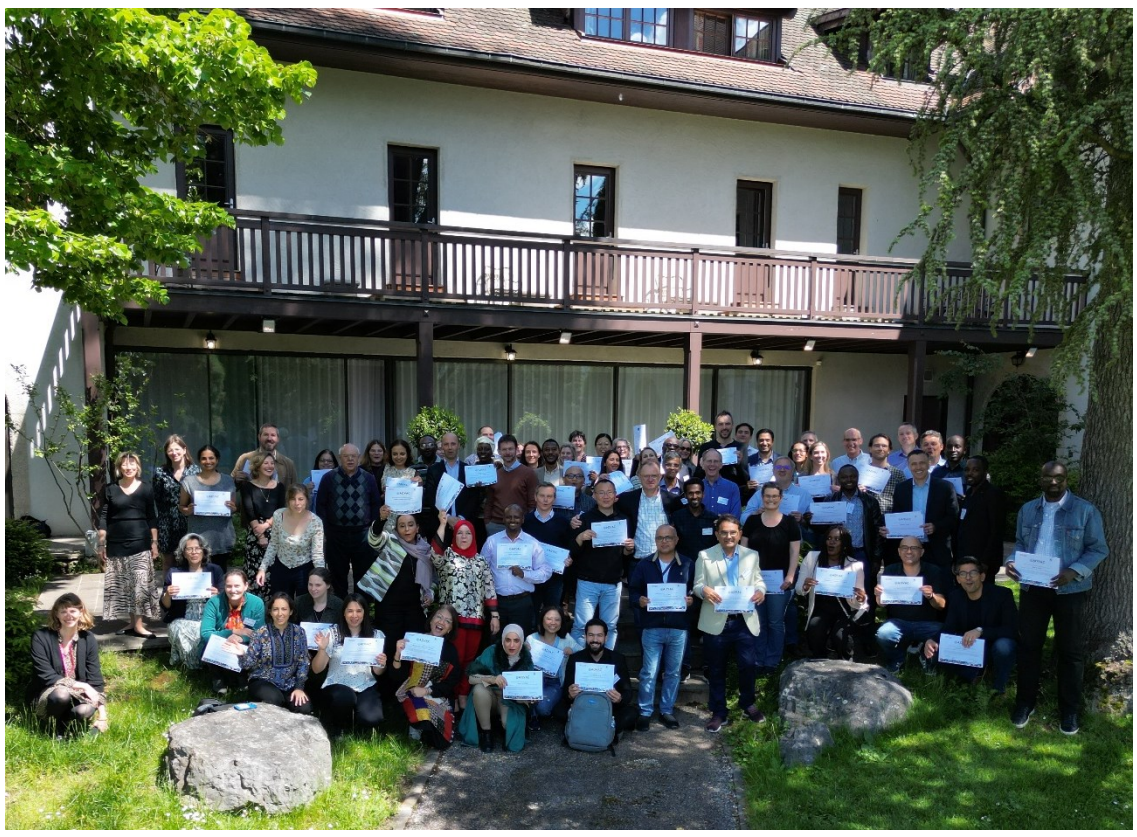
MAY 2024

ADVAC HIGHLIGHTS

JOURNAL OF 2024



ADVAC 2024 Diploma Ceremony: Congratulation on the 75 participants from 40 different countries who completed the Advanced Vaccinology Course this year!

Two special presentations

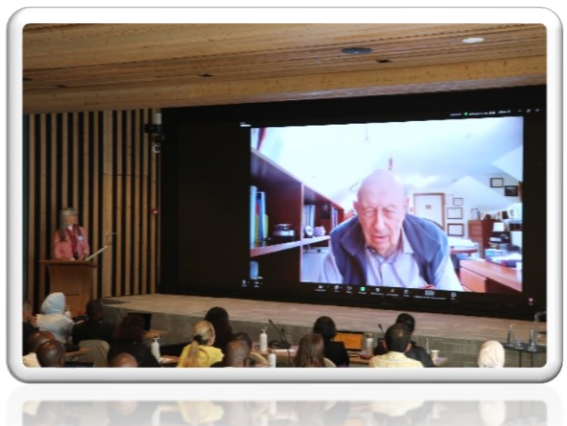
--------THE 8th LAMBERT LECTURE

Barney Graham from Morehouse School of Medicine reviewed RSV vaccines history.

How solving the pre-fusion structure of RSV F protein revealed a new antigenic site which was crucial to accelerate RSV vaccine (and COVID-19) development leading to the approval of the first maternal and elderly vaccines and first long-lasting monoclonal antibody against RSV.

