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# California HealthCare Foundation, Post-pilot Evaluation of the California Joint Replacement Registry, Final Report

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**Submitted to:**

Stephanie Teleki, PhD  
California HealthCare Foundation  
Senior Program Officer  
1438 Webster Street, Suite 400  
Oakland, CA 94612

**Submitted by:**

American Institutes for Research  
1000 Thomas Jefferson Street, NW.  
Washington, DC 20007-3835

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## Executive Summary

### Introduction

The California HealthCare Foundation (CHCF), the Pacific Business Group on Health (PBGH) and the California Orthopedic Association (COA), have collaborated to develop and pilot a statewide Level 3 joint replacement registry, the California Joint Replacement Registry (CJRR). As a Level 3 registry, the CJRR collects information on patient demographics, device characteristics, patient co-morbidities, other data about the procedure, and patient self-reported outcomes. The CJRR seeks to:

- Collect and report scientifically valid data on effectiveness, safety, and patient-reported outcomes following hip and knee replacement procedures performed in California.
- Promote the use of evidence-based information to guide physician and patient decisions and support programs for provider recognition and reward, thus driving quality and cost improvements through marketplace mechanisms.

In August 2011, the CJRR concluded a three month pilot phase. Three sites, representing 12 surgeons who perform 5 percent of the hip and knee replacements in California annually, participated in the pilot phase. CHCF commissioned the American Institutes for Research (AIR) to conduct an evaluation of the CJRR pilot program that focused on the processes and lessons learned during the planning and pilot phases to facilitate expansion of the CJRR. This report presents findings from this process evaluation.

### Methods

Qualitative interviews were conducted with 30 individuals who participated in the CJRR pilot, with representatives from leadership (e.g., Steering Committee, Technical Advisory Group), management (e.g., project oversight, project management, IT, and legal), and pilot sites. Interviewers used a semi-structured protocol and each interview lasted between 30 and 60 minutes. Interviews were conducted in the fall of 2011; therefore findings provide a snapshot of the state of the CJRR and the views of its participants during that time. Findings presented in this executive summary reflect themes most commonly discussed among the three interviewee types—leadership, management, and pilot sites.

### Findings

#### Accomplishments during the pilot

Successfully completing the pilot demonstrated the feasibility of creating a Level 3 registry—with patient-reported outcomes—thereby building credibility for the CJRR throughout California and for other Level 3 registries nationwide. Interviewees pointed out that completing the considerable amount of work for the pilot on schedule and in a short period of time was a significant accomplishment. Interviewees identified the following factors as critical for success:

- ***Effective leadership and management.*** Interviewees specifically cited the leadership and visibility of Mark Smith, David Lansky, and Kevin Bozic as critical to the success of the

CJRR and thought these individuals were uniquely positioned to lead this effort. Similarly, interviewees praised CJRR's organized, professional management. Pilot sites described the CJRR management and IT staff as efficient and responsive to problems and credited them for excellent support and for taking concerns seriously. Although some issues with communication arose during the pilot, interviewees noted that most problems were addressed promptly.

Interviewees noted the project's remarkable success in getting multiple stakeholders, particularly orthopedic surgeons, to participate and to cooperate with each other in the creation of the CJRR. With a surgeon majority, the Steering Committee was viewed by most interviewees as the "*guiders and the ultimate decisionmakers*" for the CJRR. Interviewees praised the Committee for its leadership in engaging stakeholders and regarded the surgeon involvement in guiding the data design to be an important facet of the CJRR.

- ***The IT software for developing, maintaining, and using the database ("the system solution")***. Interviewees considered the system solution to be a significant accomplishment and noted that significant work and expertise was necessary to overcome the challenges of implementing the CJRR design. As proof of the quality, a few interviewees noted that the CJRR software has been licensed to the Michigan Arthroplasty Registry Collaborative for Quality Improvement (MARCQI) for the creation of a similar registry. At the same time, interviewees indicated the need for continued development and improvement of the system solution.
- ***Caliber and commitment of staff at the pilot sites***. Interviewees frequently mentioned key individuals at participating hospitals who were critical to the day-to-day project operations and to obtaining high level institutional commitment. Further, identifying the correct technical staff at each site made discernable differences in the progress of the pilot and the successful uploading of data to the CJRR.

### **Challenges encountered during the pilot**

Overall, interviewees said that the CJRR pilot was more difficult and costly than anticipated. Despite the level of effort required, interviewees agreed that the project was worthwhile and that the potential benefits outweighed the costs. Interviewees described the perceived benefits as improved joint replacement quality, access to performance data, and being the first hospitals involved in an important process.

Across pilot sites, interviewees described the most challenging and labor intensive problems as adapting workflow and IT-related processes to collect required data for the CJRR and the Health Insurance Portability and Accountability Act (HIPAA) authorization and informed consent processes. More specifically, interviewees identified the following key challenges:

- ***Significant time required of pilot sites to understand their in-house technical systems, determine the steps in the data collection process, and adjust their workflow to gather required data***. Interoperability of IT systems within and across hospitals was limited and therefore added to the complexity and resource needs for implementation. Pilot sites were not able to extract required information from their electronic systems easily or automatically. Thus, they needed to adjust or develop workflow or write custom applications to gather the required data. In some cases, required data was still collected manually on paper or was housed at a separate location from the primary site, requiring staff to travel to collect it. In

other cases, pilot site staff did not always have sufficient system access privileges to obtain needed data.

Interviewees noted that the solutions for the pilot were unavoidably ad-hoc in nature and that, to some degree, these solutions are not sustainable. Many interviewees, particularly those from the pilot sites, talked about wanting, or having anticipated, more automated data collection processes. These interviewees cited automation as the key to improving workflow and reducing the labor burden of data collection. By and large, interviewees did not differentiate between automation efforts that would be in-house and those that would be the direct responsibility of the CJRR.

Interviewees also noted that the project was taking place in a technological context that is highly innovative and constantly shifting. The world of health information systems is rapidly evolving and changing, which will affect the CJRR's development and deployment.

- ***Aggressive timeline.*** The tight timeline moved the project forward, keeping stakeholders and interviewees engaged in the project. Yet, the timing meant that the system was being developed and deployed at the same time as sites prepared their workflows, making it more difficult to develop efficient data collection processes. The timeline and innovative nature of the system solution revealed the tensions between flexibility and accuracy during the pilot. For some interviewees, the nature of the pilot meant that the technical approach and the deployment of system needed to be flexible and adaptive, with problems solved ad hoc as they transpired. Conversely, others wanted a more structured process where staff thought through potential issues in advance.
- ***Health Insurance Portability and Accountability Act (HIPAA) authorization and informed consent.*** Almost all interviewees described HIPAA authorization and informed consent challenges as too complex and inefficient. In fact, legal advice for these issues was one of the biggest costs for the pilot.

CJRR entered into Business Associate Agreements with participating hospitals sites to meet HIPAA requirements. Negotiating these agreements was time-consuming and labor intensive. Also, to track patient outcomes over time and through various care providers or hospitals, the CJRR needs to collect social security numbers. Interviewees from all sites noted patients' reluctance to share social security numbers as the most frequently cited reason to refuse participation in the registry; some interviewees attributed this fear to a lack of knowledge about how their data are protected.

Although the CJRR and other registries could be considered exempt from patient informed consent, as having a registry is not considered research, each site's Institutional Review Board (IRB) considered the effort as research and required patient informed consent. The need to obtain consent resulted in challenges of varying intensity depending on the requirements of each IRB. For example, at one site, there was an internal policy regarding which clinical staff had to administer the consent form. Others noted that patients were daunted by the complicated 11-page consent forms. Individual patient education about the registry appeared to work well as a way to facilitate patient consent, but was extremely labor intensive.

## Recommendations for expansion and sustainability

As the CJRR expands to additional hospital sites, suggestions and recommendations from interviewees focused on improvements and overall sustainability of the effort. As these recommendations were made during the interviews in fall of 2011, the CJRR has already started implementing many of these recommendations in the months following the pilot.

**Clarify and disseminate the overall goals and priorities of the CJRR.** Many interviewees agreed that the overall goals and priorities for the CJRR needed to be clarified and disseminated to all stakeholders involved in the project, including hospital site staff. Interviewees thought that explicitly stated goals and priorities were an important part of moving the CJRR towards long-term sustainability in terms of stakeholder buy-in, expanding to additional sites, and obtaining long-term funding.

Interviewees also suggested that the sustainability of the project as a whole would be closely connected to plans for data use and reporting. Most interviewees were firmly committed to public reporting in the future, but expressed different ideas about what form public reporting might take. Some interviewees in leadership roles acknowledged that, at the time of the interviews, specific conversations about data use and reporting had yet to occur, but that it was time to initiate this discussion.

### **Ease the burden of data collection and processing work on sites to help with sustainability.**

Almost all interviewees stated that the current burden on hospital sites is unsustainable, and many interviewees recommended different ways to transfer some of the effort to the CJRR. These ranged from the more technically challenging, such as moving from a centralized to a federated database model, to the less challenging, such as providing quality technical guidance and support for participating sites. Some suggestions applied to only the pilot phase, such as fully debugging software modules prior to deployment. Other suggestions applied to ongoing participation, such as having CJRR staff take responsibility for data validation or provide technical support for custom application development at sites to help automate data collection tasks. Some interviewees also suggested that the CJRR document and disseminate techniques, solutions, and best practices to sites now joining the CJRR effort.

### **Ease the burden of work related to obtaining HIPAA authorization and informed consent.**

Many interviewees wished for an easier, more efficient, and more reliable means of obtaining patient consent. To a large extent, the challenges of the consent processes depended on the requirement of each site's IRB. Nevertheless, many interviewees viewed this as an area where the CJRR could help document and disseminate best practices and effective techniques for improving the rate of patient consent. Some interviewees suggested providing a toolkit of consent materials that sites could adapt for their own use.

**Review the composition of the Steering Committee.** Although the surgeon majority was seen as critical for success, most interviewees felt that the composition of the Steering Committee should be reviewed as the CJRR continues to expand. A variety of existing and new stakeholders were mentioned as deserving representation, including hospitals, patients, consumer advocacy groups, or device manufacturers.

### **Develop a clear business case for the CJRR and articulate the benefits of participation.**

Interviewees suggested that the CJRR should eventually be operated by an independent organization with its own staff and on-going funding stream (e.g., its own entity or 501c3). They

suggested a variety of approaches to funding the project, but acknowledged that none of the available funding options seemed to be without challenges or potential shortcomings. Numerous interviewees suggested that an eventual mandate would be necessary to ensure the continuation of the CJRR, but most preferred the idea of a revenue-based funding option.

Most interviewees thought it was important that the reasons to create and maintain the CJRR be articulated in a business plan, which was a deliverable at the end of the pilot. Although collecting Level 3 data increased the workload, interviewees noted that Level 3 data sets the CJRR apart and makes participation in the CJRR worthwhile. Further, interviewees were committed to public reporting, but most interviewees saw public reporting as something that would unfold over time, both in the content of reports and who would see them. Interviewees described the advantages of collecting and publicly reporting Level 3 data as helping surgeons and hospitals improve quality of care, helping patients choose higher quality providers, and tracking the performance of joint replacement hardware. Almost all interviewees stated the importance of this data for the shared goals of reducing costs and improving quality.



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## Section 1: Introduction

The California HealthCare Foundation (CHCF), the Pacific Business Group on Health (PBGH) and the California Orthopedic Association (COA), have collaborated to develop and pilot a statewide joint replacement registry, the California Joint Replacement Registry (CJRR). The CJRR seeks to:

- Collect and report scientifically valid data on effectiveness, safety, and patient-reported outcomes following hip and knee replacement procedures performed in California.
- Promote the use of evidence-based information to guide physician and patient decisions and support programs for provider recognition and reward, thus driving quality and cost improvements through marketplace mechanisms.

In August 2010, CHCF commissioned the American Institutes for Research (AIR) to conduct a process evaluation of the CJRR pilot program. This evaluation focuses on the processes and lessons learned during the planning and pilot phases to facilitate expansion of the CJRR.

### 1.1 Goals and objectives of the CJRR pilot

In August 2011, the CJRR concluded a three month pilot phase. Three sites, representing 12 surgeons who perform 5 percent of the hip and knee replacements in California annually, participated in the pilot phase. Short-term desired outcomes of the pilot were:

1. To provide useful insights into the operations and political aspects of establishing the CJRR
2. To identify implementation challenges and improvements that need to be made for expansion
3. To explore a business model that could ensure sufficient financing and provider support to sustain and expand the effort

In addition, the CJRR hoped to use existing software so that pilot sites would not need to make new investments; to take advantage of data already available in existing electronic information systems; to minimize staff burden to the greatest extent possible; and to work with hospital and practice staff on the front end to ensure consistency in coding and data entry across the three pilot sites.

### 1.2 Purpose and organization of this report

This report presents findings from interviews conducted with stakeholders involved in the CJRR effort after the pilot program. The purpose of these post-pilot program interviews was to identify key lessons learned about the process of building a joint replacement registry, particularly in terms of management logistics, key challenges and barriers, communication and stakeholder engagement processes, resources needed, and high-level legal and IT issues encountered.

This report has six main sections. Section 1 describes the purpose of this analysis. Section 2 explains the methods and data for the CJRR post-pilot program interviews. Section 3 describes findings about facilitators and barriers encountered during the CJRR pilot. Section 4 describes findings about the potential for sustainability. Section 5 discusses implications of the main findings. Section 6 presents AIR's recommendations for the next phase of the project.

## Section 2: Methods

This section describes the methods used in post-pilot program interviews.

### 2.1 Participant recruitment

Between September 20, 2011 and November 2, 2011, AIR conducted 30 individual interviews with key stakeholders involved in the CJRR effort.

CHCF and PBGH developed a list of 39 individuals who were involved with the CJRR pilot program; 37 of these participants were prioritized for AIR to contact requesting a post-pilot program interview. AIR contacted these 37 stakeholders via email to request participation. Four stakeholders (11%) did not respond to multiple requests for an interview, and three participants (8%) declined the invitation without further explanation. Ultimately, AIR conducted 30 interviews. Exhibit 1 displays this recruitment information by interviewee group; three broad categories are representative of the types of participants in the CJRR effort.

#### Exhibit 1. Recruitment information by interviewee group

Interviewee Group	Identified	Non-Responsive	Declined Request	Total Completed Interviews
<b>Leadership Interviewees</b>	<b>17</b>	<b>1</b>	<b>1</b>	<b>15 (50%)</b>
Steering Committee	11	1	1	9 (30%)
Technical Advisory Group	6	-	-	6 (20%)
<b>Pilot Site Interviewees</b>	<b>12</b>	<b>3</b>	<b>2</b>	<b>7 (23%)</b>
Hoag	4	1	1	2 (7%)
Cedars Sinai	5	2	1	2 (7%)
UCSF	3	-	-	3 (10%)
<b>Project Management Interviewees</b>	<b>8</b>	<b>-</b>	<b>-</b>	<b>8 (26%)</b>
CHCF	2	-	-	2 (7%)
PBGH	2	-	-	2 (7%)
Ortech	1	-	-	1 (3%)
IT Consultants	2	-	-	2 (7%)
Lawyers	1	-	-	1 (3%)
<b>Total</b>	<b>37</b>	<b>4</b>	<b>3</b>	<b>30</b>

AIR's Institutional Review Board (IRB) approved all recruitment and data collection materials. The initial contact included language regarding informed consent and notified interviewees about the confidentiality of the information provided. At the start of each interview, the interviewer

reminded interviewees about confidentiality and asked if they agreed to be interviewed and audiotaped. AIR obtained a waiver of signed informed consent from the IRB.

## 2.2 Data collection

For the interviews, AIR developed a semi-structured protocol in consultation with CHCF and PBGH (Appendix A) that addressed the following main topics:

- Interviewee background and involvement in the CJRR
- CJRR accomplishments and expectations
- Perceptions of CJRR leadership
- Pilot program experiences
- Sustainability
- Recommendations for the next phase
- Coordination with other joint replacement registries

Prior to conducting interviews, AIR held a protocol training session to ensure each of the four interviewers had a similar understanding of these priorities and objectives. Each interview was conducted via telephone and lasted about 30 minutes or one-hour, depending on interviewee availability. Interviewers audiotaped each interview, and AIR contracted with an outside firm to professionally transcribe each recording. AIR de-identified each recording and sent each file securely to the firm using a File Transfer Protocol (FTP) site to prevent unauthorized access. Of note, AIR was unable to audiotape one interview due to an equipment malfunction and relied on interviewer notes for analysis.

