GREETINGS FROM THE ISV BOARD

Jeffrey Ulmer, ISV Board Chair

As Vice Chair, it is my pleasure to provide you with an overview of the ISV Board – who we are and what we do. The Board is comprised of nine members who, along with the five Officers of ISV, meet bimonthly to brainstorm, plan and execute the key functions of the Society. The Board has representation in all corners of the globe and its members hail from academia, industry, government, and not-for-profit foundations. Hence, the Board is a diverse group of vaccinologists that reflects the overall make-up of the Society and, indeed, the universe of vaccines as a whole.

In a typical meeting, we 1) review the finances of ISV, 2) plan the upcoming annual Congress, 3) discuss public relations efforts, such as Webinars, the monthly newsletter and ISV website, and 4) brainstorm on the various strategic initiatives of the Society. These initiatives include Awards, Education, Mentorship, Global Equity & Engagement, Outreach, Vaccine Advocacy, Membership, Fundraising, and Vaccine Industry Interaction.

One of the major activities of the Society is the annual Congress, which will be held this year from October 21-23 in Seoul, South Korea. We anticipate broad global participation with over 350 attendees in person and many additional vaccinologists connecting through the virtual platform. The agenda will consist of 6 plenary sessions, 11 break out sessions (including 2 Bright Sparks competitions for PhDs and early career researchers), 28 invited speakers, 48 oral presentations selected from submitted abstracts and approximately 150-200 posters covering infectious and non-infectious diseases, human and animal health, preclinical and clinical stage programs. An important mission of ISV is providing access to the Congress and its attendees for early career scientists, particularly from LMIC. We are proud that this year we will be able to make awards to over 28 such scientists, more than in any previous year.

A key ongoing strategic initiative is to create a more financially sustainable Society better able to engage, support, and sustain the professional goals of a diverse membership in all areas relevant to vaccines and immunotherapeutics. To this end,

last year launched an effort to increase our fundraising efforts by diversifying our Congress sponsorship options, broadening our partnerships with industry, and enhancing our charitable donations outreach. As a result, we raised more funds last year than in any previous year and are on a pace to exceed that even further this year.

These are just two of the important activities of ISV that the Board oversees. Success with these and the other initiatives will enable the Society to grow and expand its influence by promoting knowledge exchange and building global capacity in vaccine sciences by providing networking, publication, career development, and entrepreneurship support to vaccine researchers.

ISV Committee Update

Linda Klavinskis, Awards and Prizes Committee Chair

The ISV **Awards and Prize Committee** is dedicated to supporting the promise and professional development of Trainees in Vaccinology. Likewise, the committee serves to identify and recommend outstanding ISV members for a variety of awards and honours.

One of our core goals is to raise funding via grant applications and personal donations to assist PhD students and early career researchers (ECRs) with awards to participate in ISV congresses. Over the past few months, we have been successful in receiving grants from the Gates Foundation and the International Veterinary Vaccine Network, in addition to greatly appreciated donations from ISV members. This funding collectively is enabling talented young scientists from countries across the globe including LMICs to attend the 2024 ISV Congress in Seoul https://isv-online.org/congress/. At the time of writing, we eagerly await the funding outcome of a highly scored application (at scientific review) that was submitted to the US NIH.

In tandem with our funding work, the committee is also responsible for reviewing and ranking the Congress attendance award applications. This year we received an unprecedented number of applications (>80) for in-person awards. Submissions from LMIC applicants for the virtual attendance awards are still open till end July, see: ISV Virtual Award Application

Another focus of the committee is to recognize the research achievements of Trainees by organising oral and poster presenter sessions with prizes. These exciting events combine competition with outstanding science and showcase our future “Bright Sparks” in the vaccine sciences. This year’s” Bright Sparks” in Vaccinology PhD and ECR oral presenter sessions as well as the judged poster sessions are well advanced in their planning. We welcome members to come forward by emailing me at President@isv-online.org and join our presenter judging panels. Participation is an

excellent way to become involved with the ISV and demonstrate commitment when running for office. Last year over 30 ISV members were involved in this highly worthy endeavour, for which we thank you.

Lastly and importantly, the committee also identify ISV members to honour at the Annual ISV Congress who have made substantial contributions either to the success of the ISV or its broad mission of supporting the vaccinology community in driving knowledge exchange and the professional development of the next generation of vaccinologists.

Members of the Awards and Prizes committee include Drs. Barbara Felber, Ed Rybicki, Margaret Liu, Xavier Saelens, Annaliesa Anderson, David Weiner and Linda Klavinskis. If you would like to be part of this committee and contribute to its mission, please contact the committee chair: Linda Klavinskis via president@isv-online.org

We look forward hearing from you!

ISV PAPERS OF THE MONTH

The ISV Outreach Committee Members review vaccine literature published in the last month and nominate 2-3 papers for consideration. Committee Members then vote on the nominated papers and the paper receiving the majority of votes is selected as the paper of the month.

JUNE PAPER OF THE MONTH

A Randomized Phase 1/2a Trial of ExPEC10V Vaccine in Adults with a History of UTI

npj Vaccines 9, 106 (2024). https://doi.org/10.1038/s41541-024-00885-1

Authors
Carlos A. Fierro, Michal Sarnecki, Bart Spiessens, Oscar Go, Tracey A. Day, Todd A. Davies, Germie van den Dobbelsteen, Jan Poolman, Darren Abbanat & Wouter Haazen

Abstract
The safety, reactogenicity, and immunogenicity of 3 doses of ExPEC10V (VAC52416), a vaccine candidate to prevent invasive *Escherichia coli* disease, were assessed in a phase 1/2a study (NCT03819049). In Cohort 1, ExPEC10V was well tolerated; the high dose was selected as optimal and further characterized in Cohort 2. Cohort 2 comprised a maximum 28-day screening, vaccination (Day 1), double-blind 181-day follow-up, and open-label long-term follow-up until Year 1. Healthy participants (≥60 years) with a history of urinary tract infection (UTI) within 5 years were randomized to receive ExPEC10V or placebo. The primary endpoint evaluated the safety and reactogenicity of ExPEC10V (solicited local and systemic AEs [until Day 15]; unsolicited AEs [until Day 30], SAEs [until Day 181], and immunogenicity [Day 30]) via multiplex electrochemiluminescent (ECL) and multiplex opsonophagocytic assay (MOPA). 416 participants (ExPEC10V, $n = 278$; placebo, $n = 138$) were included (mean age [SD], 68.8 [6.52] years; female, 79.6%; White, 96.1%). The incidence of solicited AEs was higher with ExPEC10V (local, 50.0% [$n = 139$]; systemic, 50.0% [$n = 139$]) than placebo (15.9% [$n = 22$]; 38.4% [$n = 53$]); rates of unsolicited AEs were comparable (ExPEC10V, 28.4% [$n = 79$]; placebo, 26.1% [$n = 36$]). No vaccine-related SAEs or deaths were reported. ExPEC10V elicited a robust antibody-mediated immunogenic response across all serotypes with ECL (Day 30 geometric mean fold increase, 2.33–8.18) and demonstrated functional

opsonophagocytic killing activity across all measured serotypes (Day 30 geometric mean fold increase, 1.81–9.68). ExPEC10V exhibited an acceptable safety profile and a robust vaccine-induced functional immunogenic response in participants with a history of UTI.

