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Norchem Drug Testing: A Small Company's Lean Journey

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Joe S. Anderson

The W. A. Franke College of Business Northern Arizona University PO Box 10566 Flagstaff, AZ 86011 Office: 928-523-1389 Fax: 928-523-7331 Joseph.Anderson@nau.edu

Susan K. Williams The W. A. Franke College of Business Northern Arizona University PO Box 10566 Flagstaff, AZ 86011 Office: 928-523-0940 Fax: 928-523-7331 Susan.Williams@nau.edu

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Norchem Drug Testing: A Small Company's Lean Journey

This case was prepared by Joe Anderson and Susan Williams and is intended to be used as a basis for class discussion. The views presented here are those of the authors based on their professional judgment. The name of the supplier firm, U. S. Plastics (USP) has been disguised to preserve anonymity.

It was December and the end of the year 2010 was approaching. Bill Gibbs, CEO of Norchem Drug Testing in Flagstaff, Arizona, was reflecting on the past and projecting forward into his company's future. He clearly recalled his reflections almost exactly a decade ago. At that time, Norchem's competitors had cut prices for drugs of abuse (DOA) tests. A test that had been \$15 had become \$6.50. At the time, Gibbs had wondered how in the world he would be able to help Norchem survive with margins "falling like a bowling ball off a cliff." Yet, over the last ten years, the company had survived and even thrived, thanks to its persistent application of lean thinking to all critical dimensions of the business.

Now, Norchem's competitive environment was changing again. The recession had contracted demand for their services. After sustained growth in revenues averaging 28% per year over the previous decade, 2009 revenue was down 9% from 2008. In addition, large national labs were beginning to acquire smaller, specialized, DOA testing labs. In effect these larger companies that had previously focused on the broader market like employment testing were becoming direct competitors of Norchem. Further, changes in technology were beginning to be felt in Norchem's niche. On-site testing kits had become cheaper and more accurate, allowing Norchem's clients to perform preliminary testing on-site and only use Norchem's services when their samples tested positive for the presence of drugs. Finally, Norchem was discovering issues in their relationships with suppliers. Some friction had emerged as they tried to extend lean processes outside their small enterprise, interacting with less lean suppliers that significantly outsized Norchem. All these factors figured large in Gibbs' thinking. Would lean thinking and lean processes be enough to overcome the current challenges and insure Norchem's survival and prosperity this time around?

Company Overview

Norchem Drug Testing, located in Flagstaff, Arizona, tested for the presence and identification of drugs of abuse in human specimens. This forensic toxicology laboratory provided screening and confirmation testing with results that were legally defensible in court. Norchem primarily served criminal justice clients such as law enforcement, social welfare agencies, and probation and parole agencies. Tests were to determine the presence of commonly-abused drugs, predominantly in urine specimens though some tests were also available for saliva specimens. Clients ordered customized panels selecting among tests for the presence of over 40 drugs including stimulants, opiates, narcotics, sedatives, and the relative newcomer SPICE. Sophisticated instrumentation such as Gas Chromatography/Mass Spectrometry (GC/MS) and Liquid Chromatography/Mass Spectrometry/Mass Spectrometry (LC/MS/MS) was used. In 2009, Norchem employed approximately 72 people and had revenues of \$8.98 million.

Forensic Drug Testing: Niche in the Diagnostic Testing Industry

In the U.S., lab-based testing services generated revenues of \$52 billion in 2008. DOA testing accounted for 3% of total lab-based testing services. The majority of this testing was performed in hospital labs. Approximately 35% of the testing was performed by independent labs with the three largest labs serving 27% of that market (Quest Diagnostics, LabCorp, and MEDTOX). The revenue generated by DOA testing was \$1.6 billion in 2008 and was expected to grow to \$2.5 billion by 2015, an annual growth rate of 8% (Frost & Sullivan, 2009).

Drug testing was widely promoted in the U.S. during the 1980's by the Reagan administration as part of the escalating war on drugs and had become a common feature of both the employment environment and the criminal justice system. Drug testing was seen as an effective supervision tool in closely monitoring the behavior of offenders, one that could possibly deter future drug use and criminal behavior (Williams, 2008). A majority of probationers and parolees were required to undergo periodic drug testing as a condition of their status (Drug Policy Alliance, 2010). In response to this need, drugs of abuse testing had grown as an important supporting service to the criminal justice system nationally.

Norchem was one of several smaller labs that served the criminal justice market. In general, the large labs did not compete for this business. Norchem's direct competitors were Redwood Toxicology Laboratory, Inc., San Diego Reference Laboratory, Pacific Toxicology Laboratories, Forensic Laboratories, Inc. and Kroll. In 2010, Kroll was acquired by Redwood Toxicology's parent company, Alere, a signal of the changing competitive landscape in which larger labs were acquiring specialized smaller labs to broaden their capabilities.

In the late 2000s, the industry was experiencing significant competition on both price and value-added services. Customers could specify testing for the presence of one to many drugs for each specimen. Typically a specimen in the past was a urine sample, but labs were beginning to test alternate matrices—saliva, hair, and sweat. When SPICE, a synthetic marijuana, was introduced on the streets, labs quickly developed tests for its presence. Norchem was one of the first. In addition, an increasing number of independent labs offered to interface with clients' information systems providing data where and when it was needed.

Until 2009, Norchem and the DOA testing industry in general had experienced significant growth. However, with the onset of the 2008-2009 recession, public funding for a wide variety of programs at state and local levels was reduced significantly (McNichol, Oliff, & Johnson, 2012). Police, prison, and social services of all kinds were squeezed as states' tax revenues declined. DOA testing programs were not immune to these contractions, and the companies in the industry were affected. Norchem experienced its first year of decreased demand. As described by Gibbs in December 2010:

It was the very first year in our history that we actually didn't grow revenue—a shock to our system. But it was kind of the nature of the really rotten economy. Most of the larger labs dropped 10 to 15%, they were in employment testing, and employment testing got smashed.

