International Health Regulations

Webinar

May 18, 2009

Presenters

Jose Fernandez, Senior Science Advisor, International Health Regulations Program, ASPR/HHS

Katrin Kohl, Deputy Director, Division of Global Migration and Quarantine, CDC/HHS

Steve Ostroff, State Epidemiolgist, Commonwealth of Pennsylvania

Objectives

- Establish the purpose of the IHR by providing their social and historical context
- Describe the first two years of implementation
- Allow CSTE to report on the results of the assessment and state of US compliance
- Initiate a dialog about presumptive/early reporting
  - Report suspected outbreaks before confirmation
  - Confidentiality of reports

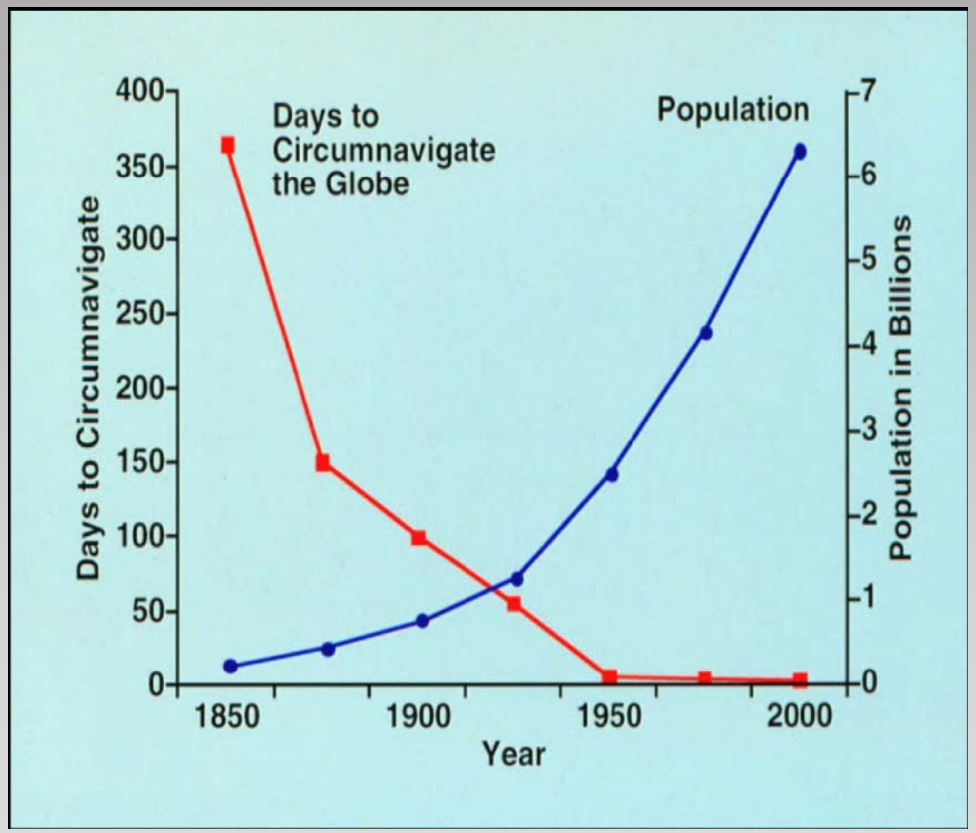
Importance

"The mandate for general global public health surveillance is moving beyond named diseases to encompass a global responsibility to detect and report in a timely manner internationally important disease events, whether they are individual cases or clusters, whether they are well-defined diseases or ill-defined diseases."

- Patrick Kelley, Director IOM Board on Global Health, "Global Infectious Disease Surveillance and Detection"

Travel Speed

Air travel rapidly connects distant geographies



Murphy and Nathanson . Seminars in Virology: 5(2). 1994.

Travel & Tourism

- 64 million Americans traveled overseas in 2007
- 56 million international visitors to the US in 2007
  - Canada & Mexico - 32 million
  - Europe – 11.5 million
  - Asia – 6.4 million
  - Central & South America – 3 million
  - Middle East – 620,000
  - Africa – 280,000
- International tourism (2007)
  - 903 million tourists (56 million – U.S.)
  - $856 billion ($97 billion – U.S.)

http://tinet.ita.doc.gov/view/f-2000-99-001/Forecast/Outlook_International_Travel_US.pdf;
Bureau of Transportation Statistics, U.S. Department of Transportation

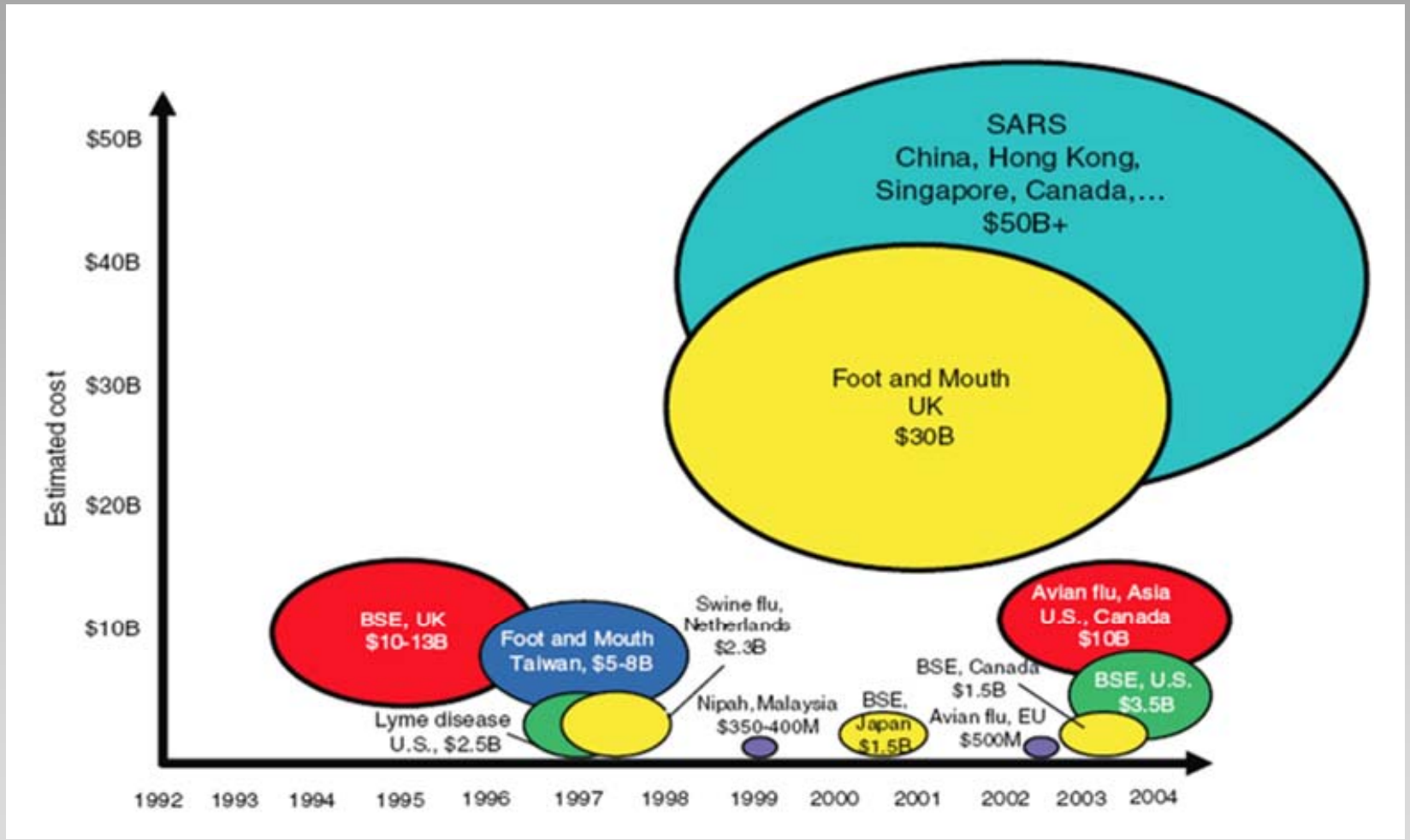
Trade

- Approximately 15% of food in the U.S. is imported from over 150 countries through over 300 ports

- Live animal importation into the U.S. (2006):
  - 136,216 mammals (including 29 species of rodents)
  - 243,000 birds
  - 1.3 million reptiles
  - 4.6 million amphibians
  - 222 million fish

Data presented at IOM workshop: “Globalization, Movement of Pathogens (and their hosts) and the revised IHRs" December 16-17 2008

Estimated Cost of Recent Disease Outbreaks



Source: Karesh(2006). Reprinted with permission from Bio-era. Copyright 2007.

History of the IHR

- 1851: International Sanitary Conference in Paris
- 1951: WHO Member States adopted the International Sanitary Regulations (ISR)
- 1969: ISR replaced and renamed - International Health Regulations
- 1973 & 1981: minor modifications to 1969 Regulations
- May 23, 2005: WHA adopted revised International Health Regulations (2005)
- July 18, 2007: IHR enter into force in United States

Purpose and Scope
IHR (2005)

- To prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade

  – *International Health Regulations, Article 2*

Philosophy of the IHR (2005)

- Avoid unnecessary interference with travel and international trade
- Focus is now on reporting **public health events of international concern** (PHEIC) including unusual incidents
- Control disease at the source as well as at the borders
- Rapid reporting and management of events
- All hazards not “merely” infectious diseases

Key Changes in IHR (2005)

- SARS and other emerging diseases were the main incentive for changes
- Focus on control at the source as well as at borders
- Respond to a broad range of public health events, rather than only the 4 defined pathogens
- Introduce the PHEIC as a standard

Public Health Emergency of International Concern (PHEIC)

- An extraordinary public health event:
  - that constitutes a public health risk to other countries through its international spread; and
  - that may require a coordinated international response.

- Time requirements for DOMESTIC assessment and notification:
  - 48 hours to assess an event once the national government becomes aware of it
  - 24 hours to report a potential PHEIC if assessment indicates
  - 24 hours to report a potential PHEIC outside of a Member State's territory

