Creating a Research and Clinical Care Partnership through EMR and Clinical Research System Integration

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Abstract

EMRs are essential in modern healthcare. At the same time there has been the rapid development of clinical research systems (CRS) which offer specific tools to facilitate research protocol development, execution and management. However, examples of integrating a commercial EMR and CRS are rare. We describe our experience in the analysis, resolution of issues, design, and implementation of EMR/CR integration in a large academic medical center with affiliated hospitals. Our initial results suggest that (1) neither the EMR nor CRS system alone will suffice to facilitate clinical research, (2) there are important benefits to integration of the EMR and CRS systems and (3) this integration can be leveraged across multiple institutions.

Introduction and Background

The electronic medical record (EMR) is rapidly becoming established as the primary tool to facilitate patient care.[1] It is generally believed that EMRs can also potentially facilitate the clinical research enterprise.[2,3] However, the design of the EMR has been fundamentally patient centric and its implementation has generally been clinically and billing driven. In addition, the EMR is internally integrated and is tightly interfaced to other systems, such as laboratory and picture archiving and communications systems (PACS), to facilitate clinical scheduling, ordering, resulting and other workflow. On a parallel path there has been the development of commercial clinical trial management or clinical research systems which facilitate the design, implementation, execution and management of clinical research. These systems are study or research protocol centric in design with a focus on calendaring, tracking recruitment goals, and a wide variety of management functions. They are also often interfaced to external systems for grant and contract management, institutional review boards and departmental accounting systems. Moreover, they must accommodate study participants who are healthy and who may receive their routine medical care at an unrelated facility.

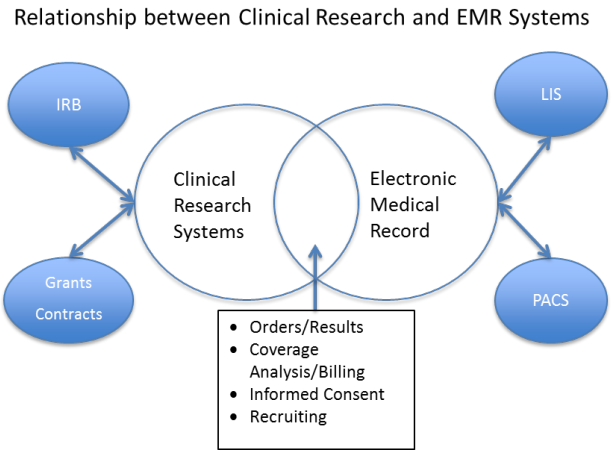

Figure 1a: Diagram illustrating the different focus of CRS and EMR systems, linkages to associated systems and overlap.

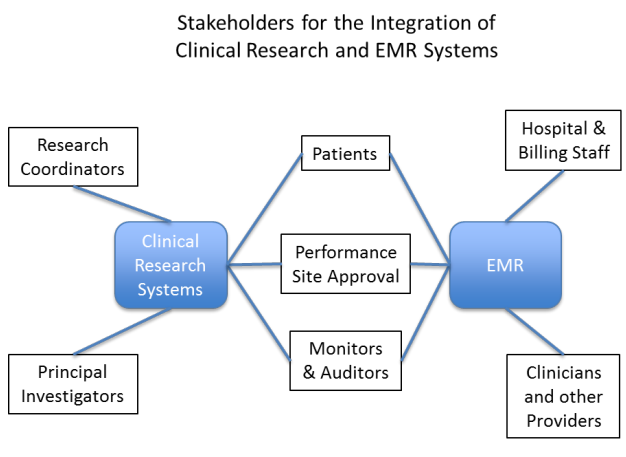

Figure 1b: Diagram illustrating some of the stakeholders for CRS and the EMR and their need for integration.

However, as illustrated in Figure 1a, there is increasingly an important overlap between the EMR and CRS. Many studies in the healthcare setting require services—laboratory, imaging, medications—which are provided through the EMR and its interfaced systems. A variety of questions emerge: In which system should recruitment occur and

be documented? How can research related orders and results be identified? How can research related charges be clearly separated from clinical charges? Moreover, patients have a reasonable expectation that their clinical care providers (when appropriate) are aware that they are participating in research and have information on research medications and critical research results that might influence clinical care. It is clear that much of the care of a person that is both a patient and a study participant requires the partnership of the clinicians and the researchers but existing technologies in both spaces creates a technological divide that causes many inefficiencies and is prone to error.

