

# 26<sup>th</sup> ADVANCED COURSE OF VACCINOLOGY

*11 - 22 MAY 2026*

## Course objectives

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### General objectives

The Course aims to facilitate critical decision-making in vaccinology by providing participants with a comprehensive overview of the various aspects of vaccinology (immunology, vaccine development, clinical trials, regulatory processes, vaccine-specific issues including new vaccines, vaccination strategies and policies, programme implementation, humanitarian emergencies, social, economic, political and ethical issues, financing, and communications...).

By the end of the course, participants should be able to:

1. Use rational criteria for decisions related to evidence-based introduction of new vaccines into immunization programs;
2. Identify requirements for vaccination strategies to be used in special conditions: eradication strategies, vaccination of neonates, elderly, immunocompromised and HIV infected persons;
3. Deal with issues regarding vaccine trials (including site selection, recruitment aspects, monitoring, evaluation and ethical considerations);
4. Identify recent developments towards new or improved vaccines and new vaccination strategies;
5. Appraise all aspects of vaccines and vaccination safety, including vaccine delivery and reporting of adverse events following immunization;
6. Initiate appropriate actions in crises associated with real or alleged vaccine adverse events;
7. Recognize the role of communication in vaccine program and policy;
8. Determine any necessary important change to their practice of vaccinology.

With its 360° vision of vaccinology, the ADVAC program describes the approaches required for the translation of scientific and epidemiological evidence into effective policy development related to vaccines and immunization.

ADVAC aims to expand the scientific foundation of the participants and their knowledge in vaccinology areas outside of their current expertise, showing the multifaceted aspects of vaccinology, allowing them to explore novel technologies and think more globally and holistically, and providing them with a unique skill set to develop their leadership in vaccinology.

Participants should not expect to become a subject matter expert after getting one lecture on this topic. They should consider the lecture to be about the basis of the topic and would need to deep-dive in the speaker-recommended material to learn more about the topic.

ADVAC represents a unique networking opportunity where participants can form valuable and sustainable professional relationships and serves as a platform where problems to professional challenges can be shared, and solutions identified.

By learning from, and alongside, other ADVAC students from other fields and organizations, ADVAC is uniquely oriented to help advance the field of vaccinology by sharing practical insights focused on implementation at a basic science level and on a public health scale. It brings together some of the leading experts in vaccinology and motivated students in a favourable environment, making it an excellent incubator for the development of concepts.

## Specific objectives for each training activity (lectures, interactive sessions, small group exercises and parallel sessions)

**SESSION 1 - THE VACCINES JOURNEY: FROM VACCINES TO VACCINATION AND THE IMPACT OF VACCINES.** The purpose of this session is to describe the various steps needed from research to immunization of individuals and the roles, responsibilities and perspectives of the multiple players involved in the field of vaccinology and describe the complexities of their tasks.

### **Lecture 1. From research to individual protection: the A-to-Z vaccine's journey**

- To describe the different steps between research and the immunization of individuals
- Highlight the complexity and uncertainty of every step behind the journey of a vaccine from fundamental research to the act of vaccinating.
- Describe the basic concepts at the basis of vaccinology: immunogenicity, efficacy, effectiveness, safety, correlates of efficacy etc.

### **Lecture 2. Vaccines Preventable Diseases' Burden and Vaccines Impact on Public Health**

- Demonstrate the public health value of vaccines beyond efficacy and safety and present a public health value proposition for vaccines.
- Describe measures and outcomes to define the public health value of vaccines.
- Explain how to calculate vaccine preventable disease incidence and number needed to vaccinate to prevent a specific outcome.
- Define total systems effectiveness.

### **Lecture 3. Where are we with vaccine-preventable diseases & immunization coverage worldwide: the state of the immunization**

- Give an overview of the epidemiology of Vaccine Preventable Diseases worldwide
- Give an overview of the Immunization coverage for the various vaccines
- Summarize the main challenges and issues behind the current immunization coverage rates in LMICs and HICs

### **Lecture 4. Measuring vaccination's impact in populations**

- Describe how to measure key epidemiological parameters (e.g. the basic reproductive number,  $R_0$ ) for serological profiles.
- Describe the impact of vaccination on epidemiological pattern.
- Define vaccination coverage levels by age to halt transmission.
- Define what an imperfect vaccine is.
- Discuss challenges in measurement and observation in the epidemiological study of mass vaccination.