We didn't lose big accounts but clients just shrunk their work down to nothing. You know—a client that was doing \$17 grand a month dropped to \$7000 a month. The way they managed it was they changed their randomization routines. Instead of testing twice a week, they tested twice a month. Big impact on us...it still continues to some extent. We had to work really hard last year to fill in and we were successful at bringing in new customers. There were more small customers as opposed to big ones.

In addition to the recession, there were trends reduced demand. One trend was the increased use of pointof-collection testing kits. With these kits, clients performed the screening test in their own facility with immediate results and only sent a specimen to a lab if the presence of drugs was detected. The lab then only performed a confirmatory test to determine what drug was present. Finally, the consolidation of some smaller labs into the three major labs had reduced demand for Norchem because some clients preferred to use a single large lab as a one-stop-shop. This also added significant downward price pressure due to the economies of scale of these large labs.

Certification

All medical testing laboratories were governed by the 1988 Clinical Laboratory Improvement Act (CLIA) that was implemented in 1992 to establish quality standards that ensured accuracy, reliability, and timeliness of patient test results. At the end of 2010, there were approximately 250,000 labs performing tests on humans (research labs were not included) that were regulated by The Centers for Medicare & Medicaid Services (CMS). Laboratories, under CLIA accreditation were required to do proficiency testing of blind samples, and their facilities were inspected by CMS every two years in order to maintain certification (Centers for Medicare and Medicaid Services, 2012).

In addition to CLIA, forensic toxicology labs could opt to obtain the much more rigorous and specific Forensic Drug Testing accreditation from the College of American Pathologists (CAP). CAP was "designed to go well beyond regulatory compliance" to make sure the needs of employers and law enforcement were met (College of American Pathology, 2011). Accreditation involved adhering to four primary standards concerning the scientific director and personnel, the physical facilities, quality management of the laboratory testing and the chain of custody documentation processes, and finally the standard for inspections, proficiency testing protocols, and self-assessment required to maintain accreditation (College of American Pathology, 2009).

Company History

In 1994, William (Bill) P. Gibbs and Dr. Thomas E. Vorpahl, and the local hospital, Flagstaff Medical Center (FMC), co-owned Alliance Medical Laboratory, a medical testing lab. Frustrated with long payment intervals and the resulting cash flow difficulties caused by health insurance companies, Gibbs and Vorpahl thought it would be nice to have revenue that was not dependent on health insurance. As they looked to diversify their income stream, they purchased a small, locally-owned toxicology lab, Northern Arizona Chemistry Lab (NACL), in Flagstaff, AZ.

At the time of the purchase, NACL had two employees and was testing approximately 70 urine specimens per day for the presence of drugs of abuse. NACL's clients were the probation departments of several counties in northern Arizona. Gibbs and Vorpahl moved the toxicology lab into Alliance's facilities at FMC. Initially, Alliance used immunoassay screening techniques followed by tests where color changes were observed on a chemically-treated paper strip to confirm the presence of drugs. These confirmation tests were 95% accurate but Gibbs knew that they needed to invest in more advanced technologies. They quickly adopted gas chromatography and bought their first GC/MS machine. Gibbs recalled:

It was crazy in the beginning; we did all these collections here in town. All of the Coconino probation officers came to our offices up at the hospital. We had a lady doing our collections in a small, little bathroom in the hallway. All my clinical staff and my accounting staff were sitting outside, right in front of the bathroom.

Norchem Drug Testing was born in 1997 when Gibbs and Vorpahl spun off the toxicology lab from Alliance Medical Labs. Alliance had received a takeover bid from LabCorp, a large, national medical testing laboratory, but the toxicology lab was not included in the offer. At that point, it was necessary to move the toxicology lab out of the hospital, so Gibbs and Vorpahl rented a space on the east side of town and had a naming contest for the newly independent company. The name, Norchem, was revealed at the company Christmas party via a modified poster of the currently-popular movie, *Speed*. The poster featured Keanu Reeves and a flaming bus with the phrase "Get Ready for Rush Hour." The movie title, *Speed*, was replaced by Norchem.

Joni was one of the original NACL employees and a credentialed medical technologist. She also had a background in sales and marketing and she quickly reminded Gibbs and Vorpahl that her skills might be better employed in helping to grow the business. They took her up on her offer and were glad they did, because in a short time she was able to sign up two out-of-state customers. These clients were large for Norchem and doubled its sales. Joni continued to be highly successful selling Norchem's services and she moved the sales office to Denver in the early 2000s.

In 2000, Norchem created a new position and hired its first Ph.D. Scientific Director. With this hire came a focus on achieving relevant industry certifications and improving the technology of the process in order to increase the accuracy and reliability of its results. As part of Alliance, the company had earned a CLIA certification. Under the direction of the new Scientific Director, Norchem worked toward and obtained the CAP Forensic Drug Testing accreditation.

As a result of both its high-quality product and customer service and the success of the sales team, Norchem experienced increasing sales growth every year until 2009 (See Table 1).

Year	Revenue	Percent Change
1995	\$ 465,793	-
1996	\$ 539,875	16%
1997	\$1,016,795	88%
1998	\$1,285,119	26%
1999	\$1,573,433	22%
2000	\$1,650,549	5%
2001	\$2,253,563	37%
2002	\$3,477,778	54%
2003	\$4,318,051	24%
2004	\$5,158,395	19%
2005	\$5,534,130	7%
2006	\$6,237,244	13%
2007	\$7,955,035	28%
2008	\$9,635,865	21%
2009	\$8,762,692	-9%
Average		28%

Table 1. Norchem Sales Revenue 1995-2009

Production Process

The service that Norchem provided its clients was simple in concept but complex in the details. Norchem was contracted by its clients to provide drug test results. For example, a probation department monitored parolees that were required by a court to have regular drug tests as a condition of their parole. The probation department or a third-party provider would collect urine specimens from the parolees (donors). The specimens were then shipped to Norchem for analysis. Norchem would perform the required analysis and provide test results (information) to the client.

