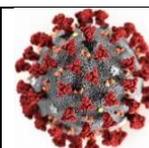


National COVID-19 Science Task Force (NCS-TF)



Type of document: Policy Brief

Expert groups involved: Digital Epidemiology Group

Date of response: 10/02/2021

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Comment on planned updates :

Requirements and Scope of Digital Certificates

Executive summary

The transition away from the global pandemic situation may lead to new public health approaches aimed at allowing a fast restart of the economic and social life while controlling the risk transmission of Sars-CoV-2. These may include the documentation of a recent negative RT-PCR test, the documented presence of neutralising antibodies, or of vaccination. Numerous international digital certification initiatives and standardization efforts are in the early phase of definition.

The situation in Switzerland is characterised by an incomplete legal basis and a pragmatic approach towards digital records used for self-documentation. Furthermore, there is no strategy that defines the medical need for vaccination certificates, nor their legitimate uses for non-medical purposes. As a result there is a void in terms of their technical requirements, scope and social acceptability.

Introduction

The transition away from the global pandemic situation may lead to new public health approaches aimed at allowing a fast restart of the economic and social life while controlling the risk transmission of Sars-CoV-2. Documentation of recent RT-PCR tests are currently required for travel into some countries, or even transit into some countries, in both Europe and the Americas.

With the upcoming broad availability of vaccines, it is expected that a proof of vaccination or the documented presence of neutralising antibodies may be considered as an alternative or an addition to a recent RT-PCR test for travel, especially if certain vaccines are found to dramatically reduce the risk of asymptomatic transmission. The request for such certificates is not limited to the travel and tourism industry. Domestically, similar demands have already been voiced, for example, by the event or sports industries.

No standards exist currently to document test results from RT-PCR lab tests. Air travellers today routinely show a receipt from the lab, resulting in complex and time-inefficient verification at airports. In addition, anecdotal cases of fraudulent RT-PCR test reports by virus-carrying persons attempting to board planes have been documented. As a result, a number of trade industries (e.g. IATA) are in discussion to establish digital certificates of recent RT-PCR tests and/or vaccination that can be automatically checked (e.g. by taking the picture of a QR-code) and that have safeguards to avoid forging.

While there may exist digital technology suitable to build digital certification, the legal, ethical, public health, societal, and economic implications of the use of such certificates are not established. This document does not attempt to answer all such questions. Instead, the goal is to raise awareness that they must be considered when providing the requirements for any digital solution to this problem, clarify the key differences between digital records and digital certificates, and to identify urgent key considerations that the Federal Council and/or FOPH must address before committing to ad hoc digital vaccine certification options.

Current Situation

Situation in Switzerland

Legal basis

The legal situation relating to the registration of vaccination is not entirely clear in Switzerland. The Federal Act on Epidemics mandates the Confederation to establish and to evaluate national programs relating to the prevention and control of epidemics. These programs must also relate to vaccination (Article 5). It is hence clear that the Confederation must build and run a data bank on vaccination which allows for the evaluation of the national vaccination program. To make such evaluation possible, Cantons must regularly inform the FOPH about the number of vaccinated persons in their Canton (Article 24). While it is hence clear that there is a legal mandate to have a national vaccination data bank and to feed it with all anonymous information necessary for the evaluation of the national program, it is less clear whether such data bank may include personal data.

Federal and cantonal authorities may process personal data when there is a legal basis authorizing them to do so (Article 17 para. 1 Federal Data Protection Act). As a rule, they may only process sensitive personal data (such as data on health), if a formal enactment (a federal or cantonal law) expressly provides therefore. It is not entirely clear whether information on vaccination qualifies as sensitive. Data on vaccination (or its absence) does not provide direct information about a person's health situation. If the personal data is considered non-sensitive, any legal basis suffices to make its processing by state authorities legal. If the personal data qualifies as sensitive, a formal enactment by parliament must provide for it. Exceptionally, however, even the processing of sensitive data (on health) is legal in the absence of an explicit legal authorization - without any legal basis in fact - "when such processing is essential for a task clearly defined in a formal enactment" or when the data subject has given his or her consent in an individual case or has made personal data publicly available and not explicitly prohibited its processing (Article 17 para. 2 Federal Data Protection Act).

Switzerland currently does not have an explicit legal basis for the authorities to maintain a centralized registry of vaccinations which includes personal data (and hence is not anonymous). This is also true for COVID-19 vaccinations. The question thus arises whether the exception allowing for the processing of personal data without legal basis applies. Such is the case when a personalised vaccination register is required to fulfil a clearly defined task. The Federal Epidemics Act defines the task of preventing and combating epidemics but does not mention the task of registering negatively tested or vaccinated persons. The legality of a registry of vaccinations thus depends on the question whether such registry is necessary to effectively combat the epidemics (or to prevent a new wave). Its answer depends on the purpose of the register and its use. If its purpose is closely linked to combating the epidemics and limited to this task, the current legal basis may suffice to have a federal database on vaccination which includes personal data. In contrast, an explicit legal basis is necessary if the vaccination registry is to be open to (some) public (as registries often are); the law

must then provide a basis, regulate access and protect privacy. This implies that a new legal basis would also be necessary if the Confederation is to issue certificates based on the register.

