<u>Comments on</u>

EU/US eHealth Cooperation Initiative – "Interoperability"

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Interoperability Use Case

- ## Use Case Scope Statement
  - "The goals are the unambiguous semantic interpretation of clinical data that meet high standards for security/privacy protection and fidelity (faithful to the source) for the international community, and enhanced care quality and safety of the patient…"

- ## Use Case Assumption #2
  - "All content in the original languages will be transmitted along with any translation"

Use and Fitness for Use

- ## Interoperability = Exchange and Use (IEEE, 1990)

- ## Key Requirement: Received Information is FIT FOR PRIMARY USE

  - ### Clinical care, interventions, decision making

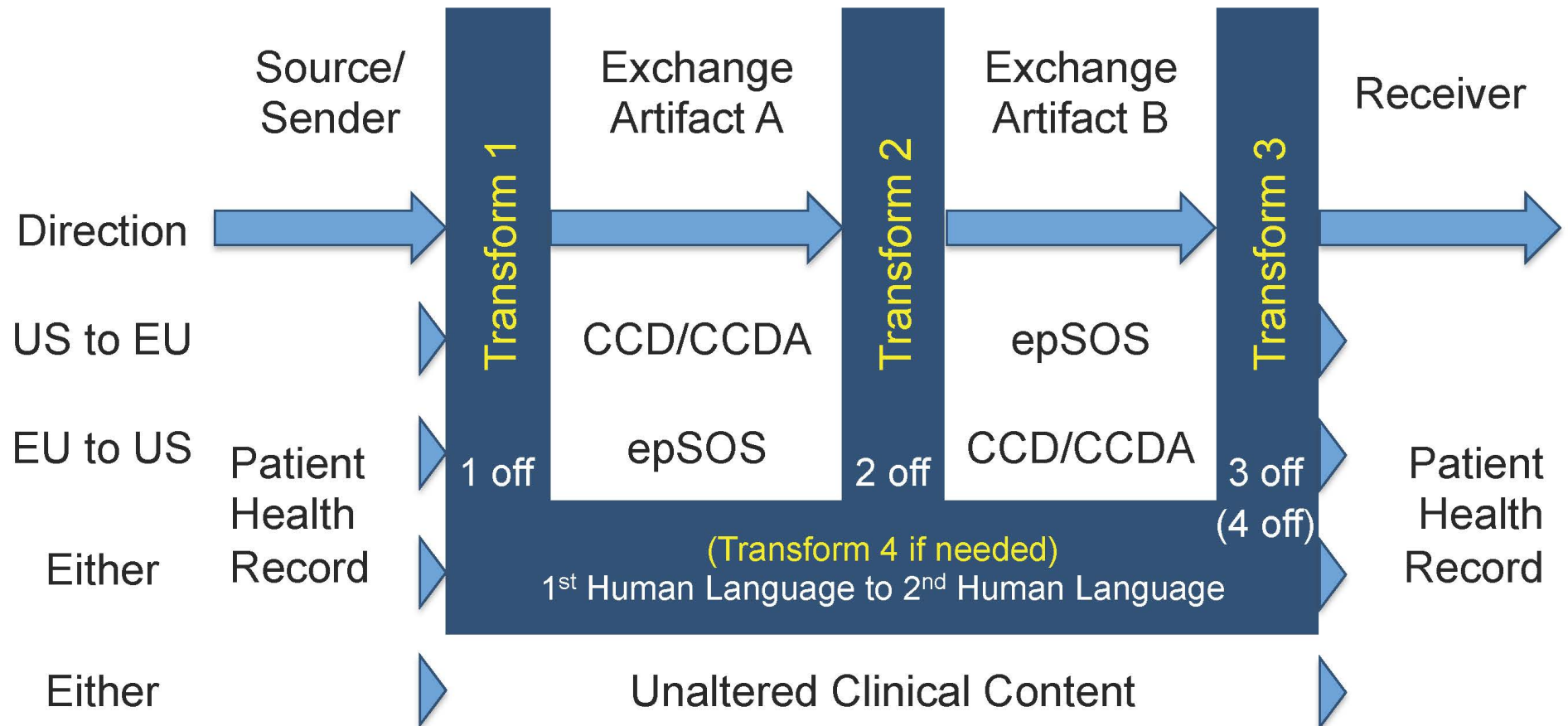- ## ALL three EU/US Use Case Scenarios describe Primary Use

