Scottish Government
Riaghaltas na h-Alba
gov.scot

E: vaccineoperationaloversight@gov.scot

Dear Colleague(s)

COVID-19 VACCINATION PROGRAMME: JCVI ADVICE ON ADDITIONAL BOOSTER DOSES FOR CLINICAL TRIAL PARTICIPANTS

This letter provides details of the Joint Committee on Vaccination and Immunisation (JCVI) recommendations relating to the administration of additional MHRA authorised COVID-19 booster doses to those participating in COVID-19 booster and sub-variant vaccination clinical trials, in order to mitigate issues linked to international travel and certification.

Key Objectives

1) To update on the JCVI's recommendations in relation to the administration of additional MHRA authorised COVID-19 booster doses to those participating in COVID-19 booster and sub-variant vaccination clinical trials.

2) To clarify operational guidance on:

- Offering additional MHRA authorised doses to those currently participating in a trial, especially those receiving a vaccine yet to be authorised/recommended as a booster by the MHRA/JCVI
- Offering additional MHRA authorised doses to those who have already completed their trial who may have received fractional doses of an MHRA authorised vaccine or doses of a vaccine yet to be authorised/recommended as a booster by the MHRA/JCVI.

Background

3) In September 2021, following concerns surrounding individuals being potentially disadvantaged for the purposes of international travel, the JCVI agreed to a set of recommendations whereby clinical trial participants could receive an additional primary course of UK-authorised vaccines.

From the Chief Medical Officer
Professor Sir Gregor Smith

18 May 2022

SGHD/CMO (2022)21

Addresses

For action
Chief Executives, NHS Boards
Medical Directors, NHS Boards
Primary Care Leads, NHS Boards
Directors of Nursing & Midwifery, NHS Boards
Chief Officers of Integration Authorities
Chief Executives, Local Authorities
Directors of Pharmacy
Directors of Public Health
General Practitioners
Practice Nurses
Immunisation Co-ordinators
Operational Leads

For information
Chairs, NHS Boards
Infectious Disease Consultants
Consultant Physicians
Chief Executive, Public Health Scotland
NHS 24

Further Enquiries to:

Policy Issues
COVID Vaccination Policy
vaccineoperationaloversight@gov.scot

Medical Issues
Dr Lorna Willocks
vaccineoperationaloversight@gov.scot

Pharmaceutical and Vaccine Supply Issues
NHS NSS National Procurement:
nss.vaccineenquiries@nhs.scot

4) A CMO letter was published on 11 November 2021 outlining the recommendations and the routes to vaccination for clinical trial pariticpants.

5) At the time, reference was not made to those participating in the Cov-Boost study as it was understood that these individuals would have already had a primary course plus a booster dose, so should not, at that time, have experienced any travel related issues. In addition, the previous recommendations did not give a specific view regarding individuals receiving variant-specific vaccines.

6) We are now seeing a movement across some countries towards requesting, for the purposes of entry to the country, evidence of an individual's most recent approved COVID-19 vaccination.

7) This means individuals participating in clinical trials for booster doses, who may not have received a vaccine approved for use in the UK by the MHRA, could experience travel issues. As such, Travel Top Up doses may be necessary to support those participants on COVID-19 booster and sub-variant clinical trials who wish to travel internationally.

8) There are currently around 323 individuals participating in COVID-19 booster and sub variant clinical trials in Scotland.

9) The Scottish Government remains hugely grateful to all trial participants, trial investigators and their teams for their commitment to trials, and it is essential we continue to identify and resolve any potential disadvantage to support ongoing enrolment and participation.

JCVI Advice

10) The Scottish Government is guided by the clinical and scientific advice on vaccination provided by the JCVI.

11) The JCVI has advised that the clinical risks of Travel Top Up doses, acknowledging the lack of data on the effects of these doses, can be assumed to be similar for individuals receiving these doses following receipt of any COVID-19 vaccine trial dose. This would include but not be limited to booster vaccines and variant-specific vaccines.

12) Therefore, as a general principle, a Travel Top Up offer can reasonably be made available to all COVID-19 vaccine trial participants, subject to appropriate clinical governance processes, and the use of Patient Specific Directives (PSD) as required.

13) Following this advice from the JCVI, the UK alignment group and clinical leaders have agreed to the following and Scottish Ministers have subsequently agreed to implement this advice in Scotland:

- Those individuals who are currently participating in a COVID-19 vaccine trial, especially those receiving a vaccine yet to be authorised/recommended as a booster by the MHRA/JCVI, are eligible for a Travel Top Up should they wish this .
- The offer of a Travel Top Up should be extended to booster and sub-variant trial participants who have already completed their trial if these individuals have received partial doses or doses of a vaccine yet to be authorised/recommended as a booster by the MHRA/JCVI.

Operational Deployment

14) The same process that was adopted for giving additional primary doses to clinical trial participants should be followed, should a clinical trial participant in one of these trials wish to receive additional Travel Top Up doses.

15) Trial participants would first discuss the need for an additional dose - for travel purposes - with the trial Principal Investigator (PI). The PI will then sends a referral letter to the local Health Board Immunisation Lead. This referral letter will act as a PSD allowing local Health Boards to arrange vaccination and record such vaccination in the Vaccine Management Tool (VMT).

16) A standard pathway for this route is highlighted in Annex A and a sample Patient Specific Direction is held in Annex B. It should be noted that further vaccine doses are not required from a health protection perspective, the main objective is to support and enable certification for international travel.

