

# Henry Ford: Using ISO 15189 to Change Patient Care for the Better

By Anne Ford



Richard J. Zarbo, MD, FCAP, Senior Vice President and Chair of Pathology and Laboratory Medicine, Henry Ford Health System

## Divide and Conquer

When Richard J. Zarbo, MD, FCAP, reflects on the strategy that helped his Detroit-based Henry Ford Health System (HFHS) achieve CAP accreditation to the ISO 15189 standard this summer, he likes to quote the system's famously methodical founder: "Nothing is particularly hard if you divide it into small jobs." Indeed, it's clear that HFHS—the largest entity to receive the prestigious laboratory accreditation, which focuses on operational systems improvement, risk mitigation, and quality management—would never have succeeded in this regard without that one-piece-at-a-time, divide-and-conquer approach (just as Ford himself couldn't have manufactured 15 million Model Ts without a little method called the moving assembly line).

## Lean as a Framework

But in light of HFHS' history of continuous quality improvement, another Henry Ford saying applies as well: "There is safety in small beginnings." That is, rather than jump directly into its 15189 journey, HFHS prepared for it gradually over a period of years, beginning by implementing Lean principles and establishing a Lean culture that would eventually serve as a robust framework for the ISO standard.

"By taking this long-term approach, we were able to close this—achieve ISO 15189 accreditation—with very little in the way of setback, if any at all, over a period of four years," says Dr. Zarbo, senior vice president and chair of pathology and laboratory medicine for HFHS.

By his reckoning, HFHS is not only the largest entity to become ISO 15189 accredited, it's the "only integrated delivery system, where all laboratories are standardized under one source of



Henry Ford West Blomfield Hospital

**"There is safety in small beginnings."**

– Henry Ford

leadership," to gain this accreditation. "There are other systems that have multiple sites, but they're not integrated under one system laboratory leadership responsible for all pathology and laboratory medicine operations up and down the waterfront," he says.



HFHS celebrated its ISO 15189 accreditation in August 2013. Above from left, Aaron Lupovitch, MD, director of regulatory quality initiatives; Rita D'Angelo; David Wolfe, CAP lead assessor; Dr. Richard Zarbo; and Michael Grilliot, CAP account manager of ISO 15189 and biorepository accreditation.

To be clear, Lean is not a requirement for ISO 15189 accreditation; only some of the 32 laboratories that have achieved this accreditation since the College introduced it in 2008 use Lean methods. But for an institution as large as HFHS to bring all 36 laboratory sites and 800 laboratory employees under the ISO 15189 umbrella, a previous grounding in Lean principles was necessary for success, the system's leaders say.

## Incremental, Small-Scale Approach

Take employee buy-in. Every quality-initiative leader wants it but knows it is notoriously difficult to achieve. When HFHS began training its hundreds of laboratory workers in Lean eight years ago, it did so in groups of 40 to 50, says Rita D'Angelo, MS, ASQ CQE, SSB, who was then the manager of quality systems for pathology. That incremental, small-scale approach, she says, made it easier for employees to understand the importance of Lean, rather than see it as just another corporate initiative imposed on them from above.

The content of this case study has been adapted in large part from the following source: Ford A. At Henry Ford, 36 lab sites now under ISO umbrella. *CAP TODAY*. 2013;27(11): 50, 52, 54, 56, 60–61.



Gaurav Sharma MD, FCAP, Senior Staff Pathologist, Associate Director of Clinical Care Laboratories, and Director of Compliance and Regulatory Affairs

“We went from managers and supervisors not wanting an active part in this Lean initiative to becoming its champions and teachers,” says D’Angelo, who recently left HFHS to open quality consulting firm D’Angelo Advantage. “Once that happened, they owned their entire processes and outcomes. So when we started ISO, they were already used to taking charge. I didn’t have to push them as I would have had to do years ago.”



A systemwide HFHS team led the 36 laboratory sites and 800 laboratory employees on its 15189 journey.

