Tool 1: Selecting Improvement Projects

Listed below are Improvement Projects (IP) by workshop that you can select from. Once selected, a detailed plan of implementation must be developed using Worksheet: Quality Improvement Project Plan. Four examples of IP assignments are provided in this tool: Workstation Set-up, Safety Audit, SOP Development, and Internal Audit.

Activity	Improvement Project	What is to be measured
Workshop #1		
Balanced Scorecard	Monitor one of the Quality Indicators presented in this activity	Chosen Quality Indicator
Floor Plan Activities	Re-design your laboratory layout	Show before and after layout (or pictures). List the number of changes made to the layout or measure by way of improved TAT before and after.
Competency Assessment	Design a competency assessment program for the laboratory and conduct some assessments	Number of staff competent on each procedure
Workstation Set-up See example	Improve workstation set-up	Availability of required items and documentation of each workstation. See example
Workshop #2		
Safety Audit See example	Conduct a safety audit using the Safety section of the Checklist	Improvement of score for the Safety section of the Checklist
Inventory Management	Introduce an inventory management system: monitor consumption, calculate minimum stock / reorder levels, stock counts, reagent inventory list, review of suppliers and list of preferred suppliers	Stock outs, number of supplies with stock cards, number of stock with documented minimum stock or re-order level, consumption rate and stock counts, number of orders tracked and inspected on receipt, number of supplier reviews and preferred supplier list created
Equipment	Equipment maintenance and service	Number of days and times (weekly, bi-weekly, monthly, etc.) equipment maintained by user as per manufacturers requirements, measure of equipment down time, number of equipment serviced on time, number of records of after service checks
Documentation	Improve documentation (Policies, SOPs, quality logs and checklists)	Number of policies available vs. required by WHO AFRO SLIPTA

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Activity	Improvement Project	What is to be measured
See example	in the laboratory	checklist. Number of SOPs available vs. required by the laboratory and the WHO SLIPTA checklist.
Workshop #3		
Quality Control	Monitor running of IQC	Number of days IQC run and reviewed by tester. Number of L-J charts plotted as the IQC is done. Number of corrective actions done for failed IQC. Number of IQC logs and L-J charts reviewed by supervisor.
External Quality Assurance	Monitor performance and documentation of EQA	Number of tests enrolled on EQA vs tests done in the lab, EQA pass rate (analytes done vs. passed), EQA submitted on time. Documentation of (i) receipt of EQA material (who received, when and in what condition) (ii) date tested and results submitted and by whom (ii) review of results, corrective action and review of corrective actions by supervisor
Specimen Management	Monitor specimen rejection	Specimen rejection rates, number of specimens rejected by sample type, test, source e.g. which ward, reason for rejection
Referral Specimens	Monitor results of referral specimens	Number of tests referred, tracking of referral results and TAT, reviews of referral logbook.
Customer Service	Customer satisfaction survey	Customer Satisfaction Survey results, follow up actions
Internal Audit See example	Conduct an internal audit using the WHO AFRO SLIPTA checklist sections 1-11	Improve of the checklist score. Document action plans with timelines and tasks assigned to personnel. Track number of non conformities (YES, Partial and NOs) from baseline to final

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Compulsory Activities

These are projects that are not extensive enough to be considered a SLMTA Improvement Project. These will be assigned as "compulsory activities" i.e. all participants must implement these in addition to the selected Improvement Project.

- Laboratory Organization - "Sort / Straighten / Shine / Standardize / Sustain" an area of the laboratory:
  - The storeroom
  - One workstation (e.g., the phlebotomy area)
  - The office
  - The records
  - Remove non-functioning equipment from the laboratory
- Duty Roster
- Management Calendar
- Equipment Master list/Inventory

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Improvement Project: Workstation Set-up

