Innovative Approaches to Accessing, Extracting and Aggregating Electronic Health Data: Experience from Five US Medical Device Registries

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ABSTRACT

This study sought to understand the innovative approaches taken by various U.S. based medical device registries as they relate to addressing the technological challenges in effectively collecting and aggregating electronic health data. This study was designed to:

- Examine the barriers and enablers for medical device registries to effectively access, extract and aggregate data from existing electronic health data sources and loading the data into secondary data sources, specifically medical device registries;
- Understand the innovative practices and key lessons learned that could potentially be disseminated to other registry developers, researchers, policy makers, and/or other interested parties; and
- Identify public policy recommendations that may address barriers to data access, extraction and aggregation and encourage innovative practices in the registry space.

Avalere Health LLC (Avalere), an advisory services firm delivering research, analysis, and strategy for leaders in healthcare business and policy, conducted a comparative case study designed to investigate the key electronic health data accessibility, extraction, and aggregation challenges associated with operating a medical device registry. The project team analyzed findings within and across each selected registry to identify common themes and innovative practices.

1. INTRODUCTION

Clinical data registries ("registries") have emerged as a valuable source of real world data (observational data) about clinical practice and patient outcomes. Gliklich and colleagues define a clinical data registry as "an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes."[1] A registry can fall in one or more of the following categories: (1) health services, which focus on patients with common clinical procedures or encounters; (2) disease registries, which focus on patients with common clinical conditions; and (3) product registries, which focus on patients who have been exposed to a particular medical device.

For the purposes of this report, the authors have focused on medical device registries. Medical device registries have increasingly grown in prominence and prevalence, as they have served as vital resources for quickly identifying device-related adverse events and as tools for risk assessment in the post-approval setting. Researchers have expanded the scope of medical device registries by using them to assess product value, measure quality of care, provide population management, and offer patient-level clinical decision support. With the rapid adoption of electronic health records (EHRs) in most care-delivery settings, there has been a shift in the approaches taken to collect data for registries. Historically, registries have used one or more of the following data collection protocols:

- Paper-based data collection, which uses a highly standardized paper tool that guides researchers through the data collection process
- Online electronic data capture (EDC) form, which involves manually documenting the results in an online version of the paper-based form
- Direct (EHR) integration, which involves developing an application programming interface (API) to routinely collect data from the EHR system
- A hybrid of two or more of these approaches

Although direct EHR integration has proven to be the most efficient approach to collect voluminous amounts of data, questions remain about the effectiveness of collecting quality data from heterogeneous electronic data sources.

One of the most significant barriers to integration is the lack of system interoperability, or the ability to electronically exchange and interpret data across disparate systems.[2] The inability to exchange data between EHRs and medical devices limits the ability to standardize data collection and aggregation practices for medical device registries. For

[1] Gliklich R, Dreyer N, Leavy M, eds. "Registries for Evaluating Patient Outcomes: A User's Guide." 3rd edition. AHRQ Publication No. 13(14)-EHC111. Rockville, MD: Agency for Healthcare Research and Quality. April 2014.

[2] HIMSS. What Is Interoperability? Available at: http://www.himss.org/library/interoperability-standards/what-is-interoperability

example, registries are expected to interpret and convert proprietary clinical vocabularies, data formats, and other internal standards to a common standard before aggregation and analysis are feasible. Other technological challenges include:[3]

- Devices lack a frequently used universal medical device identifier; unique device identifiers (UDIs) are not routinely captured in electronic health data sources, e.g., electronic health records or administrative/claims systems
- Devices may have multiple performance issues related to software, hardware, biomaterials, or sterility, making it hard to capture all problems, failures and adverse events in one registry
- Devices may exist as part of a larger system, may contain multiple components that are also considered devices, and may interact with procedural devices

As such, the project team designed a study that examines the technological barriers and enablers for effective data access, extraction, and aggregation for medical device registries, based upon the following research questions:

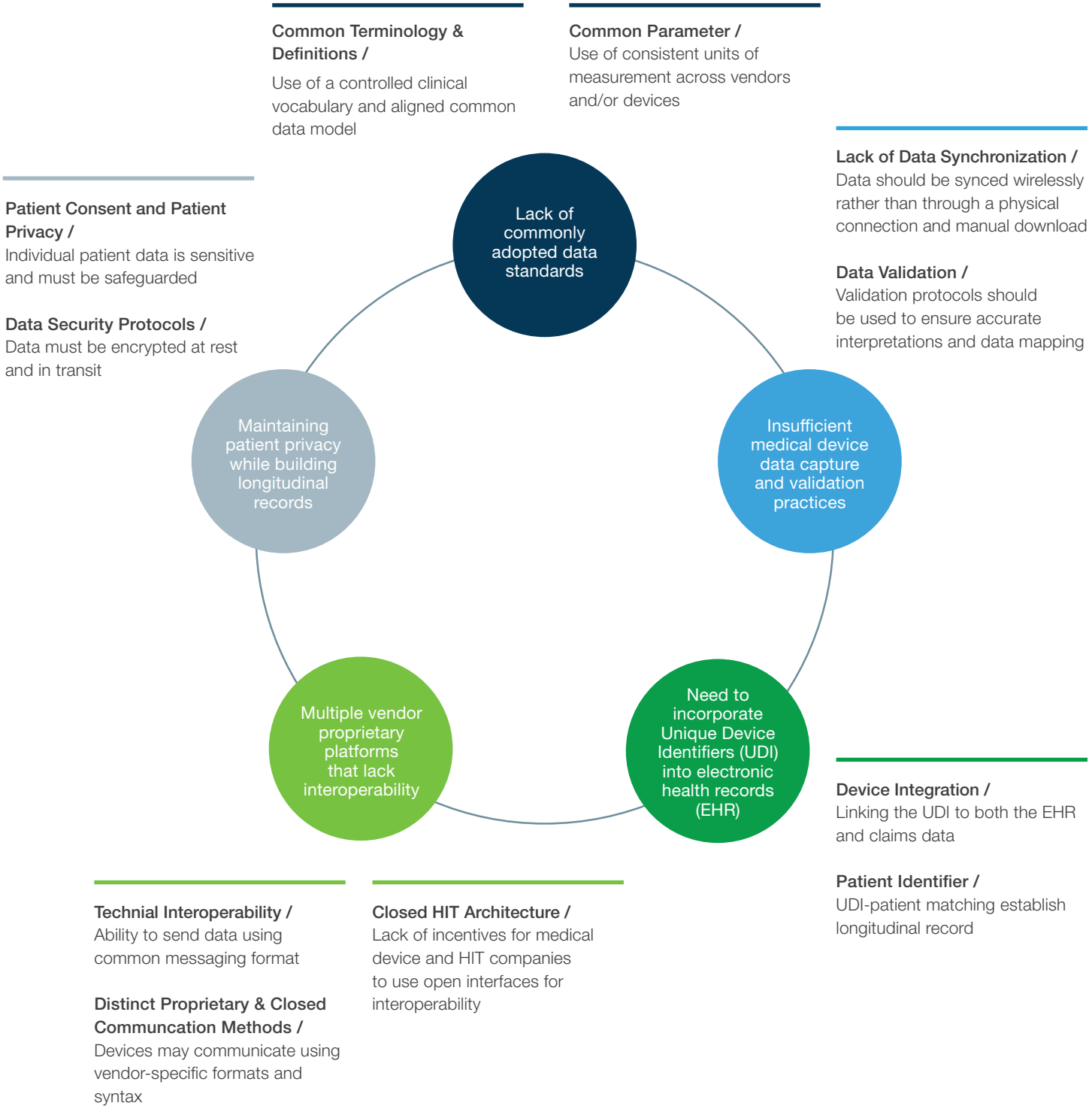
1. *What are the technical barriers and enablers to accessing and extracting electronic health data for medical device registries?*
2. *What innovative approaches have been used to overcome the barriers?*
3. *What other key lessons and innovative practices can be shared with other medical device registries?*

2. CONCEPTUAL FRAMEWORK

One of the first tasks for the project team was to develop a conceptual framework. These visual illustrations serve as critical guideposts for guiding qualitative research studies, as each systematically organizes broad theoretical concepts that focus the study on the specific research questions. The project team utilized published literature and expert input as the basis for its development. **Figure 1** represents the conceptual framework for this study.

[3] Agency for Healthcare Research and Quality. "Medical Device Based Registries Draft White Paper for Third Edition of "Registries for Evaluating Patient Outcomes: A User's Guide." Updated May, 2012. Accessed October 6, 2014. Available at: http://www.effectivehealthcare.ahrq.gov/ehc/products/454/1169/Medical-Device-Based-Registries_DraftMethodsChapter_20120626.pdf

Figure 1: Medical Device Data Accessibility and Extraction Framework



The framework highlights relevant barriers and enablers to medical device data accessibility and extraction and comprises five domains that are characterized by supporting sub-domains. More importantly, these domains provide the structure necessary to ensure the research questions are appropriately addressed and to organize the study findings.

3. STUDY METHODOLOGY

The project team conducted a comparative case study analysis using primary and secondary data collection methods.

Literature Search

The project team first performed a white and gray literature review based on publicly available material published in the last five years. The team identified 30 most relevant articles, and then prioritized a subset of 15. More details regarding the literature review strategy and complete results are available in Appendices 8.3 and 8.4.