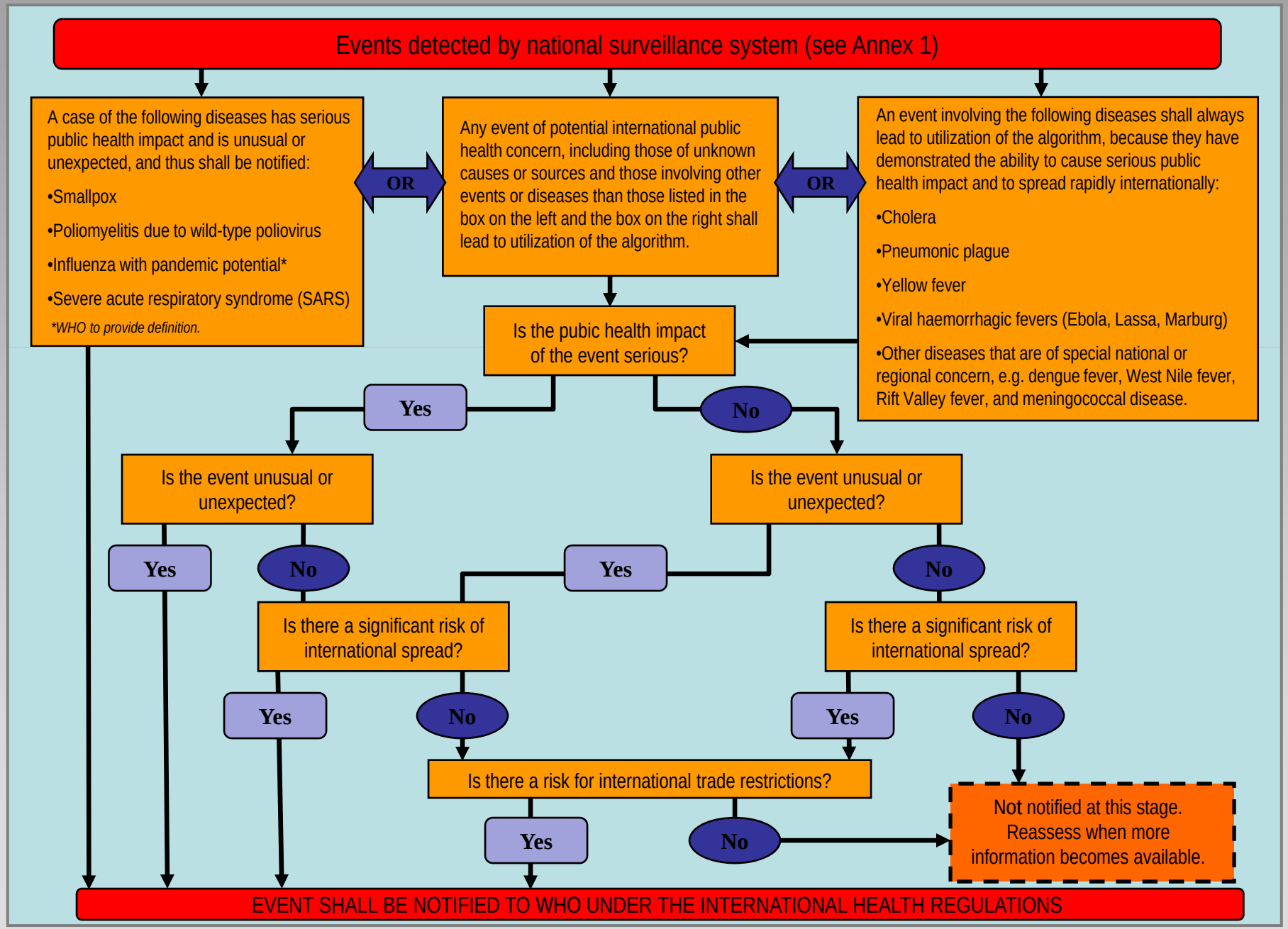
What to Report

- ***Always Notifiable*:**
- Smallpox
- Poliomyelitis due to wild-type poliovirus
- Human influenza (new subtype)
- Severe acute respiratory syndrome (SARS)

- ***Always Assess using the IHR Algorithm*:**
- Cholera
- Pneumonic plague
- Yellow fever
- Viral hemorrhagic fevers
- West Nile fever
- Other diseases of special national/regional concern
  - Dengue fever,
  - Rift Valley fever
  - Meningococcal disease

- ***Other events of international public health concern***

Decision Instrument for the Assessment and Notification of Events that may Constitute a Public Health Emergency of International Concern



Scenario

Measles Outbreak at a Mass Gathering

Public Health Event

- A Health Department is notified of 1 confirmed and 4 suspected cases of measles among unvaccinated participants in an international youth athletic competition.
- The primary case who hails from a measles-endemic country developed symptoms and a rash 2 days after the opening ceremonies which included all participants. He also participated in training events prior to the competition.
- The competition involved approx 500 athletes and coaches from 20 countries. A further 5000 spectators attended the opening ceremonies. Although the host country has a high rate of measles vaccination, many of the visiting countries have low rates of vaccination.

Public Health Response

- All cases were isolated in their hotel rooms immediately following the onset of rash.
- Immunoglobulin was offered to contacts at high risk of complications.
- The event was not closed because exposure had already occurred and would likely not have limited secondary spread.

Using the **Decision Instrument** in **Annex 2**
of the
International Health Regulations (2005)
for the **assessment and notification** of events
that may **constitute a public health emergency**
of international concern

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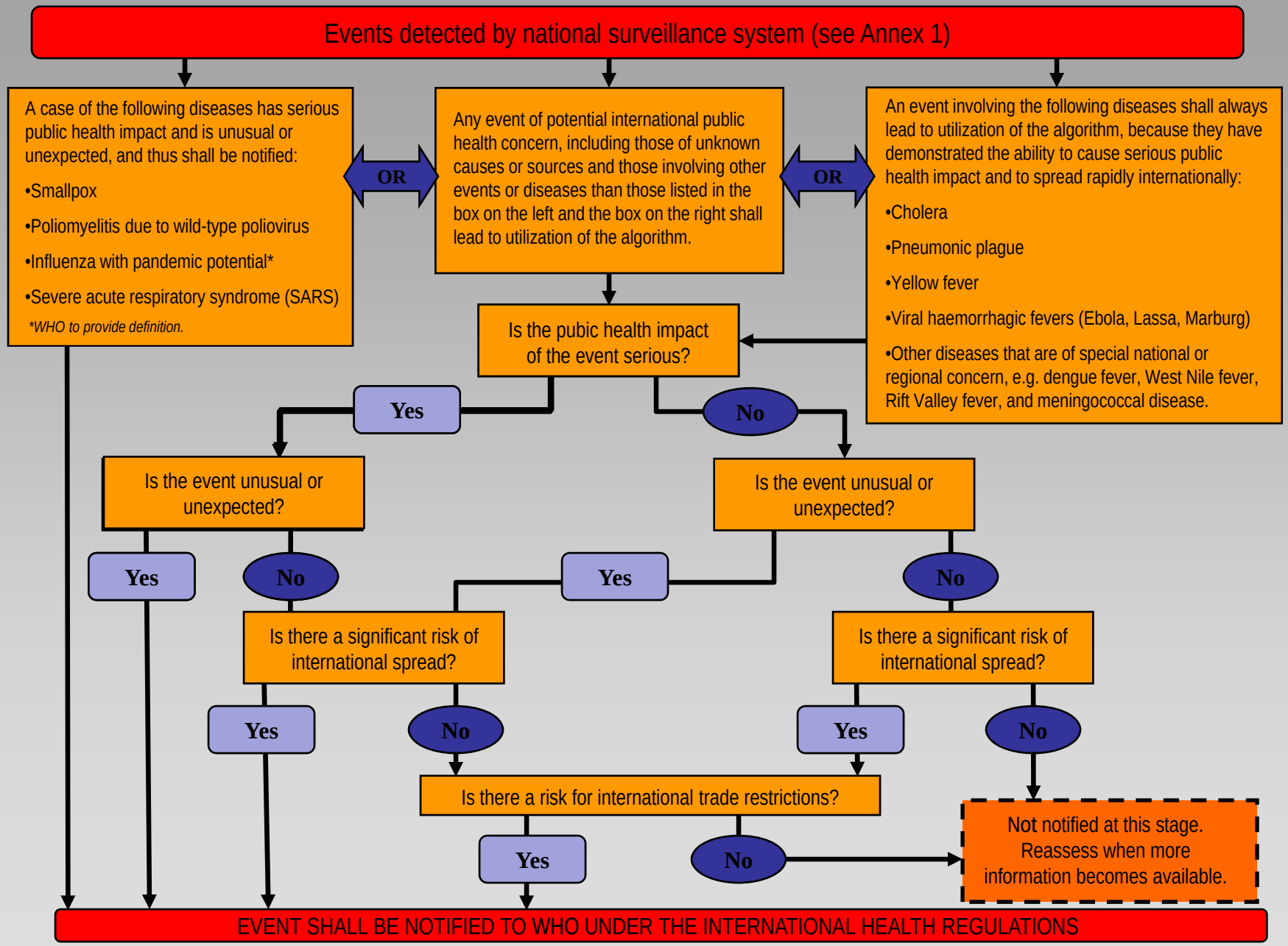

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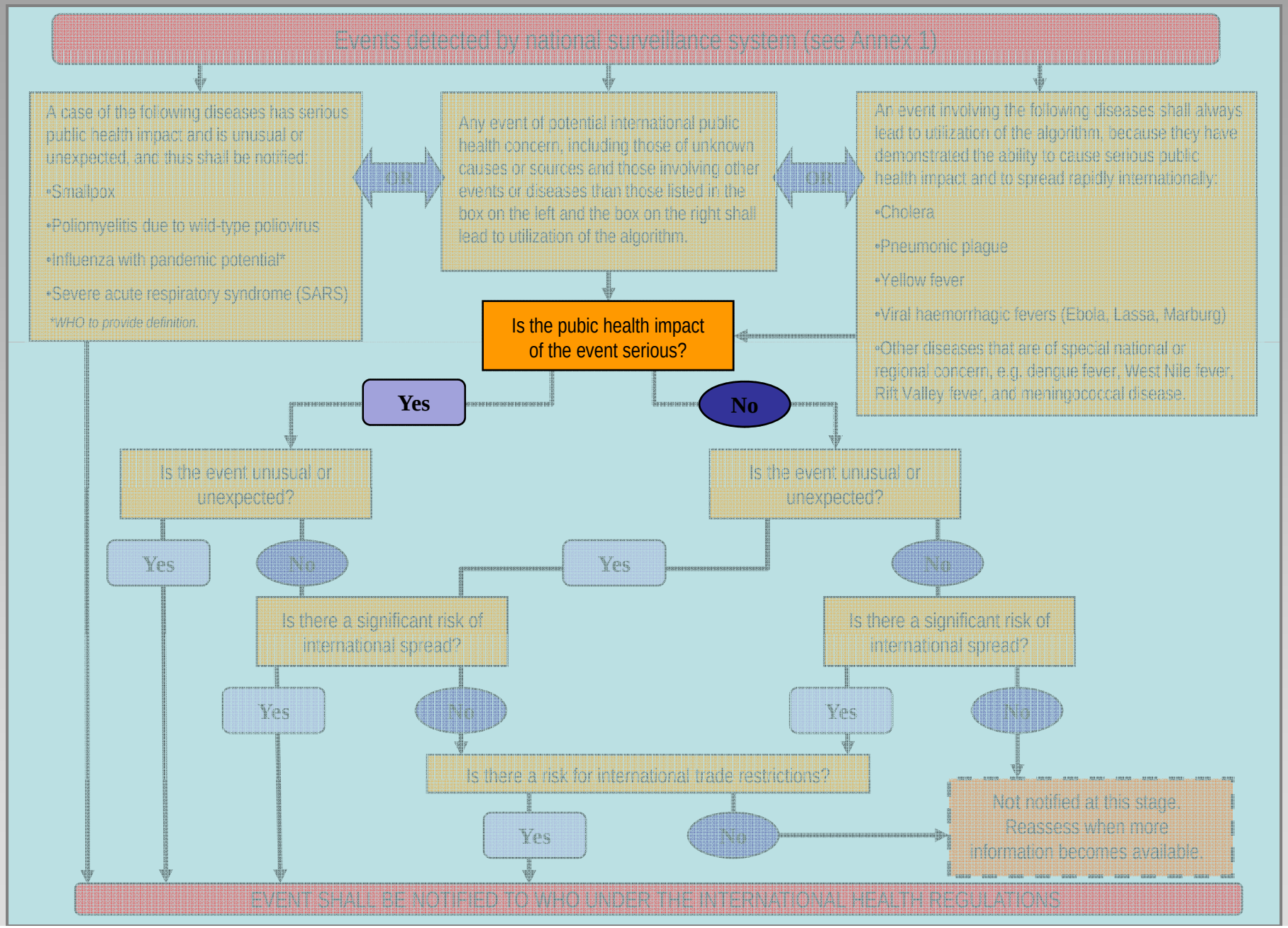

