

AUTOMATION, LEAN, SIX SIGMA: SYNERGIES FOR IMPROVING LABORATORY EFFICIENCY

AUTOMATIZACIJA, LEAN, SIX SIGMA: SINERGIJA U POBOLJŠANJU LABORATORIJSKE EFIKASNOSTI

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Summary: The Pathology Services worldwide, surrounded by products are today requesting solutions. The approach aims towards the brain-to-brain cycle between caregivers and laboratory professionals. Despite budgets limited to 2–3% of total healthcare expenses, Laboratories are providing information for >70% of medical actions. »Perianalytics« is becoming the focus; understanding information and sample flow in the whole journey and processes. Process analysis is the main component to understand and shape the best combination of components in designing a truly cost-effective Laboratory solution. Methodologies like Lean (or Toyota Production System) and Six Sigma have started recently to be adopted also in healthcare and in the Laboratory environment. Those techniques showed already successful implementations in healthcare, after their development in other sectors. Their tools are addressing the definition of »value«, »waste«, »flow« as key drivers to improve performances. The synergy among the methods allows decision makers to identify the degree of automation really necessary in their laboratory, with streamlined processes. The different platforms made available by industries, for *in vitro* diagnostic testing, could become not cost-effective or efficient without a careful assessment of needs, pathways and value-related variables. Total laboratory automation or stand-alone islands for systems can be identified and chosen after process mapping and recommendations deployed with Lean and Six Sigma techniques. This article highlights some key concepts of Lean and their fit in laboratory organization, as methodologies to be implemented before selecting and adopting automated systems.

Keywords: Lean, Six Sigma, laboratory automation, laboratory organization

Kratak sadržaj: Patološke službe širom sveta, okružene proizvodima, tragaju za rešenjima. Pristup cilja na ciklus bliske saradnje između medicinskih radnika i laboratorijskih stručnjaka. Uprkos budžetima ograničenim na 2–3% ukupnih troškova zdravstva, laboratorije pružaju informacije za >70% medicinskih postupaka. »Perianalitika« postaje fokus, razumevanje protoka informacija i uzoraka kroz čitavo putovanje i procese. Analiza procesa je glavna stavka za razumevanje i oblikovanje najbolje kombinacije komponenta u dizajniranju finansijski zaista povoljnog rešenja za laboratoriju. Metodologije poput Lean (ili Toyota Production System) i Six Sigma nedavno su počele da se usvajaju u zdravstvu kao i u laboratorijskom okruženju. Posle razvoja u drugim sektorima, te tehnike su u zdravstvu pokazale uspešnu primenu. Njihove alatke obraćaju se definicijama »vrednosti«, »otpada«, »protoka« kao ključnim pokretačima za poboljšanje performansi. Sinergija između metoda dozvoljava donosiocima odluka da prepoznaju koji je stepen automatizacije stvarno potreban u njihovoj laboratoriji, uz modernizovane procese. Različite platforme napravljene u industriji, za *in vitro* dijagnostičko testiranje, mogle bi postati finansijski nepristupačne i neefikasne bez pažljive procene potreba, putanja i varijabli vezanih za vrednost. Ukupna laboratorijska automatizacija ili samostalna »ostrva« za sisteme mogu se identifikovati i izabrati posle mapiranja procesa i preporuka primenjenih u tehnikama Lean i Six Sigma. Ovaj članak ističe neke ključne koncepte Leana i njegovog mesta u laboratorijskoj organizaciji, kao metodologije koju treba implementirati pre odabira i usvajanja automatizovanog sistema.

Ključne reči: Lean, Six Sigma, laboratorijska automatizacija, laboratorijska organizacija

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Introduction

Lean is an extremely powerful tool in identifying and eliminating waste. The roots of Lean methods have been applied to various industries for more than 100 years. In the late 1990s, Lean was introduced into healthcare. Since then, many hospitals have adopted Lean as the key method for implementing significant process improvements to drive quality, cost, safety, and delivery of care (1).

Since the late 1990s, Lean has been applied to the healthcare setting and has continued to grow across the industry. Lean is a methodology of eliminating waste by targeting the processes surrounding patient care, allowing clinicians to re-evaluate their process in the patient's eyes. Lean can be defined as:

A systematic approach to shorten the time between customer (patient, physician, nurse, other) request and service delivery by identifying and eliminating sources of waste (non-value-added activities) (2).

Simply put, Lean is focused on the elimination of waste, or non-value-added activities, from the process. Non-value-added activities (NVA) can be defined as those activities the customer is not willing to pay for (i.e., it does not affect service or outcome) (3). These activities typically account for 75–95 % of the total time needed to provide a service – the lead time. *Figure 1* represents the ratio between value-added and non-value-added activities in common laboratory.

