Using LEAN Principles to Improve Quality, Patient Safety, and Workflow in Histology and Anatomic Pathology

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Abstract: Histology and anatomic pathology have historically been slow to accept many of the process changes that have been widely accepted in the clinical laboratory. In this article, we describe the application of the Toyota Production System (LEAN) to histology and anatomic pathology as implemented at the Avera McKennan Hospital laboratory. Avera McKennan is the flagship hospital of the Avera Health System, a faith based, not for profit healthcare system based in South Dakota. Comprised of 235 hospitals, clinics, and physicians, with over 12,000 employees, Avera Health is one of the largest healthcare systems in the region. Beginning in 2004, Avera McKennan's laboratory began its "LEAN journey" and in the intervening years has expanded it throughout all areas of the laboratory. Following the example set by the laboratory, many other areas of the hospital have joined in the LEAN Process Improvement journey. In January 2009, the Avera McKennan Laboratory became the first hospital laboratory in the US to achieve the CAP ISO-15189 accreditation in both clinical and anatomic pathology.

Key Words: LEAN, LEAN process, histology, anatomic pathology, clinical pathology, processing laboratory

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All figures can be viewed online in color at http://www.anatomicpathology.com.

LEAN PRINCIPLES

Much has been written about the Toyota Production System, but it is most recognized as a result of the work of Womack and Jones (LEAN Thinking: Banish Waste and Create Wealth). LEAN is a management and process improvement philosophy that has dramatically changed the landscape in those facilities that have adopted it. Some tools and key aspects of LEAN are detailed in the following paragraphs.

Voice of the Customer

One of the key aspects of LEAN is listening to the voice of the customer (VOC). It is about delivering those things the customer wants, needs, and not adding things that are superfluous to the customer. Thus, you are specifying value from the point of view of the end customer/user. You use the VOC to determine the value added processes and outcomes that are at the core of the LEAN philosophy. In pathology, you have many customers—the surgeons and clinicians who use your services, the patients who rely on your expertise, the technical staff who work with you on a daily basis, and the patient care staff who deal with obtaining, labeling, and transporting specimens. Although all customers have needs and expectations, your end customers are the physicians and patients.

Value Stream Mapping

The value stream map identifies all of the steps across all disciplines/departments in the value stream and helps you to eliminate those which do not add value. Anything that does not add value is waste. In healthcare, we have 2 basic kinds of waste—required waste, that is, waste which is mandated either by a regulatory or similar agency; and pure waste, which can and should be eliminated. The value stream map provides a visual representation of the stream together with the times involved in the entire process (Fig. 1).

Eight Wastes

LEAN attacks waste. Depending which book you read, there are 7 (or 8) defined waste categories. These are:

- Defects (time spent doing something incorrectly, inspecting for errors, etc)
- Over production (doing more than is needed or doing it sooner)
- Transportation (unnecessary movement of the product in a system)
- Waiting (waiting for the next event to occur or the next work activity)