### **Lecture 5. Using vaccines to address a public health problem: the example of Polio eradication immunization strategy**

- Assess the progress made so far towards global polio eradication (WPV and cVDPVs)
- Analyze the unique socio-political, and epidemiologic challenges in remaining endemic areas.
- Explain how vaccines have and will support the eradication strategy for both Wild Polio and cVDPVs

### **Lecture 6. GAVI model to support countries immunization program**

- Describe the mandate and ways of working of the GAVI the Alliance
- Explain how Gavi has enabled and accelerated vaccine introduction in low- and middle-income countries, highlighting key successes and remaining challenges.
- Outline the Gavi 6.0 support model and discuss its implications for country planning, financing, and immunization policy decision-making

**SESSION 2 - HOW VACCINES WORK. The purpose of this session is to describe the relevancy of foundational immunological knowledge to practical applications. Contemporary and historical examples of successes and failures are used to re-enforce the concepts.**

### **Lecture 7. How do vaccines protect?**

- Explain vaccine-induced systemic and mucosa immune effectors that protect against diverse pathogens (including antibodies, T and B cells and mucosal immunity)

### **Lecture 8. How are vaccine responses elicited?**

- Explain the basic aspects of immunological responses

### **Lecture 9. How to use vaccine platforms to tailor immune responses?**

- Describe the immune response induced by vaccine platforms and related mechanisms, including reactogenicity
- Explain the role of the adjuvants in vaccines

### **Lecture 10. Non-specific effects of vaccines**

- Summarize the epidemiological evidence that suggests non-specific effects (NSE) exist.
- Describe the immunological evidence of NSE of vaccines in animals and humans.
- Evaluate the evidence for and against related hypotheses, e.g. gender-specific effects, live and non-live vaccine effects and discuss the gaps and limitations in current knowledge e.g. mechanisms/details of apparent effects on mortality.
- Describe strategies that have been proposed for advancing knowledge in this field that may permit NSE to be used to generate public health benefits.

### **Interactive session 1: Variability of vaccine responses in the real world**

- Describe the key factors that influence vaccine response using real life examples, including vaccination and host parameters (schedule, dosing, genetic and environmental factors)

### Lecture 11. Immunological memory

- Explain the process of immunological memory, demonstrating its practical importance including:
  - Mechanisms involved in B cell memory using the example of influenza.
  - Mechanisms involved in T cell memory with related examples.
- Define the different steps in building immunological memory and the potential effect of adjuvants or live vaccines on immunological memory.

### Lecture 12. Use and limitations of correlates of immunity in vaccinology

- Describe the different definitions of correlates/surrogates that are used.
- Explain how correlates have been derived and what is measured.
- Explain how correlates of protection can accelerate development, licensure and implementation of vaccines.

**SESSION 3 - VACCINE TECHNOLOGY AND MANUFACTURING. (PART 1/3)** The purpose of this session is to build up the basic research vaccine concepts previously presented and define the pre-clinical, manufacturing and approval considerations involved for vaccines. Efforts to identify contemporary issues and approaches being discussed in this area are highlighted, as are the various positions being debated.

### Lecture 13. Vaccine market, market shaping and regional initiatives for vaccine production

- Provide an overview of the vaccine manufacturers and their products
- Explain how vaccine pricing and production decisions are determined, including factors such as demand forecasting and procurement mechanisms.
- Describe regional and global initiatives aimed at shaping vaccine markets and strengthening regional vaccine production capacity.

### **SESSION 3 - VACCINE TECHNOLOGY AND MANUFACTURING. (PART 2/3)**

### Lecture 14. Landscape in vaccine and immunization technologies

- Describe the different technologies that are currently being applied in the research setting to address different challenges in vaccine development. Examples will include vaccine design, manufacturing, delivery, stabilization and evaluation.
- Describe the stage of development of different vaccines/vaccine technologies.

### Lecture 15. Concepts of Chemistry, Manufacturing, and Controls (CMC) for vaccines

- Describe the different components of CMC at the different level (research, clinical trial, production...)
- Explain the complexity of the quality assessment
- Describe the deviation of lots quality and the consequence on lots release
- Explain what Risk Management Plans are

### Lecture 16. From inception to regulatory submission

- Describe the vaccine journey from research to the regulatory submission
- Describe the issues and challenges of each step

### **Lecture 17. The complexity of quality control in vaccine manufacturing**

- Describe the different steps involved in the manufacturing of vaccines and the complexity of quality control
- Explain the complexity of any process modification during manufacturing and its real impact on potential shortages of vaccines.

