HL7 EHR – Immunization Functional Profile (IFP) Project

Gary L. Dickinson Mark Janczewski, MD 22 September 2016

Introduction

- This is an open project
 - All are welcome!
 - International input invited!
- Team meets most Mondays at 11AM US ET
 - https://global.gotomeeting.com/join/597758325
 - +1 (571) 317-3122 Access Code: 597-758-325

Wiki

- Links and documents:
 - Contributors, Contributions and Readiness
 - Reference Materials
 - Functional Models and Profiles
 - Federal Health Information Model (Immunization)
 - Tools
 - Meeting Notes
- http://wiki.hl7.org/index.php?title=EHR_Immunization_Functional_Profile

Related HL7 EHR/PHER Work

Public Health Functional Profile

- HL7 Public Health Functional Profile Release 2 (PHFP R2)
 - Based on EHR-S FM Release 2
 - Balloted/Published 2015
- Developed as a partnership between CDC NCHS, HL7 EHR WG and PHER Work Groups
- Approved by consensus ballot, with input from the international community
- Includes FPs for nine (9) Public Health Domains:
 - Vital Records
 - Early Hearing Detection and Intervention
 - Chronic Diseases (Cancer Surveillance)
 - Public Health Laboratory Interactions (Orders and Results)
 - Occupational Disease, Injury, and Fatality
 - Health Statistics
 - Deep Vein Thrombosis and Pulmonary Embolism
 - Birth Defects
 - Adverse Events

HL7 EHR Work Group – Functional Profiles of ISO/HL7 10781 EHR System Functional Model (Limited to HL7 Projects) Revised: 26 August 2016

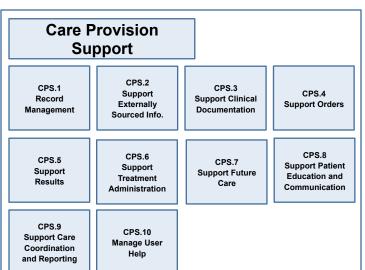
Functional Profile Subject	SDO(s)	Prior Profile	R2 Lead(s)	HL7 WGs	Contributing Organization(s)	R2 Status
-	` '	Based on	, ,		Contributing Organization(0)	
Ambulatory Care	HL7	DSTU	TBD	EHR		TBD
Behavioral Health	HL7	R1	Jim Kretz	CBCC	APA, SAMHSA	Preliminary
Child Health	HL7	R1	Pele Yu MD	Child Health	AHRQ?	Preliminary
Child Health – Developmental Screening	HL7	R2	Pele Yu MD Michael Padula MD	Child Health		In Progress
Clinical Research	HL7, ISO, CEN, CDISC	R1	Mitra Rocca	RCRIM	FDA, CDISC, eClinical Forum	Preliminary
Dental	ADA, HL7		Patrick Cannady	EHR	American Dental Association	Preliminary
EHR System Usability	HL7		John Ritter, Mitra Rocca	CIC, CQI, EHR	FDA, HIMSS, VA	In Progress
Emergency Care	HL7	R1	Laura Heerman RN James McClay MD	Emergency Care	DOD	In Progress
Lab Interactions (S&I LOI/LRI)	HL7		Riki Merrick, Bob Dieterle, Bob Yencha	EHR, Orders/ Observations	NIST, ONC S&I (LRI/LOI)	In Progress FP to Come
Long Term/Post-Acute Care	HL7	R1 (LTC)	TBD	EHR	LTPAC HIT Collaborative	Preliminary
Meaningful Use (2011/14 Edition)	HL7	`	Gary Dickinson, Diana Warner,	EHR	CMC	Published
Meaningful Use (2015 Edition)	HL7	R2	Michael Brody DPM	EUK	CMS	In Progress
Mobile Health Consumer Framework	HL7		Matthew Graham, Gora Datta	Mobile Health		In Parallel
Neonatal	HL7		TBD	Child Health		On hold
Nutrition	HL7	R1.1	Kay Howarter Lindsay Hoggle	EHR	American Dietetics Association, Academy of Nutrition & Dietetics	In Progress
Pharmacy/Pharmacist	NCPDP, HL7	R1.1	Sue Thompson	Pharmacy	NCPDP	In Progress
Podiatry	HL7		Michael Brody DPM	EHR		Preliminary
Public Health - Vital Records		R1.1				Published
Public Health - Early Hearing				EHR, PHER	CDC/NCHS, PHDSC, PHII	
Detection & Intervention						
Public Health - Chronic Diseases	-					
Cancer Surveillance						
Public Health - Lab Interactions	1		1			
(Orders and Results)			Hetty Khan			
Public Health - Occupational	HL7		John Ritter			
Disease, Injury, and Fatality			Michelle Williamson			
Public Health - Health Statistics	1					
Public Health - Deep Vein	1					
Thrombosis / Pulmonary Embolism						
Public Health - Birth Defects						
Public Health - Adverse Events	1		1			
Public Health – Work and Health	HL7		John Ritter, Michael Goldcamp PhD, Genny Luensman PhD	EHR	CDC, NIOSH	In Progress
Public Health – Immunization	HL7		Gary Dickinson Mark Janczewski, MD	EHR	ONC, NIST, CNI, AEGIS, ICSA, Results4Care, Sparx, (CDC?)	In Progress
Quality Indicators	HL7		Floyd Eisenberg MD	CQI		Preliminary
Records Management/Evidentiary Support (RM-ES)	HL7	R1	Reed Gelzer MD, Diana Warner	EHR	AHIMA	In Progress
S&I Structured Data Capture (SDC)	HL7		TBD		FDA? CDISC? ONC?	Preliminary
Unique Device ID (UDI)	HL7		TBD	00	FDA? ONC?	Preliminary