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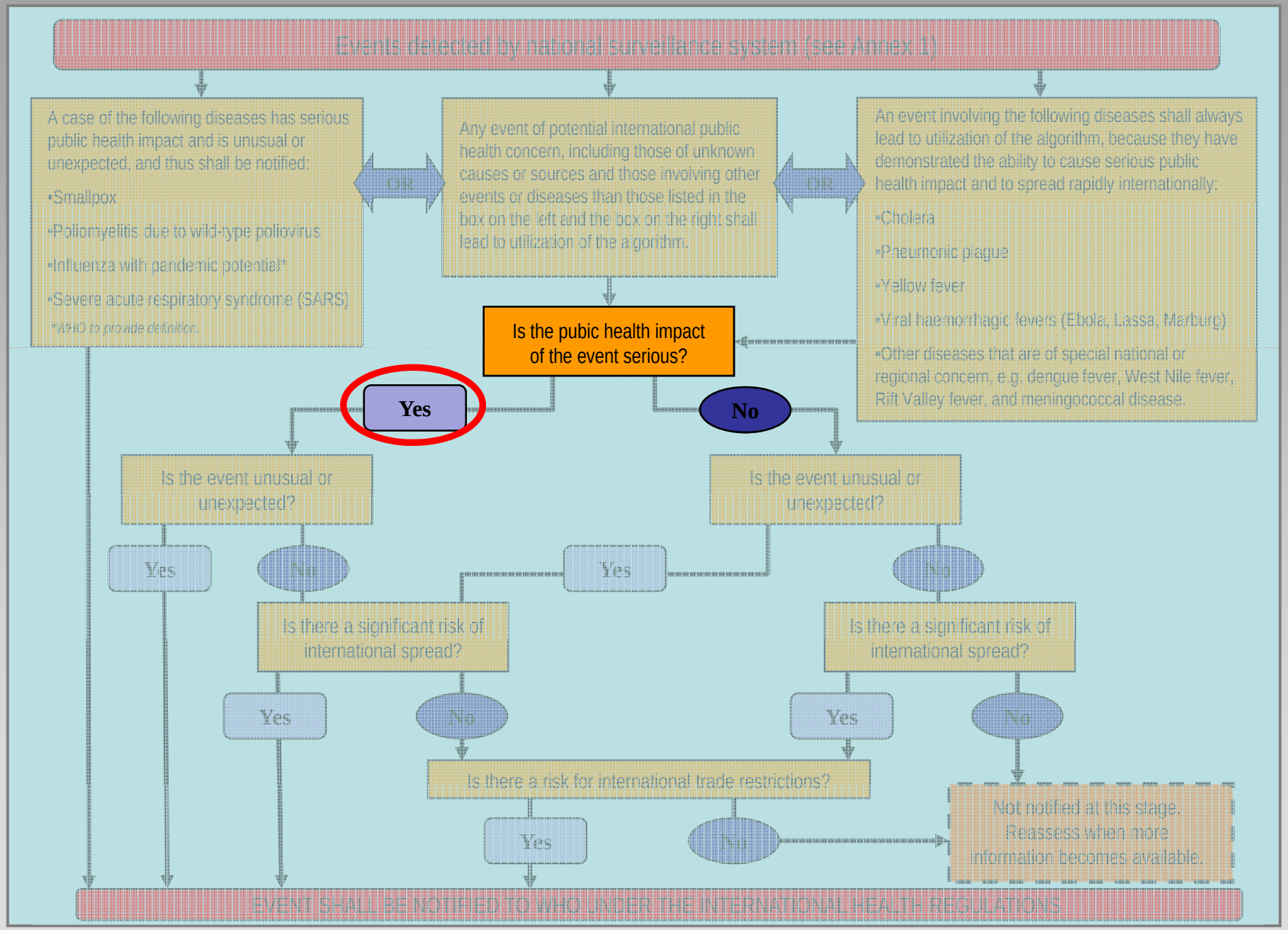

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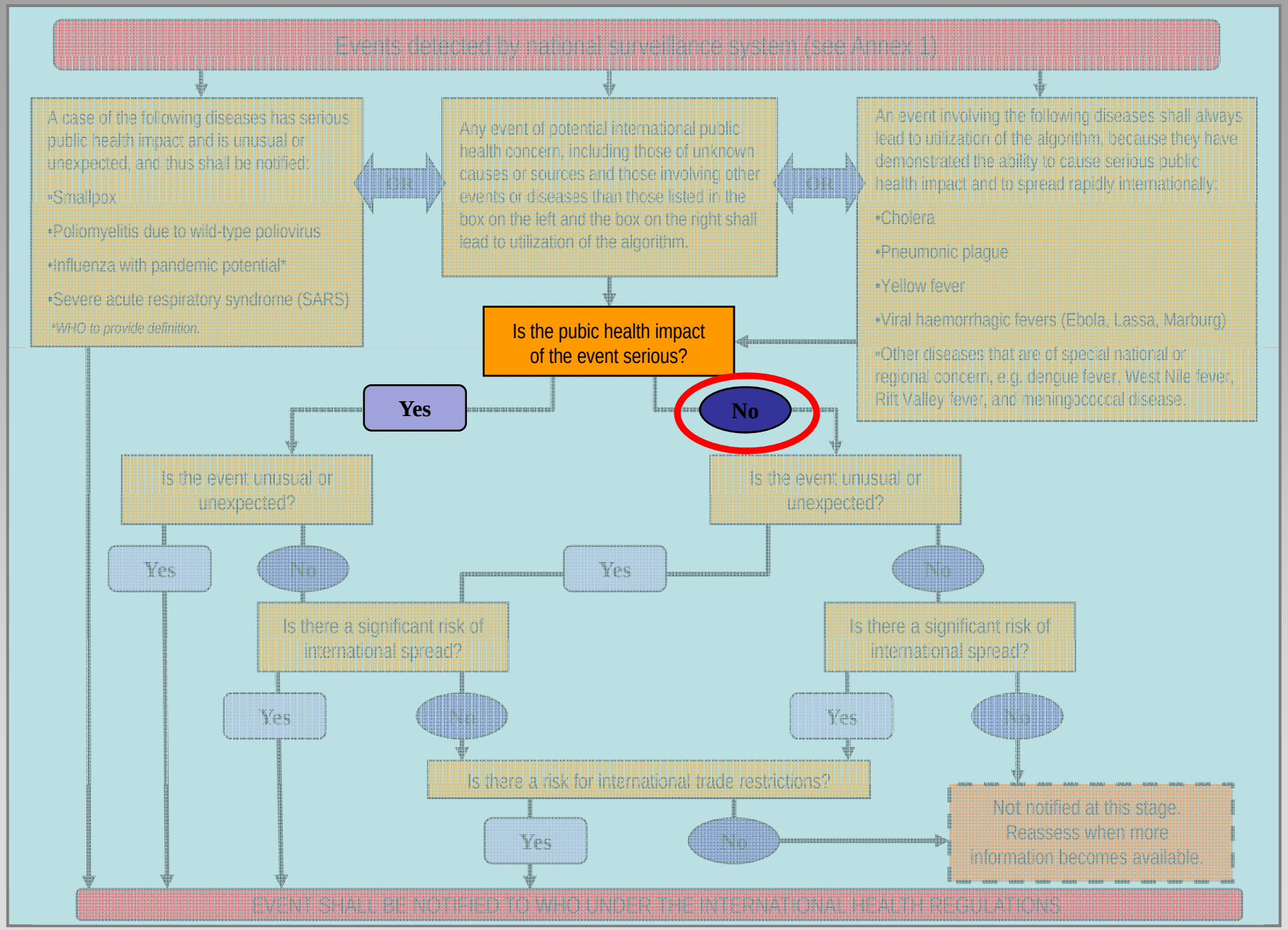

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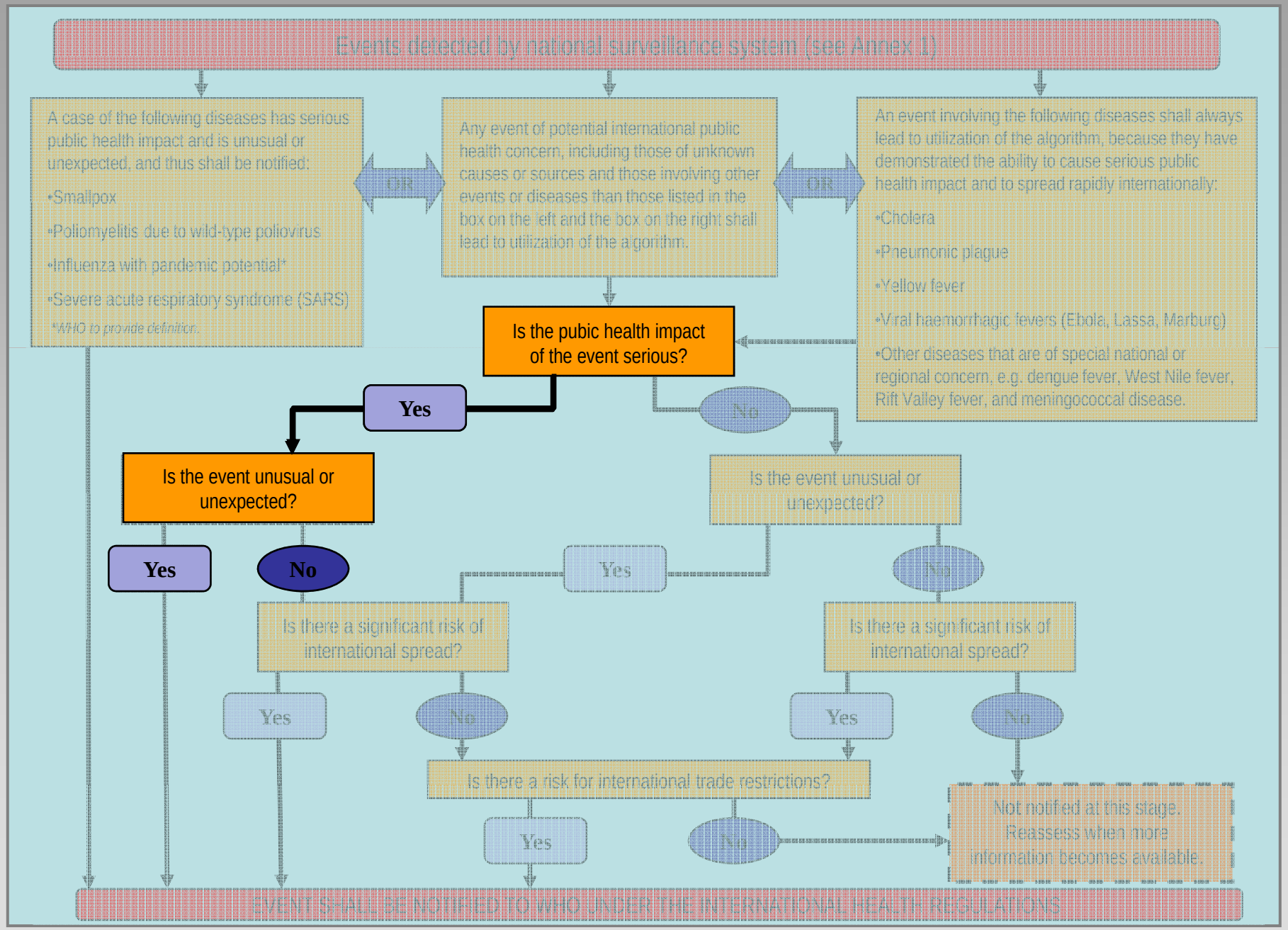

