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How ISO 9001 helped a Georgia healthcare system provide safer, more effective care

| **by Casey Bedgood**

Just the Facts

Recent shifts in the healthcare industry have changed the expectations on healthcare systems to innovate, increase agility and provide safer, more effective care. To meet those expectations, healthcare organizations are transitioning from traditional operating models to high-performance systems.

Three Navicent Health hospitals, a healthcare system in Georgia, became ISO 9001:2015 certified as part of a strategic journey toward high performance.

Prior to ISO 9001 certification, each hospital experienced significant variation in nonconformities during annual accreditation surveys. Certification and the global efforts to achieve high performance produced a 51% reduction in annual nonconformities, a 74% reduction in annual nonconformity standard deviation and the lowest number of nonconformities in the organization's history system-wide. The changes resulted in safer, more effective care for tens of thousands of patients annually.

As the healthcare industry continues to evolve and financial constraints increase due to lack of reimbursement, health-care organizations are being forced at a record pace to pivot from traditional operating models to high-performance systems. One of the biggest hurdles for most healthcare organizations is to define what high performance is and how to achieve it.

In the past few years, the healthcare market arguably has experienced more change than in the past several decades. There are three notable market phases across the country that have disrupted many healthcare enterprises.

The first relates to the traditional model or view of healthcare operations. For many years, most healthcare organizations focused on local competition and simply meeting goals tied to cost and quality. Much of this centered on local branding with a brick-and-mortar perspective of "build it and they will come." The winners during this time tended to have better brands locally—that is, customer perspectives of the care provided—and were able to set and meet goals comparable to national benchmarks.

The second phase occurred just a few years ago when the market demanded that healthcare organizations not just meet goals, but also provide better, faster and cheaper health services than others regionally (state or country). The emphasis also shifted to the value of care and services provided. Those high performers of the time who could provide the highest quality, lowest cost care with great access were positioned to be long-term market leaders.

Recently, the third phase created a convergence of high performance, innovative thinking and consumerism. This shift has accelerated the rate of change and expectations on healthcare systems to master innovation, increase agility and provide safer, more effective care when and where customers expect it. The focus has now shifted to a national view in which the long-term winners will be masters of excellence around customer requirements (cost, quality, safety, service and access to care, for example) that are tied directly to reimbursement for healthcare services rendered. The high performers and innovators will continue to thrive while the low performers will be disrupted.

The journey and significance

In 2013, three of Navicent Health's hospitals in central Georgia became accredited by the international accredited registrar Det Norske Veritas Germanischer Lloyd (DNV GL) focusing on National Integrated Accreditation for Healthcare Organizations (NIAHO) standards, which require organizations to provide safe and effective care.

In 2017, these same three hospitals became ISO 9001:2015 certified as part of Navicent Health's strategic journey toward high performance. These three facilities serve tens of thousands of customers from dozens of counties in central and South Georgia who suffer from complex medical illnesses and traumatic injuries.

ISO 9001:2015 core elements include customer focus, top leadership involvement, continuous improvement, evidence-based decision making, relationship management, process approach and engagement of people. From a practical perspective, ISO 9001 requires healthcare organizations to continually improve all activities related to service, cost, quality, safety and value based on customer requirements.

Each organization is evaluated annually on its journey toward high performance via DNV GL site surveys. During these surveys, external industry experts inspect all facets of the healthcare organization, such as clinical areas, support services and operations, to ensure the basic NIAHO standards are being met. In addition, ISO 9001:2015 organizations are required to provide objective evidence showing how they are meeting, exceeding and continuously improving goals related to customer requirements.

