Functional Requirements
For the
California Joint Replacement Registry
I.T. Infrastructure

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On behalf of the
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Outline

1 Introduction

This document contains the requirements for the technical infrastructure of the California Joint Replacement Registry (CJRR). The requirements are intended to communicate the desired functionality and features of a pilot implementation of this infrastructure, envisioned to be in place by the first quarter of 2011. The contents of this document are part of a formal RFP and will be used as the basis for procurement decisions and vendor performance evaluation.

A small set of participants will use the pilot infrastructure described here to collect, evaluate, and analyze registry data for a period of several months. Based on the participants' experience and feedback, the infrastructure may be extended or modified as needed in subsequent development phase(s). The ultimate goal is to create a registry infrastructure that will be used by many participants across California to collect and analyze joint-replacement data.

2 CJRR Overview

The CJRR is envisioned to be a repository of data on knee and hip joint replacements performed in California. The purpose of the repository is to aggregate data from many provider organizations and patients across the state into a single coherent database. The pilot implementation of this database is intended to support (1) scientific analysis of best practices in joint replacement, (2) confidential self-assessment by providers with respect to process and outcome metrics, (3) more convenient quality reporting to state and national organizations, and (4) evaluation of the feasibility of collecting and integrating data across the continuum of care for joint-replacement patients. The CJRR will be a "level 3" registry, meaning that it will contain not only information about the joint-replacement procedures and implanted devices themselves, but also data about each patient's risk factors, complications, clinical outcomes, and self-reported functional status.

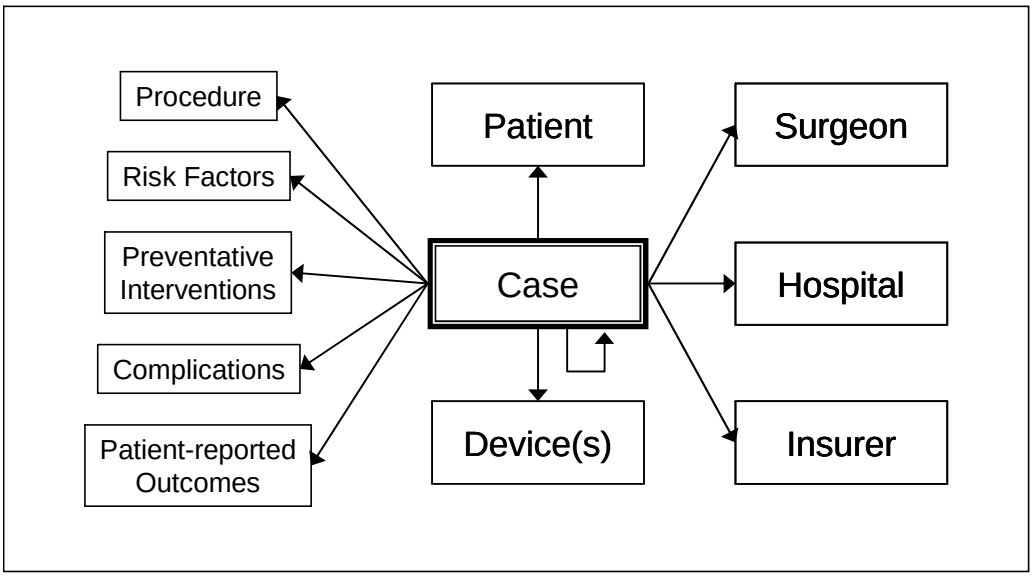
The technical infrastructure of the repository will provide four general functions:

1. Collect and import relevant data generated at provider organizations (inpatient and outpatient) and by patients themselves
2. Organize the data into coherent records of individual joint replacement "cases" that are determined to be valid and complete and that support the intended analysis and reporting functions.
3. Store the data securely and ensure appropriate access to subsets of the data and aggregated statistics based on the data.
4. Provide the necessary tools to support analysis, including tools to extract identified and de-identified subsets of the data and tools to enable appropriate access to the data on the part of provider organizations entitled to access.

2.1 The CJRR Conceptual Data Model

The conceptual data model for the registry is shown in Figure 1. The central object in this model is the "case," which is defined for purposes of the registry as a surgical procedure during which a knee or hip joint replacement took place. The occurrence of such a procedure is what qualifies a particular health-care episode and all of the information related to it as recordable in the registry. All information collected for the purposes of the registry is related to a case, as shown in Figure 1. Registries and data warehouses designed to support data analysis typically have a hub-and-spoke or "star" organization such as this.

