RÉPUBLIQUE TUNISIENNE
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Gap Analysis and Laboratories surveillance workplans of tertiary laboratories

Name of Country _____TUNISIA___

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Outline of the presentation

- Background/Introduction
- Tunisia's Laboratory Structure
- Current capacity gaps in tertiary laboratories for priority infectious disease surveillance (GHSA & NEDL context)
- Capacity strengthening workplan for surveillance (incl. KPIs, budget, lead person)
- One Health laboratory surveillance indicators for dashboard
- Potential donors to support workplan implementation
- Conclusions

Background

- Tertiary laboratories are critical for advanced diagnostics and disease surveillance.
- **Gap analysis** helps identify weaknesses in infrastructure, staff capacity, quality systems, and data reporting compared to required standards
- **Strategic frameworks :** International Health Regulations (IHR 2005), **Global Health Security Agenda (GHSA)**, WHO **National Essential Diagnostics List (NEDL)** approach; WHO SPAR and JEE (2016) as baselines; updated through After/ Intra-Action Reviews.
- Based on the findings of a gap analysis, **laboratory surveillance workplans** can be developed to strengthen the detection, confirmation, and reporting of priority diseases.

➔ enhance diagnostic capacity, data quality, and preparedness for outbreaks.

➔ align laboratory services with international standards

Introduction to Tunisian context

- **Tunisia context :**
  - Medical Biology Laboratories Unit (ULBM) : serves as national lab coordinator ;
  - National Observatory for New & Emerging Diseases (ONMNE) : oversees surveillance ;
  - University/CHU labs, regional and local public health labs + Private sector Labs : form backbone of diagnostics
- **Recent threats :**
  - COVID-19 (scaling up of genomic surveillance), seasonal influenza, TB, arboviruses (West Nile virus), food- and water-borne diseases (Shigellosis)
  - AMR : *A. baumani* imipR, ESBL, CPE, MRSA, ERV, Macrolid R Sp, ampicillin R *H. influenzae*, ….
- **Regional alignment:** Africa CDC priority pathogens (HCAT management guidlines)
- **Global alignment:** WHO 2024 pathogen lists (AMR and R&D priorities) guide preparedness.

Tunisia's Laboratory Structure

Tiered network (human health)

- **National Labs/ University Hospitals (CHUs):** e.g., Charles Nicolle, Institut Pasteur de Tunis (IPT) (Tunis), Fattouma Bourguiba (Monastir), Sahloul (Sousse). ➔ Provide advanced microbiology and molecular testing
- **Reference Lab:** includes BSL-3 Pasteur Institute, National Influenza Center (NIC), specialized reference units (virology, arboviruses, TB, rabies, etc.)
- **Regional/local Labs:** provide basic bacteriology, parasitology, basic hematology/biochemistry; refer samples/patient to CHUs/IPT for confirmation and sequencing.
- **Public health coordination:** Medical Biology Laboratories Unit (coordination); New and Emergent Disease national Observatory (For Surveillance); DSSB (reporting of notifable diseases (MDO))

Tunisia's Laboratory Structure

Animal & environmental interfaces (One Health)

- veterinary labs (IRVT)
- vector/entomology units (IPT)
- water & food safety labs (Hygiene Labs)
- academic labs

Tunisia is engaged in One Health approach

Current capacity gaps in tertiary laboratories for priority infectious disease surveillance in the context GHSA & NEDL

Functional Areas	Capacity Gaps	Root cause analysis
National Laboratory		
D1.1. Specimen referral and transport system	Cold-chain not ensured at peripheral sites; lack of standardized courier contracts; weak tracking Lack of Professional transport system	Insufficient investment in logistics; absence of national and standardised transport agreements; Weak coordination between regions.
D1.2. Laboratory quality system	Limited/absent ISO 15189 accreditation; inconsistent EQA coverage; weak corrective action follow-up and inspection	Lack of national QMS policy & enforcement; limited funding for audits and EQA participation; absence of dedicated auditors.
D1.3. Laboratory testing capacity modalities	Essential diagnostics (dengue, measles PCR, cholera) not available in all tiers; sequencing limited to SARS-CoV-2 and few pathogens.	Procurement gaps; dependence on projects/donors; lack of sustained funding for test menu expansion; weak integration of NEDL into procurement planning.
D1.4. Effective national diagnostic network	Functional but not fully formalized network; weak interoperability / integrated one health system absence of official designation of National Reference and regional referent Laboratories.	No legal/regulatory framework clarifying mandates; coordination relies on ad hoc arrangements; fragmented LIMS platforms.

