

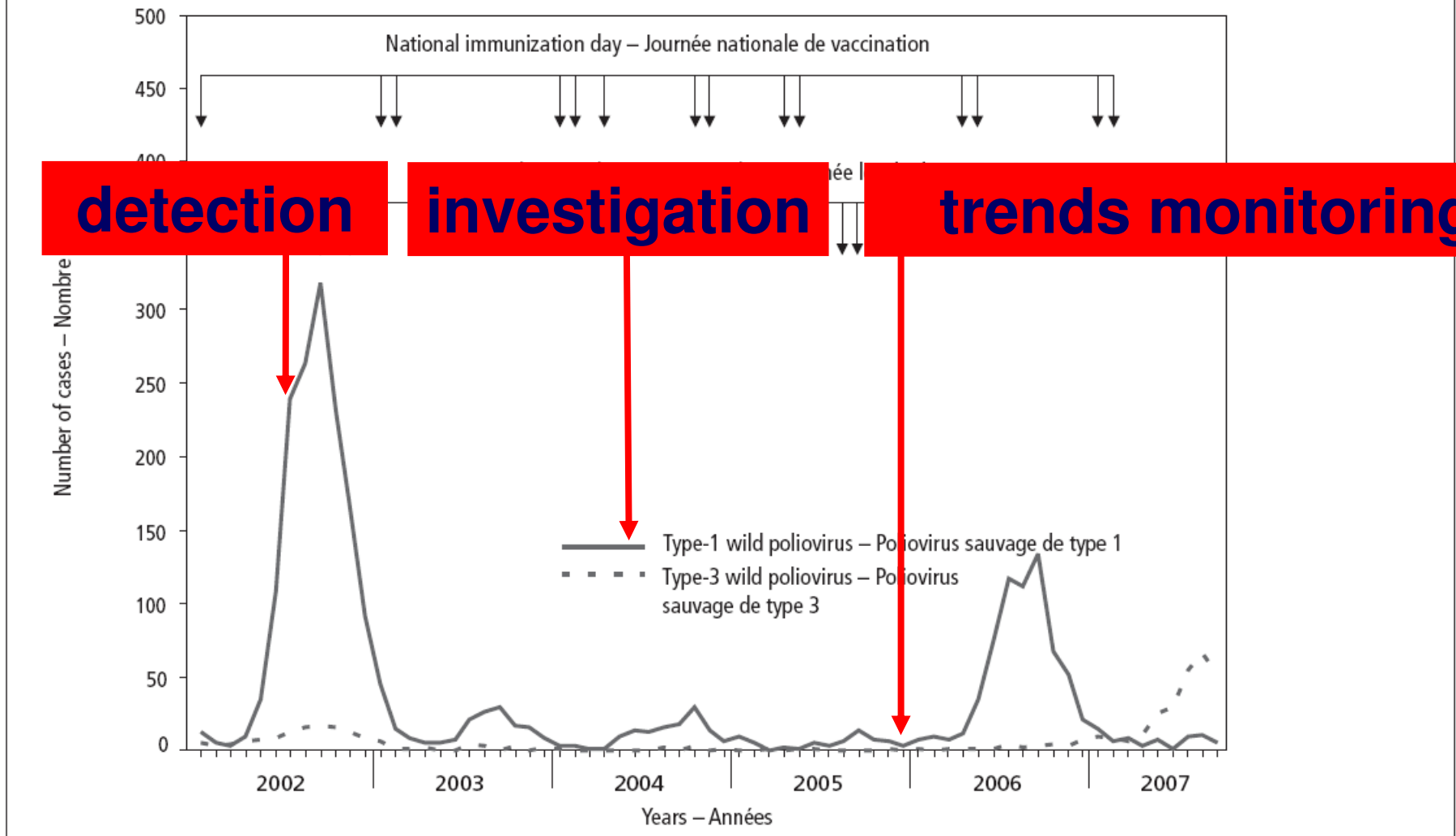


IHR Core capacity requirements for surveillance and response: What is expected from public health laboratories?



