# 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

Source: Slide from Innovation in COVID-19 Vaccine Delivery working group
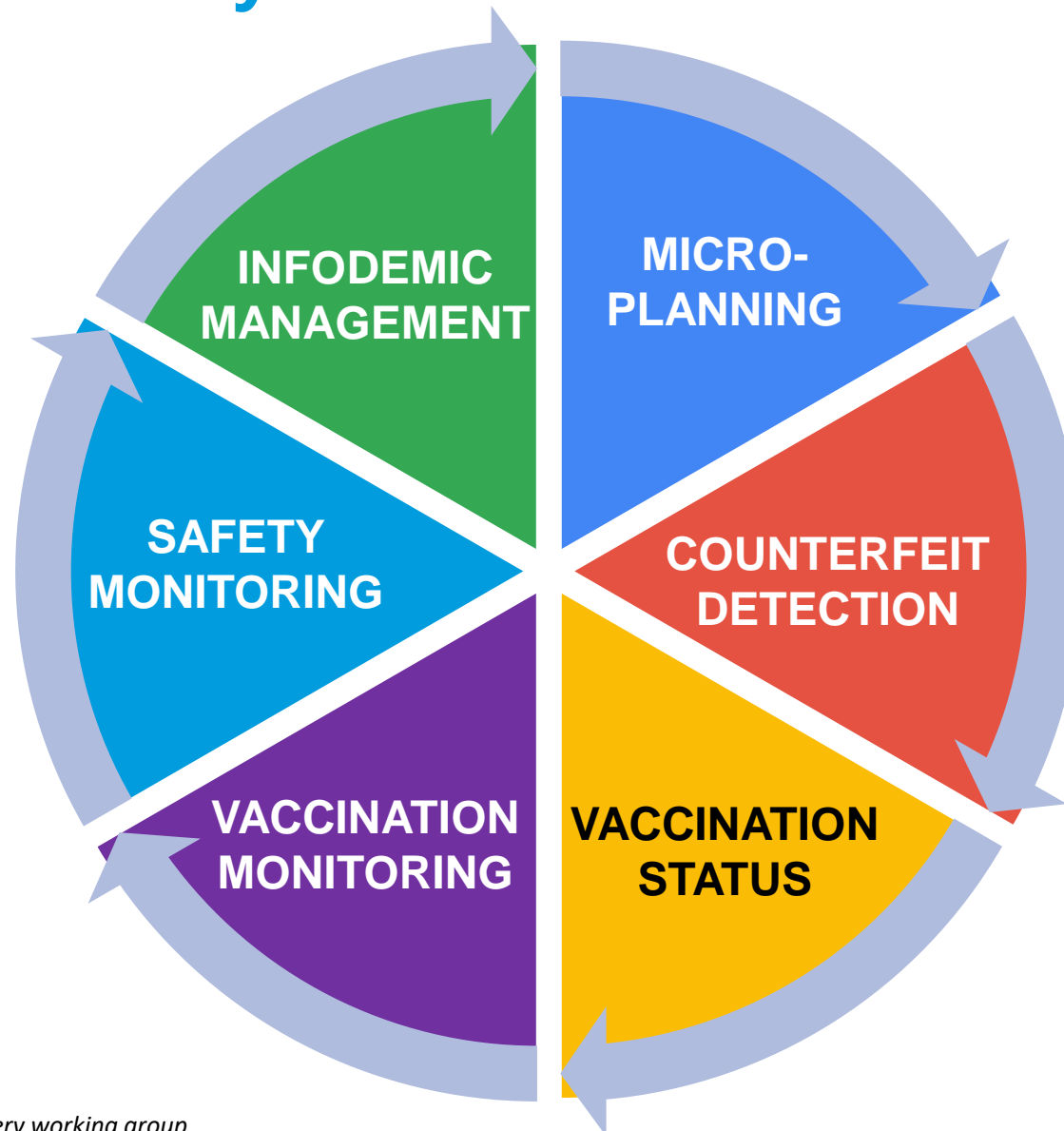
Vaccination records are an essential clinical and public health tool

World Health Organization

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).

