Vaccine effectiveness studies to guide immunization policies

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Measures of vaccine performance

Immunogenicity - individuals

- Capacity of the vaccine to induce antibody production (anti-spike anti bodies)
- Early clinical trials (e.g., phase II)

Vaccine efficacy - individuals

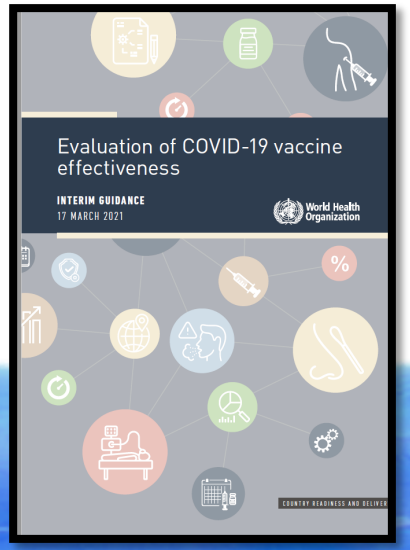
- Reduced risk of infection or disease among vaccinated individuals resulting from vaccination in carefully controlled circumstances; estimated from randomized clinical trials
- Clinical trials (e.g., phase III)

Vaccine effectiveness - individuals

- Reduced risk of infection or disease among vaccinated individuals attributed to vaccination in real-world conditions; estimated from observational (non-randomized) studies

Vaccine impact – population - complex

- Reduction in incidence of infection or disease in a population where some members are vaccinated
  - Vaccine coverage (direct effects in vaccinated, indirect effects due to herd protection)
  - Can also pertain to other measures besides disease (health systems' functioning and capacity and economic indicators)
- Understanding vaccine impact requires many different pieces of the puzzle, including vaccine effectiveness



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Vaccine effectiveness depends on the outcome considered

With the emergence of the delta variant of SARS-CoV-2, effectiveness decreased against disease but not against severe disease and deaths

- Infection
- Disease
- Severe disease / hospitalization / admission to intensive care
- Death

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Walking in the shoes of an EPI manager

What to do when faced with persistence of disease while efforts are allocated to vaccination

- Failure to vaccinate
  - The vaccine works, the coverage is too low
- Vaccine failure
  - The coverage is sufficient, but the vaccine works less well than expected
- All of the above
  - Given the way the vaccine works, the coverage is too low to impact on incidence

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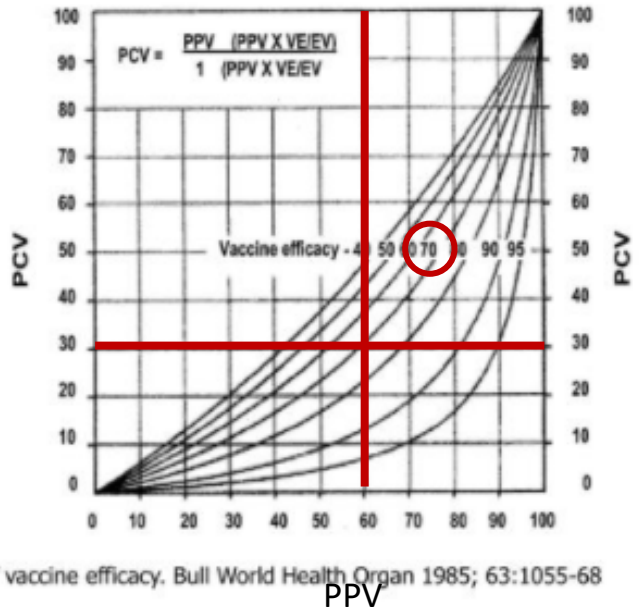
How to interpret persistence of transmission in countries that use a lot of vaccine?

Estimate the vaccine effectiveness before you make assumptions on vaccine impact

- PCV: Proportion of cases vaccinated
- PPV: Proportion of the population vaccinated
- VE: Vaccine efficacy



Orenstein WA et al. Field evaluation of vaccine efficacy. Bull World Health Organ 1985; 63:1055-68

Nomogram to estimate vaccine effectiveness using the quick screening methods in the field

Case study: 60% coverage, 30% case-patients vaccinated and persistence of transmission

- ✓ Quick field method: Compatible with 70% vaccine effectiveness in the field (consistent with published efficacy)
- × 60% coverage x 70% effectiveness = 42% protected (Explains transmission)

What to do?

