PROJECT PLAN

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Project Plan Revision History

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1. Executive Summary

This document is the Project Plan for the Guidelines Into Decision Support (GLIDES) project. 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 being performed under contract to the US Agency for Healthcare Research and Quality (AHRQ). Yale University School of Medicine has received a 2-year, $2.5 M contract from AHRQ to demonstrate a systematic and replicable process by which knowledge contained in practice guidelines can be transformed into computer-based clinical decision support and taken to scale to improve the quality of healthcare delivery in the U.S.

A team of highly talented collaborators (including representatives from primary and specialty care medicine, nursing, informatics, information systems, clinical administration, epidemiology, and quality management) from geographically and organizationally diverse institutions will:

- Select evidence-based guideline recommendations for prevention of pediatric overweight and obesity and chronic management of asthma
- Apply models, techniques, and tools developed at the Yale Center for Medical Informatics to systematically transform the knowledge contained in these guidelines into a computable format
- Deliver the guideline knowledge via electronic decision support interventions at ambulatory sites at Yale New Haven Hospital's Pediatric Primary Care Center and Pediatric Specialty Clinics in Connecticut and at Nemours Foundation primary care and specialty clinics in Florida and the Delaware Valley
- Evaluate the effectiveness of the decision support tools in improving the quality of health care at the chosen sites
- Disseminate the findings of the demonstrations in a variety of formats including direct recommendations to guideline developers and IT vendors.

This Project Plan describes in detail the objectives, goals, work plan, scope, project staffing and overall project management process and methodology for the project. It establishes the baseline information by which the project can be managed, tracked and evaluated.

Beginning in February 2008, four workgroups (Knowledge Transformation, YNHH Implementation, Nemours Implementation, and Evaluation) will convene under the direction of a Decision Support Council to plan and execute the proposed Project Plan. The project will receive national visibility through regular reports to AHRQ and its Project Advisory Committee, the Certification Commission for Health Information Technology, and national professional organizations that develop guidelines.

Richard Shiffman, MD, MCIS (Professor of Pediatrics and Associate Director of the Yale Center for Medical Informatics) serves as Project Director.

2. Project Plan

2.1 Objective and 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 will explore 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.

The GLIDES project team will develop, conduct and evaluate the implementation of clinical guidelines for Asthma and Pediatric Obesity in a total of six clinical sites, according to the following schedule:

Phase	Condition	Site	Implementation Preparation	Rollout
1	Asthma	Yale Specialty	June – September 2008	September 2008
2	Obesity	Yale Primary Care	October 2008 – February 2009	March 2009
		Nemours Delaware PC	October 2008 – February 2009	March 2009
	Asthma	Nemours Orlando	October 2008 – March 2009	March 2009 – April 2009
		Nemours Jacksonville	December 2008 – March 2009	April 2009
		Nemours Pensacola	December 2008 – March 2009	April 2009
3	Asthma	Yale Primary Care	June 2009 – September 2009	October 2009 – Nov 2009
		Nemours Delaware PC	June 2009 – September 2009	October 2009

Specific goals of the project are as follows.

2.1.1 Translation of Decision Support Guidelines Into Systems That Improve Delivery of Health Care

Development of CDS tools for use in electronic health records (EHRs), with emphasis on optimal methods of transforming the knowledge in clinical practice guidelines (CPGs) into systems that improve the delivery of health care:

- The GLIDES project has selected two evidence-based CPGs for Asthma and Pediatric Obesity, both of which are in the public domain and are described in detail in this Project Plan.
- These CPGs address both preventive services and appropriate clinical management of patients with chronic illnesses.
- The GLIDES project will demonstrate the best methods for translating guideline recommendations into electronic formats that can be accurately and effectively incorporated into CDS tools.

2.1.2 Identification of Methods and Processes For Incorporating CDS Tools Into EHRs

Identification of preferred methods and processes for incorporating CDS tools into EHRs and implementing them in busy practice settings:

- The demonstration projects will involve the implementation of CDS tools in two Certification Commission for Health IT (*CCHIT)* certified health IT products. The GE Centricity system is used at all Yale practice settings, and the EPIC Epicare system is used at Nemours.
- ANSI Health IT Standards Panel (*HITSP)* standards will be applied where available and applicable.
- This incorporation of CDS into multiple products will demonstrate cross-platform utility and will help to establish a wide range of best practices useful to the health IT vendor community.

2.1.3 Optimization Of CDS Tools For Measuring and Improving Quality of Care

Optimization of CDS tools for measuring and improving quality of care and providing performance feedback:

- The GLIDES Project Plan includes a proposal for evaluating the demonstrated work, which emphasizes assessing impact on the quality and efficiency of healthcare delivery.
- EHR systems in use at the demonstration sites have the capacity to facilitate quality measurement, especially in the clinical domains being tested.
- Other potential benefits of CDS systems on outcomes of care, including effects on patient satisfaction, efficiency, and quality of life, will also be considered by the GLIDES project.

2.1.4 Demonstrate and Evaluate Methods Of Using CDS Elements Across Multiple Clinical Sites

The GLIDES project will demonstrate and evaluate methods of creating, storing and replicating CDS elements across multiple clinical sites:

- The primary setting of the proposed demonstration project testing is ambulatory practices, in six different settings across the east coast of the United States. These practices cover a range of different types of ambulatory practices, enabling the project to test the generalizability of findings and products in multiple ambulatory settings.
- A critical component of the GLIDES project is the active involvement of stakeholders from multiple disciplines and from multiple healthcare groups whose needs can be addressed through CDS.

2.1.5 Evaluation and Dissemination Of Project Findings and Results

The GLIDES project will evaluate all critical work steps and work products to ensure the objectives and goals of the project are met, and will produce and distribute a series of reports consistent with AHRQ expectations to disseminate the project's results:

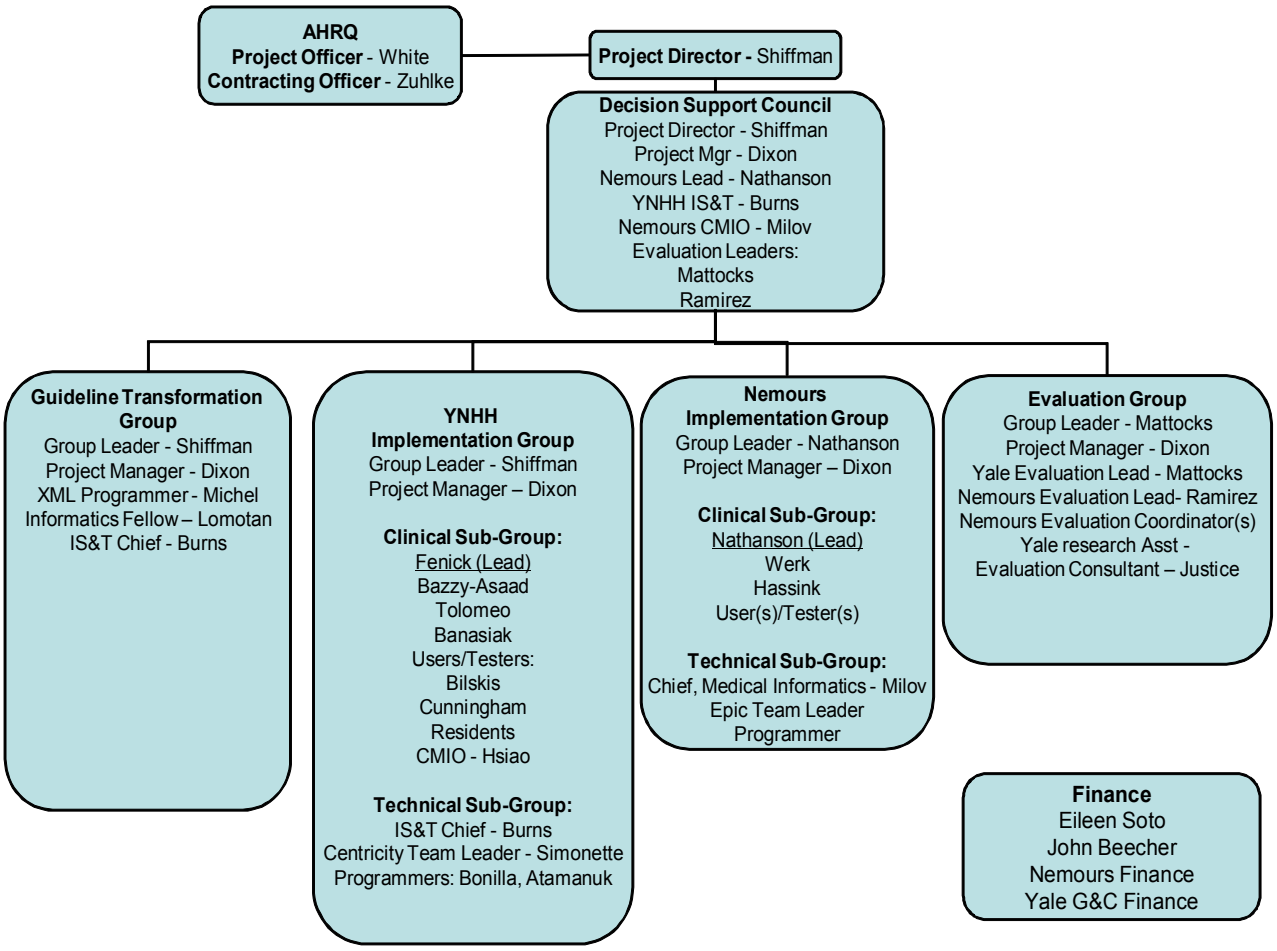
- CCHIT recommendations for certification of information systems in support of CDS.
- Interim and final recommendations to the general guideline development community, and to the developers of the specific guidelines used by the project, on best practices in guideline development regarding CDS translation and implementation.
- Prepare a final report of evaluation and findings, and present this at an AHRQ-convened conference as required by AHRQ.

2.2 Organization and Staffing

2.2.1 Project Organization

To accomplish the project objective and goals, the following project team structure and staffing will be established. This structure will remain in place until the completion of the project.

Section 2.2.2 provides a responsibility matrix showing how each project work group contributes to the attainment of the project objective and goals.



- Project Director: The Project Director is responsible for the planning, execution and day to day operation of the project, and is therefore accountable for the project team meeting its goals and objectives. The Project Director will be assisted in this role by a Project Manager who will be responsible to day to day project planning and management of the GLIDES project. The Project Director and Project Manager will be responsible for preparing the major report outputs of the project, and will also direct the Quality Assurance review program.

- Decision Support Council: The Decision Support Council (DSC) is the steering committee for the project. The DSC will monitor and review the design, development and implementation deliverables produced by the project workgroups to ensure that they are contributing to the successful attainment of the project's goals. The DSC will perform this role through regular oversight meetings, and will also support the Quality Assurance review work for the project, which is described in section 2.7.

- Guideline Transformation Group: The Guideline Transformation Group (GTG) is responsible for the translation of knowledge in clinical guidelines into computable formats. The GTG will apply the GuideLine Elements Model (GEM) and its related tools to transform the knowledge contained in the selected evidence-based clinical practice guidelines into a standardized format—i.e., XML based on the GEM Schema Standard (ASTM E2210-06). The tools the GTG will use are non-proprietary and will be made

available on the YCMI website. The GTG will carefully document progress, issues, and obstacles and use them to define a set of best practices which can be shared with the local implementation groups to ensure the best chance of effective implementation of the transformed knowledge in the local ambulatory systems and clinical workflows.

- Implementation Groups. The Implementation Groups (IGs), at both Yale and Nemours, will be responsible for incorporating the computable knowledge into the EHR systems in use at those sites, and for optimizing the tools for measuring and improving quality of care. The IGs will include Clinician Experts and other users as well as Information Technology specialists and Quality Management experts. The IGs will customize the implementation package prepared centrally by the GTG to tailor it to local workflows, systems and operating conditions. The IGs will work closely with the GTG to ensure that the local implementation does not deviate materially from the purpose and intent of the centrally prepared knowledge. The technical staff on the IGs will be responsible for preparing the CCHIT-related project reports.

