Consent and Consent Directives in Healthcare

for WHISTL

André M. Carrington

WATERLOO | ENGINEERING
SYSTEMS DESIGN ENGINEERING

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Agenda

- Context
- Consent
- Why?
- Exceptions
- Challenges
- How it works
- What it looks like

A patient encounters the health system

at many different points of service

Family Dr (EMR) | **Hospital (HIS, CIS, EPR)** | **Pharmacy (DIS)** | **Laboratory (LIS)** | **Radiology (RIS)** | **Home (Telehomecare)** ...

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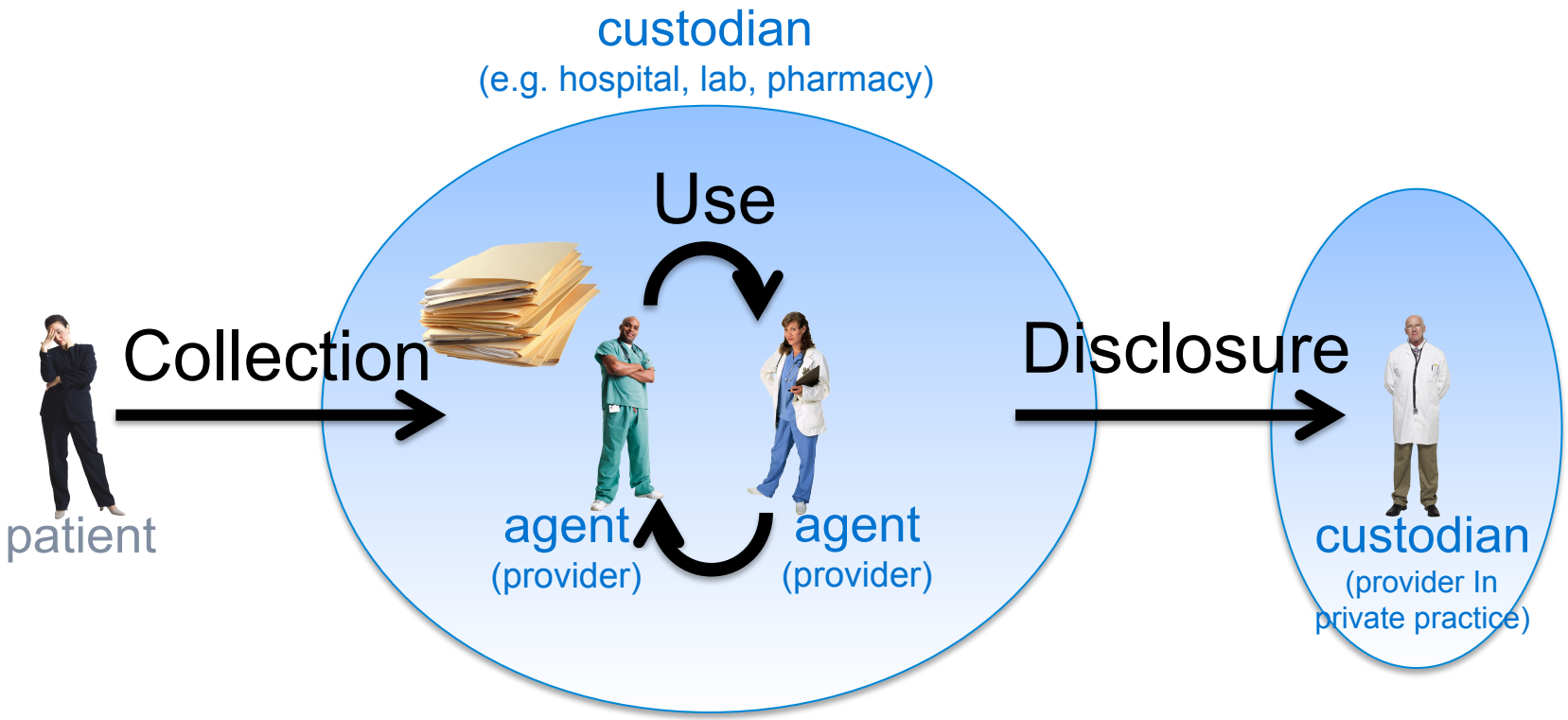
These points of service were mostly derived from Canada Health Infoway's EHRS Blueprint.

