

Adult Immunization Board - Technical meeting:

*Strategies for introducing and implementing vaccines for adults into
National Immunization Programs in Europe:
Exemplary Approaches and Key Insights*

Meeting summary



A collaboration of



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Session 1: Meeting objectives

1. **Decision-making**
2. **Implementation : planning and managing**
3. **Monitoring and Evaluation**

Meeting objectives

1. Decision-making objectives:

a. Explore and understand the **evolving criteria** influencing national decision-making processes for the introduction of vaccines for adults.

b. Identify **pivotal factors** facilitating effective decision-making in different European countries.

Session 2 : What are the criteria for inclusion in a national vaccination program?

- **National decision-making for the introduction of new vaccines.** *M.Donadel & A.Shefer*
 - Systematic literature review (SLR) to answer the question “Have vaccine-decision criteria evolved and what are the enabling factors for policymaking”, with specific examples from EU countries.
- **Vaccine delivery costing to support decision-making.** *KHT.Yeung.*
 - SLR on when and how vaccine delivery costs are included in cost effectiveness analysis (CEA) and cost benefit analysis (CBA)
- **Role of the NITAGs in the decision-making process.** *D.Martinelli*
 - Online survey. European Joint Action on Vaccination (EU-JAV; WP-6). 13/28 countries participated (via NITAG secretariat, member of NITAG, PH institute, Ministry of Health)

OBJECTIVE 1a : Explore and understand the **evolving criteria** influencing national decision-making processes for the introduction of vaccines for adults

Commonly used criteria:

- Burden of disease
- Risk-benefit balance → Vaccine efficacy and effectiveness versus Safety profile,
- Availability of financial resources & Economic evaluations
- Impact on health and non-health outcomes

Lesser used criteria

- Acceptability
- Feasibility and Programmatic aspects
- Social values, equity, ethics

OBJECTIVE 1a : Explore and understand the **evolving criteria** influencing national decision-making processes for the introduction of vaccines for adults

Criteria - Changes over time :

- Positive evolution towards **life-course approaches**
- Increase in considerations of the decision-making process including **quality of evidence**
- Increasing inclusion of **economic evaluations** *

*Cost evaluations:

- Cost-effectiveness models may not be applicable **from one setting to another**. Cut-offs may differ, with differences in willingness to pay
- Input data can be **rapidly outdated**
- Not all vaccine-related costs are included (e.g., communication , training). Should include cost of delivery separately to cost of vaccine procurement

Session 2: What are the criteria for inclusion in a national vaccination program?

■ **UK & RSV vaccination.** *H.Nair*

→ Vaccination all +75y, one off campaign, routine program when turning 75y.

- Burden of disease in adults (US, EU (RESCEU), FRANCE):
 - RSV infection and severity increases in 60y+.
 - Among +60y+ , age-related gradient found, with increasing age associated with higher burden
 - The same is observed in +60y with neurological disease, kidney disorders, or CHF (not diabetes or COPD)
- CEA from the US : cost effectiveness, especially if used across 2 seasons
- Update in recommendations? After UK-specific CEA and UK/EU data on burden in those with chronic conditions

■ **Germany & Pneumococcal vaccination.** *O.Wichmann*

→ PCV20 in +18y with chronic disease and in +60y

- Pathway: prioritizing, setting goals, PICO questions, Systematic review, GRADE of evidence, other questions (impact, feasibility, equity), decision process and recommendation
- Evidence to Decision Table for each Criteria
- Tools available : SOP, modelling methods

Session 2: What are the criteria for inclusion in a national vaccination program?

- **Belgium & Herpes Zoster vaccination.** *I.Leroux-Roels*

→ Shingrix in +60y and immunocompromised +16Y

- From recommendation to implementation : Federal level → Regional levels
- NITAG has an advisory role: Secretariat, plenary 70 members, consensus rather than voting
- Cost-effectiveness are not included in NITAG recommendations (separate) → Atypical results for HZ
- No immunization program for (older) adults at regional level
- If in vaccine program, free of charge → adults : limited to Flu in nursing homes, booster Tdap
- Reimbursement procedure : +18y, active treatment in last 5y for cancer, HIV, solid or hematological transplantation

- **Fragmented scenario, with NITAGs work autonomously, with variability in experience.**

OBJECTIVE 1b: Identify pivotal factors facilitating effective decision-making in different European countries.

