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Improving Histopathology Laboratory Productivity: Process Consultancy and A3 Problem Solving

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ABSTRACT

Objective: The ISO 17020 quality program has been run in our pathology laboratory for four years to establish an action plan for correction and prevention of identified errors. In this study, we aimed to evaluate the errors that we could not identify through ISO 17020 and/or solve by means of process consulting. Process consulting is carefully intervening in a group or team to help it to accomplish its goals.

Material and Method: The A3 problem solving process was run under the leadership of a 'workflow, IT and consultancy manager'. An action team was established consisting of technical staff. A root cause analysis was applied for target conditions, and the 6-S method was implemented for solution proposals. Applicable proposals were activated and the results were rated by six-sigma analysis. Non-applicable proposals were reported to the laboratory administrator.

Results: A mislabelling error was the most complained issue triggering all pre-analytical errors. There were 21 non-value added steps grouped in 8 main targets on the fish bone graphic (transporting, recording, moving, individual, waiting, over-processing, over-transaction and errors). Unnecessary redundant requests, missing slides, archiving issues, redundant activities, and mislabelling errors were proposed to be solved by improving visibility and fixing spaghetti problems. Spatial re-organization, organizational marking, re-defining some operations, and labeling activities raised the six sigma score from 24% to 68% for all phases. Operational transactions such as implementation of a pathology laboratory system was suggested for long-term improvement.

Conclusion: Laboratory management is a complex process. Quality control is an effective method to improve productivity. Systematic checking in a quality program may not always find and/or solve the problems. External observation may reveal crucial indicators about the system failures providing very simple solutions.

Key Words: Quality control, Histopathology, Internal-external control

INTRODUCTION

The report of the Institute for Medicine in 1999 called attention to systematic medical errors as the 8th leading cause of death in the U.S.A. (1). Quality systems in healthcare as well as in pathology have been proposed and defined since then. Implementation of these quality systems provided an improvement in healthcare service delivery and cost-effectiveness. These systems are based on reducing errors, waste, redundancies, and streamlining work processes (2).

Several practices are suggested for anatomic pathology laboratories. The College of American Pathologists (CAP) is the leading institution in laboratory quality assurance and has a specific anatomic pathology quality control and quality assurance program. The aim of the CAP Laboratory Accreditation Program is defined as "to improve patient safety by advancing the quality of pathology and laboratory services through education, standard setting, and ensuring laboratories meet or exceed regulatory requirements" (3).

There are a few accreditation programs for the development and maintenance of standards and guidelines for pathology laboratories, such as the United Kingdom Accreditation Service (UKAS) (4) and the Royal College of Pathologists of Australasia (RCPA) (5). In 2011, a pathology laboratory accreditation program was established by the Turkish Accreditation Agency (TÜRKAK) (6). The Turkish Ministry of Health has recently defined the minimum national requirements to be followed by the health institutions to establish national quality standards. These requirements also include guidelines for pathology laboratories (7).

Errors in anatomic and/or surgical pathology can occur at the pre-analytical, analytical and post-analytical stages (8). Most of the pre-analytical errors can be detected during the analytical phase (slide review). This detection includes interpretive and/or clinical sampling errors, but not the non-interpretive errors. As the pre-analytical production steps are complex in anatomic pathology, automation

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does not analyze and resolve all of these errors. Therefore, professional and technical approach is essential for error detection.

Pathology laboratory management is not different than process management. The most important step in process management is simplification, described as "Lean" (9). Pathology laboratory management may be well-defined, even it is not simplified and recorded. Also, definitions known by the employees may not be enough for simplification. Shortage of time and budget, lack of motivation, and workload may interfere in finding solutions to the problems that arise during process management. An ISO 17020-based quality control and quality assurance program has been developed at Dokuz Eylul University, School of Medicine, Department of Pathology, and accredited by TÜRKAK in 2012, under the auspices of our institution. Within these quality assurance settings, we try to improve our program by adding different and new practices to reduce errors. In this study, we aimed to evaluate the errors that we could not identify and solve by means of an external observation of process management that may be more objective and demonstrate unseen problems, and used the A3 problem solving method. A3 problem solving is an action plan written on a sheet of A3-sized paper, and aims to define the problems, analyze them, and apply corrective actions.

MATERIAL and METHODS

At the initial step, the process consultant described the A3 process consulting to the laboratory administrator and head of the department. A survey was developed to describe the assignment and define its goals as well as the time and effort required and the possible difficulties. A plan was developed based on the preliminary problem analysis (*Entry*).

A team consisting 5 technical laboratory members from 3 different departments in the laboratory was established. The roles of the consultant, team and the laboratory administrator was defined and the task plan was developed (*Contracting*).

The error rate is a part of our quality system and contains errors reported by the staff, the clinicians or patients, and the errors determined during system analysis.

