



MDIC Case for Quality Program

Product Quality Outcomes Analytics
working group

Feasibility and Effectiveness of Analytics for
Medical Device Product Quality Outcomes

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Introduction

Healthcare provider stakeholders, including physicians, clinicians and supply chain professionals utilize data to make procurement decisions for medical devices to ensure and improve patient access to high quality devices. The integrity of these decisions depends upon the accuracy and completeness of the underlying data. There are three (3) significant challenges to accurate and complete data on medical device quality:

- Lack of unbiased, relevant, consistent and available data
- Lack of consistently defined device quality dimensions, or applied analytical methods
- Lack of secure process and operating model to build stakeholder confidence and enable individual companies to be fully transparent about product quality

The Medical Device Innovation Consortium (MDIC) Product Quality Outcomes Analytics project team is a multi-disciplinary group comprised of representatives from manufacturers, providers, FDA, and Value Analysis Committees (VACs). The team's objectives are to provide information about the feasibility and effectiveness of using publicly available data and to recommend analytic techniques to enable assessments of medical device product quality. Standardized medical device performance data and analytics could be utilized for comparative analysis by several stakeholders in order to improve procurement decisions and potentially improve patient outcomes.

Executive Summary

MDIC-facilitated discussions within the Medical Device industry ecosystem clearly show that stakeholders would benefit from access to medical device quality information in order to support purchase decisions that can potentially result in improved patient outcomes and better cost management. Yet there is no formal approach to measure and provide feedback to reward the market for quality.

To address this gap, the Case for Quality Product Quality Outcomes Analytics (PQOA) team embarked on a pilot to determine whether cross-manufacturer comparative analysis of quality would be feasible and effective to support value analysis team purchase decisions. This pilot focused on knee and defibrillator implants. Voice-of-the Customer feedback was gathered through surveys and focus group sessions.

The project team developed and evaluated standardized definitions for Quality that included the following seven (7) domains:

- Safety
- Effectiveness
- Reliability
- Patient Experience
- Usability
- Availability
- Compatibility

Survey data showed that the vast majority of respondents (over 80%) thought these seven (7) domains defined medical device quality very *well* (59%) or *pretty well but would add more domains* (25%).

To evaluate if it is feasible to compare manufacturers across these domains using data and analytic techniques, the team contracted with a third-party. The subsequent dashboards developed during this effort were based on input from a multi-disciplinary group that included hospital Value Analysis Committees (VACs), manufacturers, regulators, industry SMEs and data scientists.

This report is a summary of the team's observations and recommendations for the development of a formal approach to measure medical device product quality outcomes in order to provide feedback and reward the market for Quality. Recommendations included the need to improve data robustness as well as the need to develop an operating model that would enable data access and transparency for scale and sustainability in the future.

Current State and Perceptions

From stakeholder discussions with Value Analysis Committee (VAC) team members, it was learned that VACs generally consider the triad of patient quality outcomes, employee satisfaction and finance when making medical device purchase decisions. For many hospitals, a major priority has been to measure cost per case. In general, VACs are unable to access information across all of the seven (7) quality domains identified (listed above).

VAC respondents expressed a need for product quality information to be compiled into a single report. Some expressed frustration in the effort to track adverse events for comparisons when there are too many products that have little variation or few vendors that dominate the market. Furthermore, VAC respondents noted that in the current state, there is no reliable way to determine if a small company's product is competitive. **All VAC respondents expressed the need for reliable data from more independent sources.**

VAC respondents stated that they utilize internal data only to include cross referencing based on pricing. Others use a variety of external data sources to understand product quality including: the MAUDE database, ECRI, FDA newsletters, internal recall alert team, clinical trials.gov, Procured Health, Hayes, IHI, GPOs (e.g., AHA), 510Ks (to identify comparable products), evidence-based research, MD Buyline and internal quality databases. **Most participants expressed frustration that there is a lag or delay in being able to obtain evidence-based research from third parties.**

VACs share medical device product quality information in a variety of modes, frequencies and formats. Some VACs have structured committees while others are decentralized or are working to develop a formal process. Committees meet monthly, bimonthly, quarterly, or even ad hoc; only a few had formal tracking and data dissemination processes. There is tremendous variety in how information about device quality is summarized for the committee's consumption. Preferences included: visual summaries, text summaries, detailed data in an Excel workbook, software to track all the information. VACs identified some software platforms as sources for product quality information including: Procured Health, ECRI, Cost Pricing, GPO DHA Value links. However, these did not provide analysis of quality beyond Safety and Efficacy. **In general, there is not a standard and robust method to conduct comparative analysis of all seven (7) quality domains across multiple products.**

VAC respondents were asked to identify device types for which they have the highest need for product quality information. VAC respondents rated implants as the device type of highest interest for comparative product quality information (Figure 1).

