Safety analysis of interoperability conformance profiles in Medical Information Exchange



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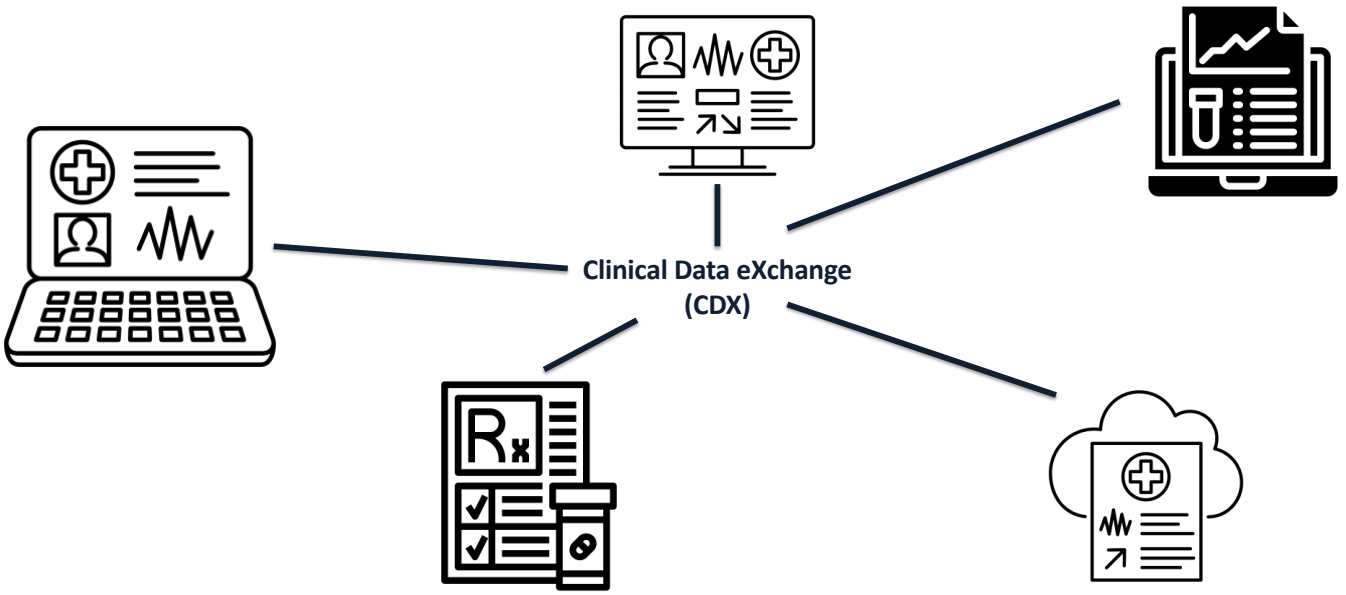
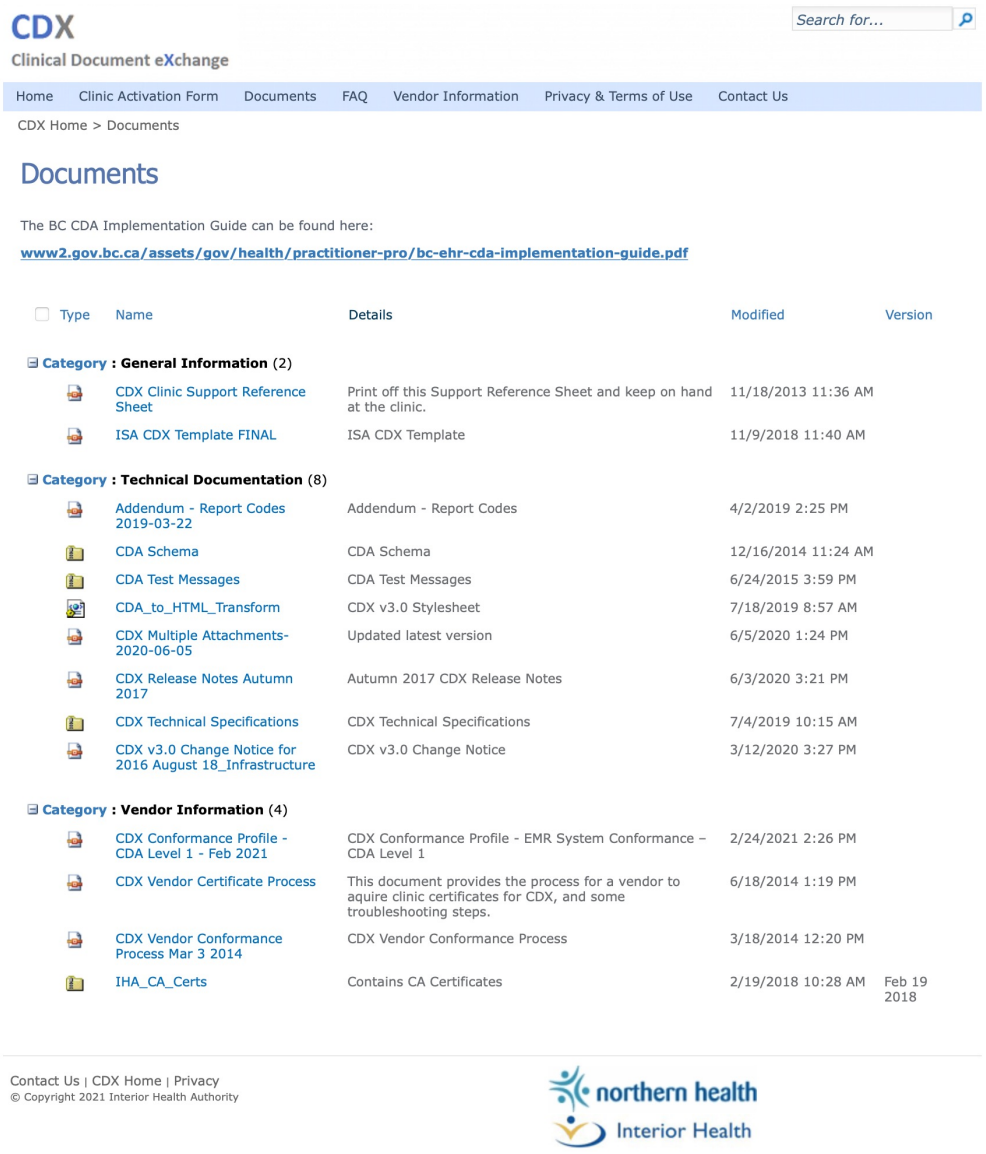
Electronic Medical Record (EMR) Interoperability



