Interoperable Proof of Vaccination

Implementation Approaches Across Europe

HL7 Europe

2/25/2021

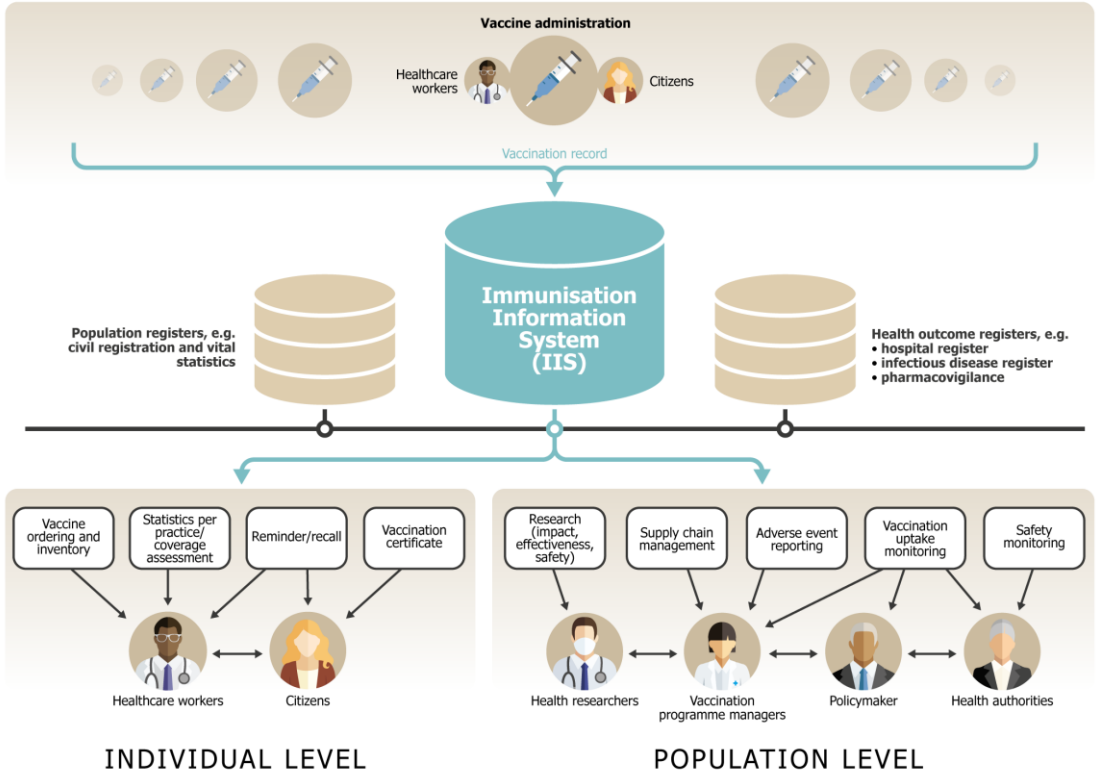
WELCOME!

Agenda

- State of play with Vaccination Standards in Europe
- Vaccination Standardization Efforts across Europe
  - Three countries in detail
  - Panel with short presentations from seven more countries
  - Discussion
- Closing Remarks

Immunization Information Flow

High level aspects of an IIS – possible system integration and outputs



from: ecdc.europa.eu, Designing and implementing an immunisation information system. Stockholm: ECDC; 2018

Vaccination data topics related to COVID-19

proof of vaccination for medical purposes

proof of vaccination and test results for other purposes
(travel, access, employment,…)

public health and research

What is the state of play of implementations across Europe?

- National activities
- eHN
  - Guidelines proof of vaccination for medical purposes - basic interoperability elements, published 2021-01-27
    - minimum dataset, unique identifiers, trust framework
  - Subgroup evaluating options for "secure vaccination certificates"
- WHO
  - close collabaration with EU-activities

HL7 Europe

HL7 Affiliate Organizations in 22 European countries

- Role of Standards?

- Role of Affiliates?

How the HL7 Affiliates contribute

collaborations

decision-making

vendor engagement

VACCINATION STANDARDIZATION EFFORTS NORWAY

LINE SAELE

SYSVAK – THE VACCINE REGISTRY

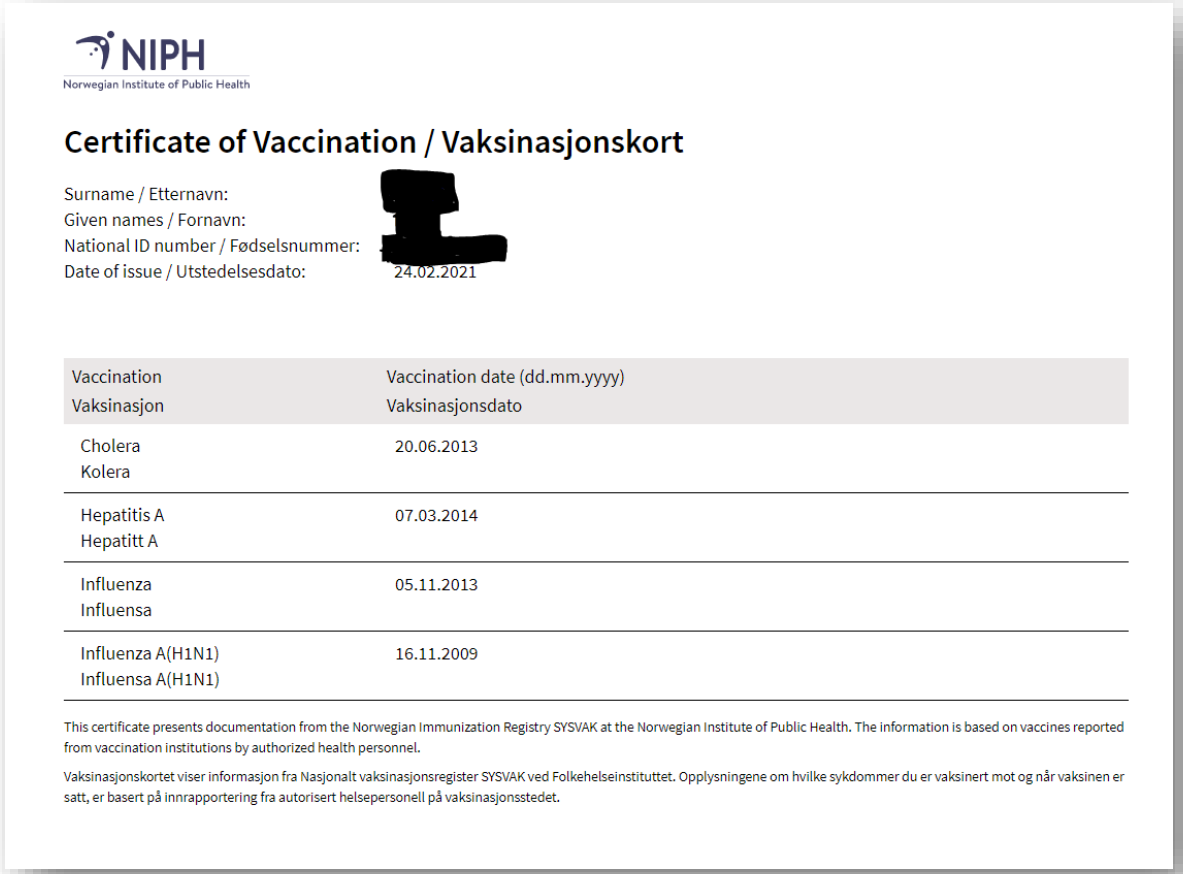
SYSVAK

- Mandatory registration of all vaccinations in Norway
- Started as a registration of all vaccinations for kids from 1976
- From 2009, all vaccines are registered into SYSVAK
- SYSVAK is owned by the Norwegian Institute for Public Health
- Proprietary standard used for reporting to the Registry

Patient portal – helsenorge.no

- The patient portal in Norway gives the patient an overview over more and more of their EHR.
- In helsenorge.no, the patient can also view what registries they are a part of
- Among these SYSVAK
- Already possibility for printing an overview of all your vaccines (but not for only one).

Certificate of Vaccination



NIPH
Norwegian Institute of Public Health

Certificate of Vaccination / Vaksinasjonskort

Surname / Etternavn: [redacted]
Given names / Fornavn:
National ID number / Fødselsnummer:
Date of issue / Utstedelsesdato: 24.02.2021

Vaccination Vaksinasjon	Vaccination date (dd.mm.yyyy) Vaksinasjonsdato
Cholera Kolera	20.06.2013
Hepatitis A Hepatitt A	07.03.2014
Influenza Influensa	05.11.2013
Influenza A(H1N1) Influensa A(H1N1)	16.11.2009

This certificate presents documentation from the Norwegian Immunization Registry SYSVAK at the Norwegian Institute of Public Health. The information is based on vaccines reported from vaccination institutions by authorized health personnel.

Vaksinasjonskortet viser informasjon fra Nasjonalt vaksinasjonsregister SYSVAK ved Folkehelseinstituttet. Opplysningene om hvilke sykdommer du er vaksinert mot og når vaksinen er satt, er basert på innrapportering fra autorisert helsepersonell på vaksinasjonsstedet.

Vaccine proof for COVID-19

- The Department of Health has asked NIPH, Norsk Helsenett and the Directorate of ehealth to respond to the demands for a Vaccine proof
- Adjusting to the EU Guidelines – step 1
- Digital solution part of step 1

Validation of the Vaccine proof

- Not established any standard of how to share the Vaccination proof with other interested parties and how to validate the authentication of the proof
  - What data should be shared?
  - Level of trust
- It is not within the policy of SYSVAK to be used as a validation from other sectors than healthcare
  - Important to keep the trust of the population for our healthcare registres

WHO Position

- “At the present time, it is WHO’s position that national authorities and conveyance operators should not introduce requirements of proof of COVID-19 vaccination for international travel as a condition for departure or entry, given that there are still critical unknowns regarding the efficacy of vaccination in reducing transmission. In addition, considering that there is limited availability of vaccines, preferential vaccination of travellers could result in inadequate supplies of vaccines for priority populations considered at high risk of severe COVID-19 disease. WHO also recommends that people who are vaccinated should not be exempt from complying with other travel risk-reduction measures.” https://www.who.int/news-room/articles-detail/interim-position-paper-considerations-regarding-proof-of-covid-19-vaccination-for-international-travellers

Considerations

- What about those who cannot be vaccinated?
- What about the children?
- What about the right to choose to be vaccinated?
- What about those who have to wait for vaccination/can’t afford vaccination?

- Expectations from the private sector
- Opening up the society

Volunteer vs pressure

- When are you voluntarily showing your healthcare data, and when does it become a pressure?
  - Keeping your job?
  - Going to a concert?
  - Travelling?

We need proof of:

- Vaccination
- Testing
- Immunization

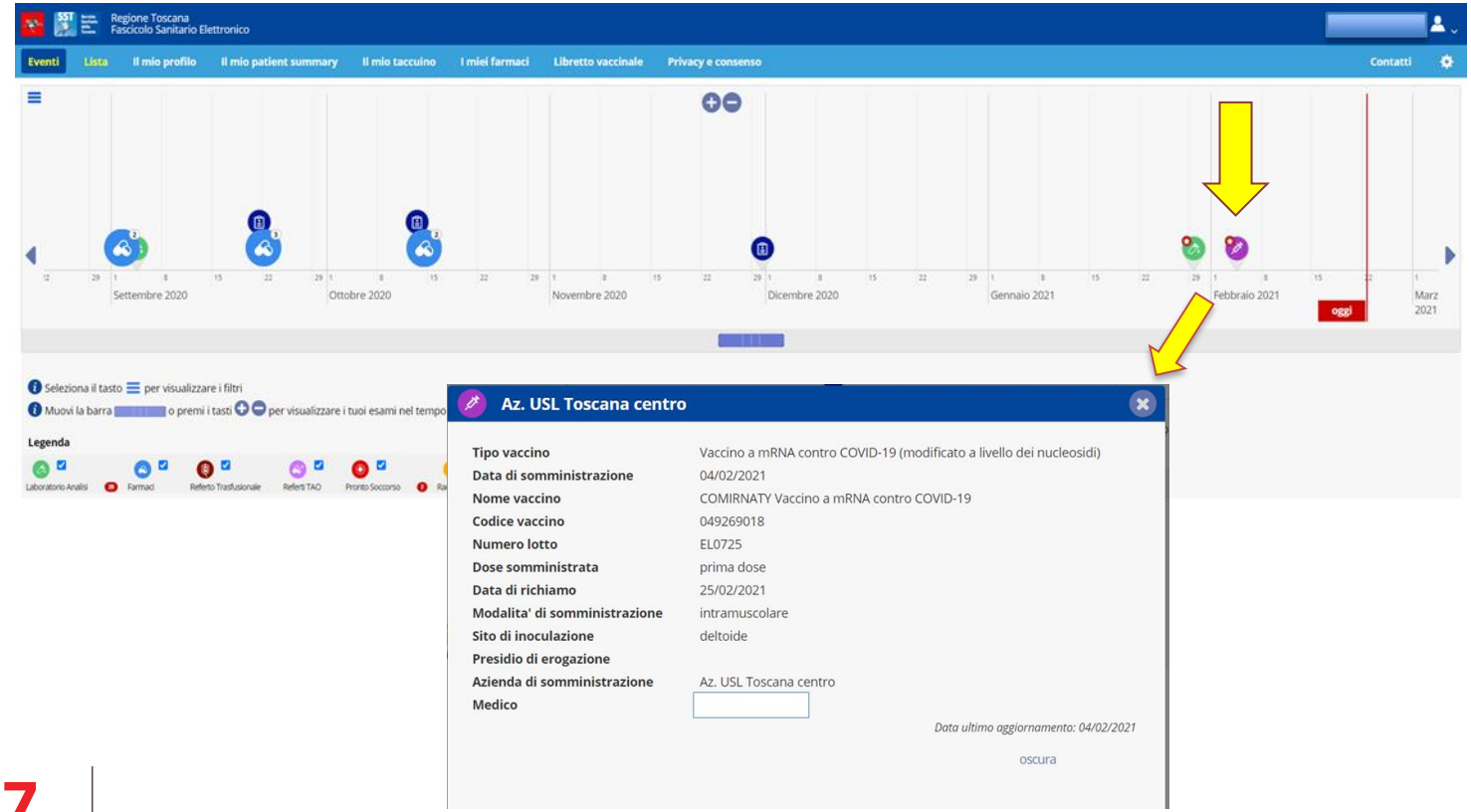
GIORGIO CANGIOLI
CHAIR HL7 ITALY, TECH LEAD HL7 EUROPE