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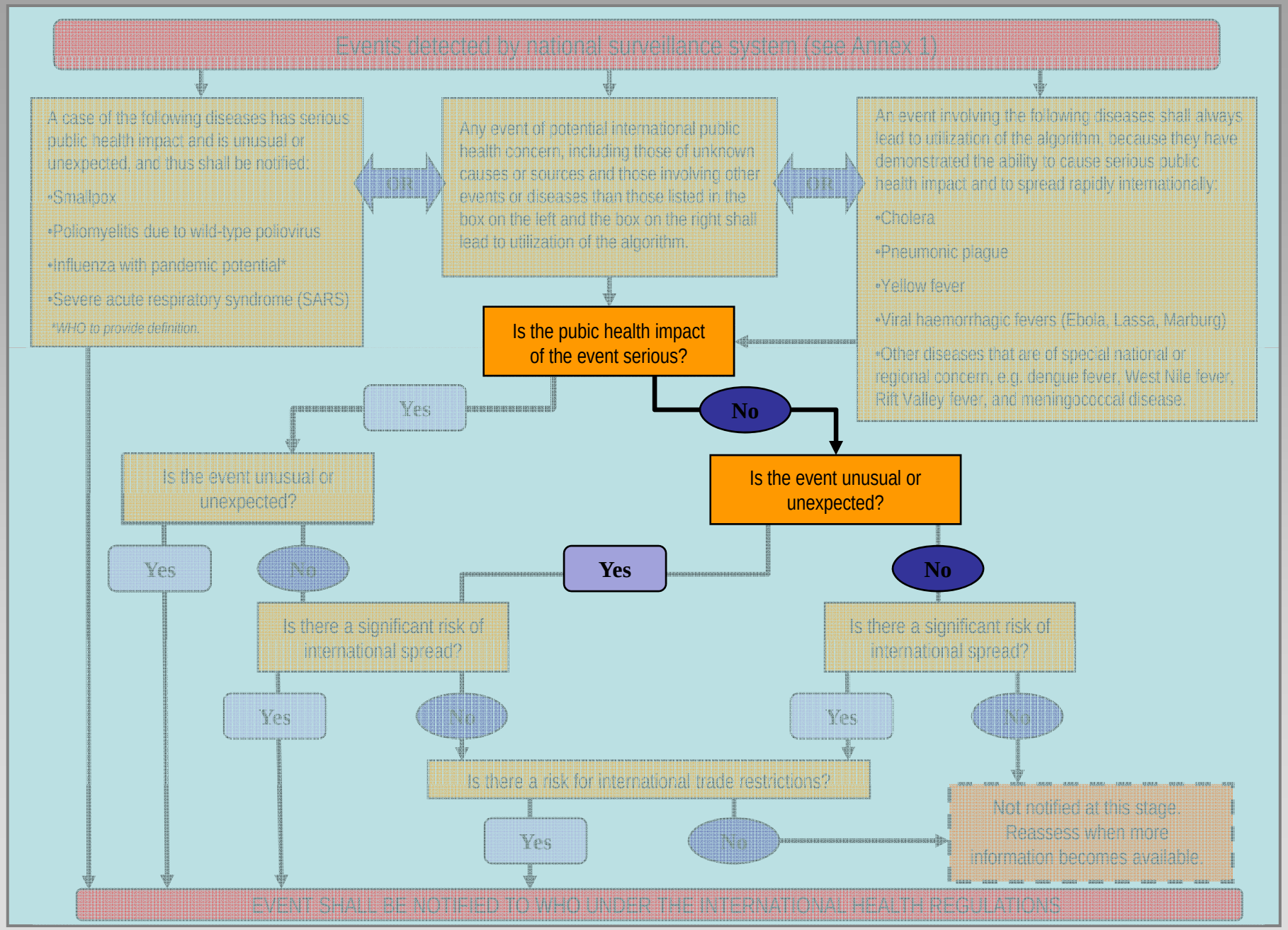

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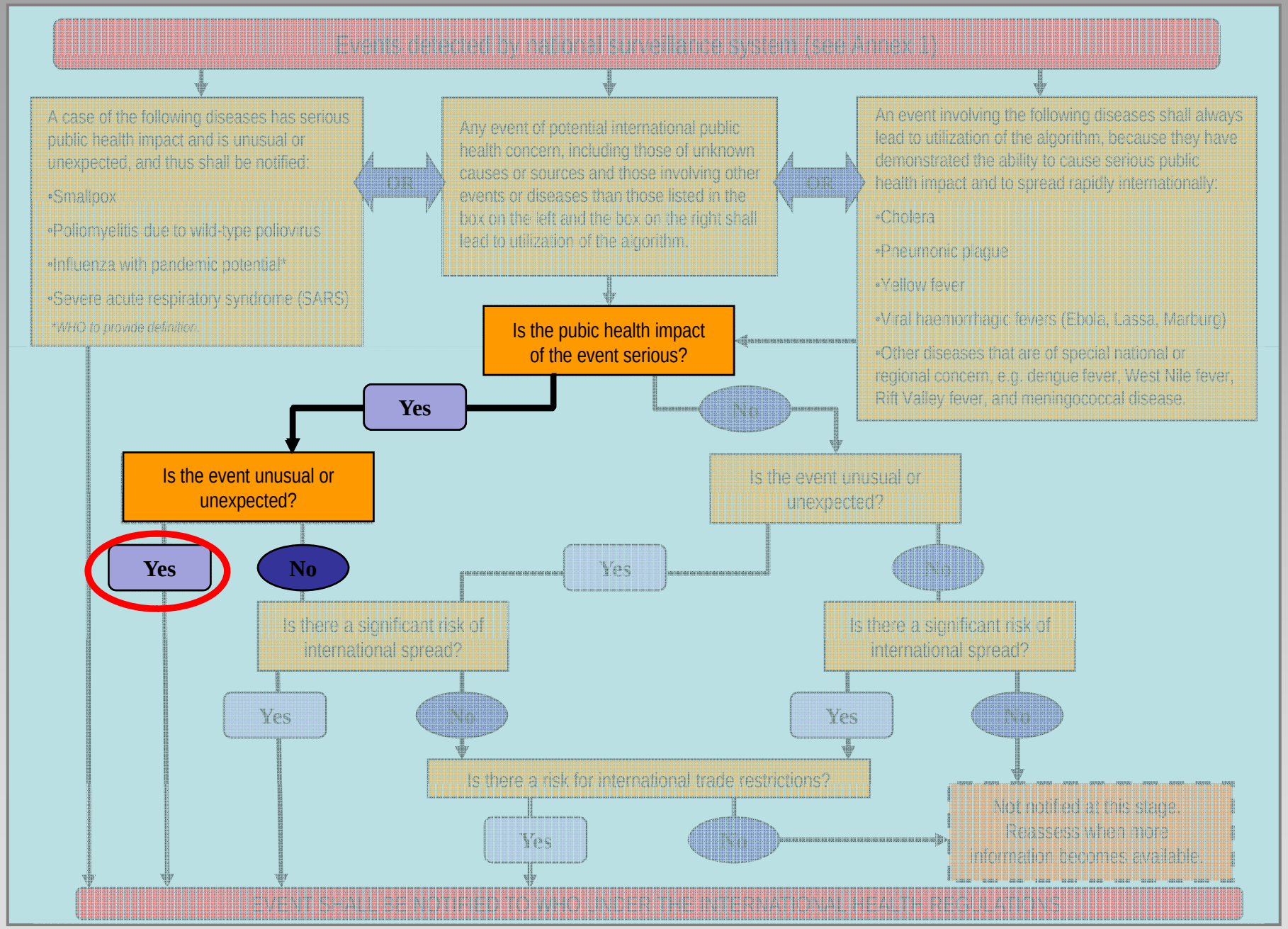

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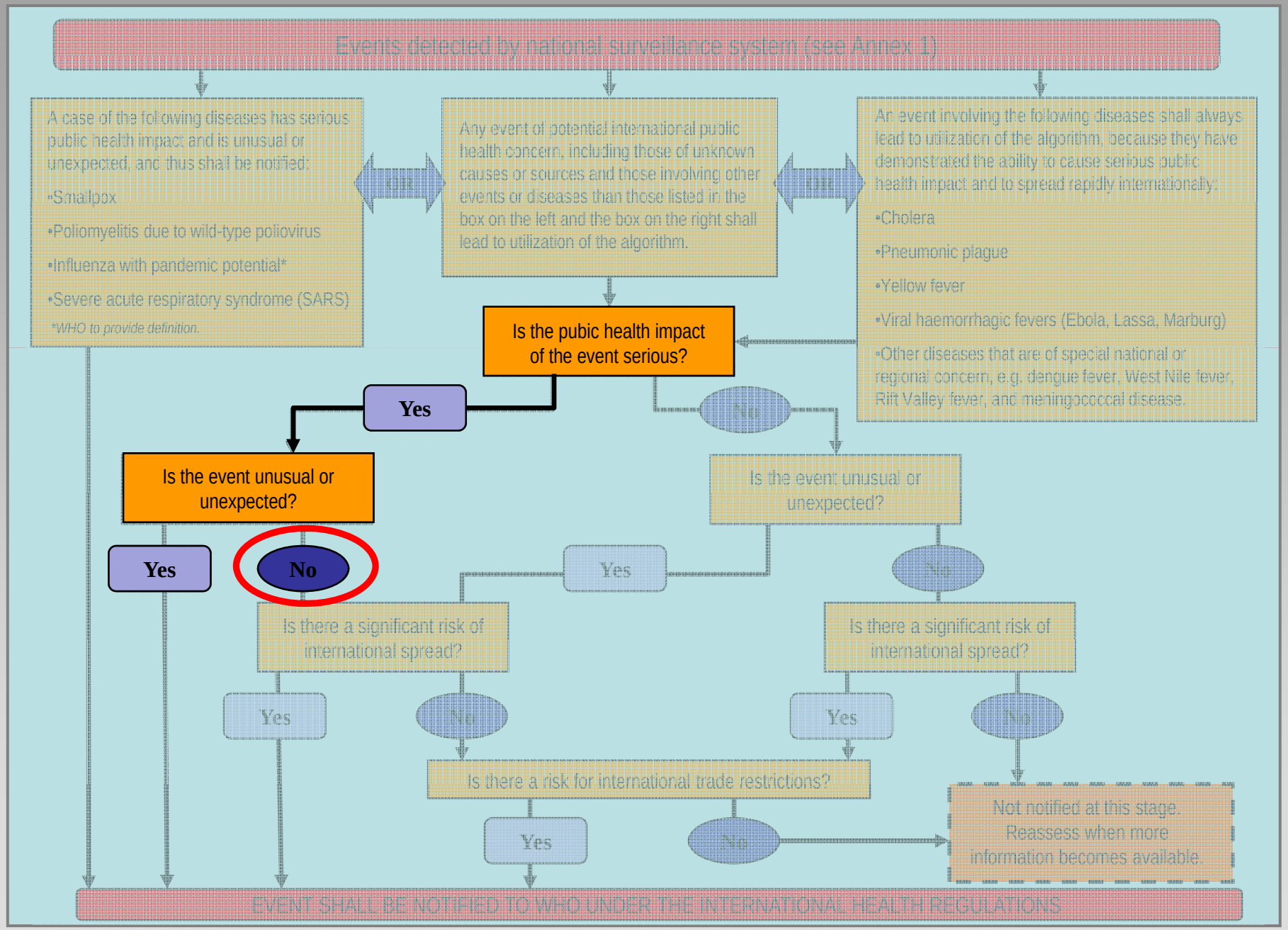

