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Developing Guideline Based Clinical Decision Support for Premature Infant Care

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1. Introduction

We developed a clinical decision support (CDS) application to assist primary care pediatricians with the care of premature infants from the time of NICU discharge through the 2nd birthday. Our CDS application addresses six areas of preventive healthcare for these vulnerable patients:

- Nutrition recommendations
- Growth assessment
- Development
- Blood Pressure
- Retinopathy of Prematurity (ROP)
- Prevention of Respiratory Syncytial Virus (RSV)

The American Academy of Pediatrics (AAP) has published policy statements addressing two of these six areas of preventative care: Retinopathy of Prematurity (RSV) and Prevention of Respiratory Syncytial Virus (RSV). AAP policy statements are structured in a format almost identical to that used in clinical guidelines. Therefore, to systematically translate the complex written language of these documents into executable CDS logic, we applied guideline translation tools and processes developed by the **G**uide**L**ines into **DE**cision **S**upport (GLIDES) Project as the foundation of our CDS project.

1.1 How To Use This Guide

This guide is a supporting document to the GLIDES website, which provides detailed information on three phases of key CDS activity:

1. **Synthesize Knowledge:** Developing clearly stated guideline recommendations for effective implementation.
2. **Formalize Knowledge:** Translating narrative guidelines into structured knowledge that can be implemented consistently as automated CDS.
3. **Localize Knowledge:** The activities necessary to design and build a local CDS solution from the formal knowledge specification.

Since our CDS project is based on translating existing clinical documents we only provide corresponding content supporting the "Formalize Knowledge" and "Localize Knowledge" phases. This document is arranged in chapters and sub sections mapped to the structure of the GLIDES site:

- 2 Formalize Knowledge
    - 2.1 Determine Clinical Objectives
    - 2.2 Markup Guideline
    - 2.3 Create Structured Rules
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- 3 Localize Knowledge
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This document can be accessed and read as a single resource from the GLIDES site. Alternatively, individual sections can also be accessed directly from the appropriate page on the GLIDES site.

1.2 Background

The CDS system for premature infant care described in this document was developed using our Care Assistant framework. Background on the Care Assistant is provided below under "Research and Technology Background." Although we believe the information in this guide could be applied to the development of guideline-based CDS systems for a wide range of patient populations, information on the specific patient population and outcomes we chose to address are described below in "Clinical Background."

Research and Technology Background

Our CDS system for premature infant care was built using our Care Assistant framework. In terms of technical innovation, the open architecture Care Assistant web-service framework that has been developed by our group permits integration of web-based external services using EMR vendor-agnostic methods, and is operated as a service by the Center for Biomedical Informatics (CBMi) (see Resources). At The Children's Hospital of Philadelphia (CHOP), this framework has supported research projects in diverse clinical domains, including asthma, otitis media, developmental surveillance, and short stature [1-4]. The Care Assistant has also supported research subject referral, and quality improvement activities related to vaccinations [5-7].

In current use at CHOP, the Care Assistant delivers relevant patient data, including demographics, history, exam findings, diagnostic test results and medications to a web-based logic engine for analysis. The output from the logic engine includes an assessment of past events, recommendations for action at the current visit, and web links to supporting information either directly in the patient's chart (e.g., in a consultation letter) or available through external reference materials.

Conceptually, the Care Assistant incorporates findings from the science on how best to deliver clinical decision support. While CDS has many potential benefits, clinicians may resist the implementation of these systems for many of the same reasons they resist practice guidelines. Several reviews have highlighted effective strategies for implementing decision support systems that overcome common barriers and effectively change clinician behavior. These strategies, as described by David Bates and colleagues in 2003 based on their experience with multiple decision support systems [8], include: (1) Ensuring that reminders appear without delays that slow workflows; (2) Anticipating the needs of clinician users and delivering information without requiring the clinician to search for it; (3) Fitting decision support into users' workflows; (4) Prioritizing usability. Experience has demonstrated that seemingly small changes in how information is delivered can dramatically alter how clinicians respond; (5) Avoiding interventions that require clinicians to stop. For example, if cancelling an order is recommended, suggest an alternative; (6) Encouraging clinicians to change direction instead of stopping is more effective.; (7) Emphasizing simplicity. If the presentation of a guideline or alert is complex, it is more likely to be overlooked; (8) Whenever possible, avoid asking for additional information; (9) Monitoring impact, getting feedback, and; (10) Managing and maintaining the system.

In 2005, Kawamoto and colleagues conducted a systematic review of 70 research studies to further define optimal approaches for CDS implementation [9]. Their work confirmed findings from Bates and distilled four rules for successful decision support. They found that decision support was most effective when recommendations were automatically provided within the context of the workflow, recommendations were provided instead of just assessments, decision support was provided at the time and location of decision making, and if decision support was computer versus paper-based. The importance of automated prompts was confirmed in a second systematic review conducted at the same time[10]. In each implementation of the Care Assistant, the tenets defined by Bates and Kawamoto have been considered at each stage of the design process with the team completing an iterative process of refinements until these goals were achieved.

Clinical Background

The care of premature infants is a rapidly growing public health concern in the United States, with almost 60,000 infants born in 2009 with a birth weight under 1500 grams[11]. With recent advances in neonatal care, more premature infants are surviving to discharge from the neonatal intensive care unit (NICU). Outpatient follow-up of premature infants in the primary care pediatric setting is a complex challenge. This challenge is particularly difficult for pediatricians who may only have a small number of these vulnerable children in their panel of patients. A primary consequence of this challenge is that children may not have optimal developmental outcomes when there is inadequate monitoring for early warning signs, which may result in missed opportunities for effective interventions. The challenges of medical problems frequently experienced by premature neonates such as failure to thrive (FTT), gastro esophageal reflux disease (GERD), broncho-pulmonary dysplasia (BPD), and apnea of prematurity also require close attention. Guidelines supporting earlier discharge for premature neonates may result in more premature infants receiving nutritional support and home oxygen, which further increases the complexity of outpatient management for these patients[12]. These health problems are frequently inter-connected and therapeutic interventions for one problem may adversely affect other problems. For example, a premature infant with BPD and GERD may present with symptoms of both conditions that are not only negatively impacting one another, but are also impacting overall weight gain and wellness as illustrated by the following vignette:

> *AG is a 1 mo old corrected gestational age former 27 week premature infant with broncho-pulmonary dysplasia (BPD) controlled with diuretic therapy and gastro-esophageal reflux disease (GERD) who presented to the office with fussiness surrounding feeds, reduced oral feeding volumes, and poor weight gain since hospital discharge. Her metabolic demands are great given her chronic lung disease, but her GERD limits the volume of nutrition she is able to consume, therefore limiting her weight gain. Interventions to treat her reflux such as acid blockade medications or increasing the caloric density of her feeds to allow for smaller necessary volumes with each feeding will enable her to meet her nutritional demands and achieve her weight gain goals.*

In addition to the inter-connected nature of these problems, another challenge highlighted by this vignette is that a single finding such as inadequate growth velocity might be a consequence of multiple underlying problems. Identifying which problem is most amenable to intervention and consequently improve growth is often not obvious. The pediatrician must also be alert to the possibility that the child may be developing new, previously unrecognized problems as an explanation for new findings even when existing problems might provide adequate explanation. For example, a child with reflux and BPD might have obvious reasons why growth velocity may diminish, but it is entirely possible that increasing metabolic demand due to abnormal neuromotor tone is occurring. This increase in muscle tone requires early therapeutic intervention for the child to have maximal functional use of their extremities.

Even though this high-risk group of premature patients is particularly sensitive to the care they receive after discharge, efforts to ensure high quality post-discharge care are haphazardly implemented. Given the complexity of problems experienced by these patients, electronic medical records with embedded clinical decision support (CDS) tools such as rules-based expert systems provide a natural opportunity to favorably affect the healthcare for these vulnerable infants. The complex decision-making for premature infants must consider large numbers of variables that change over time. The matrices of rules required to cover all possible combinations of variables are huge. There have been some preliminary efforts to address CDS tool development in the NICU setting[13-15] . However, to date no such decision support tools have been designed, implemented or evaluated to handle the complexity of decision-making required for the healthcare of premature infants in the outpatient setting.

2 Formalize Knowledge

The following four chapters map to the GLIDES website and sections describing key CDS activities under the phase, Formalize Knowledge:

- 2.1 Determine Clinical Objectives
- 2.2 Markup Guideline
- 2.3 Create Structured Rules
- 2.4 Apply Action Types and Vocabularies

2.1 Determine Clinical Objectives

We developed a clinical decision support (CDS) application to assist primary care pediatricians with the care of premature infants from the time of NICU discharge through the 2nd birthday.

This section describes two aspects of our approach in defining the clinical objectives for the project:

- Refining Clinical Objectives
- Use Case Development and Validation

Refining Clinical Objectives:

We began with a literature review to identify implementable guidelines and other evidence sources, to inform our intervention goals for each area of preventative care:

- For several areas, in particular for nutrition, there were no published guidelines that could be directly translated into recommendations.
- We found clear guidelines for growth assessment, developmental surveillance (Council on Children With Disabilities, 2006)and blood pressure screening ("The fourth report on the diagnosis, evaluation, and treatment of high blood pressure in children and adolescents," 2004), but which were only applicable to the general population of children.
- Guidance specifically for premature infants was surprisingly limited and significant refinement by local experts was required.
- We found published, implementable and well-accepted guidelines and policy statements available for RSV prevention (Committee on Infectious Diseases, 2009)and ROP screening (Section on Ophthalmology, 2006).

We also examined data from over 2,000 infants born at less than 35 weeks gestation, and who were less than 24 months of age, to help clarify CDS goals and intervention opportunities. Our understanding was also expanded through on-site discussion with our primary care clinicians. The most notable findings are described in the following sections.

Nutrition

We reviewed use of preterm formula based on dietary history documented at preventive health visits. Analysis revealed both expected and unexpected patterns of use for the specially designed premature infant formulas. Children with a lower gestational age (more premature), and younger infants, were more likely to receive premature infant formula. When adjusting for these expected associations there remained significant variability between practice locations: premature infants at some locations were 5-6 times more likely to be receiving premature infant formula than at others.

This variability suggested uncertainty among pediatricians regarding appropriate use of premature infant formula. This impression was confirmed in two ways:

1. Review of the literature revealed conflicting evidence about the utility of premature infant formula
2. Interviews with clinicians at each practice confirmed they generally continue whatever formula was recommended at the time of NICU discharge and wanted guidance on the best use of premature infant formula

Due to the clear need to help primary care pediatricians recommend nutrition, and the lack of available guidelines in this domain, our local experts interpreting the primary literature crafted the intervention.

Growth Assessment

To help primary care pediatricians assess the growth of premature infants, we first had to determine which growth chart was considered most appropriate.

- Initially, we considered use of Infant Health and Development Program (IHDP) growth charts. However, these were no longer in print and their use was not endorsed by any written guidelines.
- Fenton birth weight growth charts (Fenton, 2003)were helpful for assessing growth in the intensive care nursery, but were not appropriate for use post-discharge.
- When the World Health Organization (WHO) growth chart was adopted as the accepted standard for all children less than 2 years of age, we decided to promote use of WHO charts with correction for gestational age.

Baseline data revealed that an appropriate growth chart was used at fewer than 25% of preventive health visits. Generally this low rate was because the electronic medical record (EMR) defaulted to use Centers for Disease Control (CDC) growth charts for children of all ages, even though the CDC no longer recommend use of these charts for children under age 2 years. Also, although WHO charts were available, the EMR did not assist with calculating growth percentiles from these charts. Even for charts where percentiles were calculated (CDC), the system generally did not correct for prematurity when calculating growth percentiles. For example, it was common for the EMR to report the child's measurements at the 0^{th} percentile (i.e. very low), even though the child may have had average growth when prematurity was considered.

Developmental surveillance

Developmental surveillance is recommended at every preventive health visit and is typically performed as a series of checklist or "milestone" questions asked at the visit. This differs from developmental screening, which uses lengthier structured questionnaires at specific visits (most commonly 9, 18, 24 and 30 months). Developmental surveillance is intended to be an ongoing review of development to ensure problems are detected and treated as early as possible to improve developmental outcomes. A typical 4-month-old milestone question may be, "Can your child roll from her back to her stomach?" However, for a child born 2 months prematurely, ability to roll in this fashion at chronologic age 4 months (corrected age 2 months) is worrisome for increased tone and in extreme cases may be an early sign of cerebral palsy. In this situation if the clinician is not considering the child's prematurity, they may be falsely reassured if the family indicates that their child is rolling, when in fact concern should be raised for more ominous developmental problems.

We reviewed baseline data to determine whether surveillance milestone questions were documented correctly based on corrected gestational age. We focused specifically on gross motor milestones (e.g. rolling from back to front, sitting unsupported, and walking). Among infants with gestational age < 29 weeks (about 3 months premature) an inappropriately advanced set of gross motor milestones was documented as having been achieved at 61 out of 292 visits (about 21% of visits). Results indicated that it was common for clinicians to document developmental surveillance questions and answers based only on chronologic age, regardless of degree of prematurity.

Again, the EMR did not help clinicians to complete an important task correctly for premature infants. Many age-based documentation templates were in place (newborn, 1-month, 2 –month, 4 month, etc.), but the clinician was forced to determine the child's corrected age on their own and choose the most appropriate template. Often it was simpler for clinicians to select the template that matched the child's chronologic age.

Blood Pressure Screening

The American Academy of Pediatrics (AAP) guidance on blood pressure screening recommends annual blood pressure measurement beginning at age 3-years, with earlier screening for high-risk children such as those who were born prematurely. Premature infants are at risk for developing high blood pressure for multiple reasons (e.g. it can be caused by certain medications they receive while in the intensive care

nursery, and rarely as a consequence of central lines that may cause injury to the kidneys). Unfortunately little guidance was provided in published guidelines regarding what age earlier screening should begin.

Review of baseline data revealed that premature infants were not being screened for elevated blood pressure any earlier than full-term infants. Study team visits to clinicians clarified the key barriers to early screening:

1. Lack of knowledge that early screening for high blood pressure was important in premature infants
2. Lack of appropriate equipment to measure blood pressure in infants
3. Uncertainty about whether it could harm the infant to measure their blood pressure (i.e. by interrupting blood flow for too long to the extremity where the blood pressure is measured).

Eliminating these barriers was identified as an important intervention along with suggesting a reasonable schedule for measuring blood pressure based on local expert knowledge. We chose a goal of at least one blood pressure measurement in the outpatient setting, by 12 months corrected age.

Immunization Against Respiratory Syncytial Virus (RSV) With Palivizumab

RSV is a common wintertime virus that may cause significant health problems for premature infants (e.g. hospitalization, the need to be on a ventilator in a critical care unit, or even death in extreme cases). A vaccine (Palivizumab) can help avoid these problems, but it is expensive and requires monthly administration during the 5 month long RSV season. Due to the cost and burden of care coordination efforts involved in protecting vulnerable infants with Palivizumab, the AAP developed a policy statement on appropriate use of this product. The statement provides actionable recommendations for clinicians who treat premature infants and others at elevated risk of poor outcomes from RSV infection.

Based on these recommendations, we identified a cohort of premature infants eligible to receive 5 doses of Palivizumab in our baseline data. We also determined how many infants received the full course of the vaccine. We then reviewed charts for those infants who received fewer than 4 of the 5 recommended doses (43% of children) to identify reasons for missed doses:

- The most common problem was failure to recognize the child was eligible for Palivizumab at all.
- Other problems included failure of the practice to schedule appointments to administer the vaccine, and failure of the family to arrive for them.
- In some cases there were opportunities to give the vaccine in the office at problem focused "sick" visits, but the vaccine was not given because the clinician didn't realize the child was due to receive it.
- Insurance denial and family refusal were not common reasons for missed doses.

Our goal was to improve correct identification of children eligible to receive Palivizumab and to facilitate coordination efforts involved in administering the monthly doses.

Retinopathy of Prematurity (ROP)

Premature infants are at risk for a type of proliferative retinopathy (an eye disease) that may result in severe visual impairment or blindness if not treated. The AAP policy statement on screening and treatment for ROP primarily targets neonatologists who initiate consultation with ophthalmologist in the intensive care nursery, and ophthalmologists who must recommend appropriate follow-up. Typically premature infants at risk for ROP need to be screened every 1 or 2 weeks by an ophthalmologist until about 1 month corrected age. Often this means primary care pediatricians must ensure timely follow-up with a pediatric ophthalmologist for several visits after the infant has been discharged from the nursery. We attempted to review baseline data to identify how often this occurred.

Unfortunately, inconsistencies in available documentation made adherence to recommended follow-up difficult to measure. For example, some clinicians might mention ROP concerns in the initial visit narrative, others might document it in the EMR's birth history section and others would place it

prominently on the problem list. Given that blindness is a potential complication of untreated ROP, we felt the most important initial intervention was to improve documentation practices for infants at risk of ROP. We chose to promote use of the problem list for active ROP concerns, and to restrict birth history to describe ROP screening and treatment that occurred prior to discharge from the intensive care nursery. We decided that evaluating timeliness of ophthalmology follow-up was not feasible given inconsistencies in documentation - once consistent documentation habits are in place, then a more detailed intervention follow-up timeliness can be evaluated.

Use Case Development and Validation

With clear clinical objectives and organizational support, an additional method to consider is developing and validating use cases. This is a simple and inexpensive method to assess potential adoption of the system and/or to prioritize system functionality for each clinical objective.

Use cases are high-level descriptions mapped to each clinical objective and the tasks supporting the objective. There are many approaches to use case development, with different levels of detail, format and structure, but we feel the most important consideration (when applying use cases in early requirements gathering) is to create use cases that clearly describe the behavior of the proposed system to end users. For example, see Table 2.1.1 with three use cases from the use case validation survey (see additional resources section below):

Table 2.1.1: High Level Use Case Examples

Use Case	Detail
Presentation of Premature Infants Under 2 Years Old	The system utilizes information from the patient's birth history to identify premature infants: • The system will present information on the patient's Gestational Age, Birth Weight, Chronological Age and Corrected Age. • The system will use this information correctly in all age-based information and recommendations.
RSV and Synagis (Palivizumab)	The system applies logic derived from the AAP Policy Statement to identify patients at risk for RSV: • The system will provide comprehensive reports to better identify all patients eligible for Synagis (Palivizumab) prior to RSV season. • The system will automate the extraction of information for the completion of insurance forms. • The system will assist the coordinator in managing dose administration
Enhanced Patient Instructions/Education	The system will assist the clinician in easily locating, documenting and printing a variety of patient instruction materials: • When a new feeding goal requires formula mixing instructions (eg. 24 calories per oz.), the system allows the clinician to easily select, file and print the correct patient instructions. • A printable timeline or schedule of developmental milestones tailored to the patient's corrected age.

Use cases were presented to representative clinician users via a simple survey (see additional resources section below). Clinicians rated each use case on importance, frequency and current level of satisfaction in managing the specific use case with current systems (EMR, paper or whatever system/process is in place). Results were tabulated. See tables 2.1.2 – 2.1.5.

Use case validation for the premature infant project produced highly consistent results. Clinicians rated all use cases as both important and frequently encountered in the care of premature infants, yet by

contrast rated all use cases as quite low in adequacy of EMR support (thereby validating our initial objective assessment of clinical buy-in). Even if a use case validation produces more varied results, these can be quite useful in prioritizing project requirements, design elements, development efforts or even additional research into the clinical objectives.

Table 2.1.2 Use Case Validation Results Summary

Use Case	Description	Importance (Median)	Frequency (Median)	Adequacy of EMR (Median)
1	Presentation of Premature Infants	9	9	2
2	Growth Assessment	9	9	3
3	Nutrition	9	9	1
4	Developmental Surveillance	9	9	1
5	RSV and Palivizumab	9	9	1
6	Gastro Esophageal Reflux (GERD)	7	7	1
7	Chronic Lung Disease (CLD)	9	8	1
8	Retinopathy of Prematurity (ROP)	9	9	1
9	Hearing Screening	9	8	2
10	Blood Pressure	8	6	1
11	Enhanced Patient Instructions/Education	9	9	2
9 point Likert scale from 1 to 9 (Unimportant to Important, Infrequent to Frequent, Inadequate to Adequate)				

Table 2.1.3 Use Case Validation - Importance

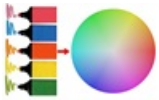
Use Case		Importance									
		1	2	3	4	5	6	7	8	9	Median
1	Presentation of Premature Infants								1	6	9
2	Growth Assessment									7	9
3	Nutrition					1			1	5	9
4	Developmental Surveillance								1	6	9
5	Respiratory Syncytial Virus (RSV)									7	9
6	Gastro Esophageal Reflux (GERD)					2	1	2		2	7
7	Chronic Lung Disease (CLD)						1	1		5	9
8	Retinopathy of Prematurity (ROP)					1				6	9
9	Hearing Screening					1			1	5	9
10	Blood Pressure			1			2		1	3	8
11	Patient Instructions/Education								1	6	9
9 point Likert scale from 1 to 9. Unimportant to Important											

Table 2.1.4 Use Case Validation – Frequency

Use Case		Frequency									
		1	2	3	4	5	6	7	8	9	Median
1	Presentation of Premature Infants								2	5	9
2	Growth Assessment									7	9
3	Nutrition					1			1	5	9
4	Developmental Surveillance								1	6	9
5	Respiratory Syncytial Virus (RSV)									7	9
6	Gastro Esophageal Reflux (GERD)					3		2		2	7
7	Chronic Lung Disease (CLD)					1		1	2	3	8
8	Retinopathy of Prematurity (ROP)			1				1		5	9
9	Hearing Screening			1					3	3	8
10	Blood Pressure			1			3			3	6
11	Patient Instructions/Education							1	1	5	9
9 point Likert scale from 1 to 9, Infrequent to Frequent											

Table 2.1.5 Use Case Validation – Adequacy of EMR

Use Case		Adequacy of EMR									
		1	2	3	4	5	6	7	8	9	Median
1	Presentation of Premature Infants	3	1	3							2
2	Growth Assessment	2	1	2	1	1					3
3	Nutrition	4	2	1							1
4	Developmental Surveillance	4	3								1
5	Respiratory Syncytial Virus (RSV)	5	1	1							1
6	Gastro Esophageal Reflux (GERD)	5	1			1					1
7	Chronic Lung Disease (CLD)	5	1		1						1
8	Retinopathy of Prematurity (ROP)	4	2	1							1
9	Hearing Screening	3	2	2							2
10	Blood Pressure	4	1	1		1					1
11	Patient Instructions/Education	3	1	2			1				2
9 point Likert scale from 1 to 9, Inadequate to Adequate											



2.2 MarkUp Guidelines (GEM/GEM Cutter)

Overview

We developed a clinical decision support (CDS) application for premature infant care. The system was designed to assist primary care clinicians in managing the care of these patients during their first two years of life. This section describes our approach in the first of three steps in translating clinical guidelines into CDS logic.

Approach

Our CDS application addresses six areas of preventive healthcare for these vulnerable patients:

- Nutrition recommendations
- Growth assessment
- Development
- Blood Pressure
- Retinopathy of Prematurity (ROP)
- Prevention of Respiratory Syncytial Virus (RSV)

The American Academy of Pediatrics (AAP) has developed policy statements addressing two of these six areas: Retinopathy of Prematurity (RSV) and Prevention of Respiratory Syncytial Virus (RSV).

AAP policy statements are written and structured in a format used in clinical guidelines. To systematically translate the written language of these documents into CDS logic, we applied guideline translation tools and processes developed by GLIDES. This section of our implementation guide describes the first of three steps in the guideline translation process.

The GEMCutter process of translating guideline text into CDS logic is iterative; each iteration produces a more detailed and refined translation. The first step is to use GEMCutter to identify and organize guideline text representing high-level recommendations, or actionable statements that will eventually be translated into detailed and precise CDS rules.

Download and install the latest version of GEMCutter to your computer workstation (PC or Mac). Launch GEMCutter, create a new project and upload the clinical document. Note, we will use the document, Modified Recommendations for Use of Palivizumab for Prevention of Respiratory Syncytial Virus Infections, as an example throughout this guide.

The next step is to identify the section of the document that contains recommendations suitable for CDS. The title, “recommendations” is often used to identify this section of a guideline, but in some cases a different heading may be used. For example, in the RSV-Palivizumab document the section is titled, “Eligibility Criteria for Prophylaxis of Infants and Young Children at High Risk.”

Once the source of recommendations is identified, GEMCutter is used in the following sequence:

1. From the eligibility criteria/recommendation section of the document, identify text representing a high level recommendation.
2. Enter a descriptive name for the recommendation in GEMCutter
3. Within the recommendation text, identify any text representing conditional or imperative statements
4. Highlight and add this text to the conditional/imperative sub section of the recommendation
5. Repeat 1 – 4 until document is complete.

Using the example document, the AAP Policy Statement, "Modified Recommendations for Use of Palivizumab for Prevention of Respiratory Syncytial Virus Infections" please refer to the eligibility criteria of patients with chronic lung disease (page 4, column 1, paragraph 3). We will use this text as an example of the guideline translation process throughout this guide. Here is the text from the document paragraph:

> Infants with CLD: Palivizumab prophylaxis may be considered for infants and children younger than 24 months with CLD who receive medical therapy (supplemental oxygen, bronchodilator, diuretic or chronic corticosteroid therapy) for CLD within 6 months before the start of the RSV season. These infants and young children should receive a maximum of 5 doses. Patients with the most severe CLD who continue to require medical therapy may benefit from prophylaxis during a second RSV season. Data are limited regarding the effectiveness of palivizumab during the second year of life. Individual patients may benefit from decisions made in consultation with neonatologists, pediatric intensivists, pulmonologists, or infectious disease specialists (AI).

While the subject of this entire paragraph refers to a recommendation on Chronic Lung Disease, it is best parsed into two separate conditionals within the recommendation:

Conditional 1) Infants with CLD

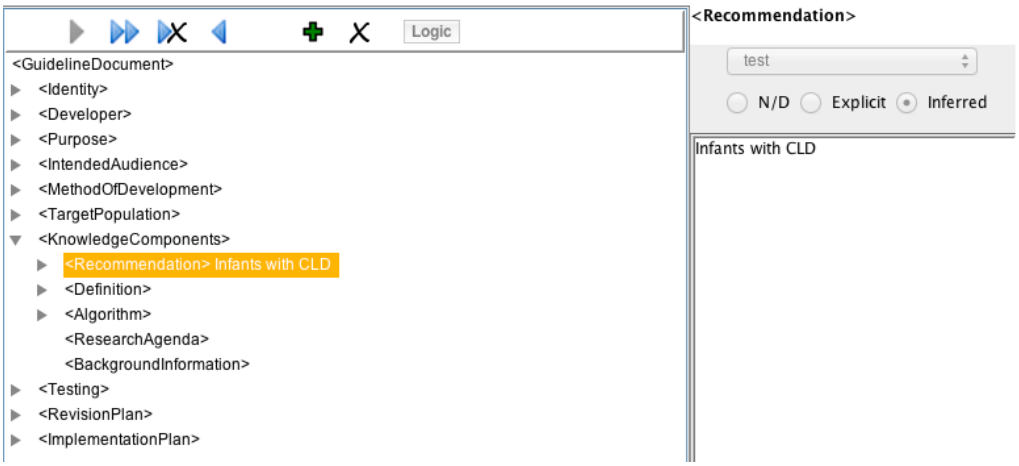
> Infants with CLD: Palivizumab prophylaxis may be considered for infants and children younger than 24 months with CLD who receive medical therapy (supplemental oxygen, bronchodilator, diuretic or chronic corticosteroid therapy) for CLD within 6 months before the start of the RSV season. These infants and young children should receive a maximum of 5 doses.

