

International Health Regulations, and Guidance on Digital Documentation of COVID-19 Certificates Linked to Trust Networks

Connectathon + Regional Meeting on Digital Transformation of the Health Sector, Santiago, Chile

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Diapositiva 1

NMNR1 Would recommend title to be "International Health Regulations, Guidance on Digital Documentation of COVID-19 Certificates, and Interoperable Digital Health Trust Networks" (separating out the trust network part, so it's clear that it's related but not the only thing)

NASH-MENDEZ, Natschja Ratanaprayul; 24-03-2022

Policy considerations regarding requirement of proof of COVID-19 vaccination as condition of international travel

World Health Organization

WHO interim position paper, February 2021

Scientific

- WHO approved COVID-19 vaccines do protect against severe disease, but currently no evidence vaccines reduce transmission
- Remaining scientific unknowns: efficacy of the vaccines in preventing disease from variants of SARS-CoV-2; duration of protection offered by vaccination; timing of booster doses; protection against asymptomatic infection; exemptions of people who have antibodies against SARS-CoV-2

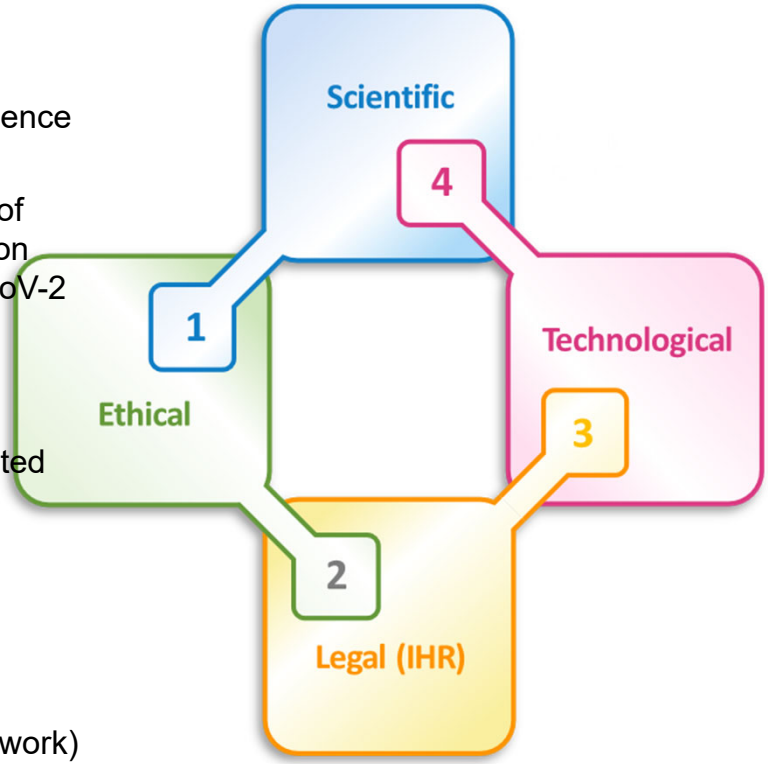
Ethical

- limited global production capacity and reduced access to vaccines
- WHO SAGE prioritization roadmap – priority groups most at risk for serious outcome if infected (front-line health workers, older age)

Legal – see next slides on IHR provisions

Technological

- Potential adaptation and digitalization of the ICVP (once legal provisions met)
- Guidance and technical documentation for digitally recording vaccination status (see DDCC work)



https://www.who.int/news-room/articles-detail/interim-position-paper-considerations-regarding-proof-of-covid-19-vaccination-for-international-travellers

Legal provisions under the International Health Regulations (2005) related to vaccination and certificates

- Vaccinations may be recommended or required for international travellers under the IHR, in accordance with provisions of Articles 18, 23, 31, 32, 36, 43, and Annexes 6 and 7.
- If vaccination of travellers is required, vaccines must be approved* by WHO, be of suitable quality, and universally available
- Vaccination recommended for international travellers under the IHR must be recorded in the International Certificate for Vaccines and Prophylaxis, based o the model in Annex 6 of the IHR
- States Parties may require proof of vaccination for international travellers:
  - In countries at risk of yellow fever, in accordance with provisions of Annex 7
  - If there are Temporary Recommendations in relation to a Public Health Emergency of International Concern – see example of polio requirements for vaccination

Temporary recommendations issued by the Director-General in the context of the PHEIC for COVID-19 pandemic do not support requirement of proof of vaccination as the only condition of travel

**Vaccines "approved" means: WHO Prequalified vaccines or included in the Emergency Use List*

Temporary Recommendations in the context of the PHEIC related to the COVID-19 pandemic



