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Standards Harmonization and Testing

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Lecture Outline

- Section A: Standards Harmonization: Interoperability Requirements
- Section B: Standards Harmonization: Standards Selection
- Section C: Testing
- Section D: Examples, Participation, and Leveraging Standards Harmonization Products

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Section A

Standards Harmonization: Interoperability Requirements

Interoperability Requirements

- Use case
  - Business case
  - Identification of stakeholders and use case perspectives/roles
  - Description of information flows

- Standard requirements analysis
  - Infrastructure
  - Security
  - Content

Use Cases

- *Use cases* are descriptions of events that detail what a system (or systems) must do to achieve a specific mission or stakeholder goals
- Use cases convey how individuals and organizations (actors) interact with the involved systems and strive to provide enough detail and context for follow-up activities to occur
- Usually, the follow-up from a use case is work that leads to the development or implementation of a specific software system

Source: American Health Information Community (AHIC).

Use Case Document Structure

- Description
- Scope
- Stakeholders
- Pre-conditions
- Obstacles
- Post-conditions
- Perspectives and scenario details

Description

- Describe the goals of the use case
  - Example: biosurveillance goals
    - Ability to detect events rapidly
    - Manage the events
    - Appropriately mobilize resources in response
    - Save lives
  - Example: public health case reporting goals
    - Electronically integrate case reporting with the EHR
    - Use data and events to support reporting requirements for public health and adverse events
    - Allow for clinical judgment during reporting
    - Integrate population-level information with EHR

Source: American Health Information Community (AHIC).

Scope

- Contain the problem
- Clearly define what is in scope and what is not
- Example: biosurveillance
  - Capture data from hospitals/emergency departments, ambulatory care, and laboratory
  - For now, no pharmacy data, or any other valuable source that is not specified (e.g., medical devices)
  - Only consider for now the information capture phase
  - Monitoring and event management currently out of scope

Source: American Health Information Community (AHIC).

Stakeholders

- List of all parties with direct or indirect interest in the use case as scoped
- Not necessarily an actor within the system as scoped
- Example: biosurveillance
  - Patient
  - Clinician
  - Health care delivery organization
  - Laboratory
  - Public health agencies (state, local, federal)
  - Resource suppliers
  - Public

Source: American Health Information Community (AHIC).

Pre-conditions

- Pre-conditions are the conditions that must be in place before the start of the use case

- Includes
  - State of a stakeholder
  - Data that must be available somewhere
  - An action that must have occurred

Source: American Health Information Community (AHIC).

Pre-conditions (cont.)

- Example: biosurveillance
  - Established network/policies for secure, consistent, reliable, and accurate information exchange
  - Procedures/agreements supporting data exchange, including privacy protections, security, sanctions, secondary data uses, and appropriate data sharing
  - Agreed to method(s) for data categorization, and defined criteria for sharing data of public health significance
  - Efforts to minimize “double counting” (e.g., pseudonymisation)
  - A consistent approach for data anonymization
  - Health care facilities’ ability to electronically collect, process, and transmit pertinent public health data in a secure fashion, in less than one day, using existing data exchange and vocabulary standards

Source: American Health Information Community (AHIC).

Issues and Obstacles

- What are the challenges for success of the use case

- Example: biosurveillance
  - In general, the absence of the prerequisites presents obstacles to implementation of the use case
  - Unwillingness to participate
  - Lack of resources
  - Regulatory conflicts
  - Lack of deployed electronic records

Source: American Health Information Community (AHIC).

Post-conditions

- Post-conditions are the conditions that will be a result or output of the use case

- Includes
  - The state of a stakeholder upon conclusion of the use case
  - Data that was created or now available
  - Identification of actions that may serve as pre-conditions for other use cases

Source: American Health Information Community (AHIC).

Post-conditions

- Example: biosurveillance
  - Clinical ER data, ambulatory data, laboratory data, and utilization data sources can share biosurveillance-relevant patient event data with public health agencies
  - Biosurveillance data messages are formulated following a standard structure, coding, and minimal required set of information
  - Surveillance data will be transmitted within 24 hours
  - Data provided will support the privacy and security of patient health information, and will also be responsive to requirements for re-identification for authorized public health investigations
  - When appropriate, a biosurveillance transmission message data and/or alert is generated, sent to, and received by the appropriate users
  - Appropriate entities are registered to send or receive biosurveillance data
  - System transactions are auditable