Figure 1. Conceptual data model for the CJRR.



Per this model, a "case" represents the replacement of a specific joint at a specific point in time. Note that this definition requires the creation and maintenance of distinct cases within the registry for the following situations:

1. Sequential replacement of different joints. When a single patient undergoes the replacement of a joint on one side (laterality) and at a later time undergoes the replacement of the same joint on the opposite side, the two joint replacements and their associated data shall be represented as two distinct cases within the registry.
2. Simultaneous replacement of different joints. When a patient undergoes the replacement of joints on both sides (bilaterally) during a single surgery, each of the joint replacements shall be represented as a separate case within the registry. Certain of the data collected related to these cases shall be common to both (surgeon, hospital, risk factors, preventative interventions, systemic complications), whereas other data shall be distinct for each case (procedure, implanted device(s), localized complications, patient-reported outcomes). The two cases shall be linked within the registry in a manner that indicates that the two joints were place during the same surgery.
3. Revisions. When a patient undergoes the replacement of a joint and then later undergoes a revision of the same joint (same laterality) in which a new prosthesis is implanted, the revision shall be represented as a separate case within the registry. The two cases shall be linked within the registry in a manner that indicates that the later case was a revision of the earlier case.

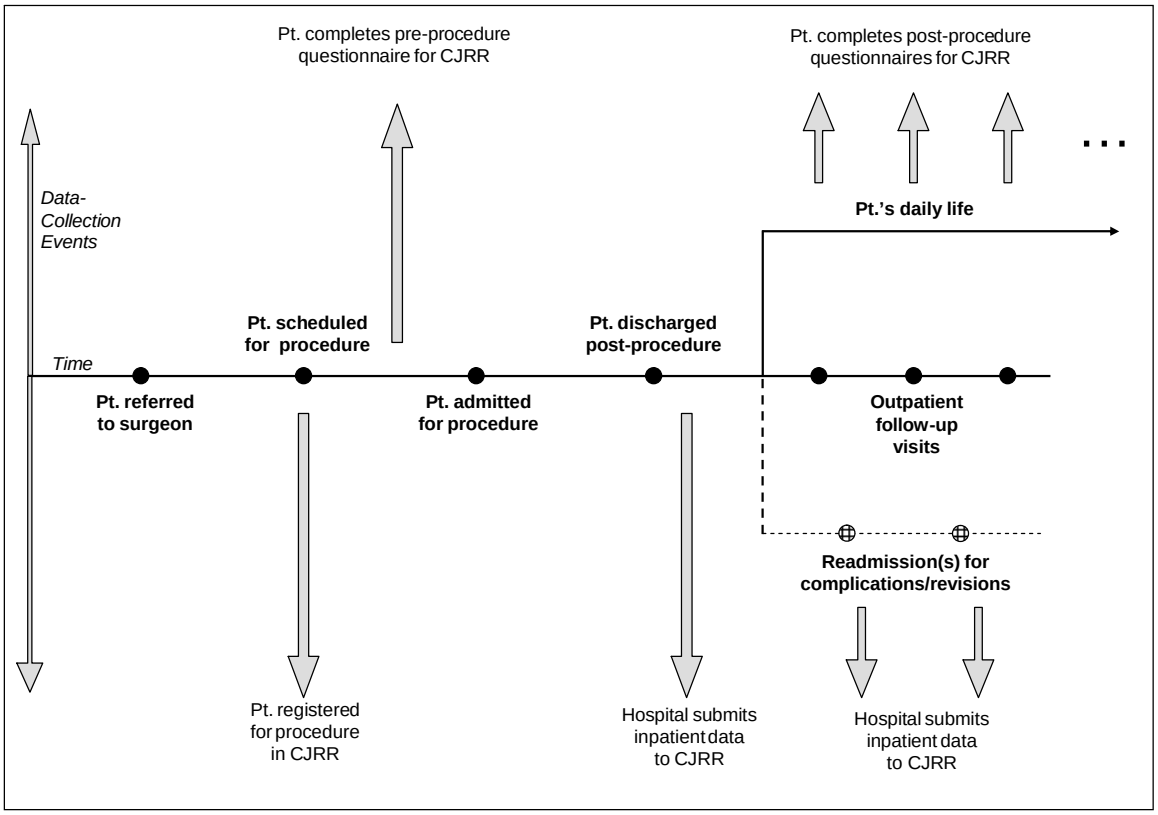
2.2 Data Acquisition – Process Workflow

Figure 2 shows the sequence of events for a typical joint-replacement case and the points of data acquisition envisioned for the pilot phase of the CJRR. Because the CJRR is a level-3 registry, data related to the same joint-replacement case must be collected and submitted to the registry at several points in time. Specifically, patient-reported outcomes data will be collected from the patient prior to the procedure as well as periodically following hospital discharge, whereas data regarding the procedure, peri-operative care, and post-operative complications and revisions will be collected from the hospital following each relevant inpatient stay.

