

Standardization: A Replicating Process

EXECUTIVE SUMMARY

This is the era of standardization in health-care. Whether it's standardizing IT for interoperability, processes for efficiency or clinical nomenclature for best practices, you'll never get fired—to paraphrase a 1960s-era axiom referring to IBM—for 'buying' standardization. The devil is in the details, however, when it comes to the arduous process of standardization within delivery systems.

Fortunately, we didn't have to go very far to find good examples to share. This issue of Information Edge looks at the issue of standardization from the perspective of two leading healthcare delivery systems that are also long-time SI members: Minneapolis-based Allina Hospitals & Clinics and Novi, Mich.-based Trinity Health. The two organizations are good proving grounds for standardization. Allina has 11 hospitals, almost all of which are in Minnesota, and Trinity has 45 hospitals in seven far-flung states.

Both organizations have developed frameworks and specific initiatives for driving standardization through their organizations. We learned there is no "either/or." Standardization must occur in both IT and clinical care at the same time and in an integrated fashion. Another important lesson: it never stops. True standardization must be built into an organization almost as a living thing that replicates itself again and again, continually struggling to bring order to a universe that we learned long ago wants to dissolve into entropy.

Trinity Health

Trinity is nothing if not disciplined in its approach to standardization, the result of nose-to-the-grindstone experience in clinical IT implementation going back to 2000 when it launched Project Genesis, led by then VP of clinical informatics Donald Crandall, MD. Now a physician informatics consultant for Trinity, Crandall outlines four levels of standardization at the organization, all of which closely integrate clinical and IT elements.

The first level standardizes data elements and clinical nomenclature to ensure a common language, whatever system an institution uses. To support that goal, Trinity has developed order, supply and financial "catalogs" that designate, for example, SNOMED as the standard for clinical nomenclature and LOINC for laboratory terminology. "It's critical that the first level of standardization be at the data element level," says Crandall.

The second level is the technical infrastructure, involving information protocols such as HL-7 and, in Trinity's case, establishing Oracle as the database standard.

Trinity's third level standardizes applications centered around "Best of Suite" as opposed to "Best of Breed." This strategy creates standards for ERP, patient administration and clinical applications, for example, but allows introduction of different vendors for unique functionality like an organ-transplant program.

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Services Office:

1660 Highway 100 South

Suite 306

Minneapolis, MN 55416

T. 952.545.5880

F. 952.545.6116

E. scottsdale@scottsdaleinstitute.org

W. scottsdaleinstitute.org



WELCOME NEW MEMBER

The Scottsdale Institute is proud to welcome new member SSM Health Care based in St. Louis, Mo.

SSM Health Care, one of the largest Catholic health systems in the U.S., was founded more than 130 years ago and is sponsored by the Franciscan Sisters of Mary. It is a private, not-for-profit healthcare system that provides primary, secondary, and tertiary health care services. The system owns, manages and is affiliated with 21 acute care hospitals and three nursing homes in Illinois, Missouri, Oklahoma and Wisconsin.

With operating revenues of more than \$2 billion, SSMHC provides a wide range of services including emergency care, surgery, oncology, mental health, obstetrics, and cardiology, orthopedic, pediatric and rehabilitative care. SSMHC has more than 5,000 physician partners and 23,500 employees providing healthcare services through inpatient, outpatient, emergency departments and ambulatory surgery settings.

SSMHC operates an innovative, automated information system which allows physicians to access clinical, patient, and other data through personal computers, personal digital assistants, pagers and faxes.

SSMHC in 2002 became the first healthcare winner of the prestigious Malcolm Baldrige Quality Award.

Welcome Sister Mary Jean Ryan, FSM, president and CEO, and Thomas K. Langston, system vice president/CIO and the entire SSM Health Care team.

TRINITY HEALTH



Donald Crandall, MD,
physician informatics
consultant, Trinity
Health, Novi, Mich.

