

With post meeting notes added: see new pages 14-15-16

Pan-Canadian Approach to Allergy, Intolerance and Adverse Reaction (interoperable EHR)

Presentation to HL7 Patient Care Working Group

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André Boudreau

Chair, Individual Care Standards Collaborative Working Group (SCWG) No. 2, Canada

Marion Lyver, md

Past Chair, Individual Care Standards Collaborative Working Group (SCWG) No. 2, Canada

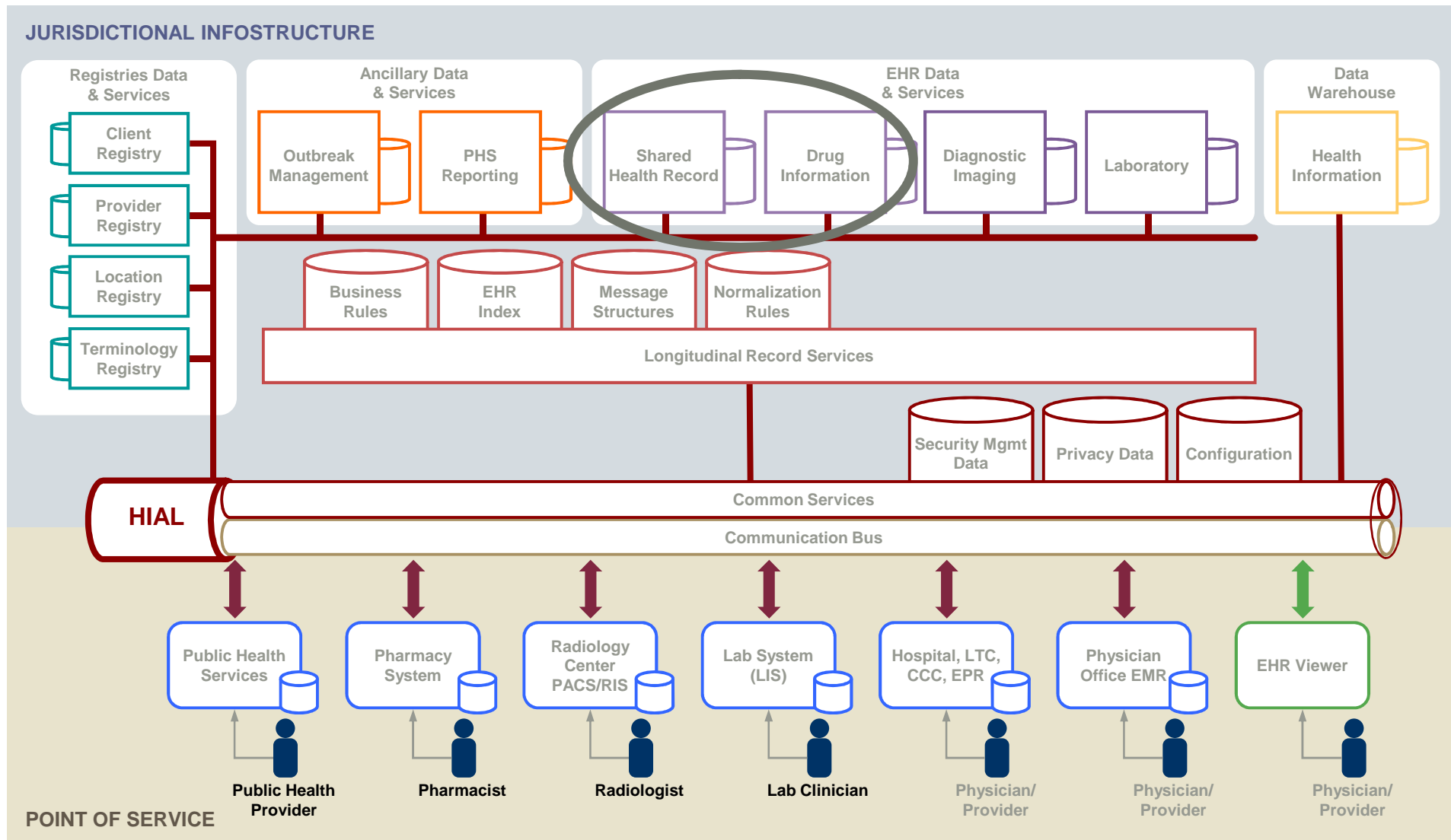
Clinical advisor to Canada Health Infoway



Objectives

- Present current pan-Canadian standards for messaging Allergy, Intolerance and Adverse Reaction information within the interoperable EHR
- Expose some issues and current actions to resolve them

