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Technical Note

Adapting lean to histology laboratories

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Abstract Histology laboratories (histolabs) can increase productivity and reduce turnaround time and errors by using any one of several available management tools. After a few years of operation, all histolabs develop workflow problems. Histology laboratories handling more than 20 000 cases per year benefit the most from implementing management tools, as occurred in the 25 facilities summarized in this article. Discontinuous workflow, lack of "pulling" between steps, accepting unavoidable waiting times while working with small batches within work cells, and a workflow with an uneven rate of completion, are some of the adaptations required by the Lean system when it is used in histology because 70% of the tasks are manual and the flow has to be interrupted to add value to the pieces of tissue during tissue processing, no matter how short that step is. After all these adaptations are incorporated, the histolab becomes as "Lean" as it can be, and the qualifier is also a recognition of the effort and personnel involvement in the implementation. Given its service nature, productivity increments do not expand the histolab customer base and could lead to staffing reductions. This is one of the causes of reluctance by some employees for implementing these techniques which are mostly driven by cost reductions sought by insurance companies and administrators, and not necessarily because of a real medical need to reduce the turnaround time. Finally, any histolab wanting to improve its workflow can follow some easy steps presented here as a guide to accomplish that objective. These steps stress the need for the supervisors to insure that the personnel in the histology laboratory are being paid at a comparable rate as other histolabs in the area.

Keywords: 5S; Six Sigma; Just-In-time; First-in-first-out; Lean; Work flow analysis, Henry Ford production system

1. Introduction

Until 1909, when the first automated clock-controlled tissue processor with a basket carrying pieces of tissue between 7 stations was invented by Arendt, only 3 other previous technological feats had any real impact on the histotechs' (histology technologists and technicians) productivity; namely, Leuckhart's metal embedding rectangles in 1881, Minot's rotary automatic microtome in 1887 and Borrmann's staining rack for multiple slides in 1894 [1], all of which had only marginal effect on productivity. The first automated tissue processor, primitive as it was, not only served as the blueprint for better instruments to come (starting with the Autotechnicon in 1945), but also reduced by half the time needed for tissue processing (TP), improved quality by introducing automated consistency, and divided the whole histolab operation into 2 well defined periods and types of operations, that is, those performed before and after TP. Advances after 1945 were aimed at obtaining improved infiltration quality and a marginal increase in productivity through allowing shorter protocols with larger batches.

It was not until the late 1980's that the introduction of microwave (MW) technology allowed very short TP periods, but the time required to complete the pre- and post-TP tasks remained completely independent of how fast the tissues are processed leading to a workflow paradigm. To obtain the fastest histolab operation, TP was required to last approximately the same time as the pre-TP tasks. This was obtainable only with a maximum of 15 cassettes processed in just 0.42 hours after 0.52 hours of pre-TP tasks followed by 1.05 hours of post-TP tasks for an overall output of up to 15 finished slides every 2 hours [2]. This can be accomplished using a small manual and inexpensive MW oven, such as the TBS SHUR/Wave from Triangle Biomedical Sciences, Inc (Durham, NC), permitting a viable throughput workflow alternative to the one offered by more expensive automated throughput tissue processors such as the Xpressx120 or the Xpressx50 from Sakura Finetechnical

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Co (Tokyo, Japan), with a production of up to 40 finished slides every 5 hours.

Besides improvements in TP the histolab has benefited greatly by other automated instruments, especially stainers and coverslippers, allowing those tasks to be completed 2.3 and 2.7 times faster than manually, respectively [3]. Other instruments, including cassette writers and slides etchers have also improved the workflow and at present there is an automated embedding instrument, the Tissue-Tek AutoTEC (from Sakura, Japan), able to cast 120 blocks per hour, which is twice the average productivity for manual embedding [4]. The Automated Tissue Sectioning System AS-200 (from Kurabo Industries Ltd, Osaka, Japan), still being assessed, is capable of producing 200 dried slides from as many as 20 blocks every 2 hours which, even if 4 times slower than the average manual sectioning productivity [4], has been proven to be more adequate for the virtual microscopy Whole Slides Imaging systems' focusing capabilities because it consistently produces thinner and flatter sections than manual sectioning [5].

A histolab equipped with the latest automated instruments available has little options left to further improve its workflow other than using its resources and personnel in the most rational and effective way possible. This is accomplished by turning to recognized management techniques. How to use those management tools for improving the histolab workflow is the subject of this article, which includes a historical account of the methods, examples of the application of some of the techniques and a general recommendation on how to improve the workflow of any histolab.

Finally, mentioning manufacturers and their instruments or management methods in the text does not constitute personal endorsement, just relevant examples of what is commercially available.

2. The evolution of some management techniques

By 1895 Gustavus Swift had already perfected a "disassembly" line that allowed him to brag that, "except for the squeal," everything else from the cattle at his Swift & Co Chicago-based slaughter house was transformed into a derivate product, with his plant being the first able to move the carcasses hanging from a conveyor belt between butchers to be quickly reduced to their smaller components. Inspired after observing this extraordinary productivity achievement, Henry Ford, in a sort of "reversed engineering" process, conceived an "assembly" workflow where all the interchangeable parts of an automobile could be assembled by moving a chassis along several fixed stations and constantly adding parts to it. This type of assembly line was introduced by Ford in 1908 to manufacture the Model T in the Ford Piquette Avenue plant and, later, in 1913, in the Highland Park plant, both in Detroit, MI. This system allowed him to produce 1,000 "Tin Lizzies" daily or 1 running out from the factory close to every 2 minutes. By doing so, Ford maximized productivity starting a world revolution in manufacturing and creating the Ford Production System (FPS). Everything started then and in the 100 years since all efforts have been aimed at improving the management methods to increase production and lower costs, the first being the analysis to optimize the workflow. Although there are no references that Frederick W. Taylor ever was in contact with Henry Ford, the great precision of Ford's conveyor belt operation was made possible by the time and motion studies pioneered by Taylor. The best example perhaps of workflow analysis and optimization came to be in January 1940 when Charles Sorensen, using all his expertise with the FPS, designed the Ford Motor Co factory at Willow Run, near Ypsilanti, MI, which was able to produce 1 B24 bomber per hour as part of the US war effort during WWII.