**SESSION 4 - VACCINE REGULATORY. The purpose of this session is to understand the roles, responsibilities and processes of regulatory agencies.**

### **Lecture 18. The Role of regulatory agencies, Issues and Challenges of submitting a dossier (including content of a dossier)**

- Explain the role and functioning of National and Regional Regulatory Authorities (NRAs).
- Describe the different stages of review and regulation of vaccines (investigational new drug application, biologics license application, post-licensure).
- Describe the evolution of vaccine regulations overtime and the current status of NRAs functionality globally, highlighting differences in HICs and LMICs

#### **Small Group Exercise 1: Vaccine Regulatory**

##### **How to manage regulatory requirements during vaccine development and vaccine production in both HICs and LMICs**

- Acquire basic knowledge about the regulatory procedure to license/register a vaccine product (e.g. process; timelines; functions involved; responsibilities; etc.)
- Understand the role differences between the parties involved in a vaccine assessment, i.e. “industry” vs. “regulator”
- Experience the potential different views (“industry” vs. “regulator”) when assessing the scientific data to evaluate the benefit/risk of a vaccine product
- Develop strategies and paths forward to enable vaccine registration and access to populations

##### **Interactive session 2: Optional lecture from industry: From ideas to implementation - the realities of funding for vaccine research and development in the private sector**

- Understand the information needed and criteria used by the manufacturers to support vaccines research (Go and No-Go” decisions) and development
- Understand the differences perspectives from the manufacturers (IFPMA versus DCVM) for vaccines targeting the high-income countries market and vaccines as global goods for LMICs

**SESSION 3 - VACCINE TECHNOLOGY AND MANUFACTURING (PART 3/3) The purpose of this session is to build up the basic research vaccine concepts previously presented and define the pre-clinical, manufacturing and approval considerations involved for vaccines. Efforts to identify contemporary issues and approaches being discussed in this area are highlighted, as are the various positions being debated.**

### **Lecture 20. Delivering outbreak vaccine in 100 Days: what does it take?**

- Identify the challenges and issues countries and manufacturers will face for a vaccine to be developed, produced and distributed in case of a pandemic

- Identify the areas where time can be gained without jeopardizing safety for a vaccine to be developed, produced and distributed
- Share about the current initiatives worldwide aiming at accelerating the delivery of a vaccines in case of a pandemic

### **Interactive session 3: What can go wrong in vaccine development?**

- Understand the issues and challenges that can impact vaccine research and development
- Hear the different perspectives from various vaccines developers regarding the issues they faced using real vaccines

**SESSION 5 - ASSESSING VACCINES IN CLINICAL TRIALS (1/2). Building on the knowledge obtained from the previous session, this session will expand into a description of vaccine clinical trials including design options for the various categories of trials. The role of the students will also expand as they participate /lead small group/individual role play involving design of clinical trials and financing of vaccine development ideas. Real world complexity and context are explained**

#### **Lecture 21. A to Z for vaccines clinical trials**

- Discuss the different trial designs in regards of the different objectives
- Describe how clinical trials fit into the progression of vaccine development, leading stepwise (Phases 1-4) to licensed products.

#### **Lecture 22. Clinical trials: an overview of issues to be considered**

- Demonstrate how the design and performance of clinical trials have changed over time, increasing in sophistication and complexity.
- Discuss the various options that may, or may not, be available to demonstrate the efficacy of a vaccine in Phase 3 trials on a track for licensure by regulatory agencies.

#### **Lecture 23. Introduction to statistical aspects of clinical trials**

- Explain key statistical concepts relevant to clinical trials, including statistical significance, power, sample size, and basic trial design.
- Describe principles of trial analysis and reporting, including statistical analysis plans, CONSORT guidelines, and common analytical approaches for two-arm trials.
- Discuss practical statistical analysis issues in trials including variable follow-up periods, adjusting for confounding variables, and sub-group analysis.
- Discuss “per protocol” and “intention to treat” analyses, case-control evaluation of vaccine effectiveness, and trial designs considered (e.g. for Ebola vaccines).

### **Small Group Exercise 2 : How to design, recruit volunteers for, and analyze the results of selected phase II trials**

#### **Design and plan a phase 2b/3 clinical trial**

- Design and write the protocol of a Phase 2/2b/3 trial
- Plan the implementation of a Phase 2/2b/3 trial

#### **Lecture 24. Assessing herd protection and vaccine effectiveness (and use for licensure)**

- Discuss the different mechanisms by which vaccine herd protection can occur, including the role of observational studies.
- Describe new methodological approaches for measuring vaccine herd protection in cluster-randomized and individually randomized clinical trials.
- Demonstrate the role of measuring vaccine herd protection in assessing vaccine cost-effectiveness.

