Health Level Seven

EHR Technical Committee – EHR Interoperability Project Team

ONC/HITSP Use Case Alignment w/HL7 EHR-S/PHR-S Models

Chapter 2

Harmonized Use Case for Biosurveillance (Visit, Utilization and Lab Result Data) (Year 1 – 2006)

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TABLE OF CONTENTS

Introduction

Since the outset of standards harmonization activities within ANSI HITSP, use cases – developed by AHIC – have driven the process (reference http://www.hhs.gov/healthit/usecases/). Use cases describe health (care) business and clinical scenarios.

This alignment document follows a process of discovery, to document applicability of HL7 Electronic Health Record System (EHR-S) and Personal Health Record System (PHR-S) Functional Models with the formalized ONC/AHIC/HITSP use cases, and to identify relevant gaps.

The use cases are organized as a four level hierarchy:

Use Case; which has one or more
Scenario(s); which have one or more
Event(s); which have one or more
Action(s).

Actions are the elemental tasks of each Use Case: Actions = discrete tasks. Actions are supported by specific EHR system functions, typically invoked as the Action is performed/provided. Also, most provider-related Actions require persistent evidence of their occurrence (in the form of a persistent Action Record).

To inform ongoing development work of the EHR TC, the analysis started with a single ONC/AHIC/HITSP Use Case. The resulting alignment document confirms applicability, detailed to the Use Case Action level, as follows:

HL7 EHR-S/PHR-S Model	**Alignment Analysis intends to…**
EHR/PHR System Functional Models (system functions)	• Specify functions required (or likely to be invoked) by each Use Case Action • Optionally, specify related conformance criteria • Identify gaps (i.e., missing functions or criteria)
EHR Interoperability Model (record interoperability characteristics)	• Show Action documented by Action Record • Show Action Record in context of Common EHR Record Unit (CRU) • Show how Action Records (as CRUs) are interoperable • Show how Action Records (as CRUs) might be implemented (ref. CDAr2 Profile) • Show how Action Record is ascribed as to Who, What, When, Where • Show how Action Record is consistent with legal record requirements (ref. Legal Profile) • Show how trust aspects of Action Record are assured – access control, authentication, audit, traceability • Show how Action Records are originated, amended and versioned (also ref. CDAr2 Profile) • Identify gaps (i.e., missing interoperability characteristics or criteria)
EHR Lifecycle Model (record lifecycle events)	• Show Action consistency with Action Record lifecycle events • Identify gaps (i.e., missing lifecycle events)

Section 1. Purpose

This document describes results of the alignment analysis of ONC/AHIC/HITSP Use Cases vis-à-vis the HL7 EHR-S/PHR-S Functional Models, including both coverage and gaps. The analyses together encompass EHR/PHR system functionality and EHR record interoperability and EHR record lifecycle. The four HL7 Models include:

.1 HL7 Electronic Health Record System Functional Model (EHR-S/FM): Normative, ANSI approved, submitted as ISO TC215/WG8 Work Item, February 2007
.2 HL7 Personal Health Record System Functional Model (PHR-S/FM): pre-DSTU, Dec 2007
.3 HL7 EHR Interoperability Model (EHR/IM): Draft Standard for Trial Use, February 2007
.4 HL7 EHR Lifecycle Model (EHR/LM): Current Working Draft

This is Chapter 2, focusing on analysis of the **BioSurveillance (Visit, utilization & Lab Results) Use Case** http://www.hhs.gov/healthit/usecases/documents/BiosurveillanceUtilizationUseCase.pdf. Subsequent Chapters will describe analyses of the remaining Use Cases.

Section 2. Objectives

Following are the objectives of this alignment analysis:

.1 To analyze specifications of ONC/AHIC (use cases) and ANSI HITSP (Interoperability Specifications) to discover how they align with HL7 EHR/PHR Models.
.2 For the EHR-S/FM, to show which EHR system functions (functional characteristics) are invoked by each Use Case Action.
.3 For the PHR-S/FM, to show which PHR system functions (functional characteristics) are invoked by each Use Case Action. [Not applicable to this Use Case.]
.4 For the EHR/IM, to show which EHR interoperability characteristics are required to fulfill (or persistently evidence) each Use Case Action.

.5 For the EHR/LM, to show which EHR lifecycle events, as specified in the EHR/LM, are invoked to fulfill each Use Case Action.
.6 To first inform continuing work of the HL7 EHR Technical Committee.
.7 To also inform development of HITSP Interoperability Specifications and CCHIT certification criteria.

Section 3. Methodology

Following is the proposed alignment analysis methodology.

.1 Review Use Case narrative, Scenarios, Events and Actions.

.2a Complete Section 5, EHR-S/FM column, specifying for each Use Case Action which EHR system function(s) it likely invokes.

.2b Specify for each Use Case Action, any EHR system function(s) that are required but absent from the current EHRS/FM.

.3a Complete Section 5, PHR-S/FM column, specifying for each Use Case Action which PHR system function(s) it likely invokes.

.3b Specify for each Use Case Action, any PHR system function(s) that are required but absent from the current PHR-S/FM draft.

.4a Many provider Actions are accountable from a clinical and medical/legal perspective and require a persistent Action Record. Determine which Use Case Actions require the origination of an Action Record, as persistent evidence of Action occurrence.

.4b For purposes of the persistent EHR, an Action is often logically combined with other closely corresponding Actions. (An Action may be comprised of one or more other Actions, thus an Action Record instance may document one or more Actions.) Determine which Actions may be logically combined in a single Action Record.

.4c Determine, as applicable, Actions which invoke Act Record Lifecycle Events (per the EHR Lifecycle Model).

.4d Complete Section 6, EHR Record Persistence and Lifecycle, specifying each Use Case Action as per Steps 4a-4c.

.5 Complete Section 7, specifying which EHR Interoperability characteristics (per Act/Action Record, Section 3 of the EHR Interoperability Model) are pertinent to evidence Action occurrence – in the form of a persistent Action Record.

Section 4. Biosurveillance (Visit, Utilization and Lab Result Data) Harmonized Use Case Narrative

Biosurveillance is an American Health Information Community breakthrough area defined as implementation of real-time, nationwide public health event monitoring to support early detection, situational awareness, and rapid response management across public health and care delivery communities and other authorized Government agencies. The use case describes the process or interaction that each primary stakeholder will invoke in the capture, discovery, anonymization, and transmission of relevant data.

The use case is for the transmission of essential data from ambulatory care and emergency department visits, utilization, and lab result data from electronically enabled healthcare delivery and public health systems in a standardized and anonymized format to authorized Public Health Agencies with less than one day lag time. The system and processes must also support the ability for authorized public health personnel to go back to the data source to seek to re-link the biosurveillance data to the data source as part of an appropriate public health investigation.

The management of data to ensure proper routing, security, privacy, and timely reporting is critical to enabling biosurveillance activities. Potential architectural solutions to data flow issues include using individual facility data sources (e.g., single hospitals or ambulatory care sites) or data a data or network system such as a multi-faculty system or supporting organization that uses data in the course of providing other services and sends data to all appropriate public health agencies. Other permutations of these two models can also be considered. The role of the data or network system can be accomplished by several different stakeholders, including hospital systems, health plans, independent laboratories, and other possibilities.

Section 5. EHR/PHR System Functionality

[See Methodology, Steps 2a-2b above.] The following specifies EHR/PHR system functions invoked by Actions of the EHR/Lab Results Reporting Use Case. Both coverage (existing EHRS/FM and PHRS/FM functions) and gaps (missing functions) are identified.

Note: It is possible that the Biosurveillance (V, U & LR Data) Use Case may invoke PHR System functions.

Use Case Ref	Use Case Event/Action	EHR-S/FM	PHR-S/FM
1.1	**Individual Health Care Delivery Organizations**		
1.1.1.0	**Event: Filter existing data to indentify data required by public health agencies**		
1.1.1.**1**	**Action**: Filter collected data records to identify biosurveillance data	DC.1.1.5, DC.1.8.3, IN.1.1, IN.1.2, IN.1.3, IN.1.4, IN.2.4, IN.6, S.2.2.2, S.2.2.3, S.3.1.1, S.3.1.5	PH.2.4, PH.2.5.3, PH.2.5.5, PH.3.1.1, PH.3.6.1, PH.6.4, IN.1.3, IN.1.4, S.4.2
1.1.1.**2**	**Action**: Aggregate identified data	DC.1.8.6, DC.2.6.1, IN.2.4, S.2.1.1, S.2.1.2	IN.1.3, IN.1.4
1.1.2.0	**Event: Anonymize data required by public health agencies**		
1.1.2.**1**	**Action**: Required data are checked to ensure full privacy requirement compliance	DC.1.1.5, DC.1.3.3, DC.2.6.1, DC.3.2.1, IN.1.9	PH.1.5, PH.3.5.3, PH.3.6.1, IN.1.4, IN.3.2, IN.3.3, IN.3.8, S.3.3.1, S4.2