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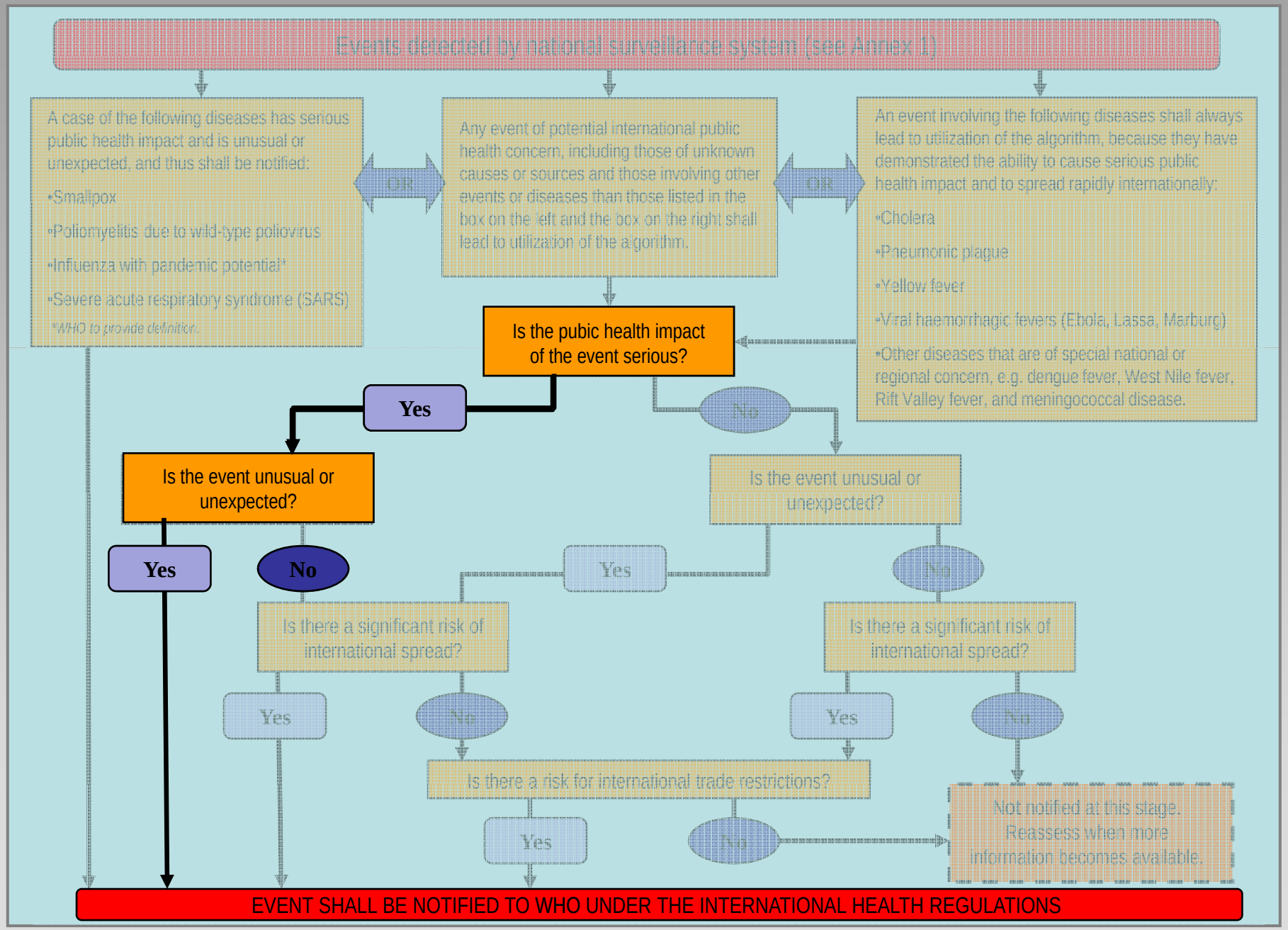

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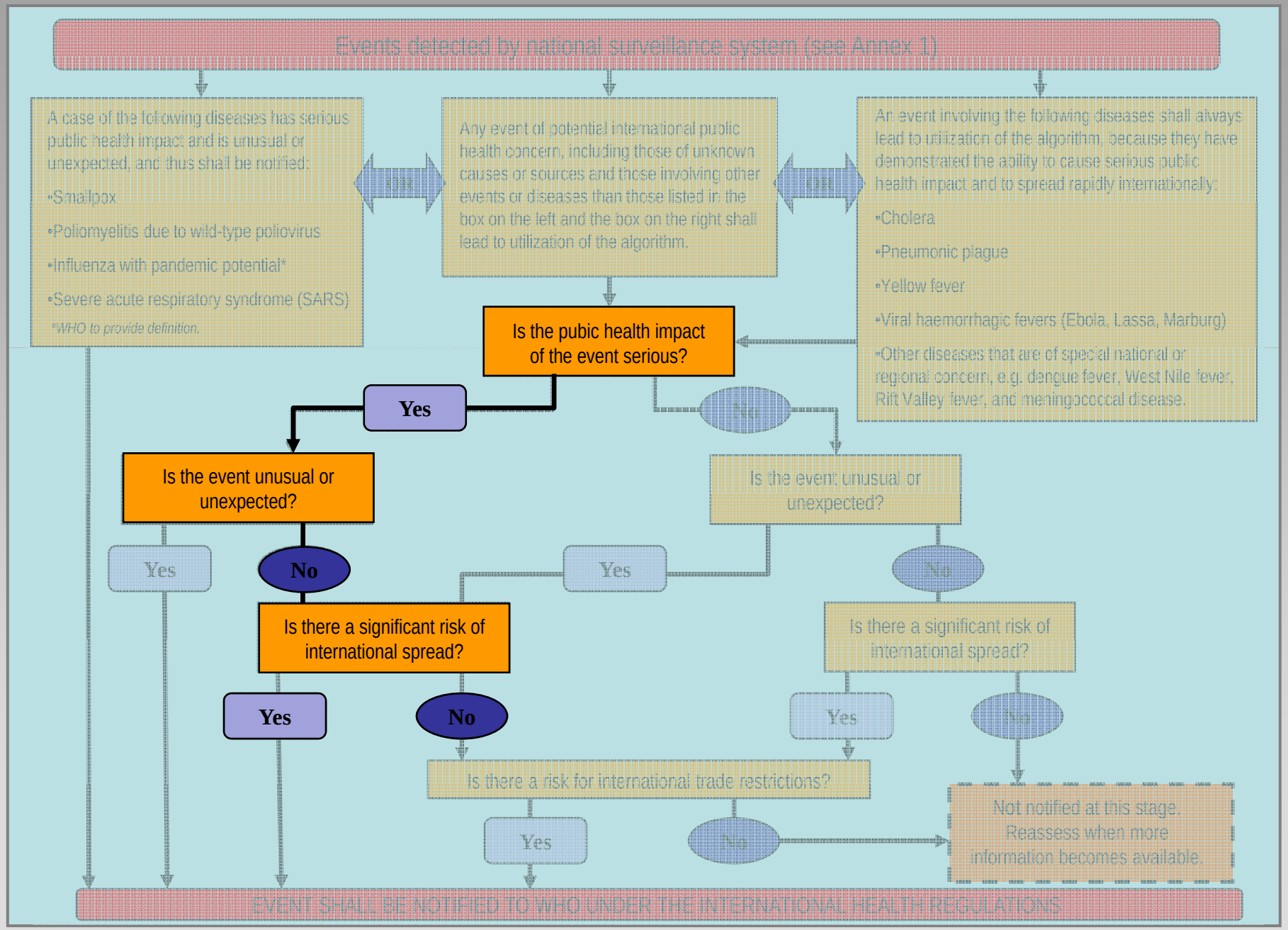

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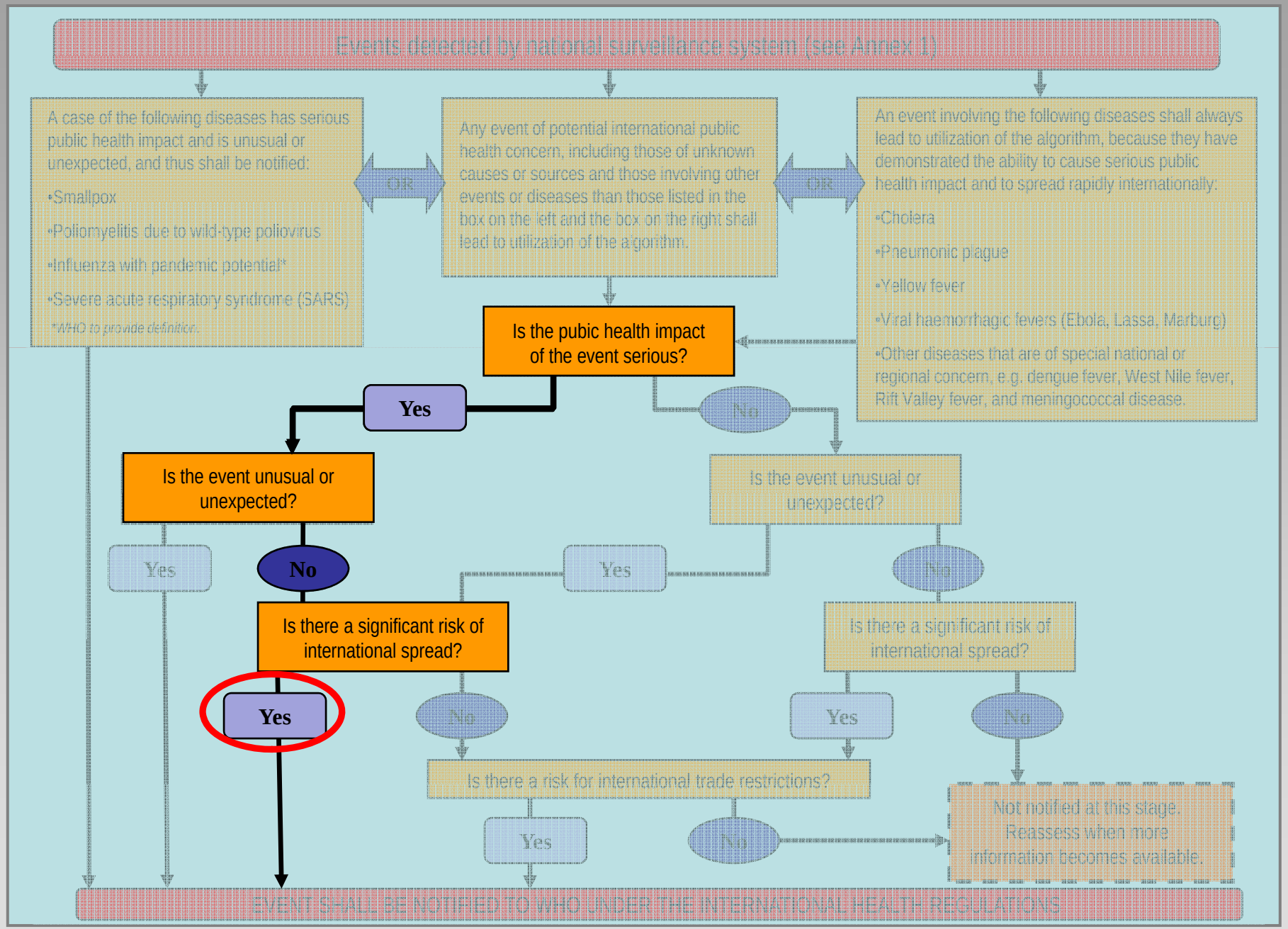

