Product Quality Outcomes Analytics (PQOA) MDIC Case for Quality Forum

7-20-2017

MDIC

MEDICAL DEVICE INNOVATION CONSORTIUM

Charter and Review of feedback from March Case For Quality Forum

Goal:
Develop a medical device quality dashboard to guide purchasing decisions

MDIC Patient Outcome Analytics Phase II Charter

Problem Description

Stakeholders require accurate and complete data to make educated decisions to improve patient access to high quality devices. Significant challenges include:

- No standards for quality or sources of data on medical device quality (defined as safety, effectiveness, reliability, usability, patient perspective, compatibility and availability)
- No standard for analytics that provide most useful information

Objectives

By December 31, 2017, propose a program to recognize independent evaluation of product quality.

Expand product categories to include surgical mesh and endovascular graft.

Develop the methods and a proof of concept dashboard to compare device related experience, and patient outcome for use healthcare provider stakeholders through use of data describing safety, efficacy, reliability, patient perspective, usability (clinician), compatibility and availability

Deliverables are the data sources, standard (template) for metrics, definitions of the parameters to be estimated- descriptions of how to calculate each metric, and documentation of principles behind approach.

Project Scope

Included	Future Effort
Phase II • Identify and analyze registry data on safety and effectiveness • Identify and analyze hospital data on safety, effectiveness, reliability and physician preference • Establish analytical methods and revise dashboards If there is sufficient bandwidth • Gather and analyze patient perspective data • Coordinate with NEST program	• 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	12/31/17	Analytical methods defined and dashboards revised

Breakout Session notes – MDIC Forum March 30, 2017

What are precise definitions of terms and metrics? Develop standards and formulas for each quality dimension

How do product quality analytics relate to the maturity model?

Interest in how product quality is measured and understand how it works; what will the data be used for?

Great ideas on data sources and access

Provider, FDA, NEST, Payer, Registries, Manufacturing

VAC, AHA, NEST, Manufacturing, GPO, Google, IBM, patient experience, consumer's report group

For 2017 need to focus on:

- better data (data type)
- industry segment

Is the analytics vision the same across device class?

How would industry use product quality outcome analytics?

Improving Data Sources and Increasing Collaboration

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Carolinas HealthCare System

CARILION CLINIC

finding better ways

MERCY

HEALTH SYSTEM

With all our heart. With all our mind.

pcori

PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

SVS | VQI

VASCULAR QUA

MUSC Health

Medical University of South Carolina

Changing What's Possible

BAPTIST HEALTH SYSTEM

le. Compassionate care.

PROVIDENCE

Health & Services

St. Joseph's

HEALTH SYSTEM

DUKE UNIVERSITY HEALTH SYSTEM

Measuring Product Quality

What are precise definitions of terms and metrics?
Develop standards and formulas for each quality dimension

Interest in how product quality is measured and understand how it works;

1	**Safety: Device does not compromise the clinical condition or the safety of patients, or the safety and health of users.**	Number of procedures related to specific ICD10 codes resulting in deaths, injuries or complications
2	**Effectiveness:** Device produces the effect intended by the manufacturer relative to the medical condition(s).	Numbers of procedures related to specific ICD10 codes with EHR discharge status of home, low pain score or indicating high function
3	**Reliability:** Device system or component is able to function under stated conditions for a specified period of time.	% of company's products associated with reliability failures Estimated days to failure from date of manufacture
4	**Patient Satisfaction:** Device was perceived to meet or exceed patient expectations of usability and outcome.	% of users in Healthcare User Forums expressing positive sentiments about company's product
5	**Usability:** Device minimizes the risk of user errors by patients or clinicians.	% of company's products associated with usability failures
6	**Availability**: Device is available to fill first request orders.	Healthcare organization back on # of backorders
7	**Compatibility:** Device is compatible with related devices or drugs, the use environment or relevant standards.	% of company's products associated with compatibility failures

Medical Device Industry Use of Product Quality Outcome Analytics

How do product quality analytics relate to the maturity model?

