GLOBAL TASK FORCE ON CHOLERA CONTROL

National Level Documentation List

Documentation which would support national level review and scoring. This list should be provided to the cholera program prior to the visit to enable them to locate and make the documents available.

These are examples, the program may name or structure their program in numerous ways and it is understood that the necessary information may be in differently named documents, separately or as a whole.

Additional documents can be viewed and verified during site visits or during the review meeting if unavailable at the time of initial staging.

Documents can be soft or hard copy and maybe named of organised in a manner other than as below.

Q. #.	Source of verification
L1	Copies of legislation either as separate bills or part of overarching bills which are cholera related, or regulations and policies related to biosafety; waste management; public health functions of the networks; and laboratory reporting of notifiable diseases
L2	Copies of documents relating to regulatory processes, how a new product is brought to market in country, copy of current list of authorized reagents for cholera testing - this could include RDTs, semi- automated or automated culture equipment and reagents, PCR equipment and cholera tests, sequencing equipment, and reagents. Reports of post market surveillance.
L3	Copy of laboratory licensing procedure, training materials, authorised certification bodies.
L4	Copies of the endorsed current national laboratory policy, national cholera plan with accompanying strategic and operational plans whenever available.
L5	Review of operational plan or relevant sections of the national laboratory plan or national cholera plan which contains the indicators and targets of the cholera program
L6	Copy of current national licensing procedure; List of laboratories licensed to carry out cholera testing.
L7	Copies of the policies, plans, regulation or legislation copies of request/reporting forms copies of standardized reporting forms and standardized procedure(s) for data collection, description of electronic system supporting the reporting of diagnostic data to local and national program
L8	Budget and national planning documents with specific lines for laboratory workforce and career development.
L9	Copies of terms of reference and organogram for national laboratory coordination unit TOR for committees Meeting minutes or other reports
L10	Earmarked budget for laboratory services and yearly balance of the government, indicating spending of laboratory services
L11	Budget and national planning documents

Q. #.	Source of verification
S1	Copies of organogram of the cholera diagnostic/ surveillance network Copies of terms of reference for each laboratory within the tiered diagnostic network List of tier-specific cholera laboratory minimal testing packages
S2	List of tier-specific cholera laboratory minimal testing packages
S3	List of tier-specific cholera laboratory minimal testing packages Evidence of implementation within the network(s): e.g., telephone directories, newsletters, meeting reports, evidence of data exchange, training, etc.
S4	Evidence of communication within the network(s): e.g., telephone directories, newsletters, meeting reports, evidence of data exchange, training, etc.
S5	Copies of terms of reference for the national reference laboratory(ies) Maps (GPS or conventional) or lists of laboratories that offer cholera services
S6	Copies of terms of reference for the national reference laboratory(ies)
S7	Program plan for facilities repairs and improvements with budget including utilities.
S8	Copies of organogram of the larger surveillance network Copies of communication between networks, meetings, trainings, telephone logs etc
C1;C3; C11	Maps (GPS or conventional) or lists of laboratories that have cholera services
C2	Estimate of the country needs for cholera diagnostic services based on epidemiology, patient accessibility, specimen referral networks, national diagnostic algorithm
C3	National cholera diagnostic algorithm as a flow chart or other documents which covers all tests, tiers and scenario
C4	Facility level confirmation through clinical interviews, request forms and data analysis
C5	Copies of procedures to ensure efficient linkage of persons or samples to testing and results. Route maps, with schedules of collection policy and procedures for result reporting back to submitting facility. Verify the availability of a specimen tracking system and evidence of recent records with review.
C6	Copies of training materials for cholera specimen collection, referral, transportation and reception.
C7	Copies of procedures to ensure efficient linkage of persons or samples to testing and results.
C8	Review national policies and SOPs for specimen transport. copies of courier's roles and responsibilities, Courier certification, evidence of sharing SOP's to all sites
C9	Examples of MTAs and MoUs
C10	Examples of facility contingency plans, and verification at facilities
R1	List of standardized reagents and evidence in facilities of compliance.
R2;	Procedure(s) for procurement and forecasting
R3	Procedure(s) for procurement and monitoring
R4	Copy of plan for standardization of equipment List of standardized equipment Regulation for control of medical devices

