JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 16, No. 9, September 2020

"Happy Trials to You"

Building a Quality Culture Based on Ethics By Tracy Morrison

An organization cannot achieve high quality by merely instituting the mechanisms of quality: standard operating procedures, training programs, quality control, etc. It must build these mechanisms on a solid foundation of quality — a quality culture. A strong quality culture ensures that quality mechanisms are interpreted and employed correctly, thoroughly and naturally throughout the organization.

It is very difficult for an external party to impose a culture of quality on an organization. For example, the U.S. government can impose a corporate integrity agreement with hefty monetary penalties on a pharmaceutical company in settlement of an enforcement action, but the result is likely to be more of a temporary and superficial box-checking exercise than a fundamental and lasting change in the attitude of the company toward quality. Deeper understanding and motivation are required to ensure a true cultural change.

Ethics as the Foundation of Quality Management

In the context of this article, ethics refers to the organization's and its members' moral commitment to deliver high-quality products and services within the organization and to the organization's customers and other external stakeholders. An organization's culture is largely defined by its values (e.g., a commitment to high quality).

The article "Regulating Ethical Culture, Behavioral Policy" highlights leadership behavior "as one of the five dimensional areas necessary to establishing an ethical culture. The other four areas are: a social contract, organizational ethos, individual perceptiveness, and response to organizational misconduct."

"Individual perceptiveness" is based on a person's ability to understand their own and others' motivations and intentions using reflection and introspection. Holistic alignment of one's true nature and true self promotes authenticity and thus promotes trust.

"Organizational ethos" consists of the principles and code of conduct that guide the behavior of all personnel in an organization.

A "social contract" is an implicit agreement among the members of a group as to how they will cooperate for mutual benefit.

A "social contract is a shared code of conduct for all members of the organization. A strong social contract requires leadership and management to act fairly, respectfully and in a trustworthy manner, remaining clear on the organization's values and goals, responding to organizational unfairness, demonstrating empathy, supporting the freedom to speak out without fear of retaliation, and enforcing the bounds of the social contract. Leading by example is one way to reinforce a social contract. Saying one thing and doing another is one way to destroy it.

"If employees are treated unfairly or observe the organization applying standards and policies in a way that shows preferential treatment, they'll likely experience organizational injustice and perceive some level of dishonesty and hypocrisy. In contrast, if employees experience trust, the prevailing perception will be that the organization and its members will not harm each other." These authors defined trust as "an employee's feeling of confidence that the organization will perform actions that are beneficial, or at least not detrimental, to

him or her." That is, "a social contract based on trust will likely strengthen the organization's ethical focus by reinforcing the perception of a shared code of conduct."³

A strong culture of quality requires a solid ethical foundation based on sound moral principles. An ethical failure (violation of a moral principle) evokes a strong reaction at a fundamental human level. A quality failure might just be considered an error or mistake, whereas an ethical failure is a wrongdoing — a breach of the organization's social contract and thus a tear in the fabric that defines the organization and holds it together.

Establishing an ethical culture takes committed leadership, time and effort. Leaders must understand how their words and behavior can drive or derail an ethical culture. For example, a simple discussion can create a misunderstanding that results in undesired behavior.

An organization's statement of values, mission statement, and code of conduct provide guidance and define right and wrong behavior for the organization. These three standard corporate documents, working together, create a framework for what will and will not be tolerated, what the consequences will be, how the organization expects personnel to align with expectations, and what to do if noncompliance is observed. Management has the responsibility to live by — and not just convey— these documents and must ensure the code is followed. Timely investigations of any reports of potential misconduct, fair and consistent investigation and resolution, and follow-up communications reinforce the organization's culture and its social contract.

An ethical culture requires training, knowledge, reflection, introspection, patience, evaluation, constant attention, cross accountability, and an ongoing ethics-based dialogue with regard to all responses, engagements, interactions and decisions. Implementation of an ethics-based quality culture requires planning, training, critical thinking, monitoring and transparency to ensure clear, honest and consistent messaging and action aligned with the organization's values, code of conduct, and mission statement.