- Evaluation Group: The EG will include representatives from both Yale and Nemours and will work with the GTG and IGs at all stages to collect and analyze data from the project. The EG will provide feedback to the Project Director, DSC and other workgroups regarding project successes and obstacles. The EG will be responsible for preparing the major evaluation report outputs of the project, and will also participate in the Quality Assurance review program.

2.2.2 Responsibility Matrix

Objectives and Goals	Program Director	Project Manager	DSC	GTG	IG – Yale	IG – Nemours	EG
Overall Objective: 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.	O	D	S	S	S	S	S
Goal 1: Translation of Decision Support Guidelines Into Systems That Improve Delivery of Health Care	O	D	S	R	P	P	E
Goal 2: Identification of Methods and Processes For Incorporating CDS Tools Into EHRs	O	D	S	P	R	R	E
Goal 3: Optimization Of CDS Tools For Measuring and Improving Quality of Care	O	D	S	P	R	R	E
Goal 4: Demonstrate and Evaluate Methods Of Using CDS Elements Across Multiple Clinical Sites	O	D	S	P	R	R	E
Goal 5: Evaluation and Dissemination Of Project Findings and Results	O	D	S	P	P	P	R

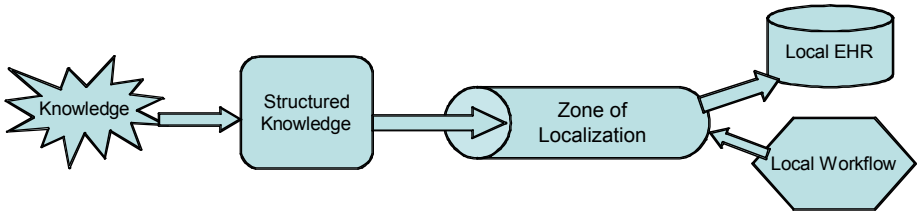
Legend
O = Overall responsible for ensuring objective/goal is met
D = Day to day responsibility for managing work to ensure objective/goal is met
R = Primarily responsible for performing the work to ensure objective/goal is met
P = Participates/supports work to ensure objective/goal is met
S = Responsible for QA, oversight and steerage of the work to ensure objective/goal is met
E = Responsible for evaluating and disseminating the project's results

2.3 Project Work Plan and Milestones

2.3.1 Project Methodology

The project timeline has been developed using an established methodology through which the clinical guidelines can be transformed into computable information, integrated into the ambulatory and EHR systems used within each clinical setting and used to inform and guide care delivery in these settings. The methodology is summarized in the following section, for both the pre-implementation knowledge transformation steps as well as the implementation activity at each demonstration site.

The diagram below explains the linkage between the pre-implementation and implementation phases. In the first phase, clinical knowledge is structured into a computable format. In the second phase, the structured knowledge is adjusted to operate within local practice technology and workflow arrangements. A major challenge of the project team is to ensure an appropriate balance between these two phases.



The methodology for accomplishing this balance is explained in the following tables. This methodology has been used to build the project work breakdown structure (WBS), GANTT chart and milestones in section 2.3.2.

Note: The EG will participate in and assess results in all stages of this work.

2.3.1.1 Knowledge Transformation Activities

Activity	Description	Work Groups	Notes
March 2008 – June 2008 During this phase, the GLIDES project team will apply the GuideLine Elements Model (GEM) and its related tools to transform the knowledge contained in the selected evidence-based clinical practice guidelines into a standardized format—i.e., XML based on the GEM Schema Standard (ASTM E2210-06). The tools the project team will use are non-proprietary and will be made available on the YCMI website. We will carefully document progress, issues, and obstacles and use them to define a set of best practices. This suite of activities will be performed for both the Asthma and Obesity guidelines.			
i. Mark up Selected Guidelines Using GEM Cutter II	GEM Cutter II accepts as input a guideline text file. Users mark up the file, classifying guideline text into appropriate elements of the standardized GEM II hierarchy	GTG	Output is a standard XML file that comprises information critical for implementation: - The guideline's intended audience - The target population of patients - The recommendations themselves including decision variables - The reason(s) for making the recommendation

Activity	Description	Work Groups	Notes
ii. Submit Guideline's GEM file to GEM-COGS Transform	Facilitate an appraisal of the guideline's quality. The Transform displays the Conference on Guideline Standardization checklist accompanied by pertinent text from the marked up-guideline (if present).	GTG	Users can judge how well the guideline text meets COGS criteria for quality and usability (see Appendix for sample report).
iii. Appraise Guideline Implementability (GLIA)	Prepare the implementation teams for challenges intrinsic to the selected guideline recommendations and contribute to the documentation in support of the implementation.	GTG	GLIA highlights obstacles that may be anticipated when the guideline and recommendation are operationalized, including problems in - Decidability - Executability - Effect on process of care - Presentation and formatting - Measurable outcomes - Apparent validity - Novelty/innovation - Flexibility - Computability
iv. Apply EXTRACTOR transforms to the GEM files	EXTRACTOR is a set of Web-based XSLT transforms that are designed to automate the process of extracting this implementation-critical information from marked up guidelines.	GTG	The EXTRACTOR transforms create a list of decision variables and actions for each recommendation. When "extracted" from context, it often becomes clearer which decision variables are vague, underspecified, or ambiguous. EXTRACTOR also highlights missing information that must be filled in locally by Clinical Experts. By cataloging and documenting these circumstances, we will provide feedback to guideline development teams about content that is critical for implementation but missing from the published guideline.
v. Adjust Level of Abstraction	Improve the decidability and executability of the recommendation statements. Clinical experts on the team will help to assure that the original intended meaning of the terms is not distorted	GTG IGs	A careful record of modifications will be logged and reviewed by an independent team of clinical experts to assure that the meaning of the implemented recommendation is consonant with the published text.
vi. Restate in Human-Readable Statement Logic	Each recommendation will be restated in human-readable statement logic that can be translated readily into computable statements	GTG	A limited number of logical operators (AND, OR, NOT, IF…THEN, GREATER/LESS/EQUAL, and parentheses) has proven sufficient to express individual guideline recommendations.
vii. Categorize Action-Types	Help select replicable patterns for implementation.	GTG	The activities associated with each of these action-types involve patterns

Activity	Description	Work Groups	Notes
	Recommendations call for a relatively small set of recurring activities (action-types).		that are useful in regimenting the translation of guideline recommendations into computer-based decision support tools. Importantly, recommendations NOT to perform any of these action-types call for different patterns of activities.
viii. Map Concept Codes	Map concept codes for each eligibility criterion, decision variable, and action in relevant controlled vocabularies, e.g., SNOMED, LOINC and RxNORM.	GTG	Terminology used by authors in the guideline document often does not match concept codes in controlled vocabularies. We will document and submit unmatched concepts to the curators of each vocabulary for future inclusion.
ix. Add Critical Terms To Recommendation Glossary	Critical terms will be added to a recommendation glossary with precise definitions supplied by the clinical experts.	GTG	We have noted a need for precise definitions of both domain-specific terms as well as common words (e.g., "routine," "severe") as applied in a particular guideline context if accurate
x. Classify Each Recommendation By Clinical Objective	Classify each recommendation by clinical objective, describing the goals to be targeted.	GTG	Osheroff and colleagues have noted that the objective class is useful in choosing specific types of clinical decision support interventions.

2.3.1.2 Local Implementation Activities

Activity	Description	Work Groups	Notes
Phase 1: June–October 2008; Phase 2: October 2008– June 2009; Phase 3: June–November 2009 The next steps will address selecting specific decision support interventions and defining detailed specifications. We will explore the tension that exists between the work in guideline transformation that can be performed centrally (e.g., by guideline developers) and that which must occur locally. Often referred to as "the curly braces issue," there is *a zone of localization* in which central specification and knowledge structuring must interact with local standards and workflow without undermining the intent of the guideline authors. The Evaluation Group will carefully monitor and document these activities in the zone of localization. Documentation created in the Transformation activities will be delivered to the local Implementation Groups who are responsible for implementation at the clinical sites. The Implementation groups will include Clinician Experts and other users as well as Information Technology specialists. At each implementation site, members of the Implementation Group will customize the centrally prepared implementation package, for each recommendation to:			
i. Choose Recommendations To Implement	Specific guideline transformation recommendations will be reviewed and selected for implemented.	GTG, IGs	Recommendations will be selected that both support the project's goals and also address local clinical needs.
ii.Define Local Workflow (for each	Specifically characterize when—in the course of longitudinal health care—	IGs	There is a need for principled methods to overcome the disconnect between the EHR representation of

Activity	Description	Work Groups	Notes
recommendation)	values for the decision variables become available and when—in the course of clinical interactions—it is appropriate for the guideline-prescribed actions to occur.		time-oriented clinical data and corresponding knowledge of domain-relevant concept. For ambulatory care, Osheroff et al. have proposed temporal categories: pre-visit, arrival check-in, start of visit, results arrival, documentation, ordering, medication administration, and post visit. We will evaluate the usefulness of this classification system in our demonstrations and augment as necessary.
iii. Define Intervention Triggers	Define how the intervention is to be triggered.	IGs	Several questions will be addressed, for example: when in the course of longitudinal health care at a particular site are *all* the decision variables likely to be satisfied? What will be the source of the data (e.g., online registration information or laboratory reports, patient-entered history, clinical data recorded in the electronic health record, clinician documented findings)? What *event*(s) will trigger the decision support intervention?
iv. Map Guideline-Related Concepts to Local Codes	Concepts that were previously defined in the glossary and translated to standardized vocabulary concepts will next be matched to the specific vocabularies used by the GE and Epic systems.	IGs	Document and compare the applicability and accuracy of the controlled vocabulary terms vis-à-vis the original guideline language in mapping to local codes.
v. Choose Appropriate Decision Support Interventions	Interventions include (but are not limited to):Documentation templates; assessment forms for completion by patients, paraprofessionals, clinicians; Data flowsheets (combination of data display and data form entry); Presentation of relevant data for documentation or ordering; Choice lists; Order sets; Tools for complex ordering including guided dose algorithms, calculators; Context sensitive links to knowledge sources (infobuttons); Encounter-linked reminders;	IGs	Each of these decision support interventions differs in its appropriateness for use in a specific circumstance, ease of development, acceptability to the intended user population, and anticipated impact on health care. Selection of an appropriate intervention for a given recommendation must take these factors into account. We will document the selection process.

Activity	Description	Work Groups	Notes
	Dynamically-generated alerts		
vi. Document Intervention Specification Form	Document an Intervention Specification Form to summarize relevant considerations. We will modify a worksheet form, partially pre-populated by an EXTRACTOR Transform developed for that purpose.	IGs	Additional details will be added by local teams to document: (1) Clinical objective; (2) Desired action; (3) Baseline performance; (4) Desired outcome; (5) Origin of data necessary for performance (workflow step); (6) Selected decision support intervention; (7) Approach; (8) Target population; (9) User interface; (10) Primary stakeholders; (11) Clinical champion; (12) Potential adverse consequences, and other relevant documentation.
vii. Design and Programming	Using the documentation provided and EHR-specific programming tools, the teams will create a variety of decision support interventions appropriate to the information being delivered and the assessed workflow patterns.	IGs	Local Information Systems Teams at each site have accumulated considerable expertise in programming and incorporating decision support into their respective EHR systems. The systems have been widely deployed for at least 7 years at both Yale and Nemours.
viii. Testing	Each proposed intervention will undergo unit testing of each software module and integration testing to highlight potential defects in the interfaces and interactions between modules to assure conformance with the specification.	IGs	The accuracy of the decision support interventions will be verified using test scripts that exercise the software, particularly at extremes of decision variable content. Members of each user community will participate as testers to judge the usability and acceptability of each intervention. An iterative process of programming refinement is anticipated.
iv. Rollout.	Identify clinical users (physicians and nurses) at each site who are regarded as leaders by their peers. Presentations will be made to staff members at each site that describe the importance and “mechanics” of each intervention. We will make documentation available before training sessions and train “trainers” who practice at each site. Information Systems personnel will work collaboratively with the users during rollout.	IGs	Implementation teams at each site have extensive experience in training and response to their users’ needs. Upper level management will endorse the proposed interventions.
v. Monitoring and	Each implementation Group	IGs	Feedback channels will be

Activity	Description	Work Groups	Notes
Support	will maintain close contact with their user communities to determine needs for corrective, perfective, or adaptive maintenance and to identify any unintended consequences of these interventions.		incorporated to assure that users can communicate effectively with both the Implementation Group and the Decision Support Council.

