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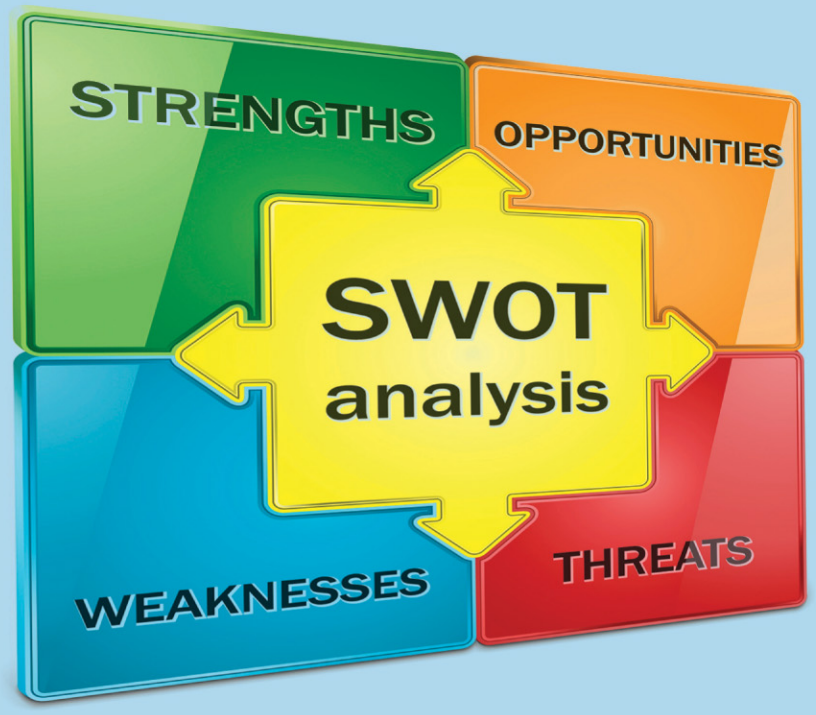

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Application of Methodology for Business Process Improvement in Specialized Diagnostic Laboratory

Elizabeta MITREVA*, Nako TASKOV**, Snezana CRNKOVIC***

Abstract

The research in this paper has the purpose of determining the existing business processes in the specialized diagnostic laboratory for the HPV (Human Papilloma Virus) analysis at the Clinic for Gynecology in Skopje, Macedonia, and the possibility of their improvement by applying the methodology of the TQM (Total Quality Management). Today, with advances in technology and new methods of testing, laboratories are equipped with modern appliances for testing, detection and diagnosis of many causes of diseases. During the recent years in Macedonia, there are economic managers responsible for managing the business processes these labs supplying reagents and apparatus, establishing standard operating procedures, cost control in operations, financial results, beside the medical personnel. These managers use a variety of tools to diagnose possible problems in the operation of laboratories, management, and taking care of the issues, following the global trend for continuous improvement of process through their management.
The methodology of the TQM relies on continuous improvement of all processes in the organization through small changes in short periods of time, including all organizational members, regardless of their hierarchical level, performed without major capital investment. The request for improvement of processes and involvement of competent people in it is very important, in order to reduce the morbidity and mortality in the country. That means preventing diseases, which significantly reduces the cost of treatment and hospitalization of patients. Improving business processes by using the TQM methodology aids monitoring, control and mandatory vaccination against HPV infections in young people and counseling for sexually transmitted diseases and their prevention. In this way, the laboratory should become a reference point for comparing the results of other laboratories in the region and the world.

Keywords: *business processes, continuous improvement, PDCA (Plan, Do, Check, Act) cycle, TQM.*

1. Introduction

Today, the trend in health care is the control of infectious diseases for the purpose of reducing the mortality of people as their result.

Laboratory practice in health care is realized through medical laboratory professionals who test samples from patients in order to prevent, diagnose, treat and control diseases. The clinical course of the disease or its laboratory and radiological findings may be changed by preventive medical interventions that will lead to recovery or continuation of disease with fewer or less severe side effects.

1.1. Approaches for improving the quality of business processes

The need for quality system design has emerged in response to the demands of patients and changes inside and outside the organization (Shiba, Walden, 2002; Koc, 2007; Reiner, 2008). The development of organizations and institutions are defined as the process of quantitative and qualitative changes in the volume and characteristics of objects, phenomena and processes in nature and society (Mitreva & Golomeova, 2013; Casadesus & Jimenez, 2000; Muppavarapu, 2011). In many organizations there is no clear picture and idea for what needs to be improved. The policy is clear, but the lack of strategy for reaching the goal for many managers is a problem. The new strategy towards quality, called integrated quality management or total quality management (TQM), answers the questions (Mitreva, et al., 2013): What patients want? What should be done? What processes should be used? We analyzed the situation, formulated a problem and used multiple methods to resolve it (Nair and Boulton, 2008; Svensson, 2006).

