HITSC Data Provenance Task Force
Panel Discussion 1/16/2015

Brief Biography: Reed D. Gelzer, MD, MPH

- 30+ years' service to health care, 11 years in rural primary care practice
- Special interest in reliability and authenticity attributes of medical records, 3 years EHR vendor.
- Co-Chair, HL7 EHR Workgroup
- Co-Facilitator, HL7 EHR Records Management and Evidentiary Support Workgroup
- Projects and clients have included CMS, ONC, HHS OIG, U.S. Navy Medicine (BUMED), clinical facilities, and private payers
- Co-Author, How to Evaluate Electronic Health Record (EHR) Systems
- Co-Author, Ave Maria Law Review "Electronic Health Records Systems: Testing the Limits of Digital Records' Reliability and Trust"
- Co-Organizer, October 2014 Johns Hopkins Division of Health Sciences Informatics conference entitled, "Foundations of Digital Records in Medicine and Law: Reliability and Authenticity"

Excerpts From

Matthew J. Ryan Law and Public Policy Forum

Delivering Quality Health Care Today
Challenges, Opportunities and the Law

EHRs as a "Handicapped Enabler"

Reed D. Gelzer, MD, MPH

Co-Chair, HL7 EHR Systems Standards

Co-Facilitator, HL7 EHR Systems Records Management

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Villanova Law School

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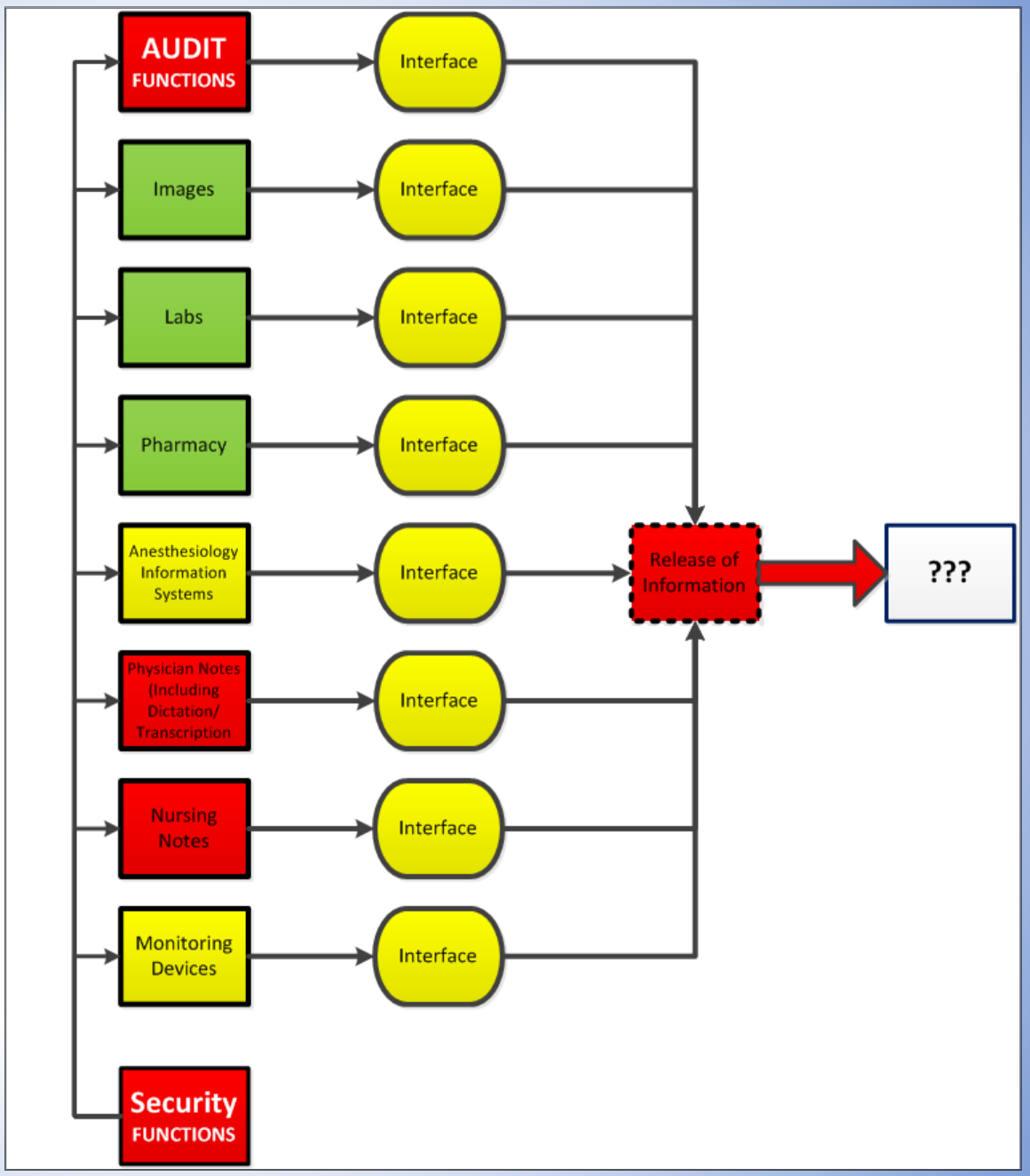
Complex Systems of Systems: Complex Information Content