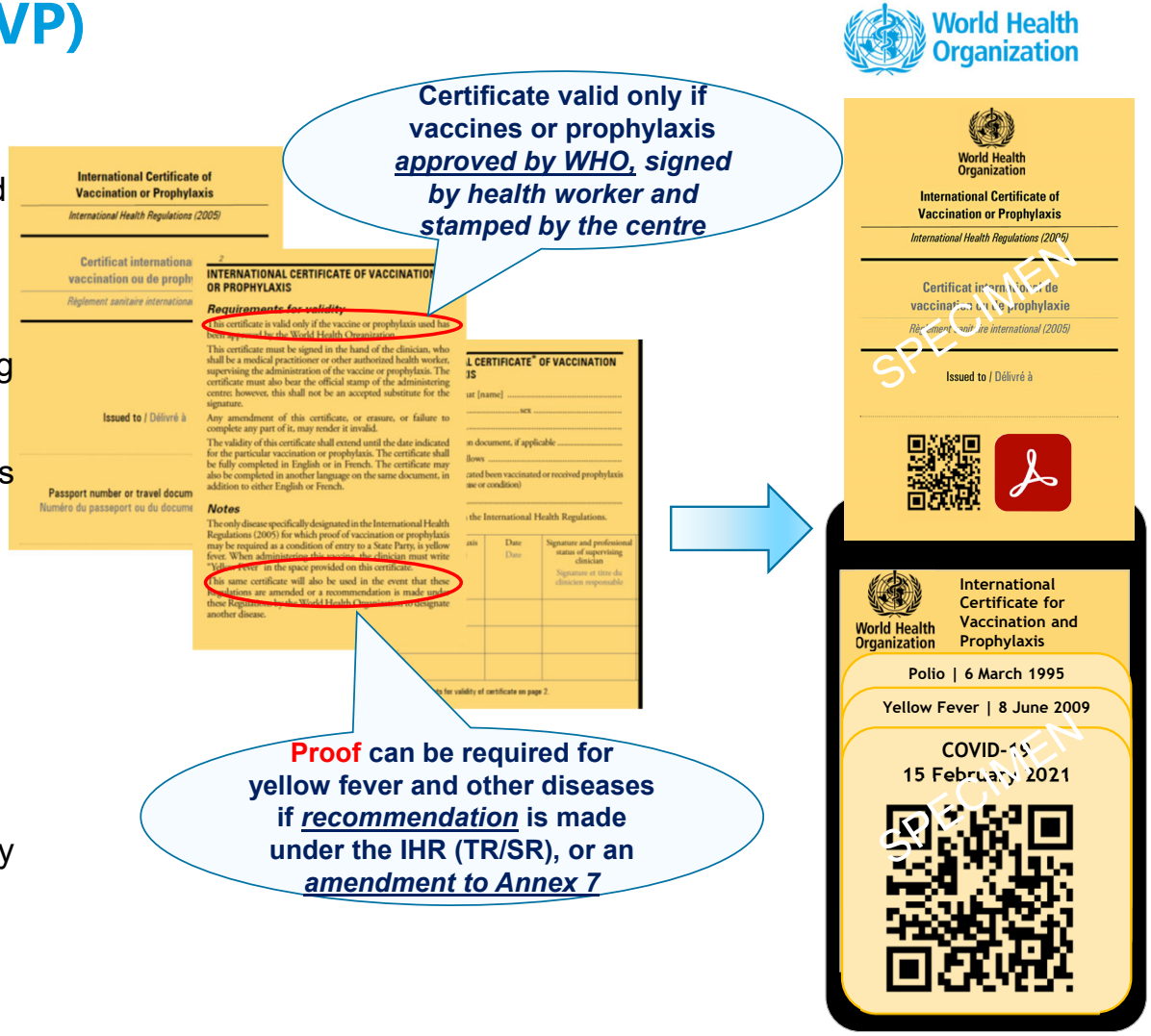
- COVID-19 IHR Emergency Committee
- Statement on the 10th meeting of the COVID-19 IHR EC

- **Lift or ease international traffic bans as they do not provide added value and continue to contribute to the economic and social stress experienced by States Parties.** Link to WHO advice for international traffic in relation to the SARS-CoV-2 Omicron variant
- **Do NOT require proof of vaccination against COVID-19 for international travel as the only pathway or condition permitting international travel** given limited global access and inequitable distribution of COVID-19 vaccines. Link to WHO interim position paper and to WHO guidance
- **Recognize all vaccines that have received WHO Emergency Use Listing and all heterologous vaccine combinations as per SAGE recommendations**, including in the context of international travel. Link to interim recommendations for heterologous COVID-19 vaccine schedules and Link to WHO Emergency Use Listing

Next IHR Emergency Committee COVID-19 will take place on **11 April 2022**

Considerations regarding the International Certificate for Vaccination and Prophylaxis (ICVP)

- Under the IHR, vaccination and prophylaxis administered to international travellers must be recorded in the ICVP, based on model in Annex 6.
- Any country can issue ICVP based on the IHR model.
- WHO publishes and sells the “yellow booklet”, containing the model ICVP and “Other vaccinations” section.
- A plethora of uncoordinated and unharmonized initiatives worldwide to record vaccination status/testing results in travellers.
- Digitalizing the ICVP/yellow booklet may facilitate recording of COVID-19 vaccination status and support mutual recognition of certificates.
- This will not change the temporary recommendation to NOT require proof as a condition of travel, but would only facilitate the recording of vaccination in a universally recognizable document.



Digital documentation of COVID-19 certificates

World Health Organization

- **Context:** The use of digital documentation for health certificates increased during the COVID-19 pandemic to prove vaccination status and test results.
- **Key challenges:** incompatibility of different solutions; lack of interoperability between countries/regions leading to challenges in validation/verification; data privacy and protection; lack of access to public key gateway software to issue or verify certificates.
- **WHO actions**:
    a. **Digital Documentation of COVID-19 Certificates (DDCC) –** Link to technical guidance for DDCC of vaccination status published in August 2021; similar guidance for test results certificates (negative results and previous infection) published in March 2022.
    b. **Reference software –** WHO is supporting the creation of open-source software tools for countries to adapt and use on their own.
    c. **Yellow booklet –** WHO is currently reviewing the paper-based yellow booklet containing the International Certificate for Vaccination and Prophylaxis (ICVP) to include an additional section on COVID-19 laboratory results and, after that, to work towards a digital format of the booklet.



Context and challenges of COVID-19 certificate leading to the need for DDCC guidance from WHO

- **Numerous competing products** for digitally documenting vaccination status and SARS-CoV-2 test results
- **Lack of criteria to** assess solutions & **lack of specifications** for product development
- **Inconsistent data & interoperability standards** being adopted leading to **incompatibility**
- **Inequitable availability** of vaccines, SARS-CoV-2 testing, and access to internet
- Possibility for **fraudulent paper and digital certificates** – undermining trust
- **Limited guidance** on ethical use, digital certificate functions, privacy of data, governance, procedures to mitigate misuse – undermining confidence

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Guidance on Digital Documentation of COVID-19 Certificates aim to:

Achieve implementable specifications and standards for COVID-19 certificates, including vaccination certificates and test result certificates, for **national and/or cross-border** purposes, to ensure **consistent data-representation, -exchange, -privacy, -security**;

ensuring **collective trust** across all types of users;

to **facilitate continuity of care**, **verifiable proof**, and **patient empowerment** related to COVID-19 certificates.

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What is *in* the guidance documents?

