20th ADVANCED COURSE OF VACCINOLOGY, 13 TO 24 MAY 2019

Course objectives

DAY 1

SESSION 1a - THE MULTIFACETED NATURE OF VACCINOLOGY:
The purpose of sessions 1a and 1b is to provide an overview of the roles, responsibilities and perspectives of the multiple players involved in the field of vaccinology. An interactive debate on vaccine policy also provides for various implementation policy perspectives to be shared and discussed and perhaps modified, among students.

How to develop a new program of immunization
- Explore reasoning associated with introduction of new vaccines into national programmes, including the reasons why they may not be introduced. Examples will be given of elements that go into 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.

Access to vaccination in Gavi countries and at global level
- Discuss the factors and forces which led to the formation of the Gavi Alliance.
- Understand 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.
- Review some of the targets set and reported against, in Gavi’s fund raising efforts, including country financing and options going forward.

The challenge of malaria vaccines and of their potential introduction
- Gain insight to the different targets/life cycle stages for malaria vaccines and understand how immune responses to different parts of the life cycle have different clinical implications.
- Understand the key role of non-vaccine measures in malaria control.
- Discuss the current status of the malaria vaccine pipeline and pilot implementation programmes.

SESSION 1b - SPECIAL LECTURES FROM INDUSTRY:

Role of DC vaccine industry for meeting global needs
- Discuss the global vaccine supply scenario, reviewing the role, capacity and impact of manufacturers based in developing countries in supplying the quality vaccines at affordable prices.
- Review the role of some emerging developing 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 vaccine industry
- Provide perspective from the large PHARMA 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 including:
  - The expected Net value of a Vaccine Development Program
  - Probability of technical and regulatory success
  - Value Maximization Strategies: Accelerated Approvals and Life Cycle Opportunities
Epidemiological, programmatic and economic considerations to assess the potential commercial value of a new vaccine candidate.

**INTERACTIVE 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-post debate-discussion voting, how opinions can be influenced by pro/con rationales and data.
SESSION 2 - HOW VACCINES WORK.
The purpose of this session is to develop a more contemporary and detailed scientific understanding of the relevancy of foundational immunological knowledge to practical applications. Contemporary and historical examples of failures and successes are used to reinforce the concepts.

How are vaccine responses elicited?
- Review and increase understanding as to where and how vaccine B and T cell vaccine responses are elicited.
- Understand the key factors that increase or reduce the magnitude of vaccine responses.

Use and limitations of correlates of immunity in vaccinology
- Provide insight into the different definitions of correlates/surrogates that are used.
- Understand how correlates have been derived and what is measured.
- Understand the value and limitations of 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.
- Provide examples of vaccine programmes that work via the indirect/population-wide effects of mucosal immunity and how these effects can influence programme design.

Vaccines and immunological memory
- Integrate the generic understanding of immunological principles and epidemiology to specific situations of immunization failures using interactive exchanges between students and lecturer using examples of specific and relevant vaccines and public health approaches of interest.

Advances in vaccine and immunization technologies:
- Provide an overview of how different technologies 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.
- Review the stage of development of different vaccines/vaccine technologies.

Immunological memory
- Provide detailed information on 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.
DAY 3

SESSION 3 - DECISION-MAKING IN VACCINE RESEARCH AND PRECLINICAL DEVELOPMENT

The purpose of this session is to build up the basic research vaccine concepts previously presented and begin to define/appreciate 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. Ample time is provided to involve students in these discussions.

How do vaccines cause adverse events?
- Identify the range of pathogenic mechanisms involved in adverse events caused by vaccines.
  - Explain how live vaccines can cause uncontrolled infections in immunocompromised individuals.
  - Explain how the injection process can result in shoulder injuries.
- Provide practical guidance for vaccine deliverers that will help prevent common adverse events associated with immunizations.

Vaccine adjuvants
- Provide an understanding of why adjuvants are included in vaccines and the benefits and risks they bring.
- Present an overview of the different adjuvants that are used or in development, and the relative pros and cons to each of these adjuvants.
- Provide, using the principles presented, general guidance on which adjuvants to consider when developing vaccines.

