BRITISH COLUMBIA
CENTRE *for* EXCELLENCE
in HIV/AIDS

BC CENTRE FOR EXCELLENCE IN HIV/AIDS CDET COMMITTEE STATEMENT ON THE USE OF COVID-19 MRNA VACCINES (PFIZER AND MODERNA) IN PERSONS LIVING WITH HIV

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Providence HEALTH CARE
How you want to be treated.

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TABLE OF CONTENTS

I RECOMMENDATION

People living with HIV (PLWH) aged 18 years or older may be vaccinated for COVID-19 if they meet current Public Health criteria for priority groups and if they have no contraindications (see below). These are not live-virus vaccines and are not expected to be associated with more serious adverse events among immunocompromised individuals. However, PLWH who have CD4 counts <200 cells/uL should be counselled regarding the unknown efficacy and safety of the vaccines given that immunocompromised subjects were not included in these vaccine studies.

II BACKGROUND

COVID-19

SARS-CoV-2 emerged in late 2019. The virus was named SARS-CoV-2 because of its similarity to the coronavirus responsible for the illness known as severe acute respiratory syndrome (SARS-CoV). This virus (SARS-CoV-2) is responsible for the clinical disease COVID-19. SARS-CoV-2 spike glycoprotein (S), which is a main target for neutralizing antibody, binds to cellular receptors to initiate infection. Disease symptoms may vary; however, respiratory infection is most common, with outcomes including pneumonia and acute respiratory distress syndrome (ARDS), leading to multiorgan failure and death[1]. Morbidity and mortality is most strongly correlated with age, being highest in those with increasing age above 50 yr, and particularly high above 80 yr. Increased risk is also associated with additional medical comorbidities such as diabetes, hypertension, obesity and cardiovascular disease[2, 3].

Health Canada approved COVID-19 vaccines

At this time only the Pfizer-BioNTech (BNT162b2 mRNA) vaccine has been approved for use in Canada. This vaccine consists of a modified messenger RNA (mRNA) molecule enclosed in a lipid nanoparticle. The mRNA encodes the SARS-CoV-2 spike protein. Receipt of two doses of the vaccine has been demonstrated to induce robust antibody and T cell -mediated immune response. In a phase 2/3 clinical trial in 37,706 adults (age 16 years or older) randomized to receive either the active vaccine or a placebo, receipt of the BNT162b2 mRNA vaccine, dosed as two doses 21 days apart, was found to have an efficacy of 95% (95% Credible Interval [CI] 90.3, 97.6%) at preventing laboratory-confirmed COVID-19 infection[4]. Outcomes were similar across age groups. Individuals with underlying immune suppressive conditions or using immune suppressive therapy were excluded from study participation, however PLWH were included in the study (See below).

Other COVID-19 mRNA vaccines under evaluation

A similar mRNA-based vaccine is currently being evaluated for approval by the US FDA[5] and Health Canada. The Moderna mRNA-1273 vaccine consists of mRNA encoding the SARS-CoV-2

spike protein and is enclosed in a lipid nanoparticle. Phase I immunogenicity data demonstrated rapid development of neutralizing antibodies in individuals aged 18 – 55 years and also in older adults[6], [7].

A phase 3 trial involving 27, 817 individuals randomized to receive vaccine or placebo dosed as two doses one month apart, with a median follow-up of >2 months post second dose, an efficacy of 94.1% (95% CI 89.3%, 96.8%) was demonstrated[5]. When stratified by age group the efficacy was 95.6% (95% CI: 90.6%, 97.9%) for participants 18 to <65 years, and 86.4% (95% CI: 61.4%, 95.5%) for participants ≥65 years of age.

mRNA-based COVID-19 vaccines and HIV

Data for use of the mRNA vaccines in PLWH are currently limited. In the BNT162b2 mRNA study, only one individual living with HIV was included in data submitted to the FDA, although supplementary data from the clinical trial indicates 121 individuals were enrolled[4], [8]. In the mRNA-1273 study, 176 PLWH were included, with data for vaccine efficacy available for 156 of these individuals in the FDA submission[5]. Only one case of COVID-19 infection was observed in this trial, in a placebo recipient.

