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NORTHWESTERN UNIVERSITY

Clinical Decision Support Systems Enabling Medication Reconciliation

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Contents

Introduction

After the number implementations of electronic health records (EHR) began to increase, focus shifted from data storage and retrieval to coordination of care with clinical decision support systems (CDSS). CDSS "link health observations with health knowledge to influence health choices by clinicians for improved care" (Wikipedia, 2010) (Liaw & Pradhan, 2010). CDSS has also been defined as a broad set of systems and applications or processes that enable health professionals to make decisions regarding care (HIMSS). These approaches to defining CDSS allude to the broad range of effects that these focused systems can have. Our project demonstrates this by showing the impact a CDSS can have on the exchange and interoperability of medication information, while simultaneously showing how narrowly focused and deep a CDSS must be to address the decision support requirements of the medication reconciliation function.

Experts in CDSS advise implementing the technology "upstream" to support literature-based, timely decisions (Rundell, 2010). How far upstream a CDSS is placed is critical to success. Downstream passage of high quality structured medication data to the CDSS with indications linked to the data allows capture of the provider's intent to treat, a key element of assessment.

Reliable data flow is especially challenging across transitions of care. As patients move from inpatient care to ambulatory or post-acute care settings, robust processes are needed to avoid errors. The goal of this CDSS is to provide a reconciled medication list in electronic form to bridge this information gap. Specifically, the objective is to provide CDSS tools that facilitate reconciliation at discharge from an inpatient facility to a nursing home. The CDSS aims to optimize medication selection of the reconciled list using knowledge of indications for use, drug therapeutic classifications, available medication formulary information and other outcomes data.

The medication reconciliation process was intended to help resolve "a critical problem that poses significant risk to patients. However, since the goal of medication reconciliation was instituted in 2005, many organizations have struggled to implement effective processes" (Joint Commission, 2010). Currently providers are given a list to assess but they must glean the necessary information for decision making from dispersed resources. This goal can be achieved if the knowledge a physician must consider can be effectively organized and presented by a CDSS, thus meeting the requirements of "Meaningful Use" (Liaw & Pradhan, 2010) by presenting the provider with key information on-demand, optimally organized, filtered for the users' activity and optimized for specific needs of the patient.

Approach[g1]

Our approach to designing this CDSS began with the creation of a use case with workflow maps to clarify current process and envision the enhanced process. Key elements of this use case included the recognition that Medication Reconciliation is an important safety measure, especially for elderly patients with chronic illnesses who often have multiple providers. Furthermore, multiple providers writing multiple prescriptions with poor communication about indications results in conditions that are unsafe for the patient and costly to the system. One of the most traceable locations patients being discharged from acute care is to the nursing home. It

is expected that the capabilities developed by our CDSS have the potential to address larger and more complex needs in the future. These steps helped to refine our goal in measureable ways. We determined that a CDSS can be designed to perform medication reconciliation in accordance with JCAHO's established guidelines, including 1) achieving improvement effects in the area of AED reduction, 2) improvement effects in the area of increasing the rate for actually doing a complete medication reconciliation, and 3) improvement effects in terms of reducing the error rate. Using this data, an information schema was created to help design the knowledge model and specify the processing logic; and finally, a plan to was developed to address the acquisition and maintenance of the knowledge base. The knowledge and logic requirements formed the basis for the logical and physical design for the system. The implementation and maintenance plan was established based on system and user needs. Validation, verification, and specific performance goals were set for evaluation.

Use Case

Medication reconciliation requires the discharging physician to perform the five tasks (Joint Commission, 2010): Develop two medications lists (1-current and 2-prescribed); 3-compare the lists; 4-make clinical decisions based on the comparison; and 5-communicate the results. We created 3 simple scenarios to study the components and complexity of the decision process. The actors are the physicians, stakeholders include the hospital, nursing home, insurance companies and accrediting agencies. We assumed this system would augment an EMR that has computerized physician order entry (CPOE), and send the list to the Discharge Summary.

Figure 1 Current Workflow

Currently providers assess the need to continue each medication. The process is often manual, paper based, with the needed information not readily available. This complex process of optimization is depicted in Figure 1. To be done properly it requires physician interaction with a broad set of knowledge bases. Not surprisingly, it is commonly abbreviated. Because of the clear inefficiencies and risk of errors there is an opportunity to automate, streamline, and apply clinical best practices to improve this process.