Registry Selection Criterion

Using a new set of search terms, the project team conducted a second literature review to identify medical device registries. Then they developed a set of criteria to identify and select potential participants. More information regarding the specifics of the search strategy can be found in Appendix 8.3. The registry selection criteria included the following:

1. *Owned and operated by a medical professional society or provider;*
2. *Currently active or under development in the US;*
3. *Ability to capture medical device data and/or data from procedures that utilize medical devices; and*
4. *Used for accessing and extracting electronic health data.*

Selected Medical Device Registries

The search identified 19 registries that met the selection criteria. As a next step, the team selected a pool of five registries representing a diverse set of therapeutic areas at different stages in the registry development life cycle. Priority was given to registries that were listed as qualified clinical data registries (QCDRs) by the Centers for Medicare and Medicaid Services (CMS). These five registries included:

1. *American College of Cardiology (ACC)*: National Cardiovascular Data Registry CathPCI Registry
2. *American Society for Plastic Surgeons (ASPS)* and the *Food and Drug Administration (FDA)*: National Breast Implant Registry (NBIR)
3. American Joint Replacement Registry (AJRR)
4. *American Academy of Ophthalmology (AAO)*: IRIS Registry
5. *Kaiser Permanente:* Total Joint Replacement Registry (TJRR)

Data Collection and Analysis

The data collection occurred in two stages. First, the team developed a profile for each participating registry using publicly available information (Appendix 8.5), which served as an input to the development of a formal interview guide. Second, the project team conducted five, 60-minute, semi-structured, open-ended interviews using the interview guide (Appendix 8.2).

4. CROSS-REGISTRY ANALYSIS

Upon completion of the data collection and analysis, several key findings emerged that aligned with the domains in the conceptual framework along with others that applied more generally to several different aspects. As such, the analysis was categorized into two sections:

1. Major Findings, comprised of the common approaches, challenges, and innovative practices discussed by the participating registries
2. Overarching Themes for Consideration, representing the broader contextual information that directly effects the design and development of effective data governance practices for the registry

4.1 MAJOR FINDINGS

Data collected from registry interviews was analyzed for content, pattern matching, and explanation-building. Furthermore, collected data was separated according to the conceptual framework, allowing for a better comparison of the registry interviewees' responses and understanding of challenges, innovations, and trends.

Lack of Commonly Adopted Data Standards

The establishment of a universal set of data standards is essential for data accessibility and extraction

A lack of common data standards has long plagued registry developers and was cited by multiple interviewees as a key barrier to data accessibility and extraction, thus preventing data sharing freely across disparate systems. Common data standards refer to clinical definitions, the presence of specific fields in the EHR, and the application of technical specifications.

Study participants expressed concerns with their inability to exchange data across Health Information Technology (HIT) systems of other medical device registries focused on the same therapeutic areas; thus precluding effective public health research. Even within a therapeutic area, there is variance in data element definitions and technical data exchange standards, which leads to variance in clinical meaning to the involved parties. Some interviewees indicated that smaller, more specialized registries have the ability to standardize data elements with greater ease because there is increased uniformity in physician training. To ensure a more standardized approach to registry data sharing, some professional societies have collaborated to establish a key set of

American Academy of Ophthalmology: Intelligent Research in Sight (IRIS) Registry

The IRIS registry was founded in 2014, and has 5,200 participating physicians. The registry collects information on cataract surgical devices, glaucoma-filtering devices and other smaller, rare optical devices. Currently, IRIS has 14 million patient records and 5 million unique patients. The registry collects data by automatically extracting it from participant EHRs and directly transmitting it to the registry database. Participating ophthalmologists then can access the data, run queries on their own patient population to benchmark practice performance, and uncover potential areas for quality improvement. IRIS participants discussed how they used ICD-10 to more accurately stage and identify ocular diseases. One interviewee said, "by doing this, [they] were able to develop a methodology for identifying the severity of disease across the country."

elements and definitions with the intent to facilitate the accurate capture of clinical data. Most notably, the American College of Cardiology (ACC) Foundation and the American Heart Association (AHA) published a foundational set of cardiovascular data elements for EHRs in 2011 with the intent to " promote the ubiquitous use of EHRs and facilitate the exchange of data across systems....and to facilitate the further development of clinical registries [among other things]."

While routine interfaces between EHRs and clinical registries are the most efficient mechanism for capturing clinical data, the lack of common data standards continues to be a challenge to this method of data capture. There are several new initiatives however, that rely on technology to seamlessly extract relevant data to populate a registry database. The IRIS Registry, for example, has tackled this issue head on by using a third-party registry services provider that provides system integration technology. At an individual practice level, physicians are able to track, monitor, and improve the care that they are providing with the data extracted from their EHRs. While there has been success in populating registries with clinical data extracted from EHRs, there may be broader implementation challenges. Because system integration technology is implemented on a site-by-site basis, there can be a lack of scalability that may impede widespread adoption. Additionally, when trying to merge data from individual practice EHRs into a national registry, there is no guarantee the information will be reliably aggregated. This then calls into question the ability to truly aggregate and interpret these data at a population level to make broader clinical decisions. In sum, it may be too early to tell if this technology is the winning solution to dealing with the lack of common data standards, or whether it is simply a short-term innovative band-aid that is at the very least offering the professional societies a more convenient way to build a clinical registry.

The development of a common data model (CDM) encourages uniformity and assists with the effective transmission of health data

The purpose of a CDM is to standardize the format and content of observational data. Mini-Sentinel, a pilot project sponsored by the U.S. Food and Drug Administration (FDA) to create an active surveillance system to monitor the safety of FDA-regulated medical products, uses this architecture to develop a distributive database. The HMO Research Network and Vaccine Safety Datalink, two additional distributive networks rely on CDM to support a more efficient way to capture and use data from disparate sources. To accomplish this goal, the CDM relies on existing standardized coding schema (e.g., ICD-9-CM, HCPCS/CPT) to minimize the need for mapping and enable interoperability with appropriate evolving healthcare coding standards, and thus becomes a living document. Partner organizations, like hospitals or physician practices, transform their data locally

according to the CDM, which enables them to execute standardized computer programs that run identically at each data partner site.

With the ongoing challenges to the effective and efficient integration of EHRs with registries, a CDM would most certainly facilitate, if not enhance, the successful interface between these data sources. All participants felt the development of a formal CDM would improve the structure of a data organization that better enables the merging and systematic analysis of datasets from disparate data sources. As it stands, there is no detailed underlying infrastructure or guidance adhered to by data sharing participants, which has led to the propagation of standards and data models, many of which are proprietary solutions. A CDM would standardize the format and content of the datasets, which increases the degree of data quality and efficiencies in transmitting the data from its original source to the registry. One interviewee noted that it would be much more efficient and effective to standardize the data model, or the underlying architecture and technical standards, instead of broadly attempting to standardize the internal practices of all electronic health record systems and other health information technologies.

American Society for Plastic Surgeons and the Food and Drug Administration: National Breast Implant Registry (NBIR)

The NBIR is currently in development for upcoming launch. The registry plans to collect information on three classes of breast implants and their sub types. The team is hoping to use electronic data capture exclusively for data collection in the future. They plan to have a web portal, as directly integrating with EHRs is cost prohibitive. They will also accept paper data collection by integrating registry data fields with a form that is currently already required for surgeons to submit via fax. The interviewees from the NBIR discussed their active participation in an international breast cancer registry consortium. Because of its early establishment, the consortium has been extremely successful in developing and disseminating uniform data elements for improved data sharing.

With a specific focus on orthopedic surgeries like total hip and/or knee replacement, where there are at least 18 independent national, state, or local registries across the country, a CDM would greatly enhance the ability to track and monitor recently approved devices. In this scenario, active post market surveillance may be enhanced by conducting analyses across these existing registries and potentially among EHRs as well. As such, the CDM would allow for standard analysis across these disparate observational data sources.

Establishing ad hoc groups or formal consortiums across therapeutic areas to enable the necessary knowledge dissemination for establishing data standards or CDMs

Several interviewees mentioned that creating ad hoc groups or more formally established consortiums, such as the International Consortium of Registries (ICOR), the International Society of Arthroplasty Registries (ISAR), and the National Quality Registry Network (NQRN), would improve knowledge sharing, development, and dissemination of best practices. Multiple interviewees mentioned the value of the NQRN in developing uniform standards and a registry framework that outlines the suggested activities for each stage of development.

Interviewees asserted that collaboration between registry developers, governments, and industry is critical for establishing collaborative groups. One interviewee noted, "Internationally, registries have existed in [their] therapeutic area for quite some time, and there is already a substantial amount of work that has been done in ensuring uniform data elements and standards to allow data sharing and analysis." Another interviewee discussed the international implant library and CDM they co-developed with eight registries based in different countries. They analyzed data using a distributed data network, which encourages participation and collaboration as well as addresses security, safety and privacy issues.

Multiple Vendor Proprietary Platforms Lack Interoperability

There is an increase in the use of third-party tools for data extraction purposes from proprietary EHR platforms

EHR vendors take significantly different approaches to clinical data capture and storage. As such, medical device registries are consistently developing approaches to access, extract, and aggregate data from these platforms. In many instances, registries are still taking a multi-pronged approach to data collection, including an EHR-to-registry system integration, manual entry into an online electronic data capture (EDC) form, and, in some cases, a paper-based submission approach to data capture. Though all of these approaches are valid, they lead to different challenges and limit the amount of standardization of best practices within registry operation. There are two primary ways registries engage third party vendors. Many professional societies have employed third party clinical data registry service providers to perform seamless data extraction and system integration between the participant's EHR system and the registry using a software connector. When registries are unable to seamlessly pull data from the EHR

system of a registry participant, the burden of registry reporting rests with the hospital's technology team, which works to interface with the registry, the EHR vendor, and the hospital's own internal information systems. Several interviewees have engaged third party data collection and integration groups to assist hospitals with setting up their systems and reporting data to the registry, which offloads some of the reporting work from both the registry's internal team and the hospital.