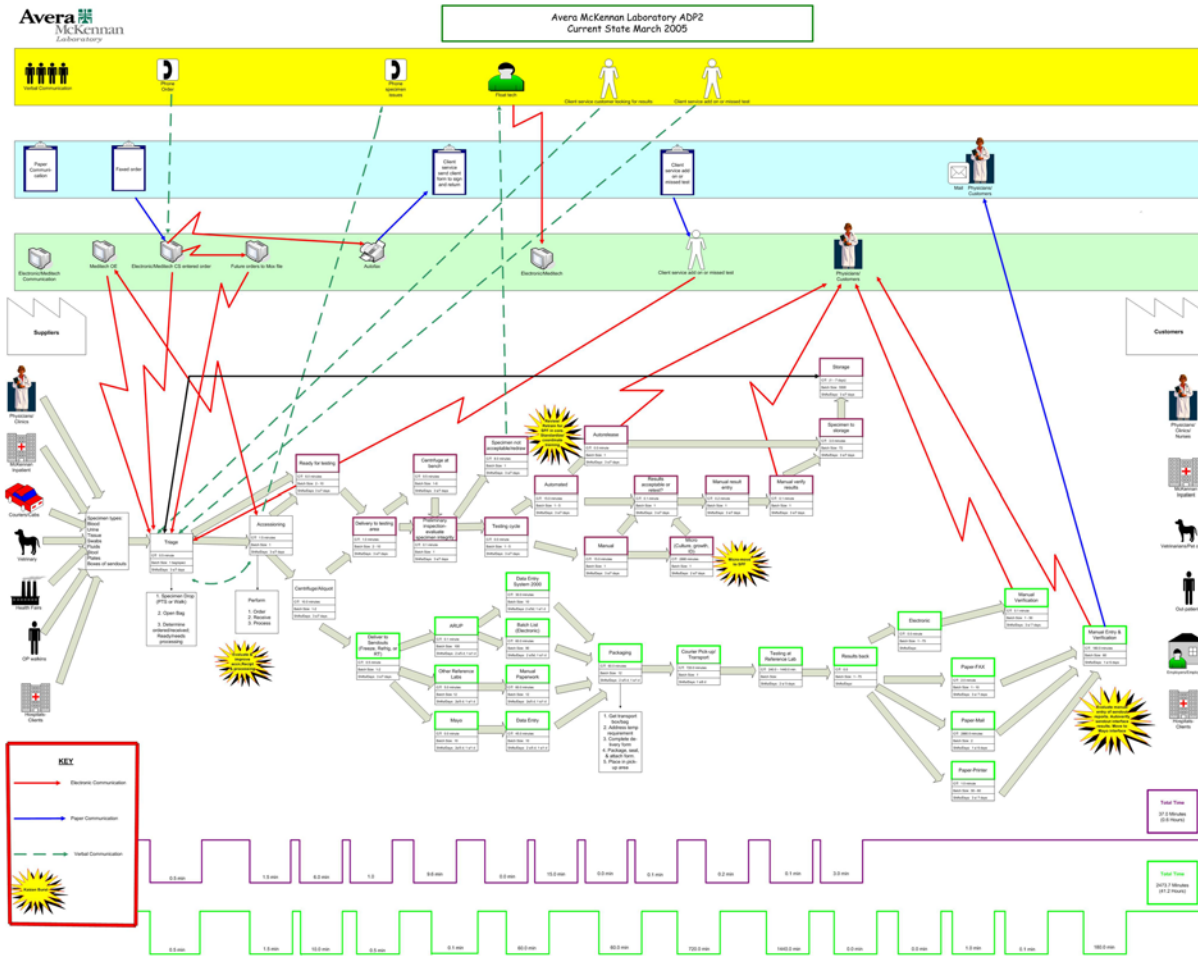

FIGURE 1. Value stream map.

- Inventory (excess inventory through storage, ordering, etc)
- Motion (unnecessary movement by employees in the system)
- Over processing (doing work that is not valued by the customer)
- Human potential (waste and loss due to not engaging employees)

All of these wastes have direct examples in histology and pathology. The goal of LEAN is to eliminate or minimize these wastes.

Spaghetti Diagrams

This is a LEAN tool that visually demonstrates the path taken by a product or employee during a given timeframe while performing their assigned duties. The goal of LEAN is to make the pattern as streamlined as possible and avoid collisions and wasted motion (Fig. 2).

Standardized Work (Work Guidance)

This is the method for developing best practices and methods in an area. A good definition of "Standardized" work (courtesy of Mark Graban) is "the current one best way to safely complete an activity with the proper outcome and the highest quality." Note that the operative word here is Standardized, not standard. Standard can sound like an absolute (identical), with zero variation or flexibility. Standardized work allows professionals to use their judgment to make certain decisions on the job, but the steps and their order of performance are always the same. Standardized work is clearly documented and provides specific guidance on the proper performance and order of tasks.

Single Piece Flow

This is a LEAN ideal where specimens or cases are accessioned, grossed, processed, worked on, or moved one at a time. In histology, this is a direction or goal as some tasks require batch work. The key is to make the batches as small as practical.

First In-First Out

This is a LEAN ideal which describes the flow of materials or specimens where the item that has been in inventory the longest is processed first. In histology, this is exemplified by the orderly accessioning and processing of specimens/cases as they arrive so that they are completed in the order received (where possible).

5 S

This is a LEAN tool that attacks waste through improved visual management and workplace organization.

