23rd ADVANCED COURSE OF VACCINOLOGY

8 to 19 MAY 2023

Course objectives

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.

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, debates, interactive sessions, small group exercises and parallel workshops/sessions)

SESSION 1 - THE MULTIFACETED NATURE OF VACCINOLOGY: The purpose of this session is to describe the roles, responsibilities and perspectives of the multiple players involved in the field of vaccinology and describe the complexities of their tasks.

How to implement and roll-out a new program of immunization

- Explore reasoning associated with introduction of new vaccines into national programs, including the reasons why they may not be introduced. Examples will be given of elements that play a role in decisions about new vaccines and the data that need to be brought together to support such decisions.
- Discuss the sources of evidence that are used by decision-makers in terms of epidemiology, economic analysis, vaccine performance, communication requirements and performance management.
- Introduce the different components necessary to successfully implement a new vaccination program.

Access to vaccination in Gavi eligible countries and at global level

- Discuss the factors and forces which led to the formation of the Gavi: The Vaccine Alliance.
- Explain the formation and evolution of the Gavi "model". Comparisons of the differences between each 5-year strategic period (Gavi 1.0, 2.0, 3.0 and 4.0) will be presented.
- Describe some of the targets set and reported against in Gavi's fund raising efforts, including country financing and options going forward.

A global perspective on the regulation of vaccines

- Explain the role and functioning of National 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.

Impact of vaccination on disease epidemiology

- 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.

SPECIAL LECTURES FROM INDUSTRY:

Role of LMIC vaccine industry for meeting global needs

- Describe the global vaccine supply scenario, reviewing the role, capacity, impact and challenges of manufacturers based in low- and middle-income countries in supplying quality vaccines at affordable prices.
- Explain the role of emerging low- and middle-income country vaccine manufacturers in development and introduction of newer vaccines which are important in achieving expectations of international agencies as well as national governments.

Development and production of vaccines for global use: the role of the vaccine industry

- Explain the perspective from the large pharmaceutical industry with respect to relative importance and value of vaccines in the competitive global health care industry, with specific emphasis on corporate social responsibility goals, portfolio management (and its alignment with the corporate strategy, vision, and mission), and productivity.
- Discuss common valuation metrics used by large pharmaceutical companies in decision-making processes to discern vaccine development projects that warrant further investment.

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.

How are vaccine responses elicited?

- Explain where and how vaccine B and T cell vaccine responses are elicited.
- Describe the key factors that increase or reduce the magnitude of vaccine responses.

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.

Vaccines and mucosal immunity

- Explain the practical and operational barriers to wider understanding and usage of mucosal immune responses to vaccines.
- Describe the immunological mechanisms that are considered to underlie mucosal responses to vaccines.
- Describe vaccine programs that work via the indirect/population-wide effects of mucosal immunity and explain how these effects can influence program design.

Vaccines and immunological memory (interactive session)

- Integrate and apply the generic understanding of immunological principles and epidemiology to specific situations of immunization failures using interactive

exchanges between students and lecturer with examples of specific and relevant vaccines and public health approaches of interest.

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.

How do vaccines cause adverse events?

- Identify the range of pathogenic mechanisms involved in adverse events caused by vaccines.
- Describe practices to prevent common adverse events associated with immunizations.

Debate: Mandatory vs voluntary vaccination

- Increase understanding how definition / context / vaccine / age and timing can influence the support of such a decision.
- Increase understanding on what grounds and how pro/con rationales can be defended
- Demonstrate, by using pre and post-debate discussion voting, how opinions can be influenced by pro/con rationales and data.

SESSION 3 - VACCINE DEVELOPMENT **The purpose of this session is to build up the basic research vaccine concepts previously presented and define the pre-clinical considerations involved in vaccine development. Efforts to identify contemporary issues and approaches being discussed in this area are highlighted, as are the various positions being debated**

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.

Vaccine adjuvants

- Explain why adjuvants are included in vaccines and the benefits and risks they bring.
- Discuss the different adjuvants that are used or in development, and the relative pros and cons to each of these adjuvants.
- Discuss which adjuvants to consider when developing vaccines.

From preclinical research to vaccine development: examples of go-no-go decisions

- Discuss the main activities in Pre-Clinical development leading to and including Phase 1, First-in-Human, including examples of “Go and No-Go” decisions commonly used in vaccine biotech/industry.

Regulatory considerations: a round table debate

- Explain the roles and complexity of regulatory decision-making by involving key players (regulatory and industry) in licensing of vaccines.
- Discuss one or two key vaccine development/implementation issues (such as the role of vaccine correlates or challenge studies) from the viewpoint of how this will influence/affect decisions made by regulators/manufacturers.

