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PROFILE

Vienna Vaccine Safety Initiative

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How and when did your organization start, and where are you located?

- We are an international think tank and non-profit organization, founded in 2008 in Vienna, Austria by an international group of doctors and scientists, who met to generate collaborative research and implementation projects in different parts of the world.
- In fact, in 2018 we will be celebrating our 10-year anniversary with a scientific workshop in Vienna, Austria.
- The Vienna Vaccine Safety Initiative (ViVI) Think Tank represents diverse geographic and professional backgrounds including in basic research, clinical trials, linguistics, infectious diseases, risk analysis, vaccines research & development, bioinformatics and computer sciences, pediatrics and family medicine, medical anthropology, global health, quality improvement, preventive medicine, and regulatory science.
- In 2011, ViVI was registered as a non-profit organization in Berlin, Germany and in 2015 as a separate legal entity (501c3 non-profit organization) in New Orleans, USA.

What are the most critical problems in vaccine/immunotherapeutics development in your field of interest?

- In an interconnected world, vaccine protection and the control of infectious diseases are of utmost importance. We now know more about the impact of infectious diseases than we ever did before, and we understand better how vaccines work to protect us. The development of new vaccines and immuno-therapeutics is advancing at impressive speed. The concept of "training" the immune system to recognize and eliminate pathogens quickly and effectively is compelling.
- At the same time, we are also learning how to tailor preventive and therapeutic measures to the individual. Novel biotechnologies and digital tools will help us to continuously improve the precision and effectiveness of vaccines, and to integrate preventive measures with the responsible use of diagnostics, antibiotics and antivirals. With more options on the table, patients ask about the "bottom line", i.e. the combined risk/benefit of any of the above interventions, weighed against each other.
- The rapid technological progress and increasing complexity of the matter have not yet been matched by a human-centered global health system. International interdisciplinary collaboration will be critical to generating sustainable immunization systems that will protect across borders and age groups while optimally serving the individual *and* the greater good.
- The recent decline in vaccine acceptance partly reflects a loss in public trust. It is up to us doctors and scientists to descend from our ivory towers and to take a stance – but first of all, we need to be willing to listen.
- The Vienna Vaccine Safety Initiative is inviting rather than confrontational, thereby bridging the communication gap between vaccine experts and the very people for whom vaccines and immuno-therapeutics are designed. The future of vaccination will require subject matter experts, who are able to swiftly recognize and resolve knowledge gaps while taking a humble and open-minded approach to being "opinion-leaders". It is our duty to translate complex scientific context into positive outcomes that will make a real difference in people's lives. This difference must be both tangible and sustainable.
- To this end, we work closely with experts in social sciences and human-centered design, who are challenging us to think outside of the box. Together, we are deeply invested in innovating the way we think about the future of health protection.

What is the mission of your organization?

The Vienna Vaccine Safety Initiative (ViVI; www.vi-vi.org) is an international scientific think tank and non-profit research organization. It is our mission

- To promote science-informed infectious diseases and vaccine safety research and communication;
- To stimulate thinking around key concepts and drive innovation in a globalised healthcare setting;
- To facilitate the implementation of high standards in vaccine safety and efficacy;
- To provide a platform for international and interdisciplinary scientific collaboration in infectious diseases and vaccines.

How does your organization facilitate vaccine/immunotherapeutics development?

- Each member of the Vienna Vaccine Safety Initiative is an active part of the scientific community looking at any given issue from a different angle, and from a different part of the world. ViVI projects and initiatives are developed and agreed upon by the Think Tank during regular meetings. Each member has the opportunity to propose new projects or manuscript ideas and to contribute to ongoing work in between sessions.

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- The interdisciplinary work process allows us to take a look at the big picture and to identify important areas of research and development that may have gone unnoticed. From the first day when we began working together until today, the momentum and productivity generated by this radically interdisciplinary work mode, has grown steadily.
- Through user-centered design, rapid prototyping and multiple iterations, we develop practical tools and solutions. In recent years, we have acquired significant expertise in combining the disruptive innovation technique of Design Thinking with the scientific scrutiny of implementation research and validation in "real-world" settings. Any successful idea or innovation emerging from the creative Design Thinking process will undergo critical appraisal and thorough scientific peer-review. The user-experience will be our guide throughout.

How does your organization engage national and international resources committed to vaccine/immunotherapy research?

- As a legal entity, we participate in expert panels, collateral partnerships, and in international research consortia. We regularly develop joint proposals to advance the important cause of vaccine safety and effectiveness. In addition to that, each member of the ViVI Think Tank represents a different national or international organization. As a group, we provide a significant representation of stakeholder agencies and institutions involved in health research and innovation.
- Rather than lamenting about the past, we are invested in improving the impact of vaccines and immunotherapy in the future. We will need a highly competent physician workforce that will be well versed in all relevant aspects of vaccine safety and the management of infectious diseases in adults and children. To this end, we are actively engaged in the training and education of doctoral students. The ability to present to and learn from international ViVI workshops and teleconferences keeps young trainees engaged and motivated. Our students have set important impulses, such as to get engaged in social media and e-health research.
- Lastly, to facilitate the communication of complex scientific content to the public, we also contribute to science-informed film/media projects and journalism when solicited for expert input.