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

World Health Organization

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

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.

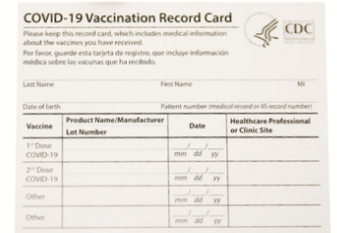# DDCC Specifications support paper-first, augmented by digital

1 International Certificate of Vaccination or Prophylaxis (i.e. yellow card)
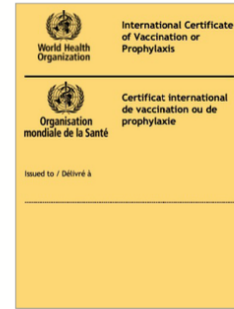
2 National Immunization Home-based Record

DIFFERENT ILLUSTRATIVE FORMATS OF DIGITAL DOCUMENTATION OF COVID-19 CERTIFICATES: VACCINATION STATUS

3 A handwritten paper certificate with only a HCID, which links to a DDCC:VS

OR

A handwritten paper certificate with a 2D barcode containing the full DDCC:VS core data set
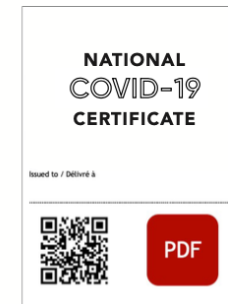
NATIONAL COVID-19 CERTIFICATE
Issued to / Délivré à

4 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
Issued to / Délivré à
PDF

5 A DDCC:VS held on a smartphone

NATIONAL COVID-19 CERTIFICATE
COVID-19 | 21 May 2021
COVID-19
18 June 2021

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

TECHNICAL SPECIFICATIONS AND IMPLEMENTATION GUIDANCE

World Health Organization

What is in the document?

World Health Organization
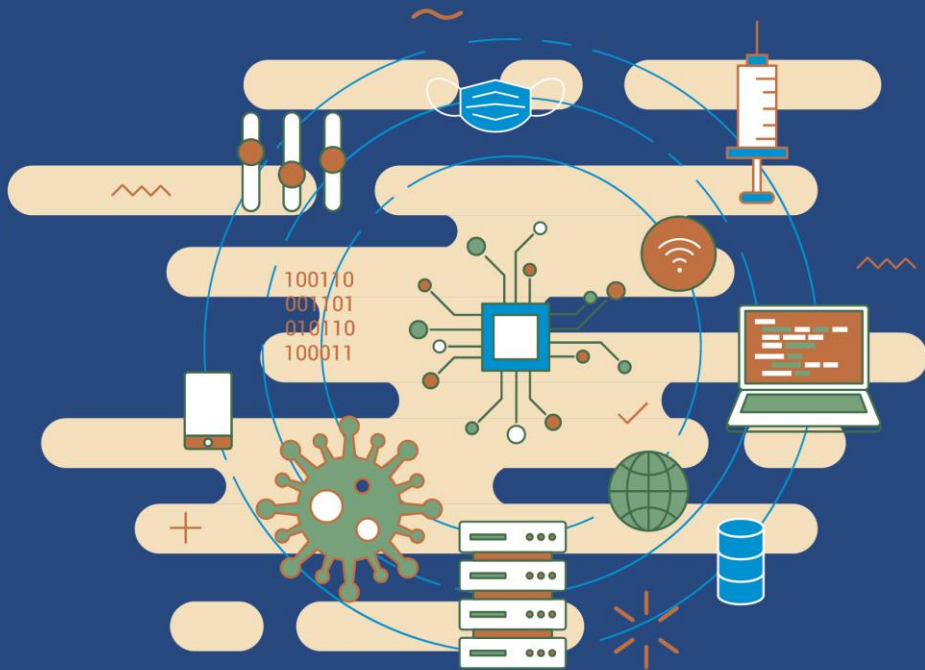
Requirements and specifications for technology implementers