The complexity of quality control in vaccine manufacturing

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

Interactive session: From ideas to implementation - the realities of funding for vaccine research and development

- Through student-led role-play, participants will be able to determine the funding streams available for vaccine development in a competitive environment and formulate key messaging approaches impacting on decision-making.

SESSION 4 - ASSESSING VACCINES IN CLINICAL TRIALS (I). **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**

Clinical trials: an overview of issues to be considered

- Describe how clinical trials fit into the progression of vaccine development, leading step-wise (Phases 1-4) to licensed products.
- Demonstrate how the design and performance of clinical trials have changed over the decades, 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.

Introduction to statistical aspects of clinical trials: defining sample size

- Describe the concepts of statistical significance and statistical power of a trial and necessary sample size and design. Examples will be given as to:
  - Use in determining the size and design of a vaccine trial.
  - Vaccine: placebo ratios other than 1:1.
  - Non-inferiority trials.
- Discuss non-statistical factors to consider when planning trial size.

Small group exercise 1: How to design, recruit volunteers for, and analyse the results of selected phase 2 trials

- Through student led design of a Phase 2 trial, after the exercise, participants will be able to identify the key elements that go into the clinical development strategy of a new vaccine.
  Objectives are reached via several methods including facilitated discussion, group work or role play, depending on the leader of the group. Each small group will consider a different vaccine, allowing the students to choose the topic that would be most relevant/interesting to them.

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.

Clinical trials: role of a Data Safety Monitoring Boards (DSMBs) (with several examples of intervention)

- Discuss the importance of DSMBs in vaccine clinical trials, including under what clinical trial scenarios a DSMB is needed.
- Describe the critical elements of the implementation of a DSMB including membership, charter, and relationship with other committees.

Introduction to Human Challenge Trials

- Explain 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.

Dealing with Human Challenge Trials: panel discussion and questions

- Discuss the pros and cons of HCTs including positions on ethics and risk-benefit values.

SESSION 5 - 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

Lessons from previous adverse events of vaccination and assessment of causal relationships

- Describe what information is necessary to determine the likelihood of a causal relationship between a vaccine administration and reported adverse events and explain the necessary process to evaluate the likelihood of a causal relationship using standard guidelines.
- Demonstrate the importance of the reporting of adverse events possibly associated with immunizations and the limitations of passive surveillance.

- Explain the role of epidemiologic studies in causality assessment.
- Describe the WHO causality assessment scheme for adverse events following immunization.

Vaccination and immune-mediated diseases

- Raise awareness on the existence of vaccine-induced unexpected immune responses (RSV, dengue, SARS?)
- Describe mechanisms which regulate immune responses to self-antigens and prevent related autoimmune diseases.
- Define a logical analytic process to assess the causality of a suspected autoimmune adverse effect. The example of narcolepsy.
- Describe approaches to assess the risk of immune-mediated manifestations with newly developed vaccines.

Population-based post-licensure surveillance

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

Thrombotic Thrombocytopenia Syndrome (TTS) following vaccination with COVID-19 non-replicant adenovirus vector-based vaccines

- Describe the process of identifying a rare severe adverse event in relation to a vector-based vaccine (signal detection).
- Discuss the different processes of validating the signal from a country and international perspectives.
- Describe the impact of such an unexpected safety event on vaccine development and uptake.

Immunization safety in low- and middle-income country vaccination programs

- Describe the range of potential immunization safety issues including differences between low- and middle- income and high income countries.
- Discuss the real problems and challenges including injection safety and waste management.
- Describe the range of necessary actions to ensure immunization safety including WHO's activities in support of global immunization safety.

Addressing vaccine hesitancy and acceptance

- Define vaccine hesitancy and the continuum to refusal.
- Identify factors that contribute to hesitancy in different contexts with different vaccines.
- Outline evidence informed strategies for addressing hesitancy and improving vaccine acceptance at the program and patient levels.
- Describe key factors (and pitfalls) in developing immunization programs and patient communication strategies to avoid hesitancy.
- Identify why supporting vaccine acceptance resiliency is important.

SESSION 6 - ASSESSING VACCINES IN CLINICAL TRIALS (II). The purpose of this session is to review Phase 3 clinical trial design/complexity. Following the session, students will be able to design a Phase 3 clinical trial

Introduction to statistical aspects of clinical trials: statistical assessment and reporting of Phase 3 trials

- Define the concept of statistical analysis plan and describe the CONSORT guidelines for reporting.
- Describe simple analysis methods for 2-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: Designing and analyzing the results of selected phase 3 trials

- Discuss methodological aspects in the design of phase 3 vaccine trial which impact the outcome of the trial.
- Demonstrate the degree of completeness of reporting of phase 3 vaccine trials according to the CONSORT guidelines.
- After participating in this exercise, participants will be able to critically appraise and compare results arising from different randomized controlled trials.