----------THE 16TH PLOTKIN LECTURE

Kate O'Brien from WHO reflected about how climate change impacts on immunization systems and how hyper-responsive vaccine platforms, distributed vaccine manufacturing, single-dose products, non-injectable vaccines, digitalized immunization records and rapid serology testing can help mitigating its effects



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A brief summary of 2024 Lectures

---------- ROMINA LIBSTER

Every year Romina Libster, Paediatrician and Director of the Vaccine Research Program at the Fundación Infant/ iTrials in Argentina and also ADVAC Alumni of 2012, reviews all the lectures and catches the highlights of the year.

The journal of 2024 outlines the main 2024 advancements in the vaccinology field compared with 2023, which were presented by the lecturers at the last ADVAC meeting.

---------- CONTENT

Some new lectures were included this year

Ozzie Berger from Hillevax discussed on the role of ***regulatory affairs*** (industry), highlighting the importance of designing a regulatory strategy throughout the entire vaccine development lifecycle and central concepts of chemistry, manufacturing, and controls (*CMC*) for vaccines.

Marco Cavalieri from the EMA presented about the role of the ***regulatory agencies.***

Jakob Cramer from CEPI discussed on the challenges and what does it take to ***deliver a pandemic vaccine in 100 Days***. From creating a library of prototype vaccines & establishing vaccine platforms, establishing global manufacturing capacity to strengthening disease surveillance and global early-warning systems.

Kawsar Talaat from Johns Hopkins Bloomberg, School of Public Health debated on ***how vaccines cause adverse events*** and how understanding the pathogenesis of adverse events can led to reductions in risk.

Keymanthri Moodley from Stellenbosch University discussed on ***applied ethics in immunization*** *Programmes*, the ethical basis for immunization laws, access and financing and how the problem-solving approach and its five steps may help in the real-world implementation programs.

Marc Brisson from Laval University disserted on the role of ***health economics*** (including modelling) as a tool in analysing vaccine policy options and main types of economic evaluations as cost-effectiveness, cost-utility and cost-benefit analysis.

Joachim Hombach from WHO described the example of the ***WHO SAGE decision making processes*** and the applied methodology from the identification of the problem to the publication of the WHO position paper.

Rudzani Muloiwa from the University of Cape Town discussed on the ***decision-making processes*** for vaccines use, vaccine decision framework and the role of SAGE, NITAGS and regional technical advisory groups on immunization (RITAGs).

Ann Lindstrand from the WHO reflected on ***life-course vaccines*** and how a world aging population requires dedicated work on "Healthy aging" including healthy diets, physical exercise and immunization to prevent disease and decrease overburdened health services.

Narendra Arora from the INCLEN presented about how to better ***reach the zero-dose***, and how can be impacted by social, political & economic handicap, access to health services, maternal education, sanitation and water, ethnicity, religion, nomadic, displaced, or migrant populations and stunting-wasting.

Eve Dubé from the Laval University discussed on how the ***determinants of vaccine acceptance*** are complex and multi-dimensional and vary across time, place and different vaccines and how to address vaccine hesitancy.

Major advancements in vaccinology

Cristina Cassetti from the NIH-NIAID reviewed on the landscape in vaccine ***and immunization technologies,*** highlighting how AI is currently used extensively to design vaccines and updating on the first self-amplifying COVID-19 mRNA vaccine which have been approved in Japan, India and other countries and could potentially reduce doses (and cost) of vaccines.

Ananda Bandyopadhyay from the Bill & Melinda Gates Foundation discussed about ***the example of Polio eradication***. How novel oral polio vaccine type 2 (nOPV2) became the first vaccine to transition from WHO EUL use to be WHO prequalified and with full licensure in the country where it is manufactured and genetic lineages of remaining WPV1 strains at its lowest (n=2).

Keith Klugman from the Bill & Melinda Gates Foundation and **Ron Dagan** from the Soroka Medical Center debated on new advancements in ***pneumococcal vaccines*** highlighting the rollout of PCV applications to Gavi in the poorest and most

under vaccinated places on the planet and the new evidence showing the reduction of PCV types causing deaths from pneumonia as measured in minimally invasive autopsies in CHAMPS.