2.3.2 Gantt Chart Summary

The summary project Gantt chart is included in this section. The detailed project Gantt chart is included at attachment G of the Project Plan.

2.3.3 Critical Activities and Milestones

Activity/*Milestone*	**Start Date**	**End Date**
Project Planning		
Review Project Plan with DSC/IGs	2/19/08	2/22/08
QA Checkpoint #1: Project Plan Review	*2/22/08*	*2/22/08*
Distribute Project Plan to AHRQ – DELIVERABLE 1	*2/29/08*	*2/29/08*
Project Plan Review With PO - DELIVERABLE 2	3/17/08	3/18/08
Final Workplan Approved - DELIVERABLE 4	*4/3/08*	*4/3/08*
Guideline Transformation		
Transform Asthma Guideline	3/3/08	4/25/08
QA Checkpoint #2: Review Guideline Transformation	*4/25/08*	*4/25/08*
Transform Obesity Guildeline	4/28/08	5/23/08
QA Checkpoint #3: Review Asthma Guideline Transformation	*5/23/08*	*5/23/08*
Phase 1 Implementation – Yale Asthma		
Local Workflow Design	6/3/08	7/1/08
Review/Validate Design	7/2/08	7/4/08
QA Checkpoint #4: Review Local Work Flow Design	*7/4/08*	*7/4/08*
System Design/Programming/Testing	7/7/08	9/12/08
Training	9/15/08	9/19/08
Rollout	9/15/08	9/26/08
Identify/Address Issues	9/29/08	10/3/08
QA Checkpoint #5: Review Phase 1 Results	*10/3/08*	*10/3/08*
Revise Plan For Phase 2	10/6/08	10/10/08
Meet PO and Key Stakeholders	10/13/08	10/14/08
Review/Revise plan For Phase 2	10/15/08	10/21/08
Phase 1 Implementation Complete	*10/28/08*	*10/28/08*
Phase 2 Implementation: Obesity		
Local Workflow Design – Delaware PCC	10/30/08	12/1/08
Review/Validate Design	12/2/08	12/5/08
Local Workflow Design – Yale PCC	10/30/08	12/10/08
Review/Validate Design	12/11/08	12/16/08
QA Checkpoint #6: Review Obesity Local Workflow Design	*12/16/08*	*12/16/08*
System Design/Programming/Testing	12/17/08	2/24/09
Roll-Out	2/25/09	3/17/09
Phase 2 Implementation: Asthma		
Local Workflow Design – Orlando	10/30/08	11/26/08
Review/Validate Design	11/27/08	12/3/08
Local Workflow Design – Jacksonville	12/4/08	1/7/09
Review/Validate Design	1/8/09	1/14/09
Local Workflow Design - Pensacola	12/4/08	12/31/08
Review/Validate Design	1/1/09	1/7/09
QA Checkpoint #6: Review Asthma Local Workflow Design	*1/7/09*	*1/7/09*

System Design/Programming/Testing	1/15/09	3/25/09
Roll-Out	3/26/09	4/29/09
Phase 2 Implementation: Review		
Identify/Address Issues	4/30/09	5/27/09
QA Checkpoint #7: Review Phase 2 Results	*5/27/09*	*5/27/09*
Revise Plan For Phase 3	5/28/09	6/3/09
Meet PO and Key Stakeholders	6/4/09	6/5/09
Review/Revise plan For Phase 3	6/8/09	6/12/09
Phase 2 Implementation Complete	*6/12/09*	*6/12/09*
Phase 3 Implementation: Asthma		
Local Workflow Design – Delaware PCC	6/15/09	7/15/09
Review/Validate Design	7/16/09	7/21/09
Local Workflow Design – Yale PCC	6/15/09	7/17/09
Review/Validate Design	7/20/09	7/23/09
QA Checkpoint #8: Review Asthma Local Workflow Design	*7/23/09*	*7/23/09*
System Design/Programming/Testing	7/24/09	10/1/09
Roll-Out	10/2/09	11/5/09
Identify/Address Issues	11/6/09	11/12/09
QA Checkpoint #9: Review Phase 3 Results	*11/12/09*	*11/12/09*
Phase 3 Implementation Complete	*11/16/09*	*11/16/09*
Evaluation		
Evaluation Planning and Preparation	2/18/08	6/19/08
Collect Data on Process and Outcomes	6/20/08	8/13/08
Perform Online Clinician Survey	8/1/08	9/15/08
Analyze Data on Process and Outcomes	7/1/09	9/1/09
Prepare Reports on Process and Outcomes	9/2/09	11/24/09
Dissemination		
Initial CCHIT Recommendations - DELIVERABLE 7	9/1/08	9/26/08
Interim Report - DELIVERABLE 8	1/1/09	1/28/09
Final CCHIT Recommendations - DELIVERABLE 9	6/2/09	6/29/09
Draft Final Report - DELIVERABLE 10	12/1/09	12/28/09
Prepare Final Report - DELIVERABLE 11	1/1/09	1/28/09
QA Checkpoint #10/Close-Out	*1/28/10*	*1/28/10*

2.5 Scope

2.5.1 Clinical Guidelines

Selection of the guidelines whose knowledge is to be transformed and the specific recommendations that will be implemented represents the first critical task in this project. Pending approval by the Project Officer we have selected two guidelines that satisfy the constraints of this RFP (evidence-based; public domain; not yet translated into broadly available decision support tools; cover preventive services and clinical management of common chronic illnesses):

1. Screening and interventions for overweight in children and adolescents from the Expert Committee on the Assessment, Prevention, and Treatment of Child and Adolescent Overweight and Obesity, convened by the American Medical Association, the DHHS Health Resources and Services Administration, and the Centers for Disease Control and Prevention. The current epidemic of adult obesity and its attendant morbidities and mortality has its onset in the pediatric age group. Weight-related hypertension, type II diabetes, hyperlipidemia, sleep disorders, and overweight-related orthopedic problems are now within the province of pediatrics. Effective recognition of and intervention against overweight and obesity can be expected to have major positive public health consequences.

2. The recently released guidelines on management of asthma from the National Asthma Education and Prevention Program of the National Heart Lung and Blood Institute. Asthma is one of the most common chronic diseases of childhood, affecting 6.2 million children (National Health Interview Study 2004) and accounting for almost one half million hospitalizations annually. In addition to its considerable morbidity, more than 4000 people die of asthma each year. This guideline revision includes recommendations regarding diagnosis, control of environmental factors, acute management of exacerbations, chronic management, and patient education and represents a superb example of the challenges that are involved in analysis and implementation of guidelines for chronic management of complex disease. Because limited decision support based on the current guideline already exists at Yale, implementation of the forthcoming revision will require particular attention to knowledge and system maintenance in the face of new statements about best practice.

The relevant guideline sections for the project are included at attachment H.

Discussions at the selected demonstration sites have confirmed that quality improvement initiatives in prevention of pediatric overweight and obesity and chronic management of asthma would be well received. Decision support is most effective when it is responsive to such local needs. The two guidelines are expected to impact on:

- Quality, safety, and cost-effectiveness of care at the patient level
- Regulatory compliance and resource use at the organization level
- Areas of considerable interest to practicing clinicians
- The existing gap between current and desired levels of care.

In selecting these guidelines, we have also aimed to identify guidelines that will provide common implementation challenges, including:

- Recommendations that contain vague, underspecified, and ambiguous language
- Recommendations that fail to include recommendation strength (an indication by the developer of expected adherence level and a concept distinct from evidence quality)
- Recommendations illustrating a range of action-types
- Recommendations "not" to perform, i.e., recommendations of omission as well as commission
- Recommendations that are difficult to identify as such, including recommendations delivered as statements rather than as prescriptions for appropriate care.

We plan to address the challenges directly and will provide feedback about them to guideline developers, health IT vendors, and other stakeholders.

2.5.2 Clinical Locations

Members of the IGs will implement the decision support intervention within the functioning electronic health record system at clinical sites in three phases. Selection of the phases and implementation sites has been performed to meet the following AHRQ expectations:

In the first phase, we will implement CDS for Asthma in one initial location – Yale Specialty clinic. Based on that, we will identify and address issues, then revise the plan for next phase. We will meet in person with the AHRQ Project Officer and key stakeholders to review progress and findings to date, and solicit feedback. Based on that feedback we will review, revise and seek PO approval of the plan for the second phase.

In the second phase, we expect to implement CDS for Obesity at Yale Primary Care and Delaware Primary Care, and for Asthma at Nemour's Jacksonville, Orlando and Pensacola facilities. Following this implementation, we will also identify and address risks, and review status with the Project Officer and key stakeholders before finalizing the plan for the final phase of implementation.

In the third and final phase, we expect to implement CDS for Asthma at Yale Primary Care and Delaware Primary care.

This implementation locations and phasing are summarized in the table below:

Phase	Condition	Site	EHR System
1	Asthma	Yale Specialty	GE Centricity
2	Obesity	Yale Primary Care	GE Centricity
		Nemours Delaware PC	EpicCare
	Asthma	Nemours Orlando	EpicCare
		Nemours Jacksonville	EpicCare
		Nemours Pensacola	EpicCare
3	Asthma	Yale Primary Care	GE Centricity
		Nemours Delaware PC	EpicCare

Asthma interventions will be developed for both specialty and primary care clinicians, while obesity prevention will focus on primary care. Beginning at the Orlando and Yale Specialty Clinic sites with asthma interventions will offer the most controlled environments for testing the interventions. These sites also have a record of innovation and a high likelihood of initial success. Asthma (in Florida) and obesity interventions in New Haven and Delaware Valley will follow. We anticipate that the primary care clinics will require different asthma

interventions from those planned at the specialty sites. In Phase 3, we will introduce asthma interventions in the primary care sites.

We believe this implementation plan will enable us to operationalize a replicable process for implementation at a wide variety of implementation sites that should demonstrate the external validity of the project's findings. Relevant characteristics of the sites are:

- Yale Primary Care Center is an academic, inner city, ambulatory care center that serves a low-income, multi-ethnic, Medicaid and uninsured population with generally low levels of healthcare literacy. Clinicians in training there (residents and nurse practitioners) will take skills in interaction with clinical decision support tools to geographically dispersed primary care and specialty practices when they finish their training.

- The Pediatric Specialty Center at Yale Children's Hospital sees children in referral from a wide range of socioeconomic segments. It is manned by academic pediatric subspecialists, postdoctoral fellows, and advanced practice RNs.

- The Nemours multi-specialty centers in Orlando, Jacksonville, and Pensacola each has a unique culture and flavor. Community-based sub-specialists provide care to a wide spectrum of patients including both those with private insurance and Medicaid coverage.

- The 41 pediatricians and 11 APRNs who practice in the 14 Delaware Valley Nemours-affiliated primary care practices cover a broad geographic area and their patients span a wide demographic range.

We believe that a clinician's employer reflects on resource availability for acquisition of EHR systems. But the issues of effective implementation of decision support and adherence to guideline recommendations cross these lines. Incentive programs that require effective practice improvement (such as pay for performance) affect academic and multi-specialty groups as well as small privately owned practices. Therefore we anticipate applicability of our findings to a broad range of American healthcare providers.

2.5.3 Evaluation Plan

The Evaluation Plan for the GLIDES project is outlined below. These activities have been included in the project schedule.