Improving EHR vendor certification programs helps ensure effective and efficient data transmission protocols

Though EHR technology is proprietary, medical device registries tend to err on the side of neutrality when it comes to EHR platforms, which means there is an open relationship to work with any platform at any given time. Though this is beneficial for registry participants, who may use different EHR platforms, it does not encourage EHR vendors to standardize their mechanism for data transmission to registries. Some interviewees discussed the development of a formal vendor certification program, which certifies that the technology meets minimal standards that enable participants to transmit data seamlessly to a registry. There are two key attributes to this concept. First, the minimum standards entail accurate data mapping and alignment of key data elements as prescribed by the data dictionary developed for the registry. Second, seamless data transmission, in this case, is relative to traditional manual data collection or data extraction practices that require the use of a third-party utility. Though there is a federal EHR certification program in place administered by the Office of the National Coordinator (ONC), there is no current requirement for the use of open standards for data transmission, or the ability to transmit data seamlessly to registries. However, in the 2015 Edition Certification Criteria notice of proposed rulemaking (NPRM) ONC has proposed a new "Application Access to Common Clinical Data Set" certification criterion that would require APIs to respond to data requests for any and all of the data referenced in the Common Clinical Data Set. A new criterion that would rigorously assess a product's content exchange standard (Consolidated Clinical Document Architecture or CCDA) performance to validate its ability to exchange health information is also included.

Despite the push toward open technology and standards, it is also common to have a registry with proprietary data collection practices. For example, one registry may develop proprietary data collection templates that strongly resemble the templates of other comparable registries that a participating site may also interface with; however, the template may lack the specificity necessary for data sharing and the merging of datasets so that the site may use it for other registries. The barrier in this case, as described by an interviewee, is the lack of a harmonized standard among peer registries in any given therapeutic area, such as cardiovascular or orthopedics.

American College of Cardiology: CathPCI Registry

Launched in 1998, the CathPCI registry currently has 1,700 hospitals participating and over 14 million patient records. The registry collects information on coronary angiography, left ventricle catheter assessment and percutaneous coronary intervention (PCI) cardiac procedures. Participants with software vendors certified by CathPCI can submit their data directly to the registry on a quarterly basis through those vendors. Participants may also use a complimentary web-based data collection tool provided by the registry that allows for online data submission. CathPCI discussed its plans to create a data dictionary of elements critical to its registry and leverage Health Level Seven (HL7) for its technical standards. This approach would allow their data elements to be easily incorporated into current EHR platforms and provide a set of open standards for others to use.

Use of common and open standards is necessary for system interoperability and data sharing

One of the common themes from the study participants was the need to collect data once, but use it multiple times across different groups. This process requires the ability to link data collected by registries across several different data sources (e.g., research platforms, EHRs and other hospital systems). According to several interviewees, the easiest way to accomplish this is to emphasize the use of common, open standards, such as those available through Health Level Seven (HL7) or Integrating the Healthcare Enterprise (IHE). Using common, open standards will allow data exchange quickly across entities without having to reformat data from more obscure or proprietary formats. The ability to merge similar datasets will improve the analyses conducted and, potentially, improve the value proposition offered to researchers seeking relevant and high-quality datasets. Another theme was the need to shift from the proprietary system philosophy to a culture that promotes inclusivity and equality as it relates to data generation and sharing practices. Many felt the open culture would facilitate quality improvement and research efforts that would benefit the society as a whole.

Insufficient Medical Device Data Capture and Validation Practices

Routine pre-submission checkpoints improve data validation practices

By implementing a data validation process for incoming data, registries are able to collect data while simultaneously verifying its quality. Putting mechanisms in place not only provides a feedback loop to participants so they can improve the accuracy of their data collection, but also prevents the registry from having to backtrack and validate its data later. All but one study participant provided the details of its existing data validation processes. It was relatively clear that each registry takes one of two approaches regarding data validation: (1) developing internal protocols and systems, or (2) outsourcing its participant data validation processes to a third party auditing company. It was common to find a process that integrated multiple rounds of pre-submission checkpoints at varying degrees of granularity to ensure high quality electronic data is imported. These data validation processes help ensure the integrity of the data.

National audits assist with maintaining the integrity of the data collection processes

The quality of clinical data is often defined as that which is complete, consistent, and accurate. Accuracy is often confirmed through a national audit[4]. The ACC conducts an annual on-site audit where hospitals are randomly selected for review. Auditors review a set number of fields from each of the registries on site and compare that information to the records submitted. Following the audit, each site receives a detailed report to assist with data collection improvements. In a quality brief published in 2012,

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American Joint Replacement Registry (AJRR)

Launched in 2009, AJRR has 388 participating hospitals and 150,000 patient records. The registry collects data on full/partial hip and knee replacements as well as semi-arthroplasty. AJRR collects data in two ways. The preferred method is via electronic data extraction from the participant's existing health care information system followed by electronic transfer to the AJRR data system. AJRR's system can conduct this data exchange automatically on a scheduled basis. AJRR can also accept data via a web-based manual data entry form. AJRR discussed their extensive data validation practices, which include a variety of ways registry participants ensure data accuracy. In particular, pre-submission checkpoints allow participants to test their data file submission for accuracy before its final load into the central repository.

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[4] Messenger JC et al. The National Cardiovascular Data Registry (NCDR) Data Quality Brief: the NCDR Data Quality Program in 2012. J Am Coll Cardiol. 2012 Oct 16;60(16):1484-8.

Messenger, et al. described the findings from a 2010 audit across three of its in-hospital registries, including the CathPCI Registry.[5] The participant average raw accuracy of data abstraction for the CathPCI Registry was 93.1% (range, 89.4% minimum, 97.4% maximum), thus indicating that many fields accurately represent the data from the medical charts and maintain the integrity of the data collection process.

Based upon input from interviewees, the establishment of a national audit program by medical device registries for registry participants appears to be a common practice. Conducting large data audits reconfirms the quality of data collected, which not only helps the registry serve its participants, but also allows the data to be shared confidently with other entities for research, since often, a different group within the registry organization evaluates it on a much larger scale. While some registries discussed their own national audit programs, other study participants described their use of a third party audit group. As part of the process, these audit groups compare the original medical record to the record created within the registry. It was widely reported that several EHR platforms do not capture the medical device catalog and lot number, other components of the device, or digital versions of the device part number. As such, audit companies periodically find missing or misaligned data. Interviewees emphasized that more complex audits involving more data and including more sites are currently a topic of discussion at many large registries, and that they are learning from one another concerning best practices.

Need to Incorporate UDI into the EHR

The Unique Device Identifier (UDI) is not difficult to access, extract, and merge into registry data collection

In the interest of improving post-market surveillance, the FDA proposed a Unique Device Identification (UDI) system. In September 2013, the FDA published the UDI Final Rule, which outlines how and when device manufacturers must include the standardized UDI code on their products and associated packaging.[6] UDI will provide several benefits once integrated throughout the healthcare system[i]:

- Improved patient access to device-specific information
- Provision of authoritative and current data to providers at the point of care
- Improved care coordination
- Reduced medical errors

[5] Messenger JC et al. The National Cardiovascular Data Registry (NCDR) Data Quality Brief: the NCDR Data Quality Program in 2012. J Am Coll Cardiol. 2012 Oct 16;60(16):1484-8.

[6] Daniel G, McClellan M, Gardina S et al. Unique Device Identifiers (UDIs): A Roadmap for Effective Implementation. Washington, DC: Engelberg Center for Health Care Reform at Brookings; December 2014

- Efficiencies in supply chain management
- Targeted approaches to active device surveillance and recalls
- Opportunities to create device specific alerts and clinical decision support
- Facilitation of research
- More accurate claims payment processes
- Overall reductions in health care costs

All interviewees stated that they plan to incorporate the UDI when it becomes available, and felt that this would not be extremely challenging to do or place additional resource or cost burden on their registry. They articulated that UDI would solve the problem of proprietary device identifiers and improve cataloging of devices. Several interviewees stated they would simply add another field for the UDI to their data collection form. One registry is currently using the tracking order information required of device manufacturers and plans to replace this information with the UDI in the future. In this way, they are actually building the registry to collect UDI as it becomes available. Almost all interviewees identified the challenges of creating the infrastructure to support UDI across different aspects of the healthcare system. The challenge will be to see what technology exists within the implanting site (hospital, surgical suite, outpatient office) to collect UDIs electronically and how difficult it will be to support the uptake of UDI. Many interviewees felt that data collection sites might not have the technology needed to support UDI collection. For example, barcode scanning, while available in many large medical centers, may not be available to smaller physicians and physician groups.

There is concern from medical device registries regarding the EHR vendors' ability to develop a platform that integrates UDI

Several interviewees felt it might take longer for EHR systems to integrate UDI due to competing priorities (e.g. Meaningful Use) and a lack of value proposition. The largest case for UDI implementation is for permanent implants and large capital equipment, according to one participant. There are already serial numbers stamped and barcodes on the backs of these devices, so switching to UDI is not a change in concept, just the standard of display. For procedurally used or smaller devices, (e.g., bone screws, gels, cement, contact lens solution), the container will need to note the UDI and be barcoded in the procedure room. For these devices especially, the interviewee felt UDI incorporation into the EHR was the only solution.

Interviewees also said that tangible demonstration of success of the UDI and the benefits it can have on daily operations for different stakeholders would increase the momentum

for its integration. One interviewee stated, “Once hospitals begin to see the value of UDI in improving billing accuracy and inventory management, [it will be] added into the EHR. Billing will be the selling point.” Policies like Meaningful Use may also eventually help adoption, particularly if incentives for using UDI are included. CMS and ONC proposed the inclusion of UDI in EHRs in their recently released Meaningful Use Stage 3 and 2015 Edition Certification NPRMs, which is a big step forward.

