APHL 2019
Where Laboratory Science and Public Health Meet

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St. Louis, MO
St. Louis Union Station Hotel

#aphl
The conclusions, findings, and opinions expressed in this presentation do not necessarily reflect the official position of the U.S. Department of Health and Human Services, the Public Health Service, or the Centers for Disease Control and Prevention
DEVELOPING SUSTAINABLE LABORATORY CAPACITY IN THE GLOBAL CONTEXT

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Priorities for Advancing Global Health Security

**PREVENT**
Build country and global capabilities to improve public health preparedness

**DETECT**
Improve detection to mitigate the impact of global disease outbreaks and other public health events

**RESPOND**
Increase rapid response to global health emergencies

**COLLABORATE**
Sustain and strengthen partnerships for global health security

PROTECTING AMERICANS AND PEOPLE AROUND THE WORLD
Prelude
I. IHR & GHSA
GLOBAL AIR TRAVEL - 1935
GLOBAL AIR TRAVEL - 2015
• Implementation of the revised IHR began in 2007.
• All nations were to be fully compliant with the revised IHR in 2012.
• This deadline was extended to 2014.
• As of 2018, most nations were not compliant.
• IHR is vital and achievable.
• IHR is even more important than ever.
• The process for monitoring and evaluating compliance with IHR is flawed.
II. IMPROVING LABORATORY CAPACITY UNDER IHR & GHSA
International Health Regulations—What Gets Measured Gets Done

Kashef Ijaz, Eric Kasowski, Ray R. Arthur, Frederick J. Angulo, and Scott F. Dowell

The global spread of severe acute respiratory syndrome highlighted the need to detect and control disease outbreaks at their source, as envisioned by the 2005 revised International Health Regulations (IHR). June 2012 marked the initial deadline by which all 194 World Health Organization (WHO) member states agreed to have IHR core capacities fully implemented for limiting the spread of public health emergencies of international concern. Many countries fell short of these implementation goals and requested a 2-year extension. The degree to which achieving IHR compliance will result in global health security is not clear, but what is clear is that progress against the threat of epidemic disease requires a focused approach that can be monitored and measured efficiently. We developed concrete goals and metrics for 4 of the 8 core capacities with other US government partners in consultation with WHO and national collaborators worldwide. The intent is on June 15, 2007, and in an unusual episode of international consensus, all 194 WHO member states ratified the agreement. When implemented, IHR should improve global capacity to detect, assess, notify, and respond to public health threats. Properly and fully implemented, IHR should usher in a new global era of international communication, cooperation, and unprecedented security against the epidemic threats that have plagued humanity since ancient times. But there is a problem.

After enactment of the revised IHR in June 2007, all member countries were required to develop and implement a minimum of core public health capacities by June 2012, the 5-year anniversary of IHR’s enforcement. Many countries did not meet the deadline and have requested a 2-year extension. In an era of limited resources, competing priorities, and political challenges, achievement of the IHR
<table>
<thead>
<tr>
<th>Capacity</th>
<th>Goal</th>
<th>Target/measure</th>
<th>Intended use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human resources</td>
<td>Ensure adequate numbers of trained personnel are available to support the response to a public health emergency</td>
<td>A national workforce plan and 1 trained field epidemiologist for every 200,000 persons</td>
<td>Document that a workforce plan exists and is maintained and updated, and monitor annual progress toward the goal of 1 trained field epidemiologist for every 200,000 persons.</td>
</tr>
<tr>
<td>Surveillance</td>
<td>Ensure that surveillance systems capable of detecting selected potential public health emergencies in any part of the country are established and functioning</td>
<td>Surveillance infrastructure that demonstrates the ability to detect ≥3 of 5 syndromes indicative of a potential public health emergency of international concern</td>
<td>Monitor and evaluate the effectiveness of the surveillance system, and identify areas for improvement within the country’s public health surveillance infrastructure.</td>
</tr>
<tr>
<td>Laboratory</td>
<td>Ensure access to laboratory diagnostic capabilities that can identify a range of emerging epidemic pathogens by using the full spectrum of basic laboratory testing methods</td>
<td>Ability to perform 10 core diagnostic tests for confirmation of indicator pathogens from any part of the country</td>
<td>Assess/measure capacity for detection will by using external/internal quality assurance for each of the 10 core tests and indicator pathogens using standard methods.</td>
</tr>
<tr>
<td>Response</td>
<td>Ensure countries have adequate rapid response capacity for public health emergencies</td>
<td>At least 1 functioning rapid response team per major administrative unit</td>
<td>Maintain an adequate number of rapid response teams with the necessary training, appropriate personnel, and regular outbreak responses.</td>
</tr>
</tbody>
</table>
### Table 2. Core laboratory tests and indicator pathogens in the International Health Regulations