The study of the turnaround time (TAT), so familiar today, became another management tool in 1926 with the introduction by the Germans of the concept of *Takt production*, derived from the word *Taktzeit* meaning timing, speed regulation, rhythm, music beat, which linked for the first time production with customers' demand [6]. The Takt production was used by Germany during WWII and was shared with Japan as a production method that was later transformed in the late 1940s into the "Just in Time" (JIT) system that changed the traditional "supply-and-demand" paradigm into a more efficient model of "demand-and-then-supply." [7] This became part of the Toyota Production System (TPS) in the mid 1950s. Tack time is at the heart of Value Stream Mapping [8] that also became a Lean tool, is equivalent to workflow and has been used to design work cells [9].

D Edwards Deming in 1933 created the control charts and from June to August of 1950 trained hundreds of Japanese engineers introducing them to the Quality Control (QC) and the Total Quality Management concepts, exemplified by his "14 principles and 7 deadly diseases" of management. This won him the title of "father of the Japanese post-war industrial revival," his teachings allowing Japanese quality to equal that of the West in 1974 and to surpass it ever since [10].

Also in 1950, Eiji Toyoda visited the Ford factory at Dearborn, MI, where 8000 cars were produced daily, and concluded that the FPS was inadequate for Toyota, which was only producing 2500 autos annually. He was not impressed because he concluded that there was too much waste intrinsic to the FPS but, on the other hand, appreciated the way in which the Piggly Wiggly Supermarkets reordered and restocked their supplies based on the customers' demands. These 2 observations were decisive in developing the TPS based in an unrelenting commitment to waste elimination, the implementation of the JIT workflow and maximizing quality through effective employee participation.

The "5 S" management tool, now an integral part of the TPS, consists of a series of steps part of the Virtual

Workplace defined in the late 1940s as a sort of "good housekeeping and workplace cosmetics," that leads to a more organized and efficient work environment and which is especially useful when the work space is shared. It is called "5 S" because the Japanese words describing each step are spelled with an "S" when translated into 5 English verbs starting with S.

In the United States, the application of statistics and mathematics to manufacturing started in 1924 with Walter Shewhart's "control charts." The concept of *QC*, continued in 1977 with John Tuckey's theoretical work at the Bell Laboratories culminating in the Six Sigma (6σ) Academy and with Bill Smith's work in 1986, based on the concept of the SD as defined by Karl Pearson in 1893. Incorporated to the Motorola Corporation in 1988, 6σ in essence is used to calculate the number of defects in the manufacturing process that cost more to eliminate than to accept [7]. After the method was adopted by General Electric in 1996 it became sort of a management "standard method."

Also in 1988, while the TPS was being studied at the Massachusetts Institute of Technology, the qualifier "Lean Manufacturing" or just "Lean" as it has come to be generally known since, was coined to describe its fundamental characteristics of unitary production, minimum waste and customer "pulling" of the production process. It is also probable that this new name was intended to disassociate these production qualities with Toyota automobile manufacturing so it could be used by any production enterprise.

All these techniques are commonplace today all around the world and as a consequence there are hundreds of consulting companies and consultants, courses and training programs, books, and Web sites about any of them constituting a new, successful and growing industry.

Six Sigma is perhaps not only the most widely used technique by a wide array of industries and activities but also the one with more training programs that go from 5 days for a "yellow belt" ($1670), 11 days for a "green belt" ($4815), 16 days for a "black belt" ($8300), or you even can become a "master black belt" for just $5515 in only 10 days. It has been pointed out, however, that most of those courses are ineffective because they do not include a practicum [11]. You can also find Six Sigma training at 60% "discount" for rates ranging from $127 to $204 per day with training courses on line. What appears inappropriate is that the training in a technique such as Six Sigma which was created in the United States is described in terms of judo belt colors, as if it were a Japanese martial art, the implication being that adding a nebulous Japanese flavor to it will lend it more legitimacy or credibility.

There are also "5 S" training programs that range from $200 to $430, and even web stores selling the supplies "needed" to correctly implement "5 S," such as bins, floor markings, forms, kits, labels, posters, signs, tags, totes, and even games and software.

Lean training courses also abound, with up to 12 seminars annually provided by some consulting companies with prices around $1800 for 2 days that include teaching how to master the Japanese terms used in the TPS, as if that were necessary and as if the concept could not be grasped or expressed in plain English.

3. Some management techniques used in the Histology Laboratory:

3.1. "5 S" or Japanese good housekeeping

The 5 Japanese "S" sounding words have been translated into English verbs starting with "S" to maintain an unnecessary fidelity to their origin, but the translations vary. They are

1. *SEIRI*, translated as Sort, Separating, Sort-and-Discard or Disposal, and imply identifying to remove/dispose all unused, old or obsolete items from the working areas.
2. *SEITON*, translated as Straighten, Stabilize, Systemize, or Set-in-Order, imposes tidiness in the workplace with all working implements easy to reach eliminating bottlenecks and assuring the correct completion of an operation in a mistake-proof manner.
3. *SEISO*, translated as Shine, Sweep, Scrub, Clean-and-Inspect or Cleanliness requires that the whole working space and equipment is clean, eliminating dirt, dust, and debris.
4. *SEIKETSU*, translated as Standardize, Schedule, Select, System Methodology or Standardize-and-Improve deals with setting work standards, it is a maintenance program to support what has been obtained with the 3 previous steps and includes personnel training.
5. *SHITSUKE*, translated as Sustain, Believe-and-Discipline, is the discipline needed to maintain the whole good housekeeping of the working place.

