

## Question 2: What are effective and sustainable mechanisms or processes to integrate local, community, sub-national, national, and regional voices, priorities, and contributions into health system strengthening efforts?

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# Process of institutionalizing the quality management system of community laboratories in Mali



### CONTEXT

On national scale in Mali, there are no statistics on the availability of laboratories at the community level. However, at the start of the USAID project to strengthen the health system, Mali had 680 health structures: 654 Community Health Centers (CSCoM) and 26 Reference Health Centers (CSRef) in the 3 intervention regions. Of those 680 facilities, only 14% had a laboratory. This situation reflects the low availability of laboratory services at community level. So access to high-quality laboratory services at the community level is a health problem to be solved in Mali.

Mali's laboratory system faces a number of challenges, including the lack of a high-quality management system that is up to standards, inadequate funding for activities under the national strategic plan for laboratories, poor availability of human resources, and lack of coordination of laboratory strengthening activities. These challenges serve to lower the quality of laboratory services at the community level, thereby exposing clients to poorly effective or ineffective treatment, inadequate public health decisions, loss of financial resources and, ultimately, lessening the credibility of the health system.

Prior to the intervention of USAID's Health System Strengthening Project, the ways in which the aforementioned problems in Mali's laboratory system were resolved were as follows:

- Investing in initial and continuing training for laboratory professionals
- Creating the National Laboratory Network in August 2004;
- Adopting and disseminating the Guide to Good Analysis Practice (*Guide de Bonne Exécution des Analyses* - GBEA) in 2005
- Training a pool of SLIPTA-certified national assessors in 2013 and 2016
- Developing a National Policy for Medical Biology Laboratories (PN-LBM) in 2012
- Devising a National Strategic Plan for Medical Biology Laboratories (PSN-LBM) in 2017
- Creating the National Institute of Public Health (*Institut National de Santé Publique* - INSP) in 2019, which houses the National Reference Laboratory.

On the other hand, CSCoM level community laboratories were not sufficiently involved in these interventions. Sub-national players (regional, districts) were also absent from carrying out these interventions. Similarly, these interventions did not take into account the implementation of a quality management system (QMS) in accordance with ISO 15189 in community laboratories at the CSRef and CSCoM levels. In addition, they did not cover 100% of the community laboratories in a given region of Mali, and laboratory staff did not receive QMS training.

Those gaps serve to limit the quality of laboratory services offered at the community level, and increase non-compliance with the QMS requirements of ISO 15189.

To address these gaps, the USAID Keneya Sinsi Wale (KSW) project for strengthening the health system in Mali is supporting the implementation of ISO 15189 QMS in CSRef and CSCoM community laboratories. In addition, the project has proposed an innovative approach to supporting laboratories through mentoring visits for setting up the QMS in laboratories, while ensuring total coverage of those laboratories in its 3 intervention regions. With this approach makes, sub-national players (regional and districts) can be involved in close collaboration with national players, thereby ensuring the sustainability of activities.

WHO-Afro considers setting up the QMS to be the best strategy for upgrading laboratory capabilities. It is an invaluable process enabling laboratories to improve the quality of their services and play their role to the fullest.

### RESULTS

The SLIPTA baseline assessment carried out in 56 laboratories in 3 regions (Sikasso, Ségou and Mopti) showed that the **average level of compliance at the baseline was 18%**. During this initial assessment, all 56 laboratories obtained 0 stars out of a possible 5. **Documentation was the weak link in these laboratories' QMS (Figure 2).**

The **15 mentors** (2 women and 13 men) selected **received a series of practical training courses between September 2021 and September 2022** with the support of the project. The level of knowledge increased from **46% to 75%** during the **training on mentoring techniques**, i.e. an average gain of 22%, during the **training on malaria diagnosis** (from **56% to 78% in parasite detection** and from **36% to 58% in parasite identification (Figure 3)** and from **55% to 80%** during the **training on preventive maintenance (Figures 4)** with the support of the project.



