

WHO Technical Specifications and Implementation Guidance on Digital Documentation of COVID-19 Certificates: Vaccination Status (DDCC:VS)

Session 1: Use cases and technical framework ITU/WHO Workshop on "Digital Vaccination Certificate" | 11 August 2021

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The vaccination certificate is part of a much larger digital innovation ecosystem for immunizations





NOT FOR DISTRIBUTION Source: Slide from Innovation in COVID-19 Vaccine Delivery working group

Vaccination records are an essential clinical and public health tool





Continuity of Care

- Basis for health worker to provide a subsequent dose and/or appropriate health services
- Provides schedule information for an individual to know if another dose is needed and when the next dose is due
- Enables investigation into adverse events by health workers as per existing adverse events following immunization (AEFI) guidance (vaccine safety).

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Proof of Vaccination

- Establishes vaccination status of individuals in coverage monitoring surveys
- Establishes vaccination status after a positive COVID-19 test to understand vaccine effectiveness
- For work
- For education
- For travel
 - International travel is a subset of this, and is governed by the International Health Regulations (IHR) 2005

Vaccination certificate context and challenges



Global level challenges	• Inconsistent data collected or interoperability standards - incompatibility \rightarrow One vaccine certificate issued by one country cannot be easily read or verified in another
Challenges faced by governments	• Numerous competing products for digitally documenting vaccination status; high opportunity for private sector to monopolize solution
	• Lack of criteria for assessment of solutions or specs for product development
	 Non-existent guidance on digital certificate functions, privacy of data, governance, procedures to mitigate misuse – undermining confidence
Individual-level challenges	• Some jurisdictions limiting individuals from travel, private and public venues - guidance on ethical use needed
	 Possibility for fraudulent paper and digital certificates – undermining trust
	• High confusion around where/how to get vaccine certificates for travel or otherwise. No understanding of what they should expect to get from their health care provider or public health authority

Objectives of the technical specifications and implementation guidance on DDCC



- To publish implementable specifications and standards for data representation, functionality, privacy, and national trust architecture for use cases;
- To develop guidance detailing governance, ethics, and implementation best practices, and links to trust architecture;
- ✓ To ensure the design of the DDCC is in a format that is accessible to all, does not increase the digital divide, and does not lead to vendor lock-in.

DDCC Specifications support paperfirst, augmented by digital



Digital Documentation of COVID-19 Certificates: **Vaccination Status**

TECHNICAL SPECIFICATIONS AND IMPLEMENTATION GUIDANCE



What is in the document?



Requirements and specifications for technology implementers

- Business processes, workflows & use cases
- Core data elements mapped to standard terminology code sets (including an annexed spreadsheet)
- Functional and non-functional requirements
- Overview of signing a digital certificate with PKI
- HL7 FHIR Implementation Guide (linked website) detailing relevant standards for consistent representation and interoperability

Implementation considerations

- Data protection principles
- Ethical considerations
- National governance considerations

Example guidance content from the DDCC:VS document





Requirement ID	Functional requirement	UC001 Paper First	UC002 Offline Digital
DDCC.FXNREQ.008	It SHALL be possible to enter or attach the HCID as a 1D barcode to any paper vaccination card issued to the Subject of Care (or the HCID card holder).	0	ø
DDCC.FXNREQ.009	It SHOULD be possible to prepare pre-printed cards with a previously generated HCID that is encoded in (at minimum) a 1D barcode.	•	0
DDCC.FXNREQ.010	It SHALL be possible to record the core data set content on a paper vaccination card issued to the Subject of Care (or the DDCC:VS card holder).	۲	0
DDCC.FXNREQ.011	It SHALL be possible to manually sign the paper card and include the official stamp of the administering centre as a non-digital means of certifying that the content has been recorded by an approved authority.	•	0
DDCC.FXNREQ.012	The data concerning the vaccination (at minimum, the HCID and the core data set content) SHOULD be entered into an electronic format as soon as reasonably possible after the vaccine is administered. This will most likely be into a Digital Health Solution, if one exists, at the point of care.	ø	0
DDCC.FXNREQ.013	It SHALL be possible to retrieve information about the vaccination(s) administered to the Subject of Care from the content in the DDCC:VS.	0	⊘
DDCC.FXNREQ.014	All data concerning the vaccination SHALL be handled in a secure manner to respect confidentiality between the health worker and Subject of Care.	0	S
DDCC.FXNREQ.015	Digital technology SHALL NOT be needed for any aspect of paper card issue/update - the process SHALL function in an entirely offline and non-electronic manner.	0	
DDCC.FXNREQ.016	Paper cards and the validation markings they bear SHALL be designed to combat fraud and misuse.	0	⊘
DDCC.FXNREQ.017	Where an offline (disconnected) Digital Health Solution exists, the Data Entry Personnel SHALL securely log in to record all pertinent information about the vaccination.		•
DDCC.FXNREQ.018	Any offline Digital Health Solution for vaccination registration SHALL include required content defined in the DDCC:VS core data set.		ø
DDCC.FXNREQ.019	Any offline Digital Health Solution for vaccination registration SHOULD be designed for quality data capture, including enforcement of data validation rules at the point of data entry.		0
DDCC.FXNREQ.020	If patients' records are held in an offline Digital Health Solution available at the time of vaccination, then it SHOULD be possible for an authorized user to view the record for the Sublect of Core includen and income medical		0