**World Health
Organization**

Fig. 1 **Monthly incidence of poliomyelitis and supplementary immunization rounds of activities, India, January 2002–September 2007**
 Fig. 1 **Incidence mensuelle de la poliomyélite et tournées d'activités de vaccination supplémentaires, Inde, janvier 2002-septembre 2007**



Weekly Epidemiological Record No. 46, 2007, 82, 401–408

International Health Regulations (2005) and laboratory

“Laboratory” or “specimens” is quoted 7 times in the text

1. Detection → **laboratory data to be reported** (annex 1)
2. Assessment of events → **insufficient laboratory capacity = serious event** (annex 2)
3. Public health response supported through the **laboratory analysis of samples, domestically or through collaborating centres** (annex 1)
4. Notification to WHO → **continuous communication of laboratory results** (art. 6)
5. Information sharing → **links with ...laboratories for the dissemination of information** and recommendations (annex 1)
6. Recommendations by WHO with respect to the persons may include the review of **laboratory analysis** (art. 18)
7. Facilitating the **transport and handling of biological substances, reagents and materials** for diagnostic purposes (art. 46)

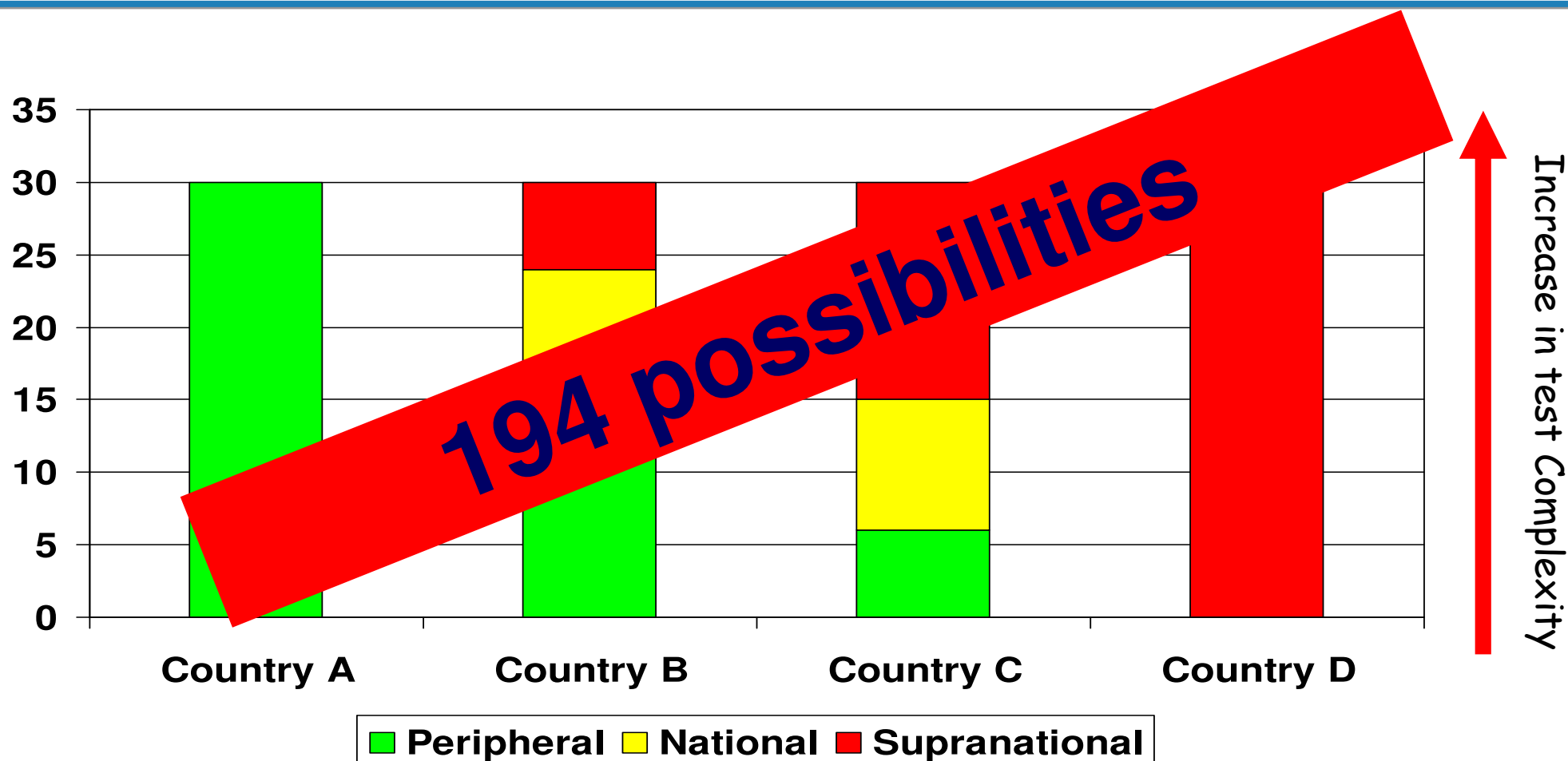


Challenges from the IHR(2005) text

- No clear instructions on laboratory requirements in terms of organization or regulations
- Large flexibility between domestic and outsourced capacity



Laboratory capacities for IHR



**INTERNATIONAL CONSULTATION ON STRENGTHENING NATIONAL CAPACITIES FOR
EPIDEMIC PREPAREDNESS AND RESPONSE IN SUPPORT OF NATIONAL
IMPLEMENTATION OF THE INTERNATIONAL HEALTH REGULATIONS (2005)
MAY 2 – 5, 2006**