Workstation Set-up: Improving workstation set up

1. Discuss and explain the Improvement Project in a team meeting. Document the minutes
2. Create an initial listing of every analytical workstation in your laboratory as follows, for example FBC workstation, CD4 workstation, sample reception workstation, sample referral workstation, TB microscopy screening, TB staining station…..Fill these in column 1 of the data collection tool below
3. List all the equipment associated with each workstation e.g. CD4 workstation: FACS Count. Also include ancillary equipment within that workstation e.g. for CD4 workstation: blood mixer, printer, 2-8°C Fridge. Fill these in column 2 of the data collection tool below
4. Assign specific individuals' specific workstations to work on for the Improvement Project.
5. For baseline data, complete columns 3. If the item is in place e.g., maintenance log indicate by marking column under Y (YES). If the item does not apply e.g. QC log in the sample collection area indicate N/A in any of the columns Y or N.
6. Count the number of Y (YES) and N (NO) for each item e.g. SOPs: Yes = 12, NO = 28
7. Add up the number of Y and N for all items e.g. if Service Stocker = 15 Yes, small parts = 0 YES, book of life = 2 YES……total YES = 15 + 0 + 2 + …. …. = 17 YES (baseline)

Data Collection Tool

Work-station	Equipment + Ancillary Equipment	Uniquely Identified		Service Sticker		SOP		QC Log		Maintenance Log		Backup Plan		Small parts		Competency Assessment checklist		Book of Life		User Manual		Quality Docs Reviewed	
		Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N	Y	N
Automated FBC	Sysmex K21																						
	Coulter Act 5																						
	Blood Rotator																						
Totals (Y or N)																							

8. Report baseline data at the next team meeting
9. Assign tasks to be completed to specific individuals within certain workstations with timelines for completion. See example below

Deficiency Identified	Cause or Reason for the Deficiency	Proposed Corrective Action	Action Plan					
			Task to be completed	Who is responsible	By When	Review 1	Review 2	Review 3
			1)					
			2)					
			3)					
			1)					
			2)					

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10. Review the progress of the Improvement Project monthly. Indicate progress of the assigned tasks under review 1 to 3.
11. At the end of the Improvement Project (1-2 weeks before next workshop), collect final data using the same data collection tool
12. Add up the total Y and N for each item and for all items as given in steps?
13. Compare baseline and final data
14. For areas still not improved, discuss how these will be improved.
15. Complete another action item for the incomplete tasks as in the above action plan
16. Prepare report to present at the workshop

This improvement project supports the following SLIPTA checklist items:

1.5 Laboratory management system documentation.

2.5 Does the Laboratory routinely perform a documented review of all quality and technical records?

3.14 Are records of personnel maintained (hardcopy or electronic copy)?

5.3 Is equipment installed and placed as specified in the operator's manuals and uniquely labeled or marked?

5.7 Is current equipment inventory data available on all equipment in the laboratory?

5.11 Is routine calibration of measuring equipment (including pipettes, centrifuges, balances, and thermometers) scheduled, at minimum following manufacturer recommendations?

5.12 Is routine user preventative maintenance performed on all equipment and recorded according to manufacturer's minimum requirements?

5.15 Are the manufacturer's operator manuals readily available to testing personnel and available in the language understood by personnel?

8.12 Are examination information and instructions available in appropriate locations?

8.15 Is internal quality control performed and verified to be within the acceptable limits before testing and release of results? Is corrective action taken and documented when quality control results fall outside the acceptable range and reviews identify non-conformities in a timely manner?

8.16 Are Quality Control results monitored and reviewed to assess the performance of the method and or identify errors over time for quantitative tests?

8.18 Are environmental conditions monitored and recorded daily?

8.21 Does the laboratory participate in EQA or alternative assessment procedure (APP) for all tests?

9.4 Does the laboratory report contain the requirements for result reporting?

11.2 Does the laboratory identify and undertake quality improvement activities?

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Improvement Project: Safety Audit

Safety Audit: Implementing, conducting and improving performance on safety audit

*The **ISO 15190:2003(E) states that** "Safety is the primary consideration; cost is of secondary importance"*

