REPUBLIC OF KENYA

MINISTRY OF HEALTH

KENYA INTEGRATED SAMPLE REFERRAL SYSTEMS PRACTICAL GUIDE FOR OPERATIONAL PLANNING

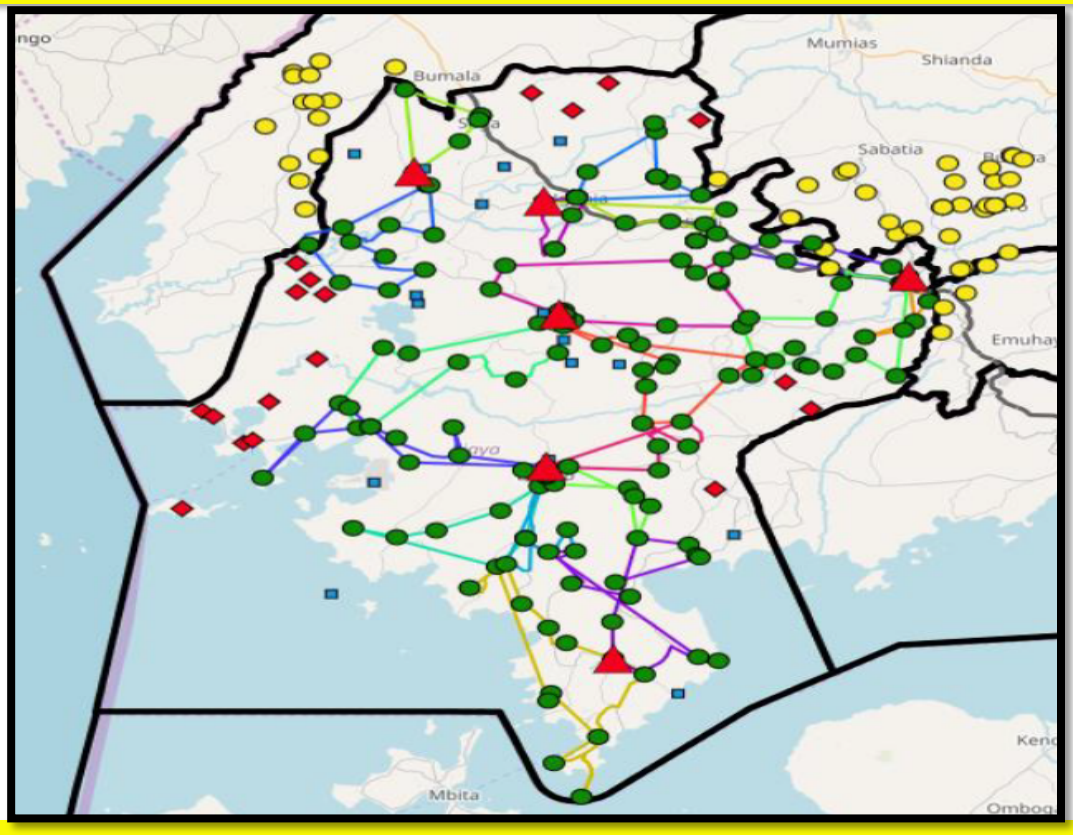

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Table of Contents

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About this guide

This guide provides practical guidance to establish integrated sample referral systems at county level, or to strengthen existing systems in line with national standards. This guide should be utilised in conjunction with Kenya's *National Guidelines for Integrated Laboratory Specimen Referral Networks (2019)*[1] and associated tools.

Target audience

This guide is intended to inform national and county Ministry of Health officials, implementing partners, programme managers, laboratory managers, donors and other key stakeholders engaged in laboratory systems strengthening or programme support.

[1] Ministry of Health. National Guidelines for Integrated Laboratory Specimen Referral Networks (2019). www.health.go.ke

Introduction

Specimen Referral Systems (SRSs) play a critical role in ensuring access to diagnostic services which underpin clinical decision-making. Referral systems can increase access to diagnostics in areas where testing is not available onsite, prevent the need and associated costs for patients to travel to access services, and contribute to equity in access to health care, improved health outcomes and enhanced disease surveillance.

Certain diagnostic tests require sophisticated equipment, infrastructure, trained staff and procedures that render them unsuitable for deployment at lower levels within a health system. Furthermore, centralized testing may be a more cost-effective way of providing quality-assured services instead of placing staff and equipment at multiple sites at lower levels of the system.

The main objectives of a specimen referral system are to:

- Increase **access** to offsite diagnostic testing,
- Meet **timeliness** requirements of diagnostic test results (i.e., meet turnaround time requirements between specimen collection and return of results),
- Ensure the **quality** of diagnostic testing by maintaining the quality of the specimens, and
- Ensure **biosafety and biosecurity** of specimen handling, storage and transportation,
- Increase **cost efficiency** of diagnostic services (which could include integration of multiple specimen or disease types, or with supplies, if integration is cost-effective), and in turn, diagnostic testing

Implementation of efficient sample referral systems has proved challenging in resource-constrained settings. Kenya has recently released its updated *National Guidelines for Integrated Laboratory Specimen Referral Networks (2019)* which is designed to guide the implementation of the laboratory element of the *Kenya Health Sector Referral Strategy (2014 – 2018)* with the application to integrated multi-disease diagnostic networks. Strengthening sample referral systems as a key objective of national disease programs, including the National Tuberculosis and Leprosy Control Programme 2019-2023 Strategic Plan[2] and NASCOP NSP (check if SRS referenced). Efficient diagnostic networks are also essential in responding in a timely fashion to disease outbreaks and for ongoing disease surveillance efforts, as well as responding to increasing burden of non-communicable diseases.

This practical implementation guide is for use at the county level and below, to translate the national guidelines, which provide a framework and standards, into actionable steps for setting up or strengthening a specimen referral system.

[2] Ministry of Health. National Tuberculosis Programme Strategic Plan, 2019-2023. https://www.nltp.co.ke/national-strategic-plan-2019-2023/

Key components of a specimen referral system are as follows:

- Program management
- Sample referral network design
- Transport
- Supplies and equipment
- Human resources and training
- Documentation, data systems, monitoring implementation and measuring impact.

Each key component area is explored in more detail in the subsequent chapters.

1. Program Management

1.1	**Establish and define roles, responsibilities, coordination and communications for county SRS technical sub-committee and other county SRS stakeholders**
1.2	**Review National SRS Guidelines**
1.3	**Conduct a situational analysis**
1.4	**Develop a strategy based on the situational analysis**
1.5	**Develop and cost annual operational plan**

Program management component includes planning, coordination and communication among key stakeholders involved in SRS.

1.1 Establish and define roles, responsibilities, coordination and communications for county technical sub-committee and other stakeholders

The county should constitute a technical sub-committee for SRSs comprised of representatives from all key stakeholders. This sub-committee should be mandated to do the following:

- Advise county health officials on SRS implementation
- Develop strategy and operational plans
- Oversee implementation of SRS
- Monitor the performance and impact of SRS
- Share best practises with other counties and national level

Representatives from the following key stakeholders may be invited to participate according to the local situation:

- County and sub-county TB coordinators
- County and sub-county HIV/AIDS coordinators
- County and sub-county laboratory technologists
- Health facility clinicians or representatives
- Implementing partners
- Monitoring and evaluation experts
- Selected representatives from national TB, HIV and other disease programmes

Defining roles and responsibilities of the sub-committee including establishing coordination, communication and reporting mechanisms should be an integral component of the planning process. There should also be a focal point for the sub-committee designated. All of the roles and responsibilities should be clearly outlined in a terms of reference (ToR) document. Active engagement of all partners involved in sample referrals at an early stage in planning, executing and monitoring sample referral systems is essential to enable an efficient and well-coordinated response.

1.2 Review National SRS Guidelines

The county SRS sub-committee should familiarise themselves with contents of the *National Guidelines for Integrated Laboratory Specimen Referral Networks (2019)*, National Laboratory Handbook (2019), the national disease control programmes' strategic plans and other applicable guidelines.

1.3 Conduct an SRS Situational Analysis

The purpose of a situational analysis is to assess the availability of current specimen referral mechanisms across the county. This analysis can help to understand key gaps and bottlenecks in the SRS system and to identify successful models that may be scaled up or replicated. The county SRS sub-committee should oversee conducting of the SRS situational analysis with input from national programs, other county leadership and other experts, where needed.

Rapid Self-Assessment

A rapid self-assessment conducted by the SRS sub-committee may be a useful first step, since it may assist in initiating reflective thinking around the SRS and refining the scope of a full assessment. This may be conducted as a workshop exercise and takes approximately two hours. The GLI Specimen Referral Toolkit (GLI SRT) has an example of a rapid self-assessment tool[3] that can be used. However, the rapid self-assessment does not provide sufficient detail to enable operational planning and therefore should be followed by a full, detailed assessment (see below).