Task	Start	Duration	Product
Perform literature review on asthma, obesity and DSS	2/18/08	3/3/08	Lit review
Define ascertainable pre-implementation variables Define post-implementation variables	2/18/08	3/17/08	Variables list
Design evaluations of process (and outcome) variables Yale PCC Yale Specialty Clinics Nemours Florida Nemours Delaware Valley	2/18/08	3/17/08	Variables list
Create online clinician satisfaction survey	3/17/08	4/1/08	Survey
Prepare Paperwork Reduction Act material	4/1/08	5/1/08	Application
Prepare HIC Yale Nemours	 4/1/08 4/1/08	 5/1/08 5/1/08	HIC application (Yale) HIC Application (Nemours)

Task	Start	Duration	Product
Submit and revise as needed			
Create Use and Usability Logs Install logs	5/1/08 6/1/08	6/1/08 6/15/08	Logs
Collect data on process and outcomes Design and test queries Extract Information	7/1/08	8/24/09	Raw data
Analyze data on process and outcomes	7/1/09	9/1/09	Statistical analyses
Prepare reports on process and outcomes	9/1/09	10/1/09	Reports
Perform online clinician survey Analyze data Prepare report	8/1/08	9/15/09	Survey results Satisfaction report

Evaluation reporting will consider those areas identified in the contract:

Issues related to guideline development, CDS implementation and clinical outcomes. For guideline development, evaluation topics should include (but are not limited to):

- How should guidelines be better written to be actionable?
- How can IT enable guideline adherence? What should guidelines include to make that happen?
- How can this be done in a replicable way across IT platforms?

The clinical subject areas of prevention and multiple chronic illness and improved care delivery should be addressed, including how best to achieve the desired results in these areas.

The current state of health IT will be addressed, including barriers and potential solutions to use of CDS to improve the quality of healthcare. Examples of potential questions include:

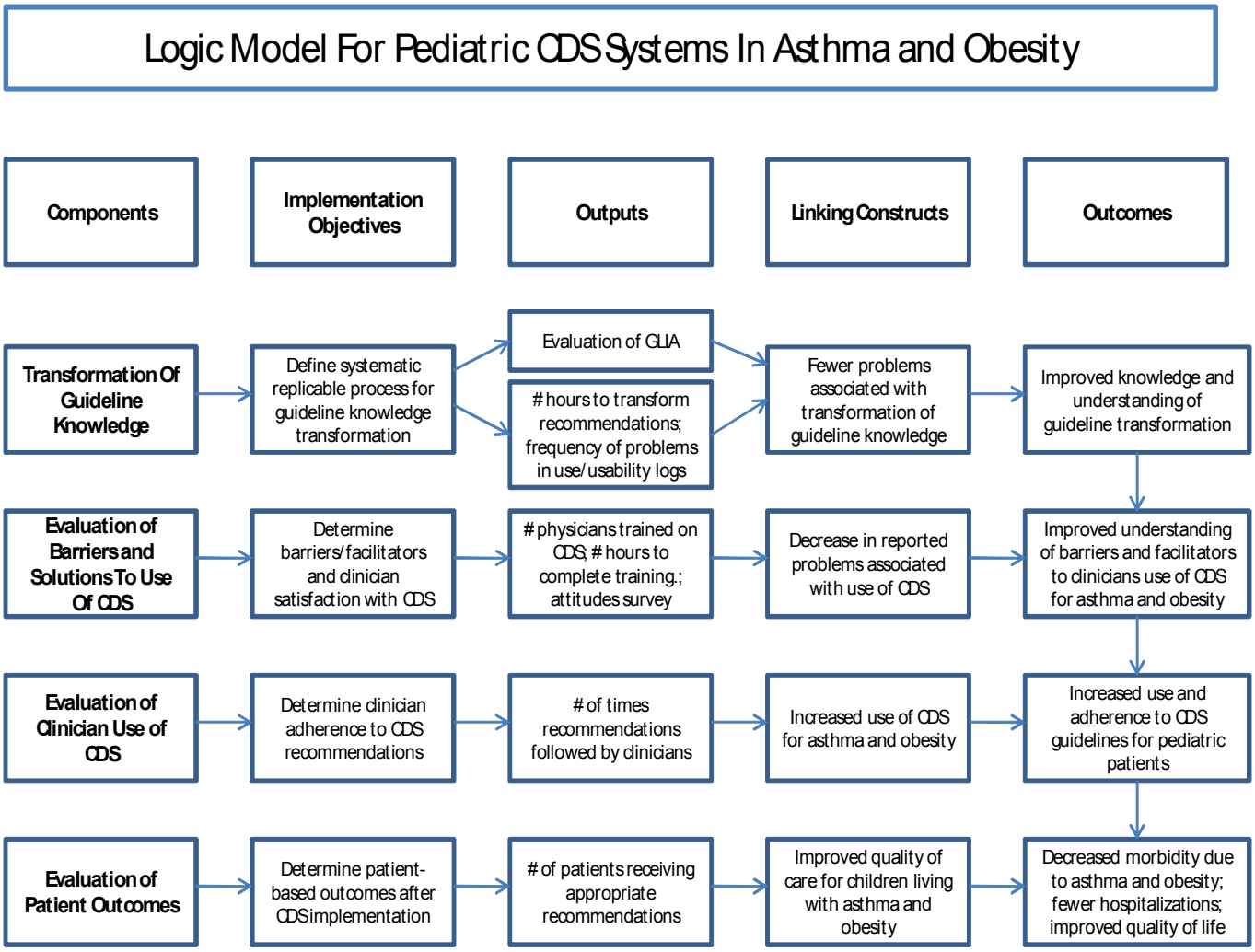
- What do all IT vendors need to do to incorporate CDS?
- What do the specific vendors involved in the demonstration need to do to improve CDS in their products?
- What are the best CDS modalities?

Clinician use of CDS will be evaluated. Potential topics include:

- Effectiveness
- Efficiency
- Clinician satisfaction
- Clinician and setting characteristics that affect successful adoption of CDS

Patient outcomes shall also be evaluated. Topics of interest include clinical outcomes and patient satisfaction (use of the CAHPS survey is recommended). Quality measurement of the demonstration's clinical topics using the proposed interventions should also be addressed.

The logic model for the evaluation of pediatric CDS systems in asthma and obesity is shown on the following page.


Logic Model For Pediatric CDS Systems In Asthma and Obesity
Components
Implementation Objectives
Outputs
Linking Constructs
Outcomes
Transformation Of Guideline Knowledge
Define systematic replicable process for guideline knowledge transformation
Evaluation of GLIA
hours to transform recommendations; frequency of problems in use/usability logs
Fewer problems associated with transformation of guideline knowledge
Improved knowledge and understanding of guideline transformation
Evaluation of Barriers and Solutions To Use Of CDS
Determine barriers/facilitators and clinician satisfaction with CDS
physicians trained on CDS; # hours to complete training.; attitudes survey
Decrease in reported problems associated with use of CDS
Improved understanding of barriers and facilitators to clinicians use of CDS for asthma and obesity
Evaluation of Clinician Use of CDS
Determine clinician adherence to CDS recommendations
# of times recommendations followed by clinicians
Increased use of CDS for asthma and obesity
Increased use and adherence to CDS guidelines for pediatric patients
Evaluation of Patient Outcomes
Determine patient-based outcomes after CDS implementation
# of patients receiving appropriate recommendations
Improved quality of care for children living with asthma and obesity
Decreased morbidity due to asthma and obesity; fewer hospitalizations; improved quality of life

2.5.4 IT Products

2.5.4.1 System Overview

Two systems groups will be used to transform and deliver the guideline information in machine readable format.

- Guide Lines Elements Model (GEM) is an XML-based document model that employs a multi-level hierarchy to store the heterogeneous kinds of information contained in clinical practice guidelines. This information includes identification of the guideline's developer, description of the development process, definition of the guideline's purpose, the intended audience, the target patient population, and a detailed model of the recommendations themselves. The hierarchy contains more than 100 semantic tags by which guideline information can be classified (marked up) and modeled at varying levels of abstraction. GEM was conceived and built in XML—and therefore can take advantage of each of the emerging XML-related technologies. GEM facilitates translation of guideline information and knowledge into a format that can be processed by computers while remaining readable by humans. In 2002, ASTM International first approved the GEM Document Type Definition as a *standard representation* for guidelines using XML. In December 2006, a revised guideline document model in XML Schema format was successfully balloted and became ASTM Standard E2210-06.

- The guideline knowledge will be implemented via electronic decision support interventions at ambulatory sites that employ CCHIT- certified, widely-used electronic health record systems. We will implement systems at Yale New Haven Hospital's (YNHH) Primary Care Center and Yale Specialty Clinics in Connecticut and at Nemours Foundation primary care and specialty clinics in Florida and Delaware Valley. Both YNHH and Nemours have implemented commercial ambulatory electronic health record (EHR) systems and have in-house Information Technology groups that have accumulated considerable experience in programming and implementing decision support functionality within their commercial EHR systems. YNHH has installed Centricity EMR (GE Medical Systems, Fairfield, Conn.) in New Haven and Nemours uses EpicCare (EPIC Systems Corp., Madison, Wisc.) throughout its enterprise. Both are CCHIT-certified, vendor-supplied systems and together these systems account for a substantial number of installed sites in North America. Both Epic and GE have expressed an interest in our work and we will maintain interpersonal communication with executives at both companies. Our reports to the Certifying Commission on Health Information Technology will assure that the vendor community-at-large is aware of both our difficulties and successes.

2.5.4.2 System Development and Testing

Knowledge Transformation work using GEM will be performed at Yale School of Medicine in New Haven, CT.

Local Information Systems Teams at each site have accumulated considerable expertise in programming and incorporating decision support into their respective EHR systems. The systems have been widely deployed for at least 7 years at both Yale and Nemours. Using the documentation provided from Transformation and EHR-specific programming tools, the teams will create a variety of decision support interventions appropriate to the information being delivered and the assessed workflow patterns.

Before deployment, each proposed intervention will undergo unit testing of each software module and integration testing to highlight potential defects in the interfaces and interactions between modules to assure conformance with the specification. The accuracy of the decision support interventions will be verified using test scripts that exercise the software, particularly at extremes of decision variable content. Members of each user community will participate as testers to judge the usability and acceptability of each intervention. An iterative process of programming refinement is anticipated.

2.5.4.3 GEM System Overview

GEM Tools – System Facts	
System Name	**GEM II**
System Vendor	**Yale Center for Medical informatics (YCMI)**
Key System Capabilities	Representation and manipulation of clinical knowledge derived from clinical practice guideline documents
CCHIT Certification Status	N/A
Hardware	N/A
Operating System	Windows, Macintosh, Unix
Database	N/A
Language	XML, JAVA
User Interface	N/A
Connectivity/ Networking	N/A
Data Center Hosting	YCMI
Disaster Recovery Arrangements	Regular on-site and off-site backups

2.5.4.6 YNHH Ambulatory/EHR Systems

The Yale ambulatory sites in New Haven use Centricity EMR (formerly called “Logician”). The Pediatric Primary Care Center (PCC) and its contiguously located Adolescent Clinic provide primary care, preventive services and illness care to approximately 8000 pediatrics patients. Seven years ago, the Logician Electronic Health Record System (now Centricity) was implemented for all patients, resulting in paperless charting.

The Pediatric PCC has 34 workstations located at check-in and throughout the clinical areas. Clinicians, social workers, and administrative staff do all clinical charting electronically. Results reporting and appointment look-up functions have been integrated into the Centricity system.

Yale New Haven Hospital Information Systems and Technology Group and YNHH leadership have recognized that information technology is key to improving processes that lead to better outcomes. The Hospital has installed inpatient computer-based order entry, PACS, and laboratory results reporting. Since 2000, the Centricity system has been the sole mediator of clinical documentation in the Hospital’s ambulatory clinics, including Pediatric and Adult Primary Care Centers, the Women’s Center, and the Adler Geriatric Center.

Based on the clinic and clinical need, each implementation has been customized. What prevails over all clinic implementations is documentation. The ability to work within a single patient chart and document episodes of care across clinics has been accomplished. Clinical documentation includes problems, Medications and allergies.

In addition, office notes are documented for all visits and used to generate handouts, referrals and patient information (back to school notices, camp forms etc.).

With a depth of clinical data residing in CEMR, reporting has been the growing effort. Report requests serve both clinical and research needs across all the clinics.