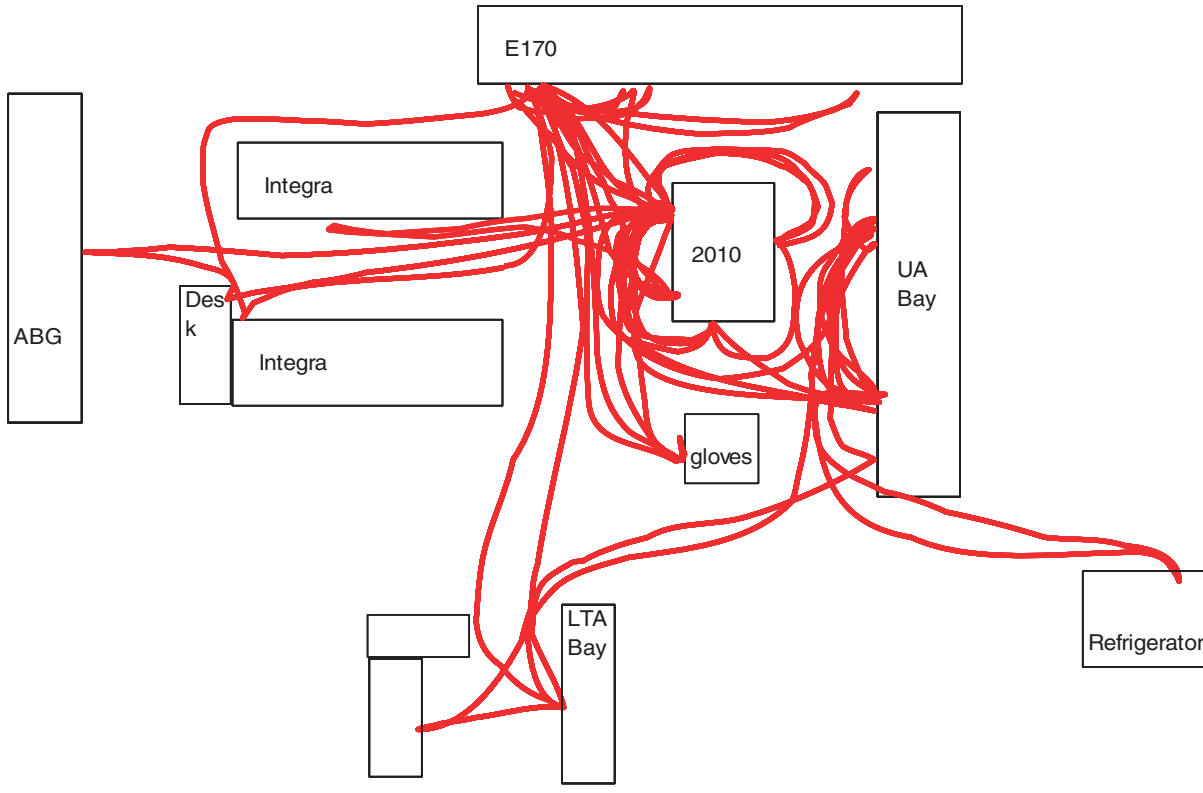

FIGURE 2. Spaghetti diagrams.

5 S is a constant ongoing process, not one time or annual thing that is carried out before inspections. The 5 S' are as follows:

- Sort—sort out unneeded items; keep items based on frequency of use.
- Straighten—organize for the reduction of wasted space.
- Shine—keeping the workplace neat and clean daily.
- Standardize—developing a consistently organized workplace.
- Sustain—a system for the ongoing support of the other 4 S.

A LEAN workplace is a neat workplace with supplies at the point of use and in sufficient quantities to do the work without excess inventory.

Double Binning

This is a supply control tool which places 2 identical bins at the workstation for each supply material (in their order of use). Each bin contains enough supply for a typical 8 hour shift. When the first bin is empty, it is used as an ANDON (visual cue) that a refill is needed. Work continues using the second bin while a designated individual fills the empty bin from the store room. When filled, it is placed behind (or under) the "in use" bin.