- **Decision-making framework** is critical to reaching evidence informed decisions
- **Enabling factors for policymaking** are identified (Donadel et Al. Vaccine. 2021)

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

- **Similar decision-making processes** on vaccine introduction do not necessarily result in same outcome (e.g., St Martin et al. *Frontiers in Public Health* 2018, on rotavirus vaccination in Scandinavian countries)
→ **Need for expanded research on decision-making processes** to provide insights into enabling factors

Meeting objectives

2. Implementation objectives: planning and managing

- a. Investigate the current status and evolution of vaccination programs for adults in EU.
- b. Analyze the implementation procedures of vaccines for adults, including setting goals and targets, defining the scope of application, identifying target populations, selecting introduction strategies, and managing the planning, scheduling, coordination, and associated costs.

Session 3 : Vaccine implementation: planning and managing

Implementation science. *M. Wensing*

- Definition :

*'... the scientific study of **methods to promote the systematic uptake** of research findings and other **evidence-based practices** into routine practice, and, hence, to improve the quality and effectiveness of health services. It includes the study of influences **on healthcare professional and organizational behaviour.**' Eccles M & Mittman BS. Sci 2016;1:1*

- 3 domains :

- Implementation strategies: planning, education, support, finance, restructure, legislation
- Recommended practices: differ in complexity, visibility level of evidence base data, costs etc
- Context : HCW, organizational leadership culture, previous experiences, financial incentives

- Evidence-practice gaps are identified. Implementation science can help :

- Identify broader range of strategies and factors for improvement
- Develop concepts and frameworks for design and evaluation of programs

Session 3 : Vaccine implementation: planning and managing

Current status and evolution of vaccine programs for adults in Europe. *H.Maltezou*

- **Young adults** have been disproportionately affected during epidemics of VPDs the last two decades :
 - Gaps in immunity, vaccine programmes, vaccine hesitancy, barriers to vaccination services
- **Lifelong strategy needed :**
 - Catch- up vaccinations and booster doses (waning of immunity)
 - Immuno-senescence, increased severity, chronic conditions in (older) adults
- **Country specificities : ECDC scheduler <https://vaccine-schedule.ecdc.europa.eu/>**
 - Cassimos et al. Vaccines (Basel). 2020: studied the vaccination policies for adults in 42 European :
 - All have vaccination programs for adults –but differences in number of vaccines, number of doses, target pop., implementation-frame, etc
- **Evolving strategies:** e.g., Pertussis : Child vaccination → Cocooning strategy → maternal vaccinations

Session 3 : Vaccine implementation: planning and managing

Setting goals/targets for an adult vaccination program

Cervical cancer elimination strategies (L.Bruni)

- *WHO 2020* - Elimination goals, triple strategy :
 - *90% girls vaccinated, 70% twice lifetime screening , 90% with disease are treated*
- However, far from 90% coverage with important differences between & within countries
 - In 2022, average programme coverage in Europe was 65% 1st dose /60% for 2nd dose (WHO/UNICEF)
- **Various strategies** can be used to accelerate road to elimination:
 - Single dose, gender-neutral vaccination, extended catch-up, faster strategies combining HPV vaccination with screening in older cohorts, outreach to vulnerable groups.
- **Specific coverage threshold** for the elimination of oncogenic HPV through herd protection
 - Depend on vaccination coverage, population, distribution of HPV types.
- **Performance of the HPV vaccine programme** during the first 2 years appears to be a strong predictor of the level of vaccine coverage in subsequent years (Bruni et al 2021 Prev Med)

Session 3 : Vaccine implementation: planning and managing

Setting goals/targets for an adult vaccination program

Lessons learned from the seasonal Influenza vaccination strategy *Kanta Subbarao*

- Why a target of 75% vaccine coverage threshold was set for the elderly? → No hard data
 - 2003 World Health Assembly, Council EU: 2014-2015, ECDC Priority Risk group guidance 2008
- **Burden in older adults** : high burden of severe influenza, complications, hospitalisations and mortality, 4- 5 times hospitalization rates compared to young adults, with **lower VE (→ HD / Adjuvanted)**
- **According to ECDC technical report 2023 : Denmark is the only country that reached >75%**
- **High coverage** during COVID-19 pandemic : achieved through tailored communication, improved reimbursement, safe /convenient access → **Sustain efforts**
- **Ways forward?** Better vaccines for longer immunity, easier access, free vaccination (including the visit), awareness of the dangers of influenza, engage specialists to promote vaccination, specific target for the highest at risk, protecting through vaccinating children (UK?)