From preclinical research to vaccine development: examples of go-no-go decisions
- Present the main activities in Pre-Clinical development leading to and including Ph 1, First-in-Human, including examples of “Go and No Go” decisions commonly used in vaccine biotech/industry.

Progress with RSV and Zika vaccines: how technologies can change viral vaccine development
- Expand the concept of structure-based vaccine design using the current status of an RSV vaccine concept in development.
- Provide in depth understanding of the use of class I fusion proteins as a vaccine target across virus families.
- Discuss the current status of ZIKA vaccine development and remaining obstacles.

Regulatory considerations: a round table debate
- Provide an understanding of the roles and complexity of regulatory decision-making by involving key players (governmental 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.
- Provide details on 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 Debate: Dealing with human challenge studies
- Discuss 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.
- Expand understanding and “weight” of the pros and cons including positions on ethics and risk-benefit values associated with shortening the time to licensure.
DAY 4

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

Building on the knowledge obtained from the previous session, this session will expand into an understanding of, and design options for, vaccine clinical 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 is provided and explained.

Clinical trials: an overview of issues to be considered

- Discuss how clinical trials fit into the progression of vaccine development leading step-wise (Phase 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

- Present the concepts of statistical significance and statistical power of a trial. 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 II trials

- Familiarize the participants on the key elements that go into the clinical development strategy of a new Dengue vaccine, through student led design of a Phase 2 trial. Contextual background, consistent with a manufacturers entire developmental plan and the data obtained to date, will be provided to assist in the design. Objectives are reached via several methods including facilitated discussion, group work or role play, depending on the leader of this group work.

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.
- Provide increased understanding regarding 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 Data safety Monitoring Boards (DSMBs) (with several examples of interventions)

- Discuss the importance of DSMBs in vaccine clinical trials, including under what clinical trial scenarios a DSMB is needed.
- Provide details as to how to implement a DSMB including membership, charter, and relationship with other committees.

The 4th LAMBERT LECTURE: Challenges and prospects for new tuberculosis vaccines

- Discuss the current state of TB vaccine development including:
  - limitations of BCG
  - challenges in TB vaccine development and innovative approaches being use to overcome these challenges.
Special “Debate”: From ideas to implementation: - the realities of funding for vaccine research.

- Provide, through student led role play, an understanding of the funding streams available for vaccine development, including insight on decision-making, key messaging approaches and the competitive nature of funding.
LESSONS LEARNED FROM PREVIOUS ADVERSE EFFECTS OF VACCINATION AND CAUSALITY ASSESSMENT

- Provide guidance regarding the investigation of adverse events reported following immunizations and collection of the information necessary to determine the likelihood of a causal relationship including:
  a. How to evaluate the likelihood of a causal relationship between the vaccine and reported adverse events using standard guidelines.
  b. Reporting adverse events possibly associated with immunizations.

VACCINATION AND AUTOIMMUNE DISEASE

- Discuss present understanding of mechanisms which regulate immune responses to self-antigens and prevent related autoimmune diseases.
- Define the level of evidence for a putative autoimmune pathological process claimed to be associated with a particular vaccination.
- Define a logical analytic process to assess the causality of a suspected autoimmune adverse effect, with an in-depth analysis of the specific case of narcolepsy following the use of an adjuvanted influenza vaccine during the 2009 pandemic outbreak.
- Understand approaches to assess the risk of autoimmune manifestations with newly developed vaccines.

POPULATION-BASED POST-LICENSESURveillance

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

VACCINATION AND NARCOLEPSY

- Describe the process of identifying a rare severe adverse event in relation to an adjuvanted pandemic 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/middle income and high income countries.
- Discuss the real problems and challenges including injection safety and waste management.
- Review the ongoing range of actions to ensure immunization safety including WHO’s activities in support of global immunization safety.

VACCINE HESITANCY AND RISK COMMUNICATION THROUGH THE LENS OF HPV VACCINE

- Define vaccine hesitancy and the continuum to refusal.
- Identify and list 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 program and patient communication strategies.
- Identify why supporting vaccine acceptance resiliency is important.
SESSION 6 - ASSESSING VACCINES IN CLINICAL TRIALS (II).
The purpose of this session is to further knowledge of clinical trial design/complexity and develop hands on experience in designing a Phase 3 clinical trial.