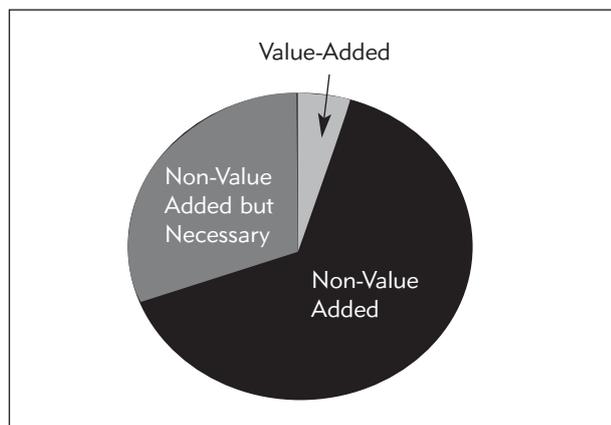


Figure 1 The ratio between value-added and non-value-added activities in common laboratory.

Regulations or quality requirements can cause processes to be redundant and non-value-added; however, they must be performed to cope with GLP. These activities fall into a third category – non-value-added, but necessary. These activities should not be excluded when driving improvement, but further ways to improve should be explored while adhering to regulations.

There are eight types of non-value-added activities or waste:

Defects: Work that contains errors, rework, mistakes, or lacks something necessary,

Overproduction: Making more, earlier, and/or faster than is required by the next process,

Waiting: Idle time created when material, information, people, or equipment are not ready,

Not utilizing employees knowledge, skills, and abilities: The waste of not leveraging people's full talents and capabilities,

Transportation: Movement of patients and materials that adds no value,

Inventory: Any supply in excess of what is required,

Motion: Movement of people that does not add value to the product or service,

Extra Processing: Additional effort that adds no value to the product or service from the customer's viewpoint.

Lean is an extremely powerful tool in identifying and eliminating these eight wastes. However, wastes are very often hidden in the processes and not seen during daily activities. It is critical to understand which Lean tools to implement and when. It is often difficult to implement and sustain improvement if there is no evidence and positive experiences; the approach is to apply Lean throughout the organization, with facilitators or consultants coaching people on practical changes with improvements. Utilization of Lean / Six Sigma techniques is fundamental to designing and running processes with efficient operations. Lean should not be perceived to work faster, but to provide a smoother process, without wastes (4, 5).

Beginning a Lean Lab Effort

Starting the Lean journey in any department can be difficult. It is critical to have alignment and clearly state the need for improvement from the beginning. There are five key steps that should be taken when starting the journey towards a Lean improvement:

1. Define goals and framework for improvement
2. Map the process and see the waste (NVA)
3. Develop the lab's specific plan for improvement
4. Implement changes
5. Measure, monitor and sustain

These steps can be applied whether the journey begins in the ED, OR, or laboratory. As Laboratory is a clearly defined process (tubes/requests are input, diagnostically valuable information are output), Lean can well support enhancements (6).

Develop goal and framework for improvement

The common perception is to adopt bigger or faster instruments to improve Laboratory Operations (7). When defining the need for change, look at it in terms of how the customer is being impacted. The customer might be the patient, family, clinician, or the hospital. Some case study examples of a burning platform for change might be:

- a) 30% of test results are not verified for physician rounds,
- b) Emergency department has increased from 1% to 4.5% in the ED over the past six months,
- c) Laboratories are merging and the consolidation trend will continue in the future,
- d) The TAT (turnaround time) needs to become more standard and predictable to improve efficiency and quality for day-hospital services,
- e) New biological markers become available for patients and Clinicians.

These statements are just a few examples of the issues that hospitals face today. It is essential to clearly define the need and then discover the detail behind the problem statement. Supporting data will be needed to support any improvement within a given department. It is critical that baseline measures are established for monitoring.

The clinical laboratory has seen an increase in volume over the past six months of 10%. As volume

increased, the average turnaround time has increased to an average of 60 minutes across the top eight tests. In addition, the percent of tests verified for morning rounds is 65%.

See the Waste

Now that the need for improvement has been defined, the next step is to understand where to target the improvements. Many improvements fail because »cherry picking« occurs, which is when the team determines what problems are causing the issue without investigating it first. This can be the downfall of any Lean improvement. A tool that can be used to avoid »cherry picking« is value stream mapping. Value stream mapping is a process by which all activities are mapped, both value-added and non-value-added, that are required to perform a service (Figure 2).

The first step in value stream mapping is to determine the product family that will be mapped. This could be viewed as a department, such as the laboratory, or it could be viewed as a certain patient-type visit to the ED. The next step is to map the current state (»as-is«) and the future (ideal) state map. This facilitates the innovative thinking that is needed to reevaluate old habits and develop an improved process that streamlines patient care (8).