Conditional 2) Patients with the most severe CLD

> Patients with the most severe CLD who continue to require medical therapy may benefit from prophylaxis during a second RSV season. Data are limited regarding the effectiveness of palivizumab during the second year of life. Individual patients may benefit from decisions made in consultation with neonatologists, pediatric intensivists, pulmonologists, or infectious disease specialists (AI).

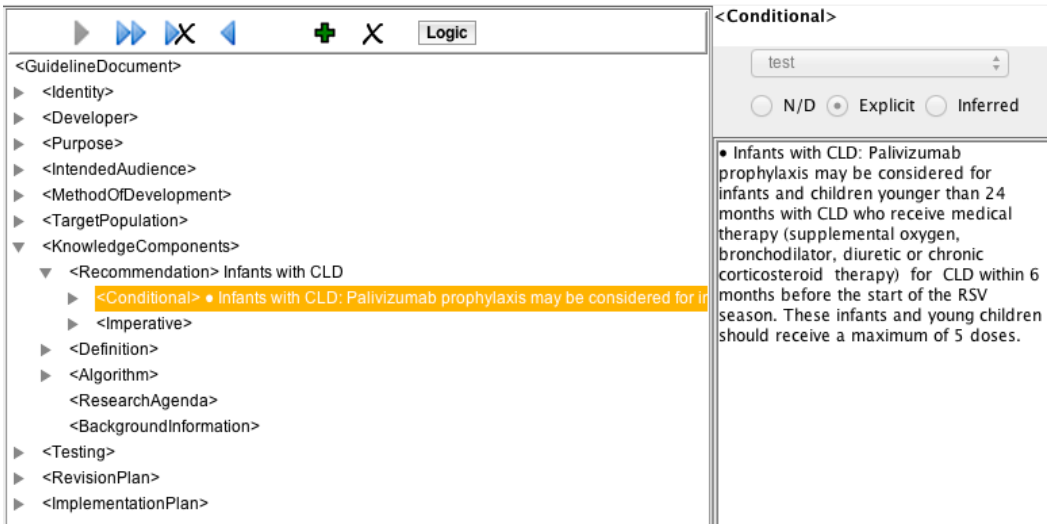
Clicking the "twisty" for Knowledge components expands the section. We clicked on Recommendation and added text in the right panel to title the recommendation.

Figure 2.2.1: GEMCutter with Recommendation



Clicking the "twisty" for Recommendation expands the next level of the hierarchy. The first recommendation contains criteria that are actionable, so "Conditional" is selected (as opposed to Imperative). The text of the recommendation is highlighted and using the single right arrow "Move text" icon the selected text is copied into the conditional statement (see Figure 2.2.2). Note, we will use this conditional as an example throughout this document.

Figure 2.2.2: GEMCutter with Conditional



Clicking the "+" sign adds a new conditional and the second conditional within the recommendation is added in the same manner. This entire process is repeated for the entire document in identifying and creating each recommendation and its component conditional/imperative statements.

2.3 Create Structured Rules

Overview

We developed a clinical decision support (CDS) application for premature infant care. The system was designed to assist primary care clinicians in managing the care of these patients during their first two years of life. This section describes our approach in the second of three steps in translating clinical guidelines into CDS logic.

Approach

For each conditional/imperative statement identified in section 2.2, the following steps are performed:

1. For conditional statements:
   a. Identify decision variables and values
   b. Identify action(s)
   c. Compose/edit Boolean logic
   d. Indicate evidence quality and recommendation strength
2. For Imperative Statements:
   a. Identify scope
   b. Identify directive
   c. Indicate evidence quality and recommendation strength
3. Repeat until document is complete.

Continuing with our example source text on infants with CLD, recall the conditional text identified and highlighted in GEMCutter:

```
Infants with CLD: Palivizumab prophylaxis may be considered for infants
and children younger than 24 months with CLD who receive medical
therapy (supplemental oxygen, bronchodilator, diuretic or chronic
corticosteroid therapy) for CLD within 6 months before the start of the
RSV season. These infants and young children should receive a maximum
of 5 doses.
```

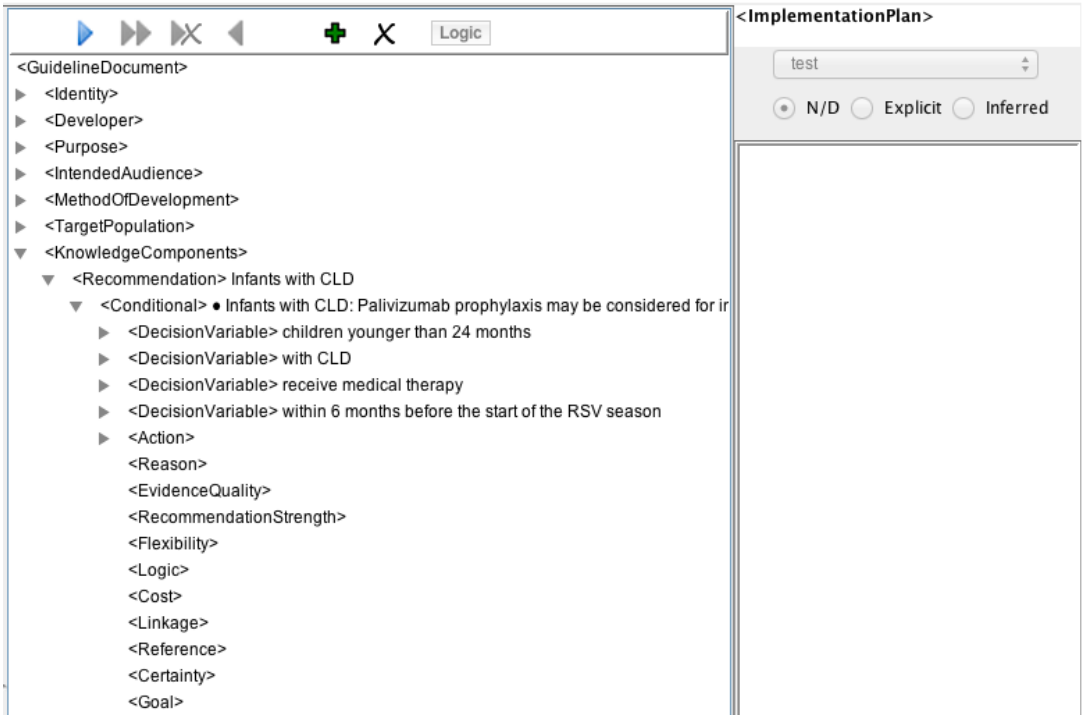
The next step in the process is to identify decision variables within this text. Within the conditional statement "Infants with CLD" we identified four decision variables:

1. children younger than 24 months
2. with CLD
3. receive medical therapy
4. within 6 months before the start of the RSV season

```
Infants with CLD: Palivizumab prophylaxis may be considered for infants
and children younger than 24 months with CLD who receive medical
therapy (supplemental oxygen, bronchodilator, diuretic or chronic
corticosteroid therapy) for CLD within 6 months before the start of the
RSV season. These infants and young children should receive a maximum
of 5 doses.
```

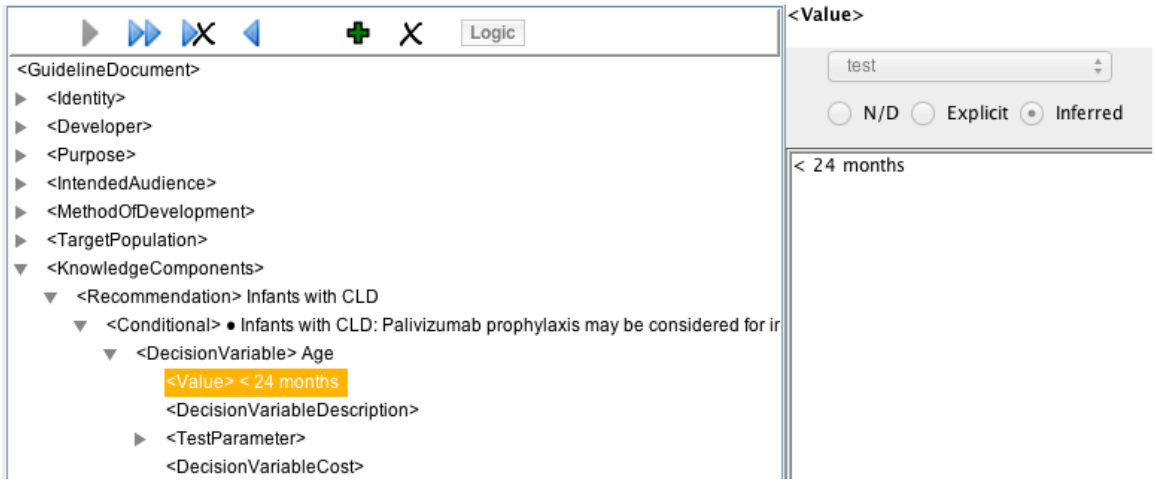
After expanding the twisty for the conditional statement, we highlighted the text representing each variable and used the "Move text" button to add this text to four corresponding Decision Variables (see figure 2.3.1).

Figure 2.3.1 Decision variables added to conditional statement



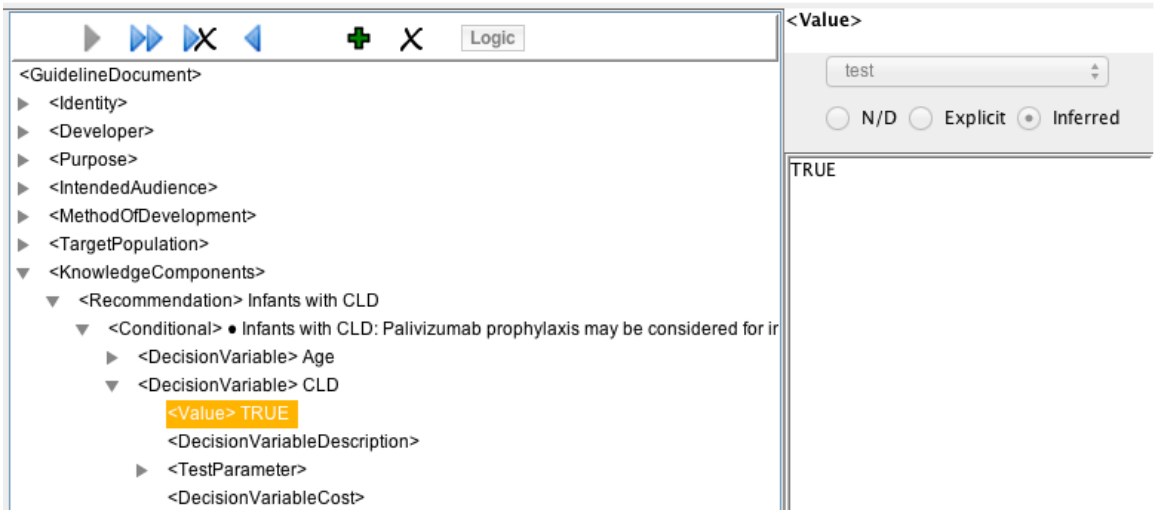
The next step in the process is to identify and add values for each decision variable. The first decision variable, "children younger than 24 months" represents a time calculation so we renamed the variable, "Age" and assigned a value of "< 24 months" (see figure 2.3.2).

Figure 2.3.2 Decision variable, Chronological Age, with value, < 24 months



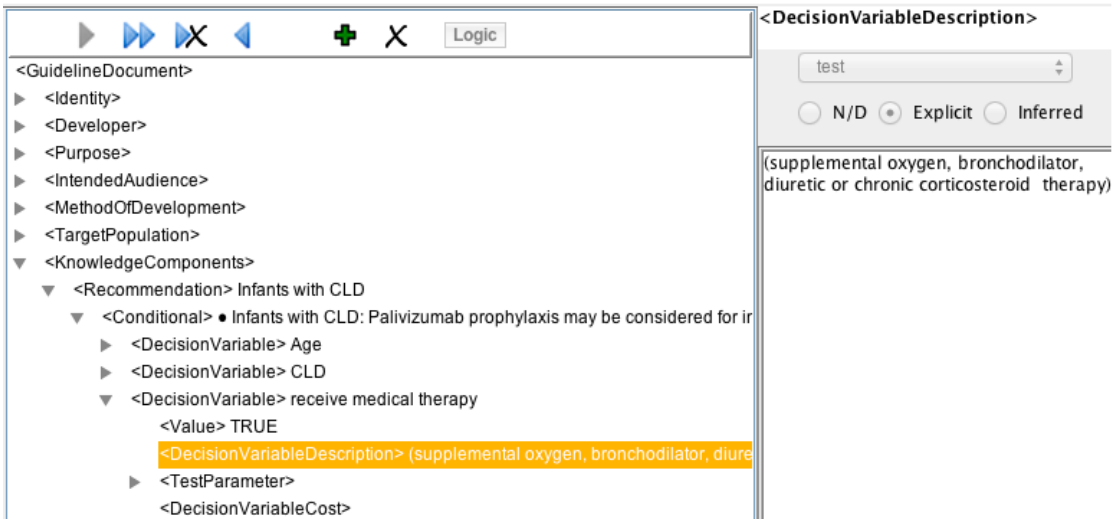
The second decision variable, “with CLD” was renamed “CLD” and given a value of TRUE (see figure 2.3.3).

Figure 2.3.3 Decision variable, CLD, with value, TRUE



The third decision variable, “receive medical therapy” was also given a value of TRUE. The document also lists a set of therapies in parenthesis, “(supplemental oxygen, bronchodilator, diuretic or chronic corticosteroid therapy).” These are critical to the ultimate definition of this decision variable, but lack the detail to generate more detailed logic at this point. So, for now we simply added this text to the decision variable description field (see figure 2.3.4)

Figure 2.3.4 Decision Variable Description



Finally, the fourth decision variable, “within 6 months before the start of the RSV season” was renamed to “Start of RSV Season” and given a value of “<= 6 months.”