Goal: Establish an ecosystem of connected EMRs with bi-directional EMR-to-EMR communication to Primary Care-centric Team Based Care



CDX

Clinical Document eXchange

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Documents

The BC CDA Implementation Guide can be found here:

www2.gov.bc.ca/assets/gov/health/practitioner-pro/bc-ehr-cda-implementation-guide.pdf

Type	Name	Details	Modified	Version
Category : General Information (2)				
	CDX Clinic Support Reference Sheet	Print off this Support Reference Sheet and keep on hand at the clinic.	11/18/2013 11:36 AM	
	ISA CDX Template FINAL	ISA CDX Template	11/9/2018 11:40 AM	
Category : Technical Documentation (8)				
	Addendum - Report Codes 2019-03-22	Addendum - Report Codes	4/2/2019 2:25 PM	
	CDA Schema	CDA Schema	12/16/2014 11:24 AM	
	CDA Test Messages	CDA Test Messages	6/24/2015 3:59 PM	
	CDA_to_HTML_Transform	CDX v3.0 Stylesheet	7/18/2019 8:57 AM	
	CDX Multiple Attachments-2020-06-05	Updated latest version	6/5/2020 1:24 PM	
	CDX Release Notes Autumn 2017	Autumn 2017 CDX Release Notes	6/3/2020 3:21 PM	
	CDX Technical Specifications	CDX Technical Specifications	7/4/2019 10:15 AM	
	CDX v3.0 Change Notice for 2016 August 18_Infrastructure	CDX v3.0 Change Notice	3/12/2020 3:27 PM	
Category : Vendor Information (4)				
	CDX Conformance Profile - CDA Level 1 - Feb 2021	CDX Conformance Profile - EMR System Conformance – CDA Level 1	2/24/2021 2:26 PM	
	CDX Vendor Certificate Process	This document provides the process for a vendor to aquire clinic certificates for CDX, and some troubleshooting steps.	6/18/2014 1:19 PM	
	CDX Vendor Conformance Process Mar 3 2014	CDX Vendor Conformance Process	3/18/2014 12:20 PM	
	IHA_CA_Certs	Contains CA Certificates	2/19/2018 10:28 AM	Feb 19 2018