Value stream maps are a very powerful tool for guiding improvements. Key benefits of value stream mapping include:

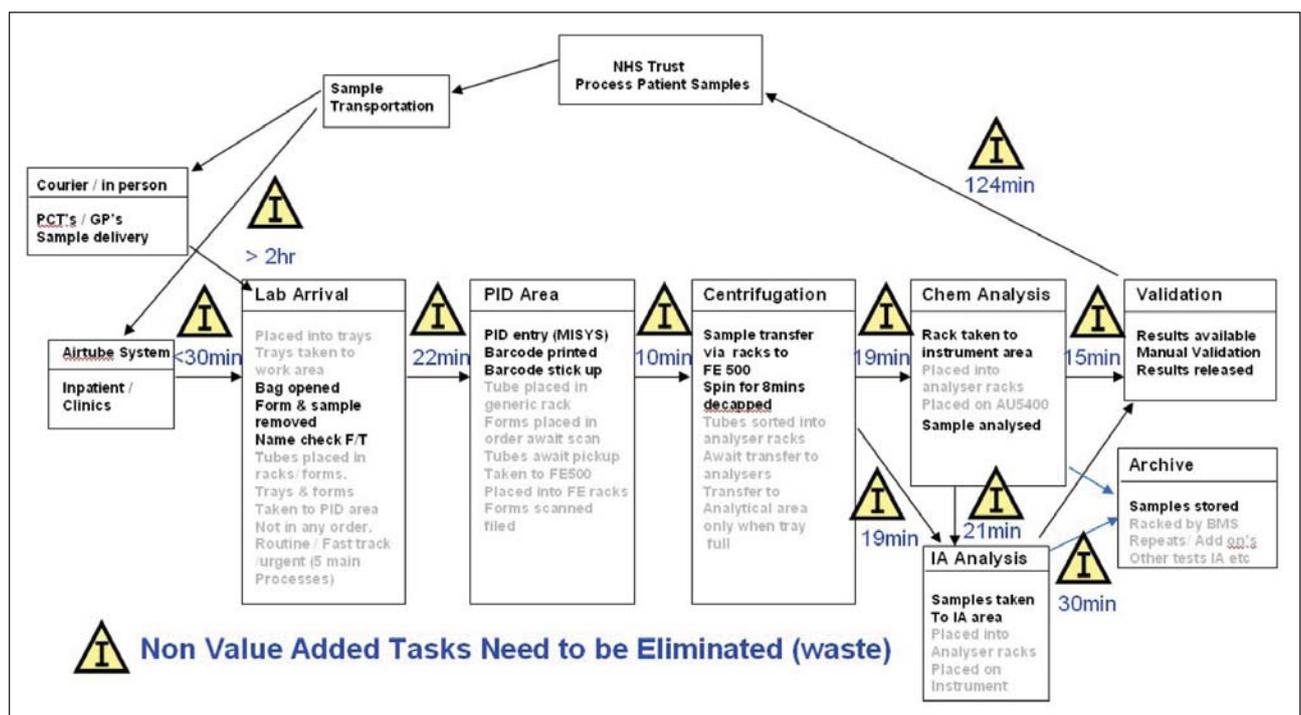


Figure 2 Value stream mapping maps not only the process activities, but also information flow and all relevant data, such as first-time quality, cycle time, batch size, and so on. It enables a view of the big picture (versus a smaller portion of the process).

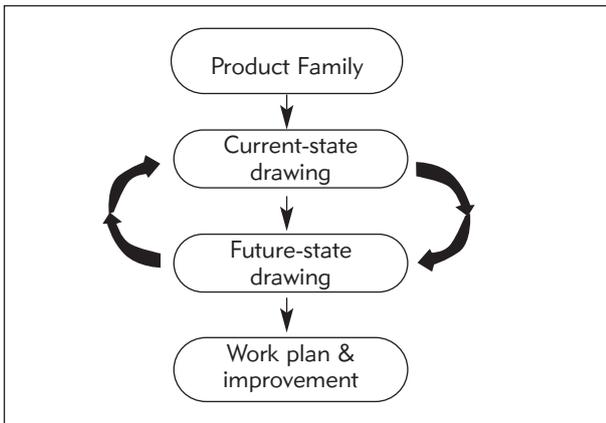


Figure 3 Value stream maps.

- a) Provides a common language for talking about healthcare processes
- b) Shows the linkage between the information flow and the patient flow
- c) Ties together Lean concepts and techniques
- d) Helps make decisions about the flow apparent for further discussion.

Value stream maps are a working document that will guide not only the first improvement, but ongoing continuous improvement efforts (Figure 3).

Develop the Specific Plan for Improvement

Next, the team will define the key opportunities for improvement, which will outline the work plan needed to achieve the desired goals. The improvement opportunities will need to be prioritized by evaluating several aspects of each opportunity. These criteria could include impact, ease, or cost – or anything that will allow the team to objectively determine the best opportunities to implement (9).

With key improvements identified, the team will need to outline the timing for implementation. A typical approach may include the value stream map (already completed), training, and multiple rapid improvement events followed with sustainment. Rapid improvement events are events that produce drastic improvement results over a one to five-day period.

Case Study Example. There are many approaches to driving Lean within an organization. A common approach might include: Lean training, Value Stream Mapping (VSM), Implementation (including rapid improvement events, named »kaizen«), Sustain.

In this case, the team determined that 5S was the first improvement opportunity to implement. As discussed in the next section, 5S is widely considered as the foundation for all other Lean improvements.

Implement the Changes

Within the »House of Lean« there are multiple tools that could be implemented. Figure 4 represents some core tools that could be implemented. It can be difficult at times to know where to start; however, the value stream map can shed light on which tools to implement.

