Preliminary results of Lean method implementation in a pathology lab from Northeastern Brazil

Resultados preliminares da implantação da filosofia Lean em um laboratório de patologia

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ABSTRACT

Oncologic care shows a growing and unmet demand, and requires the search for alternatives that allow the efficient use of limited resources, the building of autonomy, and the endeavour for continuous improvement of processes. In the present work, we present the implementation of Lean philosophy at a pathology laboratory of an oncology hospital. Among the preliminary results, we highlight the redefinition of the dynamics of the staff, and the physical reorganization of the area. Such important changes culminated in an expressive reduction of lead time, even with a significant increase in the monthly load of exams.

Key words: health care facilities; human resources; institute of cancer; hospital's department of pathology; organization and administration.

INTRODUCTION

The growing burden of cancer on the health system in developing countries is due to population growth and aging⁽¹⁾. In Brazil, the sum of federal resources spent on outpatient and hospital cancer treatments reached US\$ 2.5 billion in the 2008-2010 triennium, an amount that assumed a growing profile of US\$ 0.74, US\$ 0.85, and US\$ 0.96 billion in 2008, 2009 and 2010, respectively⁽²⁾. In Ceará, a Northeastern Brazilian state, 20,080 new cancer cases were estimated in 2014⁽¹⁾, and a significant proportion of these cases were diagnosed and treated at Hospital Haroldo Juaçaba/Instituto do Câncer do Ceará (HHJ/ICC), a high-complexity oncology assistance center (CACON)⁽³⁾.

The histopathologic exam is, in many situations, a crucial step for diagnostic accuracy in oncology. Therefore pathology laboratories are often taken as an investment and management strategy targets, in order to achieve improvements and maximize efficiency⁽⁴⁻⁶⁾.

Quality control strategies, exemplified by the prevention of sales of defective products, were devised with the industrial development in the 1920s, especially within arms industries. Statistical tools for controlling samples and defining acceptable variation limits in general industrial quality assurance culminated in the inclusion of quality control among engineering disciplines, around 1940s⁽⁷⁾. Some Japanese industries have excelled in quality control due to the necessity of economic reconstruction in the postwar period, giving birth to quality assurance based on the prevention of waste and mistakes⁽⁷⁾.

The term "Lean" is used to describe a management system based on the Toyota Production System (TPS) that has been evolving for over 70 years. Because of that, it has also been applied to a range of industries and services, including healthcare organizations⁽⁸⁾. The same industrial quality pursuing goals are applicable to healthcare, and the fundamental principles of Lean healthcare are: focusing on the end customer (the patient needs, and the fulfillment of customers' wishes); identifying value for the patient; eliminating waste; and finally, establishing a continuous improvement culture among the collaborators^(9, 10).

For laboratory medicine, it is important to mention that management systems have been widely used, along with certification processes of each country – the ones attesting that products, processes or services are provided or performed in accordance with specified and standardized requirements –. For pathology laboratories, in particular, in the 1970s, a review

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was proposed to adapt the practices of the American College of Pathologists (ACP) to the Brazilian reality⁽⁷⁾.

Herein we describe the experience of implementing Lean philosophy at HHJ/ICC, whose pathology laboratory (PL)-ICC, the focus of this report, receives medium- and high-complexity exams in the final proportions of 35%, and 30%, respectively. This deployment project began in August 2013, with classes taught by a coach of the Lean Institute Brazil to a multidisciplinary team of HHJ/ICC. Such meetings occurred weekly, following well-defined stages: (i) presentation of the TPS methodology; (ii) creation of value stream maps (VSM), the one prevailing at the time and the future one; (iii) use of a diagram to monitor internal flow (also known as Spaghetti diagram); and (iv) development of the A3 report. Here, only some central aspects of such productions will be presented, since their full publication could compromise the trade secrets and internal management.

MATERIAL AND METHODS

Lean training

Implementation of the Lean-Project ICC occurred between August and November, 2013. A team of facilitators composed of two pathologists, a pharmacist, an administrator, two technicians, and a receptionist was selected – representing approximately 20% of the total PL-ICC employees. According to the theme presented, in some occasions ICC's chief executive officer (CEO) showed up; and in some others, the entire body of employees participated, in order to assure their full inclusion in the implementation of pull processing and continuous improvement policy. The meetings occurred weekly, and in parallel with the educational content about Lean philosophy, group dynamics activities were held for process mapping and planning, culminating in the production of the documents described below.

