and guideline developers). In July and August 2012, ECRI and the GLIDES Project Director will organize the program. Presently, we expect to perform the site visits and teleconferences in two streams, one focusing on guideline developers (AAP, AAO, AUA and ASCO) and one focusing on guideline implementers (CHOP, Geisinger, Yale and Alliance). Discussion topics will include (but are not limited to):
    - How can healthcare knowledge be best specified to be actionable through CDS?
    - How can IT enable best practices? What should healthcare knowledge include to make that happen?
    - How can this be done in a replicable way across IT platforms?
    - What do the specific vendors involved in the demonstration need to do to improve CDS in their products?
    - What are the best CDS modalities?
    - Use of CDS (Effectiveness, Efficiency, User satisfaction, User and setting characteristics that affect successful adoption of CDS)
    - Clinical outcomes and patient satisfaction
    - Quality measurement of the demonstration's clinical topics using the proposed interventions shall also be addressed if appropriate.

  ECRI will develop pre-meeting surveys to help participants prepare for the meetings effectively. We expect to perform the visits and calls in Q4. This will leave the first few months of 2013 to document and consolidate the results and incorporate them into our Final Report and Dissemination deliverables. There is potential for some of these visits to be combined where logistically possible. Results of site visits will be compiled, documented and included as part of the GLIDES dissemination plan and toolkit.

Evaluation Activities

Work plan milestones for all GLIDES OY3 activities are as follows:

Task Name	Start	Finish
Evaluation	**Tue 5/1/12**	**Mon 4/29/13**
Create draft Evaluation Plan	Tue 5/1/12	Wed 6/20/12
Finalize Evaluation Plan	Thu 6/21/12	Mon 7/16/12
Perform Evaluation activities	**Tue 5/1/12**	**Mon 4/29/13**
CHOP Evaluation	**Tue 5/1/12**	**Mon 4/29/13**
Perform initial/interim analysis of ROP results	Mon 10/1/12	Thu 11/1/12
Perform final analysis of ROP results	Fri 2/1/13	Mon 4/29/13
Perform final analysis of ROP results	Tue 5/1/12	Fri 7/27/12
Create ROP results assessment paper	Wed 8/1/12	Fri 2/22/13
Geisinger Evaluation	**Fri 7/6/12**	**Sun 3/31/13**
Complete transcription/transcribing of audio recordings	Fri 7/6/12	Thu 1/31/13
Perform data analysis	Wed 1/2/13	Sun 3/31/13
Determine relevant findings/lessons learned	Fri 2/1/13	Thu 2/28/13
Compile final report	Fri 3/1/13	Sun 3/31/13
Alliance Evaluation (User Feedback)	**Wed 10/3/12**	**Sun 3/31/13**
Create content and CDS evaluation user survey	Wed 10/3/12	Mon 12/31/12
Distribute survey instrument	Tue 1/1/13	Fri 2/15/13
Assess survey results	Fri 2/15/13	Sun 3/31/13
Site Visit Program	**Mon 7/2/12**	**Thu 1/31/13**
Organize site visits (agendas, timing, participants, logisti	Mon 7/2/12	Sat 9/1/12
Perform CDS Implementer site visits	Sat 9/1/12	Fri 11/30/12
Perform CDS Developer site visits	Sat 9/1/12	Fri 11/30/12
Document site visit results	Sat 12/1/12	Thu 1/31/13



2. Detailed Evaluation Plan – OY2 Plan Updated For OY3

Evaluation Plan For CHOP CDS Implementation

OY2-3 Evaluation Plan: Complete Final CDS Development and Testing

Activities

- Complete Final Release Development: CDS beta releases for retinopathy of prematurity screening and prevention of respiratory syncytial virus (RSV) infection will be refined, tested and implemented.
- Perform Use Case Testing: Use Cases define the behavior between the user(s) and system in performing identified tasks. Use Cases are developed in the early requirements phase, but are reused throughout the development process to support design as well as system, user acceptance and usability testing. CHOP will deliver a set of detailed Use Cases for the Premature Infant Intervention defining requirements derived from addressing the three documents translated into CDS logic (retinopathy of prematurity screening, RSV prevention, and hearing screening).
- Perform Final Usability Testing: CHOP will engage representative clinical users in a usability test of the Premature Infant Intervention. Usability testing consists of having subjects perform tasks with the system (scenarios based on identified use cases) and collecting both quantitative and qualitative measures on the system's capability to support the user in performing key tasks. CHOP will deliver usability testing results on the Premature Infant Intervention.
- Deployment: Training, communications and other implementation-related activities will be completed for the final releases of the CDS.