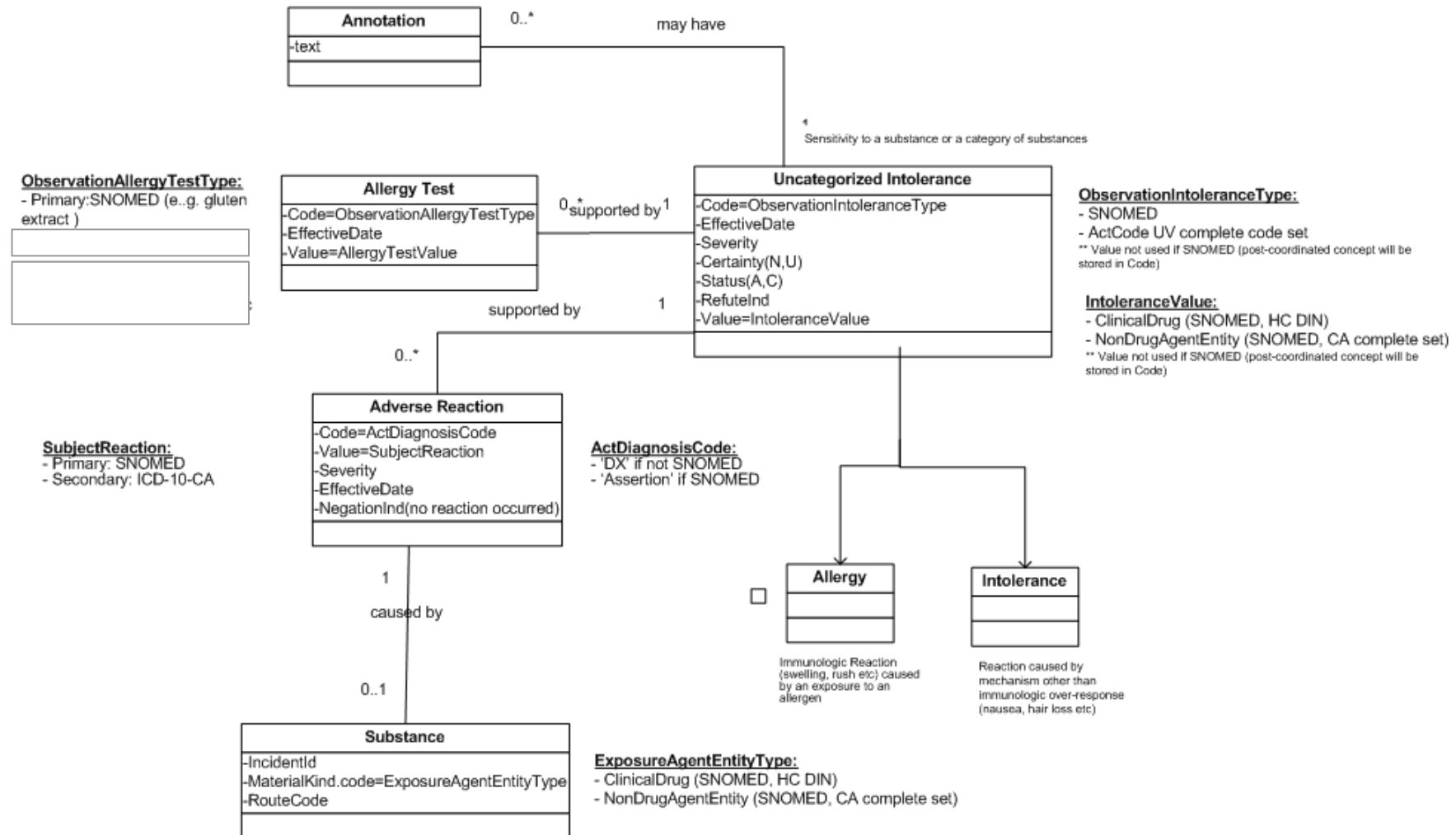
EHR Infostructure: Conceptual Architecture (2006)



DEFINITIONS AND MODELS OF KEY TERMS

- From Fall 2010 Partnership work

Static Data Model – Allergy / Intolerance



List of Terms

- Allergy
- Intolerance
- Uncategorized intolerance
- Adverse Reaction

Allergy

Definitions	Other Information	Key Discussion Points
<ul style="list-style-type: none">•Hypersensitivity caused by exposure to a particular antigen (allergen) resulting in a marked increase in reactivity to that antigen upon subsequent exposure, sometimes resulting in harmful immunologic consequences. (Source: Master Glossary MR2009 – term under review)•A hypersensitivity caused by an exposure to an antigen which results in an adverse immunologic reaction on subsequent exposures. (Source: IGuide Volume 7: SHR; also Implementation Guide Volume 8 - Pharmacy)	<ul style="list-style-type: none">•A type of uncategorized intolerance (where the category has been determined). Immunologic reaction examples include rash, hives, swelling and anaphylaxis. Allergies are intended for circumstances where the clinician has a fair degree of confidence that the identified agent is the cause of the adverse reaction, or when specific testing has been performed to confirm the presence of an allergy. (Source: IGuide Volume 7: SHR)	<ul style="list-style-type: none">•There are contradictions; to be resolved