Use Case Ref	Use Case Event/Action	EHR-S/FM	PHR-S/FM
1.1.2.**2**	**Action**: A randomized data linker is provided to allow authorized entities to re-link to patient data	DC.1.1.1, DC.2.6.1, DC.2.6.2, DC.2.6.3, IN.1.2, IN.2.3, IN.3, S.1.5	PH1.1, PH.3.6.1, IN.1.2, IN.1.4, S.4.1.2
1.1.3.0	**Event: Format data required by public health agencies**		
1.1.3.**1**	**Action:** Transform data using approved standards	IN.4.1, IN.4.2, IN.4.3, IN.5.1, IN.5.2, IN.5.3, IN.5.4, S.3.2.1	PH.2.5.5 , IN.1.8, PH.1.10, IN.2.1, IN.2.2, IN.2.3, IN.2.4
1.1.4.0	**Event: Identify Public Health Agencies that must be notified**		
1.1.4.**1**	**Action:** Determine which Public Health Agencies require notification	DC.1.8.2, DC.2.6.1, IN.3	PH.3.5.3, PH.3.6.1, IN.1.7, IN.3.2
1.1.5.0	**Event: Transmit relevant data to public health agencies**		
1.1.5.**1**	**Action:** Send results to public health agencies	DC.1.8.2, DC.2.6.1, IN.2.4, IN.3, S.1.4.3, S3.3.6	PH.3.6.1, IN.2.4, IN.3.5, IN.3.6, IN.3.10, S.4.2
1.1.5.**2**	**Action:** Log interaction between organization systems and public health agencies	DC.2.6.2, IN.2.2, S3.7.4	PH.3.6.2, PH.6.4, IN.4
1.2	**Integrated Health Care Data Suppliers**		
1.2.1.0	**Event: Filter existing data to identify data required by public health agencies**		
1.2.1.**1**	**Action:** Filter stored data to identify biosurveillance data	DC.1.1.5, DC.1.8.3, IN.1.1, IN.1.2, IN.1.3, IN.1.4, IN.2.4, IN.6, S.2.2.2, S.2.2.3, S.3.1.1, S.3.2.1	PH.2.4, PH.2.5.3, PH.2.5.5, PH.3.1.1, PH.3.6.1, PH.6.4, IN.1.3, IN.1.4, S.4.2
1.2.1.**2**	**Action:** Aggregate identified data	DC.1.8.6, DC.2.6.1, IN.2.4, S.2.1.1, S.2.1.2	IN.1.3, IN.1.4

Use Case Ref	Use Case Event/Action	EHR-S/FM	PHR-S/FM
1.2.2.0	**Event: Anonymize data required by public health agencies**		
1.2.2.**1**	**Action:** Required data are checked to ensure full privacy requirement compliance	DC.1.1.5, DC.1.3.3, DC.2.6.1, DC.3.2.1, IN.1.9	PH.1.5, PH.3.5.3, PH.3.6.1, IN.1.4, IN.3.2, IN.3.3, IN.3.8, S.3.3.1, S.4.2
1.2.2.**2**	**Action:** A randomized data linker is provided to allow authorized entities to re-link to patient data	DC.1.1.1, DC.2.6.1, DC.2.6.2, DC.2.6.3, IN.1.2, IN.2.3, IN.3, S.1.5	PH1.1, PH.3.6.1, IN.1.2, IN.1.4, S.4.1.2
1.2.3.0	**Event: Format data required by public health agencies**		
1.2.3.**1**	**Action:** Transform data using approved standards	IN.4.1, IN.4.2, IN.4.3, IN.5.1, IN.5.2, IN.5.3, IN.5.4, S.3.2.1	PH.2.5.5, IN.1.8, IN.1.10, IN.2.1, IN.2.2, IN.2.3, IN.2.4
1.2.4.0	**Event: Identify Public Health Agencies that must be notified**		
1.2.4.**1**	**Action:** Determine which Public Health Agencies require notification	DC.1.8.2, DC.2.6.1, IN.3	PH.3.5.3, PH.3.6.1, IN.1.7, IN.3.2
1.2.5.0	**Event: Transmit relevant data to public health agencies**		
1.2.5.**1**	**Action:** Send results to public health agencies	DC.1.8.2, DC.2.6.1, IN.2.4, IN.3, S.1.4.3, S.3.3.6	PH.3.6.1, IN.2.4, IN.3.5, IN.3.6, IN.3.10, S.4.2
1.2.5.**2**	**Action**: Log interaction between organization systems and public health agencies	DC.2.6.2, IN.2.2, S.3.7.4	PH.3.6.2, PH.6.4, IN.4