Centricity - System Facts	
System Name	**Centricity EMR**

Centricity - System Facts	
System Vendor	**GE Healthcare**
Key System Capabilities	• Registration/Scheduling • Orders • Results • Clinical documentation (problems, Medications, allergies, flow sheets) • Referrals • Patient educational information • Reporting
CCHIT Certification Status	CCHIT confirms that GE Centricity is certified for the 2007 standards
Other Related Systems	N/A
Hardware	Intel servers
Operating System	Windows 2000
Database	ORACLE database with intersystems CACHE
Language	CACHE ObjectScript and Visual Basic
User Interface	Windows GUI client run via CITRIX
Connectivity/ Networking	CEMR is installed on both a fat client workstation and Citrix platform
Data Center Hosting	Yale New Haven Health hosts the CEMR database
Disaster Recovery Arrangements	CEMR is configured within a clustered server environment running Oracle failsafe.

2.5.4.7 Nemours Ambulatory/EHR Systems

The Nemours ambulatory sites in Florida and the Delaware Valley use EpicCare. Nemours Children's Clinic purchased an Enterprise license from Epic systems Corporation in 2006, having previously licensed various modules form Epic on as needed basis. Nemours relationship with Epic began in 1998 with the Ambulatory documentation product. Since then Nemours has systematically augmented the system for pediatric specialty care. In addition to developing internal expertise with these products, Nemours has noted a particular cultural affinity between our organizations, increasing organizational expertise in the maintenance and customization of the application for pediatric specialty use. The Enterprise license affords the licensee rights to implement all products from Epic Systems Corporation

Nemours has chosen to implement Epic upgrades annually during the first week in May. Versions are, by choice, one year in arrears. We will upgrade to the Spring 2007 version in May 2008 to permit incorporation of field tested software while maintaining negotiated "good maintenance" discounts from the vendor.

Currently, more than 400 physicians document outpatient and inpatient medical information into the EHRs, with more than six years of historical data at approximately 20 locations. The electronic medical record systems are housed in secure environments that provide protection from natural disasters and prevent external tampering. System wide, the Nemours electronic health record houses approximately 870,000 patient records in a robust data warehouse. Since January 2007, the Nemours EHR can be accessed by 139 referring primary care physicians through NemoursLink.

EpicCare - System Facts	
System Name	**EpicCare**
System Vendor	**EpicCare Spring 2007 Version**
Key System Capabilities	• Registration *(Prelude Enterprise):* Epic's registration application • Scheduling *(Cadence Enterprise):* Epic's scheduling application

EpicCare - System Facts	
	• Epic Clinicals: o EpicCare Ambulatory: Epic's ambulatory electronic medical record product, or the Epic division that produces this product o OpTime Epic's operating room management product. o MyChart: Patient portal. Epic's application that allows patients to view their records over the Internet o EpicCare Link: A Web application that allows providers at an affiliate organization to view a patient's clinical data from Epic via the Internet. o EpicWeb: Ubiquitous web access. A Web application that allows providers to view and act on a patient's chart via the Internet o Radiant : Epic's Radiology information system o Epic UserWeb: Online forum for sharing information between Epic and our customers and among Epic customers. o KidShare: The Epic Pediatric Collaborative. KidShare is a group of Epic Pediatric Customers who share best practices and clinical content. • Billing (Professional Billing Resolute) • Billing (Hospital Billing Resolute) • ADT (Hospital Admissions, Discharges, Transfers)
CCHIT Certification Status	CCHIT confirms that EpicCare Ambulatory EMR Spring 2006 from Epic is a CCHIT Certified Ambulatory EHR product for 2006. CCHIT confirms that EpicCare Ambulatory EHR Spring 2007 from Epic Systems Corporation is a CCHIT Certified Ambulatory EHR product for 2007.
Other Related Systems	Nemours has an integrated data warehouse system that stores and updates data from billing, EHR and general ledger systems throughout the organization. Statistical and reporting software is available for data retrieval and analysis purposes.
Hardware	The database system runs on an IBM RS6000 running AIX. The client end is served via 50 CITRIX based servers. There are also about 225 full client installs on PCs.
Operating System	Database - AIX, CITRIX - Windows 2000/2003
Database	Intersystems CACHE
Language	CACHE ObjectScript and Visual Basic
User Interface	Windows GUI client run via CITRIX
Connectivity/ Networking	Multi-site WAN connected via high speed Metro Ethernet connections. Internal to sites on the LAN is 100Mbps and 1Gbps connectivity
Data Center Hosting	Enterprise systems are located within our suite at the AITC co-location facility in Jacksonville. In Wilmington, we have a newly constructed data center within the hospital grounds.
Disaster Recovery Arrangements	Within the data center, we have in some cases triple redundancy. We do have local hardware failover for much of the system design. In addition, we replicate the SAN traffic to the WLM data center for offsite redundancy and can start the Epic application in WLM in the event of a catastrophic disaster.

2.5.5 CDS Intervention Modalities

After selecting which recommendations will be implemented, we will choose appropriate decision support interventions for each recommendation. Such interventions include (but are not limited to):

- Documentation templates
- Assessment forms for completion by patients, paraprofessionals, clinicians
- Data flow sheets (combination of data display and data form entry)
- Presentation of relevant data for documentation or ordering
- Choice lists
- Order sets
- Tools for complex ordering including guided dose algorithms, calculators
- Context sensitive links to knowledge sources (info buttons)
- Encounter-linked reminders
- Dynamically-generated alerts

Each of these decision support interventions differs in its appropriateness for use in a specific circumstance, its ease of development, its acceptability to the intended user population, and its anticipated impact on health care. Selection of an appropriate intervention for a given recommendation must take these factors into account. We will document the selection process.

2.5.6 Dissemination Reports

Consistent with the AHRQ contract, the following additional reports will be produced during the lifetime of the project to disseminate the project's results:

Deliverable	Contents	Timeframe
Initial recommendations for CCHIT certification of health IT that provides CDS based on demonstration contractor work and other input.	Initial CDS certification recommendations, format to be specified by the project officer	September 2008 - within eight months after EDOC
Interim report consisting of documentation of CDS implementation to date, and describe barriers and risks to implementation encountered along with any solutions. Report will also include interim guidance to guideline developers, quality measure developers, IT vendors and clinician professional organizations.	Interim report, format to be specified by the project officer	January 2009 - within 12 months after EDOC
Follow-up recommendations for CCHIT certification of health IT that provides CDS based on demonstration contractor work and other input.	Follow-up CDS certification recommendations, format to be specified by project officer	June 2009 - within 20 months after EDOC
Draft final report	Draft final report, format to be specified by the project officer	December 2009 - within 23 months after EDOC
Final report	Final report, format to be specified by the project officer	January 2010 - within 24 months after EDOC

2.6 Risk Management Plan

The following risks and risk mitigation plans have been identified for this project. The risk plan will reviewed regularly with the Project Director and DSC members, and additional risks and mitigation plans will be added to the plan as necessary.

R#	Status	Date Identified	Risk	Potential Impact	Likelihood (H,M,L)	Severity (H,M,L)	Mitigation Strategy	Date Escalated to DSC
R1	Active	2/7/08	Lessons learned from the project could be too parochial in nature	Lessons will not be broadly applicable to users beyond those directly affected by the specific interventions we develop	L	H	Operationalize a replicable process for implementation at a wide variety of implementation sites. Implementation sites have been selected for their diversity (see section 2.5.3)	2/7/08
R2	Active	2/7/08	Deployment of new CDS functionality could be resisted by some users	Lack of enthusiastic adoption and feedback from clinical users will prevent attainment of project goals	M	M	Clinical workflows at implementation sites already reflect use of EHR systems. IGs are staffed with local experts, and IG members have extensive experience of implementing EHR-driven changes to workflows	2/7/08
R3	Active	2/7/08	Workgroups may not communicate effectively, or work collaboratively towards project goals	Poor communication between work groups, especially GTG and IGs will prevent attainment of project goals	L	H	Project manager will participate actively in all workgroups. EG will participate actively in GTG and IG work to help ensure strong communication. DSC will oversee all aspects of work	2/7/08
R4	Active	2/7/08	EG work may become separated from the core GTG and IG work and incidental to the project	Successful evaluation work is critical to the success of the plan and attainment of project goals	L	M	Evaluation steps are closely integrated into the WBS and EG staff will work closely and collaboratively with GTG and IGs throughout the project. EG leaders are also on the DSC	2/7/08
R5	Active	2/7/08	Project team members may not all understand AHRQ expectations	Failure to understand AHRQ goals will prevent attainment of these goals	L	M	Training in project plan, including AHRQ expectations, will be required for all project team staff. Project status reporting will ensure focus on overall goals and objectives	2/7/08

2.7 Quality Assurance Plan

2.7.1 Purpose

The Quality Assurance (QA) plan describes strategy and methods that the GLIDES project will deploy to ensure that:

- The project is being managed, developed, and deployed in a sound, reasonable way.
- The project's deliverables are of acceptable quality before they are delivered to the Project Officer.

2.7.2 Scope

All critical deliverables of the GLIDES project will be subject to the Quality Assurance plan, with particular focus on outputs and products from the:

- Knowledge Transformation phase
- Local Implementation phases
- Evaluation and Recommendation phase.

2.7.3 Quality Checkpoints

The QA plan will be implemented through a series quality checkpoints which have been built into the Project Plan for the following milestones:

QA Checkpoint #	Checkpoint Description	Timeframe
1	Review of Project Plan With DSC/PO	February 2008
2	Review Knowledge Transformation – Asthma	April 2008
3	Review Knowledge Transformation – Obesity	May 2008
4	Review Phase 1 Implementation Design	July 2008
5	Review Phase 1 Implementation Results	October 2008
6	Review Phase 2 Implementation Design	December 2008/January 2009
7	Review Phase 2 Implementation Results	May 2009
8	Review Phase 3 Implementation Design	July 2009
9	Review Phase 3 Implementation Results	November 2009
10	Review Evaluation Results, Assessments and Reports	January 2010

2.7.4 Roles and Responsibilities

The QA team will comprise the DSC members, who will be responsible for organizing and completing the review of deliverables according the milestone schedule above. As required, DSC members may decide to use an external expert to participate in any of the QA reviews.

3. Project Management Process and Methodology

3.1 Management Process Overview

The project will be managed according to proven and rigorous project management principles, with a focus on:

- Definition and communication of clear goals and scope for the project overall, and for project sub-groups, as documented in the AHRQ contract. These goals will be communicated and reinforced to all project team members and stakeholders. Overall project goals are documented in this Project Plan. Specific goals for project sub-groups will be documented in Project Charters developed for each sub-group and included in this Project Plan. All project activities will clearly contribute to these goals, and the ongoing status reporting and evaluation methodology will focus on ensuring these goals are being met. The scope of the project will be carefully monitored to ensure it does not deviate from the agreed goals and scope.

- Development of detailed project GANTT chart schedules, based on an effective methodology for transforming clinical guidelines into structured knowledge, and implementing that structured knowledge within clinical ambulatory and EHR systems. The GANTT chart schedules will be structured to meet the task and phase expectations documented in the AHRQ contract.

- Clear day to day communication and control of the project, overseen by the Project Director and performed daily by the Project Manager. The Project Manager will be closely involved in each work group and effective processes and tools will be in place to facilitate that control.

- Clear and effective processes for documenting, reviewing and resolving issues that could impact the quality, schedule and budget performance of the project. A project issue is any item which arises that may affect the outcome of the project. It can be a request for change, a concern arising regarding achievement of deadlines or quality criteria for a product of the project or any question raised regarding the project for which there is no straightforward answer. Issues will be tracked and reviewed regularly with the Project Manager and Project Director so that they can be answered quickly and crisply before they present a significant risk to the project.

- Clear and effective processes for documenting, evaluating and mitigating risks that could impact the quality, schedule and budget performance of the project. A project risk is defined as any item that arises that may affect the outcome of the project and which cannot be fully controlled by the project team. Risks will be tracked and reviewed regularly with the Project Manager and Project Director so that they can be escalated for review as necessary, and so that effective risk mitigation plans can be implemented to limit both the likelihood of the risk occurring as well impact of the risk.

- Time and cost reporting mechanisms that meet AHRQ reporting and control expectations, and which ensure only those costs allowed under the AHRQ contract are expended and invoiced to AHRQ.

- Effective oversight of the project through both the internal Decision Support Council and regular meetings with the external AHRQ Project Officer.