Norchem organized its production process into two major steps: specimen processing and analysis. In the first step, receipt of the specimen was recorded and the specimen was prepared for the requested tests. In analysis, all specimens were screened for the presence of drugs. Then, depending on the requirements of the client and the results of the screening, a confirmatory analysis might be performed. The complexity in

the process arose from the variety of requests received from the clients since they could request tests for approximately 40 different drugs and one specimen could be tested for any combination of these drugs. Complexity also arose from the fact that each drug had a different testing protocol—recipe for detecting a drug. Finally, each specimen had different storage requirements depending on the client requirements and test results.

The production facility started empty every morning. Specimens were received by courier (75%) or Federal Express (25%). Most specimens arrived early in the morning though a second shipment could be received mid-morning. The number of specimens that arrived per day varied significantly and could be as many as 6500. Typically, the average in 2008-2010 was 4500 specimens per day.

When received from the client, the specimen and documentation were in a plastic bag. Some clients (40%) would have already entered the test requirements into the laboratory information system (LIS) and all that was required was that receipt of the specimen be acknowledged. Other clients (60%) included a form with the specimen that specified the requested tests and the lab tech entered this information into the LIS. Documentation was an important quality aspect provided by Norchem to its clients. Some test results would be used in court and required stringent and verifiable documentation.

Once the specimen was registered with the LIS, it was loaded into a robot that dispensed a small amount of the specimen, called an aliquot, into a test tube. This machine eliminated the need for a lab technician to manually open and pour some of each specimen into a test tube. It is important to note that in the next process step, analysis, lab technicians worked with the sample in the test tube not the original specimen. The remainder of the specimen was stored temporarily. If the results were negative, the specimen was stored for 14 days in case the client needed to order additional tests. Specimens that were not negative were saved for one year and were available for retesting in the event of a court challenge.

During screening, the first analysis step, most test tubes (95%) were loaded into the process bottleneck, an analyzer (AU2700) that performed chemistry-immunoassay and other screening tests for the presence of drugs. Each sample was tested for the presence of one or more drug families—for example, opiates. Positive test results could only conclude that there was a presence of some type of opiate in the urine. This test was generally adequate for monitoring parolees but was not adequate if the results were required as evidence in court. The screening test was faster and less expensive than the more detailed, confirmatory test that could detect the presence of a specific drug.

The AU2700, a \$200,000-\$250,000 machine, used a batch size of 30 test tubes. The process time for a batch varied from a 10 to 20 minutes depending on the tests that had been requested for that particular batch of specimens. There were four of these machines and the challenge came from trying to run this bottleneck efficiently while managing the upstream and downstream processes well. The process needed to be "synchronized; like a dance" as described by Mark Mayrand, Norchem's operations manager.

As required by CAP, the forensic drug testing certification rules, Norchem was required to run quality tests on control samples to check that the analyzer was correctly calibrated and accurately running the tests. In fact, each batch of client test tubes had to be both preceded and followed by a complete batch of control samples. This represented a substantial portion of the time to process a batch and significantly affected the throughput of the analyzer.

Once the screening was completed, a technician sorted the original donor specimens for further processing. At this division point in the process there were many directions that the specimen could travel. If no drugs were detected (80%), processing was completed on the specimen, the customer notified of the results, and the specimen was stored for 14 days. If drugs were detected, processing might be completed and reported or the customer could require confirmation testing.

Confirmation testing was the second step in analysis. If a sample was determined to be positive during the screening step and if the client had requested, the specimen flowed through the more expensive and time consuming confirmatory testing. Based on the screening results, a lab tech created a new sample from the original specimen. In general, the confirmatory process steps were: create a sample with the correct dilution, add reagents, incubate (if required), extract the drug from the sample and concentrate it, and perform mass spectrometry. The mass spectrum analysis process time depended on the drug and required from 30-90 minutes for a batch of 12 samples before a scientist read the data analysis, interpreted the results, and submitted the results to the LIS. The batch size depended on the type of drug test but 10-12 was typical. Approximately 600 samples per day were processed in confirmatory testing, 50 per day were samples that were brought out of storage per customer request for additional testing.

Since each specimen that came into the lab was processed to the customer's requirement, the lab was highly customized and functioned much like a job-shop process. Each sample flowed through and exited the process uniquely depending upon the requests and the results. The product, a report sent to the client, could be generated at screening or after one or more confirmatory tests.

The Lean Journey

The Lean Journey Begins

Despite improvements in process technology and sales successes, Norchem was faced with a challenge in the early 2000s. Competitors were reducing prices and Norchem was feeling pressure to respond. However, competitors' prices were approaching Norchem's costs. Gibbs described the situation:

Why did we go to lean? The company was on the verge of disaster. Margins were falling like a bowling ball off a cliff. Competitors were cutting us by 30%. When we first began, we were getting \$15 per test, and at the beginning of lean, only \$6.50. Without lean we'd have been heading for the trash can. It was survival mode.

During this time, Gibbs read some articles in the business press about Jack Welch, CEO of General Electric, and became interested in Six Sigma. One of the developers of Six Sigma, Mikel Harry, had his Six Sigma Management Institute in Phoenix, Arizona. Gibbs and his wife, Rebecca, a medical technologist and Norchem's Quality Assurance Officer, decided to attend a Six Sigma workshop at the institute. Gibbs recalled:

It was kind of an afterthought almost; it was the last day of the program and the facilitator talked about lean and how it was this commonsense approach to removing waste from processes, being able to identify wastes. He talked about the seven forms of muda [waste] and I thought, "Aha, this makes sense to me. This is easy and I can do this." So I got all fired up about that and I started buying books and bought Womack's books and there were references in this program. I probably spent six months just reading all the books. I was pumped, all fired up and excited, and I realized this is what I needed to do.