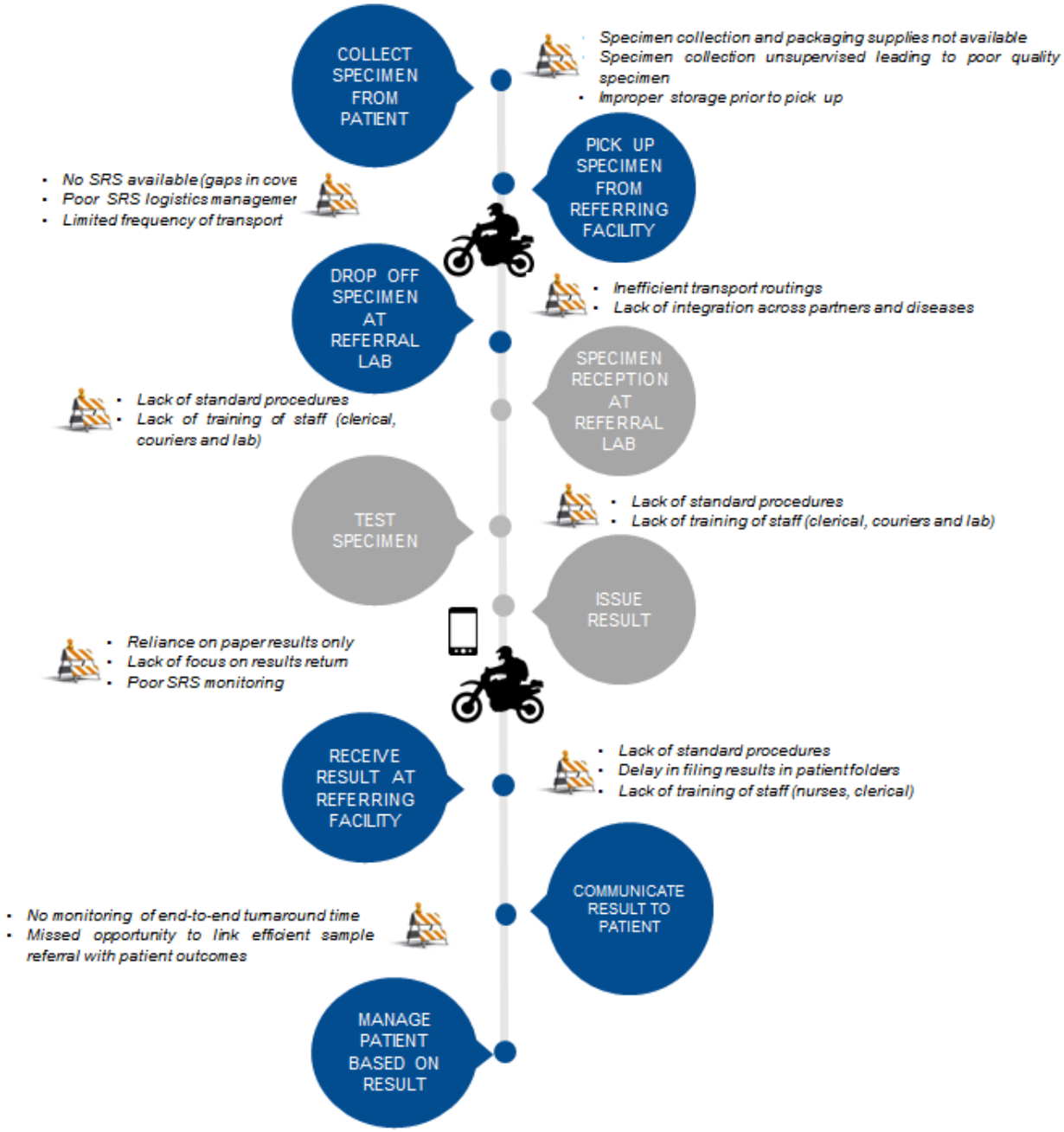
Detailed SRS Situational Analysis

The detailed SRS situational analysis aims to map out the end-to-end SRS process and identify gaps and bottlenecks in the system (see Figure 1). A questionnaire[4] can be found in the GLI SRT that can be used for collecting information on the SRSs. Situational analysis reports should include gaps identified, and a list of prioritised recommendations expected to address the gaps.

[3] http://www.stoptb.org/wg/gli/assets/documents/srt/Specimen%20Referral%20Compass%20Questions.xlsx

[4] http://www.stoptb.org/wg/gli/assets/documents/srt/ASLM%20Questionnaire%20for%20Countries%20-%20Specimen%20Referrals.xlsx

Figure 1. End-to-end sample referral system processes, with common gaps and bottlenecks in the system



1.4 Develop a Strategy

A multi-year strategy, commonly covering a 3 to 5 year period, should be developed that is aligned with national and county health strategies and priorities. The goal is to have an SRS in place for efficient and safe referral of quality samples from all health facilities in the county to enable increased patient access to services and improved patient outcomes, and enhanced disease surveillance. Scaling up access to Xpert MTB/RIF as the initial diagnostic test for those being investigated for pulmonary TB is a priority for the NTLP, therefore a strong focus on ensuring access to Xpert MTB/RIF testing at all facilities, either through on-site placement of devices or via sample referral, is essential. Additional referral of samples from facilities to referral laboratories for culture/drug susceptibility testing is also important for confirmation of drug resistance in drug-resistant TB patients. For HIV, increasing access to early infant diagnosis (EID) and viral load (VL) monitoring, are essential to reach the 90:90:90 targets[5]. Meeting disease targets requires strengthening of sample referral and results return systems, since these tests are currently mostly only available at higher level laboratories, often far from where patients seek care.

Table 1 provides a framework for development of activities according to the five objectives of SRS as outlined in the *National Guidelines for Integrated Laboratory Specimen Referral Networks (2019)*. Activities should relate to the gaps identified in the situational analysis and prioritised in terms of expected impact on programme indicators, such as increasing case notification and number of people living with HIV (PLHIV) who are virally suppressed. This framework enables county activities to be monitored according to the M&E framework provided for in the national guidelines.

Table 1. County sample referral system activity development framework

Objective	Key activity areas	Activities	Key performance indicators*
1. Increase access to diagnostic testing	• Ensure geographic coverage • Transport frequencies/ scheduling	• Map current SRS coverage and identify gaps • Conduct network optimisation analysis, or use case studies from network optimisation in other counties to inform efficient network design	• Proportion of health facilities (HFs) linked to testing sites via SRS • Number of referred specimens tested
2. Ensure timeliness of referrals and results return	• Frequency of transport • Efficient referral process and transport routes • Expedited return of results, where possible	• Issue and award tender for courier services • Conduct route optimisation analysis • Conduct turnaround time analysis • Implement electronic results return	Turnaround times

[5] UNAIDS. (0-90-90. An ambitious treatment target to help end the AIDS epidemic. 2014.

3. Ensure quality of the specimens and **4. biosafety/biosecurity** of collection, storage and in transit	• Use of correct packaging • Correct packaging procedures • Safe transport	• Develop training resources on specimen collection • Print and disseminate training resources/job aids to facilities • Provide training on specimen collection during supervisory visits	• Proportion of HFs with packaging supplies available on-site • Proportion of shipments using correct packaging • Specimen rejection rate
5. Increase cost efficiency of specimen referrals, and, in turn, diagnostics services	• Pooled pricing negotiation with service providers / couriers • Integration of transport across diseases	• Share contracts with and between SRS sub-committees • Ensure SRS can accommodate all specimen types	Average cost per sample transported

* List of indicators is illustrative; please refer to the full M&E framework in the ***National Guidelines for Integrated Laboratory Specimen Referral Networks (2019)***.

1.5 Develop and cost annual operational plan

A detailed annual operational plan should be developed based on the county strategy and incorporating all partners supporting SRS activities. Successful implementation of the plan will require financial and human resource commitment from county government, with possible support of implementing partners. Currently, SRSs rely heavily on disease-specific donor support but increasing local funding support should be seen as an opportunity to promote sustainability and integration. A comprehensive budget should be developed to address activities, as shown in Table 2 below, in collaboration with key partners. The GLI SRT contains a budget tool[6] which can be used as a guide to enable comprehensive costing and standardization across the country (which allows comparison of cost-effectiveness of different systems).

[6] http://www.stoptb.org/wg/gli/assets/documents/srt/Specimen%20Referral%20System%20Budget%20Tool_v1.0.xlsx

Table 2: Budgetary considerations for SRS

	Budgetary considerations
Program management	• Meetings for stakeholder engagement and planning • TWG meetings and workshops • Situational analysis cost – HR, travel and report writing (may be done by MOH staff or with partner support if available) • Printing and distribution costs for revised tools
Sample referral system/ network design	• Cost of more frequent distribution schedule, if applicable
Transport, logistics and scheduling	• Meetings/workshop for stakeholders involved in procurement • Cost of printing and distributing the schedule • Cost of hiring boda-boda riders or courier services
Supplies and equipment	• Procurement of backup supplies and equipment for safe and quality specimen transportation
Human resources and training	• Workshop and HR to update training packages • Training of training workshop, on-site trainings/ sensitization meetings • Printing and distribution of updated training manuals
Documentation, data systems, M&E	• Workshop and HR to update recording and reporting forms, registers, standard operating procedures (SOPs) • Printing and distribution of updated materials • Costs of reporting data to higher levels and providing feedback to reporting facilities • Meetings to update M&E system and regular meetings to review impact of transition and re-plan • M&E refresher training • Operational research study to measure clinical impact

2. Sample Referral Network Design

Sample referral network design component includes activities related to the mapping of facilities, determination of sample referral needs and considerations for designing efficient networks and developing detailed transport route plans.