Use Case Ref	Use Case Event/Action	EHR-S/FM	PHR-S/FM
1.3	**Public Health agencies (local/state/federal)**		
1.3.1.0	**Event: Provide listing of required biosurveillance data**		
1.3.1.**1**	**Action:** Notify involved organizations of data that must be transmitted to Public Health Agencies	DC.2.6.2, S.3.3.6	PH.3.6.1, S.4.6, IN.1.7
1.3.2.0	**Event: Receive biosurveillance data**		
1.3.2.**1**	**Action:** Receive clinical data from all the data sources	DC.1.1.3.1	PH.6.2, IN.3.5
1.3.2.**2**	**Action:** Verify authenticity of transmission contents	IN.1.1, IN.1.6, IN.1.7, IN.1.8, IN.2.2	PH.3.5.3, IN.3.2, IN.3.4, IN.3.5
1.3.2.**3**	**Action:** Acknowledge receipt of clinical data	DC.1.1.3.1	None!
1.3.2.**4**	**Action:** Log receipt and storage of lab results	DC.1.1.3.1, DC.2.1.3, IN.2.2	None!

Section 6. EHR Record Persistence and Lifecycle

[See Methodology Steps 4a-4d above.] The primary Action of the EHR/Biosurveillance (Visit, Utilization and Lab Result Data) Use Case is laboratory analysis of a patient specimen (ID 3.3.1). From this Action, a persistent Action Record is originated – comprising results of laboratory analysis and related context (who, what, when, where). Additional Action Records may be originated for those Use Case Actions requiring entries (and thus persistent evidence) in the EHR.

The following table specifies for each Action:
.1 Column C – Whether the Action [shall/should/may/does not] require a persistent Action Record
.2 Column D – Related Actions which may combine Action Records, if applicable
.3 Column E – Related EHR/LM Lifecycle Event, if applicable

Use Case Ref	Biosurveillance (V, U & LR Data) Use Case Event/Action	Action _____ require an Action Record	Combined Action Records	EHR/LM – Lifecycle Event
1.1	**Individual Health Care Delivery Organizations**			
1.1.1.0	**Event: Filter existing data to indentify data required by public health agencies**			
1.1.1.**1**	**Action**: Filter collected data records to identify biosurveillance data	May	1.1.1.1 + 1.1.1.2	NA
1.1.1.**2**	**Action**: Aggregate identified data	Should	1.1.1.1 + 1.1.1.2	1:Originate Record
1.1.2.0	**Event: Anonymize data required by public health agencies**			
1.1.2.**1**	**Action**: Required data are checked to ensure full privacy requirement compliance	May	NA	

Use Case Ref	Biosurveillance (V, U & LR Data) Use Case Event/Action	Action _____ require an Action Record	Combined Action Records	EHR/LM – Lifecycle Event
1.1.2.**2**	**Action**: A randomized data linker is provided to allow authorized entities to re-link to patient data	Should	NA	7.1: De-identify or Alias Records (s) 7.2: Re-identify Records(s)
1.1.3.0	**Event: Format data required by public health agencies**			
1.1.3.**1**	**Action:** Transform data using approved standards	Should	NA	2.2: Translate Record Content
1.1.4.0	**Event: Identify Public Health Agencies that must be notified**			
1.1.4.**1**	**Action:** Determine which Public Health Agencies require notification	Does not	NA	NA
1.1.5.0	**Event: Transmit relevant data to public health agencies**			
1.1.5.**1**	**Action:** Send results to public health agencies	Shall	1.1.5.1 + 1.1.5.2	5.1: Transmit and/or Disclose Record(s) – Original and Amendment(s) 5.2: Transmit and/or Disclose Record(s) – Most Recent Amendment
1.1.5.**2**	**Action:** Log interaction between organization systems and public health agencies	Shall	1.1.5.1 + 1.1.5.2	NA