#### **Lecture 25. Human Challenge Trials or other ways of assessing vaccine efficacy**

- Describe the concept of Human Challenge Trials.
- Explain the increased interest in using Human Challenge Trials (HCT) to shorten the time required to identify the best vaccine candidate and thus shorten the time/expense associated with licensure of vaccines.
- Describe the other ways to assess efficacy when clinical vaccine efficacy trials are not feasible (outbreak pathogens, or incidence is too low). Including Immuno-bridging (requiring a licensed vaccine), Animal studies post passive transfer of human antibodies, Animal studies following active immunization, Additional evidence (natural history studies etc.).

### **SESSION 6 - VACCINE SAFETY - ASSESSMENT OF ADVERSE EFFECTS. The purpose of this session is to describe in depth and synthesize all issues related to vaccine safety and ways to assess, prevent and mitigate adverse events**

#### **Lecture 26. How do vaccines cause adverse events? (Including Immune-mediated diseases)**

- Discuss the different mechanisms by which vaccine can create adverse events
- Describe the different types of adverse events
- Explain the process of identifying a rare severe adverse event in relation to a vaccine (signal detection).
- Describe the impact of such an unexpected safety event on vaccine development and uptake.

#### **Lecture 27. WHO Guidance on how to manage safety issues**

- Describe what information is necessary to determine the likelihood of a causal relationship between a vaccine administration and reported adverse events
- Explain the necessary process to evaluate the likelihood of a causal relationship using standard guidelines (including WHO guidelines)
- Demonstrate the importance of Surveillance and reporting of adverse events possibly associated with immunizations and the limitations of passive surveillance.
- Describe the management of signals (at country level, NRA, Industry etc...).

#### **Lecture 28. Population-based post-licensure surveillance**

- Discuss, with specific examples, the role of vaccine pharmacovigilance and epidemiological studies in safety assessment including study methodology for signal validation and epi studies.
- Describe the main study designs used for safety assessment.
- Explain the self-controlled case-series design, its benefits, and when it can be used.

## **Lecture 29. Immunization safety, logistics and vaccine management in vaccination programmes**

- Describe the range of potential immunization safety issues including differences between low- and middle- income and high-income countries.
- Discuss the issues and challenges including injection safety and logistics faced by a national immunization program.
- Describe the role of WHO Pre-Qualification, Vaccines Vials Monitors and Controlled Temperature chain in improving coverage and safety

**SESSION 5 - ASSESSING VACCINES IN CLINICAL TRIALS (2/2). Building on the knowledge obtained from the previous session, this session will expand into a description of vaccine clinical trials including design options for the various categories of trials. The role of the students will also expand as they participate /lead small group/individual role play involving design of clinical trials and financing of vaccine development ideas. Real world complexity and context are explained**

### **Small Group Exercise 3: Vaccine trial Phase III planning, implementation, analysis of the study results**

#### **Analyze the data and present to your leadership**

- Conduct a critical analysis of a clinical trial

Prepare recommendations for leadership for the possible introduction of a vaccine

**SESSION 7 - ETHICAL ISSUES. The purpose of this session is to describe ethical considerations and challenges and identify accepted ethical guidelines relevant to vaccines**

### **Lecture 31. Applied ethics in immunization programs and practice**

- Describe key ethical principles guiding immunization practice, including informed consent, equity in access and financing, and the balance between individual autonomy and public health goals.
- Discuss ethical considerations related to mandatory vaccination policies, refusal of immunization, and professional responsibilities toward patients and communities.
- Explain ethical obligations in immunization delivery, including AEFI reporting and feedback, pain mitigation, and respectful patient care.

### **Lecture 32. Principles, guidelines and framework for ethical considerations in clinical trials of vaccines**

- Examine ethical complexities in vaccine trials using various resources (ethics guidance; ethics frameworks; empirical data) e.g. 'community' participation; informed consent.
- Identify ethical issues to be addressed by researchers planning and implementing vaccine trials and how to best address them.

### **Small group exercise 4: Ethical considerations in vaccine trials 4**

Using a student-led role play approach to address issues arising from the trial and study objectives, context and participants' health status, after the exercise, participants will be able to:

- Appraise ethical issues related to vaccines and vaccine trials.

- Adjust the design of clinical trials to take into consideration ethical issues.