2.1 Map location and services provided by health facilities and testing sites

The first step in designing a specimen referral system is to map out the following:

- Health facilities
  - Location
  - Key services provided (TB screening, TB treatment, ART services, PMTCT etc.)
- Diagnostic testing sites
  - Location
  - List of tests performed
  - Testing capacity (number of tests that can be performed per year).

Mapping locations may be done in a number of ways, from use of specialised network optimisation software, digital mapping tools such as Google maps, to traditional manual methods (hard copy maps with colour-coded dots/pins to designate various facility types and services). GPS coordinates are preferred, and are needed when using digital options; a detailed street address is adequate for manual mapping methods.

2.2 Select facilities to be included in the SRS

After the facility locations and services are mapped, determine which health facilities will be included in the SRS and establish their referral linkages (i.e. where referral testing will take place for each test). Will samples be referred from all health facilities in the county, or only from selected facilities? When determining this, be sure to consider the plans across disease programmes, i.e. if TB samples will be picked up from all health facilities, other samples can also be collected as there will be no (or minimal) incremental cost. You may decide to initiate the sample referral system from selected facilities only, and later expand the collection to all health facilities.

2.3 Decide on sample transport frequency

The next step is to determine how often samples should be picked up from health facilities. This may be stipulated in national guidelines or may be decided at the county level. National targets for TB sample referrals recommend daily or twice weekly specimen transport. According to the number of specimens per health facility and feasibility and cost of providing transport, (e.g. in hard-to-reach counties) some counties may find it difficult to establish daily transport. When determining the frequency of sample transport counties should consider the needs of different disease programmes and weigh up desired frequencies against cost and operational considerations. All programmes may benefit from the most frequent sample transport requested, since their samples could be collected from the same facilities at no additional cost.

2.4 Estimate volume of samples to be transported

The *National Guidelines for Integrated Laboratory Specimen Referral Networks (2019)* call for establishment of integrated sample referral systems. When designing such systems counties should take into account the total number of samples to be transported and understand the type and volume of samples originating at referring health facilities. TB and HIV samples in general constitute more than 95% of specimens being transported in Kenya, therefore when designing the SRS, the volume of TB and HIV specimens may be used when determining the volume of samples to be transported. Counties that transport a greater proportion of other samples are advised to take this into account during the design phase to ensure the referral patterns required (to which laboratories are other samples referred) and the additional volume of samples is considered. Seasonal variations in the number of samples and potential outbreak situations are also relevant to planning.
Remember that the volume of samples to be transported is not the total number of samples to be tested in the county as samples collected at health facilities with diagnostic facilities on-site will not need to be transported.

2.5 Determine use of multi-stop versus point to point (direct) routes

Large volume sites should be served on multi-stop, regular routes, e.g. twice weekly or agreed frequency from 2.3. Smaller volume sites that are close to or on the multi-stop routes can also be included in multi-stop routes as the additional cost to incorporate them is zero or very low. See Figure 3 for examples of multi-stop and point to point (direct routes).

Based on sample volumes and frequency of transport estimate determine which health facilities are likely to have samples at every pickup visit. For example a facility that refers 250 samples per year would be expected to have an average of five samples per week. If sample transport was done on a daily basis you would expect to have a sample for pick up on each visit. For health facility that only has 10 samples to refer each year, it would not have samples for pick up on each occasion even if sample transport were only done weekly

Small volume facilities that are located far from large volume sites/multi-stop routes may be served by direct (point to point) only when samples are available for testing.

2.6 Consider cross-county border referrals

Some health facilities in your county may be located far from diagnostic sites, and may be better served by a closer diagnostic site in a neighbouring county. You should consider whether you wish to allow such cross-border referrals within your network. Similarly, health facilities located in your country may be better served if they are allowed to refer samples to a diagnostic testing site within a neighbouring county. Figure 3 shows examples of health facilities in Garissa County that are recommended to be served by neighbouring counties and of health facilities in neighbouring counties that are proposed to refer samples for testing in Garissa County.

However, several factors may provide a disincentive to counties for allowing cross-border referrals, such as testing targets for tests performed in a given county, county utilisation targets for diagnostic instruments, and preference of counties and/or implementing partners to use instruments in their own geographic setting. Advantages of allowing cross-border referrals include improved access to services for patients, reduced overall sample transport costs and reduced turnaround times.

It is recommended that where cross-border referrals are possible that direct routes only should be used, and that multi-stop routes are not allowed. This recommendation is due to the complexity that would be involved in trying to fund and manage multi-stop routes that include two counties, whereas direct routes can be funded by the county from which the samples are referred.

2.7 Draft out route plans

To give an accurate representation of travel distance and time, the best available road map should be used (this can be manual or digital). High-volume sites should be served on multi-stop, regular routes, e.g. twice-weekly or agreed frequency. Lower-volume sites that are close to or on the multi-stop routes can also be included in multi-stop routes as the additional cost to incorporate them is zero or very low. Low-volume facilities that are located far from high-volume sites/multi-stop routes may be served by point-to-point routing, on-demand, i.e. only when samples are available for testing.

Counties should determine the length of routes that can be covered in single day, which can be estimated based on the use of road maps and local knowledge of road conditions, terrain, etc. Stopping times for sample pick-ups and the length of the working day should also be considered. For example, a 220km route with average transport speed of 40km/h would be equivalent to 5.5 hours travel time, and including six health facilities with a pick up time of 25 minutes per facility (2.5 hours total pick up time), could be covered in one route in an eight-hour working day.

Draw rough routes on a map with locations of facilities and diagnostic sites, as illustrated in Figure 2. Note: these are illustrative only and do not represent the recommended routes for Turkana county.

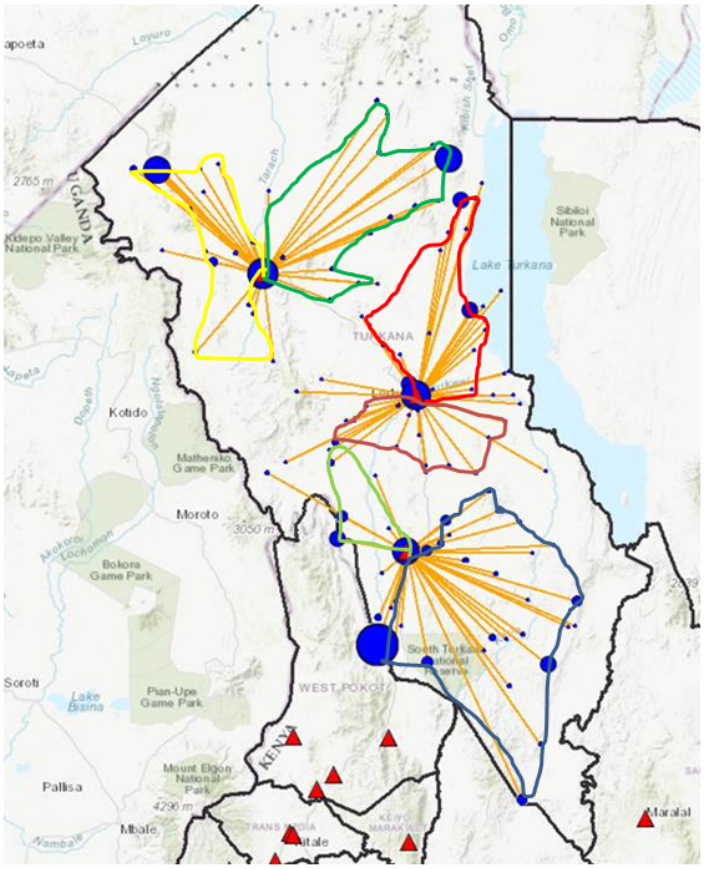


Figure 2: Illustrative example of manually-drawn route plans in Turkana County.
Blue circles represent health facilities; with the size of circles reflecting the volume of samples to be transported.
Red triangles are Xpert testing sites.
Orange lines reflect the straight line distances between Xpert testing sites and the health facilities that are allocated to each facilityXpert testing site for sample referral.
Coloured lines are examples of manually –drawn route plans. Note: these are illustrative only and do not represent the recommended routes for Turkana county.

