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LEAN SIX SIGMA SAMPLE ANALYSIS PROCESS IN A MICROBIOLOGY LABORATORY

PRIMENA LEAN SIX SIGMA U MIKROBIOLOŠKOJ LABORATORIJI

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Summary: Faced with shrinking budgets, growing volumes, and personnel shortages, clinical laboratories are increasingly moving to automation to maximize output and efficiency. The best tool for improvement is the Lean Six Sigma concept. The concept reaps the full benefits of automation. A Lean process in a laboratory is focused on testing products and materials to deliver results in the most efficient way in terms of cost, speed, or both. The goal of a Lean laboratory is to use less effort, less resources and less time to test incoming samples. On the other hand, the Six Sigma concept provides process workflow and products/services without defects. The Lean Six Sigma approach analyzes laboratory workflow to help identify inefficiencies and uncover opportunities to free capacity, reduce turnaround time and lower costs. The assessment examines the end-to-end process looking closely at workflow as well as overall laboratory efficiency. The proven techniques of Lean and Six Sigma enhance productivity in the laboratory environment and ensure the best outcomes. This article analyzes a particular process, defines the approach, and gives a review of results obtained by deployment of the Lean Six Sigma concept. The article discusses a sample analysis process in a microbiology laboratory. A traditional process that applies standard analysis methods has a number of non-value-added activities, takes too much time, and has opportunities for defects. By mapping an existing process using a SIPOC model, 12 activities were identified. With the use of Lean tools four non-value-adding activities, which are not needed if a new system is used, were identified. Six activities had opportunities for improvement in terms of significant reduction in process time, and saving resources. Only two activities in the existing traditional process, with the use of standard analysis meth-

Kratak sadržaj: Suočene sa smanjenjem budžeta, rastom obima posla i nedostatkom osoblja, mikrobiološke laboratorije se sve više okreću automatizaciji, sa ciljem maksimizacije učinka i efikasnosti. Najbolji koncept poboljšanja procesa danas je Lean Six Sigma. Ovaj koncept izvlači brojne koristi iz automatizacije. Lean proces u laboratorijama se usredsređuje na ispitivanje proizvoda i materijala, da bi se na efikasan način dobili najbolji rezultati što se tiče vremena ciklusa i troškova, ili obe komponente zajedno. Planirani rezultat Lean laboratorije podrazumeva manje napora, manje resursa i manje vremena za ispitivanje uzoraka, sa ciljem oslobađanja ljudskog potencijala. S druge strane, Six Sigma koncept obezbeđuje tok procesa i proizvoda/usluga bez defekata. Lean Six Sigma pristup analizira tok aktivnosti u laboratorijama radi utvrđivanja neefikasnosti i otkrivanja prilika za oslobađanje kapaciteta, kao i radi smanjenja vremena i troškova. Dokazane Lean Six Sigma tehnike povećavaju produktivnost u okruženju laboratorije i osiguravaju najbolje rezultate. U radu se analizira identifikovani značajni proces, definiše pristup i daje pregled rezultata dobijenih korišćenjem Lean Six Sigma koncepta. Članak analizira proces analize uzoraka u mikrobiološkoj laboratoriji. Tradicionalni proces koji primenjuje standardne metode analize obuhvata jedan broj aktivnosti koje ne dodaju vrednost, zahteva mnogo vremena i pruža prilike za pojavu defekata. Snimanjem postojećeg procesa korišćenjem SIPOC modela identifikovano je 12 aktivnosti. Primenom Lean alata identifikovane su četiri aktivnosti, koje nisu potrebne ako se koristi novi sistem. Šest aktivnosti pruža prilike za poboljšanje u pogledu značajnog smanjenja vremena trajanja procesa i uštede resursa. Samo dve aktivnosti u postojećem tradicionalnom procesu su bile optimalno rešene korišćenjem standardnih metoda i nisu

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ods were optimally solved, and this did not require redesign or removal. The application of Lean Six Sigma concepts and automated analysis systems on a new process led to only nine activities in the process that now takes much less time and uses less resources. This article presents a description of the main principles, practices, and methods used in Lean and Six Sigma. The Lean tools particularly discussed here are 5s and spaghetti diagram. For Six Sigma, DMAIC methodology is used, and a review of applied quality tools for certain process improvement phases is given.

Keywords: Lean, Six Sigma, process improvement, DMAIC methodology, 5s

zahtevale redizajn ni uklanjanje. Primena Lean Six Sigma koncepata i automatizovani sistemi analize u novom procesu utvrđuju samo do 9 aktivnosti u procesu, pa je tako potrebno mnogo manje vremena i resursa. U ovom radu se daje opis osnovnih principa, praksi i metoda korišćenih u Lean i Six Sigma konceptu. Posebno su analizirani Lean alati 5S i spaghetti dijagram. Za Six Sigma koristi se DMAIC metodologija i daje se pregled primenjenih alatki za poboljšanje kvaliteta za pojedine faze poboljšanja procesa.