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Primary and Secondary Use
Fitness for Use/Purpose

Use	Purpose	Clinical Health Record Content Exchange Source → Receiver	Fit for Purpose?
Primary	Clinical Care, Interventions, Decision Making	Without Transformation (maintains/ensures fidelity to source)	**YES**
Primary	Clinical Care, Interventions, Decision Making	With Transformation(s)	**Often NO**
Secondary	Most Everything Else	With Transformation(s)	**Typically YES**

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Exchange Transforms x3 or x4

	Source/Sender	Transform 1	Exchange Artifact A	Transform 2	Exchange Artifact B	Transform 3	Receiver
Direction							
US to EU			CCD/CCDA		epSOS		
EU to US	Patient Health Record	1 off	epSOS	2 off	CCD/CCDA	3 off (4 off)	Patient Health Record
Either							
Either			Unaltered Clinical Content				

(Transform 4 if needed)
1st Human Language to 2nd Human Language

Alterations, Errors and Omissions

Wither Transformation?

Transformation during Exchange…	typically <u>Alters</u>…	and may INTRODUCE <u>Errors</u> and <u>Omissions</u> in…	Clinical Health Record Content

<u>Types of Transformation in EU/US Exchange</u>

- One Code Set to Alternate Code Set

  (e.g., HL7, ICD, LOINC, SNOMED)

- One Value Set to Alternate Value Set

- One Human Language to Another Human Language

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Alterations, Errors and Omissions
Transformation Disjunctions

Examples	Source Clinical Content is/has…	Likely Disjunction
Mismatched	Incorrectly matched • Including Patient or Provider identity	Error
Mismatched	Structured content mapped to/from unstructured content	Error or Alteration
Mismatched	Disjoint data types: e.g., integer vs. decimal	Error or Alteration
Mismatched	Codes/values mapped one to many No corresponding target data element	Error or Alteration
Incomplete or missing	No corresponding target data element	Omission
Incomplete or missing	No corresponding code/value in target code/ value set	Omission or Alteration
Less Precise	Source codes/values mapped many to one	Error or Alteration
Skewed	As the effect of multiple transforms: 1 off + 1 off + 1 off + 1 off	Error or Alteration

Receiving Clinician View

Transforms   Primary Use – Clinician View

| 1 2 | 3 | 1 2 3 | 4 |

Blind Transforms
View Last (Sum) Result (3 or 4)
Use with Extreme Caution!

1, 2, 3, (4)

1 2 3   1 2 3 4
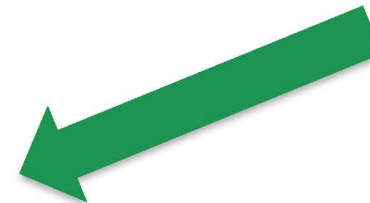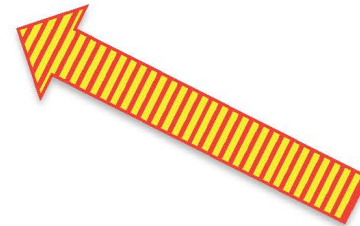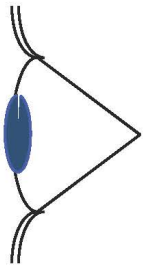
Visible Transforms
View each Result: 1, 2, 3, (4)
Be Aware!

View Unaltered Source Health
Record Content

0

Be Assured!

Receiving
Clinician

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Interoperation or Mis-Operation?

