COVID-19 Vaccination: Building Global Capacity

Q&A for Session 08: Reporting on COVID-19 vaccines (monitoring and AEFI)

Tuesday, March 30, 2021

Thank you for attending the above session for Health workers. Many questions were submitted by participants, either in the Zoom chat during the session itself, or in the two Telegram channels managed by Technet-21 supporting regions, countries, and partners in preparing for COVID-19 vaccine introduction. In this document, we share the answers from presenters to each question.

Links to the session recordings in all languages and presentations can be found on the Project ECHO website.

More information on COVID-19 vaccine introduction can be found in the resources listed below.

- General questions regarding the COVID-19 vaccines
- Preparing for COVID-19 vaccination
- WHO Coronavirus disease (COVID-2019) technical guidance
- TechNet-21 – The Technical Network for Strengthening Immunization Services
- OpenWHO COVID-19 vaccine trainings:
  - COVID-19 vaccination training for health workers

In addition, TechNet-21 manages two Telegram channels supporting regions, countries, and partners in preparing for COVID-19 vaccine introduction. In these two spaces - one anglophone and one francophone - you will be able to share your experiences, discuss key questions, and connect with experts from around the world. We'll also share new information and global guidance as it becomes available. Join us today:

- COVID-19 Vaccine Introduction – TechNet-21 (English)
- Introduction des vaccins contre la Covid-19 – TechNet-21 (Français)

With now 25 million people vaccinated in UK, there is no sufficient capacity of GPs to receive calls from hundreds of thousands of people with adverse events, or for hospitalisation or in person medical attention. Don't you think there will be inevitable inconsistencies in thresholds of reporting by country?

Yes, reporting by countries will be variable. But one should remember that all cases that are notified to (brought to the notice of) the health system should be reported using a very simple reporting form. Of the cases reported, only the very few minor numbers of serious AEFI cases need to be investigated (and not all cases need to be investigated). See content as well as annexes 5.1 and 5.3 in the Global Covid 19 safety manual https://cdn.who.int/media/docs/default-source/covid-19-vaccines-safety-surveillance-manual/covid19vaccines_manual_aefi_20210104.pdf?sfvrsn=e9c1dc49_26&Status=Master

In the case of death, who is the person eligible to apply [for the NFC Programme]? Is that decided ahead?

Anyone who is duly authorized to represent the deceased applicant can submit an application on their behalf. This person will need to submit a power of attorney and/or statement that has been notarized by a notary public or other public official legally authorized to provide notarization or legalization services within the territory where the vaccine was administered to the deceased. Please see more details on Schedule 2 of application form at the link below: https://covaxclaims.com/printable-program-forms-and-other-documents/

Do countries have enough capacity to analyse the adverse events? If not, does the WHO provide the technical support for that?

Yes many countries have capacity to analyze AEFI data. There are 2 methods offered by WHO:

1. DHIS2 Platform https://community.dhis2.org/t/dhis2-covid-19-vaccine-toolkit-new-release/42277 as well as

2. VigiLyze Platform from the WHO collaborating centre - UMC https://www.who-umc.org/vigibase/vigilyze/

In addition, several countries have their own software. if you need assistance to develop or use software, please contact the WHO country offices or regional office or send a mail to gvsi@who.int

Is there a guide on advising patients who reported AEFIs over the telephone?

This varies from country to country.

How can we attend to various unexpected adverse reactions to prevent fatalities among vaccinated recipients? In case there is any reaction after taking the vaccines, what medicine is the patient supposed to take?

There are anaphylaxis guidelines including a video that have just been developed. You can access this here https://watch.immunizationacademy.com/en/videos/760

How can we measure the PEG (polyethyleneglicol) tolerance related reaction due to the COVID-19 vaccination?

Measuring PEG tolerance is not easy. The hypothesis for the serious adverse events (SAEs) is that this is an IgE mediated anaphylaxis, but in some of the anaphylactoid-type reactions seen with pegylated doxyrubicin there was no detectable IgE so a hypothesis of complement-mediated (alternative pathway) mast-cell activation has been proposed.

So, one could measure IgE – but this will not identify all those who will have an SAE. One could do a skin-prick test – likely to be slightly more sensitive but this takes time. But question is what to do the skin prick test with? The use of soluble PEG is probably not appropriate since the alternative pathway is affected by the presentation – so one would need pegylated nanoparticles… (GMP…). Currently there is no cost-effective routine standard method to pre-screen those at risk for PEG allergies. A history of anaphylaxis to PEG is an absolute contraindication, but a history of allergy is not an absolute contraindication, just a precaution, for mRNA vaccines that contain PEG.

Prospective studies are ongoing to unravel the mystery of PEG allergies which may help us identify predictive markers. For the time being, we don`t have a screening method. The standard language is:

15 minutes observation time post vaccination for ALL vaccines in a center experienced in managing anaphylaxis.

30 minutes observation time post vaccination for all those vaccinees with a history of severe allergies.