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Vaccine Program Evaluation: Methods & Considerations for Estimating Vaccine Effectiveness

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Disclosure Statement



- I have no affiliation (financial or otherwise) with a pharmaceutical, medical device or communications organization.

Efficacy vs. Effectiveness

- Vaccine Efficacy

- *Does the vaccine work?*¹
- Examines the impact of the vaccine under ideal conditions, or “best-case scenarios”²
 - Evaluated via Phase III studies
 - Strict eligibility criteria
 - Vaccine stored, handled, administered appropriately
 - Estimate will have greater internal validity, but lower generalizability

- Vaccine Effectiveness (VE)

- *Does the vaccine help people?*¹
- Examines the impact of the vaccine under “real-world” conditions
 - Evaluated in Phase IV studies
 - Inclusive of sub-groups
 - Greater sampling ability, more power

¹Fedson, D.S. (1998). ²Weinberg GA, Szilagyi PG. (2010).

Vaccination Effects

The consequences of vaccination may be assessed at the level of the vaccine or the vaccine program:

- **Direct Effect:** effect of vaccine on vaccinated individuals,
 - We will refer to this measure as *vaccine effectiveness*
- **Indirect Effect:** effect of a vaccination program on individuals, due to changes in disease transmission and levels of immunity in the population
- **Overall Effect:** measures the impact of a vaccination program on the total population (vaccinated & unvaccinated),
 - We will refer to this measure as the *impact of a vaccine program*

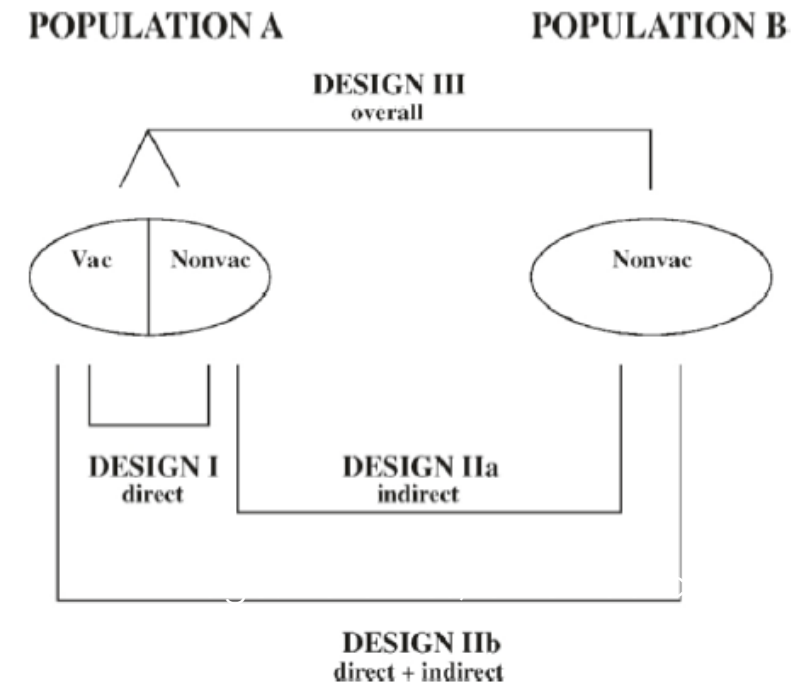
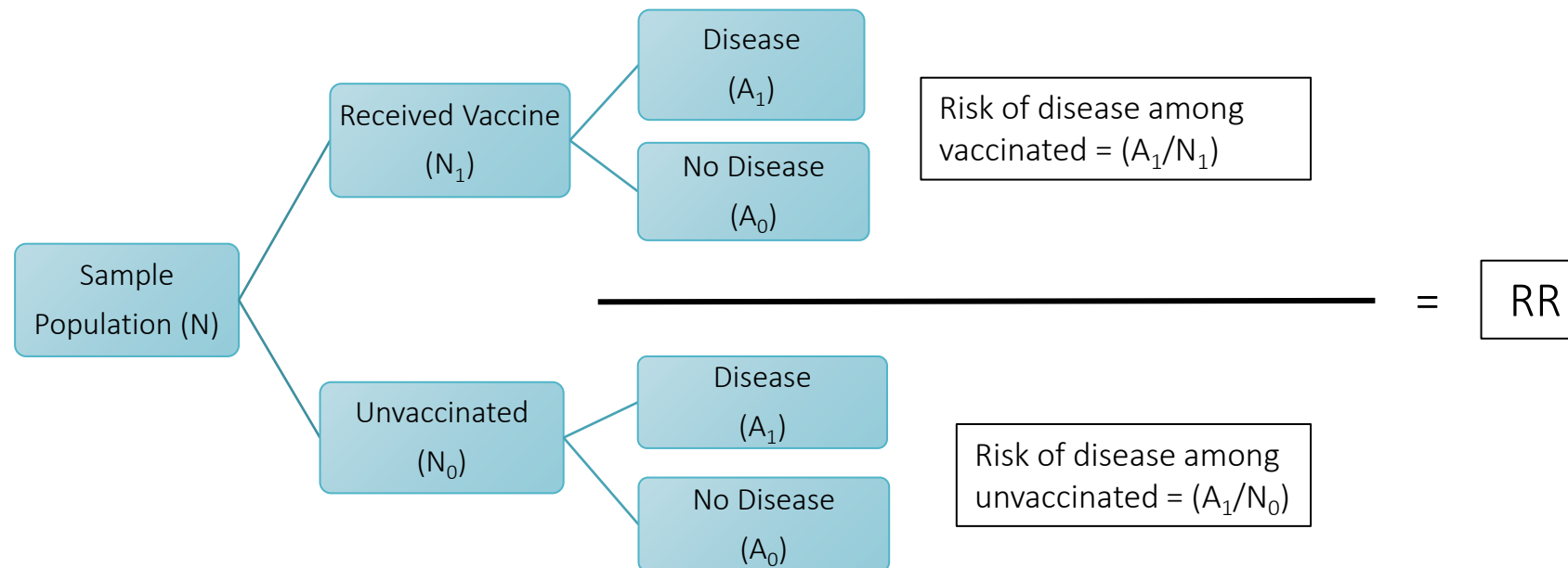


Fig. 2.3 Study designs for dependent happenings. Types of effects of vaccination programs and different study designs based on comparison populations for their evaluation (Halloran and Struchiner 1991, *Epidemiology*, 2:331–338. Reprinted with permission).

From: Halloran M.E., et al. (2010).

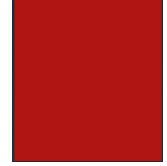
Estimation of Vaccine Effectiveness

- Proportionate reduction in disease outcome between vaccinated & unvaccinated¹
- Vaccine Effectiveness = $1 - \text{relative risk/rate (RR) of disease outcome of interest}$



¹Weinberg GA, Szilagyi PG. (2010).

Importance of Measuring Vaccine Effectiveness



- Public health planning & allocation of resources
- Inform decisions regarding vaccine program implementation
- Component of program evaluation for existing vaccine programs
- Evaluate cost-effectiveness & justify program costs
- Assess a broader range of outcomes that may be more clinically relevant/applicable to public health

References

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