

Alignment
ONC/AHIC/HITSP Use Cases
w/HL7 EHR/PHR Models

Chapter 1: Year 1 EHR/Lab Results Reporting

HL7 EHR Technical Committee
EHR Interoperability Working Group
DRAFT - 10 December 2007

Prepared for Presentation to...

- ANSI HITSP Foundations Committee
 - Per request of Robert Dolin, MD, FC Co-Chair, to Gary Dickinson (15 March 2007)
 - Per approval of EHR TC (22 October 2007)
- DHHS Office of the National Coordinator
 - Per request of John Loonsk, MD, to Gary Dickinson (13 November 2007)

HL7 Electronic Health Record Technical Committee

HL7 EHR Technical Committee

Mission

Establish requirements for:

- Functionality of EHR and PHR Systems
- Ubiquitous Record Interoperability amongst EHR and PHR Systems
- End-to-End Trust Framework for Interoperable EHR Records

HL7 EHR TC/EHR Interoperability Working Group Projects

- “Coming to Terms” White Paper
 - Compilation and Analysis of Industry “Interoperability” Definitions
- EHR Interoperability Model
- EHR Lifecycle Model
- Alignment of ONC/AHIC/HITSP Use Cases w/HL7 EHR/PHR Models
 - Starting w/Year 1 EHR/Lab Results Reporting

HL7 EHR/PHR Models

HL7 EHR Technical Committee

EHR/PHR Models

	HL7 Model	Specifies...
S Y S T E M S	EHR Functional Model (EHR/FM)	Functional characteristics (functions) of Electronic Health Record <u>Systems</u> (EHR)
	PHR Functional Model (PHR/FM)	Functional characteristics (functions) of Personal Health Record <u>Systems</u> (PHR)
R E C O R D S	EHR Interoperability Model (EHR/IM)	Characteristics of interoperable EHR <u>Records</u>
	EHR Lifecycle Model (EHR/LM)	Key events in the EHR <u>Record</u> lifecycle

HL7 EHR System Functional Model

EHR/S/FM

- Normative Standard, published March 2007
- HL7 and ANSI Approved
- Approved as ISO TC215 Work Item
- Specifies functional characteristics (functions) of an EHR System
- Is profiled for care settings, localities and uses
- EHR Systems conform to EHR/S/FM Profiles
- Used as framework for CCHIT certification of EHR Systems

Alignment Analysis:

- Specifies functions required (or likely to be invoked) by each Use Case Action
- Optionally, specifies function-related conformance criteria
- Identifies gaps (i.e., missing functions or criteria)

HL7 PHR System Functional Model

PHRS/FM

- Passed Ballot as Draft Standard for Trial Use (DSTU), Dec 2007
- Specifies functional characteristics (functions) of a PHR System
- May be profiled for sponsors, localities and uses
- PHR Systems conform to PHRS/FM Profiles
- Potential framework for CCHIT certification of PHR Systems (future)

Alignment Analysis:

- Specifies functions required (or likely to be invoked) by each Use Case Action
- Optionally, specifies function-related conformance criteria
- Identifies gaps (i.e., missing functions or criteria)

HL7 EHR Interoperability Model

EHR/IM

- Draft Standard for Trial Use, published March 2007
- Specifies characteristics of interoperable EHR records
- Establishes Common EHR Record Unit
- Establishes/anchors end-to-end “chain of trust” for EHR Records
 - From point of record origination
 - To each ultimate point of record access/use
 - Traversing multiple points of exchange, if applicable

Alignment Analysis:

- Shows each Use Case Action documented by persistent Action Record, as applicable
- Shows which EHR interoperability requirements are applicable to each Use Case
- Shows how Action Records are ascribed as to: Who, What, When, Where (Action Context)
- Identifies gaps (i.e., missing interoperability characteristics or criteria)

HL7 EHR Lifecycle Model

EHR/LM

- In Ballot as Draft Standard for Trial Use (DSTU), December 2007
- Shows record lifecycle events within System retaining EHR records
- Shows end-to-end record lifecycle events across multiple Systems and traversing points of record exchange
- Supplements EHR Interoperability Model

Alignment Analysis:

- Specifies EHRS lifecycle event(s) corresponding to each Use Case Action
- Identifies gaps, missing events

The Premise and A Simple Objective

A Simple Objective

Premises

- Patient Privacy and Confidentiality of Patient Health Records are Paramount
 - Record subject controls access, use and disclosure - within legal bounds
- Health Record Authors and Users are accountable for their specific Actions
- Health Records provide persistent, indelible evidence of Actions taken in health(care)

A Simple Objective

Premises, con't

- Health Records are protected by an End-to-End Trust Framework
 - Traceable from Point of Record Origination to each Point of Record Access/Use
- Health Records are interoperable between and amongst EHR and PHR Systems
- Health Records are interoperable across, and are neutral to:
 - Software products and architectures, technologies
 - Networks

A Simple Objective

Premises, con't

- Health Records are the immediate record (documentation) of health(care) and are
 - Integral to work flow and
 - Concurrent to clinical practice
- Health(care) occurs at points along a time continuum
- Health Records document (evidence) health(care) along the same time continuum

A Simple Objective

Ready Adoption

- Eliminate market barriers: to entry, to competitiveness
 - Make it technology, vendor and product neutral
 - Make it easy to understand
 - Make it easy to implement by small and large alike
 - Make it easy to bring to market
- Simplification drives adoption