Intolerance

Definitions	Other Information	Key Discussion Points
<ul style="list-style-type: none">•Inability to withstand or to tolerate, sensitivity, as to a drug. (Source: Master Glossary MR2009)•Any identified intolerance which is caused by a mechanism other than immunologic over response. (Source: IGuide Volume 7: SHR; also Implementation Guide Volume 8 - Pharmacy)	<ul style="list-style-type: none">•A type of uncategorized intolerance (where the category has been determined). Reaction examples include nausea, dry mouth, and hair loss. Intolerances are intended for circumstances where the clinician has a fair degree of confidence that the identified agent is the cause of the adverse reaction, or when specific testing has been performed to confirm the presence of an allergy. (Source: IGuide Volume 7: SHR)	

Uncategorized Intolerance

Definitions	Other Information	Key Discussion Points
<ul style="list-style-type: none">•A sensitivity to a substance or category of substances, such that exposure to the substance is likely to result in an adverse reaction and where it has not been possible to identify with any degree of certainty which type of adverse reaction it is. (Source: IGuide Volume 7: SHR)	<ul style="list-style-type: none">•Both Allergy and Intolerances are types of an 'Uncategorized Intolerance' (where the category has been determined) (Source: IGuide Volume 7: SHR)	

Adverse Reaction

Definitions	Other Information	Key Discussion Points
<ul style="list-style-type: none">•Any undesirable or unwanted consequence of a preventive, diagnostic, or therapeutic procedure or regimen. (Source: Master Glossary MR2009 – term under review)•Adverse reactions are undesirable effects to health products. Health products include drugs, medical devices and natural health products. Drugs include both prescription and nonprescription pharmaceuticals; biologically-derived products such as vaccines, serums, and blood derived products; cells, tissues and organs; disinfectants; and radiopharmaceuticals. (Health Canada, MedEffect - Adverse Reaction Information)	<ul style="list-style-type: none">•Allergies and intolerances are generally differentiated based on the type of reaction. Immunologic reactions such as rash, hives, swelling and anaphylaxis generally signify the presence of an allergy. Other reactions such as nausea, dry mouth, hair loss, etc. would qualify as intolerances. (Source: IGuide Volume 7: SHR)	

SHR Iguide: Allergy Discussion cont.

- *Different clinicians place different importance on the distinction between allergies and intolerances. Physician systems (EMRs) have traditionally been more likely to differentiate these concepts, while other applications (e.g. pharmacy applications) have tended to group them together. The Message Specification supports both views by allowing a particular adverse reaction to an agent to be identified as an Uncategorized Intolerance, or to be specifically categorized as an Allergy or an Intolerance. It is also possible for the categorization of an adverse reaction to an agent to change over time. An initial recording of “Allergy to Penicillin” may later be changed to “Intolerance to Penicillin” when the nature of the associated reaction becomes known.
- Note: CIHI data elements: no distinction between allergies and intolerances.

Allergy or intolerance (condition) vs. allergic reaction and intolerance reaction?

- Comments by Marion
 - Record needs to show both – the allergy or intolerance condition and then the questions regarding the nature of the allergic reaction or intolerance that is the manifestation of the condition.
 - It's clear that the current PCS model encompasses both allergy/intolerance elements (related to the condition) and elements related to the reaction that is the manifestation of the condition.
 - Status applies to the condition: A reaction goes away either on its own by removing the exposure agent or moving the patient away from the agent but the allergy or intolerance “propensity” remains intact over time until/unless something happens to change that state e.g. the allergy simply disappears which often happens in childhood asthma, or it is treated and resolved.

Other Notes from Marion

- If we want to include event type, it should be renamed Trigger Event Type or Exposure Event Type rather than Adverse Event Type in order to avoid confusion with adverse event equating to adverse reaction
- Severity should be attached to reaction, not allergy or intolerance. But no doubt clinicians would debate this point.
- Levels of certainty apply to the condition, not the reaction, and should be replaced by the concept of 'confirmed'