Session 3 : Vaccine implementation: planning and managing

Identification of target population

Assessing/improving accuracy of target populations for immunization coverage

C.Danovaro

- As coverage rises, coverage estimates are increasingly sensitive to errors in target population estimates
- **Target populations** : Live births, Surviving infants (high infant mortality rates), trickier for other ages and in particular some specific target groups (HCW, high risk)
- **Sources** of target population numbers : Civil registration and vital statistics (births/deaths); Census and projections, population registries & electronic immunization registries, others (Satellite images)
- **Assessing accuracy** : compare indicators with independent sources of data, compare national targets to sum of subnational targets, calculate annual growth rates, check implied infant mortality rates to those reported, and plotting and analysing time series.
- **Method of calculation** : e.g., Aggregation by cohort or by time period; e.g., HPV: Programme coverage (challenges with denominator) vs Coverage by 15y (challenges for numerator).

Session 3 : Vaccine implementation: planning and managing

Identification of target population

Target population of COVID-19 adult vaccination: evolution, current status. *H.Nohynek*

- Beginning : priority based on high risk, ethical considerations, logistical reasons
- Boosters : trade off boosting of elderly verses primary vaccination of low risk
- Vaccine coverages : drastically declined since peak late 2021, now highly variable across EU
- Current recommendations differ across EU/EEA in terms of :
 - Age limit - mostly 65y+ , co-administration with Flu
 - Spring boosting or not , and if yes, whom (75y+ or 80y+ and severe immunodeficiency)
 - Annual boosters to social and healthcare works
 - Risk groups (except for Pregnancy : mostly booster is recommended)
 - Recommended interval : from 3 months, 6 months
 - Whether infection is considered a “dose” or not
- European Joint purchase till dec 2025 → to become part of NIP?

Session 3 : Vaccine implementation: planning and managing

Selection of introduction strategy and implementation activities

Leveraging lessons learned from COVID-19 roll-out *R.Foreman*

- Many successes of COVID-19 vaccine roll-out, but also **specific challenges** were identified :
 - Equity challenges, sufficient manufacturing, safety and secure transport, fair vaccine allocation, prioritization, misinformation, barriers to access in minorities, ethical implications of vaccine passports and vaccine requirements
 - **Opportunity to learn lessons from experience :**
 - Multi-sectorial engagement, with identification of ENABLERS and BARRIERS, to establish a foundation for change
 - Convergence when appropriate in vaccine policy making; effective communication around necessary divergences in vaccine policy
 - Adaptive and well-trained personnel to deliver and communicate about vaccine
- All require political will and financing, but also coordination, collaboration, cooperation

Session 3 : Vaccine implementation: planning and managing

Selection of introduction strategy and implementation activities

Introduction of RSV vaccines in older adults and pregnant women in the US *M. Melgar*

- **Implementation challenges in Pregnant women :**
 - Financial concerns, lack of adequate reimbursement
 - 12 % said no vaccines in pregnancy, ~50% accept one or 2 : but 4 now recommended in pregnancy!
 - Decision making fall on obstetricians
- **Implementation challenges in elderly :**
 - Time to integrate into systems, gain wide access, increase awareness (HCW), normalize
 - Shared clinical decision-making – difficult to communicate, to implement,
 - Complex formulation for co-administration, lack of strong message saying it should be encouraged
 - Financial issues : Insurance plans not yet mandated to cover RSV
 - LTCF have additional challenges

→ Multiple actions by CDC are being taken to increase uptake (communication, education, tailored)

Session 3 : Vaccine implementation: planning and managing

Selection of introduction strategy and implementation activities

Introduction of Pertussis vaccination for pregnant women in Denmark. *I.Asse Glode Helmuth*