<table>
<thead>
<tr>
<th>Core test</th>
<th>Indicator pathogen</th>
<th>Turnaround time from receipt in the laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCR</td>
<td>Influenza virus*</td>
<td>Within 24 h</td>
</tr>
<tr>
<td>Virus culture</td>
<td>Poliovirus*</td>
<td>Within 14 d</td>
</tr>
<tr>
<td>Serology</td>
<td>HIV†</td>
<td>Within 5 d</td>
</tr>
<tr>
<td>Microscopy</td>
<td><em>Mycobacterium tuberculosis</em>†</td>
<td>Within 3 d</td>
</tr>
<tr>
<td>Rapid diagnostic test</td>
<td><em>Plasmodium</em> spp.†</td>
<td>Within 2 h</td>
</tr>
<tr>
<td>Bacterial culture</td>
<td><em>Salmonella enteritidis</em> serotype Typhi‡</td>
<td>Within 3 d</td>
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<tr>
<td>Local priority test</td>
<td>Local priority test§</td>
<td>Local priority test</td>
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<td>Local priority test</td>
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<td>Local priority test</td>
<td>Local priority test§</td>
<td>Local priority test</td>
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</tbody>
</table>

*Selected from the International Health Regulations immediately notifiable list.
‡Selected from WHO Global Foodborne Infections Network (www.who.int/gfn/en).
§Indicator pathogens selected by the country on the basis of major national public health concern.
Global Health Security Agenda

**Action Packages**

### PREVENT

1. Antimicrobial Resistance
2. Zoonotic Disease
3. Biosafety and Biosecurity
4. Immunization

### DETECT

1. National Laboratory System
2 & 3. Real-Time Surveillance
4. Reporting
5. Workforce Development

### RESPOND

1. Emergency Operations Centers
2. Linking Public Health with Law and Multisectoral Rapid Response
3. Medical Countermeasures and Personnel Deployment
III. LABORATORY ACTION PACKAGE
Detect Threats Early

**Target:**
- Surveillance with a national laboratory system
- Effective point-of-care and laboratory diagnostics

**Impact:**
- National Laboratory System providing quality-assured laboratory data for public health action

**National Laboratory Systems**
Without Laboratory Capacity

Developed from Pinner et al., J Infect Diseases 1992
If laboratory diagnostics are added...
LABORATORY-BASED SURVEILLANCE

- Outbreak detection and investigation
- Develop case definition; determine case management
- Evaluate interventions
- Monitor progress towards control
- Understand the natural history of disease
- Tracing spread by typing and characterization
- Detection of carriers and natural foci of infection
- Determine the end of an outbreak
- Develop immunization strategies
- Determine elimination or eradication of disease
- Prevalence studies
- Confirmation of etiology to resolve syndromic presentation
- Antimicrobial resistance monitoring
- Emergence of unusual isolates
- Detection of new pathogens
- Environmental monitoring
- Sero-surveillance
Laboratory Capacity — Components

• True laboratory capacity requires all major components of the laboratory network to be well integrated in the national laboratory system.

• Laboratory network components:
  • Sample management (collection, transport, processing)
  • Quality management system
  • Diagnostics & Testing strategies
  • Biosafety-biosecurity
  • Staff and training (links to workforce)
  • Facilities & infrastructure
  • Data management & Reporting (links to surveillance, response)
  • Networking peripheral, regional, and global laboratories
LABORATORY CAPACITY - MEASURED

- Priority Pathogens Identified
- Core Tests Selected
- SOPs Documented
- Specimen Management Documented
- Can Test
- Can Report
- Reported by Surveillance System
- EQAS Documented
- Staff Training Program
- Accredited
IV. Example Country