Figure 3: Practical training for mentors in microscopic malaria diagnosis



Figure 4: Practical training for mentors on preventive maintenance of laboratory equipment



Figure 5: Niono CSRef mentor and laboratory staff commit to producing high-quality documents

The **mentoring visit** was made to **88 community laboratories** in the 3 regions between **August 2022 and December 2022**. It served to upgrade in-situ the technical skills of 146 people (42 women and 102 men) in microscopic diagnosis of malaria, the and interpretation of rapid diagnostic tests (RDTs) and setting up priority quality documents in QMS (**Figures 5**).

After the mentoring visit, a second SLIPTA assessment was done in the laboratories supported by the project. The results of that second assessment showed that the **laboratories that had received USAID KSW project 4-month mentoring support improved significantly (an average gain of 10% or 27.5 points out of a total of 275 points), showing a difference compared with laboratories outside the project's intervention area that had not received support (Figure 7).**

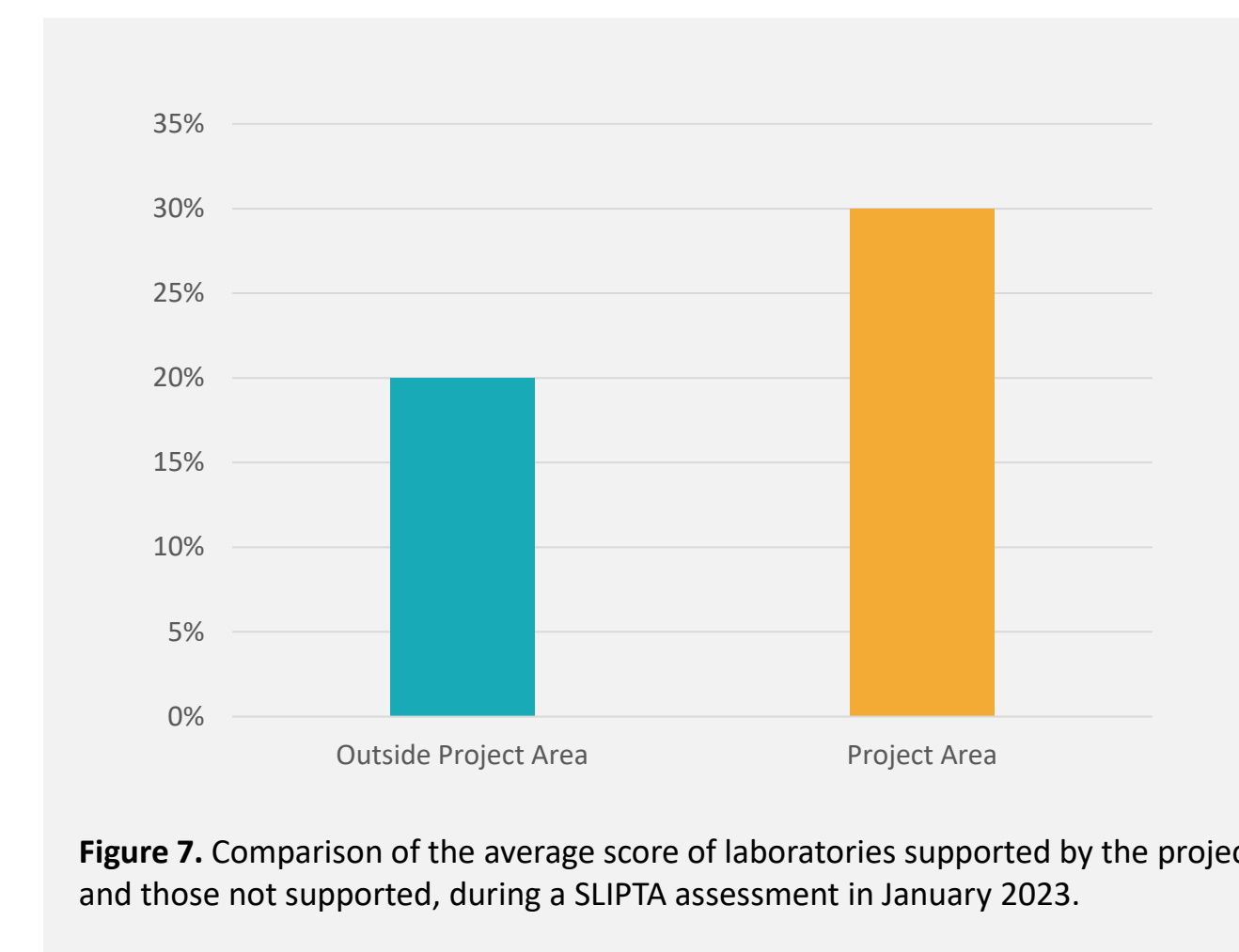


Figure 7: Comparison of the average score of laboratories supported by the project and those not supported, during a SLIPTA assessment in January 2023.

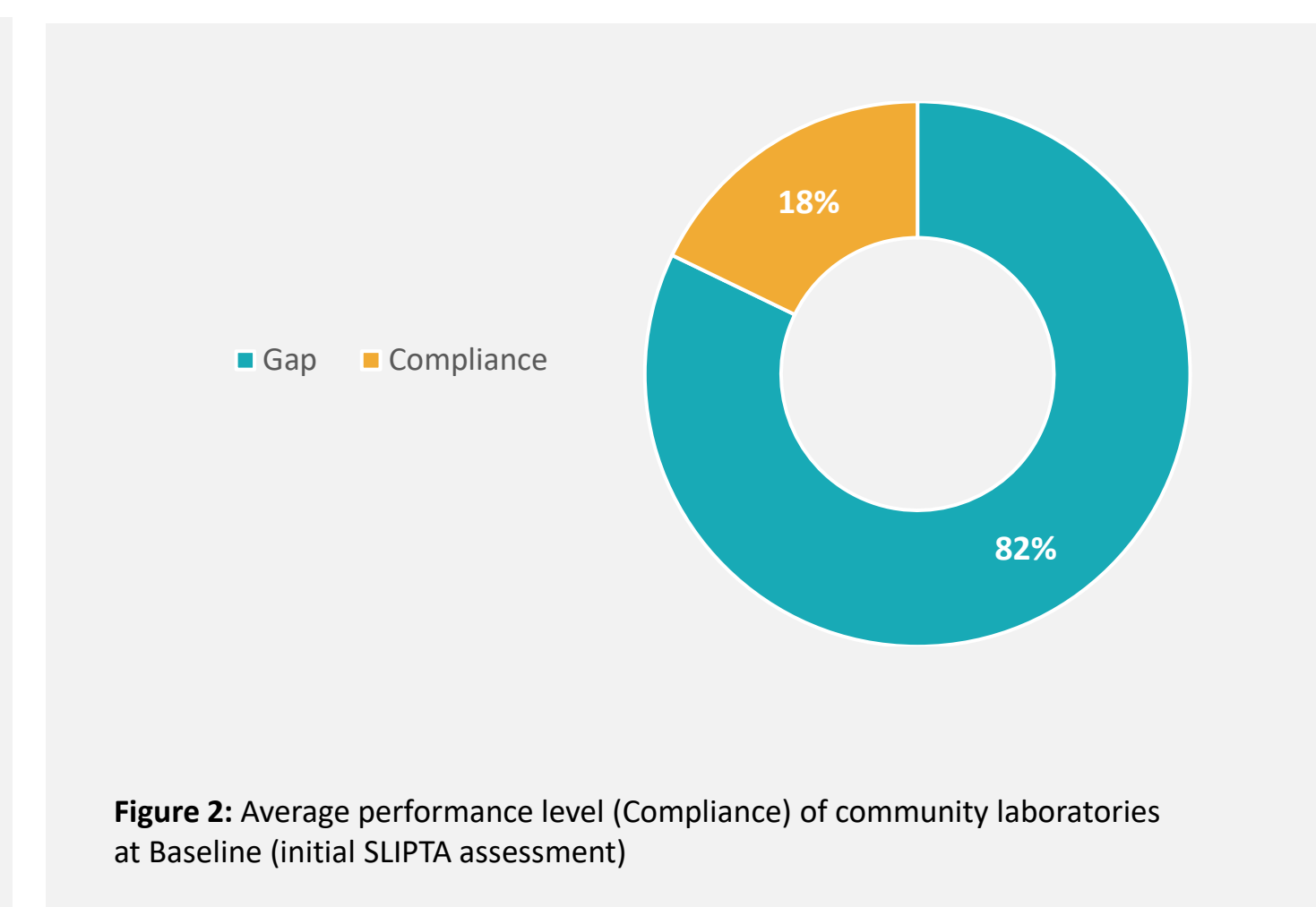


Figure 2: Average performance level (Compliance) of community laboratories at Baseline (initial SLIPTA assessment)

### ACTIVITY DESCRIPTION

The in situ mentoring approach was used to address the systemic causes of QMS gaps in community laboratories. The process of implementing this approach is described in **figure 1**. The various stakeholders in this process are :

- INSP** (National Institute of Public Health - *Institut National de Santé Publique*): is responsible for steering, coordinating and technically carrying out laboratory strengthening activities. It houses the National Reference Laboratory and the Quality and Biosafety Biosecurity Department. The execution of the activities was placed under their technical leadership in order to secure their commitment.
- DGSHIP** (Central Department of Health and Public Hygiene - *Direction Générale de la Santé et de l'Hygiène Publique*): is responsible for steering and coordinating activities conducted in healthcare facilities.
- DRS** (Regional Department of Health - *Direction Régionale de la Santé*): coordinates and supervises the implementation of activities in health facilities at the regional level. A mentor has been selected in each DRS and is involved in the process at every stage.
- Health District Executive Team** (*Équipe Cadre du District Sanitaire* - ECD) at the CSRef level: is responsible for planning, coordinating and supervising activities in the health structures at the operating level (CSRef and CSCoM). The CSRef is the first-level reference structure and, together with the CSCoM, constitutes the health facilities in contact with the community.
- CSRef level Mentors**: These mentors are part of the CSRef laboratory staff and have been selected based on their competence. The involvement of CSRef laboratory staff as mentors enables total coverage of community laboratories by region, and a gradual transfer of skills between the national and sub-national levels.

To ensure proper adoption of the in situ mentoring approach, national and sub-national players were involved at various levels in the interventions below:

- Initial status: Using the WHO Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA) tool, a baseline assessment was done in 2021 in 56 community laboratories. That was the first time that CSCoM-level community laboratories underwent a SLIPTA assessment (source INSP). It was carried out by the national assessors.**

- Producing reference documents:** A pool of national laboratory experts was mobilized to draft reference documents based on a root cause analysis of the laboratory gaps identified during the initial assessment.
- Skills upgrading:** in two phases
  - Selection of mentors:** 15 mentors were selected in the project's areas of intervention, made up of 3 pharmacists (in the Regional Health Departments: DRS) and 12 senior medical biology technicians (in the CSRef laboratories).
  - Skills upgrading for mentors:** Mentors received a series of training sessions on technical skills for mentoring: in the laboratory, **microscopic diagnosis of malaria, preventive maintenance of basic laboratory equipment, and producing and using high-quality documents.**
- In-situ mentoring visits:** mentors conducted in-situ visits to community laboratories. These visits enabled the mentors to support the laboratories in reducing their quality management system deficiencies through **in-situ skills upgrading activities for laboratory staff**. The mentors **finalized an improvement plan with the staff of each laboratory** to support the implementation of **high-priority QMS activities**.
- Measuring the results/impacts of in-situ mentoring :**
  - A second SLIPTA assessment was done in 2023 to measure the laboratories' progress** in implementing the QMS. This made it possible to compare the current average level (2023) of the laboratories with that of the initial assessment (Baseline, 2021). This 2023 assessment also made it possible to compare the current level of laboratories in the project area with that of other laboratories outside the project area.