Information flows in each encounter



Information flow is governed by privacy law

- A custodian needs to obtain an individual's consent to collect, use & disclose (CUD) personal health information, except where the law permits otherwise.

  = Informational Consent

  ≠ Consent for treatment

Consent is implied when we seek care

- "Implied consent*
  - …permits a…custodian to infer from the surrounding circumstances that an individual would reasonably agree to the collection, use or disclosure…"

- "Express consent
  - …is explicit and direct. It may be given verbally, in writing or by electronic means"; opt-in

* the vast majority of consent is implied

But consent may be withheld or withdrawn

- The patient may withold or withdraw consent for collection, use and disclosure of personal health information. A mechanism to enforce that is required by law.

- Consent directives are an electronic mechanism to enforce that.
  - in whole or in part; opt-out

What personal health information (PHI) are patients concerned about? Why?

- home address, postal code, phone #, real name
  - why: stalking of victim/witness/prosecuter/vip
- mental illness, communicable disease, disability, abortion, sexual dysfunction, infertility, substance abuse, sexual abuse, physical abuse
  - why: snooping, equitable treatment, embarrassment
- any PHI - why: snooping (by co-workers in health)

Providers can use PHI without consent re

- Significant risk of serious bodily harm to individual or group
- What is “required by law, professional or institutional practice”
- Quality of care
- Research (w specific requirements and conditions)
- etc.

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- Significant risk of serious bodily harm to individual or group
- What is “required by law, professional or institutional practice”
- Quality of care
- Research (w specific requirements and conditions)
- Risk and error management
- Education (of agents)
- Service planning and delivery
- Claims and payment, etc.

And disclose without consent re

- Significant risk of serious bodily harm to individual or group
- Reasonable health care in a timely manner; Contacting a relative
- Health system management and monitoring
- Research (w specific requirements and conditions)
- etc.

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- Significant risk of serious bodily harm to individual or group
- Reasonable health care in a timely manner; Contacting a relative
- Health system management and monitoring
- Research (w specific requirements and conditions)
- Public health surveillance
- Disease registries of prescribed entities
- Contacting a relative
- Per legal proceedings; statutory functions, etc.

But one hospital has over 200 applications.

Is a Canadian HL7v2 & v3 consent standard available?

Do products and vendors support it?

Have products been upgraded where possible?

Can hospitals afford the upgrades?