A Simple Objective

Common EHR Currency

- Establish common EHR Currency
 - A common EHR unit of record
- Simplify retention, interchange and protection to a simple common record unit
 - Not 100s of proprietary and pseudo standard formats
 - Not 1000s of message variants (see HL7 v2/v3)
- Simplify interchange triggers to key EHR lifecycle events
 - 10 or 15 record-related trigger events
 - Not 1000s of trigger event variants (see HL7 v2/v3)

A Simple Objective

Trust Protections

- Embed Health Record trust protections, ensuring accountability and traceability
 - Consent-based use and disclosure
 - Source and Author authentication
 - Content authentication: original, amended, current
 - Digital signature: Author and System
 - Access control: to Access/View Record, to Amend Record
 - Traceable Record Audit Trail encompassing:
 - Amendments, Revision History
 - End-to-End Flow and Custody
 - Lifecycle Events: originate, verify, amend, access/view, transmit/disclose, receive, de-identify/alias, archive...
 - Attestation of Record Accuracy and Completeness

A Simple Objective

In the HITSP Context

- Be Reproducible, Applicable to all Use Cases
 - 1-day Method: use case narrative to complete interoperability specification in one day
- Ensure Foundational Infrastructure for all HITSP Interoperability Specifications
 - Focused on Greatest Common Denominator
 - Ensuring Common (Simple) Core
 - Extended only in the exception
 - When necessary to incorporate isolated use case requirements

A Paradigm for Accountability

The Action + Action Record

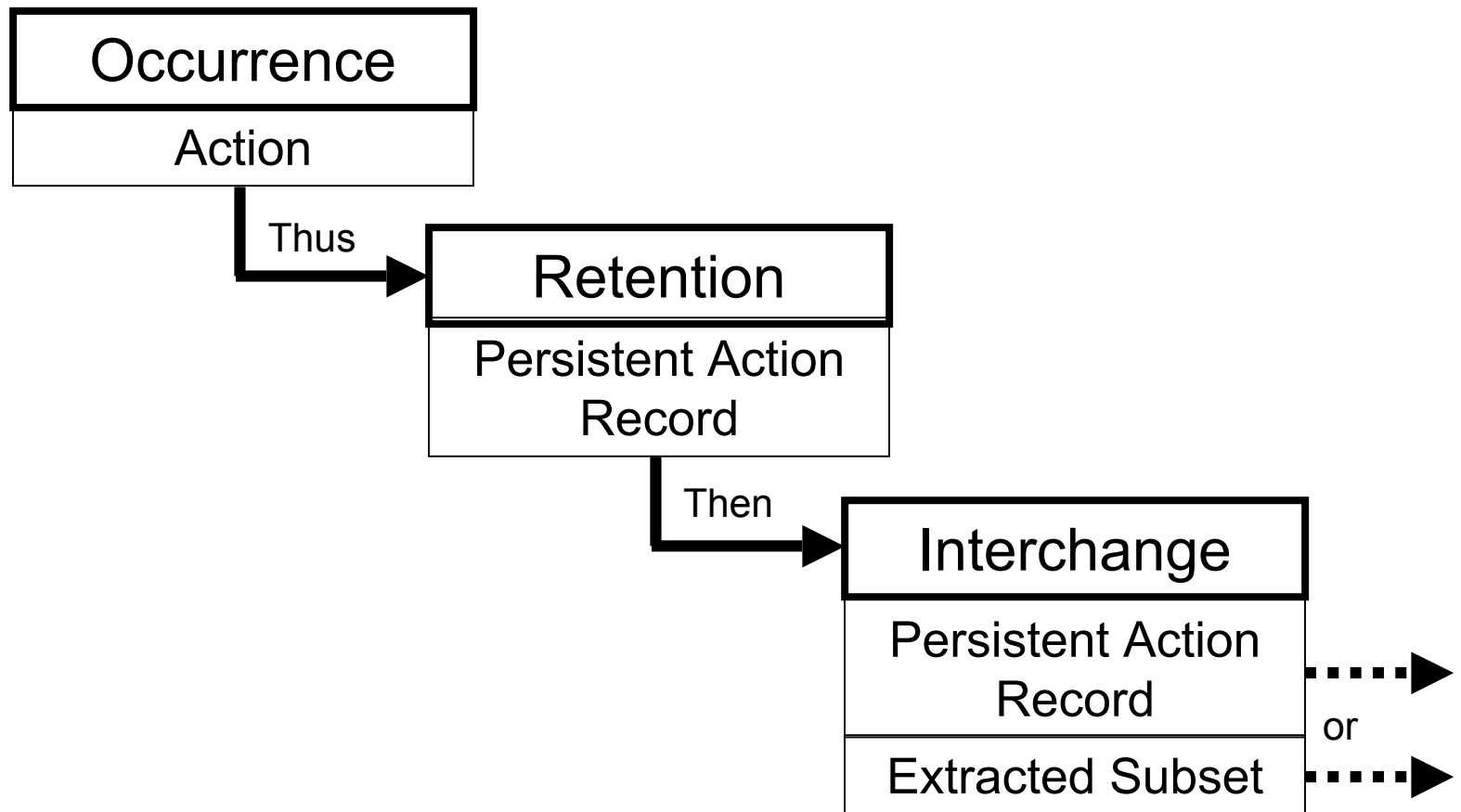
EHR Interoperability Fundamentals

Simple Paradigm

- Start with a discrete unit of service
 - Action
- Establish a corresponding EHR unit of record
 - Action Record
- Persist in EHR
 - Action Records = persistent entries in EHR