Maintaining Patient Privacy While Building Longitudinal Records

Unique approaches to patient identification and establishing the longitudinal record

Most registries aim to track patients longitudinally as much as possible, and follow them on an episode-of-care basis (e.g. revisions or procedures involving their devices) throughout the lifetime of the device. Each registry had a unique approach to patient identification (ID) to assist in collecting longitudinal patient records, including social security numbers, birthdates, names, and unique registry-specific patient ID numbers. One registry discussed its challenge in that each time a patient enters a hospital a new registry-specific ID number is generated, forcing them to develop a system to match patients across systems.

Some registries faced challenges with longitudinal data collection due to a lack of standard practice of follow-up. These patients have no need to return, so tracking any additional work they done can be a challenge. Two interviewees discussed their plan to incorporate their registry data directly into the EHR so patients can be tracked regardless

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Kaiser Permanente: Total Joint Replacement Registry (TJRR)

Launched in 2001, TJRR has 51 participating hospitals, 452 participating surgeons, and over 200,000 patient records. The registry collects data on total/partial hip and knee replacements, uni-compartmental knee, and knee resurfacing procedures. Because the registry operates in a closed health system, most data are captured directly from the EHR and into the registry’s database. However, because the EHR does not capture everything the registry tracks in discrete, extractable fields, there are some fields surgeons input directly during their procedures. TJRR takes great lengths to maintain a patient’s longitudinal record. If a patient is treated outside the system, the hospital fills out a data collection form and faxes it to the registry. TJRR follows up with patients that have left the health plan and sends them surveys to collect additional data on any surgical revisions they have.

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of where they are seen, and could eventually eliminate the registry's need for their own patient identification methods.

The UDI could potentially serve as a patient identifier, which could create privacy concerns

There was discussion regarding how the legal status of the UDI and its interaction with patient privacy could determine its success. Registries could query for device UDIs to determine which patients succeeded best with which devices. With this rapid comparative effectiveness data, the timeline of determining the most effective devices would be shorten substantially, eliminating many secondary costs associated with poorly performing devices. The interviewee who discussed this did wonder where the line would be drawn between true quality improvement and clinical research, and whether patient approval would be required for studies like these.

Medical device registries continue to avoid privacy concerns by focusing on quality improvement

All registries interviewed adhere to traditional standards for protection of personal health information, such as the Health Insurance Portability and Accountability Act (HIPAA). Most registries consider their activities quality improvement initiatives, and as a result do not need direct patient consent to collect data. One interviewee discussed at length their challenges in working with hospital legal departments regarding patient privacy and data sharing. The interviewee discussed a common problem with lack of communication between the hospital's privacy and security group, and its legal group, which leads to extensive negotiations in order to successfully enroll a hospital in the registry. The interviewee indicated this happens most frequently with larger academic medical centers, and generally creates challenges with beginning the extraction process in a timely fashion to collect data for the registry. As electronic data use increases, interactions between registries, hospitals and legal teams will become more complex. Policymakers are attempting to address this concern through legislative proposals directing the appropriate agencies to amend the regulations and provide additional clarification and guidance to registries regarding HIPAA privacy and data security, and Common Rule requirements. The ONC also recently released new guidance related to the current HIPAA regulations.

Routinely linking clinical and claims data has not been explored by participants

The study participants did not routinely collect and use claims data within its registry. Several interviewees mentioned that EHR data is more accurate and informative than anything that is collected from claims. Based on information from some interviewees, two of the registries have episodically linked to claims data and one may try to do so in the future to perform additional analyses related adverse events and certain quality measures (readmissions and mortality).

4.2 OVERARCHING THEMES FOR CONSIDERATION

The Impact of Therapeutic Area on Device Data Collection / One of the major themes that interviewees consistently discussed was the nuances associated with operating a registry in their particular therapeutic area. It was apparent that each therapeutic area, from cardiology to ophthalmology, presented challenges or benefits in aspects of data collection that arose due to the specific devices used, regulations associated with them, and the current best practices in tracking and surveillance of their particular type of device. Some interviewees discussed that their devices have paper or electronic regulatory tracking forms that users are required to send back to device manufacturers. In those instances, they are able to piggyback on the completion of these required forms with registry data to streamline reporting and ensure submission of registry data. Others mentioned that the devices captured in their registries are smaller, more numerous in volume, or less regulated, which creates challenges in determining best practices or easing burden of registry reporting. The unique aspects of different types of devices for different therapeutic areas should be further investigated to better understand the impact it has on the ability to standardize best practices for medical device registry development and overall data accessibility and extraction.

The Impact of Care Delivery Setting on Accessing, Extracting and Aggregating Electronic Data / Every interviewee discussed the impact of the care setting in which registry users operate, including hospital systems, surgical clinics, or physician practices. Some interviewees mentioned the challenge of accessing the EHR from the location in which their participants most often collect data, or ensuring that the correct data points are entered into the EHR at the point of care. Another interviewee discussed the legal challenges of working with large academic medical centers, and that they can periodically delay, or in rare instances, even prevent participation in the registry due to institution-specific patient privacy regulations. Future research could focus on the technical infrastructure of different care settings and their abilities to interact with and support registry activities.

Challenges Faced in EHR Vendor-Registry Interaction / Interviewees discussed the degree to which their registry directly integrated with EHR systems and the relationships they have developed with technology vendors. The registries range from complete, seamless data pulls from the EHR to the registry, to very limited or no integration directly with EHR systems. Most interviewees indicated some interaction with EHR vendors, and had some success with integrating new forms or fields into preexisting EHR

systems, parsing data so that the registry receives the correct materials, and extracting data from these systems on a regular basis. Despite this, not all EHR systems engage with registries or incorporate their suggested changes to improve their interactions. Some interviewees felt it would be valuable to have a more formal forum for discussing problems with EHR vendors to help understand their perspective on working with medical device registries. Additional research could explore the value proposition for EHR vendors engaging with medical device registries, including the development of standardized templates and fields that support registry data collection. Incentives or penalties for participation could prove useful in improving EHR vendor participation in registry activities.

Challenges of Unique Device Identifier (UDI) Adoption and UDI Value Proposition /
This research focused primarily on current medical device registries, but also addressed some of the opinions and thoughts registry interviewees had on the potential for the UDI system. One of the most heavily emphasized messages from interviewees was the need to articulate the UDI value proposition extensively for device manufacturers, registry operators, hospital systems, physician groups, policymakers and regulators. Though many interviewees acknowledged the very apparent positive aspects of UDI, they also noted that the infrastructure needed to support it does not currently exist within the current US healthcare system. Future research could investigate the impact of the UDI on these various stakeholders, and could suggest action plans that outline their preparation to be able to utilize UDI. Research could also elucidate challenges that certain members of the healthcare system may be faced with while trying to prepare for and implement UDI. Finally, future research could include a UDI "pilot" in a health system or hospital to demonstrate its value to a variety of stakeholders that may be hesitant to delegate time, money and resources to embrace and incorporate UDI.

5. POLICY RECOMMENDATIONS

The primary purpose of this study was to examine and understand the technological challenges in accessing, extracting, and aggregating electronic health record data, while identifying specific areas in public policy recommendation to address them. It is important to view the information collected through the interviews in a larger, policy-based context in order to draw additional implications. In some way, every interviewee discussed the complexities that have evolved due to new uses of public health data, such as academic research and technology development. **Table 1** lists the key findings attributed to each domain of the conceptual framework, as well as challenges, solutions and policy recommendations associated with each.

Table 1: Cross-Registry Findings

DOMAINS	CHALLENGES IDENTIFIED	SOLUTIONS AND POLICY RECOMMENDATIONS
Lack of commonly adopted data standards	• A lack of universal standards for data elements limits data accessibility, extraction and exchange among registries • CDMs have not been developed across therapeutic areas to facilitate international data exchange	• An industry member or research organization could create a public-private sector committee to develop and implement data governance practices for medical device registries, including a common data model for data exchange • The federal government (e.g. ONC,, FDA) could consider the development of a multi-stakeholder national registry governance body, which certifies registries based on the standards and approaches used and which participates in international registry organizations
Multiple vendor proprietary platforms that lack interoperability	• Third-party tools are increasingly being utilized for data extraction purposes with proprietary EHR platforms • Medical device registries should support as many EHR platforms as possible, but a certification program that standardizes EHR data transmission protocols would improve lacking EHR vendor interactions with registries • The use of common and open standards is not practiced, but could improve system interoperability and data exchange across multiple entities	• The ONC could finalize its proposed revised 2015 Edition Certification Criteria "data portability" certification criterion to incorporate the ability to send data extracts to third-party clinical data registries in its Certified EHR Technology (CEHRT) definition • The federal government could build on recently enacted interoperability and information sharing provisions in "MACRA" [7] and incentivize vendors that utilize open data standards and registries that participate in knowledge sharing networks, particularly internationally

[7] H.R. 2, the "Medicare Access and CHIP Reauthorization Act of 2015" (MACRA).