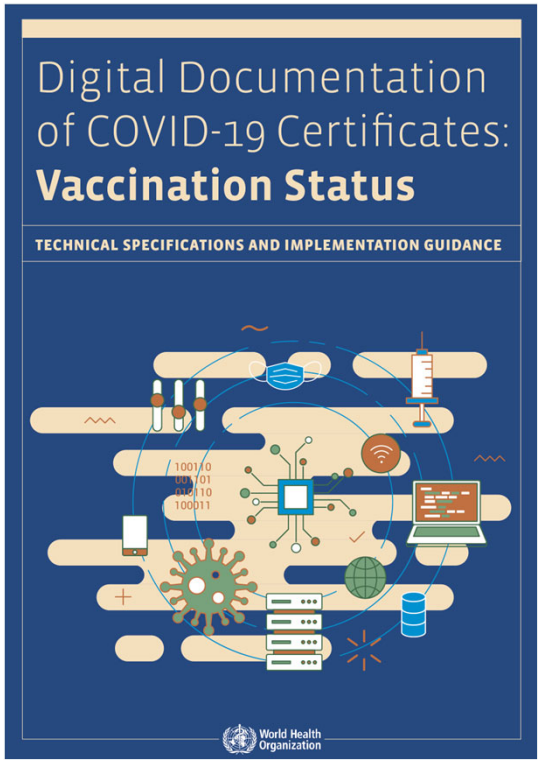
Requirements and specifications for technology implementers

- **Scenarios of use**
- 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

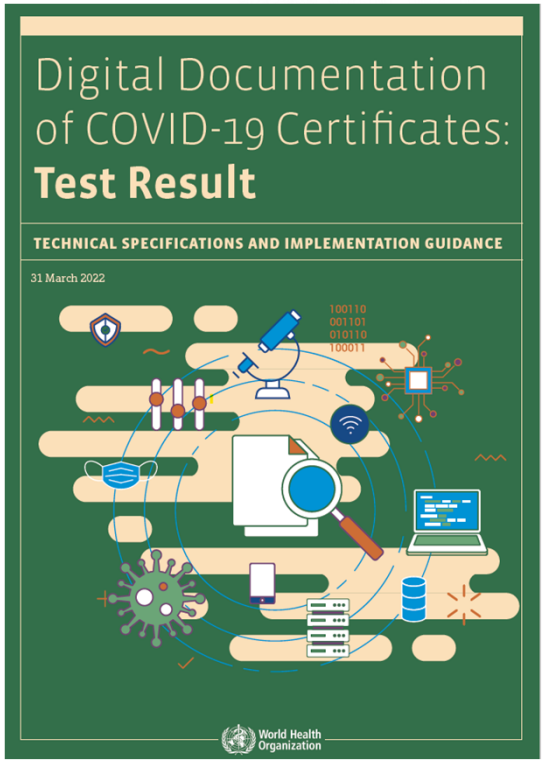
Implementation considerations

- Data protection principles
- Ethical considerations
- National governance considerations

✓ **Continuity of care**
✓ **Proof of vaccination**



✓ **Proof of negative test result**
✓ **Proof of previous SARS-CoV-2 infection**



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DDCC specifications supports countries to adopt whichever modality best fits their context

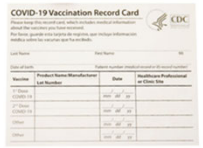
World Health Organization

Illustrative formats of digital vaccine certificates

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



2 National Immunization Home-based Record



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



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



5 A DDCC:VS held on a smartphone



Illustrative formats of digital test result certificates

1 Test report



DDCC:TR represented as various test result certificates

2 (2) a handwritten paper test result certificate with only a HCID that links to a DDCC:TR

OR

a handwritten paper test result certificate with a 2D barcode containing the full DDCC:TR core data set



3 a PDF print out test result certificate with only a HCID that links to a DDCC:TR

OR

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

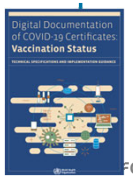


4 A DDCC:TR held on a dedicated smartphone application

OR

A DDCC:TR represented within an electronic personal health record held on a smartphone and/ or digital health wallet







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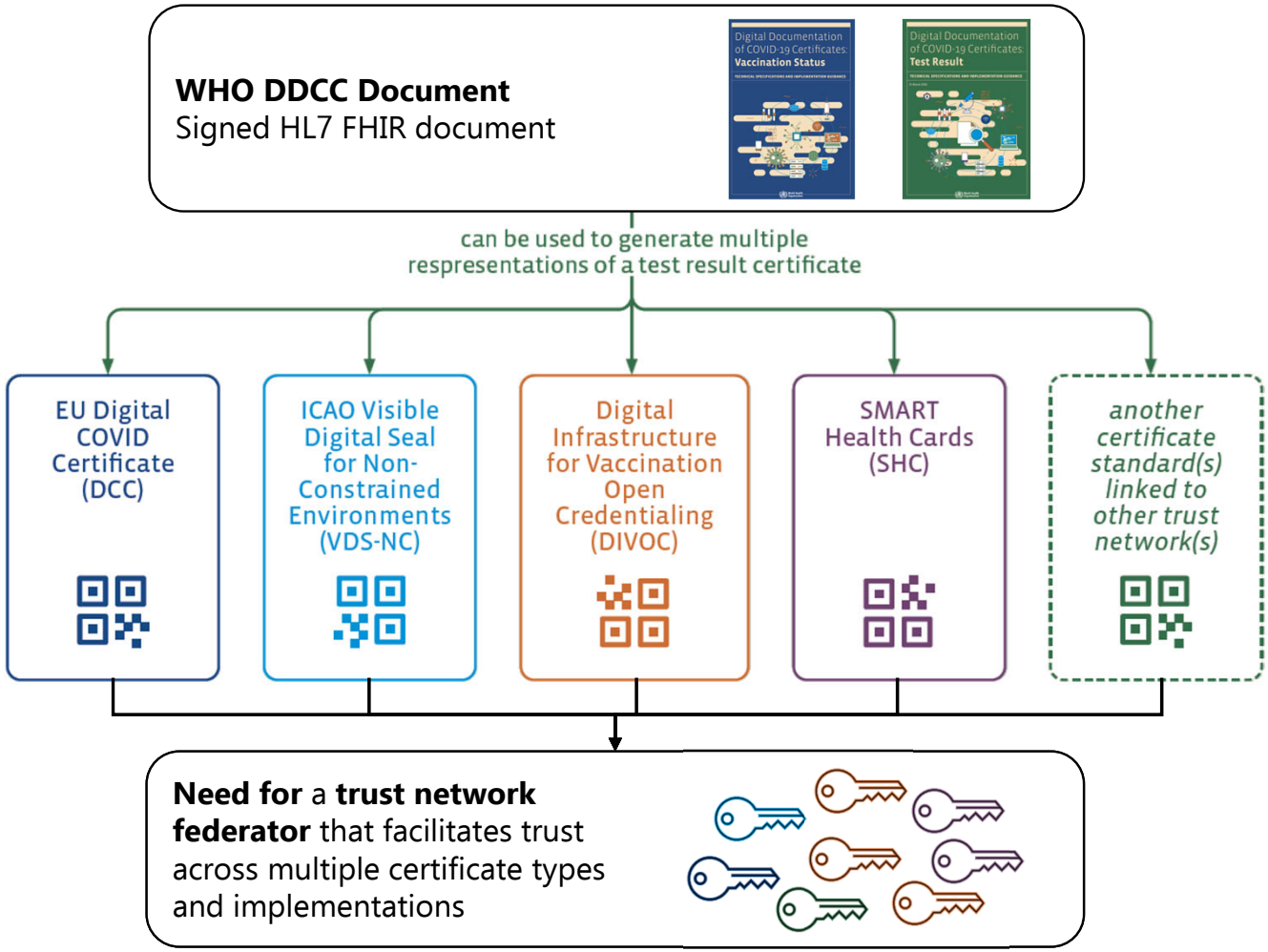
DDCC is “umbrella” specification – there is a need for directory to federate across trust networks