For primary clinical use, any transformation of source clinical content in the course of exchange introduces – or makes it susceptible to – errors and omissions in:

- Clinical facts, findings and observations
- Clinical content, context and meaning

Instead of promoting/achieving…	We see…
• Interoperation – Interoperability	• Mis-operation – Dis-operability
• Exchange and <u>Use</u>	• Exchange and reject • Exchange and use w/extreme caution
• Fidelity to Source – Immutability	• Focus on point-to-point mapping and transformation <u>not</u> end-to-end fidelity, data integrity, clinical efficacy

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Recommendations

The source of truth for all primary use – clinical care, interventions and decision making – is unaltered source health record content.

- The receiving clinician will first and always rely on this direct evidence of clinical facts, findings and observations from prior patient encounters.

Data integrity (including fidelity to source) is foundational to all aspects of clinical integrity and patient safety.

- Recommendation 1: Declare unaltered source health record content (inherently) fit for all primary uses.

- Recommendation 2: Ensure that the result of each transformation (1, 2, 3, 4) is bundled in the exchange packet – so that it can be made viewable (evidenced) to the receiving clinician/user.

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Recommendations

- Recommendation 3: Declare primary EU/US focus is on assuring conveyance of unaltered source content in exchange:
  - ✧ Primary Focus is on Primary Use.

- Recommendation 4: Ensure all data types convey unaltered source health record content.

In our experience, source health record content transformed 3 or 4 times in the course of exchange will often be compromised and not fit for primary clinical use. Health record content which is *transformed* from source best serves purposes of secondary use.

- Recommendation 5: Declare transformed health record content fit for secondary use.

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Recommendations

The EU/US eHealth Initiative should focus on the best exchange solutions – oriented to individual health, patient safety, care coordination, effective provision of healthcare services, primary use and data integrity – not political "understandings".

- Recommendation 6: Select a single exchange artifact (pick one of CCD, CCDA, epSOS, FHIR or something else).
  - 6a: Eliminate Transform 2 and the map-in-the-middle exercise;
  - 6b: Ensure Recommendation 3.

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Lack of accountability for mapping and transformation results offers myriad opportunities for mis-mapping, errors and omissions.

- Recommendation 7: (Longer-term) Engage clinical experts (e.g., professional societies) to review/approve mapping and transformation of clinical content:
  - e.g., Clinical data transform verification by UK Royal Societies.
- Recommendation 8: (Longer-term) Establish <u>voluntary</u> system certification based on transformation testing:
  - Source content in, transformed content out.

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Real World Interoperation

	Current Testing Scheme	Real World
Exchange Pairs Exchange Pairs Exchange Pairs	One System – Two Roles 1) source/sender 2) receiver	Many to many: Any Source/Sender System To Any Receiver System
Exchange Data Set	Carefully Preened	Often sparse Few sections complete
Clinical Summaries	Most sections complete	Often sparse Few sections complete
Transaction Volume	Small Transaction Set	Up to 1000s/day
End-to-End: Point of origination (source) to Point of Access/Use	Not Tested	Each Exchange Instance End-to-End
Unaltered source health record content	Not Tested	Conveyed/relied on for Primary Use

EHR System Certification Testing
Real World Interoperation

	Current Testing Scheme	Real World
Patient Identity Matching	Not Tested	• No Unique Patient ID (US) • Few Common Patient ID Domains • Multi-Factor Matching
Transformation • Code/Value Set to Code/Value Set	Not Tested	1000s Transformed daily
Transformation • Human Language to Human Language	Not Tested	[Relatively Uncommon] [Must overcome garble (e.g., Google Translate problem) particularly for medical terms]

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Recommendations

The current system certification testing program (for MU exchange) bears little resemblance to real-world exchange realities.

- Recommendation 9: (Longer-term) Establish <u>voluntary</u> certification based on end-to-end and round-trip testing:
  - System A ←→ System B
  - System A → System B → System C → System A
  - Ensuring Fidelity to Source;
  - Point of origination (source) to ultimate point of access/view.

- Recommendation 10: (Longer-term) Establish real-time assessment monitor for data integrity, inflight during exchange, based on known:
  - Alterations, errors and omissions occurring in transformation(s);
  - Transforms based on clinically verified mappings (or not).

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