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Introduction

The need for a framework for evidence-based recommendations for immunization

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Workshop on Procedures for the Development of Evidence-based Recommendations for Immunization

Role of National Immunization Technical Advisory Groups (NITAG)

- Provide guidance to the government or public health agency regarding
  - immunization policies or strategies
  - surveillance of vaccine-preventable diseases
  - collection of data needed for immunization decisions
- Give recommendations related to the national immunization program, e.g. on
  - introduction of new vaccines
  - vaccination schedules & target groups
  - evaluation of the impact of the program

Vaccine introduction decisions

- Decisions involves trade-off between likely benefits on the one hand, and downsides on the other hand
  - Likely benefits: e.g. reduction in number of deaths, hospitalizations, or cases. Eradication of a disease. Protection of unvaccinated persons through herd effects
  - Likely downsides: e.g. program costs, serotype replacements, shift in age-distribution. Adverse events following immunization (AEFI)
- Risk-benefit assessment
- Cost-effectiveness evaluation

The emerging vaccine market

<1919	4 vaccines	(tetanus, rabies, typhoid, cholera)
1920–39	4 vaccines	(diphtheria, pertussis, BCG, YF)
1940–59	4 vaccines	(influenza, IPV, DTP, JEV)
1960–79	7 vaccines	(OPV, measles, mumps, rubella, varicella, Pneumo, Mening)
1980–99	4 vaccines	(HiB, HBV, HAV, Pentavalent)
2000–19	>10 vaccines	(Pneumo conj, HPV, Rota, Mening conj, herpes zoster; Pipeline: e.g. RSV, Staph, H. pylori, EBV, ETEC, TB, HIV, malaria, dengue, HCV, shigella, tetravalent flu, cancer?)

Challenges (I)

- New technologies (adjuvants, application route, etc.)
- New product profiles (efficacy, safety, valency, etc.)
- Higher costs
- New target groups (adolescents, elderly)
- Busy vaccination schedules
- **Public acceptance** (and among healthcare worker)
  - too many vaccines?
  - disease perception
- **Limited financial resources** / fair distribution

Challenges (II)

How much do we know?

- Need for a disease surveillance system to assess disease burden and to monitor impact
- True disease burden on country level (underdetection by surveillance systems)
- Strength of evidence regarding population effects of vaccinations
- Immunogenicity vs. effectiveness of vaccines
- Rare AEFI: post-licensure safety surveillance

Development of vaccination recommendation

A systematic approach…

- helps to improve the 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

Standardisation of the process

- List of important key indicators (framework)
  - Epidemiology, clinical characteristics, vaccine characteristics, etc.
- (Systematic) literature research
- Ongoing debate:
  - Standardised grading of the quality of evidence
    - RCT vs. observational studies
    - Population effects
  - Grading strength of recommendation

Objectives of the workshop

- To review current procedures and experiences of NITAGs in developing a framework for evidence-based vaccination recommendations
- To discuss the applicability of methods like GRADE
- To discuss potential benefits of and terms of references for international working groups to facilitate the development of evidence-based recommendations for NITAGs