## 2.3 Data analysis

After each interview, the interviewer summarized the main ideas into a debrief table. Once all interviews were conducted, AIR reviewed the debrief table, the interview protocol, and the initial transcripts to create a list of thematic codes (Appendix B). AIR imported the transcripts and codebook into qualitative analysis software (NVivo9) and used the software to code the data.

Two staff coded the 30 interview transcripts. AIR assessed coder agreement between coders at the start of coding to ensure consistent use of the codes. For this check, the two coders independently coded two randomly selected transcripts, met to resolve inconsistencies, and refined the codebook as needed. Coders reached an agreement above 90 percent.

After coding all transcripts, AIR created summaries of each thematic code. The larger project team discussed the summaries to explore key patterns and themes across codes, including similarities and differences across interviewee groups and roles. This report reflects this synthesis of main themes and identifies recommendations for CJRR expansion.

## 2.4 Limitations

Participants were asked to voluntarily participate in interviews, and seven participants (19%) either did not respond to the interview request or declined to participate. Because it is unclear why these individuals chose not to participate, this may be a biased sample. Additionally, half of the interviews were conducted with Steering Committee or Technical Advisory Group members. Therefore, the findings may heavily represent this group's perspective. Similarly, fewer interviews were conducted with pilot site participants who were involved in the day-to-day operations of the CJRR; this perspective may be underrepresented in our sample.

Interviews sought open-ended responses to elicit perspectives of each interview participant. As a result, not all interviews addressed the same topics in the same level of detail. Although this method provides opportunities to obtain rich insight into the project, the nature of the interviews means that some topics are touched on only in passing and some topics are never raised at all. The absence of comments on a particular aspect of the CJRR does not necessarily indicate that this aspect was lacking in the project or that it was unimportant to interviewees.

In addition, interviews were conducted in the fall of 2011; therefore findings provide a snapshot of the state of the CJRR and the views of its participants during this time. In the ensuing months, the CJRR has started addressing challenges that participants discussed.

Lastly, two interviews were conducted after the October 21, 2011 Steering Committee meeting. These individuals may have provided different responses based on information discussed during this meeting.

## Section 3: Findings - Understanding facilitators and barriers for the CJRR pilot

This section presents findings related to the facilitators and barriers encountered by the CJRR pilot.

### 3.1 Main accomplishments: Proof of concept

Participants were asked their opinions about the main accomplishments achieved during the CJRR pilot. Responses are summarized below.

**Successfully completing the pilot demonstrated the feasibility of a Level 3 registry for joint replacements.** Most participants simply cited the main accomplishment of the pilot as “*it worked*”: the CJRR is a working database with records from three different hospitals. The pilot demonstrated to the health care community that it is possible to create a registry with patient-reported outcomes. A few participants noted that the successful pilot was critical for building credibility for the CJRR throughout California, as well as for creating Level 3 registries nationwide.

**The pilot achieved a high level of cooperation among the stakeholders, as cited by leadership interviewees.** Some participants highlighted the project’s success in getting multiple stakeholders to participate and to cooperate with each other in the creation of the CJRR. One leadership interviewee noted that “*it could not have gone forward unless all of the key constituencies had made a conscious choice to work together towards this goal.*” A few participants pointed out that the project succeeded in engaging physician stakeholders, who may be likely to resist participation. One leadership interviewee said “*part of the success of this thing, so far I think, has been that the physicians feel like this is not somebody ganging up on them for their own purposes.*”

**Overall, interviewees were impressed with the system solution (the IT software and programs for developing, maintaining and using the database).** Many interviewees pointed to the system solution as a significant accomplishment. As one project management interviewee noted, “*We really have one of the first registries in the country, not just joint registries, but registries in general that can electronically collect patient reported outcome data.*” Most interviewees referred to the application technology more generally as an accomplishment, such as the project management interviewee who said “*the application did everything that it was really envisioned to do.*” A few interviewees cited more specific accomplishments: the development of the data requirements, the dashboard, or other facets of the database. As proof of the quality, a few interviewees noted that the CJRR software has been licensed to the Michigan Arthroplasty Registry Collaborative for Quality Improvement (MARCQI) for the creation of a similar registry.

Some interviewees noted that that significant work and expertise was necessary to overcome the challenges of implementing the CJRR design. For example, one leadership interviewee said, “A



*huge challenge which I think they overcame pretty well was just the data collection infrastructure, the IT infrastructure, which is quite complicated to work at multiple institutions.”*

A couple of interviewees expressed reservations about the state and progress of the system solution. For example, a leadership interviewee noted: *“I’m still not totally happy with where we are technically but we might be in the best place we can be for now.”*

**The pilot accomplished a significant amount of work on an aggressive timeline.** A few interviewees pointed out that completing the considerable amount of work for the pilot on schedule and in a short period of time was a significant accomplishment. Although a few interviewees noted that the timeline might have been too aggressive, others noted that the project staff adjusted as needed. One pilot site interviewee said,

*“The timeline was aggressive to begin with. It slipped but it’s for all the right reasons. It did not slip because [CJRR staff] weren’t managing it. It slipped because it’s innovative and they took a stab at how long it would take and it took a little longer.”*

**Interviewees thought the CJRR was significantly different from the American Joint Replacement Registry (AJRR) and had possibly helped stimulate the AJRR effort.**

Interviewees commented that the AJRR, as planned at the time of the interviews, would collect a narrower array of data, but gather it on a national scale. Several interviewees also noted that CJRR progress seemed to propel the AJRR effort. For example, interviewees observed that the AJRR was hiring staff and putting more resources into their registry effort.

**Although most interviewees said that the pilot met their expectations, their expectations varied widely.** Interviewees had a broad range of expectations for the CJRR pilot; examples include expectations about the amount of effort required, what the pilot would actually accomplish, the scope of specific roles within the pilot, and how the technology would work. Although most felt that the pilot met expectations, a few interviewees framed their comments about expectations in qualifying language. For example, a pilot site interviewee said, *“I would say yes because, for the most part, everything worked fairly well,”* and a leadership interviewee commented, *“I think we did pretty well on most of the planning, initial execution, getting the local stakeholders to buy-in, physicians and hospitals.”*

Some interviewees said that their expectations were not met or that expectations were unrealistic. For example, one project management interviewee described the timeline and development schedule for the project as *“unrealistic”* and discussed an unmet need for revising expectations *“as the facts on the ground dictated.”* Another project management interviewee expressed the idea that, in the beginning, some people appeared to believe that the CJRR could be built quickly and in a bare-bones manner. As the project progressed, however, it became clear that the nature of the data and the amount of work required to collect it meant that a more full-fledged development process was needed. This may have contributed to the perception that timelines were unrealistic or too tight.

Four pilot site interviewees had no expectations for the pilot because the CJRR was a highly innovative project; therefore, much of the territory was uncharted. For example, one interviewee said, *“In an innovation situation, you don’t know what to expect.”*

**Interviewees described challenges during the pilot, sometimes characterizing them as “glitches” and “hiccups.”** Generally, interviewees expressed the need to keep expectations and judgments in line with the fact that the project was a pilot only. A number of unanticipated challenges presented themselves during the pilot, including difficulty obtaining administrative and IRB approvals at sites, problems associated with data collection and patient consent processes, problems with communication, and issues surrounding the development and deployment of the system solution. Quite often, these challenges were already addressed or circumvented by CJRR and site staff. A few site interviewees described these obstacles as “glitches” or “hiccups” along the way to eventual success.

**A few leadership interviewees were disappointed in the amount of data actually accumulated.** These interviewees expressed reservations about the amount of data that had been successfully accumulated. For example, one interviewee said that the database had not lived up to its promise of Level 3 data:

*“With regards to the level three data and even the level two data, which are the complications and other factors, there were some huge gaps in obtaining data. It was a little discouraging to see that only about less than 20% of the patients enrolled had actually filled out the outcomes instruments.”*

## **3.2 Structure, leadership and management of the CJRR pilot**

The sections below highlight key findings related to the overall structure, leadership, and management of the CJRR pilot. Overall, interviewees appreciated and respected the leadership from CHCF and PBGH during the CJRR pilot and largely credited them for the pilot’s success and accomplishments.

### **3.2.1 Success attributed to commitment of key people**

Interviewees attributed the success of the CJRR pilot to the commitment of key individuals. Although there were challenges, several interviewees praised the quality and caliber of staff. Interviewees specifically cited the leadership and visibility of Mark Smith, David Lansky, and Kevin Bozic as critical to the success of the CJRR. Interviewees thought these individuals were uniquely positioned to lead this effort. For example, one leadership interviewee commented, *“Between Mark Smith and David Lansky, you’ve got two fairly powerful, well-connected, influential people in the State of California who kind of know everybody and can pull lots of believers.”* Another interviewee said, *“They’re the right people, but they’re also unique people who you don’t find very often.”*

Several interviewees cited Kevin Bozic as the *“driving force”* behind the project because he was *“influential and proactive”* in generating support within the community of orthopedic surgeons. Interviewees also recognized the dedication of the staff at CHCF and PBGH who managed and led the overall project. Several interviewees commended PBGH’s *“organized and professional”* management. Pilot site interviewees often mentioned key individuals at their hospital who were critical in the day-to-day project operations.

### 3.2.2 Steering Committee offered effective guidance, even with inconsistent participation

Interviewees' views of the Steering Committee leadership and involvement during the CJRR pilot can be grouped into four themes.

**Overall, interviewees saw the Steering Committee as the “guiders and the ultimate decisionmakers” for the CJRR, but a few interviewees were unsure of the committee’s role.** Many interviewees agreed that the Steering Committee should provide guidance to the overall project. However, a few pilot site interviewees were unsure about the role of the Steering Committee and who made up the group. Additionally, some interviewees, who did not interact with the committee often, expressed difficulty differentiating between the Steering Committee and the Advisory Group.

**Interviewees generally thought the Steering Committee had done a “good job” leading the CJRR, but some expressed criticisms based on issues important from their point of view.** Overall, interviewees appreciated the Steering Committee’s leadership and guidance because “*it kind of keeps the project real. They can give us sort of immediate feedback about what's going wrong, what's not going to sell.*” Some interviewees criticized aspects of the Steering Committee based on issues apparent from their point of view.. For example, some interviewees, who were concerned about the project going forward, felt the committee should put more effort into sustainability efforts. Pilot site interviewees were generally unfamiliar with the Steering Committee’s leadership but said they “*appeared*” to be guiding the project well. As previously noted, some leadership interviewees mentioned the team’s success in generating stakeholder collaboration, but a few criticized specific members’ participation.

**Interviewees praised the level of commitment from a few key Steering Committee and Advisory Group members, but noted that some members were less involved.** Interviewees appeared to judge commitment to the CJRR based on their visibility within the project, meeting attendance, and overall participation. Several interviewees identified certain individuals that “*absolutely knock themselves out*” for the CJRR. However, some interviewees expressed concerns about the lack of commitment from specific Steering Committee and Advisory Group members, noting, “*There are some members who are more active than others and some who are more committed to the cause than others.*” Interestingly, a few interviewees, who were members of the Steering Committee or Advisory Group, were hesitant to comment about the Steering Committee because of their own “*non-central role in it.*” Despite being a Steering Committee or Advisory Group member, these interviewees implied that they were less involved with the Steering Committee’s major decisionmaking processes and were hesitant to gauge the Steering Committee’s commitment.

**The structure of three Steering Committee subcommittees (data auditing, research and reporting, and business planning) was not as effective as intended.** A few interviewees noted a lack of general commitment to accomplishing the goals set out for each subcommittee, whereas one leadership interviewee thought the groups worked well. One interviewee strongly criticized the data auditing and research and reporting subcommittees because “*it didn't seem very productive... a lot of times, the meeting would be cancelled... and [some members] don't really contribute a lot.*” For the business planning workgroup, some interviewees noted that the

members were “*not the right kind of people*” because the team lacked business planning experience.

### 3.2.3 CJRR staff experienced routine tensions

Several project management interviewees commented about their communication and interaction with each other while working on the project, noting problematic issues related to decisionmaking and deliverables that are commonplace in innovative projects.

**A lack of clarity around responsibility for decisionmaking created internal problems for CJRR staff during the project.** Some project management interviewees commented on problems and communication issues related to a lack of clarity around roles and responsibilities. A few interviewees thought that team members were not always clear about their responsibilities and sometimes worked at cross-purposes with each other. Some project management interviewees noted that these tensions were most visible during the pre-pilot phase. But, a few other project management and pilot site interviewees said the lack of clarity around roles and responsibilities continued throughout the pilot phase. Further, project management and pilot site interviewees cited mishaps where it was unclear who had the final authority to make certain decisions. For example, one interviewee commented that there was “*a lack of clarity around who made which decisions and how many people knew about those decisions and whether or not that had been thoroughly vetted.*” Some interviewees did not believe these issues could have been prevented, as staff members were adjusting to new roles on the project.

**CJRR staff experienced tensions about timelines and deliverables.** Some project management interviewees commented that at times, deliverables overlapped which caused tension and confusion among staff. Additionally, some interviewees felt timelines were too tight, especially for the creation or deployment of key technology deliverables. One interviewee thought technology timelines were unrealistic because some CJRR staff were “*very busy with many things and they're thinking about the registry at a high level and not at the detailed operational level.*” As is typical in innovative projects, participants were not always able to estimate how much time and effort specific tasks might take.

### 3.2.4 Structure and staffing at hospital sites influenced success

The sections below summarize interviewee comments about how the pilot sites’ organizational structure influenced participation in the CJRR.

**High level institutional commitment was crucial for getting appropriate resources and people allocated to the pilot.** Pilot site interviewees indicated that having onsite support from key individuals in the organization was critical to the success of the project. For example, one pilot site interviewee stated, “*A steering member is a respected leader so we all wanted to work for [the CJRR] and get it done.*” By contrast, another site encountered institutional resistance to the project, which may have contributed to the obstacles encountered during data collection. As one project management interviewee said:

*“It wasn't an institutional priority where the drive to participate came all the way from the CEO of the hospital and ... they have much less institutional support than either [of the other two sites] did.”*

Further, these sites valued innovation, and found that the CJRR aligned with the goals of their institution.

**Identifying the correct technical staff at each site was important to the success of the pilot.**

Engaging the appropriate technical leads made discernable differences in the progress of the pilot and the successful uploading of data to the CJRR. One pilot site interviewee said, *“I had two or three people in IT that did not abandon me, meaning they stuck it through, they got their people to do so.”* According to one project management interviewee:

*“Eventually, we were able to identify those correct technical leads at the project and therefore, we were able to get them to eventually get down that path and to send us the data. But there were issues where we just did not have a strong technical lead and we didn't have right people on the teams to provide us with the data that we needed.”*

**Although based on a small sample of three hospitals, the larger, more organizationally complex hospitals encountered more barriers to participation and implementation than the smaller hospital.** For example, the larger institutions reported more challenges in obtaining needed administrative and IRB approvals for participation in the pilot, in identifying staff with appropriate site data access privileges to work on the project, in collecting data, and in getting resources allocated as needed to address barriers. One pilot site interviewee said, *“Obviously, logistics and implementation are big challenges in big organizations.”* In larger organizations, tasks and roles are spread out among departments, making data collection processes harder to implement. Also, one pilot site also faced logistical problems with collecting data from different surgeons following different protocols and varying appointment schedules.

A pilot site interviewee at a smaller institution noted that their size might offer an advantage, saying, *“I'm smaller. I think that we have more people dedicated to doing these types of things. For the other [sites], they're bigger and the people are getting pulled in more directions probably.”*

### **3.3 CJRR system solution**

The sections below summarize interviewee comments about the CJRR system design and technology.

#### **3.3.1 System design created challenges for a worthwhile goal**

**Although the level of data collection was burdensome, collecting Level 3 data sets the CJRR apart and makes participation in the CJRR worthwhile.** Interviewees described the advantages of collecting Level 3 data as helping surgeons and hospitals improve quality of care, helping patients choose higher quality providers, and tracking the performance of joint replacement hardware. Specifically, pilot site interviewees recognized the importance of this data for hospital goals of *“reducing costs and improving quality.”*



A few interviewees noted that, although collecting Level 3 data presented additional challenges during the pilot, access to this data makes participation in the CJRR worthwhile and important. For example, a pilot site interviewee noted that Level 3 data are:

*“Critical in terms of making sure that as an industry, as a profession, amongst hospitals, medical providers, community, that we are holding ourselves to the highest possible standard in terms of what we're providing the patient.”*

Another pilot site interviewee said, *“I think the time and the effort and the money and the employees and all that that is necessary for it is certainly valuable.”*

Interviewees also noted that the inclusion of Level 3 data distinguishes the CJRR from similar registries. One leadership interviewee expressed: *“I do think this Level 3 data, it really adds a richness to it that you're not going to probably get anywhere else.”*

Of note, a few interviewees discussed adding additional fields to the CJRR to capture more data, but most immediately rejected this suggestion because it would create extra work. One pilot site interviewee noted that adding new data elements related to post-discharge visits late in the project created an additional burden for sites.

**Interviewees perceived surgeon involvement during the selection of data fields positively.** Interviewees generally perceived the surgeon involvement in guiding the data design to be an important facet of the CJRR. For example, one project management interviewee noted

*“It gives the project credibility the fact that we have this engaged group of surgeons that we talk to on a regular basis. So, I think it both helped us understand ... the end users, in this case, the surgeons, and their input has really helped us have a credible project. They've also helped us work through some issues about what data elements needed to be collected.”*

One leadership interviewee noted the collaborative process used to develop the design, saying *“It just seemed that the [CJRR] staff was well-versed in working with the doctors to really hone in on what they needed to get done.”*

**The design of the CJRR required that pilot sites understand their in-house technical systems and determine the steps in the data collection process; some pilot sites encountered technical problems in implementing the system.** Typically, in-house processes and systems were not well suited to the tasks required for the CJRR, so sites needed to write programs. As one project management interviewee noted, sites were not always aware of what programs would need to be written or when they needed to be complete.

### 3.3.2 Innovation meant unexpected challenges

**Some interviewees noted that the project was taking place in a technological context that is highly innovative and constantly shifting.** The world of health information systems is rapidly evolving and changing, and this had an impact on the CJRR development and deployment. One leadership interviewee said:

*“[We thought] what we needed was someone who had the right vision, so to speak, and then could go around and talk to the individual sites and develop a generalizable technology template and approach and then execute it with these first sites. What we've seemed to have*

*learned is we can't do that. It's all ad hoc, idiosyncratic and so on. What was happening in parallel with our work is the evolution of health information exchange, data standards and format and so on."*

**Implementing the IT system created challenges typical for innovative products.** Because the IT vendor developed a new technology, it took longer than expected and there were, according to one project management interviewee, *"more errors and bugs in the software than we would have liked."* In addition, the system was, at the time of the interviews, still largely a work in progress and many project management and pilot site interviewees discussed areas of weakness, features of the system that were yet to be developed and/or deployed, and areas where the design might need to be altered. The deployment of the system to sites also revealed unexpected issues that had to be addressed as they arose. For example, one project management interviewee noted that until the system was deployed, they did not realize that pilot site staff did not actually have access to the hospital systems where data was stored. As a result, new technical leads at two sites had to be identified.

**The innovative nature of the system solution revealed differences of opinion regarding flexibility and accuracy.** For some project management and pilot site interviewees, the innovative nature of the project meant that the technical approach and the deployment of system needed to be flexible and adaptive. These interviewees were more amenable to dealing with problems and situations as they transpired and focused on getting any data into the system regardless of whether it was 'perfect' or not. Conversely, others wanted a more structured process where staff thought through potential issues and prepared solutions in advance, even if that meant some data records would not be uploaded immediately or there was less time to collect actual data.

### 3.3.3 Timeline created challenges with system deployment

**Pilot site and project management interviewees noted that the timing of the deployment of the system solution created challenges because the system was being developed at the same time as sites prepared their workflows.** For example, one project management interviewee noted that the full application was not complete during the time that pilot sites were preparing to deploy, resulting in timing issues related to site staff training on the system and to the production of valid data formats. In addition, the system was deployed piece by piece, meaning that some functions were not available until partway through the pilot. One project management interviewee described it as: *"The way that they released this system was they released it in pieces. So, on day one, the application had limited functionality. You could register patients but you could not create new queries to look at data that was uploaded."*

**Problems encountered with the implementation of the system solution were often attributed to the tight timeline.** Interviewees described a range of difficulties during implementation of the system solution, including missed deadlines and software bugs. A few interviewees described that the IT vendor missed deadlines in producing the software, resulting in sites reportedly having to rush to meet deadlines.



Also, because time was not available for software testing, the application was deployed with bugs that had to be addressed as the project moved forward. For example, a project management interviewee said, *“There have been a number of occasions in which solutions, pieces of this functionality of the application were pushed out to the end users but were not ready or were not reasonably free of bugs.”*

### 3.4 Site-level experiences and support

The following sections summarize comments about pilot site experiences during the CJRR pilot and the level of support required and available for these sites.

#### 3.4.1 Pilot sites needed more resources than expected, but benefits outweighed costs

Pilot site interviewees commented about the resources required and the level of effort necessary to participate in the CJRR pilot.

**Overall, pilot site interviewees said that the CJRR pilot was more difficult and costly than anticipated.** Across the sites, interviewees noted that several staff worked on the project, but a few key individuals devoted the most time to the CJRR. For example, at one site, interviewees noted that approximately 13 to 15 staff members worked on the CJRR daily, and about half of these individuals only spent an hour or two on the CJRR per day. Likewise, at another site, interviewees noted that over a dozen people worked on the CJRR, but five spent the most time on it.

Some pilot site interviewees commented that these resource requirements were more than expected and explained *“the number of IT hours, the number of my hours. It's a lot. It's a lot more than I had anticipated.”* Other interviewees noted that although the project required a lot of resources, it was to be expected with a pilot and *“did not escalate into something that was unrealistic.”* For example, one pilot site interviewee commented:

*“It was very difficult to know in the beginning what the scope of the project was and frankly, as we evolved, it was still difficult to know what the scope of the project was because getting something off the ground is largely an unknown in terms of what the commitment is and what kind of time, effort and all the rest of it that needs to be put into it.”*

Interestingly, a few pilot site interviewees who were further removed from the day-to-day data collection and submission efforts thought *“it didn't seem like a real burden on our group or department to collect the data.”*

A few interviewees acknowledged and appreciated the small sum of money that the CJRR provided to support the pilot sites, but most thought those funds did not cover the resource requirements.

**Interviewees cited HIPAA, informed consent, and data reformatting as extremely labor intensive processes that consumed many site resources.** For HIPAA and informed consent, interviewees noted costs for labor, legal fees, and paperwork. One project management interviewee commented, *“You're hiring basically an FTE to administer that individual consent.”* project management and pilot site interviewees agreed that going forward the recruitment team

must clearly communicate the resource requirements to hospital sites, especially for these resource intensive processes.

**Despite the level of effort required, most pilot site interviewees agreed that the benefits outweighed the costs.** One interviewee noted that it was “*a lot of work*” but “*it is worth it to take part in the pilot because I think it's a worthwhile project.*” Another pilot site interviewee echoed this idea and commented, “*The time and the effort and the money and the employees and all that that is necessary for it is certainly valuable, worthwhile, reasonable, all of that sort of thing.*” Although interviewees generally agreed that benefits outweighed the costs, some were hesitant in their answers due to the resource requirements. For example, one pilot site interviewee noted, “*If I tell you benefits are worth a 10 and the cost worth is 8 on a 0 to 12 scale, I don't know how to tell you more about that. I hesitated because it was a lot of cost.*” Of note, most pilot sites thought the benefits included improved joint replacement quality, access to performance data, and being the first hospitals to be a part of an important process.

### 3.4.2 Data collection processes burdened pilot sites

Summarized below are interviewee comments about data collection processes.

**Data collection was complex and harder to do than anticipated; pilot site staff often adjusted processes to overcome unexpected challenges.** Interviewees often talked about the complications of collecting data. One project management interviewee summarized the challenges succinctly:

*“All these pieces of information were coming from multiple systems. Some were coming from existing registry systems at the sites, some were coming from the billing system, some were coming from the surgical information system; some were coming from the electronic health records system. These sites did not already have all of this information in one place or at least two of the three didn't, and asking them to pull all those pieces together for one particular event at the hospital, the joint replacement procedure, proved very challenging.”*

For the most part, interviewees understood that a certain level of problems was to be expected in an innovative pilot, but they also conveyed some frustration, especially if they thought the problems could have been avoided. For example, one leadership interviewee thought the number of data fields collected was too ambitious and that some data collection issues could have been avoided if fewer fields were required.

Several interviewees couched their statements about data collection with comments about how they were making things up as they went along, how they could not reliably anticipate issues until they arose, or about how the timeline made it hard to make course corrections mid-project. Taken together, these comments indicate that participants were aware their workflow was not necessarily ideal, but it was the best they could do under the circumstances. For example, one pilot site interviewee said, “*As a pilot site and an innovator, probably the greatest challenge is that you have no ... idea what you're doing. You have nobody to call. You got to figure it out.*”

**Pilot site interviewees desired more automated data collection processes.** Many interviewees, particularly at the sites, talked about wanting, or having anticipated, more automation of data collection processes. For example, one pilot site interviewee said, “*The day-to-day collection of*

*data, review of the data, and submission to CJRR. It's not automated well enough yet. There's too much human handling in review of information, collecting of information, cataloging of information.”* Although the CJRR tried to be proactive about this issue in selection of pilot sites, it did not appear to work as intended. One project management interviewee stated,

*“We thought we picked these participating sites partially based on that they had electronic health records and the concept is that they would be able to get this data...and submit it to this registry all electronically, but as it turned out...they can't get the information out of [the EHRs].”*

In practice, pilot sites were not able to easily and automatically extract required information from their electronic systems.

**Problems in data entry, due to poor workflow processes or miscommunication, often required time-consuming, manual procedures to resolve.** All sites encountered a range of difficulties in obtaining, formatting, and submitting data appropriately; for example:

- ***Obtaining data in the appropriate format.*** Many difficulties stemmed from logistical problems obtaining data from wherever, and in whatever format, it was stored. For example, at one site, most surgeons were not employed by the hospital; instead, they worked in separate outpatient facilities and only performed surgeries at the pilot site. Collecting data from these surgeons became a logistical challenge when required data was housed at the separate facilities. As a result, an interviewee from this pilot site needed to travel to the outpatient offices, which were often “*at least 12 to 20 miles in the opposite direction*” from each other to collect data. Pilot site interviewees also mentioned challenges with preparing data in a format suitable for submitting to the registry.
- ***Resolving discrepancies between CJRR and site-specific systems.*** Sometimes, the data collected at the pilot sites would not match the format or procedures required by the CJRR. For example, one interviewee noted that date referencing used by their site and the CJRR did not match, resulting in extra work to correct date discrepancies. Another pilot site interviewee discussed a particular medical test needed for the CJRR data that was not part of the standard procedure at that site.
- ***Misunderstanding which data should be included.*** Miscommunication was cited in a couple of contexts, such as sites not understanding the exact amount of data required for implant identification, or not realizing they had to use specific survey questions for the patient reported outcomes.
- ***Changing data definitions.*** In a few instances, needed data was not initially collected (for example, patient email addresses), or adequately defined (for example, implant device numbers).
- ***Entering data by multiple staff.*** When multiple staff in multiple locations edited records, errors arose in data entry, often resulting in duplicate or missing data.
- ***Encountering data upload errors.*** During the pilot, technological issues occurred with data upload. For example, one pilot site interviewee noted that data was missing after file uploads.

- **Clarifying data auditing rules and procedures.** A few interviewees addressed data auditing, expressing the need for rules and procedures to be developed or clarified.

### 3.4.3 HIPAA and informed consent processes were an unexpected challenge

Many interviewees spontaneously described HIPAA and informed consent issues as main challenges during the pilot, indicating that these issues were top of mind, even when interviewees were not directly asked about it.

**Although success rates varied among sites and over time, almost all interviewees recognized that the HIPAA and informed consent task was too complex and inefficient.**

Interviewees from all subgroups discussed the complexity and cost of obtaining HIPAA and informed consent from patients. One pilot site interviewee said, *“I think that the consent process is just too over-the-top and just frightening for patients, logistically challenging for the institution.”* Many site interviewees questioned the need to obtain consent at all, revealing a fair amount of confusion about when and why HIPAA authorization or informed consent is required.

Although interviewees were not specific about success/failure rates in obtaining patients’ consent, one project management interviewee suggested one site had a success rate of over 95%, whereas at the other sites the *“rate is a lot lower.”*

**All sites described challenges with the consent process; specific challenges depended on the pilot site’s IRB requirements.** Problems varied in intensity depending on the requirements of each IRB. At one site, for example, there was an internal policy regarding which staff may administer a consent form. One pilot site interviewee noted the difficulties in working with different IRBs:

*“Different institutions have different stringencies in regard to their IRBs. [Ours] happens to be very proprietary. They like to do everything themselves. They don't allow for regional IRBs or really any kind of variability. They really call the shots on these things.”*

Across pilot sites, interviewees cited the following challenges:

- **Entering consent manually.** One pilot site interviewee stated, *“The whole consent process is very manual, at least for our institution, because we don't have an electronic option for that.”*
- **Presenting daunting consent forms.** Some interviewees pointed to problems with the forms themselves, which were daunting in length and complexity. For example, one site’s form was described as 11 pages long.
- **Scheduling consent.** Scheduling the consent process within the course of a patient’s treatment was a challenge for at least two pilot sites. Another site struggled with scheduling the consent task because some surgeons are not hospital staff and pre-operative appointments take place off-site.
- **Encountering patient resistance to releasing Social Security Numbers.** Interviewees from all three pilot sites cited issues with patient reluctance to release Social Security Numbers.

A few interviewees pointed to patients' reluctance to share Social Security Numbers as the most frequently cited reason to refuse participation in the registry. Some interviewees attributed this fear to a lack of knowledge about how their data are protected.

**Several interviewees identified patient education as the principal means of facilitating consent, with individual education appearing to work better than other approaches.** For example, one project management interviewee said:

*“It really comes down to how it is presented to the patient and the methods and the quality of who is collecting patient consent. ... It really comes down to upfront selling the idea and the value to the patient of participating in this study.”*

The site most successful at obtaining consent dedicated a skilled staff person to explain consent forms to patients. One interviewee from this site attributed their success to this staff person: *“[pilot site staff member] has been a research coordinator. She could explain it to a patient in such a way that we probably had five patients out of 600 tell us no.”*

Not all forms of patient education, however, were successful for obtaining consent. One pilot site interviewee, for example, noted that patient classes were not an appropriate time to seek consent because if one patient refused, others seemed more likely to follow suit.

#### **3.4.4 CJRR support and communication with sites was sufficient for pilot**

The section below describes pilot site experiences with support and communication throughout the pilot.

**Overall, most pilot site interviewees praised the support they received during the CJRR pilot, but a few noted “fragmented” communication about meetings.** At least one interviewee from each site credited the project management for excellent support and for taking their concerns “seriously.” For example, one pilot site interviewee spoke highly about a project management person noting they *“addressed everything promptly and was very reasonable in [their] expectations, just efficient, supportive, good listener; did a very good job of getting our concerns to the right person to address any questions or problems we had.”* A few interviewees thought there were too many overlapping meetings, and one pilot site interviewee complained that they were not always informed about meeting dates.

**Although pilot site interviewees generally felt well supported during the CJRR pilot, several interviewees were confused about which CJRR staff members to reach out to when seeking support.** These interviewees said there were a lot of different people involved, and it was difficult to *“separate who is who in the whole situation.”* One pilot site interviewee elaborated that *“it's well-managed. I just think there are a lot of people managing it. I know they are doing it from different perspectives but some things overlap, so it took me a while to figure out who I ask what question.”*

**Interviewees described the IT consultant and vendor as responsive to problems, but expressed some concerns related to project management.** Most comments about the current IT staff were positive. For example, one leadership interviewee said, *“I think they've chosen a good vendor to assist with that had the right expertise and systems that could be deployed that*

*could interface with the multiple different hospital of IT systems.”* Some interviewees also described the IT consultant and vendor as responsive to problems; one pilot site interviewee noted, *“When we’ve had a question, someone needed something changed or amended, we’ve had a very fast response and with good progress.”*

However, interviewees expressed reservations related to project management. For the IT vendor, most concerns focused on their size. A leadership interviewee, for example, said, *“I think the main obstacle they have right now is staffing their small company.”* Also, some interviewees perceived the IT consultant as lacking flexibility and having unreasonable expectations, but these expectations were adjusted during the pilot. For example, one pilot site interviewee said, *“Initially, we were concerned. I was personally a little concerned initially that their expectations were not as reasonable as most people’s in the project but then they adjusted and I think it turned out fine.”*

**Most pilot site interviewees felt that the level of technical support for the system solution and data collection was sufficient for the pilot.** Although pilot site interviewees had positive comments within the context of the pilot, many interviewees felt that more support would be needed as the CJRR continued and expanded (discussed further in Section 4). Only one pilot site interviewee wanted more help in figuring out how to pull data out of databases, but another person at the same site recognized that this was not a function for the CJRR IT staff.



## Section 4: Findings - Moving to sustainability

This section summarizes findings and interviewee recommendations about moving the CJRR from concept to a sustainable product.

