

Product Quality Outcomes Analytics Update

Anticipated Connections between the Dashboard and the Maturity Model





Creating a Marketplace for Quality

“Develop a medical device quality dashboard to guide strategic procurement decisions.”



Product Quality Dashboard Domains

Effectiveness: Device produces the effect intended by the manufacturer relative to the medical condition(s).

Patient Satisfaction: Device was perceived to meet or exceed patient expectations of usability and outcome.

Compatibility: Device is compatible with related devices or drugs, the use environment or relevant standards.

2

4

7

1

Safety: Device does not compromise the clinical condition or the safety of patients, or the safety and health of users.

3

Reliability: Device system or component is able to function under stated conditions for a specified period of time.

5

Usability: Device minimizes the risk of user errors by patients or clinicians.

6

Availability: Device is available to fill first request orders.

Phase I Dashboard



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)

Dashboard 1

Overview

Intended to orient user and explains the quality domains, the data sources, KPIs, and gold, silver, bronze rankings. Also describes and explains how rankings are portrayed visually.

Dashboard 2

Rankings by Data Source

Displays a table of KPI rankings by company and at individual data source level. Each source is identified whether quality of data is high, medium, low.

Dashboard 3

Rankings by Manufacturer

Collapses the individual data sources and displays a table of KPI rankings by company. Individual data sources are aggregated using weighted average.

Dashboard 4

Rankings by Product

Displays a table of KPI rankings by company and product, similar to third dashboard.

Project Charter

Objectives	Develop a medical device quality dashboard to guide purchasing decisions		
Project Scope	Included		Future Effort
	<p>Phase II</p> <ul style="list-style-type: none"> Identify and analyze registry data on safety and effectiveness Identify and analyze hospital data on reliability, patient perspective and physician preference Establish analytical methods and revise dashboards <p>If there is sufficient bandwidth</p> <ul style="list-style-type: none"> Gather and analyze patient perspective data Coordinate with NEST program 		<ul style="list-style-type: none"> Alignment with MDIC CfQ metrics and maturity model work Collaborations with GPOs or 3rd party data analysts to ensure adoption
Metrics	Metric	Goal	Unit of Measure
	Registry data sources	2	Number of registries accessed for safety and effectiveness data
	Hospital Collaborations	2	Number of hospitals providing data for the dashboard
	Phase II completion date	12/31/18	Analytical methods defined and dashboards revised

Project Status Dashboard

Key Deliverables / Milestones

Milestones / Deliverable	Dates	Percent Complete		
		Registry	Health Care Provider	Patient
Identify collaborators	April-May	100%	exceeded	30%
Define information	June 2017 - June 2018	20%	20%	20%
Interact w source	June 2017 - June 2018	20%	20%	20%
Analyze	June 2018 to Sept 2018	0%	0%	0%
Gather feedback	October- Dec 2018	0%	0%	0%

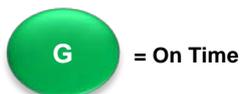
Results / Accomplishments

- Completed charter
- Expanded team
- Finished project plans
- Made connections for all teams
- Researched past and existing efforts
- Identified 2 registries
- Identified 2 device types
- Connected with 9 hospitals
- Explored industry use of data
- Revised metrics for 2018

Issues

Mitigation

- | | |
|---|---|
| <ul style="list-style-type: none"> • Potential data sharing issues | <ul style="list-style-type: none"> • Engage with multiple potential collaboration partners • Use distributed analytics • Leverage registry efforts |
| <ul style="list-style-type: none"> • Analysis plan | <ul style="list-style-type: none"> • Leverage existing analytical techniques |
| <ul style="list-style-type: none"> • Funding may be required for data access | <ul style="list-style-type: none"> • Ask steering committee for funding to support Duke and PCORI |





Sub-teams

- Registry Team
- Healthcare Provider Team
- Dashboard and Analysis Team
- Patient Perspective Team