Triggers for the new process are primarily event driven with some time-driven events related to maintenance and system function. Background processing will flag duplicates, and create two comparison lists – medications by indication and medications by effect. There is also comparison with the available formulary based on insurance and facility as well as the most significant issues reported by the nursing home. This information is based on analysis of the nursing home's clinical repository analysis and standard safety references (e.g. Beer's list and Canadian list) (PHARMACIST'S LETTER / PRESCRIBER'S LETTER, 2007). The EMR's CPOE is invoked when needed.

The system highlights choices in a complex set, helping to reduce errors by specifying and clarifying the options available. The output promotes interoperability and better communication, a key element of meeting *Meaningful Use* (Federal Register, 2010). Figure 2 depicts the enhanced workflow, designed to be a seamless supplement to the current process. Users decide whether to take advantage of the enhancements. The flexible entry methods and multiple options limit perceived threats to professional autonomy. Doctor-patient interactions are unaffected. he implementation plan assures adequate availability of hardware, technical support and training. As users experience the system they will find it integrates well into their workflows, the clinical messages will be relevant, and the information timely. It is expected that as to the system meets these criteria and is endorsed by colleagues, acceptance will accelerate (Moxey, Robertson, & Newby, 201).

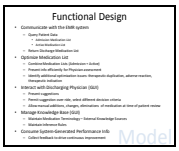
Figure 2 Future Workflow

System Design[g2]

Our approach to designing the CDSS began with a thorough analysis of needs and goals for the system, which considered the use case and workflows, both current and future envisioned. As a result of that work, we established an initial functional design. Next we analyzed the problem in detail and from a cross-functional point of view in order to flesh out the information and logic required to make decisions during the medication reconciliation process. Using both the data and logic requirements, we developed a comprehensive knowledge schema to guide implementation and plan for the acquisition and maintenance of the knowledge assets to comprise the system. Finally, to confirm completeness of the design, we developed a prototype of the user interface. The prototype allowed users to provide feedback on the envisioned functionality and permitted designers to clarify expectations about what the system would and would not be able to do.[g3]

Functional Design

The functional design formed the cornerstones for the CDSS because all subsequently identified system requirements were traced back to these high-level capabilities of the system. Requirements traceability is the ability to describe and follow the life of a requirement, in both a forward and backward direction, i.e. from its origins, through its development and specification, to its subsequent deployment and use, and through periods of ongoing refinement and iteration in any of these phases (Palo, 2003). Using requirements traceability practices allowed us to create a design that anticipated the need for ongoing change and evolution over time. Without traceability between system capabilities and functional requirements, sustainability of the system would not be feasible.



Model Figure 3 Functional Design for the Medication Reconciliation CDSS

Data, Knowledge and Logic Modeling

The analysis and design phase of a CDSS requires greater communication between users and developers because a CDSS implements not just what people do, but what people think. Conducting this type of detailed discussions between users and developers is often a much harder task than imagined and one that takes longer than expected. It usually involves an iterative process where users describe and demonstrate, and designers listen. Designers then analyze and organize the information they gathered and echo it back to the users in a more useful format. The understanding gained by the developers is confirmed or further clarified by the users. Often tools are needed to facilitate communication (Lucas, 1992).[g4]

To examine the process of medication reconciliation, we built Excel worksheets to facilitate collaboration. We used the tool to organize and shape the information into and early model of the problem. It enabled us to understand the function of the Medication Reconciliation List and clarified the types of decisions required to transform that list into a Reconciled Medication List for a patient's discharge. More important, it provided an active representation of the best practice steps documented for medication reconciliation by JCAHO (JCAHO, 2010).

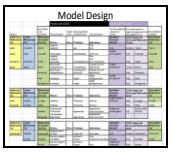


Figure 4 Excel model used to communicate detailed functionality for medication reconciliation

The Excel model was then developed into a more mature information model that considered the processing logic required by the system. It reflected the information objects, and how they were related, classified and categorized. The system logic identified the logic criteria and processing rules needed to drive the inference engine of the system.

Figure 5 Information schema and system logic for the CDSS

User Interface Modeling

Modeling the User Interface allowed deeper assessment of the system's design. It also identified subtle, but significant aspects of functionality that required additional system knowledge elements to be included in the design and others explicitly to be excluded. Due to time constraints for the project, dose and route considerations were deferred. Addressing these requirements in the medication reconciliation holds potential to substantially benefit patient safety, but adding them to the design would have represented substantial additional complexity.