- 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

World Health Organization
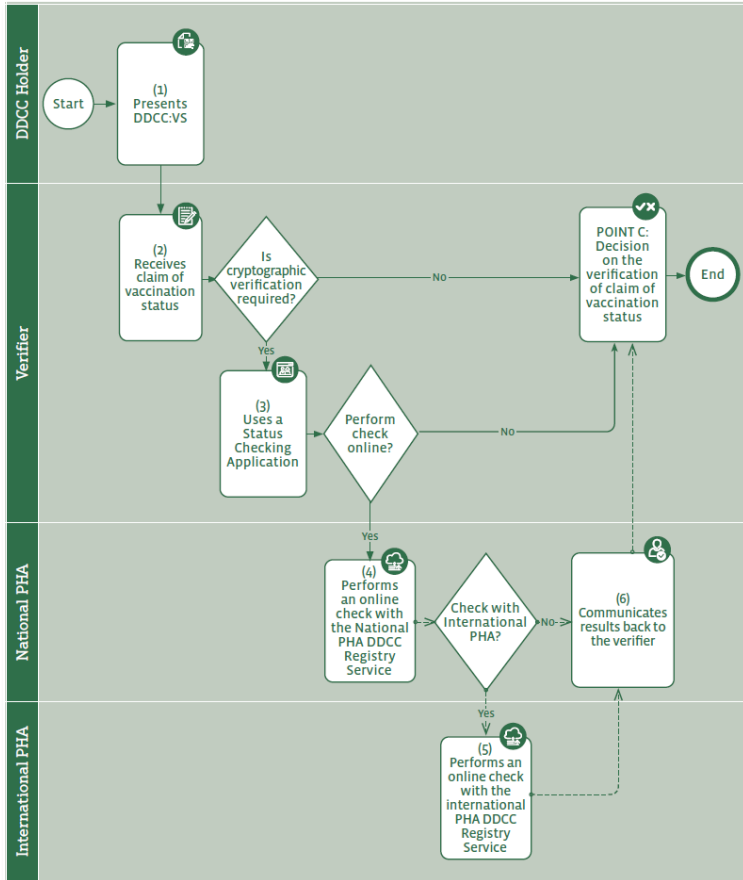
Requirement ID	Functional requirement	UC001 Paper First	UC002 Offline Digital
DDCC.FXNREQ.008	It **SHALL** be possible to enter or attach the HCID as a 1D barcode to any paper vaccination card issued to the Subject of Care (or the HCID card holder).	✓	✓
DDCC.FXNREQ.009	It **SHOULD** be possible to prepare pre-printed cards with a previously generated HCID that is encoded in (at minimum) a 1D barcode.	✓	✓
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).	✓	✓
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.	✓	✓
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.	✓	✓
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.	✓	✓
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.	✓	
DDCC.FXNREQ.016	Paper cards and the validation markings they bear **SHALL** be designed to combat fraud and misuse.	✓	✓
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 record for the Subject of Care, including pertinent medical		✓

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

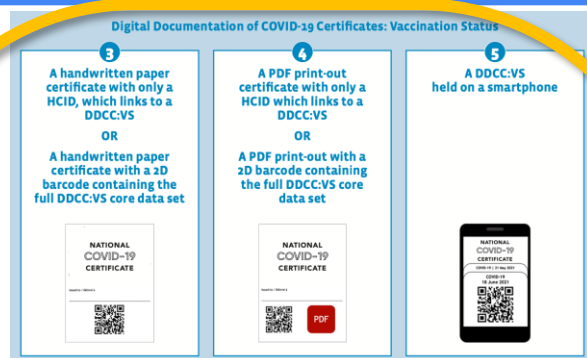# Example guidance content from FHIR Implementation Guide

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

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** → **PERSONAL HEALTH RECORD**

Digital Documentation of COVID-19 Certificates: Vaccination Status

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NATIONAL COVID-19 CERTIFICATE

- Only documents **vaccination events**

Can also document:

- **Routine immunizations for children**

Can also document:

- **Lab test results**

- **History of previous COVID-19 infection**

Can also support:

- **International patient summary standard**

- **Other health events**

- **Risk factors**

- **Allergies**

- **Etc.**

Thank you!

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