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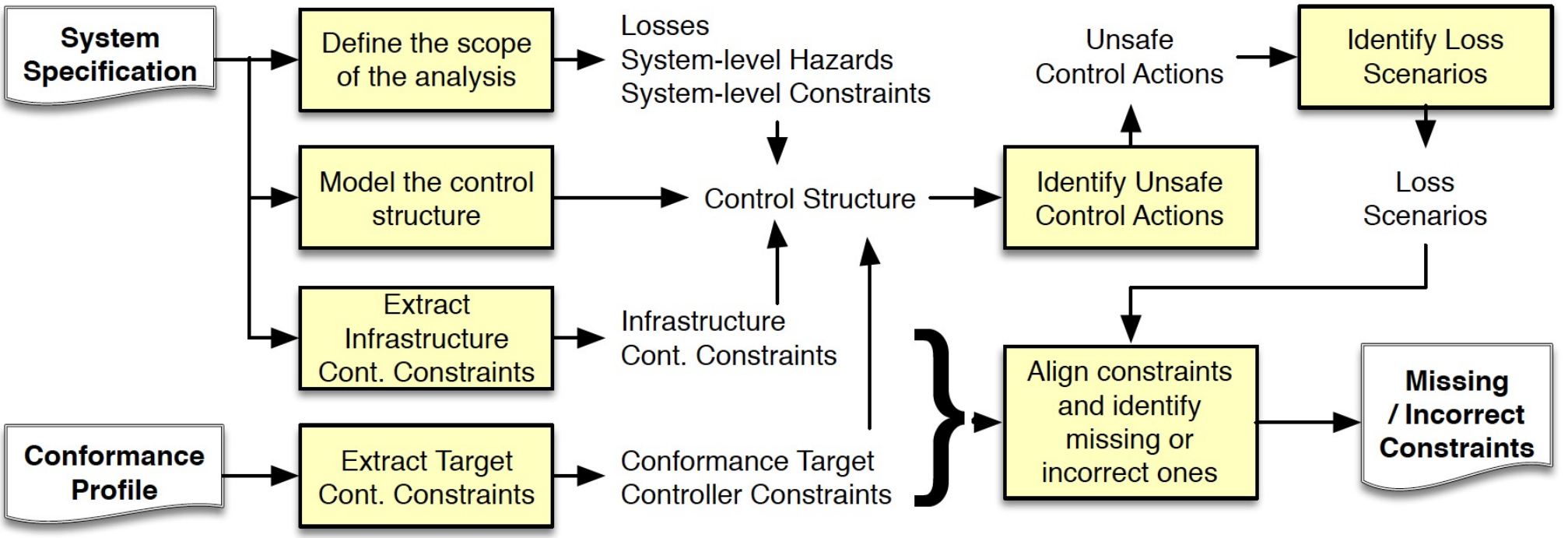
Conformance Profiles

- Requirements on participating systems
- Used in certification process
- bccdx.ca

Can we use STPA to analyze the safety of interoperability conformance profiles?