Definition of the Problem and Finding Solutions: The A3 problem solving methodology process was established. Necessary meetings with the team were organized for brainstorming and all of the team members were asked to list the problems they encountered in daily practice (Figure 1).

Current condition: The problems were categorized according to the subjects and sorted in order of importance. The dimensions of the problems (technological, organizational, informational, psychological, or other) were determined.

Target condition: The most relevant problems were listed and categorized on the priority matrix (Figure 2). The most important problems with easy solutions to apply were selected.

Root cause analysis: Information about the causes of the problems, ideas to solve the problems, and an action plan was organized. The team was requested to ask "5 why" questions for each of the relevant problems (*Diagnosis*). For example; 1) Why is the cassette mislabeled? Because

Figure 1: Value stream analysis results.

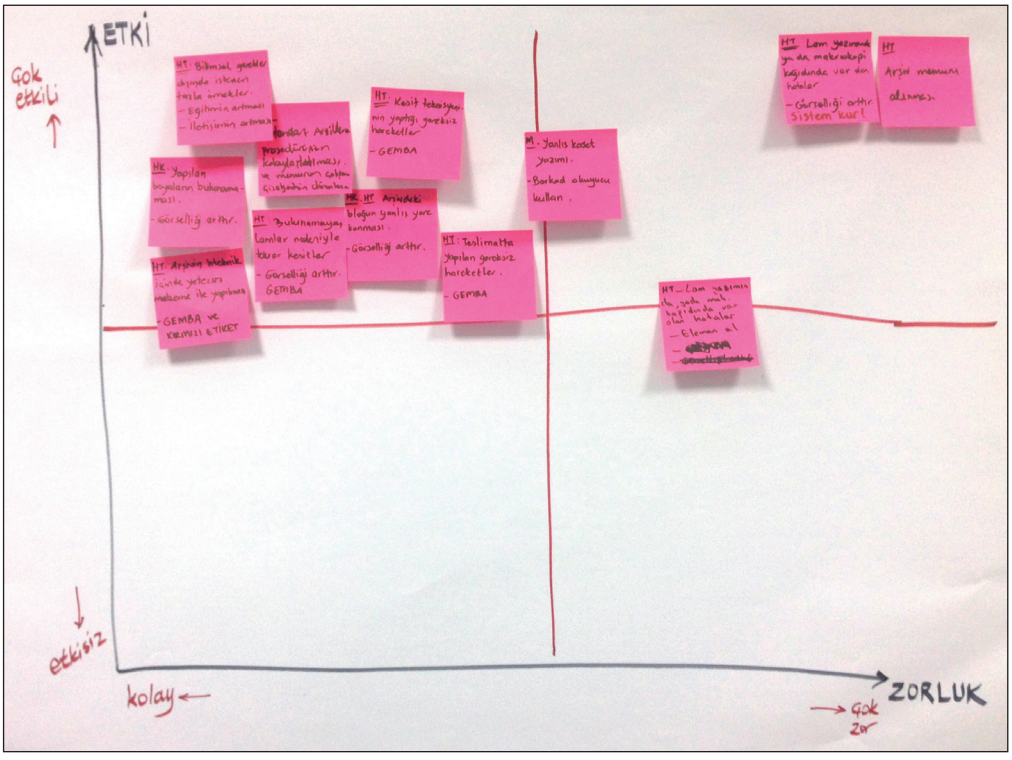

Figure 2: Priority matrix analysis of the relevant problems.

more than one people are giving orders for labeling at the same time. 2) Why is the cassette mislabeled? Because it is impossible to hear the order in a noisy environment.

Responsibility: The results of the root cause analysis were analyzed and conclusions were drawn on action proposals. Actions to be taken to deliver the results and the responsible technical staff were identified and informed (*Intervention*).

Proposed countermeasures: All of the processes were written on a map and spaghetti fields were defined (Figure 3). Alternative solutions, the evaluation of alternatives, the elaboration of a plan for implementing changes, and the proposals were presented to the client. Non-value added steps were identified and cancelled (*Withdrawal*).

Plan and follow up: A 6-S vision was created for the organization (Sort, Straighten, Scrub, Standardize, Sustain, and Safety). Solution proposals for the problems encountered in root cause analysis were listed. Applicable proposals were activated immediately. Non-applicable proposals were listed and submitted to the client in a written format. Pre-process and post-process 6-S scores were recorded.

After 1 year, the error rate and distribution were documented and compared with the previous year's results.

RESULTS

The main goal of the consultancy process was defined as a decrease in the rate of reported errors by analyzing grossing, histotechnique, immunohistochemistry and histochemistry phases and increase working staff satisfaction and efficiency. The current state showed mislabeling (either on cassette or glass slide) or syntax errors to be the main problem. For the last year; 110 errors were detected/reported, and 4 of these were from staining, 5 from tissue processing, 13 from archiving, 18 from sectioning, and 30 (28%) from mislabelling issues. 40 of the errors were from other causes (Figure 4).

Mislabeling errors were expressed by the staff to trigger other errors such as staining failures and archiving errors. The most important statement by the staff was the loss of work motivation due to cascading errors triggered by those mislabeling errors. The significant portion of time spent in the laboratory did not have an impact on the process. The target was to reduce the mislabeling error rate by 50%, and all other errors by 30%.

Spaghetti diagrams were drawn and 21 non-value added steps (Figure 5) were found. These were grouped in 8 main targets on the fish bone graphic, and included transportation, people, motion, inventory, waiting, over-

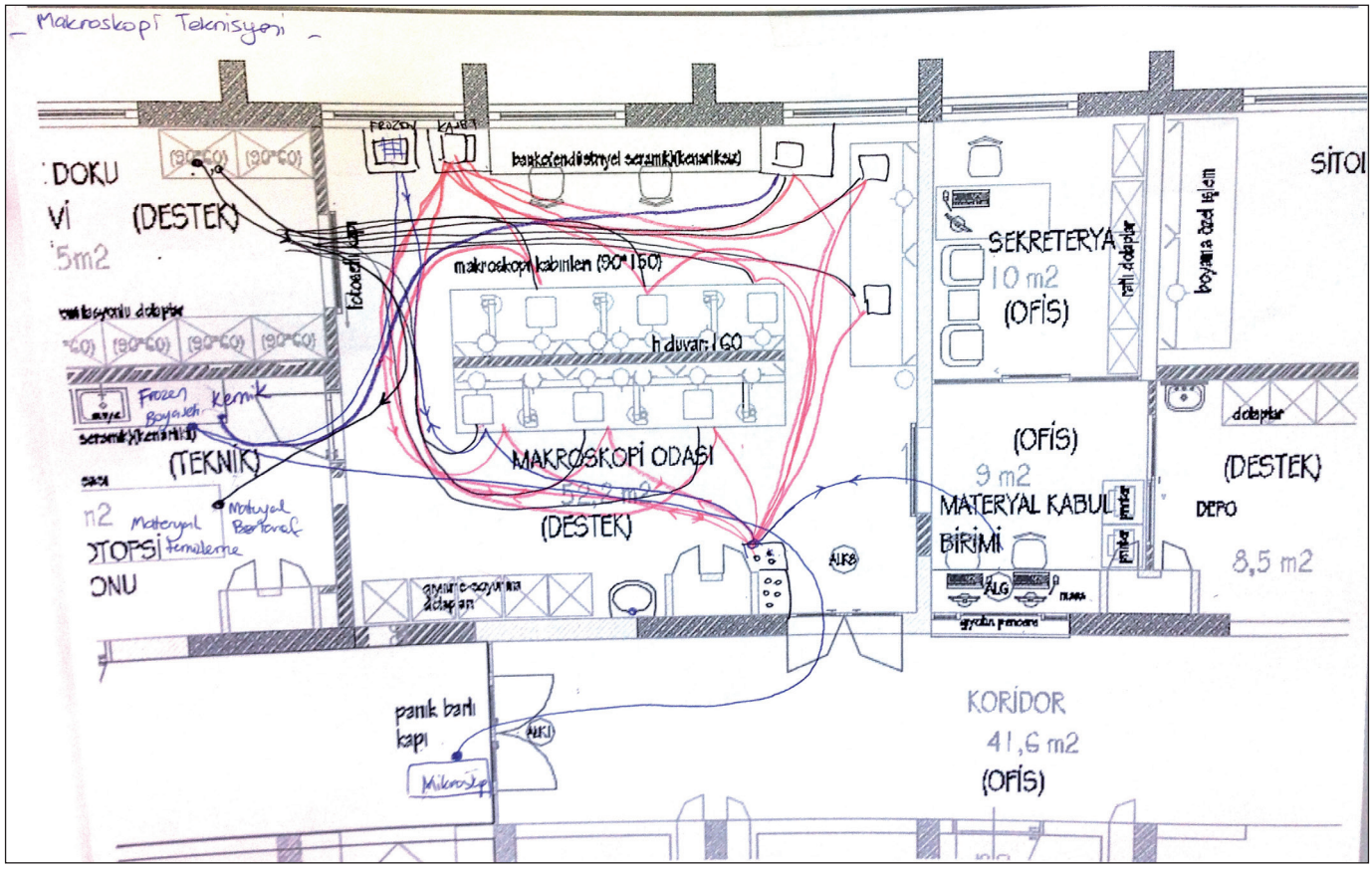

Figure 3: Spaghetti map showing all the steps of the laboratory.

processing, over-production and defects (Figure 6). Most important problems were unnecessary redundant requests, missing slides, archiving issues, redundant activities, and mislabeling errors (Figure 7). Most of the solutions were improving visibility and fixing spaghetti problems that were quick wins and would significantly improve the process (Table I):

1. The sectioning and grossing area were reorganized. Unserviceable devices and equipment were thrown away. The signs were placed to indicate how the working areas were used.