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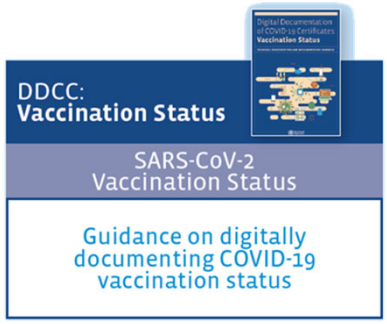
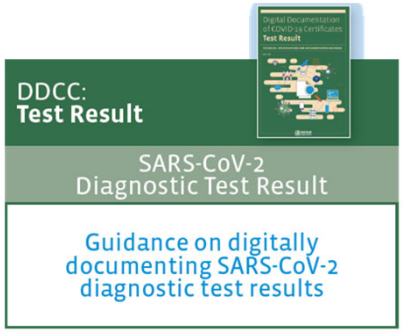
Architecting for the future

The Digital Documentation of COVID-19 Certificate specifications set the foundation for supporting an internationally recognized patient summary that is held by an individual, enabled by the HL7 FHIR interoperability standard

DIGITAL DOCUMENTATION OF COVID-19 CERTIFICATES



Documents **COVID-19 vaccination events**



Documents:

- **SARS-CoV-2 test results**
- **Proof of previous SARS-CoV-2 infection**

HL7 FHIR

Data model can also be used to document **routine immunizations for children**

DIGITAL PERSONAL HEALTH RECORD

Can also support:

- **Electronic health wallet**
- **FHIR International patient summary standard**
- **Immunization/ Maternal / Child Card**
- **Risk factors**
- **Allergies**
- **Other health events**

HL7 FHIR

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Distributed Trust Architecture

- **Interoperable Digital Health Trust networks** exist at national, sub- and supra-national regions. They comprise of:
  - Directory of trusted services
  - Federator to manage access

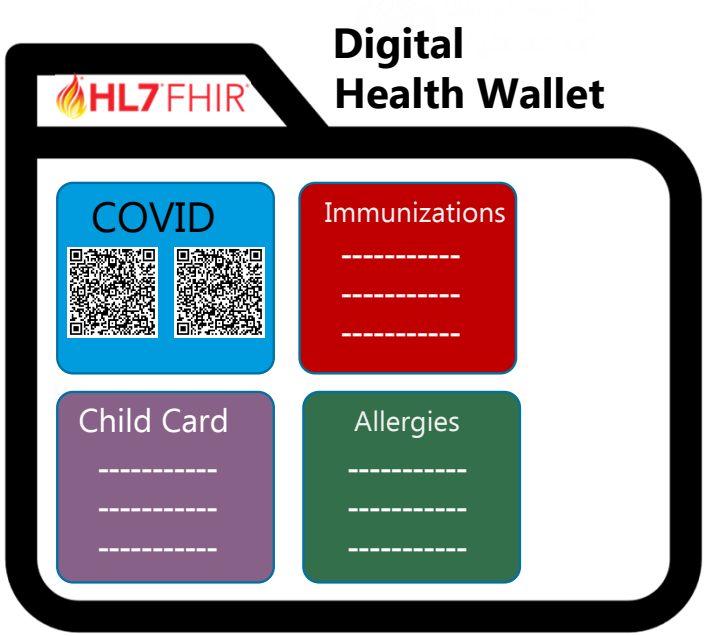
- Gateways used to **facilitate access trusted services between trust networks** depending on type of trust relationship

- Gateways provide a **directory of trusted services**:
  - **public key infrastructure** *for multiple use cases*
  - **metadata services** (e.g. terminology and health commodity catalogs)
  - **business rules library** (e.g. is a given course of vaccinations considered valid?)
  - **credential & health document issuance**



Considerations for a Digital Future

- There are many existing digital standards for COVID certificates, **which don't yet interoperate**
  - Establishing a **new standard or central solution** would not be viable at this point in the pandemic
  - A **directory federating trust networks** and keys would be of global value
- Any approach should be **architected for COVID**, **as well as** future domestic and cross-border uses for verifiable vaccines and test results, and support a **portable digital health wallet**.
- The **IHR ICVP is being digitized** by WHO, consistent with DDCC guidance, including data standards and trust networks – will take time.
- The **HL7 FHIR** (Fast Healthcare Interoperability Resources) **IPS** (International Patient Summary) digital standard is important for digital future-proofing any approach.