"5 S" system by itself or combined with Lean is said to yield excellent results but should be implemented in sequence with Sort and Straighten (or Systematize) being the 2 most important steps, leading to zero defects, cost reduction, safety improvements and zero accidents [12], and making the safety departments the main promoters of this technique designed to eliminate the waste caused by lack of orderliness in the workplace.

Some specialists add "Safety" and call it "6 S" and even others add "Security" to "6 S" to create the "7 S." The "5 S" management tool is one of the key principles of the TPS (the 5S workplace) and is always introduced with the hope of increasing productivity and performance in the whole process or in selected working stations.

In the United Kingdom instead of "5 S" they use "5 C" as clear-out, configure, clean-and-check, conformity, and custom-and-practice [12] and also has been substituted by

CANDO as an acronym for Cleanup, Arrange, Neatness, Discipline and Ongoing-improvement, which seems better for many.

The "5 S" management tool is used in Hewlett-Packard Support Centers, Boise Cascade Corp and Boeing Corp, and should be introduced in histolabs that have been in operation for many years because they all tend to accumulate old reagents, obsolete pieces of equipment and they are usually are somewhat lacking in neatness.

With a high diversity of tests and a workload of about 10 000 slides per year, the core histolab at Alfred I. DuPont Hospital for Children in Wilmington, DE [13], selected "5S" as the management tool to improve their operations increasing their slides thru-put by 20% and revenues by 12% between 2007 and 2008.

4. The Six-Sigma technique

Six Sigma (6σ) is a statistical concept, a QC program aimed at reducing the number of mistakes or defects in the workflow, with the goal of reaching an operation standard of 3.4 mistakes per million opportunities, equivalent to a 6σ deviation from the performance goal. It has been hailed as the management technique yielding the best results among 30 other methods, twice as better than Lean, and almost 6 times better than workflow analysis. Six sigma was used by 22% of US companies surveyed in 2004 [14], 38% of which were in the service and 49% in the manufacturing sectors. The latter usually operated at about 4σ, equivalent to a 0.62% error level, way below the safety level of the US airline industry that operates at a 7σ level equivalent to 2 errors per 100 million opportunities [15].

Alternatively it's almost obsessive pursuit for reproducibility and consistence with a minimum of mistakes to eliminate variability was blamed for quenching innovation when it was introduced as the standard QC program at 3M Corporation, which went from a very creative corporation to one that was more efficient but less creative, smothering its ideas culture [16].

As a QC control program can fail; such was the case of the Vit25 (OH)D test implemented by the Quest Diagnostic (QDx) Nichols Institute for Esoteric Testing Centers when they changed from the immunoassay method approved by the Food and Drug Administration to a proprietary method developed to cut operational costs [17]. It seems it was not monitored adequately because 7% of the 5-7 million results released during an 18-month period between 2207-2008 were inaccurate (usually above the real value), pointing to a systemic error that affected QDx's credibility between pathologists and industry executives regarding their esoteric testing [18]. That 7% failure rate is evidence that some of the laboratories did not monitor the procedure [19] and operated at a sigma value of 2.98, just below the lower end of the standard sigma operation level for most health systems [15].

To implement a 6σ program it is necessary first to establish a "road map" of the operation using a technique whose acronym is DMAIC [20] composed of:

1. Define processes, hazard exposures, opportunities to have defects or make mistakes, and all the waiting times and repetitions using flow charts.
2. Measure by determining the time required to complete each step of the process/operation, comparing those times under different situations or production requirements to calculate waste time.
3. Analyze by defining the opportunities to improve any and all steps in the process.
4. Improve by simplifying the process, reducing the steps and/or increasing automation.
5. Control by evaluating the whole process at regular intervals.

There is another technique with the acronym DMADV that uses Design and Verify instead of Improve and Control, and yet another known as DMADOV after intercalating Optimize, but all have the same objective of constructing a "road map," DMAIC being the most used with an expected completion time of 3 to 6 months for any 6σ project in healthcare [21].

Implementing 6σ as a strategy and methodology has been described as including Discover, Decide, Organize, Initialize, Deploy and Sustain or DDOIDS, another acronym yet to describe a general approach for business performance improvement aimed at an overall 6σ operation level [14].

In 2004 the Dahl-Chase Diagnostic Services, in Bangor, ME, an independent histolab with 60 employees servicing 16 hospitals and 500 private practices with an annual volume of about 50 000 surgicals and 65 000 Papanicolaou stained smears decided to introduce DMAIIC which is another variation of DMAIC including Innovative Improvement, to manage their operation [22]. They designed a new facility and at the end of the 6σ project the number of errors went from 15% to 0.4% (σ = 4.15), the TAT was reduced by 5 days, the number of employees by 11% and the accounts sent to collection were 26% less.

The Sonora Quest Histology Laboratory in Tempe, AZ, with an annual workload of 120 000 cases, started more than 4 years ago a 6σ project to improve their workflow [23,24] detecting bottlenecks at grossing, embedding, and microtomy with a TAT of more than 5 days and an error rate above 2% (σ = 3.53) for blocks and slides mistakes. After the project was completed, the time between reception and slides distribution to the pathologists was cut by 12 hours, the productivity increased, overtime was reduced, and the error level was lowered to 0.16% (σ = 4.45). They bought 2 Xpress tissue processors that at present process about 85% of all their tissues, implemented the "first-in-first-out" (FIFO) workflow priority scheme with small batches reducing their TAT to 2 days or less. This histolab, which started its optimization as a 6σ project, can be now classified as a Lean lab.

5. The Lean Production System of just "Lean"

When in 1988 the TPS was studied at Massachusetts Institute of Technology and qualified as a "Lean Production System" the name "Lean" became preferred by the manufacturing entities that started using its fundamental tenet, which can be summarized as "doing more with less." This was accomplished by using the paradigm of the single unit production line, waste elimination, standardization, increased automation, productivity and optimum quality by empowering all those involved in the process. It also includes pulling the work between successive steps to achieve an unobstructed throughput flow, making problems obvious and developing solutions for each [6].