Evaluation Measures

Evaluation activities for the CDS development and testing phase will be conducted with clinician subjects from two CHOP affiliated practices: Faculty Practice at 3550 Market Street, and the Care Network Chestnut Hill location. Expected outcomes from this evaluation are: (a) a set of validated clinician requirements; and (b) assessment of the system's ability to meet those requirements through a formal usability test.

Evaluation will initially focus on defining and validating clinician requirements in the primary care setting related to preterm infants at risk for retinopathy of prematurity, hearing loss, or severe RSV disease. Requirements will be validated using survey instruments that assess their priority, frequency of occurrence, and adequacy of current systems to address each requirement. After the requirements are defined, the CDS intervention will be refined in an iterative design strategy using low-fidelity mockups and functional prototypes. During each iterative step, feedback from the usability study subjects, designed to measure functionality and usability, will be incorporated into refining the design.

Using the final functional prototype the project team will conduct a usability test designed to measure the ability of subjects to perform system tasks successfully. Time spent on task and user "error rate" will be the primary outcomes. Any issues or problems discovered in the Usability Test will be addressed. If any discovered issues are of a high severity, the redesign will be further reviewed with subjects. The final usability activity in this phase will result in releasing the CDS intervention to the usability study practices where subjects will be interviewed and/or surveyed on the CDS Intervention in order to further address and address any remaining issues.

Data Sources and Collection Methods

Data collection for the usability evaluation will be performed using paper surveys and by direct observation performed by members of the study team. Up to nine clinicians will complete brief surveys during the use case validation phase. The surveys will require no more than five minutes to complete. An additional nine clinicians will participate in a scripted usability test requiring 30 to 45 minutes of effort. Ability of clinical users to successfully complete tasks using the prototype system will be scored using direct observation by two members of the study team. Data collection for the usability tests will be completed by September 2011.

Anticipated Sample Size/Analytic Plan

The sample for use case validation and formal usability testing will consist of nine clinicians. Analysis will be descriptive. The distribution of responses for each survey item will be tallied. Frequency of critical and non-critical errors in the usability test will be reported.

OY2-3 Evaluation Plan: Interim Data Analysis

Activities

CHOP will perform an interim data analysis covering patient outcomes as well as CDS usage. Bronchiolitis (RSV) season extends past April.

Evaluation Measures

During the intervention phase, the impact of the clinical decision support on guideline adherence will be examined prospectively using a cluster-randomized design. Up to 20 practices will be enrolled, with half of the practices receiving clinical decision support, and half serving as control practices. The following process outcomes will be measured: (a) receipt of all recommended doses of Palivizumab (passive RSV immunization) among eligible premature infants; (b) timeliness of Palivizumab administration on a monthly schedule; (c) adequate documentation of retinopathy of prematurity screening among high risk infants; (d) results of a second audiologic screen documented by corrected age 12 months among high risk infants.

Data Sources and Collection Methods

Electronic health records will be used to assess the process measures during the cluster-randomized intervention phase. Extracted data will include Palivizumab administration records, ophthalmology follow-up instructions, abstracted intensive care nursery documentation, longitudinal problem list diagnoses, past medical history documentation, and audiology documentation. The study team will extract these data for both an interim and a final analysis. Each data extraction will require approximately 20 hours effort.

Anticipated Sample Size/Analytic Plan

The unit of randomization for the intervention phase will be the practice. Up to 20 practices will participate, with half of the practices randomized to receive the intervention. We anticipate over 600 premature infants will receive care at these 20 practices during the study period. Results will be analyzed in a hierarchical model to account for clustering of patients within practices.