### 4.1 Overall goals and priorities of the CJRR

Several project management, pilot site, and leadership interviewees agreed that the overall goals and priorities for the CJRR needed to be decided and disseminated to all stakeholders involved in the project. Additionally, several interviewees thought critical aspects of the CJRR could not progress until these goals and priorities were clear. The sections below summarize specific areas where interviewees wanted clarification.

#### 4.1.1 Clarifying how data will be used and analyzed will help with sustainability

Many interviewees called for clarification of how data will be analyzed and reported as a first step toward moving forward with the CJRR.

**Interviewees generally agreed that the CJRR data could be used to improve quality and patient outcomes, but some acknowledged that more specific conversations on data use have yet to occur.** More than half of the interviewees specifically mentioned using the data for measuring quality and patient outcomes. Some interviewees also mentioned more specific uses such as benchmarking, cost analysis, and device recall notification for patients. Many interviewees listed more than one potential use, and often, the uses were interrelated. For example, using CJRR data to notify patients whose devices have been recalled is a way of improving patients' long-term outcomes; benchmarking is a way of helping surgeons or hospitals to provide high quality care. Further, interviewees agreed that CJRR's Level 3 data make quality improvement and clinical decisionmaking possible, even though the level of data collection is burdensome.

Some interviewees acknowledged that conversations about how the registry data will be used had yet to occur. For example, one leadership interviewee said, *"I think that probably the time has come to think long and hard about the quality metrics that could be provided."* In some cases, interviewees simply questioned whether the CJRR was clear about how the data would be used, such as the pilot site interviewee who said, *"I think that there's a lot of data being collected and I'm not sure if there are clear expectations of what they're hoping to look at in the data."*

**Many interviewees drew connections between data use and sustainability, such as surgeon participation and funding sources.** Many interviewees drew connections between data use and surgeon participation in the CJRR. For example, hospitals may have questions about how data will be used before joining the CJRR. One pilot site interviewee said, *"The analysis of the [data], how will that be handled, who will be analyzing the data, who will have access to the data? Those are important questions for CJRR that will come up as they enroll more hospitals."*



Others noted that surgeon concerns related to how the data would be analyzed and reported could prevent some surgeons from joining the CJRR effort. Conversely, knowing how the data will be used may motivate other surgeons to take part. One leadership interviewee said:

*“Once we really have a chance to analyze the initial data that's collected, then [we] would do another outreach to our members to encourage them to get their facilities or hospitals involved in the process. Hopefully, that would be receptive and then we'd be in a position to broaden the collection of the data.”*

Some interviewees highlighted the connections between data use and potential sources of funding, as the value of the data depends on what is reported and to whom. For example, one leadership interviewee stated, *“To me, the business case is describing how these data are going to be available; not necessarily to the public, as I said, but to the people that they want to fund it.”*

#### 4.1.2 Public reporting process will unfold over time

**Interviewees were committed to public reporting, but reflected little consensus on the practical issues of how, what, when, and by whom.** In general, interviewees regarded public reporting as important and valuable. A few interviewees talked about an overall commitment to public reporting in almost a philosophical sense. For example, one leadership interviewee said, *“We got into this for public reporting,”* and another stated, *“What we need to do is get the registry to protect the patient. Public reporting is critical to them.”* For some interviewees, concerns about public reporting need to be overcome so that the CJRR can fulfill its goal of improving quality and patient outcomes. One pilot site interviewee stated, *“Even though there are many, many hurdles to overcome and many uncertainties about where the course of this will lead, I think it's just a critical undertaking.”*

Most interviewees saw public reporting as something that would unfold over time, both in the content of reports and who would see them. For instance, one leadership interviewee stated:

*“I'm interested to know what is going to be available for reporting in the future when they develop an adequate database. ... I'd like to know how people are going to be able to access the data, what you intend the uses of the data are a few years down the road.”*

Some interviewees expressed concerns related to data analysis, such as sample size or risk adjustment. For example, one leadership interviewee commented:

*“I do think the risk adjustments will need to be further developed and validated before we could get to a state of public reporting. We have to address issues such as sample size so that sites and surgeons in hospitals that have low sample sizes aren't going to be penalized.”*

These interviewees expressed concerns that physicians may not want to take high risk patients if they know their individual results will be publicly reported without risk adjustment.

When describing long-term goals of public reporting, interviewees uniformly indicated that the information from the CJRR would be available to anyone, including patients and health care payers. In the short term, however, interviewees mentioned different audiences. A few

mentioned providing reports only to surgeons; others mentioned providing reports to surgeons and hospitals; and still others mentioned sharing reports among pilot sites.

There was limited discussion about who should do the public reporting, but at least two interviewees suggested that public reporting should be handled by an “*independent*” party, such as the California Hospital Assessment and Reporting Taskforce (CHART) or the CHCF. One interviewee suggested that reporting should be done through a government agency.

**Concerns about public reporting centered on the readiness of the data and the potential negative consequences to providers.** Many interviewees expressed concerns about the readiness of the data itself, particularly since much of it is not complete and may not be accurate. One leadership interviewee noted that “*it would be a mistake to individually report data too early in the process before we've really had an opportunity to validate the information and have confidence in its accuracy on an individual basis.*”

Often, the readiness of the data was linked to concerns about the potential impact on providers. For instance, one pilot site interviewee summarized these concerns as: “*No one should have access to that data ... until there is a clear cut understanding of how data will be protected, individual surgeons' results will be protected. Until we figure out what's the best way to use it, data like this should not be used to destroy, but to build.*”

Although concerns about the potential negative impact were widely acknowledged, some interviewees wanted to allay this concern. For example, one pilot site interviewee said:

*“There's concern that public reporting be accurate and that it not damage the reputation of an institution or joint replacement practice...The best we can do is to provide a mechanism by which there is accurate information that is going into the system so that when it's reported, it is accurate as well, because whether we like it or not, reporting is going to happen.”*

#### **4.1.3 Relationship between AJRR and CJRR affects sustainability options**

**Overall, interviewees' reactions were mixed about whether the AJRR and CJRR were duplicating efforts.** Several interviewees were unclear about the nature of the CJRR's relationship with the AJRR. Interviewees noted that the two registries were collecting some of the same data but emphasized that the CJRR was more comprehensive as a Level 3 registry.

Some interviewees thought the efforts could complement each other and potentially work together in the future. For example, one leadership interviewee noted that the CJRR clearly communicated that they were not competing with the AJRR and could perhaps “*fold our data into the national registry and complement what they were doing.*” Another leadership interviewee echoed this statement, saying “*it was the intent that as these different registries evolved, they would use a common data set that you be able to combine data from across them.*” If the registries coexist, interviewees thought that participation in both should be seamless. One project management interviewee thought that the ideal solution would be to have CJRR send data to the AJRR, so that participation in California's effort would mean automatic inclusion in the national effort.

Other participants thought cooperation between the two efforts would be unlikely, as the CJRR only has to accommodate rules and regulations in California, whereas the AJRR must adhere to rules and regulations nationally.

**Some interviewees expressed that the nature of the relationship with AJRR will influence the sustainability of the CJRR, especially if both registries are competing for limited resources.** Some interviewees noted that having a working relationship with the AJRR would ultimately benefit both registries. But, long-term sustainability may be more difficult if both efforts continue. For example, one leadership interviewee said, *“The success of one or the other in terms of rolling out beyond the pilot phase might well come at the expense of the other, just because there's a limited amount of time and energy of people to be thinking about this stuff.”* Another leadership interviewee also wondered how the two registries could coexist because *“we're directly competing with the American Academy's registry program. The big question in my mind in terms of long term sustainability is how CJRR is going to dovetail or exist alongside the American Academy's registry.”*

## 4.2 Technical system and support needs

The sections below summarize interviewee comments about the technical requirements of the CJRR moving forward in the next phase.

### 4.2.1 Easing burden of CJRR system recommended to help with sustainability

Most findings in this area came from pilot site and project management interviewees, and many interviewees discussed these issues at great length.

**As almost all interviewees recognized that the current burden on hospital sites is unsustainable; interviewees recommended transferring the effort to the CJRR in different ways.** For example, interviewees discussed the following changes:

- ***Make structural system changes to the CJRR and properly test modules.*** A few interviewees discussed the potential benefits of transforming the CJRR into a true federated system, in which data could be accepted in a variety of formats, or making other structural changes to the system. For example, one project management interviewee described a change under consideration, where sites would send data about a patient to the CJRR, and the CJRR would filter the data relevant to the patient's joint replacement case. Thus, *“the site would not necessarily be responsible for creating a data format. It would just need to figure out when to send a particular patient's data to the CJRR.”* Further, several interviewees noted that if the application had been more complete and more thoroughly tested, it likely would have required less work.
- ***Transfer work to the CJRR technical staff.*** Work demands could also be reduced by the CJRR taking over some tasks, such as data validation, as suggested by one pilot site interviewee. Sites with complex record-keeping systems, in addition, could receive direct assistance from CJRR in programming modules that would automatically extract and format data for uploading.

- **Provide better guidance for participating sites.** Some interviewees suggested that the CJRR develop guidelines for deployment that includes implementation and training of staff, so that each site would not have to develop strategies for themselves. A leadership interviewee suggested, for instance, that the CJRR “*ought to be able to take a package to a new hospital and say, with approximately 30 hours of IT programming time and half an FTE we can get you up and going.*”

**Selecting expansion sites that meet certain criteria may also help alleviate the work load on site participants, though pilot sites were selected for this reason.** A few interviewees noted an alternative approach to lessen site burden would be to select sites that meet certain criteria, such as having electronic systems that already capture needed data or having staff with certain levels of technical expertise and authority. For example, one project management interviewee said that the hospitals need to have electronic systems that capture data on administrative billing, surgical management and prosthetic devices implanted in patients, and patient demographics. Then, “*they need to have some type of infrastructure and competence to pull this data together, integrate and reformat them in the ways that's needed by the registry.*” Not having electronic health records in place may be prohibitive, but given the difficulty in working across systems within an institution, it is unclear whether just having electronic health records in place would be beneficial.

**Pilot site interviewees suggested ways standardization and automation could be used to minimize human interaction with the data.** Pilot site interviewees called for standardization and automation in aspects of the process that required hands-on human review and interaction. These interviewees tended not to differentiate between in-house systems and the CJRR; for them, the tasks were all part of the same workflow directed at producing usable data for the CJRR. As a result, it is not always clear whether they are suggesting improvements to their own data systems, to the CJRR, or both.

Interviewees felt that standardization and automation could be used to address, for example, the burden of collecting data from disparate sources, such as different electronic record modules or physicians in offsite facilities. Likewise, interviewees suggested replacing burdensome paper-based, in-house data collection systems with automated ones. In addition, standardization could address complications that arise when the same data may be collected in a different way or at a different time depending on the surgeon or the procedure in questions. Finally, a few interviewees also referred to automation in the context of generating data reports. In this context, one pilot staff interviewee described automation as the key to sustainability: “*I've said several times: automation. I think the idea of generating a dashboard, so to speak, of data. [Something] “push button” [that] doesn't involve personnel each time the report is created, or minimizes the number of people that have to be involved.*”

**The CJRR could identify successful workflow management strategies and help sites to share them with each other.** Project management and pilot site interviewees referred to problems that have been solved or strategies that have been found to manage workflow and suggested that the CJRR could identify some successful strategies that could be shared among the sites. One pilot site interviewee reported:

*“Well, I suspect that other hospitals, similar difficulties will be encountered and I think some sharing of best practice will help but not every hospital's information structure is*

*completely analogous to another. So, there will be some reinventing of the wheel at each site to some degree. More of this can be packaged and simplified and reproduced, the less of that will occur.”*

#### **4.2.2 Hospital sites need more technical support on- and off-site**

**Although pilot site interviewees often described technical support as responsive and high quality, they expressed that more support would be desirable in the future, particularly for expansion sites.** For example, one project management interviewee said,

*“I think it's critical that the sites have technical support in implementing their upload processes and understanding what they need to do and troubleshooting issues that arise and questions that arise in the course of their implementations. The system is not at a point where documentation of the process is sufficient yet. Things are still in flux enough that technical involvement on the part of the project with the sites remains important.”*

In addition, both pilot site and project management interviewees shared the idea that the CJRR needs to provide good technical support for the implementation process and for troubleshooting, and will need to have the staff to fulfill that function.

**Pilot site and project management interviewees want greater technical expertise on-site to support data collection and database management.** Both pilot site and project management interviewees pointed out that hospital sites will need to have staff with strong technical expertise to understand the database and workflow procedures as well as to help create efficient implementation solutions for each site’s data. As noted earlier in Section 3.2.4, identifying the correct on-site technical staff presented challenges during the pilot. As a result, project management interviewees recommended that a prerequisite for participation could be assigning a person with the required levels of technical expertise. For example, one project management interviewee said, *“I think that each site, what we'll recommend to use is that each site needs to have a dedicated IT site leader that will be responsible for working to get the data from all these different places.”*

### **4.3 Regulatory needs: Tackling HIPAA authorization and informed consent**

Due to the magnitude of the issues with obtaining HIPAA and informed consent from patients, several interviewees discussed ways to address the needs.

**Several interviewees made connections between the uses of CJRR data and informed consent.** These interviewees suggested that if the uses of the CJRR data were clarified and clearly communicated to site IRBs, then patient informed consent might be waived. One project management interviewee noted:

*“We would need a lot more legal review and spend a lot more time and money on understanding those issues and having a much clearer picture of what we are eventually going to do with the data. Part of our problems were unspecific goals of what exactly we're going to do with the data.”*



A number of interviewees expressed that, should informed consent prove impossibly burdensome to obtain, the CJRR might circumvent requirements by including or reporting only de-identified data.

**Obtaining HIPAA authorization and informed consent is critical for having complete and usable Level 3 data; as such, interviewees suggested ways to address the burdensome process for obtaining informed consent.** Many interviewees referred to the need to resolve the challenge of patient informed consent because including the Level 3 data is what makes the CJRR an appealing and worthwhile project and, distinguishes it from the AJRR. In particular, having access to the patient's social security number is critical to track patients over time and across care providers. In addition, complete data (e.g., all fields, all patients) make the CJRR more useful and valuable than partially complete data.

Interviewees suggested the following ways to alleviate the burden of HIPAA authorization and informed consent:

- ***Obtain federal waiver for authorization.*** Several interviewees expressed that, ideally, a top priority should be to obtain a federal decision or waiver related to HIPAA authorization and registries. Several leadership and project management interviewees referred to ongoing efforts that would eliminate the need to obtain HIPAA authorization.
- ***Standardize informed consent process, such as making electronic informed consent options available for all sites.*** If informed consent forms are required, however, interviewees saw this area as the prime target for standardized automation. For example, one pilot site interviewee observed: *“the whole consent process is very manual, at least for our institution because we don't have an electronic option for that. So it's all on paper and it's very difficult to track the paper down. ... Going forward, it would have to be a little more standard and uniform.”*
- ***Share best practices around informed consent related to streamlining the informed consent process and providing better patient education.*** Interviewees suggested sharing best practices across sites. For example, one pilot site was successful at obtaining informed consent, albeit through a labor-intensive strategy. Other sites made mid-project adjustments in their informed consent processes, such as abandoning the practice of trying to obtain informed consent during a patient class. Also, interviewees commented on elements of patient education that need to be addressed such as the data security that protects social security numbers or the overwhelming length of forms.
- ***Provide the informed consent forms in other languages.*** One pilot site interviewee noted that informed consent forms were available only in English at their site, meaning that non-English speaking patients were automatically excluded from the CJRR. If informed consent forms continue to be required, having individual sites provide informed consent in other languages could increase participation.

## 4.4 Management needs

Several interviewees commented on the future CJRR organization and structure; the sections below summarize these findings.

#### 4.4.1 Management would benefit from clearer roles and responsibilities

**Several project management and pilot site interviewees desired clarity around the roles and responsibilities of key CJRR players.** As noted in Section 3, a primary issue during the CJRR pilot centered on a lack of clarity around roles and responsibilities. Pilot site interviewees were confused about the responsibilities of each project management member and whom to ask specific questions. Moving forward, these interviewees agreed that these roles and responsibilities must be clarified. For example, pilot site and some project management interviewees thought it should be explicitly clear who should answer certain questions about the registry technology whether it be PBGH, the IT consultants, or the technology vendor. During the pilot, some interviewees elaborated further and explained that those answers should be logged or disseminated so that all parties can be updated.

Additionally, interviewees from each project management sub-group (CHCF, PBGH, IT) cited instances of role confusion within the internal team, noting *“that it wasn't working well and we fixed it.”* Right before the interviews, CJRR staff clearly outlined roles and responsibilities to improve communication going forward into the expansion phase of the project. Notably, some interviewees thought these new improvements should be disseminated to all individuals participating in the project so that everyone would be informed about these roles and the chain of command.