Shadowing

A LEAN tool where the exact location of equipment and supplies materials are highlighted or "shadowed" by the use of visual cue. The purpose is to allow one to immediately see "missing" or misplaced tools/supplies. This cue can be a tape outline, a taped box, or simply a permanent label identifying the tool/item.

Kaizen Event

This is a tightly focused, short time span (usually 1 to 2 wk), small scale improvement project. Kaizens are usually performed after an area has undergone an extensive, full scale (usually 14 to 20 wk) LEAN project. After the future state value stream map is completed and put into practice, kaizen "bursts" are identified and these are areas where potential bottlenecks occur. Kaizens are valuable tools once the initial project has been completed.

Genji Gembutsu (Walking the Floor or Gemba)

This is a key Toyota philosophy of management. It translates to "go and see" and is analogous to the Management by Walking Around. Managers who reside in offices and not on the floor do not get a first hand view of the issues encountered by staff. This isolation and insulation affects their judgment and decision making. Genji gembutsu can be accomplished by periodic (every few hours) walks around the department or factory floor.

BASE CONDITIONS (WHERE WE STARTED)

Like most histology laboratories (and clinical laboratories for that matter), space was added in a random fashion as it became available, with little attention to product or operator flow. Specimen flow did not follow the most efficient and effective route because of numerous layout constraints. In addition, equipment was placed where ever space could be made for it, often out of sequence of the process steps (Fig. 3).

1. Tissues were brought into histology through the common laboratory entrance and taken to the grossing

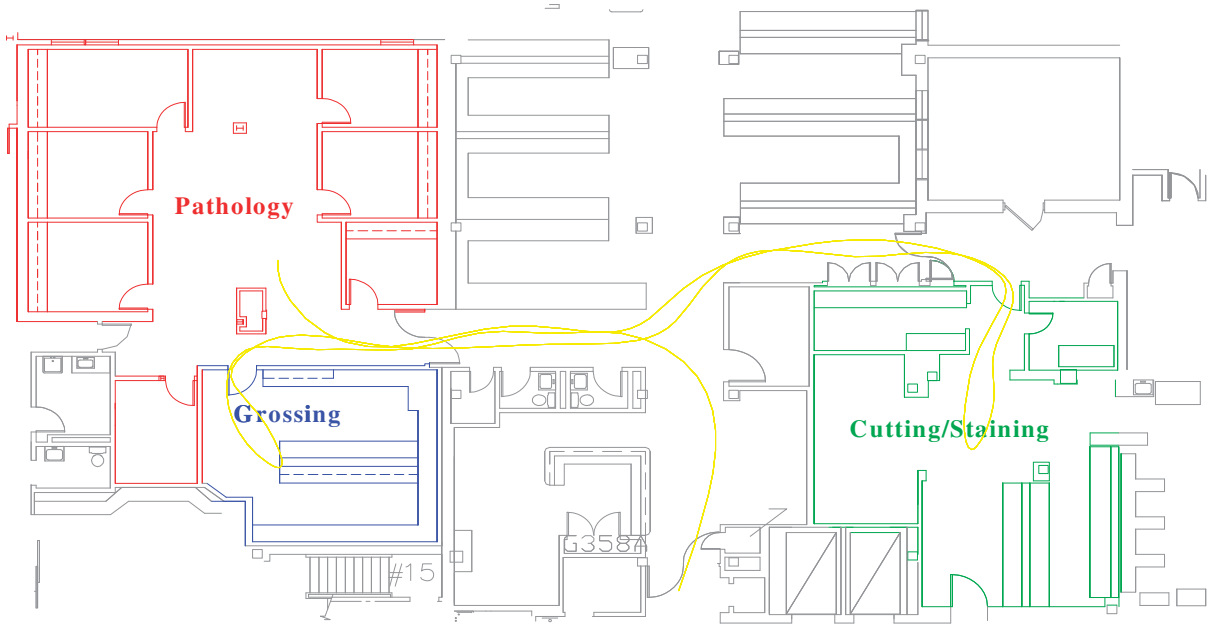

FIGURE 3. Pre-LEAN floor plan.

area which was adjacent to the pathology offices. There, the specimens were accessioned into the hospital computer system (if a private pathologist's case, also into the Pathologists computer system). After accessioning, the specimens were examined grossly and placed into cassettes. After the above step, the cassettes were placed in formalin to await transfer to the processing laboratory. Specimen containers were then stored randomly wherever space was available and disposed of only as space became limited/decreased.