So I went into the lab and it was obvious to me, all this muda. Oh, I was a tornado! I told everyone we were doing it wrong and I redesigned the process and I sat down with my senior people. "Okay here's what we're going to do, when we're going to do it, and it's all going to work, and it's not going to be that bad." Of course, it's never that easy but we did it anyway, and it was tougher than the dickens on our staff. I can remember some of my people working 16-hour days for a month with no days off. It was crazy! It was so disruptive the way I did it. I regret it to this day. Most of those people are no longer with

the company, unfortunately. There are some survivors, and the survivors today are the new leaders that endured this difficulty, and I think that they are much better tuned to how to make changes and to avoid this trauma that change can be. So, we learned a lot in that process but when the day was done we got all the benefits. It was real and it affirmed to me certainly that the path we were on was the right path.

One of the people that survived was Chris Stephens who became the Material Control Group Leader. He described the changes:

The first thing that most people would say is that it is rewarding. But if you go back to where you were when you started you can say that it is very hard. You have to break out of a mindset. Once you get used to something you get comfortable. And once you get comfortable it is so hard to undo what you are doing.

Stephens concluded that they often had to try changes that didn't work before they developed a change that improved things.

The Lean Journey Continues

One the most controversial of the changes was that lab technicians' chairs were removed and they were expected to stand while working. Some technicians actually quit because of this change and those that stayed complained about back and feet problems so much that Gibbs brought in an ergonomics expert. The expert applauded the elimination of the chairs and said it was much healthier to stand, especially since people often slouched unhealthily in chairs. The expert was concerned about other aspects of the technicians' jobs when a single motion was required repeatedly without interruption. Norchem learned how to change the processes to eliminate these potentially-harmful, repetitive motions.

By 2005, the benefits of lean were clear and Gibbs intended for Norchem to continue the lean journey. However, it was time for Gibbs to get out of the lab—some in the lab were even telling him so—and as CEO, he had plenty competing for his time. Ricardo Castillo, an industrial engineer with lean experience, was hired as the Lean Manager. His full-time responsibilities were to continuously improve Norchem's processes.

One of Castillo's first steps was to map Norchem's value streams and to identify and understand the internal and external customers of each value stream. In addition, Castillo continued the work begun when the chairs were eliminated by implementing standardized work for all processes in the lab. The work was visually documented and all work stations were 5S'd.

At first, the technicians responded to Castillo's presence in the lab with uncertainty. As Gibbs described:

Ricardo was persona non grata when he walked into the lab. They didn't want this guy hovering around with a stopwatch and clipboard. They thought he was like checking them out or something. Soon, they realized he was there to help them, to improve their lives, to make it easier, and to take away these wasteful steps. So he became a quick collaborator and they are not bothered by it now.

Transparency was an aspect of several other changes. Improvement projects were documented before and after with A3 reports that were posted in a hallway for all to see. Employee suggestions were also encouraged, rewarded, and implemented quickly. They were posted on a board in a hallway next to the entrance to the lab. Gibbs and Castillo began hoshin planning which also increased transparency in the

organization. Goals and performance measurements identified in the hoshin planning were posted. Gradually, a culture that embraced, or at least expected, change began to grow.

The benefits of applying lean in the lab continued to accrue. Increased volume was processed by fewer lab technicians using less floor space. With such significant improvement in the lab, Gibbs admitted a concern:

My great fear now is we will backslide; that we will get complacent or we will get really busy and all of a sudden being busy is more important than changing. And I know that would be our death if we go down that road. So I keep agitating Ricardo and pestering him and poking at him and asking him what are we doing about this and what are we doing about that. So he has to go in the lab and say "What are we doing about this? And what are we doing about that?"... But it lets everyone know we are still on the road here.

Diffusing Lean Thinking Throughout the Company

Having achieved successes in the lab, Gibbs and Castillo sought to spread lean thinking more broadly. Amanda Gibbs, manager of the accounting/finance area, when hired in March 2008 had been tasked with implementing lean accounting. There are two dimensions to lean accounting. First, implementing metrics and reporting systems that are capable of measuring lean improvements in the manufacturing area—for Norchem—the lab. Second, applying lean concepts to the processes that occur in the accounting/finance area. Norchem had already started working on the first and wanted to start working on the second.

Amanda had several projects in addition to applying lean thinking to accounting. First, the department needed to implement a new accounting software package, as Norchem had outgrown the current one. She also wanted to automate some processes. However, her staff had no time to allocate to improvement projects as they were fully occupied with routine tasks.

If she could free up some staff time for an improvement project, one place she wanted to start was with certifying vendors. As recommended in lean thinking, this would allow some invoice and payment processes to be automated, thereby saving staff time. In order to certify a vendor, an understanding of the needs of both the vendor and Norchem had to be developed. As Amanda described:

The idea with the certified vendor is to work out all of the nitty-gritty details to the point where we wouldn't even get invoices from the vendor. And then, we would pay based on a receiving document rather than actually getting an invoice. But there is a lot of work before we can get to that point. What are all of those details that we have to work out with the vendor?

Obviously, we have to agree on prices, we have to agree on when we pay the vendor. How are we going to reference it? If they are not sending us an invoice anymore I'm not going to be able to reference an invoice number on the payment that they receive. We would just be prompted for payment as long as it was received how it was ordered. What are the shipping details and how often will they deliver to us?

At the time, Norchem had pricing agreements with some of its large vendors, which was a start in the certification process. However, before Amanda's department staff could move any of these projects forward, she needed to free up some of her people's time. She knew that transaction processing, whether it was accounts receivable, accounts payable, or general ledger transactions, needed to be reviewed and redesigned so that it was operating more efficiently and incorporated lean thinking. Amanda described:

The accounting area, for the most part, is a non-value added activity in the lean sense. We are trying to figure out how we can process the most work with the fewest people. Our overall goal is to get cash faster from our customers and then to pay our vendors in the most efficient way possible.

