

## COVID-19 vaccine deployment in Switzerland: a Delphi consensus process

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**Background:** The ongoing COVID-19 pandemic has infected millions, killed more than 900,000 people worldwide (Sept 2020 data), necessitated important restrictions on personal movement and conduct, and caused significant economic hardship. To date, no therapeutic agent has been shown to limit the spread of SARS-CoV-2 and widespread transmission might resume in Switzerland. A vaccine providing at least partial immunity to infection is widely seen as the principal means of ending this pandemic. As of September 8, 2020, the WHO had identified 34 vaccine candidates in clinical trials, including 8 in phase 3 trials, and 145 more in pre-clinical development.<sup>1</sup> Several countries, including Switzerland,<sup>2</sup> have begun to pre-order vaccines in anticipation of expedited regulatory approval of one or more COVID-19 vaccine in early 2021.

Public health authorities will need to take several critical decisions very quickly once a vaccine becomes available. Assuming that vaccines will not be available in sufficient quantities to vaccinate the entire population, which groups should be vaccinated first? What approaches can improve vaccine uptake in priority populations? How should deployment change based on the number of vaccines available and vaccine characteristics?

To aid decision-makers, Unisanté will conduct an online Delphi consensus process between September and December 2020 to explore areas of consensus and disagreement between Swiss experts. Unisanté brings together expertise in vaccine development, clinical medicine, public health, and consensus methodologies. Previous Delphi studies by our team have examined recommendations to avoid low-value care (Smarter Medicine Top 5),<sup>3</sup> regulatory frameworks for electronic cigarettes,<sup>4</sup> and malaria prophylaxis.<sup>5</sup> We have the support of the COVID-19 Task Force, the Federal Office of Public Health, and the Federal Vaccination Commission.

**Overall objective:** Help public health decision-makers by identifying areas of consensus among Swiss experts for the management and administration of one or more novel COVID-19 vaccines

**Specific aims:** Based on scenarios with differing baseline assumptions (ex: vaccine type, number of vaccines available), we will:

- 1) Create a list of necessary criteria for the widespread implementation of a COVID-19 vaccine  
*Examples: A novel vaccine would need to prevent 50% of infections to justify widespread implementation*
- 2) Identify and define priority groups for early vaccination when a COVID-19 vaccine becomes available  
*Examples: Front-line healthcare workers; Persons at increased risk of severe COVID-19*
- 3) Identify and define groups requiring special consideration based on vaccine characteristics and phase 1-3 trial data available at the time of deployment  
*Examples: Pregnant women should not be vaccinated if a novel platform (ex: mRNA vaccine) is used*
- 4) Identify strategies for vaccine deployment and administration  
*Examples: Vaccines should be administered by general practitioners, in public and private ambulatory care settings, and on-site in pharmacies; Vaccines should be administered by Federal civil protection*
- 5) Identify strategies for improving the acceptability of a COVID-19 vaccine in priority groups  
*Examples: Vaccination should be obligatory for healthcare workers; Vaccines should be covered for all by basic insurance without deductible*

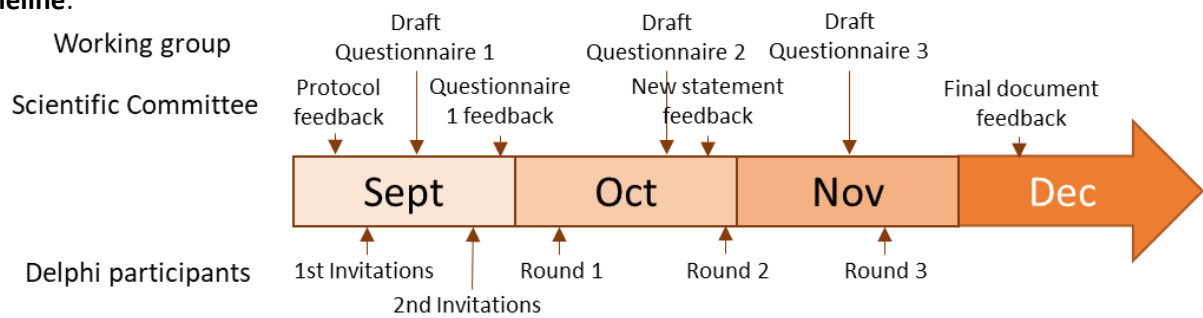
## Methods:

1. **Review and synthesis of selected documents** (Appendix 1). These documents were selected to give Delphi experts core information prior to beginning questionnaires.
  - a. Guidance documents for vaccine deployment from other countries
  - b. Important references from Switzerland
  - c. Primary vaccine types in development
  - d. Selected phase 3 clinical trials of vaccine candidates
  - e. Definition and size of potential priority groups and groups requiring special consideration
2. **Study population.** The approximately 50 Delphi expert participants will be a convenience sample from several subject area, including infectious diseases and vaccinology, public health, primary care, social sciences, medical ethics and risk management. We will invite 70 people, assuming an acceptance rate of 70%, inviting additional people if needed. We will not include key stakeholders such as government officials or members of the Federal Vaccination Commission and COVID Task Force, as our goal is to help their decision-making. The draft list is in Annex 2. The Unisanté working group and the scientific committee will not participate in the Delphi process.
3. **Online Delphi process:** We will conduct an online Delphi consensus process.
  - a. The **Unisanté working group** will draft all documents, including the study protocol, list of experts, brief evidence synthesis document, and questionnaires for the Delphi rounds. The Delphi process will produce statements accompanied by 1 or 2 phrases of explanation and/or justification. We will test questionnaires with local clinicians and researchers to ensure clarity and coherence.
  - b. The **scientific advisory committee** will include 11 experts from outside Unisanté representing a range of specialties, and with roles in key groups such as the Swiss National COVID-19 Task Force and the Federal Commission on Vaccination. They will provide feedback on questionnaires for the Delphi process to ensure the working group is comprehensive in scope and produce statements supported by available evidence. Committee members will not participate in the formal Delphi process.
  - c. The **Delphi expert participants** (appendix 2) will complete a series of three online questionnaires. In the round 1 we will ask for clarifications regarding potential consensus statements. Experts will also propose new statements based on perceived gaps. In rounds 2 and 3, we will ask participants to score statements from 0 (complete disagreement) to 10 (complete agreement). Participants will be able to choose “I don’t know” if they do not have sufficient expertise on the matter, and possibly add free-text comments. In rounds 2 and 3 we will present results from earlier rounds and new statements. We anticipate three rounds will be needed to identify statements reaching consensus. Additional rounds (e.g. a fourth or fifth one) are unlikely to provide added value.

We will collect basic demographic data about the expert participants, including whether in clinical practice, whether they have academic ties, and/or industry connections. We will use REDCap questionnaire and perform descriptive statistics (graphs, means, standard deviation) in Microsoft Excel. All documents will be in English.

4. **Conflicts of interest:** All working group and scientific advisory committee members will be required to declare potential conflicts of interest such as financial relationships with developers and manufacturers of vaccines. Employees and shareholders of such companies may be excluded.
5. **Dissemination plan:** Results will be presented in a report and initially be shared with study participants and key stakeholders (Federal office of public health, Federal Vaccination Commission, COVID-19 Task Force). A press release will be prepared. The full methodology and results will be published in an international peer-reviewed journal and local journals. Results will also be presented in a way suitable for lay audiences.

## 6. Timeline:



### References:

1. DRAFT landscape of COVID-19 candidate vaccines – 20 September 2020. 2020. (Accessed September 9, 2020, at [https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines.](https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines))
2. Covid-19 vaccine: federal government signs agreement with biotech firm Moderna. 2020. (Accessed September 8, 2020, at [https://www.bag.admin.ch/bag/en/home/das-bag/aktuell/medienmitteilungen.msg-id-80005.html.](https://www.bag.admin.ch/bag/en/home/das-bag/aktuell/medienmitteilungen.msg-id-80005.html))
3. Selby K, Gaspoz JM, Rodondi N, et al. Creating a list of low-value health care activities in Swiss primary care. *JAMA Intern Med* 2015;175:640-2.
4. Blaser J, Cornuz J. Experts' consensus on use of electronic cigarettes: a Delphi survey from Switzerland. *BMJ Open* 2015;5:e007197.
5. Calleri G, Behrens RH, Schmid ML, et al. Malaria chemoprophylaxis recommendations for immigrants to Europe, visiting relatives and friends--a Delphi method study. *Malar J* 2011;10:137.