- **Offered between 25-32 gestational week** at already established visit with General practitioners (GPs)
 - **ADVANTAGES** : Compliance to visit to GP is high (likely >90%), Vaccine advice comes from GP, with high level trust, health authorities have tools to directly communicate with GP, permanent offer avoids confusion.
 - **DISADVANTAGE** - COVID-19 and Flu are offered at vaccination centers not at GP
- **Coverage and effect of program** :
 - 85% coverage in 2023 (high media attention on the disease)
 - Proportion in infants among cases is lower than in previous years – first signs of impact?
- **Perspectives**
 - Change in law, midwives can administer vaccines
 - RSV vaccination on the horizon? 4 vaccines in pregnancy, impact
 - Better surveillance for VC and VE estimates

Session 3 : Vaccine implementation: planning and managing

Selection of introduction strategy and implementation activities

Equipping healthcare professionals and students: The role of training for implementing vaccines for adults. *K.Senouci*

- **Why** : HCW do not have strong training in immunization in initial curriculum, yet are confronted daily
- **Who** : Multiple targets → Students/young professionals – Mid-career professionals -Experts
- **Challenges** : limited time of HCW, funding, constant evolution of knowledge

ICAVT collaboration : international collaboration on Advanced Vaccinology training (March 2022): www.icavt.org . 35 courses, all regions : facilitate maintenance of global list of available courses, exchange on information and material, building capacity

ARVAC Alumni Refresher Vaccinology Course (free, online) : now being opened not just to Alumni, but also other collaborators. 3 half days, 9 plenaries.

ADVAC Advanced Course of Vaccinology (University of Geneva, Fondation Merieux) : 2 week-course for mid-career and experts that are decision makers (immunization program managers, NITAG members, Industry, 1/3 LMIC) : Facilitate critical decision making in Vaccinology

→ **Evolving to Lifelong approach (previous focus on pediatrics)**

Session 3 : Vaccine implementation: planning and managing

Selection of introduction strategy and implementation activities

Communicating with the public about vaccines: Implementation considerations *J.Dag Berild*

- **Prerequisite:** Basic statistics, evidence-base, a knowledge of attitudes to vaccination (barriers and enablers), resources (Time and money)
- **Trust !** To believe someone is good and honest and will not harm you, or that something is safe and reliable
- **Transparency :** communicated what we know/don't know, positives/negatives (Side-effects!)
- **Availability :** e.g., Social media (direct communication, listening post) → resources to respond and moderate with clear rules
- **Flexibility:** One size does not fit all, channels for communications needs to be tailored

Session 3 : Vaccine implementation: planning and managing

Selection of introduction strategy and implementation activities

The impact of pharmacist involvement on immunization uptake in Europe *M.Haems*

- Multiple studies show that pharmacist intervention, whether facilitating, educating or administering vaccines, have an added value
- This added value is related to convenience and better accessibility: in EU, there are 180 000 pharmacies, and 60% of residents have access within 5min walk, no appointment
- Across Europe, pharmacists are increasingly being used within vaccine programs, with COVID-19 being an enabler, but differences across countries in terms of involvement (specific vaccines, prescription possibilities, legislative differences, contribution to uptake, training)
- Impact ? Ireland: growth in VC, both by pharmacists and GP (collaboration >< competition)
- Complementary role of pharmacies for those not reached by GP and nurses
- Important for overburdened primary Healthcare

Meeting objectives

1. Monitoring and Evaluation objectives:

- a. Gain valuable insights from **monitoring, evaluation, and impact assessment** examples across European adult vaccination programs.

- b. **Utilize lessons learned** from real-world scenarios to enhance the efficiency and impact of adult vaccination introductions.

