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Commentary

COVID-19 vaccine safety questions and answers for healthcare providers (CONSIDER)



Sonali Kochhar^{a,b,*}, Eve Dubé^{c,d}, Janice Graham^e, Youngmee Jee^{f,g}, Ziad A. Memish^h, Lisa Menningⁱ, Hanna Nohynek^j, Daniel Salmon^k, Karina A. Top^l, Noni E. MacDonald^m

^a Department of Global Health, University of Washington, Seattle, United States

^b Global Healthcare Consulting, India

^c Quebec National Institute of Public Health, Canada

^d Laval University, Canada

^e Dalhousie University, Canada

^f GSPA, Seoul National University, Republic of Korea

^g Special Representative for Health Diplomacy, Korea Foundation, Republic of Korea

^h Research and Innovation Center, King Saud Medical City, Ministry of Health, Riyadh, Saudi Arabia

ⁱ WHO HQ Department of Immunization, Vaccines, and Biologicals, Geneva, Switzerland

^j Deputy Head of Unit, Finnish Institute for Health and Welfare THL, Finland

^k Institute for Vaccine Safety, Johns Hopkins University School of Public Health, United States

^l Pediatrics and Community Health & Epidemiology, Dalhousie University, Canada

^m Paediatrics, Dalhousie University, IWK Health Centre, Canada

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To help stem the tide of the COVID-19 pandemic and its severe global repercussions, vaccines against SARS-CoV-2 have been developed and deployed in record time. A range of both well-established and novel technology platforms are being utilized. The classic platforms include technologies used for other licensed human vaccines including protein, live-attenuated virus and inactivated virus vaccines. Several vaccine candidates approved for use and in advanced Phase 2 and 3 trials utilize novel technologies for which few (i.e. viral vectored) or no prior licensed human vaccines [i.e. nucleic acid (DNA and RNA)] exist [1].

Due to the need for widespread uptake of COVID-19 vaccines, their safety is of utmost importance. The accelerated pace of vaccine development has raised concerns among some healthcare providers and the public regarding whether critical steps in vaccine development are being skipped, especially steps in assessment of vaccine safety, to compress the usual decades long vaccine development process into 12–15 months. Vaccine hesitancy is being fueled by concerns regarding the COVID-19 pandemic response of vaccine manufacturers, regulatory agencies and their governments. There is growing suspicion regarding vaccines in some population groups [2–6]. As for all new vaccines, there is the possibility that rare serious adverse reactions will not be identified in clinical trials and only found once a larger number of people are vaccinated

* Corresponding author.

E-mail address: sonalikochhar@yahoo.co.in (S. Kochhar).

[4]. Additionally, when vaccinating a large number of people, some of them will have adverse health outcomes shortly after vaccination by chance alone [4,5]. COVID-19 vaccine safety questions need to be urgently addressed; what we know, what we do not know yet and how vaccine safety is being carefully monitored so if needed, adjustments to increase safety can be made. If not done now, vaccine hesitancy will adversely impact COVID-19 vaccine acceptance. Short, clear, evidence-based answers to COVID-19 vaccine safety questions are needed to inform and increase scientific literacy among the various stakeholders.

In recognition of the critical importance of COVID-19 vaccines and the need to understand their safety, the CONSIDER (COvid-19 vacCiNe Safety questIons and hEalthcare pROviders) working group (WG) was created in September 2020 consisting of vaccine researchers serving in their individual capacity. The WG consists of researchers with expertise in vaccine safety, clinical trials, risk communication, anthropology, pediatrics, and internal medicine. The WG aims to provide clear, evidence based answers for front line health care workers and others to questions pertaining to COVID-19 vaccine safety prior to, and during the vaccine roll out.

Rapid updates are provided as information regarding adverse events following immunization (AEFI) [4] and adverse events of special interest (AESI) [4] becomes available to:

- 1). Facilitate scientific discussion between stakeholders, including front line healthcare workers with potential vaccine recipients; and
- 2). Increase comprehension and transparency of information to facilitate COVID-19 vaccine acceptance and uptake.

Healthcare workers are on the frontline of COVID-19 vaccine safety communication, including risk communication. Supporting them with timely, evidence-based responses about vaccine safety can help improve their confidence and effectiveness as communicators so that they serve as trusted sources on vaccination. The WG hopes that the responses provided to common COVID-19 vaccine safety questions and concerns are understandable, accessible, reference publically available studies and data [7], and increase scientific discussion and transparency of information among key stakeholders. Visual aids (e.g., graphics, pictures) and examples are used to explain the information [8]. This is key as information alone is not synonymous with knowledge, with the latter implying the “skillful interpretation and application of that information” [9].