Contributor/Participant	Status	unization Project Contributions - Immunization Contribution		Individual(s)	Tool	
Contributor/Participant	Status			. ,		
		ISO/HL7 10781 EHR System Functional Model R2	Ready	Brody, Dickinson, Gelzer,	HL7 FM/FP Tool	
		ISO/HL7 16527 PHR System Functional Model R1	Ready	Janczewski, Ritter, Warner	(EA), UCAT	
	1	HL7 EHR-S Public Health Functional Profiles x 9	Ready	John Ritter, Hetty Khan,		
Health Level Seven (HL7) Electronic	HL7	Joint w/HL7 Public Health/Emergency Response WG		Michelle Williamson	 	
Health Record (EHR) Work Group	Sponsor	EHR-S Immunization Functional Profile (IFP)	In Progress	Gary Dickinson Mark Janczewski MD	HL7 FM/FP Tool (EA)	
		EHR-S FM/FP Developer Tool in Enterprise Architect (EA)	Ready	Anneke Goosen Michael Van Der Zel		
		Immunization Domain Analysis Model (IDAM)				
HL7 Public Health/ Emergency Response (PHER) WG	Interested	• Story Boards, Use Case Scenarios, Events, Actions, Actors/Roles, Data Requirements	Ready	John Roberts		
rtooponoo (i rizit) ivo		Immunization History Conformance Profile	Ready			
HL7 Clinical Information Modeling Initiative (CIMI) WG	Confirmed	CIMI Immunization Clinical Model(s)	Ready?	Galen Mulrooney Steve Hufnagel		
AFOIC (III 7 To aking a Domana an)	0 5	Immunization Test Cases	Ready	Mario Hyland	AEGIS DIL	
AEGIS (HL7 Testing Partner)	Confirmed	Developers Integration Lab (DIL)	Ready	Matthew Gereke		
		Standards & Interoperability (S&I) Framework	Dandu			
US Office of National Coordinator	Observer	Use Case Methodology	Ready	Steve Posnack		
		S&I Use Case Requirements Template	Ready		UCAT, MS Word	
Federal Health Information Model	Confirmed	FHIM Immunization Model(s)	Dandu	Calan Mulmannau	FHIM Tool	
(FHIM)	Confirmed	Immunization Data Requirements	Ready	Galen Mulrooney		
		S&I Simplification Core Matrix v3.4	Ready	Gary Dickinson	UCAT, MS Excel	
S&I Simplification WG	Confirmed	Use Case Exchange Format	Ready	Steve Hufnagel Ed Larsen	UCAT→UCAT, →NIST, →USHIK	
National Institute for Standards and		Immunization Test Cases	Ready	Kevin Brady	NIST IZ Tool	
Technology (NIST)	Confirmed	Implementation Guide Authoring & Management Tool	Ready	Rob Snelick	NIST IGAMT	
recimology (NIST)		Test Case Authoring & Management Tool	Ready	TOD SHEICK	NIST TCAMT	
Results4Care	Confirmed	Detailed Clinical Models (DCMs) for Immunization	Ready	William Goosen		
Sparx Systems	Confirmed	EA-based Use Case Authoring Tool (UCAT)	Ready	J.D. Baker	UCAT (EA)	
Prometheus	Observer	Beacon Use Case Authoring Tool (UCAT)	Ready	Art Greisser	UCAT (Beacon)	
US Agency for Health Research and Quality (AHRQ)	Invited	US Health Information Knowledgebase (USHIK)	Ready	Matthew Chudy Chuck Penoza	USHIK Tool	
US Centers for Disease Control and	Observer	Immunization Integration Program (IIP)	Ready	Craig Newman		
revention (CDC) Immunization Team		Immunization Test Cases	Reauy	Craig Newillall		
Chickasaw Nation Industries (CNI)	Interested	Immunization Integration Program (IIP)		Floyd Eisenberg MD	NIST IZ Tool	
HIMSS	Invited	- Immunization integration Program (IIP) -• Use Case Scenarios, Work Flows	Ready	Joyce Sensmeier	NIST TCAMT	
ICSA Labo (HIMSS Teating Douters)	Interested	Immunization Data Requirements	Reauy	David Tao		
ICSA Labs (HIMSS Testing Partner)	Interested	minumzation Data Requirements		Michelle Knighton		