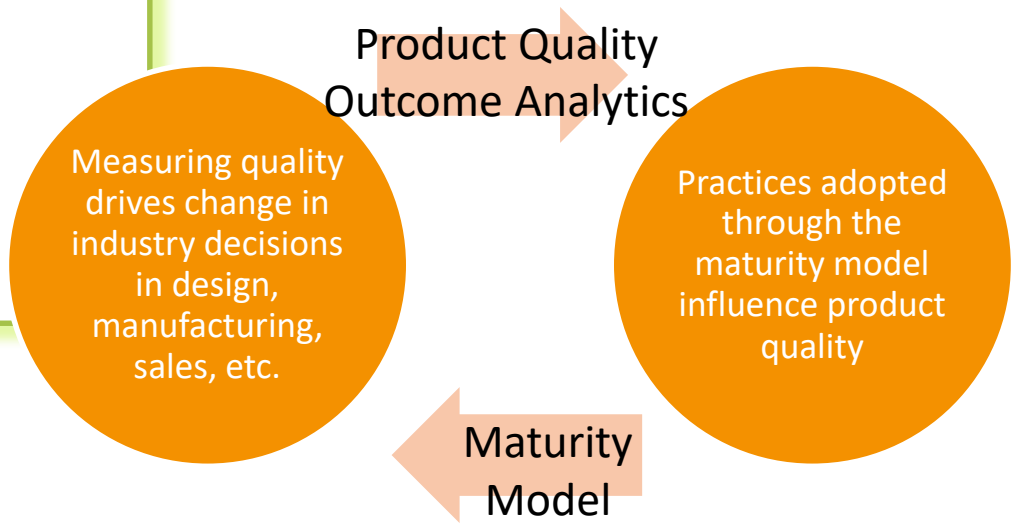
How would industry use product quality outcome analytics?

Industry accessed Sources of Patient Outcome information

- Clinical study results
- Registry information (including international registries)
- Electronic Health Record (EHR)
- Claims data
- Payer adoption
- Direct measures of Product Performance
- Integration of into Risk Management
- Healthcare Economics Outcomes Research (HEOR)
- Clinical Evaluation Reports (CER) under EU MDD requirements
- Adverse events, complaints
- Literature

Industry Users of Patient Outcome information

- Design
- Quality
- Registry- Postmarket Evaluation
- Sales and marketing



Subteam Accomplishments:

1. Registry
2. Healthcare Provider
3. Dashboards and Analysis
4. Patient Perspective

MDIC Analytics Project status: 20 July 2017

Key Deliverables / Milestones

Milestones / Deliverable	Dates	Percent Complete		
		Registry	Health Care Provider	Patient
Identify collaborators	April-May	100%	exceeded	10%
Define information	June	20%	20%	0%
Interact w source	July	20%	20%	0%
Analyze	August	0%	0%	0%
Gather feedback	October	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
- Collaborating with physicians to define data needed
- Exploring industry use of data
- Revised metrics for 2017

Analysis and Dashboard Status

Milestones / Deliverable	Dates	Percent Complete
Define data needed	May- July	20%
Define Analytics	August	0%
Revise Dashboards	September	

Issues	Mitigation
• Potential data sharing issues	• Engage with multiple potential collaboration partners • Use distributed analytics • Leverage registry efforts
• Analysis plan	• Leverage existing analytical techniques
• Communication challenges	• Intro slide deck (done) • Task NEST team (similar to proposal) • Review MDIC communications
• Funding may be required for data access	• Ask steering committee for funding to support Duke and PCORI

Registry Team

Objective	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.

