EQASIA: Improving the Quality of Bacteriology Diagnostics for AMR in the Asian region

The overall aim of the EQASIA project is to improve the quality of bacteriology diagnostics for AMR in the Asian region. The project is split into two phases and each phase is explained in more detail below.

Phase I: Mapping of coverage, availability and uptake of EQA programs across One Health (OH) sectors
In the initial phase of the EQASIA project (Jan-Sep 2020), the coverage, availability and uptake of external quality assurance (EQA) programs across the One Health sector was mapped to create recommendations on the implementation of a high quality, standardized EQA program in the Asian region.

Through an initial desktop review and a comprehensive stakeholder consultation we identified relevant National Reference Labs (NRLs) in Asia, the primary target recipients of the subsequent EQA provision across the One Health sector. Through additional online surveys and follow up interviews we obtained more detailed information on existing programs and challenges to participation in, and provision of, EQA for AMR. Figure 1 gives an overview of participation in EQAs for the human and animal health in the region, as well as EQA provision of both sectors in the region.

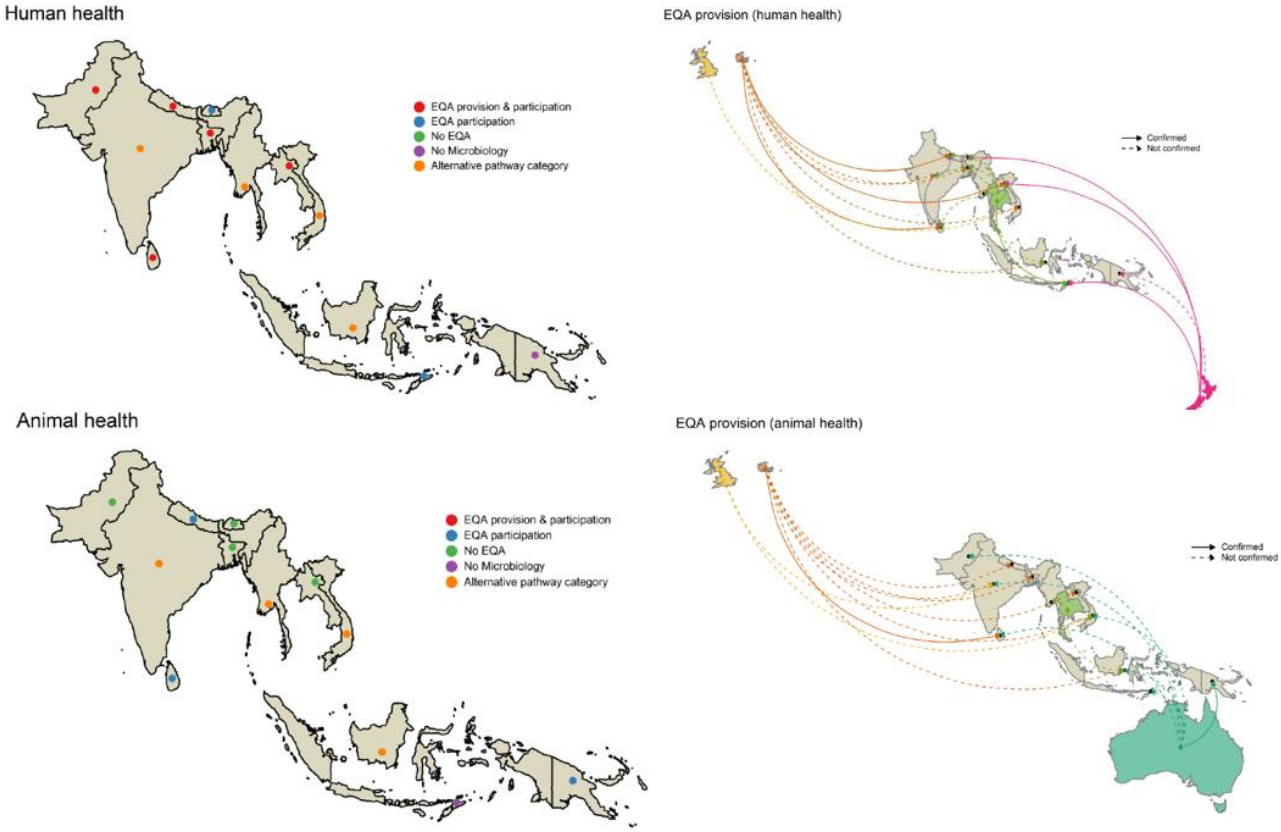

Figure 1: Overview of EQA participation and provision in the South- and Southeast region of Asia.