**In the future, a few interviewees thought clear expectations should be outlined for Steering Committee members.** One project management interviewee thought the Steering Committee should endorse the CJRR and *“go out and carry the message of how important this registry is.”* Another pilot site interviewee echoed this idea and noted *“everything related to value, quality, and cost, they've got to drive that, they've got to own that.”* Project management and a few pilot site interviewees thought this expectation should be explicitly communicated and established. One project management interviewee thought members should understand *“what exactly they are to accomplish during those meetings”* because the meetings often were off track. Some interviewees thought the Steering Committee should be expected to lead specific tasks, such as business planning and sustainability efforts. Additionally, several interviewees thought clear expectations for participation in meetings and the general project should be established. These interviewees agreed that members who were not committed to the CJRR held the project back and thought clear expectations for participation would help alleviate the problem.

#### 4.4.2 Steering Committee makeup may need to change in the future

Several interviewees commented that the makeup of the Steering Committee may need to change in the future, but no strong recommendations emerged about needing to change the composition now.

**Interviewees generally agreed that stakeholder buy-in would be harder to achieve without the surgeon majority on the Steering Committee.** Most interviewees acknowledged that maintaining a surgeon majority on the Steering Committee is important, at least in the short term. For example, one leadership interviewee noted:



*“It's important to the surgeons that the chief policymaking body have a majority of surgeons. ... It's been an important in terms of building and maintaining trust among surgeons.”*

Likewise, a project management interviewee noted, *“It's amazing how much confidence they [hospitals and stakeholders] have in the project when... the main decisionmaking body is majority surgeons... People still trust surgeons to make the big decisions about people's care.”*

**Several interviewees mentioned the need for hospital representation on the Steering Committee, but there was little agreement on how new sites could be represented.**

Interviewees thought hospital representation was crucial for site buy-in, especially in the early expansion phases of the CJRR. For example, one leadership interviewee stated that the initial surgeon majority was needed to *“get the project off the ground, but now that the pilot's done, it might be good to just make sure that [hospitals are] tied in well to the process.”* In addition, a project management interviewee was *“concerned about the lack of hospital involvement”* because *“we did not survey the hospitals and we have not engaged them in this and they are the entity that we are asking the most of by a long shot.”*

Some interviewees did not think there is room *“for every participating hospital to have a seat at the table in the Steering Committee.”* As a possible solution, interviewees from all groups (leadership, management, and pilot sites) thought that pilot site representation could be achieved through a subcommittee. Doing so could give the hospitals a voice without drastically altering the surgeon majority of the Steering Committee. Other suggestions included rotating members or having a generic hospital representative. To that end, one leadership interviewee said, *“Asking a hospital to represent the hospital perspective or having a couple hospitals represent the generic hospital perspective though would be useful.”*

A few project management interviewees were concerned about Steering Committee members *“taking up a spot”* if their sites do not participate. For instance, one project management interviewee noted, *“As a new hospital joining, I'm not sure how I would feel if the primary decision-making body didn't include somebody from my organization and did include hospitals that don't even participate.”* Another project management interviewee suggested an official process where a Steering Committee member's seat is reconsidered if their site has not joined the CJRR after a certain number of years.

**Some interviewees mentioned adding a patient or consumer voice to the Steering Committee, but most of these said it would be “nice to have right now but not absolutely critical.”** A few interviewees noted that adding patient representation is important because *“physicians can sometimes tend to be more protective of their data than the consumers would be”* (leadership interviewee). Some interviewees thought adding a consumer advocacy group representative would help, but one project management interviewee pointed out that *“they're not consumers, they're advocacy groups. It's not really the consumer voice either.”*

Conversely, two other interviewees—one pilot site and one project management interviewee—did not think patient or consumer participation was vital for the current CJRR phase. The project management interviewee spoke about the challenges involved with adding a representative to the Steering Committee who could *“represent the divergent views that exist among Californians.”*

**A few interviewees suggested including additional representatives from health plans and payers as well as including device manufacturers, but others had concerns with representing these interests on the Steering Committee.** For example, one leadership interviewee suggested adding representatives from health plans and payers as *“it would be good to get their input.”* But, a pilot site interviewee expressed that a payer representative would have to be a *“very forward thinking payer that would not wish to take that data and manage their particular patient population cheaper because they got to see the data.”* [Although the Steering Committee had representatives from health plans (e.g., United Healthcare) and payers (e.g., PBGH), these interviewees did not appear acknowledge those voices on the Steering Committee. Reasons why they did not acknowledge those voices were not explored in the interviews.]

Of the few interviewees who commented on device manufacturers, most were hesitant about this possibility because *“people are suspicious when industry is involved in a project like this. They like to think that it's completely independent of anyone's personal interest”* (pilot site interviewee).

**Steering Committee members may not be the best venue to help build the business case.**

One project management interviewee felt strongly that the Steering Committee needed to add...

*“...people who know about who would want to pay to be in a registry. Like what kinds of things could a registry do that we could sell or add value or somebody would be willing to pay for. What are some other sources of money and by the way what kind of adapt do you need to run a registry and how much might that cost and how could we get those costs down and how are we going to grow?”*

Similarly, another project management interviewee expressed frustration that when asked about how to fund the registry long-term, the Steering Committee responded with *“Well, that's somebody else's problem. We can't solve that problem.”*

## 4.5 Business Case

Overall, interviewees noted that establishing a viable, long-term funding solution and proving the CJRR's benefit with only pilot data posed challenges for creating the business case. One leadership interviewee said, *“It doesn't seem to matter to the payers; it doesn't seem to matter to the employers, and it doesn't seem to matter to the patients.”* A few pilot site and leadership interviewees were waiting for someone else to develop a clear business case that generates buy-in among stakeholders. Despite the difficulty interviewees had in articulating suggestions for the business case, some interviewees, particularly leadership interviewees, offered ideas.

### 4.5.1 Independent, nonprofit organization should manage CJRR

**When asked, most interviewees thought the CJRR should be an independent, nonprofit organization that is professionally managed with its own staff.** One leadership interviewee suggested that it could be run by a professional association such as the California Orthopedic Association. Conversely, another leadership interviewee said this would be a *“bad model”* because *“professional societies end up using registries and their role in the governance of the registries... to do things that are aligned with the interest of the profession, not with the interest*

of public health.” One pilot site interviewee suggested the CJRR be run by “a foundation that would be at an arm’s distance from any specific stakeholder in the process.”

#### 4.5.2 Variety of funding options recommended, but none seem viable

**Overall, interviewees struggled to provide concrete ideas about funding the CJRR in the future.** For example, when asked about funding options, one leadership interviewee responded, “One needs to figure it out, and this is sort of the million-dollar question.” Some interviewees provided vague suggestions such as researching how other registry databases are funded or appointing a CJRR staff person to fundraise. A few interviewees thought there might be a market for pay-per-view data reports. Conversely, a few interviewees easily identified who would *not* pay for data reports, such as government agencies or surgeons themselves. Also, a few interviewees mentioned charitable foundations as a potential funder, specifying that CHCF could continue funding the CJRR or not specifying which foundation.

#### **The pay-for-data approach may work best for sustainability, but only when the data are comprehensive and reliable enough to interest hospitals, manufacturers, and health plans.**

Some interviewees felt that a variety of entities (e.g., hospitals, manufacturers, health plans) would pay for access eventually, but the data would have to be comprehensive, reliable, and provide the value-added outcomes reports to attract paying customers. As a result, although several interviewees said that this approach was the best means of making the CJRR self-sustaining, the pay-for-data approach was not considered viable in the short-term.

#### **Health plans could reimburse surgeons and hospitals for participation in the CJRR.**

Although interviewees thought health plans might be willing to pay to maintain the CJRR, many thought “they’re interested but not interested enough to put money in the pot” as stated by one Leadership interviewee. Some interviewees suggested that health plans could create financial incentives for hospitals or surgeons to participate in the CJRR. In this case, interviewees assumed that hospitals or surgeons would pay fees to the CJRR, and then health plans would reimburse those costs.

#### **Some interviewees mentioned hospitals as a potential source of funding but were unsure of how much sites might be willing to pay or contribute in addition to labor and overhead.**

For example, one pilot site interviewee commented, “I think that hospitals would be willing to pay a subscription once it’s big enough though. Right now, I don’t know if it would be of much value.” But, a couple interviewees were not entirely sure that hospitals would be willing to pay at all, unless provided with a mandate or an incentive.

#### **Placing surcharges on devices may help to fund the CJRR, but it is unlikely that device manufacturers would pay to manage the CJRR.**

Interviewees suggested implant manufacturers could support the CJRR by adding fees or surcharges on the sale of devices or by paying to gain access to the data. Interviewees thought it would be helpful if device manufacturers would pay going forward but agreed it was unlikely. Overall, interviewees echoed one leadership interviewee who stated, “If they were willing to come in and pay without affecting

*the governance, obviously, that would be great. But, that doesn't seem to be something that they're very likely to do.”*

### **4.5.3 CJRR can attract hospitals by clearly articulating benefits to key stakeholders**

A key component to the CJRR future sustainability and success is increased participation. The sections below describe findings and interviewee recommendations about increasing participation.

**Leadership interviewees stressed the importance of getting buy-in among hospital senior leadership, the general orthopedic community, and professional societies.** These interviewees thought the CJRR would have to strategically demonstrate the benefits to executive level leaders, such as Chief Executive Officers, and the general orthopedic community at new expansion sites. Once these populations buy-in to the CJRR, the remaining staff will follow. Additionally, interviewees frequently commented that the California Orthopedic Association or another professional society is essential to get buy-in from the orthopedic community.

**Several interviewees commented that explaining the clear, concrete benefits of CJRR’s groundbreaking Level 3 data to potential expansion sites would be the best message for marketing.** One leadership interviewee said *“being able to talk about a concrete set of measures that could be publicly reported, I think that shapes people's ideas about participation, the product, and helps folks reach better informed decisions about participation.”* Interviewees thought limited interest is to be expected when the CJRR can only discuss *“in general about the kinds of things that the data might be used for.”* Other interviewees thought hospitals and surgeons would want to participate if the CJRR would be a tool to identify provider judgment standards.

Several interviewees suggested emphasizing *“that it's clinically important for public health that this be done.”* Pilot site interviewees in particular emphasized this point because *“this is really to make total joint care better for everybody, for every site. It isn't to make one site better than the other site; really to elevate total joint care, to have a stake in the bigger vision, the bigger purpose.”* Other site staff interviewees reiterated that the public benefit was a main reason their hospital participated in the CJRR pilot despite the costs. Conversely, a few interviewees, mostly in the leadership group, noted that generating buy-in using this method would be *“a soft sell”* because *“somebody who has got a better handle on the business aspect to this would need to tell me what the sales pitch is. What do I tell my hospital why they should do this other than, ‘Hey, it's for the public good.’”*

Messages may also need to address fears about data analysis, use, and public reporting. Interviewees, often surgeons or pilot site staff, commented that uncertainties about public reporting and data use might impact buy-in; therefore there needs to be a concrete plan for the public reporting process. One leadership interviewee explained *“in order to make the sale, the pitch for greater hospital and surgeon participation, you need to be able to talk about what the outcome metrics, the quality metrics would be specifically.”*

**Pilot site interviewees commented that adequate support must be available and conveyed to expansion sites when seeking their buy-in.** A few pilot site interviewees strongly felt that each hospital needs an engaged coordinator to handle day-to-day operations and problems that arise when participating in the CJRR. Additionally, one pilot site interviewee warned that the CJRR should not add more hospitals than “*that small team*” (i.e., CJRR staff) could manage. This interviewee hinted that the number of CJRR staff available for support should remain proportionate to the number of expansion sites. Overall, these interviewees implied that advertising and ensuring this support is available would help recruit sites that are hesitant to join the CJRR.

**A few interviewees noted that marketing would be easier once more hospitals join the CJRR.** For example, one leadership interviewee said, “*once we get that going as a well-oiled machine, the other hospitals will probably be anxious to participate so that they're not left out of this program.*” A couple interviewees noted the benefits of getting larger systems to participate. For example, one leadership interviewee said it “*might force others to participate if the larger systems participate.*” One project management interviewee felt strongly about this concept and explained that once several sites or larger systems join, it would be harder for new sites to resist participation. In particular, it would be difficult for sites to request additional resources because those sites would be saying “*somehow they're unique and need something that none of the others did.*”

**Several interviewees mentioned mandated participation in the CJRR, but many felt mandates would be difficult to obtain.** Interviewees agreed that mandates were extremely effective and the “*gold standard*” for a successful effort. One leadership interviewee explained that “*it seems to me that the only way these things have ever worked is if somebody is telling the hospital they have to do this thing.*” Interviewees also mentioned two main models for this mandate; one model would require legal regulation and the other would require an economic reimbursement or incentive plan. One pilot site interviewee noted that hospitals already have procedures in place to handle mandated efforts. However, most interviewees thought obtaining a mandate would be difficult “*in today's world of health reform and all the changes that are going on at a federal level,*” as noted by one leadership interviewee. Despite this hurdle, interviewees felt a mandate was necessary in the long run for a successful project.



## Section 5: Discussion of findings

This section assesses how the findings relate to the goals and objectives of the pilot, notes the interdependencies and complications of the suggestions for moving to sustainability, compares findings to pre-pilot interviews, and relates findings to external projects.

### 5.1 Assessing the success of the CJRR pilot

**Interviewees perceived that the pilot accomplished a tremendous amount of work in a short period of time; moving into the expansion phase will require a recalibration of expectations and metrics of success.** Interviewees commended the CJRR for getting three diverse hospitals to participate and for successfully submitting data in a relatively short period of time. At their in-person meeting on October 21, 2011, the Steering Committee unanimously voted that the pilot met the goal of demonstrating feasibility of collecting required data elements across three hospital sites.

Interviewees thought uniquely positioned and motivated staff contributed immensely to the project's success. Uniformly, interviewees praised several individuals for their hard work and acknowledged that the successful engagement of stakeholders was critical. But, pilot implementation was much more resource-intensive than anticipated, due in large part to IRB and HIPAA requirements and incompatible information systems at participating hospitals.

As challenging and successful as the pilot has been, expansion raises more issues about stakeholder participation and voice, feasibility of larger-scale participation on a voluntary basis, and funding to sustain the registry. The CJRR will need to establish new expectations and metrics of success for the expansion.

**During the pilot, tensions between goals to collect any data versus to gather accurate, complete data created conflict.** Some interviewees, particularly those who managed and were involved in the day-to-day pilot operations, tended to prioritize gathering any data, whereas other interviewees pushed for complete and accurate data records. Interviewees expressed confusion about which of these goals should take priority, resulting in:

- Tensions among CJRR staff members (e.g., the need for testing the system solution and data checking versus moving the pilot sites to collect data)
- Tensions between CJRR IT staff and pilot site participants (e.g., pilot site participants perceiving the IT staff as inflexible during data collection)
- Perceptions that current data collection processes were acceptable for a pilot, but not sustainable long-term (e.g., driving between private clinician facilities to obtain patient data would not be a workable long-term solution to getting data)

Clarifying the goals of the pilot in relation to these goals may have helped ease tensions, but both of these aspects of data collection—registering eligible patients and improving data accuracy and

completeness—need to be resolved for a more sustainable effort. Yet, the processes and solutions to accomplish each task will be different. For instance, to improve number of eligible patients registered, changes need to focus on recruitment and consent; to improve data accuracy and completeness, changes need to focus on system solutions, data auditing, or PRO survey methodology.

**In the absence of actual metrics about the quantity and quality of data being gathered, interviewees’ perceptions of site success during the pilot were based on subjective impressions of how well the process was unfolding.** Throughout the interviews, interviewees discussed processes and challenges in terms of the “more successful” and “less successful” sites. However, interviewees did not have any direct information about the numbers of records uploaded or the quality of the data. The CJRR is currently conducting a data audit of records acquired during the pilot. As actual data is accrued and audited, perceptions about successful participation in the pilot could change.

## 5.2 Acknowledging the interdependencies and tradeoffs of recommendations for moving to sustainability

Interviewees’ comments reveal a strong interdependency among ideas for expanding and sustaining the CJRR.

**Moving forward, making clear decisions about how the data will be used and reported will impact multiple aspects of the sustainability for the CJRR, including HIPAA authorization and informed consent processes, costs associated with participation, stakeholder buy-in, and the business case.** For example, clarity around data use may help to reduce workload and hospital burden associated with informed consent processes. If informed consent processes cannot be made less burdensome, hospitals may not be able to participate. If HIPAA authorization and informed consent issues are avoided by eliminating personally-identifiable information, the data become less complete in terms of tracking people over time and institutions, and therefore less valuable to potential funders. As another example, concerns about data analysis for public reporting, such as risk adjustment and data validity, must be addressed, or surgeons and hospitals may be less likely to want to participate in the CJRR. These issues are interrelated and should be addressed jointly.