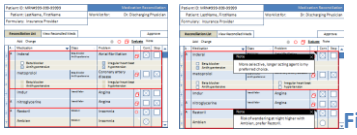


Figure 6 Prototype user interface screens.

The user interface prototype demonstrated the planned functionality of the system and made the improvements for the medication reconciliation process more tangible. It showed how the tool presented physicians with the complete set of medications that must be considered when discharging a patient. It provided a visualization of how flags would identify potential issues. We

could experience what it would be like to see the possible problem indications along with medication effects while selecting among multiple medications for a patient. We could understand how providers would have the opportunity to document their thinking and explain the choices they made.

We used the prototype to validate with users that the system, as designed, would improve the way physicians performed medication reconciliation compared to how it is done today. Further, we confirmed with system administrators that the usage information designed to be captured would help them support and evolve the system over time.

Developing a software prototype allowed us to verify our design and it provided valuable planning information for designing the software, hardware and "liveware" components of the system. Liveware is a term Ponedal coined to describe the people who develop, maintain and use the system as a third but integral component of a system working in conjunction with the software and hardware (Ponedal, 2002).

System Architecture

The system design phase allowed us to understand the requirements of the medication reconciliation CDSS in terms of the logical components of the solution.

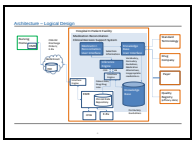


Figure 5 Logical design of the clinical decision support system

The user interface (UI) supports physicians reconciling patient medication lists at the time of discharge. It also gathers performance information while the system is being used so that administrators can review and process that information back into the knowledgebase. The inference engine processes the medication information. It utilizes information gathered from the clinical data repository about the patient and decision rules and criteria available from the knowledge base. It serves the UI with the information to be presented to the physician. (Cho I, 2010). The interface engine severs as a data traffic router and translator, providing a seamless interface between the knowledge base, the clinical repository and the EMR. Medication lists communicated between the CDSS and EMR utilize HL7 messaging protocols and are formatted as CCD compliant documents. External information sources are processed with a UI devoted to interacting with the knowledgebase. The knowledge base stores the information sources, the inference rules and decision criteria attributes.

Make Versus Buy

After surveying available system capabilities to support our design, we determined that we would develop the medication reconciliation capability as an add-on module that would work with an existing EMR. If the EMR provided drug-drug interaction testing that a customer preferred, we would supply an interface that would allow the EMR's drug interaction alert decision criteria to be utilized by our CDSS. If the EMR didn't offer that capability, then our system's drug interaction checks would be used.

We chose a service-oriented architecture (SOA) for the design of the software. SOA offered several advantages over other system architectures. It provided greater modularity which enabled the processing to be evenly distributed among the various logical components of the system. Working in harmony with a hospital's existing electronic medical record was a consideration. The SOA architecture would integrate more easily with other EMR environments. Generalized services would make it possible to take advantage of information stored in an EMR's clinical repository (Wright A, 2008).

Knowledge Acquisition and Maintenance

To minimize cost and development effort, we would utilize an open source tool to provide the knowledgebase and administrator's UI. The tool provides functionality to import terminology standards and other information sources into its knowledge representation structure. The software developers kit (SDK) provides an application interface (API) which allows the CDSS to access information in the knowledgebase (Apelon, 2010). Utilizing the open source tool to provide the capabilities needed to implement and augment the information schema would reduce development time and expense.

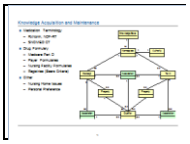


Figure 6 Knowledge representation model in the open source KB tool.

A subscription service for the needed standard terminologies is used, enabling disparate standards to be delivered in a single format that supports uniform treatment within the knowledgebase (Apelon, 2010). The information acquired includes RxNorm and SNOMED CT which are the standards designated by the HITECH Act under Meaningful Use for medications and problems, respectively (AMIA, 2010). RxNorm meets the needs of medication reconciliation, e-prescribing, formulary checking and transmission of medication information (AMIA, 2010). RxNorm is organized around normalized names for clinical drugs. The names contain information on ingredients, strengths, and dose forms (RxNorm, 2010).

