# HL7 EHR – Immunization Functional Profile (IFP) Project

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Mark Janczewski, MD
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## 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
- <a href="http://wiki.hl7.org/index.php?title=EHR Immunization Functional Profile">http://wiki.hl7.org/index.php?title=EHR Immunization Functional Profile</a>

Contributor/Participant	Status	Contribution	Readiness Individual(s)		Tool	
·		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	
		HL7 EHR-S Public Health Functional Profiles x 9	•	John Ritter, Hetty Khan,		
Health Level Seven (HL7) Electronic	HL7	Joint w/HL7 Public Health/Emergency Response WG	Ready	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		
. ,		Immunization History Conformance Profile	Ready			
HL7 Clinical Information Modeling Initiative (CIMI) WG	Confirmed	CIMI Immunization Clinical Model(s)	Ready?	Galen Mulrooney Steve Hufnagel		
AEGIS (HL7 Testing Partner)	Confirmed	Immunization Test Cases	Ready	Mario Hyland	AEGIS DIL	
ALGIS (IIL7 Testing Farther)	Commined	Developers Integration Lab (DIL)	Ready	Matthew Gereke	ALGIS DIL	
US Office of National Coordinator		Standards & Interoperability (S&I) Framework	Ready			
	Observer	Use Case Methodology		Steve Posnack		
		S&I Use Case Requirements Template	Ready		UCAT, MS Word	
Federal Health Information Model	Confirmed	FHIM Immunization Model(s)	Ready	Galen Mulrooney	FHIM Tool	
(FHIM)	Commined	Immunization Data Requirements	·	•		
		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		Ready	Rob Snelick	NIST IGAMT	
		Test Case Authoring & Management Tool	Ready		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)	
S Agency for Health Research and Invited		US Health Information Knowledgebase (USHIK)	Ready	Matthew Chudy Chuck Penoza	USHIK Tool	
US Centers for Disease Control and Prevention (CDC) Immunization Team	Observer	bserver Immunization Integration Program (IIP) Immunization Test Cases		Craig Newman		
Chickasaw Nation Industries (CNI)	Interested	petad		Floyd Eisenberg MD	NIST IZ Tool	
HIMSS	Invited	Immunization Integration Program (IIP)  • Use Case Scenarios, Work Flows	Boody	Joyce Sensmeier	NIST TCAMT	
ICSA Labs (HIMSS Testing Partner)	Interested	Use Case Scenarios, Work Flows     Immunization Data Requirements	Ready	David Tao	1	
TOOK Labs (Tillioo Testing I dittle!)	Interested	minanization bata requiremente		Michelle Knighton		

## 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)	
Testing (then Certification)	AEGIS, ICSA	DIL (AEGIS)	
Implementation	(Providers, users)		

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

Focus	Tasks	Who
3. Use Cases	<ul> <li>Identify Sources:</li> <li>HL7 Immunization DAM use cases</li> <li>CNI/HIMSS Immunization Integration Program (IIP) work flows</li> <li>Others, as discovered or submitted</li> <li>For each scenario, extract use case scenarios and events, including:</li> <li>Event steps, event description, actor, roles, inputs and outputs</li> <li>Follow pattern described in Use Case Scenario Worksheet</li> <li>Link to EHR-S FM functions and related criteria</li> <li>Add/modify functions/criteria as needed</li> </ul>	Gary Dickinson Julia Chan 

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

Focus	Tasks	Who
6. PHR-S FM (FUTURE)	<ul> <li>Review Immunization Related Functions and Criteria</li> <li>Add/modify functions/criteria as needed</li> </ul>	John Ritter, HL7 PHR WG
7. Data Objects and Elements	<ul> <li>Identify Sources: FHIM (CLIM), CIMI, FHIR, HL7 Immunization DAM and IG, IIP</li> <li>Map IIP Data Requirements to FHIM (CLIM)</li> </ul>	Galen Mulrooney? Steve Hufnagel?
8. Testing	Recommend characteristics of testable criteria	Mario Hyland, David Tao
9. EHR-S & Registries	Establish functional requirements for general purpose registry	CIC WG