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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** for **validation and verification** of COVID-19 certificates & establish agreements that outline the governance process for establishing trust (e.g., equivalence)

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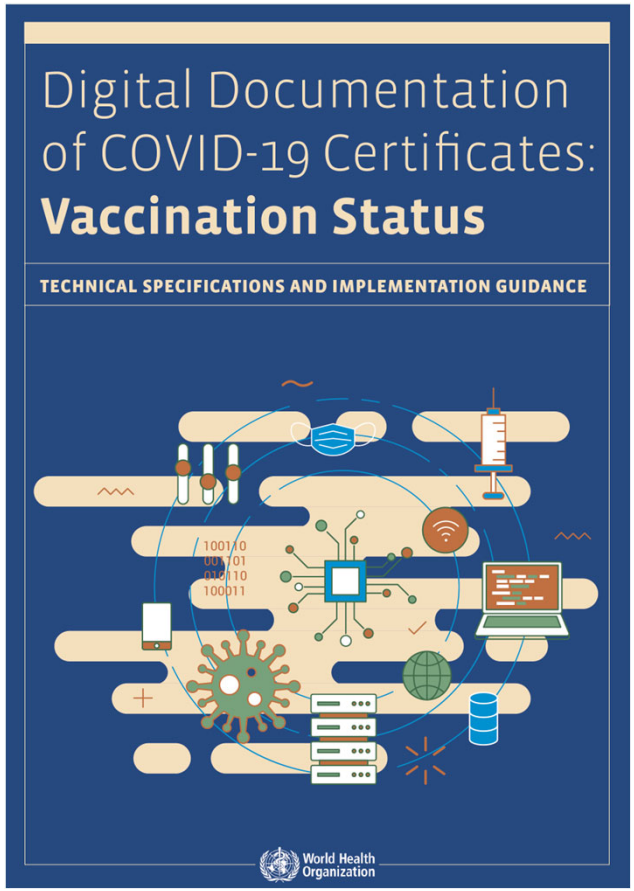
DDCC Specifications Supports Continuity of Care and Personal Health Records





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.

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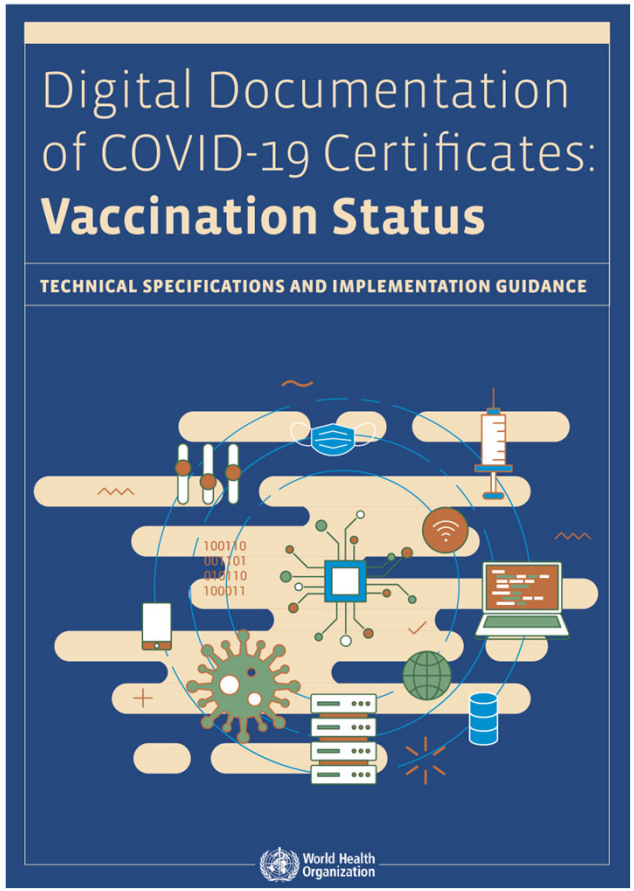
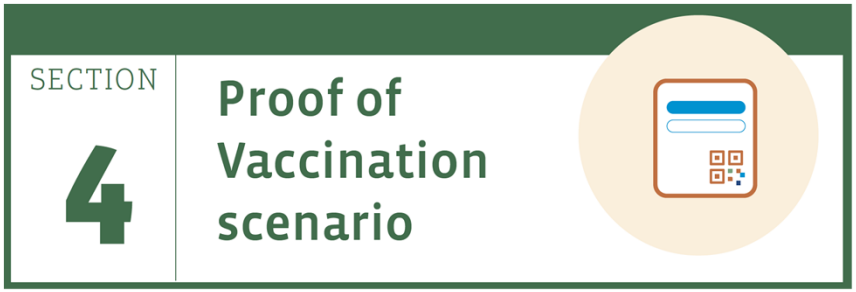
DDCC Specifications Supports Proof of Vaccination for National and Cross-border Uses