Any deviation from the standards results in the hospitals being cited in the form of a non-conformity. Organizations that receive fewer
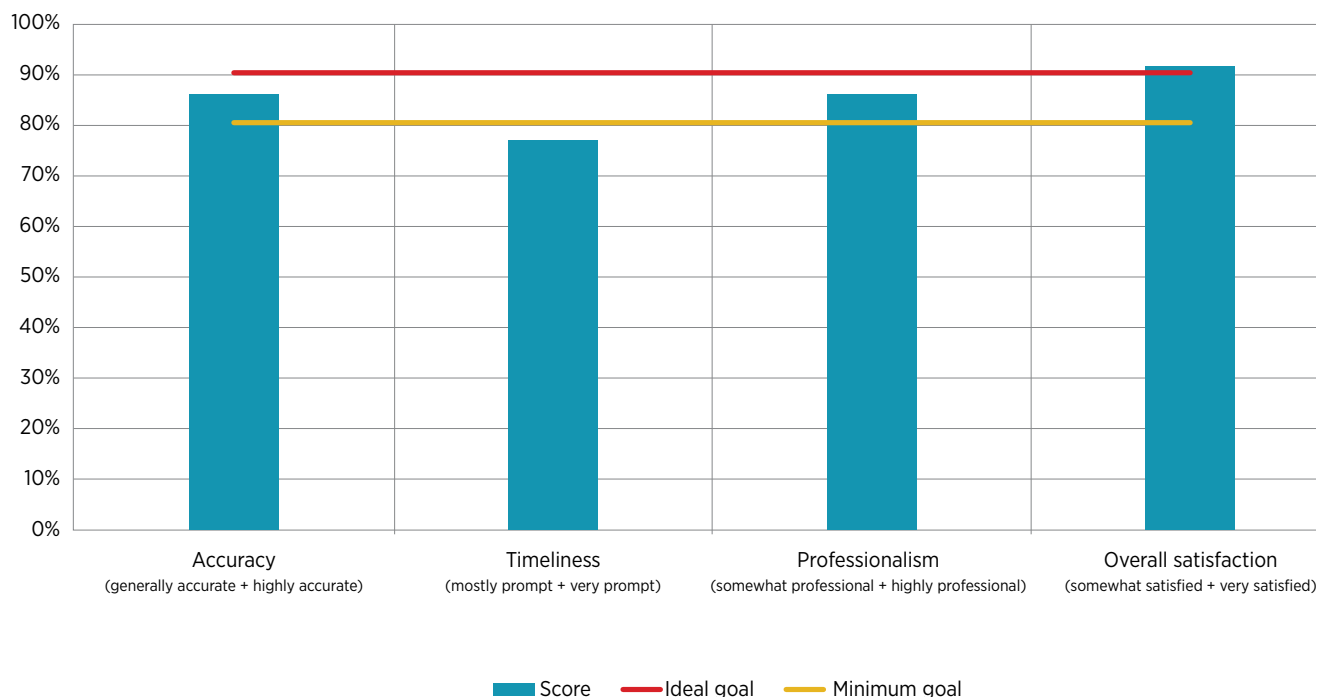
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FIGURE 1

Voice of the customer survey results (internal customer feedback survey)

Internal survey: accreditation performance (initial)

Legend: Score | Ideal goal | Minimum goal

X-axis categories:
- Accuracy (generally accurate + highly accurate)
- Timeliness (mostly prompt + very prompt)
- Professionalism (somewhat professional + highly professional)
- Overall satisfaction (somewhat satisfied + very satisfied)

nonconformities tend to provide safer and more effective customer-centric care. In extreme circumstances, hospitals that receive critical nonconformities related to safety and effectiveness can potentially lose their accreditation and subsequent government reimbursement. So, ensuring high performance and highly reliable processes is essential to achieving safe, effective and sustainable healthcare services.

Focus areas

To accelerate Navicent Health's journey to high performance, the accreditation team leveraged several innovative concepts. The team's hypothesis stated that the application of ISO 9001:2015 core elements would reduce annual nonconformities and subsequently improve organizational effectiveness. The starting point was a discovery phase that focused on three elements: customer requirements, evidence-based decision making and relationship management.

1. **Customer requirements.** ISO 9001 requires organizations to understand who their customers are and what they require. The overarching goal of healthcare enterprises should be to meet and exceed customer requirements. Historically, most healthcare organizations have focused mainly on external patient feedback surveys after care has been received to establish customer requirements.

   The accreditation team took a different approach with ISO 9001 to determine an exhaustive list of internal and
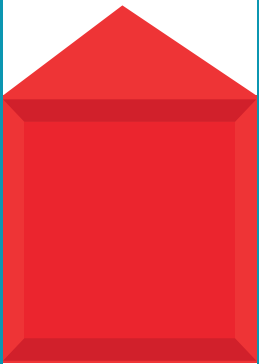
external customers. The team also ensured a feedback mechanism was present to capture their perspective for strategic planning. Next, a simple survey was distributed to hundreds of internal leaders to capture feedback about the timeliness, effectiveness, professionalism and overall satisfaction of the accreditation program.

It is important to note that internal customer feedback is a gap for most organizations. Essentially, the accreditation team is a consulting function that teaches, advises, guides and partners with system leaders to achieve high performance related to the safety and effectiveness of services provided. This internal feedback was incorporated into the strategic program goal setting and continuous improvement efforts system-wide.