OY2-3 Evaluation Plan: Post-Deployment Assessment

Activities

- Implementation Guide: CHOP will document the development of their EMR-based CDS application. This guide will include details on the centralized rules engine, web services framework and application development. It will also describe team member roles, competencies and other information supporting the development of CDS at CHOP.
- Technical Appendix will be created to permit technical personnel at other organizations to build local instances of the web-service technology used at CHOP. This will include guidance for both the EHR and web-service administrators. For those organizations using the EHR provided by Epic Systems, CHOP will provide all the tools necessary to integrate the web-service based CDS framework within the Epic software.

Evaluation Measures

The adequacy of documentation in the technical appendix will be evaluated qualitatively by non-study staff at CHOP and by collaborators within the GLIDES project. Adequately skilled technical experts who were not involved with the initial deployment will be asked to perform the software installation in a development or testing environment using these technical documents. Their feedback will be used to improve final documentation.

Data Sources and Collection Methods

Assessment of the technical documentation will be performed using telephone interviews and interactive desktop sharing. Up to three technical experts will be invited to review the documentation and to attempt to perform the implementation tasks in a software development or testing environment. The technical experts will be encouraged to "think out loud" as they work through the implementation tasks.

Anticipated Sample Size/Analytic Plan

Evaluation of the technical materials created to disseminate the CDS intervention will be qualitative. Two or three technical experts will be asked to provide feedback on these materials.

Progress Update

CHOP implemented a CDS application for management of premature infants – the Premature Infant Assistant - which utilizes real time Electronic Health Record (EHR) data mining and is integrated with a rules-based expert system and custom EHR application framework. The CDS application was applied to two clinical guidelines (policy statements) from the American Academy of Pediatrics: *Respiratory Syncytial Virus and Palivizumab* and *Retinopathy of Prematurity* (ROP). GEM was used to transform the policy statements into more than 100 rules, applied to 30+ patient variables extracted from the EHR.

Highlights of the CDS functionality include:

- Growth and Nutrition: Real time assessment of growth and tools to create feeding recommendations and education
- Development: Assess/monitor documentation of development and provide automatic age-corrected development documentation tools in the EHR.
- Blood Pressure Screening: Recommend screening at corrected age, plus data mine EHR for any abnormal readings in past and recommend screening.

CHOP followed a user-centered development process to design and build the CDS applications, with extensive use case development and validation. Multiple and iterative user interface and workflow design sessions were performed, involving over 25 clinicians. Extensive usability testing was performed on the functioning system. CHOP responded to user feedback and made user interface/workflow changes to improve usability/utility.

CHOP created an extensive implementation guide detailing the overall architecture and development process used, including a technical appendix with system diagrams, supporting files and libraries.

CHOP performed an initial analysis of outcomes and usage data. Initial results focus on usage and findings on RSV and delays in administering dosing of Palivizumab. In addition, CHOP compiled premature infant parent education content and developed a Portable Document Format (PDF) generator integrated with the EHR programming framework to auto-generate patient specific education materials from the EHR.

Independently, Jeremy Michel at Yale marked-up the Palivizumab guideline and developed a rule set for it, working with the CHOP team to reconcile the differences. This exercise was useful in identifying ambiguities with significant consequences and demonstrating how two different knowledge translation processes can generate different results.

Initial evaluation highlights include:

- Differential interpretation of the policy state on Palivizumab administration would result in significant and costly differences in the eligible pool of patients.
- The RSV Care Assistant was deployed to twenty general pediatric practices and was used to help manage the care of 343 patients in the first two months of the post intervention RSV season.
- Analysis of the subgroup of 131 children eligible to receive monthly Palivizumab for the entire RSV season revealed that 112 (85%) had received at least one dose by 12/31/2011.
- By comparison, among a cohort of 119 children eligible to receive monthly doses for the prior RSV season, only 69 (77%) had received at least one dose by 12/31/2010 (p=.095).