Regionalized Health Care

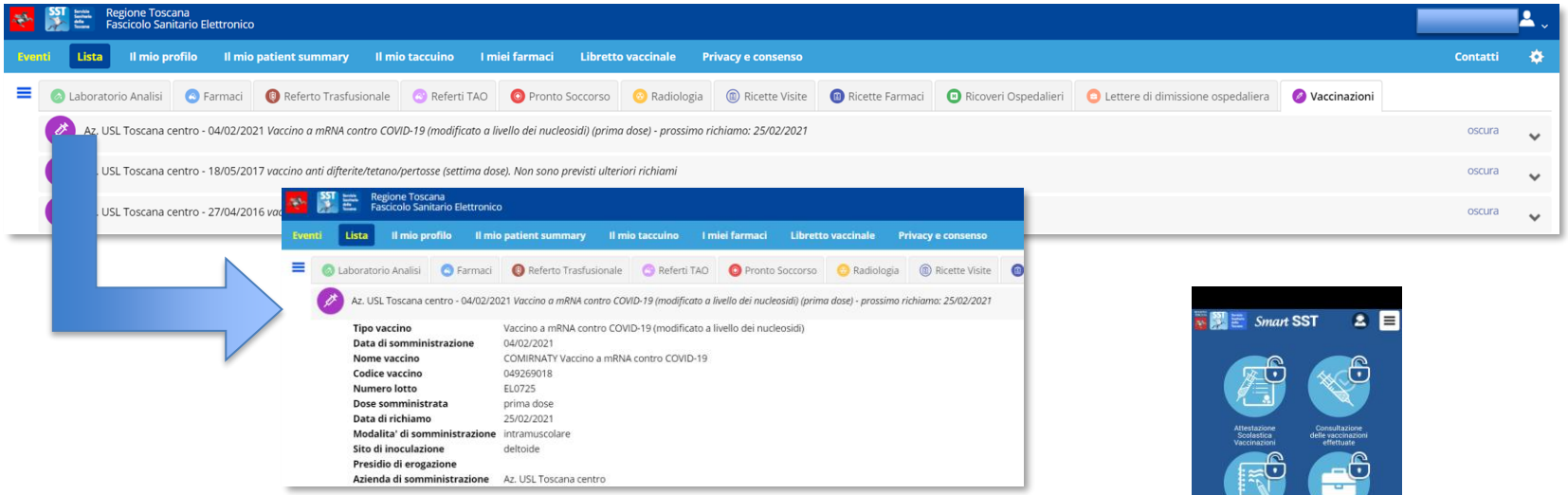
- **National** policies, projects and funds.

- Health care organized on a **regional** basis
  - 21 Health Systems
  - (Potentially) 21 different regional EHR systems and registries

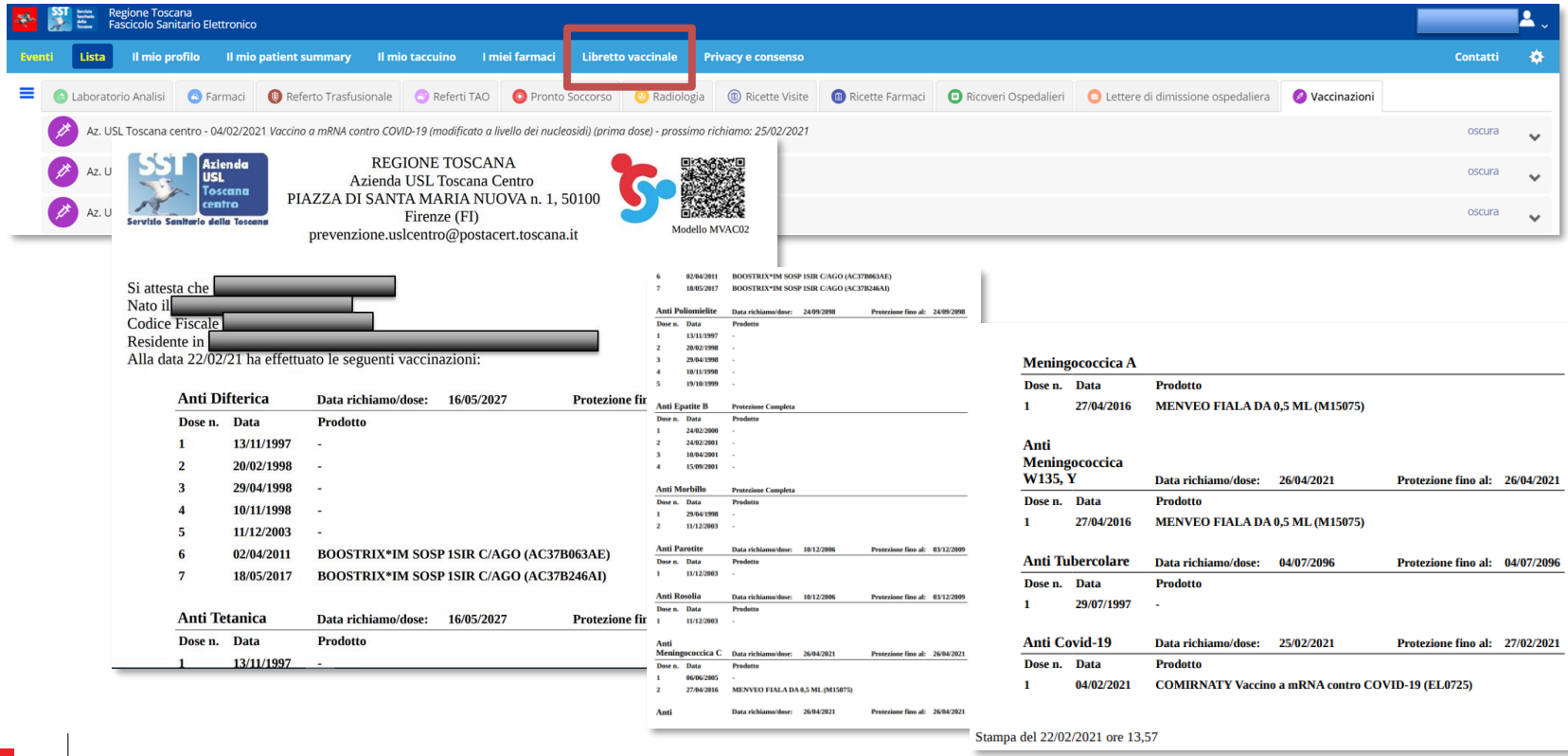
Regional system: example



Regional system: example



Regional system: example

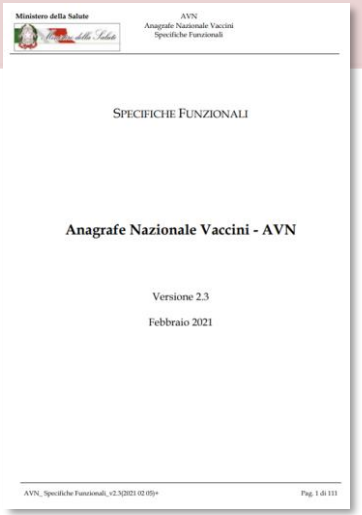


The National Context

Anagrafe Nazionale Vaccini

- Established by law on Sept 2018

National Vaccination Registry


Ministero della Salute

AVN
Anagrafe Nazionale Vaccini
Specifiche Funzionali

SPECIFICHE FUNZIONALI

Anagrafe Nazionale Vaccini - AVN

Versione 2.3

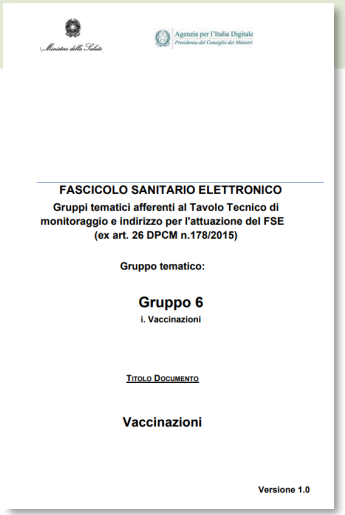
Febbraio 2021

AVN_Specifiche Funzionali_v2.3(2021.02.05)+ Pag. 1 di 111

Fascicolo Sanitario Elettronico

- Interoperability among regional EHR-systems

National EHR


Ministero della Salute

Agenzia per l'Italia Digitale
Presidenza del Consiglio dei Ministri

FASCICOLO SANITARIO ELETTRONICO

Gruppi tematici afferenti al Tavolo Tecnico di monitoraggio e indirizzo per l'attuazione del FSE (ex art. 26 DPCM n.178/2015)

Gruppo tematico:

Gruppo 6

i. Vaccinazioni

TITOLO DOCUMENTO

Vaccinazioni

Versione 1.0

The National Context

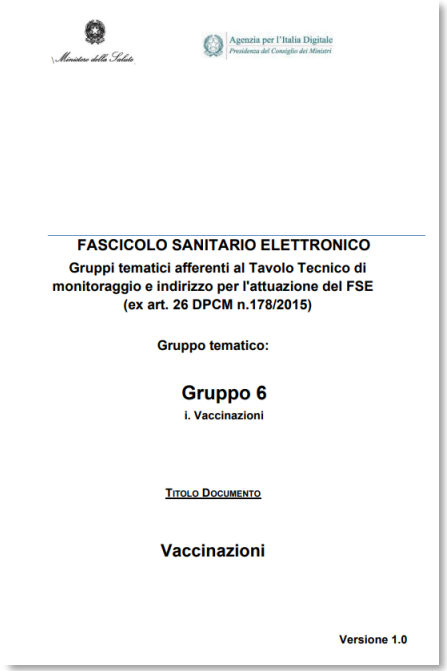
Anagrafe Nazionale Vaccini

- Defines the minimal set of data that each regional registry shall support
- By law, only **aggregated and anonymized data** can be disclosed
- Regional-national bidirectional communication
- Non-standard XML format

Fascicolo Sanitario Elettronico

- Initially conceived for sharing of **document** and data
- Support the exchange of **CDA R2** documents
- Two specifications under ballot
  - Single vaccination event [Scheda vaccinale]
  - Vaccination Summary (Certificate) [Certificato vaccinale]

The National Context



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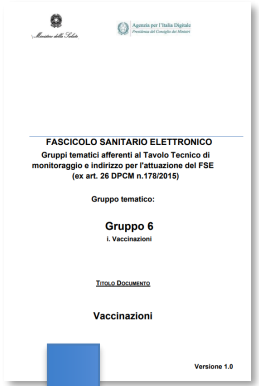
Fascicolo Sanitario Elettronico

The Vaccine Certificate

Fascicolo Sanitario Elettronico



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Gruppo tematico:

Gruppo 6

i. Vaccinazioni

Titolo Documento

Vaccinazioni

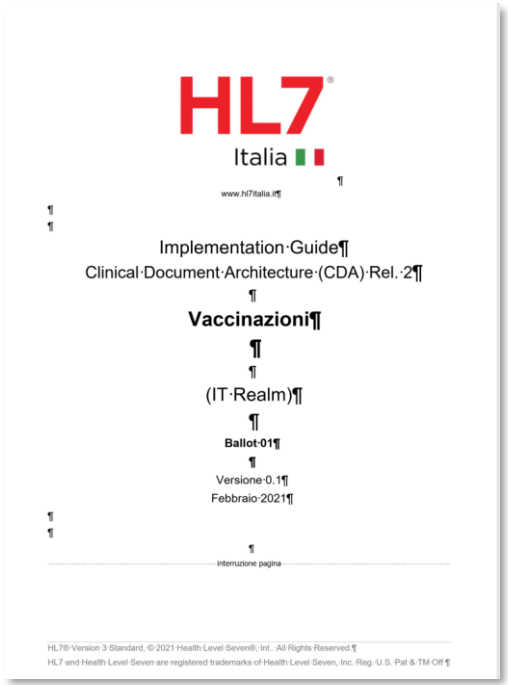
Versione 1.0

Data Set

Sezione	Elemento	Contenuto Informativo	Descrizione	obbligatorietà	Cardinalità	Testo libero / codificato	Codifica	Fonte di riferimento	Note
Somministrazione	Dati Somministrazione	Vaccinazione		obbligatorio	[1..N]	codificato			Malattia/e per la quale è stata effettuata la vaccinazione (caso1) oppure per la quale viene documentata l'esenzione (caso2)
Caso 1: Somministrazione Vaccino[3]									
Somministrazione	Dati Somministrazione	Formulazione Vaccino		obbligatorio	[1..1]	testo libero			Mono componente o combinazione (bambini-adulti) somministrata, ad es. HBV,DTaP-

[3] Gli elementi che compongono il Caso 1 - sono avvalorati nel caso di Somministrazione Vaccino; nel caso in cui vi sia Esonero/omissione o differimento (Caso2) tutti gli elementi descritti nel Caso 1 sono vuoti

CDA Specifications



HL7 Italia

www.hl7italia.it

Implementation Guide
Clinical Document Architecture (CDA) Rel. 2

Vaccinazioni

(IT Realm)