Current capacity gaps in tertiary laboratories for priority infectious disease surveillance in the context GHSA & NEDL

Functional Areas	Capacity Gaps	Root cause analysis
Surveillance		
D2.1. Early warning surveillance function	Syndromic and lab-based surveillance exist, but sentinel coverage not optimal; event-based signals unevenly integrated. Data quality / data completeness	Limited resources; weak IT integration; lack of SOP harmonization across tiers
D2.2. Event verification and investigation	Centralised Confirmation analysis during outbreaks Incomplete/slow feedback to regions/	Limited surge capacity; Weak lab–public health coordination; referral delays.
D2.3. Analysis and information sharing	Manual data entry (Paper-form declaration) weak interoperability within surveillance systems; Genomic analysis rarely available Genomic data not systematically shared.	Lack of digital infrastructure (peripheric lab); no standard data-sharing protocols; insufficient ressources and IT skills at lab level.

Current capacity gaps in tertiary laboratories for priority infectious disease surveillance in the context GHSA & NEDL

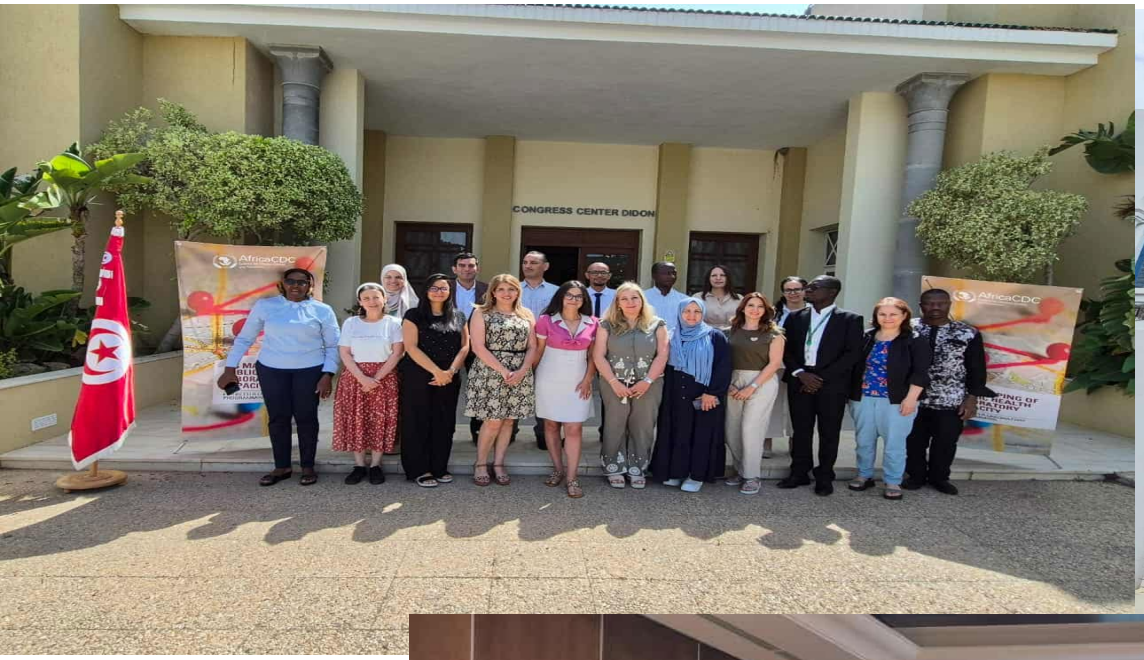
Functional Areas	Capacity Gaps	Root cause analysis
Human Ressources		
D3.1. Multisectoral workforce strategy	Workforce strategies exist in health sector, but weak integration with vet/environmental labs.	HR policies; absence of One Health HR framework; weak cross-sector planning
D3.2. Human resources for implementation of IHR	Absence of Biologists in peripheric labs Absence of bioinformaticians status Insufficient molecular, biosafety officers.	Limited recruitment; insufficient training programs; reliance on external projects.
D3.3. Workforce training	Training opportunities exist (e.g. biosafety, diagnostics), but not continuous; limited budget	No structured national training program Turnover; Donor-dependent workshops; Absence of monitoring system for staff competencies
D3.4. Workforce surge during a public health event	Surge capacity ad hoc, Absence of Multitask Team for Emergency Sit. mobilized mainly during COVID-19 but not institutionalized	No formal surge mechanism in HR regulations; lack of reserve roster; limited agreements with academic/research institutions