A challenge in applying lean with experienced, knowledge workers is that if they hear, "We want to help you do a good job," some take it to mean, "You are doing a bad job now." Despite the fact that the lab had been implementing lean for several years and the employees in accounting/finance had experienced lean training, bringing lean into the accounting/finance area was traumatic. The staff felt that they were already doing a good job—efficient with no work-in-process (WIP). As Ricardo was documenting the process, he asked one of the staff why she was stacking some paperwork off to the side, incomplete. She replied that she needed to get back to it later as it needed different handling. Ricardo said, "That's WIP." The staff person replied, "Ohhh! That's what you've been talking about." Before the implementations were completed, there were many tense conversations, some even with tears, and one employee had quit.

So transaction processing was redesigned and streamlined into a transaction cell. Traditionally, accounts receivable (AR) and accounts payable (AP) processes were handled by different people, but Amanda was dividing the work differently. Each transaction was first prepped by a staff member whether it was AR or AP or general ledger. This staff member placed the prepped transaction into a heijunka box by priority. The heijunka box gave the manager a visual cue when AR/AP was falling behind so she could balance the workload. A second staff member performed the entry of the transaction. Amanda said that as she was redesigning the processes and talking to other accounting people, she could see the red flags being raised. She continued:

I am essentially taking away the segregation of duties between AR and AP. And everybody is like "Oh, my gosh! You can't do that." When we started planning this process, I gave everybody the mandate of "don't think about controls at this point, we just want to design the most efficient process we can." Once we design the process, we'll take a step back and look at what our risks are from an internal control standpoint and figure out what controls we need to mitigate those risks. I don't want to design a process that is mandated by internal controls. I want to design a process and then figure out what controls we need in place.

Amanda worked with the controller and consulted with the AR/AP staff to redesign the process. As Amanda described:

When you are redefining the entire process you really want a higher-level person to do it. The people in the trenches don't necessarily have a high-level view. The AR/AP staff did not like that we were coming up with the processes. There was a lot of resistance because, "That's not how I do it." "Well, I realize that's not the way you do it, but we are going to try it under this new standard process for a while and see how it works."

Once the controller and I started rolling that out with AR/AP staff, there were things that we missed—little details. We needed to get that detail back into the standard work documentation and they were able to help us out a lot. But it was really doing observations, not getting too caught up in the way we do it now but looking at it from an overall theoretical perspective. How should the flow be? What's the ideal? But still wanting to understand what they do now, so we don't leave out important details.

As Amanda was designing the transaction cell, she was concerned about additional challenges:

The other thing that's hard in our area is the demand for work is so variable from day to day. One day we get one check and one invoice in the mail and another day we will get a large stack. So it just depends.

The demand was not level and was often exacerbated by erratic U.S. postal deliveries.

Amanda described another anticipated challenge—exceptions to the standardized work in the transaction cell. Amanda knew that she had not captured all transactions in the standardized work and that there would be a transition period. These exceptions had to be handled but had not been included because they were too infrequent and unusual. In anticipation of these exceptions, Amanda created a 'do-later' box for the prep person to place work that was out of the ordinary. Similarly, for the entry side of the transaction cell, if the person had no idea how to enter a transaction they were to place it in the 'oops box.' Amanda then monitored the contents of these boxes, transactions that had to be handled separately, and tried to figure out how to process them in the future without special handling.

Finally, Amanda wondered about identifying errors. Once identified, what errors could be prevented by modifying the standardized work and which would have to be corrected? A challenge to identifying the errors is that they might not be found until the end of the month, which was not very timely. So her challenge was to figure out how to capture that data as soon as possible.

While some aspects continued to evolve, the lean accomplishments in the AR/AP processes included standardized work, visual documentation, and the heijunka box. Later, a temporary employee came to fill in and said that this was the easiest place to learn the company's processes that she had worked.

Supplier Relationships

Norchem had made significant improvements by applying lean thinking in the lab, accounting/finance, and human resources. However, a challenging theme began to emerge in several improvement projects. Many of Norchem's processes did not start or end within its four walls. For example, the testing process could actually be considered to start at the client's facility when the initial specimen was collected. Likewise, many processes relied on equipment or supplies from vendors. To improve these processes, Norchem needed to understand the interface between its processes and the vendors'. Any improvement at the interface required Norchem to solicit cooperation from vendors to reduce waste.

This represents an aspect of applying lean thinking in a small business that is different from larger companies like Toyota, Honda, and Boeing. The principles are the same: determine what adds value for your customers and remove waste from the system. However, as Amanda pointed out, "Unfortunately we're not as big as a Toyota that can just kinda say, 'This is the way we do it now.'" Castillo added, "Even though some vendors are 20 times bigger in revenue or size, Bill's still trying to convince them, 'Hey, you gotta be lean, so I can be more lean.'" Gibbs expanded:

You know, I think the whole supply chain question is one of the tougher parts of being a small lean shop surrounded by other companies that are in certain stages of their journey. Those that know nothing I send them a book, trying to get them excited about lean.

Location was another difference. Amanda had been reading about lean supplier relationships that included the supplier monitoring the client's inventory, stocking it when needed, and the client paying based on its usage rate. Amanda wondered how that could possibly work for Norchem given that none of its suppliers were nearby.