## **SESSION 8 – DECISION MAKING FOR VACCINES (PART 1/2)**

**Continuing down the vaccine development pathway, this session will focus on an in-depth discussion of the science/factors/approaches involved in bringing a vaccine into the public-health setting.**

### **Lecture 33. The decision-making processes for vaccines use: global, regional and local perspectives**

- Describe the different advisory bodies at global, regional (RITAG) and national (NITAGs) levels involved to make recommendations on immunization
- Discuss challenges and solutions to strengthen NITAGs, as well as approaches to evaluate the functioning of NITAGs and safeguard their existence
- Discuss the risk of external influence and the independence of experts for country ownership

### **Lecture 34. The example of the WHO SAGE decision making processes**

- Present the WHO SAGE, including its mandate, management of possible conflict of interest, ways of working, transparency and workplan
- Describe the GRADE process used by SAGE working groups to assess the strength of evidence
- Present the upcoming policy-related questions and rationale for prioritizing them

### **Lecture 35. The decision-making processes for vaccines' use: what should experts consider**

- Describe the types of evidence and decision criteria used to formulate evidence-based vaccine policies at national level
- Explain the methods used to assess the quality and strength of evidence, including how uncertainty and evidence gaps are managed
- Illustrate how countries within the same region may arrive at different policy decisions despite drawing on similar evidence, using a specific vaccine.

### **Lecture 36. The role of health economics (including modelling) as a tool in analysing vaccine policy options**

- Describe the different health economics analysis that can support the decision making for vaccine policy (e.g. CEA, modelling...)
- Discuss strengths, limitations, and appropriate use of health economics and modelling tools in vaccine decision-making
- Share resources, support mechanisms and capacity-building opportunities to assist countries in applying health economics and modelling to immunization policy decisions

### **Small group exercise 5: Decision-making for the evaluation and impact assessment of new vaccines introduced in selected countries: safety and effectiveness.**

Through a small group exercise focusing on different vaccines and which aim to develop the rationale for the introduction of the selected vaccine to the selected target groups and culminating in a 2-3 minute oral presentation to a simulated Minister of Health, participants will be able to:

- Identify what facts are needed in a decision-making process and how other factors influence the outcome.
- Organize data needed for a policy decision to introduce a new vaccine in a country – identifying what data are available and needs for further data collection.
- Identify options for a structured monitoring of vaccine safety and effectiveness following introduction of a new vaccine.

**SESSION 9 – UPDATES ON VACCINES (1/4)** The objective of this session is to provide an exhaustive view of some key vaccines included in national programs and to give the latest information regarding those vaccines (new vaccines, changes of schedule...).

**Lecture 37. Polysaccharides and conjugates vaccines**

- Discuss the role of bacterial capsular polysaccharides, including the interaction between the human immune system and bacterial polysaccharides.
- Explain the molecular basis for the improved response to conjugate vaccines.
- Discuss the Immunology of carbohydrates and how conjugation transforms the molecules into potent antigens
- Discuss the Conjugate vaccines Correlates of Protection (examples of PCV, Men and GBS) - concepts of GMT, SBI, affinity
- Discuss the use of Controlled Human challenge (CHIM) especially the new exciting data about the pneumococcus human model

**Lecture 38. Pneumococcal conjugate vaccines: the impact of PCV, its introduction in different populations (including adults & children), the change in PCV valency stereotypes and schedules**

- Describe pneumococcal vaccines with their characteristic and immunogenicity including PCV and PPS23 and discuss their potential limitations.
- Describe pneumococcal conjugate vaccines likely to be licensed in the near future.
- Describe the variety and endpoints expected to be impacted by the use of PCV in children, including nasopharyngeal carriage, IPD, mucosal diseases, antibiotic resistance, and the extent and importance of indirect protection with PCVs.
- Describe the basics of serotype replacement post-PCV.
- Discuss the relationship between pneumococcal disease in adults and children.
- Describe the impact of PCV immunization in children on disease burden in unvaccinated populations.
- Describe adult pneumococcal disease epidemiology in settings with and without infant PCV programs.
- Discuss the possibilities of future vaccine strategies designed to maintain herd rather than individual protection.

**SESSION 9 – UPDATES ON VACCINES (2/4)**

**Lecture 39. HPV vaccines**

- Describe the burden of disease and the current prophylactic HPV vaccines (composition, mechanism of action, recommended schedules).