Ethics, by its nature, is often subjective and a matter of personal judgment. Reasonable and well-meaning people can differ in their perspectives of what defines right and wrong behavior. In the U.S., jury decisions are guided by the moral principle of what a reasonable person would do in a given situation. Organizations can apply the same principle to their own behavior.

Ethics should not be considered an exercise in perfection. We live in an imperfect world where the best we can do is find the right balance of potential benefit and harm. For example, delivering a high-quality product to a customer before a deadline might require extraordinary effort by certain individuals in the organization. Is it ethical for the organization to demand such efforts?

Ethical difficulties often have deep root causes. For example, could the organization have prevented the above-mentioned situation by not making an unrealistic commitment to the customer? Deeper still, could the organization avoid unrealistic commitments in general by instituting a better planning process? Deeper still, could the organization have allowed time for creating a better planning process by, for example, setting more reasonable sales goals?

Establishing a Culture of Quality

A strong ethical foundation that values high quality inherently supports a culture of quality. Some quality failures constitute wrongdoing (i.e., violations of the organization's social contract and organizational ethos).

When an organization has a quality mindset, it takes a hard look at everything it does through the lens of quality. It empowers every person in the organization to think critically

and accept accountability for the quality of their deliverables and their contribution to driving the culture of quality. Everyone in the organization must recognize that any quality failure risks degrading the entire culture of quality.

Critical thinking requires training and experience. It is a competency required of all roles, regardless of title or position. Critical thinking considers each deliverable, the variables, and the necessary quality process. Critical thinking considers unknown, real and possible risks. It also draws on ethical considerations, such as the harm that a defective deliverable will cause to the recipient and any other harm or benefit that may be created during the process, including quality assurance aspects.

Quality is usually not a binary property – there are degrees of quality. An organization's goals are usually to achieve or maintain a defined level of quality over time. Risk management often relates to avoiding quality deficiencies.

Implementing an ethics-based culture of quality requires eight elements:

- Hire candidates with the necessary intellectual and moral capacity for their roles.
 They must believe in doing the right thing and have the moral fiber to resist pressure that can lead to wrongdoing directly or indirectly.
- Include language in the employment contract or employee handbook that requires ethical conduct and lays out serious consequences for deviations at all levels of the organization.
- Require periodic training on ethics and quality for all personnel in the organization from top to bottom.
- Include quality and ethical competencies in organizational, departmental and personal objectives.
- Communicate regularly on quality and its ethical foundation. Active dialogue and reinforcement will sustain the desired culture in everyone's mind.
- Share how the organization measures and tracks quality, and why those measures are important to a culture of quality.
- Regularly assess and report on quality performance. Highlight successes and also failures, explaining their ethical dimension, causes and effects, and the actions that will be taken to prevent them in the future. Share this information with the entire organization.
- Maintain an open-door policy so that any quality or ethical issues can be brought to management's attention without fear of repercussions. Commit to a nonretaliation policy and incorporate it into the Code of Conduct.

Conclusion

Any organization that wishes to play a positive role in today's world must deliver high-quality products and services. To do so, the organization must holistically embrace the pivotal roles of ethics and quality. Only then will the organization fully benefit from its good citizenship.

References

1. Treviño, L., Haidt, J., & Filabi, A. "Regulating Ethical Culture, Behavioral Policy," The Journal of the Behavioral Science and Policy Association, https://behavioralpolicy.org/articles/regulating-for-ethical-culture/ (2018)

- 2. Tan, H. H., & Tan, C. S. F. "Toward the differentiation of trust in supervisor and trust in organization," Genetic, Social, and General Psychology Monographs, 126, 241-260. (2000)
- 3. Bulgarella, C. "A Two-Factor Model of Ethical Culture. A Conceptual Framework for Ethical Systems' Culture Survey. Business Integrity through Research. Ethical Systems." https://www.ethicalsystems.org/wp-content/uploads/2016/09/files_ES_A-Conceptual-Framework-for-Ethical-Culture-FINAL.pdf (2016).

Author

Tracy Morrison, MSN/MHSA, RN, CCEP, CHRC, is Associate Director, Clinical Quality at Arcus Biosciences. Contact her at tmorrisonmsn@icloud.com.