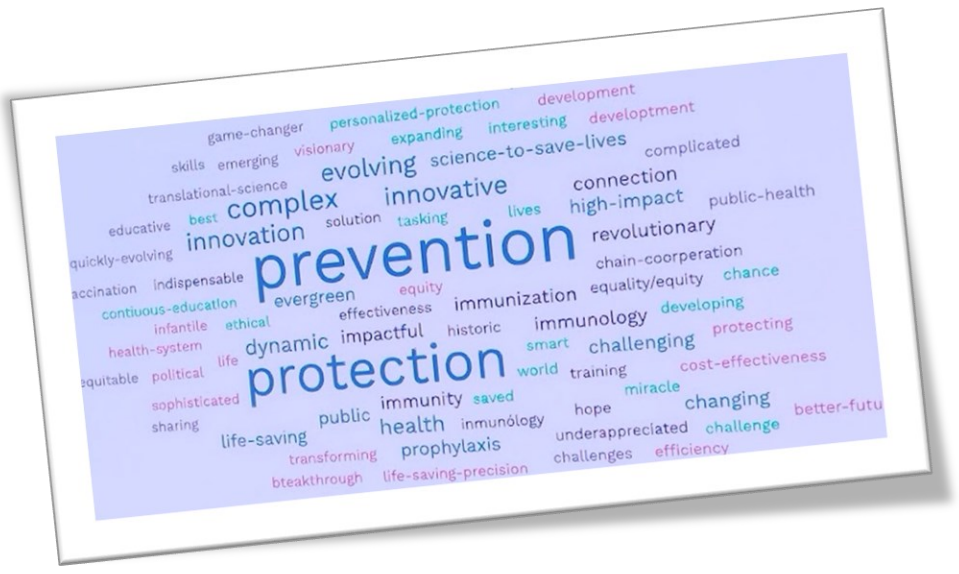
Margaret Stanley from Cambridge University reviewed new data on *HPV vaccines* from Scotland demonstrating that cervical cancer was completely prevented in women 20-30 years of age who received the HPV vaccine at ages 12-13.

Kathy Neuzil from the Fogarty International Center discussed about *typhoid vaccines* highlighting Gavi's support for typhoid conjugate vaccine (TCV) introduction and how a single dose of is safe, well-tolerated, and efficacious in children as young as 9 months of age across diverse settings. Kathy Neuzil also reviewed the new advancements on *influenza vaccines* updating on the recent reports based on surveillance data supporting the end of B/Yamagata influenza transmission. Additionally, confirmed Cases of Highly pathogenic avian influenza (HPAI) have been reported in Domestic Livestock, US, 2024.

Shamez Ladhani from UKHSA reviewed new data on *meningococcal vaccines.* New pentavalent vaccines are under development and include MenACWXY conjugate vaccine for the Meningitis Belt and MenABCWY vaccine for high income countries. Interestingly, protein-based MenB vaccine (4CMenB) also provides (~30%) protection against gonorrhea.

Anna Durbin from the Johns Hopkins Bloomberg School of Public Health lectured about *Vaccines against arboviruses*. New data for the live attenuated tetravalent *dengue vaccine* produced by the Instituto Butantan were recently released showing a vaccine efficacy against severe dengue/dengue with warning signs through the cut-off (average follow-up of 3.7 years) of 88.2% (50.8-98.2). Qdenga's 57-month follow-up data have been published showing long-term efficacy and safety against all four DENV serotypes in previously exposed individuals and against DENV-1 and DENV-2 in dengue-naive individuals. A *chikungunya* vaccine was licensed by the US FDA utilizing the accelerated pathway based on correlate of protection and stated that licensure for a *Zika* vaccine will also have to utilize the accelerated pathway, possibly using a Zika virus controlled human infection model or a correlate of protection.

Umesh Parashar from the Centers for Disease Control reviewed the status of *rotavirus* and *norovirus* vaccines. For rotavirus, progress is being made with developing non-live oral rotavirus vaccines to help improve vaccine efficacy in developing countries. For norovirus, 3 vaccine candidates are now in human clinical trials.



Hanna Nohynek from the Finnish Institute for Health and Welfare updated on *COVID-19* vaccines. Results from the Global Vaccine Data Network (GVDN) study including 99 million participants were released describing the observed COVID-19 safety profile. COVID-19 XBB-adapted vaccine products have been developed and more are in the pipeline.

Mary Hamel from WHO reflected on the learnings from the pilots and updates on implementation of *malaria* vaccines. In October 2023 WHO recommended R21/Matrix-M, 22 countries were approved by Gavi to receive support for malaria vaccine introduction and the first countries outside of pilot areas have introduced vaccine.

Janet Englund from Children's Hospital and Regional Medical Center, Seattle discussed about the updates on *maternal immunization*. Both RSV F-protein vaccine for pregnant persons and RSV-F protein monoclonal antibody have licensed in many countries.

Alejandro Cravioto from National Autonomous University of Mexico revised the topic on *cholera vaccines.* Second generation oral cholera vaccines (OCVs) are available, Euvichol-S was licensed in Korea in December 2023 and received WHO pre-qualification (PQ) in April 2024. Hillchol, is expected licensure and WHO PQ 2024. Duochol, a 3rd generation thermostable whole-cell/B-subunit OCV demonstrated excellent preclinical safety and immunogenicity and is now in clinical stage development.

Helen McShane from the University of Oxford updated on *tuberculosis vaccines.* BCG revaccination could be a useful strategy pending a more effective vaccine. A large phase III trial with M72 / AS01e is currently ongoing and results estimated to be available in 2028. H56/IC31 vaccine evaluated against prevention of relapse showed that no differences in recurrence were observed by treatment arms.