

eHealth Network

Guidelines on

verifiable vaccination certificates basic interoperability elements

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The eHealth Network is a voluntary network, set up under article 14 of Directive 2011/24/EU. It provides a platform of Member States' competent authorities dealing with eHealth.

These guidelines aim at preparing for interoperability between proofs of vaccination (also known as vaccination certificates), whereby Member States or other parties can decide to implement or use them. They are meant to drive the design of interoperable solutions. The guidelines are mostly targeting the COVID-19 vaccination but might be used in the future as a basis for asserting other vaccinations or prophylaxis.

The term 'vaccination certificates' is used intermittently in this document, referring to a reliable and verifiable proof of vaccination that can be presented by its holder upon request.

These guidelines are the result of the discussions and reflections stemming from the eHealth Network and its subgroups on Semantics and Technical interoperability so far, as well as first consultations with Health Security Committee, EMA, ECDC and WHO.

Although these guidelines have no binding character, Member States or other parties are nevertheless recommended to take them into account if and when deciding to set up their technical solutions for proof of vaccination.

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1 Introduction

Following the conclusions of the European Council of 10-11 December 2020¹ and of 21 January 2021² that called for "a coordinated approach to vaccination certificates", these guidelines establish a minimum dataset, including a unique identifier for vaccination certificates. They also set out the basis for a trust framework. These guidelines are underpinned by the following principles:

- Simplicity through a scheme that can accommodate both paper and digital means;
- Flexibility and compatibility with existing national solutions;
- **Rigorous protection of personal data,** for which necessary instruments need to be developed;
- Step-wise approach, with agreement among Member States at each step of the way.

These guidelines aim to support interoperability between vaccination certificates, if Member States or other parties decide to implement them. They are meant to drive the design of interoperable solutions.

Although these guidelines have no binding character, Member States and other parties are nevertheless recommended to take them into account if and when deciding to set up their vaccination certificates, in order to support interoperability.

The eHealth Network position is that digital and non-digital (Carte-Jaune or other paper) vaccination certificates can be used and co-exist. There shall be no unauthorised discriminatory side effects linked solely to the presentation of COVID-19 vaccination certificates. However, it is important to be prepared for different non-discriminating scenarios, with the reservation to the ongoing legal, ethical, scientific and societal discussions in Europe.

2 Purposes of use

The International Certificate of Vaccination or Prophylaxis (Carte-Jaune) has traditionally been a paper document, which was often simply presented in situ, occasionally along with the presentation of a passport. Usually, there was no further need for additional copies or proofs of veracity of the document. Even if (photo) copies were made, they would contain relatively little information, not be searchable and reveal less than the information copied from the passport.

The situation is markedly different with a digital proof of vaccination; most scenarios call for automatic processing. It is conceivable that most implementations will use digital tools to

https://www.consilium.europa.eu/media/47296/1011-12-20-euco-conclusions-en.pdf

² <u>https://www.consilium.europa.eu/en/press/press-releases/2021/01/21/oral-conclusions-by-president-charles-michel-following-the-video-conference-of-the-members-of-the-european-council-on-21-january-2021/pdf</u>

capture, store or process these digital vaccination certificates, whilst they should coexist with their paper equivalents.

The purpose of use for vaccination proofs supported by these guidelines is in line with the conclusions of the European Council³ as well as to support the upcoming regulation on Digital Green Certificate. Vaccination certificates are to be used primarily as a standardised and interoperable form of **proof of vaccination for medical purposes** Other purposes for which proofs of vaccination (e.g. in particular the travel purposes) could be used, may be decided by Member States, with the reservation to ongoing scientific, ethical, legal, and societal discussions. Among the travel purposes one could consider situations where a person arrives to a country and a verifiying authority confirms whether the person has been vaccinated as regards of the SARS-CoV-2 virus.

Among the medical purposes one could consider situations where a person can get two doses of vaccines in different countries and needs to show the information about the previous vaccine to the second healthcare provider, or situations where a patient develops side effects and the only information available to the healthcare providers is the certificate.

In future evolutions of these guidelines, other purposes of use and further requirements concerning the described purpose can be addressed. Future versions should take into account people for whom vaccination is not possible, so that these groups would not be discriminated against in cases when vaccination certificates are requested from the public.