If top management decides just to redesign business processes, which is to make small improvements or modifications to existing processes, in that case the methodology used for reactive improvement of business processes ensures identification, problem solving and standard setting (Vujovic, 2006).

The methodology for **reactive improvement of business processes** is based on different approaches of quality improvement by using methods and techniques, and begins with the PDCA (Plan, Do, Check, Act) cycle.

There are two stages in the application of this methodology:

- Phase 1: Diagnosis and assessment of the existing condition and
- Phase 2: Fixing or solving the problem and improving the quality of the overall operation.

The methodology for quality improvement supported by PDCA cycle takes place in several steps, *Tab.* 1 (Mitreva, 2009).

The movement for total quality management (TQM) is based on the notion that quality is not created at the service control, but in the business processes in all organizational units and it must be controlled everywhere. Thus, for the quality of service all sectors are responsible. With this strategy, the control comes from within the diagnostic laboratory and is expanded in all aspects of the organization, as the quality gets new dimensions, not only quality service but also quality of work and organization of the work. The message of this strategy is **"Don't control the quality for the purpose of error removal, control it so you can remove the cause of error. Repeating the error is shameful". Control deals with the consequences, and management causes** (Mitreva, 2011).

Proactive work begins with an analysis of the business organization, then continues through the analysis of the requirements of

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PDCA Cycle	Step	Activity
Plan – Planning	1	Initiative to make the improvement project
	2	Determining the subject of interest or defining the problem to be solved
	3	Collection and analysis of data, i.e. determining the severity of the problem
	4	Analysis of the cause of the problem
Do – Implementation	5	Choosing a solution to improve and establishing improvement plans
	6	Implementing the solution
Check – Control	7	Monitoring and evaluating the improvement plan results
Act – Corrective measures	8	Solution standardizing
	9	Closing the improvement project

Table 1. Steps in the implementation of the methodology

internal and external customer service and ends with a detailed definition of the process. Daily practice of each employee should not only be operation control, but employees must be trained to act proactively, rather than be occupied with detection. Employees must be given the responsibility and power to correct their mistakes and take out every problem related to quality/low quality that they discover. This creates all around care about the quality, but the process is a long term effort, commitment of top management and reliance on itself to fulfill the obligations. The design and implementation of the quality system involves the design and application of appropriate standard operating procedures and guidelines and changes in organizational structure that integrates quality as a function (Mitreva, 2012; Bugdol, 2005; Haar, 2008).

2. Subject of research and analysis

The subject of the research in this paper is the specialized diagnostic laboratory for HPV (Human Papilloma Virus) analysis at the Clinic for Gynecology, Skopje. The Gynecology Clinic is a tertiary institution where 4000 patients are admitted, treated, and cured annually. All medical cases that require more expertise or are insoluble in other medical facilities throughout the Republic of Macedonia are sent right into the clinic. Within the clinic, there is a specialist diagnostic laboratory for HPV (Human Papilloma Virus) analysis, staffed with a biologist, three laboratory technicians, and one doctor infectologist as specialist for HPV infections.

The survey was conducted by determining the existing business processes in the laboratory, diagnostics and analysis of all defects in the operation, complaints of patients, as well as determining the "bottlenecks" in the implementation of activities. Analysis of the current state allows making suggestions for improvement, i.e. improving them through the application of the TQM methodology.

The purpose of the survey is to get a real picture of the possibilities and potential that this specialist research laboratory has, effective utilization of resources and proposing corrective measures for improvement of the business processes, making their implementation in practice and bringing the laboratory at the level of a World laboratory. It would mean a greater focus on preventive measures, which would reduce the morbidity and mortality in the Macedonian population. The research methodology applied for improvement of business processes takes place in several steps (Mitreva, 2009).

2.1. The realization of the research

❑ *Step 1. Initiative to make the improvement project*

The analysis is done on the basis of observation and direct contact with some of the employees and top management, and their willingness to adopt new knowledge and techniques in order to improve business processes. In conversation with the staff it is found that there is space for improvement in the laboratory. Based on their initiative, the function bearer of the process was granted, as well as their duties and responsibilities towards the diagnosis of the current situation in the laboratory, in order to provide proposed solutions for improvement were defined.

❑ *Step 2. Determining the subject of interest*

In order to detect the problems, an analysis of several aspects that affect the successful implementation of business processes was made.