### IMPACT

- Activities to set up mentoring visits in community laboratories have provided Mali with a **pool of 15 trained mentors** capable of supporting laboratories in setting up a quality approach that meets the requirements of international standards.
- Conducting mentoring visits has laid the **foundations for a culture of continuous quality improvement** in providing laboratory services at community level.
- The activities carried out have enabled the **laboratories to improve their level of performance in terms of QMS implementation**, while also improving **compliance with international standard requirements**. In 4 months of mentoring, the average level of performance of Community Laboratories rose from **18% to 30%** in the KSW project areas (**Figure 10**).
- The progress made by community laboratories in the KSW project areas means that some of them can now **look forward to working toward ISO 15189 accreditation**.
- In the same vein, the mentoring visit approaches help to secure the commitment of the municipality and community health associations (ASACO) to equip their community health structure with laboratory services. As a result, today the **number of community laboratories has risen from 95 in 2021 to 118 in January 2023 (figure 11)** in the 3 regions of operation of the USAID KSW project, which aims to strengthen Mali's health system.
- Laboratory staff at CSCoM Sanouougou 2 received in situ training and mentoring, enabling them to produce basic quality documents, develop and validate SOPs for analyses, improve the use and preventive maintenance of essential equipment, and keep reagents up to date. Those achievements have improved the laboratory's quality compliance level from 60/275 points at baseline assessment to 85/275 after 6 months. Staff at 84 other laboratories in the Sikasso, Ségou and Mopti regions, in addition to Sanouougou 2, received similar training and mentoring from USAID KSW (figure 12).