these services may exist in a single hospital

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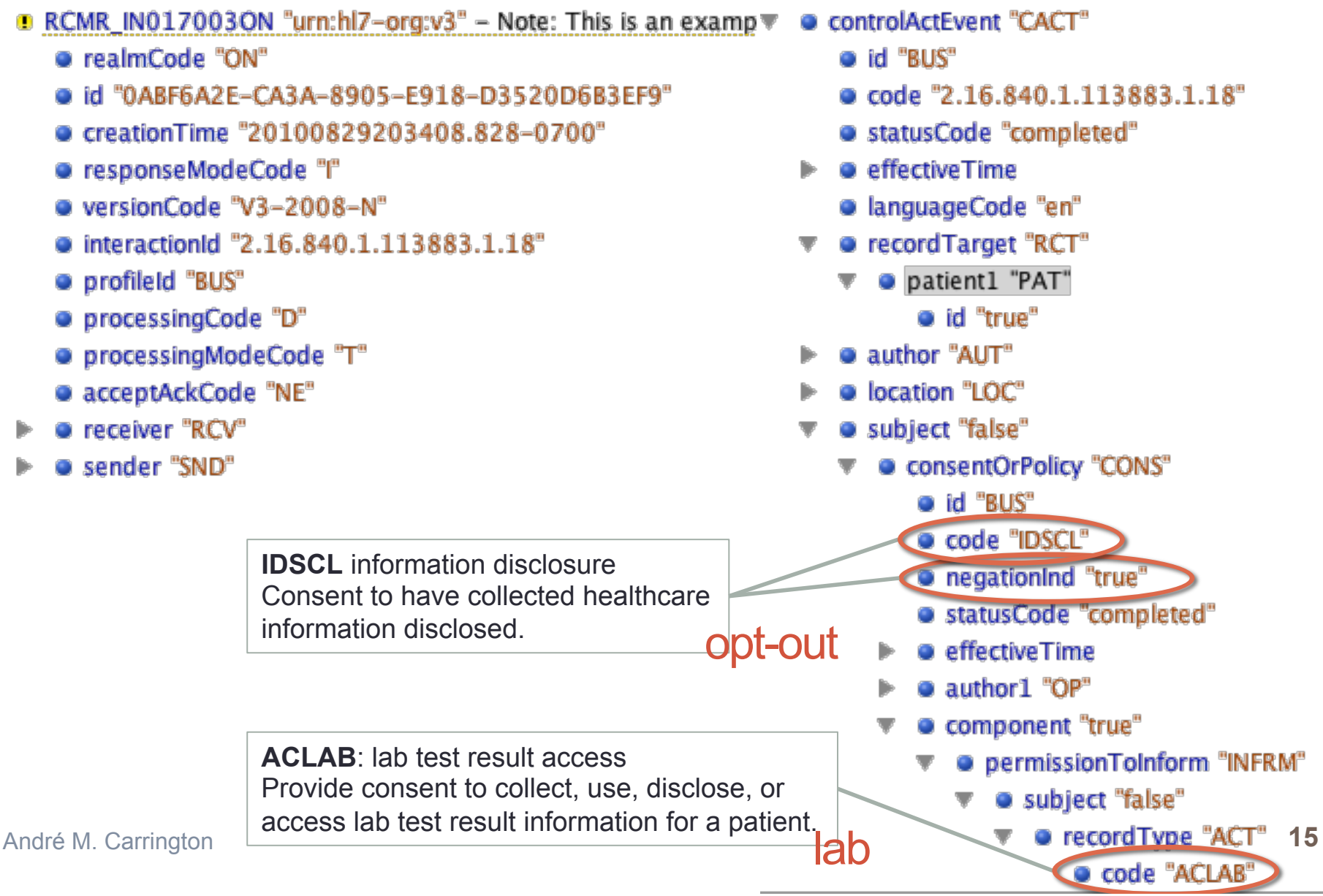
What does a consent directive look like?

Policies that deny (or permit) access to

- whole record
- domain (e.g. drugs, lab)
- service location (e.g. workplace)
- user, group or role
- specific data / encounter / time-period

Lab opt-out (xml message structure)



HL7 ActConsentType

ICOL	information collection	Definition: Consent to have healthcare information collected in an electronic health record. This entails that the information may be used in analysis, modified, updated.
IDSCL	information disclosure	Definition: Consent to have collected healthcare information disclosed.
INFA	information access	Definition: Consent to ac[illegible]s healthcare information.
INFAO	access only	Definiti[illegible]nsent t[illegible]s or "read" only, which entails that the information is not [illegible]d, emailed, stored, re-disclosed or [illegible]that data which is masked or to which [illegible]ned and then emailed or screen [illegible] purpose.
INFASO	access and save only	[illegible], which entails that access to the
IRDSCL	information redisclosure	[illegible]hout the patient's consent.
RESEARCH	research information access	Definiti[illegible]nsent t[illegible]e healthcare[illegible]formation in an electronic health record accesse[illegible] research [illegible]poses.
RSDID	de-identified information access	Definition: Consent to have de-identified healthcare information in an electronic health record that is accessed for research purposes, but without consent to re-identify the information under any circumstance.
RSREID	re-identifiable information access	Definition: Consent to have de-identified healthcare information in an electronic health record that is accessed for research purposes re-identified under specific circumstances outlined in the consent. Example:: Where there is a need to inform the subject of potential health issues.