Ključne reči: Lean, Six Sigma, poboljšanje procesa, DMAIC metodologija, 5s

Introduction

Six Sigma is a concept developed by Motorola in the 1980s. The main focus was to reduce variations in manufacturing and the target was 3.4 defects per million opportunities (DPMO). After its successful implementation, other organizations started to implement it. Tremendous results achieved by General Electric gave Six Sigma a threefold boost. Then organizations combined Lean manufacturing tools with Six Sigma and the new term was coined – Lean Six Sigma (1–7).

Six Sigma has been embraced later by many organizations and industries involved in manufacturing and transactional services, as a cost-effective way to improve quality and productivity. As a method to eliminate variation and defects, Six Sigma makes use of a structured approach (DMAIC methodology) and statistical tools to find the root causes behind problems and to drive processes toward near-perfection (8, 9).

On the other hand, Lean utilizes a unique set of tools to streamline processes and eliminate unnecessary, time-consuming steps. It seeks to enhance performance and meet customer needs by reducing complexity, improving process flow and removing unnecessary or non-value-added activities.

Both Lean and Six Sigma strategies call for product focus and customer focus in terms of their requirements. Both tools are improvement tools, but one should focus more on those that are more relevant. If wastes need to be minimized or productivity needs to be improved, then focus on Lean, and if product variation needs to be controlled, then Six Sigma must be applied.

Lean means Speed and Low Cost: Goal – Reduce waste and increase process speed; Focus – Bias for action/Implementing known solutions; Method – Kaizen events. Lean Speed Enables Six Sigma Quality.

Six Sigma means Culture and Quality: Goal – Improve performance on Customer CTQs; Focus – Root Cause Analysis/ Developing Solutions; Method – Black Belts dedicated to projects. Six Sigma Quality Enables Lean Speed – Fewer Defects Means Less Time Spent on Rework.

Lean Six Sigma for services is a business improvement methodology that maximizes shareholder value by achieving the fastest trade of improvement in customer satisfaction, cost, quality, process speed and invested capital (3, 4).

Service processes are usually slow processes, which are expensive. Slow processes are prone to poor quality which drives costs up and drives down customer satisfaction and hence revenue. The result of slow processes: more than half the cost in service applications is non-value-add waste.

Service processes are slow because there is far too much »work-in-process« (WIP), often the result of unnecessary complexity in the service offering. It does not matter whether the WIP is reports waiting on a desk, emails in an electronic inbox, or sales orders in a database. When there is too much WIP, work can spend more than 90% of its time **waiting**, which does not help your customers at all and, in fact, creates or inflicts substantial waste (non-value-add costs) in process (2).

The objectives of Lean Six Sigma are as follows:

- Provide higher-quality products and services to customers.
- Achieve customer-driven design of these products and services by
- Converting user needs into design parameters.
- Provide documentation and tracking system for future design endeavors.
- Develop delivery processes that are efficient and effective.
- Involve suppliers early in the process.
- Require data-driven decision making and incorporate a comprehensive set of quality tools under a powerful framework for effective problem solving.
- Provide tools for analyzing process flow and delay times at each activity in a process.

The most important Lean tools used in different stages of process improvement are: 5S, Kaizen, Kanban, Visual Management, Takt Time, Value Stream Mapping (1).

Six Sigma uses DMAIC–Define Measure Analyze Improve Control methodology which includes the tools as follows: SIPOC model, Process Mapping, Affinity Diagram, Brainstorming, Pareto diagram, Ishikawa diagram, SPC – Statistical Process Control – control charts, Measurement System Analysis, Process Capability Studies, QFD – Quality Function Deployment, FMEA – Failure Mode and Effect Analysis, Design of Experiment (2).

In this article we present results achieved in the Lean Six Sigma project »Improvement of a sample analysis process in a microbiological laboratory« conducted in a health care institution in Serbia. The project has been realized in collaboration with the French company bioMérieux and the Jean-Marc CASSORLA consulting company.

Sample analysis process in a microbiological laboratory

CIM Group and bioMérieux Belgrade Office, in collaboration with the consultant Jean-Marc Cassorla, developed an As-Is process flowchart based on the SIPOC (Supplier Input Process Output Customer) model. Software »Visual Processes« developed by CIM Group (11, 12) was used for gathering knowledge about the process itself as well as for creating a process flowchart. The result of knowledge acquisition and process modeling is shown in *Figure 1*.