JULY PAPER OF THE MONTH

Efficacy of live and inactivated recombinant Newcastle disease virus vaccines expressing clade 2.3.4.4b H5 hemagglutinin against H5N1 highly pathogenic avian influenza in SPF chickens, Broilers, and domestic ducks

Vaccine. 2024 Jul 11;42(18):3756-3767. doi: 10.1016/j.vaccine.2024.04.088. Epub 2024 May 9. PMID: 38724417
https://www.sciencedirect.com/science/article/pii/S0264410X24005279?via%3Dihub

Authors
Deok-Hwan Kim, Seung-Hun Lee, Jiwon Kim, Jiho Lee, Jei-Hyun Jeong, Ji-Yun Kim, Seung-Un Song, Hyukchae Lee, Andrew Y Cho, Ji-Yeon Hyeon, Sungsu Youk, Chang-Seon Song

Abstract
A Newcastle disease virus (NDV)-vectored vaccine expressing clade 2.3.4.4b H5 Hemagglutinin was developed and assessed for efficacy against H5N1 highly pathogenic avian influenza (HPAI) in specific pathogen-free (SPF) chickens, broilers, and domestic ducks. In SPF chickens, the live recombinant NDV-vectored vaccine, rK148/22-H5, achieved complete survival against HPAI and NDV challenges and significantly reduced viral shedding. Notably, the live rK148/22-H5 vaccine conferred good clinical protection in broilers despite the presence of maternally derived antibodies. Good clinical protection was observed in domestic ducks, with decreased viral shedding. It demonstrated complete survival and reduced cloacal viral shedding when used as an inactivated vaccine from SPF chickens. The rK148/22-H5 vaccine is potentially a viable and supportive option for biosecurity measure, effectively protecting in chickens against the deadly clade 2.3.4.4b H5 HPAI and NDV infections. Furthermore, it aligns with the strategy of Differentiating Infected from Vaccinated Animals (DIVA).

Click HERE to View Prior Papers of the Month and Year

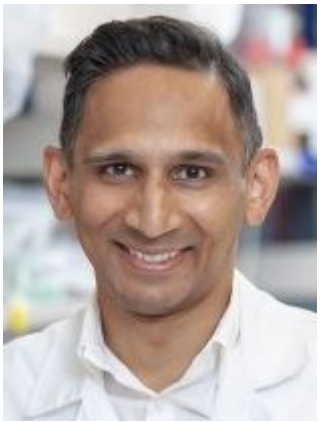
ISV WEBINAR SERIES

25 July 2024

Vinod Balachandran

Memorial Sloan Kettering Cancer Center

Pancreatic Cancer Vaccines



25 July 2024
08:00 (PDT) | 11:00 (EDT) | 16:00 (BST) | 17:00 (CEST) |
17:00 (SAST) | 23:00 (CST) |

26 July 2024
00:00 (KST)

Join Here: https://zoom.us/j/99021756132

27 August 2024

Eui-Cheol Shin

Korea Virus Research Institute

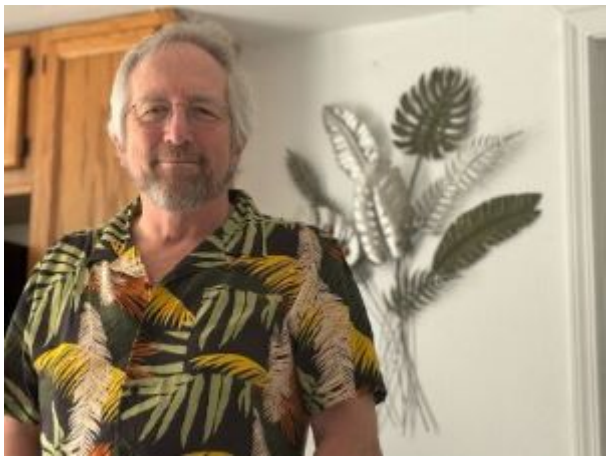
Phenotypic and functional characteristic of SARS-CoV-2 vaccine-induced T cells

27 August 2024
00:00 (PDT) | 03:00 (EDT) | 08:00 (BST) | 09:00 (CEST) |
09:00 (SAST) | 15:00 (CST) | 16:00 (KST)

Join Here: https://zoom.us/j/97714267152

ISV BOARD MEMBER INTRODUCTION

Ed Rybicki, University of Cape Town



What is your background/profession? (ie Professor, MD, PhD, director, etc)

My background is that I am a trained plant virologist – BSc, Honours, Masters and PhD degrees all from the University of Cape Town, with MSc and PhD in plant virology – who changed field in the 1990s due to funding for plant virus work drying up in South Africa. Part of the reason for the change to working on animal and human viruses (beak and feather disease virus of parrots, and HPVs and HIV) was my getting married to Anna-Lise Williamson in 1988, who said "Why don't you work on something useful?" when I was looking for what to do with myself 😊 Work on detection and genetic characterisation of HPV, HIV and other viruses led to working on vaccines for human papillomaviruses (HPV) and HIV in the late 1990s, and vaccinology became my research area until the present day.

What is your favorite/main research area/topic?

My main research area is the exploration of the use of plants to make high-value protein-based reagents, diagnostics and potentially therapeutics and vaccines, by means of Agrobacterium-mediated transient expression.

What's your main scientific achievements and contributions?

- Making HIV-1 subtype C Pr55Gag virus-like particles (VLPs) in insect cells and in plants, and demonstrating that these are potentially highly useful in prime-boost vaccination regimes in NHPs;
- Leading a team investigating the production of novel HPV L1 protein-based VLPs in insect cells and in plants that resulted in novel chimaeric VLPs made in insect cells and plants, as well as a decavalent vaccine candidate made in plants;
- Making VLPs in plants for both bluetongue virus and African horse sickness orbiviruses, and demonstrating efficacy/ immunogenicity of these as vaccine candidates;
- Pioneering the production of pseudovirions of HPV in plants; and
- Demonstrating that plant-made RNAs encapsidated in tobacco mosaic virus coat protein are viable reagents as well as being viable candidate vaccines.

Do you have any hidden talent/s?

My hidden talents are best kept hidden – however, I am a published science fiction author (two short-short stories in Nature), and a VERY bad guitarist.

Vaccine News Flash

Manon Cox, NextWaveBio & Jessica Price, AstraZeneca

In response to the avian H5N1 virus **outbreak in cattle**, first identified in March of this year multiple countries have procured vaccines to protect again this avian influenza. In addition, Reuters reported that Finland is planning to start administering vaccinations to dairy workers https://www.reuters.com/business/healthcare-pharmaceuticals/finland-start-bird-flunvaccinations-humans-2024-06-25/). To date four people have been reported to be infected. For a comprehensive update please check Center for Disease Control and Prevention (CDC) website @ Current H5N1 Bird Flu Situation in Dairy Cows | Bird Flu | CDC.

On May 31, the US Food and Drug Administration has approved a third vaccine to help protect people aged 60 and older from **respiratory syncytial virus** (**RSV**). This **mRNA** vaccine is produced by Moderna and sold under the name of mResvia. The two previously FDA approved vaccines for the prevention of RSV in adults, 60 years and older are **protein**-based and are produced by Pfizer (Abrysvo; Note: this vaccine is also approved for pregnant women 32 through 36 weeks of pregnancy to prevent RSV in babies from birth through 6 months of age) and GSK (Arexvy). Updated recommendations for RSV vaccinations were issued by CDC and can be found on RSV (Respiratory Syncytial Virus) Immunizations | CDC.

FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) met on June 5, 2024, to discuss and make recommendations on the selection of the 2024-2025 Formula for **COVID-19 vaccines** for use in the United States beginning in the fall of 2024. The committee unanimously voted to recommend a monovalent JN.1-lineage vaccine composition. The agency has further determined that the preferred JN.1-lineage for the COVID-19 vaccines (2024-2025 Formula) is the KP.2 strain, if feasible to ensure more closely match to circulating SARS-CoV-2 strains.