Overarching OV.2 **OV.1** Manage User Overarching Help

EHR System Functional Model – Release 2

Care Provision CP-.2 CP.3 Render Manage **Manage Clinical** Externally Clinical History **Sourced Info Documentation** CP.6 CP.4 CP.5 Manage Manage Orders Manage Results **Treatment** Administration Manage Patient Manage Care **Manage Future** Ed. And Care Communication. Reporting



Record

Infrastructure

Record

Record

Lifecycle and

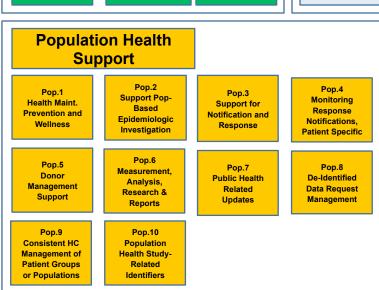
Lifespan

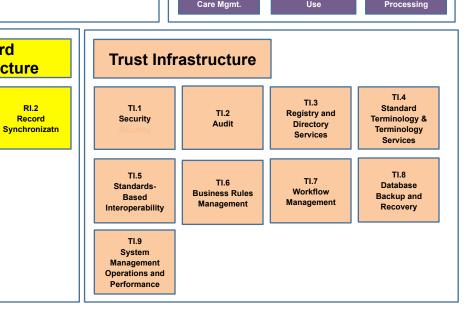
RI.3

Record Archive

and Restore







Horizontal – EHR-S FM Core Functions Vertical – Profiles (Built on Base)

				_								_					
Functional Profiles	Ambulatory	Behavioral Health	Child Health	Clinical Research	EHR-S Usability	Emergency Care	Long-Term Care	Laboratory	Meaningful Use	Mobile Health	Nutrition	Pharmacy	Public Health x 9	Immunization	Records Management Evidentiary Support (EHR as Legal Record)	Work/Occupation	and more
R2	Care Provision + Care Provision Support				ort	Population Health Support Administrative Sup					Supp	oort					
-S FM	Record Infrastructure Describes basics of EHR System managing an EHR Record Record Management, Lifespan, Lifecycle, Audit																
出	Record Management, Lifespan, Lifecycle, Audit Trust Infrastructure Identity, Accountability, Authorization, Authentication, Access Control, Audit																

Collaborative End-to-End Immunization Project

End-to-End

What	Who	How (Tools)	
Immunization Functional Profile, based on EHR-S FM R2	HL7 EHR WG	HL7 EHR-S FM/FP Tool	
Immunization Use Case(s) • User Stories • Scenarios, Events, Actions • Actors and Roles	HL7 PHER WG CNI IIP NIST	UCAT(s)	
Data Requirements	FHIM/CIMI, PHER, CNI	UCAT, FHIM	
Implementation Guides	NIST	IGAMT (NIST)	
Software Development	(Vendors, developers)	(various)	
Test Cases	NIST, CDC, AEGIS	TCAMT (NIST) DIL (AEGIS)	
Testing (then Certification)	AEGIS, ICSA		
Implementation	(Providers, users)		