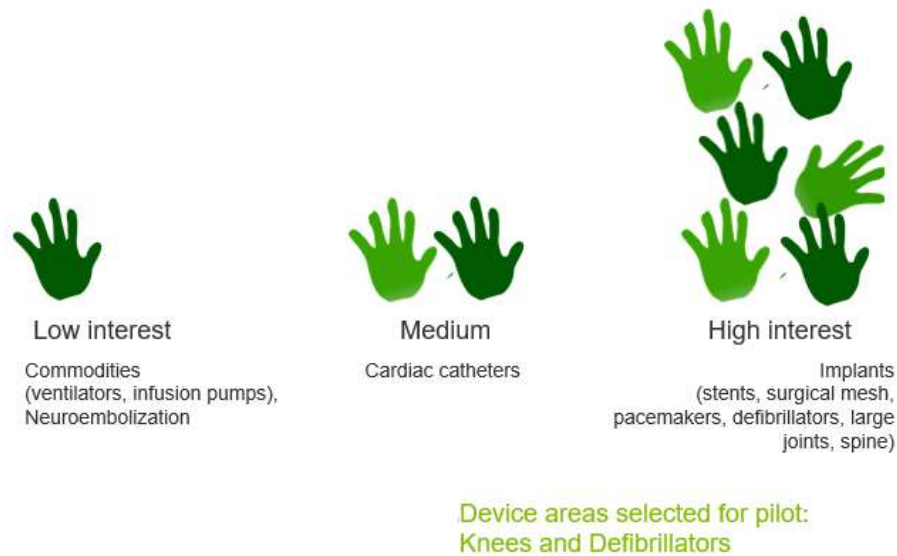


Figure 1. Ratings of VAC interest for product quality information

MDIC Pilot: Methods

The objective was to determine if a platform for manufacturer comparative analysis of product quality was feasible and potentially effective for VAC purchase decisions. Recognizing that such a mature system would be a huge undertaking and require a lengthy period of growth and development, the PQOA team chose to limit the scope of the pilot to match time and resource constraints and focus on key questions that could serve as the foundation for future expansion. The team chose to start with VACs, who are not only one of the many stakeholders for the proposed system, but are also responsible for or are heavily involved in a large percentage of device purchasing decisions.

In addition, the number of devices for which data would be collected for the pilot had to be manageable. With feedback from VACs (summarized above), devices

under consideration were narrowed down to two common but substantially different types of devices: knee implants and implantable cardioverter defibrillators.

Hypothesis and Definitions

The hypothesis to be tested in this pilot is:

"If VACs had access to specific data about product quality outcomes and they applied analytic techniques to this data, they would have information to make better purchase decisions that improve patient access to high quality medical devices."

Based on research and feedback from the broader MDIC community and VACS, the project team defined the following quality domains for measuring product quality:

- **Safety:** device does not compromise the clinical condition or the safety of patients, or the safety and health of users
- **Effectiveness:** device produces the effect intended by the manufacturer relative to the medical condition(s)
- **Reliability:** device system or component is able to function under stated conditions for a specified period of time
- **Patient Satisfaction:** device is perceived to meet or exceed patient expectations of usability and outcome
- **Usability:** device minimizes the risk of user errors by patients or clinicians
- **Availability:** device is available to fill first request orders
- **Compatibility:** device is compatible with related devices or drugs, the use environment or relevant standards

It was important to define Quality broadly and to incorporate patient and user experience in the definitions. While there is likely room for improvement in these categories and definitions, they have been met with positive feedback by a variety of stakeholders.

Project Charter

The formal problem statement is:

Stakeholders, such as hospital Value Analysis Committees (VACs) require accurate and complete data to make educated decisions to improve patient access to high quality devices. Three (3) significant challenges that need to be overcome related to data on medical device quality are:

- ***Lack of unbiased, relevant and available data.***
- ***Need for consistently applied performance measures and analytical methods.***
- ***Lack of a secure process or operating model to enable and encourage individual companies to be fully transparent about product quality.***

The intent was to provide information and analysis techniques to VACs regarding medical device quality and subsequent patient value with the goal of determining whether cross-manufacturer comparative analysis of quality for knee and defibrillator implants is feasible and effective for VAC purchase decisions. Final scope of the pilot was confined to:

- Data related to the seven (7) quality categories identified above
- Two device types—knees and defibrillators
- Data sources from the FDA, participants' internal systems, and 3rd parties as available

Two (2) other institutions are currently piloting similar programs: the Veteran's Administration and MedSun.