2. Local spaghetti effect was resolved for each area by means of very simple re-organizations.

3. Inactive devices/equipment were labeled with a newly designed label for easy recognition and to facilitate repairs (Figure 8).

Twenty-five questions were asked to team members to score six-sigma (Table II). Six-sigma evaluation scores were 100% for histochemistry, 56% for the grossing room, and 24% for sectioning/staining. After application of the corrective actions, the six sigma score was raised from 56% to 72% for the grossing room and from 24% to 68% for sectioning/staining.

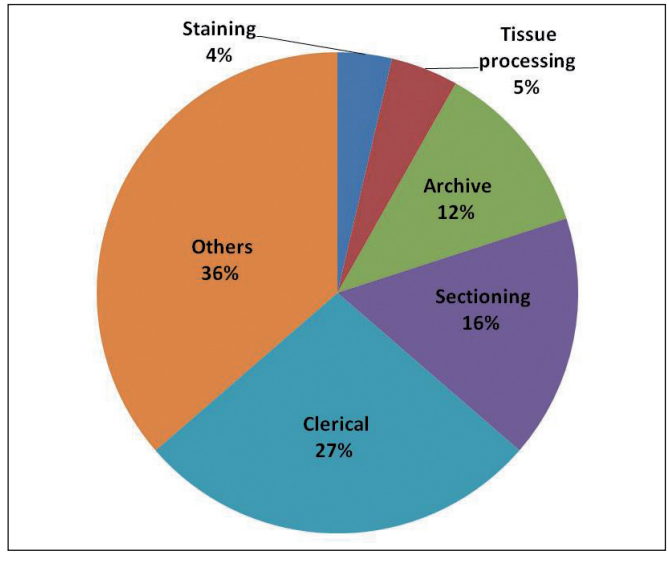

Figure 4: Distribution of error types.

After these operational modifications, proposals for long-term enhancement were presented. The major project was

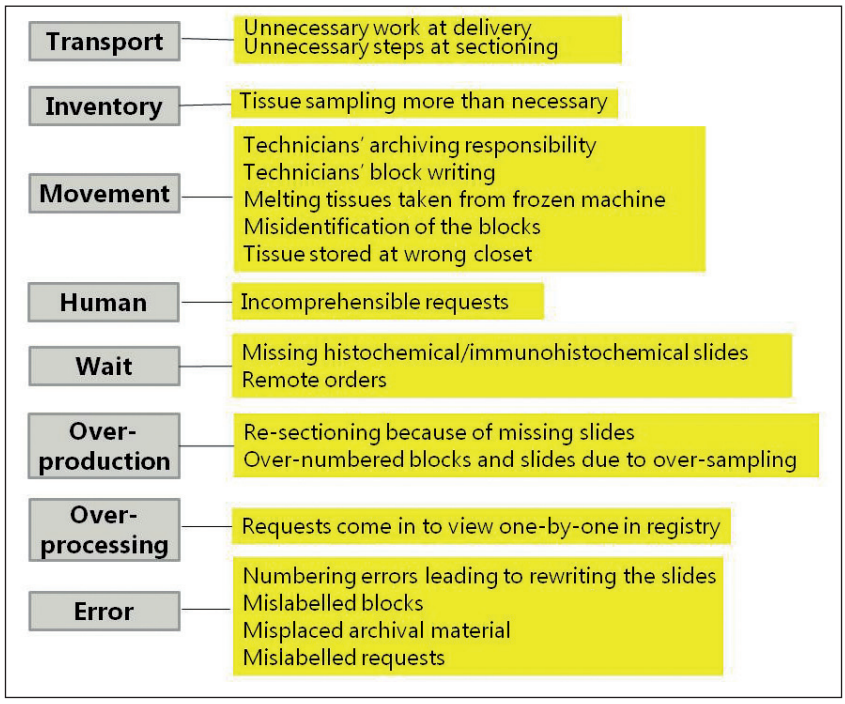

Figure 5: Documentation of the non-value added steps.

