Background and purpose of the meeting

International Workshop on
Methods for Health Economic Evaluations of Vaccines
Berlin, May 12-13 2014

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Vaccine introduction decisions

Decisions involves trade-off between potential benefits on the one hand, and downsides on the other hand

- Potential benefits: e.g.
  -reduction in number of deaths, hospitalizations, cases
  -eradication of a disease
  -protection of unvaccinated persons (herd effects)
  -decreased treatment costs in the healthcare system

- Potential downsides: e.g.
  -adverse events following immunization
  -serotype replacements
  -shift in age-distribution
  -program costs

Key issues in vaccine introduction decisions

THE DISEASE

- Public health and political priorities, alignment with global and regional recommendations
- Disease burden
- Status of other disease prevention and control measures

THE VACCINES

- Performance and characteristics of available vaccines
- Economic and financial issues
- Availability of vaccine supply

STRENGTH OF THE IMMUNIZATION PROGRAMME AND HEALTH SYSTEM

(WHO. Principles for adding a vaccine to a national immunization programme. 2014)

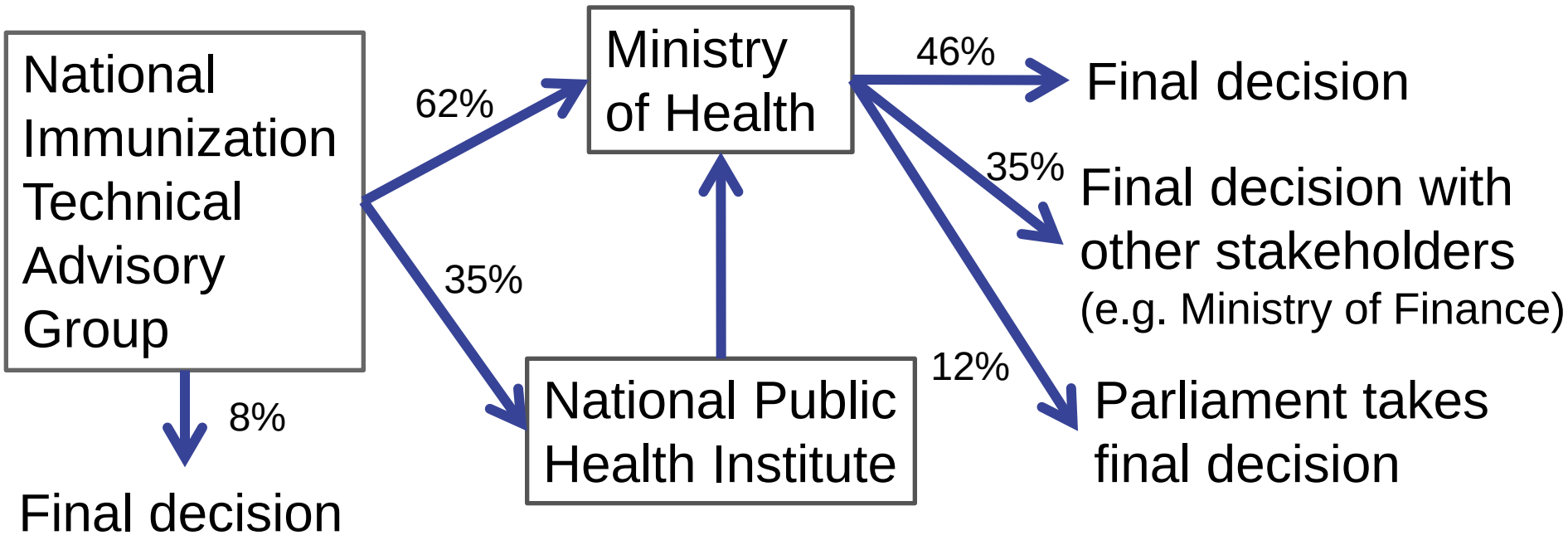
Challenges in vaccine introduction decisions

- Increasing number of new vaccines
  - new technologies (adjuvants, application route, etc.)
  - different product profiles (efficacy, safety, valency)
  - higher costs
  - often target mild/common or severe/rare diseases

- Societal & ethical issues
  - limited financial resources / fair distribution
  - busy vaccination schedules (priorization necessary)
  - public acceptance
  - new target groups

Decision-making process

- Different driving forces
  - NIP, country decision-makers, international organizations, academic community, private sector
- Each country has its own mechanism for an informed decision-making process



(Preliminary results from a 2014 VENICE survey among 26 EU member states)

2014 survey in EU/EEA member states (n=26)
-preliminary results, VENICE consortium-

- Economic evaluations routinely considered for national vaccine introduction decisions 21(81%)
- Level at which evaluation is considered
  - National Technical Advisory Group 16 (62%)
  - Ministry of Health/Finance, Parliament 14 (54%)
- Evaluation contains threshold 5 (19%)
- Cost-effectiveness threshold is final/decisive criterion 2 (8%)

Health economic evaluations

can be useful to answer questions like:

- Should a new vaccine or technology be introduced into the national immunization program?
- Which vaccine against a particular disease should be chosen?
- For a particular targeted disease, would it be more cost-effective to
  - introduce geographically targeted vs. universal vaccination?
  - target a specific age-group or risk-group?
  - introduce a vaccine alone or in combination with other interventions?