The fourth level of standardization is workflow and process redesign to eliminate variation. “It may be revenue cycle, it may be clinical process. We spent lots of time looking at workflow and future states,” says Crandall, adding that the effort started long ago with the initial scrutiny of data elements, architecture and software. “Lots of those decisions involved end-users and the technology: finance staff standardized the revenue-cycle applications; clinical pharmacists standardized the pharmacy software.

Standardize or die

Not surprisingly, Trinity is making a big effort to improve clinical workflow, which is an ongoing, evolutionary process. Seven sites are up and running with CPOE and, as each hospital comes up for implementation, Trinity also standardizes the facility’s order catalog and nursing documentation. The point is to reduce variation, but standardization also enables the organization to conduct internal benchmarking. “If you don’t have standards you won’t be talking about the same things. Ultimately to identify best practice, it’s important to have a standard language,” says Crandall.

While Trinity backed the standardization concept from its inception, it was not as rigorous early on, particularly in clinical nomenclature because national standards for that area were slow in developing. Now that national standards are clearer, Trinity is making a concerted effort to align with SNOMED and LOINC, especially as it moves more into clinical decision support. It’s never easy, as the HL-7 standard illustrates. Even though HL-7 has been under

development for two decades, it involves multiple layers of compliance and continues to evolve.

Medical terminology is a moving target. Medical concepts have not undergone as much standardization as other elements that are easier to standardize like drug names and lab results. Workflow is disease specific. In the case of an acute MI, for example, Trinity seeks to determine exactly what the standard is for evidence-based best practice for evaluation, processing and treatment of a patient as opposed to the existing ad hoc process. The effort must consider how roles of care-team members change as they move to an EMR.

“You’re using the EMR to drive the decision. That’s where resources like Zynx come in,” says Crandall, referring to the firm that provides evidence-based clinical guidelines, rules, alerts and standardized order sets to healthcare delivery organizations. “You build one application at a time and make it the best practice.”

Physicians are changing

Even though studies show that physicians believe they should have their own custom order sets, after six months or so they tend to gravitate toward the standardized ones, Crandall says. A seismic cultural shift has occurred from only five years ago when physicians were still adamant about “doing it my way.” Now, they’re saying it’s time to standardize, and ask, “By the way, why am I developing an order set from scratch?”

This cultural change is fueled by three outside influences: increased awareness among physicians of evidence-based medicine; best-practice initiatives by national organizations like the American Heart Association; and the publicity of the IOM reports. IT is an enabler but not a primary driver of this change.

Still, there’s a great deal of work to be done. “We have a long way to go, especially with

nomenclature,” he says. It’s an evolutionary process, a work in progress. “It’s never going to end. As applications get enhanced, as there are new applications, as organizations get into outcomes analysis and management, there’s more standardization to do,” Crandall says. “It’s a never-ending process—but we do have the basic groundwork.”

TRINITY HEALTH



J. Michael Kramer, MD,
CMIO, Trinity Health,
Novi, Mich.

Nobody realizes the task ahead more than J. Michael Kramer, MD, Trinity’s CMIO, who recognizes a new phase in the struggle for standardization emerging.

“Just because we have an infrastructure built doesn’t mean that we’re recognizing all the value. It may be that we’re only marginally getting value, especially if you put in CPOE but turn off all the alerts.”

Nobody wants to build it from scratch

Clinical-content standardization is a process that’s increasingly becoming open-source, he says. “Organizations are asking ‘Do we really have to build this all from scratch?’” especially given the fact that many providers are using paper order sets that are two to four years old. “It’s very underappreciated in cost and maintenance in an organization,” Kramer says of clinical standards like order sets.

Having 45 hospitals in seven states provides a great resource for learning about standardization, especially when you’ve standardized on a single database—the same physical architecture and server complex—for the entire organization. For example, at this point Trinity has a wealth of information about what works and what

doesn’t when implementing CPOE among physicians. It is using this data to standardize the IT implementation process.