After the tools and components manufacturer Danaher Corporation in Washington, DC, started using the TPS in 1987 [25], many other manufacturing companies followed suit, now mostly using the name Lean, starting a real revolution that has also spread to the healthcare industry. Nowadays, scores of medical laboratories (medlabs) are using Lean tools specially to eliminate waste in their workflow, and it is also frequent to read about "Lean Histology," a term that has been registered as a "trade mark" by Leica Microsystems (Germany), no matter how absurd that may be, but which reflects the interest of that histology instrument manufacturer in capitalizing on a growing trend sparked by the constant push in reducing TAT in histolabs despite of their uniqueness.

In contrast with the medlab in general, in the histolab, there are 10 times more types of procedures, the quantitative results are the exception and the samples are mostly irreplaceable. In addition, when faced with personnel shortages, the medlab can maintain or even increase its productivity by switching to more automated instruments. That, however, is not an option available to the histolab where more than 70% of the work is completed manually [26] creating 3 bottlenecks in the workflow at the grossing/cassetting, embedding and sectioning steps, the latter requiring a high degree of craftsmanship, with a productivity limit dependent of the individual's dexterity, thus trading inefficiency for creative results.

When the automated tissue processors were introduced a century ago as a means to reduce the TAT at least in half, they required that all the tissues were processed simultaneously and as the workload capacity of the processors increased it gave origin to the "large batch" practice that has permeated the histolab culture up to our days.

To all these inherently "anti-Lean" characteristics of the histolab workflow you have to add that most were established decades ago, some have cluttered spaces with instruments located wherever space is available but not where it is required for proper workflow, and all share the very ingrained concept that the histotech is expected to multitask. Overcoming all these obstacles has been the objective of all the pioneers in the introduction of Lean in the histolab, including redefining the single piece flow and creating the concept of *the work cell* [9], adding aides to liberate histotechs from some tasks [27], applying housekeeping techniques and using movements or spaghetti diagrams [28] to determine where time is wasted as the staff moves between the processing stations and instruments, rescheduling personnel, and bringing in more productive and integrated automated instruments when the budget permits.

In 2002, the Tissue-Tek Xpress processor appeared in the market with the capacity for automatically delivering up to 30 cassettes every 15 minutes or up to 40 cassettes every 40 minutes continuously, depending on the model, in a real throughput flow. The instrument was perfected and introduced at the Jackson Memorial Hospital in Miami, FL, histolab [29] transforming it from an old and conventional histolab into the first really Lean histolab with all the scheduling transformations for histotechs and pathologists alike, allowing them to sign 60% of all their cases the same day they were received [30]. In 2007, the same processing technology and scheduling changes were introduced at the Avera McKennan Hospital, Sioux City, SD, determining a 1.6 increase in the histotechs productivity from their 2002 base value [31]. In 2008, this same technology allowed a reduction of 24 hours in the TAT by signing cases the same day they were received at the Sheffield Teaching Hospitals, in Sheffield, South Yorkshire, UK [32].

At the Allegent Health histolab, in Omaha, NE, they redefined the single piece flow as all the blocks from a single case worked individually and moved by a laboratory assistant between the working steps (embedding, sectioning and staining/coverslipping) arranged along a work cell, allowing the histotechs to perform exclusively technical tasks [27,33]. At The Kaiser Foundation Health Plan of the Northwest, OR [34], a similar workflow was adopted reducing by 2 to 3 hours their TAT.

An open plan diamond cell arrangement from embedding to staining using conventional TP was also implemented at the Providence Healthcare Anatomic Pathology Lab, in Vancouver, BC, Canada [35], when redesigning their histolab. They also reduced the size of the batches to be delivered continuously along the morning and rescheduled the histotechs and their tasks [36] cutting their TAT by 1 day. The application of workflow streamlining and optimizing using the existing instruments to improve productivity was the approach used at Calgary Laboratories Services, in Calgary, Alberta, Canada and at the Wake Forest University, Baptist Medical Center in Winston-Salem, NC [37], as part of their Lean initiative programs.

US Labs at Irvine CA rearranged their instruments, reduced the handling of slides and integrated image analysis into their Lab Information System to improve their workflow, and Virtua Voorhees histolab in NJ [38] reported a 3.5-hour reduction for the non–value-added waiting in the cycle but the pre-TP bottlenecks they had remained in spite of using an Xpress tissue processor.

The histolab at the Mayo Clinic, Rochester MN [39], obtained a TAT reduction after increasing automation and

adjusting the staffing levels to the workflow needs. The Holland Hospital, in Michigan, and the Yuma Regional Medical Center, AZ.[40], relocated all the instruments into 1 open room following the workflow, bought a high volume MW automated processor, changed the processing protocols, and adopted a voice recognition dictating equipment that allowed them to sign 70% of all cases in less than 24 hours.

At St Paul's Hospital, Providence, RI, the Lean approach was centered in the reduction of waste between steps and by creating interaction between histotechs and their tasks. [34] At the Calderdale and Huddersfield Hospitals, West Yorkshire, UK [28], after a 5-day study of their operation using spaghetti diagrams and "5S" good housekeeping techniques, they managed to reduced the size of their batches to a maximum of 20 cassettes and the number of steps from 60 to 10, and instituted the FIFO work practice reducing by 32% their processing time.

Jackson Memorial, Avera McKennan, Sheffield Hospitals and Sonora Quest now use automated continuous throughput TP workflow and all others use some of the tools available as part of the Lean management technique with a wide range of results.

6. Combined techniques

6.1. Six-Sigma /Lean

That Medicare will not pay for mistaken results [41] has given a boost to the use of 6σ combined with Lean because 6σ adds the statistical analysis aspect to Lean [14] where applied.

This combined technique was used successfully at Baystate Reference Laboratories, Greenfield, MA [42]; at Massachusetts General Hospital, Boston, MA [43]; and at the University of Pittsburg, Pittsburg, PA [44] where they increased 73% of the total work volume and 26% the daily workload per histotech, reducing TAT by 42% and their error rate.