At the process map we can identify the three different activities: activities which produce an added value and which are optimally realized (**white color**); activities which could be improved during the analysis process by using an automated system (**yellow color**), and activities which do not add value (**red color**) and thus are not needed at all. Their removal will result in: (i) significant saving of resources and time needed for analysis, (ii) improving quality of results and (iii) standardization of the approach.

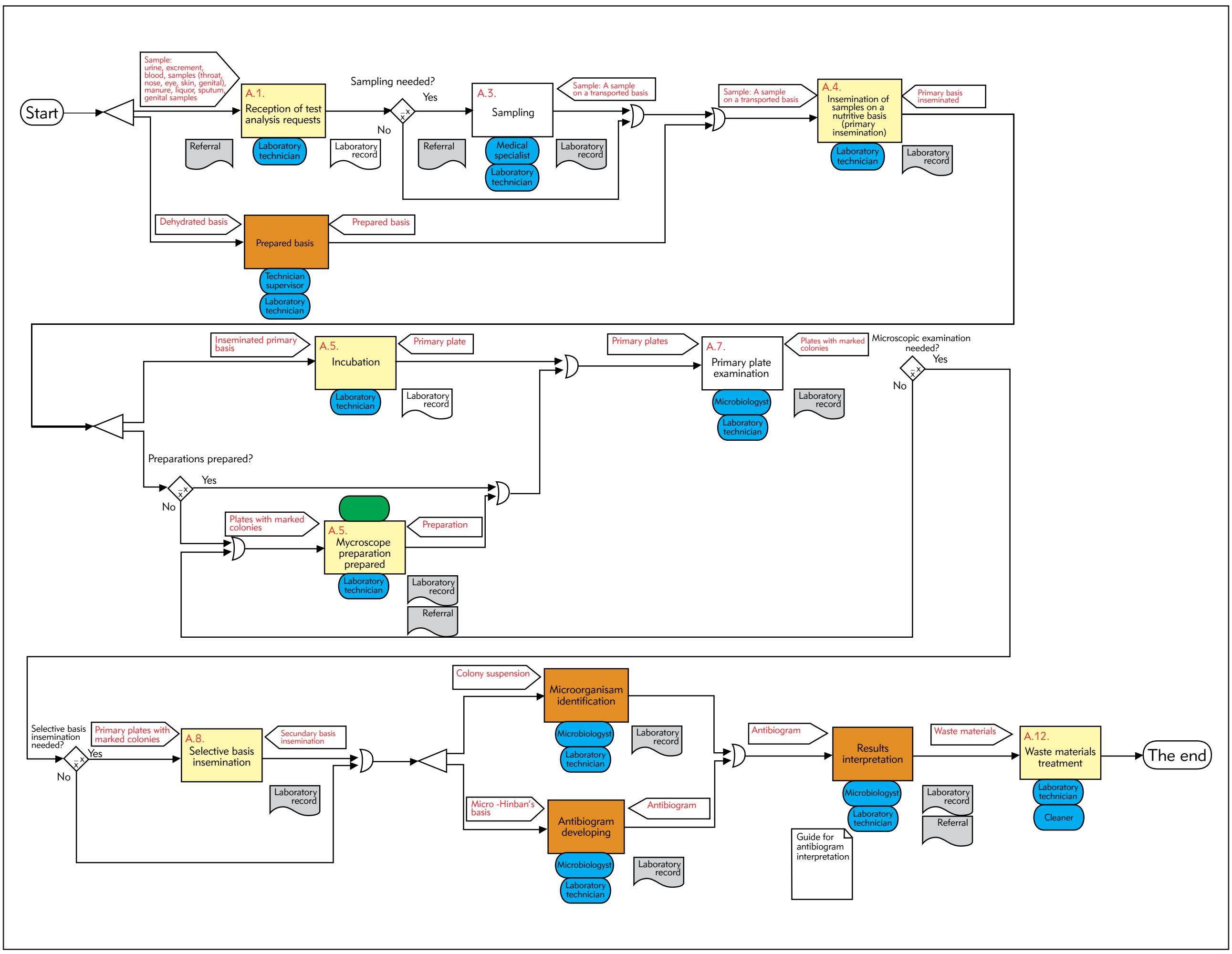

Figure 1 Sample analysis in a microbiological laboratory – process flowchart.

Losses in the existing sample analysis process in a microbiology laboratory

There are 7 big wastes in processes: non-value-added processing, overproduction, inventory, waiting, defects, movement, and transportation. In order to identify dispersion in a process, it was necessary to measure different aspects in the sample analysis process in a microbiology laboratory. Measurement was conducted in the whole process starting from reception of the samples in order to be analysed till the ending of the analysis and preparation of the resulting reports.