Using just an EMR or CRS to address these issues had significant disadvantages: (1) Given the focus of the EMR, duplicating all of the features of a modern CRS in the EMR would result in significant duplication of effort and cost. (2) Creating a parallel CRS scheduling/results/billing structure, which replicated the existing structure in the EMR, specifically for research visits, also seemed unreasonable. Interfacing the EMR and CRS offered the advantages of (1) allowing to rapidly address the specific needs of the clinicians and clinical investigators without competing for limited IT resources and (2) reducing dependence on a single vendor to implement all of the enhancements required. Thus, we proposed integration of our EMR and CRS to systems create a research and clinical care partnership.

Methods

At the University of Texas Southwestern Medical Center we chose to integrate two existing systems: the EMR (Epic, Epic Systems Corporation, Verona, Wisconsin) and the CRS (Velos eResearch, Velos, Inc., Fremont, California). A working group was assembled including stakeholders (Figure 1b) from clinical research informatics, principal investigators, study coordinators, medical informatics, information resources, hospital and professional billing, the office of research facilitation and ancillary services. This group analyzed existing workflows and functional requirements. Given the wide range of clinical research underway—survey, observation, interventional, multi-institutional, registry and more—the group determined that the EMR alone could not meet all of the functional and regulatory requirements without extensive customization. The CRS was flexible but would also require creation of interfaces to ancillary systems and customization which was essentially duplication of functions which already existed in the EMR. Thus, the approach taken was to interface the two systems.

On the basis of the analysis we developed the workflow illustrated in Figure 2. Integration is required during the enrollment process and for each research visit. The EMR was established as the source of truth for clinical demographics, whereas the CRS was the source of truth for the research study details. Ideally, the CRS would send essential study information (Study name, IRB number, PI, study contact) and the fact that the participant had enrolled in the study to EMR. For each completed research visit (clinic encounter, radiology of lab event, etc.), the EMR would notify the CRS, so that study milestones were marked as complete. Results would be placed in the clinical chart consistent with the research protocol. Charges would be assigned automatically in the EMR to the research sponsor and transferred to the CRS based on the coverage analysis. Payments would then be transferred from the CRS to the EMR to be posted to the appropriate account.

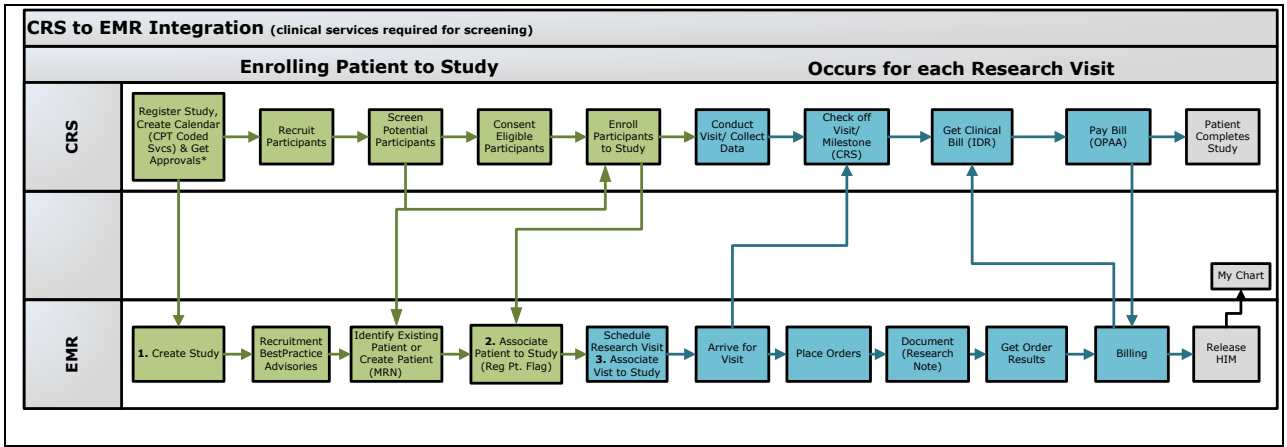

Figure 2: Swimlane diagram of overall design for CRS/EMR integration. The workflow is descibed in more detail in the text.