CNN reported on the roll-out of a second **malaria** vaccine in Africa starting June following its previously received recommendation for use by the World Health Organization's Strategic Advisory Group of Experts (SAGE) and the Malaria Policy Advisory Group (MPAG). The R21-MatrixM vaccine, was developed by the Jenner Institute at the **University of Oxford** and the **Serum Institute of India** (SII). The vaccine has shown an up to 77% efficacy in a trial of 450 children in Burkina Faso over 12 months and costs less than 4 USD per dose which is relatively cheap and has been hailed as a major milestone in the battle against one of the world's most deadly diseases. The SIII has already manufactured more than 25 million doses and has committed to producing up to 100 million doses a year, a scale that allows the vaccine to remain affordable. R21 vaccine: Children in Ivory Coast receive first doses of new malaria vaccine, hailed as major milestone | CNN

Hillevax (a Boston-based company) will discontinue its **Norovirus vaccine** HIL-214 for infants about 5 months old at the time of vaccination as it failed to meet its primary endpoint of efficacy against moderate or severe acute gastroenteritis events due to GI.1 or GII.4 norovirus genotypes in Phase 2b trial even though HIL-214 previously showed clinical benefit in adults. HilleVax to discontinue development of norovirus vaccine for infants; shares plummet | Reuters

The **FDA** issued a new draft guidance document to increase racial, ethnic and other **population diversity** in clinical studies with the objective to improve representation of populations despite higher rates of certain diseases in the underrepresented groups than in the general population. The goals for a study, or the "diversity action plan", should be set keeping in mind the estimated prevalence of a disease for which the drug or device is being evaluated. US FDA recommends steps to improve diversity in clinical trials | Reuters

Worcester HIV Vaccine reported on the successful completion of its Phase 1B Trial WHV 138. The polyvalent **DNA/Protein HIV Vaccine** candidate PDPHV was found to be safe and well-tolerated; no safety concerns were seen throughout the entire trial period. Immunogenicity analyses are ongoing and first results are similar to those of the HVTN124 trial, which have been published recently in The Lancet HIV. See: Latest News – Worcester HIV Vaccine (whvaccine.com)

Encourage your Colleagues and Peers to

Join or Renew their ISV Membership Today!

www.isv-online.org

ISV Member Benefits

- Reduced registration fee to the ISV Annual Congress
- Receive ISV members-only Newsletter, and submit news and articles for distribution in the newsletter
- Eligibility to run for ISV Officer and Board positions
- Opportunity to network and collaborate with global vaccine researchers and organizations
- Participate in various ISV Committees including Awards & Prizes; Education & Membership; Global Equity & Engagement; Industry Interaction; and Outreach and Public Engagement
- Access to career mentorship for early-career researchers
- Review and vote on Papers of the Month and Paper of the Year
- Access to online version of the journal *Vaccine* (upon request)
- 15% APC discount on the journal, *Human Vaccines and Immunotherapeutics*

To apply for the ISV Member benefit of a 15% discount to the Article Publishing Charge for the open access journal, Human Vaccines and Immunotherapeutics, contact info@isv-online.org to be provided with the guide and instructions. (A 50% discount is applicable to scientists from lower-middle-income countries; researchers from low-income countries are eligible for a full waiver (100% discount)).

Stay Engaged with the ISV through its Social Media Channels:

ISV on LinkedIn

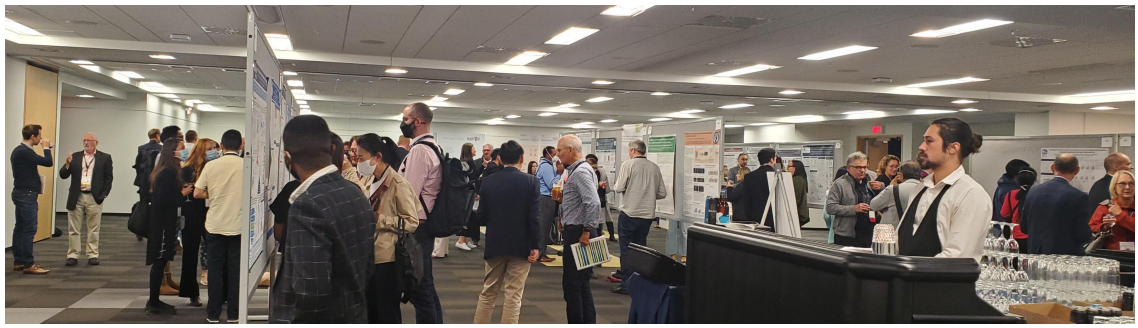
ISV on Facebook

ISV on Instagram

The 2022 ISV Congress in Québec City, co-chaired by Drs. Joon Haeng Rhee, Manon Cox, and Gary Kobinger, was a great success! This year, ISV provided a hybrid program to 183 in-person plus 131 virtual delegates.

ISV continued its traditional support for junior investigators by providing Registration Awards to students, postdocs, and LMIC researchers, awarded as in-person or virtual options. In addition, onsite Prizes were awarded to the Best Poster Presentation and Runner Up Presentation (abstracts below.)

We thank the Congress Co-Chairs, the Scientific Committee, all the invited speakers, oral and poster abstract presenters, attendees, sponsors and exhibitors for a wonderful ISV Congress and look forward to the 2023 ISV Annual Congress, co-chaired by Drs. Xavier Saelens, Ken Ishii, and Bruno Correia, held in Lausanne, Switzerland, 22-24 October 2023.



Meeting of Interest:

BioNTech Webinar Series

Vaccine Program Development MasterClass

Wednesday 2nd November 2022

16:00 CET (GMT +1)/11:00 EDT

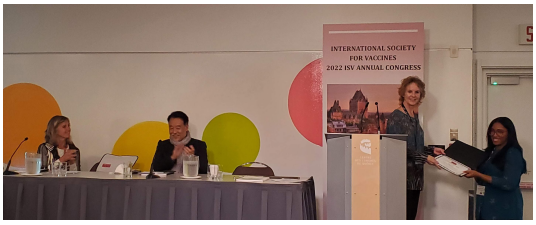
Register to BioNTech Webinar

Have News or Meetings of Interest to Share?

ISV members may submit vaccine-related news and meetings of interest for possible inclusion in future newsletters. Please email: **info@isv-online.org**.

ISV Annual Congress Best Poster Presenter Prizes

During the 2022 Congress, Co-Chairs and select ISV Board members rated all displayed poster abstracts; posters with the most votes were selected for runner up and best poster presentations.



Best Poster Presentation

Alexander Cohen, Caltech

Mosaic RBD nanoparticles protect against challenge by diverse sarbecoviruses in animal models.

In an effort to protect against future SARS-CoV-2 variants as well as spillovers from emerging SARS-like betacoronaviruses, we developed mosaic nanoparticles that co-display randomly-arranged sarbecovirus spike receptor binding domains (RBDs), as a strategy to elicit cross-reactive antibodies against conserved epitopes, rather than epitopes that are variable and immunodominant. We compared humoral immune responses elicited by mosaic-8 (SARS-CoV-2 and 7 other animal sarbecovirus strains) and homotypic (only SARS-CoV-2) RBD-nanoparticles vaccination in mice and macaques, demonstrating that mosaic-8 vaccination elicited more cross-reactive and cross-neutralizing antibody responses to both matched and mismatched (not on particle) SARS-CoV-2 variants and sarbecovirus strains in comparison to homotypic SARS-2 RBD nanoparticles which elicited predominantly SARS-CoV-2 variant specific antibody responses. Furthermore, mosaic-8 vaccination also protected mice and NHPs from challenge with a SARS-CoV-2 (matched) and SARS-CoV (mismatched), whereas homotypic SARS-2 vaccination only protected against SARS-CoV-2 challenge but did not protect against SARS-CoV challenge. Finally, we mapped antibody responses from mice vaccinated with either mosaic-8 or Homotypic SARS-2 RBD nanoparticles demonstrating that mosaic-8 elicited antibodies preferentially target conserved epitopes whereas homotypic SARS-2 RBD elicited antibodies target more variable immunodominant epitopes. Together, these results suggest mosaic-8 RBD-nanoparticles could protect against SARS-CoV-2 variants and future sarbecovirus spillovers.