VSM

VSM is a diagram with boxes, and each box represents a task (or a group of tasks) within the process in a certain job. In addition to its role in work organization, some features are given to each box, in order to make them measurable and comparable in a range of aspects, such as: the scheduling (the way a task is initiated), the processing time (PT); the time necessary to carry out a certain task; the interruption time (IT); the lead time (LT), the gross execution time; the waiting time ([WT] between tasks/steps); the number of people involved in a certain task (work capacity exclusively dedicated to the performance of a particular task, also called equivalent manforce [EM]), and the percentage of correct and complete tasks (%CC), which means the percentage of tasks done correctly without need of extra-conferences nor corrections/amendments⁽¹¹⁾.

With the VSM, it was possible to carefully and quantitatively analyze each step of our pre-analytical process. Then, the collaborators were able to accurately pinpoint what was value and what was waste within the process. Also, by consensus, the collaborators developed a new delineation of their activities in the best possible sequence of standardized work and single point scheduling, so focusing on value for the client, waste minimization, unevenness elimination, besides pull processing⁽¹⁰⁾.

As a pilot project presented here, the pre-analytical process (starting point: entrance of biological material for the record; end point: delivery of stained slides to pathologists) was mapped. The current flow at the beginning time of the project implementation was called VSM-2013, and the future VSM was called VSM-2014. We standardized pre-analytical process as all tasks/events prior to microscopic examination by pathologists.

Spaghetti diagram

The walking pattern of the employees, commonly known as Spaghetti diagram, is used to track product, paper, and people flow in a workplace. It is a representative scheme of internal movement between tasks/steps in a service. Again, the pre-analytical process was the main object of analysis, using the input of the request for specimen examination as the starting point, and the delivery of stained slides for pathologists as the end point.

A3 report

The A3 report is a one-page guide that contextualizes the key problems, indicates countermeasures and conducts employees through a systematic order for problem solving, including the establishment of deadlines and indicators for performance monitoring, besides establishing those responsible for countermeasure implementation and ascertainment^(5, 12).

A classification of some countermeasures proposed in our first A3 Lean report will be presented, according to the degree of complexity for implementation, namely:

1) low complexity – direct, isolated countermeasures, which take up to a week for implementation, and require no investment;

2) moderate complexity – measures that connect more than one group of tasks, taking up to a month to be deployed, require

low investment (time or material change in the organization of an area, for example);

3) high complexity – measures that affect more than one department or division, take over a month to be deployed, require moderate to high investment – classification based on Raab *et al.*⁽⁶⁾.

RESULTS AND DISCUSSION

VSM is the Lean tool most often applied to healthcare⁽¹³⁾, and it represents a rich source for identifying possible improvements to processes, with the advantage that such improvements are often independent of major investments⁽¹⁰⁾.

In **Figure 1**, the flowcharts at the time of project implementation, called VSM-2013, and the current one, called VSM-2014, are schematically presented. VSM-2014, which at the moment is in effect, when fully implemented will make waste minimization and unevenness elimination possible, solving the central problems shown in VSM-2013. When PL-ICC was working according to VSM-2013, the manufacturing time reached five days, with numerous points of interrupted flow which caused high WT, low grade of %CC between some steps (generating rework); and total LT ranged from eight to 10 days.



FIGURE 1 – Graphic representation of VSM for the pre-analytical process at the pathology laboratory of Haroldo Juaçaba Hospital (PL-ICC)

A) VSM-2013: an interrupted workflow, and lack of standardization between the compartmentalized tasks were pointed; B) VSM-2014: as the main gains from Lean philosophy implementation we can cite the incorporation of some tools as supermarket (³); FIFO (Δ); continuous workflow (O); and expertise sharing ($\stackrel{\sim}{\downarrow}$) at the bistotechnology area, representing an unification of the following tasks: "embedding", "cutting", "staining", and "assembly and checking" of stained slides.

V8M: value stream mapping; PL-ICC: Pathology Laboratory of Instituto do Câncer do Ceará; FIFO: first in, first out. With the successful implementation of VSM-2014 – achieved by using management tools as "first in, first out" [(FIFO) which means that the first request for examination to enter will be the first to be processed], supermarket (certain tasks were standardized, as batching tasks), and continuous flow – PL-ICC reached a manufacturing time of three days, which resulted in a total LT of five days.

Remarkable increase of %CC between steps was also achieved, what reduced the need for rework, reflecting in a lower WT. This parameter is very important, especially in the pre-analytical phase of laboratory medicine services, since the majority of laboratory mistakes have been reported to occur in this phase, mainly by labeling-related incidents, followed by lost or mixed-up specimen. Most of these incidents are followed by corrective actions on an individual basis, but all of them may pose potential harm to the service or patients⁽¹⁴⁾. Unfortunately, we are still working on a survey to evaluate critical points in the process of pre-analytical histology, as described by Morelli *et al.*⁽¹⁵⁾. Thus, so far, it is still premature to locally access Lean implementation impacts on identification and prevention of errors.