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

- Introduce concept of statistical analysis plan, including CONSORT guidelines for reporting.
- Present simple analysis methods for 2-arm trial.
- 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 for Ebola vaccines.

Small group exercise 2: Designing and analysing the results of selected phase III trials

- Analyse the methodological aspects in the design of phase 3 vaccine trial which impact the outcome of the trial.
- Understand the degree of completeness of reporting of phase 3 vaccine trials according to the CONSORT guidelines.
- Appraise and compare results arising from different randomized controlled trials.
DAY 6

SESSION 7 - ETHICAL ISSUES.
The purpose of this session is to develop a key understanding of accepted ethical guidelines for human research and to implement this knowledge in the real world design of malaria vaccine development.

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.
- Provide tools and recommendations for researchers planning and implementing vaccine trials.

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.
- Identify why reporting of AEFI and feedback to health care workers and patient /family is required for ethical practice.
- Identify why not supporting pain mitigation on immunization is unethical.

Small group exercise 3: Ethical considerations in malaria vaccine trials
- Provide student led role play approach to instill a deeper understanding of ethical issues related to vaccines and vaccine trials. These will be addressed via issues arising from the trial and study objectives, setting and participants’ health status as well as issues related to world view and religion.
SESSION 8.1 - INTRODUCING NEW VACCINES INTO VACCINATION PROGRAMMES (1).
Continuing down the vaccine development pathway, Session 8.1 and 8.2 will focus on in-depth discussion of the science/factors/approaches involved in bringing a vaccine into the public-health setting, including detailed information regarding relevant vaccines for which implementation policy decision-making is in process, or may shortly be.

Disease burden and the public health value of vaccines
- Assess the public health value of vaccines beyond efficacy and safety.
- Explore measures and outcomes to define the public health value of vaccines.
- Calculate vaccine preventable disease incidence and number needed to vaccinate.
- Develop a public health value proposition for vaccines.
- Define total systems effectiveness.

Health economics (incl. modelling) as a tool in analysing vaccine policy
- 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 program.
- Provide a decision analytical framework to systematically evaluate choices of vaccine policy.
- Evaluate uncertainty which guides a research agenda.

Challenges and solutions in making evidence-based national vaccination policies and recommendations
- Discuss the importance and role of National Immunization Technical Advisory Groups (NITAGs), including recommended structure and function.
- Update the status of development of NITAGs, globally.
- Discuss challenges and solution to establish and strengthen NITAGs, as well as approaches to evaluate the functioning of NITAGs.
- Expand on issues to be taken into consideration for the development of evidence-based recommendations including a framework for its development.
- Discuss considerations related to the development of off-label recommendations.

Dengue vaccines
- Discuss 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.
- Review the Phase 3 clinical trial results of Dengvaxia™, the first licensed dengue vaccine.
- Discuss the possible causes of the failures of Dengvaxia™ and how they have informed other dengue vaccine manufacturers.
- Update other dengue vaccines currently in Phase 3 clinical trial.

Response to polysaccharides and conjugates vaccines: basic aspects
- Discuss the role of bacterial capsular polysaccharides, including the interaction between the human immune system and bacterial polysaccharides.
- Provide an understanding of the molecular basis for the improved response to conjugate vaccines.
Pneumococcal conjugate vaccines in children and adults: Efficacy and limitations of available vaccines and existing and potential vaccination strategies

- Describe adult pneumococcal disease epidemiology in settings with and without infant PCV programs.
- Review pneumococcal vaccine options, characteristics, and immunogenicity including PCV and PPS23.
- Review adult pneumococcal vaccine use, impact on disease, transmission with a focus on limitations and future opportunities.
- Describe the existing pneumococcal conjugate vaccines, including those likely to be licensed in the near future.
- Describe the variety and endpoints expected to be impacted by PCV in children, including nasopharyngeal carriage.
- Describe the basics of serotype replacement post-PCV.
- Discuss the extent and importance of indirect protection with PCVs.
- Discuss impact vs efficacy on vaccines endpoints (IPD, mucosal diseases, antibiotic resistance).
- Discuss expectations vs. observations in PCVs (The “vaccine probe” concept).
- Discuss potential limitation with the current PCVs.
- Discuss the relationship between pneumococcal disease in adults and children.
- Describe the impact of PCV immunization in children on disease burden in unvaccinated populations.
- 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.
- Evaluate the evidence for and against related hypotheses - e.g. gender-specific effects, live and non-live vaccine effects.
- Discuss the gaps and limitations in current knowledge e.g. mechanisms/details of apparent effects on mortality.
- Provide examples of immunological evidence for NSE in animals and humans.
- Discuss strategies that have been proposed for advancing knowledge in this field that may permit NSE to be used to generate public health benefits.

