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# Current methodological procedures of the German Standing Committee on Vaccination (STIKO) to develop vaccination recommendations

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People and physicians have a right to receive recommendations for vaccinations that are based on the

best available evidence!

## People and physicians have a right to receive recommendations for vaccinations that are based on the best available evidence!

Yes of course, but

1. What is the best data for the best evidence?
2. How to provide newly required data for recommendation and later on for monitoring?
3. What is the minimum of evidence required for a recommendation?
4. How to proceed if data is missing?
5. How to get from best evidence to recommendations?

# Some Preconditions in Germany

- No formal requirement for any vaccination
  - e.g. Admission to day care, Kindergarten, schools
  - Final recommendations are released by the federal states (Bundesländer) on the basis of STIKO recommendations
- A significant number of people and physicians are opposed to vaccination.
- Most vaccine preventable diseases are not notifiable according to the IfSG.

# What is STIKO

- Established 1972 , advisory commission, RKI
- 2001 legally implemented (§ 20 Abs. 2 IfSG)
- 16 honorary specialists
  - (vaccinology, immunology, bacteriology, virology, epidemiology, evidence based medicine, tropical medicine, public health, paediatric diseases, general medicine), two representatives from public health assurance and regional hygiene and preventive medicine.
- Nine permanent guests represent federal administrations and institutions.
- The STIKO general management office is located at the Robert Koch Institute, Berlin (2 scientist positions, 1 administrative position?).

# STIKO tasks

- To provide advice on vaccinations, vaccination policy and other measures for specific prophylaxis against transmissible diseases in humans, provided that the vaccines have been approved in Germany.
- The STIKO may deal with vaccines that are in the process of being approved, if all available unpublished data are accessible.

# STIKO working procedures

- During the past years the recommendation procedure is constantly changing from “expert opinion” to recommendations based on the “best available evidence”.
- The discussion about the applicable methodology for the work of the STIKO is ongoing and a sub-commission is working on improved formal rules.
- The STIKO generally meets twice yearly, but
  - 2008: 2, 2009: 6 + 5 phone conferences, 2010: 3
- The STIKO installs task-sub commissions to elaborate specific questions and may invite additional specialists.

# STIKO Formal Questionnaire (7 pages)

1. The target pathogen

   biology, pathogenicity epidemiology

2. The target disease

   morbidity, incidence-prevalence, lethality, risk groups, therapy

3. The vaccines

   Indications, contra-indications, immunogenicity, effectiveness, safety (recipient. and population based), duration of protection

4. The vaccination strategy

   Aim, number-needed-to-vaccinate for different effects, direct and indirect positive or negative population based effects

5. The implementation

   Practicability, vaccination rates, integration into vaccine plan, „cost-effectiveness“, alternative measures, essential surveillance-systems for assessment of vaccination coverage and effectiveness

6. The final evaluation

   Public interest, analysis of individual and epidemiological benefit-risk assessment, missing data

# STIKO working procedures

- The detailed questionnaire does indicate the methodological requirements and the data sources to be used.
- A literature search is mainly performed by the STIKO general management office and by sub commissions.
- Additional specialists are invited by the STIKO.
- A recommendation draft is prepared and discussed by the STIKO before final decision.
- The methodology for priorisation of items has to be further developed.

# What we have

- A legally implemented mandate for the STIKO
- A formalized working procedure
- Experts from different areas as members of the STIKO
- Regular well prepared meetings
- Ad hoc or permanent sub-commissions
- Additional invited experts.
- Rules for potential conflicts of interests

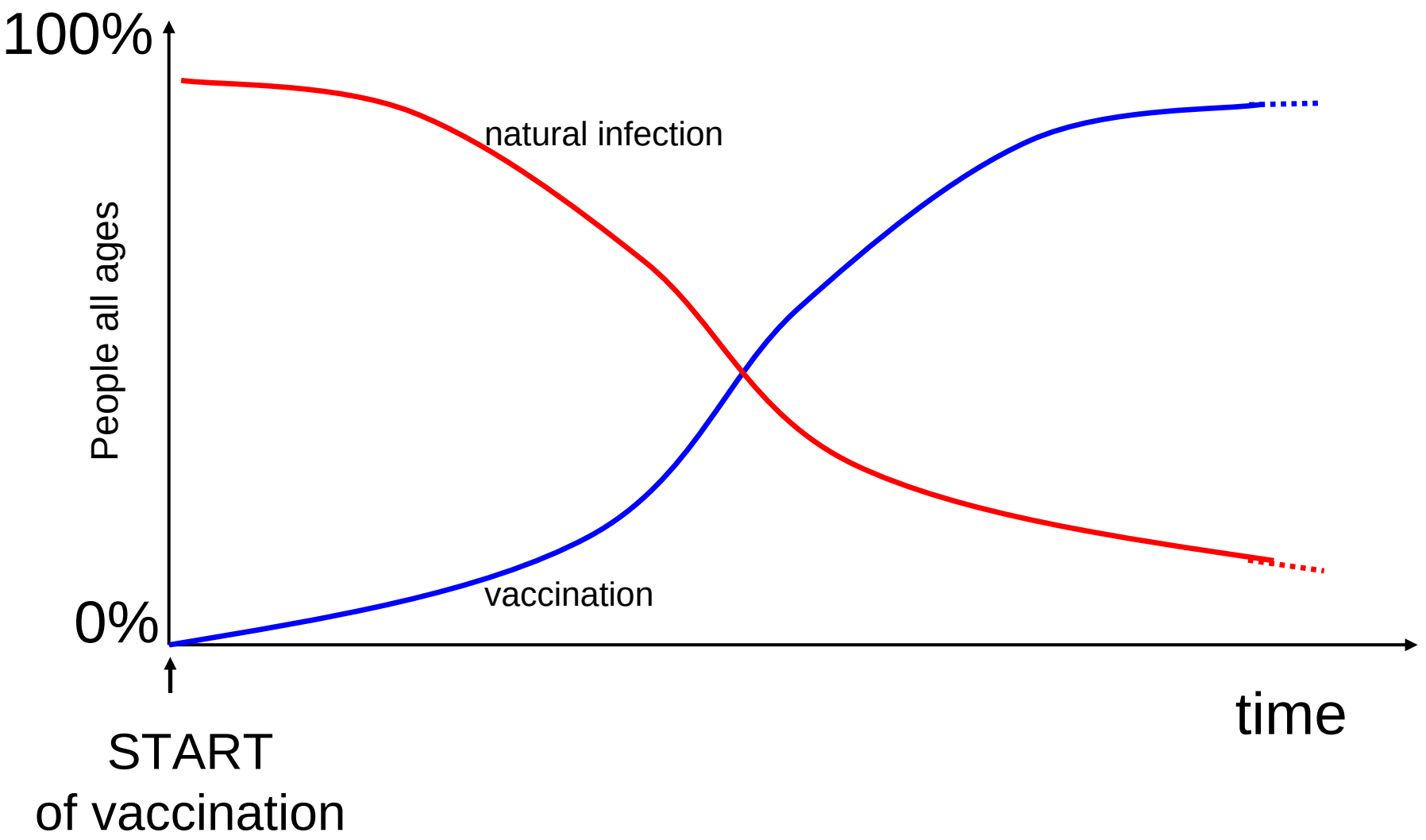
# Some Problems

1. What is the best data for the best evidence?
2. How to provide newly required data?
3. What is the minimum of evidence required?
4. How to proceed if data are missing?
5. How to get from best evidence to (best) recommendations?
6. Priorization of items