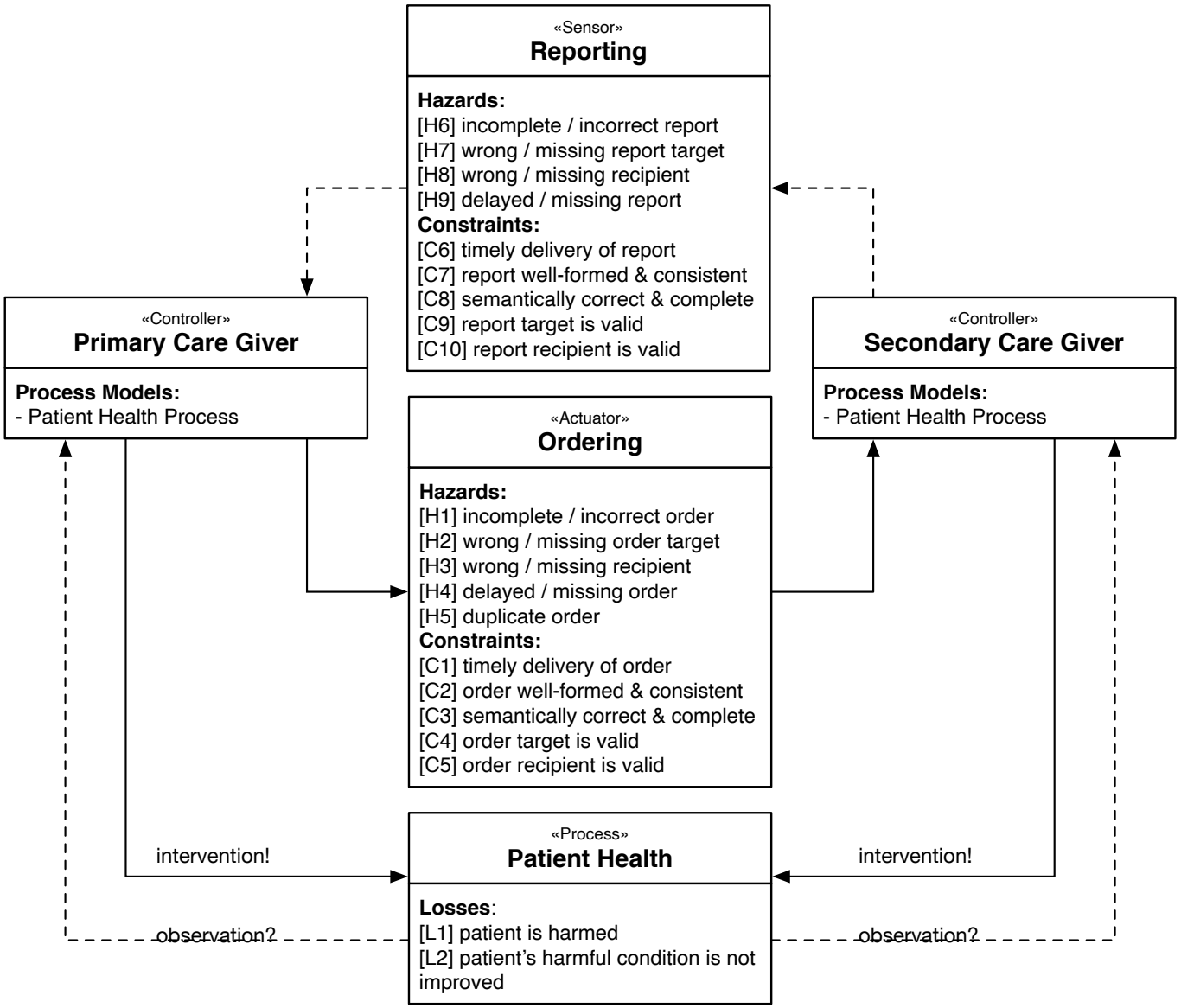
Method Overview



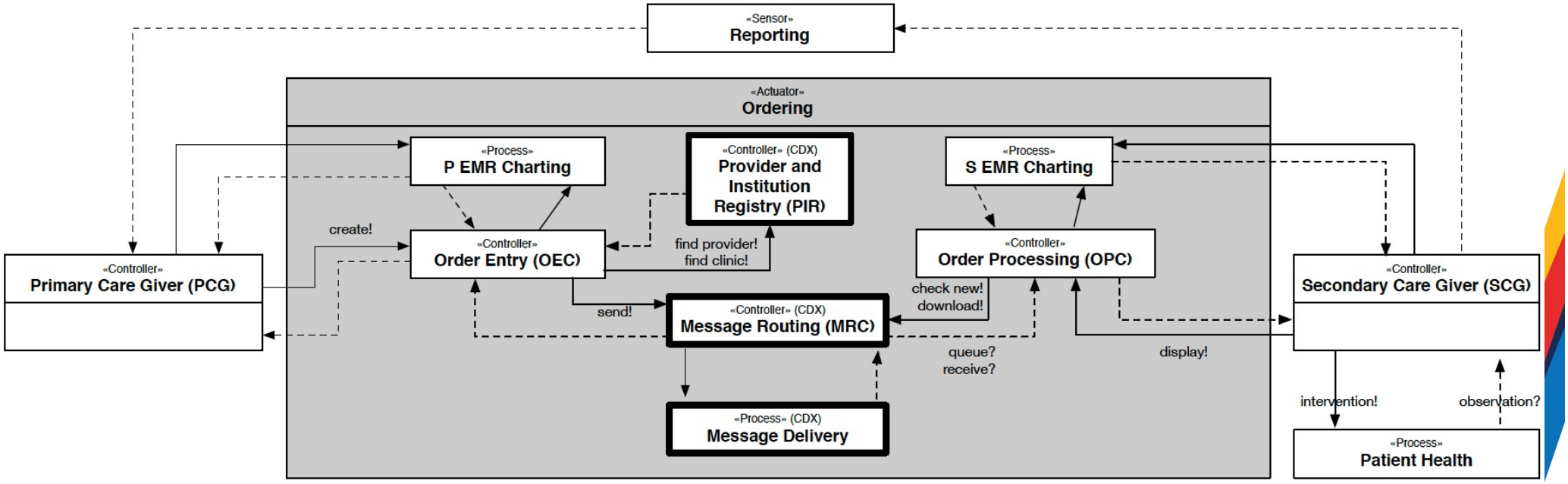
Focus: Referral workflow

Referral: [Medspeak-US]
A patient who has been sent (referred) for a second opinion or therapy to a specialist or subspecialist, because the patient has a disease or condition that the primary or referring physician cannot, or does not wish to, treat.