Specific challenges included:

- Clinician Acceptance/Buy-In: In particular, gaining clinician agreement that CDS is needed for the identified patients/issues and their commitment to use and adopt the CDS prior to implementation. To achieve this, CHOP investigators communicated closely with clinicians prior to development, engaged high-level stakeholders and engaged clinicians and stakeholders closely in their user-centered development approach. This approach, while necessary to ensure a high quality design, also creates a subsidiary problem: the need to recruit busy clinician subjects for user-centered methods/activities.
- Guideline Ambiguity/Gaps: CHOP's work demonstrated again that published guideline documents will often not provide complete coverage for logic implementation. To resolve this, CHOP formed a clinician expert panel to review, research and (where required) make informed decisions to address any ambiguity or gaps in the document translation.
- Inconsistency Of EHR Data: CHOP's project needed to resolve data quality problems inherent in the EHR system that impacted the CDS design. Some required data was either missing, in different locations and/or in different formats. To address this, CHOP performed analytics/reporting prior to development to test and validate the required data sources and queries. In addition, extensive data testing was performed early in the system development process and a limited "beta" release was introduced to a small group of clinicians to pilot the design in real world clinical environments.

Evaluation Plan For Geisinger CDS Implementation

OY2-3 Evaluation Plan

Please Note: Confirmation/finalization of this Evaluation Plan is subject to final review of IRB-related documentation, by Yale IRB Manager – expected to be complete by end of July 2012. Implementation of the Geisinger eLowBackPain was funded by a separate grant. The non-GLIDES funding contract number is 222391. GLIDES has provided funding for the activities specified below.

Activities

- Audio record patient-provider dialogues of 40 consenting patients randomized to the eLowBackPain intervention group and 40 consenting patients randomized to the usual care group.
- Transcribe and evaluate the audio recordings using the Roter Interaction Analysis System (RIAS) and analyze the content to determine if the dialogue is higher in quality for patients in the intervention group versus the usual care group.
- Measure adherence to guideline-based care for low back pain

Related activities supported by a different grant

- Measure patient satisfaction 3 days after initial visit
- Measure pain, functioning and quality of life at 3 months and 6 months

Evaluation Measures

The activities performed in Option Year 2 will be evaluated as follows: 1) by the proportion of patients who consent to the audio recording and the success rate in completing a recording; 2) by whether the quality of the patient and doctor dialogue in the intervention group is rated higher than the same dialogue in the control group; and 3) whether adherence to guideline-based care differs between the groups.

Data Sources and Collection Methods

Table 1. Description of the measures used to determine the success of the proposed activities.

Measures	Time of Collection	Method of Collection
Proportion of patients who consent to the recording and the success rate in completing a recording	During the clinical encounter with the doctor	Digital recording of dialogue
Quality of the dialogue	To be assessed after completing 80 recordings	Roter Interaction Analysis System (RIAS)
Patient satisfaction*	3 days after the initial back pain visit	Phone interviews that are not supported by the GLIDES contract but are supported by another grant

Guideline-based care	6 months after initial back pain visit	EMR data abstraction
Pain, functioning, and QOL*	3 and 6 months after the initial back pain visit	Phone interviews
*Patient satisfaction, pain, functioning, and QOL are being funded by another study		

Anticipated Sample Size/Analytic Plan

The data for this study will be from patients participating in a randomized controlled trial (RCT). The GLIDES funding in OY2 will be used to collect data from a random sample of 80 patients from among all participants (i.e., 300 patients) in the intervention and control groups. The analysis of outcomes is summarized in Table 2. The RIAS evaluation will yield semi-quantitative ordinal measures. We will compare the intervention and control groups on differences in distribution by the multi-chotomous measures and whether the distributions differ by treatment status. Depending on the results, we may explore for more specific subgroup effects. All other analyses will be completed on the 300 patients randomized to the intervention and control groups (see Table 2). We will derive measures of differences in proportions and distributions and use simple t-tests and chi-square tests to evaluate significance. The analysis will include an evaluation of the extent to which the two arms are balanced with regard to potential confounders. If necessary, we will use regression methods to adjust for potential confounding in the event that the two subgroups differ with regard to potential confounders.

Table 2. Description of the quantitative measures used.