To summarize, here are the values for all four-decision variables within this conditional statement:

1. Age — Value < 24 Months
2. CLD — Value = TRUE
3. Receives medical therapy — Value = TRUE
4. Start of RSV season — Value <= 6 months

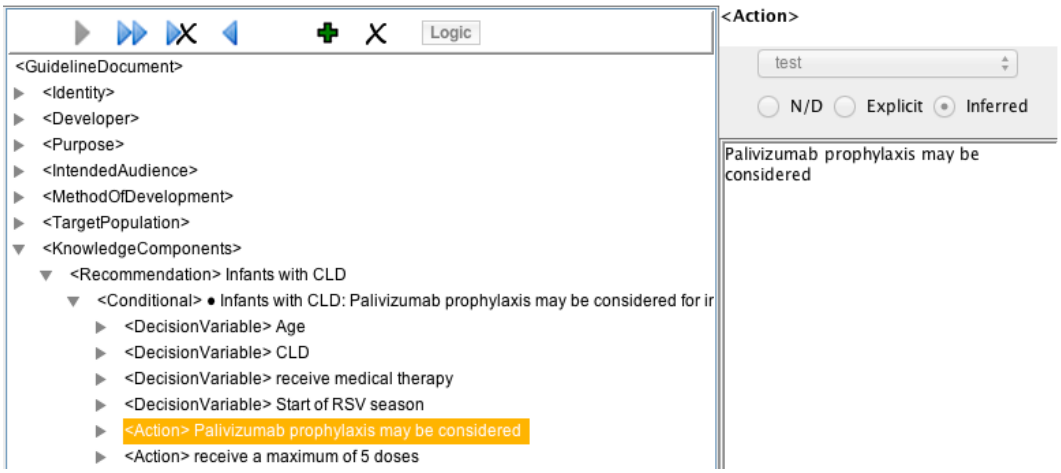
With all decision variables identified, the next step is to identify and enter Actions for each conditional statement. From the source text we identified two actions:

1) Palivizumab prophylaxis may be considered
2) receive a maximum of 5 doses

> Infants with CLD: Palivizumab prophylaxis may be considered for infants and children younger than 24 months with CLD who receive medical therapy (supplemental oxygen, bronchodilator, diuretic or chronic corticosteroid therapy) for CLD within 6 months before the start of the RSV season. These infants and young children should receive a maximum of 5 doses.

Both actions were entered for the conditional statement (see figure 2.3.5)

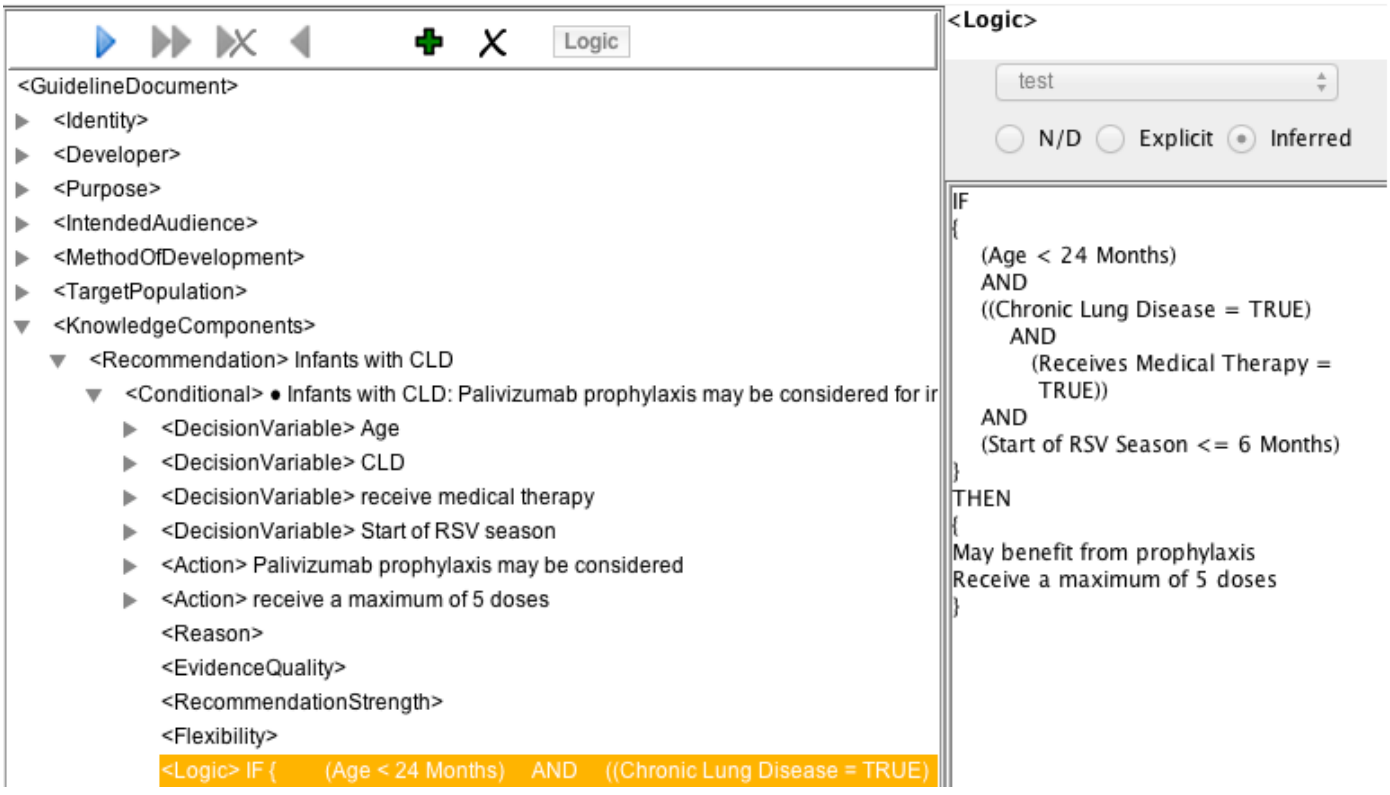
Figure 2.3.5: GEMCutter Actions



With decision variables and actions defined, we can now use GEMCutter to generate/create the initial logic statement. Using GEMCutter's logic section of the conditional statement, the Boolean text is edited and adjusted as needed resulting in the following human readable logic for the conditional statement on Infants with CLD (see Figure 2.3.6):

```
IF
{
     (Age < 24 Months)
     AND
     ((Chronic Lung Disease = TRUE)
       AND
            (Receives Medical Therapy = TRUE))
     AND
     (Start of RSV Season <= 6 Months)
}
THEN
{
May benefit from prophylaxis
Receive a maximum of 5 doses
}
```

Figure 2.3.6: GEMCutter Logic statement.



2.4 Apply Action Types and Standard Vocabularies

Overview

We developed a clinical decision support (CDS) application for premature infant care. The system assists primary care clinicians in managing patient care during the first two years of life. Continuing from Section 2.3, this section describes our approach in the third of three steps in translating clinical guidelines into CDS logic.

Approach

There are two primary tasks described in this section:

1. Refine the GEMCutter output to address all issues of ambiguity, gaps or contradictions derived from the source document.
2. Assess the feasibility of retrieving each decision variable from the EMR and applying the document-based logic to EMR data.

These two activities are best performed concurrently, as findings from one apply to and/or support the other in an iterative process. Essential to each activity are two important project roles: the Clinical Expert Panel and EMR Data analyst (see Chapter 3.5A for a complete list of project team roles):

- Our Clinical Expert Panel included physicians and nurse practitioners with expertise in premature infant follow up and neonatology. We strongly recommend that CDS projects enlist a panel with deep expertise in the clinical problem being addressed. This will be essential to the guideline translation process. The panel met weekly for many months to review and refine the guideline's recommendations.
- The EMR Data Analyst was highly experienced in using EMR data to support research. They applied the Clinical Expert Panel's recommendations to EMR data to assess the feasibility of reliably retrieving decision variables from the EMR.

We will continue with the example RSV-Palivizumab conditional statement from Step 1:

```
IF
{
     (Age < 24 Months)
     AND
     ((Chronic Lung Disease = TRUE)
       AND
            (Receives Medical Therapy = TRUE))
     AND
     (Start of RSV Season <= 6 Months)
}
THEN
{
May benefit from prophylaxis
Receive a maximum of 5 doses
}
```

The statement includes four decision variables (Age, Chronic Lung Disease, Receives Medical Therapy and Start of RSV Season) and values for each that must all occur to satisfy the conditional statement. Two of these variables are both well defined and easily measured: (1) "Age" can easily be determined from the

EMR and (2) the date for "Start of RSV Season" is a constant based on geographical area. However, source text of the recommendations section actually lacks sufficient precision to define these variables.

The decision variable "Age" requires more detail since most patients being evaluated against these criteria are premature infants. Therefore it must be determined if this variable refers to patient chronological or corrected age. The Clinical Expert Panel confirmed that the document criteria utilized chronological age, so the logic statement and decision variable were edited to: Chronological Age < 24 Months.

The decision variable "Start of RSV Season" presents similar requirements for more detail. In Philadelphia, and most of the US, RSV season starts each year on November 1. However, to be complete in our CDS translation efforts, we developed rules that could be utilized anywhere in the US. To do this we included additional logic addressing the start of RSV season in Florida (this information was provided in the policy statement, but not in the recommendation section). Therefore additional logic for defining, "Start of RSV Season" would be:

```
If location = Southeast Florida
     THEN Start of RSV Season = 7/1
ELSE
      If location = North-central Florida OR Southwest Florida
           THEN Start of RSV Season = 9/15
ELSE
     Start of RSV Season = 11/1
```

The decision variable "Chronic Lung Disease" is more complex and challenging. Corresponding ICD9 code(s) have to be identified and, while important health problems such as this are often documented appropriately on the problem list in the EMR, the rules must also determine if the diagnosis is current or active. Most EMRs are equipped with problem lists that can record this distinction. Given this, the rules must identify only diagnostic codes that are "active." Also, due to interactions between EMR design and provider training, individual providers may manage the problem list differently. In addition, clinical interpretation of what is an active problem may differ. For example, some providers in our health system tended to re-classify patients with chronic lung disease due to prematurity who continued to need bronchodilator medicines at about 12 months of age as having "asthma." The Clinical Expert Panel easily identified a set of ICD9 codes that described chronic lung disease, but discussions about what to consider "active" disease were more complex. Our panel decided to err on the side of being overly inclusive and classified patients up to age 24 months as potentially having "active" chronic lung disease even if the diagnosis had been marked as resolved on the EMR problem list. We also decided that designing CDS to account for all possible inconsistencies in EMR usage was beyond the scope of our work.

The third decision variable, "Receives Medical Therapy" presents several challenges. First, this variable is dependent on "Chronic Lung Disease" being TRUE (if the patient does not have CLD, then this need not be evaluated). This is important to consider because treatments for chronic lung disease are the same as treatments for other health problems (such as asthma or cardiac problems). Second, while therapy itself is determined by the occurrence of at least one of the four therapies (supplemental oxygen, bronchodilator, diuretic or chronic corticosteroid therapy), each of the four therapies must be further defined both clinically and in terms of the EMR data structure. Therefore each of the four therapies was reviewed by the Clinical Expert Panel and defined with more precision. The EMR Data Analyst created queries testing the feasibility of retrieving information on each therapy from the EMR. Oxygen treatment was particularly unreliable to identify based on the medication order itself. We considered searching for evidence of hypoxemia based on nursing assessments in the office or durable medical equipment orders

related to oxygen treatment such as oxygen tubing, but determined that these approaches did not provide additional precision. Bronchodilators, diuretics and corticosteroids (both inhaled and oral) were reliably identified based on a list of generic medication names. We were concerned that it may be difficult to distinguish oral corticosteroid therapy for chronic lung disease from other more acute problems (e.g. croup). The panel chose to classify any corticosteroid prescription as representing "chronic" treatment.

Managing Decision Variables

During this phase of the project we discovered a few "lessons learned" on the management and communication of decision variables.

One of the first actions we can recommend is to go through GEMCutter extractor reports and clean up all decision variable names and, in particular, identify all variables used in more than one conditional statement and apply a standard variable naming scheme.

GEMCutter extractor reports were used extensively by our Clinical Expert Panel. The panel's recommendations were applied to the GEMCutter project and the reports re-run for additional review.

We performed our project with GEMCutter version 2.5. New versions have additional features, but we found it essential to create and manage a "data dictionary" in Excel where each decision variable was further defined and tracked.

3 Localize Knowledge

The following chapters map to the GLIDES website and sections describing key CDS activities under the phase, Localize Knowledge:

- 3.1 Create Executable Rules
- 3.2 Adapt to Local Workflow
- 3.3 Design UI
- 3.4 Built and Test
- 3.5 Deploy and Evaluate
    - 3.5.1 Project Planning and Control
    - 3.5.2 Deployment and User Adoption
    - 3.5.3 Evaluation Plan

3.1 Create Executable Rules

Overview

We developed a clinical decision support (CDS) application to assist primary care pediatricians with the care of premature infants from the time of NICU discharge through the 2nd birthday. Continuing from Section 2.4, this section describes our approach in converting the guideline translation CDS logic into executable rules.

Approach

Rules derived from the translation of the ROP and RSV-Palivizumab policy statements each utilize between 20 – 30 patient variables applied to over a 100 decision points. Many EMR products do not provide an adequate environment for authoring and executing rules on this scale. Given the complexity and detail of clinical guidelines, use of an appropriate rules engine to implement complex logic is essential. The rules engine must also respond quickly under typical peak load. The following sections describe our experience choosing a rules engine for implementing the ROP and RSV recommendations.

Rules Engine Selection

We investigated two open-source, freely available rules engines: JBoss Drools Expert, and Pyke. Arden Syntax, a widely accepted as a standard syntax for clinical decision support rules, was a 3rd appealing option for a rules engine. However, the lack of a self-contained implementation of this syntax outside an EMR at the time of this project was a major barrier. As part of our investigation we implemented a subset of the Palivizumab (RSV) eligibility and immunization scheduling rules in both Drools and Pyke. Although the rules were successfully implemented in both engines, we selected the Java-based Drools engine. Key benefits of Drools included: (1) presence of a large development community for Drools; (2) several examples of its successful use healthcare settings for clinical decision support; and (3) availability of many tutorials and reference materials. Pyke, a Python-based rules engine, benefited from a simpler syntax and some additional features not currently available in Drools such as backward-chaining rule execution. However, the user community was very small, we did not find any examples of its use in healthcare, and there was limited documentation available.