The answers can also be used to help national and subnational health authorities in training and educating healthcare workers (including those providing immunization services) and in updating National Immunization Technical Advisory Groups (NITAGs) and Regional Immunization Technical Advisory Groups (RITAGs) as new questions and concerns arise and information becomes available. The answers developed have been widely shared within Vaccine Safety Net (VSN) (a global network of websites established by the World Health Organization, that provides reliable information on vaccine safety), with NITAGs and with education teams within public health agencies to help health authorities in training and educating healthcare/vaccine providers. As of February 2021, the answers have been accessed by readers in over 130 countries (including both high-income and low and middle income countries (LMIC)) and have received over 15148 views.

Each answer is written by an expert member of the WG and reviewed by two or more other members. Following the public health communication strategy of “gateway belief” [10] (a process of attitudinal change whereby a perception of scientific consensus on an issue leads to a change in people’s attitudes and support for public action, it is hoped). It is hoped that communicating scientific consensus among medical scientists on the WG about COVID-19 vaccine safety will reduce stakeholder concerns and key miscon-

ceptions. The WG members come from several different countries and do not have conflicts of interest related to the COVID-19 vaccines.

Science is evolving rapidly. This is a living document hosted on the CANVax site, (<https://canvax.ca/covid-19-vaccine-questions-and-answers-healthcare-providers>), accredited by the World Health Organization’s Vaccine Safety Net. Q&As are available in English, French, Arabic and Chinese with plans for translation into other languages. For some of the answers, there are additional audio and video explanations available on the site (to make them easier to access) and social media bites have been posted.

As more questions come to the group’s attention and more information becomes available (from COVID-19 vaccine clinical trials and early experience with vaccine introduction in countries), the answers will be updated and new answers posted. The CONSIDER WG welcomes feedback from key stakeholders, which after review may be included in further updates to the answers.

Disclaimer

The findings, opinions, conclusions, and assertions contained in this document are those of the individual co-authors. They do not necessarily represent the official positions of any participant’s organization (e.g., government, university, or corporations) and should not be construed to represent any Agency determination or policy.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

References

- [1] van Riel D, de Wit E. Next-generation vaccine platforms for COVID-19. *Nat Mater* 2020;19(8):810–2. <https://doi.org/10.1038/s41563-020-0746-0>.
- [2] Schaffer DeRoo S, Pudalov NJ, Fu LY. Planning for a COVID-19 vaccination program. *JAMA* 2020;323(24):2458–9. <https://doi.org/10.1001/jama.2020.8711>.
- [3] Lancet COVID-19 Commissioners, Task Force Chairs, and Commission Secretariat. Lancet COVID-19 Commission Statement on the occasion of the 75th session of the UN General Assembly. *Lancet*. 2020;S0140-6736(20)31927-9. doi: 10.1016/S0140-6736(20)31927-9
- [4] Kochhar S, Salmon DA. Planning for COVID-19 vaccines safety surveillance. *Vaccine* 2020;38(40):6194–8. <https://doi.org/10.1016/j.vaccine.2020.07.013>.
- [5] MacDonald NE, Dube E. Vaccine safety concerns: Should we be changing the way we support immunization?. *EclinicalMedicine* 2020;23:. <https://doi.org/10.1016/j.eclinm.2020.100402>.
- [6] Safety of Vaccines Used for Routine Immunization in the United States: An Update. US Agency for Healthcare Research and Quality Effective Health Care Program. Accessed on November 4, 2020 at <https://effectivehealthcare.ahrq.gov/products/safety-vaccines/draft-review>
- [7] Bloom BR, Nowak GJ, Orenstein W. “When will we have a vaccine?” - Understanding questions and answers about covid-19 vaccination. *N Engl J Med* 2020. <https://doi.org/10.1056/NEJMp2025331>.
- [8] Vivion M, Hennequin C, Verger P, Dubé E. Supporting informed decision-making about vaccination: an analysis of two official websites. *Public Health* 2020;178:112–9. <https://doi.org/10.1016/j.puhe.2019.09.007>.
- [9] Tomes N. Managing the modern infodemic. *CMAJ*. 2020 Oct 26;192(43):E1311–E1312. doi: 10.1503/cmaj.201905. Accessed on October 28, 2020 at <https://www.cmaj.ca/content/cmaj/192/43/E1311.full.pdf>
- [10] van der Linden SL, Clarke CE, Maibach EW. Highlighting consensus among medical scientists increases public support for vaccines: evidence from a randomized experiment. *BMC Public Health* 2015;15:1207. <https://doi.org/10.1186/s12889-015-2541-4>.