2. Upon transfer to the processing laboratory, the specimens were loaded into the overnight processors and held until 6 PM when the processors were closed and the appropriate program begun. The program completed around 4 AM and at that time, the first wave of histology technicians came in to begin embedding the cases. As the cases were embedded, the cassette molds were placed on ice to await the microtomists. As can be noted from the floor plan, the placement was not ideally located.
3. Once the blocks were faced and cleaned, they were cut according to the various protocols for the respective tissues. The slides were deparaffinized and then stained on a batch stainer. Upon removal from the stainer, the slides were drained and then cover-slipped. Slides were then placed into carriers by case number and the request forms accompanied the slides in the carriers. Again these functions were not ideally placed.
4. At this point, the cases were distributed to the pathologists for reading. Stacks of slides were placed on the pathologists desks and all processing was usually completed by 10 AM.
5. At this time, special stains ordered from the previous day, were performed and given to the appropriate pathologist as they were completed.

Staffing was staggered with 2 people coming in at 4 AM, another 2 coming in at 4:30 AM, one coming in at 8 AM, and another at 9 AM. Grossing assistants came in around 9:30 to 10 AM to assist with accessioning and grossing. They left at 6 PM and before leaving, turned on the processors.

Productivity was in the neighborhood of 8000 to 9000 hematoxylin and eosin (H&E) slides per technician per year. Staffing after 12:30 PM was limited to 2 technicians to do special stains, immunohistochemical (IHC) stains, etc.

The time for surgical specimens from accessioning to sign-out averaged 44.5 hours with a range from 23 to 104 hours (specimen dependent). Occasionally, selected complex cases took longer than 120 hours.

LEAN PROJECT IN HISTOLOGY

The LEAN project in histology was undertaken after the enormous gains in efficiency and error reduction in the clinical laboratory were realized. The decision was a joint decision by the pathologists, technical staff, and laboratory administration. The project was led by 2 laboratory employees who were LEAN green belt certified with assistance from the histology supervisor and a staff technician. The Laboratory Administrative Director, a LEAN/6 Sigma Blackbelt provided project management and mentoring to the group. Throughout the process, input from all staff and the pathologists was sought and received.

By following the LEAN 12 step process and involving the staff and pathologists, we were able to complete the project in 14 weeks. We began the process by listening to the VOC. Our customers included the surgeons, pathologists, staff (both technical and clerical), and administration. Surveys and questionnaires were completed and the key needs identified.

Along with the VOC, we collected data to begin preparation of the "Current State" value stream map. This was accomplished using videotaping of the specimen flow and the operator flow for several different types of specimens. We prepared a wall in the histology/pathology area (our "LEAN Wall") where yellow "sticky notes" representing all of the steps in both product and operator