2014 versus 2018
Global Health Security Agenda Priority Countries

**GHSA Phase I**
- Bangladesh
- Burkina Faso
- Cameroon
- Cote d'Ivoire
- Guinea
- Ethiopia
- India
- Indonesia
- Kenya

**GHSA Phase II**
- Liberia
- Mali
- Pakistan
- Senegal
- Sierra Leone
- Tanzania
- Uganda
- Vietnam

**Ebola Preparedness Countries**
- Benin
- Gambia
- Guinea Bissau
- Mauritania
- Nigeria
- Togo

*Caribbean Community (CARICOM) is an organization of 15 Caribbean nations and dependencies.*
<table>
<thead>
<tr>
<th>Priority Pathogen</th>
<th>Core Test</th>
<th>SOP</th>
<th>Specimen Management Documented</th>
<th>Can Test</th>
<th>Can Report</th>
<th>Reported by Surveillance System</th>
<th>EQAS Documented</th>
<th>Staff Training Program</th>
<th>Accredited</th>
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<tbody>
<tr>
<td>Influenza virus</td>
<td>PCR</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>Polio virus</td>
<td>Virus culture</td>
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<td>HIV</td>
<td>Serology</td>
<td>Yes</td>
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<td>Yes</td>
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<td>Mycobacterium tuberculosis</td>
<td>Microscopy</td>
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<td>Plasmodium species</td>
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<td>Salmonella Typhi</td>
<td>Bacteria culture</td>
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<td>Plasmodium species</td>
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<td>Bacteria culture</td>
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<td>Vibrio cholerae</td>
<td>Bacterial culture or RDT</td>
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<td>Shigella species</td>
<td>Bacterial culture</td>
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<td>Viral hepatitis</td>
<td>Serology</td>
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<td>Ebola virus</td>
<td>PCR</td>
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V. Lessons
LESSON 1: MEASURE & DOCUMENT!

• If it is measured, it is more likely to be completed
• If it is documented and standardized, it is more likely to be sustained
• If you don’t write it down, it never happened
**Lesson 2: Collaborate & Cooperate!**

- Existing laboratory networks – NICs, PEPFAR, Polio, Measles, Rubella
- Twinning and mentors – Association of Public Health Laboratories, Fondation Mérieux USA, Institute Pasteur, ASLM, ASM
- International Organizations – WHO, FAO, OIE, USAID
Lesson 3: “Poco A Poco”

- Systems-based approach
- Define the mission
  - Priority Pathogens
  - Core Diagnostics
  - Specimen Management
  - Facilities
  - Staff & Training
  - Equipment & Logistics
- Seek Sustainability
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For more information please contact Centers for Disease Control and Prevention

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Visit: www.cdc.gov | Contact CDC at: 1-800-CDC-INFO or www.cdc.gov/info

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Global Health Security

Laboratory
- Specimen referral network reaching > 80% of districts
- National reference laboratory performing 6 testing methods under IHR

Surveillance
- Surveillance for 3 core syndromes
- Capacity to analyze and link data for functional real-time biosurveillance system

Emergency Operations
- EOC activation when needed
- Functional IMS use for preparedness and response

Workforce Development
- National workforce planning
- Minimum of 1 trained field epidemiologist per 200,000
• Joint External Evaluation (JEE) describes the capacities to prevent, detect, and respond to public health emergencies in alignment with the International Health Regulations (IHR).

• The JEE uses the evaluation methodology developed for the Global Health Security Agenda (GHSA), combining the infectious disease targets of GHSA with the all-hazards approach to public health preparedness and response required for implementation of the IHR.
Problems & Challenges

• Supplies & Reagents
• Specimens & Shipping
• Workforce
• Maintenance and Calibration
• Information management
• Quality control and assurance
• Links to associated action packages: Antimicrobial Resistance (P1), Zoonotic Disease (P2), Biosafety and Biosecurity (P3), Surveillance & Reporting (D2 & D3), Workforce (D5)
Shared Priorities

GHSA

Laboratory
Surveillance
Reporting
Zoonotic Diseases
Human Resources

IHR
GHSA Phase I
Bangladesh
Burkina Faso
Cameroon
Cote d'Ivoire
Guinea
Ethiopia
India
Indonesia
Kenya
Liberia
Mali
Pakistan
Senegal
Sierra Leone
Tanzania
Uganda
Vietnam

GHSA Phase II
Cambodia
Democratic Republic of Congo
Georgia
Ghana
Haiti
Jordan
Kazakhstan
Laos
Malaysia
Mozambique
Peru
Rwanda
Thailand
Ukraine
CARICOM