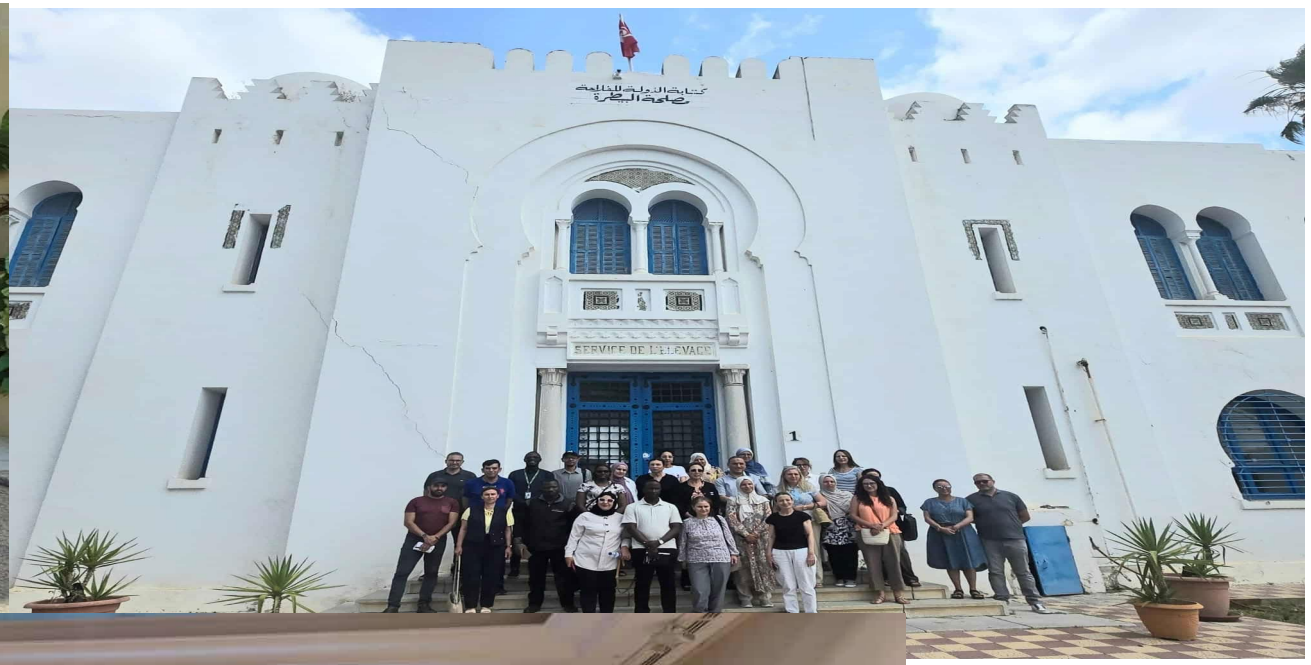
Capacity strengthening Ongoing activities for surveillance:

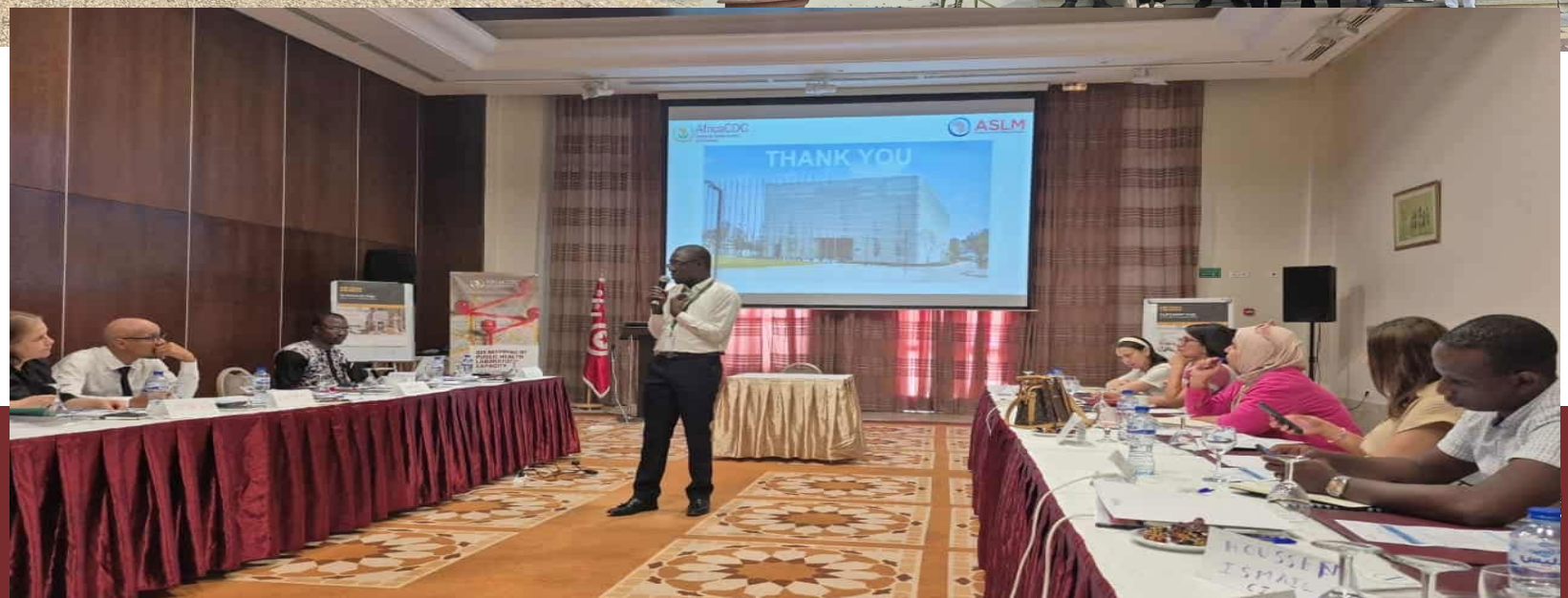
- Regulatory framework:
  - Assessement of existing framework (public health lab network)
  - Reference lab regulation text (norms)
  - Public health laboratories norms (infrastructure, workforce, equipements, analysis and technics)
- Laboratory testing capacity modalities:
  - Enhancing advanced diagnostics (Genomics, AMR)
  - Assessment and enforcement of national and regional laboratories (AMR)
- Training and competence transfer for workforce:
  - Training programs: BSBS – Good Practice – Quality (Technical staff and biologists)
- LabMAp
  - Geomapping and data collection (a first workshop on June 2025)
  - Approval has been given for executing a work plan to conduct LabMap data collection (by the end of 2025)

Capacity strengthening Ongoing activities for surveillance:

LabMap; Tunisia, June 2025







AfricaCDC
Centres for Disease Control and Prevention

Capacity strengthening Recommendations:

On a second phase, it is recommanded to plan for :