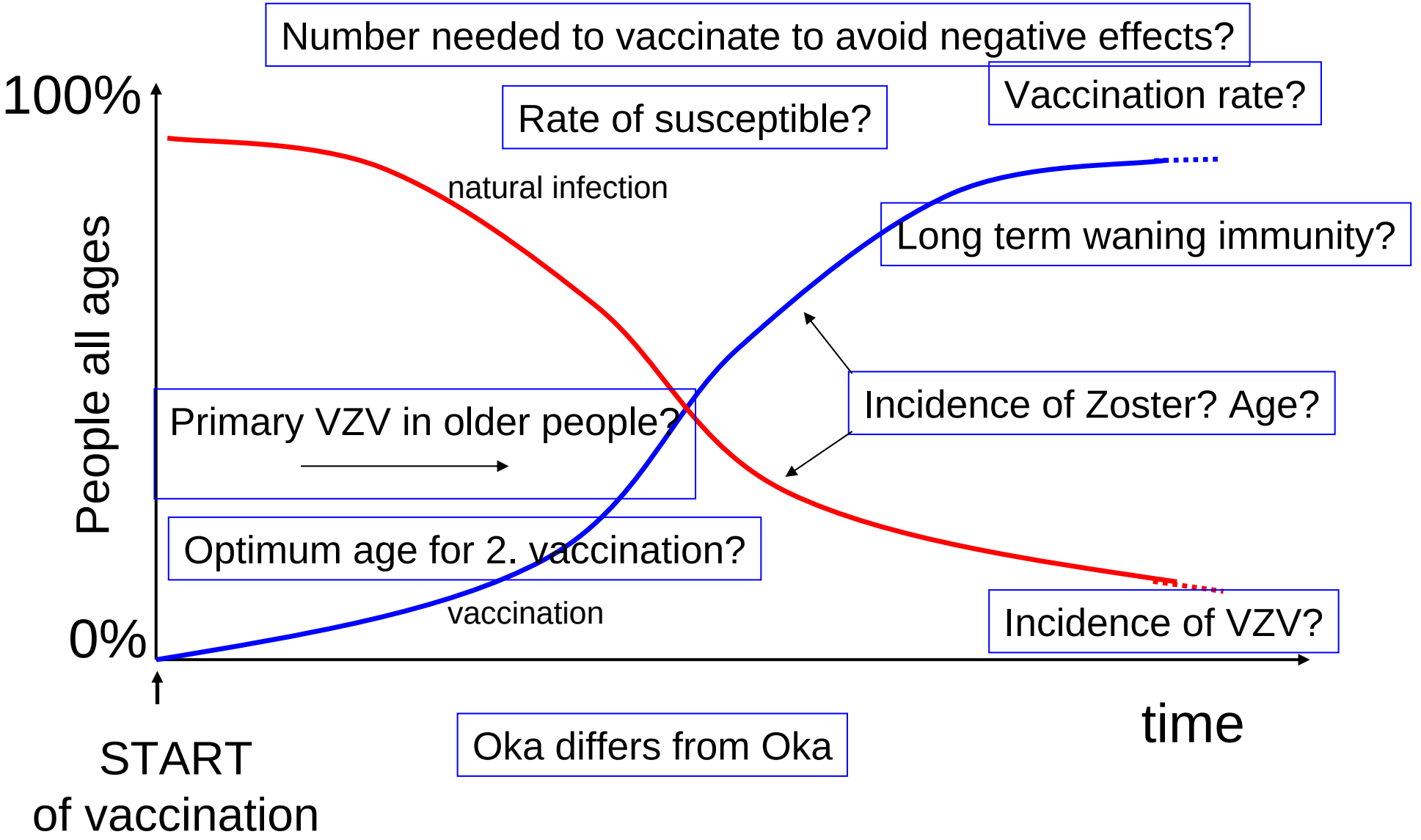
## Reminder

- No formal requirement for any vaccination in Germany
- A significant number of people and physicians are opposed to vaccination.
- Most vaccine preventable diseases are not notifiable according to the IfSG in Germany.

# e.g. VZV – a simple story?



# VZV – a story with missing data?



# Progress is Possible

1. For the best evidence one needs man power and standardized procedures for quality control of data acquisition (e.g. GRADE), and international cooperation.
2. To provide newly required data one needs money for studies, modifications of the law (IfSG), and international cooperation.
3. We need rules that define the minimum of evidence required and have to clearly publish on exactly what data a recommendation is based on.
4. The tolerance for missing data will always depend on a specific situation and vaccine.
5. We should try to formalize the process from best evidence to recommendation and introduce rules for priorization of items