System-Level Control Structure

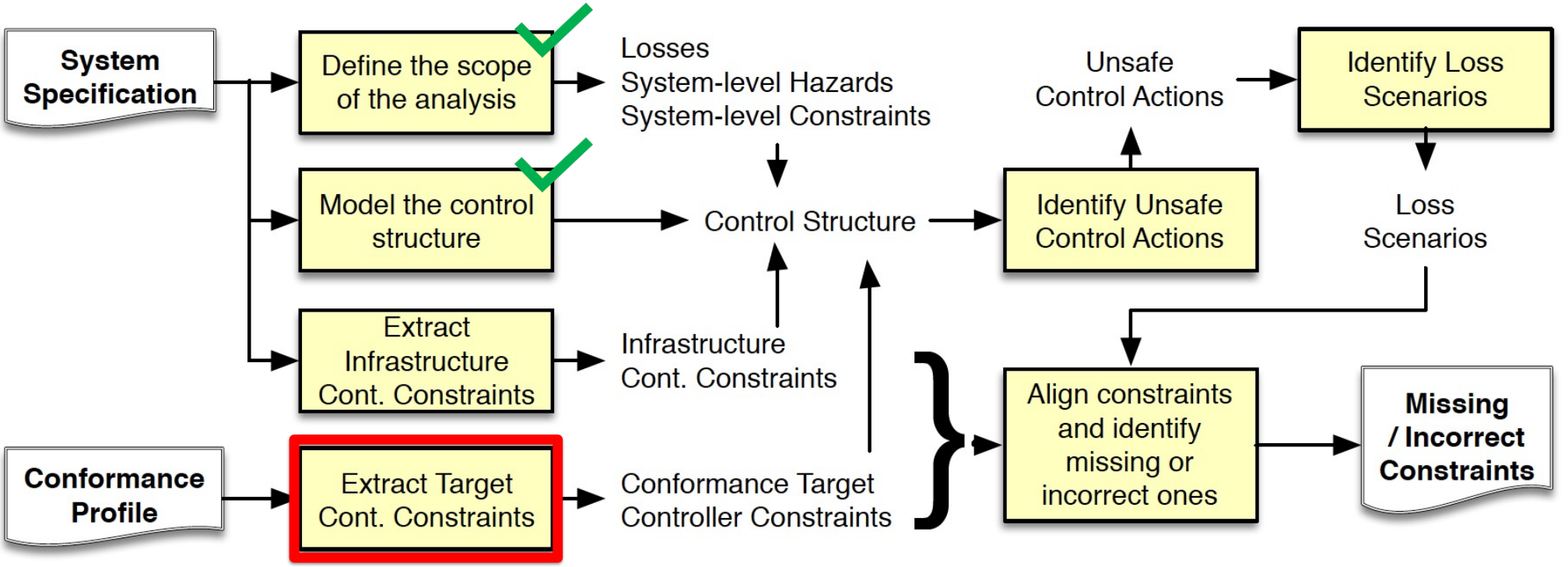


Decomposition of “Order”

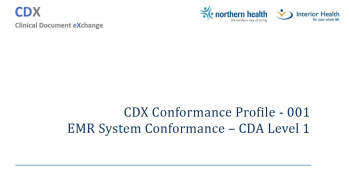


Note: bold frames are elements of the interoperability infrastructure

Method Overview



One of 62 Conformance Statements

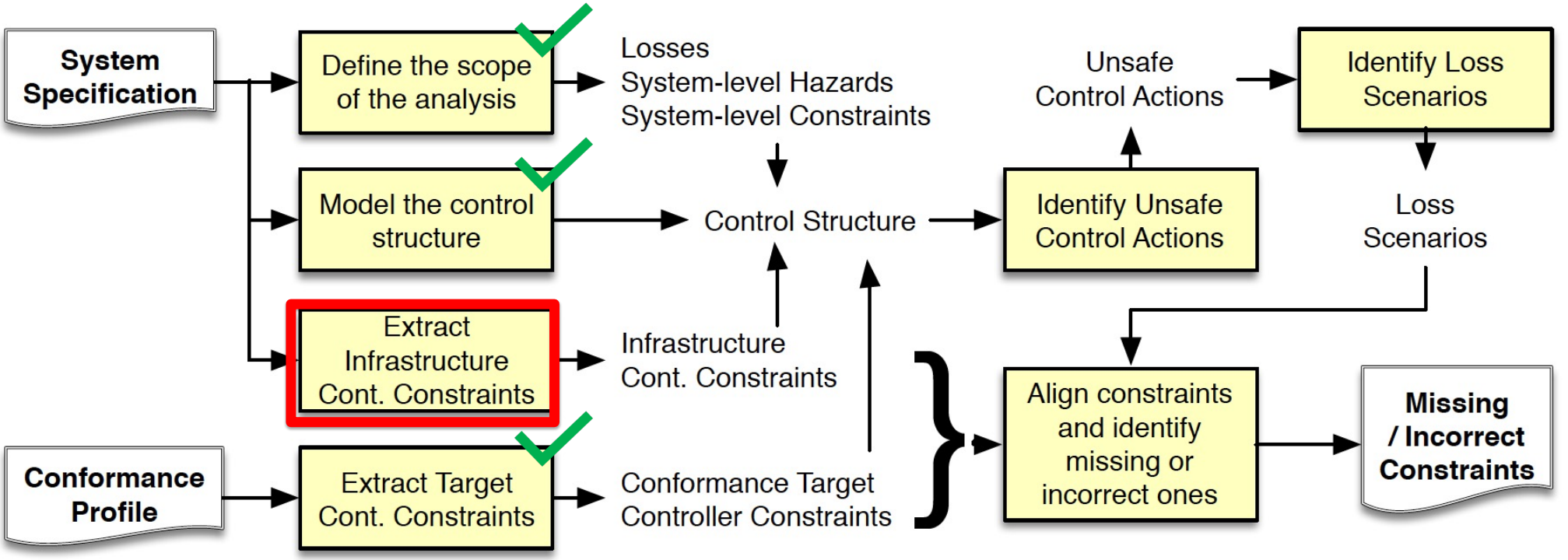


14. 	Technical	Document Handling	Supports patient matching of received clinical documents via CDX	When CDA documents are received into the EMR, the system **SHALL**, at a minimum, evaluate the message header patient demographics and apply 4 point matching criteria to ensure that documents received are attached to the correct patient's chart. The 4 points for matching are: 1. Patient PHN