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

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.

Applied ethics in immunization programs and practice

- Identify the key factors in obtaining consent for immunization in different settings.
- Outline ethical issues in financing and access to immunization.
- Describe the ethical basis for and against mandatory immunization laws.
- Outline the ethical issues of dismissing patients from practice if choose not to immunize.
- Explain why reporting of AEFI and feedback to health care workers and patient /family is required for ethical practice.
- Explain why not supporting pain mitigation on immunization is unethical.

Small group exercise 3: Ethical considerations in COVID-19 vaccine trials

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 - INTRODUCING NEW VACCINES INTO VACCINATION PROGRAMS

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. It will include detailed information regarding relevant vaccines for which implementation policy decision-making was recently made, is still in process, or may shortly be made

Disease burden and the public health value of vaccines

- 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.

Health economics (including modelling) as a tool in analyzing vaccine policy options

- Describe how to integrate biomedical, epidemiology and economic data to explicitly assess the value of health outcomes associated with vaccine benefits and costs to assess:
    - Insurance policy for individuals
    - Justify investments for public vaccine programs.
- Describe how to apply a decision analytical framework to systematically evaluate choices of vaccine policy.
- Recognize and evaluate uncertainty which guides a research agenda.

Challenges and solutions in making evidence-based national vaccination policies and recommendations

- Explain the importance and role of National Immunization Technical Advisory Groups (NITAGs) and describe their recommended structures and functioning.
- Discuss challenges and solutions to establish and strengthen NITAGs, as well as approaches to evaluate the functioning of NITAGs.
- Describe issues and tools to be taken into consideration for the development of evidence-based recommendations.
- Discuss considerations related to the development of off-label recommendations.

Dengue vaccines

- Explain the complexities of dengue virus vaccine development including the need for protection against 4 separate dengue viruses and the role of antibody-dependent enhancement of infection in more severe dengue disease.
- Describe the Phase 3 clinical trial results of the first licensed dengue vaccine.
- Synthesize the possible causes of the failures of the first licensed dengue vaccine and how they have informed other dengue vaccine manufacturers.
- Describe the other dengue vaccines currently in Phase 3 clinical trial.

Response to 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.

Pneumococcal conjugate vaccines: Efficacy and limitations of available vaccines and existing and potential vaccination strategies

- 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.

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.

Small group exercise 4: Decision-making for the evaluation and impact assessment of new vaccines introduced in selected countries: safety and effectiveness.

Through an interactive 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 minutes 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.

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.

Vaccine responses and efficacy in the elderly

- Describe the changes in the ageing immune system including the changes in disease burden in older adults.
- Explain the known limitations of vaccines in the elderly.
- Describe the purpose of vaccinations in older adults.

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.

Pathogens evolution and population immunity: methods and applications for vaccine development and policy

- Describe why understanding the population biology of pathogens (viruses and bacteria) matters including its role in selecting vaccine antigens and in assessing vaccine effectiveness
- Describe the biological, environmental, and population basis of variability in pathogens over time and in different geographical locations: the role of mutation, adaptability and transmission dynamics
- Discuss why understanding the evolution and adaptation of pathogens is important in the context of vaccine direct and indirect protection, emphasizing how genomics, environmental, and population surveillance and sequencing have revolutionized epidemiology.

Success and challenges with 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.

Cancer vaccines

- Describe the natural immune defence mechanisms against cancers.
- Describe the different vaccination approaches and immunotherapies against cancers.
- Discuss perspectives of use of anticancer vaccines in the coming years.

COVID vaccines

- Describe the existing Covid vaccines with focus on their effectiveness and brief description of safety profile.
- Describe the pipeline of new Covid vaccines.
- Discuss the optimization of vaccination schedules.

SESSION 9 - 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**

Vaccination and pregnancy: scientific basis, main issues and applications

- Discuss mechanisms of maternal antibody transfer across the placenta in healthy women and the potential for decreased transfer to those with underlying medical conditions such as HIV or malaria.
- 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.

Vaccination in early life

- Describe the unique challenges associated with immune responses in early life.
- Discuss the basic principles that shape early life immune / vaccine responses, including how this understanding should apply to considerations for an infant vaccine schedules.

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.

Influenza biology, new vaccines and vaccination strategies for different age groups

- 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).

Vaccination in immuno-compromised individuals, including HIV positive patients

- 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 pre- and post-transplantation, with HIV, or congenital immunodeficiencies.