*“The national public health system should establish the laboratory capacity to identify, monitor and report to the health authorities on agents that may cause epidemics and emergencies, including those of international importance, in a **safe, timely and reliable** manner”*

“Every national public health laboratory system should institute a national quality assurance programme which must include all laboratories participating in disease surveillance, detection and identification of diseases of public health importance. A quality management system related to the IHR requirements must be part of the laboratory policy in each country, and include standards, quality control, audits, external quality assessment, biosafety/ biosecurity and maintenance.”



World Health Assembly Resolutions

- **2006 WHA resolution relative to the immediate and voluntary compliance with IHR (2005)**

*WHO is requested to... « expand and accelerate training efforts in the areas of...laboratory capacity, including **regional networking of laboratories, biosafety, and quality control...** »*

- **2008 WHA resolution on IHR:**

*the WHA requests the WHO DG “...to **provide support to Member States with the most vulnerable health systems in strengthening core capacity requirements** for surveillance and response at airports, ports and ground crossings, **paying special attention to the sub-Saharan Africa laboratory network...** »*



Laboratory core capacities: key elements

1. Laboratory capacity mapping
2. Specimen collection and transport
3. Biosafety
4. Laboratory based investigation
5. Quality assurance
6. Reporting / communications



Laboratory core capacities: key elements

1. Laboratory capacity mapping

2.



3.

4.



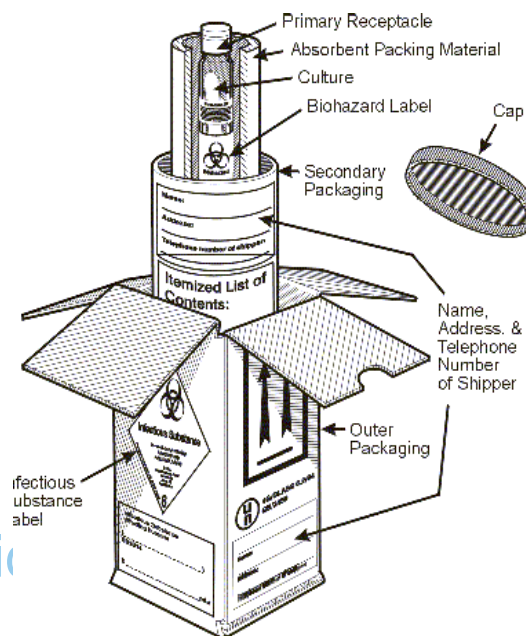
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6.