- Discuss current data on vaccine impact and effectiveness – disease, virus prevalence, herd immunity.
- Examine vaccine confidence- impact on new and established HPV vaccine programs.
- Discuss the contemporary debates – one dose regimen, elimination of vaccine HPV types.

#### **Lecture 40. Typhoid vaccines**

- Describe the burden of disease of typhoid and paratyphoid fevers
- Describe the current and future vaccines against Typhoid and Paratyphoid (composition, mechanism of action, recommended schedules).
- Discuss current data on vaccine impact and effectiveness – disease, virus prevalence, herd immunity.

#### **Lecture 41. Malaria vaccines**

- Describe the different targets/life cycle stages for malaria vaccines and explain how immune responses to different parts of the life cycle have different clinical implications.
- Identify the key role of non-vaccine measures in malaria control.
- Discuss the current status of the malaria vaccine pipeline.

#### **Lecture 42. Vaccines against arboviruses (Dengue, Zika, Chikungunya)**

- Describe the burden of disease related to arboviruses
- Describe the current and future vaccines (composition, mechanism of action, recommended schedules).
- Discuss current data on vaccine impact and effectiveness – disease, virus prevalence, herd immunity.

#### **Lecture 43. Rotavirus and norovirus vaccines**

- Describe the global burden of rotavirus and norovirus diarrhoea and the value of vaccination.
- Describe the progress with implementation of rotavirus vaccination programs, including post-licensure impact and safety data.
- Describe the progress with norovirus vaccine development.
- Discuss the remaining issues and challenges for full prevention and control of these diseases.

### **SESSION 8 – DECISION MAKING FOR VACCINES (PART 2/2)**

**Continuing down the vaccine development pathway, this session will focus on an in-depth discussion of the science/factors/approaches involved in bringing a vaccine into the public-health setting.**

#### **Small group exercise 6: Sharing recommendations with the Authorities on the impact on the immunization program.**

- Discuss how recommendations should be presented to the Minister of Health

## **SESSION 9 – UPDATES ON VACCINES (part 3/4)**

### **Lecture 44. Annual strain adaptation: the examples of Flu and COVID vaccines**

- Discuss how vaccines should be adapted annually
- Discuss seasonal and pandemic influenza including the currently available influenza vaccines, their advantages and limitations.
- Discuss tools and strategies to facilitate influenza prevention through vaccination in low- resource settings (includes maternal and paediatric examples).
- Describe the existing Covid vaccines with focus on their effectiveness and brief description of safety profile including the various vaccination schedules strategies
- Describe the pipeline of new Covid vaccines.

### **Lecture 45. Combination vaccines?**

- Discuss what elements should be considered to assess if vaccines can be combined
- Discuss the pros and cons for recent combination vaccines

### **Lecture 46. Vaccines for Non-Communicable Diseases**

- Share recent successes and challenges around vaccines targeting non-communicable diseases (Parkinson, Diabetes, etc.)

### **Debate “Mandatory vs Voluntary Vaccines”**

- Discuss the pros and cons of imposing mandatory vaccination

**SESSION 10 - SELECTING APPROPRIATE VACCINATION STRATEGIES.** The purpose of this session is to describe additional considerations to proposals for a vaccine implementation program, specifically rationales for population choice, schedules, and follow-up

### **Lecture 47. RSV and GBS vaccines, (including monoclonals)**

- Describe the existing RSV vaccines with focus on their effectiveness and brief description of safety profile.
- Discuss the various vaccination schedules strategies
- Describe the pipeline of future RSV and GBS vaccines (including monoclonals)

### **Lecture 48. Vaccination and pregnancy and early life**

- Discuss mechanisms of maternal antibody transfer across the placenta in women
- Explain when, where, and why maternal immunization should be considered
- Describe the impact of maternal immunization on the prevention of neonatal tetanus, pertussis, and influenza disease
- Discuss potential pathogens and vaccines that may be suitable for maternal immunization.
- Describe the unique challenges associated with immune responses in early life.

### **Lecture 49. Vaccination schedules: Past, present and future – is there some rationale?**

- Describe the critical elements of immunization schedule design past, present and in the future.

- Analyse the paradigms of immunization schedule research, design and implementation.
- Identify the conditional elements and challenges faced by immunization schedules around the world.