3.2 Definition and Communication of Goals and Scope

The overall goals for the project are documented in section 2 of this Project Plan. It will be imperative to the success of this project that the goals and scope are properly understood by all members of the team, and that all activities and deliverables produced by the project contribute directly to the attainment of the goals, within the agreed scope of the project. To ensure this, the following practices will be adopted by the project:

- All project oversight activities, including regular status reporting, evaluation activities, updates to the Decision Support Council and review sessions with the Project Officer and Stakeholders, will be grounded in a review of progress against the attainment of project goals, rather than only focusing on status project activities against schedule and budget expectations.
- Orientation to and training in the Project Plan will be performed for all team members, with a focus on goals and scope of the project.
- A Project Charter will be documented and communicated for the project work group that defines the work required by the workgroup and places it in the context of project goals and scope. Project Charters for each work group are included in section 4 of this Project Plan.
- Evaluation Group activities are integrated into the Project Plan and are intended to ensure we meet our overall goals.

3.3 Gantt Chart Schedules

The summary Gantt chart developed for the project is included in section 2.3 of the Project Plan. The detailed Gantt chart is included at attachment G. The Gantt chart has been built on a Work Breakdown Structure (WBS) developed using both the task and phase structure requested by AHRQ and the methodology to be used by the project team, also described in section 2.3. Consequently, the project Gantt schedule itself is closely linked to the original goals and task expectations of the AHRQ contract. This provides a built-in level of project control.

3.4 Communication and Control

The project team will ensure effective communications and control throughout the project through a combination of regular, formal status reporting and regular meetings to review status and progress. In addition, Microsoft Project will be used for regular status reporting, using a simple activity “percent complete” method.

3.4.1 Project Reporting

Report	Owner	Distribution List	Frequency	Description
Weekly Work Group Status	Work Group Leads	Project Manager	Weekly distribution	Summary status for each work group, tied to milestones and deliverables
Bi-Monthly Status Report	Project Manager	Project Director DSC Members	Weekly distribution	Status report for overall project, tied to milestones and deliverables
Monthly Project Report	Project Manager	Project Director DSC Members Project Officer	Monthly distribution	1.Narrative status report 2.Updated project work plan in MS Project format (see attachment F for MSP usage) 3.Documents as requested by PO

Examples of proposed status report formats are include in the Attachment section of this Project Plan.

3.4.2 Regular Meetings

Meeting	Owner	Attendees	Frequency	Description
Workgroup Meetings	Workgroup Leader	Workgroup Leader Workgroup Members Project Manager	Weekly, more frequently if needed	Discuss project status and progress against schedule Plan resolution of issues/obstacles Agree action items for the week Generates summary work group status report
Project Status Meeting	Project Manager	Project Manager Project Director	Weekly	Discuss project status and progress against schedule Review resolution of issues/ obstacles, plan further escalation of outstanding issues/risks
Monthly DSC Meeting	Project Director	Project Director Project Manager DSC Members	Monthly	Monthly internal steering meeting Project oversight/review Address issues which require resolution QA on deliverables
Monthly PO Meeting	Project Director	Project Director Project Manager Project Officer	Three months after EDOC and monthly thereafter	Monthly project report and teleconference with project officer
Stakeholder Meeting	Project Director	Project Director Project Manager Project Officer Project Stakeholders	Two months after EDOC, then every four months	Teleconference for the purpose of reporting and updating key stakeholders. Yale will present work to date as specified by the project officer
In-person meeting	Project Director	Project Director Project Manager Project Officer	Four months after EDOC then every four months	Meeting participation in AHRQ-arranged meeting and meeting materials, in format to be specified by the project officer

3.5 Issue Management

A project issue is defined as any item which arises that may affect the outcome of the project. It can be a request for change, a concern arising regarding achievement of deadlines or quality criteria for a product of the project, or any question regarding the project for which there is no straightforward answer. Issues will be tracked and reviewed regularly with the Project Manager and Project Director so that they can be answered quickly and crisply before they present a significant risk to the project.

The following procedures will be used to manage issues on the GLIDES project:

- Any member of the project team can document an issue.
- Issues will be documented on an issue log, with separate issue logs being maintained for each major workgroup (Project Management, Evaluation Group, Transformation Group and Implementation Groups)
- Issue logs will be stored electronically on the file folder used for storing project documentation.

For each issue logged, the following information will be captured:

Issue Log Item	Definition
Issue Number	Sequential number used for logging
Issue Description	Brief description of the issue and its potential impact on the project
Impact	Potential impact on the project outcome (High, Medium, Low)
Impact Originator	Name of person who first identified/raised the issue
Date Opened	Date that the issue was opened
Date Due	Date that the issue must be resolved
Date Closed	Actual date of resolution
Owner	To whom the issue has been assigned for resolution
Status	Ongoing status of the issue
Escalation	Indicator of whether the project work group needs the issue to be escalated to project management attention so that is can be resolved.
Resolution	Final resolution of the issue, what happened and how was it contained.

- Issue logs will be reviewed regularly during each work group meeting.

- All work group meetings will be attended by the project manager. During each workgroup meeting, the Project Manager will attempt to address and resolve as many issues as possible within the workgroup.

- Issues which require escalation to the Project Director will be flagged on the issue log. The Project Manager will review issues for escalation with the Project Director during the weekly project status meeting.

- Issues which cannot be addressed by the Project Director will be escalated for review by the Decision Support Council at the monthly DSC meeting. If required, project issue logs can be shared and reviewed with the AHRQ Project Officer at the Monthly PO meeting.

An example Issue Log template is included at Attachment B.

3.6 Risk Management

A risk is defined as any concern or event with potential to prevent the project from meeting its goals. Risk management is one of the most important responsibilities of the Project Manager and Project Director, assisted by all members of the project team and the DSC. The success of the project will be jeopardized by a wide range of risks. These risks will be identified and managed appropriately.

Current risks to the project have been identified and are included in section 2.6 of the Project Plan. Additional risks may be identified as the project progress, and will be managed as follows:

- Any member of the project team can identify a potential risk.
- Potential risks will be reviewed with the project manager, who will determine whether and how to add it to the risk log.
- A single risk log will be maintained for the project, and will be stored electronically on the file folder used for storing project documentation.
- For each risk logged, the following information will be captured:

Risk Log Item	Definition
Risk Number	Sequential number used for logging

Risk Log Item	Definition
Status	Status of the risk
Date Identified	Date that the risk was identified
Description	Description of the risk, with a focus on the risk to the project
Potential Impact	Potential impact on the project outcome
Likelihood	How likely is the risk to materialize (1 – 5)
Severity	How severe would the impact be if it did materialize (1-5)
Mitigation Strategy	Strategy to be pursued for limiting/controlling the risk
Escalation Date	Date that the risk was escalated to the DSC or PO's attention

- The risk log will be reviewed weekly by the Project Manager and Project Director.
- Risks which cannot be addressed by the Project Director will be escalated for review by the Decision Support Council at the monthly DSC meeting.
- The project risk log will be shared and reviewed with the AHRQ Project Officer at the Monthly PO meeting.

An example Risk Log template is included in the Attachment section of this Project Plan.

3.7 Time and Cost Recording and Reporting

Time and cost reporting for the project will be performed consistent with AHRQ contract expectations. Invoices will be submitted monthly to AHRQ. We will provide AHRQ with the following information in support of monthly costs submitted:

Direct Labor – Invoices will itemize all persons, listing the person's name, title, effort, hourly rate, the total cost per person and a total amount of this category

Fringe Costs - Invoices will show rate, base and total amount as well as verification/allowability or rate changes (when applicable)

Overhead or Indirect Costs - Invoices will show rate, base and total amount as well as verification/allowability or rate changes (when applicable)

Consultants - Invoices will include the name, number of days or hours worked, a total amount per consultant and a total amount for this category

Travel – Invoices will include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation, shown separately, and per diem costs. Other travel costs shall also be listed. A total amount for this category shall be provided

Subcontractors – Invoices will include for each subcontractor, the same data that is being provided for the prime contractor. A total number for this category shall be provided

Data Processing – Invoices will include all non-labor costs, i.e., computer time, equipment purchase, lease or rental, data tapes, etc. A total amount for this category shall be provided

Other – Invoices will include a listing of all other direct charges to the contract, i.e., office supplies, telephone, equipment rental, duplication, etc.

- Equipment Cost - itemize and identify separately from material costs including reference to approval in all cases
- G&A - show rate, base and total as well as verification/allowability of rate changes (when applicable)

- Fee - show rate, base and total and
- Current amount billed by individual cost element and total dollar amount and cumulative amount billed by individual cost element and total dollar amount.

Procedures for gathering this information from the Yale and Nemours financial systems, and generating the monthly invoices, are under development.

The following items should be considered unallowable unless authorized in writing by the AHRQ Contracting Officer:

- Acquisition, by purchase or lease, of any interest in real property
- Rearrangement or alteration of facilities
- Purchase or lease of any item of general purpose-office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.)
- Accountable Government property (defined as both real and personal property with an acquisition cost of $1,000 or more, with a life expectancy of more than two years) and "sensitive items" (defined and listed in the Contractor's Guide for Control of Government Property, 1990, regardless of acquisition value
- Travel to attend general scientific meetings
- Foreign Travel
- Any costs incurred prior to the contract's effective date
- Rental of meeting rooms not otherwise expressly paid for by the contract
- Any formal subcontract arrangements not otherwise expressly provided for in the contract
- Consultant fees in excess of $800/day
- Information Technology hardware or software; and
- Food and Beverages

3.8 Design and Control Documentation

Throughout the project lifecycle, a series of important documents will be produced to record and communicate the design approach to be implemented. The design documentation can be grouped into the following categories. Examples of templates and worksheets are included in the Attachment section of the Project Plan:

3.8.1 Knowledge Transformation Documentation

The following documentation will be produced during the Knowledge Transformation phase. We will provide files in electronic and paper formats the following documents:

- Management of Chronic Asthma Guideline (.pdf format, .html format, .rtf format, .text format)
- Prevention of Obesity Guideline (.pdf format, .html format, .rtf format, .text format)

The files will be supplied in .pdf format by their sources and converted to the additional formats for markup using GEM Cutter II. Following markup, each guideline will be stored as a GEM document in .xml format. Each guideline.xml document will be passed through a series of XSLT transforms to yield:

- Extractor Rules Report: Each selected recommendation will be presented as an IF-THEN rule with opportunity to comment on decidability of each decision variable and executability of each action.
- Extractor Knowledge Summary: A detailed summary of decision variables, actions, reasons, DV descriptions, action descriptions, etc.
- A GEM-COGS report will highlight guideline text that addresses each Conference on Guideline Standardization criterion.

In addition, we will perform a GLIA (Guideline Implementability Appraisal) for representative recommendations from each guideline.

3.8.2 Local Workflow Assessment Documentation

The following documentation will be produced from the initial activities for each local implementation phase, during which the recommendations from the Knowledge Transformation phase are adjusted to reflect local workflow and conditions, and are then formatted as input to the ambulatory/EHR systems development lifecycle (SDLC) process for each of the implementation sites. We plan to adopt worksheets and templates already developed for this purpose by Osheroff and colleagues. We expect to adapt and improve on these worksheets as our project proceeds:

- Stakeholders, Goals and Objectives
- Objectives and Performance
- Selecting Interventions and Workflow Opportunities to Address Clinical Objectives
- Intervention Specification Form/ Specification Form for Developers

3.8.3 SDLC Documentation - Local Implementation Sites

Both YNHH and Nemours system development organizations have adopted comprehensive systems development methodologies and documentation standards that have proven effective for their organizations. We do not intend to fundamentally change these methodologies and standards, and plan to work within the framework that they provide. Some adjustment to documentation will be required, but we intend to minimize the overall impact of this project on existing local methods and procedures. The following critical documents will be produced during both the Yale and Nemours systems development phases:

- System Requirements (derived from worksheets above)
- Functional Specifications
- Technical Specifications
- Testing Strategy, Plan and Specifications
- Training Strategy, Plan and Specifications

3.8.4 Control Documentation

To ensure the YNHH and Nemours SDLC methodologies and documentation effectively translate the clinical recommendations into system capabilities, we will supplement the SDLC process of both organizations with the following documents. These documents will provide an additional level of control to ensure that the intended clinical intervention recommendations from the Knowledge Transformation phase have been faithfully reflected in the local workflow and system changes. Again, these will be based on existing Osheroff documents, and improved and enhanced as our project proceeds:

- Pre-launch Testing
- Intervention Launch Plan
- Implementation Status
- Feedback Issues and Resolution

Other documentation will also be produced by the project, which is not discussed in this section, including project management and control documentation, and evaluation documentation.