Example route plans for five counties (developed using specialised network optimisation software, Supply Chain Guru®) are provided in Annex 3. The following inputs were used in developing these route plans:

- Sample pick-up frequency – twice weekly (100 times per year)
- Motorbike average speed – 40km/hr
- Business hours of health facilities – 8am – 5pm
- Maximum duration of route – 9 hours for Hard-to-reach counties, 10 hours for Easy and Moderate counties (see Annex 5 for county categorisation)
- Average stopping time for sample pick up – 25 minutes

The route plans provided in Annex 3 may be used as a guide by other counties when developing their own sample referral systems using other route planning methods. For SRS design, it may be helpful to characterise counties by their HIV burden / testing volume, TB burden / testing volume and the

average service distance (average distance from a health facility to a diagnostic facility). Refer to the Annex 4 to identify a county that most closely matches your county's characteristics and use their route plan as a guide. The county groupings provided in Annex 4 are suggestions and counties may use other considerations to guide their own route plan development.

2.8 Account for special considerations and finalise route plans

There are special considerations such as security concerns that need to be taken into account before the route plans are finalised.

In some counties there may be some routes that appear to be optimal in terms of the closest route to travel to the diagnostic testing site. However, upon review by country stakeholders, security concerns (or other operational considerations) may render these routes infeasible. In such cases the best alternative route should be selected and counties may need to factor in the cost and extra travel time needed to use more circuitous routes to avoid unsafe areas, as well possibly budgeting for vehicles instead of motorbikes.

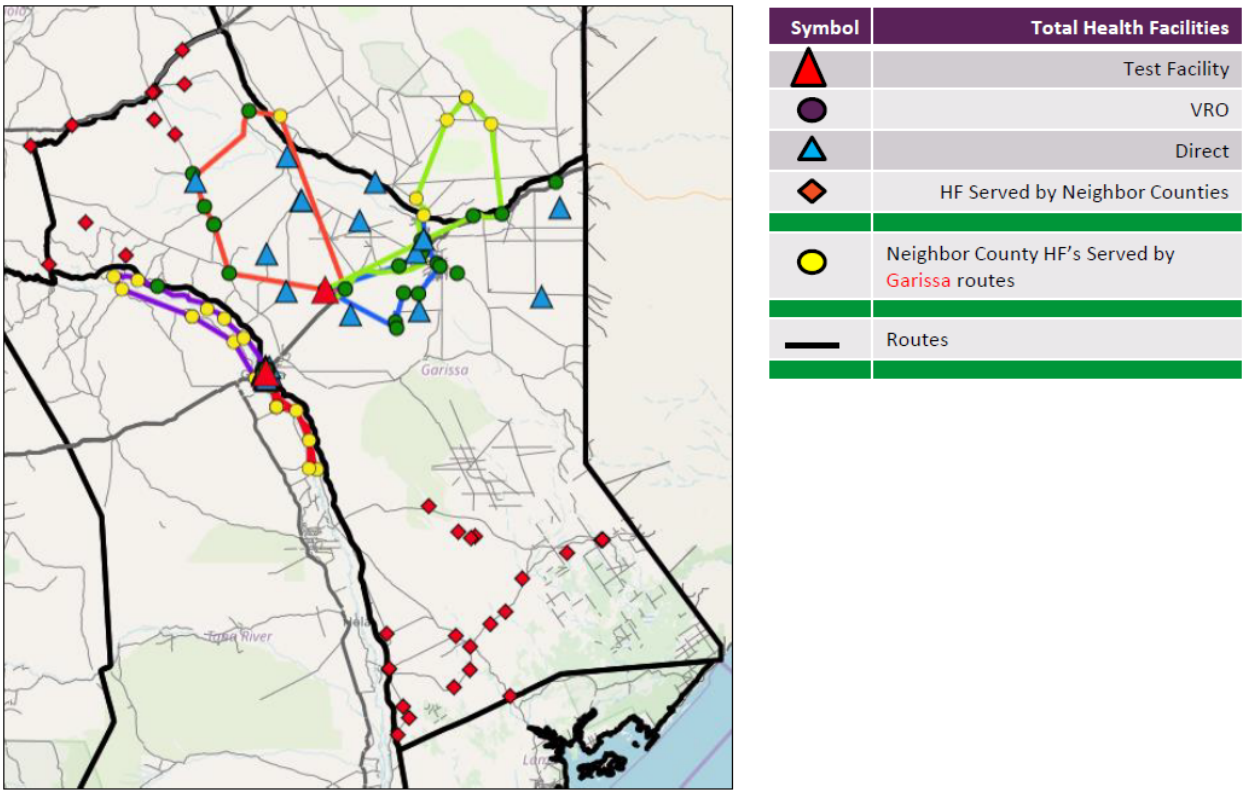


Figure 3: Illustrative route map for Garissa County showing multi-stop and direct routes. Lines shown in orange, green, blue and purple are different multi-stop routes Black lines are county borders. Note: these are illustrative only and do not represent the final recommended routes for Garissa County.

2.9 Update network designs

Diagnostic networks are dynamic entities, with new diagnostic instruments being introduced to improve capacity and access to services. In turn, the referral linkages and SRS should also adapt to these changes, as necessary. Where available, this may be done periodically to inform strategic decisions by updating network models developed using network optimisation software. However, as the changes to the diagnostic network may happen more rapidly, it may not make sense to do this each time a new instrument is added. Further, network optimisation software may not be available. In these cases, the following approach may be taken to adapt the sample referral network:

- When new diagnostic instruments have been procured, the national level programme usually provides recommendations on where to place them (which may be informed by the diagnostic network optimisation analysis conducted at national level)
- County and national technical working groups discuss and confirm placement based on local considerations
- Draw a circle around the instrument (with estimated distance) and determine which facilities fall into the catchment of the new instrument (this may be referred to as "zoning". Ensure you take account of the road network and other local factors.
- Update referral linkages of existing instruments
- Inform health facilities on the allocation to the new instrument. The addition of a new instrument will likely reduce travel distance and therefore likely reduce transport costs.
- If the facilities are on a multi-stop route, the transition will be more complex since the transport provider (courier, boda-boda, etc.) will need to update their routing. It should be written into any transport service contracts that updating of routing plans may need to be adapted as new instruments are brought into the network.
- For existing routes, there may also be an opportunity for consolidation (e.g. two routes may be consolidated into a single route) in the situation where a substantial number of health facilities on the prior routes are now to be served by the new instrument.

As the routes are redefined, all components of the SRS should also be considered, including transportation/transporters, human resources and training, supplies and equipment, and M&E.

The cost of sample referral should be reduced once a new instrument is introduced, as the individual and overall referral distances will be reduced. As distances are reduced, turnaround times should also improve. In addition, a new instrument is expected to result in an improvement in access to services and may lead to an increase in the number of samples tested

3. Transportation

Transportation component includes consideration of transport options and needs and engagement with transport service providers.

3.1 Consider transportation options

Various transport options may be considered depending on transport route distances, terrain, cost and other factors. Regardless of type of transport used (on foot, bicycle, motorcycle, car, boat, drone or airplane), the principle of safe transport for infectious material always applies. For example, transport providers should comply with the following safety requirements (which should be communicated to any transport provider prior to commencement of services):

- All drivers and riders should have a proper drivers' license and be properly trained
- Riders should wear adequate protective riding gear
- Specimens should be kept out of direct sunlight
- If a box is affixed to the motorcycle for cargo, it should be firmly attached to the motorcycle
-