Ballot 01

Versione 0.1
Febbraio 2021

Interruzione pagina

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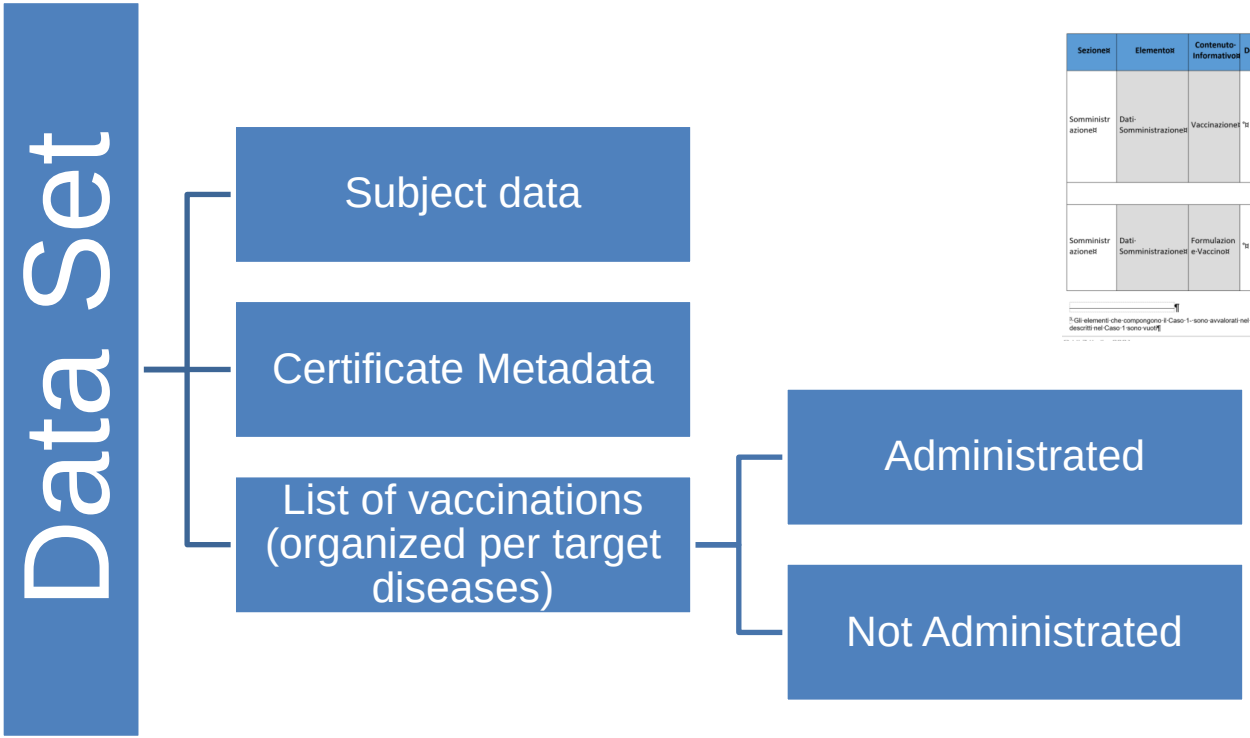
The Vaccine Certificate

Fascicolo Sanitario Elettronico

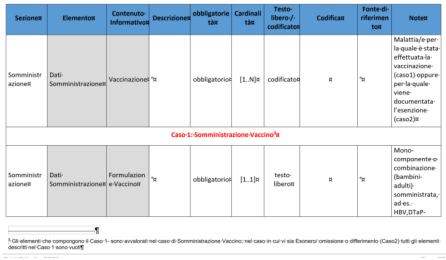


Sezione¤	Elemento¤	Contenuto-Informativo¤	Descrizione¤	obbligatorietà¤	Cardinalità¤	Testo-libero-/-codificato¤	Codifica¤	Fonte-di-riferimento¤	Note¤
Somministrazione¤	Dati-Somministrazione¤	Vaccinazione¤	"¤	obbligatorio¤	[1..N]¤	codificato¤	¤	"¤	Malattia/e-per-la-quale-è-stata-effettuata-la-vaccinazione-(caso1)-oppure-per-la-quale-viene-documentata-l'esenzione-(caso2)¤
Caso-1:-Somministrazione-Vaccino[3]¤									
Somministrazione¤	Dati-Somministrazione¤	Formulazione-Vaccino¤	"¤	obbligatorio¤	[1..1]¤	testo-libero¤	¤	"¤	Mono-componente-o-combinazione-(bambini-adulti)-somministrata,-ad-es.-HBV,DTaP-

[3]-Gli-elementi-che-compongono-il-Caso-1.-sono-avvalorati-nel-caso-di-Somministrazione-Vaccino;-nel-caso-in-cui-vi-sia-Esonero/-omissione-o-differimento-(Caso2)-tutti-gli-elementi-descritti-nel-Caso-1-sono-vuoti¶

The Vaccine Certificate

Fascicolo Sanitario Elettronico



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Somministrazione¤	Dati-Somministrazione¤	Formulazione-Vaccino¤	¤	obbligatorio¤	[1..1]¤	testo-libero¤	¤	¤	Mono-componente-o-combinazione-(bambini-adulti)-somministrata,-ad-es.-HBV,DTaP-

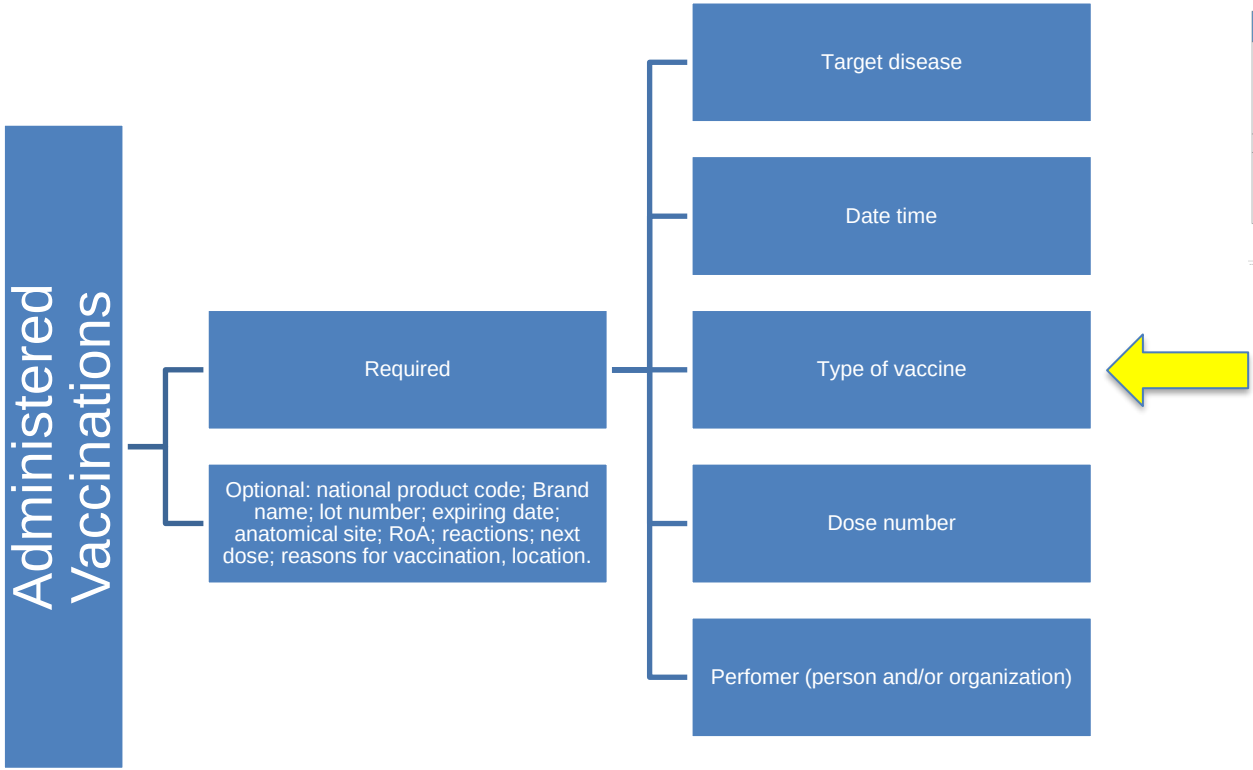
¹ Gli elementi che compongono il Caso 1- sono avvalorati nel caso di Somministrazione Vaccino; nel caso in cui vi sia Esonero/ omissione o differimento (Caso2) tutti gli elementi descritti nel Caso-1 sono vuoti¶

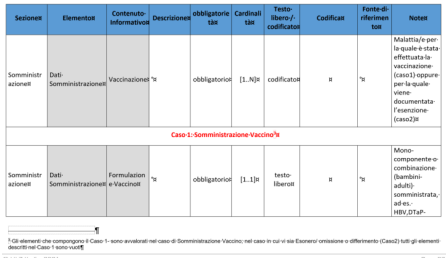
Certificate Metadata

- Creation date
- Attester data (who & when)
- Sub-regional health organization (Azienda Sanitaria)

The Vaccine Certificate

Fascicolo Sanitario Elettronico





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Somministrazione¤	Dati-Somministrazione¤	Formulazione-Vaccino¤	¤	obbligatorio¤	[1..1]¤	testo-libero¤	¤	¤	Mono-componente o combinazione (bambini-adulti)-somministrata, ad es. HBV,DTaP-

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The Vaccine Certificate

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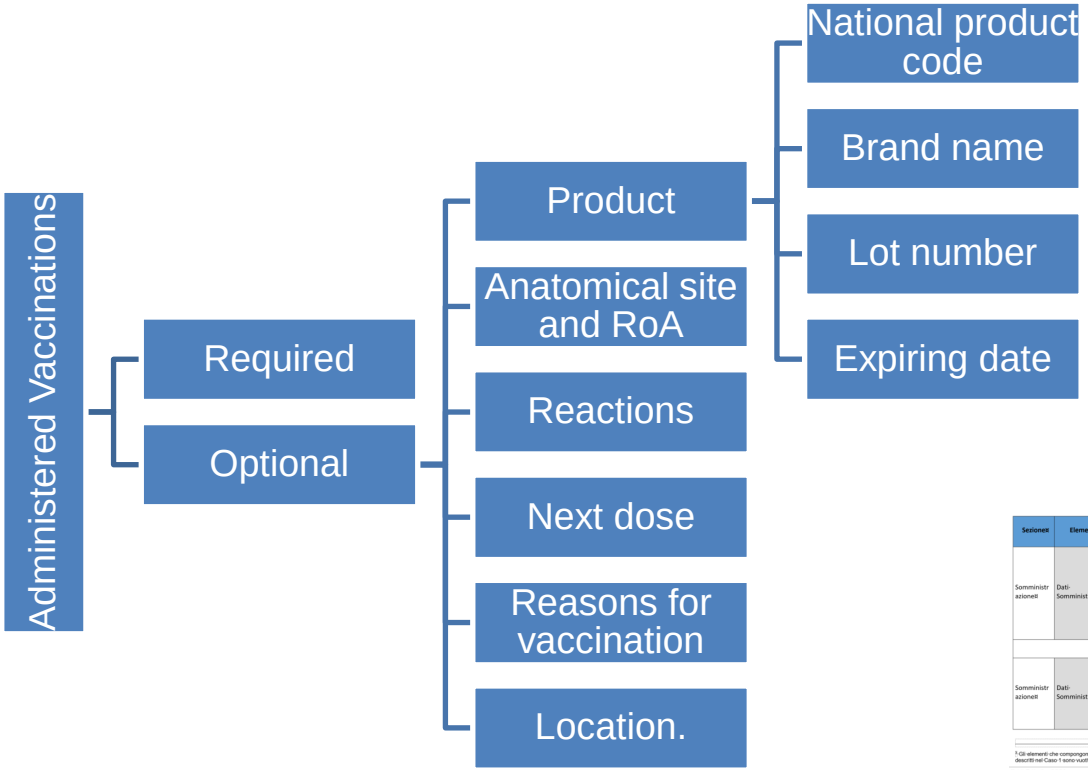

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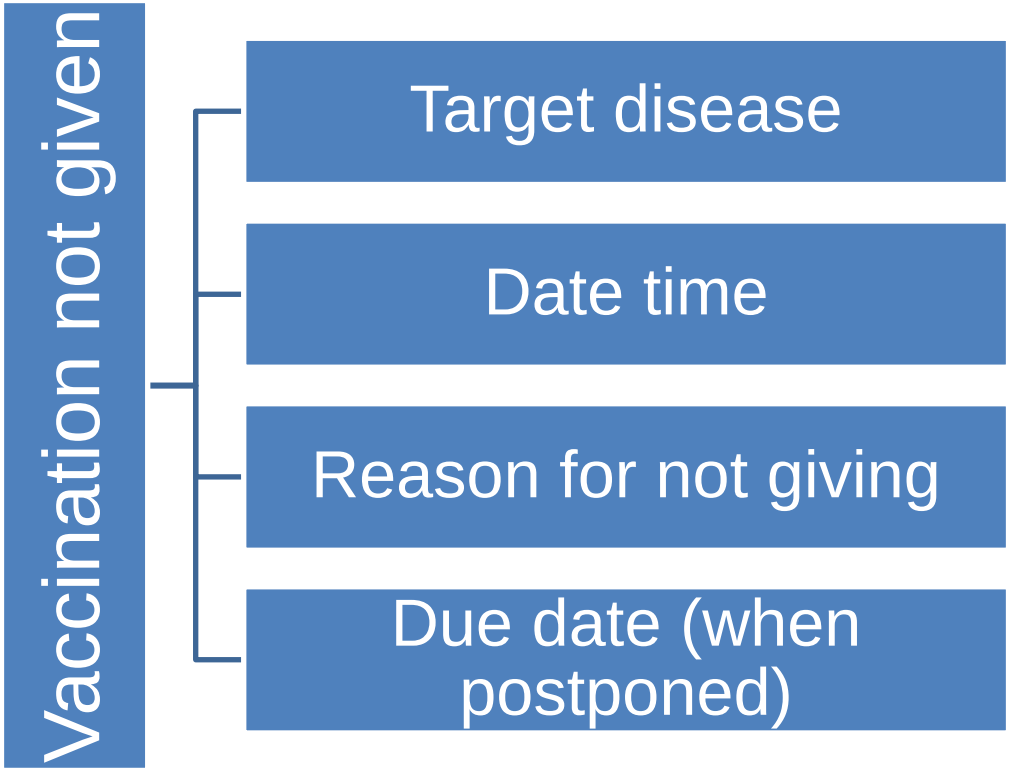
Caso-1:-Somministrazione-Vaccino²¤									
Somministrazione¤	Dati-Somministrazione¤	Formulazione-Vaccino¤	"¤	obbligatorio¤	[1..1]¤	testo-libero¤	¤	"¤	Mono-componente-o-combinazione-(bambini-adulti)-somministrata,-ad-es.-HBV_DTaP-