Similarly, choices about when and how data extraction, validation, or error correction take place directly affects choices about whether expertise and responsibility for these tasks should reside at CJRR, at the individual sites, or both. Again, these choices affect feasibility, interest in participating, and who bears the costs of this work.

**The pilot exposed the trade-offs between a centralized database model and federated database model; this choice affects funding options.** The CJRR selected the centralized database model for a variety of reasons following an extensive consideration process. Choosing to use a centralized model placed the burden of data work on the sites to extract data according to a standardized data definition file, resulting in a large portion of the direct costs falling on the hospitals and surgeons. Because these costs are currently high, the CJRR may need to find funding that reimburses or compensates hospitals for their costs. Making alterations to the database model, as some interviewees suggested, could shift the burden of data collection work

to the CJRR, but does not fundamentally solve the funding issues; it just shifts the funding issue from the sites to the CJRR. And, there is no guarantee that such an approach would result in economies of scale. However, if the CJRR finds that the burdens associated with data collection are too difficult to address, it may be worth revisiting the choice of database model to re-evaluate the costs and benefits.

**Surgeon majority on the Steering Committee was beneficial to obtain buy-in from hospitals and clinicians, but limiting other voices on the Steering Committee, such as patients, may mean that these users' needs are not addressed when developing the CJRR.** Most interviewees stated that the surgeon majority on the Steering Committee was critical for buy-in during the development phase of the project. However, this make-up leaves less opportunity for other perspectives, such as hospital leadership, payers, or patients to voice their needs for CJRR data. Although the Steering Committee included representation from health plans and payers, these perspectives may have been less visible to interviewees, perhaps because representatives from these perspectives were less vocal or the surgeon majority was perceived as so important. Because the short term priority for the CJRR has been data acquisition, the cooperation of surgeons outweighed inclusion of other stakeholders. In the long term, many interviewees see a potential role for patients or additional payers on the Steering Committee, but were unsure of when or how this might happen. A decision to limit or delay the inclusion of other voices on the Steering Committee, however, could mean that the sort of data reporting valuable to these constituencies is underdeveloped, making the CJRR less valuable to them. Similarly, the concerns of these stakeholders may be overlooked; it is conceivable that earlier inclusion of a patient stakeholder, for example, might have alerted the CJRR to patient resistance to supplying social security numbers. In addition, it may mean that these constituencies are less supportive of the registry's efforts, either in terms of support for legislative mandates or reimbursement-based incentives for participation.

**The pilot showed that larger institutions may have more difficulties collecting data for the CJRR, but recruiting those institutions may benefit long-term sustainability.** Larger institutions experienced more difficulty, at least during the pilot phase, with getting the project off the ground and with data collection processes. Larger institutions in the pilot were less nimble and adaptable, and had record systems that were more distributed, making it more difficult to extract and prepare data for the CJRR. But, recruiting larger organizations could simplify the legal and logistical challenges of bringing new sites on board. For example, once the governing IRB for a large, multi-chain organization supports participation in the CJRR, data could be collected from many sites and patients without repeating the IRB process at each facility. Additionally, larger institutions may potentially maximize the amount of data in the registry.

**Although all interviewees thought the goals of the CJRR to report Level 3 data were worthwhile, no one felt certain that stakeholders would be willing to pay to achieve these goals.** Collecting Level 3 data sets the CJRR apart from other initiatives, but it also increases the costs and burden on hospitals. Reducing the scope of data may make participation easier but would make the data less valuable to all stakeholders – surgeons, hospitals, patients, payers, manufacturers, and policymakers—resulting in less opportunity to find outside funding sources. That being said, stakeholders and potential funders will expect to see some *direct* benefit to



themselves; it is not a sufficient incentive to know that participation in the CJRR reduces overall costs or improves overall patient outcomes.

### 5.3 Comparing pre-pilot and post-pilot program findings

Prior to the CJRR pilot, AIR also conducted interviews with thirteen stakeholders involved in the project. These interviews were not transcribed, and only a couple individuals from pilot sites participated at that point. Nevertheless, AIR found it interesting to compare topline findings from the initial set of interviews to this analysis.

**Interviewees expected the CJRR to require significant resources, but post-pilot findings revealed that the level of effort was much higher than anticipated for pilot sites.** During pre-pilot program interviews, interviewees commented that the level of effort needed had not been discussed thoroughly. The lack of discussion about resource expectations early in the pilot may have contributed to the unanticipated level of effort. However, it was unknown what the level of effort would be for the pilot site participants.

**Both pre-and post-findings noted the importance of collecting and reporting Level 3 data, but exact uses of the data remain unclear.** During the pre-pilot interviews, interviewees agreed that public reporting should be seen as an educational effort and not a punitive one. From the beginning, interviewees recognized the various possible uses and goals of the data. For example, one interviewee said, *“Payers want to use it for coverage decisions. Surgeons want to use it for educational purposes. The foundation perhaps wants to share data with the public. We need to be careful with each goal, but they could coexist.”* Interviewees clearly indicated these various possibilities early in the project, but interviewees were still unclear about what exactly the data would be used for after the pilot. Interviewees agreed that the way the data are used affects buy-in and other factors critical to the CJRR’s success and thought these intents should be clear.

**Pre-pilot interviewees anticipated problems with data collection processes and the timeline, but not with HIPAA authorization and informed consent.** Interviewees initially thought it would be difficult to determine exactly what data needed to be collected and how the data collection process would work. Early in the CJRR development, interviewees predicted continuing problems meeting deadlines. During the pre-pilot interviews, one interviewee noted, *“The timetable is not reflective of the realities of the project.”* After the pilot, some interviewees, particularly those involved in IT areas of the project, cited several issues with the project deadlines. Of note, no interviewees anticipated problems with informed consent or HIPAA. A few interviewees cited the early IRB approval as a major accomplishment for the CJRR prior to the pilot, and did not foresee later problems with patient privacy and informed consent.

**A few pre-pilot interviewees observed that a successful pilot would translate to proof of concept.** A few interviewees interviewed during the pre-pilot stage anticipated that a successful CJRR pilot would *“prove that it is possible to other states and to the AJRR.”* This idea corresponds with two accomplishments during the pilot phase: that it is feasible for a registry to collect Level 3 data and that the CJRR’s success has propelled the AJRR effort.

**Pre-pilot findings helped CHCF and PBGH to clarify internal communication issues.** Pre-pilot interview analysis revealed that the lack of clarity around roles and responsibilities for

internal CJRR staff was a potential problem. During the post-pilot interviews, project management reflected on their internal communication problems and described how the issues were addressed mid-project. Of note, early CJRR staff communication issues were largely imperceptible to outside parties before and after the pilot.

**Pre-and post-pilot findings praised the guidance of the Steering Committee, but post-pilot findings revealed some problems with the working group structure and general participation.** Overall, interviewees agreed that the Steering Committee provided critical guidance to the CJRR. Prior to the pilot, all interviewees agreed that the Steering Committee had been highly engaged; however, during post-pilot interviews some interviewees identified members who rarely attended meetings or participated in the project.

Further, prior to the CJRR pilot, several interviewees thought that the Steering Committee subcommittees were a “*smart use of people’s time to divide decisions into groups*” and that they were “*working well.*” Some interviewees still held this view after the pilot, but a few interviewees thought some subcommittees had not achieved their purpose. Interestingly, one interviewee in the pre-pilot interview round noted that it would be difficult for PBGH to monitor the progress of each subcommittee and suggested appointing a subcommittee lead for each group to ensure progress.

Interviewees thought the surgeon majority was critical to the CJRR during the pre- and post-pilot program phase. Interviewees also thought additional representation from other groups, such as consumers or additional sites, might be important in the future. Both sets of findings also revealed that most interviewees did not think consumer representation was vital for the early CJRR stages. However, after the pilot some interviewees appeared to push more for additional pilot site representation.

## 5.4 Relating findings to external efforts

This section examines how the CJRR findings relate to AIR’s experience with and knowledge of external technology and quality improvement initiatives. Findings from this process evaluation are consistent with other innovative programs to improve patient outcomes.

**Innovative efforts in technology often encounter more challenges than anticipated, and technological solutions are often more costly and less transferable than desired.** Issues the CJRR experienced during the pilot related to cost and transferability of information technology are common with innovative efforts; for example:

- Healthy San Francisco’s efforts to connect providers with a unified electronic system reportedly spent millions more than anticipated on technology costs and encountered difficulties with database systems that were incompatible.<sup>1</sup>
- The Geisinger Clinic found that all aspects of the technology needed to digitize patient-reported health status for live streaming to a dashboard during the rheumatology office visit were harder to achieve than expected. The technology for capturing patient responses to a standard questionnaire had to be revised to reflect information security and work flow issues. Further, variations in medical record systems make the technology less transferable to new sites than was originally hoped.<sup>2</sup>

- A wide area network for critical access hospitals intended to create a community of practice around the adoption of guidelines for acute myocardial infarction and community acquired pneumonia had limited success, because of structural and process impediments. Of the four components of the website that served as the core of the innovation, the library, asynchronous communication, and training components received little attention from clinicians. Only the guidelines adherence measures and dashboard were adopted by the nursing staff. CEOs were internal champions, but other key staff critical to the adoption were not adequately engaged; for example, top managers, line staff, and attending physicians were less involved. The website folded when Federal funding ended because hospital staff perceived no long-term benefit.<sup>3</sup>
- A literature scan exploring electronic health record (EHR) adoption as part of the evaluation of the Regional Extension Center (REC) Program for HHS revealed numerous concerns about technical barriers that resonate with the CJRR, including concerns about vendor stability or ability to deliver services in a satisfactory way; concerns about system solution limitations; and concerns about privacy and security of health data stored in a system, such as inappropriate disclosure of patient information, illegal record tampering, or security when transmitting files and/or data fields.<sup>4</sup>

**Measures for improving patient outcomes are often developed before the dimensions on the business case are clearly articulated.** Our findings indicate that interviewees did not have a clear sense of how the CJRR data will be used or by whom, making it difficult to build a business case for the effort. External efforts encounter similar situations; for example:

- Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys, which ask consumers and patients evaluate their experiences with health care, are often developed without a clear sense of how the measures will be used or by whom. Long-term use of CAHPS instruments depends on adoption by external organizations or other institutions who find value in the measures. When CAHPS surveys have been adopted by a payer, regulator, or accrediting organization, they have entered into widespread use; for instance the Medicare health plan, hospital, and home health agency surveys adopted by CMS, and the private health plan survey adopted by NCQA.
- The PROMIS (Patient Reported Outcomes Measurement Information System, [www.nihpromis.org](http://www.nihpromis.org)) initiative developed measures that operate equivalently across multiple conditions. The initiative started without a specified user, although there was general agreement about broad target audiences. Resources devoted to developing the business case and sustainability were limited during the first 5-year cycle of PROMIS and adoption was limited as well. Subsequently, the second 5-year cycle included a budgeted component for promoting long-term use and sustainability.

From the CAHPS and PROMIS experience, it is possible to achieve widespread adoption of a data collection, measurement, and reporting system without having a clear target audience and business case identified at the outset, but it is a risky approach. If the demand for the system is not clear at the outset, then the final product will be less likely to meet the needs of potential users and to be adopted.

**Organizational context influences the success of quality improvement initiatives.** Elements of organizational context that appear to have the most impact on success include: commitment of senior leadership and internal project champions; organizational structure and culture; and alignment of external and internal incentives. Although there is much literature on this topic, two examples from AIR's work include the Lean case studies and the guidelines adherence system for critical access hospitals.

- AIR's work on Lean revealed that executive level staff not only must buy-in to the process, but they also must make their commitment apparent to all other staff. They must also take concerns of other staff into account if widespread adoption is to be achieved. Seeing this commitment at the executive level can motivate others, but does not necessarily do so if the goals are vague and the process is top down. In the ambulatory care system studied, middle managers and line staff, even when trained in Lean, were often confused about its purpose and value, because they did not see tangible benefits from participating.<sup>5</sup>
- In a project for the Agency for Healthcare Research and Quality, lack of local champions below the CEO level was a significant factor in the failure of a web-based intervention to improve provider use of guidelines in critical access hospitals.<sup>3</sup>

For the CJRR pilot program, these same factors contributed to the success in overcoming significant barriers, but they also raise concerns about whether widespread adoption and long-term sustainability are likely beyond the subset of hospitals in which top management sees value at this time. As several leadership interviewees noted, gaining buy-in from hospital executives will be vital in the next phase. However, our Lean and critical access hospitals work suggest that buy-in needs to be obtained from middle managers and line staff as well, and that support from the CEO and other top managers, while necessary, is not sufficient to obtain buy-in from lower levels in the corporate structure. Commitment from middle managers and line staff is important and obtaining it requires investment in showing and explaining the tangible benefits of participation.

## Section 6: AIR Recommendations

In this section we provide three recommendations based on findings from the post-pilot program interview analysis and our experience with other efforts mentioned in Section 5.3. These recommendations address strategy and tactics needed to achieve sustainability and expansion of the CJRR, by articulating the value proposition for the end users of the CJRR. These recommendations suggest approaches that CHCF should consider adopting for Phase II and for long term sustainability, now that the Board has committed funding for up to 5 more years. Also, as noted in individual recommendations below, the CJRR already began to address these issues and implement many of these suggestions in the period following the pilot.

### 6.1 Get buy-in from key stakeholders for the vision and goals of the expansion phase

Obtaining the necessary commitment from all kinds of stakeholders within the relevant policy and provider institutions requires clearly defining (1) the vision, purpose, and goals of the registry, (2) the relevant stakeholders whose commitment is needed, and (3) the value proposition for each type of stakeholder. Shifting from a successful pilot to the expansion phase creates an opportunity to invest in developing the vision and goals for the next phase of the project—getting buy-in from key stakeholders upfront and communicating clearly these goals to the broader group of participants and stakeholders. From the process evaluation findings, it appears that clearly communicating these goals may help ease the tensions and conflicts that arose during the pilot.

#### Action steps:

- ***Review, prioritize, and state goals clearly in writing, with specific criteria and needed resources for meeting each goal.*** In a voluntary participation environment, these goals should be tied to the value proposition of the CJRR for different stakeholders. Including key current and future stakeholders in these decisions will help to increase buy-in and acceptability of the end product. (Already being addressed by CJRR)

When developing these goals, consider the following key issues in these strategic decisions:

- ***Technology and related support.*** Consider how the decision to create a centralized database affects the value proposition and seek ways to address impacts. Selecting a centralized model was carefully, well-researched decision, but resulted in some significant implementation issues. The centralized model appears to lower the feasibility for a smooth implementation and may keep site participation costs high, thereby negatively affecting sites' benefit-cost calculations. Assuming the current centralized structure remains intact, the CJRR should develop resources that will better support data collection, HIPAA, and informed consent processes. The availability of these resources will reduce the burden on participants and will likely shift the benefit-cost calculus for potential recruits toward participation.

- *Steering Committee representation.* It is clear that orthopedic surgeons are a key stakeholder in this effort. Aside from this group, who does the CJRR need to maximize the success during the expansion? The Steering Committee should include representatives from all stakeholder groups that are essential for success. Likewise, the Steering Committee should include representatives from stakeholder groups that are needed for implementation, including the hospital administrators as well as middle managers or line staff, who do the daily work and who are more likely to understand operational barriers than top hospital management and surgeons. This is particularly important if the CJRR is to overcome the barriers that required intensive manual data collection and resulted in missing data problems. Including patient representatives may produce more effective privacy and security policies or procedures.
- *Working with other registries.* How does the CJRR position itself relative to the national effort and other state efforts? Will there be a long-term plan to merge? How will cooperation or lack of cooperation affect competition for resources and funding?
- *Metrics of success.* The CJRR should clarify what success looks like with voluntary participation. What performance metrics will be in place to demonstrate progress, especially as it relates to data collection and data quality?
- ***Clarify roles and responsibilities for leadership and staff, and align these roles with the goals of the CJRR.*** This transparency will specify where resources should be directed and reduce duplicated effort and staff frustration. For example, consider clarifying and clearly communicating who will provide technical support to the sites for each aspect of the registry. Similarly, clarify each party's role in sustainability. For the Steering Committee, identify measurable criteria for participation (e.g., attend 75 percent of meetings per year) and mechanisms for addressing lack of participation. Additionally, assigning individuals roles that are well suited for their professional strengths may help the CJRR achieve its goals. For example, interviewees indicated that choosing pilot site leaders with IT expertise and the authority to access hospital databases facilitated CJRR data collection efforts.