3.2 Estimate transport needs to service routes

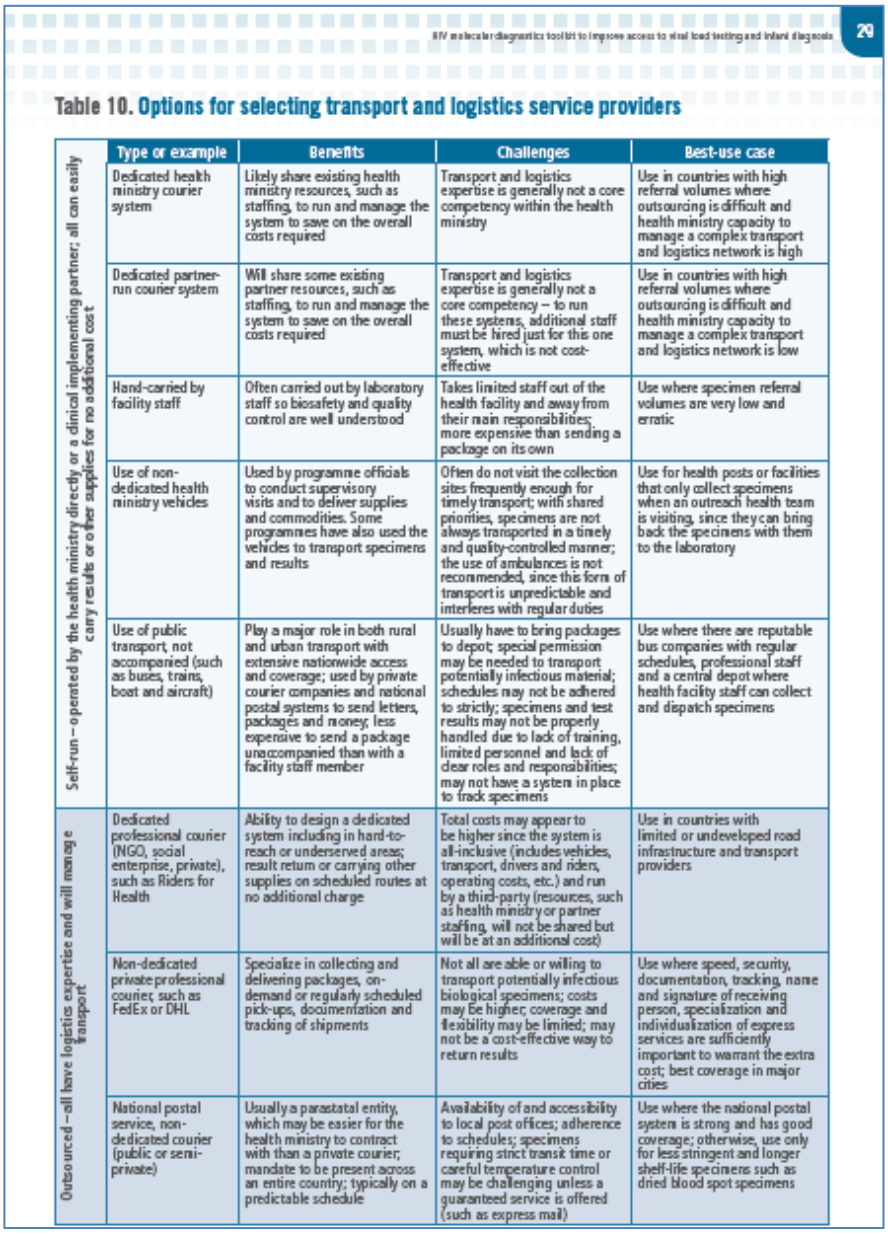
Once the finalized route plans have been completed, these can be used to estimate the number of vehicles that will be required to service those routes. For example, in a county with 20 routes that will have a twice weekly transport, there will be 40 routes in operation per week; this will require 8 motorbikes (working 5 days per week). SRS operators should also ensure that additional vehicle capacity is factored in to account for the need for servicing and repair and other operational considerations. A buffer of 20% of the estimated number of motorbikes would be reasonable, in this example adding an additional 2 motorbikes (total 22 motorbikes required).

3.3 Select transport service providers

There are various ways to implement the SRS design. In general, the transportation can be owned, managed and operated by the county or sub-county (government-run) or by another party, which could be another public institution, a private company (for-profit, social enterprise or not-for-profit), a clinical implementing partner, etc. There are benefits and drawbacks to each type of system so the SRS sub-committee must discuss which one(s) would suit the county the best. Examples of these different types of transportation providers and considerations for use can be found on the next page in Table 3. Even in one county, there may be more than one transport service provider that will be necessary, depending on the transportation coverage. Regardless of the transport service provider selected, the performance of that provider should then be monitored over time (see Section 6 for

more information). Also, county SRS sub-committees, SRS focal points and implementing partners should work together to improve cost efficiency of sample referral systems.

Table 3: Options for selecting transport and logistics service providers



HIV molecular diagnostics toolkit to improve access to viral load testing and infant diagnosis 29

Table 10. Options for selecting transport and logistics service providers

	Type or example	Benefits	Challenges	Best-use case
Self-run – operated by the health ministry directly or a clinical implementing partner; all can easily carry results or other supplies for no additional cost	Dedicated health ministry courier system	Likely share existing health ministry resources, such as staffing, to run and manage the system to save on the overall costs required	Transport and logistics expertise is generally not a core competency within the health ministry	Use in countries with high referral volumes where outsourcing is difficult and health ministry capacity to manage a complex transport and logistics network is high
	Dedicated partner-run courier system	Will share some existing partner resources, such as staffing, to run and manage the system to save on the overall costs required	Transport and logistics expertise is generally not a core competency – to run these systems, additional staff must be hired just for this one system, which is not cost-effective	Use in countries with high referral volumes where outsourcing is difficult and health ministry capacity to manage a complex transport and logistics network is low
	Hand-carried by facility staff	Often carried out by laboratory staff so biosafety and quality control are well understood	Takes limited staff out of the health facility and away from their main responsibilities; more expensive than sending a package on its own	Use where specimen referral volumes are very low and erratic
	Use of non-dedicated health ministry vehicles	Used by programme officials to conduct supervisory visits and to deliver supplies and commodities. Some programmes have also used the vehicles to transport specimens and results	Often do not visit the collection sites frequently enough for timely transport; with shared priorities, specimens are not always transported in a timely and quality-controlled manner; the use of ambulances is not recommended, since this form of transport is unpredictable and interferes with regular duties	Use for health posts or facilities that only collect specimens when an outreach health team is visiting, since they can bring back the specimens with them to the laboratory
	Use of public transport, not accompanied (such as buses, trains, boat and aircraft)	Play a major role in both rural and urban transport with extensive nationwide access and coverage; used by private courier companies and national postal systems to send letters, packages and money; less expensive to send a package unaccompanied than with a facility staff member	Usually have to bring packages to depot; special permission may be needed to transport potentially infectious material; schedules may not be adhered to strictly; specimens and test results may not be properly handled due to lack of training, limited personnel and lack of clear roles and responsibilities; may not have a system in place to track specimens	Use where there are reputable bus companies with regular schedules, professional staff and a central depot where health facility staff can collect and dispatch specimens
Outsourced – all have logistics expertise and will manage transport	Dedicated professional courier (NGO, social enterprise, private), such as Riders for Health	Ability to design a dedicated system including in hard-to-reach or underserved areas; result return or carrying other supplies on scheduled routes at no additional charge	Total costs may appear to be higher since the system is all-inclusive (includes vehicles, transport, drivers and riders, operating costs, etc.) and run by a third-party (resources, such as health ministry or partner staffing, will not be shared but will be at an additional cost)	Use in countries with limited or undeveloped road infrastructure and transport providers
	Non-dedicated private professional courier, such as FedEx or DHL	Specialize in collecting and delivering packages, on-demand or regularly scheduled pick-ups, documentation and tracking of shipments	Not all are able or willing to transport potentially infectious biological specimens; costs may be higher; coverage and flexibility may be limited; may not be a cost-effective way to return results	Use where speed, security, documentation, tracking, name and signature of receiving person, specialization and individualization of express services are sufficiently important to warrant the extra cost; best coverage in major cities
	National postal service, non-dedicated courier (public or semi-private)	Usually a parastatal entity, which may be easier for the health ministry to contract with than a private courier; mandate to be present across an entire country; typically on a predictable schedule	Availability of and accessibility to local post offices; adherence to schedules; specimens requiring strict transit time or careful temperature control may be challenging unless a guaranteed service is offered (such as express mail)	Use where the national postal system is strong and has good coverage; otherwise, use only for less stringent and longer shelf-life specimens such as dried blood spot specimens

Source: WHO/ASLM HIV molecular diagnostic toolkit to improve access to viral load testing and infant diagnosis[7]

3.4 Contracting with service providers

If the transportation is not owned, managed and operated by the county or a partner, i.e. if the transport service provision is outsourced to another party, there may need to be a solicitation of quotes or a tender for transportation services, depending on the procurement rules of the party paying for the transportation. The service may be outsourced directly to transporters or to an

[7] https://apps.who.int/iris/bitstream/handle/10665/325961/9789241516211-eng.pdf?sequence=1&isAllowed=y

entity/organization that will hire transporters – otherwise known as a third-party logistics (3PL) provider. After selection, a contract would need to be signed.

When developing an agreement, the following should be considered:

- Provide a map and/or GPS coordinates of health facilities/collection points, hubs, testing laboratoes and referral linkages
- Ensure you include the return of paper results and return of cooler boxes and the cost to be incurred
- Negotiate volume-based costs (i.e. reduced cost per sample/shipment transported at high volumes), where possible
- Ensure inclusion of all specimen types and samples being transported for the purposes of surveys or outbreaks
- Communicate with service providers (and include in contracts) the need for transport services to be flexible and responsive to changing needs. For example route plans will need to be updated from time to time, in case of new instruments being added to the network or significant changes in specimen volumes
- Ensure that key performance indicators (KPIs) and targets are defined and that the frequency of KPI monitoring, as well as the measures to be taken in case KPIs are not met, are all built into the contract. Examples of KPIs to be used are:
  - Number of shipments/packages transported to the hub or referral laboratory
  - Percentage of packages lost or damaged during transit
  - Percentage of packages picked up by the transporter according to schedule
  - Percentage of packages delivered by the transporter within the target transport turnaround time (ideally 24 hours, possibly 48 hours)

Donors/implementing partners may consider the potential efficiency advantages of transport negotiation among multiple counties to reduce costs and simplify contracting processes and weigh this against the benefit of local knowledge and capacity of contracting with local service providers directly at the country or sub-county level.

4. Supplies and Equipment

4.1 Ensure availability of supplies and equipment

Supplies and Equipment component includes considerations on ensuring uninterrupted supply of quality supplies and equipment for sample referral.