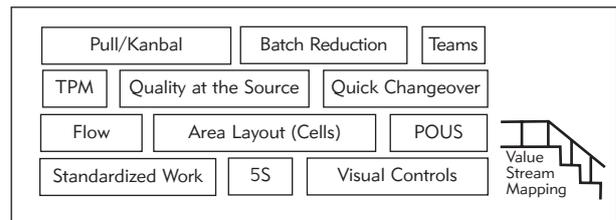


Figure 4 Key Lean tools.

To help understand which tools to implement, the chart below provides some guidance on when to use various Lean tools. It outlines some of the typical opportunities that exist in clinical labs today and the corresponding Lean tool(s) that could help drive improvement.

To further breakdown several key Lean tools, the following tools will be discussed in more detail

- Workplace Organization (5S)
- Batch Size Reduction
- Standard Work (Table I).

Table I Association of Lean tool vs. opportunity for improvements.

Opportunity	Lean Tool
Large amount of process specimen	Batch Size Reduction, Teams
Redundant Work	Root cause analysis
Multiple Handling	Standard work methods
Inconsistency in tech or phlebotomist process	Standard work methods
Re-labeling or insufficient sample volume	Quality at the Source
Not understanding current conditions or status	Visual Controls
Excessive travel / walking	Flow, Point of Use Storage Area Layout
Excessive clutter and visual noise	5S Implementation

Workplace Organization (5S)

Workplace Organization (5S) is a method for organizing and standardizing the location of materials, information, and equipment to optimize flow and to help understand when something is out of place or missing. It helps to identify and remove what is not needed from the workplace to achieve a given task. This allows the management and staff to quickly determine when something is out of place or if a problem exists. Workplace Organization can be broken into five steps (thus, 5S):

1. Sort – Sort through all items in a given area, placing a red tag/sticker on all unneeded items and moving them to a temporary holding area.
2. Set in Order – Identify the best location for remaining items, relocate out of place items, set inventory limits and install temporary location indicators.
3. Shine – Clean everything, inside and out. Continue to inspect items by cleaning them and to prevent dirt, grime and contamination from occurring.
4. Standardize – Create the rules for maintaining and controlling the first three S's and use visual controls.
5. Sustain – Ensure adherence to the 5S standards through communication, training and self-discipline.

Workplace Organization is often a great starting point for many laboratories. Over the years, the instinct to hold on to things »just in case« has allowed departments to build up endless clutter. 5S allows the team to reevaluate every item and determine what is truly needed to perform a given task at a work bench or area. 5S can be seen as the foundation for all other Lean activities. Without the 5S, it could be difficult to achieve maximum results.

Case Study Example. Oftentimes, many people believed that areas of the laboratory were not disorganized; however, if items were taken from the work area, not everyone would realize it. It might be

apparent to the tech working the bench, but it may not be discovered until they are in the middle of a test.

Implementing the 5S principles helped ensure that all needed items were where they should be kept. Below is an example of a before and after shot of a bench for sample arrival (*Figures 5a,b*).

As 5S is implemented, it is important to remember to stay flexible. Although 5S determines where items should remain, it does not mean the items cannot be moved during daily operation. There must be flexibility for the tech to become comfortable as he or she works. At the end of the shift, items should be returned to the proper location to maintain standardization and sustainment (especially among the different shifts).

Batch Size Reduction

Evaluating and minimizing the batch size of various processes can yield substantial results. Large batch sizes lead to the potential for greater quality errors and increased lead time. Reducing batch sizes throughout the process can provide better agility to respond to customer demand. In addition, large batch sizes can result in downstream constraints in the process. Reducing batch sizes allows the product or service to move on to the next process in less time, ultimately being completed faster. For example, for a batch size of ten going through three process steps (each taking one minute), it would take 30 minutes to complete the batch and 21 minutes for the first item to be processed (*Figure 6a*).

However, if the batch size was reduced by 50%, it would take 15 minutes to process the batch and 11 minutes for the first item (*Figure 6b*). Although it still would take 30 minutes to process all ten items, the first five would have already moved on to the next process or to the customer. This results in a 48% improvement in turnaround time.



Figure 5 a) *Before Lean* – The tables are holding places for everything.
b) *After Lean* – All items have clean location and porters have clear understanding for delivery and needed labels.

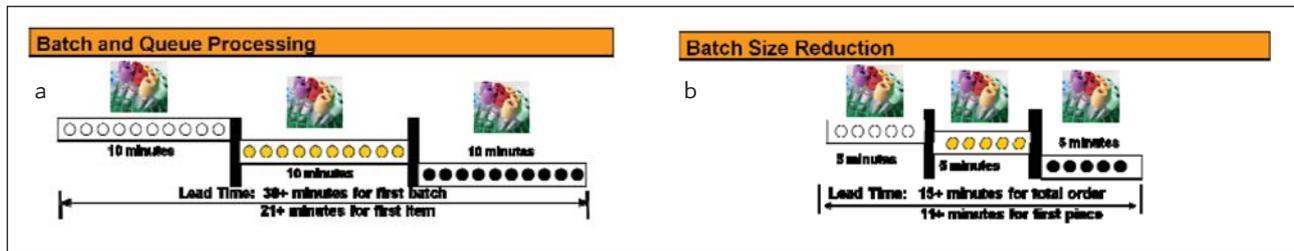


Figure 6 a) Batch size of 10 pieces requires 21 minutes for first finished product. b) Batch size of 5 pieces requires 11 minutes for first finished product.