EHR Interoperability Fundamentals

Simple Sequence



Information in Action

- All health(care) information derives from, or is attributable to, a discrete Action
- The essential context of health(care) information is indivisible from its originating Action
 - Who, What, When, Where

Health(care) Delivery	Interoperable EHR
Comprised of discrete Actions	Comprised of persistent Action Records
Action Occurs 	Action is documented by an Action Record in EHR (as Persistent Evidence of Action Occurrence)
Actions have a chronology of occurrence	Action Records have a corresponding chronology
Actions are a common unit of service in health(care)	Action Records are a common unit of record of the EHR

Action...	Action Record...
Occurs	Documents (evidences) Action occurrence
Has context <ul style="list-style-type: none"> • Who, What, When, Where 	Documents Action context
Has facts <ul style="list-style-type: none"> • Current and historical 	Documents Action facts
Has one or more Actor(s), in role(s) and participation(s) <ul style="list-style-type: none"> • Roles: physician, nurse, pharmacist, therapist, secretary... • Participations: perform, assist, observe, scribe... 	Documents Actors, roles and participations
Is complete	Documents Action completion

Action...	Action Record...
If accountable to a Provider...	<ul style="list-style-type: none"> • Is persistent evidence of Action occurrence • Is retained as a persistent EHR entry • May be attested as accurate and/or complete
If consumer initiated...	<ul style="list-style-type: none"> • May be retained as PHR (or EHR) entry - or not

Action...	Action Record...
<ul style="list-style-type: none"> • Is an instance • Is a discrete act, task or event • Is (often) an instance of care or service provided or performed 	<ul style="list-style-type: none"> • Is a record instance • Is a common unit of record • Is a common information currency for health(care) and for EHRs: spanning record origination, retention, use and interchange

Action...	Action Record...
Is confidential	<ul style="list-style-type: none"> • Is a protected unit of record • May be encrypted e.g., while “in transit” • May have embedded access controls • Is auditable as to amendment history • May be auditable as to access, “chain of trust” and custody • May be de-identified or aliased

EHR Interoperability Fundamentals

Sample Actions...

- Register Patient
- Admit, transfer or discharge Patient
- Patient Care
 - Examine, assess, observe
 - Plan care & set goals
 - Update problem list
 - Order diagnostics, medications or therapies
 - Provide care
 - Perform therapy or procedure
 - Administer medications
 - Provide nutrition
- Medications
 - Check allergies, interactions
 - Dispense, label
 - Renew
- Specimens
 - Collect, label
 - Accession
 - Analyze, report results
- Schedule exam or appointment
- Refer Patient
- Transport Patient
- Provide consult

EHR Interoperability Fundamentals

Sample Actions, con't...

- Remind of:
 - Scheduled appointments
 - Periodic screening due
 - Immunizations due
- Notify Public Health Agency
 - Forward de-identified records
- Create Summary Record
 - e.g., CCR, CCD
- Forward Record(s) to PHR on behalf of Patient
- Perform epidemiological surveys
- Create acuity report
- Create staffing summary
- Create bed census
- Extract, report quality indicators
- Test, calibrate instrument
- Repair equipment
- Perform safety and emergency drills
- and many more...

- Each (accountable)
Action instance has a
corresponding
- Action Record instance