Steps

1. Discuss the Improvement Project in the team meeting. Document the minutes
2. Using Section 12 of the WHO SLIPTA checklist or any other safety audit checklist approved by the Lab, perform a Safety Audit.
3. List all areas identified as deficient or noncompliant from the safety audit findings. Specify if the deficiency applies to all areas of the laboratory or only to specific sections of the laboratory. E.g. "the Lab does not have suitable chairs" instead of " Hematology and bleeding room have chairs that are absorbent to fluids, hence not suitable for lab use"
4. Present the audit findings to the laboratory staff and upper management. Document the minutes for these meetings.
5. Propose corrective actions for all identified areas that include an action plan developed with clear timelines. The proposed corrective action should be based upon the cause or reason for the deficiency. See table below

Deficiency Identified	Cause or Reason for the Deficiency	Proposed Corrective Action	Action Plan					
			Task to be completed	Who is responsible	By When	Review 1	Review 2	Review 3
			1)					
			2)					
			3)					
			1)					
			2)					

1) Document all corrective and follow-up actions taken.
2) Review the action plans at after each due date and document progress or proposed new dates.
3) Perform the final safety audit at the end of the Improvement Project
4) List the audit findings and action items as done at baseline
5) Review the findings
   - Which areas were able to be sustained?
   - Is there a need to train the rest of the staff in the newly introduced and sustained areas?
   - Which areas persisted as non-conformities and why? What is the plan for the Lab to resolve these?
6) Compile a report to report at the next SLMTA workshop

This improvement project supports the following SLIPTA checklist items:

All questions under Section 12 of the checklist

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Improvement Project: Documentation

Documentation: Improving documentation in the Laboratory

The clause below refers to documentation and document control from ISO 15189:

Clauses 8.3.1 and 8.3.2*: The laboratory shall control documents (internal and external) that relate to the fulfilment of this document. The laboratory shall ensure that documents: are uniquely identified; are approved for adequacy before issue; periodically reviewed and updated as necessary; relevant versions of applicable documents are available at points of use; changes and the current revision status identified; are protected from unauthorized changes and access; the unintended use of obsolete documents is prevented; and at least one paper or electronic copy of each obsolete controlled documents is retained for a specified time period or in accordance with applicable specified requirements.*

Data Collection Tool

#	Document (SOP/Policy/Works station Tasks/Log/checklist etc)	In Place (Yes/No)			
		Baseline Yes/No	Comment (Draft, authorized, expired, read by all staff)	Final Yes/No	Comment (Draft, authorized, expired, read by all staff)

Steps

1. Discuss the Improvement Project in the team meeting
2. Assign all sections to:
    - Make a list of all activities and tests conducted in their section

<u>SOPs</u>

- Using the data collection tool above, list the SOPs needed for each of the procedures and activity listed
    - E.g. In Chemistry, activities include: Chemistry testing using Selectra junior Analyzer: ***SOP for chemistry analysis using Selectra Junior***
    - Maintenance of Selectra Junior: ***SOP for Maintenance of Selectra Junior***
    - Training Plan

<u>Training Plans</u>

- Training plan for each test or workstation listed above

<u>Logs</u>

- Maintenance logs for Selectra Junior, centrifuge
- Temperature logs for fridge, freezer and room
- Cleaning of room and bench surfaces logs
- Quality Indicator monitoring logs

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Checklists

- Competency Assessment checklists for chemistry testing using Selectra Junior

NOTE: Do this for all sections of the laboratory, including sample reception, sample referral, cross check areas, store room, phlebotomy.

3. Include all SOPs and Policies required by the WHO AFRO SLIPTA checklist.
4. For each document, indicate under comments section whether it is:
   - In place or not?
   - In draft form?
   - Authorized?
   - Expired?
5. After listing all the documents count how many:
   - Are supposed to be in place?
   - Are in place?
6. For those in place how many are:
   - In draft?
   - Expired? or
   - Read by all staff?
7. After collecting baseline data, present to lab team. Document minutes.
8. List improvements that need to be put in place. Formulate an Action Item table

Deficiency Identified	Cause or Reason for the Deficiency	Proposed Corrective Action	Action Plan					
			Task to be completed	Who is responsible	By When	Review 1	Review 2	Review 3
			1)					
			2)					
			3)					
			1)					
			2)					

9. Continue monitoring the progress of the project by reviewing monthly
10. At the end of the project timeline, collect final data using the same data collection tool 1-2 weeks before next workshop
11. Compare baseline and final data results. If there are still some outstanding action items or new ones, list the action items as done at baseline
12. Compile a report to report at the next SLMTA workshop

All documents produced must follow the laboratory document control system. i.e. the document must have:

- Document control number
- Version number
- Author
- Authorizer
- Effective date
- Date of retrieval
- Laboratory name/ministry of health
- Page numbers

All documents must be listed on the document Master list

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This improvement project supports the following SLIPTA checklist items:

1.3 Has the laboratory management established and implemented a document control system to control all documents and information from internal and external sources?