Pilot Approach

The PQOA team's approach for the pilot included the following activities:

- Develop a pilot project plan and identify key milestones
- Gather data from multiple sources
- Extract information across the seven (7) quality domains

- Generate and share dashboards with stakeholders
- Gather Voice-of-the-Customer feedback
- Report observations and recommendations

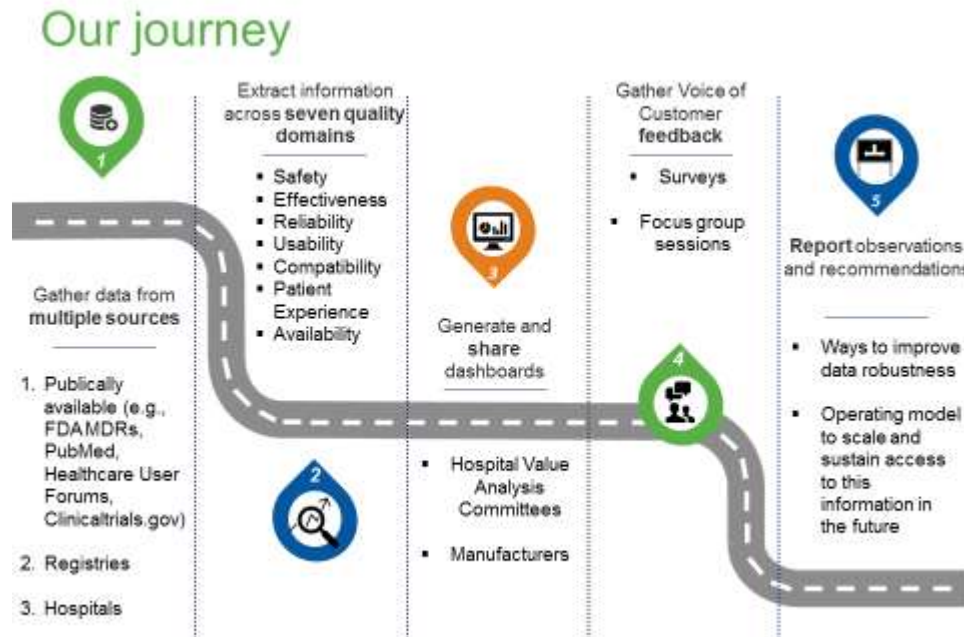


Figure 2. Roadmap for the Pilot

Several VACs were contacted to help establish requirements for a medical device product quality outcomes report. A number of VACs participated in the requirements development phase including, but not limited to:

- Baptist Health
- Kettering Health Network
- Providence Health
- Veterans Affairs

To help identify their requirements for product quality analytics, the VACs were asked how they currently support purchasing decisions.

Queries included:

- What quality factors do you consider in your purchasing decisions?
- What data sources do you use to determine product quality?
- What format/modes do you use to share out value analysis information?
- Are there certain device types that are critical to the value analysis teams?
- Are there existing services that share this type of data?

MDIC Pilot: Data, Analytics and Dashboards

The team's analytics partner developed product quality dashboards for two (2) medical device types — Implantable Cardioverter Defibrillators (ICDs) and knee implants — across the quality domains discussed above. These dashboards were developed in three stages: (1) identified and extracted available data; (2) analyzed the extracted data in order to calculate associated key performance indicators (KPIs); and (3) designed, developed, and reported on these KPIs in user-friendly dashboards. Manufacturer data were evaluated and selected to ensure that results could be comparable. All identifying information about products and manufacturers was blinded for this proof-of-concept.

Proviso:

Due to inherent limitations of the data sources used for this proof-of-concept, the numerical results shown in the Product Quality Outcomes dashboards may imply more precision than allowed by the data. While the results are mathematically accurate, implied differences should be evaluated closely. Results may change as more data sources are available and accuracy may improve as a result of a larger statistical sample. All identifying information about products and manufacturers was blinded for this proof-of-concept.

Data

Several data sources, listed in Table 1, were used to obtain information about device product quality in six of the seven (7) quality domains: medical device safety, effectiveness, reliability, usability, compatibility and patient experience. Data sources containing information about the seventh domain, medical device availability, were not available for this pilot.

Table 1. Data sources

Data source	Description	Quality domain(s) addressed
PubMed Central	An archive of biomedical and life sciences journal literature developed and maintained by the National Center for Biotechnology Information (NCBI) as part of the United States National Library of Medicine (NLM) at the National Institutes of Health (NIH).	Effectiveness
Clinicaltrials.gov	A registry of clinical trials developed and maintained by NLM.	Effectiveness
ICD Registry 2005 - 2006	A temporary database established by the United States Center for Medicare and Medicaid Services (CMS) to capture data on patients receiving ICDs. The database was transferred in 2006 to the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR).	Safety
Manufacturer and User Facility Device Experience (MAUDE)	The MAUDE database contains reports filed by manufacturers, importers, user facilities, consumers and health professionals. These reports are collected through the FDA's Medical Device Reporting (MDR) procedure.	Safety, Reliability, Usability, and Compatibility
FDA Medical Device Recalls	FDA recall databases contain reports filed by manufacturers, user facilities, consumers and health professionals. Recall data includes causes and violations.	Reliability
Healthcare User Forums	Online platforms for the public to voluntarily share their opinions about their experiences with medical products.	Patient Experience

For purposes of this pilot, quality information was extracted from four (4) ICD manufacturers and five (5) knee implant manufacturers. The information came from both structured and unstructured data sources¹.