Notes on Data Model - 1

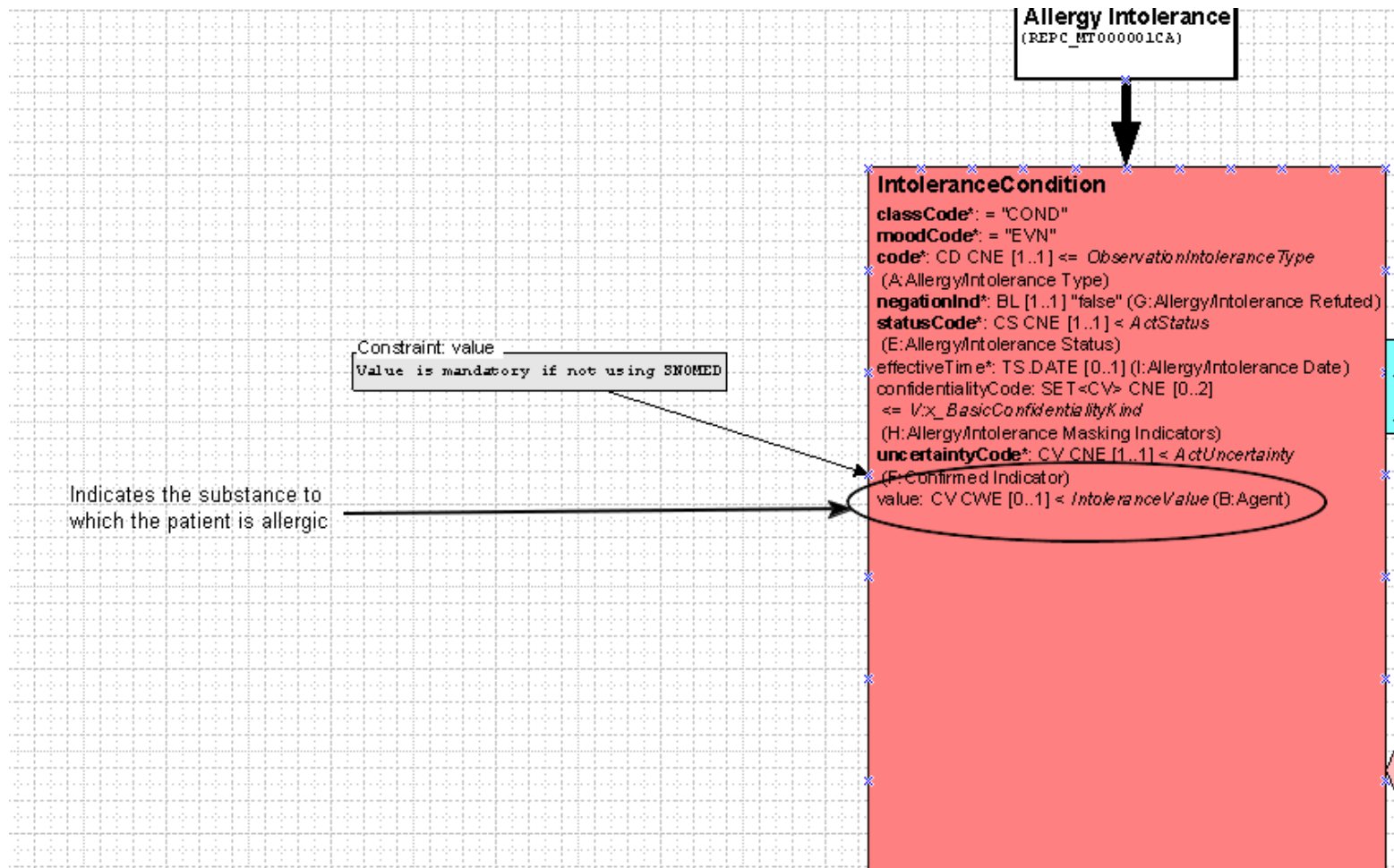
- Use of Allergy/Intolerance vs. ADR
 - The Message Specifications offers transactions which support the capturing of both “Allergies” and “Intolerances” as well as Adverse Reactions in the patient record. One obvious question is “When should a clinician record an Allergy or Intolerance, and when should they record an ADR?”
 - Allergies and Intolerances are intended for circumstances where the clinician has a fair degree of confidence that the identified agent is the cause of the adverse reaction, or when specific testing has been performed to confirm the presence of an allergy. ADRs are intended to record that an unusual reaction has occurred in the patient, but the cause of the reaction is not definitively known. One or more suspected or candidate drugs may be linked to the ADR to warn that they should be used with caution and that careful monitoring should be performed if they are used.
 - By recording adverse reactions as they occur, it may be possible at a later point to identify a trend relating to a combination of medications, to a time of year, or to some other factor that may aid the recording clinician or others in identifying the cause of the reaction. Previously recorded adverse reactions can be linked to allergy and intolerance records as supporting evidence for the presence of a particular allergy or intolerance, reducing the requirement to re-enter data.

Notes on Data Model - 2

- The Uncategorized Intolerance has a code that takes its values from the IntoleranceValue domain. It is that code that expresses what the intolerance is against. So if you were making an allergy to Opioid Analgesics, that would go in the value. The AR and its association to a substance would be used if you wanted to provide supporting information to the allergy/intolerance.
 - IntoleranceValue domain uses value sets from ClinicalDrug and NonDrugAgentEntity concept domains
 - Examples from NonDrugAgentEntity value set (SNOMED CT):
 - 255774009- latex protein (contact allergen)
 - 229952002 -white plain flour (food - wheat product)
- The ObservationIntoleranceType concept domain allows different types of allergy and different types of adverse reaction to be distinguished (e.g. allergy to food; allergy to chemical; food intolerance; drug intolerance).
 - There are primary (SNOMED CT) and secondary (ActCode) value sets. Example:
 - Primary: 235719002- food intolerance
 - Secondary: FNAINT- Food Non-Allergy Intolerance (Hypersensitivity to an agent caused by a mechanism other than an immunologic response to an initial exposure)
- See messaging model on the next page