- ➔ Get more information on who was vaccinated, on 1st and 2nd dose coverage, case fatality and mortality
- ➔ Confirm vaccine effectiveness with field studies using WHO protocols
- ➔ Continue to vaccinate
- ➔ Continue public health and social measures
- ➔ Communicate with public health officials, health care workers and the population that given the vaccine efficacy and reproductive rate, we need to increase coverage

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Note: Vaccine effectiveness studies only make sense when there are enough people vaccinated (Above 30%)

Criteria to establish the need of a vaccine effectiveness study from a programme point of view

We need to make sure vaccine effectiveness studies are done where needed

- Sufficient vaccination coverage attained in at least one group in the country (Necessary)
- Specific initiatives to reach and document high coverage in specific target groups (e.g., heath care workers (HCWs), elderly or people with co-morbidities)
- Vaccine impact not at the level expected
- Large population size
- Vaccine products used:
  - Multiple vaccines
  - Vaccines poorly documented from a VE point of view

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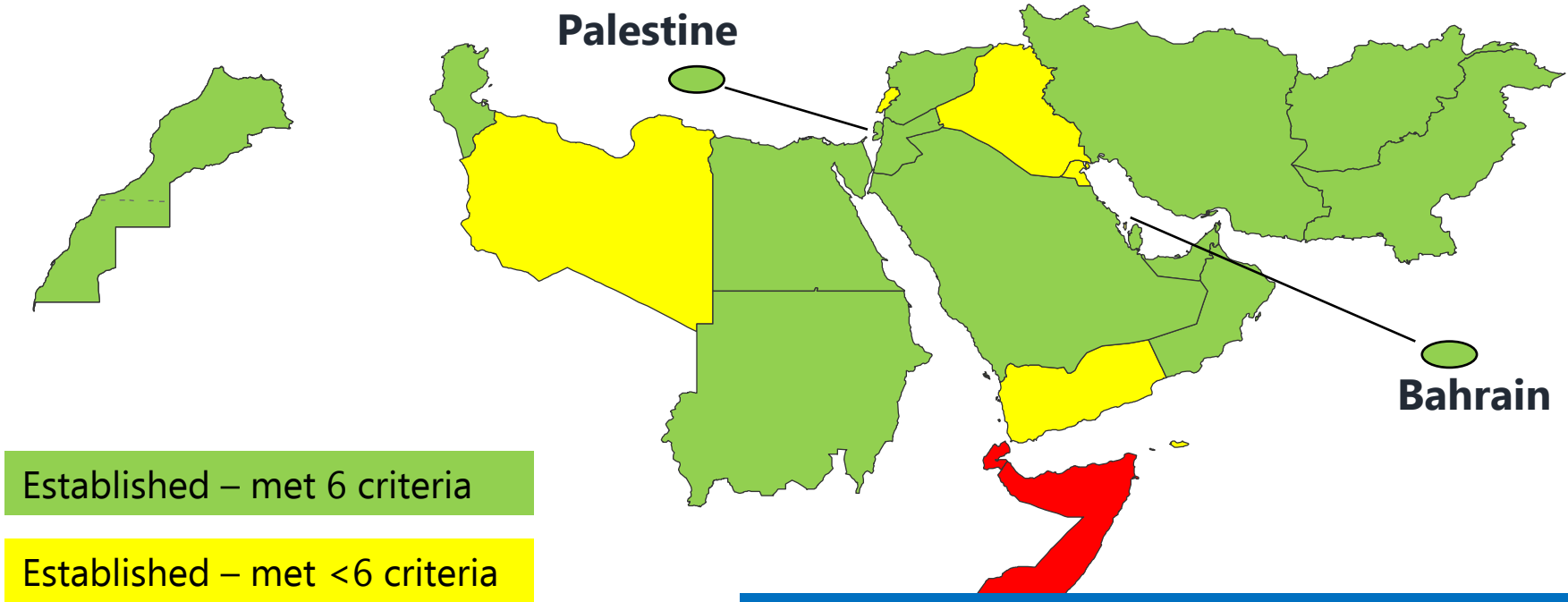
Life cycle of applied research project: Complementarity between programmes and institutional capacity building for research

Optimized programmatic input focuses on identifying the need for a vaccine effectiveness study and using the results to adapt policy

Research capacity building improves processes towards quality research and takes advantage of questions from programmes to improve research

Terms of reference for the National Immunization National Technical Advisory Groups (NITAGs)

- Advise the Ministry of Health on:
  - Optimal immunization policies and strategies
  - Monitoring immunization programme impact
  - Collection of data and information
- Identify need for additional data or research for evidence-based decision and policy-making



Status of NITAGs in EMR countries, 2018

Summary

- Vaccine effectiveness is one of the measures to understand how well vaccine work. It's a key piece of the puzzle to measure impact
- COVID-19 illustrated the importance of differentiating outcomes of vaccine effectiveness studies
- Effectiveness can be examined with a range of methods, from quick screening methods to formal studies
- Working on vaccine effectiveness includes some programmatic aspects and some operational research aspects
- NITAGs are important bodies to engage in establishing the need for a vaccine effectiveness study and making use of the results

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