Based on the obtained data, CIM Group and bioMerieux performed a Pareto analysis by considering the number of samples received for microbiological examination during a week at a frequency of every 30 minutes. This is shown in *Figure 2*.

The 80% of all samples of the subject healthcare institution were received at the following time: 12:00; 10:30; 13:00; 13:30; 11:30; 14:00; 9:00 and 9:30. The remaining 20% of all samples were received during the rest of the day.

The most of samples were received between 9:00 AM and 2:00 PM. The analysis of distribution of sample reception per day, shows that the reception varies from day to day. This gives the opportunity for the application of the LEAN principles and tools: Kaizen, 5s, Process Flow, Spaghetti/ Layout Diagram, Value Stream Map, Standard Work, 5 Why, etc. They have to ensure time rate for sample reception and sample examination as well as a pull system similar to car manufacture.

The second Pareto analysis was done for microbiological examination based on sample types and analysis types (*Figure 3*).

The Pareto diagram in *Figure 3* shows that two types of samples (i.e. urine and genital) participate with more than 80% of all sample types. This means that the focus of all the efforts for improvement should be on these two types of analysis, since they offer much more opportunities for improvement.

The next Pareto analysis considers the groups of activities in the process of microbiological examination (*Figure 4*). From the Pareto diagram shown in *Figure 4* (and from other data that is not publicized due to space limitation) it could be concluded that the group activities »Technical« appear most frequently and participate with 23.75% in the total process duration. The positions two to five are taken by the following groups of activities: movement with 23.04%, other activity with 20.43%, administration with 18.05% and walking with 14.73% (% are given by considering the total number of appearances for microbiological examination). These numbers indicate that there are many opportunities for reduction or even for elimination of dispersion for Movement and Walking. This has to be done with the modification of the technical and administrative conditions in order to reduce the duration of these groups of activities. The group of activities Other Activity should be split into activities in order to identify opportunities for reduction in duration for these activities as well.

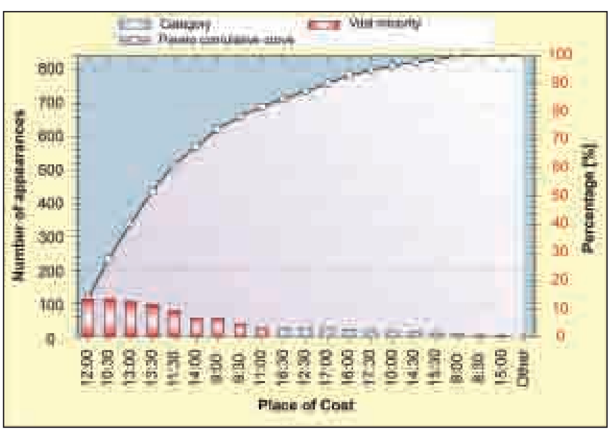

Figure 2 Analysis of sample reception during the week based on reception time.

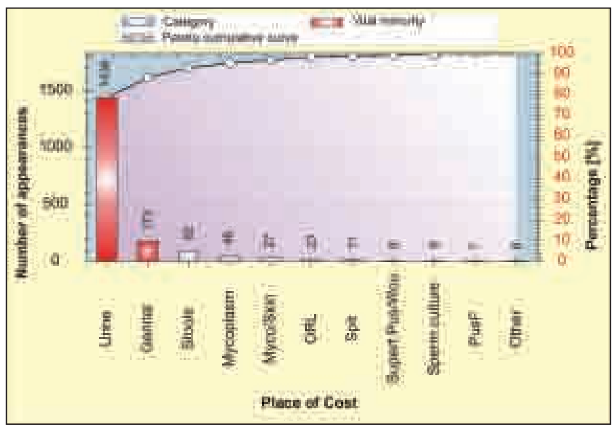

Figure 3 Analysis of the number of examination/appearance of sample types/analysis types.

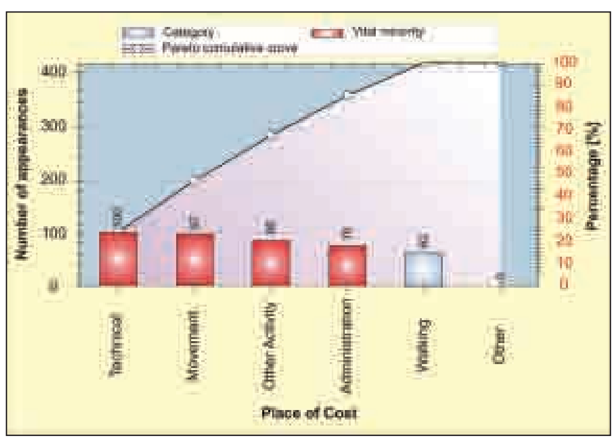

Figure 4 Pareto diagram for the analysis of the number of appearances of group activities in the process of microbiological examination.