Messages can provide agent information directly

- The substance to which the patient is allergic can be indicated directly in the pC Allergy/Intolerance messages as illustrated in the model below :



*Source: SC-2003-EN - REPC_MT000001CA - Allergy Intolerance - 20100326.doc

BUSINESS (HEALTH CARE) NEEDS

Stakeholders and Business Needs Regarding Allergy, Intolerance and Adverse Reactions - 1

Stakeholder	Patient Care	Health System Use	Other Needs
Patient	Patient safety Quality care Continuity of care		
Providers (all types within their scope of practice and role)	Patient safety Quality care Continuity of care	Practice management	Billing Familiar terminologies
Point of Care Org's incl. first nations	Patient safety Quality care Continuity of care	Quality control Program management	Uniform terminologies and concepts in EMR, CIS and EHRS, LIS, RIS. Etc. Reporting and Program funding
Telemedicine Users	Patient safety Quality care Continuity of care	Quality control Program management	Uniform terminologies and concepts
Jurisdictions and Regional Authorities incl. first nations	Patient safety Quality care Continuity of care	Quality control Program management	EMR, EHR specs, design Uniform terminologies and concepts Ensure validity / harmony of data from multiple sources
Vendors	Patient safety Quality care		Robust and stable standards Uniform terminologies and concepts in all markets Good ROI
Health Canada	Patient safety (drug approval, AR reporting)		Drug identification
Canadian Blood Services	?? No need?	?? No need?	

Stakeholders and Business Needs Regarding Allergy, Intolerance and Adverse Reactions - 2

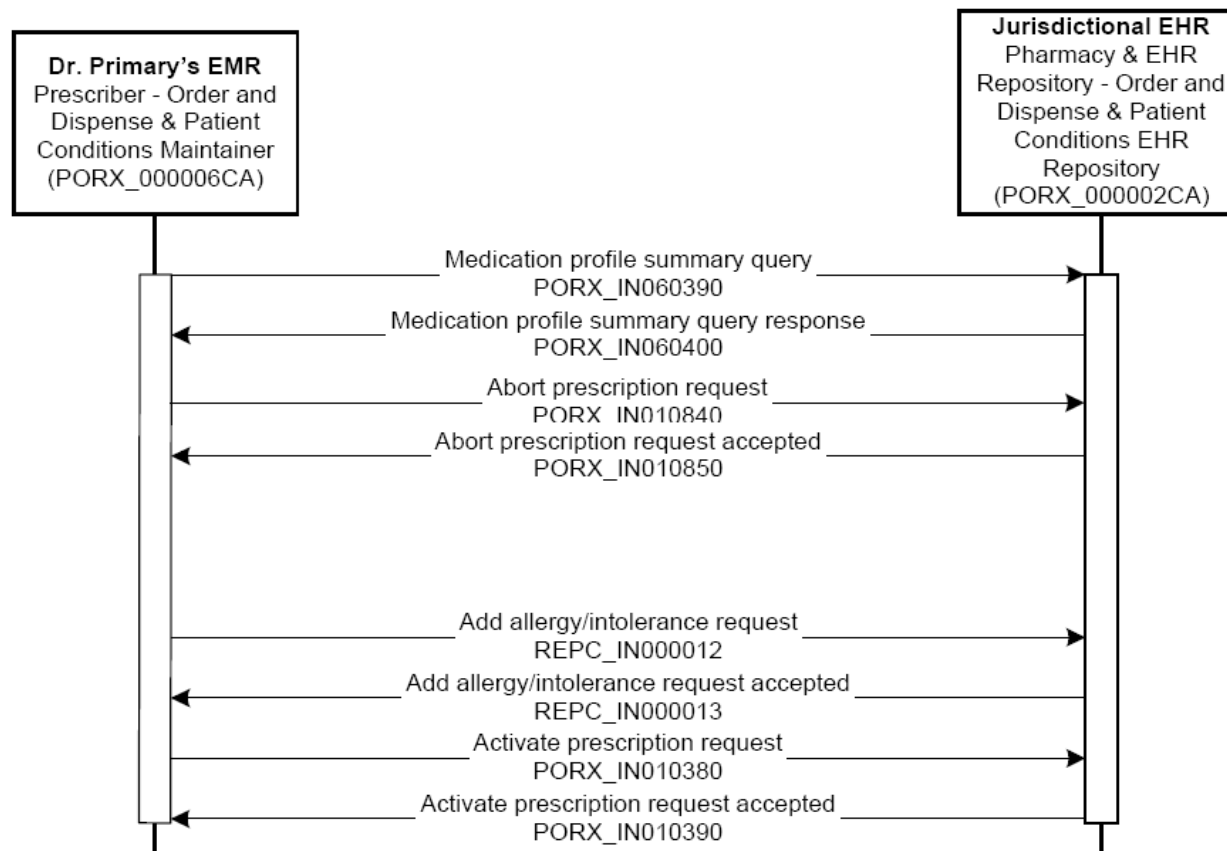
Stakeholder	Patient Care	Health System Use	Other Needs
Public Health Agency of Canada (PHAC)	Patient safety (vaccines)	Population Health	Uniform terminologies and concepts
Canadian Institute for Health Information CIHI		Population Health Research support	Uniform terminologies and concepts
Canadian MedicAlert Foundation	Patient safety		
Canadian Society of Allergy and Clinical Immunology	Patient safety Quality care		'Valid' concepts and terminologies?
Canadian Patient Safety Institute (CPSI)	Patient safety	Quality control	
Institute for Safe Medication Practices Canada (ISMP)	Patient safety	Quality control	
Patient groups (e.g. Allergy/ Asthma Information Association)	Patient safety Quality care		
SC and SCWGs			Standards that meet Infoway and members needs Alignment of concepts, terminology and standards
Infoway			Alignment with PCS Quality information standards Semantic interoperability
Canadian Immunization Registry Network CIRN			Terminology alignment.