Registry Team

- Objectives:
 - Evaluate data from at least 2 registries that cover at least 500 patients, and 6 or more device companies to evaluate the fitness, safety, and effectiveness of surgical mesh and one other device.
- Accomplishments:
 - Engaged in specific conversations with Vascular Quality Initiative (VQI) and International Hernia Mesh Registry (IHMR)
 - Worked with VQI to identify Peripheral Vascular Interventions, commitment from VQI to work through data elements and alignment with 7 quality domains
 - Alignment with RAPID Project. Summer 2018 timeline
 - Identified strong or moderate alignment on Safety, Efficacy and Reliability
- Next Steps:
 - Working session with collaborators
 - Create process of guidelines for registry engagements with PQOA
 - Work with registries to establish safety, efficacy and reliability dashboard shell



Healthcare Provider Team

- Objectives:
 - To gather and analyze patient outcomes data from a minimum of 300 EHRs by collaborating with 2 or more healthcare providers to evaluate the safety and effectiveness of surgical mesh and one other device
 - To gather physician preference information from 30 or more physicians
 - To gather reliability information by collaborating with 2 or more hospital value analysis and supply chain professionals, hospital risk managers, or safety staff
- Accomplishments:
 - Discussions with physicians, value analysis and supply chain professionals around which specific data elements to share, and how best to share them
 - AHVAP presentation and healthcare engagement
 - Identified Carolinas Healthcare and VA as data sharing partners (patient, availability and reliability)
- Next Steps:
 - Continued outreach out to VAC teams to explore data sharing options
 - Gathering hospital information on reliability, usability, availability and compatibility to integrate with registry data



Dashboard and Analysis Team

- Objectives:
 - Develop and document analysis tools for safety, efficacy, usability, patient preference, and reliability. Consider analysis tools for compatibility and availability. Refine Phase I Dashboard
- Accomplishments:
 - Evaluated the common data models for VQI and Patient Centered Outcomes Research Institute (PCORI)
 - Discussion of current aggregate measures used in VQI
 - Receipt of data model from IHMR and initial review for alignment with the 7 quality domains.
 - Initial discussions with Dell and IBM
- Next Steps:
 - Map the common data elements on IHRM to the 7 quality domains
 - Future Considerations - Sentinel data model



Patient Perspective Team

- Objectives:
 - Develop an understanding of available patient perspective data and its utility in the product quality dashboard.
 - Get data from 2 or more patient perspectives sources, develop methods for analysis and integration into the Dashboard
- Accomplishments:
 - Connected with PCORI and FasterCures.org
- Next Steps:
 - Identify synergies with Avalere/FasterCures Patient-Perspective Value Framework (PPVF)
 - Gather patient information to integrate with registry data



Planned activity during the next 2 months

- Registry Team
 - Continue work with VQI (RAPID)
 - Get commitment from IHRM
- Healthcare Team
 - Define specific physician preference questions based on SME conversations
 - Work with Healthcare organizations to understand availability
- Analysis Team
 - See if Dell or IBM efforts may lead to case study
- Patient Team
 - Follow through with PCORI and FasterCures.org
 - Identify additional patient advocacy collaborators
- Full Team
 - Meet with Maturity Model group
 - Increase NEST connections



Phase II: Product Quality Dashboard Data Sources





What are the Anticipated Connections between the Dashboard and the Maturity Model?



These slides have been prepared to show how the dashboard and maturity model could connect in the future. The slides are intended to inspire discussion and not meant as the complete description of all possibilities.

Coming Together

Maturity Model

Product Quality Dashboard

Program Creation

Dashboard Creation

Industry Assessment

Value Analysis Team Assessment

Device Quality
Improved Patient Outcomes



Product Quality Dashboard Domains

Effectiveness: Device produces the effect intended by the manufacturer relative to the medical condition(s).

Patient Satisfaction: Device was perceived to meet or exceed patient expectations of usability and outcome.

Compatibility: Device is compatible with related devices or drugs, the use environment or relevant standards.

2

4

7

1

Safety: Device does not compromise the clinical condition or the safety of patients, or the safety and health of users.

3

Reliability: Device system or component is able to function under stated conditions for a specified period of time.

5

Usability: Device minimizes the risk of user errors by patients or clinicians.

6

Availability: Device is available to fill first request orders.