Planning and Tasks

Focus	Tasks	Who
1. Environ- mental Scan	 Identify Sources for Review, Analysis, Inclusion or Reference Functional Models and Profiles EHR and PHR System Conformance Profiles Domain Analysis Models FHIM, CIMI (and RIM?) Immunization Information Models Implementation Guides Use Cases 	All
2. MU FP 2015 Edition (DRAFT)	 Review Functions and Criteria in Section §170.315(f)(1), "Transmission to Immunization Registries" and Sections (f) (2) through (f)(7) Add/modify functions/criteria as needed 	John Roberts, Noam Arzt and

Planning and Tasks

Focus	Tasks	Who
3. Use Cases	 Identify Sources: HL7 Immunization DAM use cases CNI/HIMSS Immunization Integration Program (IIP) work flows Others, as discovered or submitted For each scenario, extract use case scenarios and events, including: Event steps, event description, actor, roles, inputs and outputs Fill out Use Case Scenario Worksheet Later: determine actions taken (within each event) and link to EHR-S FM functions and related criteria Add/modify functions/criteria as needed 	Gary Dickinson and

Using S&I Use Case Basic Flow

Use Case Scenario Worksheet

Start: Capture Use Case Scenarios and Event Steps and for each Step - Actor, Role, Event, Input and Output (Col A-F)

Later: Determine Actions Taken (ultimately linked to EHR-S FM functions and conformance criteria) (Col G)

Event Step	Actor	Actor Role	Event	Data Req	Functional Requirements	
Eveni Step	ACIOI	ACIOI ROIE	Event	Input(s)		Action(s)
1-N	Organization, individual or software/device	(at this step)	Description	Data/records required to initiate or inform Event	or updated during	Task, act or process step(s) undertaken during Event
Scenario 1 [f	ollows]					
1						
2						
3						
4						
5						
6						
7						
Scenario 2 [f	ollows]	1	I		1	
<u> </u>						

Planning and Tasks

Focus	Tasks	Who
4. EHR-S FM	 Review Immunization Related Functions, Names, Statements, Descriptions and Conformance Criteria including Sections CP.6.2 and CPS.6.2 Add/modify functions/criteria as needed 	Mark Janczewski and
5. EHR-S FM	 Review ALL sections, functions and conformance criteria relevant to immunizations CP – Care Provision CPS – Care Provision Support AS – Administrative Support POP – Population Health Support RI – Record Infrastructure TI – Trust Infrastructure Add/modify functions/criteria as needed 	Mark Janczewski and

Planning and Tasks

Focus	Tasks	Who
6. PHR-S FM	 Review Immunization Related Functions and Criteria Add/modify functions/criteria as needed 	John Ritter, HL7 PHR WG
7. Data Objects and Elements	 Identify Sources: FHIM, CIMI, FHIR, HL7 Immunization DAM and IG, IIP Specify data requirements by reference 	
8. Testing	Recommend characteristics of testable criteria	Mario Hyland, David Tao and
9. EHR-S & Registries	Establish functional requirements for general purpose registry	Floyd Eisenberg MD, CIC WG and

Contact

- Gary Dickinson
 - Director, Healthcare Standards, CentriHealth
 - Co-Chair, HL7 EHR Work Group
 - gary.dickinson@ehr-standards.com
- Mark Janczewski MD
 - Co-Chair, HL7 EHR Work Group
 - mark.janczewski@verizon.net

Related Materials follow

Broad-Based Core Functionality

- Facilitates software-enabled support for individual health and provision of healthcare
- Across care settings: acute, ambulatory, emergent, same day, longterm/post acute, home health...
- Supports both business and clinical domains
 - Describes capture/management of provider business and clinical record
- Enables implementation of policy and best practice
- Specifies functions for safety, security and privacy

EHR-S FM R2

- Captures core functions/criteria from EHR-S FM R1-based FPs
- R2 Record Infrastructure captures RM-ES FP R1
- R2 profiled for Meaningful Use 2011 and 2014
 - 2015 Edition in development

Focused Functionality = Profile

Whereas the Functional Model (FM) specifies EHR system functions across many domains, a Functional Profile (FP):

- Is based on requirements of a particular domain, region, service/specialty or care setting supported by EHR systems;
- Extends and specializes EHR-S functions and conformance criteria;
- May be tailored to US and/or international realm requirements.
- See Functional Profile List.