## 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

### 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

## **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

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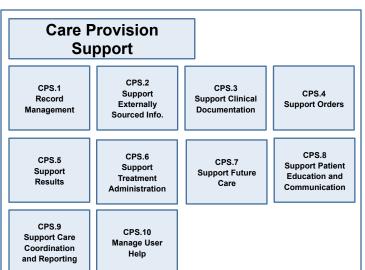
### EHR-S FM R2

- 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

### **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

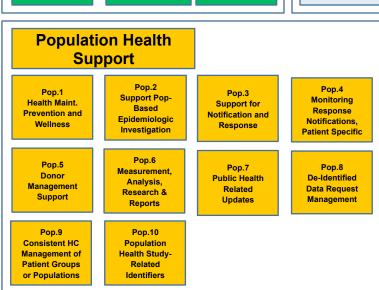
Lifespan

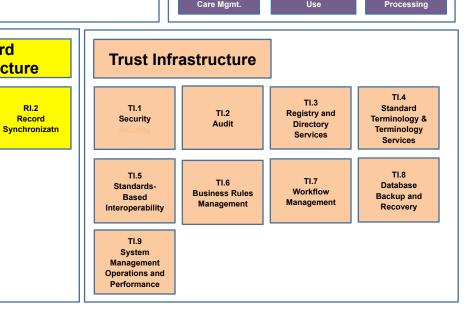
RI.3

Record Archive

and Restore







## 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.

## 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	<u> </u>	⊃opı		on Hoport	<u>ealth</u>	1	Ad	<u>mini</u>	strative	Supp	oort
R-S FM	Record Infrastructure  Describes basics of EHR System managing an EHR Record  Record Management, Lifespan, Lifecycle, Audit																
田	Record Management, Lifespan, Lifecycle, Audit  Trust Infrastructure  Identity, Accountability, Authorization, Authentication, Access Control, Audit																

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

		Prior Profile			I	1
Functional Profile Subject	SDO(s)	Based on	R2 Lead(s)	HL7 WGs	Contributing Organization(s)	R2 Status
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	CMS	Published
Meaningful Use (2015 Edition)	HL7	R2	Michael Brody DPM		CIVIS	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	•			•
Public Health - Early Hearing	1					
Detection & Intervention			_		CDC/NCHS, PHDSC, PHII	Published
Public Health - Chronic Diseases				EHR, PHER		
Cancer Surveillance						
Public Health - Lab Interactions			Hetty Khan			
(Orders and Results)	HL7		John Ritter			
Public Health - Occupational			Michelle Williamson		CDC/NCH3, PHD3C, PHII	
Disease, Injury, and Fatality						
Public Health - Health Statistics						
Public Health - Deep Vein						
Thrombosis / Pulmonary Embolism						
Public Health - Birth Defects						
Public Health - Adverse Events						
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 ZUDI)6	HL7  -	7-EHR -	mmunization Functiona	PProfile Proie	FDA? ONC?	Preliminary

## 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 <b>Ψ</b>		FHIR specifies <b>Ψ</b>
Functional + Data Requirements	Fulfilled in →	Implementable Resources
<ul> <li>EHR Record Management:</li> <li>Record Entries – Lifespan,</li> <li>Lifecycle Events</li> <li>Tracking Who did What</li> <li>When Where and Why</li> </ul>	Fulfilled in →	FHIR <u>AuditEvent</u> + <u>Provenance</u> Resources, starting with Record Entry origination/retention (initial lifecycle event) <a href="http://hl7.org/fhir/2016Sep/ehrsrle/ehrsrle.html">http://hl7.org/fhir/2016Sep/ehrsrle/ehrsrle.html</a>
<ul> <li>Immunization FP</li> <li>Long Term Care FP</li> <li>Behavioral Health FP</li> <li>Other FPs</li> </ul>	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