“It’s part of the business case for centralized IT,” notes Kramer, who acknowledges that prior to coming to Trinity he wouldn’t have thought it possible to create a sophisticated database for such a far-flung health-care enterprise. Now, he relishes leveraging the database to compare the performance metrics across the entire organization. “We can ask whether Port Huron uses the same ED intake process as other hospitals. If we want to automate for P4P we need to take standardization to the next level for acute coronary syndrome.

“There’s a lot of business-process knowledge involved. The first test case of standardization is to take workflow door to door. The standardized clinical content in the form of order sets goes above that. Vendors sell you the application suite but don’t give you the order sets or documentation templates. So, every node in that workflow has content you have to build,” says Kramer.

Variation is inevitable

Even within the same organization there can be five different Heparin drip protocols, he notes, and reducing that number to three is a victory in itself. That challenge is multiplied exponentially across the span of clinical care, which is why tools like Zynx become valuable.

Still, variation is inevitable. “We really don’t know what the best practices are” in most situations, Kramer says. “There’s a body of evidence with pulmonary, orthopedics and psychiatry, but the science isn’t there” yet with respect to definitive best practices in those areas.

There’s also lots to do in terms of standardizing clinical applications. “We don’t have a single, consistent lab system at Trinity and therefore have lost economies of scale in that area,” he says. Also,

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October 3
(co-hosted with HIMSS)
A New Patient-centric and Sustainable RHIO Model
• William A. Yasnoff, MD, PhD, FACMI, NHII Advisors, Arlington, Va.

October 6
A Collaborative for Clinicians on Clinical Systems Implementation
• Shelli Williamson, executive director, SI, Chicago
• Suzi Birz, principal, HiQAnalytics, Chicago

October 12
EHR Trends and Usage: MRI Survey Results
• Jeff Blair, VP, The Medical Records Institute, Washington, DC

October 13
Hosting an ASP-based EHR: Building a Virtual Medical Community
• Bill Miller, CIO, ProHealth Care, Waukesha, Wis.
• Dan Peterson, director, ProHealth Care, Waukesha, Wis.

October 20
The Physician Portal: Referral, Results and Clinical Management at Lucile Packard Children’s Hospital
• Edward A. Gardner, director, IT Technology Services, Lucile Packard Children’s Hospital at Stanford University Medical Center, Palo Alto, Calif.

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*Upcoming Events continued***October 25**

*(co-hosted with HIMSS)
E-Care Lessons from
HealthPartners' Primary
Care Practices*

- Kevin Palattao, vice president, Patient Care Systems, HealthPartners Medical Group Clinics, Minneapolis
- Wendy Weeks, Project Manager, e-Care Initiative, HealthPartners Medical Group Clinics, Minneapolis

October 28

*(co-hosted with AMDI)
Pay for Performance:
Leveraging IT*

- David Classen, MD, VP, FCG, Long Beach, Calif.

November 1

*SI Presents a Collaborative
Forum on Quality
Improvement*

- Shelli Williamson, executive director, SI, Chicago
- Janet Guptill, principal, KM at Work, St. Louis, Mo.

November 3

*New HIT Studies Project
Nationwide Health IT Costs
and Benefits*

- Rainu Kaushal, MD, MPH, staff physician, Brigham and Women's Hospital, Boston, and Adjunct Assistant Professor, Cornell Weill Medical College, New York
- John Glaser, PhD, CIO, Partners Healthcare, Boston
- Eric Pan, MD, CITL senior scientist, Partners Healthcare, Boston
- Amanda Adkins, director, Government and Industry, Cerner Corporation, Kansas City, Mo.

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clinical nomenclature continues to be a challenge.

“Standardization is an ongoing process. If it goes away then medical knowledge has ceased.” And Kramer brims with enthusiasm when he thinks of the potential gold to be mined from a Trinity data warehouse for orthopedic practices, given that the organization sees a whopping 1% of all orthopedic cases in the country. In addition to relying on outside parties, Trinity itself could build order sets in orthopedics, for example, and begin providing them to other providers nationally.

“The data will be there. If we implement a single process for hip replacements for 45 hospitals, in a year we'll have the answers to some very important questions” that it wouldn't be possible to address in even large clinical trials, he says. “We'll do it out of our operations.”

Allina Hospitals & Clinics

Standardization has become such a part of Allina's enterprise strategy that it has developed a specific structure to support it as a continuing process throughout the organization. The organization has developed a project management model for implementing standardization as it rolls out Project Excellian, its enterprise EHR initiative. [An Aug. 24th audio presentation of Allina's experience with standardization is available to members on the SI website at www.scottsdaleinstitute.org under Conferences/Telephone in the “Members Only” section of the home page.]



That model includes development of a decision-making structure and governance, managing change and maintaining standardization after going live. “Standardization needs a structure to support it,” says Jill Truitt, Project Excellian program director. “Our goal is to have one EHR and be paperless,”

she says, and to achieve significant clinical and financial benefits while promoting ‘systemness.’ “Our EHR implementation acts as a change management tool to drive systemness.”

A key requirement is to standardize for measurable and valuable reasons. “We didn't want to standardize just to be consistent,” she says. There are five key elements to standardization at Allina:

1) Value—What are the guiding principles or values that drive standardization? What benefits will be achieved? Who are the appropriate stakeholders whose values guide decisions?

2) Research—What are the sources of data that inform key decisions?

3) Decide—Who has the authority and/or right to decide on key design/build decisions? Is this a consensus decision?

4) Deviate—What types of variation from the standards are necessary and appropriate?

5) Enforce—How will the organization provide governance to support the change?

Truitt acknowledges those are generic guiding principles and must be taken down to the next level, but she stresses that an organization must avoid areas that don't have measurable implications. And, therefore, it's critical to define the metrics beforehand. Also, it's necessary to balance the IT viewpoint—standardization is good because it makes maintenance easier—with the end-user viewpoint that the system must be easy to use for adoption. “That's the high-wire balancing act,” says Truitt.

Pushing systemness

A lot of resources were poured into change management by implementation teams pushing systemness because of the need to overcome Allina hospitals' traditional independence. Value-based decision-making guided the standardization effort because it tied decisions to the patient first and foremost, whenever there was a stalemate between different viewpoints.



Melanie Swenson, VP, FCG, Long Beach, Calif.



Melanie Swenson, VP, FCG, which assisted Allina in the initiative, says it's important to define the source of data

that informs the standardization effort, specifically, who the internal and external subject-matter experts are. "We had huge advisory groups. Picking those people and sticking with them is key," she says. Swenson also cautions that the term "Best Evidence" can be controversial. "Don't pin your hopes on it being universal. Make sure you focus your efforts on the most widely accepted research on high-value items."

Allina uses a "Decision Rights Model"—developed early before its advisory groups were in place—to guide it in moving away from the previous Allina culture of consensus decision making. The model [a sample of this model is available on the slide presentation on SI's website] focuses on a definitive end rather than on developing consensus, and is flexible enough for high-level views or single questions.

Allina's advisory-group decision process for system design, build and validation was carefully structured to allow for both formal Detail Advisory groups as well as ad hoc groups for each of 21 project teams (ranging from ambulatory and hospital orders to ED, scheduling and billing). For each project team, up to 20 people were recruited to commit eight hours a week as adjunct members. Once decisions were made, final approval was given to one of four advisory groups: Revenue Cycle; Hospital Patient Care, Clinic Patient Care; and Physician Team.

Skill set trumps equal representation

"This team model was formulated from the beginning," says Truitt. "We didn't look for equal representation but for the best people with the best skill sets." Initially advisory groups met two to four hours a week, eventually dropping to every other week.

Subject matter experts and advisors provided expertise for the design of the EHR, validated workflow assumptions and acted as champions for the project within their constituencies. "It's been a pretty effective process for us and something we had to hit the ground running with," says Truitt.

Documenting final decisions on standards was deemed critical, so Allina developed a template for that purpose [also available on the SI website].

