Xavier Health CQO Quality Redesign

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By:

Stephanie Antoun, Nicholas Roetting,

Nicole Rogowski, Austin Shady, and Samantha Weaver

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Xavier Health

In today's healthcare environment, it is evident that many aspects of healthcare, including the way health care organizations provide quality outcomes, will need to change. Innovation and cross-dimensional forward thinkers are building the landscape of our future. One specific organization with an innovative philosophy and action plan is Xavier Health. Xavier Health prides themselves on being an innovative and collaborative organization with several initiatives and goals. The mission of Xavier Health is, "inspiring collaboration, leading innovation, and making a difference in all that we do" ("The Xavier Health Mission", 2018).

Xavier Health's medical device and pharma culture and metrics initiatives collaboration consists of many entities including the FDA, academics, industry experts, and thought leaders for the healthcare and business environment. The work being done by these experts will power differences in many industries including medical device, pharmaceutical and combination product industries. One initiative is to bring the Food and Drug Administration (FDA) and pharmaceutical companies together to promote change. Inside this initiative is a collective effort by the FDA and pharma industry to collect and analyze quality metrics. To further this work, a continuous quality improvement consortium was born with a goal to redesign the field of quality operations such that quality permeates all functions to maximally increase the value of the company for all stakeholders (Phillips, 2018).

Assignment & Goals of the Project

Xavier Health has been working with executives in the Pharmaceutical and Medical Device industries, referred to as the Chief Quality Officers (CQOs) Consortium, on ways to increase business value by observing and improving current processes and operations found within the quality department. It is our understanding that the end goal of the project between Xavier Health and the CQOs are to find a way to keep quality intact without having a quality department. Xavier Health identified two different, but related, approaches that it would like the team to look at to begin this process. The first step was for the team to analyze a set of survey responses given to the CQOs and other executives within both industry about their views on quality. The survey was composed of three questions:

- The first question was "What should the Quality Department STOP doing?"
- The second question was "What should the Quality Department START doing?"
- The final question was "If your Quality Department did not exist, what would your company do differently to ensure product quality?".

The survey was sent to a large group of CQOs and executives and received 52 responses. With this information, the team was to analyze the responses from the survey and identify trends and opportunities that can be made about quality to help inform Xavier Health and their clients.

The second related step for the team was to investigate industries other than the Pharmaceutical and Medical Device industry, find their strategies on how they maintain quality, and see if there may be some applicable use of those strategies within the Pharmaceutical or Medical Device industry. First, an understanding of how quality operates within the Pharmaceutical or Medical Device

industry was needed, so that a comparison and analysis could begin. The Pharmaceutical and Medical Device industries use audits as a process tool for maintaining quality, so finding other processes that assure quality was the primary objective of this approach.

Finally, the group would take the information obtained from both approaches to see where common themes developed between the two to inform the investigative team on specific gaps for consideration. Potentially finding processes utilized by other industries and identifying the need for those processes within survey responses were desired above anything else. With this information collected by the team, Xavier Health will now have meaningful and impactful information to identify potential processes to eliminate the role of a quality department but allow quality itself to flourish. A final business report and presentation was created to inform Xavier Health of the findings made by the team.

Data Investigation

The team was provided access to the responses of the Qualtrics survey administered to the members of the Chief Quality Officer Consortium in April, 2018. The team was tasked with summarizing the industry responses on how the quality function can become more effective. Through this summary, the team was to identify trends and opportunities that would support the future work of the Consortium.

The data set included responses to the following three questions:

- What do you wish the quality department would START doing?
- What do you wish the quality department would STOP doing?
- If your quality department did not exist, what would your company do differently to ensure product quality?

Of the 53 CQO Consortium members the survey was issued to, 47 of them provided input on at least one or more of the survey questions. The survey asked for three examples from the START question, as well as three different examples from the STOP question. As a result, respondents could provide up to 6 unique answers for the first two survey questions. With the large amount of qualitative data, our team had to create a way to quantitatively analyze the data set to identify common themes amongst the responses.