Outputs are commonly data aggregates from multiple sources to uniquely create:

+ Patient Evaluation & Management Records,
+ Inpatient Procedure records,
+ Clinical Care Summaries,
+ Legal Releases of Information

”Trust but Verify”



Falsified Physical Exam Segments

PHYSICAL EXAM

CONSTITUTIONAL: Patient is afebrile, Vital signs reviewed, Alert and oriented X 3, **Patient has mild pain distress.** (01:37 JG)

HEAD: Atraumatic, Normocephalic. (01:38 JG)

EYES: Eyes are normal to inspection, Pupils equal, round and reactive to light, No discharge from eyes, Extraocular muscles intact, Sclera are normal, Conjunctiva are normal. (01:38 JG)

ENT: Posterior pharynx normal, Mouth normal to inspection. (01:38 JG)

NECK: No meningeal signs, Cervical spine nontender. (01:38 JG)

RESPIRATORY CHEST: Chest is nontender, Breath sounds normal, No respiratory distress. (01:37 JG)

CARDIOVASCULAR: RRR, No murmurs. (01:37 JG)

ABDOMEN: Abdomen is non–tender, No masses, No pulsatile masses, No distension, No peritoneal signs, No hernias, McBurney's point, non tender, Liver and spleen normal. (01:37 JG)

BACK: There is no CVA Tenderness, There is no tenderness to palpation, Normal inspection. (01:37 JG)

UPPER EXTREMITY: Inspection normal, No cyanosis, No clubbing, No edema, Normal range of motion. (01:38 JG)

LOWER EXTREMITY: Inspection normal, No cyanosis, No clubbing, No edema, Normal range of motion, No calf tenderness. (01:38 JG)

NEURO: GCS is 15, No focal motor deficits, No focal sensory deficits, Speech normal. (01:38 JG)

SKIN: Skin is warm, Skin is dry. (01:38 JG)

PSYCHIATRIC: Oriented X 3, Normal affect. (01:38 JG)

Note: Used by patient permission provided to RDGelzer, citation verification available

- # HIT "Gaming" In Value-Based Purchasing

  See 2012 RFP on FedBizOps at

  - https://www.fbo.gov/index?s=opportunity&mode=form&tab=core&id=28d0d456d8623feb0bc26e43ea549b6b&_cview=0 and the link to RFP-Competitive 8A CPFF 7-3-12.docx, document entitled "Physician Quality Reporting System and Electronic Prescribing Incentive Program Data Assessment, Accuracy and Improper Payments Identification Support", page 6.

- # U.S. Courts and Digital Records Systems

  ABA National Institute on eDiscovery and Information Governance, 2013 and 2014

  http://www.avemarialaw.edu/lr/home/issues Summer 2014

  - George L. Paul, "Systems of Evidence in the Age of Complexity"
  - Steven W. Teppler, "Testable Reliability: A Modernized Approach to ESI Admissibility"
  - Drury, Gelzer, Trites, "Electronic Health Records Systems: Testing the Limits of Digital Records' Reliability and Trust"