By moving to single-piece flow or a reduced batch size throughout the process, constraints can be minimized by level-loading process steps with optimal batch sizes, work-in-process can be drastically reduced or eliminated, and turnaround time can be greatly improved.

Case Study Example. Clinical lab accessioning can be the most critical step in getting results to physicians, and ultimately, the patient. Accessioning truly sets the pace at which the lab processes specimens. In many labs, large batch sizes are used to draw specimens as well as receive specimens. As an example, one laboratory receives specimens with an average batch size of 30. These specimens must be time stamped, received into the LIS, centrifuged if needed, re-labelled, and staged for the analyzer. The average lead time to perform this work takes 20 minutes and is handled by three different staff (*Figure 6*).

Evaluating the constraints and process workflow, it was determined that reducing the batch size to eight specimens and having each staff member process their own batch could yield tremendous improvement in both time and capacity. This improvement resulted in an improvement of capacity per hour from 90 to 144 specimens. As a next step, new centrifuges were purchased reducing the centrifugation from ten minutes to five minutes. This increased the total capacity per hour to 288 specimens.

In summary, by implementing batch size reduction, improved process workflow, and an improved centrifugation time, the capacity per hour was improved from 90 to 288 specimens – a 220% improvement.

Standard Work

Implementing standardization of the new method is the basis for sustaining all continuous improvement activities. Many times procedures exist for nearly all work performed, but are written for regulatory bodies or lawyers instead of the employees. Standard Work differs in that the procedures or work instructions are written to further define and document the best practices determined by the staff. Standard Work needs to include multiple methods of education to ensure awareness and understanding by

the staff. Different methods to consider might be incorporating pictures of certain activities performed along with text or including process flow diagrams that provide a summary of the key steps. Employees need quick methods to help them determine that they are performing their work in the most efficient manner possible. To strengthen this standardization of new processes, consider posting the process flow diagrams in various parts of the department. Having standard work in place and incorporating various methods of education will further maintain your ability to sustain the results.

Case Study Example. Many laboratories struggle to maintain quality labelling practices. Laboratory specimen labelling became a big issue when labels needed to be positioned in a certain fashion in order for the automated equipment and analyzers to read the barcode properly (*Figure 7*).

Utilization of visual aids and standard work improves quality for operations. When specimen labels were not positioned correctly, it led to rework and costly errors. By using Standard Work principles and incorporating pictures, the error of interpretation by staff when training new hires or additional staff was drastically reduced (10).

Measure, Monitor, and Sustain: The Keys to Success

The journey through implementation can be very difficult at times, so it is critical to set goals and strive to achieve them.

However, some people like change and others do not. Across nearly every industry, the breakdown of individuals' acceptance of change can be broken down to: 20% like change, 60% are not sure of change, 20% do not like change.

A key aspect of driving the improvement is to include staff from the 20% that does not like change. The purpose behind this is that those who are on the fence may look up to staff that do not like change. Converting those who do not like change into believers will quickly win the support of the staff. This shift in culture will allow an organization to navigate obstacles and will help achieve any goals set forth.

To keep all staff involved and communicate the success to other departments, the use of a metrics tracking centre will be greatly beneficial. The tracking center might contain elements such as: current state value stream map, future state value stream map, implementation plan, key performance measures, communication.

This will allow employees involved in the process to have all the information in one place and track the success of the project. In addition, this will allow the department and team members to continue tracking the success until goals are achieved.

Typical results that can be achieved during Lean engagements within the lab can include: 25–50% improvement in turnaround time, 20–50% improvement in tests verified for morning rounds, 10–35% improvement in productivity, 5–15% improvement in staff and patient satisfaction.

Driving Lean improvements within any department can seem challenging, but with the right tools, approach, and support, it can result in drastic improvements to patient care.

Lean, Six Sigma principles and automation

Lean and Six Sigma principles mainly refer to process improvements, although their practical implementation has different impacts according to different organizational models (11).

In order to simplify existing Laboratory organization models, we can assume 3 main groups exist: stand-alone instruments, integrated instruments (with ability to perform multiple assays, using different technologies), laboratory Automation Systems (LAS), with track connectivity among instruments.

All three types of organization are widely spread in Laboratories, each with different strengths and weaknesses.

Their impacts on daily operations many times are not clearly understood, while they are selected as the preferred solution. There are different outcomes deriving from each solution, when also Lean criteria impacting process and organization are considered:

- laboratory layout,
- work-cell design,
- type of wastes.