Also, consider expanding site staff involvement to include key financial and IT managers who make decisions about long term capital investment in resources that may affect the successful implementation and sustainability of the CJRR at the sites. In the Lean case studies, participation by the institutions' financial and IT staff members in decisionmaking was essential to identifying feasible solutions, because IT solutions often require significant capital investment. (Already being addressed by CJRR)

- ***When expanding to additional sites, clearly articulate benefits and costs of participation.*** The CJRR successfully and strategically selected pilot sites that were dedicated to quality improvement efforts. During the post-pilot interviews, several pilot site interviewees noted that although the CJRR took immense effort, it was a rewarding project that strongly related to their hospital's mission. However, these three hospitals are a self-selected group of early adopters. Not all sites will be convinced of the benefits of participation without substantial evidence or be willing to put in as many resources as the pilot sites. Relating the CJRR to individual sites' overall mission and long-term vision will help clarify the benefits of participating to institutions that may be more skeptical than the pilot sites. Although predicting the levels of resources needed to participate can be difficult, it will be important



to clearly communicate what is known about the costs for participation. (Already being addressed by CJRR)

## 6.2 Clarify how the data will be used and demonstrate the benefits of planned data use

Interviewees uniformly desired clarification about plans for data use and connected data use to the long-term sustainability of the CJRR. Based on these findings, we recommend that CJRR leadership clarify how data will be used as the first step toward building the business case and articulate these uses to all stakeholder groups.

### Action steps related to the process of clarifying how data will be used:

- ***Make decisions with the overall sustainability of the CJRR in mind, not just the needs or concerns of one particular stakeholder group.*** Data elements should address the needs and concerns of all eventual audiences, even if those measures may be years away from being reported. These planned measures should reflect how the CJRR will fulfill its goals in the long run. (Already being addressed by CJRR)
- ***Share existing decision log more broadly.*** Decision logs help establish institutional memory, provide a background resource for new stakeholders, and facilitate process and outcomes evaluations by recording decision rationale and strategy. Although a decision log already exists for the CJRR, sharing this resource may be helpful for new and existing stakeholders who might not be involved with the day-to-day project operations or were not aware of decisions prior to their involvement. For example, the decision log might help new hospital representatives understand the extensive decisionmaking process CJRR leadership underwent when considering a centralized or federated model.
- ***Describe and document the benefits and intended audience for each data element.*** Identify and convey the direct benefits for each group (e.g., hospital, surgeon, staff, patient, and manufacturer) and the overall benefits (e.g., increased quality, better outcomes, lowered costs, recognition as a quality leader, or long term financial health and stability of the institution). Support these value statements by producing worthwhile sample data reports for specific audiences.
- ***Clearly establish who will have access to the data and to reports.*** Specify the terms under which specific audiences will have access to data or to data reports. For example, establish procedures for interested researchers to submit proposals and create criteria to judge the suitability of proposed research. Consider how these access procedures are affected by data ownership agreements under which hospitals retain complete control over their own data.

### Action steps related to content of the data and to reports:

- ***Implement a transparent process to address issues about data validity and risk adjustment.*** Make decisions using a transparent process in which stakeholders collaboratively determine how measures will be derived and reported. (Already being addressed by CJRR)
- ***Establish data criteria for access to data and to reporting.*** For example, minimum sample size thresholds will likely be needed to assure that individual patients cannot be identified



accidentally or deductively. Will participating institutions have access to only their own data at the individual patient level or will they have access to individual data from other institutions? If the latter, will the identity of other institutions be masked and how will this limit the kinds of individual data that can be released? Will independent researchers have access to the data and what limitations will be imposed on the data they can receive? (Already being addressed by CJRR)

- ***Establish data quality criteria.*** The pilot study encountered problems with missing data. The long term value proposition for participation must include ways to assure that participating institutions deliver the data that will be needed by all participants. Thus, clear minimum data quality and quantity standards must be established and enforced. These standards must include deadlines for submitting data so that users have a clear understanding of the population represented in the registry. Standards should specify which data elements must be included in a patient record (i.e., the minimum data set) and the quality metrics that will be applied to each element for it to be considered accurate and useful. Standards should further specify what percentage of records submitted to the registry must meet the quality standard for the institution to remain a member in good standing. (Already being addressed by CJRR)
- ***Establish a system for maintaining the quality of the data and the database.*** Databases require maintenance as technology changes and new uses of the registry become apparent. New variables of interest and their quality standards have to be defined and adopted according to a specified process. Old variables have to be retired. Data submission procedures and report formats and content have to be updated. This process is a continuing expense for the long term viability of the registry and paying for it is an important element of the business model and the business case. (Already being addressed by CJRR)
- ***Define the set of services that the CJRR will provide to its participating institutions.*** Understanding what they will receive in return for their data is an essential part of the value proposition for potential participants. For example, the CJRR should define and publicize the set of benchmarks that it plans to generate, including specifics on how it will protect the identity of specific institutions and/or patients included in the benchmark. Establish whether these benchmark reports will be available on a set schedule or can be derived interactively through an online dashboard. Define the levels of aggregation and comparison that will be available to institutions (e.g., state-wide, region, similar sized hospitals, by number of procedures performed, etc.). Provide guidelines for how these benchmarks may be interpreted and used by institutions for the achievement of their quality improvement goals.

### 6.3 Address burdens associated with data collection

Having complete and accurate data will help the CJRR meet its goals of public reporting and improving patient outcomes. To this end, several problems with complete and accurate data were identified during the pilot. First, pilot sites encountered difficulties obtaining HIPAA authorization and informed consent from eligible patients. Second, as noted in the interviews and the *Final Report on the Pilot Phase* (PBGH, Sujansky & Associates, & Ortech), full data elements and patient reported outcomes were missing in several records.<sup>6</sup>

From these interviews, interviewees noted that more automation and standardization of data processing was needed. Also, many pilot site interviewees noted that data collection worked only because certain people went above and beyond to address the problems during the pilot. Many working solutions from the pilot are not sustainable.

As such, we recommend steps below to reduce workload generally, to specifically reduce workload associated with HIPAA authorization and informed consent processes, and to reduce workload related to collecting patient-reported outcomes.

#### **Action steps to assess reductions in data collection:**

- ***Stagger implementation at new sites in the expansion phase of the CJRR.*** The CJRR plans to invest resources upfront to help minimize the burdens associated with data collection, including developing robust resources for HIPAA authorization and informed consent, as well as IT support. Developing and implementing these resources in an iterative process will help determine what works and does not work. (Already being addressed by CJRR)

#### **Action steps to reduce burden on participants:**

- ***Create a mechanism for documenting manual and resource-intensive tasks at each site, so they can be analyzed and addressed systematically in workflow processes.*** This will help identify common problems and solutions among institutions, and may help with the process of prioritizing improvements to the CJRR.
- ***Focus first on immediate, short-term issues that can be addressed quickly and provide rapid reductions to burden and costs.*** A few quick, solid fixes early in the process will have an impact on the willingness of participants to continue working on problems and avoid early burnout from working on more difficult problems.
- ***Be flexible in identifying solutions and consider trade-offs between time and resources.*** When identifying possibly solutions, consider the trade-off between time and resources. For example, some processes may be improved by the application of resources, such as funding for automation or the provision of additional technical support, whereas others may be improved by relaxing timelines or data submission requirements. For example, data that are stored on paper forms at an offsite physician's office require staff to drive for data collection. If needed, this data could be collected quarterly. Some processes may be improved by more clearly identifying the appropriate type of site staff needed to accomplish tasks.
- ***Establish a user's group or other venue to help sites share solutions and best practices.*** It is worth noting that the CJRR conducted calls routinely to address user issues, but interviewees did not explicitly describe any meetings with CJRR staff as a "user's group." Hospitals will be a vital source of ideas for how to streamline, improve, automate, and standardize data collection and submission procedures, as well as how to best make use of some types of data reports. A recognized user's group would provide them a venue in which to share their questions, problems, ideas, and solutions. A user's group or community of practice formed around CJRR participation could also be viewed as a benefit of participation. User's groups are typically conducted by the users themselves and are far more informal than the typical project meeting, allowing a broad range of issues to be discussed. A user's group would permit discussions that may not have a clear, immediate

connection to moving the CJRR forward, but help users grapple with issues they feel are important.

**Action steps to reduce workload associated with patient enrollment and informed consent:**

- ***Develop shared resources for approaching site IRBs***, including a strong argument that the implementation (actual conduct) of the CJRR is NOT research and is therefore exempt from the Common Rule. IRBs will view the CJRR differently, so it will be useful to determine which conditions of approval they are likely to require and to develop standard materials that each site can customize for its own IRB application. Once the likely options are articulated, prioritize them according to the CJRR's preferences. Demonstrate a strong security approach to both physical and electronic data at all stages of collection and storage, and have good mechanisms for communicating this approach to each audience. (Already being addressed by CJRR)
- ***Develop standard patient informed consent and HIPAA authorization forms, and cognitively test with consumers to ensure comprehension and resonance with key messages, and with IRB members to assure acceptability.*** If IRBs determine that informed consent and HIPAA authorization cannot be waived, developing standard forms that sites can adapt as needed may help reduce the burden associated with informed consent. It will be important to cognitively test these forms with patients to ensure that patients understand the benefits and risks associated with registry participation. Testing will also help identify messages that resonate most with patients about the benefits of participating in the registry. Although every IRB makes its own determination, testing the forms with a small sample of members drawn from multiple IRBs will provide information about the acceptability of the forms. (Already being addressed by CJRR)
- ***Track the reasons that patients decline to consent*** so that new messages can be developed to address emerging concerns.

**Action steps to improve collection of patient-reported outcomes:**

- ***Evaluate how well standard survey techniques increase response rates with patient-reported outcomes (PROs).*** Develop a standard system and schedule for using response rate improvement techniques based on survey research principles and practices that have been shown to be effective. Hospitals can then use these techniques to improve patient response rates for PROs. This might involve collecting the data in the physician's office, for example, during the pre-op and post-op visits. Most patients will complete the questionnaire if it is presented as part of the visit and requested by their physician's staff. The greater challenge is likely to be assuring that the staff asks the patient to complete the questionnaires, stores the completed questionnaires safely and securely, and transmits batches for keying safely and securely. Periodically evaluate the effectiveness of techniques being used to assess whether new methods should be tried.
- ***Periodically revisit PROs used in the CJRR to ensure that instruments and mode of administration are aligned with emerging standards in health care.*** The existing instruments used in the CJRR are standard in the field, but both use traditional survey technology in an era when the ability of traditional survey methods to produce high response rates is in decline. In addition, NIH initiatives like PROMIS seek to develop measures that can be used across multiple conditions and may, eventually, be

recommended or required for a variety of research and quality measurement purposes. If the CJRR is to become a research resource, common measures could be valuable and increase comparability. The CJRR Steering Committee should periodically review the “state of the art” in PROs to ensure that the measures collected remain relevant and desirable to its audiences.

## 6.4. Develop a marketing campaign

A thoughtful, organized promotion strategy and a set of standard, persuasive marketing materials are needed if widespread adoption is to be achieved. Potential participants, especially those who are not early adopters by nature, will not see the value of participating unless the CJRR makes it clear and persuasive.

- ***Conduct a process and outcomes evaluation on the use of CJRR data and products.*** So far the pilot study has demonstrated the feasibility of collecting the registry data, but it will also need to demonstrate the value that pilot participants received from participating. Undoubtedly, more time and experience with the registry will be needed before these benefits can be demonstrated. Nevertheless, the CJRR must begin to accrue information about the value of using them immediately, so that it can be used to create marketing materials. This requires process and outcome evaluation of the use of the registry data and products. Qualitative analysis and quantitative studies, such as benefit-cost, cost effectiveness, return on investment, quality improvement, and staff perception studies are all options for this kind of evaluation.
- ***Translate evaluation findings into a compelling business case.*** Using process and outcome data from evaluation findings into a business case that will be meaningful to decision makers at California hospitals that perform joint replacement surgery is essential. Effective translation requires synthesizing the findings in a way that is meaningful to each stakeholder group and presenting those arguments in a style and format that is persuasive.

## References

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## Appendix A: Interview protocol

### CHCF CJRR Evaluation: Key Informant Interviews Post-Pilot Program Interview Protocol

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#### Purpose

The overall goal of this project is to evaluate the California Joint Replacement Registry (CJRR) pilot in terms of processes and lessons learned during the planning and pilot phases. Interviews were conducted pre-implementation of the pilot program at 3 sites in California and are now being conducted post-three month pilot phase.

The purpose of the post-pilot program interviews is to identify key lessons learned about the process of building a joint replacement registry, particularly in terms of management logistics, key challenges and barriers, communication and stakeholder engagement processes, resources needed, and legal and IT issues encountered. Aggregated results of the post-program interviews will:

- (1) Provide feedback to CHCF and PBGH on the overall project to inform the next phase of the project.
- (2) Be presented to the CJRR Steering Committee – either at an in-person meeting or via webinar.
- (3) Be disseminated on CHCF's website via an Issue Brief.

#### Materials

- Interviewer clock
- Speaker phone
- Digital recorder

#### Procedures for obtaining informed consent

*FOR TELEPHONE: Participant will be sent an email describing the project. The e-mail will include the elements of consent required by the IRB. If participant agrees to do the interview, it will be assumed that they are consenting to the process. We will obtain a waiver of written documentation of informed consent from AIR's IRB before any interviews take place. At start of interview, interviewer will remind participants of confidentiality and ask participant if they agree to be audiotaped.*

## Key informant interviews (60 minutes maximum)

### Special instructions for interviewers

- **Actionable information.** Make sure to probe about actionable information for CHCF and PBGH. Attempt to gain concrete recommendations for the next phase and thoughts from participants. Whenever possible, ask participants to give examples, probe on what about the process they did not like, what could have been done differently, what went well and so forth.
- **Bolded questions** indicate key questions that should be asked of all participants regardless of time.

### Estimated time per section

Time per section	Topic	Elapsed time at end of section
5	Introduction (welcome; background; ground rules)	5
5	Background	10
30	Pilot Program Experiences (for pilot site participants) Process (for non-pilot site participants; can be 10-15 minutes for surgeon participants)	40
15	Sustainability	55
5	Closing	60



## Introduction (start at \_\_\_\_\_ – 5 min – end at \_\_\_\_\_)

### Welcome and Background—explain purpose of the interview

- Thank you for agreeing to do this interview. My name is {NAME} and I'll be talking with you today. I work for a company called the American Institutes for Research (“AIR”), which is an independent nonprofit research organization based in Washington, D.C. AIR is one of the largest behavioral and social science research organizations in the world, employing 1,500 individuals with diverse expertise and extensive experience conducting evaluation.
- We are working in collaboration with the California HealthCare Foundation—the primary funder of the CJRR-- and the Pacific Business Group on Health (PBGH)—the CJRR manager-- to evaluate the California Joint Replacement Registry (CJRR) pilot in terms of processes and lessons learned during the pilot phases.
- *[For those interviewees who participated in pre-pilot interviews]* You may remember talking with us a few months ago before the start of the pilot program. We're talking to people again at the end of the pilot to understand their experiences. Thanks for agreeing to do this followup interview.
- *[For those interviewees who did not participate in pre-pilot interviews]* During this interview, we will be seeking your input about your experiences with the CJRR pilot program, now that it has been completed.
- We know you are busy and are respectful of your time so will be moving along at a fairly quick pace, so that we cover all of the topic areas we shared with you. We expect that the interview will last about an hour.

### Go over ground rules.

- As a reminder of your rights as an interview participant, everything you tell us will be confidential. To protect your privacy, we won't connect your name with anything that you say in any reports. The information you provide will be summarized in the aggregate with the information we collect from other interviews.
- We hope you take this opportunity to share with us your honest, candid reactions to and perceptions of how the CJRR effort is progressing and where you hope it will go in the future. By understanding how the effort is going—what is working well and what isn't—the CJRR staff can make mid-course adjustments and longer-term improvements.
- At any time during our conversation, please feel free to interrupt me if you have any questions. You can also decline to answer any question or stop the interview at any time for any reason.
- We would like to audiotape our conversation for note taking purposes only. The audiotape will be destroyed as soon as the notes are complete. Is it OK if I audiotape this interview today? **{Turn on recording equipment if consent is given}**

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## Background (for all) (start at \_\_\_\_\_ – 5 min – end at \_\_\_\_\_)

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I'd like to begin by asking you some questions about your involvement with the CJRR.

- *[For those interviewees who participated in pre-pilot interviews]* How has your role in the CJRR project evolved? Was your role consistent with your expectations?
- *[For those interviewees who did not participate in pre-pilot interviews]* When did you get involved in the CJRR effort? How have you been involved?
- **What have been your main responsibilities? How would you characterize your involvement on the CJRR project?**
- What motivated your organization to get involved in the CJRR?