References

1. Cohen, A. A. *et al.* Mosaic RBD nanoparticles protect against challenge by diverse sarbecoviruses in animal models. *Science* (2022) doi:10.1126/science.abq0839. 2. Fan, C. *et al.* Neutralizing monoclonal antibodies elicited by mosaic RBD nanoparticles bind conserved sarbecovirus epitopes. *Biorxiv* 2022.06.28.497989 (2022) doi:10.1101/2022.06.28.497989.

Runner Up Best Poster Presentation

Santa Mariela Olivera Ugarte, Centre de Recherche du CHU de Québec - Université Laval

A nanoparticle-based COVID-19 vaccine candidate elicits broad neutralizing antibodies and protects against SARS-CoV-2 infection.

The SARS-CoV-2 virus, causal agent of the COVID-19 disease, has proven to be a challenging pathogen that put the world to a halt over the past two years. The emergence of highly infective variants like Delta and Omicron poses a threat to the efficacy of the currently available vaccines, indicating that SARS-CoV-2 infections will remain a recurring problem in the near future. Therefore, the development of vaccines using novel strategies for antigenic presentation that could broaden the immune response toward SARS-CoV-2 antigens is crucial.

In response to this need, we have developed a vaccine platform based on the papaya mosaic virus (PapMV) coat protein (CP). PapMV is a rod-shaped nanoparticle (nano) that has shown to be a strong stimulator of the innate immunity, via activation of the toll-like receptor 7 by recognition of the non-coding ssRNA contained inside the nano. Genetic engineering of the PapMV-CP allowed the conjugation of protein antigens to the surface of the nanoparticle, which provided great versatility and increased the immune-stimulatory potency of this vaccine platform. This approach was used to design a vaccine candidate for SARS-CoV-2 comprising the viral receptor-binding domain (RBD, ancestral sequence) attached to the surface of the PapMV nano to generate the RBD-PapMV vaccine. The potential of RBD-PapMV to induce neutralizing antibodies able to protect from SARS-CoV-2 infection was evaluated in mice models. Additionally, a non-conjugated control consisting of PapMV mixed with RBD (RBD + PapMV) was included to assess the contribution of antigen conjugation to the immune response.

Two immunizations of Balb/C mice with RBD-PapMV induced high antibody titers and T-cell mediated response towards RBD. This immune response was stronger using the conjugated nanoparticle as compared to the non-conjugated control RBD + PapMV. The anti-RBD antibodies were able to neutralize infection in vitro with the ancestral SARS-CoV-2, and efficiently cross-neutralized the Delta and Omicron variants. For assessing the protective response of the RBD-PapMV vaccine candidate, K18-hACE2 mice expressing the human ACE2 receptor were challenged with the ancestral variant of SARS-CoV-2. Mice immunized twice with RBD-PapMV were protected from infectious challenge, evidenced by significantly lower viral titers in the lung and nasal turbinate at 2 and 5 days post-infection, compared to the control groups. Additionally, vaccinated mice showed no lung inflammation or immune cell infiltration, corroborated by histopathology analysis and low levels of the pro-inflammatory cytokine IL-6 in lung homogenate.

In conclusion, the attachment of the RBD to the highly ordered surface of PapMV nanoparticles produced an optimal antigenic presentation of the RBD that contributed to a solid humoral and cellular immune response, as well as a broad neutralization of SARS-CoV-2 infectious variants. Additionally, RBD-PapMV remained stable at 4 ^{0}C for one month, which could facilitate its distribution as compared to mRNA based vaccines that require freezing at -20 to -80°C. Overall, these results constitute a strong proof of concept regarding the potential and versatility of PapMV nano as a vaccine platform to use in pandemic scenarios.

ISV PAPERS OF THE MONTH

The ISV Outreach Committee Members review vaccine literature published in the last month and nominate 2-3 papers for consideration. Committee Members then vote on the nominated papers and the paper receiving the majority of votes is selected as the paper of the month.

OCTOBER PAPER OF THE MONTH

A Bivalent Omicron-Containing Booster Vaccine against Covid-19.

N Engl J Med. 2022 Oct 6;387(14):1279-1291. doi: 10.1056/NEJMoa2208343. Epub 2022 Sep 16. PMID: 36112399; PMCID: PMC9511634

Authors

Chalkias S, Harper C, Vrbicky K, Walsh SR, Essink B, Brosz A, McGhee N, Tomassini JE, Chen X, Chang Y, Sutherland A, Montefiori DC, Girard B, Edwards DK, Feng J, Zhou H, Baden LR, Miller JM, Das R.

Abstract

Background: The safety and immunogenicity of the bivalent omicron-containing mRNA-1273.214 booster vaccine are not known.

Methods: In this ongoing, phase 2-3 study, we compared the 50-μg bivalent vaccine mRNA-1273.214 (25 μg each of ancestral Wuhan-Hu-1 and omicron B.1.1.529 [BA.1] spike messenger RNAs) with the previously authorized 50-μg mRNA-1273 booster. We administered mRNA-1273.214 or mRNA-1273 as a second booster in adults who had previously received a two-dose (100-μg) primary series and first booster (50-μg) dose of mRNA-1273 (≥3 months earlier). The primary objectives were to assess the safety, reactogenicity, and immunogenicity of mRNA-1273.214 at 28 days after the booster dose.

Results: Interim results are presented. Sequential groups of participants received 50 μg of mRNA-1273.214 (437 participants) or mRNA-1273 (377 participants) as a second booster dose. The median time between the first and second boosters was similar for mRNA-1273.214 (136 days) and mRNA-1273 (134 days). In participants with no previous severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, the geometric mean titers of neutralizing antibodies against the omicron BA.1 variant were 2372.4 (95% confidence interval [CI], 2070.6 to 2718.2) after receipt of the mRNA-1273.214 booster and 1473.5 (95% CI, 1270.8 to 1708.4) after receipt of the mRNA-1273 booster. In addition, 50-μg mRNA-1273.214 and 50-μg mRNA-1273 elicited geometric mean titers of 727.4 (95% CI, 632.8 to 836.1) and 492.1 (95% CI, 431.1 to 561.9), respectively, against omicron BA.4 and BA.5 (BA.4/5), and the mRNA-1273.214 booster also elicited higher binding antibody responses against multiple other variants (alpha, beta, gamma, and delta) than the mRNA-1273 booster. Safety and reactogenicity were similar with the two booster vaccines. Vaccine effectiveness was not assessed in this study; in an exploratory analysis, SARS-CoV-2 infection occurred in 11 participants after the mRNA-1273.214 booster and in 9 participants after the mRNA-1273 booster.

Conclusions: The bivalent omicron-containing vaccine mRNA-1273.214 elicited neutralizing antibody responses against omicron that were superior to those with mRNA-1273, without evident safety concerns. (Funded by Moderna; ClinicalTrials.gov number, NCT04927065.).

SEPTEMBER PAPER OF THE MONTH

Safety and immunogenicity of PXVX0317, an aluminium hydroxide-adjuvanted chikungunya virus-like particle vaccine: a randomised, double-blind, parallel-group, phase 2 trial.