The federal competence to issue regulation on the use of digital certificates in the private sphere is undisputed. In the absence of any federal regulation, private actors are free to decide with whom they want to conclude contracts and whom they want to exclude. As a rule, they are thus free to require customers to show a negative test result or proof of vaccination.

Obligations to conclude contracts (Kontrahierungszwang) only exist in specific situations:

- When provided for by law (e.g. for public transport);
- When the refusal to offer a contract would violate other person's rights (e.g. access to essential goods).

The Federal Data Protection Office (EDOEB/PFPDT) clarified on Jan 22, 2021 how basic data protection principles apply to existing private-sector location-tracing applications as well as potential future solutions aimed at verifying vaccination status¹.

Numerous questions, however, remain open. They relate to the qualification of actors as being public or private (e.g. publicly recognised religious communities, subsidized actors in the field of culture and sport), the extent of the obligation to conclude contracts (e.g. the qualification of goods and services as essential or not), and the use and protection of data collected by privates.

As there is a legal duty to minimise the effects of the pandemic on society and to reduce restrictions to individual rights and freedoms to the necessary, the use of vaccination documents and its potential for transition must be further examined from a legal perspective. As the introduction of certificates is increasingly likely to play an important role in the normalisation of public and private life, certificates must be reliable, their use must be regulated.

Existing self-documentation mechanisms and their limits regarding certification

Decentralized Vaccination records. All vaccinations in Switzerland are performed under the responsibility of an authorized health provider (vaccination center, hospital, pharmacy, general practitioner). Health providers are also expected to retain the vaccination as part of their medical records.

Paper-based Vaccination records. Patients expect to receive a record of their own vaccinations, for documentation purposes, e.g., to share with their physicians. Current test centers organised by the Cantons provide patients with (1) the opportunity to write the vaccination into the patient's yellow booklet and (2) a paper document (or its electronic equivalent via email) as a record of their vaccinations. That paper document is not standardized and in fact different cantonal test centers use different formats and layout².

Digital Vaccination records. The website *mesvaccins.ch / meineimpfungen.ch* is operated by a private non-for-profit Foundation partially supported by FOPH, with the explicit goal of providing patients an electronic vaccination booklet. Patients can opt-in to use this website to store a digital record of their vaccinations. For COVID-19 vaccines, the website is directly interfaced with the appointment management system (OneDoc) operated by the Confederation for the vaccination

¹ https://www.edoeb.admin.ch/edoeb/fr/home/actualites/aktuell_news.html#1739424457
https://www.edoeb.admin.ch/edoeb/de/home/aktuell/aktuell_news.html#-990152656

² Early versions of these documents are incorrectly entitled "Swiss COVID-19 Vaccination Certificate", when it is in fact just a record of vaccination.

campaign, allowing for a simple “one-click” validation of the vaccination status. The resulting electronic vaccination record exists for the primary purpose of secured self-documentation, sharing with individually selected health-care professionals and receiving reminders.

The digital records managed by *mesvaccins.ch* are accessible to the owner of the account, and to the health-care professionals selected by the owner of the account.

The patient may print a copy of his/her digital record that contains only the COVID-19-related information. That paper copy is planned to include the name, address, and date of birth of the patient; for each COVID-19 vaccination, the name of the vaccine, lot number, date of administration, location of administration, and name of the attending medical professional; and a QR code that encodes the readable information as well as a PKI-based digital signature of the content, signed with the private key of *mesvaccins.ch*.

Digital Certificates in Switzerland

Digital vaccination records, as described above, and digital certificates serve a different purpose. A **digital vaccination record** (in its electronic or paper form, complete with a QR-code for integrity) encodes the entire COVID-19 vaccination history of the patient and detailed information relevant only to health professionals. It contains medical information and should be protected as such. By definition, it does not contain an expiration date, nor does it constitute a proof of any particular immunization status. Yet, they may be accepted as a proof by third parties as they do contain information about vaccination.

A **digital vaccination certificate** describes a (set of) claim(s) about the vaccination status of a person, which may be limited in time. Certificates must be presented in standardized form. A vaccination certificate serves as a proof that the claim about vaccination status is true. This claim can be separately verified by a third-party. The certificate needs to only include the information necessary for verifying the validity of the claim.

At present, there are no digital certificate standards or solutions that have been adopted for use in Switzerland. The law does not make their requirement illegal for private venues even though the information encoded in these certificates constitutes private medical information. The lack of a legal basis makes it impossible for the public authority to directly issue certificates (unlike, e.g., a driver’s license).