Based on the EQA participation surveys, it was clear that most of the NRLs for human health (HH) participate in several different EQA programs for AMR suggesting there are some overlaps. However, gaps in the content and comprehensiveness of individual programs also seems to be a contributing factor to why NRL's choose to participate in multiple programs. Some of the HH NRLs also stated that they provide EQAs to sentinel labs within their own country. Few animal/food safety labs currently participate in EQAs. The major challenges identified by labs were cost of participation and consumables and lack of support for participation and corrective actions.

Several different international EQA providers were identified (figure 1). The major challenges identified by current EQA providers were lack of efficient IT systems for reporting and analysis and limited resources to support comprehensive follow up activities for participating labs.

Two of these regional institutions (NIH Thailand and Faculty of Veterinary Science, Chulalongkorn University) are already established EQA providers in the Asian Region supported by WHO and FAO, respectively, and will be regional providers for the implementation phase.

Based on these findings, the recommendations suggested for the second phase of the project was to

- expand the consortium with NIH and Chulalongkorn University and to form a scientific advisory board
- perform a baseline assessment in phase II and grouping laboratories in the capacity building activities
- establish a free of charge and comprehensive "One-shop EQA program" for antimicrobial susceptibility testing and ID including IT module that enables instant reports
- create a post-project steering committee for sustainability of the program, identifying potential future donors and make a cost analysis and forecasting of the EQA program to determine the post-project financial sustainability.

Phase II: Strengthening external quality assurance for AMR in Asia

In the implementation phase (Oct 2020-Feb 2022), EQASIA will provide a state of the art "One-Shop EQA program" free of charge for the Asian region through existing local providers (NIH Thailand and Faculty of Veterinary Science, Chulalongkorn University).

The program will be designed to enable labs to select and participate in relevant proficiency tests of both pathogen identification and antimicrobial susceptibility testing (AST). There will be 3 rounds of EQA during 2021. The panel options that labs can choose from will include all GLASS pathogens as well as specific food and animal sample matrices for testing.

The EQAs will be supported by training workshops, an IT module that enables instant reports as well as relevant follow up activities to underperforming labs. Financial support for procuring IT equipment, consumables etc. will also be available if needed for efficient participation.

The "One-shop" EQA program

In the "one-shop" EQA program, laboratories will be able to choose which organisms in the provided EQA they find relevant and have capacity to participate in – hence, the name "one-shop". The EQAs will focus on all 11 WHO GLASS-pathogens as well as a specific matrix EQA, which aims to assess the veterinary laboratories' ability to detect ampC beta-lactamases (ampC), extended-spectrum beta-lactamases (ESBL) and carbapenemase producing *E. coli* from animal caeca samples and food matrices.

Table 1 gives an overview of the trials and pathogens in the project. The first trial with *Salmonella* and *E. coli* will be repeated in trial 3 and will allow for a continued assessment of the capacities, allowing also the possibility to monitor improvements in the ability to correctly identify and antimicrobial susceptibility test these two organisms. The intention is to continue with two annual trials including all WHO GLASS organisms beyond the lifetime of EQAsia.

Table 1: Overview of EQA trials in EQAsia.

Trial	Pathogens
First EQA (February 2021)	*Salmonella* spp. *Escherichia coli*
Second EQA (June 2021)	*Klebsiella pneumoniae* *Shigella* spp. *Acinetobacter* spp. *Staphylococcus aureus* *Streptococcus pneumoniae* *Neisseria gonorrhoeae* Matrix EQA (ampC, ESBL and carbapenemase producing *Escherichia coli)*
Third EQA (October 2021)	*Salmonella* spp. *Escherichia coli* *Campylobacter* (*C. coli* and *C. jejuni*) *Enterococcus* (*E. faecium* and *E. faecalis*), *Pseudomonas aeruginosa*

The EQA program will be supported by an informatics EQA module for the "One-Shop EQA programme" where laboratories can sign up and also report their results and methods. The EQA administrator at DTU will have access to all data and be able to customize reports to obtain an overview of the participants' performance, as well as identify underperformance and users in need of follow-up in form of capacity building or site visit(s). "Super-user"-rights to the system can be granted to individual country NRLs, allowing them to re-use the EQA panels for launching nation-wide EQAs for local and regional laboratories providing monitoring data for the country surveillance of AMR.