Analytics

Given the range and nature of data available, it was necessary to perform several analytic techniques to infer information about medical device quality. These analytic techniques included aggregate counts, natural language processing, concept extraction and categorization, sentiment aggregation, as well as human expert

¹ Structured data is organized in a tabular format, while unstructured data is in free form text. In some cases, unstructured data can be part of a structured data set (e.g., a free form text field in a table).

reviews. This analysis was used to calculate the Key Performance Indicators (KPIs) described in Table 2.

Table 2. Medical device quality KPIs

Quality domain	KPI(s)
Safety	<ul style="list-style-type: none"> ▪ % of company's ICD or knee implant products associated with deaths ▪ % of company's ICD or knee implant products associated with injuries and complications
Effectiveness	<ul style="list-style-type: none"> ▪ # studies published in recent 6 months with statistical significance tests and associated with company's ICD or knee implant product ▪ % of studies with statistically significant positive outcomes associated with company's ICD or knee implant product
Reliability	<ul style="list-style-type: none"> ▪ % of company's ICD or knee implant products associated with reliability failures ▪ Estimated days to failure from date of manufacture
Usability	<ul style="list-style-type: none"> ▪ % of company's ICD or knee implant products associated with usability failures
Compatibility	<ul style="list-style-type: none"> ▪ % of company's ICD or knee implant products associated with compatibility failures
Patient Experience	<ul style="list-style-type: none"> ▪ % of users in Healthcare User Forums expressing positive sentiments about company's ICD or knee implant products

Dashboards

At this stage, the KPIs needed to be compared in a manner that VACs could understand and potentially act upon. To make these comparisons, standard deviations were calculated based on the assumption that the values across the population of companies followed a normal distribution.

A methodology was then devised to visually represent how these standard deviation calculations compared between manufacturers. Rankings of Gold (G), Silver (S) and Bronze (B) were assigned to each company's KPIs. If a company's KPI value was within one standard deviation of the average then the company was ranked Silver (S); more than one standard deviation better than average was ranked Gold (G); more than one standard deviation worse than the average was ranked Bronze (B).



Figure 3. Assignment of Gold (G), Silver (S), and Bronze (B) rankings to a company's KPI assuming that KPI values follow a normal distribution (lower score is better)

The KPIs and rankings described above were published in a "Product Quality Outcomes Report" that contained four (4) distinct dashboards (Figure 4) for each of the two medical devices in scope. All identifying information about products and manufacturers was blinded for this proof-of-concept.

DASHBOARD 1. The first section, Overview, is intended to orient the user and explains the quality domains, the data sources, KPIs, and the gold, silver and bronze rankings. This section also describes and explains how rankings are portrayed visually using radar charts (Figure 4a).

DASHBOARD 2. The second dashboard, Rankings by Data Source, displays a table of KPI rankings by company and at the individual data source level. Each data source is identified along with an assessment of whether the quality of the data for that source is high, medium or low (Figure 4b). The report can be filtered by data source.

DASHBOARD 3. The third dashboard, Rankings by Manufacturer, collapses the individual data sources and displays a table of KPI rankings by company. Individual data sources are aggregated using a weighted average based on data source quality. Radar charts are shown below the table and offer a visual comparison of manufacturers across different KPIs (Figure 4c). The report can be filtered by company.

DASHBOARD 4. The fourth and final dashboard, Rankings by Product, displays a table of KPI rankings by company and product, similar to the third dashboard. Radar charts are shown below the table and offer a visual comparison at the individual products level (Figure 4d). The report can be filtered by company and product.



Figure 4. The Four (4) Dashboards in the Product Quality Outcomes Report

MDIC Pilot Results: Voice-of-the-Customer Value Analysis Committees

To get input from Dashboard demonstrations were provided to three (3) VACs:

- Baptist Health
- Providence Health
- Veterans Affairs

The team collected feedback on overall thoughts about each dashboard and made note of areas for improvement and strengths.

Participant feedback was positive, ranging from “Very user friendly, especially for clinicians”, to “Extremely beneficial” and “Excited and loves the model”. All participants indicated that dashboards of this type would be valuable. They expressed concern about data bias and re-iterated the need for an independent third-party to manage the data.