Use Case Alignment Analysis

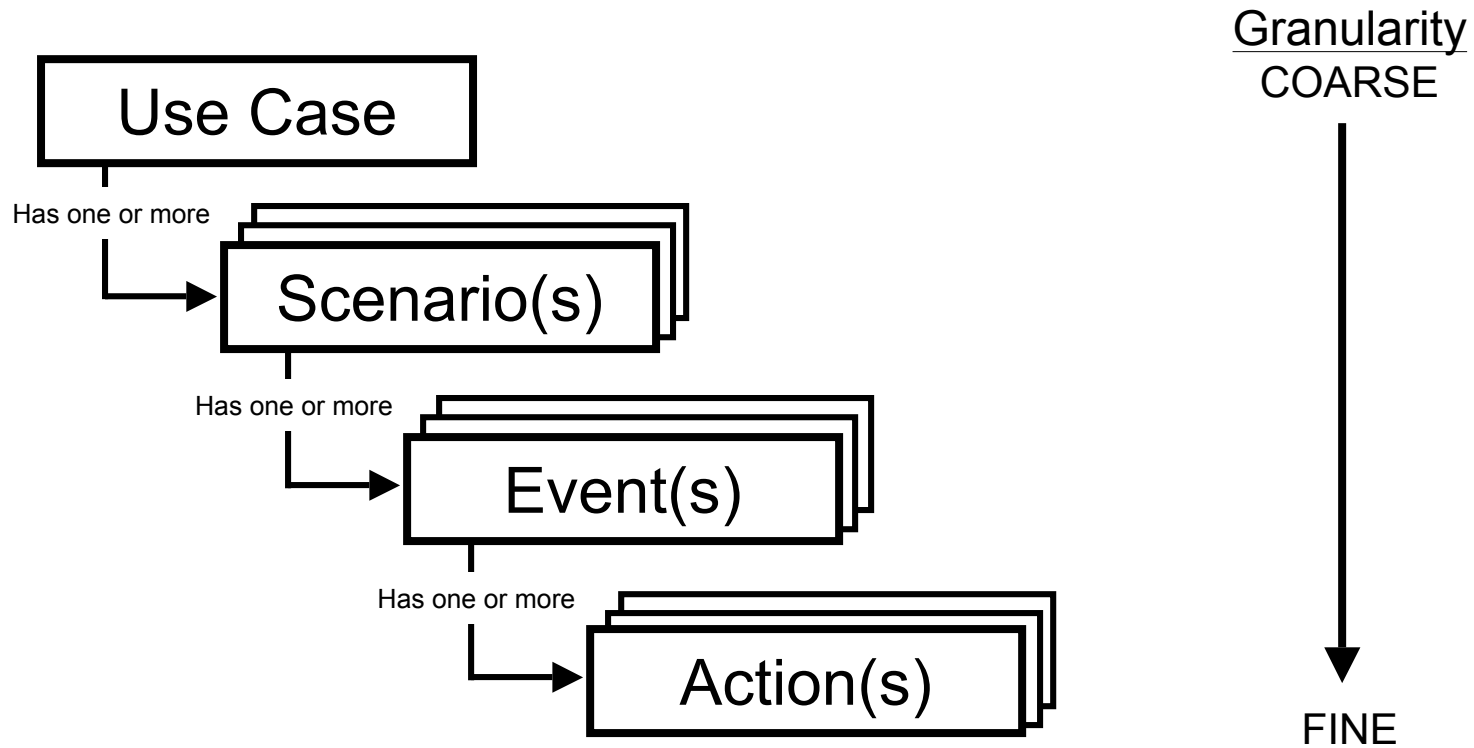
ONC/AHIC/HITSP

Year 1 Use Cases

- Care Delivery
 - EHR/Lab Results Reporting
- Consumer Empowerment
 - Demographics and Medication History
- Population Health
 - Biosurveillance

ONC/AHIC/HITSP

Use Case Hierarchy



Use Case Alignment Analysis

Methodology

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

For each Use Case Action:

2a Specify which EHR system function(s) it likely invokes.

2b Specify any EHR system function(s) that are required but absent from the current EHRS/FM (a gap).

3a Specify which PHR system function(s) it likely invokes.

3b Specify any PHR system function(s) that are required but absent from the current PHRS/FM draft (a gap).

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.

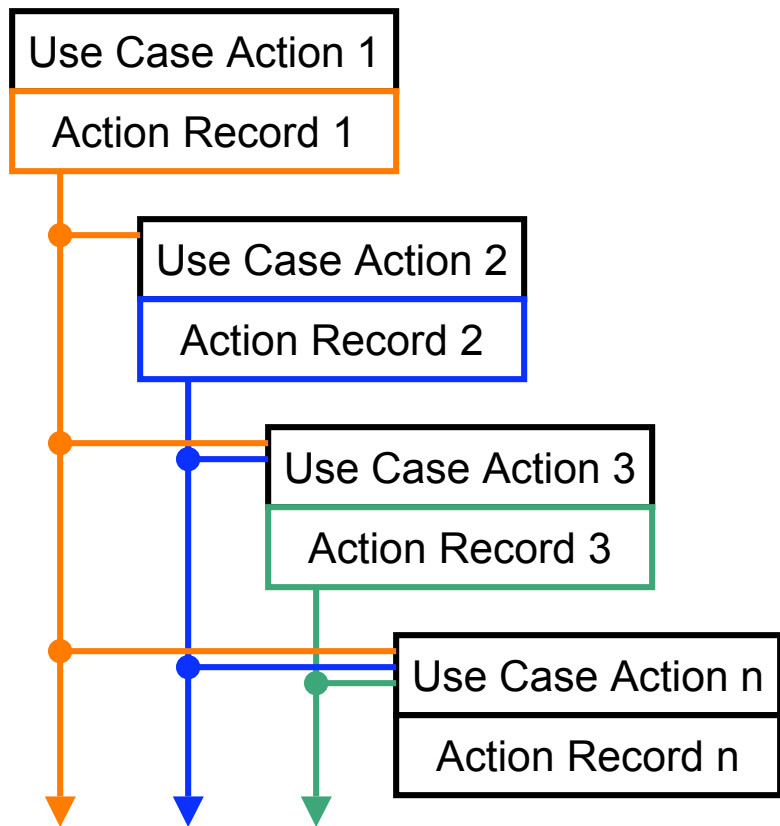
Use Case Alignment Analysis

Methodology, con't

- 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).
- 5 Specify 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.

Use Case Alignment Analysis

Record Flow




As applicable, each Use Case Action produces an Action Record which is then available as input to subsequent Action(s).

Use Case Alignment Analysis

Completeness

	Documented By	Complete
Action 1	Action Record 1	X
Action 2	Action Record 2	X
Action 3	Action Record 3	X
Action n	Action Record n	X
Use Case Scenario (Sum of Actions)	Action Records 1-n	X



Completion of each Use Case Scenario may be predicated on completion of contained Actions and Action Records.

