



STANDARD OPERATING PROCEDURES (SOPs) FOR MEDICAL QUALITY ASSURANCE (QA) AUDITS

UNITAID Private Sector RDT Project

Medical QA audits target to the wider frame of fever case management (FCM) quality standards and evaluate if activities implemented within the UNITAID project are in fulfillment with international standards on clinical service delivery. SOPs for audit are required to standardize the process that evaluates FCM quality standards in the 5 UNITAID countries. The main output of audits is a list of findings and follow-up actions to raise the bar of quality in FCM service provision.

SOPs for audit should follow the 6 main components of audits:

1. **Auditor orientation** between the auditor, country medical coordinator, supervisors and country teams,
2. **In-country management review/orientation meeting** between supervisors, country medical coordinator and country teams to review the country program approach focusing on service delivery models, type of outlets employed and supervisory systems,
3. **Document and service statistics review**,
4. **Site visits** conducted by the auditor and the country medical coordinator on project sites, supported by country teams as appropriate,
5. **Debrief** at which observations and conclusions from the visits will be discussed and at which country teams and supervisors will address any concerns with development of an action plan,
6. **Audit report** which will be reviewed by the medical coordinator. Country teams will be required to respond and develop an action plan for key findings and follow-up activities.

COMPOSITION OF THE AUDIT TEAM

The QA audit team will be composed of the auditor (the QA Advisor or an external auditor), the country medical coordinator, plus relevant country staff and supervisors. The auditor will have inside knowledge of FCM, the country program, and the country context that will allow him/her to bring a complementary perspective to the audit. The role of the programmatic auditor will be to focus on factors such as:

- Assessing supervision system to ensure it operates in accordance with the UNITAID QA plan;
- Assessing the adequacy of supervision systems, including factors such as supervision frequency, quality of feedback and appropriateness of actions taken in response to feedback, etc;
- Assessing adherence to national guidelines, FCM quality standards, SOPs, algorithms and guidelines on record-keeping, counseling, and referrals.

PLANNING FOR AN AUDIT

1. The auditor will participate in an **orientation** (in person or by phone) by the country medical coordinator, country team and supervisors. The objectives of this orientation will be to:
 - a. Review the planned agenda/schedule for the visit,
 - b. Orient the team to the evaluation philosophy, tools and instruments to be used,
 - c. Brief the team on any problematic issues they are likely to face,
 - d. Address any questions or concerns the team members might have.

Responsibility: The county medical coordinator will conduct the auditor's orientation prior to the audit. Prior to the visit, the auditor will also be responsible for reviewing country QA plans and reports from previous audits.

2. In-country **management review** by country program staff. Objectives:
 - a. The auditor will become oriented to:
 - the local "platforms" (type of providers, supply channels, outlets, etc.),
 - challenges noted by local program staff in meeting their objectives,
 - b. Review the country-specific QA plan developed by local country team with focus on assessments and monitoring systems,
 - c. Review service statistics accumulated during the evaluation period, including numbers of providers trained, clients served, outlets enrolled, etc.

Responsibility: Country teams should prepare briefing documents and presentation, while the auditor will get most of this supportive material through the DHIS2.

3. **Document review:** to audit the presence and utility of documentation being used in-country as record outlet checks, training manuals, job-aids, etc. The auditor will:

- a. Conduct a review to ensure that key QA tools are in place and assess quality and comprehensiveness of documents, including protocols and policies,
- b. Also look for documentation related to assessment records, including:
 - Evidence of sign-off by supervisors before providers begin service delivery,
 - Records and findings of provider performance assessments,
 - Documentation of steps taken following assessments, etc.

Responsibility: Prior to the document review, the county team should pull together documentation and have it easily accessible for the auditor to review. Again, the auditor will combine this information with the ones obtained through the DHIS2 and will review supervisory reports.


4. **Travel to field sites** to directly observe quality of FCM at provider level and review on-site documentation in a sampling of outlets countrywide. The auditor will:
 - a. Evaluate the components of quality being assessed (e.g. technical competence, client safety and counseling, outlet adequacy, etc.). To record the quality of FCM at provide level, the auditor will use the audit scorecard, based on service delivery standards for FCM. Refer to Annex 1 for further information.
 - b. Provide feedback to country teams and country medical coordinator concerning observations in the field,
 - c. Observe and evaluate assessments being conducted by supervisors,
 - d. Create summary of findings and recommendations.

Responsibility: the auditor should be accompanied by the country medical coordinator, supervisors where needed, and appropriate country team.

5. **De-briefing** with senior country staff. The auditor will:
 - a. Present observations, conclusions and recommendations,
 - b. Take the lead in providing service delivery “lessons learned” to project/MoH staff by other UNITAID countries,
 - c. Facilitate creation of an action plan in collaboration with local country team,
 - d. Give an update on specific topics (biological waste disposal, danger signs, treatment of uncomplicated vs complicated malaria, etc.) if desired/requested by either country team or project partners,
 - e. Listen to and record feedback or questions and concerns from local staff about challenges they face in regards to ensuring QA best practices in FCM of the UNITAID project and also concerns related to the audit visit.

Responsibility: The auditor will debrief the country medical coordinator, country teams and supervisors.

6. The country medical coordinator, supervisors and country team will write an **evaluation report** to be provided to the auditor within 2 weeks of leaving the field. The report will include



observations, conclusions and recommendations. The auditor will determine priority findings and country teams will prepare an action plan based on auditor's feedback.

Responsibility: The audit team in country will prepare the report and send it to the auditor, who will then share it with relevant UNITAID project staff.