Comments below summarize the suggestions enhancements voiced by the participants:

- Weights – ability to customize the underlying weights for individual level judgment
- New products – the ability to add new products entering the market, comparing registered products
- Device feature details – the ability to drill to the detailed feature of each product
- Physician data – the ability to have a standard measure to quickly demonstrate quality physicians
- KPI – the need to add additional KPIs, assuming dataset feasibility, related to patient outcomes
- Outcomes – the need to add device patient performance outcomes to product comparison
- Registry – the need to add medical specialty registry data
- Group Purchasing Organization- helpful to include GPO data
- Data updates – the need to update the data at least weekly

Strengths

Overall, the participant’s response to the dashboards was positive and they emphasized that the key differentiator from existing solutions is the inclusion of information about quality beyond Safety and Efficacy. Additional strengths included the overall layout:

- Easy to view at a quick glance
- User friendly, especially for clinicians
- Transparency of definitions for comprehensive understanding
- Considered the hierarchy of qualities a good feature

MDIC Pilot Results: Voice of Manufacturers

The PQOA conducted a survey of manufacturers to obtain feedback regarding the usefulness of having independent and unbiased product quality analytics for their

own use. The survey, consisting of 10 questions, was sent to 89 members of MDIC including industry, government and customer representatives.

A total of 27 or 30% of the surveys were completed and returned, of which 24 or 89% represented the Medical Device Manufacturing Industry, across a broad range of sizes (< \$1B to > \$10 B) in annual sales. Of the 24 respondents representing industry, the vast majority (23) were from the Quality/ Regulatory function.

The survey consisted of the following demographic and content questions:

- What is your specific function/department?
- What is your company's stake in medical devices?
- Does your company or function/department track information about device safety, effectiveness or performance in the field? ("In the field" means a commercialized product currently in use.)
- What data sources does your company or function/department use to track information about device safety, effectiveness or performance in the field? (enter NA if not applicable)
- What metrics does your company or function/department use to measure device safety, effectiveness, & performance in the field? (enter NA if not applicable)
- How does your company or function/department use information about device safety, effectiveness, or performance? (e.g., use it to improve design, use it to decide on purchases; enter NA if not applicable)
- This pilot will attempt to compare manufacturers across seven (7) quality domains: safety, effectiveness, reliability, compatibility, usability, availability, and patient experience. What benefits do you think this comparative analysis could add to your company or function/department?
- What are your concerns about this comparative analysis and how it may be used? (enter NA if not applicable)
- What factors should be considered to improve the validity of the comparative analysis? (enter NA if not applicable)

The last two (2) questions were aimed at understanding what benefits respondents saw in having access to such analytics as well as what concerns they had, if any.

Survey results show that respondents overwhelmingly use product quality information (23/24) that are mostly complaint related (Complaints, Adverse Events, MDR, and /or Post Market Surveillance). Regarding metrics used to assess product

quality, the majority of the respondents indicated they use external metrics, primarily complaint related (Complaints, Reportable Events, Malfunctions, Returns), Clinical Outcomes and Field Actions.

Manufacturers also reported using internal metrics such as Manufacturing Issues, Product Conformance and Process Performance to support product quality reporting. The majority of manufacturers also reported that product quality information is used to take corrective and preventive actions on existing products and processes, and/or to support their new product design processes. The responses were very consistent across manufacturers.

Most respondents saw a benefit in having access to the proposed analytics as an unbiased means to benchmark other companies with similar products. Most respondents also indicated that they would use the information as a means to improve their product quality.

30% of the respondents indicated no concerns with the proposed analytics. Of those expressing concerns a few themes stood out:

- Lack of clear definitions of metrics to be tracked or in the data gathering methodologies that could lead to inaccurate results being reported.
- The way these analytics will be used by the different stakeholders: regulators, customers and competitors, in their decision making processes.

These concerns were reported by the whole spectrum of respondents regardless of company size.

Consistent with the above mentioned concerns, survey respondents suggested ways to improve the validity of the results to ensure clear definitions, common denominators and quality and consistency of data sources. This input will be incorporated into next steps and final recommendations.



Figure 5. Product Quality Outcomes Analytics: Manufacturer Survey Results

Future State

During the pilot phase of this project, data were compiled from various data sources to develop an interactive dashboard to model cross-manufacturer comparative product quality outcomes analytics across the seven (7) quality domains. The dashboard was reviewed and revised based on VAC participants' feedback. As the team considers the future state of product quality outcomes analytics, three key areas still need to be addressed:

- Third-party adoption and development of product quality outcomes analytics across the seven (7) quality domains
- Creating demand for, and broad-based acceptance and utilization of, the quality criteria across provider stakeholders
- Development of formal feedback mechanisms to manufacturers based on the outcome of analytics across the seven (7) quality domains

However, before there is a standardized approach and broad-based acceptance – the desired future state - there are several hurdles that will need to be addressed. Data has proven to be a challenge. At a high level, these challenges include access

to, cost of, and lack of any reporting standards. These challenges have made it extremely difficult to coalesce the available information into actionable or reportable data, as well as the development of a comprehensive solution.

The limited number of unbiased reports available is another hurdle that may need to be cleared. However, the volume of manufacturer reports available may be attributed to product review and approval requirements.

Will there be a point when the scales strike a balance between manufacturer and third party medical device performance and outcome reports?