(adapted from: WHO. Principles for adding a vaccine to a NIP. 2014)

Development of vaccine recommendations

A systematic approach…

- helps to improve quality of the recommendation
- reduces anticipated or actual arbitrariness
- improves transparency →facilitates critical appraisal
- builds trust
- contributes to acceptance of the recommendation in the professional community and the public
- helps to compare recommendations endorsed by different countries / states

German NITAG (STIKO)

- Established in 1972
- 12-18 members, appointed by MoH for 3 years
- Executive secretariat at RKI

- Since 2005: Developed set of key questions to be addressed for developing recommendations
- 2008: Established working group on methods
- 2010-11: Two international meetings on evidence-based vaccination recommendation
- 2012: New Standard Operating Procedure

(www.stiko.de/en)

Key questions to be considered by STIKO

1. Pathogen
   -e.g. pathogen characteristics, sub-type distribution
2. Target disease
   -disease incidence/burden/epidemiology/risk-groups
3. Vaccine characteristics
   -efficacy/effectiveness, safety, duration of protection
4. Immunization strategy
   -goal of the recommendation
   -expected population-level effects
   -potential barriers to the success (e.g. public acceptance)
5. Implementation of recommendation
   -integration into existing schedule
   -cost-effectiveness, if available for Germany….

Outcomes

define & ranking

Patient relevant outcomes (vaccine efficacy & safety)

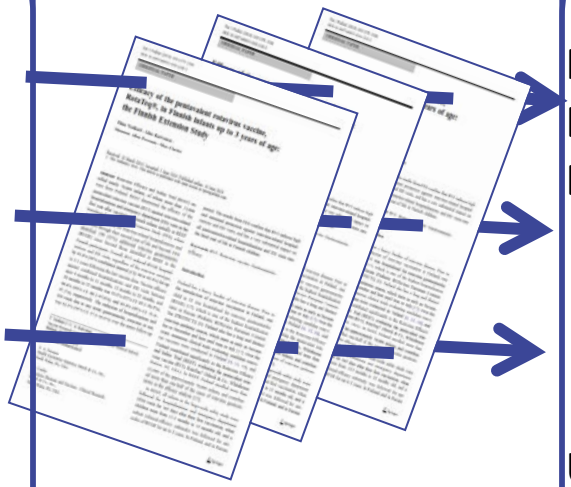
→ critical

→ critical

→ important

P = Population
I = Intervention
C = Comparison
O = Outcome

→ Less important



Systematic Review
(Outcomes across all studies)

GRADE-ing („body of evidence“)

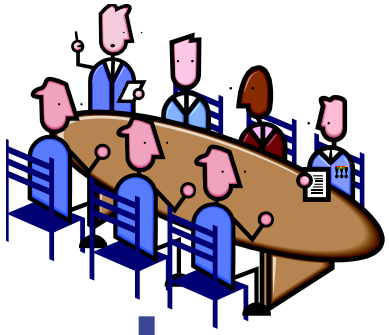
RCT initially high,
Epi-studies initally low

Down: 1.Risk of bias
2.Inconsistancy
3.Indirectness
4.Imprecision
5.Publ. Bias

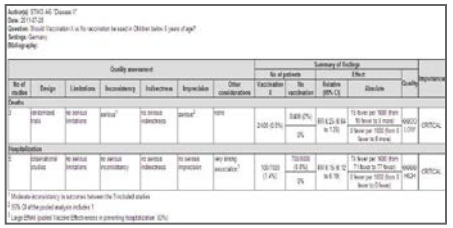
Up: 6.Strong effect
7.Dose-response
8.Confounder

For each outcome final evidence level:
-High
-Moderate
-Low
-Very low

Risik-benefit-assessment



Other key question from STIKO SOP:
-Disease burden / incidence
-Acceptance of vaccination
-Integration into schedule
-Population-level effects
-Costs / cost-effectiveness



Evidence on vaccine safety, efficacy and effectiveness

Recommendation

(for / against)

Adapted from GRADE

Project: STandardization of Economic Evaluations of vaccINes in Germany (STEErING)

- 2-year project initiated by RKI in 2013
- Funded by the Federal Ministry of Health
- Advisory group / collaboration
  - Prof. J. Wasem (University Duisburg Essen)
  - Dr. M. Perleth (Federal Joint Committee)
  - O. Damm (University of Bielefeld)
- Aims

  1) Identify minimum requirements for a health economic model to be considered by STIKO

  2) Develop a methodology how economic aspects can be integrated in the decision-making process

Objectives & outcome of the workshop

Objectives

- To identify best practices in conducting health economic evaluations for vaccines
- To identify adequate practices in decision-making based on (besides others) results from health economic evaluations

Planned outcome

- Meeting report to be submitted to an international journal / abstract to ISPOR