These data-acquisition patterns create several notable requirements for the CJRR:

- Data collected from different sources at different times will have to be integrated into a coherent record in the registry. For example, data submitted by a hospital following the joint-replacement procedure will need to be correctly associated with the pre-operative patient survey data collected earlier. Data regarding re-admissions for complications or revisions will need to be correctly associated with the data on the original joint-replacement event that was submitted earlier.
- Different modalities for submitting data to the registry will have to be supported. Specifically, hospital data will primarily be submitted in the form of batch files containing data on multiple patients and cases (see Section 3.3). Patient-reported outcomes will be submitted via online or paper forms on a case-by-case and patient-by-patient basis (see Section 3.4).

Figure 2. Sequence of events and points of data collection

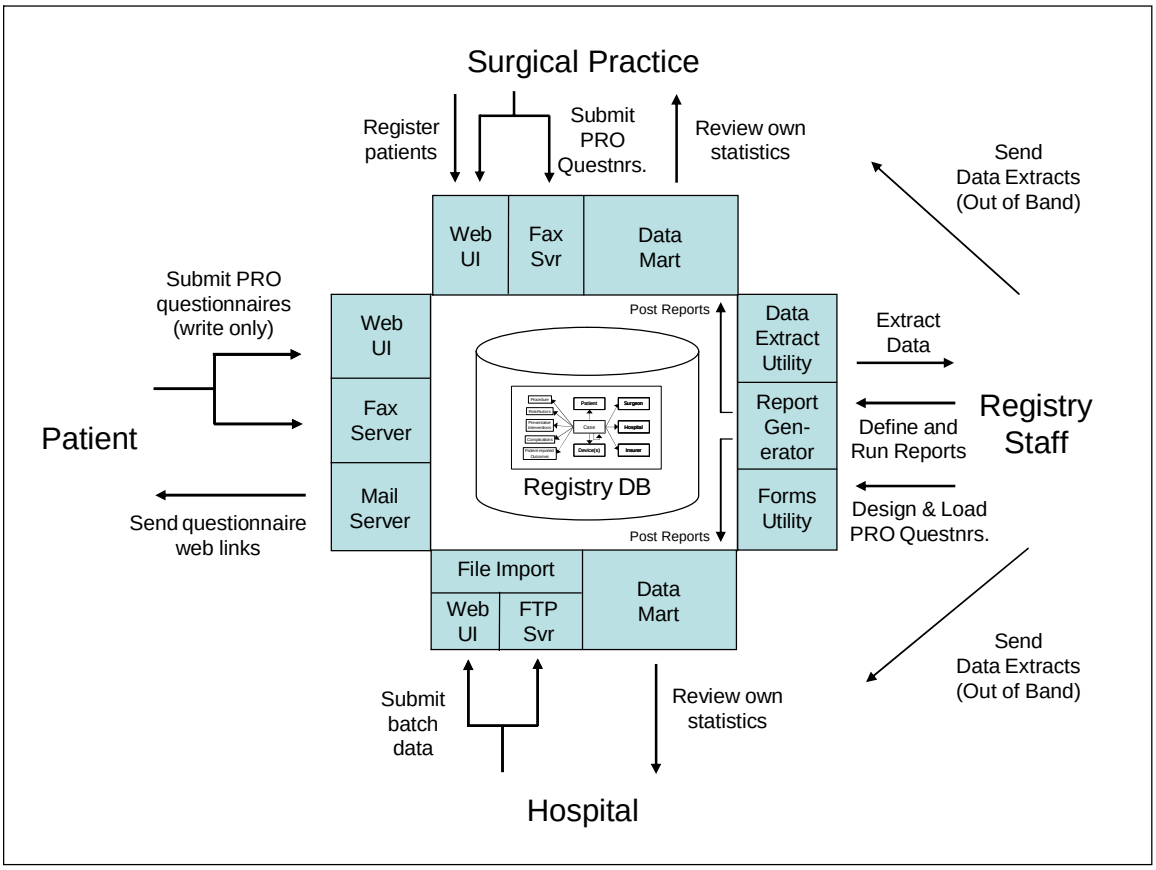


Note that the pilot registry will not attempt to capture data from outpatient follow-up visits via either a batch-file or forms-based methods. Many surgical outpatient practices do not yet use an EHR capable of capturing the needed complications and outcomes data in a coded form, and it is unclear whether surgeons are willing to perform additional forms-based data entry during these follow-up visits. During the pilot phase, the registry will continue to explore which electronic data capture or forms-based methods may be feasible in the outpatient surgical practice. Future versions of the CJRR will include mechanisms to capture data from outpatient follow-up visits (see Section 4.1), and the architecture of the registry should be capable of supporting this functionality.

2.3 Architecture of the CJRR Infrastructure – Inputs and Outputs

Figure 3 shows the general architecture of the CJRR with respect to the inputs and outputs, and the various modules envisioned to provide those services. The details of the input and output operations depicted in Figure 3 are covered in the functional requirements (Section3).

Figure 3. Architecture of CJRR with respect to inputs and outputs



Please note the following correspondence between the operations depicted in Figure 3 and the sections of the functional requirements:

Operation	Functional Requirement
Register Patients	3.2 Patient Registration
Submit PRO Questionnaires	3.4 Forms-based Data Acquisition
Send Questionnaire Web Links	3.4 Forms-based Data Acquisition
Review Own Statistics	3.6.2 Online Access to Reports 3.7.2 External Access to Aggregated Reports and Data Extracts
Submit Batch Data	3.3 File-based Data Acquisition
Extract Data	3.6.1 Data extracts 3.6.3 Quality Reporting 3.7.1 Internal Access to Entire Registry Database 3.7.3 Data Access Rules
Send Data Extracts	3.6.1 Data extracts
Define and Run Reports	3.6.2 Online Access to Reports 3.7.3 Data Access Rules