All previously mentioned Pareto analyses were conducted by considering days per week in order to discover dispersion per days. Please note that these results are not shown in this article, but are included in the project reports.

Besides Pareto analyses for the groups of activities, we also conducted a Pareto analysis for activities that appear in a process of analysis of samples in a microbiological laboratory. In the process of microbiological examination there are many activities. In the previous analysis, the activities were grouped into five groups. Here we give an analysis of the number of appearances for every activity regardless of the group the activity belongs to. Additionally, we show an analysis of the number of appearances of activities within some of the groups of activities (this is not shown in the article).

The highest number of appearances had the activity *Reading 24/48H Other Samples*, followed by the activities *MSB (Microbiology Security Benc)*, *Reading 24/48H Urine and stool* etc.

The above-mentioned Pareto analysis shows where the highest dispersion is and where to put effort for improvement. One of the biggest losses is Movement, i.e. unnecessary motion. This leads to the phenomenon of Spaghetti diagram. CIM Group and bioMerieux created movement of samples through premises where the sample analysis has been performed. As a result, they created several Spaghetti diagrams.

Figure 5 illustrates dispersion which is a result of unnecessary motion. Routes of movement are large enough which leads not only to movement but also to unnecessary transport of samples and wastes which emerge during the sample analysis process.

Besides the previously mentioned analyses, we conducted an analysis of variation of sample analysis duration. For this purpose, the ImR – Individual Moving Range Chart control card (10, 11) was used. This analysis we have done by using the software SPC.Net developed by CIM Group (12–14).

From the control card it can be concluded that there is a huge variation in sample analysis duration. There is a rapid increase of lead time duration for the samples 48, 50 and 51. This means that the process ability is low, which could be seen in results shown in *Table I*. In order to reduce variation in delivery of samples for analysis, it is mandatory to reengineer the process in the whole supply chain, i.e. to all health institutions which deliver material for analysis. This includes (i) determination of points for taking over of material; (ii) planning of vehicle routes; (iii) extension and improvement of capacity of car park; (iv) education of external institutions about the concept of an »extended« organisation in the supply chain.

As it is shown in *Table I*, Cpk is equal to 0.8339, which is significantly less than 1.33 which represents a minimum for a process to be capable. Variation of sample analysis duration is very high, which means that this process could be drastically improved.

Table I Capability of the characteristic lead time in the sample analysis process.

USL = 250	Cr = 0.94168185
Target value = 150	Cp = 1.06192780
LSL = 50	CpkUp = 1.28993235
UCL = 141.0846	CpkDn = 0.83392721
$\bar{x}$ = 128.5294	Cpk = 0.83392721
LCL = 115.9742	Cpm = 0.87650119
Moving range chart: UCL = 15.42496 MR average = 4.72; LCL = 0	

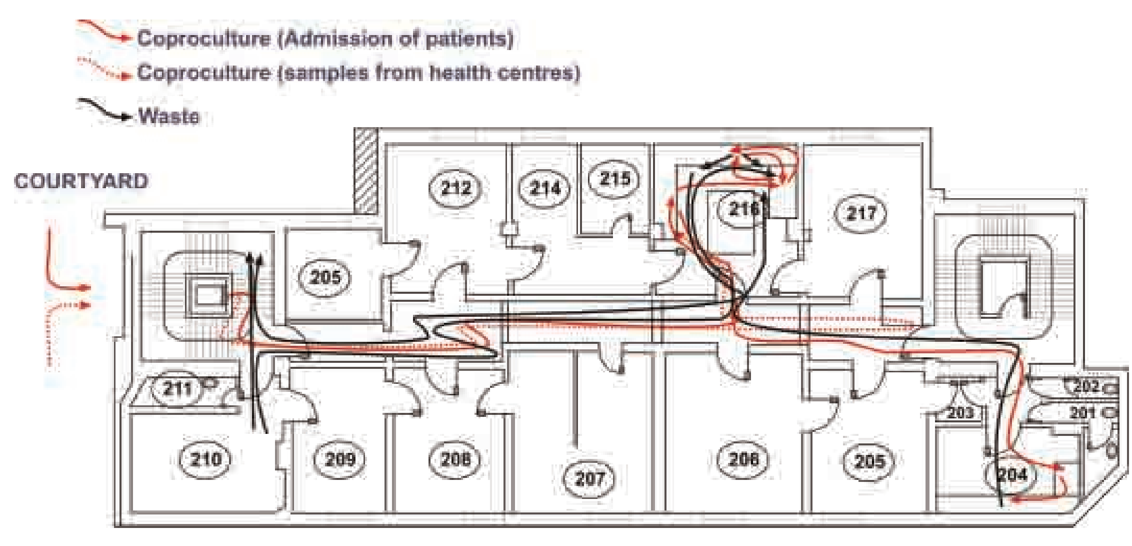

Figure 5 Spaghetti diagram for the analysis of coproculture.