Major Types of Needs -1

- Patient care
 - Treating adverse reactions (AR) and allergic/ intolerance conditions
 - Preventing AR: drugs, interventions
- Medication management: prescription, dispense, control
- Immunization: preventing vaccine AR
- Health Canada MedEffect™ program: report adverse reactions (side effects) to health products, including prescription and non-prescription medications, biologics (including fractionated blood products, as well as therapeutic and diagnostic vaccines), natural health products and radiopharmaceuticals, to the [Canada Vigilance Program](#).
- Health System Use
 - Clinical Program Management
 - Surveillance
 - Research
 - Health System Management

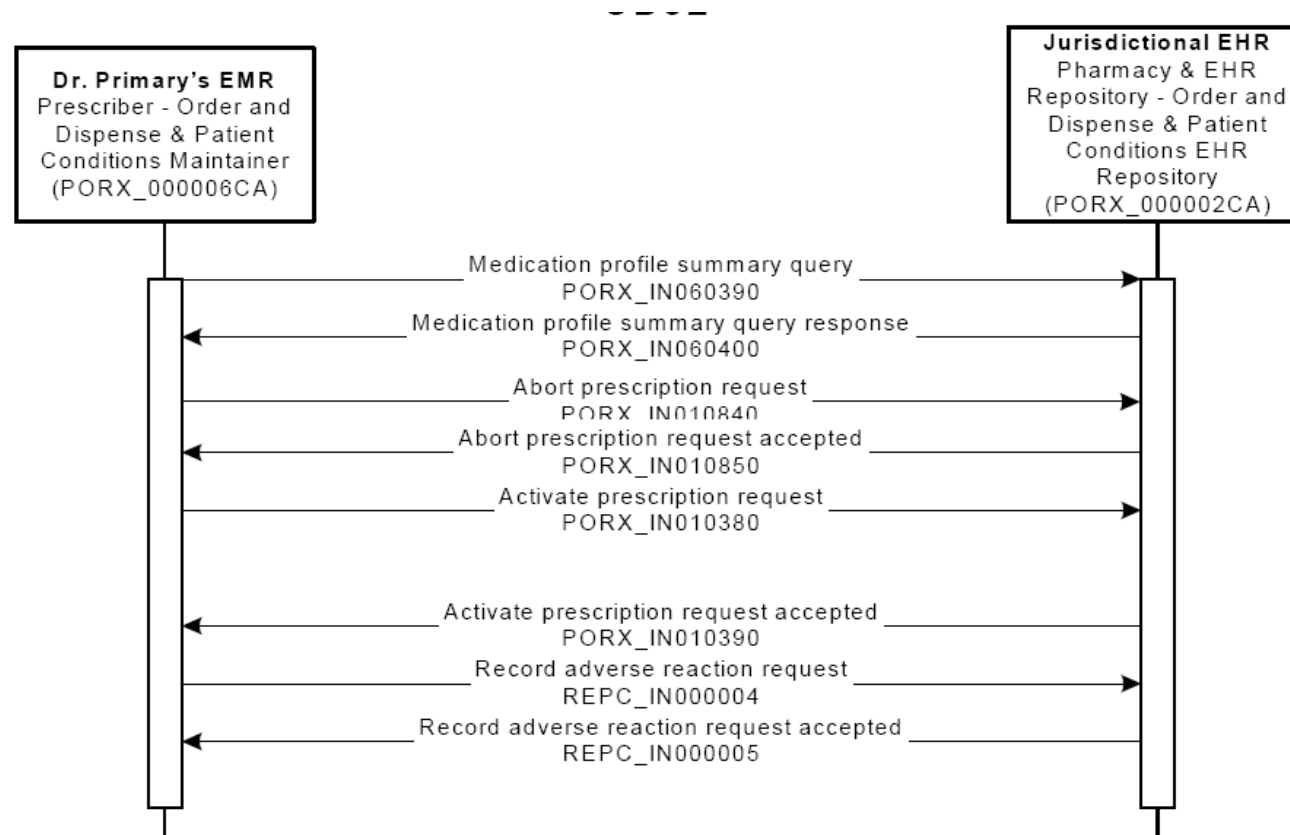
SHR: Allergy/Intolerance Interaction Diagram