Use Case Ref	Biosurveillance (V, U & LR Data) Use Case Event/Action	Action _____ require an Action Record	Combined Action Records	EHR/LM – Lifecycle Event
1.2	**Integrated Health Care Data Suppliers**			
1.2.1.0	**Event: Filter existing data to identify data required by public health agencies**			
1.2.1.**1**	**Action:** Filter stored data to identify biosurveillance data	May	1.2.1.1 + 1.2.1.2	NA
1.2.1.**2**	**Action:** Aggregate identified data	May	1.2.1.1 + 1.2.1.2	4:Access/View Record Content
1.2.2.0	**Event: Anonymize data required by public health agencies**			
1.2.2.**1**	**Action:** Required data are checked to ensure full privacy requirement compliance	Shall	NA	2.1: Amend Record Content 7.1: De-identify or Alias Record(s)
1.2.2.**2**	**Action:** A randomized data linker is provided to allow authorized entities to re-link to patient data	Should	NA	7.2: Re-identify Record(s)
1.2.3.0	**Event: Format data required by public health agencies**			
1.2.3.**1**	**Action:** Transform data using approved standards	Should	NA	2.2 Translate Record Content
1.2.4.0	**Event: Identify Public Health Agencies that must be notified**			
1.2.4.**1**	**Action:** Determine which Public Health Agencies require notification	Does not	NA	NA
1.2.5.0	**Event: Transmit relevant data to public health agencies**			

Use Case Ref	Biosurveillance (V, U & LR Data) Use Case Event/Action	Action _____ require an Action Record	Combined Action Records	EHR/LM – Lifecycle Event
1.2.5.**1**	**Action:** Send results to public health agencies	Shall	1.2.5.1 + 1.2.5.2	5.1: Transmit and/or Disclose Record(s) – Original and Amendment(s) 5.2: Transmit and/or Disclose Record(s) – Most Recent Amendment
1.2.5.**2**	**Action**: Log interaction between organization systems and public health agencies	Shall	1.2.5.1 + 1.2.5.2	NA
1.3	**Public Health agencies (local/state/federal)**			
1.3.1.0	**Event: Provide listing of required biosurveillance data**			
1.3.1.**1**	**Action:** Notify involved organizations of data that must be transmitted to Public Health Agencies	NA?	NA	NA
1.3.2.0	**Event: Receive biosurveillance data**			

Use Case Ref	Biosurveillance (V, U & LR Data) Use Case Event/Action	Action _____ require an Action Record	Combined Action Records	EHR/LM – Lifecycle Event
1.3.2.**1**	**Action:** Receive clinical data from all the data sources	Shall	1.3.2.1 + 1.3.2.2 + 1.3.2.3 + 1.3.2.4	3.1: Verify Record Content 3.2 Ensure/Attest Record as Complete 3.3: Ensure/Attest Record as Accurate 5.1: Transmit and/or Disclose Record(s) – Original and Amendment(s) 5.2: Transmit and/or Disclose Record(s) – Most Recent Amendment
1.3.2.**2**	**Action:** Verify authenticity of transmission contents	Shall	1.3.2.1 + 1.3.2.2 + 1.3.2.3 + 1.3.2.4	NA
1.3.2.**3**	**Action:** Acknowledge receipt of clinical data	Shall	1.3.2.1 + 1.3.2.2 + 1.3.2.3 + 1.3.2.4	NA
1.3.2.**4**	**Action:** Log receipt and storage of lab results	Shall	1.3.2.1 + 1.3.2.2 + 1.3.2.3 + 1.3.2.4	NA

Section 7. EHR Record Interoperability

[See Methodology Step 5 above.] The following specifies which EHR Interoperability characteristics (per Action Record, Section 3 of the EHR Interoperability Model) are applicable – to evidence Action occurrence – in the form of a persistent Action Record. Note that Action (Use Case term) is equivalent to Act (EHR Interoperability Model term).

In Column C, requirement is specified as "shall", "may" or Not Applicable ('N/A").

EHR/IM Ref	EHR Interoperability Characteristic	Applicability
3	An Act is documented by an Act Record instance.	Shall
3.1	An Act/Act Record instance is uniquely identifiable.	Shall
3.2	An Act Record is persistent legal evidence of Act occurrence.	May
3.3	An Act Record is a unit of record of the Health Record.	Shall
3.4	An Act Record is comprised of multiple attributes (elements).	Shall
3.5	An Act Record may contain attributes:	
3.5.1	Current to the Act	Shall
3.5.2	Of an historical nature	May
3.6	An Act Record is (one of):	
3.6.1	Patient related and patient identifiable.	May
3.6.2	Not patient specific.	May
3.6.3	Patient related but aliased.	May
3.6.4	Patient related but anonymized.	May
3.7	An Act Record is (one of):	
3.7.1	A non-attestable unit of the health record	May
3.7.2	An attestable (signature specific) unit of the health record, which is (one of):	
3.7.2.1	Attested by one or more Actor(s)/ Author(s)	Shall
3.7.2.2	Not yet attested	May
3.8	An Act Record has (may have):	May
3.8.1	One or more originating Actor(s)/Author(s)	Shall