#### **Lecture 50. Vaccine responses and efficacy in the elderly**

- Describe the changes in the ageing immune system including the changes in disease burden in older adults.
- Describe the concept of waning immunity and its consequences
- Describe the concept of frailty and health aging
- Describe the added value of immunization in elderly populations and the immunization strategies but also the known limitations of vaccines in the elderly.
- Share about the ideal characteristics of vaccines for the elderly population

#### **Lecture 51. Vaccination in immuno-compromised individuals**

- Describe safety concerns of vaccines in the immuno-compromised patient.
- Describe the mechanisms of vaccine effectiveness in patients with different immunocompromised states.
- Devise individualized vaccine plans for patients with HIV

### **PARALLEL WORKING GROUP SESSIONS**

The six proposed working group activities will be highly interactive and foster an exchange of views. During the parallel sessions, students will be able to choose and attend two of the working group activities offered. (2 sessions of 45 mn each).

- 1. National decision-making for immunization programs:** Through case-studies and an interactive session building on the experience, expertise and perceptions of the entire group, participants will after the workshop be able to:
  - Identify the key stakeholders and how they should interact with/within NITAGs and discuss their role in decision making (including NRAs, industry, medical societies, CSOs...).
  - Describe the effectiveness of NITAGs and factors affecting the credibility and performance of NITAGs.
  - Discuss the challenges for NITAGs to make off-label recommendations
- 2. Clinical vaccinology: patients' problem solving:** Through an interactive session, participants after the working group session will be able to:
  - Design approaches for providing a patient with a “catch-up” vaccine dose.
  - Discuss approaches for dealing with potential vaccine-induced adverse events.
- 3. New approaches towards vaccination e-registries:** Through an interactive session, participants will after the session, be able to:
  - Identify the organization and funding needed for the development and maintenance of electronic immunization registers.

- Describe the minimum data set for an electronic immunization register to collect data on vaccines administered.
  - Discuss the different uses of such a register on individual and population level (e.g. to generate reminders and recall vaccination notices for each client or to provide official vaccination certificates, and to allow vaccination coverage and timely assessments).
  - Assess the possibilities for data linkage of different electronic health care databases (vaccine impact assessment, both for effectiveness and safety).
  - Recognize the implications of data protection laws when setting up and using the e-immunization registers.
- 4. Monitoring immunization program performance:** After the working group session participants will be able to:
- Describe what information is needed to manage and monitor an immunization program and the various tools used in immunization programs
  - Describe the different measures used to measure vaccination coverage with their advantages and limitations.
  - Discuss the issue of poor data quality and challenges related with secondary data sources and how one can ensure reporting of good quality data.
- 5. Global and Regional Data for global immunization strategies**
- Describe how data are collected at country level and consolidated, validated, and analyzed at global level, including through the WHO-UNICEF Joint Reporting Form and WHO-UNICEF Estimates of National Immunization Coverage
  - Explain how global and regional immunization data are used to define, monitor progress, and assess performance against global and regional immunization strategies (IA20230, SAGE, GAVI 6.0, Regional Strategies etc.)
- 6. AEFI: WHO causality assessment:** Through an interactive case-study session, participants will after the workshop be able to:
- Apply the principles and concepts of AEFI causality assessment to review and classify an AEFI.
  - Describe the benefits and challenges of such assessments.

**SESSION 11 – REACHING SPECIFIC GROUPS (part 1/2) During this session, participants will explore the challenges and solutions for reaching out all the populations that can benefit from immunization (hard to reach, life-long immunization etc...).**

**Lecture 52: How to better reach the zero-dose or under-vaccinated children in LMICs**

- Describe the current global targets, achievements and challenges with respect to vaccinate hard-to-reach children including zero-dose children
- Identify the current major barriers to increasing or maintaining immunization coverage (weak health systems, missed opportunities, vaccine shortages, vaccine hesitancy, disruption of immunization, availability of quality data).
- Show how to apply best practices to increase vaccination coverage and options to simplify and facilitate vaccine delivery.

**SESSION 9 – UPDATES ON VACCINES (PART 4/4)** The objective of this session is to provide an exhaustive view of some key vaccines included in national programs and to give the latest information regarding those vaccines (new vaccines, changes of schedule...).

**Lecture 53. Cholera vaccines**

- Describe the current situation of the cholera outbreaks.
- Describe the existing cholera vaccines with their characteristic and immunogenicity.
- Describe the situation of the cholera vaccines stockpile and the production capacity perspectives.
- Describe the other vaccines currently under development and the possible future strategies for cholera outbreaks prevention and response.

**Lecture 54. Meningococcal vaccines**

- Describe the benefits of conjugate over polysaccharide vaccines.
- Explain the importance of understanding carriage dynamics, including the difference between direct and indirect immunity and importance of herd protection and the importance of whole genome sequencing in monitoring spread of meningococci globally.
- Synthesize information on the new sub-capsular vaccines for serogroup B disease.

