Web-Accessible Orthopaedic Outcomes Engine: The Harris Joint Registry at MGH

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1. OVERVIEW

One of the problems facing medicine today is that we seek to cure problems that do not occur often enough in individual clinical practice to see a pattern of causation. The obvious disadvantage to this is that it's difficult to solve that which one can rarely observe. Computerized databases now allow data to be collected and analyzed from many medical colleagues. This provides physician-researchers with the opportunity to study a larger group of patients and enables them to see patterns where none were apparent before. Our software project's aim is to facilitate the gathering of clinical and radiographic data and an analysis of that data through studies. We expect that the synthesis of this data may help physicians find answers to clinical problems.

Our system retrieves data from disparate sources such as operative notes from the Research Patient Data Registry (RPDR), an IRB approved central database within Partner's, and the surgical schedule from the nursing system's web-interface. The data gathered creates a foundation for a research-oriented database for orthopaedic patient records with minimal input from physicians. Authorized investigators for IRB approved studies can then use this data. A web-interface now exists for study management and will be highlighted as we explain the workings of the system. However, to understand how patient data is gathered, the system's data import schemes and data storage must first be explained.

As Figure 1 illustrates, two major components of the architecture for the Harris Joint Registry at MGH are the database and the web server. The web server makes the software web-accessible, a key feature of the system. It also enables web pages to exist for data entry. The section labeled Data Import/ Update illustrates how web pages for data entry might be used: the entry of patient information or surgical information by a system user (i.e. surgical fellow or resident) and the entry of questionnaire data by a patient are good examples of manual data entry possibilities.

Fortunately manual data entry is a minor method of data gathering for the Harris Joint Registry at MGH. As Figure 1's Automated Data Import section illustrates, we can gather patient, surgical, and radiographic data from a number of Partners systems. The details of this data import are explained in section 1.1 found below. The data is imported to the Harris Joint Registry at MGH database where it is associated with other relevant data. Data associations are explained in section 1.2. Once data is stored in the Harris Joint Registry at MGH database, it can be manipulated and analyzed. Images may be exported and analyzed through an external tool such as MDESK™ (RSA Biomedical, Umea, Sweden), a radiographic

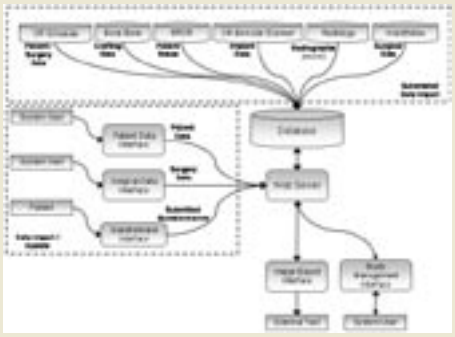

Figure 1: System Architecture

Table 1: Data Sources and what they provide

Data Source	Data Retrieved
Nursing System	OR schedule, basic patient data like name and MRN
Bone Bank	Bone graft data
RPDR	Op Notes, Discharge Summaries, Office Notes
Bar code scanner	Details on surgical implants used
Radiology	All orthopaedic images for patients in our database
Anesthesia's Saturn system	Surgical data including antibiotics administered and patient's height and weight
Questionnaire web-interface	Patient's clinical outcome score (general health, disease specific and activity) as calculated by responses to questionnaires
Manual entry of patient and surgical data	Any data that remains to be entered for a patient and surgical record to be complete

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templating and measurement software program. Surgeries may be grouped into studies for analysis via the study management interface. Both image export and study management are illustrated in Figure 1.

1.1 Data Import

While gathering data and running studies are the main purposes of the Harris Joint Registry at MGH, we understand that limiting the amount of manual data entry required will improve our chances of success. To this end, we have recruited numerous existing electronic systems from which we can gather patient and surgical data. Table 1 describes these systems and the information they provide the Harris Joint Registry at MGH.

Figure 1 explains how the data sources listed in Table 1 are integrated into the software architecture.

The import of data from these various systems occurs with a frequency that is appropriate to the data gathered. For example, the OR schedule is retrieved daily while the bar code scanning of implants occurs in the operating room after surgery.

1.2 Data Storage

Once data is imported, it must be stored. Data we store must be both protected and associated with other data. The data storage mechanism, designed for this registry, isolates data by organization and limits data access within an organization by login. Figure 2 explains the relationships between data items.

Through observation of current clinical research practice, we created the data model which is described in Figure 2. Surgeons operate and so are associated with zero or more surgeries. They also function as primary investigators and so can be associated with zero or more studies. Patients are operated upon and so are associated with zero or more surgeries. For each surgery performed on a patient, there will be a set of questionnaires the patient is asked to fill out. Therefore a surgery is associated with zero or more questionnaires and a patient is associated with zero or more questionnaires. For each surgery performed there are radiographs taken, implants inserted, and notes (op notes, office notes, discharge summaries) recorded. Using this data model allows the storage and manipulation of data related to any type of surgery such as hips, knees, shoulders and spine.

Figure 2:
Basic Data Model

1.3 Study Management

Conducting a study requires that a physician have enough surgeries available for analysis to make the study worthwhile. The Harris Joint Registry at MGH allows a physician to search all the surgeries in the database for specific features for study. For example, a search may be run on different post-op complications or on the type of implants used.

As Figure 2 indicates, studies are run against individual patient's surgeries, not on the patients themselves. Once enough surgeries are found to make a valuable study, these surgeries can be formally grouped into a study. The process of creating a study in the Harris Joint Registry at MGH includes recording the study's name, primary investigator, status, and several other details. Then the surgeries of interest are selected and added to the study. One surgery may be found in multiple studies.

Because the Harris Joint Registry at MGH records contact information for each patient as well as contact status and study consent status, it is feasible to follow-up with patients after their surgery to keep track of their surgical outcome. A timeline exists for each patient based on their surgeries and the studies with which they are involved. This timeline helps keep the patient on track for getting x-rays needed for the study and for answering relevant questionnaires such as the disease specific Harris Hip Score[1] or the general health score EQ-5D[2] or any other patient administrated questionnaire. In the past, questionnaires have been delivered to patients by mail or at the time of their clinical visit. Then the results have been scanned into the database by the office staff. In the latest release of the Harris Joint Registry at MGH, the questionnaires will be available for touch-screen input during a patient's office visit. We intend to offer the patients the possibility to do the questionnaires on-line via a secure website. We expect that this will increase the number of questionnaires completed by patients and thus provide more data for the physician-researcher.

1.4 Data Manipulation

Radiographic images are automatically requested from Radiology for each patient's surgery in the database. Because radiographic images are associated with a surgery, these images will be available for analysis with each surgery in the database. This means that these radiographs can be viewed from the web browser and selected for study inclusion without requesting them from the Radiology department or going to AMICAS. As indicated in Figure 1, images from the Harris Joint Registry at MGH can be exported or pushed via the Dicom protocol to an external tool, such as MDESK, for analysis or templating.

Once a patient's surgical data has been entered, this data can be reviewed and edited. Also available for editing is the patient-specific data such as patient contact information.

2. STUDY EXAMPLE

While the elements that make a study have been explained, it may be easier to understand how the system works with an example that takes us from importing the data to managing a study.

First a patient is scheduled for surgery. On the morning of that surgery, the Harris Joint Registry at MGH retrieves the OR schedule from the nursing system's web-interface. The OR schedule contains enough patient information to create a patient record including name and MRN. The patient is then

listed in the Harris Joint Registry at MGH as a scheduled surgery.

After the surgery is complete, several steps occur. The authorized surgical fellow or other responsible party logs in to the Harris Joint Registry at MGH, goes to the list of scheduled surgeries, and finds the patient whose operation was just completed. Next to the patient's name is a link that says "Enter Bar Codes." Entering this link and using the scanner attached to the computer in the OR, the authorized fellow scans the two codes (a catalog number and a lot code) that are on all implant boxes used in the OR. The Harris Joint Registry at MGH records these implants and inserts information about the implants into the patient's surgical record such as head size, liner design, or polyethylene type. When the authorized fellow finishes scanning implants, he or she logs out of the Harris Joint Registry at MGH.

Meanwhile, the anesthetist for the surgery finishes his or her record of the surgery and submits this to the anesthesia record system. At MGH, the system is called Saturn. Once the data is available in Saturn, it is available to the Harris Joint Registry at MGH. The Harris Joint Registry at MGH pulls this data from Saturn and puts it into the patient's surgical record along with the data that was gathered from bar code scanning.

Next, the Harris Joint Registry at MGH reaches out to the bone bank, radiology, and RPDR databases for information on this patient's surgery. If a bone graft was used, that information will be pulled from the bone bank's database and inserted into the surgical record. The radiology system automatically sends all the DICOM images related to this patient's surgery. RPDR will send any notes that have been made regarding the patient's surgery including office notes, op notes, and a discharge summary. The bone graft data is inserted into the surgical record while the images and notes are simply associated with the surgery and made available to anyone who looks at this surgical record.

