BTS - Frequently Asked Questions regarding new JCVI advice on:

Third primary dose COVID-19 vaccines for those aged ≥ 12 years and over **with severe immunosuppression**.

How quickly do I need to act on this advice?

The request is to identify relevant patients and inform their GPs as soon as feasible. It is important that these vaccines are offered as soon as possible to try and improve protection for these 'at risk' patients as we rapidly head towards winter.

The Joint Committee for Vaccination and Immunisation (JCVI) advice refers specifically to detailed dosages and combinations of immunosuppression regimes. We recognise that at varying points of the patient journey, drugs and doses are often in 'flux', for example as patients are initiated on therapies which are up-titrated over the course of a few months or as corticosteroids are weaned and transitioned to second line agents. A patient's dose this week may be different to next. What should I do – advise a 3rd vaccine dose or not?

It is recommended that the advice from the JCVI is followed as closely as possible. However we recognise that a pragmatic or common-sense approach should be adopted where there is uncertainty. Given the varying and dynamic patient, disease and therapeutic variables exact drug doses will be difficult to calculate for all patients and time points advised in a timely manner. Doses may change over future weeks. A balanced and clinically led decision is required in these situations and would be fully supported.

For example a patient treated with combined methotrexate 15mg/week and a dose of prednisolone which the patients is permitted to adjust between a small dose range depending on their symptoms as advised by their doctor. One week they may hit the JCVI 'threshold of 'severe' immunosuppression as they take 7.5mg of prednisolone per day but 2 weeks later they may be on 2.5mg per day as they have improved. Where there is dose uncertainty but the patient sits at the 'edge' of the dosing deemed to be at risk clinicians are recommended to make sensible pragmatic decisions. It is felt that the number of patients such as this, at the 'edges' of the JCVI advice, is likely to be small overall.

Another group of patients that may be hard to identify precisely are patients with airways disease (COPD and asthma mainly) who may have received doses of steroids that fit the JCVI definition of 'severe' immunosuppression. Hospital specialists may not be aware of all doses given in primary care or by community respiratory teams. Once again we ask for clinicians to make pragmatic decisions regarding the need for the 3rd primary vaccine based on best available knowledge. Sensible decisions will always be supported.

It is implied that clinicians will be responsible and act ethically when recommending administration of the 3rd primary dose. It is important that the vaccines are administered to those at the greatest risk at this stage. The JCVI advice is clear that some patients on lower immunosuppression regimes do not fulfil the criteria **for this round of vaccinations**. Please follow their guidance as closely as possible. Bear in mind we expect news soon from JCVI on booster vaccines too.

I am uncertain about the exact drug doses the patient is on - shall I contact the patient and ask then to self-identify to their GP? I feel I have time to do this.

We do not recommend this strategy unless you feel this is the only way you can achieve what is being requested. The guidance is specific in that it is the patients' specialist who is requested to directly inform the GP. Some patients may find an approach to 'self identify' confusing. The GP may not be able to confirm the patient's approach for a vaccination is appropriate particularly where the immunosuppressive drugs are being prescribed by the hospital team. If specialist teams need to

contact their patients to check on doses before writing to GPs they should do this but in a timely manner so as not to delay the delivery of this vaccine round.

We do recommend that patients are copied into their GP letter from the specialist so they are made aware they are suitable to be offered this 3rd vaccine. We hope that patients will be reassured that they have been identified. It may reduce queries to specialists and GPs freeing up healthcare professional time to deal with this work.

Who will offer and arrange (where accepted) for the 3rd vaccination to be given to these patients?

GPs have been requested to offer and deliver vaccines where needed. We expect that on receipt of the specialist letter advising that the patient is suitable the GP practice will then contact the patient and arrange the jab if it is accepted. Some patients may contact their GP on receipt of their letters.

Where I need to advise GPs of a 'specific time window' in which to give the jab in a patient on a complex regime of immunosuppression e.g. IV Cyclophosphamide or rituximab how much notice should I give GP and patient?

Please give the GP and patient a reasonable timeframe during which to arrange the vaccination. Where possible we advise considering a 2 week vaccination window with a 4 week notice period to GP. If a tighter time scale is needed for a small number of patients we advise close communication may be sensible with GP to ensure timeframes are met particularly where they might be tight for clinical reasons.

What timeframes are best between the vaccination and restart of complex potent immunosuppression regimes?

The JCVI states: The decision on the timing of the third dose should be undertaken by the specialist involved in the care of the patient. In general, vaccines administered during periods of minimum immunosuppression (where possible) are more likely to generate better immune responses. The third dose should be given ideally at least 8 weeks after the second dose, with special attention paid to current or planned immunosuppressive therapies. Where possible the third dose should be delayed until two weeks after the period of immunosuppression, in addition to the time period for clearance of the therapeutic agent. If not possible, consideration should be given to vaccination during a treatment 'holiday' or at a nadir of immunosuppression between doses of treatment.

It is confusing because many of these patients eligible for this '3rd primary dose vaccine' received the 'standard 2 dose' primary COVID-19 vaccinations more than 6 months ago. Are these jabs now not just 'booster' vaccines in effect?

We agree the terminology can seem a little confusing. COVID-19 is still a relatively new disease to us with key data still emerging. This advice for 3rd primary vaccines for patients with 'severe' immunosuppression (JCVI defined) has been developed after analysing the performance of the 'standard 2 dose' primary regime. New data has shown that some patients may not mount a robust immune response to the 2 dose vaccine schedule due to their underlying health conditions. This had led to a change in advice from the JCVI. It is correct that for many of the previously vaccinated patients who will now receive a 3rd primary vaccination it will be >6 months post their primary vaccines. However newly diagnosed patients who fit the severe immunosuppression criteria will in future be offered a triple primary vaccine dose regimen from the start given at intervals. Currently intervals are about 8 weeks apart (if not altered by immunosuppression drug treatment schedules) although dosing schedules could change if new evidence emerges.