First, the data team exported the survey responses to MS Excel and cleaned up the data set (i.e. eliminated the no responses, formatted the data, etc.). The answers to the questions were then read individually, and a general theme (i.e. sub-theme) was identified. After the individual team members read and categorized each response, consensus was achieved. For example, one question was, “I wish the quality department would stop… just reacting to problems and start preventing them.” This question was assigned the sub-theme “Reactive vs. Proactive. There were a total of 109 responses for the STOP question and 110 responses from the START question for a combined total of 219 unique responses. Survey responses that were unable to be construed by the data team were discarded. Table 1 below shows the breakdown of the STOP question response sub-themes.

Table 1: Summary of STOP Question Sub-Themes

Stop Theme	Frequency of answer (n = 107)
Partnership with business operation & an understanding of customer expectations	17
Proactive (front end) quality checks vs. Reactive/Inactive	16
Collaborating vs. Working in a Silo	15
Clear & comprehensible documentation & processes	15
Empowering	13
Risk-Tolerant	7
Big Picture (i.e. Enterprise thinking)	7
Shared Responsibility of Quality	6
Value-added work	6
Innovation and Technology	4
Continuous (process) improvement efforts	1
Data supported decision making	0
Participatory	0

In the table above, the top 3 sub-themes identified were: *Partnership with business operation and an understanding of customer expectations, Proactive (front end) quality checks vs. Reactive/Inactive,* and *Collaborating vs. Working in a Silo*. The same process was repeated, using the data from the START questions. Table 2 shows the breakdown of the START response sub-themes.

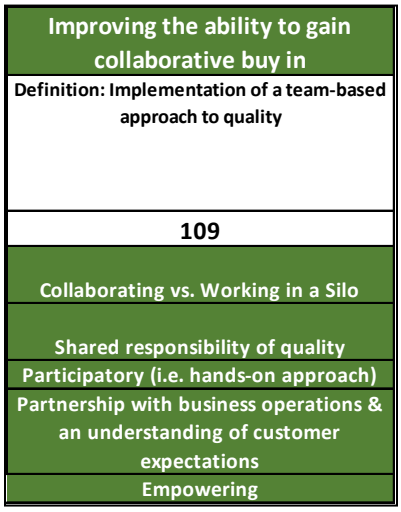
Table 2: Summary of START Question Sub-Themes

Start Theme	Frequency of answer (n = 102)
Collaborating vs. Working in a Silo	26
Partnership with business operation & an understanding of customer expectations	17
Big Picture (i.e. Enterprise thinking)	10
Empowering	9
Innovation and Technology	6
Data supported decision making	6
Participatory	6
Proactive (front end) quality checks vs. Reactive/Inactive	5
Clear & comprehensible documentation & processes	5
Risk-Tolerant	5
Continuous (process) improvement efforts	5
Value-added work	2
Shared Responsibility of Quality	0

The top 3 sub-themes identified in the START question were: *Collaborating vs. Working in a Silo, Partnership with business operation & an understanding of customer expectations,* and *Big Picture (i.e. Enterprise thinking*). With 13 different sub-themes identified in the first pass, the team began a secondary review of the data to whittle down the sub-themes into a manageable grouping of overarching (i.e. major) themes.

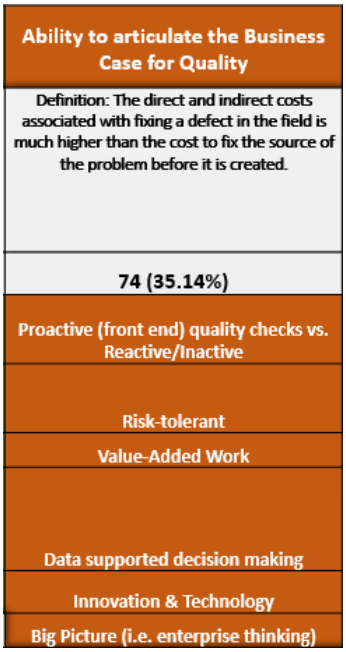
The first theme, *Improving the Ability to Gain Collaborative Buy In*, was the most prominent. This category was defined as the implementation of a team-based approach to quality. Many of the answers from the survey indicated that quality should be something that the whole organization was actively engaged in, not just the quality department. Over half of the survey responses (109/209) were rooted in this theme. Figure 1 below shows the breakdown of what was included in this category

Figure 1. Definition, number of responses, and categories for *Improving the Ability to Gain Collaborative Buy In*.