Functional Profile Development

The FP Development process:

- Identifies discrete EHR-S FM functions and conformance criteria applicable to that domain (immunization);
- Adds specific EHR system functions and conformance criteria where there are identified gaps

Then, the FP:

- Is balloted by HL7 as a US realm or <u>international</u> standard, either informative or <u>normative</u>;
- After approval by consensus ballot, is published;
 - HL7 IP is free to non-members 90 days post publication;
- May be used as the basis for EHR system conformance claims (by vendors, by provider implementers);
- May be used as the basis for criteria in EHR system certification or inspection programs;
- May be promoted for adoption by ISO.

Profile Development Process

Typical steps, some in parallel:

- Identify lead(s), Include FP veterans
- Scope project, Develop HL7 Project Scope Statement and Get project approval (HL7 EHR WG, SSD SD, TSC)
- Schedule teleconferences, Make announcement
- Gather SME team members, including international folks
- Review previous FP(s)
- Do environmental scan, Find sources and references
- Identify functions/criteria not captured in core EHR-S FM
- Develop FP content
- Learn then use the FM/FP tool, Prepare ballot draft
- Consensus ballot, Reconcile, repeat if needed
- Approve, Publish, Publicize

Tooling Support for FMs and FPs

- Based on Sparx Enterprise Architect 10 and up
- Supports EHR-S FM Releases (starting with R2)
 - Develop, ballot, reconcile, publish, maintain
- Supports R2 Functional Profile Development
 - From base FM and from other FPs
 - Develop, ballot, reconcile, publish, maintain
- Supports R2 Language Translation
 - See National Program List
- Next Stage: Capture/manage PHR-S FM R1

Looking Forward

EHR-S FM on FHIR!

- HL7 FHIR = Fast Health Interoperable Resources
 - New, widely-promoted, HL7 "Standard" data container
 - Built on current Web and mobile app technologies
 - Addition (or ultimate successor?) to HL7 Version 2/3 messages, HL7 CDA/CCDA documents (also data containers)
 - Balloted/published as HL7 Draft Standard, 2nd Edition, Sep 2015
- FHIR Resources are data containers (objects), with elements
- FHIR Resource instances may be:
 - Transient (single exchange only)
 - Persistent (native) data objects in source (or any) system

- For exchange, FHIR Resource instances may be:
 - Queried then *pulled* from source system: e.g., via RESTFUL APIs
 - At trigger events, pushed to receiver system

Objective: To show how EHR-S FM R2 requirements are fulfilled in FHIR implementation(s)

Starting with R2 Record Infrastructure

EHR-S FM/FPs and FHIR

Req'ts Fulfilled in Implementation

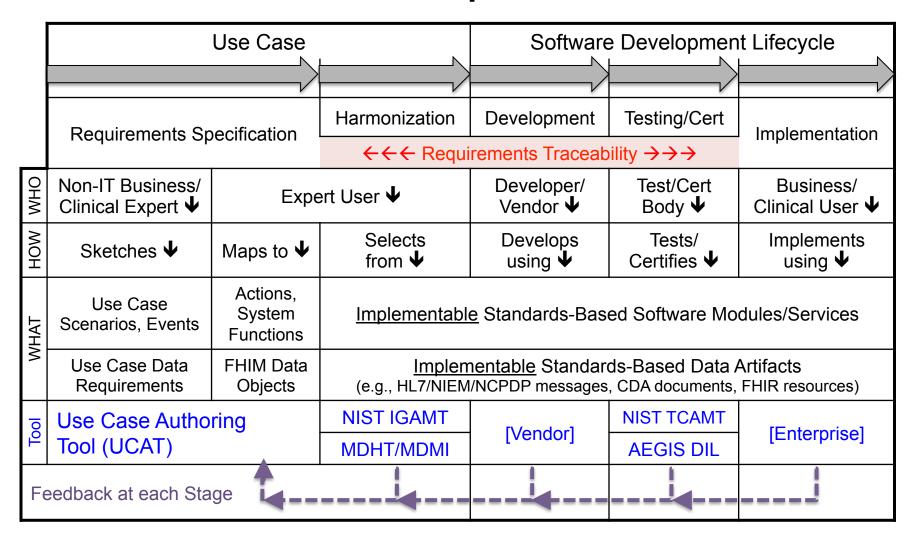
EHR-S FM/FP specifies Ψ		FHIR specifies Ψ
Functional + Data Requirements	Fulfilled in →	Implementable Resources
 EHR Record Management: Record Entries – Lifespan, Lifecycle Events Tracking Who did What When Where and Why 	Fulfilled in →	FHIR <u>AuditEvent</u> + <u>Provenance</u> Resources, starting with Record Entry origination/retention (initial lifecycle event) http://hl7.org/fhir/2016Sep/ehrsrle/ehrsrle.html
 Immunization FP Long Term Care FP Behavioral Health FP Other FPs 	Fulfilled in →	Relevant FHIR Resources such as: <u>Assessment, CarePlan,</u> <u>DiagnosticOrder, Goal, Immunization, ImmunizationRecommendation, Observation, ReferralRequest</u>