Then, too, one HFHS hospital had a major advantage in this regard. Henry Ford West Bloomfield Hospital opened in 2009, at which time the Lean culture had already taken hold in the health system. “It was a brand-new hospital and brand-new laboratory, and we were able to start out with the Lean framework in place,” says Deborah Chapman, director of the hospital’s laboratory services. “The culture was there from day one, when we opened the facility.”

### Reinventing Quality Professionals for Health Care

Even before the West Bloomfield hospital opened, laboratory leaders had begun to discuss the possibility of working toward ISO 15189 accreditation. That conversation began earlier in 2009, a time when—because of the looming national economic downturn—many quality-improvement professionals from the automotive industry found themselves jobless. Some of those professionals asked D’Angelo if they could volunteer in her office, in hopes of eventually reinventing themselves in the health care industry. Out of curiosity about the ISO 15189 standard, D’Angelo asked one of them, a former quality engineer for GM, to perform an assessment against it.

That curiosity grew the following year, when Dr. Zarbo led a CAP laboratory inspection at Avera McKennan Hospital and University Health Center, Sioux Falls, South Dakota, which had recently become the first hospital laboratory in the United States to receive CAP accreditation for ISO 15189. “That inspired us to come back and more actively pursue a path toward ISO accreditation,” he says.



Many quality improvement professionals from the automotive industry reinvented themselves in the health care industry through the Henry Ford Health System.

He already knew that, unlike some multisite institutions that have pursued ISO 15189 accreditation through the CAP, he wanted all of the HFHS laboratory sites to be accredited. “We didn’t want to do ISO for just one hospital,” he says. “It’s about equity of quality for our patients. You can’t have one site that’s identified as the best.” Then, too, HFHS had recently consolidated its laboratories into one service line. It only made sense, he felt, for all of the labs to be accredited to the same standard.

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### Developing a QMS in a Fiscally Savvy Way

The HFHS journey to systemwide ISO 15189 accreditation began in earnest in 2010. There was just one problem: Becoming accredited to the standard requires a huge amount of work—reviewing existing processes and policies, creating new ones, identifying deviations, educating staff members—and HFHS pathology quality-systems staff consisted of exactly three people, including D’Angelo. “There were three of us running quality systems for 36 sites,” she says wryly. “Most hospital laboratory systems this size would have 25 people.”

So she got creative. Remembering all those laid-off quality professionals from the auto industry, she created the Henry Ford Production System internship, a 480-hour program through which volunteers could gain experience in health care quality systems, and D’Angelo could gain a lot of much-needed help with the ISO 15189

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Gaurav Sharma MD, FCAP, speaking at Lab Quality Confab

accreditation preparation process. She sought assistance from engineering students from the University of Michigan, as well. “I had tons of volunteers, all making incremental gains toward the goal,” she says. “I’ve never heard any other organization say that. I’m blessed.”

In another cost-saving move, Dr. Zarbo created a partnership with Toronto’s Institute for Quality in Laboratory Medicine: HFHS would train the institute’s staff in Lean processes, and in exchange the institute would train five HFHS staffers to become ISO auditors. “This was an opportunity for us to develop our own people in regulatory aspects of quality, and in a fiscally savvy manner to boot,” he says.

### MasterControl Investment Pays Off

Document control, which ensures that only the most up-to-date policies and procedures are followed, is often cited as one of the most intimidating and expensive parts of the ISO 15189 accreditation process. D’Angelo knew from her previous employment at the American Red Cross, where she was tasked with achieving document control, that “it’s very time-consuming if you don’t have an electronic program that tracks revision,” she says. But at HFHS, “we didn’t have that problem.”

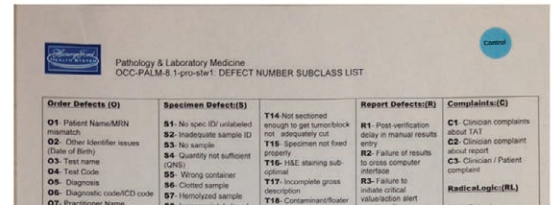
As it happened, MasterControl document control software was purchased as part of the laboratory strategic plan in 2006 and implemented incrementally at all HFHS labs over a period of four years before they even thought about ISO. So while she and her team continued to standardize and simplify the document control process, they escaped the burden of having to implement one from scratch. “If we didn’t have the software originally, that would have been the hardest part,” she says.