From Requirements to Implementation

CDA Reference Profile for

EHR Interoperability

Basics

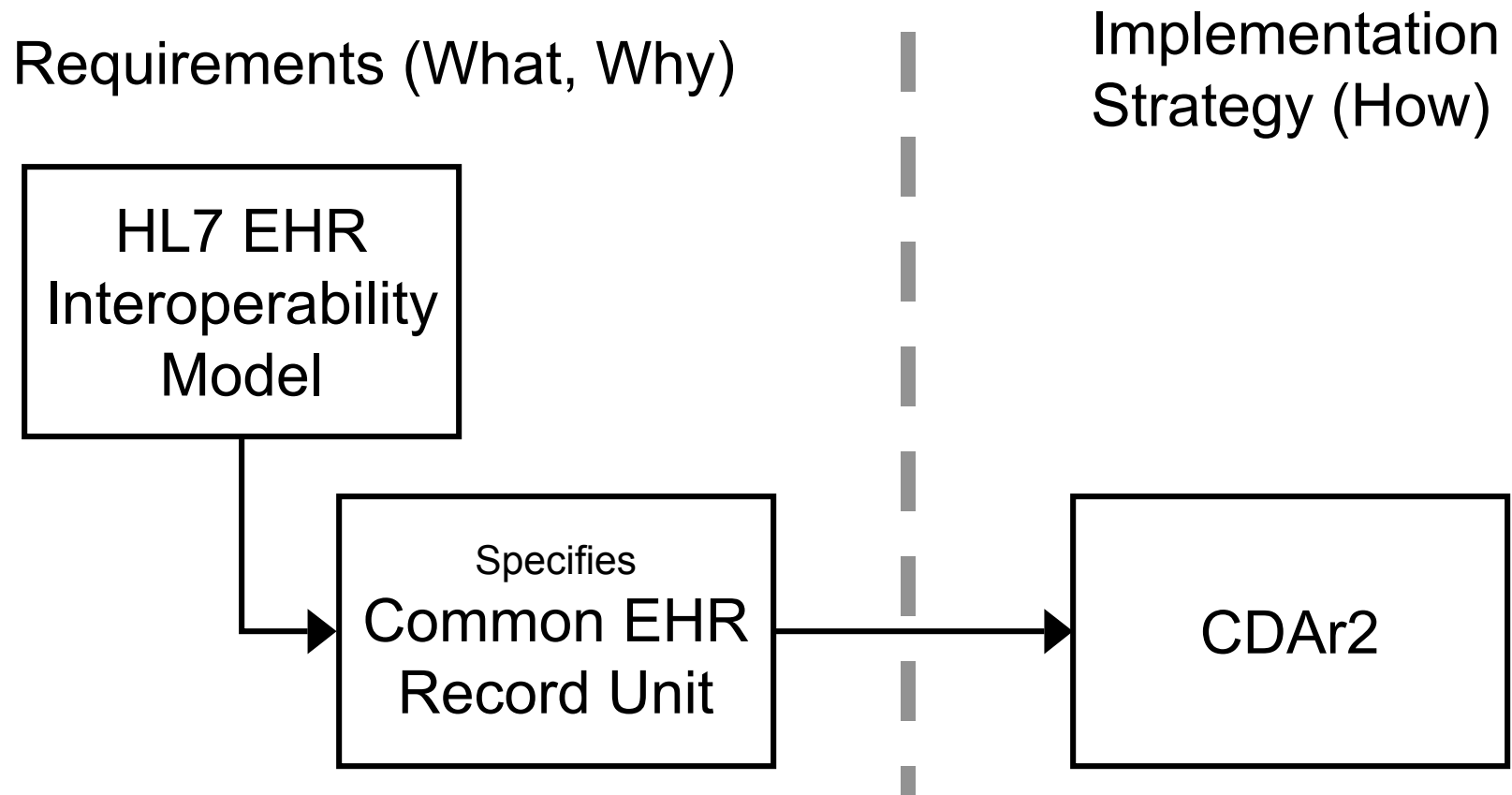
- HL7 Clinical Document Architecture Release 2
 - Mature, deployed standard
 - Included in many HITSP Interop Specs
 - Proposed for HIPAA Claims Attachments
 - Incorporated in IHE XDS strategy
 - Readily transformed (repurposed) from “Document” to “Common EHR Record Unit”

CDA Reference Profile for EHR Interoperability Profile

- Shows how CDAr2 meets/fulfills specific EHR interoperability requirements
 - Common EHR Record Unit
 - HL7 EHR Interoperability Model Sections 3 & 4
- Currently
 - In ballot as a Draft Standard for Trial Use

CDA Reference Profile for EHR Interoperability

Requirements Satisfied



A Forward Strategy

Generations

1G - 1980s to Now

Point to Point
w/Transient Messages

2G - Next (transitional)

3G - Goal

End to End
w/Persistent Records



1G - 80s to Now	2G - Next	3G - Goal
	Action Record external to System architecture	Action Record native to System architecture
Customized Point to Point	Uniform (Back) End-to-End	Uniform (Front) End-to-End
Transient Messages <ul style="list-style-type: none"> • Originated at System back-end interface, ready to transmit 	Persistent Action Records <ul style="list-style-type: none"> • Originated at System back-end interface, ready to transmit • Digitally signed by System • Authenticate-able (traceable) to Originating System 	Persistent Action Records <ul style="list-style-type: none"> • Originated at System front-end (often at point of care/service) • Digitally signed by Author and System • Authenticate-able (traceable) to Originating System and Author