Lancet Infect Dis. 2022 Sep;22(9):1343-1355. doi: 10.1016/S1473-3099(22)00226-2. Epub 2022 Jun 13. PMID: 35709798

Authors

Bennett SR, McCarty JM, Ramanathan R, Mendy J, Richardson JS, Smith J, Alexander J, Ledgerwood JE, de Lame PA, Royalty Tredo S, Warfield KL, Bedell L.

Abstract

Background: Chikungunya virus (CHIKV) disease is an ongoing public health threat. We aimed to evaluate the safety and immunogenicity of PXVX0317, an aluminium hydroxide-adjuvanted formulation of a CHIKV virus-like particle (VLP) vaccine.

Methods: This randomised, double-blind, parallel-group, phase 2 trial was conducted at three clinical trial centres in the USA. Eligible participants were healthy CHIKV-naïve adults aged 18-45 years. Participants were stratified by site and randomly assigned (1:1:1:1:1:1:1:1) to one of the eight vaccination groups using a block size of 16. Group 1 received two doses of unadjuvanted PXVX0317 28 days apart (2 × 20 μg; standard); all other groups received adjuvanted PXVX0317: groups 2-4 received two doses 28 days apart (2 × 6 μg [group 2], 2 × 10 μg [group 3], or 2 × 20 μg [group 4]; standard); group 4 also received a booster dose 18 months after the first active injection (40 μg; standard plus booster); groups 5-7 received two doses 14 days apart (2 × 6 μg [group 5], 2 × 10 μg [group 6], or 2 × 20 μg [group 7]; accelerated); and group 8 received one dose (1 × 40 μg; single). The primary endpoint was the geometric mean titre of anti-CHIKV neutralising antibody on day 57 (28 days after the last vaccination), assessed in the immunogenicity-evaluable population. Additionally, we assessed safety. This trial is registered at ClinicalTrials.gov, NCT03483961.

Findings: This trial was conducted from April 18, 2018, to Sept 21, 2020; 468 participants were assessed for eligibility. Of these, 415 participants were randomly assigned to eight groups (n=53 in groups 1, 5, and 6; n=52 in groups 2 and 8; n=51 in groups 3 and 7; and n=50 in group 4) and

373 were evaluable for immunogenicity. On day 57, serum neutralising antibody geometric mean titres were 2057·0 (95% CI 1584·8-2670·0) in group 1, 1116·2 (852·5-1461·4; p=0·0015 vs group 1 used as a reference) in group 2, 1465·3 (1119·1-1918·4; p=0·076) in group 3, 2023·8 (1550·5-2641·7; p=0·93) in group 4, 920·1 (710·9-1190·9; p<0·0001) in group 5, 1206·9 (932·4-1562·2; p=0·0045) in group 6, 1562·8 (1204·1-2028·3; p=0·14) in group 7, and 1712·5 (1330·0-2205·0; p=0·32) in group 8. In group 4, a booster dose increased serum neutralising antibody geometric mean titres from 215·7 (95% CI 160·9-289·1) on day 547 to 10 941·1 (7378·0-16 225·1) on day 575. Durability of the immune response (evaluated in groups 1, 4, and 8) was shown up to 2 years. The most common solicited adverse event was pain at the injection site, reported in 12 (23%) of 53 participants who received the unadjuvanted vaccine (group 1) and 111 (31%) of 356 who received the adjuvanted vaccine. No vaccine-related serious adverse events were reported.

Interpretation: PXVX0317 was well tolerated and induced a robust and durable serum neutralising antibody immune response against CHIKV up to 2 years. A single 40 µg injection of adjuvanted PXVX0317 is being further investigated in phase 3 clinical trials (NCT05072080 and NCT05349617).

Click HERE to View Prior Papers of the Month

Join or Renew Your ISV Membership Today!

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- Access to career mentorship for early career researchers
- Chance to work alongside ISV colleagues in public engagement
- Opportunity to collaborate with global vaccine organizations
- Reduced registration fee for the ISV Annual Congress
- Receive the ISV member-only newsletter
- Eligibility to run for ISV Officer and Board positions
- Access to online version of journal *Vaccine* (upon request)

Please visit our website to join or renew today: **www.isv-online.org**.

The **Immunization Action Coalition** is a member of the WHO-led project Vaccine Safety Net (VSN). Links are provided to resources from IAC, the CDC, the American Academy of Pediatrics, the US Department of Health and Human Services, the US Food and Drug Administration, WHO, and more.

ISV is pleased to partner with **MJH Life Sciences™** as part of its Strategic Alliance Partnership (SAP) program.

The SAP program provides medical associations, health plans, advocacy groups and medical institutions with a national reach and visibility.

The International Society for Vaccines is an organization that engages, supports, and sustains the professional goals of a diverse membership in all areas relevant to vaccines.

GREETINGS FROM THE ISV BOARD

Jeffrey Ulmer, ISV Board Chair

As Vice Chair, it is my pleasure to provide you with an overview of the ISV Board – who we are and what we do. The Board is comprised of nine members who, along with the five Officers of ISV, meet bimonthly to brainstorm, plan and execute the key functions of the Society. The Board has representation in all corners of the globe and its members hail from academia, industry, government, and not-for-profit foundations. Hence, the Board is a diverse group of vaccinologists that reflects the overall make-up of the Society and, indeed, the universe of vaccines as a whole.

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ISV Committee Update

Linda Klavinskis, Awards and Prizes Committee Chair

The ISV **Awards and Prize Committee** is dedicated to supporting the promise and professional development of Trainees in Vaccinology. Likewise, the committee serves to identify and recommend outstanding ISV members for a variety of awards and honours.

One of our core goals is to raise funding via grant applications and personal donations to assist PhD students and early career researchers (ECRs) with awards to participate in ISV congresses. Over the past few months, we have been successful in receiving grants from the Gates Foundation and the International Veterinary Vaccine Network, in addition to greatly appreciated donations from ISV members. This funding collectively is enabling talented young scientists from countries across the globe including LMICs to attend the 2024 ISV Congress in Seoul https://isv-online.org/congress/. At the time of writing, we eagerly await the funding outcome of a highly scored application (at scientific review) that was submitted to the US NIH.

In tandem with our funding work, the committee is also responsible for reviewing and ranking the Congress attendance award applications. This year we received an unprecedented number of applications (>80) for in-person awards. Submissions from LMIC applicants for the virtual attendance awards are still open till end July, see: ISV Virtual Award Application

Another focus of the committee is to recognize the research achievements of Trainees by organising oral and poster presenter sessions with prizes. These exciting events combine competition with outstanding science and showcase our future "Bright Sparks" in the vaccine sciences. This year's" Bright Sparks" in Vaccinology PhD and ECR oral presenter sessions as well as the judged poster sessions are well advanced in their planning. We welcome members to come forward by emailing me at President@isv-online.org and join our presenter judging panels. Participation is an excellent way to become involved with the ISV and demonstrate commitment when running for office. Last year over 30 ISV members were involved in this highly worthy endeavour, for which we thank you.

Lastly and importantly, the committee also identify ISV members to honour at the Annual ISV Congress who have made substantial contributions either to the success of the ISV or its broad mission of supporting the vaccinology community in driving knowledge exchange and the professional development of the next generation of vaccinologists.

Members of the Awards and Prizes committee include Drs. Barbara Felber, Ed Rybicki, Margaret Liu, Xavier Saelens, Annaliesa Anderson, David Weiner and Linda Klavinskis. If you would like to be part of this committee and contribute to its mission, please contact the committee chair: Linda Klavinskis via president@isv-online.org

We look forward hearing from you!