The second theme to emerge from the data set was an *Ability to Articulate the Business Case for Quality*. This theme was defined as, "The direct and indirect costs associated with fixing a defect in the field is much higher than the cost to fix the source of the problem before it is created." This category was about understanding the importance of quality from a business perspective. Many of the answers in the survey indicated that the quality department was so far separated from operations, that employees outside of the quality department didn't understand why it was important to get things done right the first time. Figure 2, below, shows which subcategories were included in the theme.

Figure 2. Definition, number of responses, and categories for *Ability to Articulate the Business Case for Quality*



The last theme that stood out to the team was a *Focus on Practical Process Development*. This theme was defined as, "Knowledge of process history so as not to repeat a past problem. Process standardization to achieve consistency and an understanding of the way the product is produced at any given time." This theme was about making sure that there is clear and comprehensible documentation for processes and that continual process improvement efforts are undertaken. Figure 3, below, shows which subcategories were included in the theme.

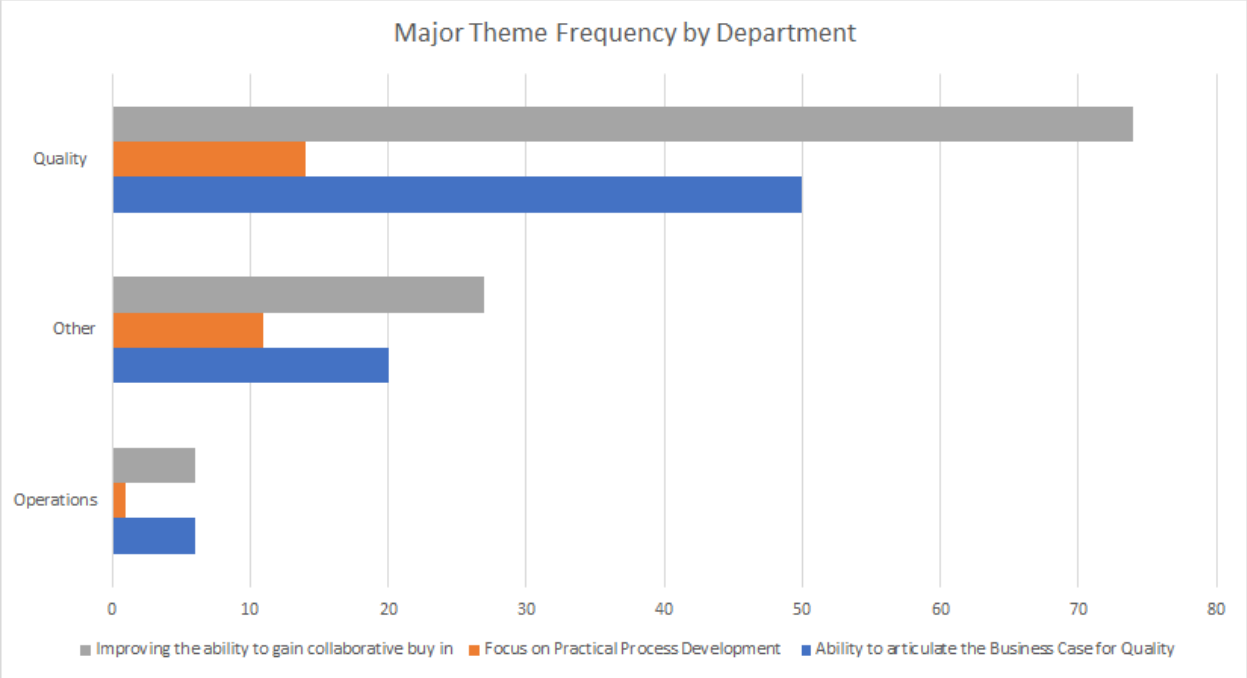
Figure 3. Definition, number of responses, and categories for *Focus on Practical Process Development*