Seeking Supplier Support for One-Piece Flow

One-piece flow is an ideal of lean operations. As Mark Mayrand, operations manager, described, "Any type of batching is considered muda, even though it might provide benefits in other areas of your operations." At Norchem, much of the batching was driven by the sophisticated testing equipment. The immunoassay analyzer worked in batches of 30. The aliquot machines in specimen processing also worked in batches of 30. These aliquot machines were purchased in 2005. Before that time, Norchem had been processing the specimens by hand. Gibbs had wanted to automate this process and began exploring the possibility of acquiring machines from U. S. Plastics (USP). USP was a supplier of the collection kits Norchem sent to its clients and other plastic supplies needed in the lab. USP also sold aliquot machines and was willing to finance the purchase of these machines provided Norchem would purchase the collection kits from them during the finance agreement period, which would last about five years. Under this agreement, there would be a machine service fee and a machine cost on every collection kit purchased. USP was not primarily in business to sell the machines but as Mayrand explained:

What they want to do is just get their money back on their equipment. But they really want to tie you into a long-term relationship on buying their plastic. And the way they do that is they are willing to finance those machines as long as you are paying the percentage, but they are really making the money on the sale of their plastic. And you can't go anywhere...

Norchem agreed to purchase two aliquot machines from USP and that tied them into a five-year agreement to purchase USP plastic.

As Norchem moved further in their lean journey, Gibbs and Castillo realized that the batch size required by the aliquot machines was preventing them from reducing WIP. In order to move specimen processing toward one-piece flow, Norchem ultimately needed an automated piece of equipment that worked with a batch size of one. Further, as the end of the contract was approaching, Norchem was having increasing difficulty with the reliability of the USP aliquot machines. The summer before the contract expired, the machines frequently broke down.

In addition, there was the introduction of a leak-proof specimen vial, an innovation that USP developed that had the potential to reduce costs. With the old vials, a specimen might leak. The shippers wanted any leakage contained so a specimen had double protection, the lab package and a box or bag similar to a biohazard package. USP's leak-proof specimen vials allowed the second level of packaging to be omitted, saving Norchem 45 cents on each specimen from the client. Ironically, the USP aliquot machines could not reliably open these new ones. The machines only worked well with old-style USP containers. Additionally, they could not open containers from other suppliers. This was a problem because sometimes Norchem received vials from clients that Norchem had not supplied. Each day there were more that had to be processed as exceptions, which was time consuming and could quickly offset the packaging cost savings.

This was not the first time that USP had changed the collection vials without informing Norchem. As Stephens described:

They've changed resins, to save money and not make us pay more as a customer, and every time they did that, there were problems. There were also design changes, actually, quite a few times.

The operations manager, Mayrand, added that suppliers would make changes in a product in order "to save a dime or nickel or even half a cent" and the repercussion to Norchem could be

significant. The "poor techs on the line have to live with trying to make it work." Norchem would learn about the changes after the fact because there would be problems at the aliquot machine or a client would complain about leakage.

Due to the quality issues with the machines, the history of variation in the plastics, and its idealized goal of one piece flow for specimen processing, Norchem started to explore other options for the aliquot machines. First they approached USP asking if it had a machine that worked with smaller batches or if it would be interested in developing such a machine. The supplier did not currently have such a machine in its product portfolio but was willing to explore the market potential. Unfortunately, they found no interest in the market and were not interested in pursuing the idea further.

Gibbs explained why other companies were not interested in a single-piece flow machine:

It's counterintuitive to build a machine that requires a person to touch it with every sample and other testing labs are thinking, "Why would I spend 80,000 bucks to build an aliquot device that only takes care of one person? That doesn't make sense, does it?" You want a big, giant robot that does a bazillion things with 100 people feeding it. That's not lean, that violates all of the lean concepts. Lean concepts say single piece flow, man-size machines that maintain a pace with the person's productivity.

Not to be discouraged from its goal of one-piece flow, Norchem worked with local engineers to design and build the machine that it envisioned. This gave Norchem a unique opportunity to affect the design of the aliquot machine. Much of what it learned during the five years using the USP machines and implementing lean thinking went into the specifications and requirements for the new machine. Flexibility and the ability to handle variation was a priority. As Mayrand explained, the more lean the processes, the more problems due to variability were exposed. In particular, due to their experience with USP's machines, Mayrand had the engineers design the Mini-Merit opener to account for all the variability that might be expected in a vial lid regardless of the supplier—a universal opener (analogous to a universal remote).

Initially, a single machine, the Mini-Merit, was built and the efficacy of the design was tested. Pleased with its experience with the new machine, Norchem ordered three more Mini-Merits to replace the USP machines. After installing the four machines, the current state of the value stream map for specimen processing was revised. Norchem found significant improvements on several dimensions: the percent of value-added time was increased from 25% to 97%, the downstream process was loaded earlier in the day, which improved the first hour of production by 28%, and required floor space for the process was reduced by 26%. Gibbs explained their lean thinking:

So we work really, really hard to make the upstream activities as efficient as we can, where they can go at the same rate of speed as our bottleneck, our very expensive analyzer [AU2700]. You have this quarter of a million dollar investment sitting there. You want to make sure that the analyzer has every opportunity to meet its performance specifications. You have to devote yourself to that. If you devote yourself upstream of that or downstream of that and it doesn't support 100% of its performance metrics then you are wasting money. We balanced very carefully to that bottleneck and now we are able to feed the machine with one individual. That's kind of unusual. Most labs need more than one person to feed the immunoassay analyzer. But we've been able to engineer that process upstream so that one individual given this robot, this man-size robot, can feed that bottleneck constraint.