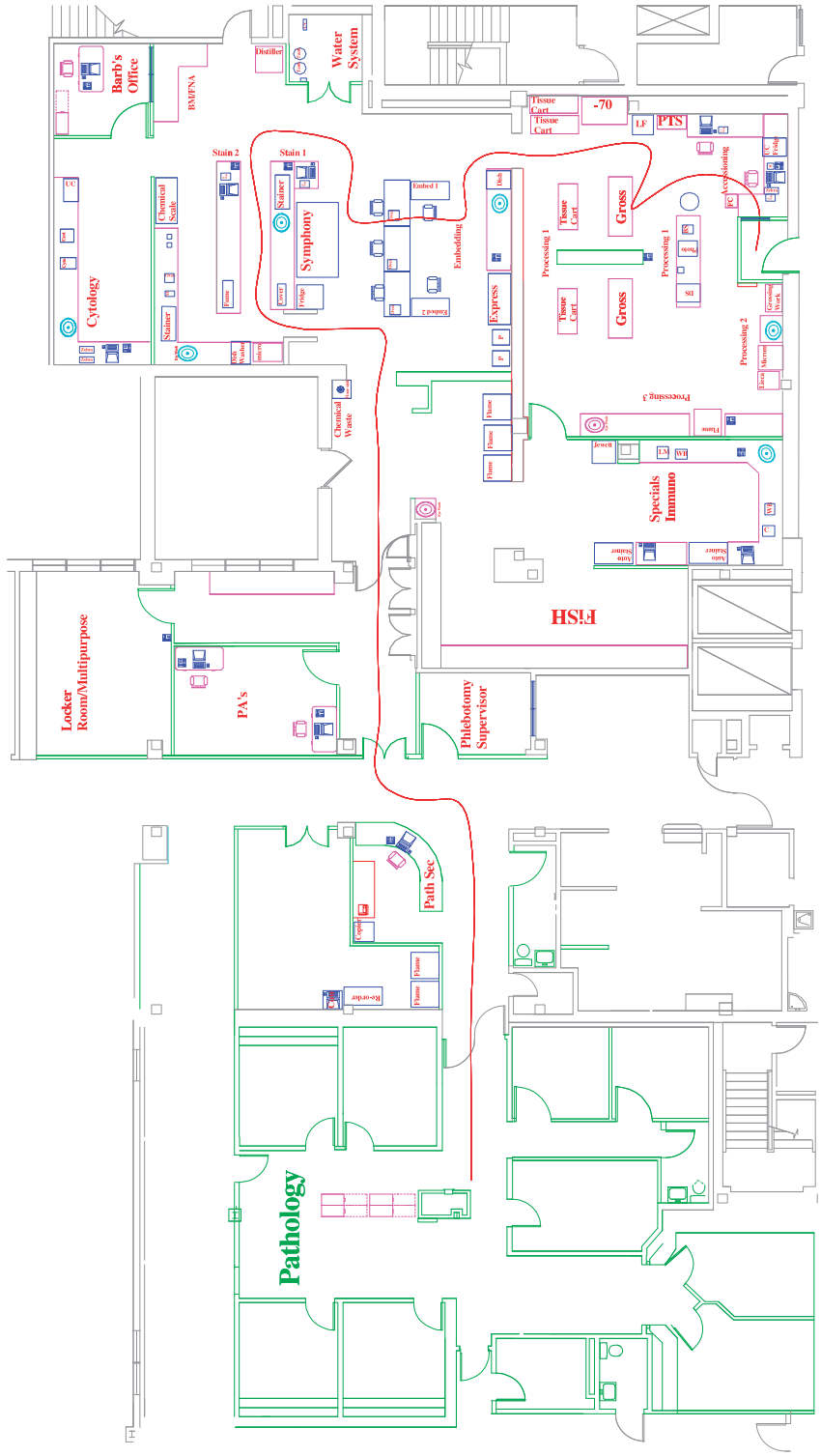

FIGURE 4. Post-LEAN floor plan. FISH indicates fluorescent in-situ hybridization.

flow together with the times for each step as noted in the video tapes. As we evaluated the video tapes, we were able to identify areas that stood out as "issues" that would need to be addressed. This wall in the midst of the work area allowed all staff to be aware and involved in the processes. It enhanced our communication with all stakeholders.

Once we had assembled the current state value stream map; a tedious and carefully documented process, we were able to identify the issues or kaizens that would be required to improve the total process. Furthermore, we now had a solid baseline of functions and times, both productive and wasteful so that we would have meaningful metrics for future comparison. We could now do a "Future State Process Map" that would reflect the "ideal" workflow we envisioned. It also allowed us to design a new laboratory layout that would facilitate a LEAN workflow (Fig. 4).

ORDER OF THE PROJECT

The team realized that the supply portion of the project would impact all phases so part of the team was assigned to the supply chain/store room portion. Their function was to organize the department store room in a LEAN fashion. Kanban cards were prepared for all supplies; the store room reorganized and double binning of stock supplies begun as each area would be affected in their respective order of implementation.