Existing and Emerging International Proposals

Paper-based solutions. For diseases like yellow fever, precedents requiring proof of vaccination status to board flights or cross borders already exist. Currently, such a proof is provided in a paper form in the so-called International Certificate of Vaccination, commonly known as Yellow vaccination booklet. Such a booklet is accepted as a vaccination proof to cross international borders. This booklet is not designed with strong protections against forgery.

Digital solutions. In the last months, a number of initiatives, mostly in the private sector have appeared with the goal of providing digital certification means to prove a recent negative RT-PCR test result or vaccination status. Among them, those started by WHO, with the aim to establish a technical specification for digital vaccination certificate to support COVID-19 vaccination delivery,

with a deadline by July 2021; the proposal by the European Commission's eHealth Network³, TravelPass⁴, proposed by IATA (International Air Transport Association), who propose a decentralized approach to be integrated in airlines mobile apps for both RT-PCR test and vaccination; or CommonPass, promoted by WEF, or the Vaccination Credential Initiative, by a Coalition including big companies such as Oracle or Microsoft.

Most of these solutions rely on cryptography to provide high assurances of authenticity of content and authenticity of origin, in order to avoid fraud. Some of these solutions are also based on decentralized designs so that verification does not require access to any central database. None of these solutions, however, have their specification public yet, and their efficiency, security, and privacy properties are not well-understood.

Looking ahead

At present, FOPH has a strategy for **optional digital records** and has given mesvaccins.ch the mandate to offer an opt-in solution for Swiss patients. This strategy is pragmatic in the absence of a legal basis for a national vaccination registry documenting vaccinations. While pragmatic, the approach is suboptimal and has led to the proliferation of disjointed systems, many of which operate with short data retention rules (e.g., 1 year for reservation system) or on an opt-in basis (e.g., mesvaccines.ch).

However, FOPH does **not** have a clear strategy w.r.t. to **digital certificates**. This lack of clarity has generated public confusion about how vaccination will be documented as well whether such documentation will be associated with privileges. Having a clear end-to-end strategy to end the pandemic will increase overall trust in the vaccination campaign.

A decision of whether such an integration is desirable and a clear strategy on its extent is key, as should international travel policies require such a certificate a system will be needed to enable Swiss residents to travel around the world. In addition to the question of vaccinations, this may require Switzerland to have RT-PCR test sites and laboratories trusted to issue tests results must be both accredited by a national authority in order for them to generate valid digital certificates. The creation of authorities that hold the capability to generate, and delegate, certification powers has to be considered.

Guidance is urgently needed. The FOPH must take responsibility and give direction for the legitimate and ethically acceptable choices in relation to vaccine certification, including support of certain internationally-recognized certificates. The Federal Data Protection Office (EDOEB/PFPDT) should provide further guidance building on its Jan 22, 2021 note to ensure that only proportional solutions are authorized for use in Switzerland.

Recommendations

The paper copy of the vaccination record of *mesvaccins.ch* should be designed with purpose-limitation in mind. The role of the QR code is only to ensure the integrity of the document with health professionals. The document should not directly be usable as a vaccination certificate by commercial third-parties.

³ https://ec.europa.eu/health/sites/health/files/ehealth/docs/vaccination-proof_interoperability-guidelines_en.pdf

⁴ <https://www.iata.org/en/programs/passenger/travel-pass/>

Experts should continue to actively participate in the discussions towards international digital certificate solutions and standards to ensure that they comply with our expectations of privacy, our vaccination strategy and information systems, and our system or laws.

The Federal Council should clarify the national strategy with respect to vaccine certificates and provide a mandate for FOPH to :

1. Determine explicitly whether vaccination certificates are a necessity for domestic purposes.
2. If so, develop a vaccination strategy and policy and clearly define its scope; (e.g. distinguish from vaccination documentation/record; distinguish from immunity; from transient serological status etc.; establish updating process to ensure scope is consistent with constantly evolving scientific understanding re epidemiology and vaccinology);
3. if certification is deemed necessary in Switzerland, determine whether a digital form is necessary and clearly define its scope, legitimate uses in public or private settings, and legitimate uses of the infrastructure built to support digital certificates.
4. establish specific technical and legal requirements with emphasis on data protection, in particular data minimization and purpose limitation, including special attention to issues relating to cross-border data flows.
5. clarify the period for which the use of vaccination certificates are legitimate based on the epidemiologic situation.
6. examine appropriate formats for international use depending on international agreements for travel.
7. In light of possible international requirements as well as possible domestic uses, determine whether an official national registry of COVID-19 vaccination would be appropriate (would require a change in the law).

Transparently disclose the mandate given to any private not-for-profit or commercial third party involved in the management of the vaccination campaign and eventual digital certificates.