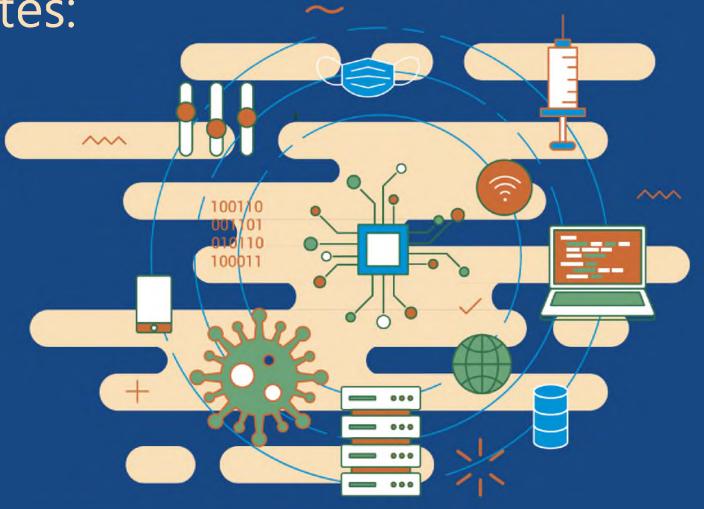
Digital Documentation of COVID-19 Certificates:

Vaccination Status

TECHNICAL SPECIFICATIONS AND IMPLEMENTATION GUIDANCE

Web Annex B. Technical briefing

27 August 2021



World Health

Organization

What is the "Digital Documentation of COVID-19 Certificates: Vaccination Status Technical Specifications and Implementation Guidance" document?



The "Digital Documentation of COVID-19 Certificates: Vaccination Status (DDCC:VS) Technical Specifications and Implementation Guidance" document is a baseline requirements document for technology partners that are creating or overseeing the development of a digital vaccination certificate solution for COVID-19. It is written so that Member States:

- Do not oversimplify the development of digital vaccination certificate solutions, at the risk of compromising ethical and data protecting design choices;
- Can adopt and adhere to digital health interoperability standards;
- ✓ Have the flexibility to determine which digital solutions
 work best for their context and local technology partners.

The "DDCC:VS Technical Specifications and Implementation Guidance" is NOT A POLICY DOCUMENT.

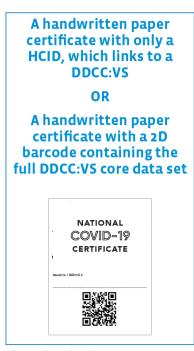
Policy guidance regarding the use of COVID-19 vaccination certificates is available in the following WHO guidance documents:

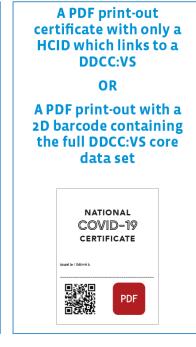
- Technical considerations for implementing a risk-based approach to international travel in the context of COVID-19: Interim guidance, 2 July 2021
- Policy considerations for implementing a risk-based approach to international travel in the context of COVID-19
- Interim guidance on considerations for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

What is a DDCC:VS?



- Digital Documentation of COVID-19 Certificates, or DDCC:VS, is a digitally signed representation of data content that describes a vaccination event. DDCC:VS data content respects the specified core data set and follows the Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR) standard detailed in the FHIR Implementation Guide.
- The International Certificate of Vaccination or Prophylaxis and a national immunization homebased record are *not* considered DDCC:VS because they are not available in a digital format and do not meet the requirements outlined in this technical specifications and implementation guidance document.







2D: two-dimensional

What can the DDCC:VS be used for?



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.

- Provides a basis for health workers to offer a subsequent dose and/or appropriate health services
- Provides schedule information for an individual to know whether another dose, and of which vaccine, is needed, and when the next dose is due
- ➤ Enables investigation into adverse events by health workers, as per existing guidance on adverse events following immunization (AEFI) (vaccine safety)

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.