**Lecture 55. Tuberculosis vaccines**

- Share the limitations of BCG vaccine on the prevention of TB infection
- Discuss the current state of tuberculosis vaccine development and the challenges in tuberculosis vaccine development and innovative approaches being used to overcome these challenges.
- Describe what future vaccines strategies will be for TB (targeting young adults...)

**SESSION 11 – REACHING SPECIFIC GROUPS (Part 2/2).** During this session, participants will explore the challenges and solutions for reaching out all the populations that can benefit from immunization (hard to reach, life-long immunization etc...).

**Lecture 56. Life-course vaccines: how to better reach individuals from childhood to elderly?**

- Describe the concept of life-long immunization
- Describe the current global targets, achievements and challenges with respect to vaccinating teenagers, adults, pregnant women, elderly population
- Identify the current major barriers to increasing or maintaining immunization coverage for those populations
- Show how to apply best practices to increase vaccination coverage and options to simplify and facilitate vaccine delivery.

**Lecture 57. The determinants of vaccine acceptance**

- Describe the spectrum of vaccine hesitancy/acceptance/anti-vaccine sentiments
- How to measure vaccine hesitancy and for what?
- Describe the determinants of vaccine hesitancy
- Describe the individual and collective solutions trying to address vaccine hesitancy

## **SESSION 12 – Communication and vaccine hesitancy**

### **Small group exercise 7: Identifying & Collecting Evidence to advise on demand generation**

- Differentiate between vaccine hesitancy and other drivers of low vaccine uptake, such as access, service delivery, or supply issues.
- Identify appropriate quantitative and qualitative data sources to assess vaccine coverage and understand community perceptions.
- Apply evidence-based reasoning to determine whether and how hesitancy is contributing to lower vaccination uptake in a given context.

### **Interactive Session 4 and Q&A: Vaccination in the face of information chaos: from Analysis to Strategic Response**

- Describe the key features of the current information ecosystem affecting vaccination, including misinformation, disinformation, and information overload
- Explain key principles distinguishing communication from information
- Analyze real and AI-generated communication content to assess impact, identify personas, underlying arguments, and core values
- Discuss the opportunities and risks of using AI in vaccine communication, including how to detect AI-generated content and how AI tools can be used responsibly

### **Lecture 58. Introduction to Communication Strategy design**

- Describe the key components of an effective communication strategy for immunization, including objectives, audiences, messages, channels, and messengers.
- Analyze examples of successful and unsuccessful immunization campaigns to identify factors that contributed to their impact or failure, such as context, trust, timing, and execution.
- Highlight resources that can support the design of more effective, context-specific communication strategies for immunization programmes.

### **Small group exercise 8: Communication strategy design**

- Practice making evidence-informed communication decisions under time constraints, comparing two different evidence contexts.

### **Lecture 59. Introduction to Empathetic Communication**

- Describe the core principles of empathetic communication and explain how they differ from information-based or corrective communication approaches.
- Recognize the patients' motivational system (attitude root) to provide a counterpoint to misinformation that is in alignment with the attitude root

### **Small group exercise 9: introduction to empathetic communication**

To gain awareness of the principles of empathetic conversations, listening and understanding patient concerns, and gradually introduce evidence-based responses to support informed vaccine acceptance.

- Apply principles of empathetic and patient-centered communication when engaging

with individuals who express vaccine hesitancy.

- Demonstrate active listening and respectful response techniques to explore patient concerns and address misinformation
- Understand how empathetic conversation can guide patients towards informed acceptance of vaccination while maintaining trust and autonomy.

## **SESSION 13 – INNOVATION ON IMMUNIZATION**

### **Lecture 60. Artificial intelligence and vaccines**

- Describe how AI can help vaccine development (epitope definition, clinical trials etc.)
- Describe how AI can support the improvement of immunization programs delivery

## **SPECIAL LECTURES**

Each year special lectures are delivered on a current topic of interest by world renowned experts allowing to present state of the art developments on immunological, vaccine development and strategy issues.

### **Lecture 19. LAMBERT LECTURE**

- **The 10<sup>th</sup> LAMBERT LECTURE: Immune fitness**

### **Lecture 30. PLOTKIN LECTURE**

- **The 18<sup>th</sup> PLOTKIN LECTURE: Advancing CMV Vaccine Strategies: From Bench to Bedside**