

WHO Technical Specifications and Implementation Guidance on Digital Documentation of COVID-19 Certificates, Vaccination Status

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Vaccination certificate context and challenges



Global level challenges

- Inconsistent data collected or interoperability standards incompatibility
- → 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

Goal for the Digital Documentation of COVID-19 Certificates (DDCC) work



Achieve implementable specifications and standards for any application of a digital vaccination certificate for national or cross-border purposes and ensure consistent data-representation, -exchange, -privacy, -security; while facilitating continuity of care, enabling verifiable proof of status, and individual empowerment.

Objective of the technical specifications and implementation guidance on DDCC



✓ To publish 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.





Policy guidance regarding the use of COVID-19 vaccination certificates is available in the following WHO guidance documents:

- ✓ <u>Technical considerations for implementing a risk-based approach to international travel in the context of COVID-19: Interim guidance, 2 July 2021</u>
- ✓ <u>Policy considerations for implementing a risk-based approach to international travel in the context of COVID-19</u>
- ✓ <u>Interim guidance on considerations for implementing and adjusting public health and social</u> measures in the context of COVID-19

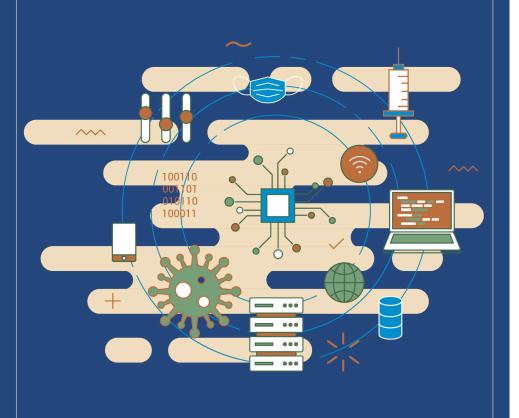
Assumptions for country responsibilities



- 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)

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

DDCC Specifications support paperfirst, augmented by digital

International
Certificate of Vaccination
or Prophylaxis
(i.e. yellow card)

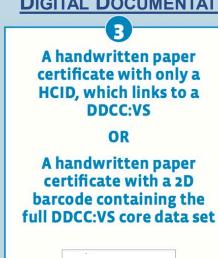


National Immunization Home-based Record



DIFFERENT ILLUSTRATIVE FORMATS OF

DIGITAL DOCUMENTATION OF COVID-19 CERTIFICATES: VACCINATION STATUS





A PDF print-out certificate with only a HCID which links to a DDCC:VS

OR

A PDF print-out with a 2D barcode containing the full DDCC:VS core data set

NATIONAL COVID-19 CERTIFICATE

PDF



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A DDCC:VS

held on a smartphone

DDCC:VS Specifications support two key scenarios



Continuity of Care + Personal Health Records

SECTION

3

Continuity of Care scenario



The vaccination certificate is presented to a medical authority so that the bearer's vaccination status can be considered as part of continuing to provide care to the individual. It forms part of the personal health record.

Proof of Vaccination for National and Cross-border Uses

SECTION

4

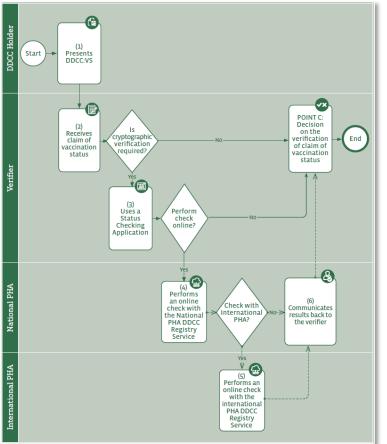
Proof of Vaccination scenario



The vaccination certificate is presented as proof that the bearer has received vaccine for COVID-19, and this claim can be checked and validated by an interested party.

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).	Ø	0
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.	Ø	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).	Ø	•
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.	•	•
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	•
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.	Ø	•
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.	Ø	•
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.	Ø	
DDCC.FXNREQ.016	Paper cards and the validation markings they bear SHALL be designed to combat fraud and misuse.	Ø	Ø
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.		•
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.		•
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		•

Table 11

Data for each vaccination event, with preferred code system

Data element label	Description	Data type	Preferred code	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

How does the DDCC:VS relate to other initiatives?



- > DDCC:VS core data set guidance laid out in this document may be leveraged to generate DDCC:VS compatible with other initiatives:
 - International Civil Aviation Organization (ICAO) Guidelines on visible digital seals for travel-related health proofs
 - EU Digital COVID Certificate (DCC)
 - Additional technical details can be found on the DDCC vaccination certificate implementation guide available at: https://worldhealthorganization.github.io/ddcc/
- ➤ The technical specifications laid out in this document can help inform other private sector initiatives on best practice & establish alignment on data collection and interoperability.
- ➤ Member States can use this guidance to guide their technology partners on minimum requirements for a DDCC:VS

Additional upcoming resources



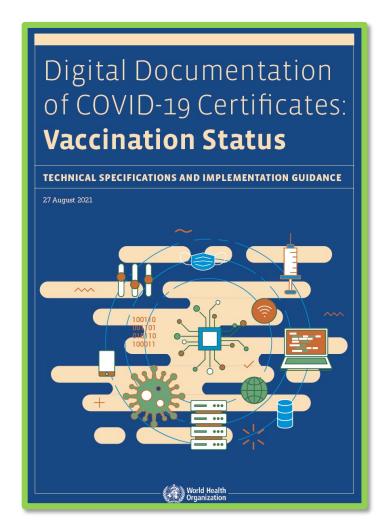
- ✓ Digital Documentation of COVID-19 Certificates: Lab Results Technical specifications and implementation guidance:
 - ✓ Certificates for SARS-CoV-2 Negative Test Results
 - ✓ Certificates for History of SARS-CoV-2 infection



- ✓ Open-source reference software for:
 - ✓ Recording COVID-19 vaccinations in a digital format
 - ✓ Generating DDCC:VS in multiple compatible formats (e.g., ICAO VDS-NC, EU DCC, DIVOC)
- ✓ **Mechanism to facilitate testing compatibility** with WHO specifications through connectathons organized by standards organizations (e.g., HL7 FHIR) for possible inclusion in a Clearinghouse

Documents will be available at 5PM CEST, 27th August (today)





- ✓ Digital Documentation of COVID-19 certificates: Vaccination status Technical specifications and implementation guidance, 27 August 2021 (main document)

 https://apps.who.int/iris/bitstream/handle/10665/343361/WHO-2019-nCoV-Digital-certificates-vaccination-2021.1-eng.pdf
- ✓ Web annex A. DDCC:VS core data dictionary https://apps.who.int/iris/bitstream/handle/10665/343264/WHO-2019-nCoV-Digital-certificates-vaccination-data-dictionary-2021.1-eng.xlsx
- ✓ Web annex B. Technical briefing
 https://apps.who.int/iris/bitstream/handle/10665/344456/WHO-2019-nCoV-Digital certificates-vaccination-technical briefing-2021.1-eng.pdf