One sustainable solution to data challenges will be the Unique Device Identification (UDI) ruling released in 2013. September 2014 saw all Class III implantable medical devices required to incorporate a UDI label. September 2015 saw the balance of implantable devices, life sustaining, and life supporting medical devices required to incorporate an UDI label. September 2016 will see all Class II medical devices required to be labeled with an UDI. As a result, a majority of medical devices will now bear a unique device identifier.

One of the many impacts of UDI include improving data quality in post-market surveillance, making comparative-effectiveness research available on device performance and patient outcomes. UDI information strongly aligns with this pilot's goals and objectives to provide unbiased information and analysis techniques to stakeholders regarding medical device quality, subsequent patient value, and patient outcomes through standardized and normalized medical device and performance data.

Challenges to Adoption: Data Source Limitations

Multiple data sources, all publicly available, were identified as potential sources for cross-manufacturer comparative medical device quality information. In all likelihood, these data sources were not initially compiled for the purpose of cross-manufacturer comparative analysis. While the data sources may be sufficient for the purpose originally intended, the PQOA team's analytics partner made the following observations about these data source's ability to enable cross-manufacturer comparative medical device quality analysis.

- **Data quality:** product identifiers (e.g., manufacturer, make, model) are not always available in a consistent and reliable form.

- **Data bias:** variation in manufacturer’s abilities to sponsor studies or variations in criteria applied to disclose malfunctions or variations in threshold to recall products may lead to bias in the volume of information available.
- **Data availability:** During the pilot the team was not able to identify comprehensive sources of data for effectiveness, patient preference or usability.

The following actions, if taken, can help to address these issues:

- Use barcode technology to capture product identifiers
- Automatically validate product identifiers against a standard master data for product identifying information (e.g., the GUDID)
- Ease access to unbiased data sources for the purpose of comparative quality analysis (e.g., registries)
- Define standard measures for effectiveness, patient preference and usability

PubMed Central

Strengths for cross-manufacturer comparative medical device quality information:

- Publicly accessible search function
- Maintains some free open source content
- Inherent peer-review process to assess data accuracy and reliability
- Archives nearly 4-million biomedical and life sciences journal publications

Limitations for cross-manufacturer comparative medical device quality information:

- Requires clear understanding of research question and well defined search criteria to avoid false positive
- Sifting through search results can be time consuming
- Data analysis and interpretation requires scientific understanding
- Limited volume of studies with statistical significance testing results
- Results not always broken down by specific product information
- Private sponsorships can lead to bias in volume and types of studies published

Clinicaltrials.gov

Strengths for cross-manufacturer comparative medical device quality information:

- Publicly accessible search function
- Inherent review process to assess that data are clear and informative
- User can download / analyze complete studies
- Provides abbreviated studies for efficient presentation of main points
- Results are broken down by device information (manufacturer, make, model)

Limitations for cross-manufacturer comparative medical device quality information:

- Data not always available, even for closed/completed studies
- Less technical than PubMed, but data analysis still often requires scientific understanding
- Limits to automated data analysis because data is usually presented in text format
- Does not include information on all US clinical trials, as not all are required to register by law
- Limited volume of studies with statistical significance testing results
- Private sponsorship of clinical trials can lead to bias in volume and types of studies published

CMS ICD Registry 2005 – 2006

Strengths for cross-manufacturer comparative medical device quality information:

- Publicly accessible search function
- Contains real world evidence of medical device quality from unbiased sources (hospitals)
- Data is available in a structured tabular format
- Leading practice for registry data includes an inherent review process to ensure data validity and reliability

Limitations for cross-manufacturer comparative medical device quality information:

- Lacks controls for surgeon factors
- Lacks long-term follow-up information
- Product information lacks data consistency due to manual entry

Manufacturer and User Facility Device Experience (MAUDE)

Strengths for cross-manufacturer comparative medical device quality information:

- Publicly accessible search function
- Contains real world evidence of medical device quality from multiple sources

- Data is available in a structured tabular format

Limitations for cross-manufacturer comparative medical device quality information:

- Includes only reports on malfunctions
- Manufacturers use different criteria to determine what reports to disclose to the FDA
- Product information lacks data consistency due to manual entry

FDA Medical Device Recalls

Strengths for cross-manufacturer comparative medical device quality information:

- Publicly accessible search function
- Contains real world evidence of medical device quality from manufacturers
- Data is available in a structured tabular format

Limitations for cross-manufacturer comparative medical device quality information:

- In cases of voluntary recalls, manufacturers use different criteria to determine when to recall a product
- Recalls can be voluntary and manufacturers use different criteria to evaluate what level of failure or malfunction constitutes a recall
- Product information lacks data consistency due to manual entry

Healthcare User Forums for ICDs and Knee implants

Strengths for cross-manufacturer comparative medical device quality information:

- Availability of many forums and social media platforms that contain user comments on medical device quality

Limitations for cross-manufacturer comparative medical device quality information:

- Lacks process to assess validity of user identity and accuracy of comments
- Lacks standards for data inclusion
- Lack of consistency in disclosing product information
- Irrelevant posts pose significant noise for statistical analysis

Challenges to Adoption: Data Access

Access to unbiased data about product outcomes is crucial for cross-manufacturer comparative analysis. While journal publications have processes to control data accuracy and reliability, potential bias in the volume of available information may be introduced when manufacturers sponsor studies. Sources such as FDA MAUDE and FDA Recalls that rely on manufacturers' self-reports also introduce potential bias in the volume of information disclosed due to the manufacturer's varying interpretation or risk threshold for disclosure. During the pilot, the team identified hospitals and registries as sources for unbiased product quality information.