Results

The first phase of the project involved implementation of the study registration and patient enrollment process. This is shown in Figure 3. All clinical research studies are registered in the CRS. When the study has received all necessary approvals (IRB, coverage analysis, radiation safety, performance site review, etc.) so that active enrollment can begin, an xml message is sent and received by the EMR (Step 1). The message contains the title of the study, the local IRB number, the principal investigator, the principal contact and a link to ClinicalTrial.gov. In addition, there is indication if the study has a certificate of confidentiality. This information is vital to allow the medical release group to protect the privacy of the patients on these studies. These data are inserted into a table of research studies in the EMR. Although many status flags exist in the CRS which facilitate clinical research workflow, we found that the terms were confusing to some clinicians not involved in the study. For this reason we mapped the CRS flags into three states in the EMR: pre-enrollment, active and inactive to reflect the participant's status in the study.

Screening of potential participants occurs in the CRS which can query the EMR to determine if the participant already exists as a patient in the EMR. If so, then basic patient demographics are transferred back to the CRS. If the participant does not exist, the EMR record is manually created using standard hospital workflow (Step 2). The hospital affiliates did not approve creation of EMR records via the interface. After the participant has given informed consent for the research, the study coordinator associates the participant with the study in the CRS. The CRS then sends this message to the EMR where the patient record is now associated with research study in the EMR. In addition, it also sets the research status flag in the chart display header for clinical and administrative staff. When the patient goes "off study" (Step 3), the study coordinator makes the change in the CRS which sends a message so that the patient is dissociated from the study in the EMR and the research status flag is set to inactive. This helps insure that no further charges can be associated with this study. The EMR retains a record of all studies in which the patient has participated and makes this available for review.

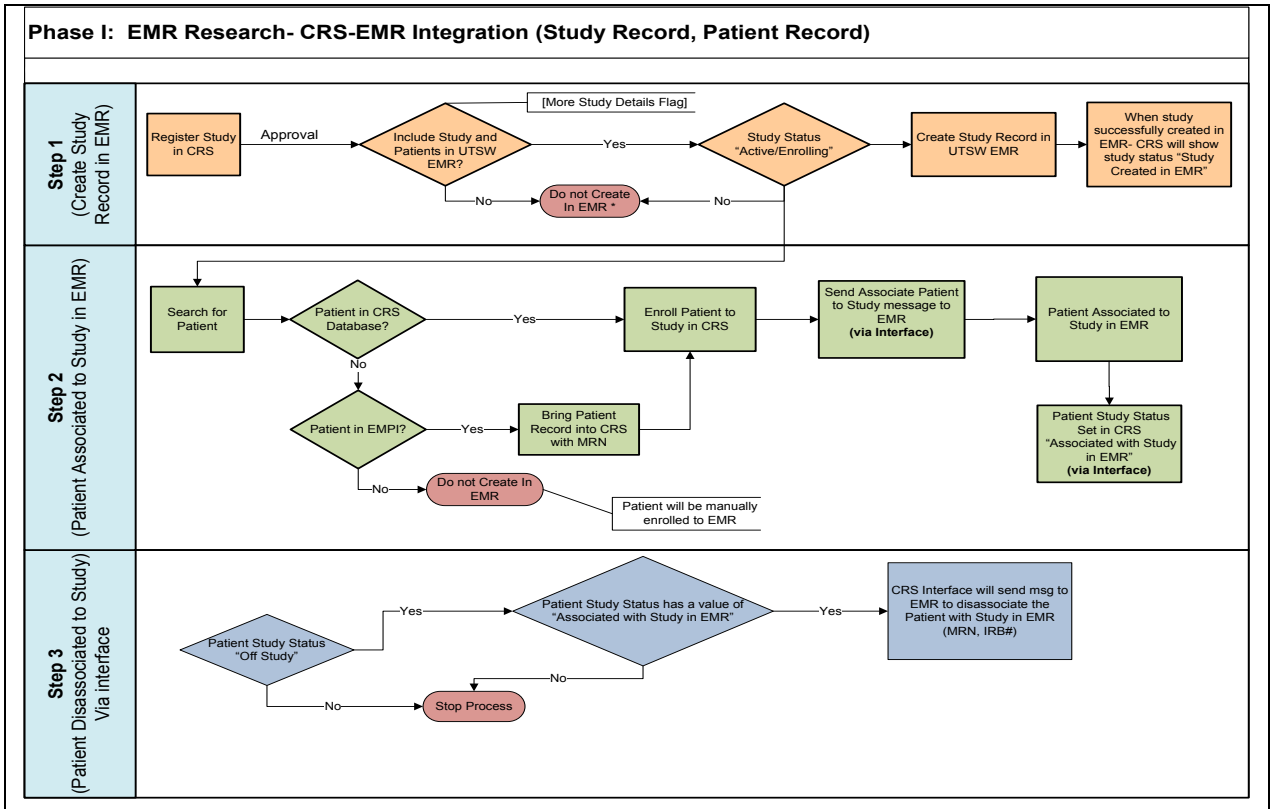

Figure 3: Flow charts illustrating the CRS EMR Integration during creation of the study record in the EMR (Step 1), association of the patient to the study in the EMR (Step 2) and disassociation of the patient to the study via the interface (Step 3).

After implementation and testing the interface between the CRS and EMR, it was moved into production in February 2012. A gradual rollout plan was used to minimize the workload on study coordinators from the standpoint of registering their existing study participants in the CRS. We elected to begin the rollout in the cancer center due to the presence of a large clinical trials unit which could provide feedback to optimize the process. Simple to use training materials provided both online and in live training classes have been used to train coordinators in other areas. A summary of the integration data as of 9/5/2012 are shown in Table 1.

Table 1. EMR/CRS data integration status summary

Number of studies in CRS	5,154
Number of studies sent to EMR	1,411
Number of studies with Certificate of Confidentiality	69
Number of studies with ClinicalTrials.gov number	351
Number of patients in CRS	10,411
Number of patients with Research Flag in EMR	5295

To test the portability of the design the same interface was implemented with a second healthcare system with a separate instantiation of the same EMR (Epic). Using a similar workflow and the same interface an additional 148 participants have been associated with clinical studies at this new site since the second go-live 9/5/2012. Thus, the basic design appears to be adaptable to additional sites and our plan is to link our CRS to an additional hospital EMR in the near future.

To investigate the use of the research flag, we utilized the audit trail which records fields accessed in the EMR for HIPPA audits. Using standard reporting we were able to determine that the research flag had been "clicked" or queried 836 times by the following individuals: research coordinators – 64, health information management – 99, nurses – 116, resident physicians – 19, faculty physicians – 30, other clinic and hospital staff – 508. These early data suggest that the research flag and the accompanying information about the study are being used by the clinicians and hospital staff. In addition, feedback from the physicians in the both the Research and EMR Governance Committees was positive and focused not on the usefulness of the flag but on how it could be expanded to include even more information.

Discussion

Our results show that it is possible to create a real-time interface between a commercial EMR and a commercial CRS to facilitate both clinical care and the clinical research process. We believe that this approach is more realistic in most clinical research settings compared to the alternatives of customizing the EMR or CRS to meet all of the functional requirements of both processes. It has the potential to improve safety in clinical care of research participants in that it guarantees the association of the patient with the study in the EMR. Via the research flag, it alerts physician, nurses and other staff that the patient is on a research study, providing them fundamental information to assist with their care. From the standpoint of the CRS this lays the foundation for taking advantage of ordering, resulting, auditing, billing and reporting functions which are already well established in the EMR. In addition, it can fit well with workflow that already exists in the EMR for clinical processes such as the routing of images or laboratory samples. Finally, the present work lays the basis for the enhanced use of research related order sets and reporting completion of study milestones back to the CRS.

The use of an xml message to transfer the information to different EMRs is well established.[4] Thus, our use of xml to transfer study information should be generalizable to facilitate interoperability with other EMR systems as long as they support the concepts of a research study and research participant. As with any interface development, there is involvement with more than one vendor. However, there were no unusual issues encountered in this development compared to any other interface, such as one between an EMR and a lab system. Thus, our approach should not be beyond the capability of hospital IT departments who presently interface systems to their EMR.

Conclusion

Electronic medical records and clinical research systems each meet important needs of the participants and clinical researchers. We believe that, rather than continuing to enhance the functionality of the two systems to match the

other, improving the integration between these systems will play a more significant role in improving the research and clinical care partnership.

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