Another Challenge with Plastic Supplies

So while Mayrand anticipated variation in the vial lids and specified the universal opener, there were other unanticipated variations. One of the supplies was a plastic tip that was used by the aliquot machine to pipette some of the specimen from the vial and place it in a test tube. To prevent cross-contamination, the tip had to be changed for every specimen. Norchem continued to use the USP supplied tips when it switched from the USP machines to the Mini-Merits. During that summer when Norchem first tested the Mini-Merit, USP, without advising Norchem started providing a competitor's tip instead of its own tip. Mayrand surmised that USP was moving production during this time, so USP was unable to produce the product. Norchem used what was sent and the competitor's tips worked fine on both the USP machines and the newly installed, experimental Mini-Merit. In the fall, the rest of the Mini-Merits were installed and all of the USP machines were decommissioned. Then, again, without communication, USP changed the tips, no longer shipping the competitor's tips but USP's own again. At this point, Norchem began having problems. The Mini-Merit would pick up a new tip but sometimes wouldn't detect it, so it would pick up a second tip. With two tips fitted, the aliquot could not be performed until an operator manually pulled off the extra tip, re-homed the machine, and restarted the process. This would happen 3-4 times per 100 tip changes. Since a tip change must happen with each specimen, this significantly slowed production and frustrated the operators.

Mayrand called the USP sales representative and his response was to blame the new machines. Mayrand requested to go back to the competitor's tips that USP had been shipping for about six months, but the sales representative said that could not be done. More investigation showed that some of the dimensions of the tips had changed. The sales representative was more responsive when Mayrand presented these details and the rep suggested that Norchem contact the process engineer. Mayrand tried to reach the process engineer but was unable to connect with him for two months. USP had been acquired and there had been a lot of movement and assimilation of the USP staff that Norchem had been working with. Meanwhile, since Norchem no longer had to purchase the tips from USP, it contacted the competitor whose tips had been working well with the new machines. Norchem entered into a one-year contract to purchase the tips, though at a 50% cost increase. Mayrand summarized his frustration in working with the newly-acquired USP.

And so that's probably the best indication. I mean how do you deal in this maze if you are trying to be lean and if you don't have piles of inventory? How can you run when you have a vendor that essentially says, "I can't help you" for two months?

Go to the Gemba

Not all aspects of Norchem's relationship with USP had been as frustrating. Another supplier relationship issue concerned the collection kits supplied by USP. The collection kits arrived at Norchem's dock on pallets. The collection kits were boxed in quantities of 100. There were two types of kits: female and male. The 100-kit boxes were stacked on pallets and shrink wrapped. Norchem had been receiving damaged collection kit boxes. If the boxes were seriously damaged, the tamper resistant packaging could be broken and the vials could even be crushed. USP had been using R+L Carriers and then switched to FedEx Direct with a resulting temporary improvement. However, the number of damaged boxes increased again to where Norchem received 5-10 damaged 100-kit boxes on a pallet of 45 boxes. Some of the pallets of the female-kit boxes were damaged around the entire perimeter of the pallet which meant that half the boxes were damaged and the other half had to be repackaged into 100s or sent in smaller quantities only for the 'call-in' orders. This required a significant repackaging effort so that the boxes of 100 were complete with no damaged kits. Shipping collection kits was requiring a full day of staff time each week.

Stephens, the Material Control Group Leader, decided to 'go to the gemba.' That is, he decided to visit USP where the work was being performed. When Stephens visited, he watched the pallets of kits being built and shrink wrapped and loaded onto the truck. He noticed that since the female boxes were larger, when 45 boxes (3x3x5) were placed on the pallets, the boxes overhung the pallet. This made the boxes more vulnerable to damage when they were being loaded and during transport. Stephens requested that instead of placing 4500 kits on a pallet that only 3000 kits be loaded (3x2x5). That way the boxes did not overhang the pallet. He also observed that for another customer, USP used corner protectors on each of the pallets to protect the box corners. The supplier would shrink wrap one layer, place a guard on each corner and then shrink wrap another layer. Stephens requested that these be used on Norchem's shipments. Norchem was very happy with the reduced number of damaged collection kits that resulted from the supplier's positive response to Stephens' advocacy. In addition, staff time to handle and re-ship the collection kits was reduced so that 70% of their collection kit fulfillment could be completed in thirty minutes. Stephens found that the visit to USP was worthwhile. He met the people he had been working with and found them more responsive after his visit.

Quest for Just-in-time Shipment

On a day that a shipment of collection kits was received, Norchem's small dock would be filled with pallets, sometimes enough collection kits for over a week. This concerned Gibbs and Castillo. One of the most recognized dimensions of lean operations was just-in-time (JIT) inventory policies, ordering and receiving in small quantities what is needed when it's needed. The collection kits were one of the largest components of Norchem's inventory. To reduce its collection kits inventory, Norchem would have to modify the ordering/shipping arrangements. This meant collaboration with the supplier, USP, again.

The current state. The current order unit was a complete pallet of either all female or all male kits. After the palletizing was improved, there were 30 boxes of 100 female kits on a pallet or 45 boxes of 100 male kits on a pallet. USP, located about 1700 miles away, paid for shipping. Typically, it shipped 12,000 collection kits (one female pallet and two male pallets) every 2-3 days. However, there had been as many as 3 female and 4 male pallets on the dock, 27,000 kits, a six day supply.

Norchem sent these kits to their clients on a regular basis to replace kits that had been shipped to Norchem with specimens to be tested. Whenever a collection kit from a client was received and scanned as it entered the lab for a test, the shipping system made a note to replace it, much like a POS system in a retail store. When the client needed 100 kits, a shipment was made. Before shipping the new kits to the client, Norchem placed chain of custody forms (one for each kit) in the 100-kit box. The chain of custody form had information about the client and was unique to that collection kit. This inventory was an unusual type of inventory. It was owned by Norchem but sent to clients without payment. The kit cost was included in the charge for the test and could not be known until the client shipped the collection kit to Norchem for testing.

Norchem occasionally ran out of collection kits and could not send kits to clients until the next shipment arrived from USP. Gibbs and Castillo thought that more frequent, smaller shipments would create a smoother flow and reduce the number of stock outs. If Norchem's clients ran out of collection kits, the ramifications varied. For some clients, it was an inconvenience to ask donors to come another time to provide the urine sample and this was not quality service. For other clients it was more serious as they had probationers that were on a court-ordered testing schedule.