- Establishes the vaccination status of individuals in coverage monitoring surveys
- Establishes vaccination status after a positive COVID-19 test, to understand vaccine effectiveness
- > For work
- For university education
- For international travel*

*In the context of international travel, in accordance with advice from the 8th meeting of the International Health Regulations (2005) Emergency Committee on COVID-19, held on 14 July 2021, countries should not require proof of COVID-19 vaccination as a condition for travel.

What is the data required for a DDCC:VS?



Data requirements will depend on the scenario of use and the format of the DDCC:VS. Member States will need to determine whether they want to include Optional data elements, depending on the local context and agreements that establish trust with other Member States.

Requirement status for Continuity of Care	Requirement status for Proof of Vaccination	Section	Data Element Label	Description and Definition
REQUIRED	REQUIRED	Header –	NAME	The full name of the vaccinated person.
REQUIRED	REQUIRED	input once	DATE OF BIRTH	The vaccinated person's date of birth (DOB) if known. If unknown, use assigned DOB for administrative purposes.
OPTIONAL	OPTIONAL		UNIQUE IDENTIFIER	Unique identifier for the vaccinated person, according to the policies applicable to each country. There can be more than one unique identifier used to link records (e.g., national ID, health ID, immunization information system ID, medical record ID).
OPTIONAL	NOT NEEDED		SEX	Documentation of a specific instance of sex information for the vaccinated person.
REQUIRED	REQUIRED	Data	VACCINE OR PROPHYLAXIS	Generic description of the vaccine or vaccine sub-type, e.g., COVID-19 mRNA vaccine, HPV vaccine.
REQUIRED	REQUIRED	needed for	VACCINE BRAND	The brand or trade name used to refer to the vaccine received.
CONDITIONAL	CONDITIONAL	each vaccination	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.
CONDITIONAL	CONDITIONAL	event	VACCINE MARKET AUTHORIZATION HOLDER	Name of the market authorization holder of the vaccine received. If market authorization holder is unknown, vaccine manufacturer is REQUIRED.
REQUIRED	REQUIRED		VACCINE BATCH NUMBER	Batch number or lot number of vaccine.
REQUIRED	REQUIRED		DATE OF VACCINATION	Date in which the vaccine was provided.
REQUIRED	REQUIRED		DOSE NUMBER	Vaccine dose number.
OPTIONAL	OPTIONAL		VACCINATION VALID FROM	Date upon which provided vaccination is considered valid. This data should only be considered valid at the time of issuance, as guidance is likely to evolve with further scientific evidence. Any user of this data (Vaccinator, Verifier) should validate this date according to their national policy. In the case of repeated doses, the data field for a subsequent dose should override the data field for a predecessor dose.
OPTIONAL	OPTIONAL		TOTAL DOSES	Total expected doses as defined by Member State care plan and immunization programme policies.
REQUIRED	REQUIRED		COUNTRY OF VACCINATION	The country in which the individual has been vaccinated.
REQUIRED	OPTIONAL		ADMINISTERING CENTRE	The name or identifier of the vaccination facility responsible for providing the vaccination.
OPTIONAL	CONDITIONAL		SIGNATURE OF HEALTH WORKER	REQUIRED for PAPER vaccination certificates that have been filled out with handwriting ONLY. A printed paper vaccine certificate does not require the handwritten signature of a health worker. The health worker who provided the vaccination or the supervising clinician's hand-written signature.
OPTIONAL	OPTIONAL		HEALTH WORKER IDENTIFIER	OPTIONAL for DIGITAL and PAPER vaccination certificates. The unique identifier for the health worker as determined by the member state. There can be more than one unique identifier used. (e.g., system generated ID, health profession number, cryptographic signature, or any other form of health worker unique identifier). This can be used in lieu of a paper-based signature.
OPTIONAL	OPTIONAL		DISEASE OR AGENT TARGETED	Name of disease vaccinated to protect against (such as COVID-19).
OPTIONAL	NOT NEEDED		DUE DATE OF NEXT DOSE	Date on which the next vaccination should be administered, if a next dose is required.

What is the standard operating procedure for implementing DDCC:VS?



Determine the intended uses for a digital vaccination certificate system.

The value proposition of digitizing a vaccine certificate will need to be clear.

See Table 1 in the Executive Summary for the

multiple uses of a DDCC:VS.