Capacity building activities

As an initial step, a baseline symposium will take place to bring together NRLs/CEs and other relevant participants, such as FF country grantees and FF Regional Hubs in Asia. The meeting will be an opportunity to assess in more detail the individual NRLs participants' interest, needs and readiness to participate in the implementation phase of the project as well as to provide more information about the planned EQAs and associated workshops.

Training workshops

To build further capacity in the Asian region and to support the participation in the EQAs, two workshops will be arranged. The workshops will take place before each of the first two rounds of EQAs. Figure 2 gives an overview of the workshops.

The workshops will be split into two groups with different training scopes. Group 1 will consist of EQA providers, whereas group 2 will be NRLs/CEs with a need for training to facilitate participation in the EQAs.

The training for group 1, the EQA providers, will focus on general requirements for proficiency testing scheme providers, which include building knowledge of ISO17043:2010. The providers will also be

trained in the two major Quality Management Systems (QMS); International Organization for Standardization (ISO) and CLSI.

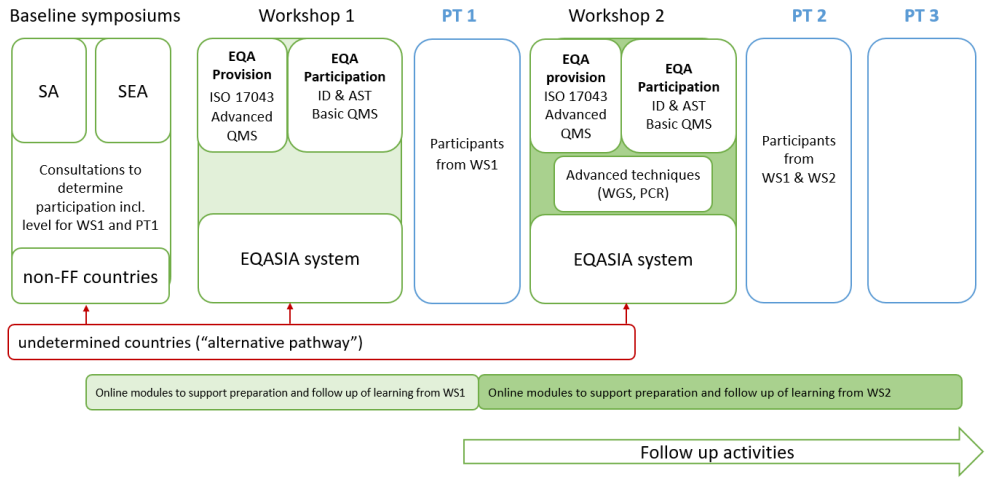

Figure 1: Overview of the capacity building activities in the project.

The training for participants in group 2 will focus on effective and safe participation in EQAs. The training will be hands-on, demonstrating quality assured methods for basic AST including disk diffusion, broth micro-dilution and gradient strip tests, as well as ID of test strains. Participants in group 2 will also be trained in basic QMS.
On the last day of the workshop, there will be joint training for both groups on the EQASIA informatics EQA system. Here, the participants will receive hands-on training on e.g., how to enroll in the program, choose relevant EQA modules, submit results, review of performance and corrective actions exercises.

The second workshop will have the same overall scope as workshop 1 to allow for later inclusions of countries/labs not ready to participate in workshop 1. To further build capacity for participants from workshop 1, there will, however, be an additional module in workshop 2 concentrating on training in advanced techniques. This training will focus on the conceptual application of WGS including the theory, outsourcing for whole genome sequencing, as well as practical exercises.

Evaluation and improvement of EQAs in the laboratories
To evaluate and improve the participant's ability to obtain correct results in the EQAs, the participant's scores for the EQAs will be evaluated to detect underperformance, which will be addressed by follow up visits to the laboratory. The aim of the follow up visit is to determine the root cause for the identified gaps by the EQA and develop targeted corrective and preventive actions to improve pathogen identification and AST services in AMR NRLs.

Sustainability
The EQASIA project is supported by a scientific advisory group with representatives from WHO, FAO, OiE and regional centers of excellence in EQA provision.
To sustain the EQASIA program beyond the project period, it is crucial that the EQAs remain free of charge to ensure participation and prioritization and that the program will be adopted by a supranational organization, e.g. WHO or FAO, and supported with additional funding.

Considering this need for a “free of charge” EQA program and to determine the post-project financial sustainability, a cost analysis and cost projection component will be conducted to give an overview of expenditures and future needs for funding.
As a separate activity, the consortium will also map potential regional and local donors including current funders for capacity development in the Asian region.
The final sustainability plan for the EQA program will be drafted at an interim meeting and decided on the exit meeting, where a post project steering committee will also be established.