Laboratory layout

To fit in a laboratory a solution that is bigger than expected has been sometime a very challenging and costly operation. It is evident that small systems (both stand-alone or integrated) have better flexibility

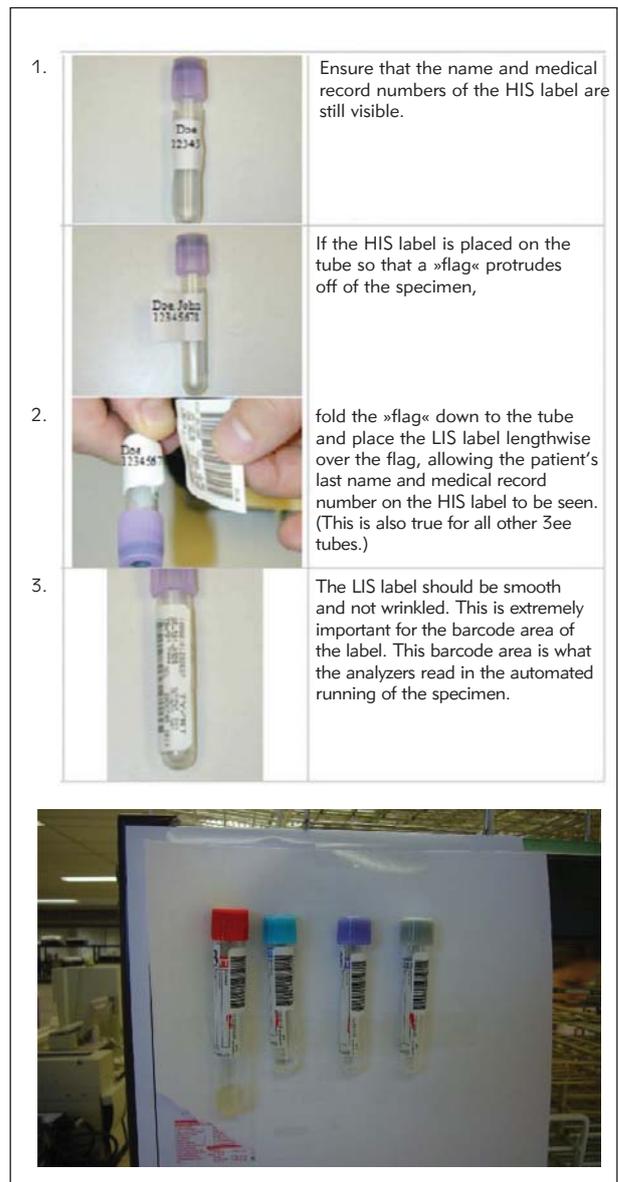


Figure 7 Example of Visual instruction for tube labelling.

to fit in laboratory space; not only for their footprint, but mainly for their impact on operations (walking, operator interactions with instruments, etc.).

Studying and analyzing the best workflow and best location of instruments is a recommended practice during selection of the solution. Several times only the instrument or track footprints are considered, underestimating the necessary space for operators and auxiliary components (fridges for reagents, water purification systems, UPS, working places, clearance for maintenance, etc.). Also utilizing simple tools, it is possible to simulate layout design with different solution and use Lean tools (as Spaghetti Chart) to understand differences (Figure 8 and 9).