Finally, the authorized surgical fellow or other responsible party logs into the Harris Joint Registry at MGH, finds the patient listed under scheduled surgeries, and clicks the link next to the patient's name that says "Enter op data." The authorized fellow reviews the record to be sure no required data is missing. If any data is missing, the authorized fellow, who is a member of the study staff, enters that data. When the record is complete, the authorized fellow submits the record, which then remains in the scheduled surgery list with a status of "Complete." Prior to this, the record will be listed as "Not Entered" or "Incomplete." At the end of the day, an authorized research nurse in the Orthopaedic Biomechanics and Biomaterials (OBBL) lab reviews the list of scheduled surgeries and marks all the "completed" surgical records as "done" which removes them from the scheduled surgeries list.

Using this data, an authorized physician could run a study on, for example, all primary hip surgeries that have used Durasul components in patients that had been operated on 5 years ago or more. The authorized physician would log into the Harris Joint Registry at MGH and go to the Hip Advanced Search page. Once the search was defined, the authorized physician would perform a search and observe how many surgeries matched the search criteria. This search can be refined or a totally new search can be run until the search produces desirable results.

Next the authorized physician would go to the Outcome Studies menu in the Harris Joint Registry at MGH and create a new study. The authorized physician will re-run the search to reproduce the results found earlier. Then all of the results will be selected and added, with the click of one button, to the newly created study.

Now that the study exists, the authorized physician researcher can use the study tools available to analyze x-rays associated with surgeries in the study or to review patient questionnaire results or to track the patients with a timeline.

3. INTEGRATION OUTSIDE OF PARTNERS

To date the Harris Joint Registry at MGH has functioned as a tool inside of the Partners System. However, several other institutions have expressed a desire to use the software, so it is imperative to the goal of improving patient outcomes that this is made possible. To that end, the following problems have been identified:

- How do we partition the data between organizations?
- How do we gather information from diverse hospital systems?
- Where should images from other organizations be stored and how should they be referenced?
- How do we address issues of confidentiality and HIPPA regulations?

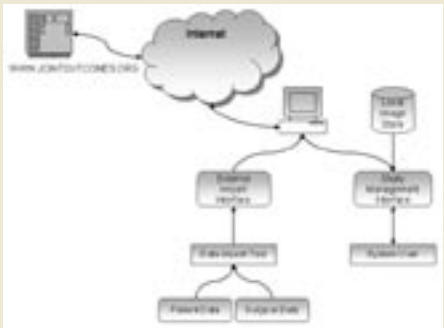

Figure 3: External Data Integration

3.1 Data Partitioning: Creating a Sandbox

In order to partition the data between authorized organizations, each authorized organization's data set is defined as being unique from other authorized organizations' data sets. When an authorized user logs in, they belong to a particular organization and can only see data in that organization's data set. Within an organization, limits of data visibility can be set so that one user may have more data access than another.

3.2 Web-services Data Import:

Hospital systems vary between organizations. In order to map outside organizations' data to the data model used by the Harris Joint Registry at MGH, we will provide interfaces as a web service (using the standard HTTP/SOAP data transfer

protocols) for data import to the system. This requires external organizations to map their data to our web-interface. Once the data is mapped, it can be pushed, via the web-interface, into our data model and displayed by the Harris Joint Registry at MGH. This allows data import solutions to be customized for organizations without ever changing the Harris Joint Registry at MGH data model. Note the box in Figure 3 that is labeled "Data Import Tool." This is where a customized data-mapping solution would be placed in relationship to external organizations' data and our web-interface.

3.3 Local Radiograph Management:

Digital images require a very large storage capacity and organizations are not accustomed to release data to other organizations. For these two reasons we have decided to store external organizations' images locally to the individual authorized organization. We can then provide a local applet-based radiographic management tool to allow the integration of images to the Harris Joint Registry at MGH. Choosing this solution avoids the overhead of remote image storage and transfer for what are potentially extremely large data sets.

References

1. **Harris, W. H.:** Traumatic arthritis of the hip after dislocation and acetabular fractures: treatment by mold arthroplasty. An end-result study using a new method of result evaluation. J Bone Joint Surg Am 1969 (51:4): 737-55
2. **"The_EuroQol_Group",** *EuroQol--a new facility for the measurement of health-related quality of life.* Health Policy, 1990. 16(3): p. 199-208.