### System Inspired by the Department of Motor Vehicles

Not that there wasn’t work to be done around document control, specifically in the area of “job aids”—those procedural cheat sheets that tend to sneak up on the walls near workstations. “We noticed that in some hospitals, there were job aids in the laboratory that were quite old. They were made by the person working on the bench, but they were specific to that bench, and maybe they were outdated,” says Gaurav Sharma, MD, senior staff pathologist, associate director of clinical core laboratories, and director of compliance and regulatory affairs.

So he helped create a system inspired by, of all places, the Department of Motor Vehicles. “If you drive a car, the state gives you a small tag for your license plate every year, so that if you get stopped, the police instantly know whether you renewed

your plate by looking at the color of your tag,” he says.



HFHS job aid with colored sticker in upper right-hand corner

“So we said, ‘We will standardize all these job aids, and then we will stick a small colored sticker, which will be year specific, on them.’ That way, a supervisor can instantly look at it and say, ‘That’s the wrong color; it hasn’t been updated in 2013,’ and go fix it. This is a low-cost system you can use without much training. And our supervisors love it, because now they don’t have to read each and every piece of paper in detail.”

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In addition, the system makes it easy to tell when an unauthorized document has made its way onto the wall. “If it’s a piece of paper at the workstation without a controlled sticker on it, it’s removed, because it’s not a controlled document,” says medical technologist Jacqueline Jabczynski, MT(ASCP), who works in the core laboratory. In addition, says Jabczynski’s colleague Leslie Anderson, MT(ASCP), “we found an easy way to use job aids that we only refer to every once in a while. On our desktop, we have a link to our pathology homepage, where everything is under ‘Document Control.’ It was all on the bench before, but now it’s on the computer.”

### Identifying Deviations

If document control wasn’t the hardest part, what was? Deviation management was identified—that is, systematically identifying and documenting any variation from procedure. At the beginning of the ISO journey, “we didn’t have any program whatsoever that would identify deviations,” D’Angelo remembers. “So if, for example, you received a specimen from another location that didn’t have all the correct information, no one wanted to document that, because it was extra work. But we needed that information.”

With the help of her volunteers and the services of an Excel consultant, she devised an electronic spreadsheet for the recording of deviances. Getting

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staff to use it proved trickier. “That was the most difficult thing, getting 50 people in a room and telling them, ‘Everything that goes wrong today, you have to put on a spreadsheet,’” she says. “Oh, my God. The pushback was incredible. I rolled that out in 2010, and it took two years for people to get on board. It was painful.”

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In the end, persistence won out. “We educated everyone, and we made it as simple as possible,” says D’Angelo. “In the beginning, managers just thought, ‘Here we go again—she’s giving me something else to do.’ After two years, they realized, ‘Oh, this is good stuff,’ because they had control of their department.”

### Tracking Daily Deviations on Whiteboards

That realization has trickled down to the bench level as well. Jabczynski is especially enthusiastic about the whiteboard her lab uses to track daily deviations such as missed critical values or modified test results. “It’s visual and public, but it’s not a way to point fingers,” she says. “We track what caused the deviations, and we were able at a couple of workstations to find out that we had consistent problems, and we were able to change those by changing the workflow or making things a little more standardized at that bench. We’ve seen fewer defects, because those deviation boards, they really do hold you accountable.”

Anderson, her colleague, agrees. “It’s as simple as a green or a red dot,” she says. “If we made our goal for the day, it’s a green dot; if we didn’t, it’s a red dot. Did we make our turnaround time? Was there an instrument issue? It’s easy to see: ‘I missed my turnaround time yesterday; today I really need to change that.’ If there’s a red dot for both the instrument (indicating it’s not working properly) and the turnaround time, it’s really easy to see what the cause was. It’s just a dot, but everybody in the lab knows what it means.”

In the last six months of 2012, the HFHS team worked feverishly to close its self-identified deficiencies. When the formal gap analysis took place in January 2013, it identified one major and 10 minor gaps—many fewer than D’Angelo and Dr. Zarbo had expected. “I was actually shocked,” D’Angelo says. “We had worked so many years to get to where we were that by the time they gave us the gap analysis, it was really minor stuff.”

### Simple, Intuitive Fix for Temperature Issues

One of those gaps was about temperature control of freezers and refrigerators. Different laboratories were using different forms to record temperatures, and some of those forms weren’t intuitive, Dr. Sharma says. “In a large laboratory system, people may have varying levels of experience with the use of temperature charts, and we realized our charts did not intuitively drive the next step,” he explains.

“So rather than rely on tabular entries of numbers, we took inspiration from Levey-Jennings charts and made a visual chart with lines that divided the chart into three distinct temperature zones, acceptable range and nonacceptable ranges (too hot or too cold), with ‘notify supervisor’ mentioned for the latter. Whenever the daily temperature entry on the chart is in a nonacceptable range, the staff can instantly detect this as a nonconformance and notify supervisors for a corrective action. I think this is a simple, intuitive, and instant fix.”

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### Consistent Treatment of Equipment Issues

Another gap: policies regarding nonfunctioning or unnecessary equipment. “When you’d go into a laboratory and the equipment was not in operation, some hospitals had documentation showing that, and some didn’t,” D’Angelo explains. “Or sometimes equipment was in a room that didn’t need to be there, so that was a gap.”

That gap, along with the others, was addressed by mid-June. “In less than six months, we closed all the gaps,” Dr. Zarbo says proudly. “We sailed through them. And the rest is history.”

Hospitals and laboratories that are considering undergoing the ISO 15189 accreditation process will surely want to know: Exactly how has achieving this accreditation changed care for the better at HFHS? D’Angelo and others share a few examples.

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## Quicker Feedback on Labeling Errors

First, rigorous tracking of deviations has resulted in improved specimen labeling, particularly in HFHS clinics, D'Angelo says. "For patient safety, that is definitely a benefit, to have real-time information on deviation. That way we can go to the clinic and say, 'Hey, we received six of your specimens today that were unlabeled,' instead of going back to them a month later (with that information), like we used to."



Henry Ford Wyandotte Hospital

## Visible Cues Improve Performance

The blood bank at West Bloomfield Hospital has undergone several process improvements as a result of the accreditation journey. When a manufacturer sends a recall or recommendation to one department, that information should, of course, be communicated to departments at other sites. Amanda Poxon, laboratory supervisor, says, "We were doing that already, but we hadn't identified it in our procedure." The accreditation process changed that.

In addition, the blood bank has implemented visible cues on the outside of its refrigerators that indicate the date on which reagents should be switched out. "It's just a laminated card that you can write on with an erasable marker, and it's velcroed to the outside of the fridge," she says. That has eliminated the problem of the day shift running QC at 3:00 PM, a reagent expiring at midnight, and midnight-shift workers suddenly finding themselves unable to run an assay.

"We have a similar situation," says laboratory supervisor Debra Stewart, "where you might have two different reagents, but the packaging is the same except for one little identifying color. Before, we were storing them on a shelf together. Now, if it has an orange label on it, we put it in an orange bin; if it has a blue label on it, we put it in a blue bin, so somebody doesn't grab the wrong thing by accident. We've done that also with our blood gas analyzer reagent bottles; we've carried it through

chemistry. Also, with storing them in the bins, we're able to rotate the stock a little more easily. We're going to try to carry this through other departments."

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## Driving Down Callbacks and Result Modifications

Dr. Sharma points to critical value callbacks as another area that has seen marked improvement thanks to the accreditation process. "Because we were pursuing ISO, we have a system to follow our performance in this regard on a daily basis," he says. "When a physician cannot be contacted within the assigned time period, that's logged as a nonconformance, and there is consequent corrective action that includes figuring out what went wrong and what could be improved. I'm very happy to report that within three months, our callback defect rate went down from about 0.6 percent to 0.1 percent. That translates into superior and safer patient care."