Session 10 – VACCINES UNDER DEVELOPMENT

The status of the vaccine development pipeline for high impact/visible vaccines will be described and discussed

Vaccines against epidemic and orphan diseases: How new technologies can change vaccine development

- Describe the concept of structure-based vaccine design and status of RSV vaccine development.
- Explain how stabilizing class I viral fusion proteins in the prefusion conformation is an approach which can be generalized for vaccine antigen design across virus families.
- Show how platform manufacturing technology impacted the development of early ZIKA candidate vaccine.
- Explain how new technologies can support a prototype pathogen approach for pandemic preparedness and facilitate rapid vaccine development for pandemic response.

The challenges of 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.

Global challenges of 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.

HIV vaccines

- Explain the need for and review the challenges of designing an HIV vaccine.
- Describe past HIV vaccine approaches and completed efficacy trials.
- Describe main/current approaches for the development of an efficacious HIV vaccine, including current HIV vaccine efficacy trials.
- Describe the different paths towards elicitation of broadly neutralizing antibodies through vaccination.

Challenges and prospects for new tuberculosis vaccines

- Discuss the current state of tuberculosis vaccine development, the limitations of BCG and the challenges in tuberculosis vaccine development and innovative approaches being used to overcome these challenges.

Session 11 – OUTBREAKS' CONTROL: ELIMINATION AND ERADICATION STRATEGIES

The challenges and the status on eradication/elimination programs will be described together with the challenges and ways to increase vaccination coverage. New implementation tools will also be described

Immunization coverage gaps: overcoming the chronic challenges

- Describe the current global targets, achievements and challenges with respect to immunization coverage.
- 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.
- Identify important elements to implement vaccination in humanitarian emergency situations.

Polio

- Assess the progress made so far towards global polio eradication and analyze the unique socio-political, and epidemiologic challenges in remaining endemic areas.
- Explain the evolving clinical evidence base on polio vaccines and demonstrate how it impacts vaccination policy for the end-game and beyond.

Measles and rubella

- Describe the historical perspective on measles and rubella elimination efforts globally.
- Explore issues related to the elimination feasibility – biological, epidemiologic, and economic.
- Identify options under consideration for future elimination and eradication efforts.
- Identify the reasons for the continued occurrence of outbreaks of VPDs such as measles and strategies to control these.

SESSION 12 - FACING THE MEDIA: WHAT THE VACCINOLOGIST SHOULD KNOW IN THE CONTEXT OF VACCINE HESITANCY AND ANTI-IMMUNIZATION LOBBY

Introduction to media dynamics: how to best deliver vaccinology-related messages to different interest groups

After this highly interactive session, students will gain confidence to discuss the complexities of vaccine with multiple audiences. The learning will apply to all kinds of communication with the public including 1-2-1, with patients, in panel discussions and video conferencing. Specific objectives include the ability for participants to:

- Discuss how people perceive confidence in others and make judgements using emotions, rather than facts.
- Identify their professional Brand Values.
- Project confidence, expertise and personal warmth through body language, voice and words
- Appear (and sound) more authoritative and trustworthy.
- Match their image to their Brand Values (allowing for cultural differences).
- Bring science to life – make it real for people.
- Learn the ABC technique for media interviews.
- Win hearts as well as minds.
- Calm their nerves and 'anchor' their confidence.

SESSION 13 – RECAP

The purpose of this session is to answer any remaining questions from participants of general interest building on the body of information presented during the course and to help solidify knowledge through briefly reviewing the entirety of critical information received during the course flagging the most important points from each lecture/training activities

Panel: answers to important questions from participants either received beforehand or live during the panel session

Highlights from ADVAC 2023

PARALLEL WORKING GROUP SESSIONS

The six proposed working group activities grouped in two separate parallel sessions will be highly interactive and foster an exchange of views.

During each of these parallel sessions, students will be able to choose and attend one of the working group activities offered. The other activities will be recorded so that the students will be able to benefit from the recording of any other working group discussions of interest:

Parallel Working Group Session 1

1) AEFI: 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.

2) Monitoring and evaluation of vaccine programs

After the working group session 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.
- Describe Global immunization monitoring

Parallel Working Group Session 2

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:

- List factors that should be considered in making recommendations.
- 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 factors affecting the credibility and performance of NITAGs.
- Assess the effectiveness of NITAGs.

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) Cold Chain management

Through an interactive session, participants will after the session be able to:

- Describe the importance and important elements of cold chain.
- Identify the important elements of satisfactory cold chain management.
- Identify the different tools and devices to facilitate cold chain management.
- Apply necessary changes to their practices.

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.

LAMBERT LECTURE IN RELATION TO SESSION 4

- **The 7th LAMBERT LECTURE: Perspective for CD8+ T cell-based vaccines**

PLOTKIN LECTURE IN RELATION TO SESSION 9

- **The 15th PLOTKIN LECTURE: Monkeypox**