Insufficient medical device data validation practices	• Routine pre-submission checkpoints improve registry data validity but are not common • National audits are not common, but should be conducted to validate a larger set of data through a more formal process to create datasets that can be disseminated for research	• Research/academic organizations could provide policy and/or technical guidance to support routine registry data validation processes and audits • A committee of public and private stakeholders could formalize processes for certifying registries that adopt and adhere to leading practices for data validation to ensure quality
Need to incorporate UDI into the EHR	• There is concern from registries regarding the EHR vendors' ability to integrate UDI, though it will improve device identification and tracking and will not be difficult for registries to merge into their current data collection processes	• The FDA could lead a public-private sector effort to develop and implement a national UDI strategy • CMS and ONC could finalize their Meaningful Use 3 and 2015 Edition Certification Criteria proposals to include incentives within their programs to spur UDI adoption by device manufacturers, EHR vendors and healthcare providers
Maintaining patient privacy while building longitudinal records	• There are several unique approaches to patient identification and establishing longitudinal records • The UDI could potentially serve as a patient identifier, but this could trigger patient privacy concerns • Medical device registries establish themselves as quality improvement initiatives to avoid privacy concerns • UDI linkage to clinical and claims data simultaneously has not been explored substantially by participants	• The federal government, state health departments, and/or research foundations could convene groups to examine and harmonize existing privacy regulations as suggested in recent legislative proposals. • Per recent legislative proposals, the federal government could amend current HIPAA privacy and security and Common Rule regulations to better support protection of patient data as data sharing increases on behalf of public health research

In discussing the ownership and use of this data with participants, one of the most pervasive issues identified was patient privacy and the impact that current policy will have on the flexibility and decision-making of medical device registry operators. Though authorized to collect private data from the population governed by HIPAA, public health agencies are also responsible for the protection of the individual data collected. Medical device registries, which as quality improvement programs contribute to public health, are responsible for the protection of their patient data. With more routine use of electronic data for medical device surveillance, patient privacy issues could become more numerous if not managed from a regulatory perspective.

There are several risks associated with the use of patient-related health data, including privacy breaches, discrimination and special targeting, propagation of incorrect and harmful research conclusions, and litigation.[8,9] Privacy breaches are typically the first risk that comes to mind, though the HIPAA Privacy Rule, the Privacy Act, and many state-specific privacy laws govern disclosure of medical records. However, these regulations do not cover all data holders who may make medical information available to the public. In addition, most data used for public activity is presented in de-identified form, which can make them exempt from disclosure restrictions established in these regulations. Many users, registries especially, also indicate explicitly that they are not conducting human subject research and therefore are not required to obtain direct patient consent for this quality improvement work.

Medical device registries work to extensively de-identify patient records and in many cases ask for patients' consent to disclose data. Despite this, it can be challenging to de-identify data while simultaneously offering a variety of quality benchmark reporting to registry participants that includes patient-level drill-down capacity. HIPAA offers guidance on what is truly de-identified data, but even so, de-identification practices vary substantially and the data does still have the potential to be re-identified.

The risk that data will be re-identified can never be fully eliminated, but it can be minimized substantially through legal and policy interventions. "Human non-subject data is a new categorization proposed for de-identified human data. Proponents suggest that this category would not necessarily need full IRB review and could instead use a set of best practices to minimize re-identification and give subjects the ability to opt-out of research projects."[10] The HIPAA definition of "covered entity" could be expanded to parties that store and disclose health information, including government entities and

[10] Robert Wood Johnson Foundation Health Data Exploration Project. Personal Data for the Public Good. Arch, 214. Available at: http://www.rwjf.org/content/dam/farm/reports/reports/2014/rwjf411080

[9] Hoffman S. Citizen Science: The Law and Ethics of Public Access to Medical Big Data. August, 2014. Available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2491054

[9] Panhuis WG, Paul P, Emerson C et al. A systematic review of barriers to data sharing in public health. BMC Public Health November 2014,14:1144.

database operators, which would improve privacy protection for data subjects. By modifying only the definition, this "would not create hurdles for healthcare treatment, payment, administration or the activities of law enforcement and public health officials."[11] It is an important policy to acknowledge and address the risks associated with open access to patient-related health information while incentivizing the improvement of health data sharing for quality improvement and population health management. Strategic partnerships among professional societies, providers, payers and industry will be critical to providing a multi-stakeholder perspective and driving the most effective policy surrounding the interoperability of medical device data.

6. AREAS FOR FUTURE RESEARCH

Though this research covered a wide variety of relevant topics, additional research involving emerging trends in health data could provide further insight. Below, three additional topics are detailed that could be investigated in the context of medical device interoperability and surveillance.

Contextual or Clinical Common Data Model Development

Modeling of widespread interoperability across medical devices, EHRs, mobile health devices, and health information technology (HIT) systems projects savings of around $30 billion per year.[12] Reuse of models and tools provides a direct benefit for the organization and the end user.[13] A common discussion among interviewees as well as in the literature was the need to develop a CDM to facilitate true interoperability of health data. The JASON Report Task Force, enlisted by the ONC to assess the state of Health Information Exchange (HIE) in the US, also suggested that the lack of success from health data management legislation (e.g. Meaningful Use Stages 1 and 2) is due largely to the lack of a comprehensive nationwide or international architecture for HIE.[14] Several organizations like HL7 and IHE have worked extensively to develop and disseminate international, open-source standards to improve health data interoperability, but the standards have been developed without a guiding CDM. A global perspective will be required to develop a CDM, which will invariably increase consistency across standards. Additionally, a CDM will provide a framework that will stimulate the use of common, open standards for health data exchange.

[11] Hoffman S. Citizen Science: The Law and Ethics of Public Access to Medical Big Data. August, 2014.Available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2491054

[12] Four Dimensions of mHealth. Deloitte Consulting. Available at: http://blogs.deloitte.com/centerforhealthsolutions/2014/01/the-four-dimensions-of-effective-mobile-health-people-places-payment-and-purpose.html#.VK38RCvF8ZH

[13] Hammond WE, Jaffe C, Kush R. The Value of Nurturing Collaboration. Available at: http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_043995.hcsp?dDocName=bok1_043995

[14] JASON Report Task Force Final Report. October 2014. Available at: http://www.healthit.gov/facas/sites/faca/files/Joint_HIT_JTF%20Final%20Report%20v2_2014-10-15.pdf

Movement to Mobile Health (mHealth) Devices

Currently, 75% of physicians use a smartphone, and more than 10,000 mobile health applications are already in use.[15] Mobile health applications, sensors, medical devices and remote patient monitoring products can help both improve healthcare delivery and lower costs by facilitating the delivery of care and connecting patients to providers. mHealth applications can assist in healthcare training, managing chronic disease, and monitoring of critical health indicators. They "enable easy to use access to tools like calorie counters, prescription reminders, appointment notices, medical references and physician or hospital locators," which improves care coordination and shared decision making between physician and patients. mHealth devices also support current value-based health reforms and new service delivery models by providing tools to improve "communication, coordination, monitoring, and data collection capabilities."[16] Even still, there are barriers to mHealth technology adoption, including the regulations surrounding the management of patient health information, as well as the capability for rural and underserved areas to effectively use mHealth technologies due to broadband gaps. However, perhaps the largest barrier is the general lack of interoperable systems and analytic capabilities required to use incoming streams of data.

This connectivity requirement extends across medical devices, EHRs, mobile devices and HIT systems. Several healthcare apps, such as WellDoc's mobile-integrated diabetes management therapy and AliveCor's mobile ECG recorder, were integrated with EHRs to allow data sharing with physicians across the country.[17],[18] Additional research around the interactions between mHealth devices, EHRs and registries could prove valuable in understanding the best way to integrate all of these evolving healthcare technologies. Furthermore, it will be important to understand the most critical barriers to mHealth technology adoption, and the best way to direct regulatory policy to support innovation while addressing security of patient data.

Data Access from Cloud Infrastructures

Cloud computing "promotes the growth of centrally coordinated applications that can be delivered to any device," and will be critical in enhancing health data interoperability.[19] Healthcare applications that utilize cloud storage will help with connectivity problems

[15] Bockrath M. KellyOCG. Medical Devices Begin to Drift Into Cloud. Available at: http://www.kellyocg.com/uploadedFiles/Content/Knowledge/Ebooks/Medical%20Devices%20Begin%20to%20Drift%20Into%20Cloud.pdf

[16] Four Dimensions of mHealth. Deloitte Consulting. Available at: http://blogs.deloitte.com/centerforhealthsolutions/2014/01/the-four-dimensions-of-effective-mobile-health-people-places-payment-and-purpose.html#.VK38RCvF8ZH

[17] Comstock J. Tips for Integrating Health Apps and EHRs. Mobihealthnews . May, 2013. Available at: http://mobihealthnews.com/22039/tips-for-integrating-health-apps-and-ehrs/

[18] Alivecor. AliveCor Offers Integration With Practice Fusion's Electronic Health Records Platform. February, 2014. http://www.alivecor.com/press/press-releases/alivecor-r-offers-integration-with-practice-fusions-electronic-health-records-platform

[19] Gartner. Gartner Identifies the Top 10 Strategic Technology Trends for 2015.October, 2014. Available at: http://www.gartner.com/newsroom/id/2867917

and will better facilitate communication across different information regimes.[20] Cloud-based solutions allow providers and patients to access medical information securely wherever they are, including medical imaging reports, lab tests, and medical background information. The cloud also provides opportunity for continuous care management from multiple devices, whether it is a patient's personal tablet or a hospital's information system. Further, the cloud "lowers the barrier to entry for smaller entities. Whether a practice owns a thousand wireless devices or two, the data can be accessed using the same interface."[21] Cloud computing can be used to improve the speed and contain costs of clinical trials through rapid data collection, outsourcing specific parts of the trial, and rapid multi-center updates to software. Cloud computing offers a mechanism for storage and exchange of the UDI by anyone with access, which would improve the interoperability of device related information as well as offer a business case for UDI adoption.

Cloud computing does pose challenges for the FDA, which has responsibility over medical products shipped across states, but lacks authority over the practice of medicine. Cloud computing can be considered a service as opposed to a product, which creates regulatory confusion. The FDA also faces increasingly complex cloud-based software solutions as well as the security of personally identifiable healthcare information.[22] The challenges and benefits to cloud based computing solutions should be explored further to understand their potential benefit to the medical device industry.