National Drug File – Reference Terminology (NDF-RT) is used because early adopters of RxNorm, such as the FDA and VA are utilizing linkages to NDF-RT to classify drugs from multiple perspectives (Carter, 2006). A study of the categorical information in pharmaceutical terminologies reported that NDF-RT's categorical reference model accommodates more than 76% of the information identified in drug class names (Carter). One of the major challenges facing the use of NDF-RT in this CDSS remains disagreement regarding the classifications of physiological effect and therapeutic intent (Carter, 2006). The WHODRUG dictionary will additionally be acquired as another medication classification source based on Anatomic-Therapeutic-Chemical (ATC) classification (Dark).

Other external lists, such as the Beers Criteria from the Duke Research Institute, provide information on drugs that are potentially inappropriate for the elderly (Beers Criteria, 2010) and would need to be manually created. Drug formulary information would be solicited in an electronic feed from insurance carriers or entered manually.

Because of the complexity associated with maintaining the many specialized information assets in the knowledgebase, the partnership between user and developer domain experts, required to

design and implement the system, really never ends. Ongoing interaction will be needed over the full life of the system.

Physical Design

The physical design of the system takes requirements of both the developed and purchased aspects of the solution. Interfaces to external information sources and the EMR system ensure the CDSS functions as a modular solution that can be added to any hospital IT environment.

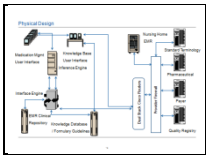


Figure 7 Physical design for the medication reconciliation CDSS.

Scalability and Sustainability

A performance study was performed to capture and quantify volume information which we analyzed to determine the number and type of transactions that would be needed to support 50 discharges in one day, and the timing associated with those transactions as well as other system administration functions. We factored in foreseeable growth in the number of decision criteria, inference rules and information sources over time (Wright A, 2008). Expectations regarding the need for almost constant change were taken into account, so the system's performance was optimized to address ongoing change. We took these performance requirements into consideration for the design the software, hardware and liveware, so that the system would meet current needs and envisioned growth. Affordability, from a cost of ownership perspective, was also a key design consideration. In order for a system to be sustainable its future operation must be affordable.

Evaluation and Results[g5]

To validate our system and demonstrate that we built 'the right system' we based an evaluation plan on the Medication Review tool from the Institute for Healthcare Improvement (Institute for Healthcare Improvement, 2004), the focus to be on discharges. This tool will allow us to gather baseline and post implementation data in a standardized fashion so that we can have objective information that will let us determine whether the goals have been met.

The baseline and post implementation results will be evaluated at 3 months intervals for the first year. Using these metrics will be used to demonstrate that the system can 'improve care coordination' (as outlined in the Meaningful Use Matrix, 2009), by providing "medication reconciliation at each transition of care from one health care setting to another" as well as "clinical decision support at the point of care". It will also contribute greatly to "improving quality, safety, and efficiency" by helping to maintain a fully reconciled active medication list that is shared with all providers as well as the patient.

In order to *verify* our CDSS at all stages of development and demonstrate quality improvement it will be important to ensure that our system is "built right". Toward that end, stringent

traceability requirements will be used at all stages of development, as previously described. Multiple system checks will be performed prior to "go-live" to ensure that the CDSS is fully functional and that there are no obvious glitches. Concurrent error tracking with swift response from our "liveware" team to apply "fixes" and updates to the system in a timely manner. This "liveware" team will also oversee subscription maintenance and contracts with entities that support the knowledge base and intercept any notices of glitches, errors, or quality issues that may be reported.

The system will also include a "fix-it" button that will allow the end user to report problems or complaints in "real-time", with the ability to "grab" a screen shot to be transmitted to the "liveware" to be evaluated and responded to within a reasonable amount of time, with response time tailored to the severity of the problem. The remainder of the change management cycle for follow-up, fixing, testing deploying and training for the needed changes would be a documented process that was controlled by the quality system governing system development.

To assess user satisfaction a survey of stakeholders (i.e. clinicians, pharmacists, patients, nursing homes, other providers) will occur at regular intervals (e.g. every 3 months for the first year, then every 6 months for 1 year, then annually). These surveys will elicit qualitative feedback regarding ease of use, quality of information, quality of presentation, and perceived benefit to professional practice and to patient care and outcomes. The feedback from these surveys will be evaluated and changes incorporated into the system as appropriate.

The value of the system to users and the organization will be evaluated using considering time to complete reconciliation both in the hospital and in the receiving facility, reduction in ADE's and other adverse outcomes, and reductions in error corrections required. This data will be available from the knowledgebase and the review of records.

Recommendations and Conclusions

Based on the information learned in the process of developing this tool regarding the limitations of the current system, we would recommend that this tool be considered as a starting point in the development of a more robust medication reconciliation process. We feel that this will help EHR's move from being just data storage and retrieval, to systems that provide coordination of care with clinical decision support in a standardized environment.

This CDSS was created with the intent this it be validated and verified by users of the system. This will best be accomplished by investing future users in the development of effective criteria to match the organization's measurements of success. This can be started with GUI links to the available knowledgebases and partnering with standards bodies to clarify the linkage between medications prescribed and the intent of provider as needed. Super-users can begin to create decision criteria based on their experiences and receiving facilities can be engaged in the process of data collection. Implementation is likely to be enhanced by partnering with users in a non-threatening, sustainable approach - starting simply by determining what the user's know; building in natural improvement phases and learning modules that fit their skills. It is reasonable to expect implementation in 6 months, with evaluation at 1 year, with a full life cycle of between 3-10 years.

In conclusion, although this CDSS can provide simple, straightforward benefits to any organization, it is not without its limitations. Providers can bypass the link between intent and prescription, leading to incomplete data collection, limiting the ability of the knowledgebase to provide clear, reliable information. In addition to misleading recommendations, there is no currently capability to track specific problems to specific patients or track specific problems to specific medication for research purposes. The system also relies on good data from admission medication list to be most effective. Finally, there is no dominant design on medication classifications or universally accepted method of describing indications for medication use. This increases the risk of confusion or miscommunication between information systems.

What this system does provide is consistency with what is being done now and the ability to meet not only the current criteria for National Patient Safety Goal #8 -"to completely reconcile medications across the continuum of care" (Joint Commission, 2010) - but those that are anticipated in the future as well. It is a convenient system for providers, allowing them to be efficient and effective in their decision making with organized presentation of critical data at the time most useful to the provider. It provides clarity to the patient, the provider and other caregivers about the information and thought behind their plan of care. Easy access allows the users to feel comfortable and confident by recording the decision process. Using helpful highlights, broad information access, logical data filtering, and well defined communication tools, promote common understanding. The system also assures that all of the active problems are considered and that all parties vested in the patients' care are involved, providing comprehensive coverage and closing the communication loops of this inter-agency process.

In the future we see that this system can be readily improved, beginning with resolution of the standards limitations listed above. Increased information collection can potentially allow the system to offer dosing recommendations and error checking based on stage of illness (e.g. higher doses for critically ill patients). The most significant potential of this system would come from its extension to other transitions of care. Including more transitions would enhance the capabilities of the knowledge base, providing better options based on the patient's environment of care and stage of illness, not just the diagnosis and drug interactions.

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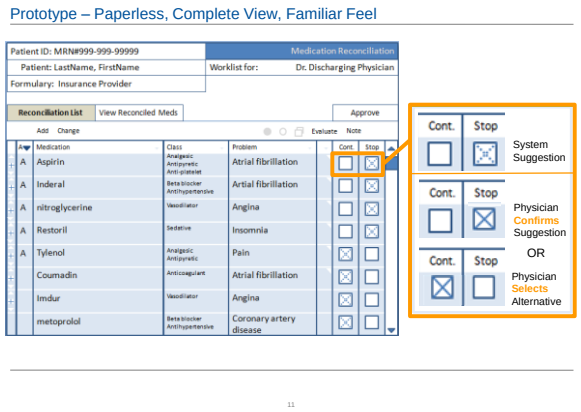
Glossary

Effect (of medication) - the set of clinical or biological consequences that result from taking a medication.

Indications - the reasons for which a treatment (e.g. medication) is commonly used. The indication may not be the same as the Problem for which the treatment is prescribed. *Atrial fibrillation causes blood clots to form in the atrial chambers of the heart. This causes strokes in 25% of untreated patients. Coumadin is used to prevent blood clots and therefore is used to prevent the clots that cause the strokes. The Problem list will usually include Atrial Fibrillation, but not 'prevent blood clots' or 'stroke prevention'. It has been acceptable practice to use the Diagnosis that causes the risk factor as the indication for the (medication) treatment.*

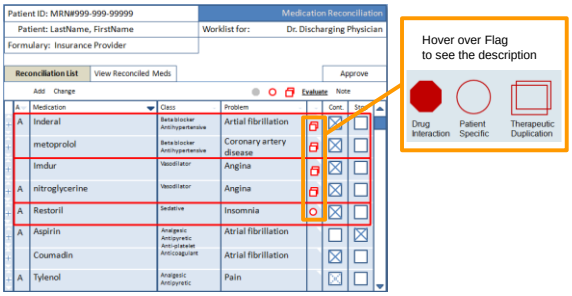
Problem – a diagnosis assigned to a patient, or a statement regarding a circumstance which may affect the persons health e.g. risk of blood clots, low education level, low income level. The most common use of the Problem list is as a list of Diagnosis.

Appendix B. Prototype demo



This prototype shows that our CDSS provides a complete view of the medication reconciliation list in a familiar excel-like way, making it easier to train physicians on its use. The initial sort order makes it easy to identify Admission Medications that may have been stopped or are still active as well as other currently active medications. A simple, efficient view automatically combines the two lists to be reconciled.

Prototype – Identify Potential Issues

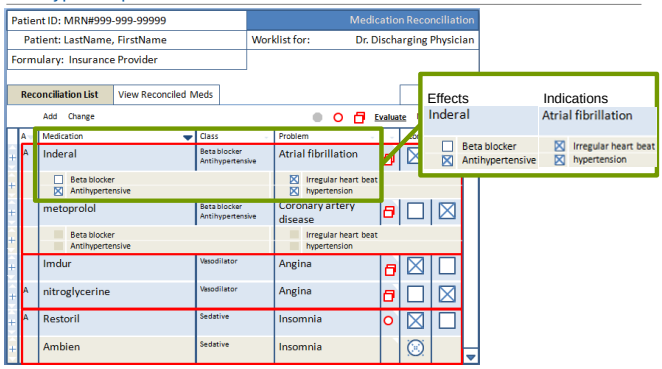


12

If the physician chooses to have the system provide additional evaluation, pressing **evaluate** reveals potential issues for consideration. Flags indicate the type of problem: drug interaction, something specific to the patient's condition or environment, or therapeutic duplication.

Medications associated with a particular issue are grouped together by a red box making it easy to see the number and type of issues detected.

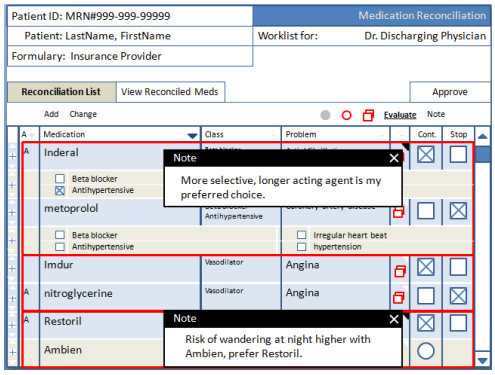
Prototype – Expand Issue to Reveal Details



13

A red boxed area can be expanded to reveal additional details about the effects associated with each medication and the indications associated with that problem. When there are duplicate therapies, these details help a physician decide which medication to continue and which to stop. The relevant effects and indications for this patient's particular situation can be easily recorded by checking those that apply.

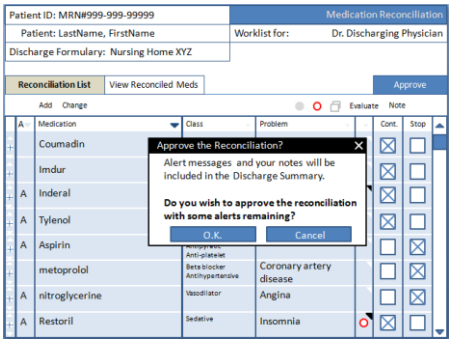
Prototype – Physician Thoughts Captured



14

The physician has the opportunity to add a quick note explaining the assessment. This information can travel forward with the medication data to offer future explanation. It can also be harvested by system developers and analyzed to support decisions about ways to improve and evolve the system.

Prototype – System Supports, Physician Decides



15

This example demonstrates that a physician has the ability to approve a reconciled medication list that includes alerts. The alerts do not prevent finalizing of the reconciliation.

When a physician overrides an alert, the system produces a message explaining that the alert message and the physician's notes about the issue will be included in the Discharge Summary.

This demonstrates a guiding principle of the design. Our CDSS functions to support decision making, but keeps the decision-making control in the hands of the physician.