Q. #.	Source of verification
R5	Protocol for pre-service evaluation and validation reports (both pre-service and in-service)
R6	National maintenance plan, service records, budget allotments and planned equipment purchases
R7	Copies of relevant training curricula and schedules for managers, certification, degrees, evidence of review.
R8	Copies of trainer certification Copies of relevant training curricula for testing, biosafety, quality, management activities etc. Evidence of review and update.
R9	Competency criteria relevant to staff performing cholera testing and documentation of competence performance, list of staff currently passed competency etc.
R10	National staffing plan, routine and surge latest inventory of laboratory staff.
R11	Latest inventory of laboratory staff.
R8	National licensing procedure for laboratory professionals Copies of all training curricula, including retraining and continuous education of existing staff National staffing plan
R9;R10	Latest inventory of laboratory staff National human resource development strategy for laboratory workers
R11	Job descriptions and competency criteria relevant to staff performing cholera testing
B1	Biosafety legislation, policy and procedures available.
B2	Biosafety legislation, policy and procedures available.
B3	Policy, legislation, terms of reference, job description of safety officer functions safety officer training curriculum schedule or results of safety audits carried out.
B4	Policy documents, Verify training records and history, certification, competence, curriculum and training schedules etc.
B5	Policy in safety manual or similar.
B6	National waste management policy.
B7	Review equipment lists for autoclaves/ incinerator Verify with laboratories.
D1	Data unit roles and responsibilities Staffing records, training or competency records, data records, data system manuals, budget lines etc.
D1	Procedures that reflect the policy, Personal training records or curriculum or demonstrated staff knowledge and adherence to the policy. Verify policy is available with laboratories. Routine reports from all facilities, tracking of reporting
D3;D4;	Copies of national cholera request/reporting forms/line lists
D5	National data reports for most recent period of testing

Q. #.	Source of verification
D6	National data reports, schedule of completion, examples of feedback to laboratories, logs, planning documents showing actions taken based on aggregate data etc.
D7	Selection criteria and scoring of current electronic system, Request for proposal for electronic systems (RFP)
D8	Copies of training materials for all connectivity systems in use within the cholera laboratory network. SOP's personal training records or curriculum or demonstrate staff knowledge and adherence to the policy.
D9	Copies of reports generated by the electronic system, dashboards.
Q1	Quality management documentation including cholera specific algorithms, SOPs, forms, quality/key indicator reporting, corrective action form Verify availability of the necessary quality documents and a document control system at all levels of the diagnostic network.
Q2	National testing advice provided to facilities, distribution lists. Verified in facilities
Q3	National level has determined and communicated minimal quality (performance) indicators: number of tests performed, number of positive tests, number RDTs confirmed by culture, no growth, discordant results, requesting facilities, time for transportation, time to results time to report to surveillance unit, etc.
Q4	National policy/ guidance; QC guidelines for cholera activities
Q5	Policy or appropriate implementation EQA programs for microbiology conducted at all laboratories performing cholera testing. Verify results at laboratories.
Q6	NRL plan for visits, reports from previous months, action plans for improvements, verify with laboratories.
Q7	Policy, legislation, terms of reference, job description of safety officer functions safety officer training curriculum schedule or results of safety audits carried out.
Q8	Internal or external audit enrolment in relevant programs, laboratory quality management schedules, training materials, audit reports, action plans etc
Q9	Policy documents, Certification or enrollment into quality programs Quality program score from internal/external audits Tools or guidelines used to implement quality management activities. Meeting minutes, improvement projects, non-conformity, corrective actions etc.