7. The Henry Ford Production System for Anatomic Pathology

Developed in the early 2006 at the Henry Ford Hospital in Detroit MI, part of the 7 hospitals that form the Henry Ford Health System [15], it bears their founder's name as homage to the pioneer and creator of the automobile mass production system and founder of this healthcare system in 1917.

The Henry Ford Production System (HFPS) is fundamentally a culture change more than a method in itself [45] defined as "it is more important to do the job well than fast." The HFPS for Anatomic Pathology (AP) has an emphasis in personnel training and involvement (as in the TPS) and uses several techniques such as the "5S" good housekeeping approach, the "7 sources of wastes" also known as the "7 deadly management diseases," the "JIT" idea, the throughput pull of Lean and the detailed definition of a total of 494 mistakes opportunities along their AP workflow all integrated and aiming at a "zero defects" performance more than at the reduction of the TAT [15]. So far they have obtained sigma values between 4.3 and 4.8 for their workflow which is better that the average of 3 to 4 σ in health care operations, but they are still unsatisfied.

The HFPS has allowed the AP department to cut their defects rate from one third to one eighth for all the opportunities in the workflow of about 48 000 surgical cases in just 1 year, increase the slides production rate by 12%, and standardize cassetted tissue sizes improving TP quality [46].

Recently [47] they have developed a bar code technology created through the CoPath Plus system (Tucson, AZ), producing pre-stain resistant labels at U-shaped redesigned microtomy stations and reducing the misidentification case rate by about 65%, the overall misidentification by 95% and increased microtomy 1.25 times, equivalent to 0.37 full-time employee.

8. Just-In-Time and 6σ/Lean

Adding bar-coding tracking of pathology specimens to 6σ/Lean software and JIT at the University of Michigan Health System, in Ann Arbor, MI [48], is a proposed approach to the integration of several management techniques to improve performance.

9. Workflow analysis and optimization

Since Ford first introduced the conveyor belt assembly line it began to be studied trying to make the workflow more efficient and productive, with techniques such as the "stopwatch timing" of the operations developed by FW Taylor in 1909 allowing an extraordinary increase in work output and productivity between the Ford automobiles factory in 1913 and the one visited by E Toyoda in 1950.

Using Workflow analysis requires determining the initial conditions of the workflow in what is called an "As-is" or baseline analysis, including the assessment of the collected data to prepare a "To-be" plan to implement, including indices to analyze the project progress.

Using work flow analysis (WFA) at the *South Florida Quest Histology Laboratory at Miramar.*

In April 2002, the senior management at Quest Diagnostics for South Florida (at Deerfield Beach) became concerned with an increase in the TAT at their AP Department in Miramar, attributed by its Director as being the result solely of a slowdown in the histolab, leading to a 4 days visit by the author in early May to prepare an "As-is" report of the histolab operation including a "To-be" plan of action to solve the situation.

The histolab was well equipped for its annual workload of close to 120 000 cases with a cassette writer and slides etcher

besides standard tissue processors, automated stainers and a film coverslipper, and the root of the problems was identified as being related to personnel including lack of enforced work schedules, not well defined tasks and multitasking, lax discipline and lack of accountability, causing a below-average embedding and sectioning productivity, with poor time use.

Changing the schedules, controlling the completion of the daily workload and the time use, as well as contracting 2 laboratory aides to limit the work of the histotechs just for embedding, sectioning and doing special procedures were among the proposals that started to be implemented at the end of May 2002. The variables selected to monitor as indicators of the work improvement were the daily number of leftover (uncut) blocks and the average time use per pay period. Both indicators were charted, made available to the personnel, and discussed in monthly staff meetings. In June, all the microtomes were serviced, the illumination at the work stations improved, and a reclassification of the histotechs aimed at reviewing their wage scale was started.

During April and May, the number of leftover blocks were equivalent to one and sometimes almost 2 days' worth of work, but they were reduced to an average of 180 during June and from July through October to an average of 4 blocks, equivalent to a 0.47% error rate corresponding to a $\sigma = 4.10$ in 6σ terms, meaning that the initial problems detected in the histolab had been solved by early August 2002, in 2 months time (Fig. 1).

By early June it became evident that the slow TAT in issuing the final reports was caused by reasons other than just the production of the slides, so the author decided to quantify the workflow of the entire AP department, from grossing to issuing of the report. The study was conducted between 17 and 21 of June by selecting the first 2 cases grossed/described at the start of each hour between 11 PM and 4 AM of the next day during 5 successive working days for a total of 50 cases, determining when each major step was completed.

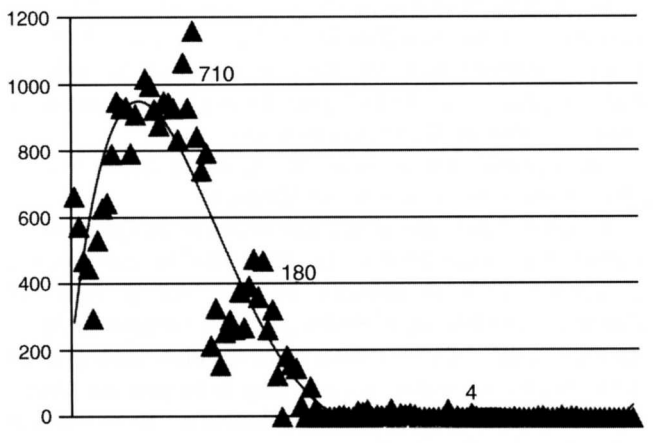

Fig. 1. Daily leftover (uncut) blocks (ordinate) between April 1 and October 31, 2002, at South Florida Quest histolab.