7. CONCLUSION

The research conducted in this project represents only part of a much larger picture of the challenges faced by medical device registries and the innovations and best practices that developers have created to improve device tracking and surveillance, contribute to quality improvement, and collect data that can be used effectively for population health management. Additional research is required to better understand opportunities to leverage the medical device registry community's infrastructure in incorporating electronic health data.

[20] West D. Improving Health Care Through Mobile Medical Devices and Sensors. October, 2013. Available at: http://www.brookings.edu/~/media/research/files/papers/2013/10/22%20mobile%20medical%20devices%20west/west_mobile%20medical%20devices_v06.pdf

[21] McMullin S. Cloud Computing, Big Data, and Healthcare IT: The Trifecta. May, 2014. http://www.wired.com/2014/05/cloud-computing-big-data-healthcare-trifecta/

[22] Mailhot, S. The Impact of Cloud Computing on FDA's Regulation of Medical Products. http://www.fdalawblog.com/2013/02/articles/legislation/the-impact-of-cloud-computing-on-fdas-regulation-of-medical-products/

8. APPENDICES

8.1 STUDY SAMPLE

The following individuals participated in interviews for this research on behalf of their registry:

REGISTRY NAME	REGISTRY OWNER	INTERVIEWEES
American Joint Replacement Registry (AJRR)	Multi-stakeholder, non-profit organization	Caryn Etkin, Director of Research Randy Meinzer, Director of Information Technology
CathPCI Registry	American College of Cardiology	Kathleen Hewitt, Vice President Connie Anderson, Registry Manager
Intelligent Research in Sight (IRIS) Registry	American Academy of Ophthalmology (AAO)	Dr. Flora Lum, AAO Policy Director Dr. Bill Rich, AAO Medical Director of Heath Policy
National Breast Implant Registry (NBIR)	American Society for Plastic Surgery (ASPS) and the Food & Drug Administration (FDA)	Dr. Benjamin Eloff, Senior FDA Scientific Program Manager Keith Hume, Vice President, ASPS Legislative, Regulatory & Scientific Affairs
Total Joint Replacement Registry (TJRR)	Kaiser Permanente	Liz Paxton, Director of Surgical Outcomes and Analysis Rebecca Love, Surgical Outcomes & Analysis Unit Project Manager

8.2 SEMI-STRUCTURED INTERVIEW GUIDE

Medical Device Registry Interview Discussion Guide

Introduction (~ 5 minutes)

Thank you for taking the time to participate in our research. I am joined by my colleague, [name], who will be taking notes. As you may recall, Avalere Health is conducting primary research on behalf of The Pew Charitable Trusts to assess the key data collection, extraction and aggregation challenges associated with operating a medical device registry. Although there is publically available information on the [registry name] website, we are seeking to gain a deeper understanding on certain aspects of [registry name], particularly the following:

- Technical barriers and enablers to extracting and aggregating electronic health data for medical device registries;
- Innovative solutions and techniques used to overcome these barriers; and
- Key lessons and specialized practices that could be broadly shared with other medical device registries

Before we get started, we would like to note that the information you provide today is completely confidential. As a part of our analysis, we will aggregate all of our interview summaries to identify key themes and de-identify specialized practices so this information will not be attributed to you and/or your organization, unless permission is granted. In order for us to accurately capture our discussion, we would like to record this interview if you permit us to do so. The interview today will last approximately 45 minutes to an hour.

Background Information and Overview (~ 5 minutes)

This section, in combination with the pre-interview survey responses, aims to gain general background on the interviewee, the registry's goals and value proposition.

1. Please describe your current role and responsibilities at [registry name]
2. In your words, what is the primary purpose (e.g. physician/hospital performance, device performance or some combination) and major goals of this registry?
    a. PROBE:
        i. Device surveillance
        ii. Quality measurement, reporting, and improvement

iii. Research

iv. Fulfillment of Regulatory Requirements (e.g. FDA, CMS)

v. Continuing Medical Education

vi. Maintenance of Certification

3. What do you feel is the value proposition of this registry for participants?

   a. PROBE:

      i. Researchers?

      ii. Payers?

      iii. Regulators?

Data Collection and Validation (~ 5 minutes)

This section will provide insight to the device-related data collected by the registry, the process and frequency by which it is collected, and data validation mechanisms.

4. What specific medical devices and/or medical device procedures does this registry collect information around?
5. How often do you receive data from participants and what is the process by which it is collected (e.g. wireless, manual download) and stored?
6. What is the process by which completely new devices or additional procedure-associated devices are added to the registry for data collection?
7. By what process do you validate data input from various sites to ensure consistency, completeness and accuracy? Is there an objective auditor who assists in validation?
8. What mechanism does the registry use for patient matching (e.g. with claims data, across institutions)?
9. Do you collect patient-reported outcome (PRO) data? If so, how do you collect it?
10. What is the process to validate the PRO data against the clinical data from the EMR and/or other paper records?
11. Does your registry utilize claims data? How do you integrate collected data with claims data for longitudinal analyses?

Technical Infrastructure and Interoperability (~10 minutes)

This section will establish the technology and associated processes used by the registry to collect, store and exchange data. The section will also elucidate challenges and innovations of this registry as it relates to medical device data collection and general data interoperability.

12. Please describe the technical infrastructure that supports your registry's data collection, storage, and exchange? (e.g. third party vendors, software platforms, EHRs supported) Please describe the relationship between the participant EHR vendors and the registry.
13. What have you found to be your three biggest challenges in collecting data about medical devices and the outcomes associated?
14. What have you done to mediate those challenges?
15. Please describe any solutions or innovative practices your registry has developed to help enhance interoperability of device-related data (e.g. in data collection, transmission, storage or dissemination)
16. Does your registry use proprietary technology (e.g. internally developed software) in its operations? If so, how does that impact your data collection and exchange (if at all)?

Data Standards (~5 minutes)

This section aims to discuss data standardization, mechanisms to account for discrepancy in data presentation, and the impact of technology on the ability to develop and disseminate common data standards and clinical terminology.

17. How do you ensure data standardization in the registry?
    a. PROBE: Please describe your data dictionary or common clinical vocabulary?
18. How do you account for different units or measurements across vendors and devices?
19. How are the data standards used by your registry impacted by its method of data collection (e.g. EHR extraction, participant data entry)? How do you feel the adoption and application of standards for data representation and clinical terminology coding are impacted by EHRs and other health information technology?
20. Do you participate in or are you aware of active collaboration among vendors and other registries to standardize data and form common metric definitions?

Unique Device Identification (~10 minutes)

This section aims to determine the extent of the registry's collection of Unique Device Identifiers (UDIs), the process and purpose for doing so, and the technical challenges the registry has faced with UDI collection.

21. Does your registry capture and/or utilize UDIs? If not:
    a. How do you identify devices used?
    b. What is your future plan for capturing UDIs? What types of registry revisions would be necessary to accommodate it? What is the estimated cost and effort?
22. Though the integration of UDI into existing technology has increased in recent years, it is still not ubiquitously captured and tracked. What do you think would improve the widespread adoption and integration of UDIs by HIT companies and registries moving forward?

Patent Privacy & Data Security (~10 minutes)

This section aims to discuss patient consent for participation, longitudinal data collection as it relates to medical device registries, and the protection of patient data within the registry.

23. Do patients consent to participate in the registry? If so, how is that achieved?
24. How do you follow up with patients to longitudinally collect data? What challenges do you find with longitudinal data collection for medical devices?
25. What steps do you take to ensure that patient data is protected in the registry through data collection, transmission and storage?
26. What privacy protocols or standards do you use?
27. How does your team work with participants' IRB and/or Privacy Boards?

Future Direction and Policy Implications (~ 5 minutes)

This section aims to document the interviewee's perspective on future trends and policy activities as they relates to medical device registries.

28. What role do you currently see medical device registries playing in healthcare?
29. What are the emerging trends you see in medical device registries going forward?

30. What aspects of the following would you say are currently hindering the expansion and use of medical device registries?

    a. Legislative Policy

    b. Regulatory Policy (e.g. Common Rule)

    c. Business Practices

    d. Technology (e.g. Vendor modifications)

31. How do you see medical device registries contributing to policy decisions in the future?

Conclusion

Thank you for your participation today, we know that you are very busy and we appreciate you taking the time to provide your insight to inform Avalere in their study.

8.3 LITERATURE REVIEW SEARCH STRATEGY

Objectives

The purpose of this document is to describe the various search strategies conducted as part of the targeted literature review for this engagement. Each search strategy has unique objectives focused on different project tasks. The first search strategy is designed to identify and generate a top-level listing of US-based medical device registries. The second strategy is a targeted literature review of the grey and white literature describing the informatics challenges associated with them.

Methodology

Based on input from our expert advisers, Avalere identified important concepts for each of these searches, chose keywords that represented these concepts, and determined which search features were most applicable. Avalere utilized PubMed, Google Scholar, and Google search to execute each search with the selected keywords, as outlined below.

Preference was given to articles written in English within the last five years, and registries identified were limited to those based in the United States. For the first search, unique medical device registries from PubMed, Google Scholar, and Google search sources were identified with the corresponding bibliographic citation listed below. For the second search, articles and websites that were of most relevance are itemized by title, with the corresponding bibliographic citation below. Articles of relevance were identified by their discussion of the challenges related to medical device registries, use of unique device identifiers, medical device data collection, and medical device informatics. The following sections highlight the two searches (medical device registries and associated informatics challenges); the keywords used to conduct each search, the individual search term yields for each search, and lists of relevant results and associated bibliographic references.