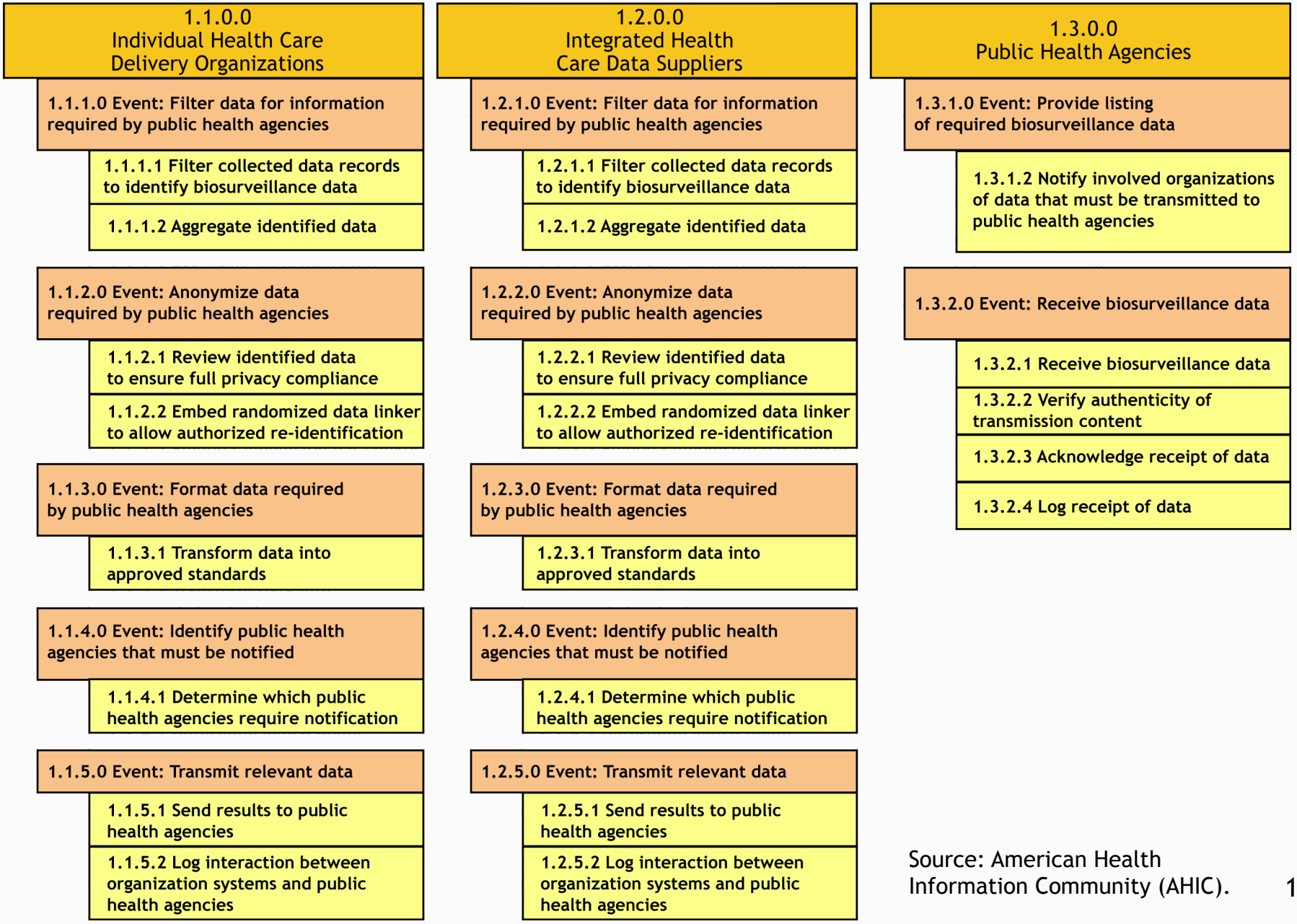
Source: American Health Information Community (AHIC).

Perspectives and Scenario Details

- Detailed descriptions of use case
  - Workflows
  - Events
  - Actions within the event
  - Interactions