Maturity Model Practice Areas



EST

Estimating- Estimate the size, effort, duration, and cost of the work and resources needed to develop, acquire, or deliver the solution. Estimation provides a basis for making commitments, planning, and reducing uncertainty, which allows for early corrective actions and increases the likelihood of meeting objectives.



PLAN

Planning - Planning includes developing budget and schedules based on estimates; developing and getting commitment to the work plan; and determining the necessary resources. Provides a comprehensive set of plans describing the work to be performed, dependencies, who will perform the work, and when it will be performed. These plans describe what is needed to accomplish the work within the constraints of the available budget, schedule, resources, quality, and functionality requirements. Optimizes cost, functionality, and quality to increase the likelihood that objectives will be met.



MC

Monitor and Control - Provides an understanding of the work progress so appropriate corrective actions can be taken when performance deviates significantly from plans. Increases the probability of meeting objectives by taking early actions to adjust for significant performance deviations.



CM

Configuration Management - Manages the integrity of work products using configuration identification, version control, change control, and audits. Reduces loss of work and increases the ability to deliver the correct version of the solution to the customer.



MPM

Managing Performance and Measurement - Manage performance using measurement and analysis to achieve business objectives. Maximizes business return on investment by focusing improvement efforts on cost, schedule, and quality performance.

Maturity Model Practice Areas (continued)



Requirements Development and Maintenance - Elicit requirements, ensure common understanding by stakeholders, and align requirements, plans, and work products. Ensures that customers' needs and expectations are satisfied.



Process Quality Assurance - Verifies and enables improvement of the quality of the performed processes and resulting work products. Increases the consistent use and improvement of the processes to maximize business benefit and customer satisfaction.



Governance - Provides guidance to senior management on their role in the sponsorship and governance of process activities. Minimizes the cost of process implementation, increases the likelihood of meeting objectives, and ensures that the implemented processes support and contribute to the success of the business.



Implementation Infrastructure - Ensure that the processes important to an organization are persistently and habitually used and improved. Sustains achieving goals and objectives efficiently and effectively by establishing a process infrastructure.



Product Integration - Assemble and deliver the solution that addresses functionality and quality characteristics. Increases customers' satisfaction by giving them a solution that meets or exceeds their functionality and quality requirements.



Technical Solution - Design and build solutions that meet customer requirements. Provides a cost-effective design and solution that meets customer requirements and reduces rework.



Anticipated Connections between the Dashboard and the Maturity Model

- There are practice areas in the maturity model which will **benefit from input** from the Product Quality Outcomes Analytics Dashboard



- There are practice areas in the maturity model which will **drive changes** in medical device quality directly measurable with data from the Product Quality Outcomes Analytics Dashboard





Considering the Dashboard Domains as **Inputs** to specific Maturity Model Practices



Reliability: Device system or component is able to function under stated conditions for a specified period of time.



Monitor and Control - Provides an understanding of the work progress so appropriate corrective actions can be taken when performance deviates significantly from plans. Increases the probability of meeting objectives by taking early actions to adjust for significant performance deviations.



Monitor and Control

- Knowledge of variations in the functioning time for medical devices can inform key areas of focus.
- The significance of observed performance deviations may be assessed through understanding of device reliability information.



Considering how the Maturity Model Practices could Drive Measurable Change within specific Dashboard Domains

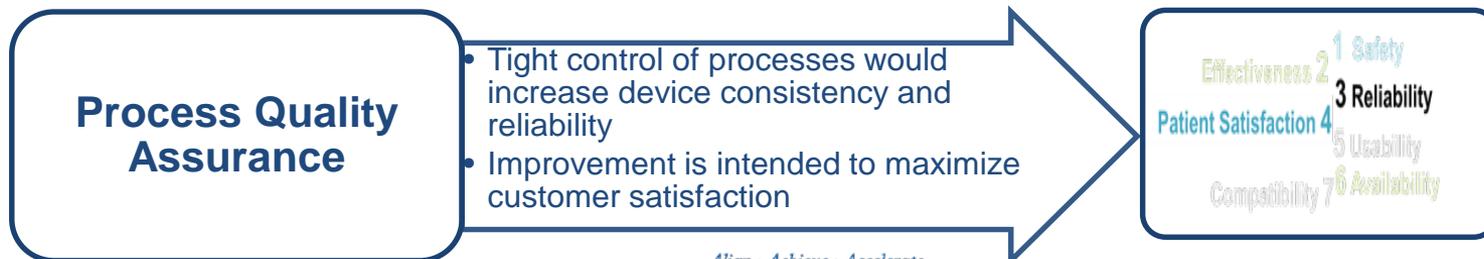


Process Quality Assurance - Verifies and enables improvement of the quality of the performed processes and resulting work products. Increases the consistent use and improvement of the processes to maximize business benefit and customer satisfaction.