2. **Evidence-based decision making.** This focus area requires organizations to use data and objective evidence during decision making to meet and exceed customer requirements. At Navicent Health, the team set goals related to annual nonconformities per entity, nonconformities system-wide, nonconformity standard deviation for all hospitals and annual internal voice of the customer (VOC) surveys.

The goal for each entity was a 20% reduction in annual nonconformities, at least a 20% reduction in nonconformity standard deviation and, at minimum, 80% goal attainment for all four elements of the annual internal VOC survey related to timeliness, effectiveness, professionalism and overall satisfaction.

In addition, the team also used basic root cause analysis tools, such as Pareto diagrams, to identify high nonconformity areas for each entity as well as the entire system. Strategic focus areas for continuous improvement were chosen by leadership based on the Pareto chart

data to reduce nonconformities, thus improving organizational performance. The team reported the goals and performance updates to leaders and board members throughout the journey.

3. **Relationship management.** In early 2018, the organization shifted from a hospital-centric system to a system model related to accreditation. The team was restructured with systemwide responsibilities and began to implement basic system integration strategies. The focus was on establishing relationships and contacts with each entity to transfer knowledge and drive high performance.

The team also began breaking down hospital-centric silos and focused more on a team or system approach that would produce greater outcomes than the individual entities working alone. For example, entity and system leaders were assembled for a team strengths, weaknesses, opportunities and threats analysis of accreditation program functions. The focus was on identifying internal strengths and weaknesses as well as external opportunities and threats. Each leader and entity had an equal voice and input into the direction of the program used to prepare the organization for annual surveys. Much of the relationship-building initiatives were championed by senior leaders identified as ISO champions for organizational improvement efforts.

The results

Prior to ISO 9001 certification, each hospital experienced significant variation in nonconformities during annual accreditation surveys. Subsequently, performance was hard to predict. Also, no internal VOC surveys were conducted to assess the level of satisfaction organizational leaders experienced as the accreditation team prepared them for annual surveys.

As the journey to high performance began, the accreditation team conducted an internal survey for feedback. Figure 1 (p. 27) outlines the initial internal survey results. More than 100 organizational leaders were surveyed. The minimum goal for the survey was 80% satisfied while the ideal high-performance goal was 90% or better for each measurement. The initial survey resulted

Voice of the customer survey results post-improvements (internal customer feedback survey)

Internal survey: accreditation performance (post-implementation)

Legend: Score | Ideal goal | Minimum goal
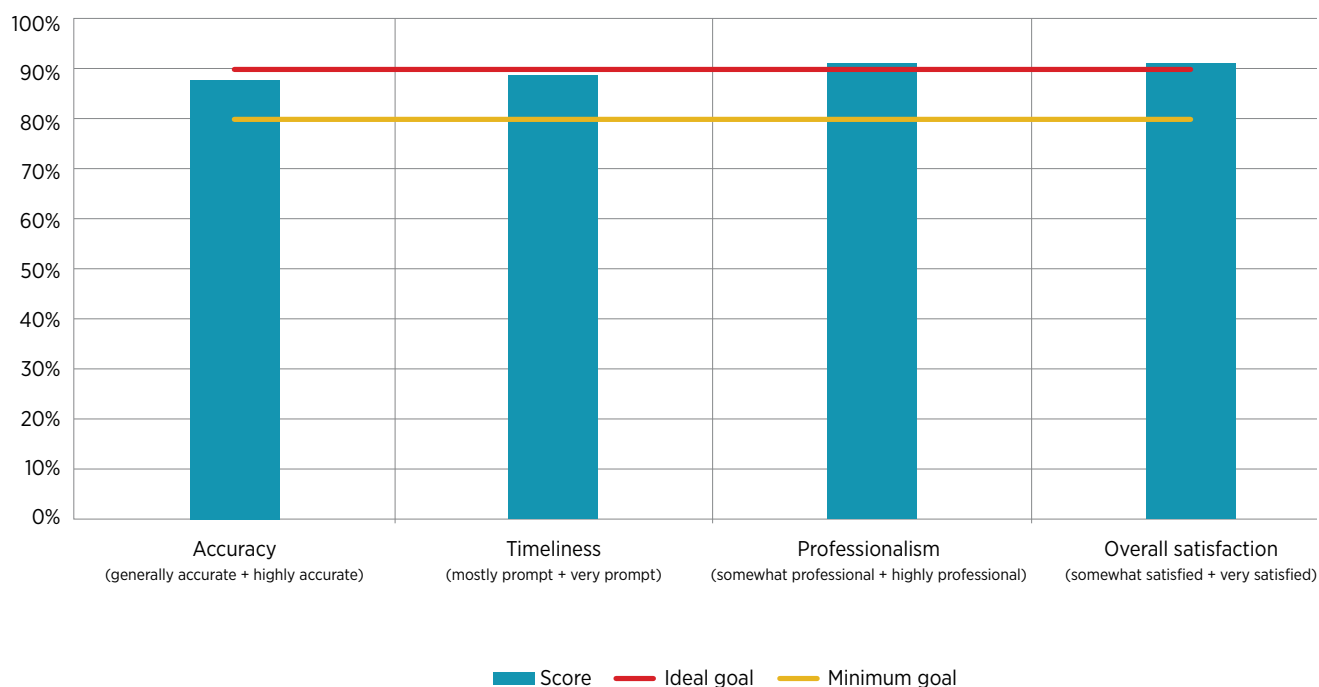
in three of the four measurements for the accreditation program scoring below 90%, with overall satisfaction at 91% favorable.