Rules Engine Programming

Once the detailed data definitions from the guideline translation process were defined and validated the rules engine was programmed. The following sections work through our example conditional statement derived from the guideline translation process, which addressed patients with chronic lung disease:

```
IF
{
     (Age < 24 Months)
     AND
     ((Chronic Lung Disease = TRUE)
       AND
            (Receives Medical Therapy = TRUE))
     AND
     (Start of RSV Season <= 6 Months)
}
THEN
{
May benefit from prophylaxis
Receive a maximum of 5 doses
}
```

Decision Variables

The first task in creating the rules is to translate the required decision variables into "facts" that can be asserted in the rules execution environment. Our preference was to adhere as closely as possible to the description of the decision variables that was provided in the text, with one "fact" per decision variable.

The Decision variables required for example conditional statement were:

1. Age
2. Chronic lung disease (CLD)
3. Receives medical therapy
4. Start of RSV Season

All decision variables in healthcare require some consideration about the time point at which the value was observed or interpreted. For example, the value of "age" is constantly changing when the relevant time point is the present moment. However, in this case the value of interest is actually the child's at the onset of the RSV season. Additional complexity about how to assign a value to each decision rule arose from our intention to use the rules both prospectively (i.e. to make recommendations for the current or upcoming season) and retrospectively to interpret guideline adherence in prior seasons. Similar issues arose for interpretation of whether chronic lung disease (CLD) was present and whether medical therapy for CLD was present during the time period of interest.

Choosing the best definition for each decision variable in the Drools environment required several iterations. For example, we initially were very stringent about requiring that chronic lung disease have a documented onset date and resolution date. However as we applied this definition to our existing data we quickly realized there were very different opinions among clinicians about the meaning of chronic lung disease (CLD). Some providers consider CLD to be a life-long risk and consider it an active problem at all times. Other providers replaced the chronic lung disease diagnosis with asthma at surprisingly young ages if the treatment consisted primarily of bronchodilator (albuterol) treatment. Ultimately we chose to consider the presence of any diagnosis for CLD before the second birthday to indicate that the problem was present from birth through the second birthday (the age range during which the RSV risk criteria for CLD apply).

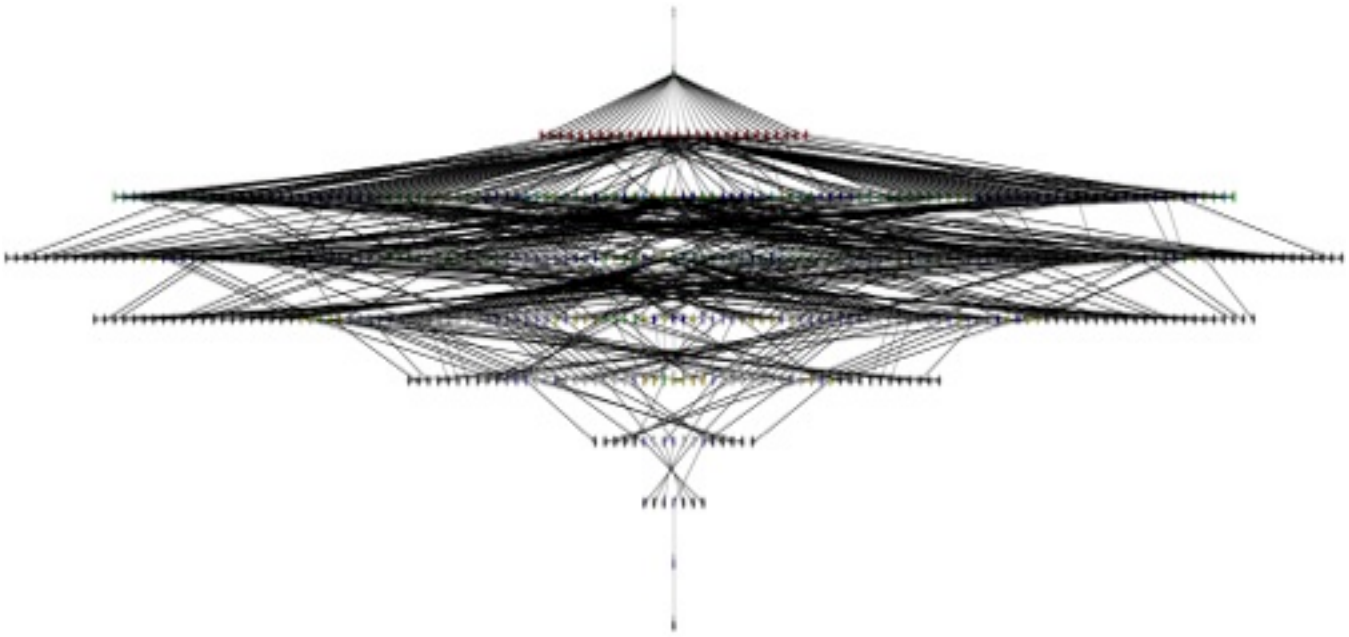
Executable Rule

Shown below is example conditional statement in the final step of the translation process – written as a DROOLS rule. We have placed comments (lines beginning with a # character) in each rule to clarify where in the source guideline document the recommendation was found. Note for retrospective analyses that eligibility must only be considered for RSV seasons that ended after the child's birth, which is not explicitly stated in the guideline. Also, writing this rule raised a question about whether children who meet eligibility criteria based on CLD should receive 5 doses even if they reach their second birthday (see TODO comment below). In this case we chose to recommend 5 doses, even if some doses would occur after the child's 2nd birthday.

```
# Criteria 1. Infants with CLD (Page 4, Column 1, Paragraph 3) - Conditional - 1.1 Infants with CLD
# Infants with CLDz <24 mo (at start of season)
# who received medical therapy (O2, inhaled meds or diuretics)
# for CLD within 6 mo prior to start of season ï¿½ should receive up to up to 5 doses
rule "Eligible for 5 doses due to chronic lung disease"
    ruleflow-group "rsv-risk-eligibility"
    when
        # find patients with chronic lung disease as a risk factor
        $p: Patient()
        $cldz: RSVChronicLungDisease()
        # determine the start date for the relevant RSV season.  be sure patient was
                born before the season end
        RSVSeason($startSeason: startDate, $endSeason: endDate >
                ($p.getBirthDate()))
        # check to make sure age < 24 months at start of season
        # TODO: clarify, if child reaches 24 months during season is immunization
                stopped
        $ageMonthsStart: Integer(intValue < 24) from $p.ageMonthsAt($startSeason.minusDays(1))
        # check to see if at least one prescription related to chronic lung disease
                was active
        # within the 6 month period preceding the season
        # qualifying prescriptions: supplemental oxygen, bronchodilator, diuretic or
                chronic corticosteroid therapy
        exists (Prescription(endDate == null || endDate >= ($startSeason.minusMonths(6)),
                            pharmClass matches
"(?ism).*\\b(?:diuretics?|corticosteroids?|oxygen|antiasthmatics?)\\b.*" || generic matches
"(?ism).*\\b(?:oxygen?)\\b.*")
                            from $p.getPrescriptions())
    then
        # eligible for 5 doses
        RSVEligibleCandidate fact = new RSVEligibleCandidate();
        fact.setStartDate($startSeason);
        # calculate patient age in months at the end of the season to determine maximum doses possible
        fact.setDoses((int)Math.min(5, $p.ageMonthsAt($endSeason) + 1));
        fact.setReason("chronic lung disease on treatment");
        insert(fact);
end
```

After the rules have been written, Drools can calculate a visualization of the RETE algorithm that is used to optimize rules execution (see Figure 3.1.2). In this view each node represents an individual processing step in the rules and illustrates the surprising complexity that arises computationally when converting guideline statements to executable form.

Figure 3.1.1: RETE Diagram/Visual Representation of Rules Translated from RSV/Palivizumab Policy Statement



3.2 Adapt to Local Workflow

Overview

We developed a clinical decision support (CDS) application to assist primary care pediatricians with the care of premature infants from the time of NICU discharge through the 2nd birthday. This section describes our approach to integrating our system with our commercial electronic medical record (EMR) and established clinician use and workflow of the EMR.

Approach

Balancing the design of our CDS system with established EMR workflow and processes was a critical step towards successful adoption of our system. From previous experiences with other CDS tools we have found that achieving this balance is based on an approach where EMR deficiencies are addressed with additional functionality. Discovering and developing this functionality requires the following:

1. EMR training
2. Detailed study of clinician use of the EMR
3. Detailed study of clinician use of other tools and artifacts
4. EMR automation and documentation
5. Cognitive tools
6. Patient education
7. Clinician control

EMR Training

We believe it is essential that staff involved in the design and development of the system be trained in the EMR. While clinicians involved in the project all had extensive EMR experience and training, both our user interface design analyst and developer completed extensive EMR training and certification. While expensive and time consuming, we feel such training is critical to more effectively apply their expertise to the design and functionality of the system.

Detailed Study Of Clinician Use Of The EMR

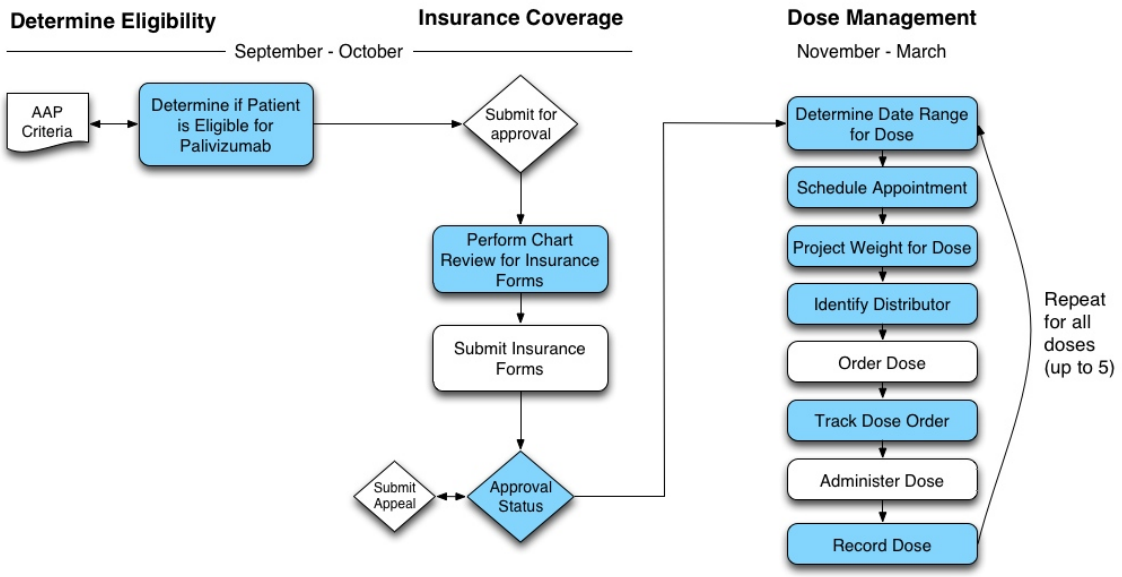
While EMR training/expertise is essential in the development of CDS, it is no substitute for direct observation and study, and can make such study more effective. Our user interface design analyst and developer spent a great deal of time shadowing clinicians in the process of caring for premature infants. This combination of EMR training and direct observation was valuable in identifying workflow issues and potential solutions.

A simple, descriptive example involves use of EMR-based growth charts for assessing premature infants. Based on usability heuristics, and user interface design best practice, the EMR growth chart screens had potential to confuse clinicians as to which chart to select for premature infants or whether the correct chart was selected. During clinician shadowing this exact scenario was observed – the clinician, an expert in premature infant care, was highly engaged in discussions with the parent and while quickly scanning the growth chart failed to recognize an incorrect chart was being displayed. Discussions with clinicians revealed dissatisfaction with this aspect of the EMR. We then used EMR data analysis to study a broader range of clinicians and patient data and discovered that nearly 50% of premature infant encounters included the clinician viewing the incorrect growth chart. From this we determined that a useful function of the CDS system would be to present to the clinician a detailed assessment of the child's growth using the correct growth charts.

Detailed Study Of Clinician Use Of Other Tools And Artifacts

For many complex patients and care scenarios, clinicians often rely on tools outside the EMR. In developing CDS functionality to support our GLIDES translation of the RSV-Palivizumab document we discovered a highly complex paper-based workflow performed by nurses and/or office managers. While the guideline based translation produced logic supporting the critical task of identifying all at-risk patients, we discovered the EMR lacked the care coordination and communication functionality to support the insurance approval workflow and the management of dose administration (see Figure 3.2.1).