Terrie Reed
FDA, UDI Adoption

Mike Schiller
AHRMM

Andrew Yoo
Johnson & Johnson

Peter Goldschmidt
World Dev Group

Pat Zimmerman
Medtronic

Vizma Carver
Carver Global Health Group

Registry

Accomplishments:

- Connected with PCORI and VQI
- Identified Endovascular grafts as having sufficient data for the dashboard
- Identified National Pelvic Disorder Registry
- Identified registry common data models

PCORI http://www.pcornet.org/pcornet-common-data-model/
VQI http://www.vascularqualityinitiative.org/wp-content/uploads/Data-Import-Whitepaper-11.28.16-2.pdf

- Exploring sharing registry data beyond research purposes
- Consider summary data (~$50k) vs raw data ($$$$)
- Discussed methods to quantify patient outcomes
- Agreed on potential mechanisms to leverage registry data in dashboard

Healthcare Provider Team

Objectives	To gather and analyze patient outcome data from at least 300 Cerner EHRs and 300 Epic EHRs by collaborating with 2 or more healthcare providers to evaluate safety and effectiveness of surgical mesh and one other device. To gather physician preference information from 30 or more physicians To gather reliability or service information by collaborating with 2 or more hospital risk managers, materials management or safety staff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Michael Waters
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Mike Ruhlen
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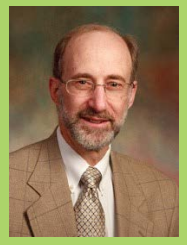
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Nathan Soderborg
Exponent


Dan Matlis
Axendia

Healthcare Provider

Accomplishments:

Participation from 9 hospital organizations:

- Carolinas
- Carilion
- VA
- Providence
- St. Joseph
- Mercy
- Baptist
- Medical University of South Carolina
- Duke

Working toward Analysis plan

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 the Phase I dashboards.

Accomplishments:

- Gathered insight on data and formulas used by Deloitte for Phase I
- Collaborated with external experts (e.g. Dell)
- Evaluated whether to build on last year or not
- Collaborating on data requirements developed by the registry and healthcare provider teams (see next slide)

- Further follow up with Deloitte to access 2016 data (MDIC action item)
- Brainstorming models and sources of guidance for using medical device data
  - RAPID core data elements mapping to 7 domains

Dashboard and Analysis


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Deloitte


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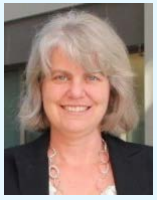
Patient Perspective Team

Objectives	Develop an understanding of available patient perspective data and its utility in the product quality dashboard. Get data from 2 or more patient perspective sources, develop methods for analysis for integration in dashboard

Patient

Dan Matlis
Axendia

Jeff Kaser
DePuy



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Accomplishments:

- Researched existing efforts (MDIC NEST, NHS PROMs, AHRQ consumer assessment of healthcare systems)
- Contacted sources of patient perspective (PCOR net, hospitals, NHS PROMs)
- Leveraging MDIC Patient committee
- Focus on gathering patient perspective in 2017; gathering patient feedback after dashboard is refined

Phase III- Gather feedback from patients and develop report

- Focus on 7 dimensions of quality What is more important to patients?
- When talking to healthcare provider how can they discuss outcome? During a clinical trial, S&E is defined from a clinician/industry perspective. Different needs other than S&E?
- What differences are there with patient perspective? Meaningful answer from patient perspective
- Gather feedback from collaborators such as Cardiovascular- American Heart Association

NEST Update

1) NESTcc announced this week the inaugural members of their Governing Committee for NEST. You can find the press release and biographies for the Governing Committee in the website below (click on each member's picture):

http://mdic.org/wp-content/uploads/2017/07/NESTcc-GC-Press-Release_07132017.pdf

http://mdic.org/cc/governing-committee/

2) NESTcc also announced this week their first call for demonstration projects. You can find more information here:

http://mdic.org/demonstration-projects/

References

MDIC Case for Quality Program - Product Quality Outcomes Analytics working group
Feasibility and Effectiveness of Analytics for Medical Device Product Quality Outcomes
September 20, 2016
http://mdic.org/wp-content/uploads/2016/08/Final.MDIC-Product-Quality-Outcomes-Analytics-Report.pdf

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