Known National Programs using EHR-S FM

Nation	Language	Lead(s), if known	Contact	Status/Use
Australia	Frantiala	Queensland Health	maniana natar@amail.com	Complete
Australia	English	Peter MacIsaac	macisaac.peter@gmail.com	Queensland Ambulatory EHR Adoption Program
Brazil	Portuguese	Beatriz Leao	beatriz.leao@zilics.com.br	R1.1 Translation: Complete R2 Translation: Partial (in progress) EHR Developers Reference
Canada	English	Canada Health Infoway Grant Gillis	ggillis@coachorg.com	On Hold Provincial EHR Adoption Programs
Denmark	Danish	TBD		Preliminary
Finland	Finnish	Juha Mykkanen	juha.mykkanen@uef.fi	Preliminary
France	French	Francois Macary	francois.macary@sante.gouv.fr	R2 Translation: Partial (awaiting resources) National EHR Adoption Program
Italy	Italian	Stephano Lotti Giorgio Cangioli	slotti@invitalia.it giorgio.cangioli@gmail.com	R2 Translation: Complete Regional EHR Adoption Program Underway
Ireland	English	General Practice Information Technology (GPIT) Group Brian O'Mahony	bom@iol.ie	Complete GP EHR System Certification Program
Japan	Japanese	Noriko Inaoka, PhD Hideshige Hasegawa	inaoka@jp.ibm.com hide.hasegawa@mx8.ttcn.ne.jp	R1.1 Translation: Complete R2 Translation: Partial (in progress) EHR System Developers Reference
Korea	Korean	Center for Interoperable EHR (CiEHR) II Kon Kim	ikkimgg@gmail.com	R1 Translation: Complete Public and National University Hospital EHR Framework
Netherlands	Dutch	William & Anneke Goosen Robert Stegway	agoossen@results4care.nl robert.stegwee@capgemini.com	R2 Translation: Partial (in progress) Behavioral Health FP and Others
New Zealand	English	Peter Jordan	peter.jordan@patientsfirst.org.nz	Preliminary National EHR Adoption Program
Norway	Norwegian	Line Saele Andraessen	line.sele@nasjonalikt.no	R2 Translation: Partial (in progress) National EHR Adoption Program
Mexico	Spanish	José Manuel Castañeda Casas Marco Pardavé	castaneda.jmanuel@gmail.com mapardave@gsprogress.us	R1.1 Translation: Complete R2 Translation: Preliminary National EHR Adoption Program
Sweden	Swedish	Helen Broberg	Helen.Broberg@skane.se	R2 Translation: Partial (in progress) Regional EHR Adoption Program
US	English	Various		Original EHR-S Certification Program Basis for CCHIT Certification Criteria

Reference – S&I Simplification

From Sketch to Implementation



Issues and Discussion Points

- Normative or DSTU?
- US (specific) or International (more general)?
- Filling EHR-S Functionality Gap as US MU has ventured more toward "interoperability"
- PHR-S FM Profile?
- Relationship with Other Projects
 - CIC: EHR-S and Any Registry
- Data requirements: How best to reference?
 - Specify SHALL/SHOULD/MAY at data element level?