Table 11

Data for each vaccination event, with preferred code system

Data element label	Description	Data type	Preferred code system	Requirement status for Continuity of Care	Requirement status for Proof of Vaccination
Vaccine or prophylaxis	Generic description of the vaccine or vaccine sub-type (e.g. COVID-19 mRNA vaccine, HPV vaccine).	Coding	ICD-11	Required	Required
Vaccine brand	The brand or trade name used to refer to the vaccine received.	Coding	As defined by Member State	Required	Required
Vaccine manufacturer	Name of the manufacturer of the vaccine received (e.g. Serum Institute of India, AstraZeneca). If vaccine manufacturer is unknown, market authorization holder is REQUIRED.	Coding	As defined by Member State	Required – conditional	Required - conditional
Vaccine market authorization holder	Name of the market authorization holder of the vaccine received. If market authorization holder is unknown, vaccine manufacturer is REQUIRED.	Coding	As defined by Member State	Required – conditional	Required – conditional
Vaccine batch number	Batch number or lot number of the vaccine.	String	Not applicable	Required	Required
Date of vaccination	Date on which the vaccine was provided.	Date	Complete date, following ISO 8601	Required	Required
Dose number	Vaccine dose number.	Quantity	Not applicable	Required	Required
Total doses	Total expected doses as defined by Member State care plan and immunization programme policies.	Quantity	Not applicable	Optional – recommended	Optional – recommended
Country of vaccination	The country in which the individual has been vaccinated.	Coding	ISO 3166-1 alpha-3 (or numeric)	Required	Required
Administering centre	The name or ID of the vaccination facility responsible for providing the vaccination.	String	As defined by Member State	Required	Optional – recommended

Example guidance content from FHIR Implementation Guide



0.2.1 - CI Build

Narrative Business Requirements - Data Models and Exchange - Deployment - Ind

Table of Contents > Narrative

WHO Digital Documentation of COVID-19 Certificates: Vaccination Status (DDCC:VS) - Local Development build (v0.2.1). See the Directory of nublicity

1 Narrative

5.5.1.1 Formal Views of Profile Content &

The WHO Digital Documentation of COVID-19 Certificates: Vaccination Status (DDCC:VS) Implementation Guide details how to use Hei De Fast Healthcare Intercoperability Resources (FHIR) for consistent digital representation of COVID-19 vaccination certificates and intercop

STU Note

- This version of the implementation guide is based on the current content at https://WorldHealthOrganization.github.io/ddcctd
 This implementation guide and set of artifacts are still undergoing development.
- The DDCC-V5 technical specifications and implementation guidance is being issued to facilitate implementation of effective and solutions for vaccination certificates for the purposes of continuity of care and proof of vaccination. The DDCC-V5 document or of high level use cases for digital COVID-19 vaccination certificates including workflows; core data elements mapped to standar functional requirements; an overview of digitally signing a certificate with public key infrastructure (PK1) technology; implement considerations, privacy and data protection principles, and national governance considerations; and this linked FHIR Implement This content is for demonstration ourposes out.

1.0.1 Summary

This implementation guide contains a standards-compliant specifications for the DDCC:VS technical specifications and guidance docum encodes computer-interoperable logic, including data models, terminologies, and logic expressions, in a computable language to suppo proof of vaccination use cases by Member States.

Supporting guidance, recommendations, resources, and standards are included in the References and Dependencies lists.

1.0.2 About this implementation guide

- This implementation guide is broken into the following levels of knowledge representation
- Narrative Contains references to the guidance, guidelines, policies and recommendations underpinning this implementation. guide
- Business Requirements Contains the requirements for this implementation guide including the definition of key concepts, use cases
- Data Models and Exchange Contains the data models and data exchange protocols with actors and transactions defined.
 Deployment Guidance Contains relevant technical specifications and guidance, as well as supporting guidance for adaptation to loci
- 1.0.3 Disclaimer

The specification herewith documented is a demo working specification, and may not be used for any implementation purposes. This di completeness or consistency, and the official publication supersedes this draft. No liability can be inferred from the use or misuse of thi

IG © 2021+ World Health Organization (WHO) C. Package fhir.who.ddcc-vs#0.2.1 based on FHIR 4.0.1 C. Generated 2021-07-2 Links: Table of Contents | QA Report | Issues C | Version History C C |