Nevertheless, it is possible to infer, by the available international literature, that the majority of near-miss events in surgical pathology are process-dependent (90%), instead of operator-dependent (10%); and that these operator near-miss events are very likely associated with organizational faults, as lack of standardized protocols, inappropriate knowledge transfer, or overburden of employees⁽¹⁶⁾.

So far, the reported improvement of the %CC parameter reflects the reduction of waste, defined as anything that consumes resources but does not contribute to creating value for the costumer. Thus, a reduction of actions taken for re-checking or re-doing tasks for preventing near-miss events is in accordance with two major Lean-thinking statements: (i) that eliminating errors or defects can be achieved by fixing the process, and (ii) that Lean must help people to work smarter, instead of driving them to work harder⁽⁸⁾.

Besides, it was quite remarkable that PL-ICC has easily supported a growing demand of exams in 2014, shown by the highest monthly balance, and by the fastest takt time (defined here as the time elapsed between the units of production, the formalin-fixed paraffin-embedded tissue [FFPET], and the output) (**Table 1**).

The introduction of continuous workflow in the PL-ICC technical area of histotechnology was one of the most striking gains. In the VSM-2013 scheme, each employee worked in a

Parameter	VSM		Performance
	VSM-2013	VSM-2014	increase (%)
LT (days, average)	9	5	80%
%CC	36%	80%	122.2%
Shared expertise (with technical employees, %)	3/9; 33.3%	7/11; 63.6%	90.9%
Monthly balance (number of procedures, average)	4,633	6,703	44.7%
Takt time (space of time – in minutes – for each new produced FFPET)	Each 2 min	Each 1.4 min	42%

TABLE 1 – Quantifiable gains with VSM-2014 implementation compared to the previous VSM-2013

VSM: value stream mapping; LT: lead time; %CC: percentage of correct and complete tasks; takt time: sbythm of the work; FFPET: formalin-fixed paraffin-embedded tissue.

> compartmentalized form, disconnected from peers. Tasks were performed repeatedly and monotonously by the same operator. With continuous workflow, the entire group of technicians started to share their own expertise and learn from others', creating a confluence of tasks, which are now carried out collaboratively in teams that alternate throughout the month. This rotation activity ensures that the technicians are now equally skilled in all tasks, reaching a climate of cooperation, and autonomy – thus minimizing the tedious component of certain laborious, time-consuming, and repetitive tasks⁽¹⁷⁾.

> Unevenness of workflow is often a consequence of a poorly designed process, in which capacity and demand are not equalized⁽⁸⁾. Thus, with the new workflow, new dynamics of interpersonal relationships emerged in PL-ICC, where the service has gone from "push processing" to "pull processing" with standardized and shared skills among technicians, and also with established checkpoints to avoid errors, since the responsibility for the entire process is now held by the team as a whole, instead of having only one employee answering for a task at an endpoint of the process.

Spaghetti diagram

PL-ICC usually receives samples to analyze from inside HHJ/ ICC (outpatient departments, and operating room), as well as from outside the hospital. We notice that, before the implementation of Lean philosophy, there were three different local inputs for specimens and exam requests registration, depending on the demanding place.

The analysis of the Spaghetti diagram (SD-2013) prevailing at the time of the initial deployment of Lean philosophy has shown a high degree of internal movement of employees, and even simultaneous occurrence of disparate tasks in shared areas at the same time (e.g., specimen receiving areas from outpatient services, and assembly of newly stained slides).

The construction of this diagram was therefore decisive for the adoption of a high-complexity countermeasure: the architectural restructuring of the PL-ICC, leading to the new SD-2014 (**Figure 2**), which prioritizes the streaming of all pre-microscopy stages, and avoids the intersection of disparate tasks.



FIGURE 2 - Walking pattern of the employees at PL-ICC (Spaghetti diagram)

A) Spaghetti diagram of PL-ICC in 2013; B) actual Spaghetti diagram of PL-ICC, after laboratory renovation. In the upright direction of each schematic representation of the walking patterns, the representation of activities follows as if in the architectural plan of the laboratory. Scheme for the identification of the mapped tasks: 1) reception of the biological material; 2) reception of exam requests; 3) fixation; 4) macroscopy; 5) tissue processing; 6) embedding; 7) cutting; 8) staining; 9) assembly; 10) checking quality and definition of batches for each pathologist; 11) microscopy; \circ : biological material; \Box : printed exam request. The arrow represents the workflow from each specimen entrance place: \rightarrow : common flow; \rightarrow : operating room; ---: outpatient departments; ---: outside the bospital; Δ : critical problems (Figure 2A, 2013 Spaghetti diagram); or \rightarrow : actual unidirectional workflow after Lean philosophy implementation (Figure 2B, 2014 Spaghetti diagram)

A3 report

The A3 report pointed some countermeasures (**Table 2**) to solve the initial problems of PL-ICC pre-analytical phase management. Low-complexity countermeasures took effect increasing interaction among employees. Moderate-complexity countermeasures gave tools and support to teams that autonomously generated some important control charts for daily checking and weekly performance review. The highly complex countermeasure taken was PL-ICC architectural renovation, which not only led to the creation of a continuous workflow at PL-ICC, but also endorsed the institutional support for Lean philosophy implementation.