Collect
Use
Disclose
Research

HL7 ActInformationAccessCode

ACADR	adverse drug reaction access	Description: Provide consent to collect, use, disclose, or access adverse drug reaction information for a patient.
ACALL	all access	Description: Provide consent to collect, use, disclose, or access all information for a patient.
ACALLG	allergy access	Description: Provide consent to colle e, disclose, or access allergy information for a ient.
ACCONS	informational consent acc	escription: Pr sent t se, disclos access informational inform
ACDEMO	demographics access	D or access demographics
ACDI	diagnostic imaging acc	access diagnostic
ACIMMUN	immunization access	munization
ACLAB	lab test result access	Desc use, or access lab test result infor ior
ACMED	medication access	Description: Pro nsent to c , use, disclose, o access medical condition informa or a patient.
ACMEDC	medical condition access	Definition: Provid onsent to view or access medical condition information for a patient.
ACMEN	mental health access	Description:Provide consent to collect, use, disclose, or access mental health information for a patient.
ACOBS	common observations access	Description: Provide consent to collect, use, disclose, or access common observation information for a patient.

Lab
Medication
Demographics
Mental Health
etc.

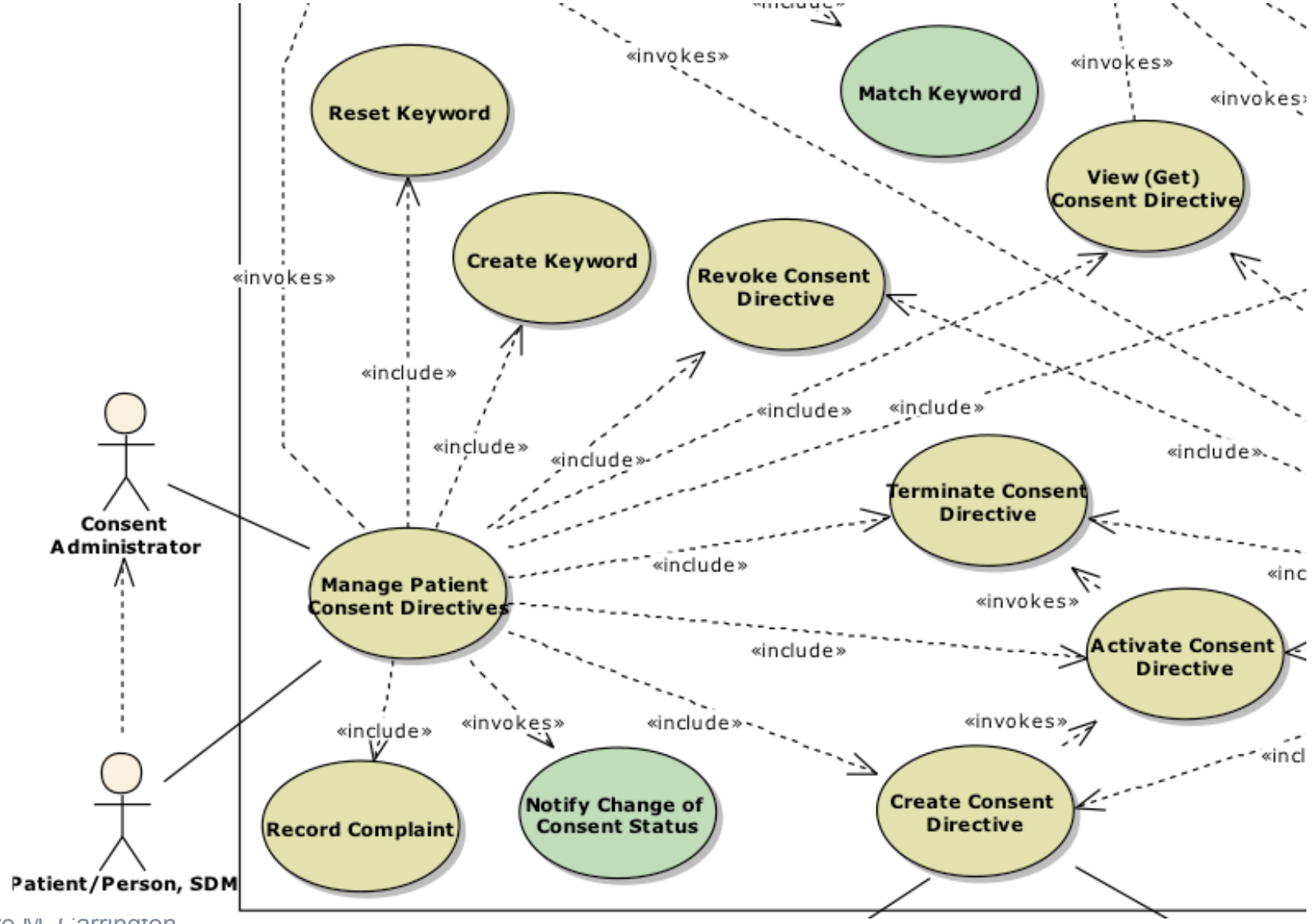
How does it work?