START

Conduct an impact assessment to understand the potential risks, benefits, and costs for establishing a DDCC:VS.

Use this to inform the design of your system and key policy decisions.

See **section 2** for recommendations on ethical and privacy protecting design, development, and implementation of DDCC:VS.

Establish policies and a legal framework to support your intended uses of the DDCC:VS.

Countries should have policies and a legal framework for appropriate use, data protection, and governance of the DDCC:VS to reduce the potential harms, while achieving the public health benefits. This includes any relevant national or international policy agreements.

See **section 1.6** for a list of other WHO policy guidance publications and **section 7** for additional governance considerations.

Determine whether to leverage existing digital systems that document vaccination status or adopt a new system.

This should be based on the existing digital health enterprise architecture and the country's overall digital health strategy.

See **section 8** for additional implementation considerations.

Gather health content requirements and system requirements for the intended use of your DDCC:VS.

This document focuses on providing the technical specifications necessary to create an interoperability standards-based DDCC:VS. The system requirements should be informed by the supporting policy and legal framework, including the ethical and privacy considerations.

See **sections 3, 4, 5,** and **6** for workflows, data requirements, and functional requirements for the various scenarios of use of a DDCC:VS.

Develop, deploy, implement, and scale your DDCC:VS solution.

A clear mechanism for obtaining and responding to feedback from end users will need to be established, including a mechanism to consistently push updates.

See **section 8** and the <u>Digital Health</u> <u>Implementation Investment Guide (DIIG)</u> for additional details.

The design of the DDCC:VS solution should depend on feasibility of implementation



The availability of infrastructure at the Care Site will determine the possible format in which a DDCC:VS can be issued.

The availability of infrastructure where proof of vaccination is needed will determine the mechanism for which verification can be done.

Scenarios for issuing DDCC:VS

Paper first

- Health certificate identifier (HCID) barcode is preprinted on a paper card.
- Core data set is expected to be handwritten.
- Data about the vaccination event is entered into a Digital Health Solution afterwards to create a digital record.

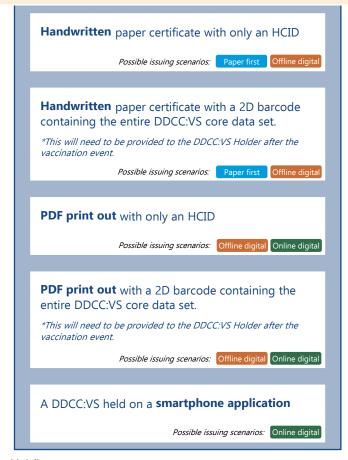
Offline digital

- HCID barcode is pre-printed on a paper card.
- Core data set can be printed or handwritten.
- Data about the vaccination event is recorded using an offline Digital Health Solution, with the content uploaded once connectivity is available.

Online digital

- The HCID barcode can be printed at the same time as the core data set at the time of the vaccination event.
- The Digital Health Solution can update the data about the vaccination event in real time.

Formats of DDCC:VS



Scenarios for verifying DDCC:VS

Offline status check

Manual verification

A Verifier verifies a DDCC:VS by looking at the certificate and decides its legitimacy based on their subjective judgement. No digital technology is required.

Offline cryptographic verification

A Verifier verifies a DDCC:VS using digital cryptographic processes in an offline mode.

*Only possible with DDCC:VS formats that contain a 2D barcode with the entire DDCC:VS core data set or a smartphone application

Online status check

National DDCC:VS

Uses digital cryptographic processes in an online mode that includes a status check against the PHA's DDCC:VS Registry Service and optionally the DDCC:VS Repository.

International DDCC:VS

Uses digital cryptographic processes in an online mode that includes a status check against the National PHA's DDCC:VS Registry Service; and an International PHA's DDCC:VS Registry Service and optional Repository, if such services exist and agreements for use are in place.

What are the key considerations to determine the format of the DDCC:VS?



The selected design format, or formats, of the DDCC:VS will have implications on how the content of the DDCC:VS is stored and verified.