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Name	Flags	Card.	Туре	Descriptio	on & Constraints	
DDCCCoreDataSe	t	0*	Element	Base for a	l elements	
💶 name		11	string	Name		
- 🛄 birthDate		01	date	Date of bir	th	
- 🕥 identifier		01	Identifier	Unique ide	ntifier	
- 🍅 sex		01	Coding	Sex		
	T	0*	BackboneElement		AdministrativeGender (required)	
	-			who-ddco	-data-1: Manufacturer or Market Authoriza	tion Holder SHALL be pr
· () vaccine		11	Coding		prophylaxis WHO Vaccine List (COVID-19) (preferred)	
- 🌔 brand		11	Coding	Vaccine br		
- () manufacture	er	01	Coding	Vaccine ma	anufacturer	
- () maholder		01	Coding	Vaccine ma	arket authorization holder	
- 💷 lot		11	string	Vaccine lot	number	
💶 date		11	date	Date of va	ccination	
- validFrom		01	date	Vaccinatio	n valid from	
🛄 dose		11	positiveInt	Dose num	ber	
- I totalDoses		01	positiveInt	Total dose:	5	
- () country		11	Coding	Country of	vaccination	
					so3166-1-3 (preferred)	
- Centre		01	string	Administer	-	
- () signature		01	Signature	2	of health worker	
- () practitioner		01	Identifier		ker identifier	
- ()) disease		01	Coding		agent targeted WHO Disease or Agent Targeted (COVID-19)	(preferred)
- nextDose		01	date		of next dose	(preferred)
🖃 🌔 period		01	Period	Certificate	Validity Period	
🛄 start		01	date	Certificate	valid from	
- 💷 end		01	date	Certificate	valid until	
		01	BackboneElement	Certificate	Metadata	
- 🗹 issuer		11	Reference(DDCC Organization)	Certificate	issuer	
- 🅥 hcid		11	Identifier	Health cer	tificate identifier (HCID)	
version		11	string	Certificate	schema version	

5.5.9 Logical Model: DDCCCoreDataSetPoV - JSON Profile

JSON representation of the DDCCCoreDataSetPoV logical model.

Raw json | Download 🕹

"resourceType" : "StructureDefinition",

"id" : "DDCCCoreDataSetPoV",

"text" : {

"status" : "extensions",

"div" : "<div xmlns=\"http://www.w3.org/1999/xhtml\"><table border=\"0\" cellpadding=\"0\" cellspacin g=\"0\" style=\"border: 0px #F0F0F0 solid; font-size: 11px; font-family: verdana; vertical-align: top;\"> tyle=\"vertical-align: top: text-align : left: background-color: white: border: 0px #F0F0F0 solid: paddin g:0px 4px 0px 4px\" class=\"hierarchy\">Name<th style=\"vertical-align: top; text-align : left; background -color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px\" class=\"hierarchy\">Flags style=\"vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; paddi ng:0px 4px 0px 4px\" class=\"hierarchy\">Card.<th style=\"widt h: 100px\" class=\"hierarchy\">Type<th style=\"vertical-align: top; text-align : left; background-col or: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px\" class=\"hierarchy\">Description & Con straints style=\"border: 0px #F0F0F0 solid; padding:0px; vertical-align: t op; background-color: white\"><td style=\"vertical-align: top; text-align : left; background-color: whit e; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px; white-space: nowrap; background-image: url(tbl bck 1.png)\" class=\"hierarchy\"> DDCCCoreDataSet F0F0F0 solid; padding:0px 4px 0px 4px\" class=\"hierarchy\"/><td style=\"vertical-align: top; text-align : left; background-color: white; border: 0px #F0F0F0 solid; padding:0px 4px 0px 4px\" class=\"hierarchy \">0..*<td style=\"vertical-align: top; text-align : left; background-color: white; border: 0px #F0F 0F0 solid; padding:0px 4px 0px 4px\" class=\"hierarchy\">Element<td style=\"vertical-align: top; text-align : left; background-color: white; bo rder: 0px #F0F0F0 solid; padding:0px 4px 0px 4px\" class=\"hierarchy\">Base for all elements
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🦩 Documentation for this format

Assumptions for country responsibilities



- 1. Countries choose the **modalit(ies)** to implement COVID-19 certificates (e.g. paper, smart phone application, etc.)
- 2. Multiple point of service solutions operating, based on **what countries want** to implement
- 3. Countries responsible for implementing necessary **policies to support** the issuance and verification workflows
- 4. Countries **determine which mechanism for unique identification** (e.g. health ID, national ID number, passport number, etc.) and whether they wish to bind the certificate to identity
- 5. Countries determine **which trust frameworks** to use for validation of COVID-19 certificates & establish agreements with other countries that outline the governance process for establishing trust (e.g., equivalence)

Architecting for the future – Digital Documentation of Certificates

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The Digital Documentation of COVID-19 Certificate specifications set the foundation for supporting an internationally recognized patient summary that is held by an individual

VACCINATION CERTIFICATE



DIGITAL DOCUMENTATION OF COVID-19 CERTIFICATES

Can also document:

- Lab test results
- History of previous COVID-19 infection

PERSONAL HEALTH RECORD

Can also support:

- International patient summary standard
- Other health events
- Risk factors
- Allergies
- Etc.

Can also document:

 Routine immunizations for children

Thank you!

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