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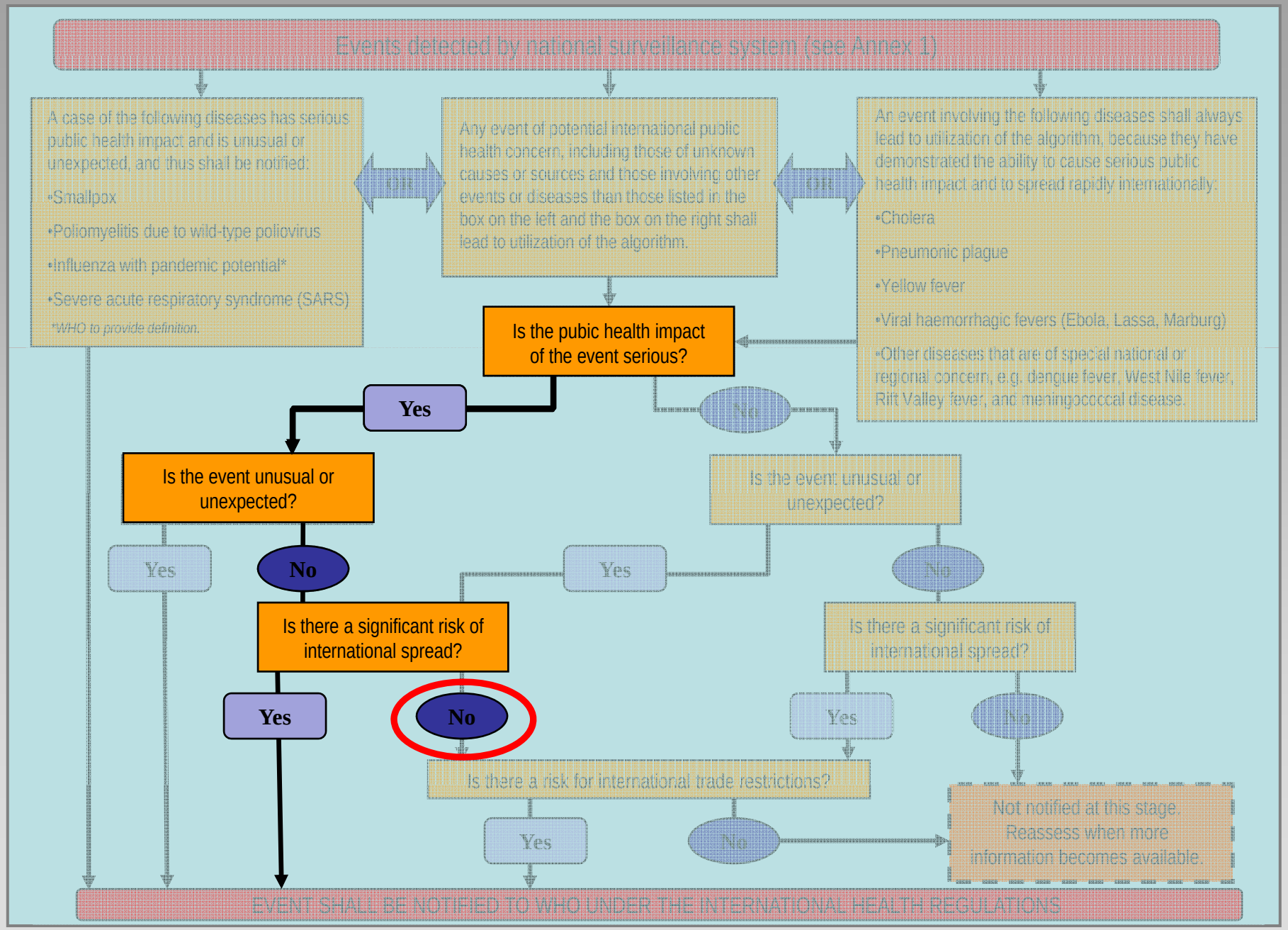

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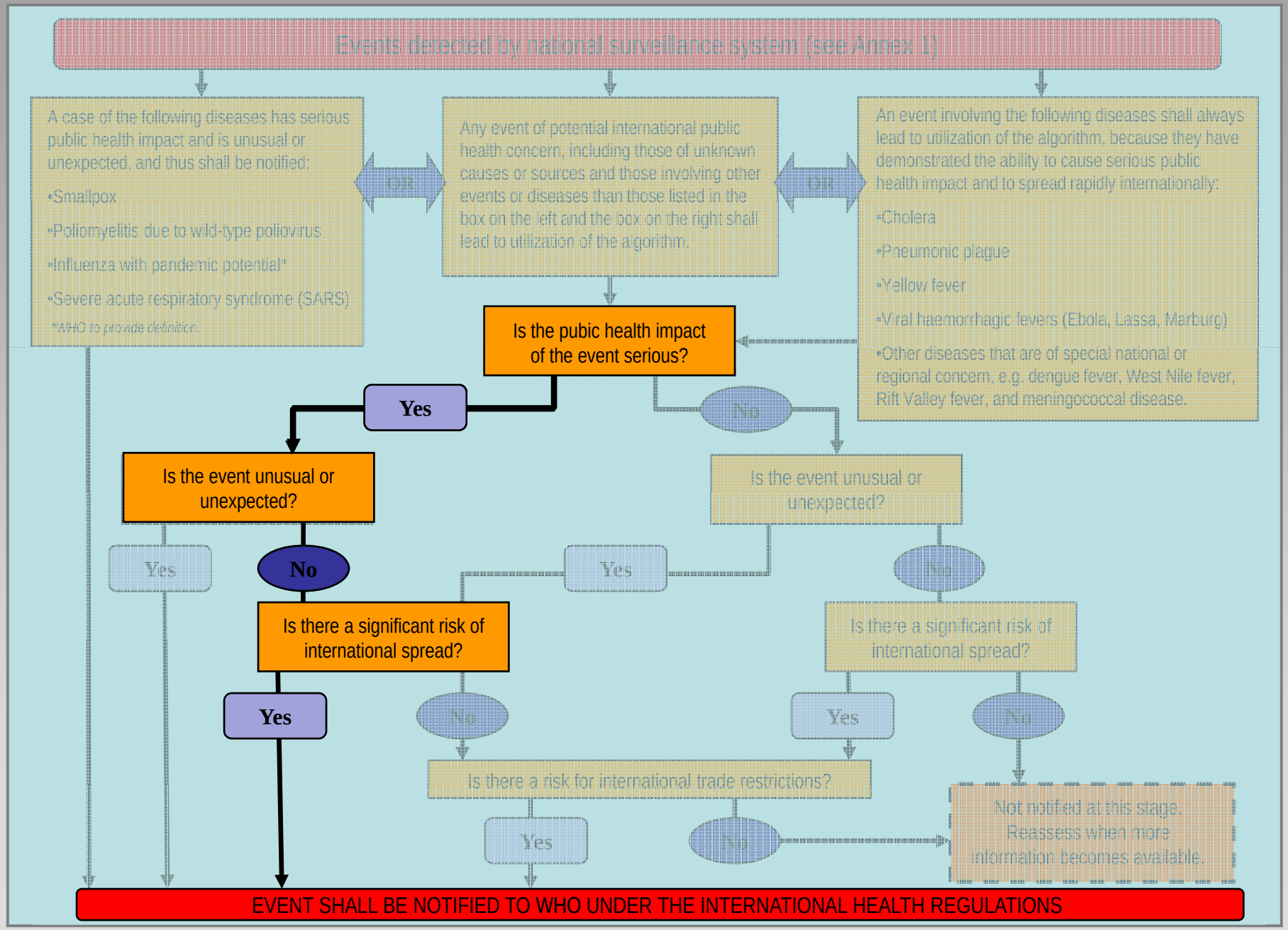

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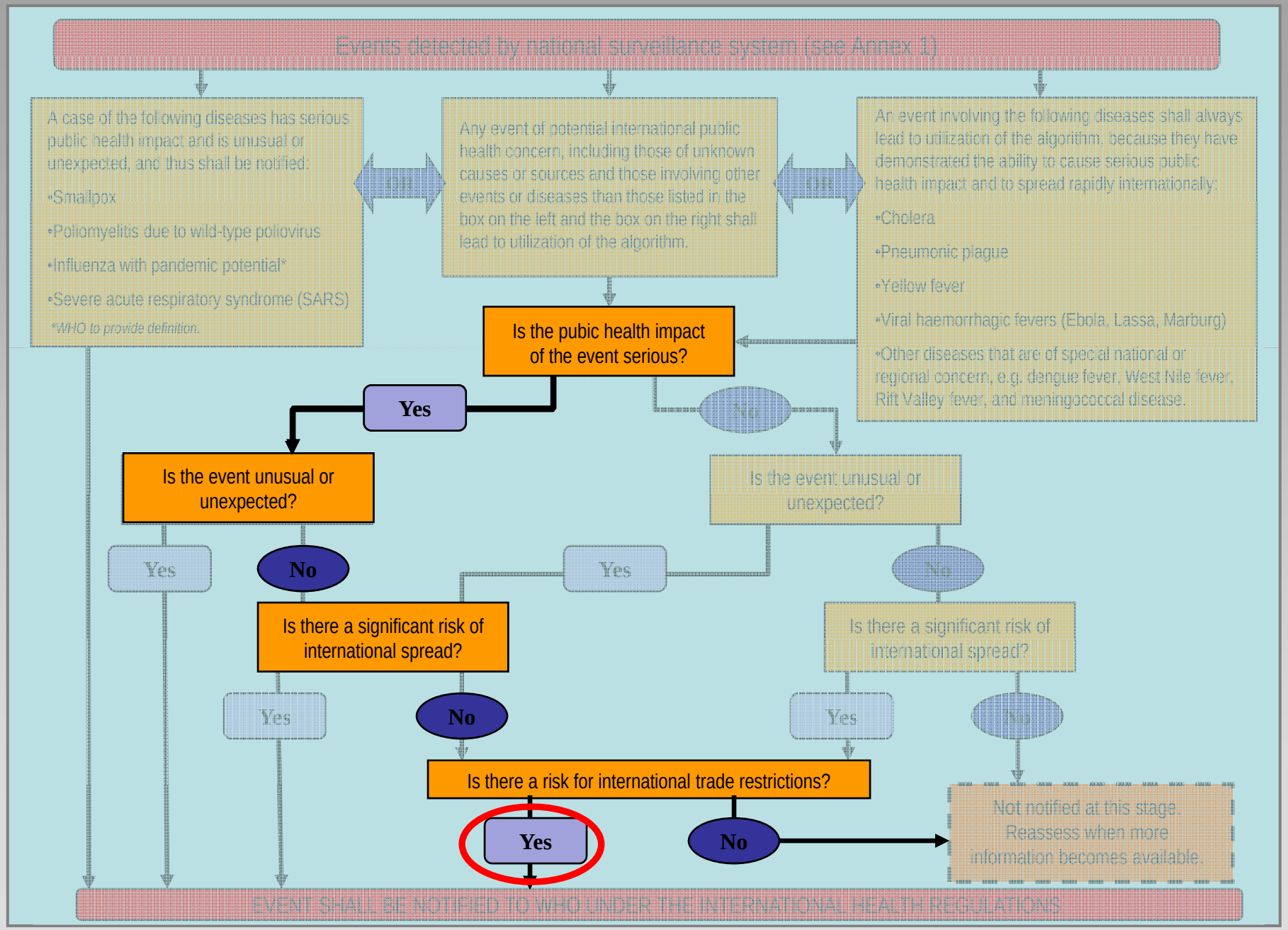