PLWH are expected to have similar vaccine responses to those without HIV, although immune response may be sub-optimal in those with immune compromise. Further outcome studies are anticipated to address this concern.

III PRIORITY POPULATIONS FOR VACCINE COVERAGE IN BRITISH COLUMBIA

At present, priority populations identified for vaccination by the National Advisory Committee on Immunization (NACI) and adapted by BC Public Health include[9]:

- Long-term care residents and staff
- Residents and staff of assisted living facilities
- Health-care facility staff for COVID-19 patients in settings like Intensive Care Units, COVID-19 wards and emergency departments
- Indigenous people living in rural or remote communities
- People living in group settings like shelters
- People over 80 years old

PLWH who meet these criteria should be evaluated for vaccination.

It is expected these criteria will be updated based on vaccine availability and as further trial data from the mRNA vaccines, as well as other types of COVID-19 vaccines become available.

Criteria for vaccine eligibility will be available at the BC Centre for Disease Control as new recommendations are made: Vaccine Eligibility (bccdc.ca)

IV CONTRAINDICATIONS TO THE PFIZER-BIONTECH (BNT162B2 MRNA) VACCINE

The Pfizer-BioNTech (BNT162b2 mRNA) vaccine should not be administered if there is:

a) A history of **severe allergic reaction** (e.g. anaphylaxis) to a previous dose of the same mRNA vaccine, or

b) A history of **severe allergic reaction** (e.g. anaphylaxis) to any component of the mRNA vaccine.

V PRECAUTIONS

a) Allergic reactions. Those who have a past history of other life-threatening allergic reactions (e.g. anaphylaxis to other vaccines, injectable medicines, foods, venoms, etc) should consult with their physician before receiving the vaccine). Epinephrine should be immediately available for potential anaphylactic reactions for all vaccinees, not just those with an allergic reaction history.

b) Pregnancy and breast feeding. Pregnant or breast-feeding individuals should not receive the vaccine due to the absence of evidence for its use in these settings. However, there is no know evidence to indicate toxicity in pregnancy. Pregnancy should be avoided for at least 2 months after the second dose of the vaccine. Pregnant or breast-feeding individuals who are in a priority group for COVID-19 vaccination (e.g. health care workers) may choose to be vaccinated after informed consent and a risk assessment of the possible benefit and risk for the individual and the fetus or infant.

c) Acute febrile illness. Vaccination should be postponed until there is complete resolution of the acute illness. Postponing the vaccination will avoid the confusion associated with the inability to differentiate vaccine-related adverse effects from those caused by the acute febrile illness. It will also reduce the risk of infection transmission (COVID-19 or others) to vaccine health care providers.

d) Anticoagulation and bleeding disorders. Since the vaccination is only to be given as an intramuscular injection, the possibility of bleeding and hematoma formation at the injection site requires caution. The risk/benefit considerations should be discussed with the vaccinee. If possible, coagulopathies should be corrected prior to vaccination. Individuals on stable anticoagulation therapy (including warfarin, when the up-to-date INR testing shows an INR below the upper level of the

therapeutic range) may be vaccinated, but a fine needle (23 or 25 gauge) should be used followed by firm pressure applied to the site without rubbing for at least 2 minutes.

e) Immune suppression and HIV. Individuals who have impaired immunity due to HIV, immunosuppressive therapies, or other disorders were excluded from the vaccine clinical trials mentioned above. As a result, those with impaired immunity should be counselled regarding the unknown efficacy and safety of the vaccine among those who are immunocompromised. However, since the Pfizer and Moderna vaccines are not live virus vaccines, they are not expected to be associated with an increased risk of adverse events in immunocompromised patients. People living with HIV on HAART with undetectable pVL and CD4 counts above 200/mm^3 are likely to be at no additional risk if vaccinated with the Pfizer or Moderna vaccines. On the other hand, the risk is less clear among those with detectable pVL or low CD4 counts below 200/mm^3. All such persons may be offered the vaccine after risk/benefit counselling.

VI REFERENCES

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