In order to get a realistic picture of the current situation in the laboratory, analysis of the existing organization of the Clinic of Gynecology, Skopje and the laboratory for HPV (Human Papilloma Virus) analysis, that functions as a separate unit in which the staff has a working biologist, three laboratory technicians and one doctor – infectologist has been conducted, *Fig*. 1. This staffing is insufficient for this type of laboratory, especially the fact that the unit lacks a responsible person or head of the department.

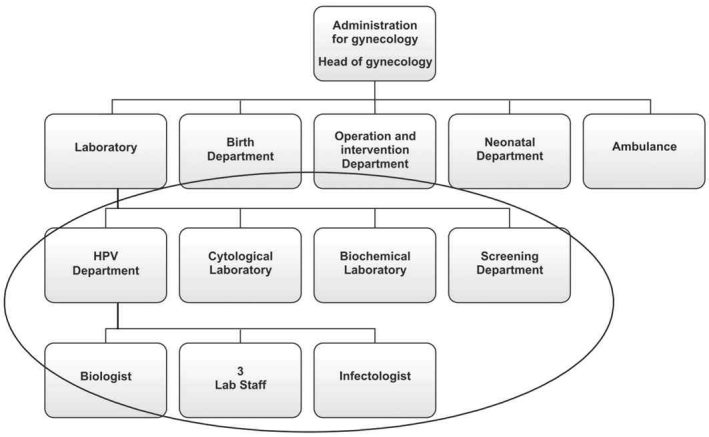

Figure 1. Organization of the Clinic of Gynecology, Skopje

The analysis of the technical equipment of the laboratory for HPV analysis showed that it has: three modern thermo cyclers, capillary electro extractor for DNA (Deoxyribonucleic Acid) and RNA (automated electrophoresis), magnetic extractor of nucleic acids, simple PCR (Polymerase Chain Reaction). This appliances are testing samples from patients from gynecology and they detect many causes for disease, but there are now only reagents for HPV (Human Papilloma Virus) analysis and some microorganisms. These reagents are used for microbiological and virological testing.

***Analyzing the technical specifications of the machines**, the main problem found is that they have great features, but are rarely used*. Possibilities of biochemical technology or PCR (Polymerase Chain Reaction) in the field of molecular biology for amplification of one or more copies of a piece of DNA through multiple levels of amplification until you get millions of copies of DNA sequences are required. These needs include DNA (Deoxyribonucleic Acid) cloning for sequencing (if it can get any infectious agent potentially present in a given sample for analysis) something that will be used to determine the required infectious agents. Polymer chain reaction relies on thermal cycles (which use three thermal cyclers), which denotes cycles of repeated heating and cooling of the reaction to separate the two DNA chains and the enzyme required to replicate the DNA sequence. The primers (short DNA fragments) containing sequences complementary to the target region along with a DNA polymerase are key components that provide repeatable and selective amplification. As it progresses, the polymer chain reaction generates DNA that serves as the basis for replication and it starts a chain reaction in which the basic DNA fragment is amplified exponentially. **This technique can be modified in order to perform a wide range of genetic modifications.**

The research and analysis of existing technical equipment showed that this technology is able to analyze:

- DNA phylogeny or functional analysis of genes;
- diagnosis of inherited diseases (laboratory would be serving the cytogenetic department that deals with determination of the potential for hereditary diseases in pregnant women) after performing amniocentesis or sampling amniotic fluid that surrounds the fetus. This way the current practice of making analysis based on subjective opinion of the person that sees the sample under a microscope will be overcome;
- determining the genetic print (option used in forensics to determine paternity) and
- detection and diagnosis of infectious diseases.

The laboratory has three new machines that were donated by the Ministry of Education:

- multi DNA – where the camera performs automated electrophoresis or a sample or process that is necessary for the functioning of the PCR (Polymerase Chain Reaction) technique. This bridges any potential subjective errors that might occur during manual electrophoresis. With this camera you can isolate any DNA or RNA Ribonucleic acid) sequence of the electrophoresis gel. Process after which begins the PCR (Polymerase Chain Reaction) analysis;
- magnetic extractors of nucleonic acids, nucleic acids which are extracted and separated from the sample by means of magnets. This way bridges and accelerates the extraction process which, if done manually takes a lot longer and is prone to errors and could get a false positive or false negative results;
- real time PCR – allows for quantifying the presence of an infectious agent in a given sampling time. This device may affect the prevention of miscarriages caused by the Chlamydia trachomatis infection such as intracellular parasites and microbial detection which requires special conditions (appropriate sampling and sample transport, proper subjective analysis). The use of this device would remove all subjective factors in the health system that are quite pronounced and approaches to target application of the infectious agent with an objective method.