Quantitative Measures	Anticipated Sample Size	Proposed Analytic Plan
Proportion of patients who consent to the recording and the success rate in completing a recording	80 equally divided into the control and intervention groups	Simple statistical test of difference in proportions and chi-square tests of differences in distribution by multichotomous outcomes. 95% confidence intervals (CI) will be derived for all measures of interest
Quality of the dialogue		
Guideline based care	300 patients (200 into the intervention and 100 into the control group)	Simple statistical test of difference in proportion of patients for whom different procedures (e.g., imaging, specialty referral, etc) were ordered but not supported by guidelines and for which opioid treatments were ordered by not supported by guidelines. 95% confidence intervals will be derived for all measures of interest
Patient satisfaction*	40-50% response rate of total sample size (n=300)	Mean difference and 95% CI for the overall satisfaction score and related sub-scores. Multiple linear regression if needed to address differences between the intervention and control groups in distribution of patients by confounders
Pain, functioning, and QOL*	70% response rate of the total sample (n=300)	Mean difference and 95% CI for measures obtained at each time point. Multiple linear regression if needed to address differences between the intervention and control groups at each time point. Use of GEE regression to evaluate overall differences between the intervention and control groups on measures obtained at all time points
*Patient satisfaction, pain, functioning, and QOL are being funded by another study		

Progress Update

In OY2, Geisinger introduced the audio-recording protocol in one of the five clinic sites and will consider implementation on other clinic sites in OY3. Geisinger investigators commenced work on the transcription and analysis activities in OY2. Approximately 25% of the patient consents and recordings and transcription and coding analysis work was completed. The balance of this work, and related evaluation, will be completed in OY3.

Specific challenges included:

- Institutional Review Board (IRB) Approval: Geisinger were required to submit a separate IRB application for the AHRQ funded work. They originally submitted an amendment to the original study, but the sponsor concluded that their protocol review would not accept that method of approval. While Geisinger do not anticipate any problems with gaining approval for a separate IRB application, additional time and effort was required to assemble and submit the application for review.
- Technology: The Geisinger IT team had to create a new classification on the exam room computers to account for the recording software and microphone. This had to be added to the classification setup used for the e-health back pain protocol and tested to make sure it was secure and the necessary components were locked down for patient use.

A key objective was to determine if the e-health back pain protocol resulted in superior dialogue and shared decision making between the patient and provider. Patients and providers who consented would be audio recorded during the back pain visit and their recordings would be evaluated by an expert team using a well standardized protocol for coding and rating the quality of the doctor-patient interactions. This evaluation work is now in progress, which includes the transcription and analysis activities noted above. This work has not yet progressed to a stage where specific evaluation findings can be drawn. This work will be completed in OY3.

Evaluation Plan For Yale Patient-Centered Data Capture

OY2-3 Evaluation Plan

Activities

- Assess usage in practice
- Assess any barriers to success: technical, physician-related, patient-related
- Assess impact of patient-centered data capture on physician use of decision support for asthma management.

Evaluation Measures

Technical considerations in the implementation of iPad technology for patient-centered data capture will be described qualitatively based on real-time capture of key decisions and technical barriers. Particular attention will be paid to software architecture design, integration strategies with local EMR, security management, teamwork, and clinical workflow.

Evaluation of iPad usage in practice will examine rates of usage, comfort and skill of clinic staff and patients with the technology, rate of data capture by the EMR, and identification of barriers and facilitators.

Evaluation of the impact of patient-centered data capture on physician use of decision support for asthma management will include assessment of the frequency with which CDS is triggered and viewed by clinicians in real-time during the patient visit.

Data Sources and Collection Methods

The implementation evaluation will include interviews with key decision-makers, review of meeting minutes and technical documents, and observation of implementation meetings. iPad usage evaluation will include direct observation of workflow and patient activities during clinic hours, abstraction of data elements from the EMR, and qualitative interview with clinic staff, the three physicians in the practice, and up to nine patients. Impact of the iPad implementation on real-time use of CDS will be assessed through direct observation and review of time-stamped data elements in the EMR.

Anticipated Sample Size/Analytic Plan

There are three physicians and three clinic staff in the implementation practice. Up to nine patients will be observed and/or interviewed. We anticipate being able to obtain EMR-based information from 100 patients using the system after six months. Interviews and direct observations will be described qualitatively; data capture and real-time use will be assessed using descriptive statistics. There are no specified control or comparison groups in this study; however, if not all physicians in the practice adopt the technology, non-adopters will be used as comparisons.