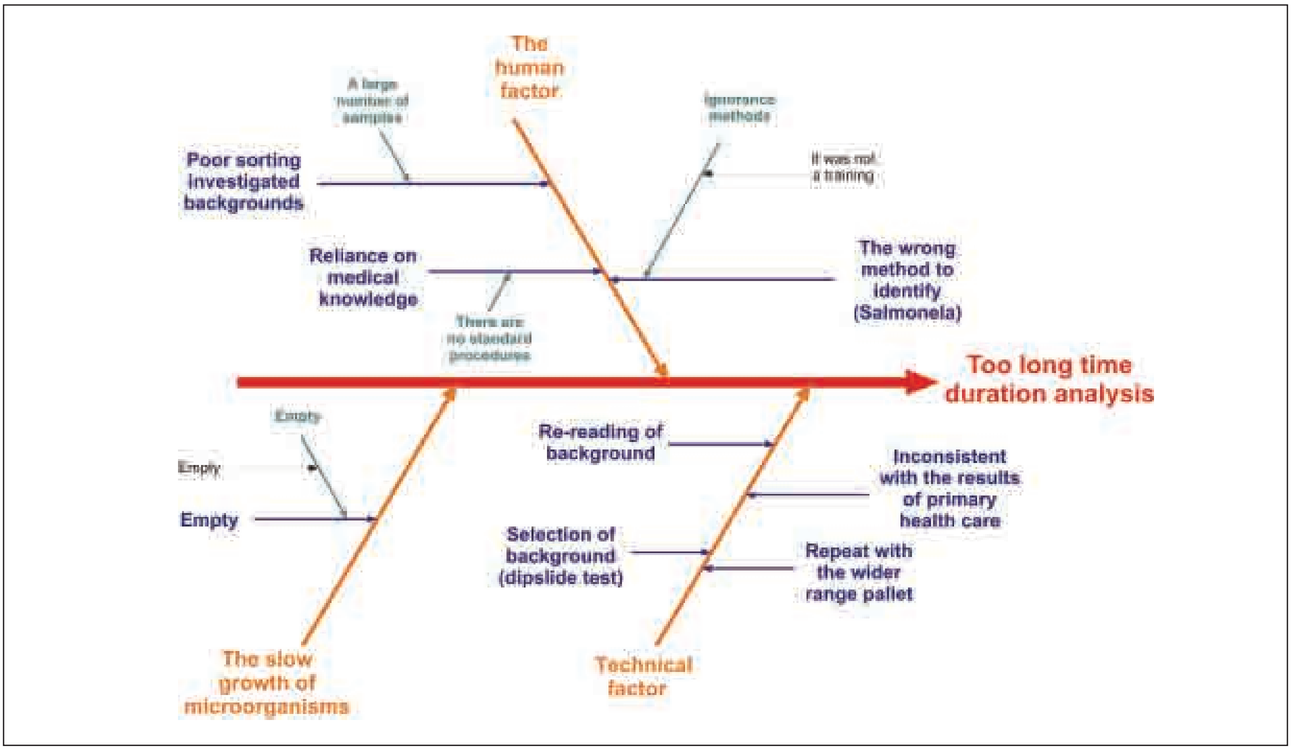

Figure 6 Ishikawa diagram for the consequence »*Too long duration of analysis*«.

Too long duration of analysis is the consequence of a disorganized process, i.e. causes that lead to that effect. To resolve this problem, we conducted an Ishikawa analysis by using the software Ishikawa. Net developed by CIM Group (*Figure 6*).

After creating a process map of the As-Is process, performing measurement in the process and conducting analyses, we came to the conclusion that it is mandatory to: (i) reengineer the existing process in order to eliminate activities which do not create added value; (ii) replace a part of equipment for laboratory examination; and (iii) reorganize the existing layout in order to eliminate dispersion.

Lean process for the sample analysis process in a microbiological laboratory

The sample analysis process in a microbiological laboratory is recorded, measurement is performed, an analysis using quality methods and tools is conducted and the conditions are created in order to consider proposals for improvement of the existing process. The new Lean process for sample analysis in a microbiological laboratory is shown in *Figure 7*. This process does not contain activities which do not create added value. This is achieved by redesigning the process and by using new equipment which enables fulfilling the Lean principles, i.e. eliminates dispersion in the process.