Reliability: Device system or component is able to function under stated conditions for a specified period of time.

Patient Satisfaction: Device was perceived to meet or exceed patient expectations of usability and outcome.



Align > Achieve > Accelerate



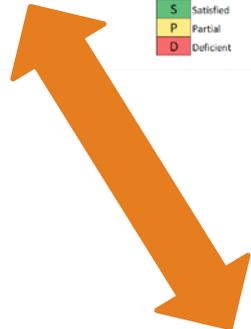
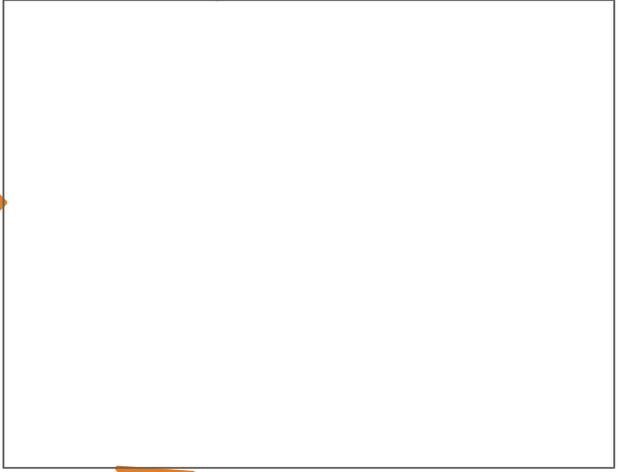
Notes on Anticipated Connections between the Dashboard and the Maturity Model

- Device quality data wouldn't be the only inputs to the Maturity Model Practices.
 - For example, other inputs could include: Financial, market, intellectual property, firm strategic information and clinical trial data
- A Maturity Model Practice may leverage data or drive measureable changes in device quality to a greater or lesser extent
 - Not all maturity model practices directly connect to quality

Looking toward Correlation between Maturity Model Heat Map, Firm Internal Metrics and Product Quality Dashboard

	1.1	1.2	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	66%
Estimating (EST)	S	S	S	S	P	S					80%
Planning (PLAN)	S	S	P	P	P	P	S	S	P	D	56%
Monitor and Control (MC)	S	S	P	P	P	P					57%
Configuration Management (CM)	P		P	S	S	S	D	S			63%
Managing Performance and Measurement (MPM)	S	S	S	S	S	S	S	P	S		84%
Requirements Development and Maintenance (RDM)	P		S	D	P	P	P	D			36%
Process Quality Assurance (PQA)	P		P	P	S	S					60%
Governance (GOV)	S		S	S	P	P					70%
Implementation Infrastructure (II)	S		S	S							90%
Product Integration (PI)	S		D	P	P	S	S	S			63%
Technical Solution (TS)	P		P	S	S						65%

S Satisfied
P Partial
D Deficient



Effectiveness: Device produces the effect intended by the manufacturer relative to the medical condition(s).

Patient Satisfaction: Device was perceived to meet or exceed patient expectations of usability and outcome.

Compatibility: Device is compatible with related devices or drugs, the use environment or relevant standards.

- 1 **Safety:** Device does not compromise the clinical condition or the safety of patients, or the safety and health of users.
- 3 **Reliability:** Device system or component is able to function under stated conditions for a specified period of time.
- 5 **Usability:** Device minimizes the risk of user errors by patients or clinicians.
- 6 **Availability:** Device is available to fill first request orders.



Questions for Consideration

1. Are there additional connections between the dashboard and the model?
2. Are there internal quality system metrics or maturity model practice assessment which directly quantify device quality?
3. How does the mapping vary for different types of firms?