Focus on Practical Process Development
Definition: Knowledge of process history so as not to repeat a past problem. Process standardization to achieve consistency and an understanding of the way the product is produced at any given time.
26
Clear & comprehensible documentation & processes
Continuous (process) improvement efforts

It was inherently clear from the data that *Improving the Ability to Gain Collaborative Buy In* was the most common theme present in the survey responses. The need for shared responsibility and accountability is paramount in making sure the team functions well, and ensures the utmost quality in a company's products. Not only does everyone need to participate, but in order for the company to survive, they have to make good business decisions. The *Ability to Articulate the Business Case for Quality* is important because without making data supported decisions, the company is, at best, making blind guesses for what to do next and will waste precious resources reacting to problems instead of proactively improving processes. Lastly, a *Focus on Practical Process Development* allows companies not to get bogged down in overly complex processes and ensures that quality is a continuous process instead of one-time checks.

As important as it is to understand the breakdown of responses at their face value, it is also important to understand how the departments (e.g. the quality department or the IT department) answered the questions. To do this, the team broke down the survey responses by individuals' departments in their respective organizations. The data is somewhat skewed, since the majority of the answers (66%) came from individuals' in the quality department. The results were interesting though, with the quality department itself saying that quality was something everyone needed to collaborate on. Figure 4, below, shows the breakdown of the responses by department.

Figure 4. Responses grouped by department



After the team analyzed the data by departments, it was important to understand how people in different positions answered the STOP and START questions. For the first theme, *Improving the Ability to Gain Collaborative Buy In*, over a quarter of the 109 responses (26%) were from the Vice President level. The next biggest groups, at 20%, were directors, followed by Heads at 17%. This means over half the responses (63%) were from the Head level or above. The data on this question would indicate it is middle and upper managements' feeling that quality has been put in its own silo, and that needs to change. Figure 5, 6 and 7 below, shows the breakdown of the themes responses.

Figure 5. Distribution of executive level survey themes

As shown above in **Figure 5**, 48% of employees at the Executive level believe that quality needs to improve its ability to gain collaborative buy in. 40% of executives believe that quality needs the ability to articulate the business case . For executives, it appears as if collaborative buy in is the most important thing that a quality department can start to improve. It would appear that executives need to issue general guidelines about how they would like the quality functions to run within a business. How does this compare with Middle Management?

Figure 6. Distribution of middle management level survey themes

In **Figure** 6 which shows the themes for Middle Management, 55% of the group believed that they needed to improve the ability to gain collaborative buy in. This group also believed that it was imperative for the quality team to understand why the cost of doing business would go up if they were not proactive in their approach to quality. It was also seen as important to follow data supported decision making, and make sure that everyone was seeing the big picture. Finally, front-line workers were analyzed.