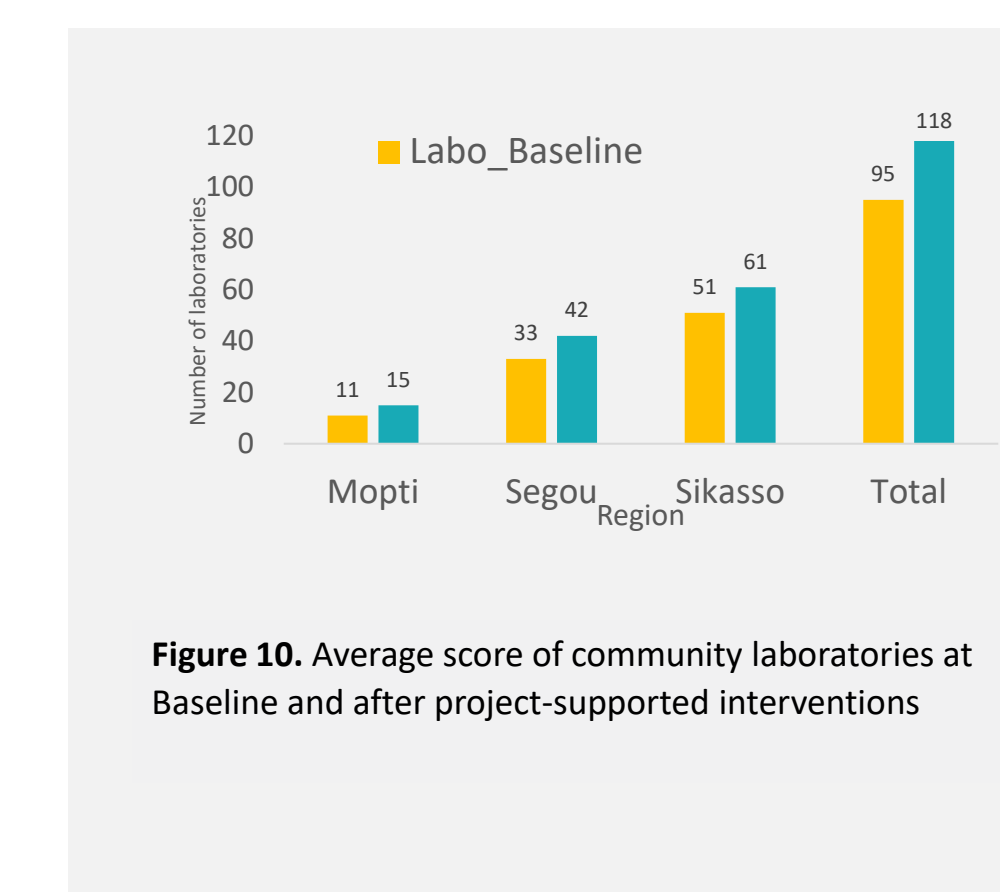


Figure 10: Average score of community laboratories at Baseline and after project-supported interventions

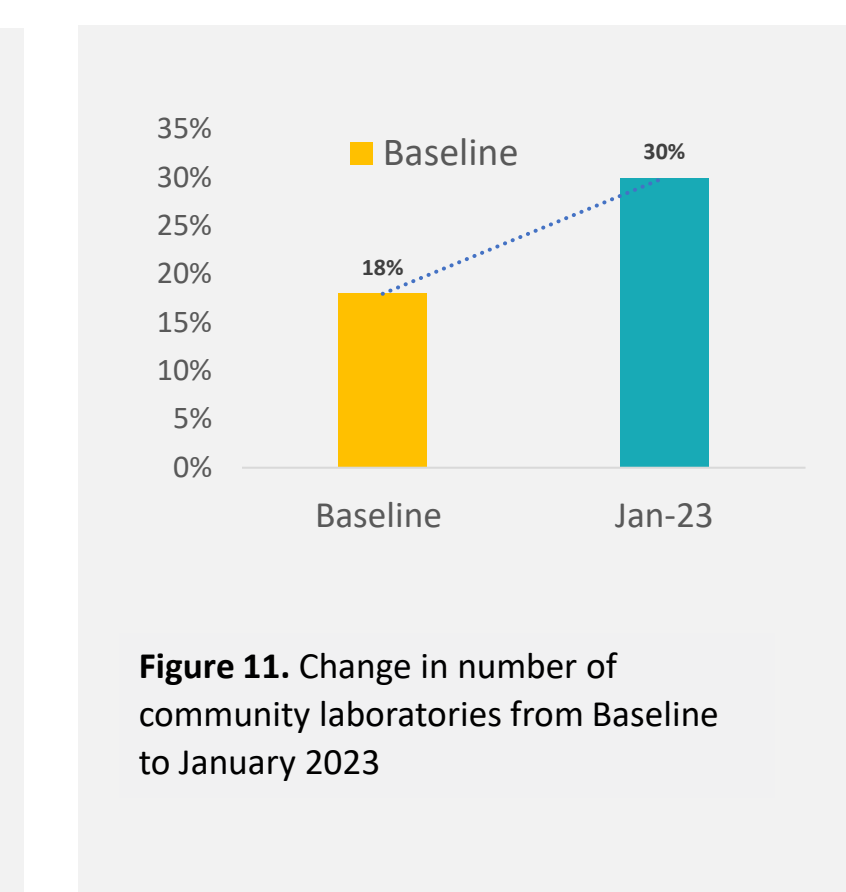


Figure 11: Change in number of community laboratories from Baseline to January 2023



Figure 12: Success story based on direct recipient's testimonial about the impact of mentoring visits (USAID | Mali site)