Does a vaccine have to protect against a VPD that kills to matter to politicians and parents? A debate

Using pro/con debate format:
- Discuss the broader, sociological and economic perspectives to vaccine implementation.
- Discuss some of the challenges facing NITAGs in having politicians and decision makers agree with the implementation of a vaccination program and prioritize it over other health investments.
- Discuss important elements of creating demand and how similar facts can be interpreted differently in different setting and/or lead to different decisions.
DAY 8

SESSION 8.2 - INTRODUCING NEW VACCINES INTO VACCINATION PROGRAMMES (2)

Influenza biology, new vaccines and vaccination strategies for different age groups
- Review 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).

Vaccine responses and efficacy in the elderly (including the example of the Zoster vaccine)
- Describe the changes in the aging immune system including the changes in disease burden in older adults.
- Review the known limitations of vaccines in the elderly.
- Describe the purpose of vaccinations in older adults.

Population biology of bacterial pathogens in vaccinology
- Describe the importance of why understanding population biology of bacteria matters including its role in selecting vaccine antigens and in assessing vaccine effectiveness.
- Describe the basis of variability in bacterial populations over time and in different geographical locations; the role of mutation, lateral gene transfer and transmission dynamics, including population bottlenecks.
- Discuss why understanding the population structure of carriage and disease isolates is important in the context of direct and indirect protection by vaccine, emphasizing how whole genome sequencing of bacterial pathogens has revolutionized epidemiology.
- Provide in depth analysis of specific pathogens, including *Bordetella pertussis* and *Neisseria meningitidis*, to illustrate the major points outlined above.

Meningococcal vaccines
- Discuss the benefits of conjugate over polysaccharide vaccines.
- Emphasize 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.
- Provide for an understanding of the new sub-capsular vaccines for serogroup B disease.

Success and challenges with rotavirus and norovirus vaccines
- Emphasize the global burden of rotavirus and norovirus diarrhea and the value of vaccination.
- Review, for rotavirus, the progress with implementation of vaccination programs, including post-licensure impact and safety data.
- Review, for norovirus, the progress with vaccine development.
- Discuss the remaining issues and challenges for full prevention and control of these diseases.
Small group exercise 4: Decision-making for the evaluation and impact assessment of new vaccines introduced in selected countries: safety and effectiveness.

- Learn what facts are needed in a decision-making process and how other factors influence the outcome.
- Discuss how to best 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.
- Develop structured monitoring of vaccine safety and effectiveness following introduction of a new vaccine – options to be discussed.
- Present to the Minister of Health in an oral 2-3 minutes presentation the rationale for introduction of the selected vaccine to the selected target groups.

History of vaccines and vaccination

- Identify the people whose work led to the use of important vaccines.
- Discuss the changes in vaccine technology that have occurred over the last 200 years.
- Discuss some of the historical controversies.
SESSION 9 - SELECTING APPROPRIATE VACCINATION STRATEGIES.

The purpose of this session is to add additional considerations to proposals for a vaccine implementation program, specifically rationales for populations choice, schedules, and follow-up. The status of the vaccine development pipeline for high impact/visible vaccines will also be discussed, as will status on eradication/elimination programs and new implementation tools.

Vaccination and pregnancy: scientific basis, main issues and applications - Optimizing infant protection through maternal immunization

- 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.
- Provide an understanding for 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?

- Provide an understanding of 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.

Special Lecture: Impact of vaccination on disease epidemiology

- Introduce the basic concepts of infectious 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.
- Provide examples of the impact of current mass vaccination programmes in different regions of the world.
- Discuss challenges in measurement and observation in the epidemiological study of mass vaccination.