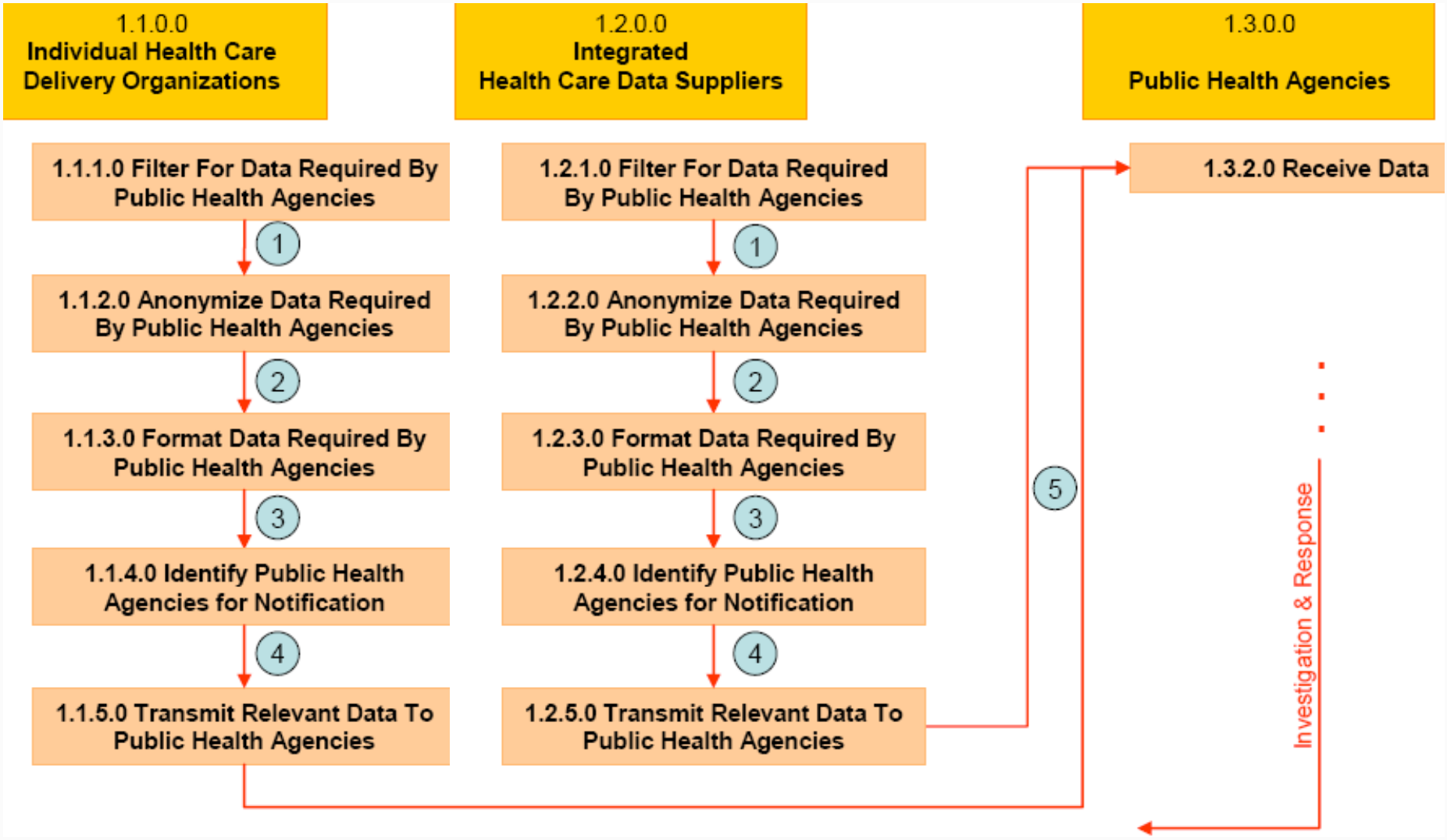
Source: American Health Information Community (AHIC).

Biosurveillance



Source: American Health Information Community (AHIC).

Biosurveillance



Source: American Health Information Community (AHIC).

Individual HC Delivery Organizations Perspective

1.1 Individual Health Care Delivery Organizations Perspective

Code	Description	Comment
1.1.1.0	**Event:** Filter existing data to identify data required by public health agencies	Referencing data requirements communicated by Public Health Agencies in Event 1.3.1.0, all data that is appropriate to provide to public health agencies is identified so that it can be formatted using the approved data and technology standards to allow processing across the stakeholders in this use case.
1.1.1.**1**	**Action:** Filter collected data records to identify biosurveillance data	Relevant data are marked for inclusion in a transmission, via EHR or web-enabled system, to public health agencies.
1.1.1.**2**	**Action:** Aggregate identified data	All essential data are aggregated.
1.1.2.0	**Event:** Anonymize data required by public health agencies	Data readied for transmission is anonymized to withhold direct patient identifiers. The process should allow for the data to be re-linked to a specific patient if required for and authorized public health investigation. All associated, randomized links are included with the data package.
1.1.2.**1**	**Action:** Required data are checked to ensure full privacy requirement compliance	Ensure that all data included in biosurveillance package are anonymized and meet all applicable privacy and security considerations.
1.1.2.**2**	**Action:** A randomized data linker is provided to allow authorized entities to re-link to patient data	Functionality is provided to re-link data to patient when required as part of an authorized public health investigation.
1.1.3.0	**Event:** Format data required by public health agencies	Anonymized data are formatted using approved technology and data standards.
1.1.3.**1**	**Action:** Transform data using approved standards	

Harmonized Use Case for Biosurveillance (Visit, Utilization and Lab Result Data)

Source: American Health Information Community (AHIC).

Use Case Requirement Analysis

- For ***each*** event and action
  - Infrastructure requirements
  - Security requirements
  - Data/content requirements

Infrastructure Requirement Analysis

- Transport requirements
  - Point-to-point
  - Information shared with more than one entity
- Patient identity requirements
  - Persistent across multiple care events
- Terminology services
- Notifications
- Alerts

Security Requirement Analysis

- User/system authentication and credentials
- Collect/communicate audit trail
- Secure transport
- Digital signature
- Access control
- Verify patient consent, authorizations, and advance directives
- Anonymize and pseudonymize data
- Maintain consistent time across enterprises

Data/Content Requirement Analysis

- Laboratory results
- Medical summaries (ambulatory)
- Medical summaries (inpatient)
- Radiology results
- Pharmacy data
- Insurance data
- Immunization data
- Anonymized content