Establishing a Quality Index: One Eye Bank's Experience Developing a Quality Measurement Tool for Reporting on Tissue Safety and Regulatory Compliance

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The Eye Bank Association of America (EBAA) requires that accredited eye banks formally establish a quality assurance department capable of monitoring and evaluating functions performed at the eye bank.[i] The Food and Drug Administration (FDA) similarly requires that an organization performing manufacturing steps related to human cells, tissues and cellular and tissue based products (HCT/Ps) have a quality assurance program that performs periodic audits for management review.[ii] At the time of this editorial, it is largely at the discretion of eye banks to develop internal evaluation systems concerning tissue safety and regulatory compliance. This is reasonable given that eye banks vary in size, resources, and functions performed. Rates of growth, evolution, and maturation of the quality assurance programs themselves are also unique.

At Lions VisionGift (LVG) we believe there is an inherent responsibility to our donors, recipients, and staff to continually ask the question "how are we doing?". In 2011 we examined this question in depth. This process brought to life many other questions requiring an answer such as "What does quality really mean to our organization?", "How do we define quality and what are its measurable parts?", and "How do we communicate information about quality in a way that is transparent and accessible to all levels of the company?".

We knew that the answers to these questions had to work across different departments and address the difficulty of comparing the many complex and specialized systems within the eye bank. For example, we needed to address evaluating the performance of a 15-person Recovery Department (in charge of recovering precious donor tissue) in relation to a 4-person Eligibility Department (responsible for eligibility determinations and releasing tissue for trans-

plant). To address these differences we sought a common denominator, a metric that could be measured, analyzed, and communicated across all departments. This allowed for creation of a grading system to consistently evaluate our level of "quality" over time. This grading system is based on performance indicators for individual departments,with findings weighted differently depending on their nature and severity. In this editorial we discuss our experience developing the LVG Quality Index System and present some hypothetical cases for comparison.

LVG started at the same place as everyone else: with a mission to provide safe and effective corneal tissues for clinical and non-clinical use, a stack of regulations telling us what to do but not necessarily how to do it, and a group of dedicated people doing their utmost to get it all right.
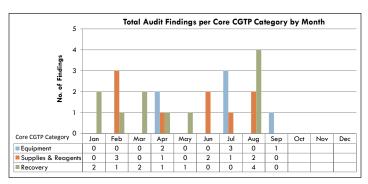
We were exploring different indicators that might be relevant to identifying performance trends and defining benchmarks. We looked to our internal audit program for data to communicate to management how well each department was complying with tissue safety regulations. Audit findings were tagged with the audit type, the relevant Core Current Good Tissue Practice (CGTP).[iii] Standard Operating Procedure, responsible department, source of documentation, and severity of the finding.

We were primed for evaluating data in a multitude of ways but were not yet sure what indicators would be most revealing.

Internal audit results were categorized by CGTP and reported in bar graphs according to the audit type they were discovered under (Figure 1). We knew the total number of findings per category but could not account for fluctuations in our sample size per audit period. Individual departments

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Figure 1: *Total Audit Findings per Core CGTP Category by Month*

Hypothetical example of audit findings by category. Blue bars = Equipment Findings

Orange bars = Supplies & Reagents Findings Green bars = Recovery Findings

were also struggling to understand how their performance related to the whole as multiple departments may be assessed under one type of audit. We concluded that a ratio would be suitable for comparison purposes and that the changes in this ratio over time would be an appropriate tool for establishing benchmarks.
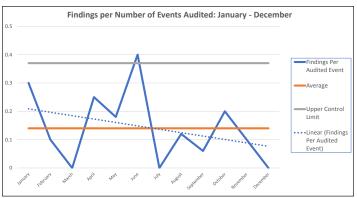
Adding a ratio was not as easy as it seemed. We first needed to define an audit event. This varied based on the department and the type of work they produced. With input from managers, we agreed upon the most sensical denominator for each department and made sure it was transparent for the organization to understand. For example, the department that performs donor risk assessment interviews may have the number of interviews audited as their denominator, while the department that determines eligibility may use an entire donor chart. It had to account for the differences in the work being measured.

Questions quickly arose. What if we have 5 findings in a single chart but the other 9 charts are perfect? Do we report that as 5 findings per 10 charts (50% finding rate), or do we report it as 1 in 10 of our charts have findings (10% finding rate)? Is it even reasonable to compare charts to each other when complexity and number of auditable items vary by donor? How is this information most effectively communicated, and can we rely on it to set goals and drive improvement?

We opted for a straight forward approach to define the rate: Total number of findings divided by the total number of events audited. (e.g. 5 findings / 10 charts = 50% finding rate). We preferred this method because it focused on the total number of findings compared to work completed as opposed to only counting auditable events which may have

one finding or a cluster of findings. The latter introduces the potential for misrepresentation of actual performance because multiple errors identified in one auditable event would be reported as a singlefinding.

Establishing the finding rate allowed us to introduce department specific run charts, replacing the less helpful bar graphs (Figure 2). We used the data to explore what "normal" looked like in the hope of defining performance benchmarks. A year was selected as an appropriate amount of time for calculating average audit finding rates and led to instituting an upper control limit (UCL) of 2 standard deviations above the mean. Spikes above the UCL were investigated and explanations, where available, were

Figure 2: *Findings per Number of Events Audited Hypothetical example of audit findings charted monthly. Blue solid line = Findings per Audited Events*

Orange line = Average

Grey line = Upper Control Limit Blue dotted line = Linear Trendline

communicated in the audit report. This gave us the ability to evaluate fluctuations and determine which variances required attention. We could also see what our performance looked like over time and identify trends in the data.