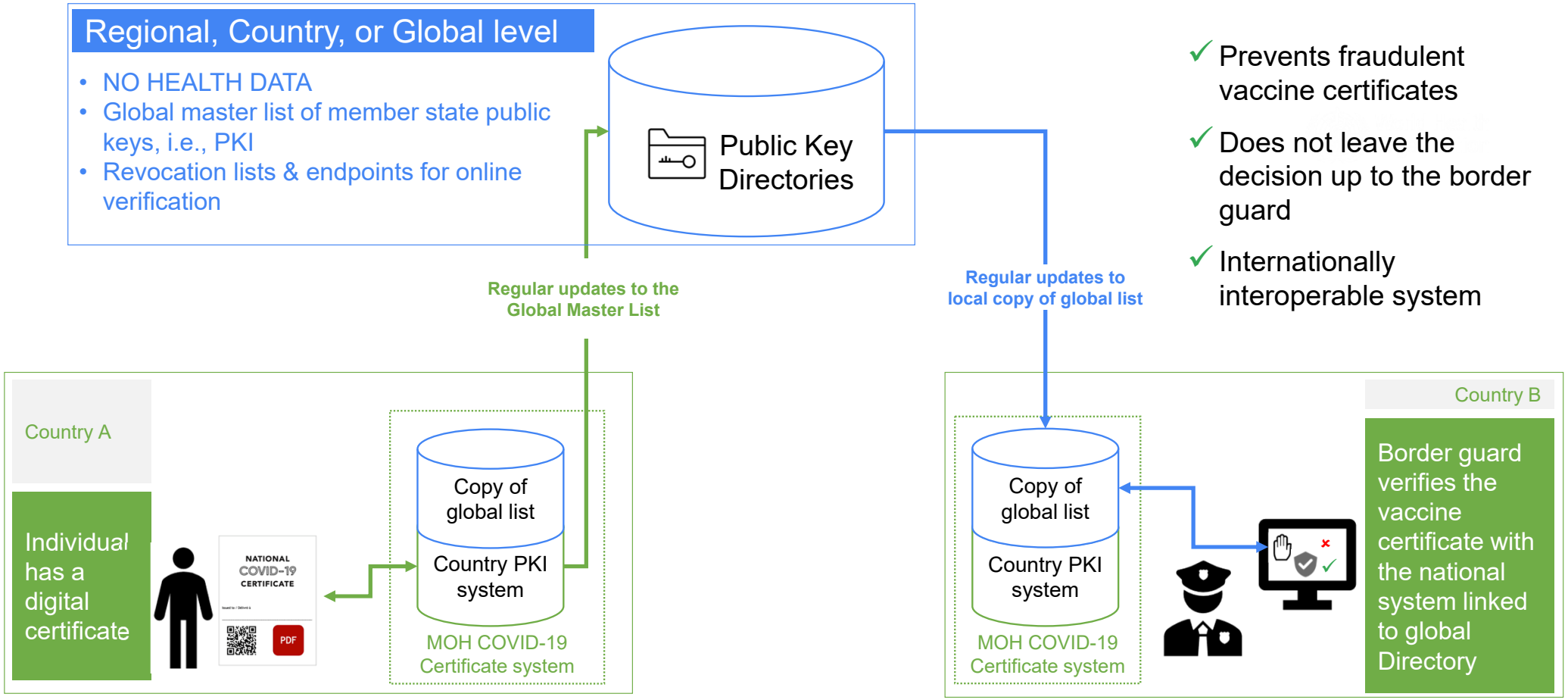


The vaccination certificate is presented as proof that the bearer has received vaccine for COVID-19, and this claim can be checked and validated by an interested party.

NMNR6

Public Key Infrastructure for verifying and validating certificates linked to global trust frameworks

World Health Organization

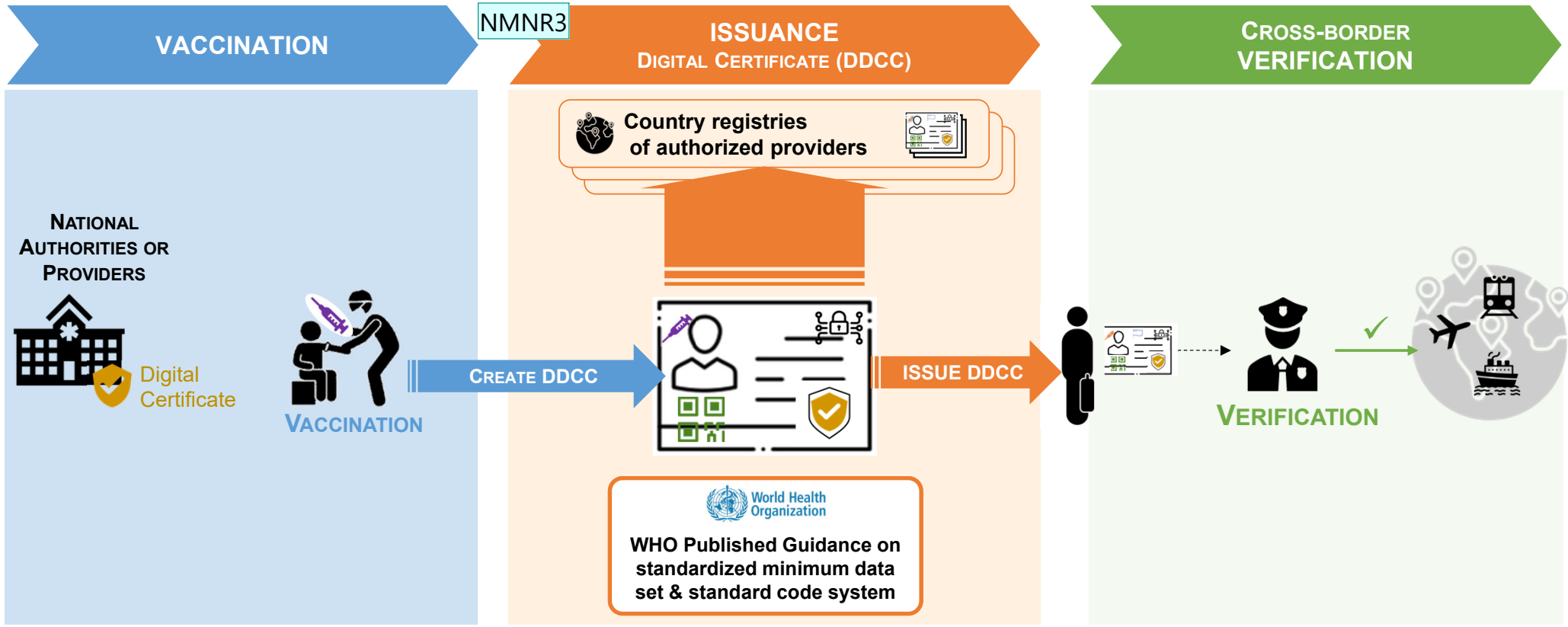


- ✓ Prevents fraudulent vaccine certificates
- ✓ Does not leave the decision up to the border guard
- ✓ Internationally interoperable system

Diapositiva 18

NMNR6 This doesn't really represent what we're trying to do now - I would recommend removing
NASH-MENDEZ, Natschja Ratanaprayul; 24-03-2022

Scenarios of use including issuance, verification



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Diapositiva 19

NMNR3 Same comment re: testing
NASH-MENDEZ, Natschja Ratanaprayul; 24-03-2022

NMNR5

Objectives: Digital Documentation of COVID-19 Certificates (DDCC)

World Health Organization

- To **publish specifications and standards** for data representation, functionality, privacy, and national trust architecture for use cases;
- To **document and learn from successes and challenges** via reference implementations and community of practice;
- To **identify and curate multiple digital solutions** that conform to specifications; and
- To **develop guidance** detailing governance, ethics, and implementation best practices, and links to trust architecture.

