

# USAID'S INFECTIOUS DISEASE DETECTION AND SURVEILLANCE (IDDS) Specimen Referral Systems Technical Approach

## **Overview**

Effective referral systems enable the timely and safe delivery of biological specimens to the appropriate diagnostic facility while maintaining specimen integrity. These systems enable the required tests to be performed and the results to be returned to patients, clinicians, veterinarians, and public health officials in a timely manner. This is critical to patient care, disease outbreak early warning systems and response, and surveillance. To function optimally, specimen referral systems must have adequate geographical coverage, use efficient and timely transportation systems, maintain specimen integrity, protect the safety of those transporting the specimens, and have adequate financial resources to ensure sustainability. Specimen referral systems must also be resilient and adaptable in the face of epidemics and disease outbreaks. Without these components, diagnostic networks cannot efficiently transport quality-assured specimens to the closest diagnostic facility that offers the appropriate testing.

# **Technical Approach**

The Infectious Disease Detection and Surveillance (IDDS) five-year technical approach to strengthen specimen referral systems builds on well-documented practices to support the following areas: optimization of the specimen referral network; specimen collection mentoring to ensure integrity; specimen transportation, including commodities and equipment that maintain integrity and ensure safe storage (including compliance with national or international regulations as applicable); and sustainable financing. Efficient and effective specimen referral systems will lead to timely testing of quality specimens and facilitate diagnosis-based clinical and public health decision-making.

IDDS scoping visits have revealed that investments in disease-specific specimen referral systems are common

in the countries in which IDDS will be working, but these systems are usually stand-alone and geographically limited. Linkages with animal health sectors do not exist. Countries have made nascent efforts to support integrated national specimen referral and transport systems. However, countries and stakeholders may not be cognizant of the comprehensive mapping data needed to inform optimization of specimen referral systems, or the relationship of past mapping exercises to this need.

Initially, IDDS will focus on understanding existing fragmented specimen referral systems, including reviewing existing Geographic Information System data and supporting governments (or multi sectoral coordination committees) to establish effective governance structures that bring these fragmented systems together. If efforts are already underway to establish a national specimen referral system, IDDS will



join them and ensure that they support timely specimen referral and return of results for Global Health Security Agenda priority pathogens, antimicrobial resistance, and tuberculosis. In the absence of such efforts, IDDS will hold discussions with all relevant national stakeholders to establish a national specimen referral system and then support the agreed-upon next steps. Year 1 activities are focused on the following:

- Understanding the current systems for specimen referral and transportation (including which diseases are supported), who is supporting those efforts and where, and what are the gaps
- Supporting the revisions, completion, or development of integrated national specimen referral system policies, plans, and standard operating procedures (SOPs)
- Mentoring personnel in the handling and transportation of biological specimens
- Developing cost plans for an integrated national specimen referral network

IDDS has currently proposed to provide support for specimen referral system strengthening in Ethiopia, Guinea, Kenya, and Liberia.

#### **Network Optimization**

With nonexistent, fragmented, or disease-specific specimen referral systems, it is necessary to design an integrated specimen referral system that meets stakeholder needs, is optimized, and maintains stakeholder support through implementation. IDDS will work with governments and stakeholders to convene meetings to design, enhance, or integrate an optimized system. Questions for consideration will include right-sizing capacity, planning for the introduction of new technologies and decentralization, and current models (centralized vs. decentralized [hub and spoke]). Through this participatory process, IDDS will use Geographic Information System mapping to provide information on catchment areas and diagnostic facilities, as well as disease incidence and prevalence in humans and animals. Using models and algorithms, this process will lead to the creation of an optimized network map for the system that will lead to shorter turnaround times and prompt return of results. Inherent to the network mapping will be route optimization, which will evaluate alternative routes to facilities, include constraints (e.g., vehicle type, national curfews, driver breaks, security, seasonal weather conditions), and create detailed pick-up schedules for the tiered level of service. IDDS will explore using standardized tools, such as LabEQIP, LabMAP, ArcGIS, Llamasoft, and tools created from the joint African

Society for Laboratory Medicine-Innovative Support to Emergencies, Diseases, and Disasters initiative to undertake these efforts. As requested, IDDS will provide technical assistance (TA) for countries to ultimately undertake the mapping on their own. Where effective specimen referral systems exist, IDDS will collaborate with those partners and is prepared to extend coverage of those systems to include additional geographical regions and priority pathogen testing.