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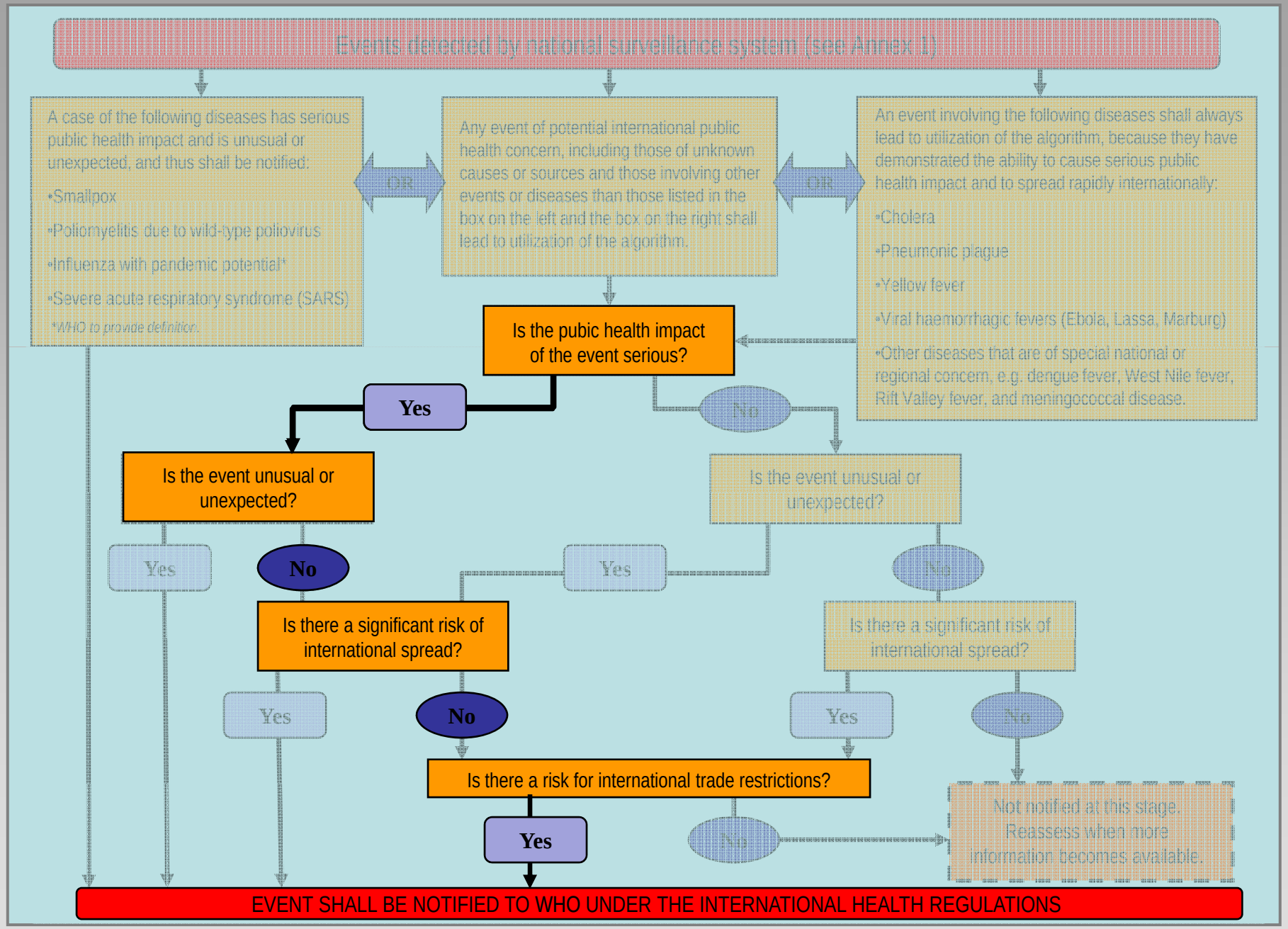


Role of the WHO

- Determines if reported incident is a PHEIC
- Disseminates information as necessary
- Develops and recommends critical health measures during a PHEIC
- Provides technical assistance and support for national surveillance and response systems

United States Implementation

IHR Implementation Timeline

- **Entry into force**
  - 191 WHO Member States: June 15, 2007
  - U.S.: July 18, 2007

- **Assessment Phase**
  - 2007–2009: Assess the ability of existing national structures and resources to meet the minimum requirements described in Annex 1

- **Implementation Phase**
  - 2009-2012: Develop, strengthen, and maintain the minimum requirements described in Annex 1

U.S. Adoption of IHR

The United States…

- reserves the right to assume obligations under these Regulations in a manner consistent with its fundamental principles of federalism.

Federalism Reservation

- Maintains the current division of state and federal responsibilities for surveillance
- Reiterates that US state, territorial and local jurisdictions have primary governmental authority to respond to public health events in their jurisdiction

United States IHR Implementation
Initial US Government Process

- Interagency process (January - July 2007) involving 20 USG departments and agencies; coordination by HHS/ASPR; joint oversight by the Homeland and National Security Councils.

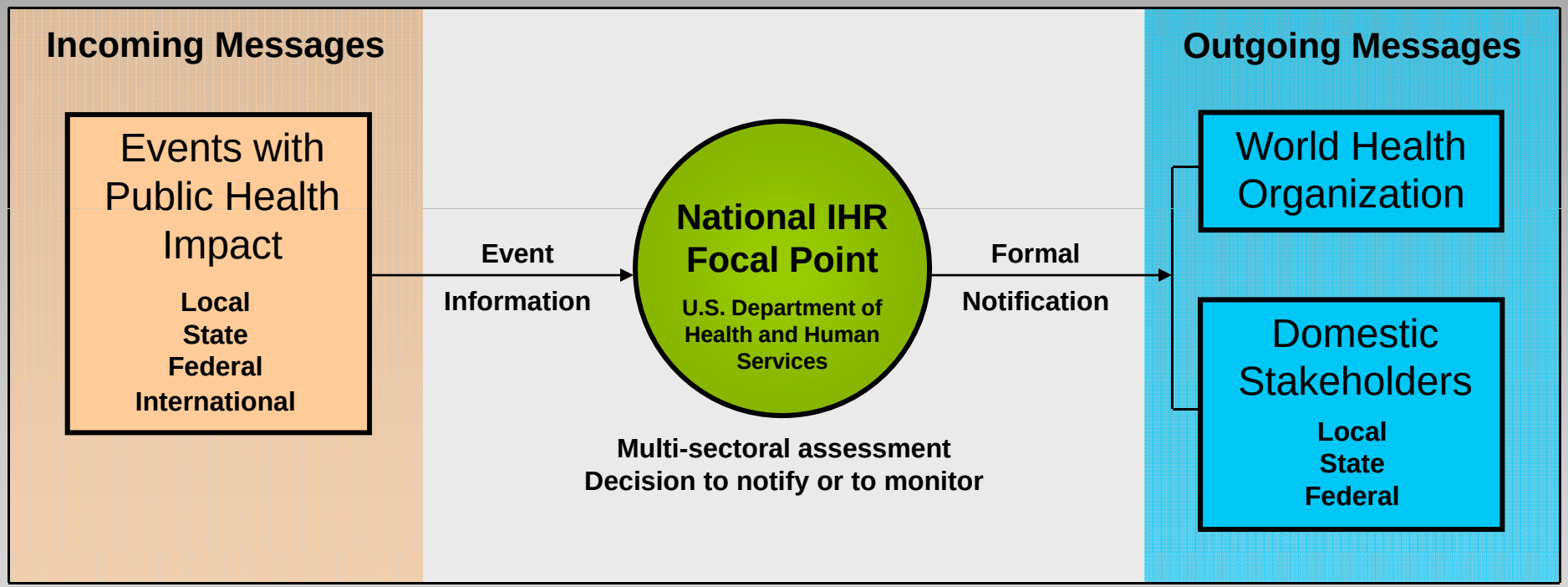
- Identification of requirements; assessment and identification of gaps.

- Build on existing systems, policies, and procedures wherever possible.

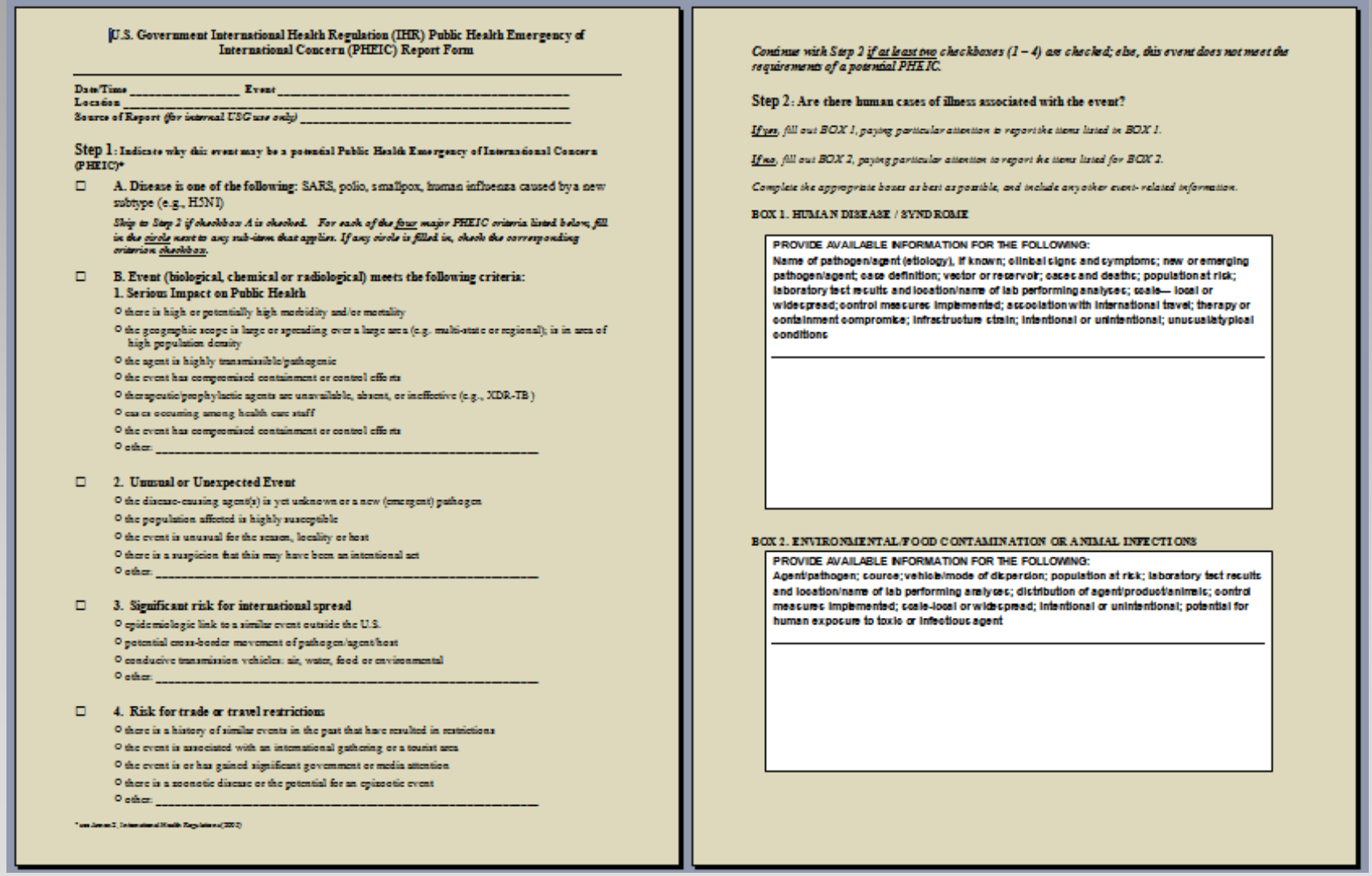
Capacities Developed for IHR

- HHS Secretary's Operations Center is the U.S. National IHR Focal Point
- National Focal Point Policy
  - Roles and responsibilities
  - Message flow
  - IHR Program
- Interagency coordination procedures
- Standardized PHEIC assessment/report form

United States IHR Communication Flow



PHEIC Report Form



U.S. Government International Health Regulation (IHR) Public Health Emergency of International Concern (PHEIC) Report Form

Date/Time _____ Event _____
Location _____
Source of Report *(for internal USG use only)* _____

Step 1: Indicate why this event may be a potential Public Health Emergency of International Concern (PHEIC)*

☐ **A. Disease is one of the following:** SARS, polio, smallpox, human influenza caused by a new subtype (e.g., H5N1)

Skip to Step 2 if checkbox A is checked. For each of the four major PHEIC criteria listed below, fill in the circle next to any sub-item that applies. If any circle is filled in, check the corresponding criterion checkbox.