EHR/IM Ref	EHR Interoperability Characteristic	Applicability
3.8.2	One or more amending Actor(s)/Author(s)	May
3.9	An Act Record is sourced by an originating application.	Shall
3.10	An Act Record allows revision by additive amendment only.	May
3.10.1	Each Act Record amendment may include a reason for amendment	May
3.11	An Act Record is timestamped according to:	
3.11.1	Act Date/Time	Shall
3.11.2	Act Duration	May
3.11.3	Act Record Origination Date/Time	Shall
3.11.4	Act Record Amendment Date(s)/Time(s)	Shall
3.12	An Act Record is oriented to physical locations:	
3.12.1	Act Location	Shall
3.12.2	Act Record Origination Location	Shall
3.12.3	Act Record Amendment Location(s)	May
3.13	An Act Record is originated/amended at a specific device and network location.	May
3.14	An Act Record may contain uniquely identified multi-media elements.	May
3.15	An Act Record may contain uniquely identified document elements.	May
3.16	An Act Record may be signed or attested as complete, by declaration or by algorithmic measure.	May
3.17	An Act Record may be designated as accurate, by declaration or by algorithmic measure.	Shall
3.18	An Act Record may embed access controls to allow only permitted:	
3.18.1	Record access/view	Shall
3.18.2	Record creation/amendment	Shall
3.19	An Act Record has an embedded audit trail, tracing:	
3.19.1	Original record content along with each successive amendment, timestamped	Shall
3.19.2	Point of record creation and amendment	Shall
3.19.3	Point of record access/use	Shall
3.19.4	Point of record content translation	Shall
3.19.5	Point of record transmittal or disclosure (to external entity)	Shall
3.19.6	Point of record receipt (from external source)	Shall

EHR/IM Ref	EHR Interoperability Characteristic	Applicability
3.19.7	Point of record de-identification, aliasing	May
3.19.8	Point of record completion	Shall
3.19.9	Point of record attested accurate	Shall
3.20	An Act Record may be:	
3.20.1	Part of a patient encounter	May
3.20.2	Related to an identified patient problem	May
3.20.3	Related to a specific order or care plan	May

Section 8. Discoveries and Comments

The following discoveries/comments are, categorized by group that we will be taking these observations to, for clarification & resolution:

1. Common EHR-S functions that apply across to all Event/Action pair (IN.1.1 to IN.1.3, IN.1.6, IN.1.7, IN.1.9, IN.1.12, DC.1.1.1 Create a paragraph at the beginning of section 5 to include these functions. Similar comments about PHR-S also. (what about Public Health non-patient situation?)

2. PHR – Registry and Authorization: should this be moved to top level?

3. How about noting down corresponding CC along with the Function mapping (for both EHR-S and PHR-S)?
   Ans: Yes buy we will wait for EHR-S and PHR-S model to freeze/finalize before attempting to map the CC to the UC.

4. For Section 6 “EHR Record Persistence and Lifecycle”, it seems like the Action Record in most cases could be handled at the Event level rather than the Action level. In other words, systems could combine all of the actions taken under a single event into a single Action Record. Is this correct? – discovery comment - take this back to the EHR/LM team

For ONC/AHIC group:

5. ONC Use Case 1.1.2.2: “randomized” data linker….is confusing since the appropriate word may be “anonymous” rather than “randomized”

6. EHR DC.2.6 (Population Health) --- applies to this Use Case in general! – linked to #1.

7. For UseCase 1.1.1.1 & 1.2.1.1: Should this Action be split into two part a) Filter, b) View of the filtered data i.e., display?

8. For UseCase 1.1.1.1, 1.1.1.2, & 1.2.1.1: The term “BioSurveillance data” may require further elaboration! Who defines it, What does it constitute of etc etc. The answer may have impact on what function do we map to.

9. We may have a Use Case gap: there aren't any specific actions covering notifications from public health agencies back to data suppliers?

10. For Use Case 1.1.4.1 & 1.2.4.1 mapping to EHR-S DC.1.8.2: What about non-IZ related Reporting requirement? Where/how is that covered? Two option: expand EHR-S FM and/or clarify the ONC Use Case.