- # *"Would not admit these records as evidence without scrutiny"*

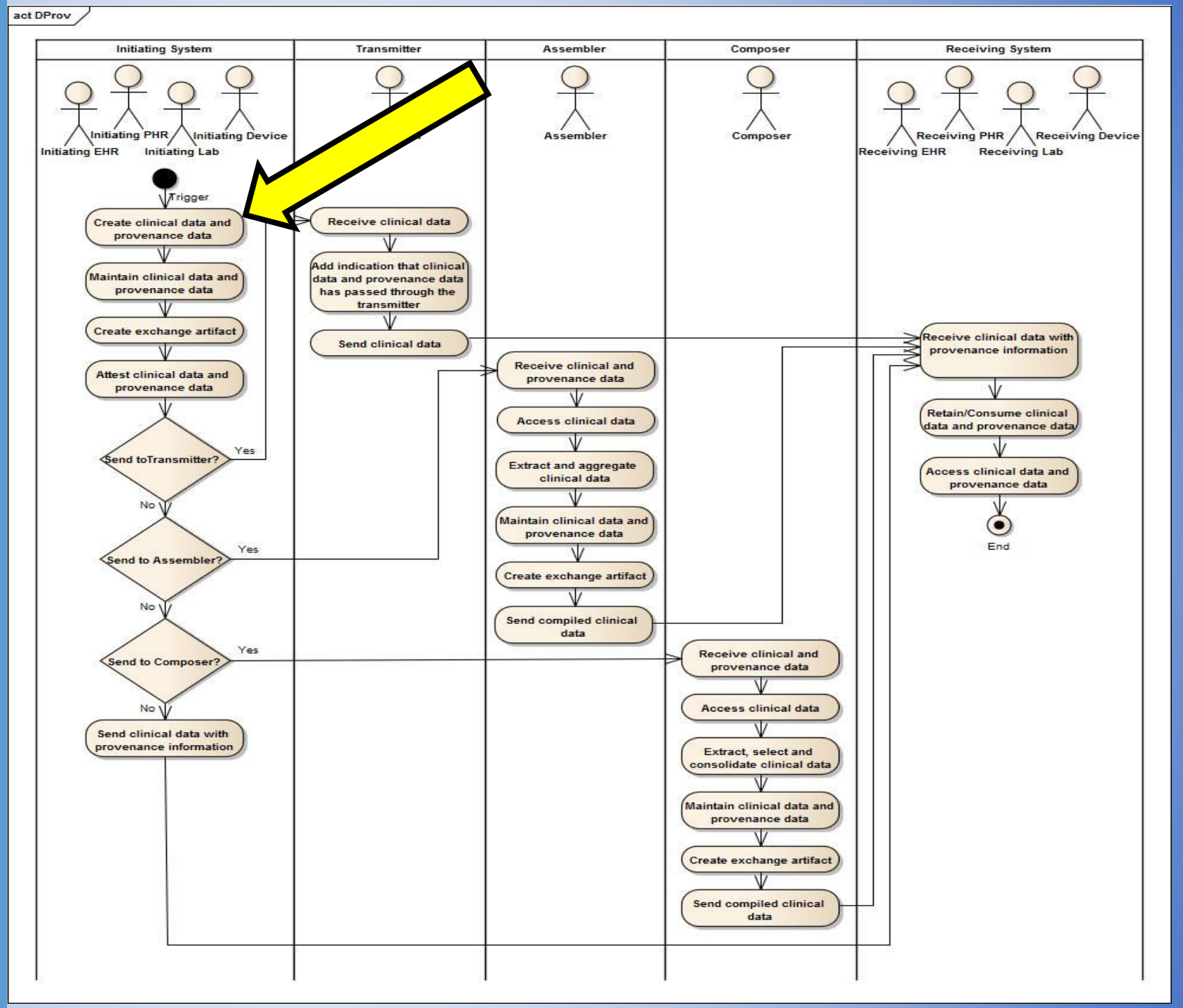
Q1: Missed Opportunity

Define:

"Create Clinical Data and Provenance Data"

Either clearly include or clearly exclude the origination of the patient care event Record Entry.

Data Provenance Initiative Use Case Summary



Origination of the Patient Care Event Record Entry

Provenance Is Advanced Either Way

If Excluded: Very readily translated into the project scope

We would then define the *preconditions* for Provenance, including specifying support data that must *necessarily exist* in the EHR System to support of the exchange of data already existing in that EHR System.

This leaves the origination of that support data for a future project.

This limited (exchange) Provenance defers requiring reliability of the source system and the authenticity of the source records and their data content.

This nonetheless moves Provenance forward.

Origination of the Patient Care Event Record Entry

Provenance Is Advanced Either Way

If Included: Also very readily translated into the project scope

The necessary, reliable, and authentic existence of Provenance support data would be a requirement for an EHR to assert conformance with Provenance.

We would then define the preconditions for Provenance for data originated and for exchange at the instant of origination in the EHR system, in terms of minimum necessary support data.

We would therefore be defining minimum requirements for EHR Systems at the origination of the patient care event record entry.