3.9 Documentation Management and Change Control

Each of the major documentation deliverables identified in section 3.8 will undergo review and sign-off by the Project Manager and Project Director. Once these sign-offs have been accomplished these documents will be frozen and subject to change control.

We anticipate that requests to change these documents will arise once these documents have been signed-off. The following procedure will be implemented to evaluate and control change requests:

- A Change Request form will be documented for any change of any sort to a deliverable that has been completed, reviewed and signed-off. Only the Project Officer, project manager, Project Director, members of the DSC or workgroup leaders will be able to raise a Change Request.

- The Project Manager and Project Director will assess each Change Request prior to initiating a more thorough review of requested changes. Change Requests which are expected to have an unacceptable impact on project quality, schedule and budget will not be pursued further. Reasons for rejection will be documented and communicated to the requestor.

- Change Requests approved for assessment will be assigned to an appropriate project team member who will analyze the impact of the request change on project schedule, quality and budget.

- Change Request assessments will be reviewed with the DSC periodically to determine whether the cost of the proposed change, or its impact on the project schedule, is worth the expected benefit. DSC decisions will be documented and communicated to the requestor. Change Requests which are approved for implementation will be factored into the project schedule and assigned to the appropriate work group.

3.10 Automated Project Management Tools

The following automated project management tools will be used

- Microsoft Project will be used for project planning, scheduling and progress reporting
- Microsoft Office tools will be used for all project documentation
- Existing Yale and Nemours financial systems will be used for time and cost reporting
- Email
- YCMI website

4. Project Charters/Statement of Work

4.1 Decision Support Council

<table>
<tr><th colspan="2">Work Group Charter: Decision Support Council</th><th>February 15th, 2008</th></tr>
<tr><td>Purpose of DSC</td><td colspan="2">The Decision Support Council (DSC) is the steering committee for the project.</td></tr>
<tr><td>Roles and Responsibilities</td><td colspan="2">The DSC has three main roles:
- Provide oversight to the project, and address and resolve any issues that cannot be resolved by the project team and which are escalated to the DSC.
- Ensure that the project team meets the overall goals and objectives stated in section 2.1.
Lead the Quality Assurance review work for all project deliverables, as described in section 2.7.</td></tr>
<tr><td>Work Group Members</td><td colspan="2">Project Director – Rick Shiffman
Project Manager – Mark Dixon
Nemours Lead – Ian Nathanson
YNHH IS&T – Paula Burns
Nemours CMIO – David Milov
Evaluation Leaders: Kristin Mattocks, Gabriela Ramirez</td></tr>
<tr><td colspan="3">Contribution To Project Goals</td></tr>
<tr><td colspan="2">Overall Objective: 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</td><td rowspan="6">As the oversight body for the project, the DSC is responsible for ensuring the project accomplishes all objectives and goals</td></tr>
<tr><td colspan="2">Goal 1: Translation of Decision Support Guidelines Into Systems That Improve Delivery of Health Care</td></tr>
<tr><td colspan="2">Goal 2: Identification of Methods and Processes For Incorporating CDS Tools Into EHRs</td></tr>
<tr><td colspan="2">Goal 3: Optimization Of CDS Tools For Measuring and Improving Quality of Care</td></tr>
<tr><td colspan="2">Goal 4: Demonstrate and Evaluate Methods Of Using CDS Elements Across Multiple Clinical Sites</td></tr>
<tr><td colspan="2">Goal 5: Evaluation and Dissemination Of Project Findings and Results</td></tr>
<tr><td>Critical Success Factors</td><td colspan="2">To be effective, the DSC will need to stay closely engaged in the work of the project. This will be accomplished in the following ways:
- DSC members will meet monthly, to review project progress against plans and milestones
- DSC members will also participate in specific project activities
- DSC members will be assigned to perform portions of the QA plan</td></tr>
<tr><td>Key Milestones</td><td colspan="2">Monthly DSC Meetings To Oversee Project
QA Checkpoint #1: Project Plan Review — February 2008
QA Checkpoint #2: Obesity Guideline Transformation — April 2008
QA Checkpoint #3: Asthma Guideline Transformation — May 2008
QA Checkpoint #4: Phase 1 Local Work Flow — July 2008
QA Checkpoint #5: Phase 1 Results — October 2008
QA Checkpoint #6: Phase 2 Local Work Flow (Obesity) — December 2008
QA Checkpoint #6: Phase 2 Local Work Flow (Asthma) — January 2008
QA Checkpoint #7: Phase 2 Results — May 2009
QA Checkpoint #8: Phase 3 Local Workflow — July 2009
QA Checkpoint #9: Phase 3 Results — November 2009
QA Checkpoint #10: Project Close-Out — January 2010</td></tr>
</table>

4.2 Evaluation Group

Work Group Charter: Evaluation Group (EG)	February 15th, 2008
Purpose of EG	The main purpose of the Evaluation Group is to ensure that the project team remains focused on and meets its overall objective and goals, and to prepare and publish reports explaining these goals.
Roles and Responsibilities	The EG will monitor and review the design, development and implementation deliverables produced by both the GTG and IGs to ensure that they are contributing to the successful attainment of the project's goals. The EG will: - Prepare a thorough Evaluation Plan for the project that is well integrated with all key project activities. Define pre and post-implementation variables and approaches to evaluating process variables across all implementation sites. Prepare HIC and Paperwork Reduction Act material. - Create Use and Usability logs and survey instruments for data collection, including online clinician satisfaction survey documentation. - Participate closely in the guideline transformation work. EG members will perform a GuideLine Implementability Appraisal (GLIA) on each clinical recommendation selected for implementation to help highlight obstacles that may be anticipated when the guideline and recommendation are operationalized. - Collect, organize, and report the artifacts generated in the course of transformation of guideline knowledge into guideline-based decision support interventions, to clarify how guidelines might be better written to be actionable. - Participate in and review the local design work for implementing the transformed guideline knowledge at each site, carefully monitoring and documenting implementation activities in the "zone of localization", to help ensure that the local site design remains consistent with the goals and intention of the guideline transformation work. - Assist with training preparation, training delivery and roll-out support to help ensure that site implementation and roll-out remains consistent with the goals and intention of the local site design. - Work closely with the GTG and IGs at all stages to collect and analyze data and to prepare the critical evaluation reports for the project. Organize implementation findings into Use and Usability Issues Logs by the Evaluation Groups at YNHH and Nemours, which will serve as the basis of reports.
Work Group Members	The EG includes representatives from both Yale and Nemours: Group Leader – Kristin Mattocks Project Manager – Mark Dixon Yale Evaluation Lead – Mattocks Nemours Evaluation Lead- Ramirez Nemours Evaluation Coordinator(s) Evaluation Consultant – Amy Justice Yale research Assistant
Contribution To Project Goals	

Overall Objective: 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	Responsible for QA, oversight and steerage of the work to ensure objective/goal is met
Goal 1: Translation of Decision Support Guidelines Into Systems That Improve Delivery of Health Care	Responsible for evaluating and disseminating the project's results
Goal 2: Identification of Methods and Processes For Incorporating CDS Tools Into EHRs	Responsible for evaluating and disseminating the project's results
Goal 3: Optimization Of CDS Tools For Measuring and Improving Quality of Care	Responsible for evaluating and disseminating the project's results
Goal 4: Demonstrate and Evaluate Methods Of Using CDS Elements Across Multiple Clinical Sites	Responsible for evaluating and disseminating the project's results
Goal 5: Evaluation and Dissemination Of Project Findings and Results	Primarily responsible for performing the work to ensure objective/goal is met

Critical Success Factors	Active participation of EG members, from both Yale and Nemours, in all stages of the project. Evaluation work cannot be coincidental to the plan, nor can work focus only in back-end assessment and results: - Thorough and structured evaluation plan with measureable goals/variables established before implementation and measured after implementation. - Selection of variables that are associated with the best evidence of clinical impact and most feasible to measure. - Selection and analysis of indicators of important clinical patient outcomes. - Effective tools and procedures for Use and Usability logs and online clinical satisfaction surveys. - EG members must have prior evaluation experience. - EG must obtain IRB Approval prior to any data collection on patients and clinicians.
Key Milestones	Perform Literature Review on Asthma, Obesity and DSS 2/18/08 3/3/08 Define Ascertainable Pre-Implementation Variables 2/18/08 3/17/08 Define Ascertainable Post-Implementation Variables 2/18/08 3/17/08 Design Evaluations of Process and Outcome Variables 2/18/08 3/17/08 Create Online Clinician Satisfaction Survey 3/18/08 4/2/08 Prepare Paperwork Reduction Act Material 4/3/08 5/5/08 Prepare/Submit/Revise HIC 4/3/08 5/5/08 Create Use and Usability Logs 5/6/08 6/4/08 Install Use and Usability Logs 6/5/08 6/19/08 Ongoing Evaluation and Assessment 6/20/08 11/24/09 Collect Data on Process and Outcomes 6/20/08 8/13/09 Perform Online Clinician Survey 8/1/08 9/15/09 Analyze Data on Process and Outcomes 7/1/09 9/1/09 Prepare Reports On Process and Outcomes60d 9/2/09 11/24/09

4.3 Guideline Transformation Group

Work Group Charter: Guideline Transformation Group (GTG)	February 15th, 2008
Purpose of GTG	The main purpose of the Guideline Transformation Group (GTG) is the translation of knowledge in clinical guidelines into computable formats.
Roles and Responsibilities	The GTG will: - Apply the GuideLine Elements Model (GEM) and its related tools to transform the knowledge contained in the selected evidence-based clinical practice guidelines into a standardized format—i.e., XML based on the GEM Schema Standard (ASTM E2210-06). - The key steps are as follows: o Appraise Guideline Implementability (GLIA) o Mark up Selected Guidelines Using GEM Cutter II o Submit Guideline's GEM file to GEM-COGS Transform o Apply EXTRACTOR transforms to the GEM files o Adjust Level of Abstraction o Restate in Human-Readable Statement Logic o Categorize Action-Types o Map Concept Codes o Add Critical Terms To Recommendation Glossary o Classify Each Recommendation By Clinical Objective. - Carefully document progress, issues, and obstacles and use them to define a set of best practices which can be shared with the local implementation groups to ensure the best chance of effective implementation of the transformed knowledge in the local ambulatory systems and clinical workflows. - Participate in local site design and implementation activities to both advise and guide on how to implement the centrally transformed guidelines, and also to adjust the transformed guideline information where absolutely necessary to accommodate local workflow and care delivery considerations.
Work Group Members	Group Leader – Rick Shiffman Project Manager – Mark Dixon XML Programmer – George Michel Yale Informatics Fellow – Lomotan Yale IS&T Chief – Paula Burns

Contribution To Project Goals	
Overall Objective: 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	Responsible for QA, oversight and steerage of the work to ensure objective/goal is met
Goal 1: Translation of Decision Support Guidelines Into Systems That Improve Delivery of Health Care	Primarily responsible for performing the work to ensure objective/goal is met
Goal 2: Identification of Methods and Processes For Incorporating CDS Tools Into EHRs	Participates/supports work to ensure objective/goal is met
Goal 3: Optimization Of CDS Tools For Measuring and Improving Quality of Care	Participates/supports work to ensure objective/goal is met
Goal 4: Demonstrate and Evaluate Methods Of Using CDS Elements Across Multiple Clinical Sites	Participates/supports work to ensure objective/goal is met
Goal 5: Evaluation and Dissemination Of Project Findings and Results	Participates/supports work to ensure objective/goal is met