Figure 7. Distribution of Front-Line employee survey themes

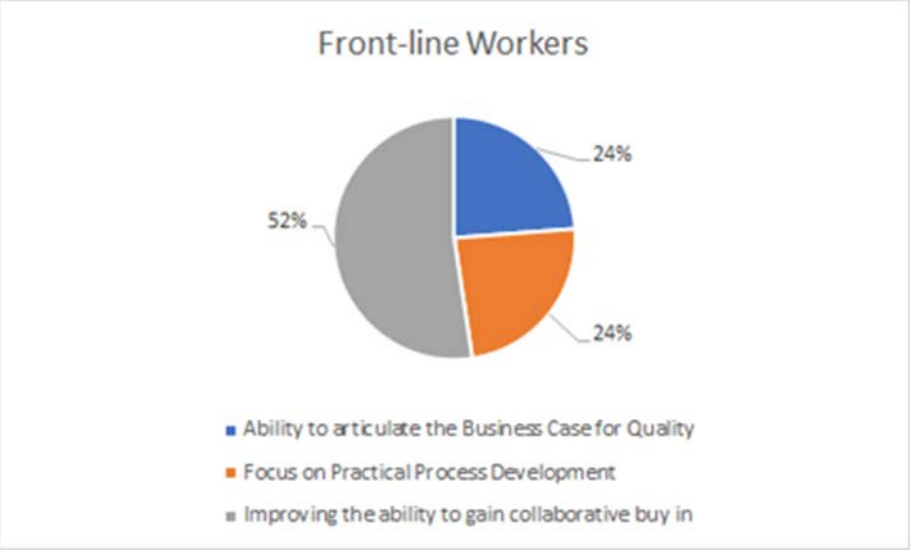


Figure 7 shows the distribution of front-line level employees. Although they thought getting collaborative buy in was important, 48 percent were split on articulating the business case for quality, and a focus on practical process development. This could indicate that front-line employees feel bogged down by overly complex SOP's, or that they don't believe management understands the business case for quality.

Quality Investigation

The Quality investigation was completed through an online literature review and identifying to interview quality-subject matter experts. Two of the individuals interviewed work in manufacturing, and the third is a manager who works with data quality outcomes at an academic medical center. The manufacturing interviews consisted of talking to Sue Weaver, CEO of BESI Inc., and Kyle Mueller, Quality Engineer at Hill-Rom. Nicky Kurtzweil works at the University of Cincinnati Cancer Institute, Clinical Trials as a Data and QA manager. Utilizing the three culture themes identified by the data team helped bring out more supporting evidence of their importance to quality. The quality investigation team went through the three interviews to identify where these organizations were using, or hoped to use the cultural themes. Research was also done to support the cultural themes and to find new areas to potentially consider in regards to quality.

Through the interview process, the quality investigation team was able to identify common themes that reflected the survey culture themes identified by the data team. The four questions asked were:

- How does your organization do quality?
- What works well in regards to quality in your organization?
- What does not work (either currently or in the past, if they have changed how they do quality, what that process was like, did it work)?
- What does the future of quality look like for your organization (implementing technology to assist)?

Through all the responses and conversations with everyone, it was noted that culture is a foundation of superior quality. Culture drives a lot of what an organization does, along with how successful they are. The three culture themes the data team identified are described and supported through the interview responses and research.

The first theme that was identified was *Improving the Ability to Gain Collaborative Buy In*. Through key interviews, experts from Hill-Rom, BESI, and UC Cancer Institute Clinical Trials office, they all agree with this culture theme. BESI Inc. stated that by putting an ISO in place, this forced them to write all processes down, opposed to having just one or two people hold the information themselves. This supports collaboration vs. working in a silo and shared responsibility of quality. The ISO collaboration also identifies the partnership with business operations to help set the business quality standards.

Another aspect of improving the ability for collaborative buy in is for it to be participatory (hands-on). In a smaller manufacturing organization, like BESI Inc., they are very hands on with the products they make, thus every person working on that product will have to evaluate each piece and

understand if anything is wrong with the product before sending it out. It is also making sure that the product meets the quality standards as it goes through the manufacturing process. These hands-on tasks are not necessarily completed at larger companies due to the machinery or processes that they have. If as opposed to it, a larger organization can have quality checks, or standardization on larger manufacturing equipment processes, they can still achieve the same goal with checks and balances.

Collaboration can happen easily in teams, it is a natural occurrence. However, people who work in different roles and departments are less likely to collaborate. If an organization can collaborate cross functionally, it helps with business performance and quality. Advantages of cross functional collaboration: different perspectives spur innovation, increased momentum change, everyone learns more, old ideas are challenged, and the playing field is leveled. While collaborating cross functionally seems great, in reality it is very difficult to actually achieve. There are many reasons as to why an organization has difficulties implementing it: Lack of trust, social loafing, poor communication, misaligned goals and objectives, and divergent technologies. While collaboration can be difficult to implement successfully, it helps drive quality (Nexus, 2018).

The second theme which states that organizations *Should Focus on Practical Process Development*. Process development is accomplished through standard operating procedures (SOPs), this helps employees understand how to accomplish specific tasks appropriately. The UC Cancer Institute identified that in utilizing SOP standardization tools that are currently being worked on as to support the culture theme of a clear and comprehensible documentation and processes. Utilizing continuous manufacturing under continuous process improvement efforts is important and something that P&G emphasizes. Continuous manufacturing is exciting new technology that can replace the current pharmaceutical approach of “batch” technology.