After review and strategic planning, the accreditation team and organizational leaders implemented improvements focused heavily on customer requirements, performance to goals and relationship management. The end goal was to achieve at or above 90% ratings in timeliness, effectiveness, professionalism and overall satisfaction.

Within 10 months, another survey polled hundreds of internal leaders after improvements were implemented and each of the four elements scored at or above 90% favorable (see Figure 2). The feedback from internal customers played a strategic role in pivoting the organization to high performance, resulting in safer and more effective services, as noted in nonconformity improvements systemwide.

Moreover, the global efforts to achieve high performance produced a 51% reduction in annual nonconformities, a 74% reduction in annual nonconformity standard deviation and the lowest number of nonconformities in the organization's history systemwide each consecutive year post-ISO 9001:2015 certification. In short, the organization produced fewer nonconformities each year and performed better. Subsequently, organizational performance became predictable, with successful goal attainment annually.

The reduction in nonconformity standard deviation is greatly significant because it shows a reduction in variation of services among hospitals and ensures tens of thousands

of customers at all locations receive the same high quality, safe and effective care. See Figure 3 for nonconformity standard deviation trends.

Test of hypothesis (paired comparison small sample size) was used to determine whether the historical nonconformity improvements post-ISO 9001 certification were statistically significant. The null hypothesis states that there is no change in organizational effectiveness while the alternative hypothesis states that ISO 9001 certification reduces nonconformities and improves organizational effectiveness. The conclusion of data analysis is the t test > t table (1 tail test).

Therefore, reject the null hypothesis and accept the alternative hypothesis. ISO 9001:2015 reduced nonconformities at the 95% confidence level, resulting in safer and more effective care. See Figure 4 for test of hypothesis analysis details.

Lessons learned

Here are a few key takeaways:

+ **Always begin the high-performance journey with VOC.** It is vital to determine who your customers are and what they need, expect and want from the organization. Ensure the organization regularly measures feedback from internal and external customers, and reports the results to senior organizational leaders for continuous improvement.