Hospitals collect data associated with purchased products in a variety of databases (e.g., maintenance logs). These databases vary widely across hospitals; it is important to understand each hospital's systems and requirements for data capture. Pilot projects such as FDA MedSun's computerized maintenance management system (CMMS) attempt to aggregate maintenance log information across hospital groups in order to determine if there are trends in device issues across hospitals. Any biases in pooled hospital data would be due to each hospital's criteria for purchase and can be controlled by pooling from a wide range of hospitals. Registries can either contain primary data collected as part of a specific study protocol or bring together data from multiple secondary sources such as hospital Electronic Medical Records, Medicare and Medicaid claims files, among others.

The following factors limit access to these data sources for use in cross-manufacturer comparative product quality analysis:

- **Unknown territory:** these data sources are not traditionally used for cross-manufacturer comparative product quality assessments and the impact to stakeholders is not clearly understood.
- **Process limitations:** these data sources are governed by privacy and legal process that typically prohibit sharing record level data.
- **Lack of comprehensive product library:** these data sources typically do not have a comprehensive product library that can be used to match model numbers and product characteristics in a validated way.

The integration of GUDID into data capture systems should help to provide a comprehensive product library and improve data quality. To encourage adoption of

cross-manufacturer comparative product quality analyses, the impact to stakeholder must be understood and processes and governance structures that encourage data sharing must be implemented.

Adoption

Achieving adoption by VACs, and other stakeholders, is the stated goal of this effort. However, more work needs to be done before wholesale adoption can be realized. Some of the challenges have been discussed in detail: data challenges, adoption and incorporation of dashboard data by third party vendors, development of a formal feedback loop to the manufacturing community, generating increased demand for, and meeting the data requirements of, the provider, VAC, and patient communities.

What are the tangible next steps that need to be taken? Who are those organizations--those stakeholders that should be involved in collaboration as the necessary next steps are developed? As this effort progresses, there will no doubt be solutions to the challenges currently faced as well as new challenges that will arise. The need to collaborate with and engage with the appropriate stakeholders during the course of this project will be critical to the overall success of adoption efforts.

Third Party Implementation

Successful adoption and continued use of the information from the analysis model described in this paper will first depend on the governance model established to ensure consistent interpretation and application of the Quality domains.

Ensuring Consistent Applicability of Quality Domain Model

FDA is responsible for protecting public health by ensuring the safety and efficacy of medical devices. One method for FDA to accomplish this task is by providing public guidance on how the quality of medical devices can be evaluated by the public. Providing a standardized framework can aid in ensuring that decisions made by various healthcare providers consider all available information about medical device safety, not just that provided by the manufacturer. As such, it is recommended that FDA publish a guidance document entitled "Industry Guidance on Evaluating the Quality of Medical Device Performance". This guidance would define the seven (7) domains of quality, the analysis methods and formulas to be used, as well as

provide caution to readers about the reliability of certain data sources. FDA can use the public commenting process to gather feedback from various stakeholders about the application of the model.

This guidance would serve multiple purposes. First, it provides information to manufacturers about how their products will be evaluated. By knowing the measures that will be used, manufacturers have the ability to incorporate continuous improvement efforts to drive improved product quality. For non-quality professionals (e.g. executive management) it provides a standard mechanism for understanding how the company's products are performing compared to their competitors. The desire to create a competitive advantage will drive investment decisions made by executive management.

Second, the guidance provides criteria to users (e.g. Value Analysis Committees) about the factors they should be considering when making the decisions about the best product(s) to serve their patient's needs. Defining the standard criteria can ensure that decisions become more standardized across different health care systems. The end result is better patient outcomes driven by data driven decisions.

Third, since the use of this model will require one or more companies to gather, analyze and maintain access to data sources, it provides a mechanism to ensure that these companies will provide the same results regardless of their specific data processing method. Consistent presentation of information provides for more predictable outcomes and therefore more consistent application across various health care providers.

Note: Language within this new guidance could be drafted to coincide with the recently released draft guidance *Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions* (June 16, 2016).

Dashboard Maintenance

When establishing a new product/service (e.g. product quality information) one must first consider who the customer is and what the demand is for that type of product/service. Analyzing barriers to entry and the ability to create a truly differentiated product also help to establish adoption and longevity of

product/service acceptance. These factors govern market competition and the supply to meet that customer demand.