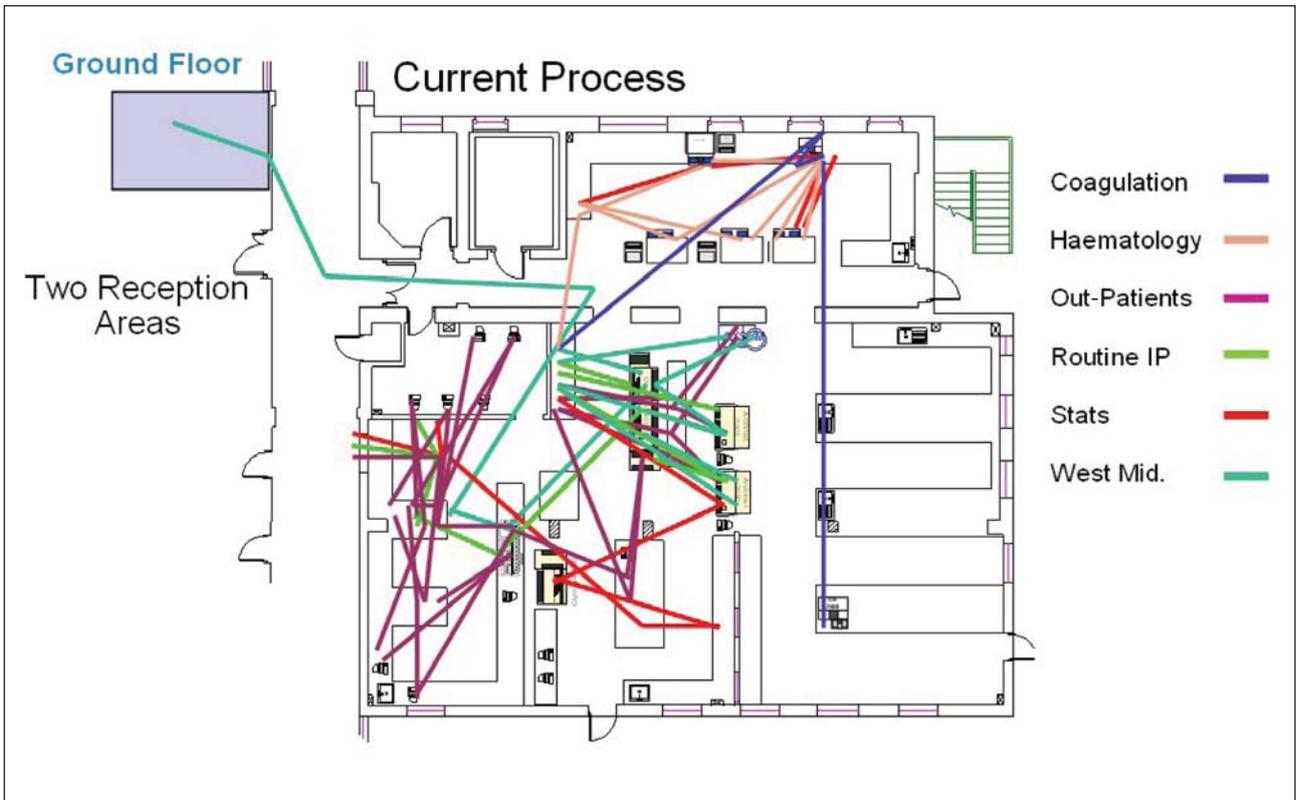


Figure 8 Spaghetti diagram at reception before Lean.

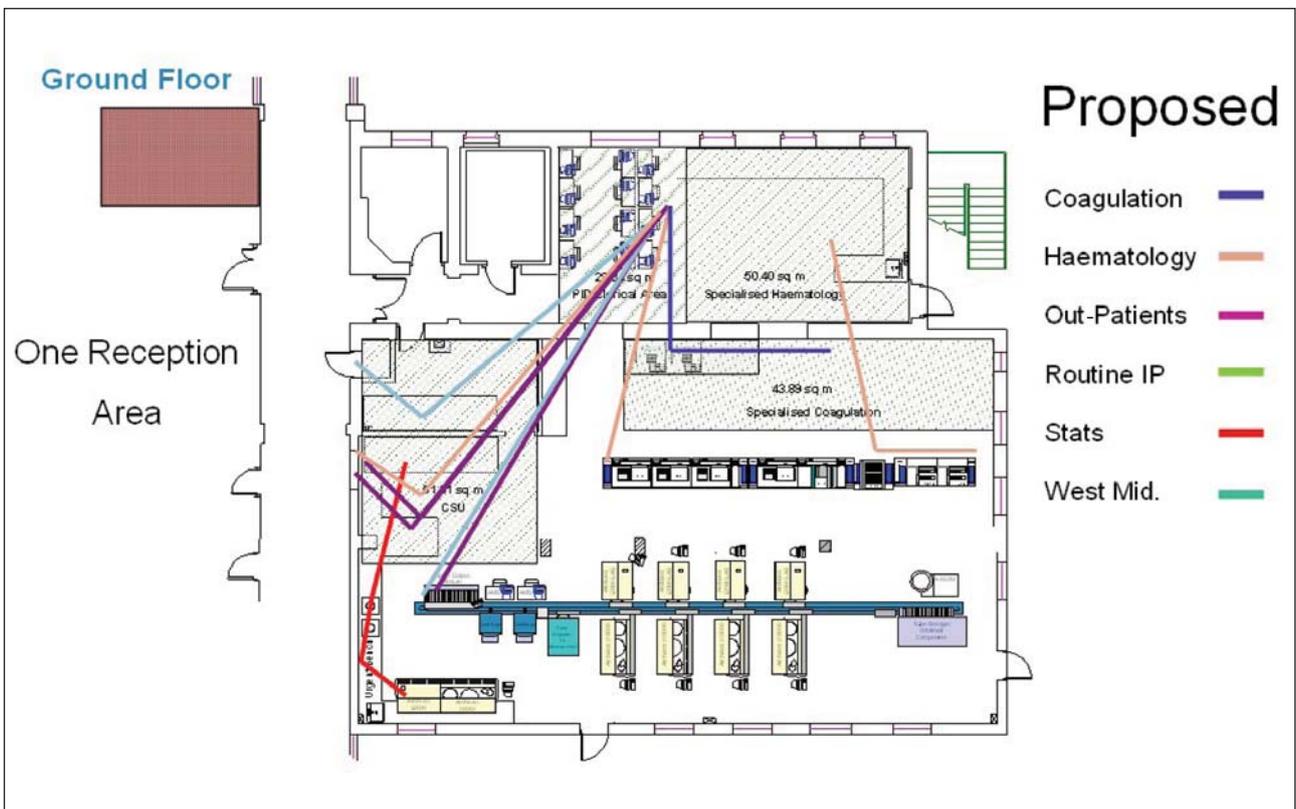


Figure 9 Spaghetti diagram at reception after Lean.