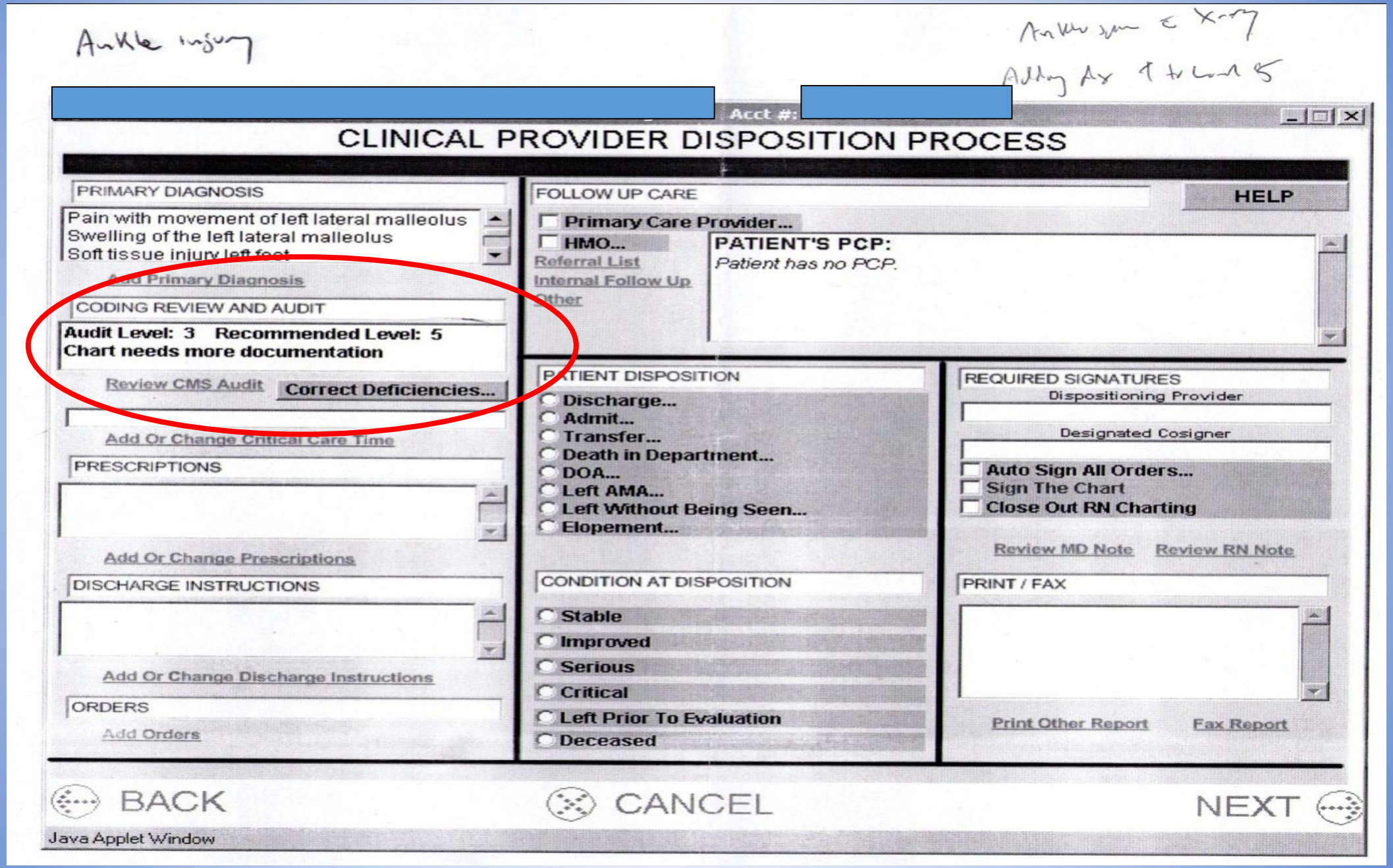
Example: Origination Out Of Scope

Example: A given EHR supports the option of amending of an EHR episode of care record after it has been finalized, “signed” or etc.

The EHR does not capture “amendment” as a unique type of update event, does not create an “Amended” state indicator, and the finalized record and its component data elements show no indication of amendment.

In this context: If origination of the patient care event record entry is deemed out of scope, then (exchange) Provenance has no way of knowing whether the source system meets the expectations that “Amended” is recognized, available for representation in Provenance metadata.

Therefore (exchange) Provenance expresses an expectation, but not a requirement, that an Amended provenance designation SHOULD accompany this to assert actual provenance.


