In-deployment studies: Trial designs to evaluate additional vaccines

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Even without importantly new variants, there would be uncertainties about the choice of vaccines, of vaccination schedules, and of target populations.

Could large-scale randomisation during deployment help study some of them?
A key requirement in such a study is that it should not interfere with ordinary vaccination.

Nothing extra should be added to what the vaccinators have to do with each individual.

Follow-up depends on what’s locally possible; electronic records may well not be available.
As newer vaccines target new variants, further uncertainties are likely to arise.

Could large-scale randomisation during deployment help address some of them?

(NB Trials assess effects on individuals, not any effects on viral evolution rates.)
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Could **1 million** consent to join a research study that they know ensures all will get their first invite within 4 months, knowing that some will get it soon, and some at month 4?

For high compliance, consent teams first cover a small area house-to-house. Randomisation (by household??) lists those to be vaccinated promptly by house-to-house vaccination team visits, and those to be vaccinated later.
Massively large randomised comparisons need not be expensive, and could NIMBLY AND RAPIDLY resolve SOME uncertainties.

They may usefully complement observational studies of clinical outcomes and lab studies of immunological responses, especially if many of the vaccine failures in such trials get genotyped.
With large numbers randomised & unbiased follow-up, the magic of randomisation will yield reliable evidence; so-called “real-world” evidence may not *

* The magic of randomization vs the myth of “real-world” evidence

NEJM 2020; 382: 674-78