Logistics of Clinical Research in the Age of Electronic Medical Records

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ABSTRACT
The increasing adoption of electronic medical record (EMR) systems has added complexity to performing clinical research in today’s care environment. Each of the contributions from Duke University within this journal has interfaced with the systems for performing clinical research described in this study. While the increased use of EMRs has aided many aspects of clinical care, the logistics of doing the work of clinical research is seldom discussed. In this review, we briefly outline current practices regarding clinical research as they relate to interface with the EMR.


INTRODUCTION
The increasing adoption of electronic medical record (EMR) systems has added complexity to performing clinical research in today’s care environment. Each of the contributions from Duke University within this journal has interfaced with the systems for performing clinical research described in this study. While the increased use of EMRs has aided many aspects of clinical care, the logistics of doing the work of clinical research is seldom discussed. In this review, we briefly outline current practices regarding clinical research as they relate to interface with the EMR.

Beginning in 2013, Duke University Health System incorporated the Epic EMR into our version of this platform, which we call Maestro Care. Along with the overall implementation of the day-to-day clinical workflows in Maestro Care, we have an additional module known as the Maestro Care for Research. Duke University was one of the first sites to implement this module of clinical research in the Epic EMR platform. The primary functionality of the Maestro Care Research module is to coordinate patient care events that are associated with a clinical research protocol. In some cases, research-related documentation can be collected during a clinic visit or hospital admission, i.e., part of the patient’s planned health care. Examples of such research-related documentation may include specific aspects of physical examination, patient-reported outcomes, or radiographs that would normally be documented in an EMR. In other cases, an entire health care encounter, such as a clinic visit, can be entirely related to research.

In the current system at Duke University, the project initiation begins with the clinical faculty. The protocol may be derived independently by the faculty or in concert with an external sponsor from industry or grant funding. A protocol is submitted to the electronic institutional review board (eIRB) review process, and during that process the study is determined to have what we internally refer to as “billing risk.” A billing risk study is one in which the research protocol requires the patient enrolled in the study to undergo a clinic visit, an X-ray, lab draw, or some other patient interaction that could potentially generate a bill in the normal course of health care delivery. The goal of the Maestro Care Research module is to enable the system to discern two important objectives: (1) To communicate planned research-related events for patients who are enrolled in billing risk clinical research protocols. This communication is done by developing a “study calendar” in the EMR. The second key objective is to clarify whether the costs of specific aspects of the patient care should be assigned to a research project rather than to routine health care costs. When costs associated with a particular episode of care are to be paid from a research protocol, this clarification needs to be identified and documented with the EMR. The study calendar allows the research team to document three key aspects of the study protocol: (1) The specific dates on which the patient is to be seen either in clinic or in the hospital, (2) which particular studies or interventions are to be performed related to research for that particular patient and the given protocol, and (3) indicate where costs should be allocated for the research-related studies.

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The process of clinical research has evolved to include research infrastructure with the Department of Orthopaedic Surgery and centrally in the School of Medicine. Figure 1 illustrates the overall process of research at Duke University.¹

Infrastructure for clinical research in the School of Medicine has evolved in a number of ways. We have adopted an eIRB protocol submission and review process. In addition to the eIRB review for every protocol, externally funded studies frequently require a substantial amount of review from the research support offices. These include the Office of Corporate Research, the Office of Research Administration, and the Office of Grants and Contracts. Review and approval from some or all of these offices may be required to achieve institutional approval for a protocol to move forward.

Within our department, research infrastructure is primarily provided through the Clinical Research Unit (CRU).³ The purpose of this unit is to ensure that overall there is basic internal quality control for research performed at Duke and that studies proposed have appropriate budget and resource needs identified before the study begins so that we can work to provide a successful environment for clinical research. The CRU includes our Finance Practice Manager, Research Practice Manager, and Clinical Research Coordinators and Clinical Trials Assistants. The Clinical Research Coordinators and Clinical Trial Specialists are a team of trained staff who help the faculty interface and coordinate with clinical research.

Currently, for patients enrolled in clinical trials, at each visit that they are seen for either preoperative or

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Fig. 1: Duke post-epic research study submission and approval process
postoperative related to their protocol, a documentation of this visit and the research conducted during their particular visit is performed manually in the EMR by the Clinical Research Coordinators. As is required for all prospective clinical research, a regulatory binder for each study is generated in which the active consents, enrollment logs, and delegation logs are maintained; in addition, clinical trials registration may be required. The enrollment logs would indicate the patients who have actually been approached and are enrolled in the study. A delegation log indicates which personnel are designated as key personnel for the institution and who are appropriately credentialed to be performing and obtaining informed consents for the research protocol. These logs are not continued in the EMR and must be maintained separately. Clinical trial registration is required for all applicable clinical trials that meet requirements described in Section 801 of the Food and Drug Administration Amendments Act (PDF), known as FDAAA 801.4

For complicated trials, a formal study initiation meeting may occur, which allows the coordination of elements of finance, compliance, and all the various research offices that contribute to the development of the calendar for Epic. The Principal Investigator, Research Coordinator or designee, Financial Practice Manager, and Research Practice Manager are required to attend study initiation meetings. The addition of Steven George as Vice Chair of Clinical Research for the Department of Orthopaedic Surgery has strengthened our relationship to the Duke Clinical Research Institute (DCRI). This relationship increases the Department’s capacity to do large-scale clinical research projects (e.g., large pragmatic or multicenter trials). Dr George has a joint appointment in DCRI as the Director of Musculoskeletal Research. We are hopeful that the complexity and impact of Duke’s Orthopaedic Clinical Research will continue to grow under Dr George’s leadership.

Performing clinical research at Duke now requires the interface of multiple systems including the eIRB, Maestro Care, and Sponsored Program System, which identifies the details of the grant and particular protocols and milestones that need to be transferred from the protocol to the individual patient’s calendar within Epic. Over the next year, we anticipate that Duke will be bringing on a new clinical research management system that will replace the current eIRB system and provide greater coordination and interface with the Maestro Care medical record. I look forward to providing you with updates in the future years’ versions of the Duke Orthopaedic Journal on this topic.

REFERENCES