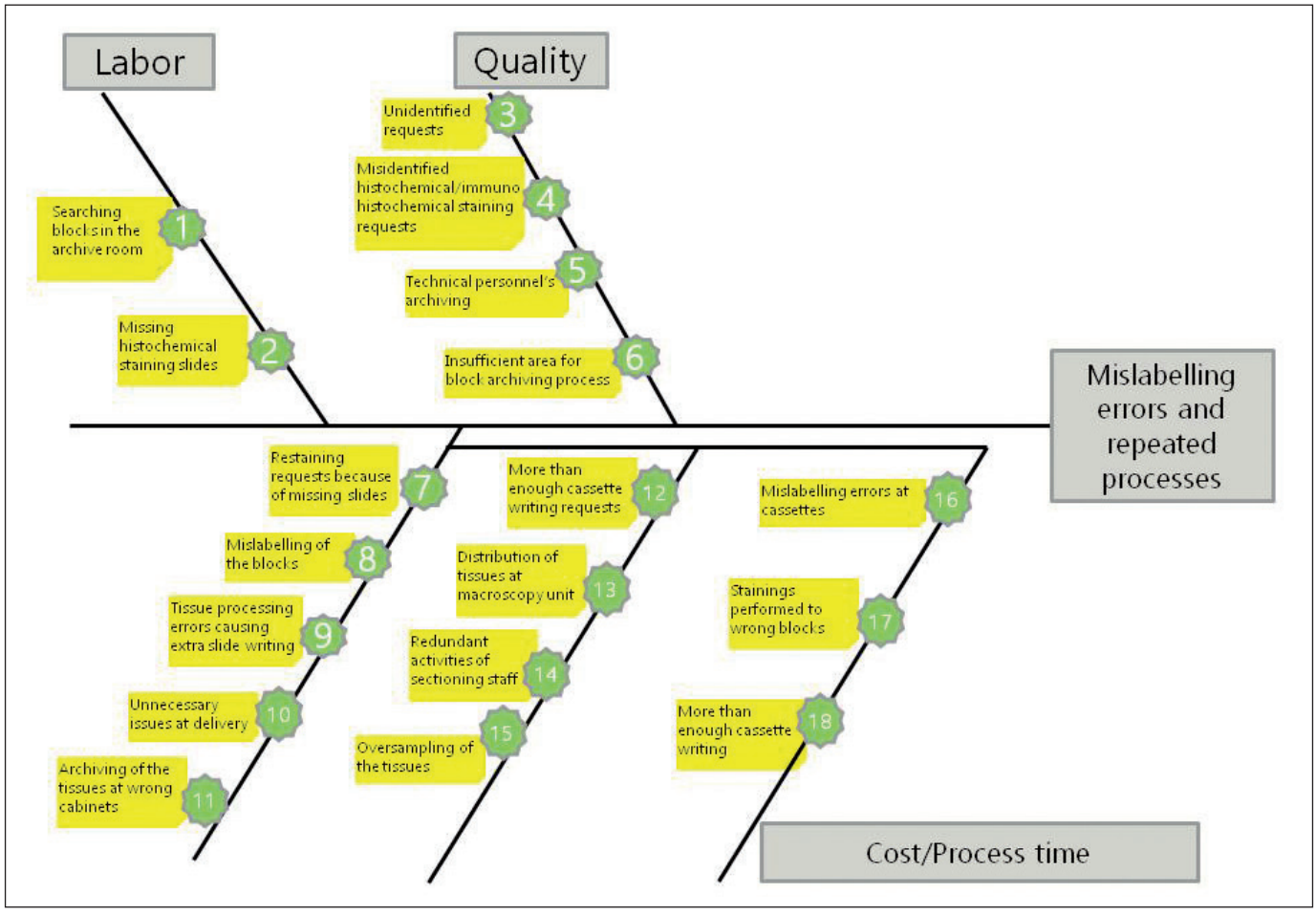

Figure 6: Fish-bone graphic consolidating the process foci to quality, laboring, cost/process time.