11. How does PHR-S apply to BioSurveillance Use Case?

12. PHR-PH.2.5.5 – What about non-IZ Reporting?

13. PHR-UC in general – looks like it doesn’t cover PH Agency to User Alert situation.

For EHR TC for EHR-S observations:

14. For Use Case 1.1.4.1 & 1.2.4.1 mapping to EHR-S DC.1.8.2: What about non-IZ related Reporting requirement? Where/how is that covered? Two option: expand EHR-S FM and/or clarify the ONC Use Case

15. When considering EHR interaction with Public Health functionality in general, and the HITSP Biosurveillance UC in particular, there appears to be a short fall in the description of the EHR functionality. Specifically, the directly applicable EHR function S.3.3.6 - Health Service Reports at the Conclusion of an Episode of Care, explicitly describes the generation of such reports to occur solely “at the conclusion of an episode of care”. Acknowledging variance across jurisdictions, there are PH reports and notifications of specific conditions that should (must?) occur upon discovery of the condition (or even during the investigation process) and not wait until an episode of care has completed (I am assuming ‘episode of care’ correlates in duration to the underlying ‘episode of illness’).
    i. Quoting directly from S.3.3.6 Function Statement: “Support the creation of health service reports at the conclusion of an episode of care. Support the creation of health service reports to authorized health entities, for example public health, such as notifiable condition reports, immunization, cancer registry and discharge data that a provider may be required to generate at the conclusion of an

episode of care." This issue can be resolved by enhancing the first statement to read, "Support the creation of health service reports *as required by jurisdictional authorities*." (Italics and underline added for visual contrast.)

For PHR WG for PHR-S observations: This TASK was completed on Jan23, 2008 at the PHR WG call.

16. ONC UseCase: 1.1.2.2: calls for "re-link" to patient data but there is no corresponding function in the model.

1.1.2.0	**Event: Anonymize data required by public health agencies**	**PHR-S FM MAP**
1.1.2.**1**	**Action**: Required data are checked to ensure full privacy requirement compliance	
1.1.2.**2**	**Action**: A randomized data linker is provided to allow authorized entities to re-link to patient data	PH1.1, PH.3.6.1, IN.1.2, IN.1.4, S.4.1.2

Specifically, UC 1.1.2.2 calls for "re-linking" of patient data.

Is this well covered in the PHR-S FM? PHR-S PH1.1 and PH3.6.1 has some details on "re-link"; is this sufficient?

17. ONC UseCase: 1.3.2.2 through 1.3.2.4: shows a gap in terms of what a PHR-S FM can/may request an (Public Health) Agency to perform (verification, acknowledgement, logging and storage).

1.3	**Public Health agencies (local/state/federal)**	
1.3.1.0	**Event: Provide listing of required biosurveillance data**	**PHR-S FM MAP**

1.3.1.**1**	**Action:** Notify involved organizations of data that must be transmitted to Public Health Agencies	PH.3.6.1, S.4.6, IN.1.7
1.3.2.0	**Event: Receive biosurveillance data**	
1.3.2.**1**	**Action:** Receive clinical data from all the data sources	PH.6.2, IN.3.5
1.3.2.**2**	**Action:** Verify authenticity of transmission contents	PH.3.5.3, IN.3.2, IN.3.4, IN.3.5
1.3.2.**3**	**Action:** Acknowledge receipt of clinical data	None!
1.3.2.**4**	**Action:** Log receipt and storage of lab results	None!

In Section 7, are we referring to a complete EHR system or the health record for a particular patient? This relates to whether records must be kept for system-wide interactions with public health agencies such as receiving general alerts.

July 29, 2008 Update: Once the DSTU version of PHR-S:FM is released, UC1.3.2.0 for the PHR-S part needs to be updated.

FEEDBACK RECEIVED FROM Kristi Eckerson (PHER WG volunteer and a member of the BioSurveillance Task team)

The comments follow:

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1. Common functions that apply across to all Event/Action pair (IN.1.1 to IN.1.3, IN.1.6, IN.1.7, IN.1.9, IN.1.12, DC.1.1.1 (?-what about Public Health non-patient situation))

Function EHR-S IN.1 is 'Security'.
IN.1.1 Entity Authentication
IN.1.2 Entity Authorization
IN.1.3 Entity Access Control
IN.1.6 Secure Data Exchange
IN.1.7 Secure Data Routing
IN.1.9 Patient Privacy and Confidentiality
Function DC.1 is 'Care management'
DC.1.1 Record Management
DC.1.1.1 Identify and Maintain a Patient Record

All these common functions apply in all cases, whether the identified 'patient' is an individual, adult human being, or a flock of chickens, they simply may be governed by other, slightly different business rules (e.g. the chicken's identity may not be 'confidential', but the farmer's may well be). Considering possible impact on implementation designs, it is not dissimilar to the slightly different rules in place if the patient is an infant, as opposed to an adult.

To address the concern raised by this question, the discussion of Function 1.4 – Patient Access Management could be enhanced to acknowledge the fact. The 'Functional Statement' currently reads, "Enable a healthcare delivery organization to allow and manage a patient's access to the patient's personal health information." If the statement were to discuss the "patient &/or legal guardian/Agent" rather than the singular 'patient', IMO most of this concern could be addressed.

An explicit scope constraint, limiting the EHR-S FM to non-aggregating functions, addressing individual human subjects only may address the question, but seems unrealistic. An EHR *System* should include aggregate reporting functionality to providers and system administrators, as well as to public health authorities. Limiting EHRs to human patients

unnecessarily constrains the potential market for such products. As more is learned about emerging zoonotic diseases, more emphasis will be placed on veterinary medical information systems.

General PHR-S acknowledgement of Public Health functions

In Function IN.1.4 “Extraction of Health Record Information”, the function description includes the following statements (italics added for emphasis):

> A PHR-S enables an *authorized user* to access and aggregate the distributed information, which corresponds to the health record or records that are needed for viewing, reporting, disclosure, etc. A PHR-S should support data extraction operations across the complete data set that constitutes the health record of an individual and provide an output that fully chronicles that individual's healthcare experience. Data extractions are used as input to patient care coordination between facilities, organizations and settings. In addition, *data extractions can be used for administrative, financial, research, quality analysis, and public health purposes.* However, information should be extracted and *used only in conformance with the privileges the account holder has granted*; these *may be defined by* user status, acceptance of product terms and conditions, contractual information, organizational policies, and/or *jurisdictional law.*

Function IN.1.7 “Registry and Directory Services” also cites Public Health directly:

> **Statement**: Enable the use of registry services and directories *to uniquely identify, locate and supply links for retrieval of information related to*:
> - patients and providers for healthcare purposes;
> - payers, health plans, sponsors, and employers for administrative and financial purposes;
> - *public health agencies for healthcare purposes*, and
> …

Explicit PHR-S acknowledgement of Public Health functions

In Function PH.3.6 “Population Health and Wellness”, the function description includes the following statements (italics added for emphasis):

> **Statement**: The PHR may serve as a communication tool to *help control public health risks to the population and to the account holder specifically*.
> **Description**: A formal and well defined communication channel between public health agencies and the account holder's PHR is useful. It provides for monitoring public health threats through data and observations captured within the PHR. Additionally it alerts the account holder to take corrective actions in response to public health threats.

PHR seems to have addressed PH functions…Re-reviewing EHR-S, Functions S.3.2 , "Information Access for Supplemental Use" may provide the parallel 'generic public health functionality' statement(s)…

EHR-FM function DC.2.6 also provides some 'blanket' coverage of PH functional needs

Our final question/comment, "In Section 7, are we referring to a complete EHR system or the health record for a particular patient?" provides a key to any confusion about where we can/should expect support for various aspects of PH functional support.

Editorial Comments

It is the opinion of the task team that the "BioSurveillance Use case Mapping" has brought out some significant gaps both in the AHIC/ONC/HITSP Use cases itself and also the HL7 Functional Models. This is due to the fact that Public Health functions are not treated uniformly in the functional models.

We see the following options:

1. For the Use cases: Take the comments back to AHIC/ONC/HITSP for revising/clarifying the Use Cases.
2. For HL7 EHR WG, we suggest three options (in collaboration with HL7 PHER WG) :
    a. **Enhance the EHR-S and PHR-S functional model** to incorporate Public Health functions in greater clarify (at present, the PHR-SFM in comparison to the EHR-S FM does a better job of handling Public Health function, this is a consequence of the fact that PHR-S FM was developed after the EHR-S FM was made available and therefore had the advantage of time!)
    b. **Create a PbH (Public Health) Functional Profile** to bring out the Public health functionality that is currently lacking in the two FMs (EHR-S and PHR-S)
    c. **Create a HL7 PbH-S Public Health Function Model** [similar to EHR-S and PHR-S FM) to deal with Public Health functionality that some time are in contrast with EHR-S and PHR-S functions (for example non human and non patient functions!)]

A BIG THANK YOU TO ALL PARTICIPANTS OF THE BIOSURVEILLANCE MAPPING TEAM & REVIEWERS WHO CONTRIBUTED TO THIS DOCUMENT!

THIS IS A WORK IN PROGRESS…