The results generated from the mapping exercise will allow IDDS to convene stakeholders to update, revise, or create national specimen referral system policies, plans, and SOPs. IDDS activities will also promote dissemination of the products. In addition, IDDS will support implementation efforts to pilot new or improved systems, including laboratory information systems that incorporate electronic tracking and return of results for the chain of custody cycle. To ensure that stakeholders are able to propose further optimizations in the future, IDDS will mentor them in continuing to use and update the mapping data and develop evidence-based recommendations for change.



#### Specimen Integrity

Even with adequate transport systems, in many countries considerable numbers of specimens are rejected prior to testing or are unable to be assayed at the referred diagnostic site. In many cases, this is due to integrity being compromised at the collection site. IDDS aims to ensure the integrity of the specimen from the time of collection to delivery at the diagnostic facility. At the collection site, technical assistance will be provided to enhance protocols for quality specimen preparation and handling, including collection (centrifugation, pipetting, aliquoting, sorting, etc.), packaging, and pretransport storage. This will also include creating biosafety SOPs for handling specimens and creating documentation



for requisition forms. If necessary, IDDS will procure standard transportation containers, packaging materials (including cold packs), and storage materials, as well as computers, tablets, scanners, and real-time temperature monitoring devices (e.g., data loggers).



### Transportation

A reliable and efficient transport system is an essential component of a functional specimen referral system. When permitted or already established through vertical systems (and when biosafety is ensured), IDDS can work with national postal systems and local transport services to facilitate specimen referrals from urban, rural, and remote locations. IDDS will identify reliable courier systems, vehicles, and bikers in countries or areas where a transport system does not yet exist, taking into consideration road conditions, especially with seasonal variations in rain. This could encompass new transportation arrangements with private courier companies and would most likely occur when integrating human and animal health transport. Other options include establishing public-private partnerships (such as the President's Emergency Plan for AIDS Relief-Becton Dickinson publicprivate partnership for dried blood spots and early infant diagnosis). In later years, other innovations could explore commodities and reagents that abolish the need for cold chain (such as OMNIGene Sputum for tuberculosis). IDDS will also reach out to the United States Agency for International Development Center for Accelerating Innovation and Impact to explore the potential of piloting unmanned aerial vehicles for transport. It should be noted that unmanned aviation

vehicles may not be an option due to uncertain regulatory restrictions, acceptability, and biosafety. For new courier services, IDDS will provide personal protective equipment as necessary, as well as technical assistance (such as training of trainers) on specimen handling and chain of custody. IDDS will also establish transport logs and other tracking systems if they do not exist, and a strong monitoring and evaluation framework to monitor that the upgraded systems are working and yielding the desired improvements in safe and timely specimen delivery.

### Financing

Quality-assured laboratory results depend on how well specimens are collected, processed, packaged, and handled during transportation to the referred laboratory, so it is crucial for countries to adequately plan for and dedicate the financial resources to support comprehensive specimen referral systems at all tiers. IDDS health economists will support countries in discerning the financial resources needed to develop and implement their specimen referral systems. In collaboration with countries, IDDS will determine the best approach to cost specimen referral networks and will conduct additional analysis as needed, such cost-benefit analyses. A key component of the support provided by IDDS will be the establishment of sound financial management systems, which can link budgets to annual operational plans and track budget and expenditure information, to facilitate the use of financial data for decision-making. Specimen referral system interventions will be accompanied by activities focused on the mobilization of domestic resources and advocacy, as well as efforts to identify innovative financing approaches to support sustainability.

The project will support government agencies to establish strong monitoring and evaluation systems for specimen referral systems to allow governments to monitor the performance of the referral system and to generate data that can articulate the contribution of strong referral systems to the diagnostic network. This will draw on performance indicators outlined in the Global Laboratory Initiative Guide to TB Specimen Referral Systems and Integrated Networks, and adapting associated forms and registers as needed to support Global Health Security Agenda priority pathogens and antimicrobial resistance.