The vaccination certificate will be issued as a confirmation to the fact that a person has been vaccinated; it can be issued at any time; and its validity can differ from the expected immunisation period; the certificate asserts one completed or partial vaccination course, which may cover one or multiple doses.

3 Basic interoperability elements

This document identifies and outlines basic interoperability elements for a COVID-19 vaccination certificate, namely:

- 1. Minimum dataset with the essential information included in a vaccination certificate;
- 2. Unique Vaccination Certificate/assertion identifier, referring to a completed or partial vaccination course, that is globally unique and verifiable.
- 3. **A trust framework**, including digital infrastructure, that is needed for establishing the authenticity and validity of certificates presented by certificate holders.

The **Unique Vaccination Certificate/assertion identifier** and the **Trust Framework** are further specified in the eHealth Network document on"Interoperability of health certificates – Trust Framework".

The certificate shall be presented at least in English. In addition, the certificate may also be presented in other languages.

³ <u>https://www.consilium.europa.eu/en/press/press-releases/2021/01/21/oral-conclusions-by-president-charles-michel-following-the-video-conference-of-the-members-of-the-european-council-on-21-january-2021/pdf</u>

3.1 Minimum dataset

A minimum dataset enables basic information to be captured and represented in a structured manner that facilitates sharing and interpretation. It is a foundation to enable possible future initiatives with a cross-border dimension on vaccination, such as the ongoing efforts by WHO to develop smart vaccination certificates. A minimum dataset is necessary to ensure interoperability and cross border cooperation on vaccine certificates.

The minimum dataset for a vaccination certificate is organised in 3 sections:

- 1. Person identification
- 2. Vaccination information
- 3. Certificate metadata

The minimum dataset proposed for vaccination certificates is comprised of data elements and linked to the preferred EU code systems. Mappings to these code systems should be considered by the Member States when a Member State is not using any of the preferred code systems. The additional workload caused by the use of the preferred code systems should be kept reasonable.

The dataset is defined as a minimum from the perspective of data registration relevant for the issuance of certificates. Certain fields may or may not be shown to the recipient of the certificate. Even if the defined purpose of use could be supported by the Patient Summary Guidelines, the vaccination certificate provides a complementary solution in which the certificate holder provides the data to the health professional directly. In the medium and longer term, all the vaccination information should be shared through MyHealth@EU, as part of the Patient Summary. However, vaccination certificates will remain useful outside the EU.

Beyond providing input to the certificate minimum dataset, ECDC (European Centre for Disease Prevention and Control) and NITAG (National Immunization Technical Advisory Group) are willing to support the upcoming work related with the minimum dataset for Immunisation Information Systems (IIS) existing or to be developed at the Member State level. The work on IIS minimum dataset will build on top of the discussions and insights regarding the vaccination certificate minimum dataset.

The vaccination certificate system should be designed in such a way that the data subject can control the use of the certificate data. This will be further clarified as part of the development of the trust framework. Information should be disclosed to the recipient of the certificate following the principle of data minimization of the GDPR.

Details on the minimum dataset for vaccination certificates are available in Annex 1.

3.2 Unique Vaccination Certificate/assertion identifier

It is critical to ensure that each certificate about a partial or completed vaccination procedure/course that takes place in EU Member States is uniquely identified by a *Unique Vaccination Certificate/Assertion Identifier* (UVCI). This UVCI shall be included in any issued certificate of vaccination.

The UVCI may be used, at later stages, to verify the certificate and also as a key linking to additional information about the vaccination, once the modalities and platforms have been developed and deployed. The UVCI is needed at the EU level to support the interoperability of the vaccination certificates, while it should be implemented under the responsibility of the Member States in a way that leaves them in full control of how they do so.

At the core of each purpose of use is the fact that at the moment of presentation of the UVCI a person is asserted to be partially or completely vaccinated. The UVCI is a means to verify the veracity of the certificate and, if required, to link to a registration system (for example, an IIS). These identifiers will also enable (paper and digital) assertions by the Member States that individuals have been vaccinated.

The UVCI structure could evolve over time to accommodate additional requirements that may emerge. It should take into account the digital readiness of Member States and be flexible for Member States to accommodate the coexistence of paper and digital versions of certificates as they wish.

Such an identifier would follow a common structure and format easing interpretability of information and could relate to elements such as country of vaccination, the vaccine itself and a Member State specific identifier. It should ensure flexibility to Member States to format it, in full respect of data protection legislation.