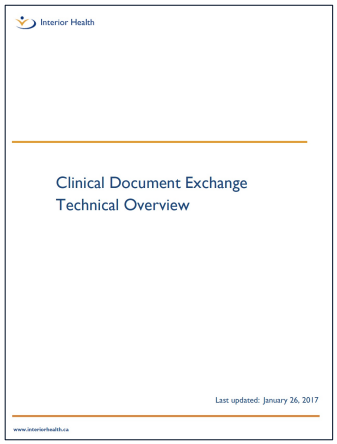
Extracted Conformance Target Controller Constraints

Controller Constraint	Reference[26]	Controller(s)	Action / Feedback
CC1: sent orders are standards conform	R39	OEC	send!
CC2: receiver can link orders to patients manually if automatic linking is not possible	R16	OPC	**link patient!**
CC3: receiver can create a new patient chart with the demographic information provided	R16	OPC	**create patient!**
CC4: receiver alerts users of cancelled orders (MAY)	R23	OPC	**cancelled?**
CC5: standards-conform orders can be received	R1,2,3,4	OPC	download! receive?
CC6: standards-conform orders can be rendered	R1,2,3,4	OPC	render?
CC7: order routed to at least one provider at clinic	R12,13	OPC	
CC8: no automatic deletion of orders	R12,13	OPC	
CC9: automatic patient linking requires at least 4-point match	R14	OPC	
CC10: users are alerted of inconsistencies between order and EMR data (demographics)	R15	OPC	**inconsistencies?**
CC11: inconsistencies between EMR data and order data can manually be resolved (SHOULD)	R15	OPC	**resolve inconsistency!**
CC12: User alerted of unlinked patient	R16	OPC	**unlinked patient?**
CC13: Order authoring status displayed (preliminary, updated, final, cancelled)	R18,19,20	OPC	**authoring status?**
CC14: a order with "final" authoring status that is received after a version of the same order with "preliminary" status replaces the latter; they are not concatenated	R21	OPC	receive? authoring status? **replace!**
CC15: if order with "cancelled" authoring status is received after previous order version, cancelled order replaces previous one; history is maintained	R22	OPC	receive? replace!
CC16: if order with "updated/corrected" authoring status is received, previous version of	R24	OPC	receive?

Method Overview



One paragraph in System Specification



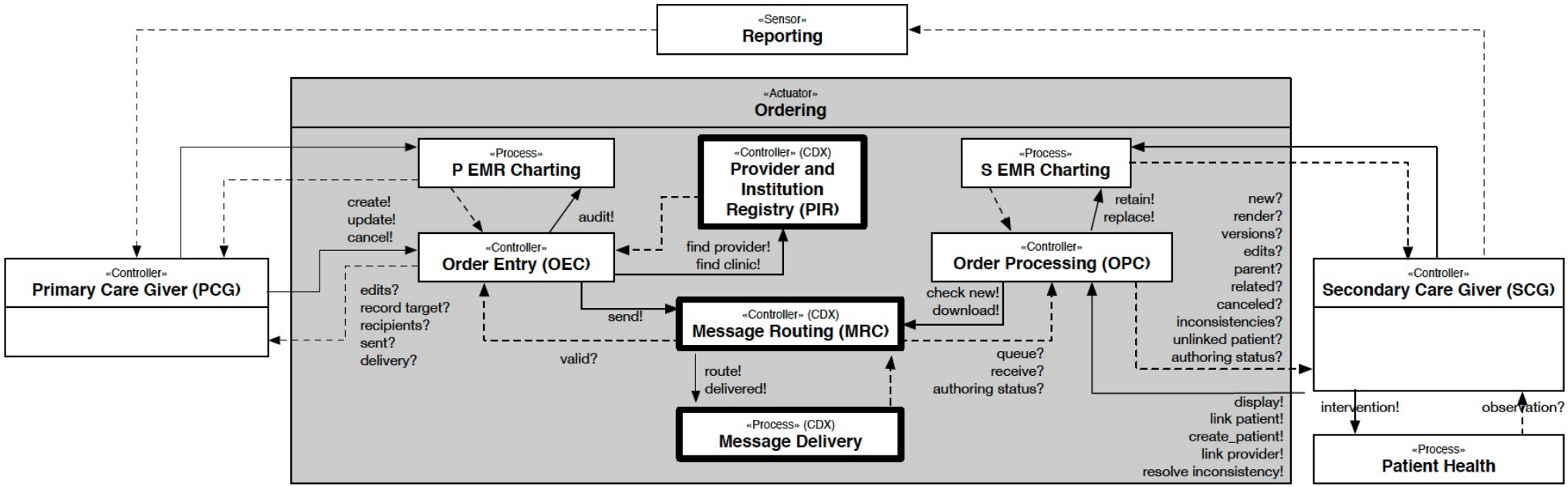
It is expected that software requesting a list of new documents persist the list prior to performing the individual document get. In the event of a failure during the request, the requesting software will be responsible for ensuring that all documents identified in the list are retrieved.