Low Market Demand

In the case of the Product Quality Outcomes Analytics dashboard, potential customers have been defined through the efforts of the project team. However those customers (VACs) have not coalesced around a common defined need (e.g. no product/service demand). There is a fair amount of market development that needs to be conducted to educate the customer on how a product/service of this nature serves their needs. Market development efforts will require helping the customer understand their needs, providing standardized messaging of how a product/service meets those needs and demonstrating the product value to the customer.

Low Product Differentiation

The intent of the guidance document noted above is to remove inconsistencies in how data is analyzed and presented. The end result of this is the removal of methods for product/service differentiation. Some flexibility still exists with the sources of data analyzed and the visual nature of how the information is presented; but these would be considered minor product/service differentiators. The lack of the ability to differentiate product/service from the perspective of the user will result in a lower number of companies entering the market.

Financial Barriers to Entry

Finally, barriers to entry into this market appear to be technology (e.g. hardware, software) and resource (e.g. funding for data access, personnel) driven. Although the not-for-profit business model may be most desirable, it offers considerably more barriers to long term success due to the continued need of establishing a renewable funding model. On the for-profit side, without significant market development occurring, first profitability for this product/service is also limited. As such, initial entry into this market is more than likely best served by a larger firm that has the ability to maintain the availability of product/service while the market demand continues to be developed.

With all this in mind, it is recommended that FDA/MDIC not choose a single partner to maintain the draft dashboard that has been created. Instead it is recommended that efforts be focused on ensuring analysis consistency (e.g. release of draft

guidance) and education of user (e.g. VACs) on the usefulness of the product/service. Market demand will naturally promote new entrants into the market to serve the needs of early adopters. With continued market development and increased demand this will be followed quickly by additional companies entering the market thus forming an oligopoly.

Note: It is critical for continued market development that examples of the Product Quality Outcomes Analytics dashboards be available to educate the potential user. By their very nature, the existing dashboards must continue to be refined based on user input and their access remain open for use in market development efforts of FDA and MDIC. Therefore, efforts initiated during this pilot phase must be maintained during the remainder of the market development efforts.

Recommendations

To address the challenges of data quality, data bias and data availability, further development should be completed.

In FY2017, the MDIC Product Quality Outcome Analytics team should:

- Conduct a pilot in partnership with a specific registry. Not all registries collect adequate information to identify specific devices or to determine long term comparative safety and effectiveness. By partnering with a specific registry, the team could work with registry staff to make appropriate changes and also have improved access to relevant data.
- Work with a specific professional organization to develop methods to measure and track usability. For prescription devices, surgical devices and implants, clinician preference and clinical perspectives on usability are essential to understand quality. By partnering with a professional organization, the team could gain a better understanding of device usability.
- Work with specific patient advocacy groups to develop patient preference metrics. Many devices are non-prescription and purchased by patients. Some prescription and hospital purchased devices treat patients with strong patient advocacy groups. By working closely with one or more patient advocacy groups, the team may be able to include appropriate data in a revised dashboard and make recommendations on data sources to third party analysis vendors.
- Conduct a pilot with a set of hospitals willing to pool data. The initial proof of concept hospitals were not able to pool data. Information on many devices will never be available through registries or clinical trials. MDIC should work

with a few hospitals willing to pool data to track safety, effectiveness, reliability, usability, patient preference, availability and compatibility. Many hospitals have existing quality programs that may be leveraged to improve understanding of device quality.

- Using the enriched data, improve the initial dashboards. The PQOA team received positive feedback on the initial set of dashboards. In order to promote a viable concept to third party data analysis firms, the data problems need to be addressed and better sources of data need to be identified. If better sources of data can't be found, the seven (7) quality domains may need to be modified to quality domains with reliable and available data.
- Pilot enriched dashboards with a larger set of hospital value analysis teams.
- Begin conversations with group purchasing organizations and 3rd party data analysis groups to understand the information they would need to make use of the team's work.
- Coordinate with the National Evaluation System for health Technology² (NEST) to leverage methods for tracking medical device data and patient-reported outcomes through the use of real-world evidence. Evaluate how NEST real-world evidence could be used to support Product Quality Outcome Analytics.

By the end of 2017, the goal would be to have a well-documented system for accessing and sharing device quality data. If this goal is reached, 3rd party data analysis teams could use the methods developed to consistently provide accurate information about device quality.

Due to inherent limitations of the data sources used for this proof-of-concept, the numerical results shown in the Product Quality Outcomes dashboards may imply more precision than allowed by the data. While the results are mathematically accurate, implied differences should be evaluated closely. Results may change as more data sources are available and accuracy may improve as a result of a larger statistical sample. All identifying information about products and manufacturers was blinded for this proof-of-concept.

² <http://mdic.org/CC/>