The Third and final culture theme that was identified and researched was the *Ability to Articulate the Business Case for Quality*. This theme had the most responses through the interviews. Almost every sub category underneath this theme had a response regarding what the organization is doing, or is aiming to do in the future.

The Hill-Rom expert Kyle Mueller identified that being proactive is a significant part of quality. Kyle stated that identifying quality partners and sub-contractors is important to ensure quality standards are met. One important theme identified under the sub- theme of *Ability to Articulate the Business Case for Quality* of proactive quality is predictive quality. Using predictive quality checks applies statistical algorithms to determine patterns. Another sub theme identified was innovation and technology. Innovation and technology is critical for managing quality and to gather accurate research results as stated by UC Cancer Institute expert, Nicky Kurtzweil. Nicky Kurtzweil worked at University of Wisconsin and stated that the University pulled data directly out of their EMR to their database system in order to capture data correctly for studies and to eliminate human error.

Another trend identified under *Ability to Articulate the Business Case for Quality* is a philosophy of crowd sourcing. Crowd source testing can offer an alternative for enterprise testing by testing different group or functions with a process that could offer more diversity, flexibility, speed and cost-effectiveness for industries that lack resources or time to carry out the testing process ("A 5-Minute Guide to Crowdsourced Testing", 2017). Enterprise thinking also emerged as a trend. Enterprise thinking reworks and rethinking the roles and values of organizational leadership. At Proctor and Gamble, they show enterprise thinking by having more than the industry standard number of engineers in their quality department and in senior leadership.

Continuing process improvement is also very important when it comes to quality. The UC Cancer Institute recognized the need to develop and implement robust QA systems and culture of compliance is a first step to ensuring quality at UC. The current leadership is actively seeking culture and process change in a real way, this top-down buy-in is present and appreciated. Re-structuring of oversight/management with continued partnership with physician-researcher training/education on best practices, healthy turnover and hiring of qualified staff in all areas (including a dedicated QA team) and development of SOPs and accountability practices/metrics capture and reporting will lay a foundation that will take at least 6-10 years to mature into standard quality practices within this organizational unit.

The last sub- theme under *the Ability to Articulate a Business Case for Quality* is seeing the big picture. The UC Cancer Institute wants to become a national cancer institute. In order to achieve this, the department's research needs to be perfect in regard to the quality of data that is collected. This in turn shows a business need for the department to have these quality projects and innovations to be put into place. Each organization has a big picture that they are ultimately trying to achieve. Communication of the big picture the organization has is a critical aspect of developing buy-in to the business case.

Conclusion

It is important to note, a secondary interpretation of survey data is unequivocally subject to some degree of reviewer bias. The Capstone data team attempted to uphold the integrity of the original survey responses when inferring sub-themes, and subsequently major themes. If the same process was to be repeated by a different review team, a subset of responses could potentially be interpreted differently. To minimize reviewer bias, having access to the 53 individuals surveyed in order to clarify respondent intent would have been helpful in maintaining the integrity of the responses. Additionally, to strengthen the effectiveness of the external quality investigation, the team would have recommended performing the 2 project components in succession as opposed to in parallel. This way, the survey themes would have been identified upfront, and industries specifically doing these items well would have been sought out versus a more random investigation approach. Due to the strict project deadline, the Capstone project team decided to focus on a thorough analysis of the survey data. As a result, limited time remained to work on the external quality investigation once the survey themes had been identified. As a result, it is the recommendation of the Capstone team that a second external industry quality investigation be conducted based on the culture themes identified in the survey analysis.

The purpose of the Capstone team's work was to lay the foundation for future initiatives to be carried out by the Xavier Health CQO Consortium. In addition to a second quality investigation, the Capstone team proposes identifying a group of front-line operations staff to be surveyed. It would be beneficial to compare responses provided by front-line staff to those provided in the initial survey, which consisted primarily of executive level staff. Given the fact that the dominant survey theme is collaborative buy-in, an organizational quality assessment provided by all staffing levels seems like an appropriate next step if feasible. Additionally, the Capstone team feels that front-line operations staff might provide more insightful answers to the third survey question, because there would be no conflict of interest in terms of the hypothetical elimination of the quality department.

