



Quality in Clinical Laboratory-III: Gap and SWOT analyses as indicators for analytical and Diagnostic Excellence.

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Abstract

Quality indicators including several quality analyses tools are much need system improving methods that, if used, assessed, implemented and redo properly, will certainly induce better quality diagnostic services and manifest into timely and good clinical decisions. Quality management system and its initiatives, in accordance with organizational requirements (Vision, mission) and criteria of establishment are two key elements that favors existence of error free services and quality assured pledges, especially in a setup like clinical laboratories. Wide variety of informative resources, generating from symptomatic and asymptomatic events, such as untoward incident and SWOT and gap analysis, respectively, can be part of improvement opportunities for Total Testing Processes and over all phases to avoid errors and build a trust worthy environment and services for physicians and patients. Presented review describes the ways and means, as well as impact of SWOT analysis and how does it improves our own system as an example.

Keywords: SWOT analysis, Gap analysis, Total testing process, Quality indicators.

1. Introduction

Improvement processes regarding quality in clinical laboratory services involves, human, technology, support services and integration components and how they were administered and correlated with each other, in other words symbiotically. Quality management system and its initiatives, in accordance with organizational requirements (Vision, mission) and criteria of establishment are two key elements that favors existence of error free services and quality assured pledges, especially in a setup like clinical laboratories [1-4]. An old saying is “that which is not measured cannot be improved on”, is the vital essence in organization structure to induce, sustain and improved quality and better services in continuum. Interestingly, suggested, existing, implemented improvement steps in clinical laboratories are varied, complexit and multi-hierarchal in similar manner as the integrations and interactions between multilevel processes and activities of laboratory services. Success of improvement in clinical laboratories and sustainability depends on committed leadership, sensibility and obligation of teams responsible, in addition to the way suggestive or required improvements implemented in the system; and the tools, applications and techniques acquired for and during implementation and improvement processes [5-7].



2. Quality indicator and SWOT analysis:

It is well documented and advocated that improvement prospects within clinical laboratories should involve all pre-pre, pre-analytical, analytical and post analytical phases, which means encompassing complete TTP [5-9]. Furthermore, all the extra-analytical phases, which incorporates pre-pre, pre-analytical and post analytical components should be assessed and proactively rectified, if errors occurred, because of its correlation directly with patient safety and care. Management of TTP and quality indicators that controls and encompasses TTP pertains to evaluation, monitoring and improvement. Wide variety of informative resources, generating from symptomatic and asymptomatic events, such as untoward incident and SWOT analysis, respectively, can be part of improvement opportunities for TTP and over all phases to avoid errors and build a trust worthy environment and services for physicians and patients. Patients and end-user surveys, external and internal audits, external quality control programs, non-conformance reports are some of the tools that can be part of SWOT analysis and improvement regiments [10-13].

In our setup, we introduced improvement in our system and services by expanding the department area to accommodate more standalone instruments and total lab automation system. To assess and evaluate the weakness, strengths, opportunities and threats of expanding the department and having more sophisticated instruments, we performed SWOT analyses with the support and guidance of institutional Quality assurance department. Table 1 and 2 describes the required changes (Tables 1A, 2A) and then SWOT analyses of the same (Table 1B, 2B). Some of the components of required change are project name, requested by, and presented to, change name, description of change, reason for change, effect on deliverables (including a list of any affected deliverables), effect on organization, effect on schedule (including estimated completion date for this change), effect of not approving this change, reason for rejection (if applicable), followed by SWOT analysis. For SWOT of expansion of bio lab (Table 1B), strengths identified were Extended Spacious area for better placement of equipment and working, more accessibility, bench specific working areas, weakness identified was needs additional resources to cater a more spacious area, opportunities were Available area for more stand-alone and other more sophisticated equipment's, enhance test menu, accessibility for patient for enhanced STAT menu and threats, area more accessible to walk in public and people who are not authorized. For SWOT of installation of TLA (Table 2B), proceeding analyses was done; **Strength**- Minimal human error with enhanced precision and accuracy, enhanced acceleration of analytical and reporting timeline, sample specific analytical system and archiving, simultaneous movement, analysis and archiving for multiple tests and samples, **weakness**- Larger system of TLA requires multiple engineering expertise to assess and rectify any problem arising within the system, mechanical, technical, electrical issues within TLA or any individual component can cause hindrance in services and damages to credibility; **opportunities**- Enhance test menu (new test will be added in menu), offering for further STAT profile, data storage and retrieval for research purpose, enhanced system available to train Postgraduate trainees and medical technology students; **threats**- Urgent availability of larger size mechanical automated components of TLA, mostly import items.

Table 1 A: Change management-extension of Biochemistry lab-LNH

Project Name	Extension of Biochemistry Lab for TLA	Change Number	03
Requested By	HOD Clinical Biochemistry lab services	Date of Request	10 th Nov2021
Presented To	Management		
Change Name	Extension of clinical Biochemistry Lab		
	Description of Change:		
	Extension of area including old Blood bank and existing biochemistry lab		
	Reason for Change:		
	Relocation & installation of TLA and existing stand-alone instruments		
	Effect on Deliverables (including a list of any affected deliverables):		
	Not applicable		
	Effect on Organization:		
	Spacious area will be used to install Total Lab automation that will enhance capabilities of Clinical Chemistry Lab with existing 2.5 million tests/year, more efficient, proficient, STAT, accurate reports		



Effect on Schedule (including Estimated Completion Date for this change):

Dec 2022

Effect of NOT Approving this Change:

Will cause delays in installing TLA, which is required for better patients care, STAT reporting, further enhancing accuracy and credibility

Reason for Rejection (if applicable):

Not applicable

Table 1B: Change management: SWOT analysis: Extension of Biochemistry lab-LNH

SWOT ANALYSIS	
Strength	Weakness
<ul style="list-style-type: none"> Extended (Spacious area for better placement of equipment and working). More accessibility. Bench specific working areas 	<ul style="list-style-type: none"> Needs additional resources to cater a more spacious area
Opportunities	Threats
<ul style="list-style-type: none"> Available area for more stand-alone and other more sophisticated equipment's. Enhance test menu. Accessibility for patient for enhanced STAT menu. 	<ul style="list-style-type: none"> Area more accessible to walk in public and people who are not authorized.

Table 2 A: Change management: Installation of Total Lab automation-Cobas pro-Bio lab-LNH

Project Name	Installation of Total Lab Automation analyzers	Change Number	04
Requested By	HOD clinical Biochemistry lab services	Date of Request	20-03-2022
Presented To	Management		
Change Name	Installation of Total Lab Automation (TLA) Solution, p471, p512, c503, e801, p501		
	Description of Change:		
	Procurement and installation of TLA system including Pre analytical, analytical and post analytical units.		
	Reason for Change:		
	Modernization, enhancement of existing analytical facilities		
	Effect on Deliverables (including a list of any affected deliverables):		
	Better timeline, minimal chance of human error, enhanced accuracy, precision and enhance test menu.		
	Effect on Organization:		
	Enhance credibility, sustainability of service, and goodwill among customers		
	Effect on Schedule (including Estimated Completion Date for this change):		
	January 14 th 2023		
	Effect of NOT Approving this Change:		
	Shall remain redundant, without advancement of analytical services, deterioration of capabilities		
	Reason for Rejection (if applicable):		
	Not applicable		

Table 2B: SWOT analysis: Installation of TLA-Biochemistry Lab-LNH

SWOT ANALYSIS	
Strength	Weakness
<ul style="list-style-type: none"> Minimal human error with enhanced precision and accuracy. Enhanced acceleration of analytical and reporting timeline Sample specific analytical system and archiving Simultaneous movement, analysis and 	<ul style="list-style-type: none"> Larger system of TLA requires multiple engineering expertise to assess and rectify any problem arising within the system Mechanical, technical, electrical issues within TLA or any individual component can cause hindrance in services and damages to credibility



archiving for multiple tests and samples

Opportunities

- Enhance test menu (new test will be added in menu).
- Offering for further STAT profile.
- Data storage and retrieval for research purpose
- Enhanced system available to train Postgraduate trainees and medical technology students

Threats

- Urgent availability of larger size mechanical automated components of TLA, mostly import items

3. Importance of SWOT analysis, quality indicators and Conclusion:

SWOT analysis provides an overview of things that we have, planned, and needed to be executed in future, its strengths, possible weaknesses and opportunities inclusive of changes of errors. Need to manage, facilitate and implement processes in all phases of analysis is to eradicate errors, deviations, possible risk for decision and treatments, delays [11-14]. Several national and international quality organizations, PENAC, ISO (ISO 15189-2012), CAP are regularly evaluating the processes of quality clinical lab services, methods, procedures, surveys, etc to identify and avoid adverse events. In past two decades or so, several quality indicators have been not only developed but identified by international organizations, to observe possible errors, critical processes that control the systems, deviations in clinical laboratories dependent on internalized characteristics and pledges made to end-users and customers [13-15]. As stated earlier in our review and shown herewith, one of such monitoring tool is SWOT analysis and gap surveys/analysis. Several thousand clinical laboratories routinely participates in EQA programs, ISO QMS system audits, and several specified hospital-labs with CAP and JCIA programs, ensuring quality services, good diagnostic and analytical practices, thus eventually supporting good and timely clinical decisions.

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