ISV PAPERS OF THE MONTH

The ISV Outreach Committee Members review vaccine literature published in the last month and nominate 2-3 papers for consideration. Committee Members then vote on the nominated papers and the paper receiving the majority of votes is selected as the paper of the month.

JUNE PAPER OF THE MONTH

A Randomized Phase 1/2a Trial of ExPEC10V Vaccine in Adults with a History of UTI

npj Vaccines 9, 106 (2024). https://doi.org/10.1038/s41541-024-00885-1

Authors
Carlos A. Fierro, Michal Sarnecki, Bart Spiessens, Oscar Go, Tracey A. Day, Todd A. Davies, Germie van den Dobbelsteen, Jan Poolman, Darren Abbanat & Wouter Haazen

Abstract
The safety, reactogenicity, and immunogenicity of 3 doses of ExPEC10V (VAC52416), a vaccine candidate to prevent invasive *Escherichia coli* disease, were assessed in a phase 1/2a study (NCT03819049). In Cohort 1, ExPEC10V was well tolerated; the high dose was selected as optimal and further characterized in Cohort 2. Cohort 2 comprised a maximum 28-day screening, vaccination (Day 1), double-blind 181-day follow-up, and open-label long-term follow-up until Year 1. Healthy participants (≥60 years) with a history of urinary tract infection (UTI) within 5 years were randomized to receive ExPEC10V or placebo. The primary endpoint evaluated the safety and reactogenicity of ExPEC10V (solicited local and systemic AEs [until Day 15]; unsolicited AEs [until Day 30], SAEs [until Day 181], and immunogenicity [Day 30]) via multiplex electrochemiluminescent (ECL) and multiplex opsonophagocytic assay (MOPA). 416 participants (ExPEC10V, $n = 278$; placebo, $n =$

138) were included (mean age [SD], 68.8 [6.52] years; female, 79.6%; White, 96.1%). The incidence of solicited AEs was higher with ExPEC10V (local, 50.0% [$n = 139$]; systemic, 50.0% [$n = 139$]) than placebo (15.9% [$n = 22$]; 38.4% [$n = 53$]); rates of unsolicited AEs were comparable (ExPEC10V, 28.4% [$n = 79$]; placebo, 26.1% [$n = 36$]). No vaccine-related SAEs or deaths were reported. ExPEC10V elicited a robust antibody-mediated immunogenic response across all serotypes with ECL (Day 30 geometric mean fold increase, 2.33–8.18) and demonstrated functional opsonophagocytic killing activity across all measured serotypes (Day 30 geometric mean fold increase, 1.81–9.68). ExPEC10V exhibited an acceptable safety profile and a robust vaccine-induced functional immunogenic response in participants with a history of UTI.

JULY PAPER OF THE MONTH

Efficacy of live and inactivated recombinant Newcastle disease virus vaccines expressing clade 2.3.4.4b H5 hemagglutinin against H5N1 highly pathogenic avian influenza in SPF chickens, Broilers, and domestic ducks

Vaccine. 2024 Jul 11;42(18):3756-3767. doi: 10.1016/j.vaccine.2024.04.088. Epub 2024 May 9. PMID: 38724417
https://www.sciencedirect.com/science/article/pii/S0264410X24005279?via%3Dihub

Authors
Deok-Hwan Kim, Seung-Hun Lee, Jiwon Kim, Jiho Lee, Jei-Hyun Jeong, Ji-Yun Kim, Seung-Un Song, Hyukchae Lee, Andrew Y Cho, Ji-Yeon Hyeon, Sungsu Youk, Chang-Seon Song

Abstract
A Newcastle disease virus (NDV)-vectored vaccine expressing clade 2.3.4.4b H5 Hemagglutinin was developed and assessed for efficacy against H5N1 highly pathogenic avian influenza (HPAI) in specific pathogen-free (SPF) chickens, broilers, and domestic ducks. In SPF chickens, the live recombinant NDV-vectored vaccine, rK148/22-H5, achieved complete survival against HPAI and NDV challenges and significantly reduced viral shedding. Notably, the live rK148/22-H5 vaccine conferred good clinical protection in broilers despite the presence of maternally derived antibodies. Good clinical protection was observed in domestic ducks, with decreased viral shedding. It demonstrated complete survival and reduced cloacal viral shedding when used as an inactivated vaccine from SPF chickens. The rK148/22-H5 vaccine is potentially a viable and supportive option for biosecurity measure, effectively protecting in chickens against the deadly clade 2.3.4.4b H5 HPAI and NDV infections. Furthermore, it aligns with the strategy of Differentiating Infected from Vaccinated Animals (DIVA).

Click HERE to View Prior Papers of the Month and Year

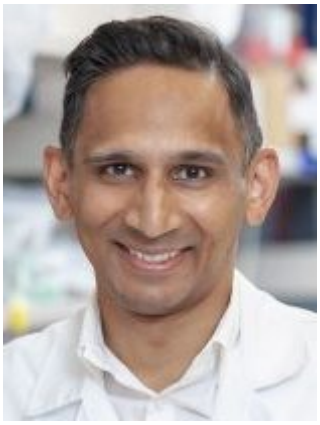
ISV WEBINAR SERIES

25 July 2024

Vinod Balachandran

Memorial Sloan Kettering Cancer Center

Pancreatic Cancer Vaccines



25 July 2024
08:00 (PDT) | 11:00 (EDT) | 16:00 (BST) | 17:00 (CEST) |
17:00 (SAST) | 23:00 (CST) |

26 July 2024
00:00 (KST)

Join Here: https://zoom.us/j/99021756132

27 August 2024

Eui-Cheol Shin

Korea Virus Research Institute

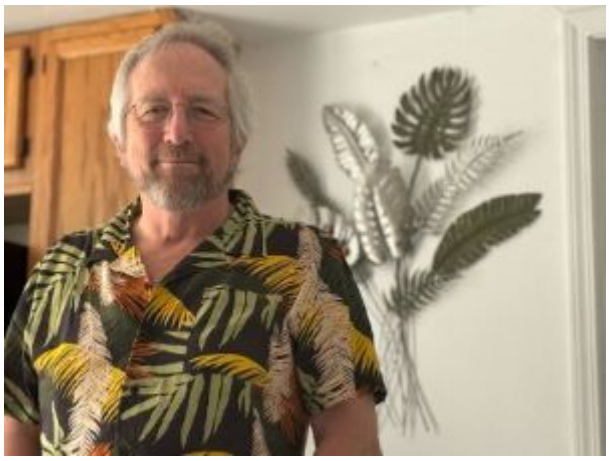
Phenotypic and functional characteristic of SARS-CoV-2 vaccine-induced T cells

27 August 2024
00:00 (PDT) | 03:00 (EDT) | 08:00 (BST) | 09:00 (CEST) |
09:00 (SAST) | 15:00 (CST) | 16:00 (KST)

Join Here: https://zoom.us/j/97714267152

ISV BOARD MEMBER INTRODUCTION

Ed Rybicki, University of Cape Town



What is your background/profession? (ie Professor, MD, PhD, director, etc)

My background is that I am a trained plant virologist – BSc, Honours, Masters and PhD degrees all from the University of Cape Town, with MSc and PhD in plant virology – who changed field in the 1990s due to funding for plant virus work drying up in South Africa. Part of the reason for the change to working on animal and human viruses (beak and feather disease virus of parrots, and HPVs and HIV) was my getting married to Anna-Lise Williamson in 1988, who said "Why don't you work on something useful?" when I was looking for what to do with myself 😊 Work on detection and genetic characterisation of HPV, HIV and other viruses led to working on vaccines for human papillomaviruses (HPV) and HIV in the late 1990s, and vaccinology became my research area until the present day.