SEARCH STRATEGY 1: MEDICAL DEVICE REGISTRIES

Sources

1. PubMed/Medline
2. Google Scholar
3. Google

Search Term Yields

SEARCH TERMS	YIELD
PubMed	
(“medical device”[MeSH Terms] OR “medical device”[All Fields]) AND (“registry”[All Fields])	Return: 29 English: 27 Five Years: 20
(“medical device”[MeSH Terms] OR “medical device”[All Fields]) AND (“clinical registry”[All Fields])	Return: 0 English: 0 Five Years: 0
(“medical device”[MeSH Terms] OR “medical device”[All Fields]) AND (“patient registry”[All Fields])	Return: 1 English: 0 Five Years: 0
(“medical device”[MeSH Terms] OR “medical device”[All Fields]) AND (“data source”[All Fields])	Return: 4 English: 3 Five Years: 1

(“medical device”[MeSH Terms] OR “medical device “[All Fields]) AND (“data repository”[All Fields])	Return: 4 English: 3 Five Years: 1
(“medical device”[MeSH Terms] OR “medical device”[All Fields]) AND (“prospective cohort study”[All Fields]	Return: 3 English: 3 Five Years: 3
(“medical device”[MeSH Terms] OR “medical device”[All Fields]) AND (“observational study”[All Fields])	Return: 8 English: 8 Five Years: 5
(“medical device”[MeSH Terms] OR “medical device”[All Fields]) AND (“clinical data research network”[All Fields])	Return: 0 English: 0 Five Years: 0
(“medical device”[MeSH Terms] OR “medical device”[All Fields]) AND (“patient-powered research network”[All Fields])	Return: 0 English: 0 Five Years: 0
(“medical device”[MeSH Terms] OR “medical device”[All Fields]) AND (“practice-based research network”[All Fields])	Return: 0 English: 0 Five Years: 0
(“medical device”[MeSH Terms] OR “medical device”[All Fields]) AND (“electronic medical record”[All Fields])	Return: 2 English: 2 Five Years: 2
(“medical device”[MeSH Terms] OR “medical device”[All Fields]) AND (“post-marketing surveillance”[All Fields])	Return: 10 English: 10 Five Years: 7
Google	
“medical device registry,” “medical device clinical registry,” “medical device patient registry,” “medical device database,” “ medical device data source,” “medical device data repository,” “medical device observational study,” “medical device prospective cohort study,” “medical device clinical data research network,” “medical device patient powered research network,” “medical device practice-based research,” “medical device electronic medical record,” “medical device post-market surveillance”	Returns were in the thousands, therefore the first 150 were reviewed

Google Scholar	
"medical device registry," "medical device clinical registry," "medical device patient registry," "medical device database," " medical device data source," "medical device data repository," "medical device observational study," "medical device prospective cohort study," "medical device clinical data research network," "medical device patient powered research network," "medical device practice-based research," "medical device electronic medical record," "medical device post-market surveillance"	Returns were in the thousands, therefore the first 150 were reviewed

Medical Device Registries Identified

UNIQUE MEDICAL DEVICE REGISTRIES	REF #
PubMed	
Kaiser Permanent Registries: Total Joint Replacement Registry (Knee, Hip, Total Shoulder Arthroplasty, ACL Reconstruction, Hip Fracture, Spine)	1
Kaiser Permanente Registries: Cardiac Device (ICD, Pacemakers, Leads, Heart Valve, Endovascular Stent Graft)	1
Total PubMed Count = 1	
Google Scholar	
Society for Thoracic Surgeons and American College of Cardiology: Transcatheter Valve Therapy (TVT) National Registry	2
HealthEast Joint Replacement Registry	3
Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS)	4
American College of Cardiology National Cardiovascular Data Registry CathPCI Registry	5
American College of Cardiology National Cardiovascular Data Registry IMPACT Registry	6
American College of Cardiology National Cardiovascular Data Registry ICD Registry	7
American College of Cardiology Peripheral Vascular Intervention Registry	8
Veteran's Affairs Cardiovascular Assessment, Reporting and Tracking (CART) System	9
Total Google Scholar Count = 8	

Google	
American Joint Replacement Registry	10
University of Massachusetts Global Orthopedic Registry (GLORY)	11
HSS/CERT Total Joint Replacement Registry	12
Mayo Clinical Joint Replacement Database	13
Virginia Joint Registry	14
American Academy of Ophthalmology IRIS Registry	15
International Bariatric Surgery Registry	16
Society for Vascular Surgery Vascular Quality Initiative Registry	17
American Society for Plastic Surgeons and the FDA National Breast Implant Registry	18
US Wound Registry	19
Total Google Count = 10	
GRAND TOTAL = 19	

Bibliographic References

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SEARCH STRATEGY 2: MEDICAL DEVICE REGISTRY INFORMATICS CHALLENGES

Sources

PubMed/Medline

Google Scholar

Google

Search Term Yields

SEARCH TERMS	YIELD
PubMed	
(medical device registry) AND challenges	Return: 65 Humans: 62 English: 29
(medical device registry) AND informatics	Return: 16 Humans: 10 English: 9
(medical device registry) AND unique device identifier	Return: 13 Humans: 11 English: 9
(medical device registry) AND data collection	Return: 111 Humans: 56 English: 54
(medical device) AND post-market surveillance	Return: 58 Humans: 37 English: 32
Google Scholar	
"medical device clinical registries challenges," "medical device informatics," "medical device interoperability," "medical device integration challenges," "medical device convergence challenges," "unique device identifier challenges"	Returns were in the thousands, therefore the first 150 were reviewed
Google	
"medical device clinical registries challenges," "medical device informatics," "medical device interoperability," "medical device integration challenges," "medical device convergence challenges," "unique device identifier challenges"	Returns were in the thousands, therefore the first 150 were reviewed

Relevant Articles Identified

RELEVANT ARTICLES & WEBSITES	REF #
PubMed	
Unique device identifiers for coronary stent post-market surveillance and research: A report from the FDA Medical Device Epidemiology Network Unique Device Identifier Demonstration	1
Statement regarding the pre and post market assessment of durable, implantable ventricular assist devices in the United States	2
Assessing the Safety and Effectiveness of Devices After US Food and Drug Administration Approval: FDA-Mandated Post approval Studies	3
Unique device identification system final rule	4
How does medical device regulation perform in the United States and the European union? A systematic review	5
Design and implementation of a seamless and comprehensive integrated medical device interface system for outpatient electronic medical records in a general hospital	6
FDA adverse Event Problem Codes: standardizing the classification of device and patient problems associated with medical device use.	7
FDA regulation of cardiovascular devices and opportunities for improvement	8
Improving medical device regulation: the United States and Europe in perspective	9
Post-market surveillance of medical devices: current capabilities and future opportunities	10
Kaiser Permanente National Total Joint Replacement Registry: aligning operations with information technology	11
Implementing unique device identification in electronic health record systems: organizational, workflow, and technological challenges	12
Total PubMed Count = 12	
Google Scholar	
Post-marketing surveillance of medical devices - filling in the gaps	13
Achieving meaningful device surveillance: from reaction to proaction	14
Medical devices—balancing regulation and innovation	15
Using Informatics to Improve Medical Device Safety and Systems Thinking	16
An evaluation of a distributed medical device safety surveillance system: DELTA network study	17

Medical device interoperability and data integration to clinical information systems: medical device data alignment	18
Total Google Scholar Count = 6	
Google	
Medical Device-Based Registries: Registries for Evaluating Patient Outcomes	19
Groups press FDA to encourage medical-device registries	20
Registries for Evaluating Patient Outcomes: A User's Guide	21
Medical Device Registries: Recommendations for Advancing Safety and Public Health	22
The Value of Medical Device Interoperability	23
How EHRs can promote safety of medical devices using UDIs	24
Strengthening our National System for Medical Device Post-market Surveillance	25
Unique Device Identification Overview	26
Medical Devices: Current and Future Market Challenges	27
Navigating the Intersection of Medical Devices, Health IT to Boost Patient Safety	28
Letter from Pew Trusts to Committee on Finance	29
Wearable Technology – Market Assessment	30
Total Google Count = 12	
GRAND TOTAL = 30	

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8.4 LITERATURE REVIEW RESULTS

From the 30 articles identified through the literature review, the team prioritized 15 articles for more detailed review. The prioritized articles addressed challenges faced by medical device registries, informatics as it relates to devices, device integration with EHRs,

ARTICLE TITLES
Unique device identifiers for coronary stent post-market surveillance and research: A report from the FDA Medical Device Epidemiology Network Unique Device Identifier Demonstration
Design and implementation of a seamless and comprehensive integrated medical device interface system for outpatient electronic medical records in a general hospital
Post-market surveillance of medical devices: current capabilities and future opportunities
Implementing unique device identification in electronic health record systems: organizational, workflow, and technological challenges
Post-marketing surveillance of medical devices - filling in the gaps
Achieving meaningful device surveillance: from reaction to proaction
Using Informatics to Improve Medical Device Safety and Systems Thinking
Medical device interoperability and data integration to clinical information systems: medical device data alignment
Medical Device-Based Registries: Registries for Evaluating Patient Outcomes
Registries for Evaluating Patient Outcomes: A User's Guide
Medical Device Registries: Recommendations for Advancing Safety and Public Health
The Value of Medical Device Interoperability
How EHRs can promote safety of medical devices using UDIs
Strengthening our National System for Medical Device Post-market Surveillance
Medical Devices: Current and Future Market Challenges

medical device regulation, and medical device post-market surveillance. These articles

AMERICAN JOINT REPLACEMENT REGISTRY	
Registry Owners/ Sponsors	Multi-stakeholder, independent, not-for-profit organization
Date of Establishment	2009
Stated Purpose	Optimize patient outcomes through collection of data on all primary and revision total joint replacement procedures in the US Enhance patient safety, improve quality of care, and reduce the cost of care
Medical Device Data Collected	Full/partial hip and knee replacements, semi-arthroplasty
Number of Patient Records	150,000
Number of Participants	388 Hospitals
Fee Structure	A participation fee is required of hospitals interested in submitting data to AJRR as well as have electronic access to the AJRR data system The participation fee is a 12-month subscription that provides one user account per hospital allowing for benchmarking and identifying attributes that may modify clinical approaches for total joint replacement. Fees range depending on the number of institutions contributing to the submission. Institutions can also receive discounts for signing a three-year agreement.
Data Collection Process and Technical Architecture	The AJRR can accept data in two ways. The preferred method is via electronic data extraction from your existing health care information system followed by electronic transfer to the AJRR data system. AJRR can also accept data via a web-based manual data entry form. The AJRR has selected a software system that has the capability to automate data exchanges. The AJRR can accept extracted Level I electronic data for inclusion.
Longitudinal Aspects	AJRR aims to track patients longitudinally as much as possible in order to see revisions made to joints over time
Reports Provided	Individual, hospital-based reports are available to those sites that have submitted their payment of the annual participation fee. AJRR also accepts requests for custom reports based on additional hospital metrics or the national data set. Fees for custom reporting are established on an individual basis.
Use of Claims Data	AJRR does not currently use claims data, but they will receive access to it as a QCDR. This could be helpful for advanced levels of data collection and complications.