- Lock-box. Access contents with
  - the patient's keyword
  - an (emergency) override

- Centralized. Interoperable.

- Policies must: follow constraints, be consistent.

Use Cases


Reset Keyword
Match Keyword
View (Get) Consent Directive
Create Keyword
Revoke Consent Directive
Terminate Consent Directive
Activate Consent Directive
Create Consent Directive
Notify Change of Consent Status
Record Complaint
Manage Patient Consent Directives
Consent Administrator
Patient/Person, SDM
«invokes»
«include»

How upgrade and integrate?

- 200 HL7v3 interfaces. Where is that v3 broker?

- 200 (one-time?) changes to
  - access control logic
  - user interface
  - transient data model / store (ODS)
  - possibly the production data store (PDS) & logic

- Bigger risk and low-hanging fruit: EHR

THE END

Questions?

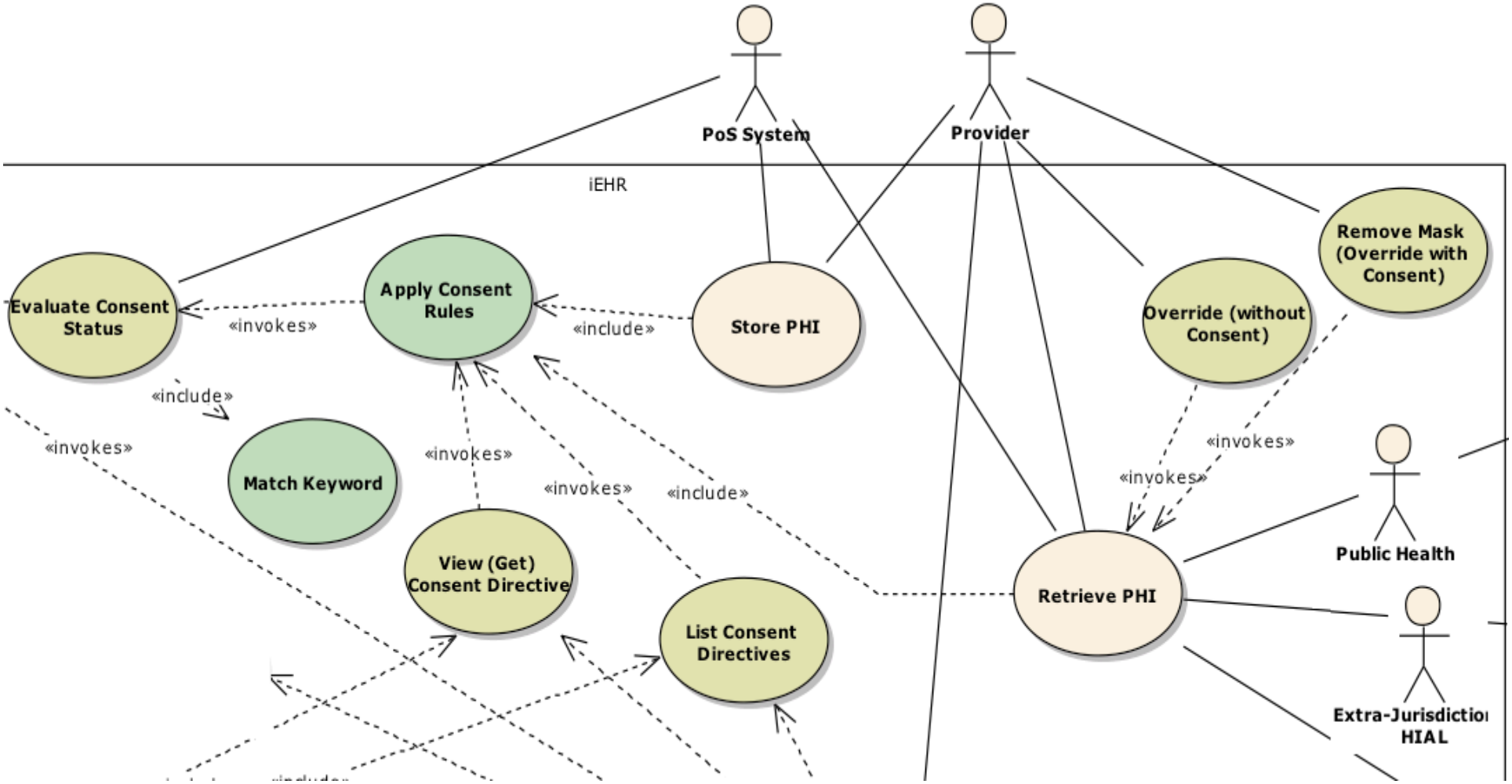
amcarrin@uwaterloo.ca

Implications of consent directives

- Providers that obtain information must be alerted if something is excluded
- Risk to quality of care & decision-making
- Service can be delayed or refused

Ontario Consent Directives

Use Case	Scenario(s) Involved	Trigger Event	Interaction Identifier
Manage Consent Directives by Client or Client Service Representative	Create Consent Directive	Create Consent Directive	RCMR_IN011003ON
	Delete Consent Directive	Delete Consent Directive	RCMR_IN012003ON
	Activate Consent Directive	Activate Consent Directive or Override Request	RCMR_IN017003ON
	Deactivate Consent Directive	Deactivate Consent Directive	RCMR_IN013003ON
	Modify Consent Directive	Modify Consent Directive	RCMR_IN014003ON
	Reinstate Consent Directives	Reinstate Consent Directives	RCMR_IN015003ON
	Consent Directive Request Accepted	Record consent or override request accepted	RCMR_IN010001ON