It is therefore recommended that the UVCI contains no personal data – its primary purpose is to be a unique 'primary key' that allows Member States' health authorities to verify an individual's vaccination status.

Details about the composition of the UVCI are available in Annex 2.

3.3 Trust framework

Vaccination certificates must be issued by trusted entities, and it must be possible to verify the authenticity and validity of a certificate and the trustworthiness of its issuing authority.

Depending on the medium (i.e. paper, paper with digital elements such as QR-codes, or purely digital), verification scenarios and protocols will differ. Details of these protocols will need to be elaborated as part of ongoing technical design work, also in line with global initiatives. In the design, security analysis and risk assessment should be used, in order to assure sufficient level of protection against forgery of certificates or reuse of valid certificates issued for other persons.

Digital elements enable reliable verification and protection against forgery, at the same time increasing speed and improving usability of the verification process. For a coordinated approach at EU level, further work is needed in the realm of the eHealth Network in collaboration with other relevant groups and organisations in order to:

- Provide mechanisms for establishing authorisation of certificate issuers;
- Support the verification of vaccination certificates;
- Provide support for additional features, such as the revocation of issued certificates;
- Analyse legal implication for a trust framework; and
- Design possible solution while complying with EU data protection legal framework and implementing its data protection principles.

4 Further steps towards vaccination certificate interoperability

The guidelines on the basic interoperability elements of a COVID-19 vaccination certificate will be followed by additional work towards the implementation of the Digital Green Certificate regulation.

In close cooperation with the WHO, a common specifications framework to guide the implementation of interoperable solutions could be developed by the eHealth Network, subject to the consultation of the Health Security Committee.

The Commission is invited to support the development of a toolbox to provide means to issue, read and facilitate the verification of vaccination certificates.

If a person cannot be vaccinated due to a medical reason, or cannot receive the next dose of the ongoing vaccination course, a separate certificate stating so should be implemented for such cases. Support for such certificates and other Covid-19 related proofs (tests etc.) will be explored later by the eHealth Network as part of the further work on vaccination certificates and the toolbox supporting them.

In addition, the Member States are encouraged to develop immunisation information systems and, more broadly, take initiatives to further digitise the health sector, for instance through the Recovery and Resilience Fund (throughout 2021-2022).

Annex 1 – Minimum dataset for proof of vaccination

In the table below, the asterisk * means that a field or the whole section may be repeated. The minimum dataset is primarily designed for medical purposes. Should Member States decide to use proof of vaccination for other purposes, the contents could be less extensive⁴. Optionality is described in the data element section and (--) means not applicable.

Section	Data element	Description	Preferred Code System	Purpose of use	
				Care Travel	
Person identification	Person name	The legal name of the vaccinated person (surname(s) and forename(s) in that order		Х	Х
	Person date of birth	Vaccinated person's date of birth.	Complete date, without time, following the ISO 8601.	Х	Х

⁴ Fields such as Sex, Batch/lot number, Administering centre, Health Professional identification, Next vaccination date may not be needed for purposes other than medical use.

Section	Data element	Description	Preferred Code System	Purpose of use	
				Care	Travel
	Person identifier (optional)	The type of identifier and identifier of the person, according to the policies applicable in each country. Examples: citizen ID and/or document number (ID- card/passport) or identifier within the health system/IIS/e- registry.		Х	Х
	Sex (optional)	Administrative gender		X	X
*Vaccination / prophylaxis information * means that	Disease or agent targeted	Disease or agent that the vaccination provides protection against	ICD-10 or SNOMED CT (GPS) In the future ICD- 11.	Х	Х
the whole section may be repeated	Vaccine / prophylaxi s	Generic description of the vaccine/prophylaxis or its component(s) Example: J07BX03 covid-19 vaccines (temporary code, to be implemented in ATC 2022) 1119349007 COVID-19 mRNA vaccine 1119305005 COVID-19 antigen vaccine	SNOMED CT and ATC Classification (J07 therapeutic subgroup); In the future substances from the ISO IDMP Implementation- EU-SRS system	X	X
	Vaccine medicinal product	Medicinal product name Example: COMIRNATY concentrate for dispersion for injection	For the time being, this should be the name of the medicinal product as registered in the country. In the future the information on the medicinal product can incorporate the identifiers from the implementation of the ISO IDMP Standards and the medicinal package's unique identifier	X	X