The real business process for taking and testing the material in practice is as follows, *Fig.* 2.

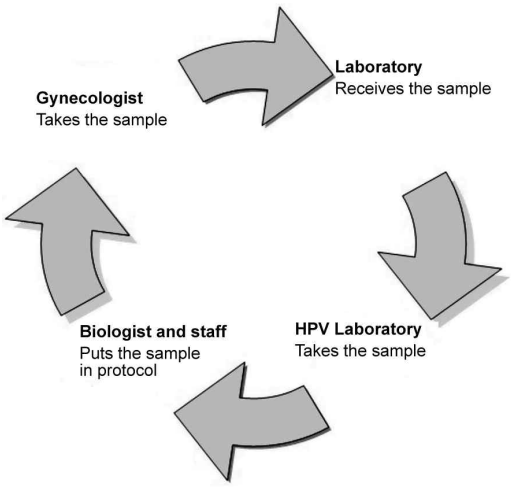

***Figure* 2. Procedure for taking and testing the sample in practice**

The biggest problem in this lab is the lack of utilization of the medical equipment and the non-inclusion of the infectologist in the process of sampling, diagnosing of patients and establishing protocols for established diagnosis of patients.

This paper proposes that the a doctor – infectologist is required to interpret the results and together with a doctor, the gynecologist that received the patient, make treatment protocols and management of pregnancy, based on analysis derived from the patient (individual protocol) thus minimizing the risk of miscarriage.

The previously explained technology allows identification of slow growing organisms as micro bacteria, anaerobic bacteria, or viruses from tissue or blood sample. Then by searching some virulent genes in microorganisms themselves it can be seen if it is a virulent or a non-virulent.

This technique can detect viral DNK and RNK in ways that used primers (short DNK fragments) are complementary to the nucleic sequences of the required virus for this technique and can be used for diagnosis and sequencing of the viral genome. The high sensitivity of this technique allows the detection of virus immediately after infection and long before the emergence of a disease (to act preventively). Such early diagnosis gives the doctors, the edge in the treatment.

The analysis of the financial and the health benefits have demonstrated that there have been large amount of funds invested in the laboratory for its modernization, but the devices have not been used and thus the investment does not yield results. In everyday practice, the activities related to disease occurrence in the patient's make the healing process take place through his hospitalization and treatment. This costs more than the preventive action taken by doctors. With prompt diagnosis and preventive medicine, the cost would be substantially reduced. The clinic does not work on prevention of diseases that would lead to a reduction in morbidity and mortality. The prevention would mean disease management or possible prevention of disease. But the tendency of the top management is getting quality service at minimal cost in performance. The previous activities follow an initial plan for process improvement in the unit.

❑ ***Step 3. Collection and analysis of data, i.e. determining the severity of the problem***

To use all the potential of the existing laboratory, but also to follow the trend of international medical guidelines required for creating a new department of the Clinic as a separate functional part that is integrated with the rest is needed. It would fit the existing laboratory and HPV molecular diagnostics as a structural and functional unit. This section should include counseling about the usefulness of vaccines and infectious diseases, to work on certain days of the week with a defined time. Counseling will be on the use of vaccines and their effectiveness, gaining knowledge regarding infectious diseases and their treatment and their potential role in pregnancy and childbirth.

This way the infectologist will possess the following duties and responsibilities:

- protocols for the gynecologists for delivery of women with an infection and thereby having the smallest risk in terms of infant and staff;
- protocols for purification of semen by the team of *in vitro* fertilization clinic, etc.;
- protocols for antibiotic treatment of women who have been proved by a gynecologist to have an infectious agent;
- and protocols for antibiotic treatment in women who are already pregnant and have an infection.

In order to realize the proposed improvement measures, the institution will need to hire additional medical staff to schedule checkups and eventually drew blood for further analysis proposed by the head – infectologist.

In order to enhance and to manage the business processes, it is necessary to equip the department with set computer database for:

- the number of vaccinated girls and their results of the checkups and HPV typology over the years with the possibility of prospective studies;

- all HPV analysis (those of Gynecology and those made in other institutions where there are pathological processes that are proven and considered that HPV is directly responsible as Clinic for Ear Nose and Throat, Clinic for Maxillofacial Surgery, Clinic for Thoracic surgery, The Pulmonology Clinic and Clinic of dermato-venereology).

This way a huge database from which data can be drawn for analysis in section and longitudinal studies by all interested specialists will be made. The infectologist will regulate and control the database.