Another recommendation for information would be additional subject matter expert interviews from external industries. For example, the P&G discussion with Stu Merdian and William Brenneman unveiled key differences in manufacturing's approach to quality (S. Meridian, personal communication, June 28, 2018). Specifically, the importance of front end predictive quality control to determine what will happen on the back end, and not the other way around. Also, the importance of eliminating "touches" (i.e. the fewer times a product must be touched by human hands the less likely it is to have errors).

In conclusion, the task of reviewing 219 survey responses seemed like a daunting task at first, but after several passes through the data, commonalities among responses quickly began to emerge. This occurrence supports the statement of purpose and goals of the Xavier Health CQO Consortium by quantitatively providing evidence into the shared issues and opportunities for improvement facing the pharmaceutical and medical device industries. By translating the responses from the survey, it was demonstrated that the ownership of quality lies with the total enterprise, and not just the quality department. The survey responses further demonstrated that there is a business case to support this team ownership. The Consortium can use the survey outcomes as their set of guiding principles for achieving quality across the industry. The next step will be to identify tangible process changes for achieving a collaborative approach to enterprise-wide quality.

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Appendix

Appendix A- Interviews for Quality Investigation

Interview with Sue Weaver, CEO of BESI Inc.

How does your organization do quality? We follow a process called International Standard Operation (ISO) we have our own internal auditors and we are audited by an outside company, the outside company can recommend us for certification or issue minor or major if not following the standard. The standards are written by us within the guidelines of ISO that we state we will follow.

What works well in regards to quality in your organization? Having ISO in place, we have several manufacturing facilities and having a written standard on how we do things is very important. By having this in place we are accountable for our actions and reactions. We also have a process that is measurable, which helps us monitor and track how well we are doing.

What does not work? (Either currently or in the past, if they have changed how they do quality, what was that process like, did it work?) The process only works if everyone is following procedure, and the checks and balances are in place. Being a family owned business with just one facility most everyone is on the same page. When we started opening up other facilities is when we saw the need for having written processes in order to keep our quality consistent. By putting ISO in place this forced us to write everything down, therefore not having information with just one or two people. This really became evident with the passing of the founder and two of the sons left the company as they were the ones with most of the information stored in their heads.

What does the future of quality look like for your organization (implementing technology to assist?) Within our business we have made the decision to continue with ISO, we believe if we didn't certain aspects of what we do to measure consistence's would laps over time. We do track most everything via input into a computer, however a lot of what we do has to involve a manual process because of making the products.

Interview with Nicky Kurtzweil, Data & QA Manager at the University of Cincinnati Cancer Institute

1. How does your organization do quality?

- As a clinical research site housed within an academic medical center, quality assurance processes and systems need to be incorporated into almost every aspect of the organization. Quality in a clinical research setting is meant to ensure: patient safety is protected; our site is in compliance with all laws & regulations; and, that all data collected is accurate and complete. We "do" quality by following our research protocols and internal workflows in a standardized and consistent manner. We accomplish this by implementing internal QA controls such as: SOPs, CRFs, checklists, routine training, internal audits of work performed, compliance metrics reporting and trend analysis, etc.… We also utilize external controls such as data safety monitoring board reviews, IRB annual reviews, industry sponsor monitoring, and monitoring by central campus to provide an external check on our performance.