What is your favorite/main research area/topic?

My main research area is the exploration of the use of plants to make high-value protein-based reagents, diagnostics and potentially therapeutics and vaccines, by means of Agrobacterium-mediated transient expression.

What's your main scientific achievements and contributions?

- Making HIV-1 subtype C Pr55Gag virus-like particles (VLPs) in insect cells and in plants, and demonstrating that these are potentially highly useful in prime-boost vaccination regimes in NHPs;
- Leading a team investigating the production of novel HPV L1 protein-based VLPs in insect cells and in plants that resulted in novel chimaeric VLPs made in insect cells and plants, as well as a decavalent vaccine candidate made in plants;
- Making VLPs in plants for both bluetongue virus and African horse sickness orbiviruses, and demonstrating efficacy/ immunogenicity of these as vaccine candidates;
- Pioneering the production of pseudovirions of HPV in plants; and
- Demonstrating that plant-made RNAs encapsidated in tobacco mosaic virus coat protein are viable reagents as well as being viable candidate vaccines.

Do you have any hidden talent/s?

My hidden talents are best kept hidden – however, I am a published science fiction author (two short-short stories in Nature), and a VERY bad guitarist.

Vaccine News Flash

Manon Cox, NextWaveBio & Jessica Price, AstraZeneca

In response to the avian H5N1 virus **outbreak in cattle**, first identified in March of this year multiple countries have procured vaccines to protect again this avian influenza. In addition, Reuters reported that Finland is planning to start administering vaccinations to dairy workers https://www.reuters.com/business/healthcare-pharmaceuticals/finland-start-bird-flunvaccinations-humans-2024-06-25/). To date four people have been reported to be infected. For a comprehensive update please check Center for Disease Control and Prevention (CDC) website @ Current H5N1 Bird Flu Situation in Dairy Cows | Bird Flu | CDC.

On May 31, the US Food and Drug Administration has approved a third vaccine to help protect people aged 60 and older from **respiratory syncytial virus** (**RSV**). This **mRNA** vaccine is produced by Moderna and sold under the name of mResvia. The two previously FDA approved vaccines for the prevention of RSV in adults, 60 years and older are **protein**-based and are produced by Pfizer (Abrysvo; Note: this vaccine is also approved for pregnant women 32 through 36 weeks of pregnancy to prevent RSV in babies from birth through 6 months of age) and GSK (Arexvy). Updated recommendations for RSV vaccinations were issued by CDC and can be found on RSV (Respiratory Syncytial Virus) Immunizations | CDC.

FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) met on June 5, 2024, to discuss and make recommendations on the selection of the 2024-2025 Formula for **COVID-19 vaccines** for use in the United States beginning in the fall of 2024. The committee unanimously voted to recommend a monovalent JN.1-lineage vaccine composition. The agency has further determined that the preferred JN.1-lineage for the COVID-19 vaccines (2024-2025 Formula) is the KP.2 strain, if feasible to ensure more closely match to circulating SARS-CoV-2 strains.

CNN reported on the roll-out of a second **malaria** vaccine in Africa starting June following its previously received recommendation for use by the World Health Organization's Strategic Advisory Group of Experts (SAGE) and the Malaria Policy Advisory Group (MPAG). The R21-MatrixM vaccine, was developed by the Jenner Institute at the **University of Oxford** and the **Serum Institute of India** (SII). The vaccine has shown an up to 77% efficacy in a trial of 450 children in Burkina Faso over 12 months and costs less than 4 USD per dose which is relatively cheap and has been hailed as a major milestone in the battle against one of the world's most deadly diseases. The SIII has already manufactured more than 25 million doses and has committed to producing up to 100 million doses a year, a scale that allows the vaccine to remain affordable. R21 vaccine: Children in Ivory Coast receive first doses of new malaria vaccine, hailed as major milestone | CNN

Hillevax (a Boston-based company) will discontinue its **Norovirus vaccine** HIL-214 for infants about 5 months old at the time of vaccination as it failed to meet its primary endpoint of efficacy against moderate or severe acute gastroenteritis events due to GI.1 or GII.4 norovirus genotypes in Phase 2b trial even though HIL-214 previously showed clinical benefit in adults. HilleVax to discontinue development of norovirus vaccine for infants; shares plummet | Reuters

The **FDA** issued a new draft guidance document to increase racial, ethnic and other **population diversity** in clinical studies with the objective to improve representation of populations despite higher rates of certain diseases in the underrepresented groups than in the general population. The goals for a study, or the "diversity action plan", should be set keeping in mind the estimated prevalence of a disease for which the drug or device is being evaluated. US FDA recommends steps to improve diversity in clinical trials | Reuters

Worcester HIV Vaccine reported on the successful completion of its Phase 1B Trial WHV 138. The polyvalent **DNA/Protein HIV Vaccine** candidate PDPHV was found to be safe and well-tolerated; no safety concerns were seen throughout the entire trial period. Immunogenicity analyses are ongoing and first results are similar to those of the HVTN124 trial, which have been published recently in The Lancet HIV. See: Latest News – Worcester HIV Vaccine (whvaccine.com)

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www.isv-online.org

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- 15% APC discount on the journal, *Human Vaccines and Immunotherapeutics*

To apply for the ISV Member benefit of a 15% discount to the Article Publishing Charge for the open access journal, Human Vaccines and Immunotherapeutics, contact info@isv-online.org to be provided with the guide and instructions. (A 50% discount is applicable to scientists from lower-middle-income countries; researchers from low-income countries are eligible for a full waiver (100% discount)).

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ISV on LinkedIn

ISV on Facebook

ISV on Instagram

GREETINGS FROM THE ISV BOARD

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Vaccine. 2024 Jul 11;42(18):3756-3767. doi: 10.1016/j.vaccine.2024.04.088. Epub 2024 May 9. PMID: 38724417
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Authors
Deok-Hwan Kim, Seung-Hun Lee, Jiwon Kim, Jiho Lee, Jei-Hyun Jeong, Ji-Yun Kim, Seung-Un Song, Hyukchae Lee, Andrew Y Cho, Ji-Yeon Hyeon, Sungsu Youk, Chang-Seon Song

Abstract
A Newcastle disease virus (NDV)-vectored vaccine expressing clade 2.3.4.4b H5 Hemagglutinin was developed and assessed for efficacy against H5N1 highly pathogenic avian influenza (HPAI) in specific pathogen-free (SPF) chickens, broilers, and domestic ducks. In SPF chickens, the live recombinant NDV-vectored vaccine, rK148/22-H5, achieved complete survival against HPAI and NDV challenges and significantly reduced viral shedding. Notably, the live rK148/22-H5 vaccine conferred good clinical protection in broilers despite the presence of maternally derived antibodies. Good clinical protection was observed in domestic ducks, with decreased viral shedding. It demonstrated complete survival and reduced cloacal viral shedding when used as an inactivated vaccine from SPF chickens. The rK148/22-H5 vaccine is potentially a viable and supportive option for biosecurity measure, effectively protecting in chickens against the deadly clade 2.3.4.4b H5 HPAI and NDV infections. Furthermore, it aligns with the strategy of Differentiating Infected from Vaccinated Animals (DIVA).