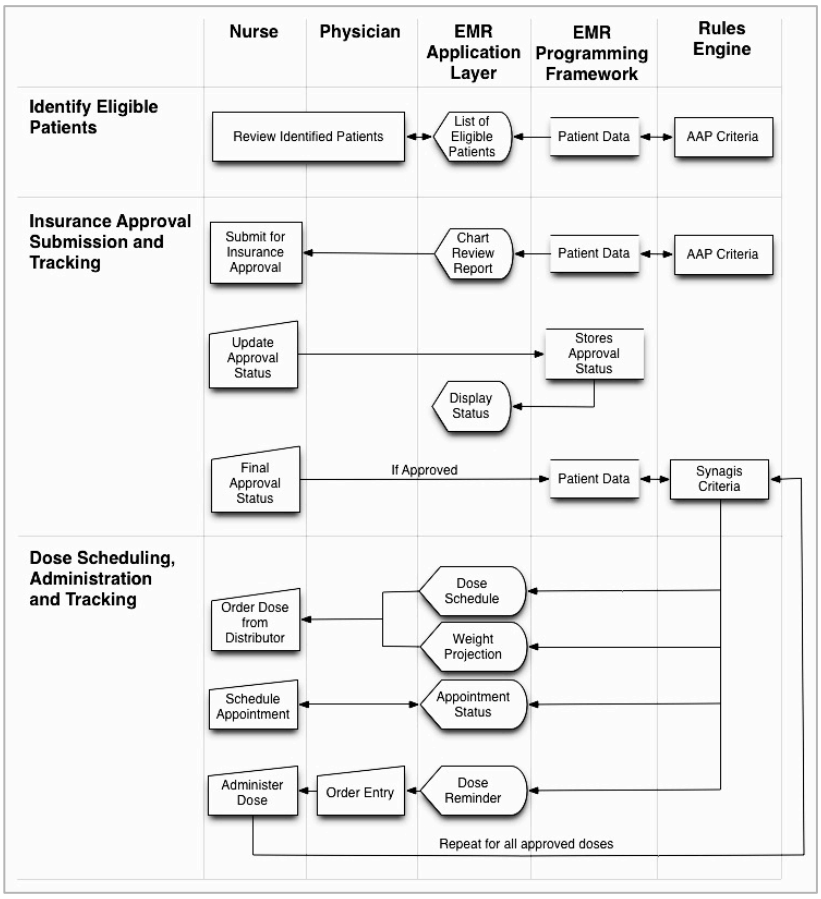
Figure 3.2.1: RSV-Palivizumab Workflow *



* Elements in blue represent tasks where additional EMR support could be provided

Practice staff responsible for this workflow used binders and notebooks to manage the process and estimated the effort at 10-20 hours per patient over the five-month season. With some of our practices managing the care of 50 or more patients eligible for Palivizumab this is a highly significant demand on staff resources, presenting opportunities for improved efficiency and outcomes. We studied the format and use of these paper "shadow charts" and developed EMR-based solutions to support the entire workflow. Figure 3.2.2 represents the system flow between clinicians and components of the CDS system.

Figure 3.2.2: System Flow Diagram



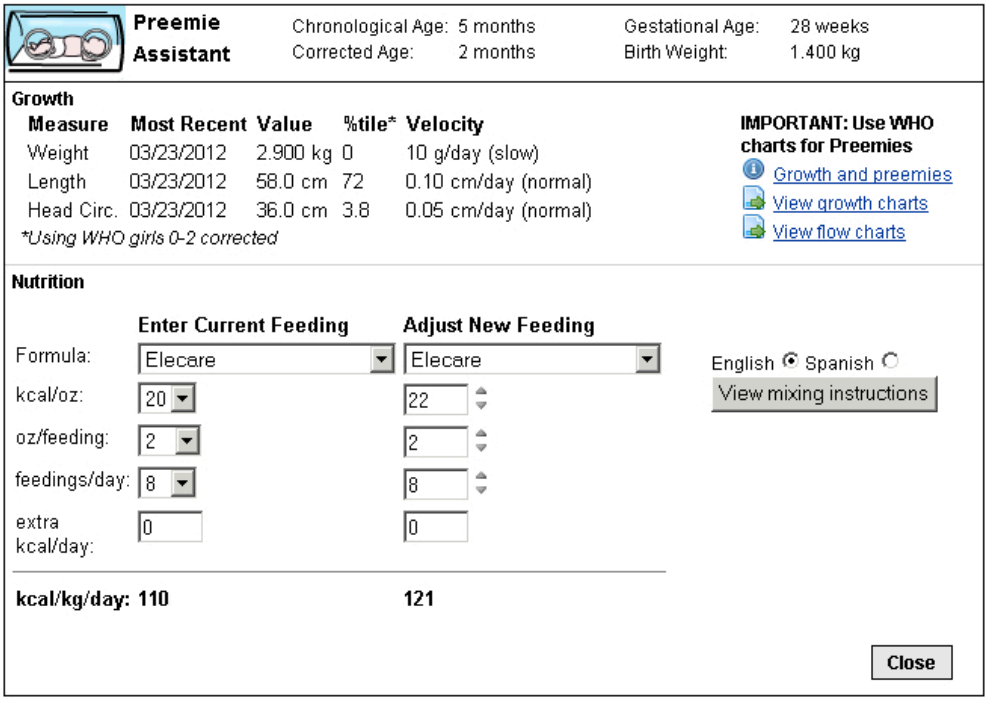
EMR Automation And Documentation

While technically outside the scope of CDS, we discovered that providing additional features to support repetitive and time consuming EMR tasks can also help incent clinician adoption of the CDS tool. Our CDS system included multiple documentation resources, both EMR-based and custom. Our study of clinicians discovered gaps in EMR-based templates for premature infant care, so we developed new templates based on clinician requirements. For example, we developed a new NICU history template for the birth history section of the EMR for physicians and a RSV-based template for nurses. In addition, using our custom decision support framework, we automated note-writing features such as automatically entering the patient's growth assessment and adjusting well visit developmental screening questions for the patient's corrected age.

Cognitive Tools

Clinicians often perform analytical tasks not supported by the EMR. Physicians often calculate feeding in Calories per kilogram per day for premature infants by performing the following: "Calories per ounce" X "Ounces per feeding" X "Feedings per day" / "Patient Weight." We observed some physicians performing this calculation with a hand held calculator while others did the math in their head. From this we determined an EMR-based feeding calculator would have many advantages. First, although physicians are adept at math, the tool would relieve them of a task that might distract from patient engagement. Second, the tool might facilitate discussion with the parent in determining more feasible feeding recommendations. Third, by entering the data in the EMR we could automatically insert the assessment and recommendations in the progress note (See Figure 3.3.3).

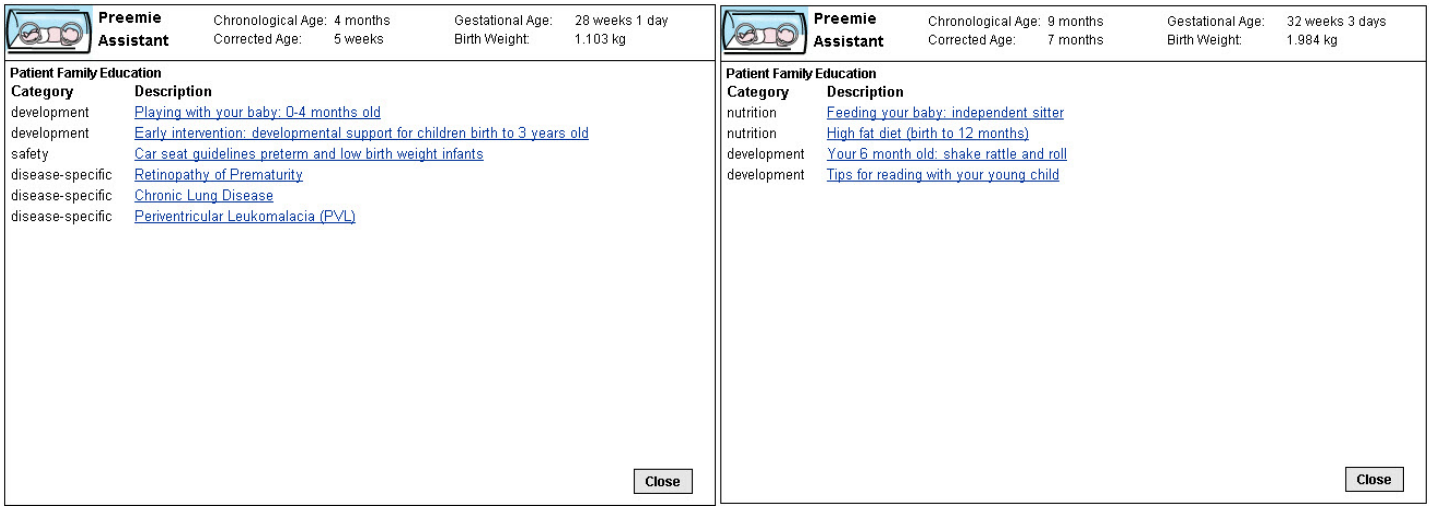
Figure 3.3.3: Screen Shot of "Feeding Calculator"



Patient Education

Another highly effective approach in promoting CDS adoption is to automatically provide clinicians with context-based patient education content. Our hospital intranet includes a library of over 1,300 patient education documents, but in the hectic environment of the exam room, the time taken for searching and retrieving these documents is a significant demand on the clinician's time and attention. Therefore our CDS system provides automatic retrieval of many different forms of patient education, all based on patient data. For example, the feeding calculator described above also includes automatic retrieval of the formula mixing instructions for the new feeding recommendations and even provides an option to select Spanish translation. In addition, we auto insert documentation of the education being delivered to the parent in the progress note. We also provide a complete set of recommended patient education content based on the patient's age and diagnoses (see Figure 3.3.4).

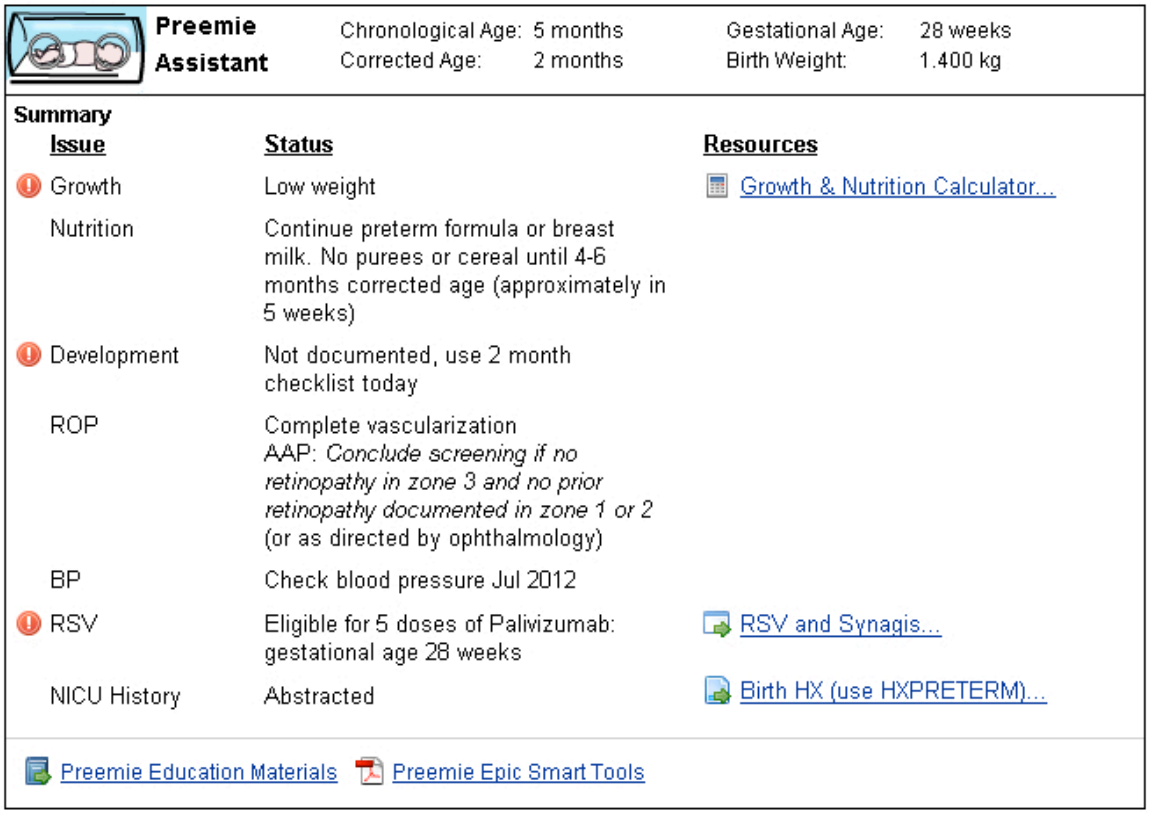
Figure 1.3.4: Patient Education Recommendations



Clinician Control

Finally, we believe a critical aspect to CDS adoption is to follow what may be best described as a passive or nonintrusive approach. Whether clinicians use the EMR efficiently or not, many seem to have well established workflows and a disruption of these preferences may lead to dissatisfaction with the CDS system. In addition, it is impossible to predict every patient care scenario. Therefore providing clinician user control and freedom is essential. User control is maintained by providing clinicians with information and tools, but never forcing them to apply these tools. Figure 3.3.5 shows the main screen of the CDS application that appears via our custom decision support framework directly in the EMR. Each of the six areas of preventative care are presented and summarized. Where applicable, each provides a passive alert and/or a link to optional tools to assist the clinician. The screen provides additional information and links for presenting patient's chronological vs. corrected age, NICU history documentation, patient education and a guide to dedicated EMR-based templates and other documentation aids.

Figure 3.3.5: Summary Screen of Premature Infant CDS Application*



* Note, the application is displayed directly within the outpatient encounter screens of our commercial EMR. Due to vendor restrictions, we are unable to share EMR screen shots.

3.3 Design UI

Overview

We developed a clinical decision support (CDS) application to assist primary care pediatricians with the care of premature infants from the time of NICU discharge through the 2nd birthday. This section describes our user-centered approach in designing and testing the user interface for the CDS system.

Approach

Our CDS system for premature infant care included an extensive set of tools and information displays delivered through our EMR custom decision support framework. To support the design and development of this system we performed a series of integrated user-centered methods. While such methods are essential for a system of this complexity, we feel they can and should be applied to the development of any CDS project. Our approach was based on the following activities, each described in more detail below:

1. Use case development
2. Iterative design
3. User interface mockups
4. Design walkthrough
5. Usability testing
6. Limited beta release

There is no shortage of online information, guides, tutorials and books detailing a wide array of user-centered methods. While such resources are valuable in educating team members on these methods, we also recommend including a team member with expertise in usability, user experience, information architecture, user interaction, human factors and human computer interaction.

Use Case Development

Use cases define the interaction between users and the system by describing patient care scenarios and the clinician-based tasks required to address those scenarios. Our approach was to define and validate as many use cases as possible and to design the system to address each use case. Given this, use cases were the foundation of all our design and user testing activities.