2. What works well in regards to quality in your organization?

- UW: QA that works well at UW relies on robust internal processes for ensuring staff education levels remain high and that accountability for work performed is transparent. Monthly internal trainings for all staff, formal 3 day hands on trainings, 1:1 trainings for new staff within specialized disease teams help ensure all SOPs and good clinical practices are known to staff and Investigators.
  Accountability for quality of work is ensured by QA by internal auditors at 1st enrollment, 6 months, and by robust DSMB reviews (all SAEs, AEs, industry monitoring, internal monitoring, lapses in IRB approval, deviations, turnovers, and all grade 5 events reviewed). Committees of staff members meet to design new tools and forms and this allows for buy-in by staff. DSMB/PRMC are well staffed and have robust practices. Reporting of QA compliance and training metrics to leadership is routine and occurs for staff performance as well.
  Ongoing quality is achieved by the use of a single CTMS for all processes (PRMC, DSMB, effort, QA, invoicing). It is critical for capturing the metrics needed to help spot compliance trends and reduce human errors (data is captured directly from EMR). SOPs are updated regularly and are used as daily reference points for staff. External controls such as industry monitoring, central campus auditing, continuous incorporation of best practices through peer organization networking (Big 10 Cancer Consortium, AAHRPP, PRIMR, UW ICTR & PAMs, AACI etc..) and IRB reviews all aid in ensuring ongoing QA.
- UC: Recognition of the need to develop and implement robust QA systems and culture of compliance is a first step to ensuring quality at UC. The current leadership are actively seeking culture and process change in a real way, this top-down buy-in is present and appreciated. Re-structuring of oversight/management with continued partnership with physician-researcher training/education on best practices, healthy turnover and hiring of qualified staff in all areas (including a dedicated QA team) and development of SOPs and accountability practices/metrics capture and reporting will lay a foundation that will take at least 6-10 years to mature into standard quality practices within this organizational unit.

3. What does not work? (either currently or in the past, if they have changed how they do quality, what was that process like, did it work?)

- UW: in the past had each research group following its own SOPs, negotiating its own contracts, and this led to poor revenue streams and inconsistent practices. Now, budgeting is performed by a single group of dedicated specialists and a single QA team handles SOP management for all disease groups.
- UC: There are *many* systems which do not work well. See response to #2.
  A lack of accountability for staff work through failure by managers/leadership to create and enforce SOPs, protocol standardization tools such as CRFs, checklists, standard file organization and office records organization, and no formal training mechanisms for both staff and Investigators is leading to serious quality issues in the manner data is collected and studies are performed.
  A licensed CTMS which is limited in its functions (no financials usage, no EMR draw, no ability to use for PRMC/DSMB, and limited compliance reporting) and whose use by staff is incomplete or inconsistent at best, coupled with no other standard method for tracking staff effort, protocol or

staff specific compliance issues, etc.…has led to a complete lack of reliable QA metrics and oversight.
Moreover, a lack of effective external controls (ineffective and often conflicted PRMC/DSMB) have allowed trial volumes to increase which have compounded the present QA risks.

4. What does the future of quality look like for your organization (implementing technology to assist?)

- UC: See the response to #2. In addition, the potential acquisition of a CTMS in the near future may potentially reduce the timeline to 3-5 years.
  Quality relies on accurate metrics in clinical research – technology is critical for managing the volume of data a clinical research program of this size will generate.

Interview with Kyle Mueller, Hill-Rom Quality Engineer

What is not working: European issue surrounding breast implants. Entire scandal caused by suppliers not keeping their man faction process in line with company. EU changing how the regulate devices.

Look at predictive quality. Not a lot of companies do this well.

What is working: Things that each company does well, but nothing across the board the everyone does well. Companies keep what they do well confidential.

If a company is willing to pay for technology, it can help. Companies have to be set up to this this, it doesn't happen overnight. Robust system put in place means hard to change.

How do you turn quality upside down: Look outside your processes.

2 main aspects of quality:

Quality Assurance: manufacturing, work instructions, SOP's (drive requirements), post market surveillance.

Regulatory Affairs: dealing with regulations, country-by-country requirements which are similar but not the same. Currently have 250 countries. How do you maintain the same quality with all the different standards? Some countries have reciprocity. This is hard for the markets, how do you consolidate markets so it's easier for companies?

In reality, we should not have quality, it should be built in. Develop quality system that has forms that inherently comply with quality. Poke yoke. Have to be prescriptive for someone to use the form.

Pharmaceutical and medical device are two different things. Pharmaceutical's are ingested.

*It seems like a mixed bag of wanting to have a robust system where there is no room for error and creating flexibility to inspire critical thinking and change to improve. Which culture do you create?