 TABLE 2 – Adopted countermeasures, pointed in the first A3 report for the PL-ICC Lean philosophy implementation project

Countermeasures	Complexity
Forming teams (and choosing their leaders for a two-month commitment) in different sectors of PL-ICC: receptionist, macroscopy and histotechnology	Low
Creating a <i>framework for ideas</i> to expose employees' suggestions – with visibility to all teams, and rapid feedback from immediate supervisors, who can accept the suggestion or not, stating the reasons	Low
Drawing visual charts that delimit those responsible for each task in each particular week or weekday	Low
Using visual control tools for controlling supplies and reagents from the exams registration, and macroscopy areas (<i>Kanban</i> Inventory System)	Moderate
Each team leader's going through <i>checklists</i> with questions about the availability of supplies and reagents, number of received samples, number of generated FFPET blocks, staff/employee possible day off, equipment maintenance, etc.	Moderate
PL-ICC's architectural renovation	High

PL-ICC: Pathology Laboratory of Instituto do Câncer do Ceará; FFPET: formalin-fixed paraffin-embedded tissue.

Final considerations

The essential dynamics of Lean philosophy principles include: continuous improvement attitude, value creation, common purposes for the team(s), respect for front-line workers, visual control, and autonomy and flexibility in working dynamics⁽¹⁸⁾.

The manufacture-simile way of working at most pathology laboratories – that permeates the whole process of getting stained slides from FFPET sections – makes it somewhat more natural to use methodologies from industry to improve processes. In this work, we demonstrate that the implementation of Lean philosophy, focusing mainly on the management of PL-ICC's preanalytical level, resulted in immediate gains such as reducing both processing time and full lead time.

In a place where, before Lean implementation, people did not recognize themselves as teams, a visible and sustained change in the employees' work dynamics occurred (by creation of continuous workflow and expertise sharing), which resulted in a markedly collaborative work environment. This new paradigm of employees' autonomy has helped to generate checkpoints to continuously assist the – from now on, recognized – team to pursue set goals, by the establishment of visual charts that delimit those responsible for each task in each particular week or weekday, visual control tools for supplies and reagents (Kanban Inventory System), and daily checklists – interventions of low to moderate complexity, with no costs. Also, all those changes helped LP-ICC to support well the exam demand growth in 2014 (around 40% higher in comparison to the same period of 2013).

As well observed in a previous work, the efforts for Lean philosophy implementation depended on both the support and the sponsorship of companies' CEOs – mainly concerning the adoption of high-complexity countermeasures (e.g., the renovation) – as the direct involvement of multi-hierarchical and multi-disciplinary teams, what enriches the possibilities of assistance from facilitators^(19, 20).

As Lean philosophy is not an end in itself, nor even its improvements happens overnight, our group still has challenges to overcome through successive cycles of plan-do-check-act (PDCA): the consolidation of visual management; and the expansion of the Lean Project to other areas of PL-ICC as cytology, immunohistochemistry, and molecular biology. Systematical analysis of each end-to-end process, besides the search for the root causes of problems – through the "Five whys" and A3 Form – will sustain the expected continuous improvements^(8, 12). The present work confirms that the implementation of Lean in pathology laboratories can be successfully achieved.

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RESUMO

A assistência em oncologia possui uma demanda crescente e reprimida e requer a busca por alternativas que viabilizem o uso eficiente de recursos limitados, a construção de uma cultura laboral de autonomia dos colaboradores e a melhoria contínua dos processos. No presente trabalho, apresentamos a experiência de implantação da filosofia Lean em um laboratório de patologia especializado em oncologia. Entre os resultados preliminares, destacamos a redefinição da dinâmica de trabalho do corpo técnico e a reorganização física do laboratório. Tais alterações culminaram em uma expressiva redução do tempo total de execução, mesmo com o aumento significativo da carga mensal de exames.

Unitermos: instituições de saúde; recursos humanos e serviços; instituto de câncer; serviço hospitalar de patologia; organização e administração.

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