Developing use cases requires extensive study of clinicians and patients. We took several approaches to use case development including shadowing clinicians in practice, clinician interviews and surveys and the analysis of patient data. However, what was unique about this project is how the GLIDES guideline translation process not only provided us with CDS logic, it also defined the bulk of our most important patient care use cases.

Additional resources:

See chapter 2.1 for more information on our use case validation survey.

While there is no standard for use case formats, there are many online and print resources on developing use cases and applying them to a user-centered development process. We recommend the book, “Writing Effective Use Cases,” by Alistair Cockburn as an effective primer on the subject.

Iterative Design

Our approach was iterative, where designs were repeatedly presented to users and modified based on feedback/results. With each iteration, the designs evolved in usability and functionality detail.

Additional resources:
This article by the Nielsen-Norman Group demonstrates the rationale for iterative design:
http://www.nngroup.com/articles/iterative-design/

User Interface Mockups

Developing fully functional prototypes is expensive, time consuming and counter-productive to an iterative design approach where extensive and repeated modifications are expected. To better support the iterative process we relied heavily on user interface mockups that could be developed and modified quickly and at low cost.

A number of dedicated tools can be used to develop user interface mockups such as Balsamiq or Axure. In addition, many people use common applications such as Visio, Omnigraffle or even Power Point. Even paper prototypes have been proven to be an effective resource. Whatever tool, option or approach is available or preferred, the primary objective is to provide mockups that represent the task flow of use cases the system is being designed to support, and can be used to obtain meaningful user feedback.

Additional resources:
Dedicated applications used in our CDS UI design work include:

- Balsamiq is a unique, easy to use application that focuses on creation of "low fidelity" mockups presented with a hand drawn effect. The intention is to avoid distraction on visual detail, bringing more focus to interactivity. It can be used to create static mockups or to combine mockups in a more interactive format: http://www.balsamiq.com/
- Axure is a highly detailed, comprehensive UI design tool that supports development of realistic looking and interactive UI prototypes. Some of our Axure prototypes were sufficiently detailed and interactive to be used in usability testing: http://www.axure.com/

Design Walkthrough

Of course the primary purpose of user interface mockups is to present them to representative end users for feedback. In our development process we chose the design walk through method that is well suited to early phase prototypes that lack interactivity.

The design walkthrough is performed by creating a set of sequential user interface mockups to represent the task flow for a set of use cases. Users (individually or in groups) are presented the basic scenario for each use case. Users are then presented the first screen shot of the mockup and are asked what action they would perform. If the subject correctly identifies the next action, the next screen shot is presented. If the subject fails to identify the next action a problem is noted and will be addressed via redesign and additional user reviews. Please note, the design walkthrough also relies on a great deal of open-ended comment and discussions to further ascertain user requirements.

Usability Testing

Our final user-centered method was a low cost usability test to validate the usability and functionality of our CDS system. Usability testing is a widely established method of assessing the usability and utility of an application, based on representative users performing a set of task-based scenarios by directly interacting with the system (fully functioning system or interactive prototype). Unlike a Focus Group where only subjective data is collected, a usability test produces a diverse set of objective and subjective results including the ability of participants to complete real world tasks, errors committed, time-on-task and subjective ratings of participant satisfaction with various attributes of the application. These metrics can be used to set specific testing targets that must be achieved before the system is deemed ready for release.

Limited Beta Release

CDS systems are subject to many complex combinations of patient data and clinical scenarios. Even with successful usability testing results and a foundation of data analysis, we strongly recommend that a CDS system be released at first to a small group of subjects to further assess its functionality and usability. For our project we released the CDS system for premature infant care to a small group of clinicians who were willing to provide feedback on their direct experience with the system. This limited release helped raise many useful scenarios and issues to be addressed prior to release to the entire study population.

3.4 Build and Test

Overview

We developed a clinical decision support (CDS) application to assist primary care pediatricians with the care of premature infants from the time of NICU discharge through the 2nd birthday. This section describes our approach in building and testing the system.

Approach

Prior to deployment we iteratively designed, built and test all components of the decision support intervention over a 12-month period. This section emphasizes the testing aspect of this process related to the rules engine. Phases of testing included: (1) unit testing with fabricated data; (2) testing with production data; (3) load testing to assess system response time; and (4) limited release at a single care location.

Unit Testing with Fabricated Data

Test cases were coded in Java to allow testing of specific scenarios in the development environment. We used the Eclipse development environment, which allows unit testing to be performed interactively. Unit tests can help verify that the recommendations produced by the rules engine do not change in unexpected ways as rules are edited or created. Unit tests can also focus testing on unusual situations or "edge cases" where the value of selected variables fall exactly on thresholds specified in the guideline document. For example, age 24 months at the start of the RSV season is an edge case in the recommendations related to eligibility for RSV vaccine due to chronic lung disease. Shown below is an example of fabricated patient data for a child born on 30/31/2009 who was eligible to receive RSV vaccine during two RSV seasons (2009-2010 and 2010-2011).

```
Patient p = new Patient();
p.setBirthDate(new DateTime(2009,10,31,0,0,0,0));
p.setEvalDate(new DateTime(2010,8,25,0,0,0,0));
p.setEvalInterval(new Interval(p.getBirthDate(), p.getEvalDate()));
p.addIdentifier(new Identifier(Identifier.DEPARTMENT_ID, "50601012"));
p.addIdentifier(new Identifier(Identifier.MRN, "01234567"));
p.getDemographics().setState("PENNSYLVANIA");
p.setBirthHistory(new BirthHistory(30,1.4,"the child was born at HUP"));
p.getBirthHistory().setDischargeDate(p.getBirthDate().plusDays(30));
p.setSocialHistory(new SocialHistory("Exposed to smoking: yes"));
p.addImmunization(new Immunization("RSV",new DateTime(2009,11,5,0,0,0,0)));
p.addImmunization(new Immunization("RSV",new DateTime(2009,12,15,0,0,0,0)));
p.addImmunization(new Immunization("RSV",new DateTime(2010,1,1,0,0,0,0)));
p.addDiagnosis(new Diagnosis("770.70",new DateTime(2010,3,1,0,0,0,0),"chronic lung disease"));
p.addPrescription(new Prescription(new DateTime(2010,1,1,0,0,0,0),"diuretic","furosemide"));
```

We chose to develop a modest number of unit tests with fabricated data and relied heavily on subsequent testing with retrospective data from our production EMR. In the future we plan to spend much more time on unit testing, and likely will write one or two unit tests for each rule.

Testing with Production Data

Our testing efforts benefited from readily available electronic data from prior RSV seasons. We developed a data extraction method that packaged and sent data from real patients to the rules engine so the output could be inspected. In the case of RSV we used the rules engine to make a determination whether each patient was eligible to receive RSV vaccine. We then examined two groups of patients: (1) children who the rules engine indicated were eligible but did not receive RSV vaccine (potential false positives); and (2) children who actually did receive the vaccine but were not recognized as eligible (potential false negatives). We resolved discrepancies by expert review and iteratively edit the rules until we were satisfied with the results.

After the retrospective testing was satisfactorily completed, it was late summer 2011 and our clinical practices were preparing for the upcoming 2011-2012 RSV season. Consequently we used this natural opportunity to produce lists of established patients in our primary care network who met eligibility criteria for the upcoming season, and delivered those lists for review to the sites. At that time each site had their own "ad hoc" tracking system in place to keep lists of children that they felt were likely eligible to receive RSV vaccine. Reconciling our lists with the on site lists gave use deeper understanding of charting idiosyncrasies between sites. For example, the diagnosis of "stridor" at some sites generally meant "critical airway issues" while at other sites meant "noisy breathing." In most cases we were able to accommodate these differences with minor revisions to the rules. For example, we chose to include "stridor" as clinically significant airway issues for purposes of the rules logic, but added a clarifying comment in the explanatory text of the rule output indicating that the child "is eligible to receive RSV vaccine if critical airway issues exist."

Load Testing and System Response Time

Prior experience with other web-service decision support projects revealed that the load experienced by these systems is significant during peak utilization. In our primary care network, peak demand occurs between 3-4 pm in the afternoon with a lesser peak between 10-11 am. Generally there is a load threshold at which system response time degrades catastrophically and it is important to know this threshold before production usage. We knew from our testing with production data that the maximum load for our 4 CPU Linux server with 4 Gb RAM could process was about 1,500 requests in 20 minutes. This translates to slightly more than 1 request per second when the system was under load.

For some of our decision support systems (e.g. immunization alerts) more than 10 requests per second may need to be processed for sustained periods of time with sporadic peaks higher than 20 requests per second. In the case of the premature infant decision support system, peak utilization was expected to be less than 1% that of the immunization system due to the limited number of children who were born prematurely, and because the system was only implemented for use from birth through the 2nd birthday, whereas the immunization alerts are used for all children regardless of age. If greater performance had been required we would first have "profiled" the rule system to determine the rate limiting steps and attempted to optimize those portions. After optimization efforts were completed we would resort to balancing load across multiple servers.

As a final test we purposefully overloaded the server and attempt to use the system from within the EMR to ensure that a suitable message is disable to the user indicating that the premature infant decision support tools is not available. We also verify that there are no secondary consequences on other functionality in the EMR such as poor response time for other decision support alerts.

Limited Release at a Single Location

Before the start of the formal decision support intervention period, we activate the tool at a single care location and obtained critical feedback on a frequent basis from the clinical users. This pilot phase lasted 5 months (5/9/2011 to 10/3/2011) and resulted in modest additional improvements in both the rules and user-interface. New features were incrementally during the pilot to focus the clinician's attention on each clinical domain in the sequence shown below:

- **May 2011**: Growth assessment, nutrition recommendations and family educational materials were released
- **June 2011**: Growth assessment rules corrected based on feedback, and blood pressure recommendations were released
- **July 2011**: More corrections to growth assessment were applied, and developmental surveillance recommendations were released,
- **August 2011**: RSV recommendations were released
- **September 2011**: RSV recommendations were refined

At the end of the limited release all members of the study team and pilot location were comfortable with the functioning of the system and a go-live date (Tuesday October 4, 2011) was selected.

3.5 Deploy and Evaluate

The following sub-chapters map to the GLIDES website and sections describing key CDS activities under the phase, Localize Knowledge – Deploy and Evaluate:

- 3.5 Deploy and Evaluate
  - 3.5A Project Planning and Control
  - 3.5B Deployment and User Adoption
  - 3.5C Evaluation Plan

3.5A Project Planning and Control

Overview

We developed a clinical decision support (CDS) application to assist primary care pediatricians with the care of premature infants from the time of NICU discharge through the 2nd birthday. This section describes our approach in developing our project team and in managing the project.

Project Team

A key factor in successfully implementing a comprehensive CDS system is assembling the project team. Table 3.5.A1 presents the roles, responsibilities and skills of those took part in developing our CDS system to support premature infant care.

It is important to note that different organizations may combine or divide roles to better match the skills and/or availability of personnel. For example, our physician lead is also a developer and contributed to the coding effort. Our healthcare informatics specialist is also our user centered design specialist. Technical roles are especially dynamic as well and in our case a single developer performed all three development roles. The EMR analyst role was actually shared among our developer, physician lead and healthcare informatics specialist, all having extensive EMR analyst training.

Table 3.5.A1: Roles, Responsibilities and Skills

Role	Responsibilities	Skills
Physician Lead	The physician champion of the project.	Informatics expertise (research or operational), strong relationship with clinicians, IT and organizational leadership.
Physician Panel	Identify clinical objectives, review guidelines and translation for ambiguity/contradictions and make recommendations as needed.	Clinical expertise in the patient population being addressed.
Healthcare Informatics Specialist	Guideline translation, production of data dictionaries and other support materials.	Advanced degree in Information Science. Experience with healthcare information technology (HIT), clinical workflow and/or research.
User Centered Design Specialist	Perform user-centered activities and requirements for developers.	Advanced degree in human factors, human computer interaction or information science with a concentration in user centered design methods.
Data Analyst	Performs data analysis supporting every phase of the project.	Database manager skills and expertise. Oracle/SQL or other database tools specific to the EMR vendor. Familiarity with the structure and content of EMR data.
Study Coordinator	Manages relationship and communication with clinicians at study practices.	Clinical background and training or MPH. EMR experience and communication skills.
Developer – Rules Engine	Development and programming of the rules-based expert system	Programmer (Java recommended) with healthcare experience. Does not require specific EMR vendor experience.
Developer – EMR Programming Framework	Development and programming of the EMR data mining and enhanced decision support capabilities.	A programmer, preferably with training/certification from the EMR vendor where implementation will occur.
Developer – EMR Application Layer	Development and programming of EMR-based decision support application, user interface and functionality.	JavaScript/HTML user-interface programming experience important. Knowledge of clinical workflow, usability, design, HCI are all a plus but not essential.
Testing and Quality Assurance Analyst	Tests all technology development work for intended functionality and "bugs."	Experience in developing and implementing test plans.
EMR Analyst	Configures and manages EMR order sets, documentation templates and other EMR functionality. Consults on EMR functionality.	EMR training and/or certification as required.

Tables 3.5.A2 and 3.5.A3 map the project team roles to the key CDS activities outlined in the GLIDES site and this document for Formalize Knowledge and Localize Knowledge respectively.

