Case for Product Quality Outcomes Analytics
26-October-2016
Agenda

- Who we are and how we fit into Case for Quality
- What is quality?
- Hypothesis and pilot journey
- Key outcomes
- Challenges and mitigation options
- Envisioned future
Product Quality Outcomes Analytics Project Team
### Our place in Case for Quality

**Device Quality Metrics**

- **Comprehensive Improvement**
- **Quantity Management**
- **Process Standardization**

**Maturity Model**

<table>
<thead>
<tr>
<th>Level</th>
<th>Capability</th>
<th>Result</th>
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</thead>
<tbody>
<tr>
<td>5</td>
<td>Organizational alignment, deployment, and integration</td>
<td>Productivity &amp; quality</td>
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<tr>
<td>4</td>
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<tr>
<td>3</td>
<td>Organizational alignment, deployment, and integration</td>
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<tr>
<td>2</td>
<td>Project Management</td>
<td>Productivity &amp; quality</td>
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<tr>
<td>1</td>
<td>Resource</td>
<td>Productivity &amp; quality</td>
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**Competency**

<table>
<thead>
<tr>
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<tr>
<td><strong>Leadership</strong></td>
<td>X</td>
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<tr>
<td><strong>Project Management</strong></td>
<td>X</td>
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<tr>
<td><strong>Innovation</strong></td>
<td>X</td>
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<tr>
<td><strong>Analysis</strong></td>
<td>X</td>
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<tr>
<td><strong>Execution</strong></td>
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**Product Quality Outcomes Analytics**

- **Outcomes Management**
- **Analytics**
- **Analytics**

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What is quality?

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

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

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

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

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

6. **Availability**: Device is available to fill first request orders.

7. **Compatibility**: Device is compatible with related devices or drugs, the use environment or relevant standards.
“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.”
Our journey and key outcomes

**Extract information across seven quality domains**
- Safety
- Effectiveness
- Reliability
- Usability
- Compatibility
- Patient Experience
- Availability

**Generate and share dashboards**
- Hospital Value Analysis Committees
- Manufacturers

**Gather Voice of Customer feedback**
- Surveys
- Focus group sessions

**Report out observations and recommendations**
- Ways to improve data robustness
- Operating model to scale and sustain access to this information in the future

**Gather data from multiple sources**
1. Interviews with Value Analysis teams to understand current state
2. Publically available (e.g., FDA MDRs, PubMed, Healthcare User Forums, Clinicaltrials.gov)
3. Registries

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1. Interview with Value Analysis teams to understand current state.
2. Publically available (e.g., FDA MDRs, PubMed, Healthcare User Forums, Clinicaltrials.gov).
3. Registries.
Current state for value analysis teams

1. VACs want more reliable data from independent sources.

2. VACs are frustrated by lack of availability and delay in being able to obtain research from third parties.

3. Data and analytic models lack a standard method to harmonize across sources for a holistic view of quality, while maintaining source data meaning and integrity.
Response from manufacturers
24 manufacturers responded

23/24 respondents from manufacturers said their company tracks data about quality or performance of commercialized products in the field.

Currently use information about product quality to improve product design & lifecycle take corrective actions.

Added value of this pilot:
- benchmark
- unbiased information
- drive product improvement

Specific concerns:
- Use of data by regulators, competitors and customers
- Privacy concerns
- Difficulties for companies to provide required information
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.
VAC feedback on dashboard effectiveness

“Extremely beneficial.”

“Excited and loves the model.”

“Very user friendly, especially for clinicians.”

“Easy to view at a quick glance.”

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.
Challenges and mitigation options

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

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<thead>
<tr>
<th>Challenges</th>
<th>Mitigation Options</th>
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<tr>
<td>Data Source Limitations</td>
<td>Data Access</td>
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<tr>
<td>• Data quality</td>
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<td>• Data bias</td>
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<td>• Lack of comprehensive product library</td>
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<td></td>
<td>• Use barcode technology for data capture</td>
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<td>• Ease access to unbiased data sources</td>
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<td>• Encourage adoption</td>
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Data Source Limitations:
- Data quality
- Data bias
- Data availability

Data Access:
- Unknown territory
- Process limitations
- Lack of comprehensive product library

Adoption:
- Market demand
- Product differentiation
- Financial barriers to entry
2015
Leveraged the MDIC FDA CfQ platform to bring together a multidisciplinary team

2016
Partnered with 3rd party to pilot comparative product quality outcomes dashboards

2017
Proposed next steps for the team:
1. Conduct pilot in partnership to specific registry.
2. Work with specific professional organization to develop methods to measure and track usability.

Plan
Developed a charter and plan to pilot analytics for comparative analysis of product outcomes

Feasibility Pilot
Recommend that **three key areas still be addressed:**
1. Third-party adoption and development of quality domains.
2. Creating demand for the quality criteria across provider stakeholders.
3. Development of formal feedback mechanisms

Access and Adoption Pilot
3. Conduct pilot with set of hospitals to pool data improve dashboards.
4. Conversations with group purchasing organizations and 3rd party data analysis groups.
5. Coordinate with the National Evaluation System for health Technology (**NEST**).