Post Reports	3.6.2 Online Access to Reports 3.7.2 External Access to Aggregated Reports and Data Extracts
Design & Load PRO Questionnaires	3.4 Forms-based Data Acquisition

2.4 Architecture of the CJRR Infrastructure – Data Storage

For the pilot implementation of the CJRR infrastructure, it is envisioned that all of the registry data will be stored and maintain in a single centralized and secure data repository (as depicted in Figure 3). In this architecture, all data required to fulfill the operational goals of the registry will be sent to and incorporated into this data repository. Access to the data will be tightly controlled through technical security mechanisms (physical security, authentication, access control) as well as formal data-access policies (data-access rules, review of research requests).

In subsequent versions of the CJRR infrastructure, it is possible that a more distributed or federated data architecture may be desirable. The purpose of such an architecture would be to accommodate provider organizations and other data sources that may not be comfortable contributing their data to a shared centralized repository (even if rigorous security and formal access-control policies exist). In this alternative architecture, certain data needed to fulfill the operation goals of the registry could remain in the physical possession of the provider organizations, stored within their local I.T. infrastructures. When access to these data were required to compute aggregate statistics, to compare data across provider organizations, or to support research studies, the provider organizations would release the data on a case-by-case basis. At that time, the technical mechanisms would exist to correctly aggregate the data with data made available by other provider organizations.

Respondents to the RFP are requested to indicate whether and how their proposed solutions could support a distributed or federated data architecture in the future. For example, respondents should address whether they can support the "just-in-time" aggregation of registry data that are stored across provider organizations and/or whether the database management system they use has the capability to support distribution of data across multiple physical sites and they have experience with building and operating registries stored within distributed databases.

3 Functional Requirements

[Omitted from public version]

4 Appendix A. Envisioned Future Requirements

The features below are not required in the pilot implementation of the CJRR technical infrastructure. The developed infrastructure, however, must provide an evolutionary path to support these features. The list of future features below are not necessarily complete.

4.1 Collection of Data from Outpatient Setting

[Omitted from public version]

4.2 Dynamic Generation of Reports and Extract Files

[Omitted from public version]

5 Appendix B. Sample Questions for PRO Surveys

[Omitted from public version]

Appendix C. Data Format for Hospital Submissions

[Omitted from public version]