1.4 Are there records detailing all documents of the laboratory management system and indicating their editions and distribution?

1.6 Are quality documents (paper based and or electronic copies) easily accessible, available, and written in a language commonly understood and communicated to all relevant personnel?

1.7 Do all quality documents have a record to reflect when it was approved for use, its review and revision history, its version, its location and when it was discontinued?

1.8 Are invalid or discontinued quality documents identified, clearly marked, removed from use and one copy retained for reference purposes?

3.9 Is there a program for training, continuing education and professional development?

3.11 Does the Laboratory assess the competency of its personnel according to its defined criteria for all relevant activities?

4.8 Is laboratory information available for patients and laboratory users in the language understood by the community?

5.12 Is routine preventive maintenance performed on all equipment and recorded according to the manufacturer's minimum requirements?

8.2 Has Laboratory management developed and implemented a continuity and emergency preparedness plan covering all laboratory operations (including equipment failure)?

8.12 Are examination information and instructions available in appropriate locations?

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Improvement Project: Internal Audit

Internal Audit: Implementing, conducting and improving performance on internal audits

The clause below refers to internal audit from ISO 15189:

Clause 8.8.3.1*: The laboratory shall conduct internal audits at planned intervals to provide information on whether the management system conforms to the laboratory's own requirements for its management system and to the requirements of this document and is effectively implemented and maintained*.

Data Collection Tool

Section 1: Documentation							
	Baseline			**Final**			**Comment**
	Y	**P**	**N**	**Y**	**P**	**N**	
Is there a SOP on how to conduct Internal Audit?							
Is there a person trained in conducting internal audits (Manager, Quality Manager or someone else)?							
Is there an internal audit checklist							
Section 1: Total Marks							
Section 2: The Audit							
	Baseline			**Final**			
Total Internal Audit Marks							
Total number of conformities (YES)							
Total number of Partials (P)							
Total number of non conformities (NO)							

Steps

1. Discuss the Improvement Project in the team meeting.
2. Set action items relate to the Improvement Project. Some of the action items will have specific activities to be dome to achieve the action item e.g. if there is no internal audit SOP
    - Action Item: Quality Officer to write SOP
    - Activities:
        - QA Officer draft SOP
        - Supervisor review SOP
        - QA Officer train staff on SOP
3. Using the internal audit checklist perform an internal audit.
4. List all areas identified as deficient or noncompliant from the internal audit findings. Specify if the deficiency applies to all areas of the laboratory or only to specific sections

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of the laboratory. E.g. instead of saying "Lab not performing IQC consistently but say CD4 section not performing IQC on the FACS Count"

5. Present the audit findings to the laboratory staff and upper management. Document the minutes for these meetings.
6. Propose corrective actions for all identified areas that include an action plan developed with clear timelines. The proposed corrective action should be based upon the cause or reason for the deficiency

Deficiency Identified	Cause or Reason for the Deficiency	Proposed Corrective Action	Action Plan					
			Task to be completed	Who is responsible	By When	Review 1	Review 2	Review 3
			1)					
			2)					
			3)					
			1)					
			2)					

1) Document all corrective and follow-up actions taken.
2) Review the action plans at after each due date and document progress or proposed new dates.
3) Perform the final internal audit at the end of the Improvement Project
4) List the audit findings and action items as done at baseline
5) Review the findings
   - Which areas were able to be sustained?
   - Is there need to train the rest of the staff in the newly introduced and sustained areas?
   - Which areas persisted as non conformities and why? What is the plan for the Lab to resolve these?
6) Compile a report to report at the next SLMTA workshop