The results showed a fundamental bottleneck while matching the finished slides with the paperwork and this task that is normally almost 29 times faster and requires as an average 4% of the time needed to produce a slide [49], was taking 7% more time (Table 1). The delay was due to personnel shortages and a convoluted existing procedure that included sorting the cases to comply with established quotas for the pathologists (some of which worked at Deerfield Beach, 34 miles away from the histolab in Miramar, and who received/returned their slides by courier). It also became evident that the pathologists had a workload 2.4 times larger than the national average [4] with a constantly growing number of cases waiting to be signed causing them, in Lean terms, not to pull the finished slides, this being one contributing factor to the attitude of the histolab personnel detected in early May.

By mid July the workflow problems in the histolab had been 97% solved but because the overall TAT remained slow, another study was done between 23 and 29 July with another 50 cases following the same methodology as in June and this second study showed that the TAT for all the tasks were shorter, but that the distribution of the slides remained as the fundamental bottleneck in the flow (Table 1). The TAT in the production of slides (the main task of the histolab) was cut in half, as well as transcribing the gross description, but signing the cases only improved by 14% because the distribution of the slides remained essentially unchanged. This second study was reported to the AP Director showing the fundamental bottlenecks in the department workflow.

Between June and October 2002, the histotechs' productivity while embedding increased 1.4 times (from 40 to 57 blocks per hour) and 2.3 times while sectioning (from 12 to 28 blocks per hour). The average time use during the 12 pay periods from 28 May to 2 November was 1.8 times better, going from an average of 46% to 84% (Fig. 2), and the 2 laboratory aides determined a 2.4 times increment on the histotechs' overall productivity indicating that the workflow optimization measures implemented had succeeded.

In addition, as part of the "To-be" plan, 20% of all the cases received between 29 August and 30 September were processed with mineral oil [50] as part of an effort to eliminate xylene from TP in this and all other Quest histolabs, this being a major commitment of this author [51]. All the pathologists signed these cases without knowing how the tissues had been processed, as in a blind test, without there being any complaints. Using mineral oil also increased the microtomy productivity an additional 5%, the histotechs being ignorant of which blocks were processed with mineral oil, which was similar to previously obtained results [50], but unfortunately, this processing methodology was discontinued after the author retired in November 2002.

Table 1
Daily accumulated completion (%) of 6 tasks in June and July 2002

Day	Gross		Transcribe		Slides		Distribute		Diagnose		Report	
	June	July	June	July	June	July	June	July	June	July	June	July
1	94	100	74	93	52	90	28					
2	100		80	100	78	97	48	35	3	4	3	4
3			100		80	100	56	60	13	15	13	15
4					94		64	70	38	42	31	41
5					100		100	80	56	65	36	60
6								100	86	83	74	83
7									94	96	94	96
8									97	100	97	100
9									100		97	
10											100	
TAT	25.4	24	52.8	25.7	97.4	48.7	104.6	100.8	168.7	145.0	192.7	145.0
dt		−1.4		−27.1		−48.7		−3.8		−23.7		−47.7
%		−6%		−51%		−50%		−4%		−14%		−25%

Gross, gross description, cassetting, and start tissue processors; Transcribe, transcribe description; Slides, embed, section, stain, coverslip; Distribute, slides distributed to the pathologists; Diagnose, diagnosis ready; Report, reports released to clients; dt, time variation (July end time −June end time) in hours; %, 100 dt/TAT in June, time reduction for the task (in %).

10. Obtaining a shorter TAT in the histolab: how, why, and who benefits?

The performance of all the 25 summarized histolabs improved even when using different management tools. Fifteen histolabs used some aspect of Lean or the automated throughput workflow; 4 used a 6σ/Lean combination; 2 used 6σ alone, and the remaining 4 used "5S," "JIT" with 6σ/Lean, a culture change modeled after the TPS identified as HFPS, and WFA (one each). All 25 histolabs were able to increase productivity and reduce TAT, error levels, overtime, and obtain almost any objective the histolab was set to accomplish with varying degrees of improvement and overall impact. In absolute terms, the largest productivity increase (2.4 times) was obtained with WFA, the highest sigma value (4.8) with HFPS and the greatest TAT reduction (5 days) with 6σ. When using Lean tools, the TAT reductions were from 3.5 hours to 1 day with productivity increments of up to 1.6 times, or the pathologists were able to sign 60% of the cases the same day they were received with automated throughput tissue processors.

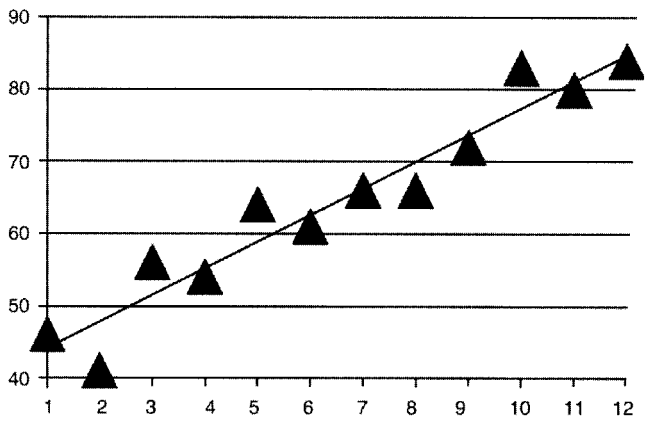

Fig. 2. Personnel percentage time use (ordinate) for the 12 pay periods between May 28 and November 2, 2002, at South Florida Quest histolab.

Why did all the methods work? Essentially because any histolab with some years in operation has intrinsic workflow defects resulting from wrong work practices compounded over the years and any management tool that is applied will render a more efficient operation, regardless of which one is used.

Using TP throughput technology with small batches as if they were a "unitary workflow" have accomplished the most dramatic changes in signing cases a few hours after receiving the specimens, but have also required a complete personnel rescheduling that has shifted the histolab from an early morning buzzing workplace, to a continuous flow of cases ready to sign from midday to late afternoon, the rescheduling impacting both histotechs and pathologists alike.