Result modification rates have seen improvement as well. "We started monitoring each and every result modification in the core laboratory as a nonconformity, and there was some variation among how our technologists handled those tests," Dr. Sharma explains. "We standardized how result modifications were being handled, and our result modification rates in the core laboratory have been cut in half."

## Value Stream Mapping and Urine Specimen Quality

One change has resulted not only in better specimens arriving at a particular bench, but also made the technologists who work at that bench much happier. "When we started the whole ISO process, we took on a Lean tool called value stream mapping," says Jabczynski. (A value stream map illustrates the flow of materials to a particular point in the process.)

"I took that tool to our urinalysis workstation," she says. "We were receiving a lot of urine in a collection cup rather than in an instrument-ready tube, and that was causing a lot of backflow. Once that urine cup travels miles to get here, it's messy;

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– Amanda Poxon

it's not a quality specimen. Urinalysis was not everybody's favorite bench to work. It was all because of a lack of communication with our medical centers about the laboratory submission container type."

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– Jacqueline Jabczynski, MT(ASCP)

Once that communication issue was remedied, the percent of urine specimens arriving in a cup each day dropped from 30 to eight. "We were able to improve turnaround time and increase our productivity," Jabczynski says. "Things aren't sitting in a cup any longer, the process at the bench is a lot cleaner, people are happier to work there, and we're able to get results out faster." She and Anderson are now applying the same process to hematology, looking for similar ways to increase productivity and reduce waste.

### Collaboration Based on Standard Work

One major cultural shift that the accreditation process has engendered: an increased sense of teamwork. "There's a sense of being even more bonded, even more collaborative than we were before," Dr. Zarbo says. "Now, that's extremely important when you have economic stress. Even though we have gone through reductions, the pursuit of this high-level goal has created much stronger satisfaction in the entire workforce."

Jabczynski and Anderson, for their part, are grateful for the ease with which staff at different locations can assist each other, now that so much has been standardized. "If an instrument goes down in a HFHS laboratory, they can call us at main and say, 'We're going to send some samples over,' and we can work on them because they know it's the same here as it is there," Anderson says. And, Jabczynski adds, the deviation management tools within laboratories have worked well to foster a sense of teamwork: "Not that there was competition (among staff) before, but I think some people felt they were pulling more of their weight than others were."

### ISO 15189 and Lean Drive Down CAP Inspection Deficiencies

One unexpected but welcome result of the 15189 accreditation process: Regular CAP inspection results have improved. Says Dr. Zarbo: "We have managed to dramatically reduce our CAP

inspection deficiencies using Lean and ISO—even the little niggling things we usually got dinged for. We've reduced our citations incredibly, and I couldn't be more pleased. That shows that as you focus on quality, everything gets better."

Now that HFHS has received its ISO 15189 accreditation, what do its leaders want other institutions to know about the process? "I want them to know it's actually very simple to implement ISO," D'Angelo says. "You have a cookbook—that is, the standard—and it tells you what you need to do. It's really common sense, right? Standardize everything, get rid of the variation and the waste, and make sure the documents are under control. It's simple."

### Closing One Gap at a Time

Simple, perhaps, but not easy. D'Angelo acknowledges that the process can seem overwhelming at first. She recommends that, as a first step, an institution considering ISO 15189 accreditation cross-check its existing policies and procedures against the standard. "That's the first step: Identify what you're lacking," she says. "And then take each of those gaps and give an owner to it. Take one of your leaders who's gung-ho, and give them one of these gaps. Have them develop a team to develop whatever you're lacking.

"Let's say you don't have an equipment policy in place," she continues. "Let them own that, and follow up weekly with them. In the next couple months, that team is going to have that policy in process, and the next team is maybe going to work on that training program you didn't have, and the next team might work on that validation protocol you didn't have." Multiple teams working on multiple gaps.

She says with satisfaction, "You review progress with them, constantly making sure that everybody's following through. And at the end of six months, your gaps are closed."



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– Rita D'Angelo, MS

For more CAP 15189 program information, go to [cap.org/cap15189](http://cap.org/cap15189)