Critical Success Factors	Besides the choice of knowledge representation, a plethora of issues regularly face implementers charged with creating guideline-based decision support, all of which will need to be faced and tackled successfully by the GTG: - Tierney and coworkers described their frustration in creating a computer-based implementation for an evidence-based guideline to assist with management of heart failure. That guideline—like many others—lacked explicit definitions, focused on omission errors (rather than errors of commission), and did not account for co-morbid conditions, concurrent drug therapy, or timing of interventions. - The language used to define recommendations is often undecideable, i.e., it fails to specify in a clear, consistent manner the parameters upon which decisions are based. Likewise, actions may not be executable as written. Grol found that clinicians were considerably less likely to adhere to vague and non-specific recommendation. - Often, the level of abstraction at which decision variables and actions are described is inappropriate for implementation. We have described a taxonomy of ambiguity, vagueness, and under-specification as it applies to guideline recommendations, and plan to apply it in this work to avoid and remediate the problem. - Guidelines are often incomplete, i.e. they regularly fail to describe appropriate behavior for an exhaustive set of situations that may befall practitioners. - For optimal implementation all guideline recommendations must be integrated within clinical workflow. - Therapeutic recommendations for patients with multiple coexisting conditions are not prioritized. - Attention to knowledge deficits and attitudinal issues is also critical in the design of successful systems. Cabana has created a useful conceptual framework that describes critical barriers to successful implementation, including awareness of, familiarity, and agreement with guideline content, and clinicians' self efficacy, outcome expectancy, and ability to overcome inertia of previous practice.
Key Milestones	Commence Asthma Guideline Transformation — March 3, 2008 Complete Asthma Guideline Transformation — April 25, 2008 Commence Obesity Guideline Transformation — April 28, 2008 Complete Obesity Guideline Transformation — May 23, 2008

4.4 Yale Implementation Group

<table>
<tr><th colspan="3">Work Group Charter: Implementation Group (Yale)</th></tr>
<tr><td>Purpose of IGY</td><td colspan="2">The main purpose of the Implementation Group Yale (IGY) is incorporating the computable knowledge into the Centricity EHR systems in use at the Yale implementation sites, and for optimizing the tools for measuring and improving quality of care.</td></tr>
<tr><td>Roles and Responsibilities</td><td colspan="2">The IGY will customize the implementation package prepared centrally by the GTG to tailor it to local workflows, systems and operating conditions at the Yale Primacy Care and Specialty clinics. The IGY will include both Clinician Experts and Quality Management experts, as well as Information Technology specialists. The methodology for local site implementation is explained in more detail in the Project Plan, and includes the following steps for each condition:
• Define Local Workflow
• Define Intervention Triggers
• Map Guideline-Related Concepts to Local Codes
• Choose Appropriate Decision Support Interventions
• Document Intervention Specification Form
• Design and Programming
• Testing
• Training and Rollout
• Monitoring and Maintenance

Throughout these steps, the IGY will work closely with the GTG and EG to ensure that the local implementation does not deviate materially from the purpose and intent of the centrally prepared knowledge</td></tr>
<tr><td rowspan="2">Work Group Members</td><td colspan="2">Group Leader - Shiffman Project Manager – Dixon</td></tr>
<tr><td>Clinical Sub-Group:
<u>Fenick (Lead)</u>
Bazzy-Asaad
Tolomeo
Banasiak
Users/Testers:
Bilskis
Cunningham
Residents
CMIO - Hsiao</td><td>Technical Sub-Group:
IS&T Chief - Burns
Centricity Team Leader - Simonette
Programmers: Bonilla, Atamanuk</td></tr>
<tr><td colspan="3">Contribution To Project Goals</td></tr>
<tr><td colspan="2">Overall Objective: 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</td><td>Responsible for QA, oversight and steerage of the work to ensure objective/goal is met</td></tr>
<tr><td colspan="2">Goal 1: Translation of Decision Support Guidelines Into Systems That Improve Delivery of Health Care</td><td>Participates/supports work to ensure objective/goal is met</td></tr>
<tr><td colspan="2">Goal 2: Identification of Methods and Processes For Incorporating CDS Tools Into EHRs</td><td>Primarily responsible for performing the work to ensure objective/goal is met</td></tr>
<tr><td colspan="2">Goal 3: Optimization Of CDS Tools For Measuring and Improving Quality of Care</td><td>Primarily responsible for performing the work to ensure objective/goal is met</td></tr>
<tr><td colspan="2">Goal 4: Demonstrate and Evaluate Methods Of Using CDS Elements Across Multiple Clinical Sites</td><td>Primarily responsible for performing the work to ensure objective/goal is met</td></tr>
<tr><td colspan="2">Goal 5: Evaluation and Dissemination Of Project Findings and Results</td><td>Participates/supports work to ensure objective/goal is met</td></tr>
</table>

Critical Success Factors	There are several success factors for the site implementation stage of the project: - During local workflow design and development activity it will be important to achieve the right mix and facilitation of central and local project staff to ensure the best possible design balance between the centralized, transformed guideline knowledge and it's effective implementation in the local care delivery setting. - Availability of adequate, expert information technology resources to implement and test the local design in the Yale ambulatory and EHR systems according to the required project schedule. - Strong and effective collaboration between the IGY and EG work groups to ensure the guidelines are not just implemented effectively but that the evaluation and dissemination goals of the project are clearly met. - Effective test scripts that exercise the software, particularly at extremes of decision variable content, prior to site roll-out. - Members of each user community must participate as testers to judge the usability and acceptability of each intervention. An iterative process of programming refinement is anticipated. - Effective training in both the revised workflows and systems and the tools and protocols for data collection and evaluation. - Upper level management will endorse the proposed interventions. - Effective feedback channels to assure that users can communicate effectively with both the Implementation Group and the Decision Support Council.
Key Milestones	<u>Phase 1 Implementation – Yale Asthma</u> Local Workflow Design 6/3/08 7/1/08 Review/Validate Design 7/2/08 7/4/08 *QA Checkpoint #4: Review Local Work Flow Design 7/4/08 7/4/08* System Design/Programming/Testing 7/7/08 9/12/08 Training/Rollout 9/15/08 9/26/08 *QA Checkpoint #5: Review Phase 1 Results 10/3/08 10/3/08* <u>Phase 2 Implementation: Obesity</u> Local Workflow Design – Yale PCC 10/30/08 12/10/08 Review/Validate Design 12/11/08 12/16/08 *QA Checkpoint #6: Review Obesity Local Workflow Design 12/16/08 12/16/08* System Design/Programming/Testing 12/17/08 2/24/09 Training/Roll-Out 2/25/09 3/17/09 <u>Phase 3 Implementation: Asthma</u> Local Workflow Design – Yale PCC 6/15/09 7/17/09 Review/Validate Design 7/20/09 7/23/09 *QA Checkpoint #8: Review Asthma Local Workflow Design 7/23/09 7/23/09* System Design/Programming/Testing 7/24/09 10/1/09 Roll-Out 10/2/09 11/5/09 *QA Checkpoint #9: Review Phase 3 Results 11/12/09 11/12/09*

4.5 Nemours Implementation Group

<table>
<tr><th colspan="3">Work Group Charter: Implementation Group (Nemours)</th></tr>
<tr><td>Purpose of IGN</td><td colspan="2">The main purpose of the Implementation Group Nemours (IGN) is incorporating the computable knowledge into the EpicCare systems in use at the Nemours implementation sites, and for optimizing the tools for measuring and improving quality of care.</td></tr>
<tr><td>Roles and Responsibilities</td><td colspan="2">The IGN will customize the implementation package prepared centrally by the GTG to tailor it to local workflows, systems and operating conditions at the Nemours Orlando, Jacksonville, Pensacola and Delaware Valley sites. The IGN will include both Clinician Experts and Quality Management experts, as well as Information Technology specialists. The methodology for local site implementation is explained in more detail in the Project Plan, and includes the following steps for each condition:
• Define Local Workflow
• Define Intervention Triggers
• Map Guideline-Related Concepts to Local Codes
• Choose Appropriate Decision Support Interventions
• Document Intervention Specification Form
• Design and Programming
• Testing
• Training and Rollout
• Monitoring and Maintenance

Throughout these steps, the IGN will work closely with the GTG and EG to ensure that the local implementation does not deviate materially from the purpose and intent of the centrally prepared knowledge</td></tr>
<tr><td rowspan="2">Work Group Members</td><td colspan="2">Group Leader - Shiffman Project Manager – Dixon</td></tr>
<tr><td>Clinical Sub-Group:
<u>Nathanson (Lead)</u>
Werk
Hassink
User(s)/Tester(s)</td><td>Technical Sub-Group:
Chief, Medical Informatics - Milov
Epic Team Leader
Programmers/testers</td></tr>
<tr><td colspan="3">Contribution To Project Goals</td></tr>
<tr><td colspan="2">Overall Objective: 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</td><td>Responsible for QA, oversight and steerage of the work to ensure objective/goal is met</td></tr>
<tr><td colspan="2">Goal 1: Translation of Decision Support Guidelines Into Systems That Improve Delivery of Health Care</td><td>Participates/supports work to ensure objective/goal is met</td></tr>
<tr><td colspan="2">Goal 2: Identification of Methods and Processes For Incorporating CDS Tools Into EHRs</td><td>Primarily responsible for performing the work to ensure objective/goal is met</td></tr>
<tr><td colspan="2">Goal 3: Optimization Of CDS Tools For Measuring and Improving Quality of Care</td><td>Primarily responsible for performing the work to ensure objective/goal is met</td></tr>
<tr><td colspan="2">Goal 4: Demonstrate and Evaluate Methods Of Using CDS Elements Across Multiple Clinical Sites</td><td>Primarily responsible for performing the work to ensure objective/goal is met</td></tr>
<tr><td colspan="2">Goal 5: Evaluation and Dissemination Of Project Findings and Results</td><td>Participates/supports work to ensure objective/goal is met</td></tr>
</table>

Critical Success Factors	There are several success factors for the site implementation stage of the project: - During local workflow design and development activity it will be important to achieve the right mix and facilitation of central and local project staff to ensure the best possible design balance between the centralized, transformed guideline knowledge and it's effective implementation in the local care delivery setting. - Availability of adequate, expert information technology resources to implement and test the local design in the Nemours ambulatory and EHR systems according to the required project schedule. - Strong and effective collaboration between the IGN and EG work groups to ensure the guidelines are not just implemented effectively but that the evaluation and dissemination goals of the project are clearly met. - Effective test scripts that exercise the software, particularly at extremes of decision variable content, prior to site roll-out. - Members of each user community must participate as testers to judge the usability and acceptability of each intervention. An iterative process of programming refinement is anticipated. - Effective training in both the revised workflows and systems and the tools and protocols for data collection and evaluation. - Upper level management will endorse the proposed interventions. - Effective feedback channels to assure that users can communicate effectively with both the Implementation Group and the Decision Support Council.
Key Milestones	<u>Phase 2 Implementation: Obesity</u> Local Workflow Design – Delaware PCC 10/30/08 12/1/08 Review/Validate Design 12/2/08 12/5/08 *QA Checkpoint #6: Review Obesity Local Workflow Design 12/16/08 12/16/08* System Design/Programming/Testing 12/17/08 2/24/09 Training/Roll-Out 2/25/09 3/17/09 <u>Phase 2 Implementation: Asthma</u> Local Workflow Design – Orlando 10/30/08 11/26/08 Review/Validate Design 11/27/08 12/3/08 Local Workflow Design – Jacksonville 12/4/08 1/7/09 Review/Validate Design 1/8/09 1/14/09 Local Workflow Design - Pensacola 12/4/08 12/31/08 Review/Validate Design 1/1/09 1/7/09 *QA Checkpoint #6: Review Asthma Local Workflow Design 1/7/09 1/7/09* System Design/Programming/Testing 1/15/09 3/25/09 Training/Roll-Out 3/26/09 4/29/09 <u>Phase 3 Implementation: Asthma</u> Local Workflow Design – Delaware PCC 6/15/09 7/15/09 Review/Validate Design 7/16/09 7/21/09 *QA Checkpoint #8: Review Asthma Local Workflow Design 7/23/09 7/23/09* System Design/Programming/Testing 7/24/09 10/1/09 Training/Roll-Out 10/2/09 11/5/09