FIGURE 3

Nonconformity standard deviation systemwide

Nonconformity STDEV: MCNH, RHNH and MCPC
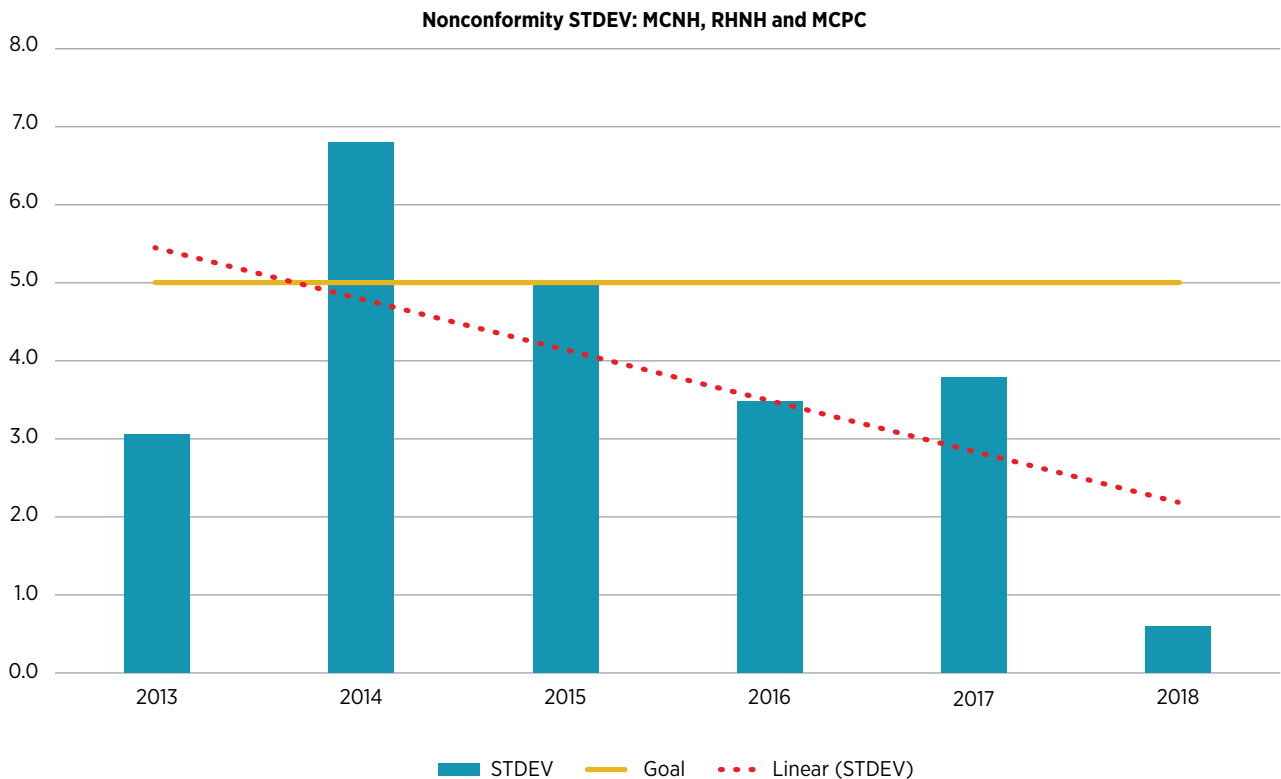
STDEV = *standard deviation*

Test of hypothesis
(paired comparison: small sample size)

Hypothesis

ISO 9001 certification—coupled with system integration/ knowledge transfer—improves nonconformity performance for DNV GL ISO 9001:2015 organizations. Moreover, ISO maturity reduces organization nonconformities and improves effectiveness.

Conclusion: T test > T table (1 tail test); Reject null hypothesis and accept alternative hypothesis. ISO 9001 certification coupled with system integration/ knowledge transfer reduced DNV GL nonconformities at the 95% confidence level.

Test of hypothesis
(paired comparison)

dbar: -3.8
Standard deviation: 4.44
Sample: 9
alpha: 0.05
t test: 2.57
1 tail t table: 1.86

Significant at 95% confidence level
(t test value > t table value)

DNV GL = Det Norske Veritas Germanischer Lloyd
ISO = International Organization for Standardization
Note: System integration = right structure + right process + right skill set mix + relationship management

+ **Focus on data, goals and trends to drive high performance.** Start with the end in mind. These goals must be tied to strategic priorities, aligned with organizational direction and championed by senior leaders to increase buy-in while reducing resistance. Also, do not forget to monitor data trends regularly and report the findings to leadership champions. If trends are unfavorable, respond immediately to recover and sustain the organization's past high-performance wins.
+ **Relationship management is the key to achieving and sustaining high performance long term.** If your team desires system-level change, removing silos and incorporating a system focus is vital to achieving sustainable synergistic outcomes. It always is important to remember that all parts working together can produce greater results for customers if orchestrated correctly.
+ **Assign a sustainment champion for organizational wins.** These champions should be strategic change agents that possess the ability to create burning platforms, justify the need for change and incorporate high-performance concepts across the system of care. Many organizations can achieve a goal, but the real challenge is sustaining transformational improvements long-term when the organizational focus shifts.

Raising the bar

As the healthcare market continues to evolve, the new minimum threshold for organizations is high performance. For those enterprises that are high performing and agile, and that innovate to meet ever-changing customer requirements, the future is exciting and promising. For those that cannot pivot and evolve, the healthcare journey surely will include some form of disruption. The only question is, how many healthcare organizations will be able to meet these new expectations?

High performance is a journey predicated on continuous improvement, customer focus, evidence-based decision making and great relationship management. The goal of all healthcare organizations is to ensure each customer receives safe, timely and effective care when and where desired. Navicent Health's continuous journey to providing safe and effective care coupled with innovative solutions shows that ISO 9001:2015 drives high performance. Moreover, optimal performance can be achieved relatively quickly depending on organizational resource availability, culture and scope of change. QP

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