	Consent Directive Request Refused	Record consent or override request refused	RCMR_IN010002ON
Manage Policies	Create Privacy Policy	Create Privacy Policy	RCMR_IN011004ON
	Delete Privacy Policy	Delete Privacy Policy	RCMR_IN012004ON
	Activate Privacy Policy	Activate Privacy Policy	RCMR_IN016004ON
	Deactivate Privacy Policy	Deactivate Privacy Policy	RCMR_IN013004ON
	Modify Privacy Policy	Modify Privacy Policy	RCMR_IN014004ON
	Reinstate Privacy Policy	Reinstate Privacy Policy	RCMR_IN015004ON
	Privacy Policy Request Accepted	Record consent or override request accepted	RCMR_IN010001CA
	Privacy Policy Request Refused	Record consent or override request refused	RCMR_IN010002CA
View Consent Directives/Policies	List (Get) Consent Directives/Policies	Consent Directives Query Request	RCMR_IN010009ON
		Consent Directives Query Response	RCMR_IN010008ON
Manage Keywords	Update keyword request accepted	Update keyword request accepted	RCMR_IN010004CA
	Update keyword request refused	Update keyword request refused	RCMR_IN010005CA
	Update keyword request	Update keyword request	RCMR_IN010006CA


PoS System
Provider
iEHR
Remove Mask (Override with Consent)
Evaluate Consent Status
«invokes»
Apply Consent Rules
«include»
Store PHI
Override (without Consent)
«include»
«invokes»
«invokes»
Match Keyword
«invokes»
«invokes»
«include»
«invokes»
Public Health
View (Get) Consent Directive
Retrieve PHI
List Consent Directives
Extra-Jurisdictio
HIAL

Related terms/concepts I did not discuss

- Implications of consent directives
- Substitute decision makers, minors, mature minors
- Masking, taboo flags, disclosure directives
- CeRx/HL7 ConfidentialityCode, HL7 Data Consent CMET, IHE BPPC, QC DSQ Consent Messages
- HL7 Consent DAM, HL7 Composite Privacy Data Consent, XACML