Formats of DDCC:VS

Handwritten paper certificate with only an HCID

PDF print out with only an HCID

Handwritten paper certificate with a 2D barcode containing the entire DDCC:VS core data set.

containing the entire DDCC:VS core data

A DDCC:VS held on a smartphone



Implications

STORED DDCC:VS FORMAT (DDCC:VS CONTENT STORED IN A CENTRAL REPOSITORY):

- ➤ Leverages a centrally stored copy of the signed DDCC:VS content;
- > The HCID on the paper certificate is used as a "lookup token";
- > Verifiers can use the HCID for online retrieval of the digitally signed DDCC:VS document from a central web service;
- > Verifiers can confirm if the online content matches the content on the DDCC:VS paper certificate;
- > Requires online access for verification (no offline digital verification option).

DISTRIBUTED DDCC:VS FORMAT (DDCC:VS CONTENT IN A 2D BARCODE):

- > Digitally signed 2D barcodes as the verifiable DDCC:VS format will require that each issuer can:
 - 1. Generate a 2D barcode from the DDCC:VS document;
 - 2. Digitally sign the 2D barcode using a Document Signer Certificate (DSC); and
 - 3. Distribute the 2D barcode to DDCC:VS Holders. For DDCC:VS Holders who do not have smartphones, 2D barcodes would need to be printed for them.
- > Verifiers will need to leverage an application to read the 2D barcode and verify both its content and its digital signature. To work offline, the application will need to have downloaded the necessary DSC public keys.



application



What are the architecture implications for issuing and verifying DDCC:VS?



Some centralized infrastructure is required regardless of DDCC:VS format, as the DDCC:VS Digital Health Solutions will need to be able to generate and sign the DDCC:VS. At least one DSC is needed with information about each DDCC:VS saved to a DDCC:VS Registry Service.

Centralized

Architecture

Implications on Issuing DDCC:VS

- ➤ A centrally-deployed DDCC:VS generation service may be **leveraged by the entire ecosystem**.
- > PKI requirements are significantly simplified.
- Centralized solutions present a single point of failure, so service level requirements can be onerous.
- ➤ There may be regulatory and/or data governance challenges associated with centralized processing.

Decentralized Architecture



- ➢ If there are multiple DDCC:VS issuers (e.g., hospitals, pharmacies, etc.), each QR code issuer will require a Document Signer Certificate (DSC). This will require national public key infrastructure (PKI) and Public Key Directory (PKD) deployment.
- ➤ **Printing capacity** would need to be widely available so that DDCC:VS Holders without a smartphone can receive a printed QR code.

Implications on Verifying DDCC:VS

- ➤ Only the **HCID** is needed to do an **online lookup** of the DDCC:VS content.
- ➤ Network access is required for verification against the central server; it does not work in offline mode.
- > Revoked certificates can be identified.
- ➤ A Public Key Directory (PKD) is not required.
- Citizens' concerns regarding data privacy and online surveillance may need to be addressed.
- > Each verifier needs a QR code reader which can:
 - Access and download the public keys (e.g., from a global PKD) of every QR code issuer.
 - Decode each supported QR code format (e.g., EU DCC, ICAO VDS-NC).
- > The reader supports offline verification.
- > Certificate revocation is not supported.

What are the digital health interoperability standards required?



- > The preferred **semantic standard** is the International Classifications of Diseases, 11th edition (ICD-11)
 - ICD-11 is recommended as the most suitable and future-proof value set for use in the DDCC:VS data dictionary. Implementers
 may use the DDCC:VS core data set as defined or may continue to use their existing terminology with a map to the
 DDCC:VS core data set data elements, so long as it contains the required data elements in the DDCC:VS core data set. The
 recommended core data set is intended to include the critical data required for interoperability, specific to the scenarios of use
 defined, and driven by the public health need.
- > The preferred syntactic standard is Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR)®
 - The FHIR implementation guide for DDCC:VS contains a standards-compliant specification that explicitly encodes computer-interoperable logic, including data models, terminologies and logic expressions, in a computable language sufficient for implementation of continuity of care and proof of vaccination use cases.
- Additional details can be found on the DDCC:VS FHIR Implementation Guide, accessible at: https://WorldHealthOrganization.github.io/ddcc