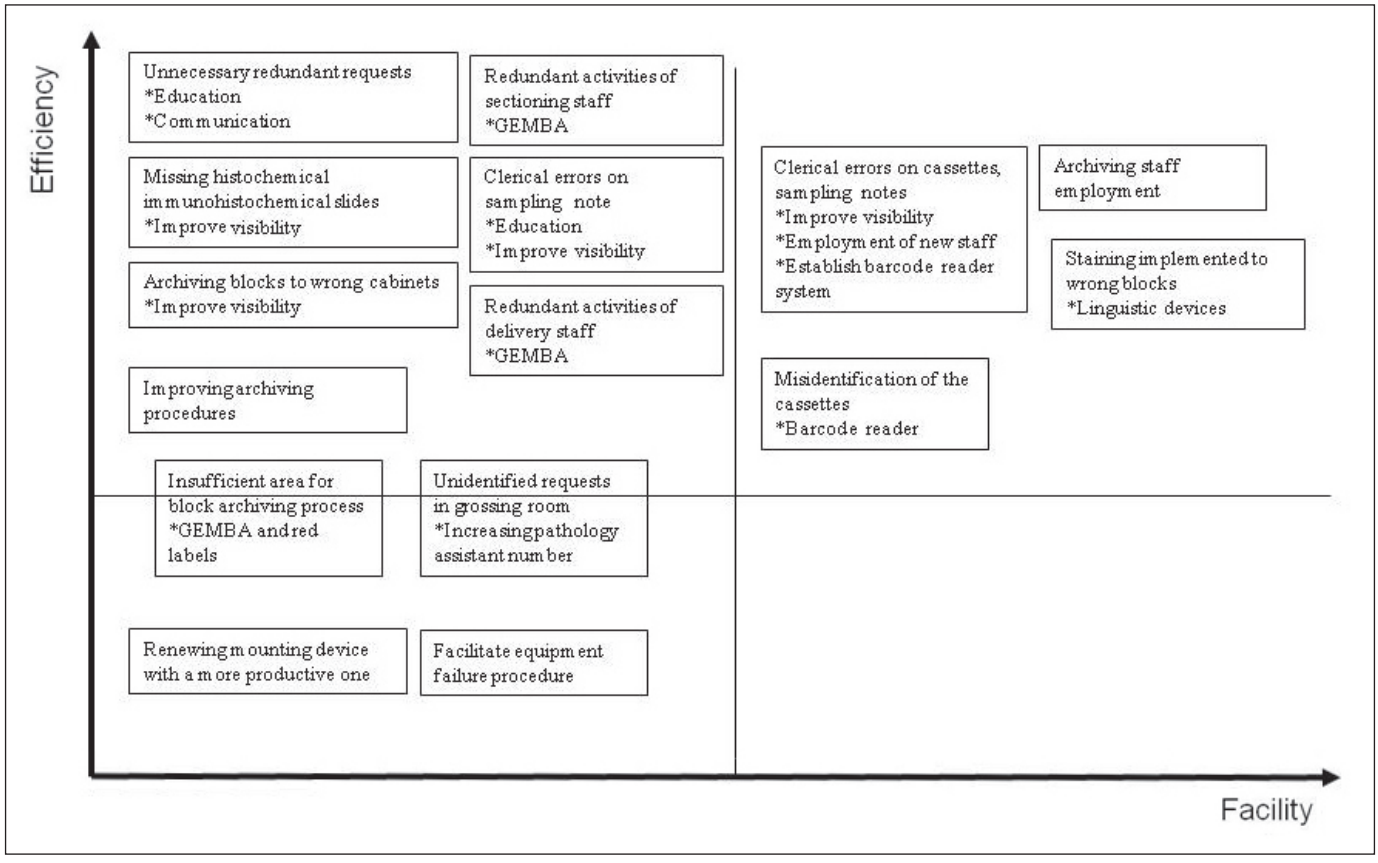

Figure 7: Priority matrix showing most important problems that could be solved easily.

			RED LABEL
Situation or Problem			**Label #**
Action (Comments if any) **1. Dispose 2. Organize 3. Improve 4. Remove 5. Other (please define)**			
Label date	**Category (if any)**	**Termination date**	
Labeling technician	**Informed staff**	**Responsible staff**	**Supervisor**
Transaction			

Figure 8: Red label formed to take attention to inactive devices/ equipment.

histology laboratory re-designing to eliminate the spaghetti effect (Figure 9).

Another proposal was implementation of pathology laboratory system to automate all of the phases by barcode readers. This system included recording at accession, and usage of the same barcode at the following steps.

After 1 year, there were 64 errors detected/reported. 4 of these were from staining, 2 from tissue processing, 7 from archive, 7 from sectioning, while 15 of the reported errors were mislabeling issues. 26 of the errors were from other causes. The mislabeling error rate declined to 15 (24.6%) from 30 (28%).

A spaghetti diagram was not re-drawn without making any changes in the general organization as it was a recommendation.

DISCUSSION

Anatomic pathology is a complex process. The quality in histopathologic examination has many dimensions and depends on change for the better. There are several available management tools to increase productivity and reduce errors (10). All of these systems aim to improve histopathology services for the patients.

All humans make mistakes. The mistakes in a pathology laboratory are called errors. The meaning of 'error' is a conflicting issue. Mistake and error are synonymous in terms of quality control. Most people do not use the term mistake but errors to include all errors includıng human

Figure 9: Histotechnique room re-designing proposal for lean management.

and machine errors. Mistake is a choice but errors are more formal determinations of wrong outcomes. Some consider only the mistakes in the final report as errors (11). Others consider every mistake as an error made throughout the process from obtaining the specimen from the patient to receipt and handling of the information in the report (12). However, it is obvious that the mistakes at any processes other than diagnosis may interfere with the diagnosis and cause a diagnostic error (8). Efficacy of documenting and correcting errors has been documented (13).