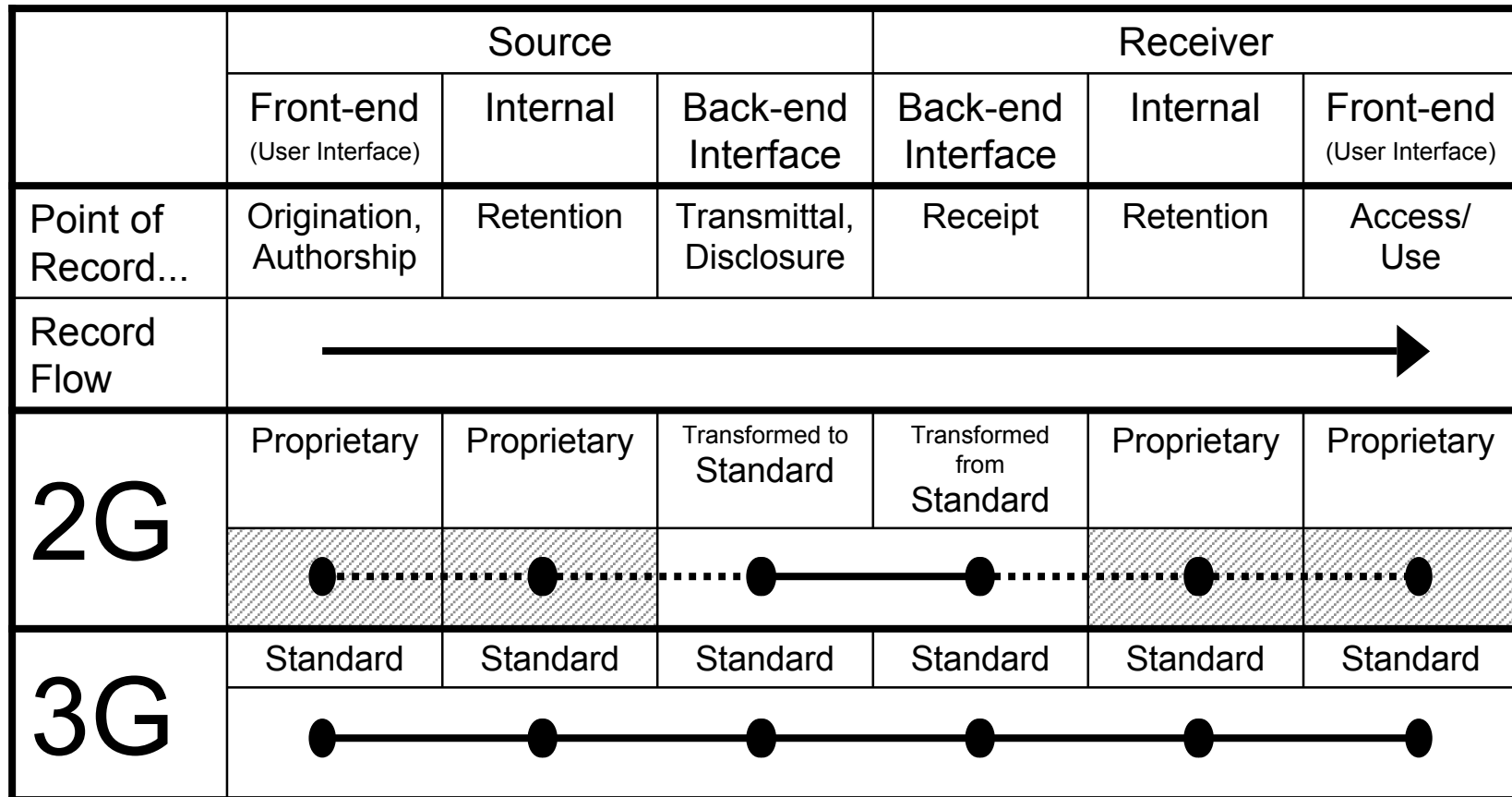
Health Information Capture, Retention and Exchange

The Transition Forward

1G - 80s to Now	2G	3G - Goal
Transitive, Volatile, Lossy	→	Persistent, Indelible, Lossless
Incomplete	→	Complete, As Originated
Piecemealed, Fragmentary	→	Whole, Uniform
Divergent Implementations	→	Common Currency, Consistent Exchange