RECEIPT AND ACCESSIONING

We chose to begin the project in the order of specimen flow; so we began with the receipt and accessioning areas. The first and easiest area to tackle was the 5 S phase in receipt and accessioning. We evaluated the necessary supplies and began by applying the double bin system of supply replacement in the order of use and shadowing their exact location. Standardized workstation layout is a basic tenet of Standardized Work. On account of unique issues with accessioning (half of the workload is Avera McKennan and the other half is private pathology business each having a different computerized information system), we established 2 separate accessioning stations. All specimens are accessioned into the Avera McKennan Meditech Client Server Pathology (Meditech, Westwood, MA) system but only specimens from the private pathology business are entered into the separate SoftPath (SCC, Clearwater, FL) system. Accessioning of private specimens into the AMcK Meditech system was accomplished using a short form outreach order and required about 30 seconds of time to accomplish. McKennan specimen demographics were already in Meditech so they only took about 30 seconds to accession. Thus together accessioning took an average of 1 minute per specimen. A standardized work document for accessioning and receipt was developed using many inputs, shared with all staff and implemented.

We already had a process in place with surgery such that specimens were being received several times a day (about every 2 h) with histology picking up one in the AM and once in the PM and surgery delivering once in the AM and once in the PM. The processes of receipt and accessioning revolved around these delivery times so they were already in small batches. With some minor changes in delivery times, it was relatively easy to change accessioning into a First In-First Out (FIFO), Single Piece Flow (SPF) mode, and eliminate batching altogether. This meant that now the grossing step could proceed in a FIFO, SPF fashion so that specimens were available for processing in a timelier manner. Thus, simply by improving receipt and accessioning, we were able to improve the grossing process.

We now had receipt and accessioning performing standardized work, double binning supplies in order of use, shadowing, using a Kanban system of ordering just in time, following SPF and FIFO methodology for all routine histology specimens. We also had developed a system for the handling of frozen sections, renal biopsies, and other exceptional specimens.

GROSSING PROCESS

With the advent of the changes in the receipt/accessioning process, gross examination could now proceed unabated in a single case manner. This made best use of both the Pathologists Assistants and the Laboratory Technical Assistants who assisted with the grossing process. Instead of larger batches, grossing specimens were available in a steady, constant flow so that work proceeded at a steady pace; not a rush/lull as previously. Again, 5 S, supplies in the order of use, shadowing, streamlined workflow, reduced paper-work, and standardized work was all implemented. We also "Leaned" the specimen container storage into 2 large, wheeled metal storage units where they are kept in date order, and discarded 2 weeks after sign-out. This improvement became seamlessly tied to changes in processing changes in the histology laboratory.

Processing of Tissues

As the accessioning and grossing changes occurred, the need for more rapid processing became apparent to all. This was not unanticipated and we had a few months earlier acquired a Sakura Xpress tissue processor (Sakura Finetek, Torrance, CA). Although originally intended to process biopsies for faster turnaround, we found that we were able to use it for many other cases/specimens. We still maintained our conventional processors for those tissues that had not yet been validated on the Xpress (validation of tissues is an on-going process). Our goal is to process as many tissues on the Xpress as possible.

The Xpress allowed us to process cases in significantly smaller batches (10 to 40 cassettes) as opposed to 300 cassette batches with our traditional processors. As we were able to successfully develop 1 hour protocols, we could keep our workflow and our "Work In Progress" down to a very manageable level. Cassette batches could be loaded every 20 minutes and we were now able to embed a batch, hand it off for microtomy and routine H&E staining in a fairly constant, easy pace; no more hurry-up and wait. For embedding and microtomy, we reduced batches to a maximum of 10 cassettes or 1 large case. Although not single case flow, it did allow for maximum time utilization and reduction of waste. Again, as before, we double binned supplies, shadowed workstations, placed supplies in the order of use, and developed standardized work documents. In addition, we began to fully use the features in the Pathology Module (which had heretofore been ignored) to our advantage. Features such as assign to, slide labels, and specimen labels were used to reduce errors. Features such as tying current procedural terminology codes to tissue types and specimen types further improved performance both functional as well as financial. All of this contributed to improved work processes and increased patient safety.

It was in the processing step where we began to evaluate new equipment to facilitate the new work philosophy. We had great success with the Xpress, we used conventional embedding stations, conventional microtomy, but we were still using batch H&E staining. We tried the Ventana Symphony H&E stainer (Ventana Medical Systems, Tucson, AZ) as it seemed to be nicely designed for a SPF/FIFO process. Unfortunately, it did not work for us. We instead modified our work to use our backup Sakura DRS stainer and a Sakura cover-slipper (Sakura Finetek, Torrance, CA). We simply reduced the number of slides per stain cassette rack and used more racks so that we had a continuous flow process.