- All hazards approach
- Licensure/registration
- International partnerships

Laboratory core capacities: key elements

1. Laboratory capacity mapping
2. Specimen collection and transport
3. Biosafety
4. Laboratory based investigation
5. Quality assurance
6. Reporting / communication



- Laboratory's responsibility
- Compliance with national and international regulations
- Pre-positioned materials

Laboratory core capacities: key elements

1. Laboratory capacity mapping
2. Specimen collection and transport
3. **Biosafety**
4. Laboratory based investigation
5. Quality assurance
6. Reporting / communications



- Risk assessment
- Personal protective equipment, infrastructure and equipments
- Dangerous pathogens containment and storage

Laboratory core capacities: key elements

1. Laboratory capacity mapping
2. Specimen collection and transport
3. Biosafety
4. Laboratory based investigation
5. Quality assurance
6. Reporting / communications



Ebola virus detection; PCR workstation in Mbomo, Congo (from Bull Soc Pathol Exot, 2005, 98, 3, 205-209)

- Standardized operating procedures & algorithms
- Deployable solutions
- Simulation exercises

Laboratory core capacities: key elements

1. Laboratory capacity
2. Specimen collection and transport
3. Biosafety
4. Laboratory based investigation
5. Quality assurance
6. Reporting / communication

National Polio Laboratory Checklist

**National Polio Laboratory
Check List for Annual WHO Accreditation**

Laboratories are to be notified in advance of the accreditation review and provided a copy of this form to assist in gathering information. Accreditation for Calendar Year: _____

Dates of Review: _____

Laboratory: _____ **E-mail:** _____

Address: _____ **Fax:** _____

Phone: _____

Head of Department: _____

Head of Laboratory: _____

Technical Supervisor: _____

Reviewers: _____

Name of National Accrediting Authority and current accreditation status: _____

Part I: Summary of Review

Recommendation: (check one):

Accredit: Laboratory meets all criteria

Provisionally accredit: Laboratory passed the most recent proficiency test, but failed to achieve one or more of the remaining criteria

Do not accredit: Laboratory did not pass the most recent proficiency test

Findings:

1. Test results on at least 80% of all AFP specimens are reported within 28 days:	00
2. Tests are performed on at least 150 stool specimens annually:	00
3. Accuracy of poliovirus typing is at least 90%:	00
4. At least 80% of AFP poliovirus isolates are forwarded for ITD within 7 days:	00
5. Internal quality control procedures for cell cultures are implemented:	00
6. Result on most recent isolation PT is at least 80%:	00
7. Score on annual on-site review is at least 80%:	00

Annual NPEV isolation rate is: _____

Version: January 2005

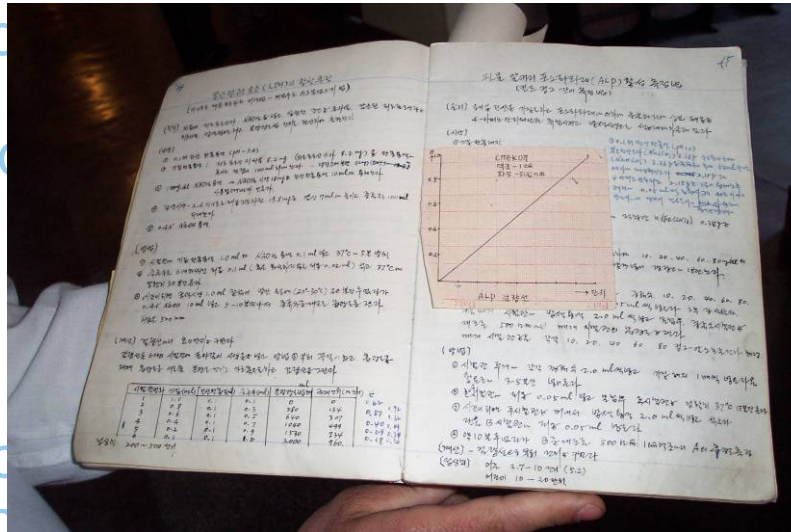
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- National norms and standards
- Inspection, certification, accreditation
- External Quality Assessment (proficiency-testing / rechecking)