Parallel working group sessions/student choice:

1) National decision-making for immunization programmes

- Identify factors that should be considered in making recommendations.
- Identify the key stakeholders and how they interact with NITAGs and discuss their role in decision making (including NRAs, industry, medical societies, CSOs...).
- Describe factors affecting the credibility and performance of NITAGs.
- Describe proposed self-evaluation process to determine the effectiveness of NITAGs.

2) Interactive Session: Clinical vaccinology: patients’ problem solving

- 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**

- Provide an understanding of organization and funding needed for development and maintenance of electronic immunization registers.
- Discuss the minimum data set for an electronic immunization register to collect data on vaccines provided.
- Examine 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 timeliness assessments).
- Discuss the possibilities for data linkage of different electronic health care databases (vaccine impact assessment, both for effectiveness and safety).
- Examine the implications of data protection laws when setting up and using the e-immunization registers.

**Vaccines for the immuno-compromised (IC) patient**

- Describe safety concerns of vaccines in the IC patient.
- Provide for an understanding of 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.

**SPECIAL LECTURE: The 12th PLOTKIN LECTURE: The Coalition for Epidemic Preparedness Innovations (CEPI) and emerging infections**

- Each year a new theme on the outer frontiers of vaccinology is selected for the Plotkin lecture
DAY 10 Session 9 continued

HPV vaccines: successes, setbacks, where next?
- Provide information on burden of disease, need for prophylactic HPV vaccines, composition of current products, dosage schedules, cohorts for immunisation, mechanism of action of current vaccines.
- Discuss current data on vaccine impact and effectiveness – disease, virus prevalence, herd immunity.
- Examine vaccine confidence- impact on new and established HPV vaccine programmes.
- Discuss the contemporary debates – one dose regimen, elimination of vaccine HPV types.

CMV vaccines in development
- Describe the reasons a CMV vaccine is needed.
- Discuss the different technologies being proposed to make a CMV vaccine.
- Review the state of vaccine development.

Global challenges for pertussis vaccines
- Discuss the components of the whole cell and acellular vaccines and their comparative efficacy for the prevention of laboratory confirmed disease in infants.
- Describe both the global burden of pertussis disease and vaccine coverage rates.
- Discuss the emergence of pertussis disease in countries with acellular vaccine programs.
- Review the baboon model and what it tells us about the impact of vaccine on disease transmission.
- Review maternal immunization programs and their impact on infant disease.
- Discuss the immunologic responses to both acellular and whole cell pertussis vaccines and why matter.
- Propose solutions to the problems with the current pertussis vaccines.

HIV vaccines
- Explain the need for and review the challenges of designing an HIV vaccine.
- Describe the nonhuman primate models of HIV infection.
- Review 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.
- Review the different paths towards elicitation of broadly neutralizing antibodies through vaccination.
- Explain how broadly neutralizing antibodies develop in a fraction of HIV-infected individuals.

Outbreaks’ control: Elimination and eradication strategies

Immunization coverage gaps: overcoming the chronic challenges
- Identify the current global targets, achievements and challenges with respect to immunization coverage.
- Review 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).
- Identify best practices to increase vaccination coverage.
- Review some 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.
- Interpret the evolving clinical evidence base on polio vaccines and assess how it impacts vaccination policy for the endgame and beyond.
Diphtheria, measles and rubella:

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

Vaccine research in low and middle-income countries: the example of rotavirus:

- Discuss how to anticipate the last mile for the control of rotavirus with vaccines.
- Review vaccine introduction as a mass population experiment.
- Expand on the challenge of vaccine pricing vs. coverage in high income countries.
- Reassess the decision to withdraw Rotashield.
- Discuss the need a next generation vaccine for Rotavirus.
SESSION 10 - FACING THE MEDIA:

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

The purpose of this highly interactive session is to provide students with the 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 to:

- Discuss how people perceive confidence in others & make judgements using emotions, rather than facts.
- Identify your professional Brand Values.
- Project confidence, expertise & personal warmth through body language, voice & words.
- Appear (and sound) more authoritative and trustworthy.
- Match your image to your 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 your nerves and ‘anchor’ your confidence.