Information lead time. An additional challenge of the current situation was the information lead time that Stephens, the Material Control Group Leader, had to consider. Many clients and suppliers were in different time zones than Norchem. Stephens worked directly with the clients and "When they want something, it's not like 'hey, go ahead and take your time.' It's, 'I need this now! I need this within a

week." The supplier, USP, was an hour ahead of Norchem. Some clients were in California, an hour behind Norchem. If Stephens received a call from a California client near the end of the client's day it was too late to get a shipment from USP. So, Stephens' solution was to maintain some limited inventory at Norchem which allowed him to respond immediately to the client. It was even worse when it used a supplier in North Carolina. Stephens described:

They were three hours ahead of us most of the year; for a few months just two ahead of us, and when I needed them to do something, anything that was overnight, I couldn't do it. So that's why we brought it in-house. You know, we have the information lead time between us. Every time they did something wrong, I had to wait to the next day. So bringing it in house, if there's a problem and our client calls me, I walk back and talk to whoever my tech is at the time and say 'Hey, can you ship this please.' Done. Really, if you think about it, I have my inventory in house, I have my inventory on the way, and I have my inventory that hasn't shipped that's being ordered. And that's all part of the calculation of how much inventory, total inventory that I have to have.

The future state. Norchem wanted a just-in-time (JIT) supply shipping arrangement with USP. As Gibbs described:

So I think that that's probably an area that I'm always interested in, how they could supply us on a just-in-time basis. 'Cause any inventory that they hold until I'm ready for it is money off my balance sheet. So I like that.

Within Norchem, there was not a clear consensus about the details of a JIT shipping arrangement. Gibbs and Castillo would like to have a shipment every day. However, the purchasing manager did not want a daily shipment since a shipment every day would be smaller than a pallet, the current order unit. If shipped every day then mixed pallets would arrive, requiring more time from Norchem's packager. A further complication to daily just-in-time shipments was the uncertainty of Flagstaff weather. Unlike the stereotypic desert climate touted in Arizona travel brochures, Flagstaff is at an altitude of 7,000 feet, and receives an average of 100 inches of snow each year. Norchem was located on Interstate 40 and nearly every winter, I-40 closed due to weather conditions and a shipment might not get through. If they were relying on this shipment and it was delayed a day or two, it would be problematic.

Drop shipping the collection kits directly to the clients from a plastic supplier would eliminate having to ship them to Norchem's inventory and then to its clients. At one time, a supplier did ship directly to the client but that did not work well for several reasons. First, Norchem's competitive advantage was customer responsiveness but the supplier's business model was built on low cost. The supplier did not have the skills and processes in place to manage Norchem's clients in the responsive manner that Norchem needed. Stephens anticipated that asking USP to drop ship would be problematic for the same reasons. As Stephens explained:

USP knows nothing about our clients; absolutely nothing. They want to ship you cases of stuff and that is it. They want to make the cheapest, but good quality, plastic possible. When I went there, they were producing this stuff non-stop, 24/7/365 days a year. They have such a large operation, I think that it dissolves a lot of those costs so that they are one of the cheapest in the US. But on the client side, they don't know what to do. They don't know where to send, how many to send, you know, all that stuff.

In addition, since Norchem added a chain of custody form to each collection kit, the supplier would need more information about each of Norchem's clients. If the relationship was more collaborative this might

be appropriate. However, since the supplier was not organized to provide customer responsiveness there were risks in sharing all of this information, especially confidential information like for those clients involved with the courts. So there was not a clear consensus at Norchem on a realistic target condition to reduce collection kit inventory. Though Gibbs was clear on his ideal state, an implementation that reduced inventory without adding muda in other places so far had eluded his team.

Continuing Challenge

Norchem started on its lean journey because competitors' prices for tests had dropped significantly and Gibbs realized that he had to reduce costs in order to continue to compete, even though it had built its client base on customer responsiveness. As Gibbs described Norchem's position:

We are never going to beat pricing from these giants that are running 30,000-40,000 samples per day. Their economies of scale are huge so they are going to be hard to beat on price. We have to do at least one of the principle competitive three things: quality, turnaround time, cost. Quality is pretty much a standard in our industry because we have these regulators so we're all held to an equal requirement. We have been extremely competitive with speed because we have focused on it. We really put a lot of work into getting it back to the client very quickly. Today we can process work faster than any lab in the country, 80% of our confirmation testing is out the same day that we receive the sample. Most labs if they have 25%, they're doing great.

Also we are committed to flexibility in customizing things for them. We do a lot of work on information systems. We'll build a custom interface to their program, so that their program now can reach out to our program and get the information it needs and populate that for their users. We will place employees in their facilities to do collections; we'll set up collection sites outside their facilities with our staff or with contract staff to do collections. We'll put specialized couriers on the road to pick up samples at oddball times. We do a lot of specialization.

Mayrand emphasized this from a customer responsiveness perspective:

So lean is hugely important from Gibbs' point of view in making the place successful. When I look at our business model, I see a customer intimate organization that provides it the way the clients want it. And we are willing to modify things all along the chain, all along the value stream to give them what they want.

So a combination of customer responsiveness and applying lean thinking had helped Norchem compete effectively in a niche where customers valued responsiveness, flexibility, and speed. Lean had been particularly significant in reducing turnaround time and cost. However, the industry continued to shift. Larger labs had stepped into Norchem's market niche by acquiring some smaller labs and increased use of point-of-collection test kits had reduced demand for initial screenings. Would customer responsiveness continue to be a competitive advantage?

Stephens summarized the dilemma well:

We deem ourselves an operationally excellent company because we can produce that real low cost unit. But I think Mayrand is right. It is really hard to say. What do you put your money into? You know, where are you trying to get the ROI? Is it the client, because you are willing to do whatever they want? Or are you trying to get clients because you can sell them a really cheap product like a Wal-Mart?

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