Ankle injury
Acct #:
CLINICAL PROVIDER DISPOSITION PROCESS
PRIMARY DIAGNOSIS
Pain with movement of left lateral malleolus
Swelling of the left lateral malleolus
Soft tissue injury left foot
Add Primary Diagnosis
CODING REVIEW AND AUDIT
Audit Level: 3 Recommended Level: 5
Chart needs more documentation
Review CMS Audit
Correct Deficiencies...
Add Or Change Critical Care Time
PRESCRIPTIONS
Add Or Change Prescriptions
DISCHARGE INSTRUCTIONS
Add Or Change Discharge Instructions
ORDERS
Add Orders
FOLLOW UP CARE
HELP
Primary Care Provider...
HMO...
Referral List
Internal Follow Up
Other
PATIENT'S PCP:
Patient has no PCP.
PATIENT DISPOSITION
Discharge...
Admit...
Transfer...
Death in Department...
DOA...
Left AMA...
Left Without Being Seen...
Elopement...
CONDITION AT DISPOSITION
Stable
Improved
Serious
Critical
Left Prior To Evaluation
Deceased
REQUIRED SIGNATURES
Dispositioning Provider
Designated Cosigner
Auto Sign All Orders...
Sign The Chart
Close Out RN Charting
Review MD Note
Review RN Note
PRINT / FAX
Print Other Report
Fax Report
BACK
CANCEL
NEXT
Java Applet Window

[redacted] - Lost Charge Analysis 1.1

For Date(s) of Service in October 2006

	0628900433	0091615	10/16/2006	99284	$317.00	DC 5 PE,PFSH,ROS	99285	$450.00	$133.00
	0628900679	0091641	10/16/2006	99283	$203.00	DC 5 HPI	99285	$450.00	$247.00
	0628800031	0091988	10/15/2006	99284	$317.00	DC 5 PE,PFSH	99285	$450.00	$133.00
	0628900530	0092014	10/16/2006	99284	$317.00	DC 5 ROS	99285	$450.00	$133.00
	0628900276	0092035	10/16/2006	99283	$203.00	DC 4 HPI	99284	$317.00	$114.00
	0628700025	0092603	10/14/2006	99283	$203.00	DC 5 HPI	99285	$450.00	$247.00
	0628900560	0092606	10/16/2006	99283	$203.00	DC 5 HPI	99285	$450.00	$247.00
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									00 $114.00
	0629800931	0094970	10/25/2006	99284	$317.00	DC 5 PE	99285	$450.00	$133.00
	0629800955	0095028	10/25/2006	99284	$317.00	DC 5 PE	99285	$450.00	$133.00
	0629800962	0095068	10/25/2006	99284	$317.00	DC 5 PE	99285	$450.00	$133.00
	0629800967	0095122	10/25/2006	99284	$317.00	DC 5 PE	99285	$450.00	$133.00
	0629900169	0095198	10/26/2006	99284	$317.00	DC 5 PE	99285	$450.00	$133.00
	0630300951	0096769	10/30/2006	99281	$80.00	DC 3 ROS	99283	$203.00	$123.00
	0630300935	0096984	10/30/2006	99284	$317.00	DC 5 PE	99285	$450.00	$133.00
	0630400146	0097001	10/31/2006	99284	$317.00	DC 5 PFSH	99285	$450.00	$133.00
	0630400162	0097012	10/31/2006	99283	$203.00	DC 4 HPI	99284	$317.00	$114.00
	0629300607	0097154	10/20/2006	99283	$203.00	DC 5 HPI,PFSH	99285	$450.00	$247.00
	0630400155	0097183	10/31/2006	99283	$203.00	DC 5 HPI	99285	$450.00	$247.00

Total Loss Amount	$12,511.00
Total Actual Charges	$90,658.60
Loss Percent of Actual	13.80%

[illegible]	[illegible]	
99285	$450.00	$247.00
Total Loss Amount		$12,511.00
Total Actual Charges		$90,658.60
Loss Percent of Actual		13.80%

Questions

1) Did the DPROV Initiative community miss something potentially more impactful?

- Not so much “miss” as “postpone”
- Recommend defining the project scope to *either* include or exclude Origination of the Patient Care Event Record Entry. The ambiguity on this point was a substantive challenge in the initiative. Clarification will be impactful in either path by necessarily calling out the core requirements of EHR system reliability and source record authenticity, principally Authorship, Amendments, and Auditability

2) Where in the Use Case should we start in terms of evaluating standards to meet Use Case requirements?

- See the arrow on slide 6 and focus on standards that support clarification of “Create” in alignment with current applicable vocabularies and vocabulary alignments underway.

3) Are there any architecture or technology specific issues for the community to consider?

- The community will necessarily confront challenges of technical feasibility as a major market discriminator among existing major EHRs and EHR implementations

Discussion/Questions

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