Any histolab optimizing its workflow becomes more efficient but *why is that transformation needed*? In a manufacturing enterprise, it is a survival strategy to increase productivity and lower costs to achieve a larger output of manufactured goods to compete with similar enterprises all targeting the same consumer base. Supposedly the one producing the most, cheaper and with better quality will be able to dominate the market, this mass production being the mantra of any large scale manufacturer. Also expanding the activity of a large manufacturer assures its survival and that their workers can expect higher compensation even when the productivity keeps increasing.

But the medlab is not a manufacturing enterprise although it can be argued that within it the histolab manufactures the stained sections by adding value onto the glass slides during several consecutive steps. The manufacturers also can aim at reaching consumers outside their natural boundaries "going national or even international," but the medlab is a service entity receiving samples for analysis from a customer base that is usually limited to a certain geographical radius, except

for large reference laboratories that expand their sphere of action by contracting the work from satellite medical offices or smaller laboratories using sales persons and developing a long distance sample collection and transportation system.

Also the bulk of the medlab work is of the screening type, analyses requested as part of a routine "blood work" to determine the health baseline of individuals whose results mostly fall within normal levels and can be completed automatically by extremely efficient instruments. In the histolab, on the other hand, except for the PAP smears screened by cytotechnologists [52] and whose results mostly fall within normal limits, the rest of the work rests on pieces of tissue considered at the moment they were removed from the patient as suspected of harboring some type of pathological entity and sent to the anatomic pathology laboratory to rule it out.

The calculated number of histotechs [53] times the billable tests/year by each [54] amount to about 234 million tests nationally, which is 30 times less than the annual workload of all medlabs, calculated at around 7 billion tests [55], this being another difference between the two.

But yet again *why is there a need for a shorter TAT*? In the medlab one of the selling points used by the laboratory representatives among the clinicians is the guarantee of quick reporting, and this is especially important in a hospital setting where the tests are done for inpatients requiring a decision about their treatment, but is a less pressing issue in samples received from private practices as part of a routine checkup.

The concept of *TAT* was defined in 1926 as "the action of receiving, processing and returning something," it is also called "Lead time" [9] and is the time required for one specimen to travel through the entire stream of all the operations that "add value" to it in the form of modifications that will finalize with the completed product, the diagnosis in this case. One study of TAT in small histolabs found [56] that 96% of all surgeons were satisfied with 86% of their biopsies being signed during the second working day, and 98% believed that receiving a hard copy of the diagnosis had no effect on the length the patients remained at the hospital so it could be concluded that the surgeons are not pulling for a shorter TAT, so *why the pressure to reduce the TAT*?

In the histolabs it has been called "The Tyranny of Turnaround" [57] measured as the rapidity with which the report is created from the moment the specimen is received resulting in TAT as being universally adopted as a measure of Quality Assurance, even when the real measure should be based on the accuracy of the diagnoses and not in how fast it is created, because some cases cannot and should not be rushed [57]. The College of American Pathologists (CAP) has recommended that 80% of routine biopsies should be reported within the first 48 hours and 80% of large specimens (resections) within the first 72 hours, both times from accessioning on. Some biopsies should be reported sooner, as in rejection cases, in medical complications, when a vital structure is threatened by a rapidly growing tumor or when starting chemo- or radiotherapy depends on the biopsy diagnosis, all these being actual clinical emergencies for which every histolab has instituted urgent or "rush" procedures [57]. However, other than that, there is no major practical difference between reporting within 24 or 48 hours, except for the psychological effect on the patient. On the other hand, for more than 60 years the frozen section intraoperative consultation has been a methodology that is used to cover the need for a quick report providing the fundamental diagnosis as to malignancy or lack of it to the surgeon within 15 minutes of reception and while the patient is still in the operating table, this being the shortest specimen TAT within the histolab and shorter than many a medlab procedure from the moment of reception.

So again, if the surgeons are not pulling for a quicker TAT and the CAP accepts reporting within 48 hours, *why the need for an ever shorter TAT*? The real cause is costs and that the hospital cannot release an inpatient until the pathology report is issued and will have to absorb the costs differences between that moment and the time the insurance companies will reimburse the hospital, which is determined by even shorter time guidelines. In addition, in the case of large histolabs, it is a survival strategy to remain competitive by offering a faster service than others and it can be added that some manufacturers also have a vested interest in pushing their instruments aimed at a faster TAT.

But *who benefits from these costs savings*? Essentially the insurance companies, the hospital and the histolab managements that will operate at lower costs increasing profitability and allowing them to reduce their charges and increase the number of accounts, this being especially important for large reference labs. But in no way will greater profitability or reduced TAT increase the customer base for a histolab whose customer base is completely different and far much more limited than the base of any manufacturer determining that a productivity increment does not automatically translates into an increase in the supply of cases to analyze.

11. How would this increased productivity affect the laboratory professional?

Medtechs and histotechs are professionals traditionally concerned with the way their work impacts upon patient care, but it is also true that practicing either profession allows them to earn a living and to take care of themselves and their families. A reduction in the TAT and a productivity increase leads inevitably to an overall salary reduction in the form of less working hours, the elimination of overtime, or it can even lead to personnel reduction, which is an unwelcome outcome for the histotech.

A better or Lean operation in the histolab benefits a minority of patients in real need for a report in a shorter time, the benefit being just marginal to those whose diagnosis does not impact any treatment if it is ready in 24 or 48 hours of receiving the sample, so, simply put, the real beneficiaries of

the workflow improvement are the histolab administrators who will become more competitive when reducing their operations costs, but the logical outcome of this improvement if the client base is not expanded is that the personnel can be reduced.

In a study of 100 medlabs that used the 6σ/Lean approach, they were able to do a better job with 40% less technical personnel [58] or about 1750 medtechs less and it can be asked whether those medtechs who lost their jobs were benefited by that workflow improvement.