Besides the redesigning of the existing process and renewal of equipment for analysis, it was necessary to redesign the existing layout in the rooms used for analysis. This has to be done in order to enable elimination of dispersion in movement, transport, stock and defects. It is to be expected that the conducted changes in the process will lead to a significant reduction in the duration of analysis as well as increase of the available space.

Figure 8 shows flows of samples for all analyses which are performed in a healthcare institution. If we compare the routes of movement shown in *Figure 5* (which represents the status before transition of the considered process into the Lean process) with the routes shown in *Figure 8*, we can easily observe simplifications and improvements that the new Lean process offers.

Simultaneously with the redesign of the sample analysis process in the microbiological laboratory, we applied the 5S concept which ensured that every »thing« is in its place and that everything is orderly and clean. This results in a Lean automated process.

Modification made in the sample analysis process in a microbiological laboratory by the introduction of Lean and Six Sigma concepts led to significant savings (see *Table II*).

Using **Previ Isola-e** potentially frees staff 5.7 hours a day with activities and preparation of samples semination. Using a **Vitek II** potentially frees 11.6 staff hours per day with activities after leaving the samples from the first incubation.

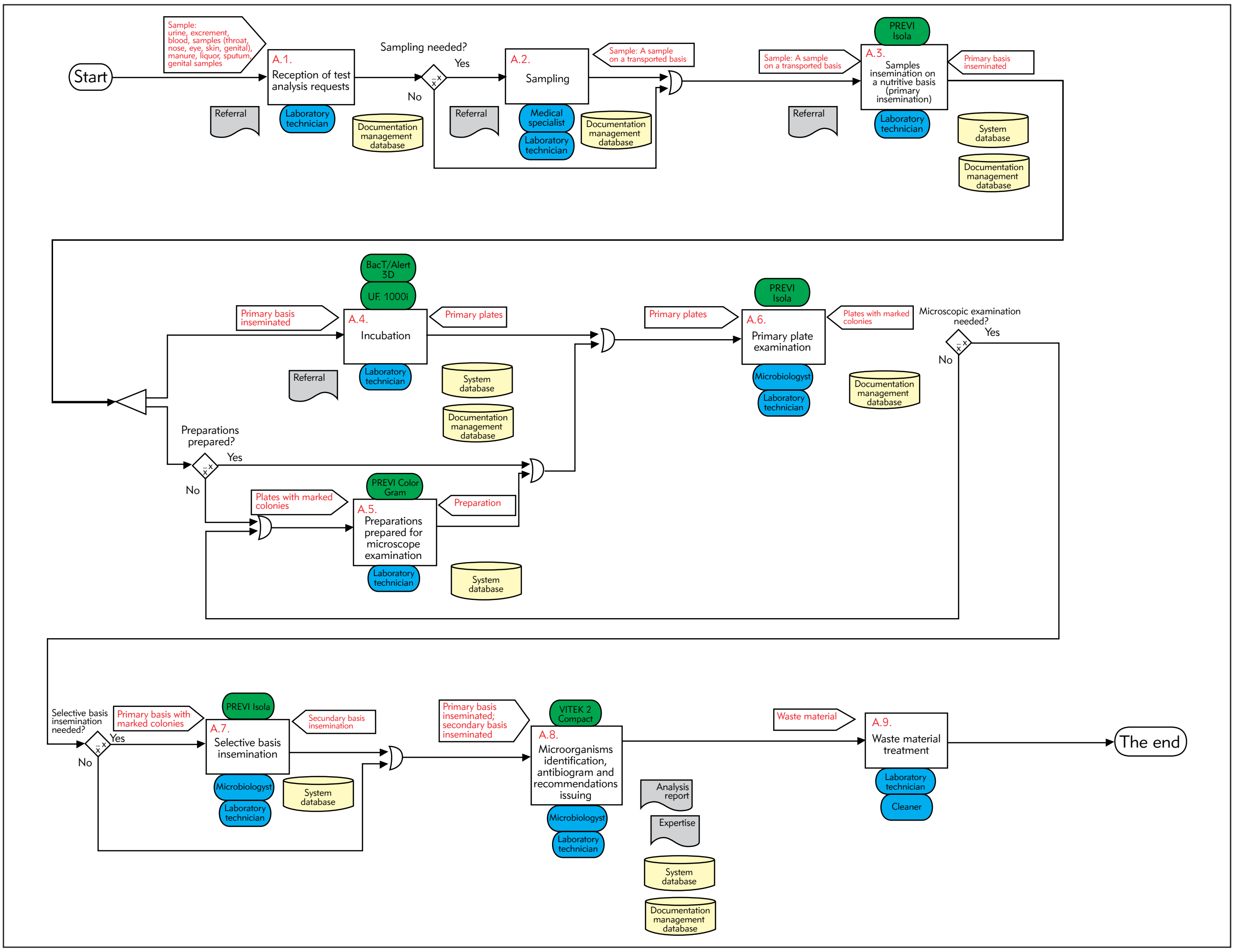

Figure 7 Lean process for sample analysis in a microbiological laboratory.

