

## 博士後期課程

令和3年度

武蔵野大学大学院 薬科学研究科 薬科学専攻 博士後期課程 入学試験問題 (3月7日)

[ 英語 ] 次の文章を読み、各問に答えよ。

Two coronavirus disease 2019 (COVID-19) vaccines are currently authorized for use in the United States. The Food and Drug Administration (FDA) issued Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine on December 11, 2020, and for the Moderna COVID-19 vaccine on December 18, 2020; each is administered as a 2-dose series. The Advisory Committee on Immunization Practices issued interim recommendations for Pfizer-BioNTech and Moderna COVID-19 vaccines on December 12, 2020, and December 19, 2020, respectively; initial doses were recommended for health care personnel and long-term care facility (LTCF) residents. Safety monitoring for these vaccines has been the most intense and comprehensive in U.S. history, using the Vaccine Adverse Event Reporting System (VAERS), a spontaneous reporting system, and v-safe, an ( ① ) surveillance system, during the initial implementation phases of the COVID-19 national vaccination program. CDC conducted descriptive analyses of safety data from the first month of vaccination (December 14, 2020–January 13, 2021). During this period, 13,794,904 vaccine doses were administered, and VAERS received and processed 6,994 reports of adverse events after vaccination, including 6,354 (90.8%) that were classified as nonserious and 640 (9.2%) as serious. The symptoms most frequently reported to VAERS were headache (22.4%), fatigue (16.5%), and dizziness (16.5%). A total of 113 deaths were reported to VAERS, including 78 (65%) among LTCF residents; available information from death certificates, autopsy reports, medical records, and clinical descriptions from VAERS reports and health care providers did not suggest any causal relationship between COVID-19 vaccination and death. Rare cases of anaphylaxis after receipt of both vaccines were reported (4.5 reported cases per million doses administered). ② Among persons who received Pfizer-BioNTech vaccine, reactions reported to the v-safe system were more frequent after receipt of the second dose than after the first. The initial postauthorization safety profiles of the two COVID-19 vaccines in current use did not indicate evidence of unexpected serious adverse events. These data provide reassurance and helpful information regarding what ( ③ ) and vaccine recipients might expect after vaccination.

VAERS is an existing national passive surveillance system for adverse events after vaccination that accepts reports from ( ③ ), vaccine manufacturers, and the public.

Reported signs and symptoms are coded using Medical Dictionary for Regulatory Activities (MedDRA) terminology. Serious adverse events are followed up by the VAERS program to obtain additional information, including medical records, information from ( ③ ), and, in the case of death, death certificates and autopsy reports.

V-safe is a safety monitoring system established by CDC specifically for the COVID-19 vaccination program. V-safe participants voluntarily self-enroll and receive smartphone text messages providing hyperlinks to web surveys. During the first week after vaccination, enrollees complete daily surveys asking about local injection site and systemic reactions. Enrollees are asked if they missed work, were unable to perform normal daily activities, or received care from a medical professional because of reported symptoms or health conditions. Enrollees who report seeking medical care are contacted, and a VAERS report is completed if clinically indicated. Persons who do not report their sex as male are asked about pregnancy status at time of vaccination (initial survey) and about a positive pregnancy test result (3- and 6-week surveys); reported pregnancies are followed up through the v-safe pregnancy registry.

(MMWR Morb Mortal Wkly Rep 2021;70:283–288. より引用)

問 1 VAERS との対比から ( ① ) に入る適切な 1 語を記載しなさい。

問 2 下線部②を和訳しなさい。

問 3 3 か所の ( ③ ) に共通に入る語句 (3 語) を、問題文から抜き出して記載しなさい。

問 4 VAERS と v-safe の特徴について、問題文の記載に基づいてそれぞれ日本語で説明しなさい。

問 5 VAERS に報告された死亡とワクチン接種との因果関係について、問題文の記載に基づいて日本語で説明しなさい。

問 6 最初の段落に適切なタイトルをつけなさい (日本語と英語で)。