☐ **B. Event (biological, chemical or radiological) meets the following criteria:**

1. Serious Impact on Public Health

- ○ there is high or potentially high morbidity and/or mortality
- ○ the geographic scope is large or spreading over a large area (e.g. multi-state or regional); is in area of high population density
- ○ the agent is highly transmissible/pathogenic
- ○ the event has compromised containment or control efforts
- ○ therapeutic/prophylactic agents are unavailable, absent, or ineffective (e.g., XDR-TB)
- ○ cases occurring among health care staff
- ○ the event has compromised containment or control efforts
- ○ other: _____

☐ **2. Unusual or Unexpected Event**

- ○ the disease-causing agent(s) is yet unknown or a new (emergent) pathogen
- ○ the population affected is highly susceptible
- ○ the event is unusual for the season, locality or host
- ○ there is a suspicion that this may have been an intentional act
- ○ other: _____

☐ **3. Significant risk for international spread**

- ○ epidemiologic link to a similar event outside the U.S.
- ○ potential cross-border movement of pathogen/agent/host
- ○ conducive transmission vehicles: air, water, food or environmental
- ○ other: _____

☐ **4. Risk for trade or travel restrictions**

- ○ there is a history of similar events in the past that have resulted in restrictions
- ○ the event is associated with an international gathering or a tourist area
- ○ the event is or has gained significant government or media attention
- ○ there is a zoonotic disease or the potential for an epizootic event
- ○ other: _____

* [illegible]

Continue with Step 2 if at least two checkboxes (1 – 4) are checked; else, this event does not meet the requirements of a potential PHEIC.

Step 2: Are there human cases of illness associated with the event?

If yes, fill out BOX 1, paying particular attention to report the items listed in BOX 1.

If no, fill out BOX 2, paying particular attention to report the items listed for BOX 2.

Complete the appropriate boxes as best as possible, and include any other event-related information.

BOX 1. HUMAN DISEASE / SYNDROME

PROVIDE AVAILABLE INFORMATION FOR THE FOLLOWING:
Name of pathogen/agent (etiology), if known; clinical signs and symptoms; new or emerging pathogen/agent; case definition; vector or reservoir; cases and deaths; population at risk; laboratory test results and location/name of lab performing analyses; scale— local or widespread; control measures implemented; association with international travel; therapy or containment compromise; infrastructure strain; intentional or unintentional; unusual/atypical conditions

BOX 2. ENVIRONMENTAL/FOOD CONTAMINATION OR ANIMAL INFECTIONS

PROVIDE AVAILABLE INFORMATION FOR THE FOLLOWING:
Agent/pathogen; source; vehicle/mode of dispersion; population at risk; laboratory test results and location/name of lab performing analyses; distribution of agent/product/animals; control measures implemented; scale-local or widespread; intentional or unintentional; potential for human exposure to toxic or infectious agent

Work to Date: Notifications

August 2007:

- *Clostridium botulinum*-contaminated chili
- Measles at in international Little League game

September 2007:

- MDR-TB on an international flight

December 2007:

- MDR-TB on an international flight

March 2008:

- MDR-TB on an international flight
- Contaminated heparin products

July 2008:

- *Salmonella* Saintpaul outbreak

January 2009:

- *Salmonella* Tymphimurium outbreak

March 2009:

- Influenza A H1N1 (swine flu)
- MDR-TB on an international flight

April 2009:

- Influenza A H1N1 (swine flu)
- Influenza A H1N1 (swine flu)

PHEIC
25 April

Council of State and Territorial Epidemiologists Assessment of State Reporting Surveillance

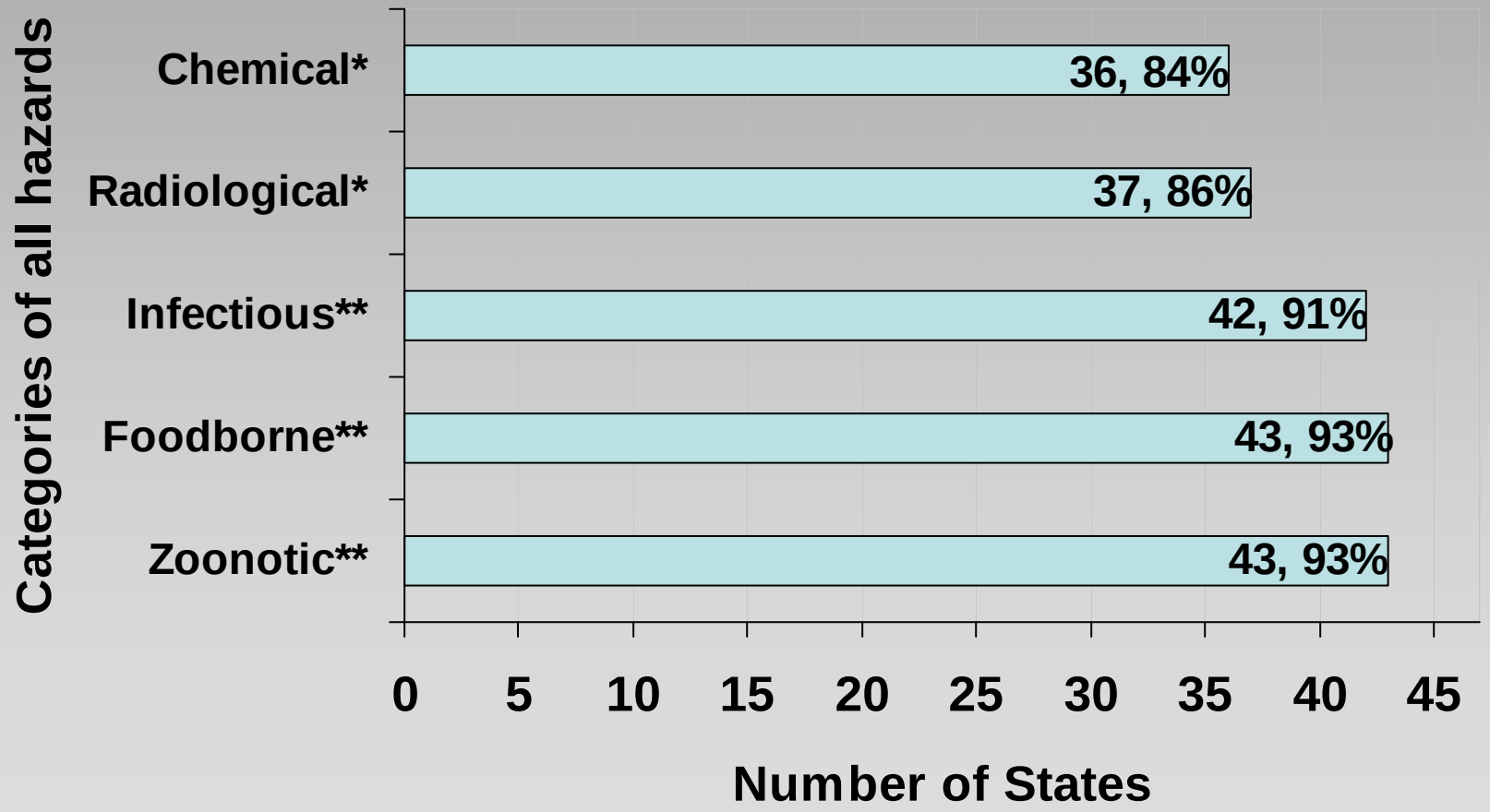
Survey Methods

- CSTE sent an electronic self-assessment to its members in February 2009
  - More than 90% response rate (n=47)
  - Assessment was analyzed in conjunction with data in the State Reportable Conditions Assessment (SRCA)
  - Designed and completed before the recent notification to WHO of novel H1N1 A influenzas
  - Assessment was of all hazards

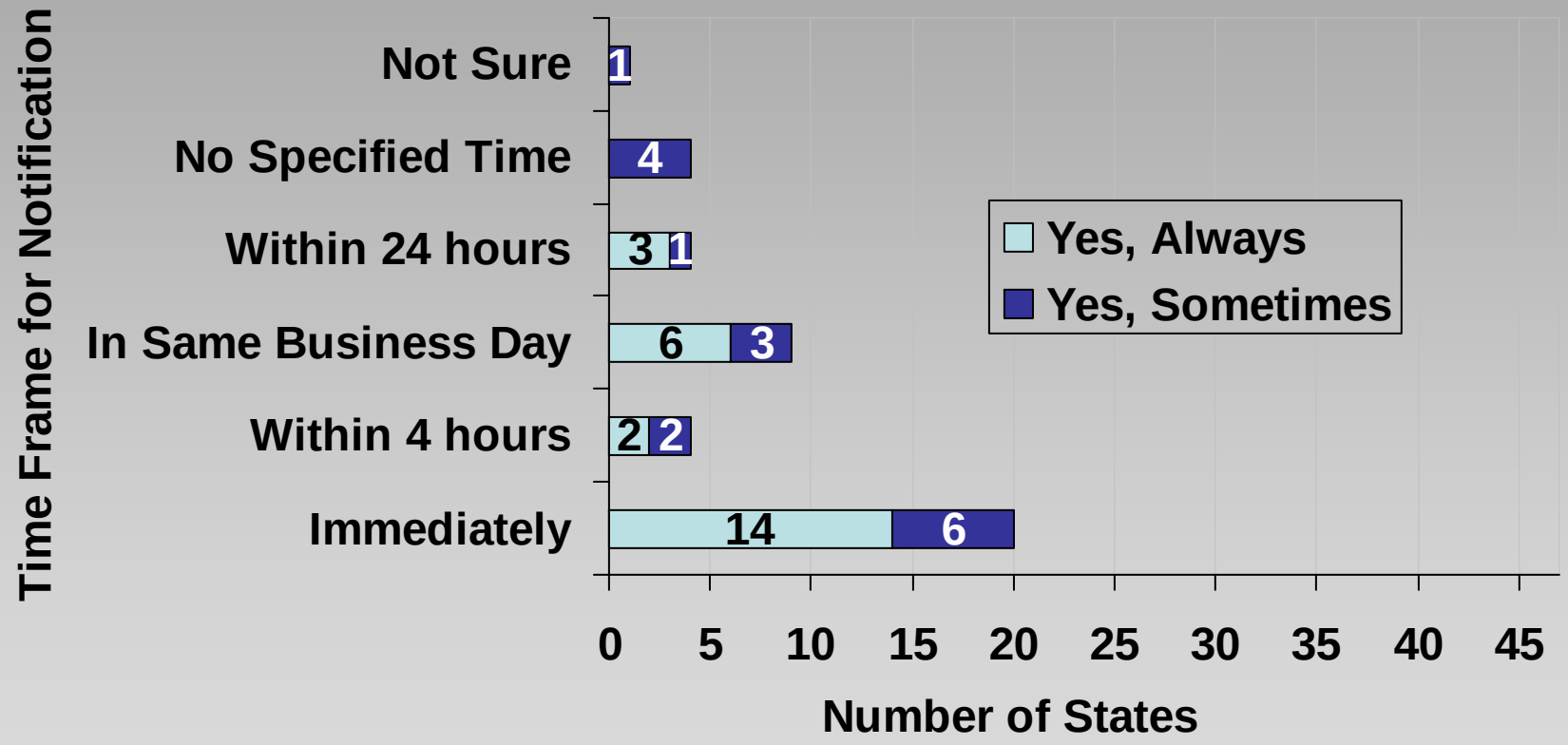
Survey Results

- 81% (N=47) reported they were able to transmit records to the CDC on a daily basis
- 51% (N=45) reported they participated in cross-jurisdiction electronic surveillance and reporting systems for foodborne and infectious disease
- 80% (N=45) reported the use of risk assessments to determine CDC notification for “unusual or unexpected” events

Frequency of States with Points-of-Contact within Categories for Reporting Potential Public Health Emergencies



Number of States Who Notify CDC of an Unusual or Unexpected Case or Outbreak of Disease, by Timeframe, 2009



State Control Measures

- Majority have information-sharing systems or mechanisms with other state government agencies
- About half of states reported cross-jurisdictional electronic surveillance and reporting systems
- All but three of the 50 states and Washington D.C. included “unusual or unexpected” events on their reportable conditions lists for 2007 according to the SRCA
- **Majority have the capacity to comply with the requirements of the IHR.**

Summary

- IHR implementation builds upon existing state capacity
- IHR focuses on timeliness of reporting not always timeliness of identification
- IHR implementation is an ongoing process not a specific end point

To send comments and other questions about the IHR, please email:

jose.fernandez@hhs.gov