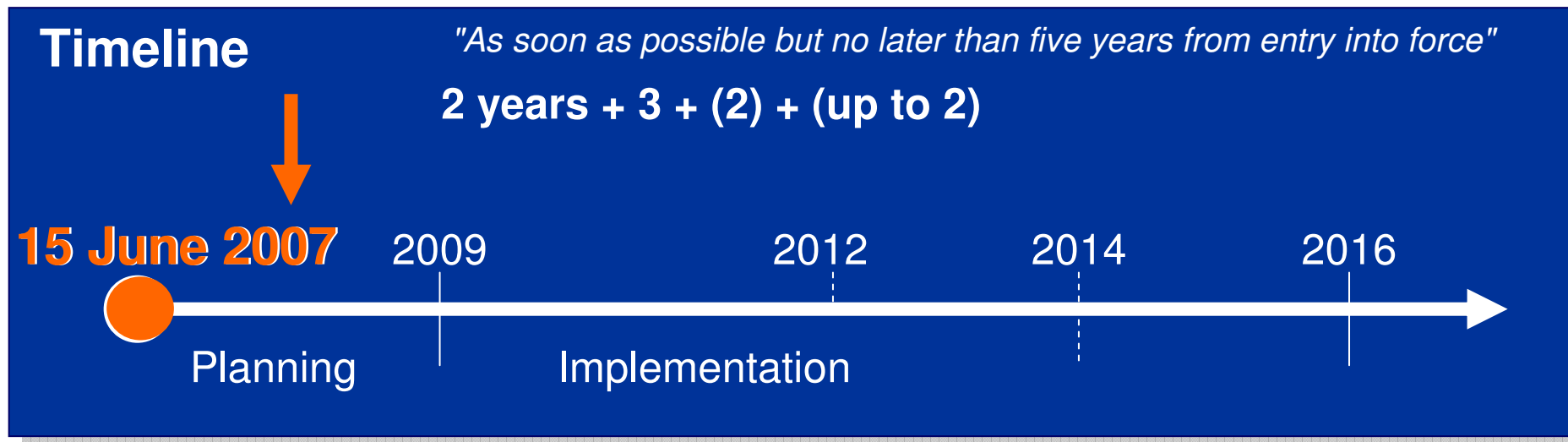
Laboratory core capacities: key elements

1. Laboratory capacity
2. Specimen collection and transport
3. Biosafety
4. Laboratory based investigation
5. Quality assurance
6. Reporting / communications



- Data management (Laboratory Information Systems)
- Reporting procedures to the public health authorities
- Ethics
- Risk communication

Building laboratory core capacities



- Country responsibility / WHO support
- Building on existing capacities
- Cross-sectoral issues
- Coordination NFP ↔ laboratory structures



Examples of WHO activities aiming at strengthening laboratory capacities

- Development of assessment tools/checklists
- IHR Awareness and training workshops for laboratory specialists
- Assistance to on-site evaluation and planning
- Twinning projects between resource-limited and specialized laboratories
- Accreditation, reagents distribution, External Quality Assessment



www.who.int/ihr

**International
Health
Regulations**

Building global public health security



**World Health
Organization**