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## Pilot program experiences (for pilot site participants) (start at \_\_\_\_\_ – 15 min – end at \_\_\_\_\_)

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*[For pilot sites specifically]* As a member of the pilot program, I'd like to talk about your experiences. As we talk, I would also like you to think about what is specific to your organization and what may be applicable to other *[insert type of organization: e.g. academic medical centers]*.

### Goals and overall activities

- What did you (or did your organization) hope to accomplish with the CJRR pilot?
- **What have been the main accomplishments to date in the CJRR pilot? Has the pilot met your expectations? Why or why not?**
- **Overall, do you think the pilot was a success? Why or why not?**
  - What did you see as the main challenges in the pilot program? How were those challenges addressed, if at all? If so, who addressed the challenges (your site, the CJRR team, others)?
- *[For pilot site participants]* Is there anything about your medical center that you think made the pilot successful or challenging (for example, as an academic medical center or private nonprofit)? What recommendations would you make as the CJRR expands to additional sites?

Now, I'd like to talk about some of the issues in more detail. *[Note to interviewer: Start with main issues identified and probe in more detail, but circle back to all topics.]*

## Burden and staffing

- **What has been the overall level of effort for your participation in the pilot?**
  - **How much do you think your site spent to take part in the pilot in terms of staff and other resources?**
  - **Was this consistent with your organization's expectations?**
  - **In your opinion, was the level of effort worth it to take part in the pilot?**
  - **What do you think is a reasonable amount for a hospital to spend to take part in the CJRR in terms of time and resources?**
- Did you feel you were able to get buy-in from internal staff at your site? Why or why not? What were some of your successes and challenges in getting the buy-in you needed?
- What took the most time on the project? Are there any actions that could have reduced the time spent? If so, what?
- Would you expect to spend the same amount of time on the project going forward?

## Data collection and IT issues

- **What were the biggest challenges related to CJRR data collection? How were these challenges addressed? Who addressed these challenges? What IT challenges remain, and how could those be addressed?** [*Want to get at scalability in terms of next phase.*]
  - How do you anticipate these challenges will affect the expansion of the CJRR to other hospitals? [*If they indicate barriers to overcome*] How do you think these challenges could be lessened to make sure other organizations can participate in the future?
- How was data collection integrated into current processes? How was data collection standardized throughout your organization, if at all? What worked well? What didn't? How could this process have been made easier? What could be improved going forward?
- **Overall, did you feel like you received sufficient technical support? Why or why not?**
  - Who provided technical support? [*If more than one person noted: Who was most helpful? Least helpful? Why?*]
  - Are you familiar with the IT consultant hired by PBGH and the Foundation, Walter Sujansky? Do you think having an IT consultant has been helpful to the process, or not? What has been helpful? What, if anything, about his involvement could be improved?

- Tell me about your interactions with Ortech, the registry development vendor. What worked well about Ortech's involvement? What, if anything, could have been improved?
- **What IT support do you see as critical to the success of the CJRR? That is, what kind of support is needed going forward in the next phase of the project?**
  - What data infrastructure and other IT components should be in place at organizations that are considering joining the CJRR?
- **How do you feel about the decision to build a level 3 registry, including patient reported outcomes? How has this aspect added challenges, if at all? Does the requirement for level 3 data make the CJRR more or less valuable to participating organizations, if at all? Please describe.**
  - What do you think of the feasibility of collecting patient reported outcomes during the next phase of the CJRR?
  - How could the process of collecting this data be streamlined or made easier for hospitals?

### **HIPAA and IRB issues**

- **Tell me about how the process of obtaining HIPAA authorization from patients to contribute their data to the CJRR worked at your organization. What worked well? What could have been improved?**
  - *Probe on the following issues if not brought up spontaneously:* amount of staff time it takes, patients who do not speak English, patients' concerns about privacy
  - What changes, if any, need to be in place at your organization related to HIPAA authorization to support ongoing participation in the registry? Have these changes been made? What issues could be addressed by education or training of hospital staff?
- Did your hospital obtain informed consent from patients? If so, tell me about that process. What worked well? What could have been improved?
- Based on your experience, what IRB or HIPAA issues should organizations that may participate in the CJRR in the future be aware of or try to anticipate?

### **Management and timeline**

- **What do you think about the overall management of the CJRR process? Do you think there are opportunities to restructure the management to improve the process, or not? If yes, how so? If not, what about the current management structure works well?**

- Did you work with staff from PBGH? What about PBGH's management of the effort? What have they done well? Can you give me a specific example? What about their involvement could be improved? Can you give me a specific example?
- [*For interviewees who interacted with CHCF*] What do you think about the overall leadership of the CJRR? Can you give me a specific example? What about CHCF's leadership could have been improved, if anything? Can you give me a specific example?
- **Did you feel well-supported as a pilot site? Why or why not?** If so, what was the source of the support? If not, how do you think you could have been more supported?
  - During the next phase of the project, do you think it would be beneficial to have a staff liaison from the CJRR available to work with the hospitals? Why or why not?
- **Was the timeline for the project manageable, or not? Why or why not?**

## **CJRR process (for non-pilot participants)**

(start at \_\_\_\_\_ – 15 min – end at \_\_\_\_\_)

### **Main activities and process**

- **What do you see as the main accomplishments of the CJRR pilot? Did these accomplishments meet your expectations?**
- **What do you think has worked well during the pilot program?**
- **What do you think have been the main challenges during the pilot program? In your opinion, have these challenges been addressed? How so?**
- **What is your perception of the California HealthCare Foundation's leadership in the development process? What have they done well? What about their involvement could be improved?**
- **What about PBGH's management of the effort? What have they done well? What about their involvement could be improved?**
- **Are you familiar with the IT consultant hired by PBGH and the Foundation, Walter Sujansky? Do you think having an IT consultant has been helpful to the process, or not? What has been helpful? What, if anything, about his involvement could be improved?**
- **Are you familiar with Ortech's involvement with the CJRR? What have they done well? What, if anything, about their involvement could be improved?**
- **In your opinion, has the process overall for developing the CJRR been credible and transparent? If so, how? If not, why not? What would make the process more credible or transparent?**



## Sustainability (for all) (start at \_\_\_\_\_ – 15 min – end at \_\_\_\_\_)

### Stakeholder involvement

- **[If needed] Are you familiar with the Steering Committee for the project? Has the Steering Committee been useful in guiding the project? If so, how? If not, why not? What about the Executive Committee?**
  - To what extent does the Steering Committee represent all perspectives that are important for the CJRR? What perspectives, if any, do you think could be added to the Steering Committee and within what timeframe should they be added in the future? *Probe for consumer and hospital representation since mentioned in interim report*
  - How do you feel about adding additional members to the Steering Committee from newly joining hospitals?
  - What are your impressions of the level of commitment of the Steering Committee members? Do you think it is sufficient for the next phase of the project, or not? Why or why not?
  - What should the role of the Steering Committee be going forward?

### Public reporting

- **As you know, a key tenet of the CJRR is the commitment to public reporting. What, if any, are your concerns about public reporting? How have your concerns been addressed, if at all?**
  - *[If applicable]* Have providers in your organization been engaged in discussions about public reporting? If yes, in what ways? If no, when, and how, should they be?
  - *[If applicable]* How has participating as a pilot site impacted your views on public reporting, if at all?
  - Do you have any thoughts about who you think should analyze and disseminate the public reports?
  - Do you think the commitment to public reporting will affect stakeholder buy-in long-term, particularly for clinicians?

### Key elements and recommendations for the next phase

- **Do you believe the CJRR pilot has been a successful endeavor? Why or why not?**
- **What do you think is critical to ensure the successful expansion of the CJRR? Is there a critical element, in your view, that is not being addressed or anticipated?**

## Business model

- **What do you see as the main benefits to your organization specifically of participating in the CJRR?**
  - Do you think that the benefits of the CJRR outweigh the costs of participating? Why or why not? What are the costs of participating?
  - What are the direct benefits to you of participating? How long will it take to realize benefits of participation, if you are not already?
- **Part of the challenge of disseminating the CJRR statewide will be developing a business model that is sustainable. If you were to lead this effort, how would you proceed?**
  - Who do you think could or should pay for the continued operation of the registry?
  - How would you obtain the needed revenue? (*e.g., user fees, subscriptions*)
  - What features would you pay for? What features would you not pay for? What additional features would be valuable to you?
  - Who should operate the CJRR if it has a life beyond the pilot?
- [*For non-site participants*] Who at your organization would be responsible for making decisions about whether to join the CJRR or not? This includes paying the subscription fee and making sure staff have the time to get it up and running. [*For site participants*] Who would make decisions to remain involved in the CJRR?
- **What would make it more likely that your organization would provide financial support for the CJRR? What would your organization be willing to pay?**
  - What does your organization do to financially support other registry efforts (*e.g. cardiac*)?
  - What do you think is needed to get different organizations to pay for the CJRR?
  - What do you see as the barriers to getting your organization to pay for the CJRR?

### Application to other efforts *[if time allows]*

- There other joint replacement registry projects with goals similar to the CJRR. Are you familiar with these efforts, for example the American Joint Replacement Registry (AJRR), the Michigan Arthroplasty Registry Collaborative for Quality Improvement (MARCQI) Consortium, or the Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement (FORCE-TJR) efforts? How do you see these registries complementing each other, if at all? How do they duplicate each other, if at all?
  - What can be done to ensure that lessons learned from the registries are mutually shared?
  - Do you think the CJRR should merge with any of these other efforts? If so, how?

*[For interview background or if participant requests additional information on the other efforts]*

- AJRR: Created by the AAOS and related stakeholders, such as surgical societies, hospital associates and device makers, this proposal calls for an independent, nonprofit, funded and governed by the stakeholders. The AJRR would gather level 1 data on all replacement and revision surgeries, including younger patients who are not recipients of Medicare – with a goal of 90% participation – starting as early as 2010. The funding does not have an end date, and it is anticipated that it would continue as an essential patient-safety practice. (<http://www6.aaos.org/news/pemr/JointRegistry/JointRegistry.cfm>)
- MARCQI: Blue Cross Blue Shield of Michigan and Blue Care Network are developing a new Collaborative Quality Initiative for the fourth quarter of 2011 – Michigan Arthroplasty Registry Collaborative for Quality Improvement (MARCQI) Consortium. MARCQI will follow the example of Sweden and Norway which have used nationwide registries of arthroplasty procedures to significantly reduce their rate of revision operations. ([http://www.bcbsm.com/newsletter/hospitalupdate/HU\\_0411/HU\\_0411g.html](http://www.bcbsm.com/newsletter/hospitalupdate/HU_0411/HU_0411g.html))
- FORCE-TJR: In Fall 2010, the Agency for Healthcare Research and Quality (AHRQ) awarded the University of Massachusetts Department of Orthopedics and Physical Rehabilitation funds to establish a nationwide Total Joint Replacement research registry of surgical and patient-reported outcomes. The FORCE-TJR research registry will collect data from more than 30,000 TJR patients, develop tools with which to assess the patient's assessment of success and failure of the surgery, and conduct research to guide both clinical care and health care policy. (<http://www.force-tjr.org/>)

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## Closing (start at \_\_\_\_\_ – 5 min – end at \_\_\_\_\_)

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That's all the questions I have.

- Is there anything else that you would like to add about any of the topics we have discussed or other areas we didn't discuss but you think are important?

Thanks for your time and participation in this interview. Your comments have been helpful and will provide important feedback to CHCF, PBGH and the CJRR Steering Committee on the overall process for this effort. [*NOTE: END RECORDING*]

[*If participant asks about getting a copy of the report*] One of the end products is a CHCF issue brief that will be available on the CHCF Web site. Would you like us to call or email you when this is available, or send you the report when it is final? [*TRACK IN INTERVIEW SPREADSHEET*]



## Appendix B: Codebook

CJRR Codebook		
<b>CASE SETS</b>		<i>Sources will be coded into one of three groups designating their general role within the registry project.</i>
S1	CJRR Staff	CHCF, PBGH, IT Sujansky, IT Ortech, Legal
S2	Steering and Advisory	Steering Committee and Advisory Group; group members who are also site employees will be included in Site Participants and not included in Oversight
S3	Site Participants	Hospitals and doctors affiliated with hospitals
<b>TAGS (Site Tag Codes)</b>		<i>Site tag codes will be used to tag comments related to specific sites and by participants affiliated with that site, so that these can be cross-referenced with content.</i>
T1	UCSF	Academic medical center example
T2	Cedars	Medical center example (physicians not employed)
T3	Hoag	Community hospital example

CODES			<i>Topical codes will be used to tag comments by topic.</i>
No.	Short Name	Code Information	Content Description (Inclusion and exclusion)
<b>Secondary codes</b>			
1	Facilitators	Facilitators	Apply this as a secondary code, when participants explicitly state something was a facilitator or worked well in the project. Do not use code if participant did not explicitly identify as a facilitator.
2	Barriers	Barriers	Apply this as a secondary code, when participants explicitly state something was a barrier or did not work well in the project. Do not use code if participant did not explicitly identify as a barrier.
3	Improvement	Ideas for Improvement	Apply this as a secondary code for comments revealing concrete ideas for aspects of the CJRR that could be improved as the project moves forward.
<b>Pilot goals</b>			
4	Accomplish	Accomplishments	Comments revealing opinions regarding the concrete accomplishments of the pilot. This code may overlap or dovetail with Expectations.
5	Expectations	Expectations	Comments about what the participant's expectations for the pilot were and whether those expectations were met. This code may overlap or dovetail with Accomplishments.
6	Data Use	Registry Use and Data Acquisition	Comments about participant's understanding of the purpose and goals of the registry, the type of data collected (Level 3 versus Level 1), how the data will be used in the future, fears about registry data use, and comments related to the number of fields or the amount of data collected. Comments about logistics and workflow of data acquisition should be coded at Data Collection.
<b>Pilot processes</b>			
7	Comm	Communication	Comments about specific and concrete examples of communication strategies and processes during the project, including meetings, emails, and other forms of in-person communication



CODES			<i>Topical codes will be used to tag comments by topic.</i>
No.	Short Name	Code Information	Content Description (Inclusion and exclusion)
8	Data	Data collection processes and workflow	Comments providing specifics about how data was collected and how workflow was addressed, including facilitators and barriers. Use HIPAA code for comments about HIPAA and informed consent. Use sustainability code for comments about whether processes and workflow are sustainable.
9	HIPAA	HIPAA/Informed Consent	Comments about what worked and what was challenging about the HIPAA authorization and informed consent process
10	Ethics	Other Ethical Issues	Comments about ethical issues that arose or could arise in the future, not related to HIPAA or informed consent
11	Tech	Technology issues	Comments about specific issues (factual descriptions of the process or problems with deployment, implementation, testing, and refinement of technical solutions) in terms of technology (software and hardware).
12	Steering	Steering Committee and Advisory Groups	Comments about the Steering Committee, technical advisor groups, and workgroups, including makeup of membership, leadership, and how well the committee worked to guide the project.
13	Roles Other	Others' Roles and responsibilities	Code comments about participant perceptions and comments for other people's roles and responsibilities.
13.1	Roles Know	Roles: What people do and know	Code comments about participants' specific roles, responsibilities, and knowledge.
13.2	Roles Don't Know	Roles: What people don't do and don't know	Code comments regarding what participants do not do or do not know, with particular attention to comments such as "So-and-so would know that." Also code comments about what participants would have liked to have known/wished they knew.
<b>Business Case</b>			
14	Resources	Resource requirements	Comments about resources that were needed or will be needed in the future, including personnel and technology. Also code comments about whether resource demands were reasonable and achievable. Comments about sustainability of resource commitments should be coded at Sustainability.

CODES			<i>Topical codes will be used to tag comments by topic.</i>
No.	Short Name	Code Information	Content Description (Inclusion and exclusion)
15	Sustainability	Sustainability	Comments related to the sustainability of the project, including discussions of possible funding models, the scalability of IT and software solutions, and scalability of the data collection process/workflow within sites, and the appropriateness of the governance for long term operation of the registry.
16	Buyin	Buy-in and Stakeholder Involvement	Comments related to how the pilot got buy-in from stakeholders, CJRR sites, surgeons, etc., as well as how to get buy-in from additional entities as the project moves forward. What made/makes individuals and sites interested in participating?
17	AJRR	AJRR and other registries	Comments about overlap and relations with the AJRR and other registries.
18	CJRR-Management	CJRR management processes	Comments about the day-to-day management of the CJRR.
<b>Other codes</b>			
19	Needs review	Needs review	For codes that needs review by second coder.
20	Coder	Coder Noticed	For comments that stand out to the coder but do not fit in pre-defined categories.