- Secure specimen transfer: establishing national protocol for materiel transport (Cold chain, BSBS SOPs, Professional transport service, etc.)
- Strenghthen QC management: Encourage Accreditation to ISO15189 (informative and training sessions, internal Auditors, etc.)
- Establish a fully integrated surveillance system : Digitalize and encourage community-level reporting
- Establish and train Multisectoral Rapid Response team in all governorates and with « One Health Approach »
- Put on place KPI to monitoring and evaluating Surveillance system

What are some of indicators (KPI) for one health laboratory surveillance system for dashboard

1. **Coverage**
   - **% of essential tests :** level of the lab network (local, regional, national reference) that has the diagnostic tests listed in the WHO Essential Diagnostics List (NEDL).
   - **Number of active surveillance sites (human, veterinary, environment):** sites functional across all sectors.

2. **Quality**
   - **EQA (External Quality Assessment) pass rate: P**roportion of labs that pass international proficiency testing schemes, (reliability of results)
   - **% corrective actions closed:** Tracks whether labs actually fix problems identified in audits or EQAs, (continuous quality improvement)

3. **Biosafety**: **% of biosafety cabinets (BSC) certified:** Ensures that key biosafety equipment is regularly validated and safe to use.

4. **Specialised analysis capacity:** Number of equipments / coverage

5. **Antimicrobial Resistance (AMR) Lab Network:** Coverage – Capacity testing – Data sharing rate

6. **number of labs meeting national norms in:**
   - Human Ressources: Specilaised profiles rates – Capacity building – Training policies
   - Diagnostic Reagent and equipment: Stock tracking and Maintenance capacity
   - Infrastructure

What are some of the potential donors to support implementation of workplans?

Until allocating a national fund, Tunisia will need support for financing implementation of workplans, from potential donors :

Multilaterals: WHO, Africa CDC, WB, Global Fund, UNICEF, FAO/WOAH.
Bilaterals: CDC, GIZ, JICA.
Foundations/Networks: Fondation Mérieux, Pasteur Network, ASLM, FIND, etc.

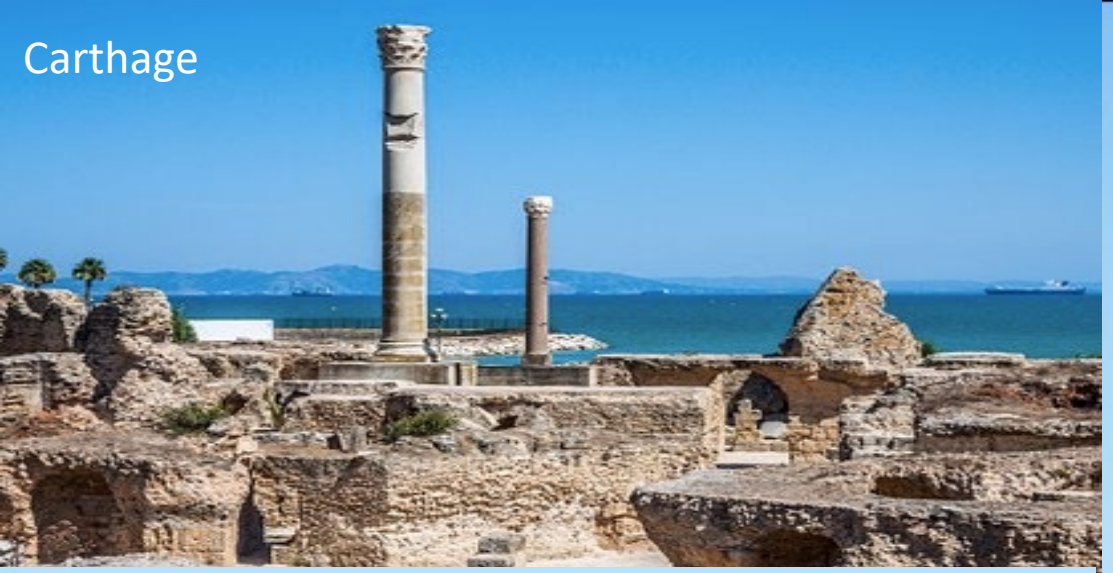
Approach:

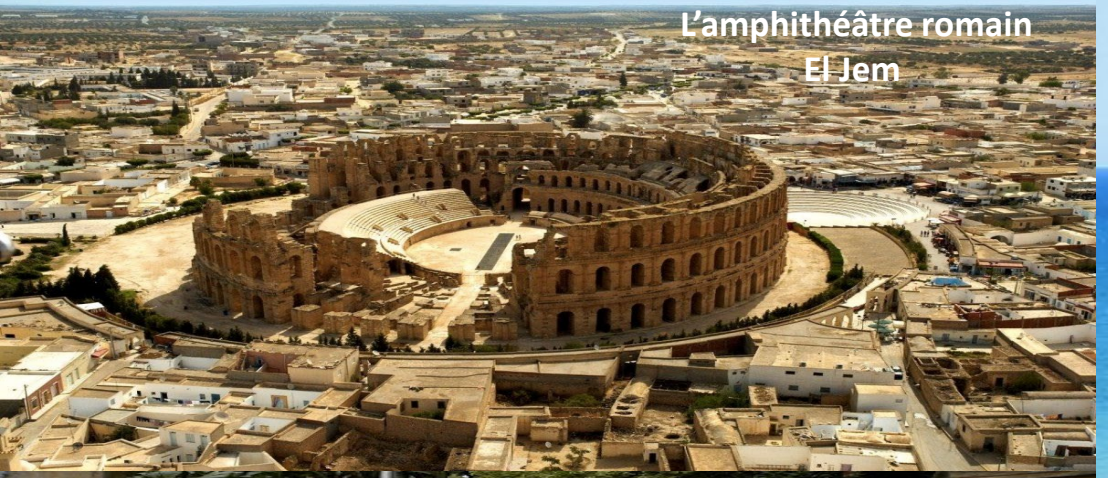
- Government for Regulation/infrasructure/HR/consumables;
- Donors for expertise, equipment, IT, External Quality Assessment, training.

Conclusions

- Tunisia has strong pillars
  - International and national regulation
  - ULB coordination, Surveillance governance (ONMNE-DSSB)
  - genomic and specilized analysis capacity
  - AMR network
- Yet major gaps persist:
  - Officialised Reference lab network
  - Training policies
  - data interoperability, logistics,
  - Fragmented regulatory framework.
- workplan should defines measurable KPIs for monitoring
- Donor engagement and national reforms will ensure sustainability.

Carthage





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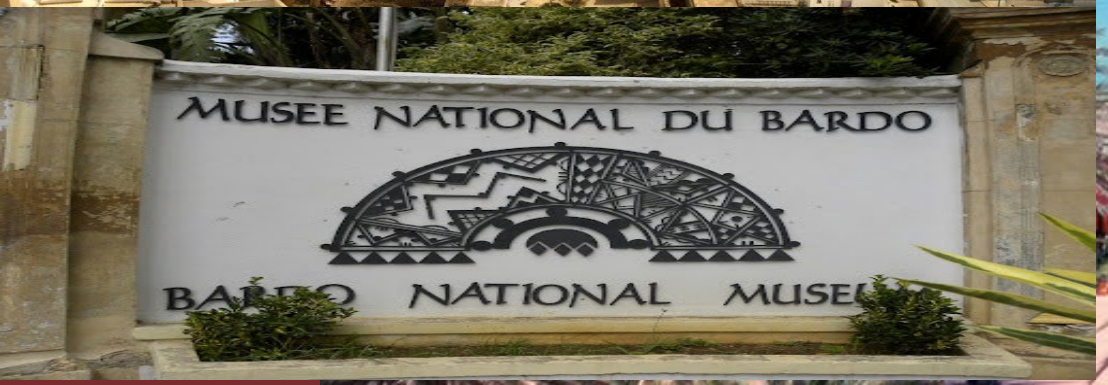

Thank you for your attention