p. 15, Clinical Document Exchange – Technical Overview

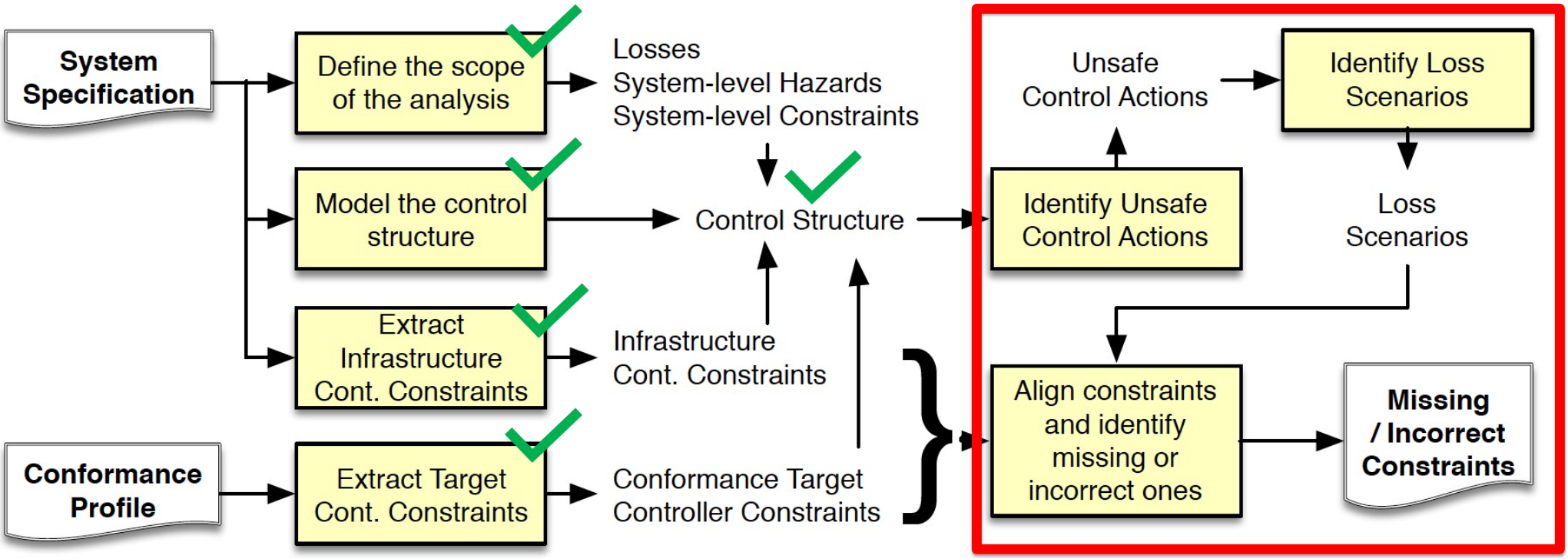
Extracted Infrastructure Controller Constraints

Controller Constraint	Reference[27]	Controller(s)	Action / Feedback
CC43: Participating parties periodically check in with CDX for new documents	p. 11	OPC or SCG	check new!
CC44: if message specifies recipient provider but no clinic, then it is routed to all locations associated with provider	p. 11	MRC	**route!**
CC45: if message specifies recipient provider with specific clinic → route only to specified clinic	p. 11	MRC	route!
CC46: if recipient clinic is specified but no provider → route to clinic	p. 12	MRC	route!
CC47: if message specifies recipient provider as well as a clinic, but (according to CDX) the provider is not associated with the specified clinic, route to clinic	p. 12	MRC	route!
CC48: providers and clinics have unique identifiers	p. 12	PIR	
CC49: send messages must be valid in order to be routed. validation result returned to sender.	p. 14	MRC	**valid?**
CC50: message cannot be received by a party who is not a recipient	p. 14	MRC	receive?
CC51: a message is considered "new" (i.e., undelivered) for a location if and only if that location has not attempted to download it (download!)	p. 15	MRC	**delivered!**
CC52: receiver ensures that all messages indicated as new (i.e., undelivered) are eventually successfully downloaded	p 15	OPC	*queued? download!*
CC53: messages are re-downloadable for a finite period of time	p. 17	MRC	*download!*