In the near future this lab should become a central laboratory in Macedonia for HPV analysis, which will send material for analysis not only of secondary health facilities but also the primary and the private health sector. In addition, the full potential of existing equipment will be utilized for routine diagnostics that will be credible and lucrative. In this way, the MANU laboratory and the laboratory of PMF (Faculty of Mathematics and Natural Science) primarily having a basic research role, will be replaced.

These capabilities will enable the clinic to realize positive financial results and the state will receive a laboratory with a reputation of which database data for experts and scientific research purposes could be drawn.

To realize the proposed solution it is necessary to employ experts, more laboratory biologists, especially for molecular diagnostics, to expand the diagnostic and other infectious agents, not only in gynecological population treated at the clinic, but in the neonatal population, where now lies the greatest morbidity and mortality of this clinic. Also, the department will be responsible for the control of intra-hospital infections in collaboration with obstetricians, gynecologists and pediatricians.

- ❑ *Step 4. Analysis of the causes of problems, i.e. identifying the cause of the problem*

As the main cause of the current utilization of the laboratory is the organizational structure of the unit, lack of physician involvement – the infectologist within the investigation, detection and treatment of patients, utilization of the machines for laboratory testing and lack of necessary kits i.e. reagents. Cause of the problems is the lack of adequate information technology to collect information, lack of adequate space, office (medical room) for the doctor infectologist. Causes are also the lack of protocols for treating recurrent conditions and diseases in patients, lack of information and training of the employees about the opportunities and the capacity of the laboratory.

- ❑ *Step 5. Choosing a solution to improve and establish improvement plans*

In order to improve the performance of the unit Department of HPV (Human Papilloma Virus) analysis and molecular diagnosis of other infectious agents should be established for their prevention, diagnosis and treatment. The obligations and responsibilities of the head of the department would be sexual education and sexually transmitted disease in patients and women in collaboration with NGOs. Sexual education can be performed by infectologists in secondary level health facilities throughout the country.

There should be a laboratory in this section, in which at least two biologists work, along with an infectologist trained for laboratory analysis of highly specific research (those who deviate from routine diagnostics). The department should be staffed by professional nurses who already have a practice of infectious diseases to guide counseling and work on prevention of intra-hospital infections.

The infectologist in certain time frames will submit reports to the Ministry of Health for infectious agents most responsible for morbidity and mortality in patients at this clinic (women and infants), for the current condition in the early management period of the clinic, the measures used to combat these infectious agents and the effects of the applied methods in practice.

From all stated, the duties and responsibilities of this department are: *laboratory – diagnostic, consultative, advisory and research activities*.

3. Improvement, innovation and learning key element in studied organization

The proposed solutions based on detection of the current situation are given to top management for implementation following the directions for improvement of processes which can be shown by:

- ❑ matrix of duties and responsibilities by applying the solution;
- ❑ assessment of the effects of the problem in terms of a confirmations of improvement;
- ❑ assessment of the effect and orientation activities in process improvement;
- ❑ standardizing the solution in the existing solution;
- ❑ closing the improvement project and validating that the problem is identified and a responsive to new problems.

By introducing system of proposals, employees will be able to continuously provide ideas, comments, suggestions and opinions to improve the performance.

The survey shows that the laboratory is equipped with technical devices whose ability is underused. It is established that there is a lack of qualified staff; the doctor infectologist is insufficiently involved in the analysis, detection, diagnosis and treatment of patients. The institution does not have protocols for preventive treatment after diagnosis and has lack of kits (reagents) for faster, accurate, timely detection of certain infectious diseases. The laboratory is not equipped with information technology that would collect, analyze, and store all data obtained from patients in order to form a database that will be used for technical and scientific studies. The laboratory analysis of HPV primarily differs from others by having fast and easily available material for tests and the cost of transporting the samples are minimal. The request for improvement of processes and involvement of doctors – infectologist therein is essential to reduce the morbidity and mortality in the country.

4. Conclusion

The proposed measures and solutions for business processes improvement in this paper would mean prevention of diseases, which could significantly reduce the cost of treatment and hospitalization of patients. Preventive measures in improving the business processes would mean monitoring, control and mandatory vaccination against HPV infections in young people and their counseling for sexually transmitted diseases and their prevention. By applying the proposed solutions, this practice lab should become a reference for comparing the results with other similar laboratories worldwide as the laboratory Ruger Boshkovic in Zagreb, DKFZ – German Cancer Research Center and others. This collaboration means sharing experiences, knowledge and innovation in the treatment of cancer, counseling and lifelong learning for the medical staff.

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