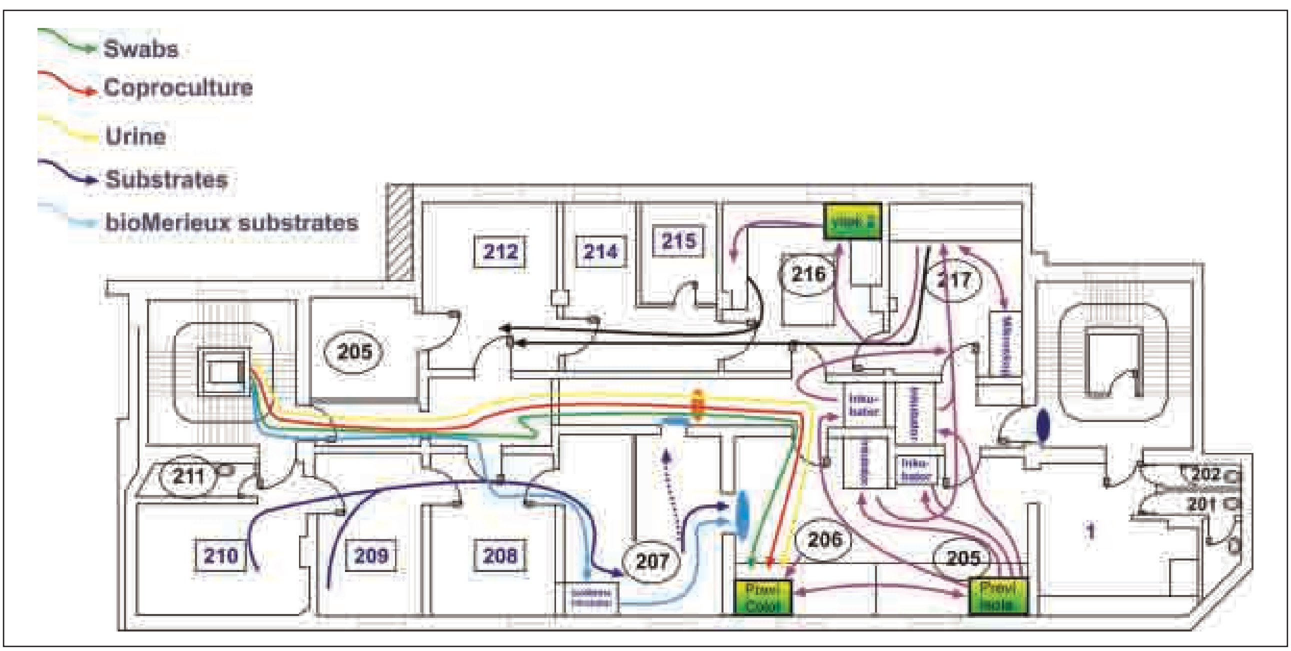

Figure 8 Lean process without a Spaghetti diagram.

Table II Situation before and after process improvement.

Before		After	
	While using the work station /day		While using the workstation/day
Day 0 (Preparation)	35.1 hr/day	Day 0 (Preparation)	29.4 hr/day
Day 1 (1st reading)	25.4 hr/day	Day 1 (1st reading)	18.1 hr/day
Day 2 (1st reading)	36.8 hr/day	Day 2 (1st reading)	31.6 hr/day
Parasites	1.1 hr/day	Parasites	1.1 hr/day

Conclusion

The Lean Six Sigma process for a sample analysis process in a microbiological laboratory removed the most of dispersions in the process, reduced variation, reduced duration of analysis and reduced opportunities for appearance of defects (15–19). Additionally, the Lean process enabled: merging of doubled functions of admission and sanitary units wherever possible; merging of laboratories based on best practices from France, Germany, Spain and Portugal by release of space; processing of several different types of samples in one bigger laboratory; the same processing route for the same types of samples received from admission and sanitary units; better exploitation of a corridor; multipurpose exploitation of existing and new apparatuses (e.g. Previ Isola and Viteka II).

There are still opportunities for improvements. Here we mention some of them: lifting of the accreditation of the city institute to a higher level by the implementation of the standard ISO 15189 that will be confirmed by a renowned international certification house; saving in materials consumption by using modern equipment for automation of the sample analysis process; introduction of an electronic document management system; institutional use of quality methods and tools related to the improvement of process performances and reaching the »world-class« processes.

Conflict of interest statement

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

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