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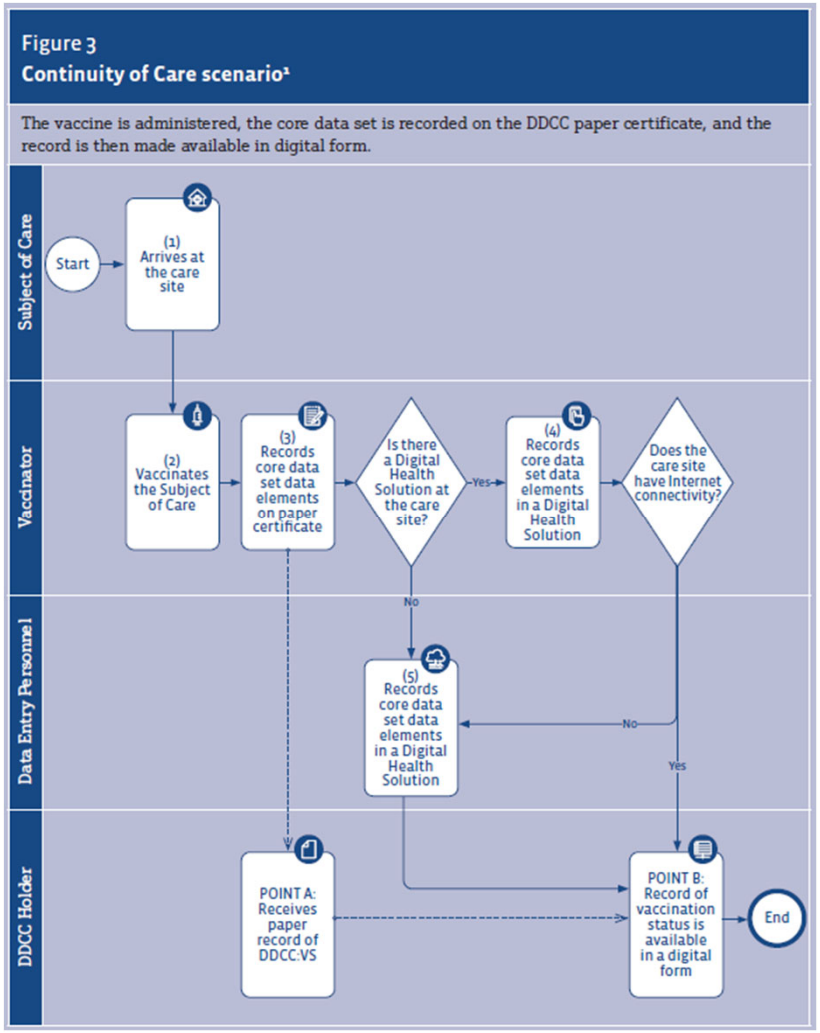
Diapositiva 20

NMNR5 This is a repeat of slide 7 - would recommend removing.
NASH-MENDEZ, Natschja Ratanaprayul; 24-03-2022

Illustrative Functional Requirements (paper & digital)



Requirement ID	Functional requirement	UC001 Paper First	UC002 Offline Digital	UC003 Online 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		✓	

SECTION

5 DDCC:VS core data set



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
Signature of health worker	The health worker who provided the vaccination or the supervising clinician's handwritten signature. **REQUIRED for PAPER vaccination certificates that have been filled out with handwriting ONLY.** A printed paper vaccination certificate does not require the handwritten signature of a health worker.	Signature	Not applicable	Optional – recommended	Required – conditional
Health worker identifier	**OPTIONAL for DIGITAL and PAPER vaccination certificates.** The unique ID for the health worker as determined by the Member State. There can be more than one unique ID used (e.g. system-generated ID, health profession number, cryptographic signature, or any other form of unique ID for a health worker). This can be used in lieu of a paper-based signature.	ID	Not applicable	Optional – recommended	Optional – recommended
Disease or agent targeted	Name of disease that vaccine given to protect against (such as COVID-19).	Coding	ICD-11	Optional – recommended	Optional – recommended
Due date of next dose	Date on which the next vaccination should be administered, if a second dose is required.	Date	Complete date, following ISO 8601	Optional – recommended	Not needed

HPV: human papilloma virus; ICD-11: International Classification of Diseases 11th Revision; ID: identifier; ISO: International Organization for Standardization; mRNA: messenger ribonucleic acid.