Section	Data element	Description	Preferred Code System	Purpose of use	
				Care	Travel
	Vaccine marketing authorizati on holder or Vaccine manufactu rer	Name of the market authorization holder of the vaccination. If market authorization holder is not available, vaccine manufacturer is REQUIRED. <i>Example:</i> <i>BioNTech Manufacturing GmbH</i>	EMA's Organisations System data (SPOR), WHO emergency use listing	X	X
	Number in a series of vaccinatio ns / doses	Order in the vaccination course Example: 1 out of 2 doses, 2 out of 2 doses 1 out of 1 dose		X	X
	Batch/lot number (optional)	A distinctive combination of numbers and/or letters which specifically identifies a batch of vaccines		Х	
	Date of vaccinatio n		Complete date, without time, following ISO 8601	Х	X
	Administeri ng centre	Name/code of administering centre or a health authority responsible for the vaccination event		Х	
	Health Profession al identificati on (optional)	Name or health professional code responsible for administering the vaccine or prophylaxis		X	
	Country of vaccinatio n	The country in which the individual has been vaccinated	ISO 3166 Country Codes	X	Х

Section	Data element	Description	Preferred Code System	Purpose of use	
			, ,	Care	Travel
	Next vaccinatio n date (optional)	Date on which the next vaccination should be administered	Complete date, without time, following ISO 8601	Х	
Certificate metadata (minimum dataset)	Certificate issuer	Entity that has issued the certificate (allowing to check the certificate)		Х	Х
	Certificate Identifier	Unique identifier of the certificate (UVCI), to be printed into the certificate; the unique identifier can be included in the IIS		Х	Х
	Certificate valid from (optional)	Certificate valid from (required if known)	Complete date, without time, following ISO 8601	Х	Х
	Certificate valid until (optional)	Certificate valid until (validity can differ from the expected immunisation period)	Complete date, without time, following ISO 8601	Х	Х
	Certificate schema version (optional)	Version of this minimum dataset definition - currently set at 1.0.0	Semantic versioning (ISO, <u>https://semver.or</u> <u>g/</u> version 2.0.0 or newer).	X	-

All fields that contain non-enumeration/numeric data should be encoded in UTF-8 must be fully canonicalised and normalised according to <u>http://unicode.org/reports/tr15/</u>.

Annex 2 – Composition of the Unique Vaccination Certificate/assertion identifier

The Unique Vaccination Certificate/assertion identifier (UVCI) will follow a common structure that will enable human- or machine-interpretability in all Member States and is designed for the Internet. The order of the separate elements follows a defined hierarchy that can enable future modifications of the blocks while maintaining its structural integrity.



The possible solutions for the composition of the UVCI form a spectrum wherein the modularity and human-interpretability are the two main diversifying parameters and one fundamental characteristic:

- Modularity: the degree to which the code is composed of distinct building blocks that contain semantically different information
- Human-interpretability: the degree to which the code is meaningful or can be interpreted by the human reader
- Globally unique; the Country or Authority identifier is well-managed; and each country (authority) is expected to manage its segment of the namespace well by never recycling or re-issuing identifiers. The combination of this ensures that each identifier is globally unique.

General requirements

The following overarching requirements should be satisfied:

- Charset: Only uppercase US-ASCII alpha numerical characters ('A' to 'Z', '0' to '9') are allowed; with additional special characters for separation from RFC3986⁵, namely {'/','#',':'};
- 2. Maximum length: designers should try to aim for a length of 27-30 characters;6
- Version prefix: This refers to the version of the UVCI schema. The version prefix is '01' for this version of the document; the version prefix is composed of two digits;
- 4. Country prefix: The country code is specified by ISO 3166-1. Longer codes (e.g. 3 characters and up (e.g 'UNHCR') are reserved for future use;
- 5. Code suffix / Checksum:
 - 5.1 Member States should use a checksum when it is likely that transmission, (human) transcription or other corruptions may occur (i.e. when used in print).
 - 5.2 The checksum must not be relied upon for validating the certificate and is not technically part of the identifier but is used to verify the integrity of the code. This checksum should be the ISO-7812-1 (LUHN-10)⁷ summary of the entire UVCI in digital/wire transport format. The checksum is separated from the rest of the UVCI by a '#' character.

Backwards-compatibility should be ensured: over time Member States that change the structure of their identifiers (within the main version, currently set at v1) must ensure that any

⁵ Ibid.

⁶ In the event of implementation with QR codes, Member States could consider an extra set of characters up to a total length of 72 characters (including the 27-30 of the identifier itself) may be used to convey other information. The specification of this information is up to the Member States to define.

⁷ The Luhn mod N algorithm is an extension to the Luhn algorithm (also known as mod 10 algorithm) which works for numeric codes and is used for example for calculating the checksum of credit cards. The extension allows the algorithm to work with sequences of values in any base (in our case alpha characters).

two identifiers that are identical represent the same vaccination certificate/assertion. Or in other words; Member States cannot recycle identifiers.

Proposed options

The different options presented below are available to Member States and other parties and can co-exist among different Member States. Member States can even deploy different option in different version of the UVCI schema. The UVCI should clearly allow distinguishing which option is applied in a given Member State.

In both Options 1 and 3, vaccine manufacturers should preferably be internationally identifiable; this necessitates agreement on common terminology and identifiers to ensure that this is consistently applied. Although EMA has the Organisations Management Service (SPOR) database that includes identifiers for the Marketing Authorisation Holders, and which could serve as a candidate EU-wide solution, not all Member States may be ready to accommodate it.

Option 1 - identifier with semantics

Version	Country	Issuing Entity	Vaccine	Opaque Unique String	Checksum
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This is the most modular approach and consists of three blocks. The issuing entity refers to the authority issuing the certificate while the vaccine block provides information about the vaccine shot used. Finally, the opaque unique string pertains to the vaccinated individual. Member States are free to determine how each block is coded. For example, the vaccine block could encode different data elements in different Member State implementations (i.e. vaccine product identifier, vaccine/lot identifier(s)), depending also on the data availability. Each block will be able to be understood by a human reader (assuming they can interpret the coding). This solution gives the greatest latitude to Member States to populate each block in the manner they see fit by exploiting existing event or evidence/status identifiers, for the registries of authorised vaccination providers.

Each block should consist of alphanumeric characters (i.e. special characters are not allowed within a block). Alphanumeric blocks should be separated by the special character '/'. If two UVCIs are identical up until the first and/or second slash, this means that they are issued by the same issuing entity and/or that the same vaccine lot/batch has been used. Member States are responsible for defining the specifications of each block as they see fit. For instance, the Member States can determine the length of each block based on their actual needs, as long as the total cumulative length of all the blocks as well as the separators does not exceed the defined total length of the identifier (see requirement 2 of the General Requirements).

This will result in greater heterogeneity but will also enhance the possibilities for offline and analogue verification. The option makes it easy to generate and write down the UVCI (e.g. by hand in paper-based documents).

To avoid having the UVCI include personally identifiable information (PII), Member States are strongly urged to refrain from using, for example, a Social Security number or similar long-term stable identifier.

It is recommended therefore that countries use a non-guessable, random event identifier rather than an identifier that reveals something about the bearer. And use the country's IIS or other registration system to hold the provenance and identity of the bearer.

Option 2 - opaque identifier - no structure



Apart from the country code and the code version in the beginning and the checksum of at the end, the code is not modular but it consists of a single field. This single field serves as the unique identifier of the vaccination in the national vaccination registry of the corresponding country. It is the Member states' responsibility to come up with the mechanism for generating and indexing the aforementioned single unique vaccination identifiers.

The opaque unique string should consist of alphanumeric characters exclusively; no other characters (e.g. "/") are allowed. This option provides the maximum flexibility to the Member States in the management of their UVCIs.

Option 3 - some semantics



This option consists of two fields: the issuing entity and the opaque unique string. As opposed to Option 2, the opaque unique string does not need to contain information about the issuing entity. The use of an opaque unique string transfers the responsibility to the Member State for generating the opaque unique string while removing the human interpretability requirement. As in Option 2, Member States will be responsible for determining the mechanism for generating and indexing the opaque unique strings.

The two blocks should consist of alphanumeric characters exclusively; no other characters (e.g., "/") are allowed. The blocks are separated by the slash ("/") character and if two UVCIs compare identical up until the slash, this means that they are issued by the same issuing entity.

It is possible that the definitions of fields change in the future; and that fields need to be added. The use of RFC3986 allows for such; in a manner well understood in internet engineering and available libraries⁸.

⁸ <u>https://tools.ietf.org/html/rfc3986</u>