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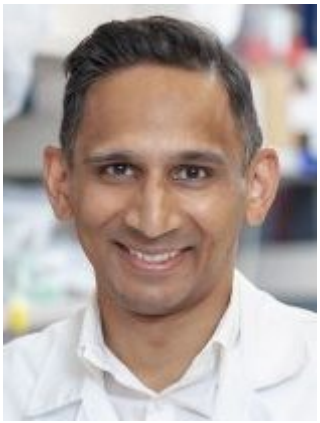
ISV WEBINAR SERIES

25 July 2024

Vinod Balachandran

Memorial Sloan Kettering Cancer Center

Pancreatic Cancer Vaccines



25 July 2024
08:00 (PDT) | 11:00 (EDT) | 16:00 (BST) | 17:00 (CEST) |
17:00 (SAST) | 23:00 (CST) |

26 July 2024
00:00 (KST)

Join Here: https://zoom.us/j/99021756132

27 August 2024

Eui-Cheol Shin

Korea Virus Research Institute

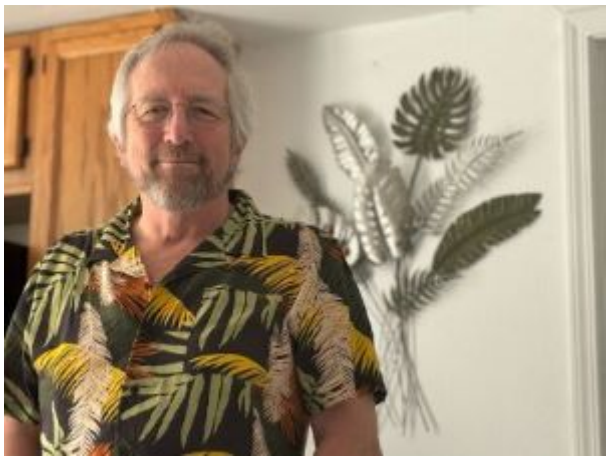
Phenotypic and functional characteristic of SARS-CoV-2 vaccine-induced T cells

27 August 2024
00:00 (PDT) | 03:00 (EDT) | 08:00 (BST) | 09:00 (CEST) |
09:00 (SAST) | 15:00 (CST) | 16:00 (KST)

Join Here: https://zoom.us/j/97714267152

ISV BOARD MEMBER INTRODUCTION

Ed Rybicki, University of Cape Town



What is your background/profession? (ie Professor, MD, PhD, director, etc)

My background is that I am a trained plant virologist – BSc, Honours, Masters and PhD degrees all from the University of Cape Town, with MSc and PhD in plant virology – who changed field in the 1990s due to funding for plant virus work drying up in South Africa. Part of the reason for the change to working on animal and human viruses (beak and feather disease virus of parrots, and HPVs and HIV) was my getting married to Anna-Lise Williamson in 1988, who said "Why don't you work on something useful?" when I was looking for what to do with myself 😊 Work on detection and genetic characterisation of HPV, HIV and other viruses led to working on vaccines for human papillomaviruses (HPV) and HIV in the late 1990s, and vaccinology became my research area until the present day.

What is your favorite/main research area/topic?

My main research area is the exploration of the use of plants to make high-value protein-based reagents, diagnostics and potentially therapeutics and vaccines, by means of Agrobacterium-mediated transient expression.

What's your main scientific achievements and contributions?

- Making HIV-1 subtype C Pr55Gag virus-like particles (VLPs) in insect cells and in plants, and demonstrating that these are potentially highly useful in prime-boost vaccination regimes in NHPs;
- Leading a team investigating the production of novel HPV L1 protein-based VLPs in insect cells and in plants that resulted in novel chimaeric VLPs made in insect cells and plants, as well as a decavalent vaccine candidate made in plants;
- Making VLPs in plants for both bluetongue virus and African horse sickness orbiviruses, and demonstrating efficacy/ immunogenicity of these as vaccine candidates;
- Pioneering the production of pseudovirions of HPV in plants; and
- Demonstrating that plant-made RNAs encapsidated in tobacco mosaic virus coat protein are viable reagents as well as being viable candidate vaccines.

Do you have any hidden talent/s?

My hidden talents are best kept hidden – however, I am a published science fiction author (two short-short stories in Nature), and a VERY bad guitarist.

Vaccine News Flash

Manon Cox, NextWaveBio & Jessica Price, AstraZeneca

In response to the avian H5N1 virus **outbreak in cattle**, first identified in March of this year multiple countries have procured vaccines to protect again this avian influenza. In addition, Reuters reported that Finland is planning to start administering vaccinations to dairy workers https://www.reuters.com/business/healthcare-pharmaceuticals/finland-start-bird-flunvaccinations-humans-2024-06-25/). To date four people have been reported to be infected. For a comprehensive update please check Center for Disease Control and Prevention (CDC) website @ Current H5N1 Bird Flu Situation in Dairy Cows | Bird Flu | CDC.

On May 31, the US Food and Drug Administration has approved a third vaccine to help protect people aged 60 and older from **respiratory syncytial virus** (**RSV**). This **mRNA** vaccine is produced by Moderna and sold under the name of mResvia. The two previously FDA approved vaccines for the prevention of RSV in adults, 60 years and older are **protein**-based and are produced by Pfizer (Abrysvo; Note: this vaccine is also approved for pregnant women 32 through 36 weeks of pregnancy to prevent RSV in babies from birth through 6 months of age) and GSK (Arexvy). Updated recommendations for RSV vaccinations were issued by CDC and can be found on RSV (Respiratory Syncytial Virus) Immunizations | CDC.

FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) met on June 5, 2024, to discuss and make recommendations on the selection of the 2024-2025 Formula for **COVID-19 vaccines** for use in the United States beginning in the fall of 2024. The committee unanimously voted to recommend a monovalent JN.1-lineage vaccine composition. The agency has further determined that the preferred JN.1-lineage for the COVID-19 vaccines (2024-2025 Formula) is the KP.2 strain, if feasible to ensure more closely match to circulating SARS-CoV-2 strains.

CNN reported on the roll-out of a second **malaria** vaccine in Africa starting June following its previously received recommendation for use by the World Health Organization's Strategic Advisory Group of Experts (SAGE) and the Malaria Policy Advisory Group (MPAG). The R21-MatrixM vaccine, was developed by the Jenner Institute at the **University of Oxford** and the **Serum Institute of India** (SII). The vaccine has shown an up to 77% efficacy in a trial of 450 children in Burkina Faso over 12 months and costs less than 4 USD per dose which is relatively cheap and has been hailed as a major milestone in the battle against one of the world's most deadly diseases. The SIII has already manufactured more than 25 million doses and has committed to producing up to 100 million doses a year, a scale that allows the vaccine to remain affordable. R21 vaccine: Children in Ivory Coast receive first doses of new malaria vaccine, hailed as major milestone | CNN

Hillevax (a Boston-based company) will discontinue its **Norovirus vaccine** HIL-214 for infants about 5 months old at the time of vaccination as it failed to meet its primary endpoint of efficacy against moderate or severe acute gastroenteritis events due to GI.1 or GII.4 norovirus genotypes in Phase 2b trial even though HIL-214 previously showed clinical benefit in adults. HilleVax to discontinue development of norovirus vaccine for infants; shares plummet | Reuters

The **FDA** issued a new draft guidance document to increase racial, ethnic and other **population diversity** in clinical studies with the objective to improve representation of populations despite higher rates of certain diseases in the underrepresented groups than in the general population. The goals for a study, or the "diversity action plan", should be set keeping in mind the estimated prevalence of a disease for which the drug or device is being evaluated. US FDA recommends steps to improve diversity in clinical trials | Reuters

Worcester HIV Vaccine reported on the successful completion of its Phase 1B Trial WHV 138. The polyvalent **DNA/Protein HIV Vaccine** candidate PDPHV was found to be safe and well-tolerated; no safety concerns were seen throughout the entire trial period. Immunogenicity analyses are ongoing and first results are similar to those of the HVTN124 trial, which have been published recently in The Lancet HIV. See: Latest News – Worcester HIV Vaccine (whvaccine.com)

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