In our quality control and quality assurance program, isolated events are reported as errors and kept in a permanent log. The internal inspection of a quality program is getting increasingly complex and detailed because of the evolution of technology and the need to cover the governmental regulatory requirements. Some aspects of the program may be overlooked in internal inspection. An external audit related to the laboratory quality program may provide different contributions. We aimed to consult someone standing out of the system regarding our basic problems to.

Quality management programs with databases are powerful tools to monitor performance improvement. We have been using a quality management program in our laboratory for the last four years. We noticed that the program we used and the staff had become complacent. The program was not sufficient to solve the same basic problems that could be solved earlier. We decided to utilize an external audit mechanism and consider its proposals. This external consultation was done with the A3 solution method.

A consulting process has 5 phases: 1) the Entry phase includes client contact, preliminary problem diagnosis, and consult contract, 2) the Diagnosis phase aims at problem analysis, fact analysis and feedback to the client, 3) the Action Planning phase analysis develops solutions with alternatives and planning, 4) the Implementation phase adjusts proposals and education, and 5) the Termination phase is the evaluation and reporting stage of the process (14). The A3 problem solving process is a powerful lean management tool. Its main principles are defining the problem, analyzing it, and applying corrective action or an action plan written down on a single sheet of A3 size paper (15). It is not a new technique; it is based on the Toyota Production System (TPS). An A3 paper is composed of boxes arrayed in a template. The boxes are filled in order by the author; 1) finding out the conditions of the company, and the importance of specific problems, 2) describing the contemporary conditions causing the

Table I: Solution proposals' applicability, ease and cost

Step on fishbone graphic	Cause/Priority	Solution proposal	Referring box on A3 paper and strength	Facility	Efficiency	Cost
1	Archive room/1	Improve visibility	c	**x**	**x**	
2	Missing slides/1	Improve visibility	c	**x**	**x**	
3	Unidentified requests/1	Employment of pathology assistant	a	**x**	**x**	
4	Misidentified requests/3	Improve visibility, education	c a	**x**	**x**	
5	Archiving by technical staff/1	Implementation of a new archiving procedure	A c	**x**	**X**	
6	Archiving area/1	Red label and lean process	A b c	**x**	**x**	
7	Restaining requests/1	Lean process and visibility	C	**x**	**x**	
8	Block misidentification/1	Barcode reader for cassette writing device	C b	**x**	**x**	
9	Extra slide writing/2	Easier equipment failure procedure	B a c	**x**	**x**	
10	Delivery issues/1	Lean management	B c	**x**	**x**	
14	Redundant staining activities/1	Lean management	B c	**x**	**x**	
15	Oversampling/1	Periodical education on sampling and communication	C a	**x**	**x**	
16	Block misidentification/3	Pathology laboratory integration programme	C A b		**X**	**X**
17	Staining to wrong blocks/3	Pathology laboratory integration programme	C A b		**X**	**X**

Uppercase letters: Not easy to apply, Lowercase letters: Easy to apply, Aa: Quality, Bb: Cost and process time Cc: Human.

problem(s), 3) identifying the outcome, 4) analyzing the situation to establish causality, 5) propose prevention and adjusting, 6) concerting an action plan, and 7) defining the follow-up process (16,17). The A3 problem solving process is not simple but it has become popular recently with manufacturers because it does not require expensive training or software. Some conditions are essential when processing TPS, A3, or lean management. A systematic real-time root cause analysis is the core of these systems. The philosophy of the systems should be well understood. A leadership support with frontline staff engagement is essential for successful implementation. "Any improvements must be made in accordance with the scientific method, under the guidance of a teacher, at the lowest possible level in the organization." (18). The consultant does not try to help the team as an expert; instead, the consultant helps the team to help itself.

We have organized a working group from frontline staff under the leadership of a 'Workflow, IT and Process Manager'. This working group has identified the main problems. All identified problems were placed in the first quadrant of A3 paper. They tried to simplify the description of the problems. Then, all group members were requested to ask 5 "whys" for each question to investigate the problem and find the root cause. The answers were again written in the second box of the A3 paper. All problems and causes were grouped according to the analytical or spatial features and placed on the fishbone graphic. The target conditions were analyzed and written on the third box of the A3 paper. Then, the 6S exercise was performed. The 5S exercise is a management technique leading to zero defects and accidents, safety improvements, and cost reduction (9). It refers to the steps named after Japanese as 1) Sort (Japanese term: *seiri*), 2) Set in order (*seiton*), 3) Scrub (*seiso*), 4) Standardize (*seiketsu*), and 5) Sustain (*shitsuke*). Some add safety as the sixth S. The action plan designed by the 6S exercise was written on the fourth box of the A3 paper.