- Current SHR storyboard are medication related: demonstrate recording of a drug allergic reaction on the EHR



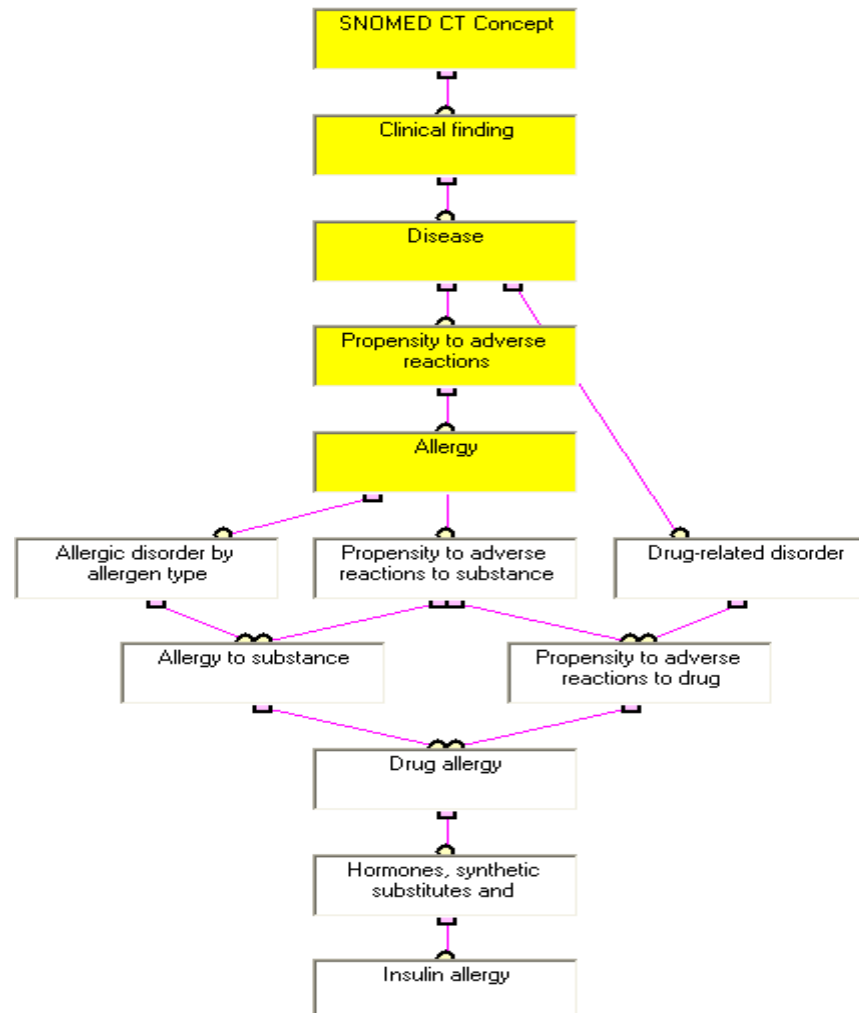
SHR: Adverse Reaction Interaction Diagram

- Current SHR storyboard are medication related. This illustrates a scenario where a health care provider needs to record an adverse reaction to a prescribed drug on the EHR.



ALLERGIES, ADVERSE REACTIONS AND INTOLERANCES IN SNOMED CT

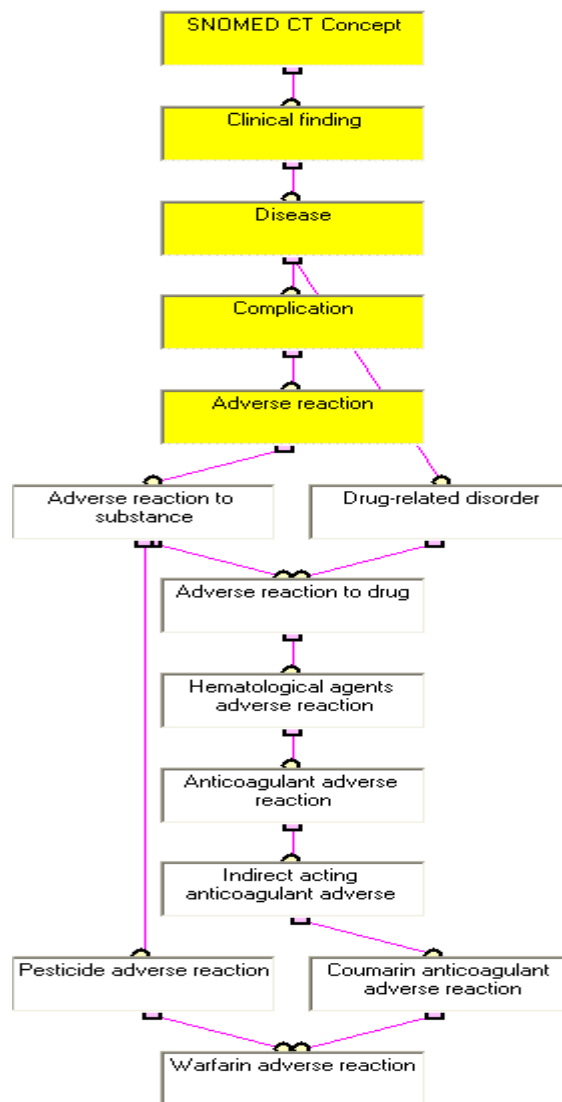
SNOMED CT Graphic View of Insulin Allergy