Trending rates were informative in a broad sense but did not account for severity of individual findings. For example, 5 insignificant findings counted the same as 5 impactful findings making the run charts potentially misleading. It was necessary to break down audit findings into more categories.

We drew a simple line using the terminology of major versus minor findings. Major findings, defined as nonconformances related to tissue safety, carried the possibility of CAPA (corrective action/preventive action) as well as evaluation for deviation and external reporting. We wanted to highlight these so that proper resources could be devoted to correction and prevention. Minor findings, defined as

nonconformances not related to tissue safety, were evaluated for trends and opportunities for improvement but often did not require follow-up beyond the initial correction.

Separating results by severity gave a level of context previously absent. Managers were empowered to make decisions about how or if to follow up and staff had a better idea what parts of the data applied to them. Efforts could be focused on areas needing improvement instead of vague attempts to decrease the overall number of findings.

At this point we decided to circle back to our original question. Did the data and the method for reporting it answer the question "how are we doing?". The run charts certainly addressed events that were subject to audit, but the picture was incomplete. It did not consider other factors that measured companywide performance such as external complaints, departures from procedure, or CAPA activities. We needed to re-evaluate our definition of quality to know if we were truly addressing the question.

To define quality, we looked at the company mission and identified the functions supporting it.

Quality indicator categories emerged and were evaluated for their relevance to overall quality.

Assigning significance allowed for creation of a point system where categories were weighted based on their impact. We used historical data to establish benchmarks and create goals (Figure 3). Achieving or exceeding a goal earned full points. Falling beneath it took away points incrementally. The individual scores could then be added up into a total score, which was the first iteration of our quality index.

Quality Indicator Category	Weight	Quarter 1	
		Rate	Points
Category 1	10%	8%	8
Category 2	15%	6%	13
Category 3	10%	0%	10
Category 4	30%	13%	27
Category 5	25%	1%	24
Category 6	10%	0%	10
Total	100%		
Quality Index Score			92

Figure 4: *Quality Index Score*

Conversion of Quality Indicator scores to Quality Index score using weighted scale.

we doing?", and is supported by more detailed figures for managers to use in creating department specific performance goals.

The system is designed to be tailorable. Each quarter's goal is based on the previous 12 months of data allowing for continuous validation of our benchmarks. Managers have the option of adjusting their goals when circumstances apply that make the goal inappropriate. They can also provide information as to why certain periods experienced unexpected or undesirable results.

The adaptability of the quality index is driven by the contributions of our staff. As our organization grows and evolves so does our concept of quality, and so must our methods for measuring performance. In the last year alone we have identified the need for certain quality indicators to be more detailed than others and thus developed more sensitive measurement tools to examine the data. For example, our eligibility department is the last line of review before releasing tissue for transplant and is responsible for verifying that work performed by other departments is complete and accurate. A finding for the eligibility department may also need to be counted as a finding for a secondary department. Our audit program indicator must therefore be sensitive to how different departments interface with each other and how that interaction may impact interpretation of the data. This is in addition to considering the benchmarks.

For this reason the LVG quality index is replicable in concept but not directly transferrable to other agencies wishing to implement a company scorecard. We fully expect the quality index to continue transforming overtime as our priorities and goals adapt to our company's trajectory within the industry. One of the greatest benefits of developing the quality index is that it has given us a language for discussing these challenges as well as a structure for thinking

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Quality Indicator 1

Average Rate for previous 12 months = 10%

Maximum Points Available: 15

Point Assignment for Current Year

If rate is 0%	15 points assigned
If rate is > 0% and ≤ 5%	10 points assigned
If rate is > 5% and ≤ 10%	5 points assigned
If rate is > 10 %	0 points assigned

Figure 3: *Point Assignment for Current Year.*

Example of historical data used to generate quality index points for current year.

The quality index is reported as a table showing the points for each quality indicator category as well as the overall company score. (Figure 4). It provides high level information to the executive team answering the question "how are

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about them. When we ask, "how are we doing?", we now understand it to be more than just a snapshot of today. It is framed in the context of our benchmarks and can be used as a portal for seeing where we want to go tomorrow as well as measuring if we have achieved that vision.

LVG will continue to strive for the highest level of quality in all aspects of our company mission.

The quality index is an asset as we advance our culture of quality ensuring tissue safety, regulatory compliance, and stewardship of the donation gift.

REFERENCES

[i] Eye Bank Association of America, Medical Standards, Section G1.000 Quality Assurance, November 9, 2017

[ii] Food and Drug Administration Guidance for Industry Current Good Tissue Practice (CGTP) and Additional Requirements for Manufacturers of Human Cells, Tissues, and Cellular and Tissue Based Products (HCT/Ps), Section V. Establishment and Maintenance of a Quality Program, December 2011

[iii] Food and Drug Administration Human Cells, Tissues, and Cellular and Tissue Based Products Current Good Tissue Practices Final Rule, 21 CFR Part 1271, Subpart D. November 4, 2004.