No errors would be collected in laboratories that do not have a mechanism to collect events. When an error is identified, this event should be directly and immediately

Table II: Six S evaluation checklist

#Yes: /25= %: Room/Section:	
Organize (remove if unnecessary)	
Unused equipment thrown away	Yes No
Unused devices, materials thrown away or diminished	Yes No
Devices/equipment with uncertain efficiency taken to the red zone (max. 7 days)	Yes No
Unused goods removed from working area	Yes No
Sort (linear workflow)	
All devices and equipment labeled and placed in order	Yes No
All devices and equipment put on labeled areas	Yes No
Broken and junk equipment labeled and taken to another area	Yes No
Standardized instruction information boards	Yes No
Scrub (clean and solve)	
Workplace, devices, equipment all clean	Yes No
Garbage collected ant recycled to containers	Yes No
Workplace is suitable (air quality, temperature, climatization, humidity, lighting, noise, pollution)	Yes No
Polluted workplace cleaning procedure	Yes No
Safety (make safer)	
Safety procedures defined and staff informed	Yes No
Fire first aid equipment easily accessible and working	Yes No
Occupational risks defined and staff informed	Yes No
Dangerous situations cleared away	Yes No
Standardize	
Steadiness and sanitary tasks defined	Yes No
Steadiness and sanitary tasks assigned	Yes No
Steadiness and sanitary formal checking procedure	Yes No
Steadiness and sanitary tasks realized easily	Yes No
Sustain	
Implementation of defined standardized procedures	Yes No
Implementation of standardized sanitary, montage, maintenance procedures	Yes No
All documents easily accessible and up-to-date	Yes No
Boards containing essential and actual information	Yes No
Clean, lean, solid workplace	Yes No

reported to the quality commission. In our laboratory, a quality program has been used for four years and all errors are identified and reported regularly. According to these data and A3 analysis, the main problem was found as mislabeling errors occurring almost in every pre- and analytical step. This error was expressed to occur from workload and unnecessary/redundant extra-works. Very simple solutions were realized. These solutions were mainly organization fixing to resolve the spaghetti effect, redundant activities and requests, improving visibility. For a more effective long-term and future solution, operational transactions such as pathology laboratory system implementation was suggested (19). However, these simple steps raised the six-sigma score by 50%.

Total quality in anatomic pathology includes 1) clinical test selection, 2) specimen collection and handling, 3) grossing and sampling, 4) laboratory processing and analysis, 5) reporting, and 6) interpretation/evaluation of the report. In the provision of these six steps, patient, clinician, specimen collector, laboratory staff and pathologist share the responsibilities (20). Quality indicators in anatomic pathology are well defined (21) and include some parameters such as turnaround time, cytopathologic-

histopathologic correlation, false positive or negative rates, and diagnostic discrepancy (22). However, focusing only on diagnosis-related rates may cause omission of some important events related to quality and directly influence the diagnosis. In this respect, real-time root cause analysis has recently been popular for laboratories (15).

There are 10 common pitfalls in A3 reports (23): 1) The A3 report background is not clear to an external audience, 2) problem definition may not be clear, 3) statement may cross the line, 4) the target condition may be disguising, 5) problem analysis is not always relevant, 6) countermeasures may not address root causes, 7) solution and follow-up methodology may be difficult and unprecise, 8) the problem solver and operator may not function properly, 9) A3 review cycle is not a part of normal work, and 10) improvements comes true by developing people. The team should be aware of these pitfalls. Most of these pitfalls may be eliminated by education and integration of the staff to the process.

In this study, process consultancy enabled significant errors to become visible and provided simple solutions to solve the problems. We achieved partial recovery and increase in the client satisfaction. The main goals were reached as mislabeling errors were reduced by 50%, and overall errors by 42%. These numbers may be accepted as satisfactory. However, we concluded that a barcoding system should be in use in order to prevent all of the mislabeling errors.

As Voltaire said: "We are all full of weakness and errors; let us mutually pardon each other our follies – it is the first law of nature." One of the foci of a quality program should be human mistakes but there should be no desire to put the blame on laboratory staff. Frontline staff should be engaged to engage in problem finding and problem solving. Such an approach was shown to be successful in the 1800's by the Ford and Toyota automotive companies (24, 25). The main rule of quality is stated as: "It didn't happen if it is not written". So, all errors and events should be monitored and recorded regularly to be analyzed systematically, anytime. "Insanity is doing the same thing, over and over again, but expecting different results" (Albert Einstein). As in our case, this thing may be very simple, causing different errors in different phases or places. Systematic and regular checking may not always let the problem be clarified. In those circumstances, external observation of the system may reveal crucial indicators about the system's failures.

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CONFLICT of INTEREST

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