

Joint statement to consolidate the pharmacovigilance systems for securing safety of the COVID-19 vaccine products

issued by
Japanese Society for Pharmacoepidemiology
Japanese Epidemiological Association
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The challenge of emerging, life-threatening novel corona virus outbreak is the ongoing, global public health crisis, affecting people's life and society extensively. All-out battle by all the nations of the world against COVID-19 virus entails every countermeasure including the existing public health, medical, and social interventions, however, it is expected that containment of COVID-19 pandemic and prevention of its resurgence would not be achievable without effective, brand-new vaccines against novel corona virus and medical interventions for the infection. Such high expectation of the public and substantial support of the national governments have prompted the medical and pharmaceutical communities to facilitate the development of multiple COVID-19 vaccines at unprecedented speed and we see a likelihood that those vaccine products become available in the market within 2020. Vaccination program is a medical intervention to the whole society and needs tens of thousands of healthy people being vaccinated to be effectively implemented. Therefore, it is essential that high standard of vaccine safety should be met for successful implementation of vaccination programs. A safety issue of a COVID-19 vaccine, once it arises after the launch, itself could be greatly and extensively impactful to the whole society and enhance the public's distrust of vaccine, potentially resulting in unsuccessful intervention.

Thus, we believe that the system securing the post-authorization safety of approved COVID-19 vaccines be the most urgent issue to be addressed, regardless of following the precedent frameworks of existing pharmacovigilance methods used for pharmaceuticals and vaccines. The proactive pharmacovigilance system of COVID-19 vaccine be established in advance in cooperation and collaboration with vaccine suppliers, health authorities and the public by taking full advantages of leading-edge social infrastructure, to capture safety concerns instantaneously and infallibly, and to implement real-time, proactive countermeasures against safety concerns arising post-authorization. In addition, many vaccine products under development need multiple shots and adherence to predefined vaccination schedule is essential for securing efficacy and safety, and then the record sharing of vaccination among healthcare professionals is necessary.

To this end, it is an imperative to construct and operate the national registry to enroll and follow all the vaccinees of approved COVID-19 vaccines, allowing collection of vaccination records and outcome data after vaccination systematically.

Thus, we PROPOSE that the following actions 1 -3 shall be taken;

1. **Construct the online electronic registry system and mandate the entry of the vaccination coupons of approved COVID-19 vaccines into the registry via the Internet at vaccination, to register and follow all the vaccinees in a centralized manner. Vaccinee's consent to the use of the registry data and retrieval of relevant health records should be obtained on registration.**
2. **Allow linkage between the registry and various types of electronic health records (EHRs) database such as claims and hospital administrative databases, to enable real-time and formal epidemiologic analyses by combining the health and social data with vaccination data at individual level. Otherwise, incorporating or recording the data related to vaccination into the claims database by any means should be sought where record linkage is impossible.**
3. **Utilize the clinical information obtained through the linkage of vaccine registry and EHR databases for assessing causal inference between vaccination and an occurrence of health hazards in a reported case, to provide quick remedy for and rational countermeasures against potential adverse reactions due to vaccination.**

To provide effective and safe vaccination to everyone is vital and locomotive to overcome the pandemic caused by this novel corona virus at the earliest possible time. We believe that it is a MUST to consolidate the pharmacovigilance system of COVID-19 vaccines which enables the proactive and rapid data collection about emerging safety concerns in advance.