² Gli elementi che compongono il Caso 1- sono avvalorati nel caso di Somministrazione Vaccino; nel caso in cui vi sia Esonero/ omissione o differimento (Caso2) tutti gli elementi descritti nel Caso 1 sono vuoti¶

The Vaccine Certificate

Fascicolo Sanitario Elettronico



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² Gli elementi che compongono il Caso 1- sono avvalorati nel caso di Somministrazione Vaccino; nel caso in cui vi sia Esonero/ omissione o differimento (Caso2) tutti gli elementi descritti nel Caso 1 sono vuoti¶

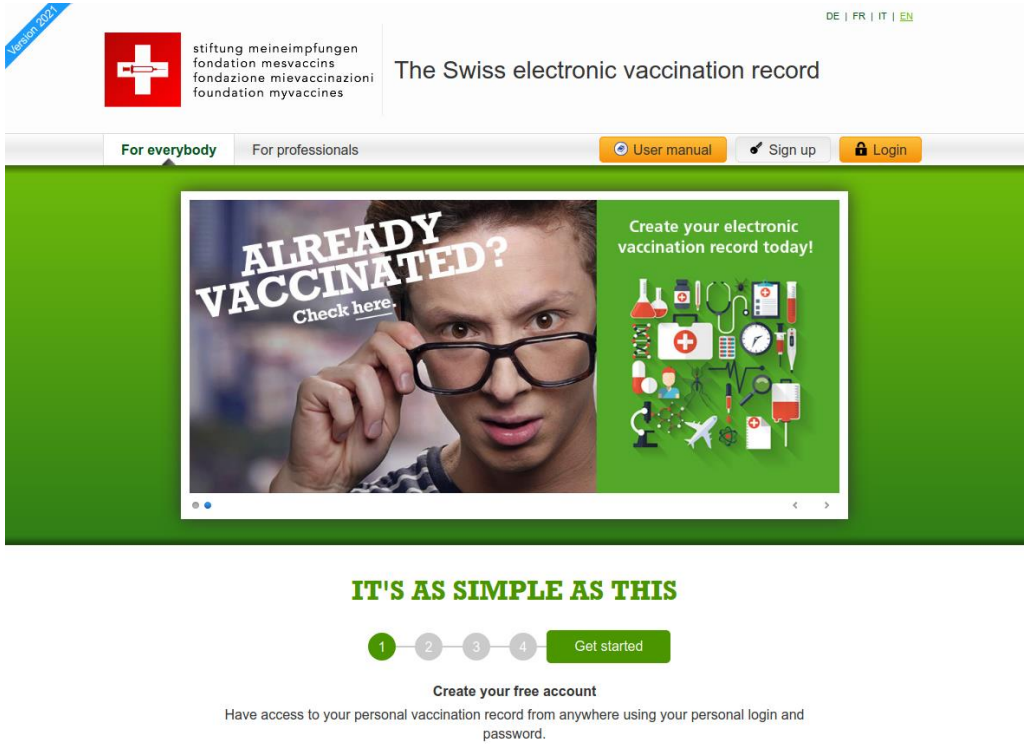
Personal Considerations

- (FSE specifications) space for refinements. It is in ballot, not yet implemented
- Synergies and overlaps between the Fascicolo and the National registry
- Mapping and coverage with the EU and WHO core data set to be further analyzed
- Contribute to the ISO TS 5384 – “Categorial Structure and Data Elements for the Identification and Exchange of Immunization Data”
- ..extend to HL7 FHIR ?

EVACCINATION IN SWITZERLAND
ROELAND LUYKX, HL7 SWITZERLAND

THE SWISS VACCINATION PATIENT RECORD

Web-based Platform for Vaccination Records

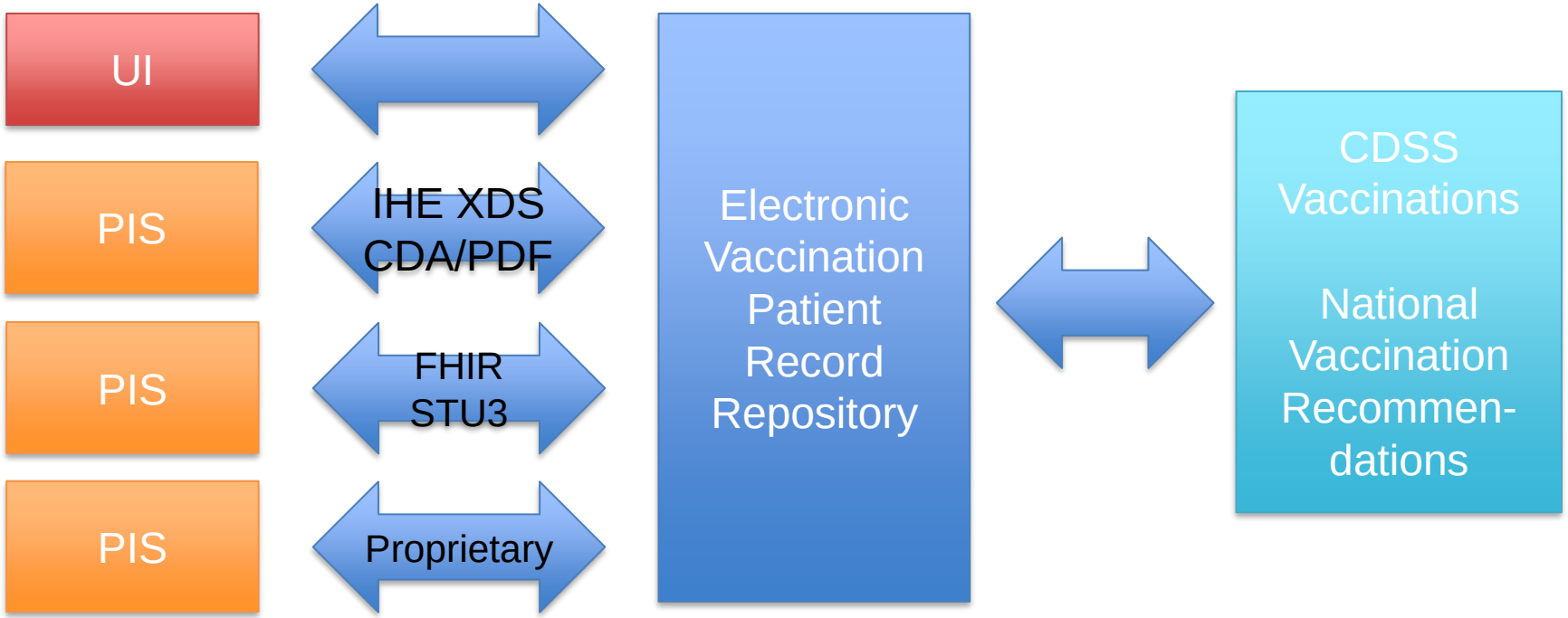


- Online since April 2011
- CDSS for Vaccinations
- 360’000 Records
- 12’000 HCP
- 4 Mio. Vaccination Entries
- Free for PAT and HCP

Web-based Platform for Vaccination Records

- Private initiative by Aerztekasse, Arpage and Viavac
- Stiftung meineimpfungen (Foundation) since 2015
- Expert Professor MD Claire-Anne Siegrist-Julliard
  - Head of the Vaccinology Center HUG
  - Swiss Advisory Committee for Immunizations
  - Strategic Advisory Group of Experts on Immunization (SAGE/WHO)
  - President of the Foundation Board meineimpfungen.ch
- Supported by the FOPH

Architectural Overview



THE SWISS EXCHANGE STANDARDS FOR IMMUNIZATION

Standards for Immunization in Switzerland

- 2016 eVACD V1 based on CH-CDA-I (art-decor)
- 2020 eVACD V2.1 based on CH-CDA-II (R2) (art-decor)
- 2021 IG ch-vacd on FHIR R4 (in informative ballot) (fhir.ch)
- 2021 FHIR <-> CDA Mapping (in development)

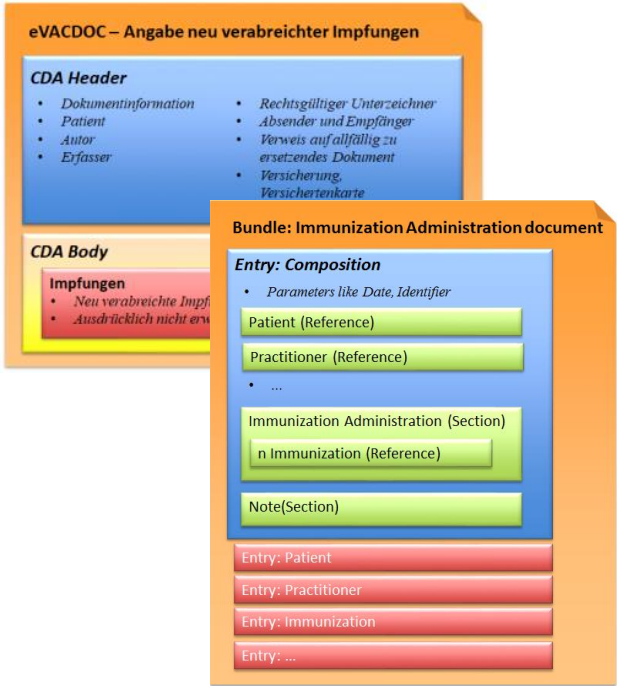
These standards are published by eHealth Suisse (GOV near ORG) in co-work with HL7 Switzerland

CDA/FHIR Immunization Document Types

Five different Document Types in CDA and FHIR

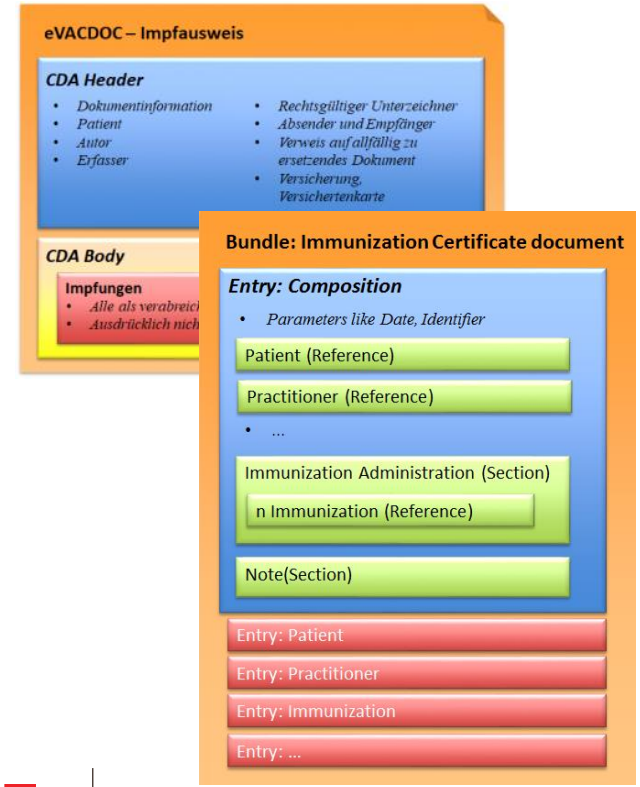
1. Immunization Administration
2. Immunization Certificate
3. Vaccination Record (Complete data set)
4. Immunization Recommendation Request
5. Immunization Recommendation Response

CDA/FHIR Immunization Administration



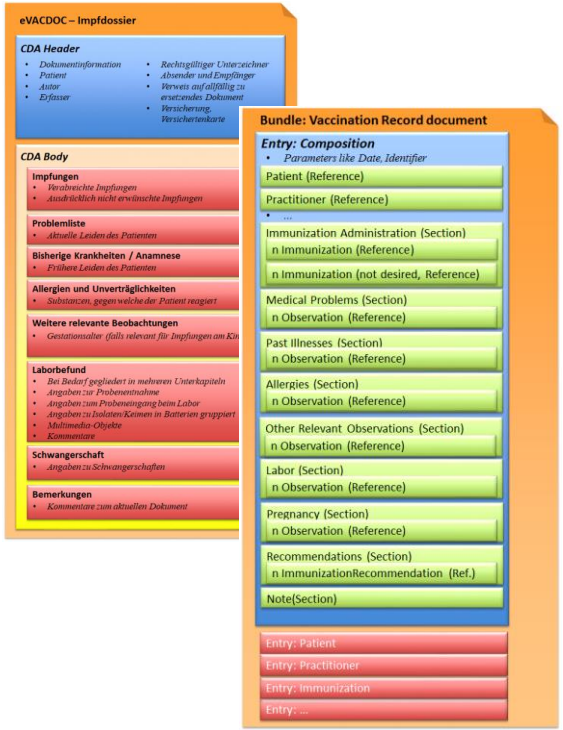
- Patient
- Practitioner
- Organization
- Section with immunization entries (applied)
- …

