

**National decision-making for the introduction of new  
vaccines:  
a global systematic review, 2010-2020**

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# Context of work

- Competing priorities & limited resources for vaccine introduction
- Under Global Immunization Vision and Strategy, WHO developed guidelines for vaccine introduction
- UN member states endorsed [Global Vaccine Action Plan](#) “commit [ting] to immunization as a priority”
- For >10 years, [WHO had recommended that countries establish independent expert advisory groups](#) as a way to improve quality and ownership of national immunization programs
- [Burchett et al. \(2012\) systematic literature review](#)
  - 85 studies included: describes frameworks used by countries for national decision-making for new vaccine introduction
  - Paucity of literature on **process** for vaccine adoption

## 2010-2020 Systematic review

- **Goal** — Document the evolving criteria that affect vaccine policy decisions since 2010 and identify enabling factors for vaccine policymaking
- **Research questions:**
  - To what extent have the vaccine decision-making criteria evolved?
  - What are enabling factors for vaccine policymaking?
- **Outputs/ use:**
  - Provided for consideration by SAGE in April 2017
  - Global/regional strategies, guideline development
  - Global manuscript

# Methods

1. Literature database search: MEDLINE, EMBASE, Global Health, Cochrane Library, CINAHL, Scopus
2. Analysis: Characterizes quantity and quality of literature
3. Synthesis: Narrative and tabular

# Screening process

- Abstracts & full texts screened by 1-2 independent reviewers
- **Exclusion criteria:**
  1. Did not focus on human vaccination
  2. Did not focus on policy decision-making around vaccine adoption (i.e., considered decision-making at the clinical, individual level, or focused on implementation issues only);
  3. Focus on hypothetical vaccines (e.g., HIV vaccine) and did not present a framework for decision-making
  4. Did not consider factors that directly affected decisions
  5. Focused on the economic evaluation of introducing a new vaccine and did not present any other factors that affected decisions
  6. Was published in a language other than English, Spanish, or French

# Article classification based on pre-defined categories

- 1) Articles that present a **framework of decision-making** for vaccine adoption
- 2) Studies that collect or analyze **empirical data on decision-making** for vaccine adoption
- 3) Theoretical and empirical articles that provide insights into the **process of vaccine policymaking**

# Data abstraction

- **Basic characteristics:** country; country income level; Gavi, the Vaccine Alliance eligibility status; type of vaccine
- **Results:**
  1. Vaccine decision-making criteria: importance of the health problem; vaccine characteristics; programmatic considerations; acceptability; accessibility, equity and ethics; financial/economic issues; the impact of vaccination; consideration of alternative interventions; and the decision-making process.
  2. Process of vaccine policymaking: Main themes or factors facilitating successful vaccine policymaking

# Results

- N=116 references included & extracted
  - 27 frameworks, 45 empirical studies, 44 policymaking process articles
- 38% not a specific vaccine
  - HPV, rotavirus, pneumococcal conjugate
- 23% HIC, 12% UMIC, 17% LMIC, 3% LIC
- 20% WHO AMR, 16% EUR, 15% AFR, 12% SEAR, 6% WPR
- 15 articles from EU countries: Belgium, Denmark, France, Finland, Germany, Italy, Luxembourg, Poland, Spain, Sweden, the Netherlands, the UK



# Criteria used in decision-making frameworks globally (N=27)

Criteria	%
Burden of disease	96
Vaccine efficacy / effectiveness	96
Vaccine safety	93
Economic evaluation	93
Cost-effectiveness of alternatives	89
Impact on health outcomes	70
Quality of evidence	67

Criteria	%
Accessibility, equity, and ethics	48
Feasibility issues	41
Vaccine acceptability	41
Delivery issues	41
Others e.g. political priority, affordability, financial sustainability, funding sources.	<41

# Criteria used in decision-making frameworks globally (N=27)

Criteria	%
Burden of disease	96
Vaccine effectiveness	83
Vaccine safety	78
Economic burden	74
Cost-effective alternatives	70
Impact on health outcomes	70
Quality of evidence	67

10 years after Burchett et al. review:

- **Increased use of economic evaluations**
- **Increased consideration of decision-making process incl. quality of evidence**

Criteria	%
Delivery issues	100
Others e.g. political priority, affordability, financial sustainability, funding sources.	<41

# Enabling factors for policymaking globally (N=61)

Enabling factor	%
National, regional, or global evidence-informed recommendation	82
National governance, political will	70
Policy dialogue, networks, champions	57
Public private partnerships	57
Institutionalized process for vaccine introduction	56
Robust health system	52
Lessons learned from other countries or regions	43