Communications

17) Messaging will emphasise that we have always been guided by the clinical and scientific advice on vaccination provided by the JCVI and that this offer aims to support and enable certification for international travel, where required

18) This messaging will be shared with Health Boards for distribution through their channels, and we will ensure this is also shared with the helpline to respond to any enquiries from members of the public.

19) There will be no proactive communications regarding the availability of Travel Top Ups, instead the NIHR (BePartOfResearch) and NHS Inform websites will be updated to make it clear that this offer is available.

Action

20) Health Boards should accept a PSD issued by PIs for COVID-19 vaccine clinical clinical trial participants and vaccinate individuals in accordance with such PSDs.

21) Local Vaccination Planning Leads should work with PIs to agree a process locally to facilitate the attendance and vaccination of clinical trial participants, where required.

22) Health Boards should cascade a briefing to all clinical vaccination centres, teams and individual vaccinators to ensure all elements of this letter are clearly understood.

23) Vaccines given to clinical trial participants via PSD should be recorded by vaccinators in VMT in line with the national programme.

We remain very grateful for your continued support and ongoing efforts in relation to the national COVID vaccination programme.

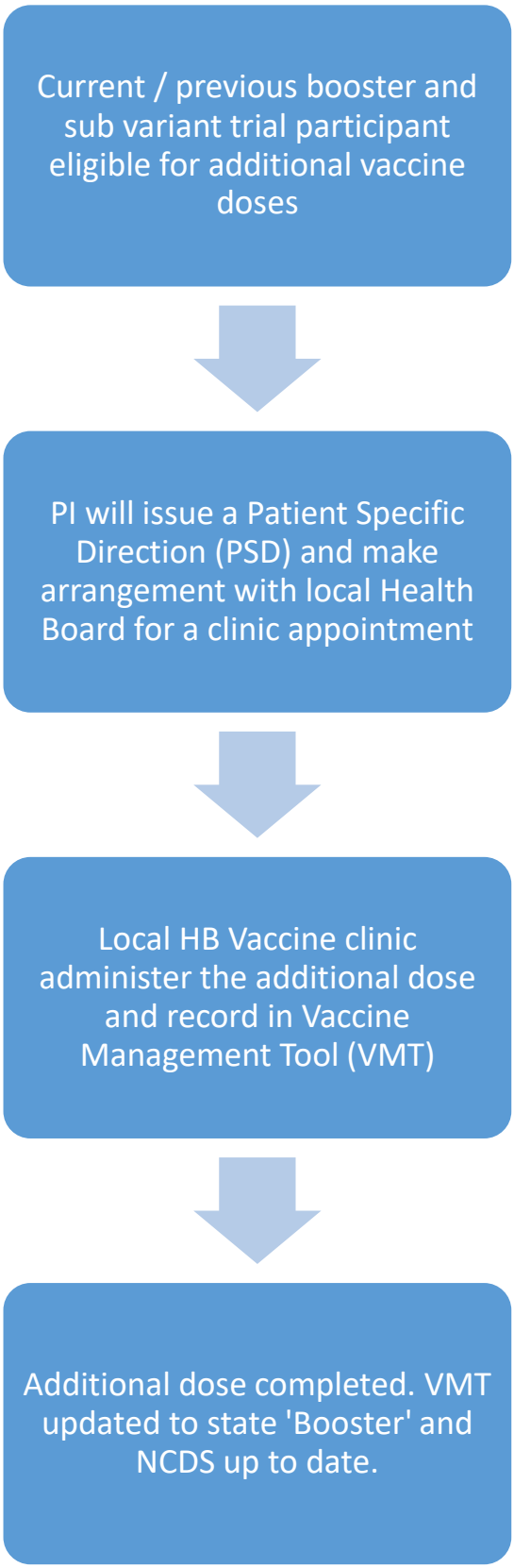
Yours sincerely

Gregor Smith

Professor Sir Gregor Smith
Chief Medical Officer

ANNEX A

Standard pathway: Facilitating additional vaccine booster doses - for the purpose of international travel – for individuals participating in clinical trials for COVID-19 vaccine clinical booster doses who have not received a full dose of a UK authorised booster vaccine



Annex B

Sample Patient Specific Direction (PSD)

Glasgow Clinical Research Facility
5th Floor, Neurosciences Building,
Queen Elizabeth University
Glasgow
G51 4TF

Email: covidresearch@ggc.scot.nhs.uk
Tel: 0141 232 7600

Date:

PATIENT-SPECIFIC DIRECTION FOR DEPLOYED VACCINATION

Dear colleague

PATIENT DETAILS

CHI:

Name:

Address:

I enclose a Patient Specific Direction (PSD) for deployed vaccination for this participant in the NOVAVAX / VALNEVA / COV-BOOST/ OTHER _____ (DELETE AS NECESSARY OR ENTER TRIAL NAME) clinical trial who has elected to receive deployed vaccination at your centre."

This is for (DELETE AS NECESSARY) Primary vaccination (two doses) / Booster vaccination (single dose) with the currently deployed vaccine appropriate for their age.

The route of administration is ……..

The vaccine can be given from …../…../…..

This PSD expires on …../…../…..

I can confirm that the participant has been counselled regarding vaccination and has elected to proceed with deployed vaccination following an individual assessment of circumstances.

Yours faithfully

PI NAME:

SIGNATURE: