

**Randomisation during deployment
of monkeypox vaccination to the categories of
people currently being prioritised for invitation**

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Summary:

**When inviting people in the current priority group,
randomise the order in which they are invited,
then see when any cases of monkeypox arise**

Compare the group randomly allocated to be invited earlier
versus the group randomly allocated to be invited later.

Evidence about efficacy comes from any differences between
these two randomised groups in disease onset rates during the
“informative” period in which there was a substantial difference
between these two groups in the proportions already vaccinated.

Background: limitations of vaccine availability

Suppose that in one country (or part of that country) the category of people currently being prioritised for vaccination appointments somewhat exceeds the current local availability of monkeypox vaccine (or other vaccination-related resources).

Vaccination invitations for this prioritised category may then have to be spread out over some weeks, or even months.

It would then be medically informative for the vaccination program to randomise the order of these invitations.

Medically informative results from random ordering

There may be some intermediate weeks or months during which the proportions vaccinated differ substantially between people randomly allocated to be invited earlier, or to be invited later.

An unbiased “intent-to-vaccinate” analysis then compares the monkeypox onset rates during any such “informative” periods.*

- * Formally, within each time period the analysis will relate the difference in the proportions already vaccinated to monkeypox onset numbers. It will then do an appropriate meta-analysis of these separate analyses.

Requirements (nationally or locally)

Vaccination of priority groups by an appointment system

Random allocation of the order of vaccination appointments
(even if actual dates of some or all appointments are not yet known)

Records of actual vaccination dates of those randomly allocated

Ability to link those randomly allocated to monkeypox onset
(regardless of whether they have yet been vaccinated)

Practicalities

If randomisation during deployment doesn't get done during the initial rush to vaccinate the highest-priority category of people, it could still be done later, in some subsequent category.

Randomisation must not interfere with rapidity of deployment, so it must not involve placebo injections, extra form-filling, or having to see those who are not attending for vaccination.

Randomisation during deployment complements, rather than competes with, any placebo-controlled trials.