CDA/FHIR Immunization Certificate



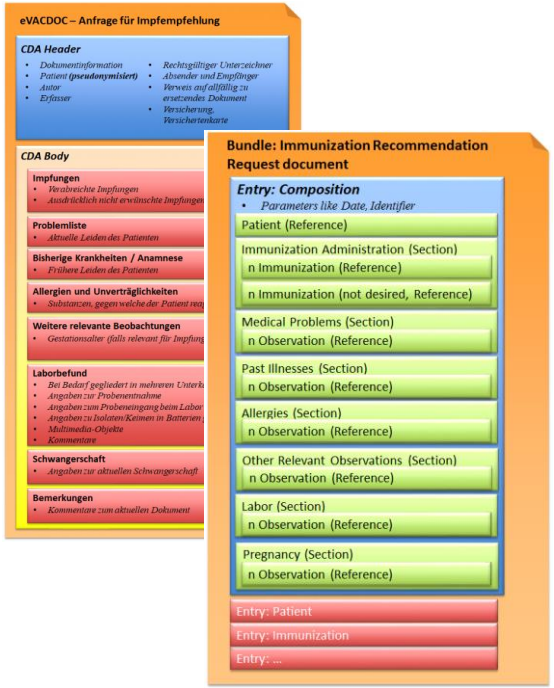
- Patient
- Practitioner
- Organization
- Section with immunization entries
  - Applied
  - Not desired
- …

CDA/FHIR Vaccination Record (Complete Set)



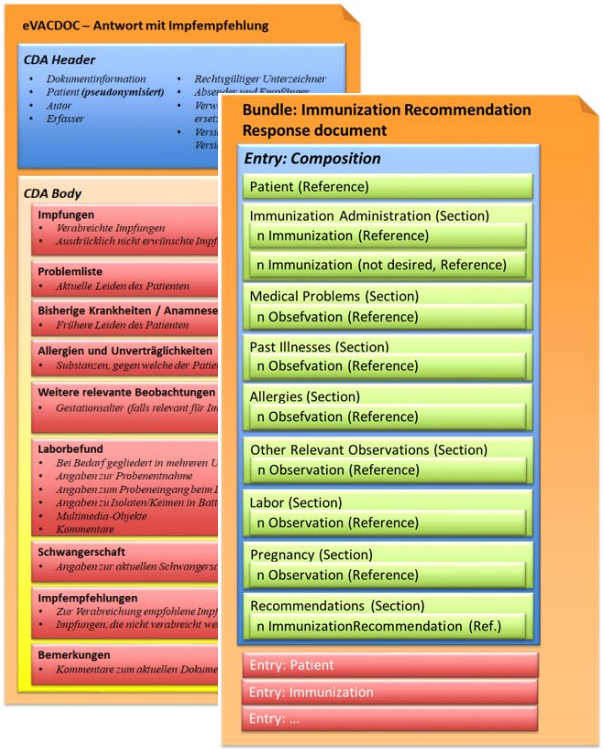
- Patient,Practitioner,Organization
- Sections
  - Immunization Entries
  - Undergone Illnesses for Immunization
  - List of Problems (Medical/Exposition Risks)
  - Allergies/Intolerances
  - Laboratory/Serology
  - Pregnancy (Date of delivery)
  - Recommendations

CDA/FHIR Immun. Recom. Request



- Pseudonymized Person Data
- Sections
  - Immunization Entries
  - Undergone Illnesses for Immunization
  - List of Problems (Medical/Exposition Risks)
  - Allergies/Intolerances
  - Laboratory/Serology
  - Pregnancy (Date of delivery)

CDA/FHIR Immun. Recom. Response



- Pseudonymized Person Data
- Sections
  - Immunization Entries
  - Undergone Illnesses for Immunization
  - List of Problems (Medical/Exposition Risks)
  - Allergies/Intolerances
  - Laboratory/Serology
  - Pregnancy (Date of delivery)
  - Recommendations

Final

- Austria adopted the CDA upon the Swiss specifications
- Integration into the Swiss EPR
- FHIR API based on R4

Thanks to all people in Switzerland who made the story of electronic vaccination data exchange with standards possible!

VACCINATION & IMMUNIZATION INTEROPERABILITY: IMPLEMENTATION IN BELGIUM

JOSÉ COSTA TEIXEIRA

Interoperability at Regional and Federal level

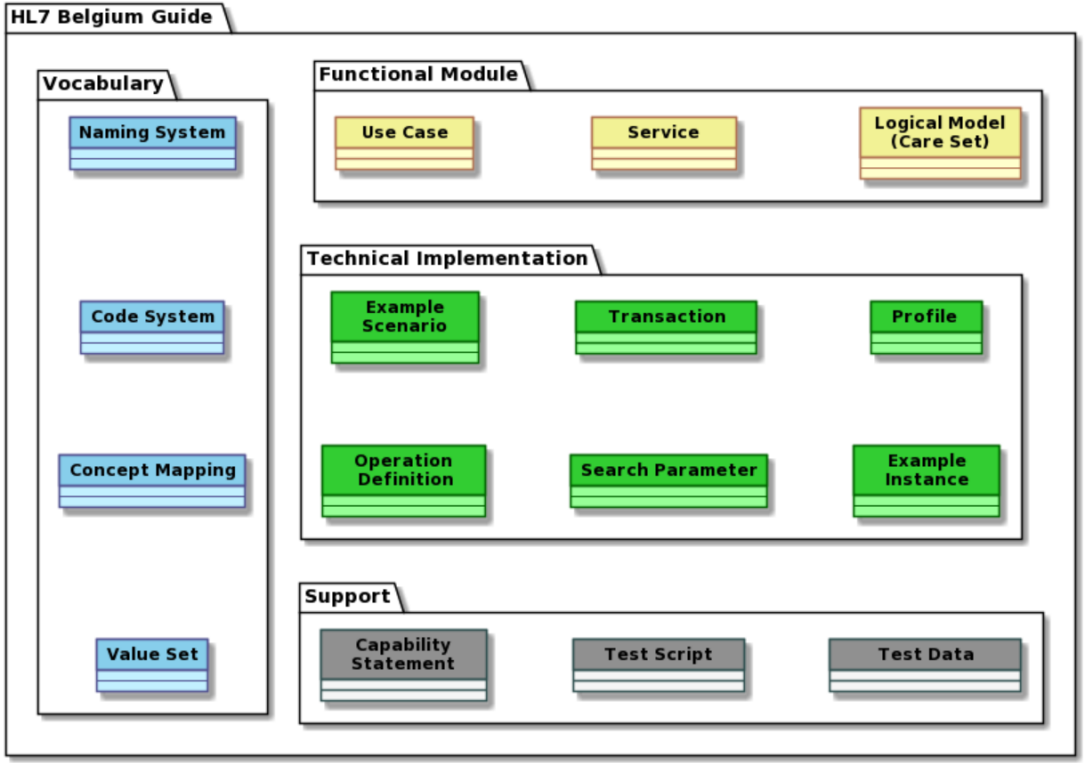
- Different regions, different languages, different responsibilities and goals
    - Each region has their “vault”
    - Provides a range of requirements
- One federal standard (KMEHR) - similar to CDA
    - Implies attention to compatibility
- Adoption of FHIR in the federal roadmap since 2019
    - Driven by projects (community or government)
    - With a clear (optional) path to official publication - FHIR specifications can become federal standards
        - Requires a Roadmap and an Operating Model

COVID vaccination

- Belgian FHIR vaccination profiles were finished mid 2020
- The Belgian standard existed, and vaults supported it

Decision to not force a FHIR transition during the pandemic

Way of Working



Start with a functional agreement

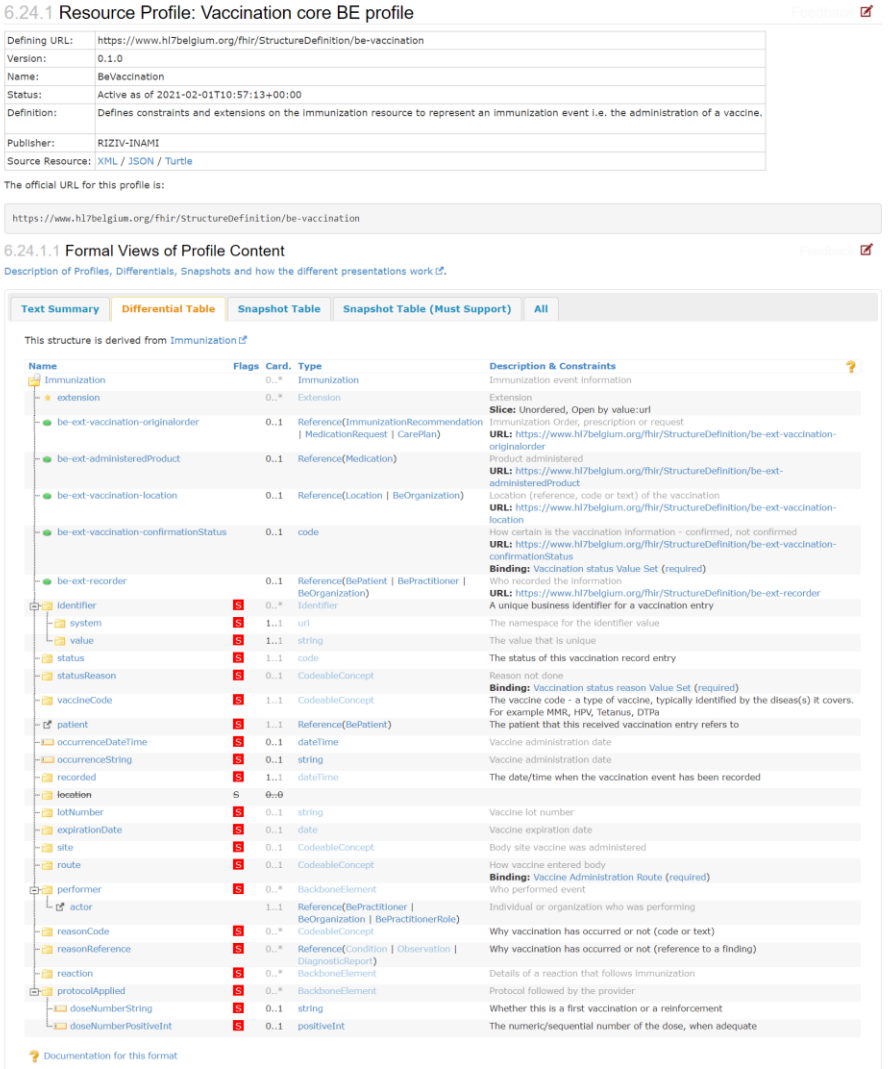
- Use cases
- Logical data model
- Vocabulary needs

Then, technical implementation

- FHIR profiles

Belgian artifacts

- Scope: **IMMUNIZATION** event
  - Logical model
  - Discussions, extensions and changes to FHIR
  - One profile, 4 extensions, 4 ValueSets, NamingSystems…
  - Many examples
  - COVID examples survived first test



6.24.1 Resource Profile: Vaccination core BE profile

Defining URL:	https://www.hl7belgium.org/fhir/StructureDefinition/be-vaccination
Version:	0.1.0
Name:	BeVaccination
Status:	Active as of 2021-02-01T10:57:13+00:00
Definition:	Defines constraints and extensions on the immunization resource to represent an immunization event i.e. the administration of a vaccine.
Publisher:	RIZIV-INAMI
Source Resource:	XML / JSON / Turtle

The official URL for this profile is:

https://www.hl7belgium.org/fhir/StructureDefinition/be-vaccination

6.24.1.1 Formal Views of Profile Content

Description of Profiles, Differentials, Snapshots and how the different presentations work.

Text Summary | Differential Table | Snapshot Table | Snapshot Table (Must Support) | All

This structure is derived from Immunization

Name	Flags	Card.	Type	Description & Constraints
Immunization		0..*	Immunization	Immunization event information
extension		0..*	Extension	Extension **Slice:** Unordered, Open by value:url
be-ext-vaccination-originalorder		0..1	Reference(ImmunizationRecommendation | MedicationRequest | CarePlan)	Immunization Order, prescription or request **URL:** https://www.hl7belgium.org/fhir/StructureDefinition/be-ext-vaccination-originalorder
be-ext-administeredProduct		0..1	Reference(Medication)	Product administered **URL:** https://www.hl7belgium.org/fhir/StructureDefinition/be-ext-administeredProduct
be-ext-vaccination-location		0..1	Reference(Location | BeOrganization)	Location (reference, code or text) of the vaccination **URL:** https://www.hl7belgium.org/fhir/StructureDefinition/be-ext-vaccination-location
be-ext-vaccination-confirmationStatus		0..1	code	How certain is the vaccination information - confirmed, not confirmed **URL:** https://www.hl7belgium.org/fhir/StructureDefinition/be-ext-vaccination-confirmationStatus **Binding:** Vaccination status Value Set (required)
be-ext-recorder		0..1	Reference(BePatient | BePractitioner | BeOrganization)	Who recorded the information **URL:** https://www.hl7belgium.org/fhir/StructureDefinition/be-ext-recorder
identifier	S	0..*	Identifier	A unique business identifier for a vaccination entry
system	S	1..1	url	The namespace for the identifier value
value	S	1..1	string	The value that is unique
status	S	1..1	code	The status of this vaccination record entry
statusReason	S	0..1	CodeableConcept	Reason not done **Binding:** Vaccination status reason Value Set (required)
vaccineCode	S	1..1	CodeableConcept	The vaccine code - a type of vaccine, typically identified by the diseas(s) it covers. For example MMR, HPV, Tetanus, DTPa
patient	S	1..1	Reference(BePatient)	The patient that this received vaccination entry refers to
occurrenceDateTime	S	0..1	dateTime	Vaccine administration date
occurrenceString	S	0..1	string	Vaccine administration date
recorded	S	1..1	dateTime	The date/time when the vaccination event has been recorded
~~location~~	S	~~0..0~~		
lotNumber	S	0..1	string	Vaccine lot number
expirationDate	S	0..1	date	Vaccine expiration date
site	S	0..1	CodeableConcept	Body site vaccine was administered
route	S	0..1	CodeableConcept	How vaccine entered body **Binding:** Vaccine Administration Route (required)
performer	S	0..*	BackboneElement	Who performed event
actor		1..1	Reference(BePractitioner | BeOrganization | BePractitionerRole)	Individual or organization who was performing
reasonCode	S	0..*	CodeableConcept	Why vaccination has occurred or not (code or text)
reasonReference	S	0..*	Reference(Condition | Observation | DiagnosticReport)	Why vaccination has occurred or not (reference to a finding)
reaction	S	0..*	BackboneElement	Details of a reaction that follows immunization
protocolApplied	S	0..*	BackboneElement	Protocol followed by the provider
doseNumberString	S	0..1	string	Whether this is a first vaccination or a reinforcement
doseNumberPositiveInt	S	0..1	positiveInt	The numeric/sequential number of the dose, when adequate

Documentation for this format

HL7 Europe

Vaccination certificate

- No new standardisation effort
- Vaccination certification was already required for some activities/services (schools). This is a self-issued declaration.
- Digital interoperability is only by the patient’s summary (KMEHR)

Cooperation

- Discussions with IHE International to ensure international exposure

- Joint discussions with HL7 Public Health – Likely a Gemini project

- Vaccination approach is on the right track.
- Vaccination certificate – we'll learn

VACCINATION STANDARDS: STATUS IN DENMARK

JENS KRISTIAN VILLADSEN
CHAIR, HL7 DENMARK; MEMBER, HL7 EU BOARD OF DIRECTORS

Vaccination certificate is being prepared

- The Ministry of healthcare and the digitalization agency is currently in the preparing phase of the introduction of a digital COVID-19 vaccination certificate passport
- Currently, a paper version exists, available to all vaccinated citizens
- It has not yet been disclosed how the digital version of the passport should be used nor in what form it will be presented
- QR codes containing the data will probably be a part of the solution

State of the (DK) union – in terms of healthcare information standardization

- There has been no widespread use of HL7/IHE standards in Denmark, historically
- CDA and IHE XDS introduced in ~2014
- HL7 FHIR is yet to experience national use
- Major part of healthcare information is (successfully) routed through proprietary services and standards with some exceptions
- A consequence of this probably points to an initial setup where the first danish version of the passport will be tailor fit for danish use only
- Next iterations should adhere to data standards and formats from the proposal of WHO and/or EU commission

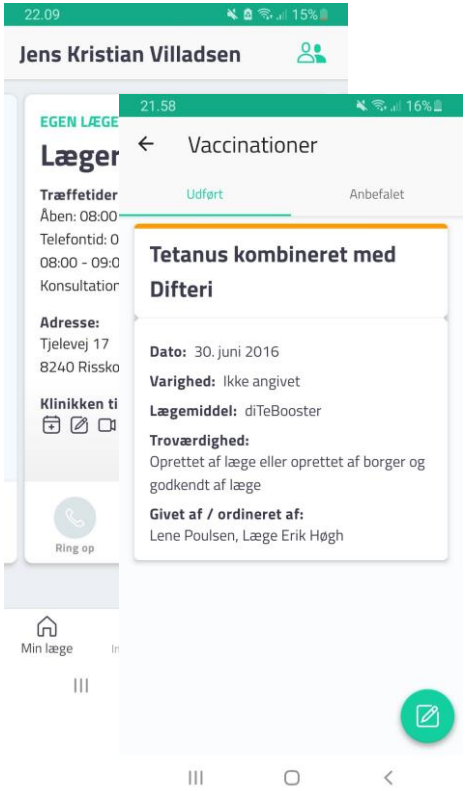
Technically, its an easy task

- Denmark has had central service for all medication and vaccination since ~2014 (Shared Medication Record). In use across all healthcare sectors
- The vaccine information is already accessible to all practitioners and all citizens through the national portal (sundhed.dk) and the national app MyDoctor (Min Læge)
- Not built upon international standards

Accessibility

sundhed.dk

Min Læge



VACCINATION STANDARDS: STATUS IN FINLAND
MIKAEL RINNETMÄKI
FHIR AMBASSADOR, HL7 FINLAND

Kanta Services

FI

- Patient Data Repository
- Patient Portal
- Prescription Service
- Pharmaceutical Database

Based on HL7 v2, CDA2

Kanta PHR for patient-generated health data based on HL7 FHIR

https://www.kanta.fi/en/professionals/what-are-kanta-services

Vaccination Certificate is being prepared

The Ministry of Social Affairs and Health is currently preparing the introduction of a digital COVID-19 vaccination certificate. The certificate would show that the person has been vaccinated against COVID-19.

The certificate would be available in the My Kanta Pages service. In practice, data on COVID-19 vaccinations would be recorded in the My Kanta Pages where people could view their own vaccination data. The certificate could be digital vaccination data, a barcode, a QR code or a combination of these available in the My Kanta Pages and people could display the certificate on their phones or have it printed on paper.

https://stm.fi/-/suomessa-valmistellaan-sahkoista-rokotustodistusta-koronarokotteen-saaneille?languageId=en_US

Implemented by public sector bodies

The Finnish Institute for Health and Welfare (THL) is responsible for the implementation and scheduling of the project.

Finland is closely monitoring international solutions related to vaccination certificates. It will take account of such solutions in its own national project in order to make the Finnish certificate compatible with the international model.

HL7 Finland is not directly involved. THL is a member of HL7 Finland, though.

Challenges in how data is stored in Kanta

Structured format for vaccinations exists since 2016, but not all connected EHRs use it.

THL will guide providers and support vendors in implementations.

Codes for vaccinations exist on the national code server.

https://koodistopalvelu.kanta.fi/codeserver/pages/download?name=2185_1479095915165.xml&pKey=pubfiles0

https://thl.fi/fi/web/tiedonhallinta-sosiaali-ja-terveysalalla/-/koronarokotustietojen-ajantasainen-ja-sujuva-kirjaaminen-hyodyttaa-rokottajia-ja-kansalaisia

https://thl.fi/fi/web/infektiotaudit-ja-rokotukset/tietoa-rokotuksista/rokottamisen-vaiheet/rokotusten-kirjaaminen/koronavirusrokotusten-kirjaaminen-rakenteisesti-potilastietojarjestelmaan

https://www.kanta.fi/web/guest/ammattilaiset/tiedote/-/asset_publisher/HFU2lnkQbmnX/content/koronarokotustodistus-perustuu-kantaan-tallennettuun-tietoon-terveydenhuolto-saa-kohdennetut-ohjeet

VACCINATION STANDARDS: STATUS IN FRANCE
THIERRY DART
ANS, HL7 AFFILIATE

DMP: “Dossier Médical Partagé”

- https://www.dmp.fr/
- PHR: Personal Health Record (Patient centric)

- National document repository (IHE XDS)
- CDA documents
- > 200 Softwares / systems

Vaccination Card

The Ministry of Social Affairs and Health is preparing the introduction of a digital vaccination card (#MyHealth2022)

- **Vaccination card**
  - **National extension of IHE – Immunization Content (HL7 CDA)**
  - **https://esante.gouv.fr/volet-vac-vaccination**
  - **First projectathon in November 2020**

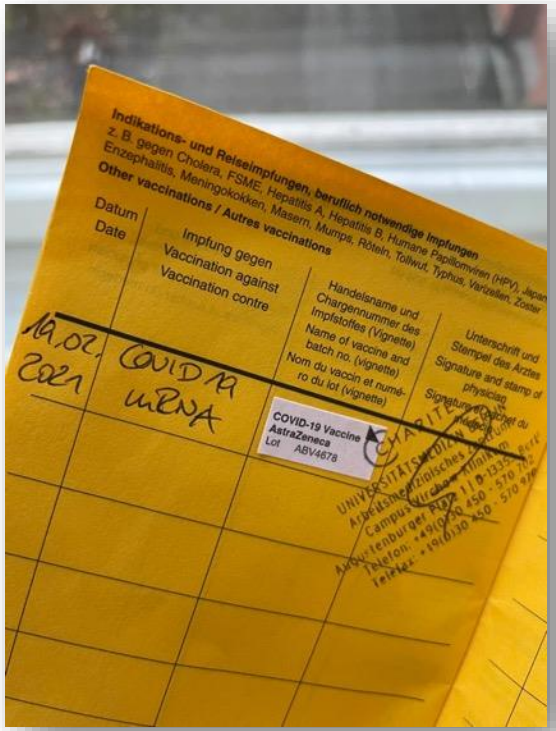
- **Decision support system for immunization recommendation**
  - **FHIR profile**
  - **https://esante.gouv.fr/volet-acces-aux-recommandations-vaccinales**

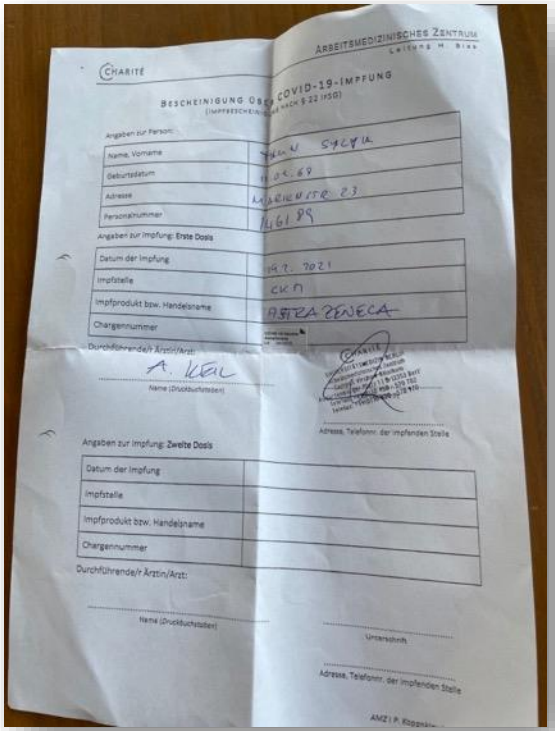
VACCINATION IN GERMANY: DIGITAL SOLUTIONS AND STRATEGY
SYLVIA THUN

Vaccination Standardization Efforts in Germany

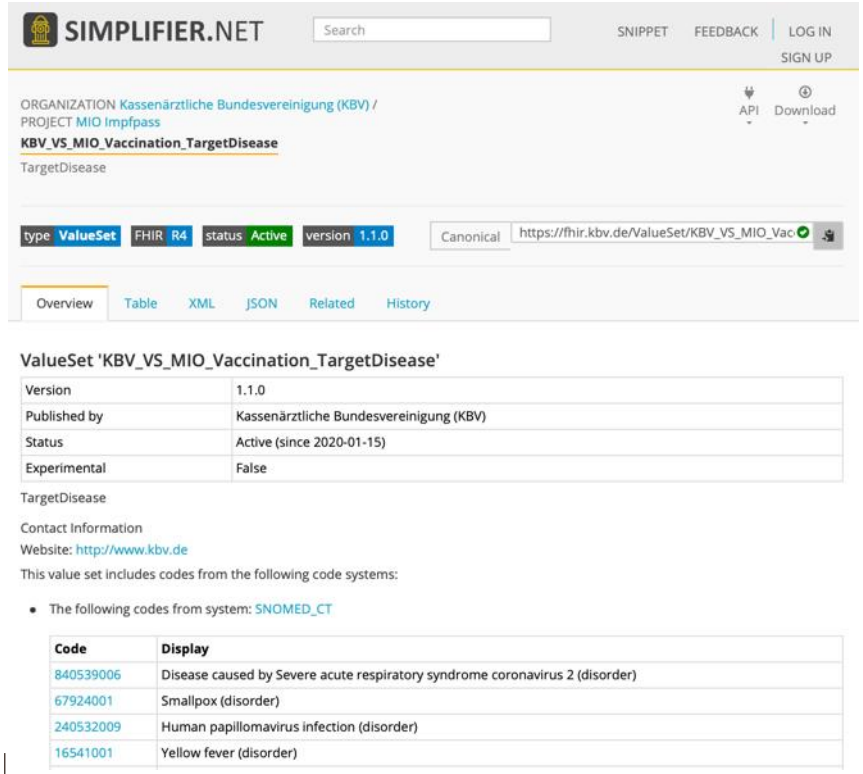
- Vaccination certificate
  - analog
  - digital
- Clinical Trials: GECCO
- Immunization statistics to Robert-Koch-Institute
- Pharmacovigilance

Certificate of vaccination



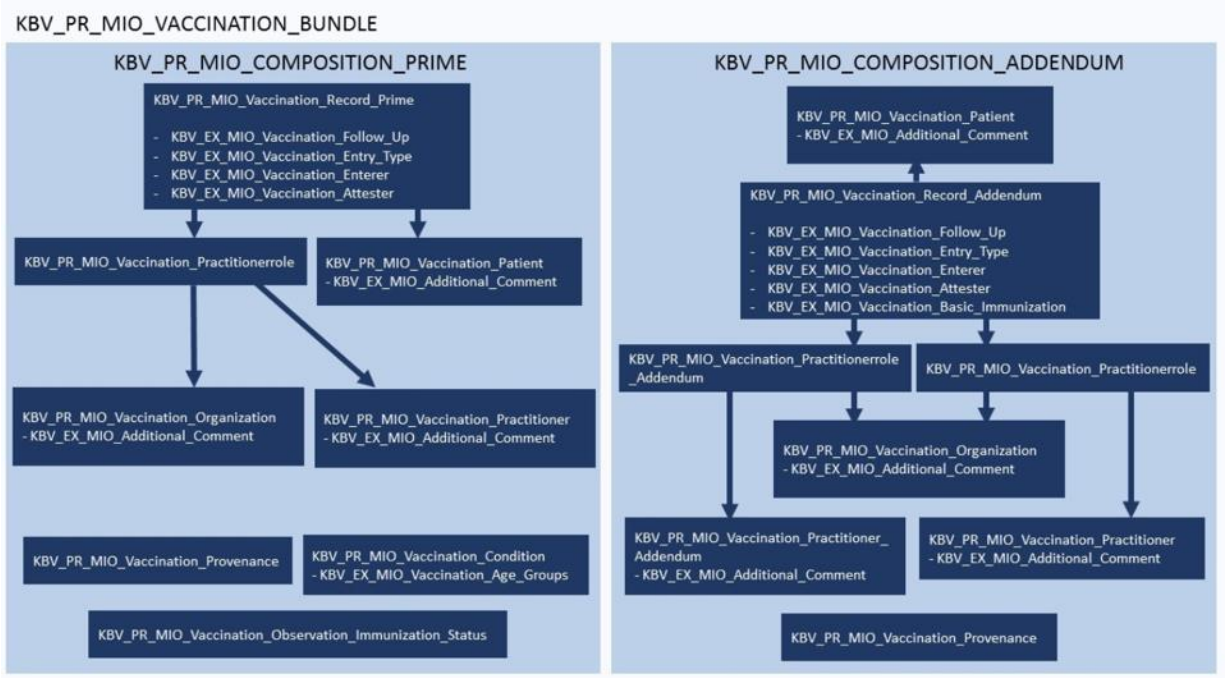


Vaccination Certificate



Observation			0..*	Observation
meta	Σ		1..1	Meta
status	Σ	?!	1..1	code Binding Fixed Value
code	S	Σ	1..1	CodeableConcept
coding	S	Σ	*1..2*	*Coding*
snomedCT	S	Σ	1..1	Coding Binding
system	S	Σ	1..1	uri Fixed Value
version	S	Σ	1..1	string
code	S	Σ	1..1	code
display	S	Σ	1..1	string
userSelected		Σ	0..1	boolean
loinc	S	Σ	0..1	Coding Binding
system	S	Σ	1..1	uri Fixed Value
version	S	Σ	1..1	string
code	S	Σ	1..1	code
display	S	Σ	1..1	string
userSelected		Σ	0..1	boolean
subject	S	Σ	1..1	Reference(KBV_PR_MIO_Va...
issued	S	Σ	1..1	instant
interpretation	S		0..1	CodeableConcept Binding
coding	S	Σ	1..1	Coding
system	S	Σ	1..1	uri
version	S	Σ	1..1	string
code	S	Σ	1..1	code
display	S	Σ	1..1	string
note	S		0..1	Annotation

Digital: Vaccination in EHR



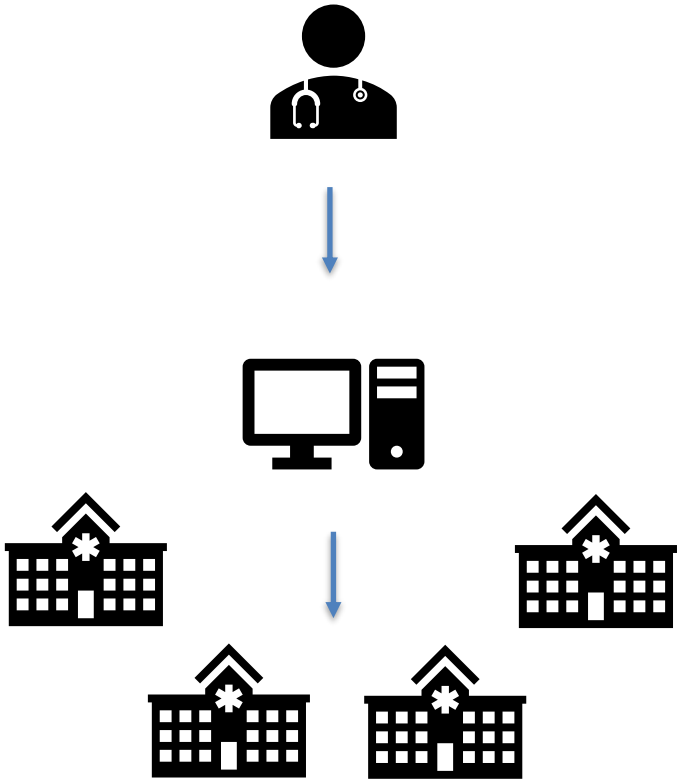
Minimal Dataset to RKI (XSL)

Der von der Impfstelle an das RKI zu übermittelnde Datensatz besteht aus folgenden Angaben („Minimal-Datensatz“):

1. Kennung der Übermittlungsstelle
2. Datum der Impfung
3. Impfstoff-Produkt bzw. Handelsname
4. Chargennummer
5. Beginn oder Abschluss der Impfserie (1. oder Folgedosis)
6. Patientenpseudonym
7. Alter in Jahren (wird berechnet bei Angabe des Geburtstages)
8. Geschlecht
9. Land- bzw. Stadtkreis des Wohnortes (in der Anwendung: Angabe der 5-stelligen Wohnort-PLZ)
10. Impf-Indikation nach STIKO:
    a. Eine Indikation nach dem Alter liegt vor: ja/nein
    b. eine medizinische Indikation liegt vor: ja/ nein / unbekannt
    c. BewohnerIn eines Pflege-/Seniorenheimes: ja/nein
    d. eine berufliche Indikation liegt vor: ja/ nein

Robert Koch Institute

GECCO Dataset → Clinical Trials



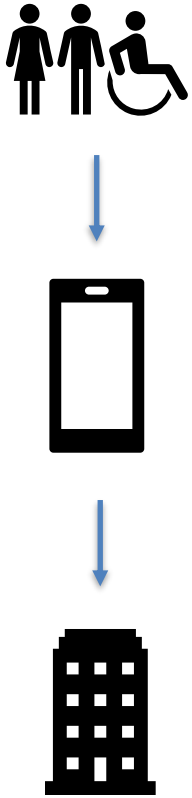
Example in GECCO: Corona vaccination

```
<Immunization xmlns="http://hl7.org/fhir">
    <id value="c17f192c-f765-4729-818a-4ee55be5c87b" />
    <meta>
        <profile value="https://www.netzwerk-universitaetsmedizin.de/fhir/StructureDefinition/immunizati
 />
    </meta>
    <status value="completed" />
    <vaccineCode>
        <coding>
            <system value="http://snomed.info/sct" />
            <code value="1119349007" />
            <display value="Vaccine product containing only Severe acute respiratory syndrome coronaviru
 />
        </coding>
    </vaccineCode>
    <patient>
        <reference value="Patient/21acfc9c-1fd6-43e6-a8fe-c6b6341b0fab" />
    </patient>
    <occurrenceDateTime value="2020-12-27" />
    <protocolApplied>
        <targetDisease>
            <coding>
                <system value="http://snomed.info/sct" />
                <code value="840539006" />
                <display value="Disease caused by Severe acute respiratory syndrome coronavirus 2 (disor
 />
            </coding>
        </targetDisease>
        <doseNumberString>
            <extension url="http://hl7.org/fhir/StructureDefinition/data-absent-reason">
                <valueCode value="unknown" />
            </extension>
        </doseNumberString>
    </protocolApplied>
</Immunization>
```

SafeVac : Incident Reporting

SafeVac 2.0 – Smartphone App to Survey Tolerability of COVID-19 Vaccines

COVID-19 vaccines are an important tool in managing the pandemic. On 21 December 2020, the European Commission authorised the first COVID-19 vaccine, with additional approvals in the pipeline. The nationwide vaccination campaign will start before the end of the year. Shortly, a very large number of people will be vaccinated with newly authorised COVID-19 vaccines. It is therefore important to record the tolerability of the vaccines promptly and on a broad data basis. To this end, the Paul-Ehrlich-Institut has developed the smartphone app SafeVac 2.0, which vaccinated people can use to provide digital information on how they tolerated the vaccination. That way, participants in this observational study will actively contribute to gaining further knowledge about COVID-19 vaccines.



Federal Institute for Vaccines and Biomedicine

USE OF HL7 STANDARDS IN COVID-19 VACCINATION PROCESS: STATUS IN POLAND

Roman Radomski
Chair of HL7 Poland

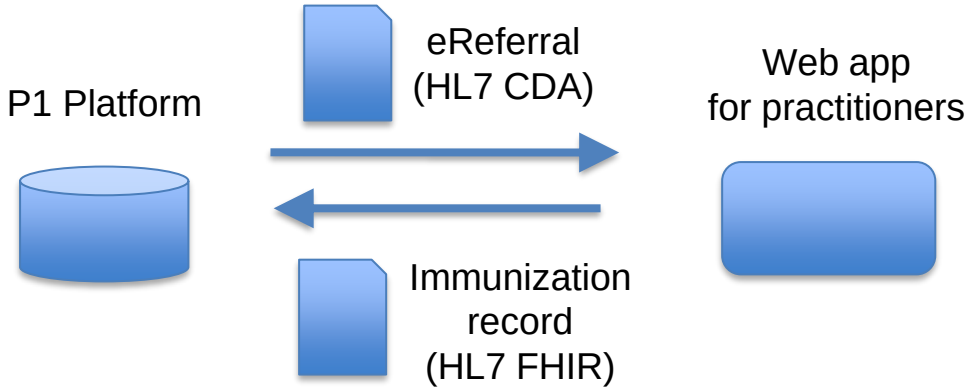
HL7 Europe

Before COVID-19

- Polish National Implementation Guide for HL7 CDA
  - Developed and gradually implemented since 2013
  - Contains more than 270 CDA templates, including **Immunization Card Entry**
  - Obligatory use for electronic clinical documents

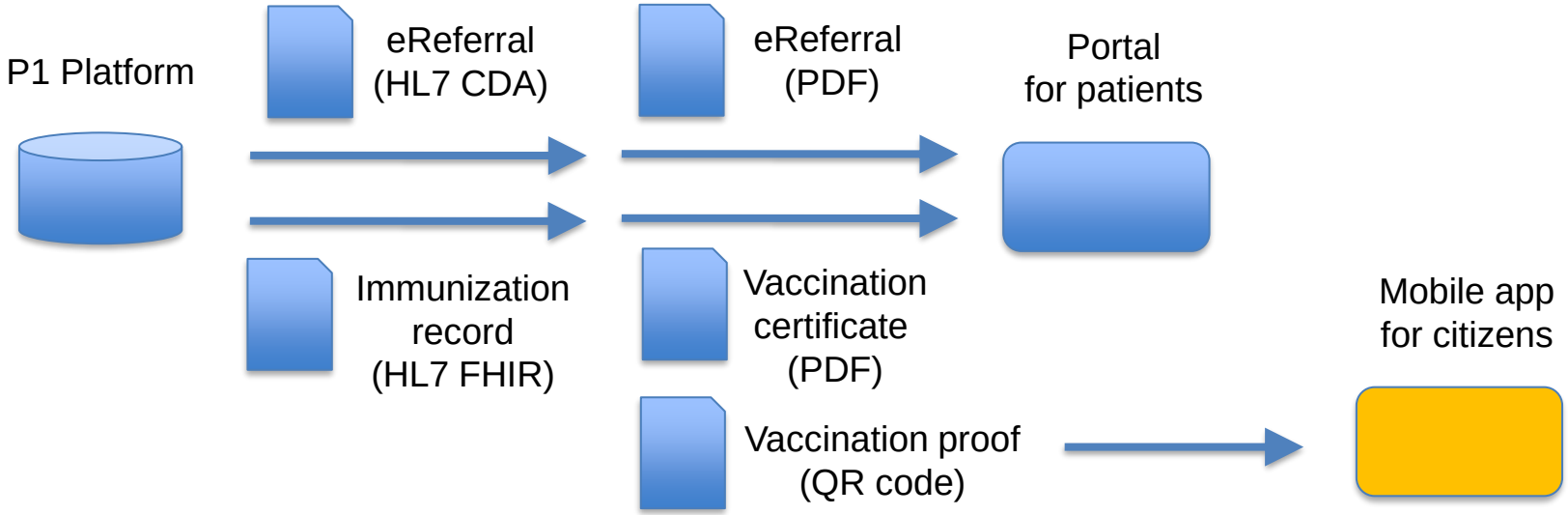
- P1 Platform – central system based on HL7 CDA and HL7 FHIR
  - Handling of selected documents conformant to national IG for HL7 CDA
    - ePresciption – covering almost 100% drug prescriptions and dispensations
    - eReferral – obligatory for selected types of referrals
  - Registry of Service Events – being implemented in HL7 FHIR

COVID-19 Vaccination Data Flow (1)



Central solution developed and rolled out
by Polish eHealth center (government agency)

COVID-19 Vaccination Data Flow (2)



Vaccination proof can be read and verified by mobile app for citizens

Current status

- The solution used for all COVID vaccinations (ca. 3 mln jabs).