# Targeted vs. universal Hepatitis B vaccine policy in the Netherlands (2010)

- Decision-making framework with 5 thematic headings: seriousness and extent of disease burden, effectiveness and safety of vaccination, acceptability of vaccination, efficiency of vaccination, and priority of vaccination
- 2 ethical principles: (1) that the best possible protection should be afforded to the population as a whole and (2) that benefit should be fairly distributed across population groups, with protection provided on the basis of need
- *“Use of standardised criteria furthers a trustworthy, transparent and accountable process of decision making about inclusion of new vaccinations and may help to retain public confidence in public vaccination programmes”*

# Policy-making process for HPV vaccine introduction in the Netherlands (2019)

- Many stakeholders involved, with central roles for Ministry of Health and parliament, with National Health Council and the Health Insurance Board as advisory bodies
- Media played a more indirect role by initiating many of the questions asked in parliament, through reporting on developments in Dutch society
- Financial and economic issues (64%), especially economic evaluations (48%), played an important role, particularly in the prioritization and development phases of policy making process
- Importance of considering acceptability of vaccination throughout the policy process

# Recommendation for routine rotavirus vaccination of infants in Germany (2013)

- Following STIKO's Standard Operating Procedures for the development of evidence-based vaccination recommendations
- key questions was addressed and systematic reviews were performed with a focus on the efficacy, effectiveness, impact and safety of RV vaccines
- Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology was applied to assess the quality of available evidence
- Data from randomized controlled trials, post-marketing observational studies, impact studies
- STIKO recommended routine rotavirus vaccination of children under the age of 6 months with the main goal of preventing RV-associated hospitalizations in Germany, especially among infants and young children

# Policy-making process for HPV vaccine introduction in Poland (2017)

- Health technology assessment considered value for money and budget impact, given the high government investment required, but did not include social perspective in estimating costs
- Despite Poland technical advisory committee recommendation to introduce vaccine in national immunization program, influence of socio-politico-economic factors was determinant on final decision (non favorable)
- Highlights critical need to consider social values in vaccine policy-making process

# Decision-making processes for rotavirus vaccine introduction in Scandinavian countries (2018)

	Rotavirus vaccine included in the national childhood vaccination program	NITAG established	National decision process on vaccine introduction				Main drivers for/ against introduction
			Formal framework exists	Has cost-effectiveness (CE) analysis been applied	Results CE analysis, Societal perspective	Conclusion CE assessment health sector perspective	
Denmark		+		+	Cost- effective when indirect costs included	Not cost-effective	Severity (mortality) criteria
Finland	+	+	+	+	“Reasonably” cost-effective	Not cost-effective	High morbidity burden, safe vaccines
Norway	+	+	+	+	Cost- effective when indirect costs included	Unlikely cost-effective	High morbidity burden
Sweden		+	+	+	Cost- effective and cost-saving when indirect costs included	Cost-effective but not cost-saving	High morbidity burden

St-Martin *et al*, Selection and Interpretation of Scientific Evidence in Preparation for Policy Decisions: A Case Study Regarding Introduction of Rotavirus Vaccine Into National Immunization Programs in Sweden, Norway, Finland, and Denmark. *Frontiers in Public Health* (2018). Available at: <https://doi.org/10.3389/fpubh.2018.00131>



# NITAGs & immunization policymaking in European countries (2013)

- Key role in the decision-making and recommending processes is played by National Immunization Technical Advisory Groups (NITAGs)
- Survey performed in Feb 2013 among EU member states, Norway, Iceland
- 4 main factors addressed by all: disease burden in country, severity of disease, vaccine effectiveness/efficacy, vaccine safety at population level.
- Differences in the relative weighting of these key factors, differences in data or assumptions on country-specific key factors, differences in existing vaccination systems and financing, are likely reasons for differences in NITAG recommendations, and eventually NIPs, across Europe.
  - Depending on the country, adult vaccine recommendations range from almost non-existent to over-abundant
- Systematic reviews and the development of mathematical/economic models could be performed at supranational level, thus sharing resources and easing the present workload of NITAGs

# Conclusion

- Increased global interest in **strengthening evidence-based policymaking for vaccines**
- **Decision-making framework** is critical to reaching evidence informed decisions for allocating and prioritizing scarce resources
- **Criteria** included in national frameworks: burden of disease, vaccine efficacy/effectiveness, vaccine safety, economic evaluation, vaccine impact on health outcomes, and cost-effectiveness analysis (CEA)
- Increased use of **economic evaluations**, especially CEA
- Increased considerations of **decision-making processes** including quality of evidence
- Expanded research on **vaccine decision-making processes** providing insights into enabling factors for vaccine introduction

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