4.1 Ensure availability of supplies and equipment

Packaging supplies and equipment are the materials necessary for following triple-packaging procedures. These materials include the primary container (collection tube, for example), the secondary container and absorbent material, and the tertiary container, which is often a cool box, plus any ice packs, etc. Uninterrupted availability of packaging supplies and equipment at the collection sites is essential to ensure consistent use of fit-for-purpose materials enabling safe referrals of quality specimens. Although the supplies and equipment are likely procured and distributed above the county-level, it will be important for the county SRS sub-committee to properly quantify and submit its needs. The number of samples to be transported per route should be calculated for primary packaging and considered when determining the size of cooler boxes that will be required. Guidance on packaging requirements is provided in the *National Guidelines for Integrated Laboratory Specimen Referral Networks (2019)* and the *National Laboratory Handbook (2019*).

The county SRS sub-committee should be aware of any supply chain issues causing stock-outs and work with the responsible bodies to address gaps and bottlenecks in the system. If packaging supplies and equipment are not available through a central level, the county SRS sub-committee should be empowered to make a decision on the appropriate packaging to be used and/or should have back-up plans in place to procure supplies.
SOPs for packaging should be available from the National Laboratory Handbook (2019) and the National Guidelines for Integrated Laboratory Specimen Referral Networks (2019) and all relevant parties (referring health facility staff, referral laboratory staff, transporters) should be trained on these procedures (more on human resources and training in the next Section 5).

5. Human Resources & Training

5.1 Develop or adopt training curricula for key staff cadres
5.2 Conduct training
5.3 On-site supervisory support and refresher training

Human resources and training component includes recommendations for training of all cadres involved in SRS and on-site supervisory support to monitor effectiveness of training.

5.1 Develop or adopt training curricula for key staff cadres

The county SRS sub-committee should adopt national level training curricula if available, or should be involved in development of training curricula and deciding who will participate in trainings. Task-based trainings including correct documentation, such as completion of logbooks and forms (test requisition, chain-of-custody/transport, incident, etc.), reporting processes, and proper packaging and biosafety procedures. This training should be based on SOPs and should include practical training for the following stakeholders:

- Referral laboratory staff (for key diseases)
- Clinical and laboratory staff at referring facilities
- Transporters
- SRS program managers

SOPs should be available to all trained and the use of job aids may also be helpful. Resources for development of training programs can be found in the GLI SRT (http://www.stoptb.org/wg/gli/srt.asp).

5.2 Conduct training

Once the training materials are developed, initial training will likely take place in a training-of-trainers format at county-level. This training can be done with one audience (i.e. all of the four stakeholder groups previously mentioned) or can be broken up by audience. Where disease-specific laboratories are operating, e.g. at referral level, training should include participants from the key diseases. After the centralized training at county-level, this training can then be delivered at the sub-county level.

5.3 On-site supervisory support and refresher training

To monitor the effectiveness of the training, the county can take advantage of the supervisory visits to facilities to assess the competency of training participants from each stakeholder group. In order for training (and other aspects of the SRS) to be assessed, there must be questions related to the SRS in the supervisory questionnaire, which the SRS sub-committee can share with the county health management team and referral laboratories. A schedule for supervisory visits should be planned in advance and adherence to the schedule should be monitored. Collecting this data onsite will help to monitor process indicators such as the completeness of filling forms and logbooks. If facilities/staff are falling behind on certain process indicators, targeted refresher trainings can be done. Regardless, it is good practice to plan at least one refresher training per year for SRS stakeholders.

6. Data Systems, Monitoring Implementation and Measuring Impact

6.1 Standardize and disseminate SRS data collection tools
3.3 Establish reporting system and processes
3.4 Monitor and evaluate SRS
3.5 Use data for SRS improvement and system re-design

Data systems, monitoring implementation and measuring impact component includes recommended activities to establish a monitoring and evaluation system, processes and indicators to track the performance of the SRS and use data for program improvement.

6.1 Standardize and disseminate SRS data collection tools

The National Laboratory Handbook (2019) should be referred to in conjunction with the *National Guidelines for Integrated Laboratory Specimen Referral Networks (2019)* for standardized SOPs, data collection tools such as forms and logbooks. The *National Laboratory Handbook* also provides the following information on laboratory services in the country (location of laboratory services, test menu, operating times, contact details, turnaround times, and requirements for collection of quality specimens) and discusses the collection, storage, packaging and transit of specific specimen-types and return of results.

Where standardized documents exist, they should be adopted by the county SRS sub-committee and its stakeholders such that all programs and partners implementing the SRS are working with the same recording and reporting forms. Where there are not examples available through the *Guidelines* and *Handbook*, documents already in use by various implementing partners across disease programs should be examined, harmonized/standardized and adopted across the county. If there are no documents available in the county, new data collection tools should be created to fill the gaps of the national level, where necessary. These data collection tools will be important for monitoring and evaluating (M&E) the SRS.

Once the data collection tools, SOPs, job aids and other resources are standardized, adopted and available, they may be printed at the national or county level. Counties should organize for dissemination of the materials to the referring facilities and testing sites. Sensitization of personnel on the use of these materials should be arranged during regular county or sub-county meetings, during supervisory visits or during dedicated training (see previous Section 5 on Human resources and Training).

6.2 Establish reporting system and processes

Once the data collection tools are in place, staff are trained on how to use them, and data is being collected, there also must be a system and processes for reporting this data to higher levels of the health system, analysis, review and, importantly, developing a feedback loop back to the collection sites. The county SRS sub-committee should ensure that data collection tools, locations, staff responsible, frequency of reporting and to whom the data is reported are all well-defined.

6.3 Monitor and evaluate SRS

To properly monitor and evaluate the SRS, the national M&E framework and indicators provided in the *National Guidelines for Integrated Laboratory Specimen Referral Networks (2019)* should be adopted by the county. All indicators may not initially be feasible to collect, so a useful activity to start with is for the SRS sub-committee to go over each indicator and prioritize the ones that can be monitored immediately.

Certain process indicators, as mentioned before, such as availability and completeness of key SRS documentation, can be incorporated into existing on-site supervision visits by county or sub-country personnel. Supervisory checklists will need to be revised to include questions related to whether standardized documents are available at sites, and the extent to which they are routinely implemented as intended. Other opportunities for assessment may also be considered based on existing activities. However, harmonization of assessment questions is recommended to enable tracking of performance.

It is important to monitor the workload of the referral laboratories, as a robust SRS is likely to increase testing volumes. The county must ensure that the laboratories are prepared and able to cope with additional workload, in terms of human resources, equipment and reagents/supplies. Review and forecasting should be done relatively frequently, especially in early stages. If the workload increases beyond the capacity of the laboratory, the county should also consider using its data to re-design the diagnostic network (more on this in next sub-section 6.4).

Beyond measuring operational performance of the SRS, as part of the larger disease programs' and surveillance systems' M&E framework, the impact of the SRS on disease targets should be measured. Measuring this impact requires close collaboration with the disease-specific M&E teams to ensure that there is an indicator included in the M&E framework.

All of the findings should be shared and discussed with stakeholders through regular feedback sessions.

6.4 Use data for SRS improvement and system re-design

Data collected through M&E activities should then be used to improve the SRS through targeted (re-)training, onsite mentoring/supportive supervision, etc. In addition, when the county is considering any change to the diagnostics network – for example, to increase coverage of and access to GeneXpert testing or to cope with increasing testing volumes from improved specimen referrals – the data from

the SRS is critical to use to consider a re-design of the system (which was discussed in Section 2). The county SRS sub-committee should at least, on a quarterly basis, review the indicators and where necessary, make an improvement plan.

References

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Annexes

Annex 1: SRS Operational planning template showing illustrative activities by phase and SRS component

Setup and Implementation Workplan - Specimen Referral System						
Phase	**Component**	**Planned activities**	**Timelines**	**Outputs**	**Cost**	**Responsible**
Phase 1: Detailed situational assessment of current specimen referral systems	3. Data collection, monitoring and evaluation	Landscape assessment	4 weeks: 1-2 weeks on the ground plus 2-3 weeks of due diligence and report writing	Shared report of specimen referral landscape in a country		
	1. Management (including Strategic Planning & Performance Management)	Setup of integrated specimen referral technical working group as an offshoot of a laboratory or logistics TWG - the first meeting of which should be a stakeholders' meeting to discuss assessment report	1 week to setup and plan then half-day every 2 months to start (more frequently if needed) - first meeting soon after landscape assessment report is submitted	Group that can discuss and advise on all specimen referral systems in a country		
Phase 2: Design of a specimen referral system pilot	1. Management & 4. Human Resources	Appointment of individual AND department to oversee specimen referrals within MoH	1 day, the sooner the better to have someone in place early on for management and continuity purposes	Individual and department within the MoH assigned to oversee specimen referrals		
	6. Network design, scheduling and transportation	Laboratory and route network optimizations, including integration of various specimen types, wherever possible[7]	4-6 weeks: 1-2 weeks on the ground plus 3-5 weeks of offsite data analysis	Final referral laboratories determined and mapped; routes to reach the referral laboratories from the health facilities mapped and optimized		
	1. Management	Development of specimen referral strategy or policy at national level that provides a long-term vision of specimen referral design, oversight, and performance and guides strengthening initiatives	2-3 months	A strategy or policy document to guide the specimen referral networks at a national level		
	2. Financing and costing	Determine a high-level budget to use to explore potential funders and funding mechanisms, depending on the proposed structure of the referral network (i.e. if outsourced); and then will cost out a more detailed workplan	3-4 weeks with possible one-on-one or larger donor meetings, and will include results of the laboratory and route network optimizations	Detailed and high-level budget and workplan that can be used to guide activities and used to advocate for funds, which will be secured		
	1. Management & 4. Human Resources	Develop M&E framework and strategy, including key performance indicators (KPIs)	3-4 weeks	M&E framework document that will plan for M&E as well as data tools, data collection (frequency and what to include),		
	1. Management & 3. Data collection, monitoring and evaluation	Tendering of services, awarding of service provider, negotiation and signing of contract	3-6 months including advertising time and review of applications	A transparent and competitive bidding process ending in a fairly awarded contract with a suitable service provider		

Phase 3: Setup and implementation of pilot	3. Data collection, monitoring and evaluation	Print and provide all logbooks, guidelines and other documents to ST couriers and stakeholders	2-4 weeks, depending on printing time and printing/delivering mechanism	All data collection tools are available to those who will fill them out		
	4. Human Resources	Training of service provider (courier), including biosafety/biosecurity training[14]	1 day centrally and then time to train the couriers in the regions	Couriers are trained on how to properly and safely handle potentially-biohazardous materials		
	5 Equipment	Procurement of equipment and supplies including packaging	Depends on local or international procurement and border clearing times	All sites will have access to proper packaging using approved equipment		
	4. Human Resources	Training and sensitization of health facilities and laboratories and ensure all stakeholders have a copy of the ST schedule	4+ weeks depending on the size of the country and size of the system and the number of training teams	All sites will understand how to properly package specimens, when to request for tests and know when their pickups will be		
	6. Network design, scheduling and transportation	Pay monthly courier costs	Likely invoiced on a monthly basis after the service is provided	Costs are paid for, according to an invoice, on a monthly basis		
	3. Data collection, monitoring and evaluation	Monthly data reporting by health facilities and laboratories	Monthly basis, likely due on the 5th day of every month	All reports are collated and submitted to the central MoH oversight body on a monthly basis		
Phase 4: Review of pilot	1. Management	Supervision and management visits	Every 2-3 months; possibly more frequently at the start	The central MoH oversight body provides regular supportive supervision using a standardized data collection tool and provides sites feedback		
	1. Management	Biosafety, biosecurity and quality control are monitored by the laboratory quality department/ team	Every 2-3 months; possibly more frequently at the start	The laboratory QA unit ensures biosafety and biosecurity of the system		
	1. Management	M&E officer visits sites every 3-6 months to collect/verify data and then analyse to inform operational processes and to share information with partners	Every 3-6 months	Data is complete, verified and analyzed, then shared with TWG to inform decision-making		
	1. Management	Contract management including monthly meeting with service provider to discuss performance and challenges	Monthly basis	Direct communication between service provider and contract manager is regularly made		
	1. Management	Stakeholders meeting to discuss progress	1 day	TWG reviews progress of specimen referral system		

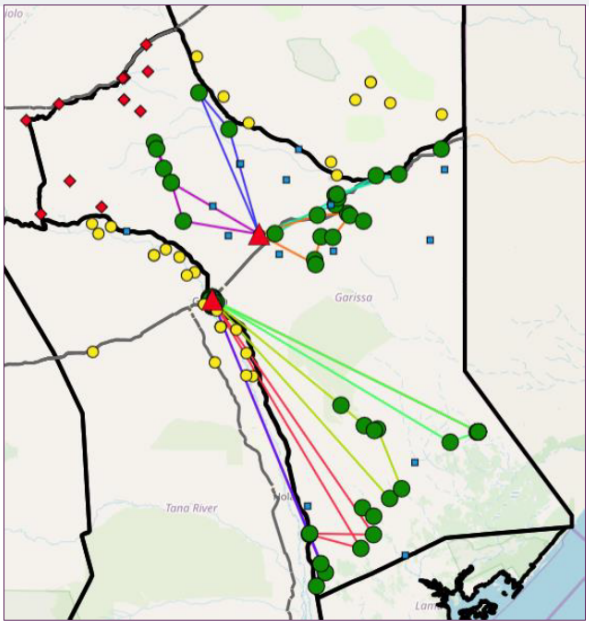
Phase 5: Scale-up of the specimen referral system	1. Management	Stakeholders meeting to discuss scale-up	1 day	TWG makes decisions on future scale-up, integration, etc.		
		Other activities depending on the scale-up decisions made by the	NA	NA		
Phase 6: Ongoing monitoring and evaluation, and continuous improvement	3. Data collection, monitoring and evaluation	Refresher training	4+ weeks depending on the size of the country and size of the system and the number of training teams	All sites and couriers will be reminded how to properly package and transport specimens, when to request for tests and know when their pickups will		
		Other activities depending on the scale-up decisions made by the TWG/stakeholders	NA	NA		
				TOTAL:		

Annex 2: Summary of policy statements from *National Guidelines for Integrated Sample referral networks*

Structure and Organization	Laboratory specimen referrals networks shall be integrated to support detection, monitoring and surveillance of priority diseases of Public Health concern in line with the spirit of UHC in Kenya
	Laboratory specimen referrals networks shall support national and global health security, in line with the International Health Regulations (IHR)
	Healthcare facilities without certain testing capacity shall refer specimens to higher-level facilities where such services are available
Roles, Responsibilities, Communication and Coordination	The National Public Health Laboratory (NPHL) will serve as the ultimate manager and owner of the specimen referral network in Kenya
	At the national level and each county, there will be a specimen referral technical sub-committee that will coordinate all specimen referral activities in their respective regions
Specimen and Results' Management	All staff and personnel involved in specimen referrals (and paper-copy results' return) shall be properly trained and supervised using approved materials and relevant curricula to assure quality and safety of the specimen referral systems
	The Laboratory Handbook shall be provided to and used by all facilities and staff at all levels to detail safe, ethical and quality processes for specimen referrals and results return
	All specimens being referred shall be packaged using standardized triple packaging materials and processes, and transported according to appropriate regulations, approved by the safety regulatory committee at national level
Effective and Efficient Network	Specimen referral system shall be financed within both National and County budgetary planning including attracting co-financing from development partners and private-public partnerships (PPP)

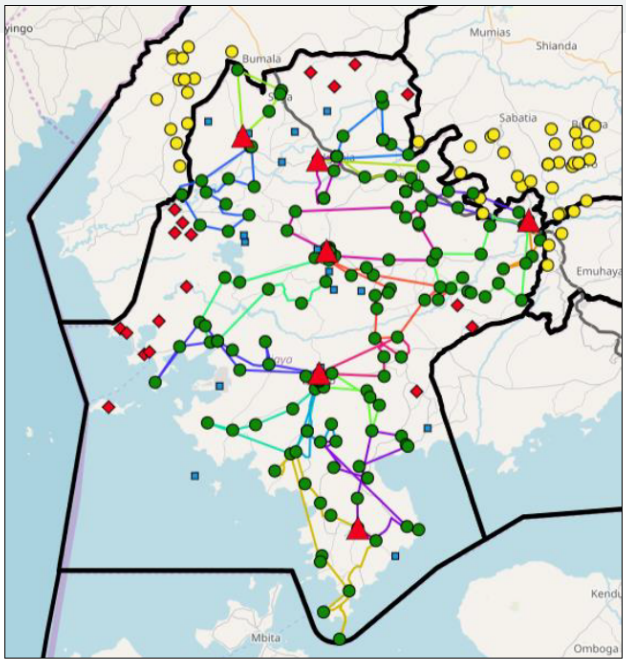
Annex 3: Illustrative county sample referral system routes for five counties (Garissa, Siaya, Makueni, Baringo, Nakuru).

Garissa



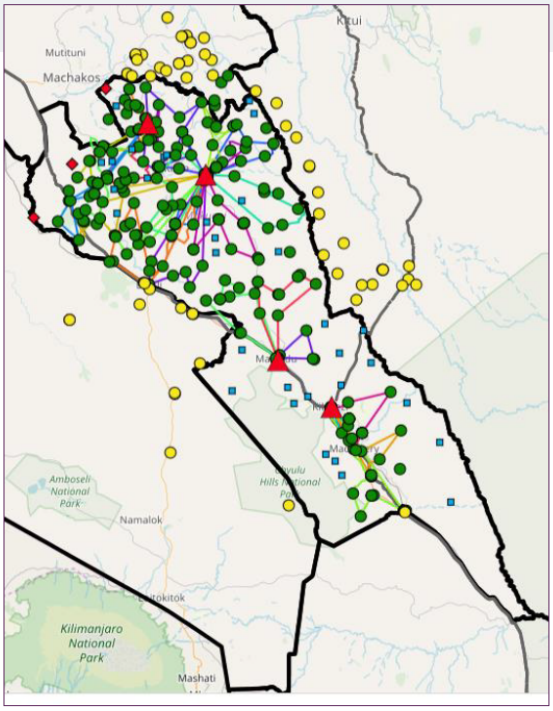
Symbol	Total Health Facilities
	Test Facility
	HF on **multi-stop route**
	HF referring to Test Facility **Direct**
	HF Served by Neighbor Counties
	Neighbor County HF's Served by Garissa routes
	Routes

Siaya



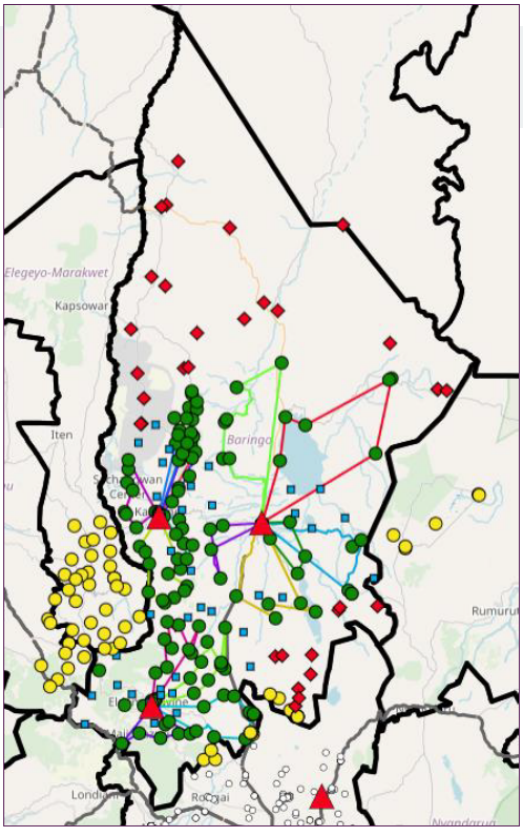
Symbol	Total Health Facilities
	Test Facility
	HF on **multi-stop route**
	HF referring to Test Facility **Direct**
	HF Served by Neighbor Counties
	Neighbor County HF's Served by Siaya routes
	Routes

Makueni



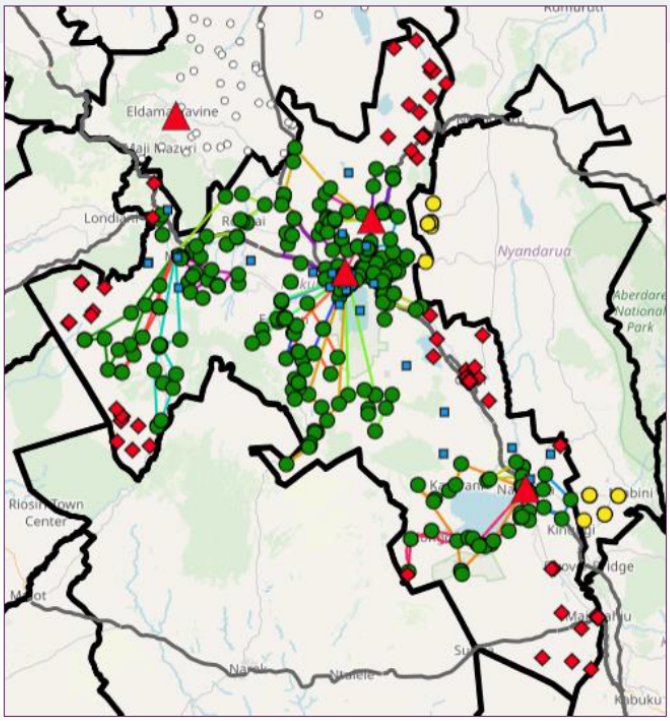
Symbol	Total Health Facilities
	Test Facility
	HF on **multi-stop route**
	HF referring to Test Facility **Direct**
	HF Served by Neighbor Counties
	Neighbor County HF's Served by Makueni routes
	Routes

Baringo



Symbol	Total Health Facilities
	Test Facility
	HF on **multi-stop route**
	HF referring to Test Facility **Direct**
	HF Served by Neighbor Counties
	Neighbor County HF's Served by Baringo routes
	Routes

Nakuru



Symbol	Total Health Facilities
	Test Facility
	HF on **multi-stop route**
	HF referring to Test Facility **Direct**
	HF Served by Neighbor Counties
	Neighbor County HF's Served by Nakuru routes
	Routes

Annex 4: Table showing suggested groups of counties that can be "matched" to those counties with detailed route maps

	EID test volume per year	VL test volume per year	Total HIV tests per year	TB test volume per year	Total Tests	Average distance from health facility to Xpert site	No. health facilities
MOMBASA	4,777	43,992	48,769	16,138	64,907	2.1	405
NAIROBI	18,521	149,822	168,343	29,770	198,113	3.1	1070
VIHIGA	1,753	15,819	17,572	6,237	23,809	5.7	108
KISUMU	14,310	117,805	132,115	23,777	155,892	6.2	230
KIAMBU	4,590	37,777	42,367	7,377	49,744	7.0	611
KIRINYAGA	1,110	10,616	11,726	4,432	16,158	7.8	328
KISII	3,188	30,637	33,825	6,236	40,061	7.8	218
NYAMIRA	1,265	14,101	15,366	4,520	19,886	7.9	154
BUSIA	3,909	35,419	39,328	9,690	49,018	9.2	130
HOMABAY	15,911	113,515	129,426	13,205	142,631	9.7	282
SIAYA	**12,158**	**97,869**	**110,027**	**17,714**	**127,741**	**9.9**	**218**
MERU	2,270	19,617	21,887	10,436	32,323	9.9	570
KAKAMEGA	5,218	42,047	47,265	15,006	62,271	11.0	317
MIGORI	10,239	72,057	82,296	7,332	89,628	11.2	255
BUNGOMA	2,648	24,678	27,326	7,830	35,156	11.3	236
NYERI	1,422	18,061	19,483	5,240	24,723	11.5	462
KERICHO	1,504	14,218	15,722	9,264	24,986	11.9	240
NANDI	1,187	10,455	11,642	4,741	16,383	12.2	231
EMBU	960	9,189	10,149	2,153	12,302	12.8	207
TRANSNZOIA	1,678	15,555	17,233	3,178	20,411	12.8	205
NYANDARUA	829	8,878	9,707	3,287	12,994	14.1	204
NAKURU	**4,652**	**38,543**	43,195	**12,328**	**55,523**	**14.3**	**501**
BOMET	1,109	10,087	11,196	5,160	16,356	15.0	156
UASINGISHU	2,847	33,461	36,308	6,775	43,083	15.6	226
MACHAKOS	2,905	29,086	31,991	18,854	50,845	15.9	434
THARAKANITHI	689	7,569	8,258	2,683	10,941	16.0	154
MURANGA	1,520	15,237	16,757	8,734	25,491	18.1	345
ELEGEYOMARAKWET	529	3,654	4,183	2,439	6,622	18.5	124
KWALE	1,293	9,518	10,811	4,755	15,566	18.8	154
MAKUENI	**2,016**	**22,607**	**24,623**	**9,757**	**34,380**	**18.9**	**349**
KILIFI	2,567	22,956	25,523	6,562	32,085	19.3	308
BARINGO	**517**	**3,877**	**4,394**	**2,728**	**7,122**	**19.4**	**262**
WESTPOKOT	222	2,662	2,884	1,783	4,667	20.1	151
LAIKIPIA	832	8,723	9,555	5,226	14,781	21.8	190
KITUI	1,814	21,522	23,336	8,219	31,555	23.1	457
KAJIADO	2,086	12,914	15,000	3,987	18,987	24.6	383
TAITATAVETA	681	5,864	6,545	5,602	12,147	26.2	106
NAROK	1,159	8,987	10,146	3,509	13,655	31.7	197
ISIOLO	221	1,520	1,741	2,243	3,984	32.8	57
SAMBURU	141	998	1,139	1,121	2,260	37.4	107
LAMU	102	1,670	1,772	6	1,778	44.3	76
GARISSA	**238**	**1,264**	**1,502**	**1,548**	**3,050**	**45.7**	**162**
TURKANA	1,205	7,710	8,915	1,923	10,838	49.4	247
MARSABIT	109	984	1,093	2,006	3,099	49.7	119
TANARIVER	109	989	1,098	723	1,821	50.6	83
WAJIR		149	149	1,601	1,750	67.4	164
MANDERA	38	368	406	935	1,341	109.5	131

Counties shown in bold text are those for which a detailed route map have been developed, see Annex 3. Colour-coded groups show groups of counties that have similar characteristics to the counties with detailed route maps with respect to, average distances between health facilities and Xpert sites and the number of health facilities per county and HIV and TB testing volumes to be transported. These groupings are merely suggestions and counties may use other considerations to select which route maps they use to guide their own route plan development.

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