Legend:

- Yellow box: Primitive concept
- White box: Fully defined concept
- Half square symbol: A supertype (parent) of the linked concept below
- Half circle symbol: A subtype (child) of the linked concept above

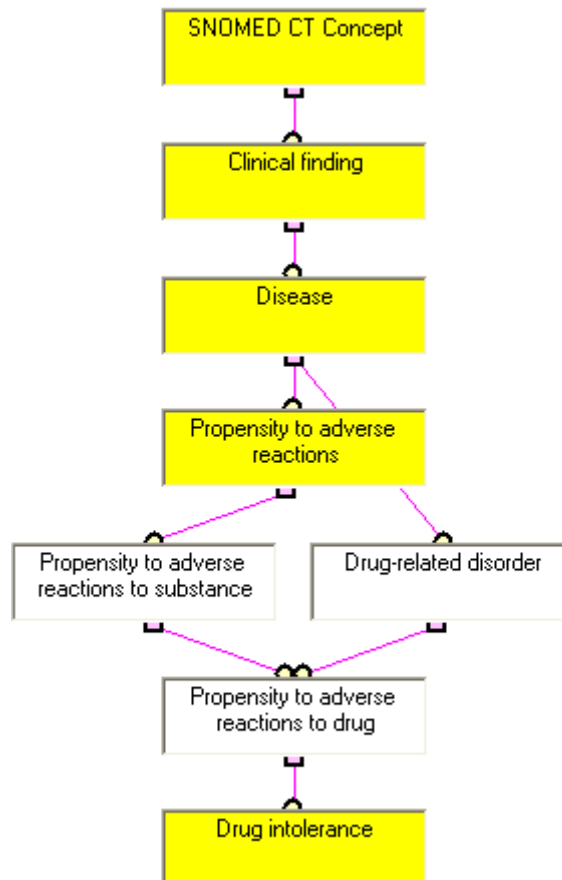
SNOMED CT Graphic View of Warfarin Adverse Reaction



Legend:

- Yellow box: Primitive concept
- White box: Fully defined concept
- Half square symbol: A supertype (parent) of the linked concept below
- Half circle symbol: A subtype (child) of the linked concept above

SNOMED CT Graphic View of Drug Intolerance



Legend:

- Yellow box: Primitive concept
- White box: Fully defined concept
- Half square symbol: A supertype (parent) of the linked concept below
- Half circle symbol: A subtype (child) of the linked concept above

ISSUES AND ACTION PLAN

Major Needs Surfaced- Fall 2010 Partnership

- Standards need to address clinical business needs of the major stakeholders in Canada
- Standards should be based on solid information model and definitions for core concepts
- Terminology and value sets need to be adjusted to meets business needs
- PCS need to be updated

Fall 2010 Partnership – Action Items

- Conduct research to clarify business/clinical requirements (use existing messages as a source of use cases) and propose an overall model for intolerance, allergy, AR, Adverse Drug Reaction (ADR), conditions, and an overarching concept that encompass them all (main parent)
 - Model of terms need to meet business/clinical requirements overall, not just for medication management
 - Ensure that definitions have solid / credible sources. We need to include references to these sources
 - Examine the most recent HL7 DSTU (Sept. 2009) material for allergy messages. They represent an enhancement over the existing SHR messages.
 - Update the PCS
- Ensure alignment with vocabulary of Health Canada, the Canadian Patient Safety Institute (CPSI), Institute for Safe Medication Practices Canada (ISMP), Canadian Public Health Association, Public Health Agency of Canada (PHAC), and obtain if possible endorsement by relevant Canadian professional associations (e.g. Canadian Society of Allergy and Clinical Immunology) and other groups (e.g. Allergy/Asthma Information Association), etc.

Progress Achieved

- Consultation with Standards Collaborative Clinical Sub-Committee
- Discussion with Infoway SC
 - Collaboration with existing project teams, namely PHC-HSU for RefSets
- Search for models and concept definitions: fairly advanced
 - Multiple sources at international level, on 'spare' time (volunteer efforts)
- Survey jurisdictions and organizations on use of these concepts: underway
 - SCWG 2 volunteer effort