- HL7 conformant clinical data objects are stored at P1 Platform:
  - eReferral for vaccination (HL7 CDA document)
  - Immunization record (HL7 FHIR resource)

- Citizens have access to verifiable data objects:
  - COVID vaccination certificate (PDF signed by electronic stamp)
  - COVID vaccination proof (QR code, semi-anonimous, verifiable by mobile app)

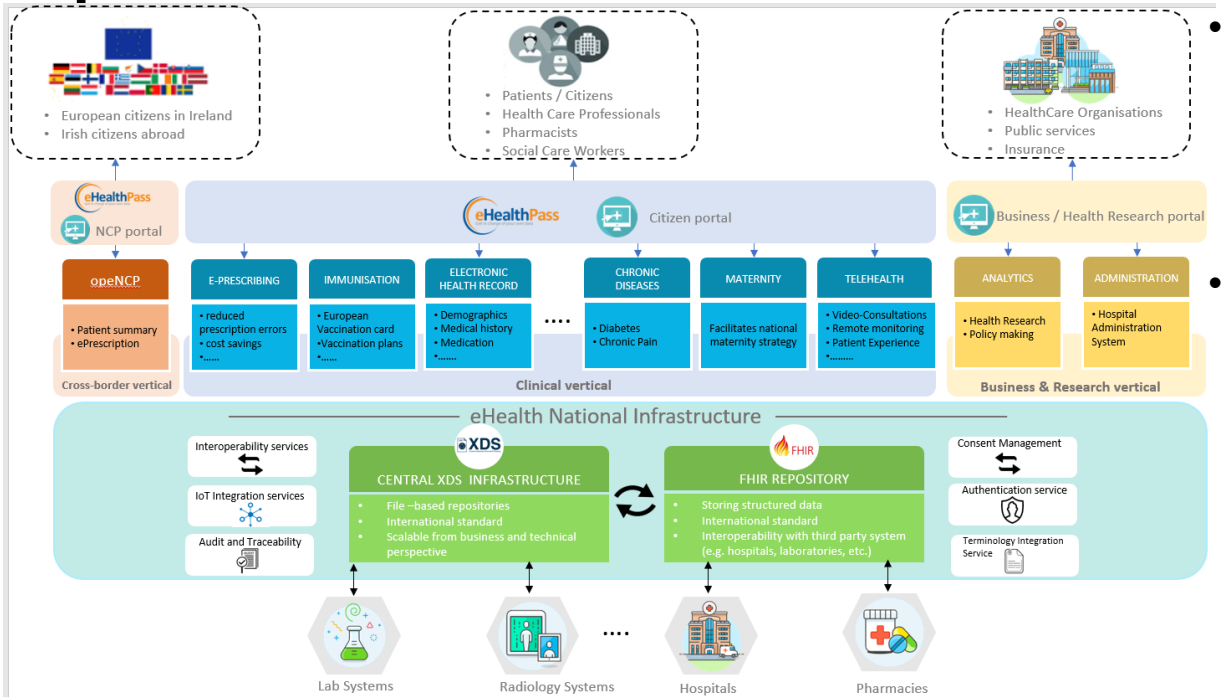
IRISH SMART VACCINATION CERTIFICATE IMPLEMENTATION

HEALTH SERVICE EXECUTIVE IRELAND

Eamon Coyne

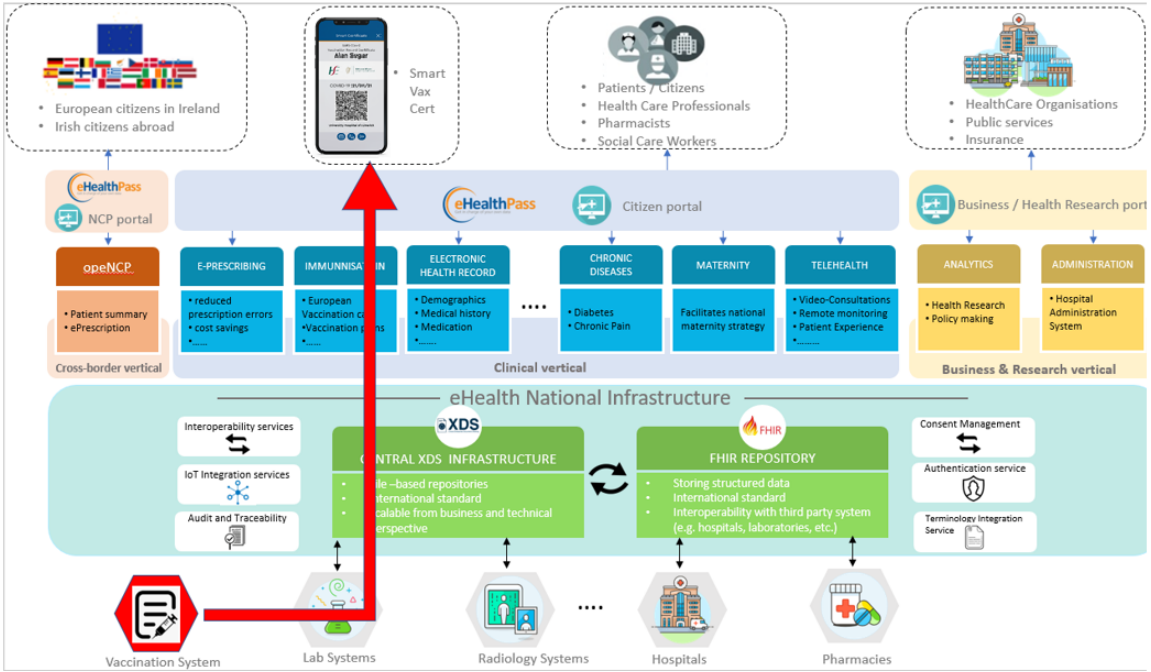
National Enterprise
Technical Architecture Lead, Office of the CIO

Background: XDS based architecture



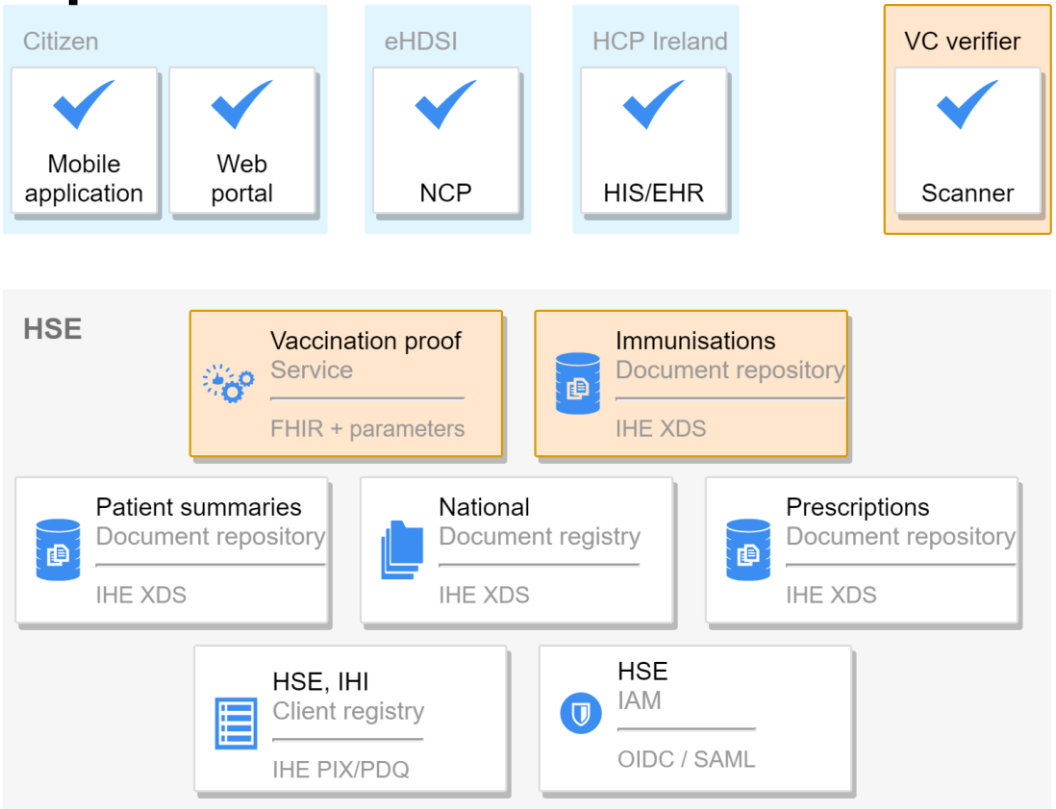
- Traditionally the **Irish ecosystem** primarily based on **HL7 2.4 point to point messaging.**
- In **addressing** the Open NCP eHDSI **Cross Border** Patient Summary and ePrescription **Use Cases,** the supporting **XDS** infrastructure acts as the lynchpin for the other eHealth Initiatives called out in Sláintecare and National Service Plan

Extending the architecture for Smart Vaccination Certificate



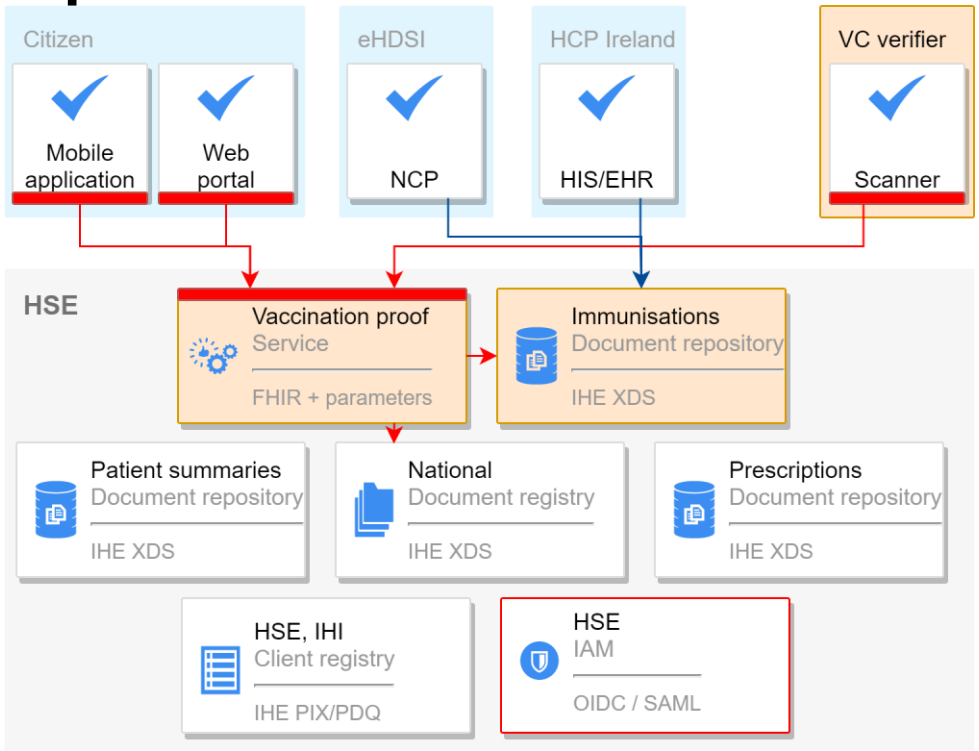
- Leveraging the existing **XDS** architecture and the supporting infrastructure and standards **to encompass the Smart Vaccination Certificate use case**.
- As the architecture is based on **open standards** thereby enabling support and alignment to **EU and WHO requirements**.

Proof of vaccination as a service



- The HSE **added the Immunisation repository**, in addition to existing HSE infrastructure offering
  - IHE XDS document repositories
  - IHE XDS national document registry
  - IHE PIX/PDQ patient registry
  - IAM with SAML and OIDC providers
- Relying on the Immunisation repository there is a new service capable of **reading immunisation records and producing the proof of the vaccination** based on clinical immunisation record(s).
- Immunisation records in the **standard format (HL7 CDA via IHE XDS/XCA)** for continuity of care purposes are available to healthcare professionals in Ireland and Europe.
- **The proof of vaccination is available** for medical and non-medical purposes for citizens, healthcare professionals and other verifiers.

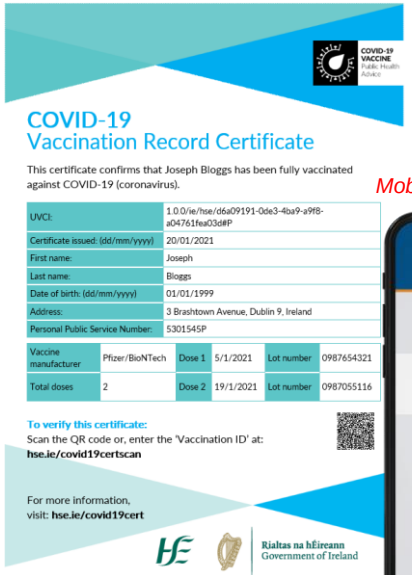
Proof of vaccination as a service



- Vaccination proof is available via a secure service capable of providing confirmation of vaccination.
- The service is dynamic and it relies on **clinical data** inside the **immunisation repository.**
- The service (and the proof of vaccination) is always **available to a citizen and empowers them** to manage whom has **(controlled) access** to the proof of vaccination.
- **Vaccination records for medical purposes** and via standard compliance access are also **available for healthcare professionals** through IHE XDS/XCA integrations inside Ireland and in Europe via eHDSI and NCP.

Proof of vaccination on FHIR

Full Vaccination Certificate Sample



COVID-19
Vaccination Record Certificate

This certificate confirms that Joseph Bloggs has been fully vaccinated against COVID-19 (coronavirus).

UVCI:	1.0.0/ie/hse/d6a09191-0de3-4ba9-a9f8-a04761fea03d#P
Certificate issued: (dd/mm/yyyy)	20/01/2021
First name:	Joseph
Last name:	Bloggs
Date of birth: (dd/mm/yyyy)	01/01/1999
Address:	3 Brashtown Avenue, Dublin 9, Ireland
Personal Public Service Number:	5301545P

Vaccine manufacturer	Pfizer/BioNTech	Dose 1	5/1/2021	Lot number	0987654321
Total doses	2	Dose 2	19/1/2021	Lot number	0987055116

To verify this certificate:
Scan the QR code or, enter the 'Vaccination ID' at:
hse.ie/covid19certscan

For more information,
visit: **hse.ie/covid19cert**

Rialtas na hÉireann
Government of Ireland

Mobile Smart Certificate Sample

- The proof of vaccination is **modelled with standard HL7 FHIR R4 resources.**
  It is a self contained Bundle (Collection) of resources/embedded resources (and references between them) and it is available as structured XML (also as JSON) for **various presentations** via XML transformations.
  Although it uses various parameters it is **still standard compliant** without posing any specific requirements to understand it (e.g., it does not use any custom extension)

- QR code is an image resolving in the URL where the UVC is available for verification.

- **It utilises the eHN guidelines for IOP elements based on the dataset and the UVCI for identifier.**

Sample UVCI: https://vc.hse.ie/1.0.0/ie/hse/d6a09191-0de3-4ba9-a9f8-a04761fea03d#P

Thank you

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PANEL DISCUSSION