Table 3.5.A2: Suggested Project Roles Mapped to Key CDS Activities for Formalize Knowledge

Roles and Key CDS Activities	Formalize Knowledge			
	Determine Clinical Objectives	Markup Guideline	Create Structured Rules	Apply Action Types and Vocabularies
Physician Lead	●	●	●	●
Physician Panel	●		●	●
Healthcare Informatics Specialist		●	●	●
User Centered Design Specialist				
Data Analyst	●		●	●
Study Coordinator	●			
Developer – Rules Engine				
Developer – EMR Programming Framework				
Developer – EMR Application Layer				
Testing and Quality Assurance Analyst				
EMR Analyst				●

Table 3.5.A3: Suggested Project Roles Mapped to Key CDS Activities for Localize Knowledge

Roles and Key CDS Activities	Localize Knowledge						
	Create Executable Rules	Adapt to Local Workflow	Design UI	Build and Test	Deploy and Evaluate: Project Planning and Control	Deploy and Evaluate: Deployment and User Adoption	Deploy and Evaluate: Evaluation Plan
Physician Lead	●	●	●	●	●	●	●
Physician Panel		●	●				
Healthcare Informatics Specialist	●	●	●			●	●
User Centered Design Specialist		●	●	●		●	
Data Analyst	●	●	●	●			●
Study Coordinator		●			●	●	
Developer – Rules Engine	●						
Developer – EMR Programming Framework		●		●			
Developer – EMR Application Layer			●	●			
Testing and Quality Assurance Analyst				●			
EMR Analyst		●	●				

General Project Management

A project of this complexity requires a great deal of communication and collaboration. We held a series of regular project meetings dedicated to particular aspects of the project. For example, the Physician Lead, Physician Panel and Informatics Specialist met weekly for many months to manage the entire guideline translation process (in effect from Determine Clinical Objectives through Adapt to Local Workflow). Concurrent to these meetings were working groups dedicated to application design and development and to preparing the evaluation plan.

To manage project materials and development we utilized a number of collaboration tools:

- The internal Wiki, Confluence, for storing notes about the guideline translation process, document sharing and meeting minutes
- Robust version control strategy using Git and Mercurial.
- FogBugz for tracking UI design, development tasks, bugs and system testing.

3.5B Deployment and User Adoption

Overview

We developed a clinical decision support (CDS) application to assist primary care pediatricians with the care of premature infants from the time of NICU discharge through the 2nd birthday. This section describes our approach in deploying the system and promoting user adoption.

Approach

We applied a number of communication and education activities around the deployment of our CDS system. We feel the following approaches and activities contribute to a successful deployment and adoption of CDS systems.

1. Organizational support
2. Education and training

Organizational Support

While clear clinical objectives define a CDS project, organizational support is critical for successful development, support and adoption. We recommend an assessment of four organizational elements as key requirements in developing a comprehensive CDS system.

1. Mature EMR Implementation

A stable EMR implementation is critical to the success of a comprehensive guideline-based CDS system. We recommend any organization attempting this type of implementation have their EMR active or "live" for at least one year. The system's stability, performance and level of IT support are important indicators of a mature implementation.

At the Children's Hospital of Philadelphia (CHOP), the majority of primary care locations had been using the EMR for more than five years at the time our CDS project began. Two practices joined the CHOP Care Network and began using the EMR a few months before the project started. These two practices were not invited to participate in the CDS project, but will be approached for future projects.

2. Clinician Training, Comfort and Acclimation with the EMR

Indicators of clinical user population capable of adopting new forms of CDS are the status and success of EMR training programs, as well as EMR adoption and end-user satisfaction ratings. Previous projects in the CHOP Care Network have used various methods to assess clinician ability to adopt advanced tools such as CDS. For early projects, where the abilities of our clinicians were less clear, we used self-assessment "skill inventory" questionnaires and direct observation. For the premature infant CDS project we already were comfortable with the clinicians ability to use CDS.

3. Stakeholder/ Executive Support

Stakeholder support is essential to a successful, comprehensive guideline-based CDS system deployment. We secured support from a wide range of executive leaders including the Chief Executive Officer, Chief Information Officer, Chief Medical Information Officer as well as VP and Director level executives from Information Systems, Ambulatory Care, Research and more. In addition, while our own CDS team included developers and other technical specialists, collaboration with hospital information services EMR specialists was essential and only possible with leadership level support.

We included several clinical leaders on the project team with recognized expertise in initial treatment and follow-up of premature infants. Our work was also aligned with a quality improvement project

for RSV vaccination that was promoted by the clinical director of the primary care network. Our CEO is also a strong proponent for CDS that improves the effectiveness and quality of healthcare.

4. Clinician Buy-In:
Clinician buy-in is the final element essential to organizational support. Buy-in is achieved by presenting a high level description of the system and its goals to clinicians prior to development. If clinicians respond that the system is needed and will be useful to improving outcomes and clinical workflow, the project should continue. If the response is less than positive, we strongly recommend further work to determine the reason for the response and/or abandoning the project in favor of one that clinicians agree is more important.

We periodically distribute surveys to our primary care network clinicians to identify priorities for future research projects. We have developed eight comprehensive CDS systems and the majority, but not all, had strong clinical support. In all eight projects there was a strong outcomes-based rationale for creating the intervention. The few projects with low clinical support still produced measurable improvements, but adoption rates were low in some cases, and even occasional complaints were received from some participating clinicians. Pushing ahead on projects with low clinician buy-in may promote "alert fatigue" and negatively impact future CDS efforts.

Education and Training

While we applied a user-centered design approach to create a system that was easy to use and could be used with no prior training, we believe that performing dedicated education and training sessions was an essential component to the deployment of our CDS system. These sessions proved to be useful in not only describing how the system functioned, but, perhaps most importantly, in engaging the clinicians in a discussion on the outcomes-based rationale for developing the system.

We arranged one-hour training sessions for each of the 20 primary care practices that received the CDS intervention. To accommodate the patient care demands of the practices and gain as much attendance as possible we arranged the sessions to take place at the practice during lunch. The sessions occurred a few weeks prior to the CDS system go live. In developing the training session we worked with our education office and achieved approval for both Continuing Medical Education (CME) credit for providers and Contact Hours for nurses.

At the training session the project lead physician gave a presentation that described the purpose and goals of the CDS system with a focus on outcomes. The remainder of the presentation included a walkthrough or demonstration of the system in addressing common patient care scenarios.

We provided a set of printed handouts with brief instructions on use of the CDS system and provided all clinicians with contact information (email and phone) and encouraged them to communicate with us any and all feedback including positive and negative.

3.5C Evaluation Plan

Overview

We developed a clinical decision support (CDS) application to assist primary care pediatricians with the care of premature infants from the time of NICU discharge through the 2nd birthday. This section describes our approach in developing and implementing our evaluation plan.

Approach

Concurrently with developing and refining the RSV decision support intervention and its objectives (see Section 2.1), we used baseline data to identify measurable outcomes to evaluate the intervention. With IRB approval, we performed chart review to better understand the reasons why eligible children did not receive RSV vaccine. This section describes the steps in refining our evaluation plan for RSV intervention.

Baseline Data

We extracted data from our EMR at the end of the 2010-2011 RSV Season. We focused on the subgroup of children who had established outpatient care in the primary care network prior to the season, were seen at least once during the season, and eligible to receive 5 doses of RSV vaccine. Knowing that the primary care network had significantly different patient populations in the urban locations compared to the suburban locations we examined these practice locations separately. Baseline vaccination rates are shown in the table at right. As expected, there were a significantly lower proportion of children in the urban practices receiving at least 4 doses of the RSV vaccine.

Doses	Urban (N=57)	Suburban (N=72)
3 or fewer	41 (72%)	16 (22%)
4 or more	16 (28%)	56 (78%)

Within each group of practices we performed detailed chart review on the 41 urban and 16 suburban children who received 3 or fewer doses to determine the reasons why doses were not received (see table at right). Out of these 57 children the most common reason doses were not received was because the clinical team failed to recognize that the child was eligible (N=27). Scheduling appointments in a timely fashion and immunizing at all opportunities in the office were additional problems that we hoped to reduce or eliminate with the RSV decision support intervention. Ensuring that patients arrive for appointments (reducing "no shows") is a more challenging problem to address. Our approach to addressing "no shows" was to facilitate the process of re-scheduling appointments, but we did not expect that the intervention would have a significantly reduce this problem. Insurance denial and family refusal were relatively uncommon reasons why RSV vaccine was not given.

Reason	**N=57***
Not recognized as eligible	27
Patient did not arrive for appointment	20
Office staff did not schedule an appointment	13
Missed opportunity in office	10
Insurance denial	2
Family refusal	2
**Several patients had multiple reasons why vaccines were not given*	

Desired Outcomes

Considering that most CDS interventions are directed at clinicians during a face-to-face encounter with patients, only "missed opportunities in office" could reasonably be expected to change with a standard CDS approach. Our intervention included tools to support to nursing staff when patients are not in the office (e.g. tracking list for RSV eligible children and tools to forecast when upcoming

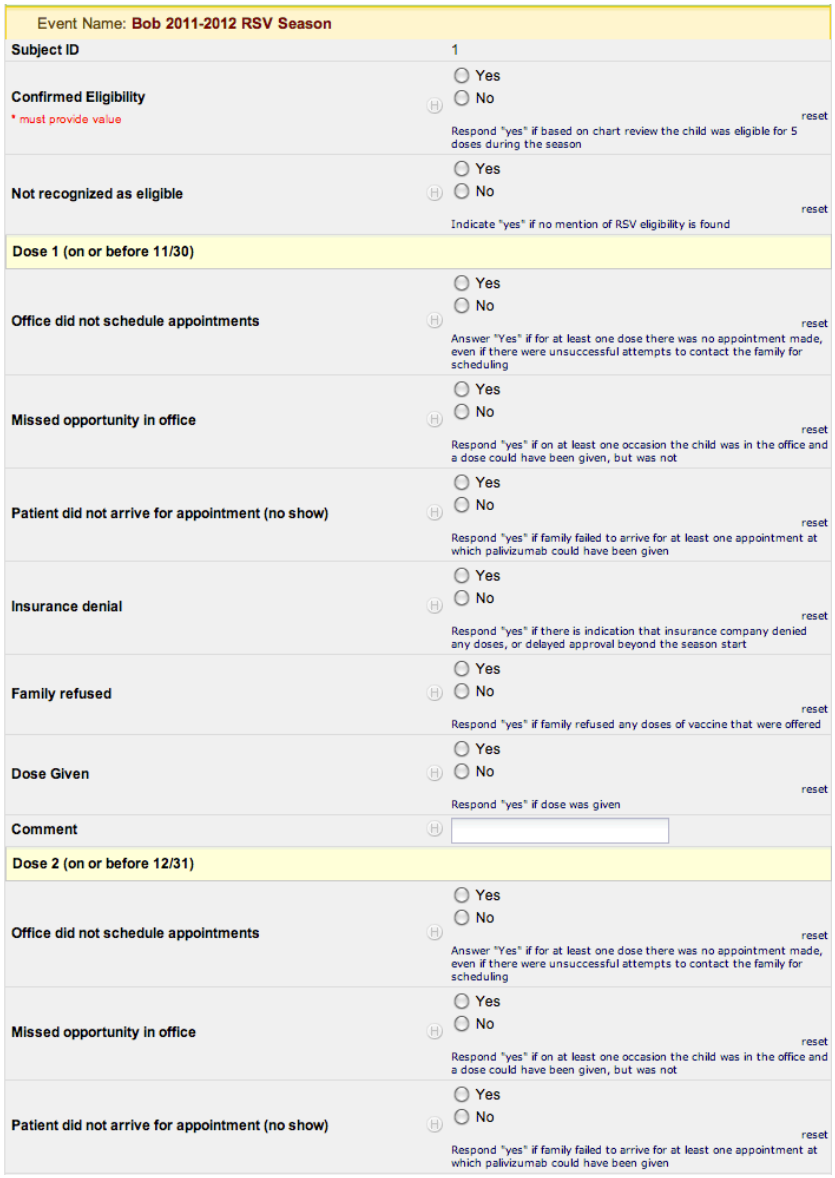
doses are due). Consequently, prior to the start of the intervention, we identified the following desirable outcomes to evaluate the success of our RSV intervention

- Reduce the number of patients who were not recognized as being eligible
- Reduce missed opportunities to vaccinate in office
- Increase the number of patients where were scheduled to receive doses in a timely fashion
- Increase overall proportion of eligible children who received at least 4 doses of RSV vaccine

Measuring Outcomes

Two of the desired outcomes are an overall assessment of the season (recognizing eligible children, and proportion who received at least 4 doses), and two must be assessed for each of the 5 doses (missed opportunities, and failure to schedule appointments). A data collection sheet was developed in a REDCap database to facilitate the manual review of charts by two independent reviewers. A small portion of the data collection form is shown below in Figure 3.5C1.

Figure 53C.1: Data Collection Form



Data collection is currently ongoing. We have chosen to re-examine data from two baseline seasons (2009-2010 and 2010-2011) in addition to the 2011-2012 intervention season. Fortunately the scale of chart review is manageable and can be reasonably completed by two independent reviewers for all eligible children who received 3 or fewer doses of RSV vaccine (N=173 chart reviews required by each reviewer). After the independent reviews are completed any discrepancies will be reconciled by a verbal discussion between the two reviewers.

Note that this approach to evaluation is challenging when the numbers of eligible subjects are significantly higher. For example, if manual chart review is required for about 200 charts, it may be appropriate to consider relaxing the requirement that two reviewers review each chart independently. Strategies to solve this problem include adding additional reviewers so that each chart is still reviewed twice, or randomly assigning the chart reviews into 3 cohorts: a group reviewed only by reviewer #1, a group reviewed only be reviewer #2, and a group reviewed by both to assess inter-rater reliability. For evaluations where the numbers of subjects are large enough that adequate statistical power can be achieved by reviewing a subset, then a statistician can help determine an appropriate and feasible sample size for chart review to complete the evaluation.

Summary

The guideline transformation process described in this document was fundamental to the development of our CDS application to assist primary care pediatricians with the care of premature infants. While the learning curve for this process required some up-front investment in time and effort, we feel this investment was worthwhile for several reasons. First, we know of no other method to systematically translate the content of published guidelines into CDS logic. Without such a process we are certain we would have expended additional and ultimately inefficient effort in manually deriving our CDS logic. Second, the process itself more effectively drives the development process by serving as the foundation for guiding both back end system code and front end user interface requirements.

Despite the length of this document we are aware that this document leaves out many details in our development process. Anyone wishing to contact us is free to do so at the addresses listed below.

Finally, we wish to express our gratitude to both the GLIDES team and the ECRI Institute for repeatedly sharing their advice and expertise in applying this process to our development project.

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