Even though in true LEAN fashion, it is the responsibility of each and every worker to detect and correct defects as they are detected, a final quality check before release was felt to be necessary and of value. Thus, we introduced the "block check" station. Here, as a quality control step, the finished slides, case blocks, and requisition form are matched and evaluated immediately before placement in the slide trays for distribution. This is also the station where the slide stain quality is evaluated before routing to the pathologist end user. This step is designed to catch any deviations before the finished product is delivered to the end user (the pathologist).

SLIDE DISTRIBUTION/READING

Instead of slides being distributed during a short period and accumulating on the pathologists' desk, slides are distributed as completed in an ongoing fashion. This does create a change in work pattern and flow. As work comes out in a continuous stream, the pathologists are fed slides throughout the day. An unintended consequence of this is that it does not allow for them to determine their individual workload and read accordingly; they simply work at a steady pace. Each pathologist reads their cases as presented. Requests for Special Stains, IHC stains, or recuts/deeper sections are all processed as requested with a goal of completing the cases as soon as possible.

TRANSCRIPTION/SIGN-OUT

Changes to transcription have been minimal except that only 1 transcriptionist/secretary remains on site. The others work from home through Virtual Private Network. Transcription is accomplished as the cases are dictated again on a FIFO basis. As they are transcribed, they are available to the dictating pathologist for review and sign-out. In most cases sign-out occurs between trays of slides such that work is turned around in a timely fashion. Once a case is signed out, it is immediately available in the Electronic Medical Record and thus to the clinician. We are now preparing to evaluate voice-recognition software and its impact on workflow and work processes.

UNIQUE/INNOVATIVE FEATURES

As part of the redesign of the area, certain safety and work process features were incorporated into the design. As in most histology laboratories, room air exchange, solvent recovery, and waste are major issues. We incorporated recycling systems for both alcohol and xylene into the design of the laboratory. There is a dedicated area for the recyclers with exhaust vents directly above and behind to remove vapors. The entire histology laboratory air conditioning system was redesigned to permit a minimum of 12 full volume air exchanges per hour with full outside exhaust. In addition, a novel solvent waste disposal system (for solvent concentrates, etc) was designed with a dedicated sink connected to a 75 gal collection container one floor below. The sink has a one way valve to allow solvent to drain down while keeping vapor from rising up through the drain. There is a "fill level monitor" that alerts the histology laboratory when the collection container is approaching a level where it must be drained. The collection container has a drain valve so that the container may be emptied into 55 gal drums for proper disposal by the Hazardous Waste Disposal Contractor. All of this can be carried out without having to lift and dump heavy containers.

A separate area for IHC and fluorescent in-situ hybridization staining was designed. This system allows separation of the processes and avoids interference with the routine histology processing. As a result of the work redesign processes, IHC and special stains can be requested for same day resulting if they are received by 2 PM. The routine histology department operates 24 hours a day Monday through Friday and Saturdays until 3 PM.

POST-LEAN IMPROVEMENTS

As a result of the project, we have experienced a number of changes and improvements in our histology/anatomic pathology department. We have redistributed the staffing matrix and implemented the use of nontechnical Laboratory Assistants to perform accessioning, gross assistance, and assist with bone-marrow and fine needle aspiration procedures at the bedside. As a result, the histology technicians perform technical duties and maximize our most limited of resources. We have increased productivity to a level in excess of 17,000 H&E slides per tech per year and reduced surgical turn around time (TAT) by 67%. Other improvements include:

1. Linear workflow with markedly reduced walking and time waste.
2. In excess of 70% of specimens are processed using rapid processing.
3. Block check/quality check has dramatically reduced rework and improved quality of the end product.
4. TAT currently averages 27.3 hours for all specimens with a range of 6 to 48.5 hours from receipt to sign-out. This is a 67% improvement from our pre-LEAN average TAT of 44.5 hours (range: 24 to 104 h).
5. Many cases are signed out on a same day basis and nearly 80% are available within 24 hours of receipt.
6. As a result of process improvements and automation, staff productivity is higher with less stress.
7. Customer satisfaction (Medical Staff and Patients) is at an all time high.

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