Session 4 : Monitoring and impact assessment

Setting goals/targets for an adult vaccination program

From insights to implementation: using behavioural and cultural insights to increase vaccine uptake. *T.Likki*

- BCI was identified as priority in WHO European programme of work 2020-2025
- WHO TIP : Tailoring Immunisation Programmes
 - Developed by the WHO Regional Office for Europe to support countries to achieve high and equitable vaccination uptake
- COM-B model for behaviour change : C : Capability, O :Opportunity, M: Motivation
- Theory of change :
 - Allows to be explicit on why an intervention is selected, and to evaluate its effect (case e.g., Georgia)
 - Situation analysis : target group, what we know
 - Research: barriers and drivers
 - Design: tailored interventions
 - Implement and evaluate: impact evaluation

Session 4 : Monitoring and impact assessment

Setting goals/targets for an adult vaccination program

Adult vaccination program as part of the life-time vaccination in Spain- its cost/investment L. Sanchez-Cambronero

- Vaccinating = approx 1,500€/healthy person's lifetime
- Total health expenditure in Spain: 1115,512 millions → Vaccination: 0.25% - 0.5% of the budget (2023)
- Cheap for high impact (cost of the disease prevented) → Strengthening of immunization programmes

Session 4 : Monitoring and impact assessment

Setting goals/targets for an adult vaccination program

Monitoring Influenza/COVID-19 VE in Europe I-MOVE/VEBIS. *E. Kissling*

- **Vaccine effectiveness (VE)** using a well established publicly funded monitoring network
- I-MOVE (Vaccine evaluation research EU 2007-2022) → ECDC VEBIS (VE Burden and Impact Study)
- **Primary and hospital care** setting, **Test-negative design** (embedded in existing surveillance networks) and **cohort studies**. Generic common protocol pooling multi-country results.
- VE studies : **key research questions** : by time since vaccination, by clade and variant, Immunological imprinting, against outcomes of different severity, impact.... **Early VE results for policymaking**
- Challenges : Sustainability, access to data, robustness in crisis, geographical diversity (vaccines and their coverage), validity of data (variable sources), residual confounding-> **Evaluation studies**

Session 4 : Monitoring and impact assessment

Setting goals/targets for an adult vaccination program

Safety monitoring of COVID-19 and other vaccines for adults in the EU. *J-M. Dogne*

- **COVID-19:** Innovations (mRNA and viral-vector vaccines), mass vaccination (**Volume of AE data**, 500-1000 events/week not seen in CT to assess and evaluate), vaccination of high-risk populations (with lesser data from clinical trials), new clinical entities: e.g., TTS
- **Pandemic preparedness :** Prompt detection, evaluation, communication and transparency
 - **Good data :** patient exposure data, background incidence rates of adverse events of special interest.
 - Safety assessments need to **combine methods** (observed verses expected analysis, Imbalance analysis , time to onset to AESI) → benefit-risk evaluations.
 - Use of **risk minimization activities:** good RMP, traceability of vaccine, monthly summary reports, skilled clinician team for signal management and communication of the data → Role of spontaneous reporting (has limitations, but *picked up all signals* and rapid) verses Post Authorization Studies?
 - COVID-19 lessons learned are now published (HMA/EMA)→ communication (infodemics) & cooperation

BREAK-OUT SESSION FEEDBACK

Strategies to overcome barriers to effective implementation of adult vaccine implementation

- **Collaborations** : data across countries, harmonization of models (CEA), NITAG collaboration
 - EU-NITAG (exchange, Cochrane collaboration for SLR with working groups nominated by countries)
- **Political engagement**
- **Infrastructure** : diversification of access points, improved registration system, digitalisation,
- **Sustainability**: innovation funding models for vaccines, shared costs, negotiation of prices together
- **Tailored communications** : Surveys on public perceptions, Working with community champions, collaboration with specialist societies (channel to patients)
- **Transparency**, open publication on decision-making

TAKE-HOME MESSAGES

- **Key criteria for decision-making process were identified:** burden of disease, benefit-risk balance, economic evaluations; While acceptance, feasibility and equity are used to a lesser extent
- **Expanded research on decision-making processes are needed** to provide insights into enabling factors
- **Many differences exist across European vaccine programmes,** that are evolving to **life-long strategies**
- Importance of **monitoring and evaluation of interventions:** VE and impact studies, monitoring of safety, but also tools including Implementation science, Behavioural and Cultural insights,
- **Tailoring communication and interventions**
- **Importance of education,** with harmonising medical curricula across EUROPE on infectious disease prevention and vaccinology (set minimum). EU competence
- **Barriers and strategies to implementation were identified**

Cooperation, Collaboration and Coordination!