Progress Update

The pilot application was enhanced and improved. Technical performance was improved, in areas such as security, performance and integration with IDX. Functional performance was also improved, in areas such as access to information types and access to the patient registry. Appointment registry data is now fed from the clinic's IDX system (GE Health, UK) to insure accurate patient identification before receipt of the device in the clinic waiting room. A series of multiple-choice questions (English or Spanish) are displayed on the iPad and answered by tapping on the desired answer. Upon completion, responses are sent wirelessly over the secure clinic network to the web application server, creating a lab Health Level Seven (HL7) message with patient responses as observation terms. This information is then sent to the enterprise interface engine (eLink) and directed into the Centricity EHR.

All of the pulmonologists at the Long Wharf expressed satisfaction with the system. Prior concerns regarding additional burdens on the registrar staff (responsible for distribution of the iPad devices) did not materialize. Patients were able to use the system with minimal training and expressed satisfaction.

As of April 2012, 116 patients have been seen for asthma: 111 (95.7%) patients were willing and successfully used the iPad application without any formal training or orientation to the device. Five (4.3%) patients declined to try using the device. Server problems resulted in 14 (12.1%) lost transmissions but the root cause of these problems were permanently corrected in OY2. Overall, 97 (83.6%) patients had successful completion and transmission to EHR of asthma interval history into Centricity from the iPad application.

In March, the Yale team developed a poster summarizing the project's results, for presentation at the upcoming Pediatric Academic Societies Conference. The posted is entitled: *Pediatric Asthma History Review By Patients Using iPads: Challenges & Adoption.* The poster notes that: "While there are many technical and security steps to

consider, an easily adopted, touchscreen graphical user interface device, such as an iPad can be used to successfully and securely collect and transmit data into an EMR. Provider and patient enthusiasm was extremely positive".

The main challenge was how to acquire hardware (iPad equipment) to expand the pilot. The pilot is currently functioning in the Yale Long Wharf clinic, with three clinicians using the application regularly. We could extend the pilot for use at Yale's main pulmonology clinic in New Haven. It could also be implemented at other primary care clinical locations at Yale. However, the terms of the GLIDES contract do not allow for acquisition of new hardware.

Evaluation Plan For Alliance Of Chicago CDS Implementation

In OY2 GLIDES began collaboration with a new implementation partner, Alliance of Chicago, to implement clinical decision support interventions. Alliance investigators are using the Yale-site designed Asthma CDS. Alliance's intent is to customize and reuse it for implementation across the Alliance network, carefully noting barriers and facilitators of transferring a working CDS from one site to another where both sites use the same vendor-supplied EHR (GE's Centricity).

In OY2, the Alliance team performed the bulk of design and development work and was able to successfully adapt the CDS content from Yale. In OY3, Alliance will focus on rollout and evaluation work. In doing so, Alliance will contribute to GLIDES' growing body of CDS implementation experience, expertise and lessons learned through developing insight into:

- Local Factors: The extent of changes necessary to be made to the Alliance version of the CDS reflect the importance of differences in technical, workflow, clinical policy and other factors that vary from one implementation organization to another. This demonstrates that successful CDS configuration and implementation is a complex challenge, and not just a question of "plug and play" of software modules.
- Guideline Complexity/Need For Testing: Despite the "head-start" provided by leveraging the Yale CDS, the complexity of the content and calculations included within the CDS application still required extensive testing within the Alliance environment.
- Clinician Buy-In. Expert opinion and buy in from clinical providers was still critical for success when adapting EHR decision support. As with other implementations, few providers have significant free time to volunteer on calls, testing draft content, and provide specific feedback.
- Cost and Effort: While not completely unexpected, the amount of effort and time to incorporate the Yale content, specifically the complex programming functions, was greater than initially planned.

Alliance investigators were able to successfully adapt the CDS content from Yale. Revised CDS forms (and additional content such as Handouts for Asthma Action Plan and Asthma Control Test) were developed and reviewed by Alliance subject matter experts. Form and content is currently being reviewed by usability testers, who are providing feedback. Although Alliance was able to work within the overall framework and structure of the Yale CDS, several detailed changes were incorporated into Alliance's version of the EHR "Asthma Management Form". These various changes illustrate the types of "on the ground" changes needed to customize a CDS application to allow it to operate effectively from one clinical context to another:

- The Control and Severity Form was added as a single tab in the Alliance Asthma form. This required:
    - Navigation changes: Removed radio buttons to select "visit type"; Removed radio buttons to jump to other forms; Added display to show previous Severity to enable providers to better select if Severity has been

assessed; Added simple option to document Severity Classification in the case it had been determined by a provider prior to patient being seen in the clinic; Updated chart note translation to be easier to read and to reflect if both Control and Severity were documented in a single visit.

- Changes to the look and feel of the Control/Severity including: Shortening the descriptions of some questions, adding popup buttons to offer the additional information that was removed; Added functionality to have provider accept the Control Assessment and the Severity Assessment; Shortened some responses to fit into available space (this resulted in the need to modify the 'calculation' to determine Control and Severity); Added pop up buttons with help in use of the form.
- Functions to be updated to remove logic related to EHR document summary lines specific to Yale workflows: The Yale workflows had specific Encounter types for new Asthma visits that would default a specific summary line, thus triggering functions to load. Since Alliance cannot rely on a standard Encounter type used by all sites, this logic had to be removed and developed elsewhere; Text Components getting loaded into the update based on the summary line had to be moved to Visual Form Editor function library so that the library would be loaded whenever the form was added to any update.

- Changes to the Medication form: Removed radio buttons to select visit type; Removed radio buttons to jump to other forms; Updated look and feel to match Alliance Standard (button colors and fonts); Removed Refill buttons from individual lines and added a global button at the bottom of the tab; Functions moved to Visual Form Editor function library; Updated Text Files with new GPI codes to ensure all medications are added when selected; Updated functions to check if medication already on medication list and prompt user to update the medication list; Updated logic to add medications to observation terms.

- Changes to the Assessment Form: Removed radio buttons to select visit type; Removed radio buttons to jump to other forms; Updated look and feel to match Alliance Standard (button colors and fonts); Reduced size of 'image' to have tab without scroll bar; Removed items to display previous Control Classification, Impairment and Risk, and Severity Classification, Impairment and Risk. The Alliance form has a summary page that displays this information. Added just display for classification of Severity and Classification. Updated logic for displaying recommendations to simplify based on provider classification. Moved functions to Visual Form Editor function library and form. Added section for documenting education of inhaler, control and medication adherence.

In OY3, Alliance's formal evaluation program will be limited to analyzing user feedback from the provider users of the application. It will not be possible, in the timeframe of OY3, to perform meaningful evaluation of outcomes. The results of the analysis will be compiled, assessed and summarized in the final GLIDES OY3 report.

Evaluation Plan For Guideline Tool Development and Implementation

OY2-3 Evaluation Plan

Activities

Recognizing the critical importance of transparently developed and clearly stated guideline recommendations to effective implementation, GLIDES is working closely with AAP and AAO-HNS to provide tools and guidance to improve guideline development and reporting processes. The effectiveness of the tools and guidance will be evaluated and, in future GLIDES' years, will be promoted for use by other guideline development organization.

Evaluation Measures

Evaluation will address the following:

- How can "knowledge transformation", necessary for successful CDS implementation, be simplified by improving the clarity and specificity of guidelines during development?
- What portions of the current knowledge transformation stack can potentially be moved "upstream" to the guideline development process?
- What tools and authoring techniques, such as BridgeWiz and eGLIA, can facilitate this shift? How do we measure effectiveness of BridgeWiz and eGLIA for targeted guidelines?
- What knowledge products and specifications should guideline developers provide to integrate with "downstream" CDS design work performed by guideline implementers (at Level 3 and 4)?
- Can performance measurement considerations be embedded into the guideline authoring process?
- How do we measure impact of improved implementability sections in targeted guidelines?

Plan Specifics

- **Testing and Enhancement Of Guideline Editor – BridgeWiz:** BridgeWiz is a software program designed to help guideline committees write recommendations that are decidable and executable. The software has been tested by its developers, but needs testing with a wider audience to determine whether it can be used more broadly by our collaborators and by other developers. AAP and AAO-HNS guideline developers will use BridgeWiz to develop guidelines and key action statements for the upcoming guidelines. GLIDES will review the resulting action statements developed in BridgeWiz and will evaluate the extent to which BridgeWiz can be deployed to guideline developers to improve the clarity of action statements. We will also consider ways that BridgeWiz can be used to train guideline authors in creation of actionable key action statements.

- **Implementation Planning Tools:** The Recommendation Profile Template and GLIA (GuideLine Implementability Appraisal) are tools that can be used for increasing transparency in and implementability of guidelines, and are currently being used by AAO-HNS. We will evaluate use of GLIA and Recommendation Profile Templates as tools to help identify potential obstacles to effective implementation. Performance measures help measure adherence to guideline recommendations. To date measures have been developed following the completion of a guideline. We will evaluate attempts to define a process that will allow for development of measures concomitant to the development of the guideline.

Progress Update

AAP's guideline committees continue to utilize BridgeWiz. AAO-HNS has fully integrated CDS tools BridgeWiz and eGLIA, into its Guideline Development processes and is in the process of updating its Guideline Development Manual. In addition, AUA and ASCO are now actively engaged in the GLIDES project. AUA is working on the urodynamics guideline, using BridgeWiz, and plan to move on to the urotrauma guideline next.

Feedback on BridgeWiz has been positive. A general conclusion is that it "takes a lot of the guess work out of developing the action statements and ensuring that they truly are actionable". In addition, GLIDES has received several suggestions for improving the BridgeWiz tools:

- While creating action statements, if a user gets halfway through creating the full statement (ie going through each step) and decide that they need to revise the actual statement in the first window, change a keyword, etc. they are forced to start the process over. There does not currently appear to be the ability to go back and edit.
- The evidence-grading table is not applicable to diagnostic tests. AAO-HNS referenced the Oxford Centre for Evidence-Based Medicine evidence quality tables for diagnostic tests during both the SHL and IVO guidelines. The AAO-HNSF suggests the incorporation of additional evidence grading tables into the BridgeWiz software, allowing the user to switch between tables as necessary.
- The IVO panel also suggested that during 'Deontic' section where the level of obligation is determined, that a star or some other symbol, identify the evidence quality and benefit to harm assessment that was assigned.
- Remove the word 'consider' as a potential action verb – See activity 'CONCLUDE'.

Evaluation Plan For Knowledge Management and Transformation Toolkit

OY2-3 Evaluation Plan

GLIDES will update the Guideline Elements Model and increase GEM adoption nationally and internationally. GLIDES will collaborate with ECRI to accomplish this goal.

Evaluation Measures

Evaluation will address the following:

- What challenges are limiting GEM adoption by guideline implementers?
- How can these limitations be most easily resolved?
- What modifications to the Guideline Elements Model are necessary to reflect advances in the state-of the art for guideline knowledge representation? How can the Guideline Elements Model accommodate concepts relevant to performance measurement?
- Increase in number of new users of GEM methods and tools across the guideline implementation community.

Plan Specifics

We will track and summarize current GEM use, performing a systematic search of literature for indications of GEM use and reviewing Web logs of GEM site to identify users. We will consolidate this information into an assessment of current GEM use, related critiques, that will inform the development of new release of the GEM model and related tools.

We will extend the current Yale- ECRI NGC pilot project to explore scalability and further implementation of GEM-ified, downloadable output that can be offered at the NGC website. Markup conventions will be specified. Guideline developers will verify/validate/review the GEM-cut versions of their guidelines created during the current pilot project. ECRI will create PDFs of the GEM cut guidelines, and then engage with each guideline developer to ensure that they agreed with the GEM representation of their guidelines. Planning for modifications of the NGC website to accommodate GEM-parsed guideline content will be undertaken. We will evaluate ECRI's experience of using GEM.

Progress Update

The third revision of the Guideline Elements Model (GEM III) was submitted in January 2012 to ASTM International for balloting as an international standard for representation of guideline knowledge. The newest version adds a number of new elements. By February 1, only a single negative comment had been received that questioned the display of the model in the standard. The balloting was completed successfully.

Jeremy Michel continues work on mapping the action-types taxonomy developed at Yale Center for Medical Informatics (YCMI) to the Quality Data Model from the National Quality Forum.