Figures from Mayo Clinic white paper. Although it is easier to drop stencils or images for instruments with small footprint, the same approach applies also when the solution foreseen is an LAS. In this case it becomes very important to understand the location of input/output of samples and interaction points for users and operators. The feature of automatic sample transportation should not be misleading (via conveyor belt or other track devices), as robotic sample movement should not become a benefit at the expense of travelling distance for users. Differences might not be intuitive at first pass, but have impacts during the length of the system utilization. Therefore, it is important to consider total walking distance for operators from/to different working interface (a table, a bench, an instrument, a screen, etc.); this approach is aligned with

Lean principle of reducing wastes (motion, waiting). A practical approach is to identify the most relevant criteria derived from layout solution and compare different options to select the highest in score. Optimal layout design improves overall efficiency, minimize specimen handling and operators walking distances.

Work-cell design

How operators interact with their instruments (and accessories) can result in effective process or not. Multiple variables apply when a process is designed with human interactions: how much work each operator is doing and the necessary time for operation, defined by technology used.

Goal is to balance all factors and operations, considering elimination of unnecessary steps (12). Systems have to be located not only with proper layout criteria (see previous section) but also considering the attributes for a flexible utilization of resources (Figure 10). Human resources are the most important asset in modern Laboratory services.

They are never redundant because extra staff can be redeployed on new activities or field of applications, preserving the flexibility of the Laboratory to cope with increased workload or quality requirements.

The best work-cell is defined by the limited wastes and higher flexibility. The following example provides the possibility to escalate production capabilities, just activating a higher number of systems (on demand). As optimal work-cell design is a combination (balance) among systems and users in timely operations, it is recommended to consider the procedures of operators. The following example shows how an optimal amount of resources could be appointed in a work-cell.

Type of wastes

Different solutions and technology selected have different relationships with 8 types of Lean wastes already described. The Table II aims to be a comparison among different types of wastes affected by the model adopted.

Table II Type of Lean waste impacted by different solutions (red = negative, green = positive)

Type of Lean waste	Stand-alone systems	Integrated consolidated	LAS
Defects/errors	↓	↗	↑
Overproduction	↑	↑	↓
Waiting	↓	↑	↗
Intellect	↑	↗	↓
Transportation	↓	↗	↑
Inventory	↓	↑	↗
Motion	↓	↗	↑
Extra processing	↗	↑	↓

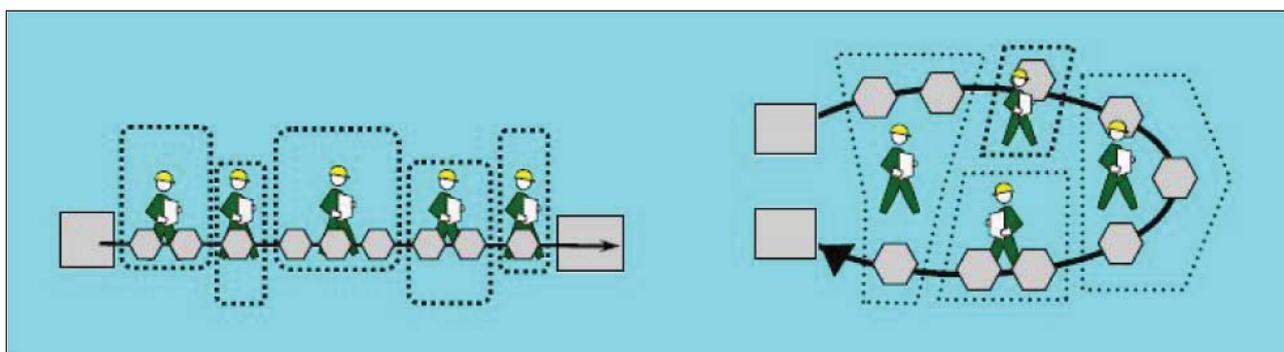


Figure 10 Work-cell design helps resource allocation.

Arrows direction reflects trend of the specific kind of waste for the specific scenario (using same resources):

- up (green) means improvement
- slightly up (yellow) means limited improvement
- down (red) means deterioration.

There seems to be no ideal solution, but each organizational model has different impacts according to different type of Lean wastes.

Other interesting criteria to benchmark performance goals versus different organizational solutions, are displayed in the following *Table III*.

In conclusion, there is no model that is »always the best« having in mind different attributes and Lean criteria: it appears only that an organization with integrated/consolidated platforms shows more balance considering all rationales.

Recommendations become a thorough analysis of criteria, benefits and features of a solution (and corresponding technologies) matching the Lean principles and aspects for a tailored made, efficient and cost-effective organization.

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Table III Laboratory requirements effected by different solutions (red = negative, green = positive).

	Stand-alone systems	Integrated consolidated	LAS
TAT	Short	Shorter	Longer
Cost	Lower	Low	Higher
FTE	Few	Few	Fewer
Back-up	High	High	Low
Flexibility	High	High	Low
Footprint	Small	Small	Large
Standardization of process	Poor	Good	High

The next steps and activities should focus on metrics and quantification of differences between the proven organizational models, to back-up with data future and value based decisions.

Conflict of interest statement

The authors stated that there are no conflicts of interest regarding the publication of this article.

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