Revised Control Structure

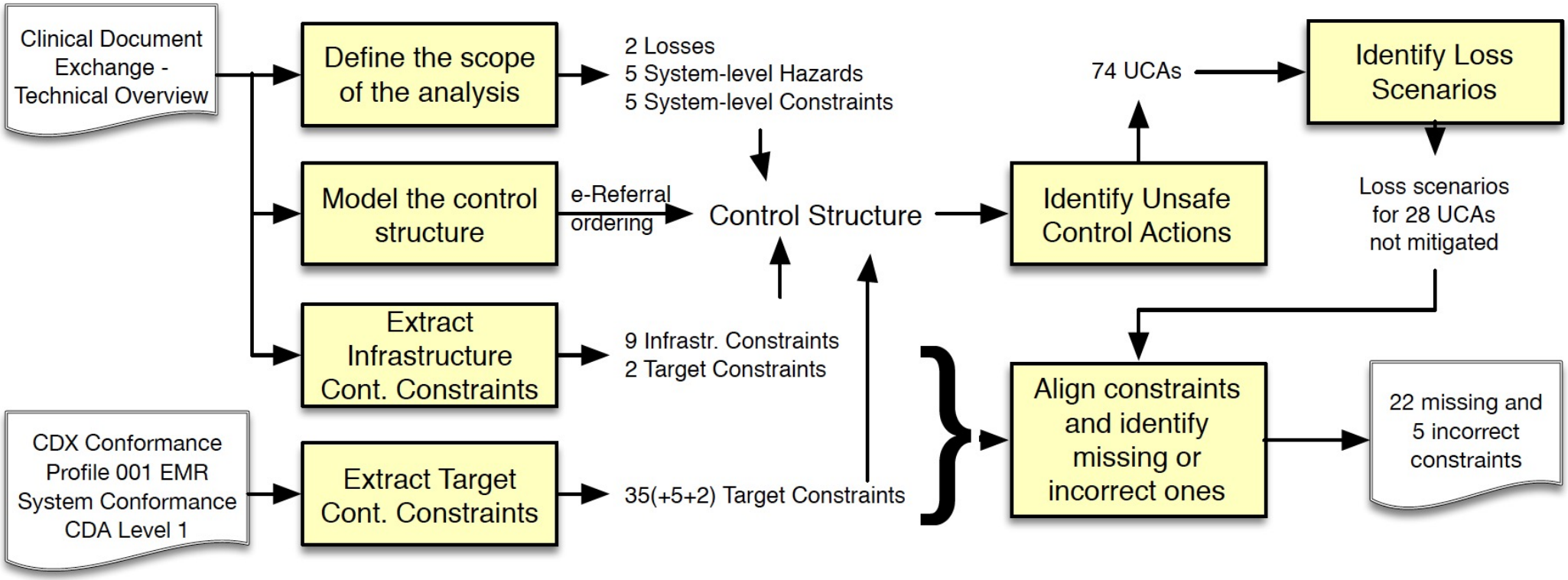


Method Overview



UCA	Loss Scenarios	Controller Constraints
UCA1.1: PCG provides *create!* with mis-identified / ambiguous / missing record target [H2]	• PCG picks wrong patient with similar name • PCG has multiple patient charts open and creates order for wrong chart • PCG enters name / ID incorrectly • PCG forgets to specify patient	CC1: sent messages are standards conform (implies record target present) CC24: record target shown clearly in user's view (while creating order) CC25: record target identified with 4-point info in order *(Assumption: PCG validates shown record target is)*
UCA1.3: PCG provides create! with incomplete/ incorrect order content [H1]	• PCG creates order while the OEC attaches data directly from the EMR; PCGs mental model of the attached data is not consistent with the actual data attached by the OEC; • The data incorporated into the order is incorrectly/ incompletely transformed to the interoperability standard. • The OEC displays order data to the PCG that is not (or not correctly) displayed to the SCG	(**missing**) Compiled order content is rendered completely in user view (OEC) (**missing**) CC17: order is rendered with approved viewer (OEC)
UCA1.4: PCG stops providing create! too soon, before providing send! for it [H4]	• PCG creates order but inadvertently exits before sending it (e.g., browser window is closed too soon). • PCG creates order, attempts to send it but the CDX infrastructure cannot be contacted or is slow; PCG dismisses the dialog assuming that it will be sent later.	(**missing**) Dismissing the order entry view requires confirmation if order not sent; unsent orders are saved (OEC) (**missing**) The existence of unsent orders is indicated in PCGs regular work view (OEC).
UCA2.1: PCG provides update! with updated (different) record target [H1,H2]	The PCG creates and order for a patient, which is sent to the receiving system and linked to the corresponding patient record. The PCG later finds that the patient was misidentified and updates the order with the correct record target; The update is received and matched to the previous version of the order by means of the document ID. Since the first version of the received order has already been linked to a patient record, the updated order remains linked to the same (wrong) record.	**(missing)** the record target of a sent order cannot be updated. (OEC) *(an order created for the wrong record target must be cancelled and a new order must be created)*

Summary of Results



Conclusions

- STPA has been effective in safety analysis interoperability conformance profiles
  - We implemented profile for OSCAR EMR
- Only considered e-referral workflow
  - Other workflows have similarities & differences
- We currently work on tool support for *reuse*
  - *Weber, J. H., & Costa, O. (2020). Adapting a System-Theoretic Hazard Analysis Method for the Analysis of an eHealth Interoperability Conformance Profile. AMIA Joint Summits on Translational Science proceedings. AMIA Joint Summits on Translational Science, 2020, 693–702.*

Thank you



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