Variations from standards were expected for lots of reasons, including situations where the scope of care differs because a hospital is not staffed to use specific drugs or treatments, where pharmacies or formularies differ greatly or where available technologies are different. Also, in certain areas there may be no solid evidence favoring one direction over another and an institution can develop and maintain multiple order sets. "The important thing," says Swenson, "is to use values to define when to deviate. Do not allow deviation from the standard in areas of critical value."

Practical hurdles may arise, for example, to using an order set at a 30-bed hospital that would not be the case at a 600-bed hospital. "There may be differences in the scope of care, the stock of medications and available lab devices between the two facilities," Swenson says.

Slippery slope of variation

In the end, however, customization of order sets is a slippery slope and requires a careful balance between the need for

Upcoming Events continued

November 8
Zero Tolerance for Downtime – A Roadmap
 • Jerry Kevorkian, divisional VP/chief technology officer, Sentara Healthcare, Norfolk, Va.

November 9
(co-hosted with HIMSS) Vista: Past, Present and Vista-Office EHR Future
 • Don Meehan, project manager, DSS Inc., Juno Beach, Fla.

November 10
Healthcare Business Intelligence and Data Warehousing: The Big Return from EHR/EMR Investment
 • Dale Sanders, CIO, Northwestern Medical Faculty Foundation, Chicago

November 15
CPOE Rollout at Northwestern: The Embedded Coach
 • Paula Elliott, Impact, project director, Northwestern Memorial Hospital, Chicago and implementation director, FCG

November 16
SI Presents a Collaborative Forum on Quality Improvement
 • Shelli Williamson, executive director, SI, Chicago
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standardization and the need to allow variation for usability or accommodating a rainmaker.

Above all, it's critical to start any standardization process with governance and change management: building prototypes, conducting multiple workflow walk-throughs and dress rehearsals to involve end-users—and operational experts. “We had more than 1,000 people involved in Detail Advisory roles,” notes Swenson.

A case example of using the five key elements of standardization can be seen in Allina's standardizing the registration process:

- The **Value** was in consolidating and streamlining similar functions to control and manage performance and quality within the most cost-effective and efficient business models.
- **Research** involved using the FCG Patient Access Accountability Model as well as industry best practice.
- The **Decide** factor involved having design finalized and recommended by an advisory group of hospital access managers, and presented for approval to Allina's revenue cycle advisory group comprised of Allina financial leadership.
- It was ok to **Deviate** in cases where the staffing model was unsustainable by the organization (at small rural hospitals, for example).
- The **Enforce** factor meant that the standard was implemented and managed by hospital access managers with the support of site and corporate leadership.

Stopping standards erosion

For patient registration Allina first gathered information about patient satisfaction and the impact of denials, using the Patient Access Accounting Model to capture that data up front. Lessons learned included the fact that because jobs changed with the new registration process, new skill sets were required and associated new job

pricing—and that meant working closely with HR and individual sites.

“The sites should be involved early on and have new process change in place before implementation of systems,” says Truitt. “We're finding that because of new workflow functionality, there's a need to push that across sites. It's key to redesign jobs ahead of implementation. That was an example of where we used value-based decision-making.”

For standardization in general, Allina found it was key to develop a Production Change Control Process because erosion of standardized design can begin with the first post-live support call. Site managers and leadership can support standardization by monitoring and managing production change requests from end-users.

“If you don't have production change control, you run into problems,” says Swenson. “By controlling what requests go through the change-control process, you balance the need to restrain bureaucracy with the fact that you don't want to be victimized by instantaneous changes.”

Conclusion

There's little mystery as to why healthcare organizations are standardizing nearly all aspects of IT-enabled clinical and operational processes: variation is poison to efficiency and quality. Absent standardization, healthcare organizations won't be able to measure any aspects of their business, and, as everyone knows, you can't manage what you can't measure.

Standardization is the vine that intertwines both IT, clinical and operational knowledge. It is both a goal and a process, but it's never an end-state. As both Trinity and Allina have found, standardization is an ongoing, evolutionary process that will only end when the growth of medical knowledge ends.