Using 6σ the Dahl-Chase histolab at Bangor, ME, was able to reduce their complement by 7 employees [22], and similarly, it can be asked how the histotechs in any histolab that can reduce the number of shifts from 3 to 2 or eliminate the overtime compensation or even cut personnel as the result of a workflow improvement benefit from the change? No histotech has a vested interest in the application of any of these tools if they are going to have a negative effect on their salary or job security. That an economic benefit for the laboratory administration does not equate into an economic benefit for the technical personnel sometimes causes a reluctance in the application of these management tools by the personnel, and that is why it is so important to first incorporate the personnel into the process through adequate leadership, and to study the existing salary scale while implementing any of these productivity-increasing methods to make sure that the personnel is at least equivalently compensated with their colleagues in the area [59].

12. Improving the workflow in any histolab

Any histolab, no matter how efficient it may seem, can improve its workflow with simple administrative measures to increase the number of cases its able to process without personnel increments and have the slides ready in less time, but the ones benefiting the most are those with above average annual workloads because they have more personnel and productivity issues.

About half (48%) of US histolabs have an annual workload of less than 20 000 (average of 12 000) cases with 3 blocks/case; they have 5 pathologists and 6 histotechs and even if only half of the histotechs are preparing the routine slides, the daily workload for each (~50 blocks) can be completed in less than 4 hours [4,49]. If this "average" histolab can benefit by taking steps to improve its workflow, those with more than 20 000 cases annually are in more need and likely to benefit more as in the case of the summarized histolabs with an annual median workload of 38 500 (range, from 22 500 to 120 000) cases.

The improvement measures should be implemented by the histolab supervisor and include:

1. Describe, as accurately as possible, all the steps in the workflow, including where those steps are done, by whom, when and how long do they take to complete.
2. Check with the pathologists when they want the cases ready to be signed and once this "start of sign-out" hour is known, program the tissue processor to finish 2 hours earlier and start embedding immediately to have the first slides ready about 1 hour later.
3. Check the location of the instruments trying to place them in a sequence following the workflow (processing, embedding, microtomy, staining and coverslipping), ideally in a single room.
4. Write the competencies and standards of performance for each task as a way of defining all the sources of possible mistakes and to eliminate waste of time in the workflow and use them also as personnel cross training tool.
5. Monitor the mistakes vs the opportunities to develop a very consistent QC program based on the calculation and evolution of the sigma value of the operation of the histolab or at least the evolution of the errors rate.
6. Discriminate between "rush" and normal cases using color coded cassettes, placing the rushes to be taken out of the tissue processor first.
7. Any conventional tissue processor can be used with short protocols if there are many small specimens or some "rushes" that are desired to be completed quickly, leaving the other cases for overnight processing.
8. While embedding do not accumulate blocks because that wastes time, and always embed all the blocks of a single case and prepare the sections as soon as the blocks are ready. In this way the first slides will be completed about 30 minutes after the embedding started.
9. Never accumulate blocks to cut, slides to stain or cover, or finished cases. Try to have a continuous flow of completed cases for the pathologists to sign.
10. Any histolab with 10 000 cases/year or more should have a laboratory aide to take care of all the nontechnical tasks thus allowing the histotechs to just embed section and carry out special procedures.
11. A histolab of the above size should budget to purchase an automated stainer and a coverslipper to be attended, along with the tissue processor, by the aide.
12. Transform the histolab and all work stations into areas comfortable to work in by applying the "5S" good housekeeping technique that is probably the easiest, cheapest and most rewarding of all.
13. Finally all supervisors should aim at not only improving the histolab operation from the management point of view, but also become interested in the wellbeing of the histotechs and conduct at least annual surveys concerning the salaries in the area to make sure that the staff remains paid at the commensurate rate.

Any histolab implementing these steps can increase its productivity and develop an effective workflow and if all the cases are received between early morning and late afternoon

of any given day and all the slides are ready from early morning till noon of the next, the TAT of the histolab will be of 24 hours or less, well within the CAP requirements and any administrator's expectations.

13. Adapting Lean to histology

With the fundamental tasks of grossing/cassetting, embedding and specially sectioning completed manually, and a workflow interrupted by the need to add value to the pieces of tissue during TP while the personnel wastes time waiting or doing other tasks unrelated to the processing that is taking place, and not working with single units along the workflow, these tasks need redefining.

The workflow unit now to include all the blocks from a single case, no matter how many, that are handled consecutively with obvious waiting periods in between. The instruments used in the workflow are arranged, when the space allows it, in a single room in sequence to the workflow and usually the tasks of microtomy, staining and cover-slipping are gathered in a work cell, but not the pre-TP tasks of accessioning, grossing and cassetting.

That the modifications have to adjust to the existing space conditions, unless a large investment in reconstruction is undertaken, also conspire against the existence of a real Lean workflow that no longer is the guiding force behind its material setting, but has to adapt to the existing conditions.

The need for interrupting the workflow while processing batches has to be accepted, no matter how small they are, and in an "un-Lean" fashion the need of each task pulling for the results of the previous one is obviated because usually the histotechs multitask and sometimes the same histotech takes care of consecutive tasks, thus eliminating the critical appreciation of the results between them, as well as the pulling effect. If the person in charge of a task is no longer the "client" for the previous one and cannot appreciate the quality or point out defects and their solution, one of the fundamental tenets of the Lean process collapses.

After all these changes are introduced, what needs to be applied to the histolab workflow to transform it into a so-called Lean operation? Some histolabs apply "5S," others "JIT," others "FIFO," some a combination of these or reschedule the personnel around high throughput automated instruments during part of the day (not the whole day as in a Lean operation), and others apply "6σ" or WFA even when they are part of neither Lean nor the TPS. Does the application of some of these techniques or their combination make the histolab really Lean? Not in a "traditional" way, but that is as Lean as any histolab can be, including getting the personnel involved after changing their mental attitude.

Attaching the Lean qualifier to any histolab that has seriously engaged in improving its workflow through the use of any of the numerous management tools available offers recognition and a certain degree of pride to those involved in their implementation.

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