Table 12
Vaccination certificate metadata

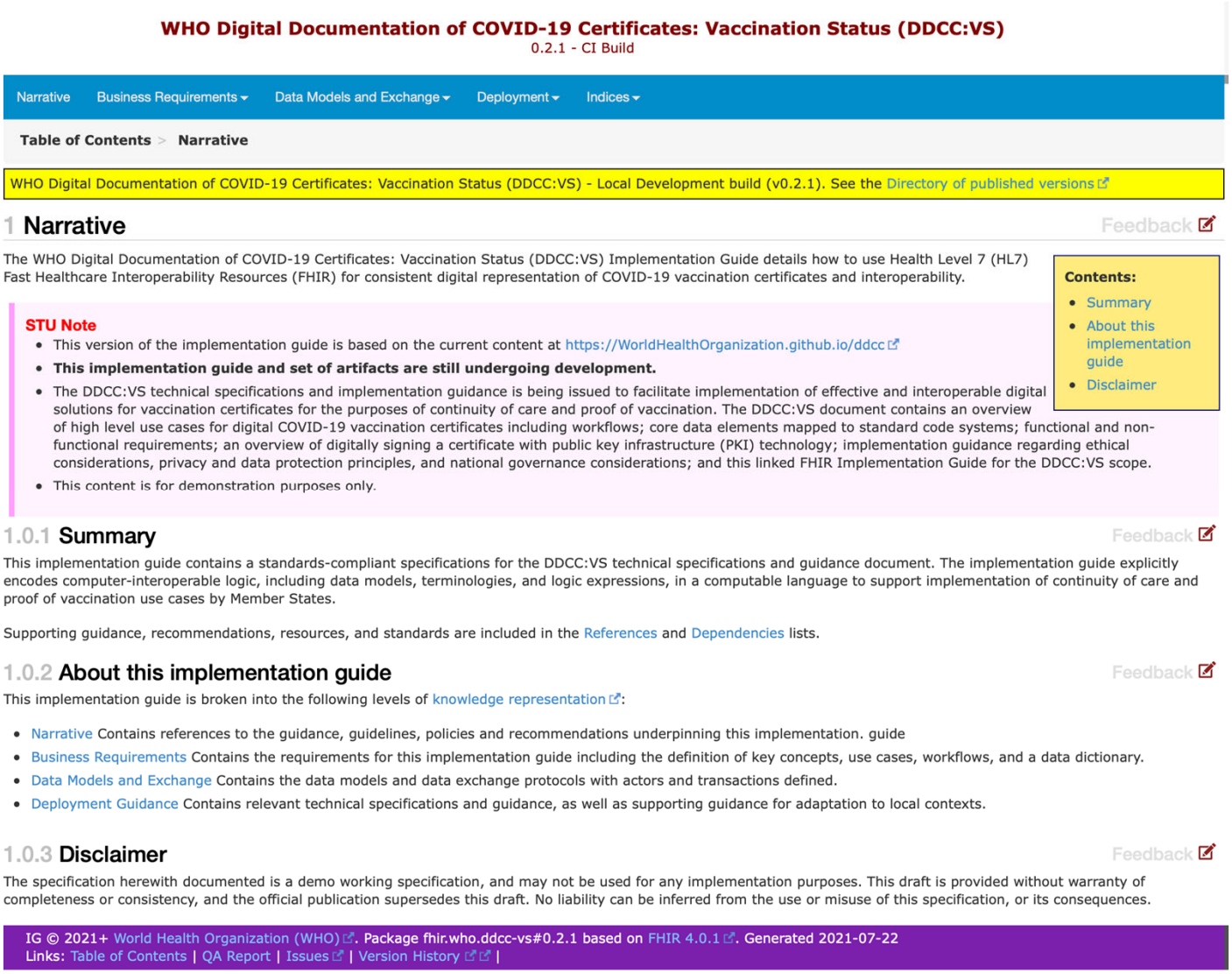
Data element label	Description	Data type	Preferred code system	Requirement status for Continuity of Care	Requirement status for Proof of Vaccination
Certificate issuer	The authority or authorized organization that issued the vaccination certificate.	String	Not applicable	Required	Required
Health certificate identifier (HCID)	Unique ID used to associate the vaccination status represented in a paper vaccination card to its digital representation(s).	ID	Not applicable	Required	Required
Certificate valid from	Date on which the certificate became valid. No health or clinical inferences should be made from this date.	Date	Complete date, following ISO 8601	Optional	Optional
Certificate valid until	Last date on which the certificate is valid. No health or clinical inferences should be made from this date.	Date	Complete date, following ISO 8601	Optional	Optional
Certificate schema version	Version of the core data set and HL7 FHIR implementation guide that the certificate is using.	String	Not applicable	Required	Required

FHIR: Fast Healthcare Interoperability Resources; HL7: Health Level Seven; ID: identifier; ISO: International Organization for Standardization.

WHO DDCC:VS FHIR Implementation Guide

HL7 Fast Health Interoperability Resources (FHIR) Implementation Guide details:

- Machine readable standards
- Terminologies mapped to standards (ICD, SNOMED)
- Business requirements
- Supports consistent representation for data exchange



WHO Digital Documentation of COVID-19 Certificates: Vaccination Status (DDCC:VS)
0.2.1 - CI Build

Narrative | Business Requirements | Data Models and Exchange | Deployment | Indices

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 published versions

1 Narrative

Feedback

The WHO Digital Documentation of COVID-19 Certificates: Vaccination Status (DDCC:VS) Implementation Guide details how to use Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) for consistent digital representation of COVID-19 vaccination certificates and interoperability.

Contents:
- Summary
- About this implementation guide
- Disclaimer

STU Note
- This version of the implementation guide is based on the current content at https://WorldHealthOrganization.github.io/ddcc
- **This implementation guide and set of artifacts are still undergoing development.**
- The DDCC:VS technical specifications and implementation guidance is being issued to facilitate implementation of effective and interoperable digital solutions for vaccination certificates for the purposes of continuity of care and proof of vaccination. The DDCC:VS document contains an overview of high level use cases for digital COVID-19 vaccination certificates including workflows; core data elements mapped to standard code systems; functional and non-functional requirements; an overview of digitally signing a certificate with public key infrastructure (PKI) technology; implementation guidance regarding ethical considerations, privacy and data protection principles, and national governance considerations; and this linked FHIR Implementation Guide for the DDCC:VS scope.
- This content is for demonstration purposes only.

1.0.1 Summary

Feedback

This implementation guide contains a standards-compliant specifications for the DDCC:VS technical specifications and guidance document. The implementation guide explicitly encodes computer-interoperable logic, including data models, terminologies, and logic expressions, in a computable language to support implementation of continuity of care and 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

Feedback

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, workflows, and a data dictionary.
- 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 local contexts.

1.0.3 Disclaimer

Feedback

The specification herewith documented is a demo working specification, and may not be used for any implementation purposes. This draft is provided without warranty of completeness or consistency, and the official publication supersedes this draft. No liability can be inferred from the use or misuse of this specification, or its consequences.

IG © 2021+ World Health Organization (WHO). Package fhir.who.ddcc-vs#0.2.1 based on FHIR 4.0.1. Generated 2021-07-22
Links: Table of Contents | QA Report | Issues | Version History |

https://worldhealthorganization.github.io/ddcc/


Thank you!
smartvaccination@who.int