Patient Privacy	AJRR considers their research a quality initiative and not human subject research. As such, they do not require patient consent but do adhere to traditional personal health information protection standards. AJRR informs hospitals of this and they in turn verify AJRR processes with their IRBs. Typically, only academic hospitals complete their own IRB consent forms to enroll in AJRR.
QCDR Status	Yes

CATHPCI REGISTRY	
Registry Owners/ Sponsors	ACC
Date of Establishment	1998
Stated Purpose	Assess the characteristics, treatments and outcomes of cardiac disease patients who receive diagnostic catheterization and/or percutaneous coronary intervention procedures
Medical Device Data Collected	Coronary angiography, left ventricle catheter assessment and percutaneous coronary intervention (PCI) cardiac procedures
Number of Patient Records	Over 14 million
Number of Participants	1,700
Fee Structure	Participation fees are $5,700 and there is a 10% discount for systems of three or more hospitals
Data Collection Process and Technical Architecture	Certified software vendors allow participating facilities to submit data to the NCDR on a quarterly basis. Many software applications do much more than collect and export registry data, and some can be integrated into existing hospital systems. Participants are encouraged to consider their own software requirements when reviewing vendor information. Participants may instead choose to use a complimentary web-based data collection tool provided by the NCDR. Use of this tool allows hospitals to collect basic data for internal reporting, provides a data export feature for the creation of custom queries and allows interoperability among shared data fields.
Longitudinal Aspects	CathPCI does not capture post-discharge data as there is no standard clinical practice requirement for follow-up. Data is considered complete upon discharge; readmission or a new procedure would generate a new episode of care.

Reports Provided	Quarterly risk-adjusted benchmark reports that compare against volume-based peer groups and the nation Executive summary dashboards for big-picture reviews, at-a-glance assessments and patient level drill-downs Data quality reports that help ensure that the data you submit are complete and consistent Physician dashboard that provides on-demand access for ACC members, more than 40 physician-level process and quality metrics generated from registry data, performance feedback, and opportunities to meet ABIM MOC Part IV requirements
Use of Claims Data	CathPCI does not collect claims data; they do link to it for research purposes around certain quality measures (readmissions and mortality).
Patient Privacy	The CathPCI registry does collect patient consent through a form associated with the registry.
QCDR Status	No

IRIS REGISTRY	
Registry Owners/ Sponsors	AAO
Date of Establishment	2014
Stated Purpose	As the nation's first EHR-based comprehensive eye disease and condition registry, use observational study methods to collect and perform statistical analysis of patient data to produce easy-to-interpret, national and inter-practice benchmark reports.
Medical Device Data Collected	Cataract surgical devices, glaucoma-filtering devices, and other smaller, rarer devices
Number of Patient Records	14 million encounters and 5 million unique patients
Number of Participants	5,200 (93% of AAO Members)
Fee Structure	Free of charge to participants
Data Collection Process and Technical Architecture	Data relevant to the registry will be extracted automatically from the participant's EHR and transmitted on a scheduled basis directly to the IRIS Registry. Participating ophthalmologists then can access the data, run queries on their own patient population to benchmark practice performance, and uncover potential areas for quality improvement.

Longitudinal Aspects	IRIS aims to collect longitudinal patient data by incorporating ophthalmology data into the EHR.
Reports Provided	Quality reports that provide clinician-, practice- and national-level results for all measures; each person also has access to their own performance data and can compare their performance and outcomes to similar practices at the regional and national level. It is also possible to generate comparative analysis within an ophthalmologist's own practice. The IRIS registry also allows users to run queries based on the demographics of an ophthalmologist's patient population for those conditions addressed in the ophthalmology registry.
Use of Claims Data	IRIS does not use claims data but they did purchase a 5% sample of Medicare claims to do studies and assessments on certain trends.
Patient Privacy	The IRIS Registry collects, stores and reports data on an ophthalmologist's behalf, taking every measure possible to safeguard it. The Academy's technology partner, FIGMD, is compliant with all local and federal regulations governing these areas, including HIPAA provisions and the recently updated provisions as part of the American Recovery and Reinvestment Act/Health Information Technology for Economic and Clinical Health Act.
QCDR Status	Yes

NATIONAL BREAST IMPLANT REGISTRY[23]	
Registry Owners/ Sponsors	ASPS and the FDA
Date of Establishment	In Progress
Stated Purpose	Collect data on all subjects who receive breast implants in the US to serve as a vehicle for post market surveillance, post-approval studies, device tracking, quality improvement and observational research
Medical Device Data Collected	Three classes of breast implants and their three sub types (saline silicone gel and highly-cohesive silicone gel)
Number of Patient Records	Not yet launched
Number of Participants	Not yet launched
Fee Structure	This has yet to be determined.

[23] This registry has not yet been launched and is still in development, so information provided reflects only current plans. November 2014,14:1144.

Data Collection Process and Technical Architecture	The team is looking at multiple options, hoping to eventually use electronic data capture entirely. They plan to have a web portal, as currently direct integration with EHRs is cost prohibitive right now. They will also accept paper data collection by integrating the registry's data fields with those in a form that is currently already required for implant surgeons to fill out and submit via fax.
Longitudinal Aspects	The registry plans to track patients at implant and reoperation. It is very challenging to track these patients as they very infrequently come back for follow-up. If a patient comes back for a replacement or another procedure, the registry would capture that information.
Reports Provided	The team will offer benchmarking reports for physicians but the extent of those reports and the frequency has not yet been determined.
Use of Claims Data	Implants are used in breast reconstruction and breast augmentation (cosmetic) procedure s. There is a limited population from which claims data can be drawn since the majority of cosmetic procedures are patient-paid, so this data will not be incorporated routinely in this registry.
Patient Privacy	The team is positioning their work as a quality improvement initiative, so they may be able to omit patient consent or utilized a less intensive "opt-out" process. Some of this may depend on what IRBs require.
QCDR Status	Not yet launched

TOTAL JOINT REPLACEMENT REGISTRY	
Registry Owners/ Sponsors	Kaiser Permanente
Date of Establishment	2001
Stated Purpose	• Help health care providers identify best practices, evaluate risk factors associated with revision surgeries, and assess the clinical effectiveness of implants • Provide information that can be used to study patient demographics, implant characteristics and surgical techniques in relationship to post-operative complications such as infections, revisions and re-operations • Immediately identify and notify patients about recalled or defective implants prior to an official recall notice
Medical Device Data Collected	Total/partial hip and knee replacements, uni-compartmental knee, and knee resurfacing procedures, along with the implantable materials used during the procedures

Number of Patient Records	Over 200,000
Number of Participants	More than 452 contributing surgeons and 51 medical centers
Fee Structure	This registry is internal to Kaiser Permanente facilities and does not have any participation fees
Data Collection Process and Technical Architecture	Because registry operates in a closed health system, most data are seamlessly captured from the EHR and into the registry's database. However, because the EHR does not capture everything the registry tracks in discrete, extractable fields, there are some fields the surgeons fill in directly during their procedures. If a Kaiser Permanente patient is treated outside the system, the hospital fills out a data collection form and faxes it to the registry directly.
Longitudinal Aspects	Follow the patients for the lifetime of the device, as well as follow up on a patient-level.
Reports Provided	Outputs include a patient risk calculator for joint replacement revision, a patient risk calculator for deep surgical site infection, reports, confidential surgeon practice profiles, and publications and presentations. Reports include quarterly internal reports that highlight trends and noteworthy statistics, such as devices with poor performance, which improves decision-making. Each medical center within the Kaiser system receives customized reports, which include: risk adjusted medical center reports, dynamic web-based medical center reports, and medical center quarterly quality reports.
Use of Claims Data	The registry uses claims data for contract facilities to capture outcomes, but only in a limited fashion for patients that receive treatment outside of the Kaiser system.
Patient Privacy	Patient consent is not required as these quality registries are considered a part of the Kaiser standard of care.
QCDR Status	No

included the most detail about these topics and covered them more thoroughly than other sources.

8.5 REGISTRY PROFILES

8.6 STUDY LIMITATIONS

A few limitations to this study exist and must be acknowledged. First, the sample size

ENDNOTES

i Tcheng JE, Crowley J, Tomes M et al. Unique device identifiers for coronary stent postmarket surveillance and research: A report from the Food and Drug Administration Medical Device Epidemiology Network Unique Device Identifier Demonstration. Am Heart J. 2014 Oct;168(4):405-413.e2.

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