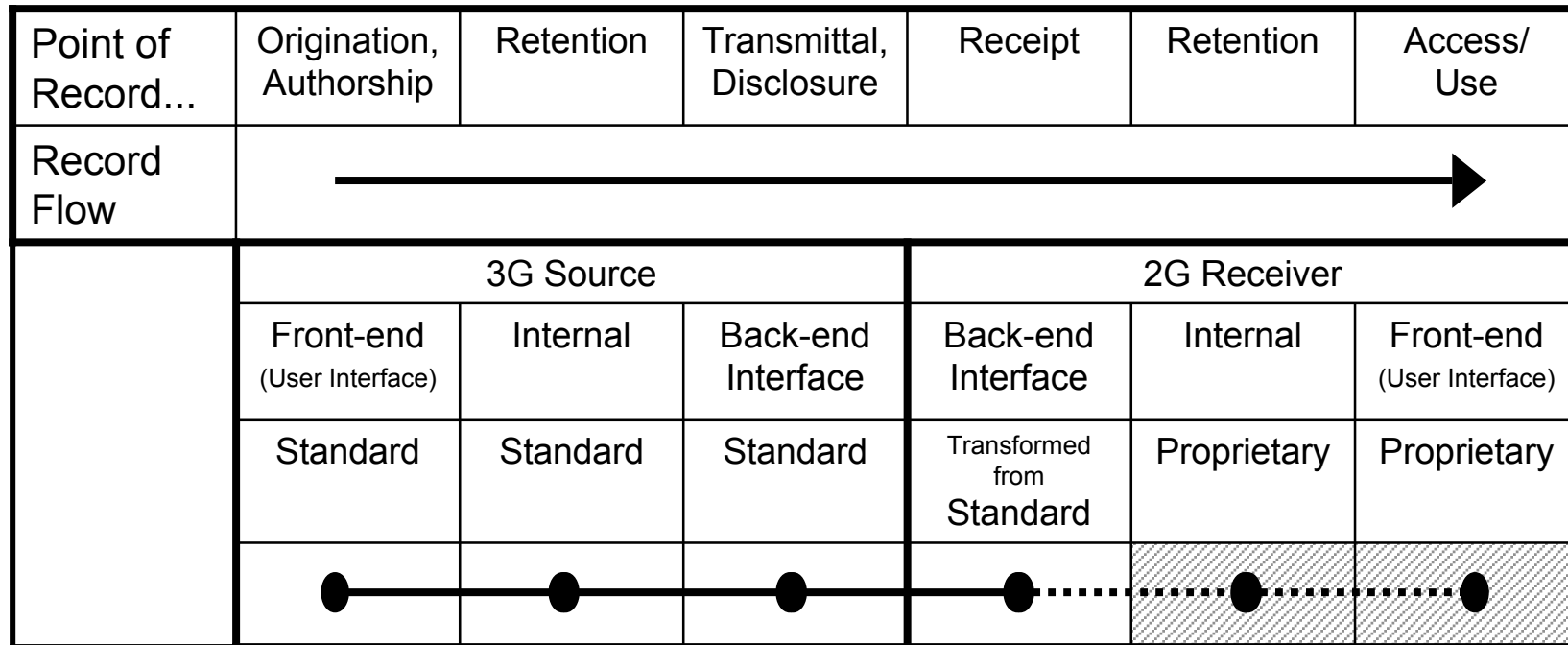
Generational Transition

“Standard” Action Record Flow



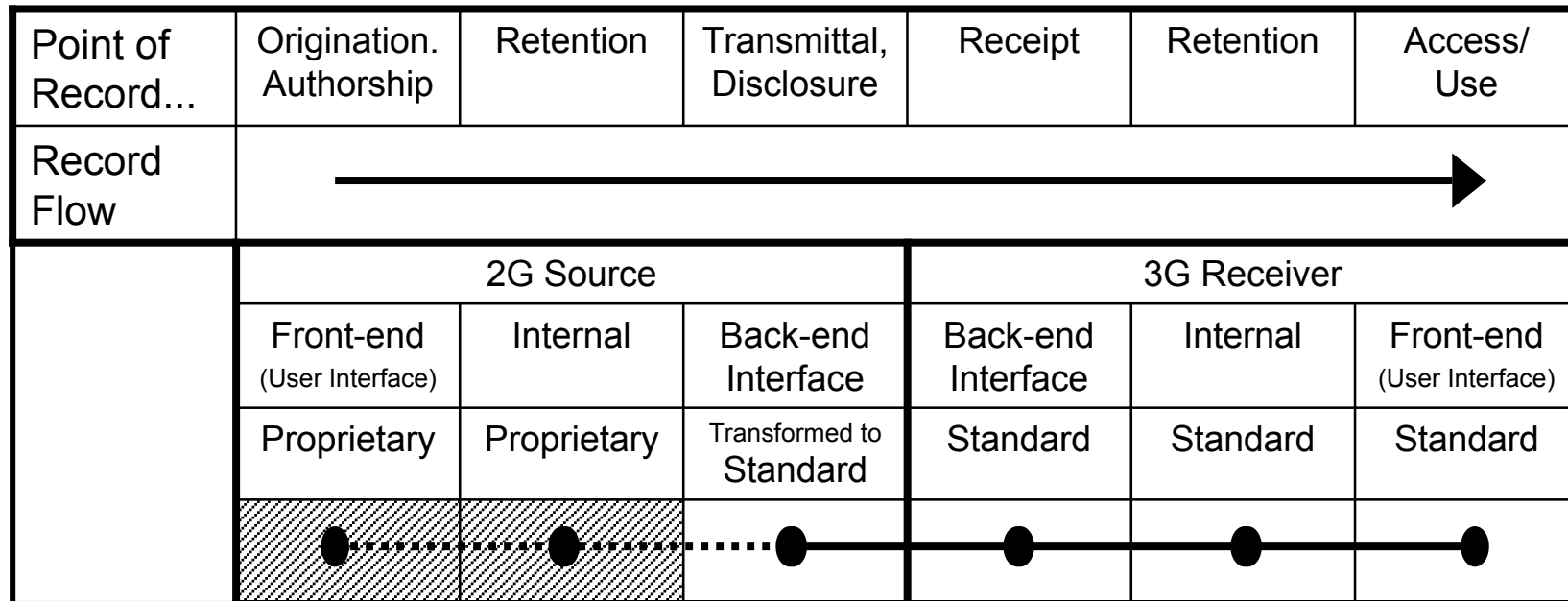
Transition Strategy

3G to 2G Record Flow



Transition Strategy

2G to 3G Record Flow



Characteristics of Action Record

Identifiable, Contextual

Action Record...	2G	3G
Is uniquely identifiable	Yes	Yes
Has a context: <ul style="list-style-type: none">• Who - Record Subject• Who - Record Author• Who - Action Participants• What - Action• When• Where	Asserted by System, digitally signed by System	Asserted by Author, digitally signed by Author and System

Characteristics of Action Record

Persistent, Indelible

Action Record...	2G	3G
Is persistent As EHR entry	Yes	Yes
Is indelible	From point of originating <u>System</u> digital signature on	From point of originating <u>Author's</u> digital signature on

Characteristics of Action Record

Accessible

Action Record...	2G	3G
May be accessed or viewed: e.g., to recall Action context + facts	Yes	Yes

Characteristics of Action Record Access Controlled

Action Record...	2G	3G
<p>Is accessible, based on access control rules:</p> <ul style="list-style-type: none"> • Record access/view • Record amendment 	<p>If asserted by Originating System Based on:</p> <ul style="list-style-type: none"> • Established business rules • Patient/Consumer or Provider request <p>May be:</p> <ul style="list-style-type: none"> • Role based • Person or organization specific <p>Coverage:</p> <ul style="list-style-type: none"> • Confidentiality code, limiting access to whole record or section (see CDAR2 Reference Profile) • Fine grained, constraining access to specific record attributes 	

Characteristics of Action Record

Authenticate-able

Action Record...	2G	3G
Is authenticated, at point of origination	By Originating <u>System</u>	By Originating <u>Author</u>
Is authenticate-able, as to source and author <ul style="list-style-type: none"> • By any record recipient, downstream from point of origination 	Yes, to Originating System	Yes, to Originating Author

Characteristics of Action Record

Accurate, Complete

Action Record...	2G	3G
<p>May be attested as to accuracy</p> <ul style="list-style-type: none"> • By Author's assertion, and/or • By System algorithm 	<p>Asserted by System, based on algorithm</p>	<p>Attested by Author, and/or asserted by System, based on algorithm</p>
<p>May be attested as to completeness</p> <ul style="list-style-type: none"> • By Author's assertion, and/or • By System algorithm 		

Characteristics of Action Record

Auditable, Traceable

Action Record...	2G	3G
Has audit/trace log <ul style="list-style-type: none">• Showing amendments and revision history	Asserted by System at back-end record origination	Maintained and updated within native Action Record
Has audit/trace log <ul style="list-style-type: none">• Showing “chain of trust” and custody		Maintained and updated within native Action Record

Characteristics of Action Record

Auditable, Traceable, con't

Action Record...	2G	3G
Has audit/trace log, showing points in record lifecycle: <ul style="list-style-type: none">• Origination, amendment and verification• Retention• Access/view• Interchange: transmit, disclose, receive• De-identification, aliasing, re-identification• Archival	Asserted by System at back-end record origination	Maintained and updated within native Action Record

Characteristics of Action Record

Protected at Rest, in Transit

Action Record...	2G	3G
<p><u>At Rest:</u></p> <ul style="list-style-type: none"> • Is persistent EHR entry (for legal retention period) • Is continuously protected 	<p>N/A (not native to System architecture)</p>	<p>Native to System architecture</p>
<p><u>In Transit:</u></p> <ul style="list-style-type: none"> • May be interchanged: <ul style="list-style-type: none"> –Transmitted, disclosed –Received • Is continuously protected (e.g., may be encrypted) 		

Actions and Action Record Content

Who Specifies?

- SDOs, using consensus ballot
- Accreditation and governance bodies
- Professional societies
- Provider organizations
- and others...

-
- Based on national, regional or local requirements
 - Possibly catalogued in public registries
 - e.g., NIST registry of EHRs/FM Profiles

HL7 EHR Technical Committee

References

- ONC/AHIC/HITSP Use Case Alignment with HL7 EHR/PHR Models
 - Chapter 1, Year 1 EHR/Lab Results Reporting Use Case
- HL7 EHR System Functional Model
- HL7 PHR System Functional Model
- HL7 EHR Interoperability Model
- HL7 EHR Lifecycle Model
- HL7 Implementation Guide for CDA Release 2: Reference Profile for EHR Interoperability
- HL7 “Coming to Terms” White Paper
- HL7 EHR System - Records Management and Evidentiary Support Functional Profile

Alignment Continues

- Teams formed, analysis underway
 - Year 1 Consumer Empowerment
 - Demographics and Medication History
 - Year 1 Population Health
 - Biosurveillance
- Anticipated in 2008
 - Year 2 Use Cases (x4)

HL7 EHR Technical Committee

Resources

- EHR TC
 - <http://www.hl7.org/ehr>