What important partnerships does your organization have?

- The Vienna Vaccine Safety Initiative collaborates with academic and research institutions, NGO's and non-profit organizations in Europe, the United States, as well as in Africa, Asia and Latin America.
- Several of our m-health projects emerged from collaborations with the School of Design Thinking at the Hasso Plattner Institute in Potsdam, Germany, Europe's first Innovation School.[11]
- The implementation was then accomplished through collaboration with data standards organizations, software developers, bioinformaticians and computer scientists, as well as with experts in risk analysis and graduate medical education.
- To ensure that with everything we do, we meet an unmet need, we put great emphasis on working with patient and parent organizations that are active in the area of infectious diseases and vaccines. Projects inspired by questions from patents and parents, have lead us to collaborate with public health institutions and regulatory agencies.
- The Vienna Vaccine Safety Initiative is a founding member of the International Association of Innovation Professionals and an institutional member of the European Forum for Good Clinical Practice. We also contribute regularly to international panels such as WHO expert consultations, the EU Health Policy Platform, the Society for Risk Analysis, the Institute for Healthcare Improvement, the Coalition for Life-course Immunization, the Monarch Collaboration (aiming to improve the health of migrant and refugee populations through Immunization), the Asia Pacific Tropical Medicine Alliance, as well as scientific societies and advisory boards.

What is your position in the organization?

- I am the co-founder and chair of the Vienna Vaccine Safety Initiative.

What "highlights" would you select in recent vaccine/immunotherapy research, development, or use?

Here are three recent examples:

The ViVI Score™ – Measuring and reporting disease severity at the point of care

Challenge:

- Acute respiratory infections and flu-like illness are among the most common reasons for doctor's visits. In most cases, patients leave the clinic without knowledge of the cause of their illness and/or whether their symptoms could have been prevented or lessened by a vaccine.
- Parents and caretakers would like to know how severely their children are affected compared to others, and what to watch for as they return to home after a clinic visit. Many are uncertain as to when they need to go back to see the doctor.

Solution:

- We developed a standardized disease severity score (the ViVI Disease Severity Score™, (https://score.vi-vi.org) allowing healthcare professionals to monitor patients consistently and immediately, at the point of care.
- Use of the ViVI Score™ has been shown to improve quality of care, doctor-patient communication, vaccine effectiveness surveillance, pandemic preparedness, antibiotic stewardship, as well as the accuracy and interoperability of clinical trial data.[7,6,12]
- The tool works across the pediatric and adult age spectrum, for patients with mild cold symptoms all the way to severe cases requiring intensive care, and during initial evaluations as well as during follow-up visits.[3,8] The mobile application is available in multiple languages; a special edition for patient reported outcome measures is underway.
- The Score has since been validated in more than 7000 patients at major academic hospitals in Europe in collaboration with public health agencies, and is now also used in decentralized community clinics in the USA.[9]

- To support quality improvement programs at community clinics and emergency rooms, we established the PEDSIDEA project (Partnering of Enhanced Digital Surveillance of Influenza-Like Disease and the Use of Anti-infective and Vaccines). The PEDSIDEA Network consists of partner sites using the ViVI Score™ for the real-time surveillance of disease severity, antibiotic use, vaccine effectiveness and quality of life.

The VACC-Tool™ – A precision medicine approach to vaccine safety surveillance

Challenge:

- Adverse events following immunization (AEFI) are rare and hard to pick up in routine care.
- In an effort to standardize the reporting of adverse events, stakeholder organizations have developed and published international case definitions that should help to classify adverse events, regardless of the trigger.
- Most of these case definitions are hardly, if ever, put to use at the time a patient is seen. Some case definitions are complex consisting of several subcategories according to age or risk groups, and diagnostic accuracy levels. Once a patient has left the hospital, the data required for the case definition algorithms can no longer be retrieved.[13]
- A precision medicine approach to vaccine safety surveillance would require immediate and accurate differentiation between closely related disease entities, such as complex neuro-infectious/immunological adverse events.[5]

Solution:

- We developed the ViVI Automated Case Classification Tool (VACC-Tool™), a mobile application allowing doctors to assess the patient's status at the point of care – thereby comparing the disease presentation to multiple case definitions at the same time.[2]
- Most immunizations are performed during early childhood. This is why the VACC-Tool™ was specifically designed to perform across the pediatric and adult age spectrum.
- In the future, the VACC-Tool™ may be used to improve data quality in clinical trials and post-marketing surveillance. This will facilitate the reporting of vaccine safety signals to regulatory agencies. The data are in full compliance with international standards thereby facilitating meta-analysis and head-to head comparison of vaccines and/or anti-invectives.

The VAccApp™ – empowering parents to be well-informed about vaccinations in their family.

Challenge:

- Parents often feel poorly informed at the time when vaccinations are administered to their children. Too many parents leave the physician's office with very limited understanding of which vaccines were administered, which diseases their child should now be protected from, how extensive this protection may be and how long it may last.[11]
- Exploratory research revealed critical barriers to timely childhood immunizations and improved vaccine acceptance.[11] Parents are often asked to provide information on their children's immunization history based on memory; at the time when immunizations are administered however, they are not directly involved.
- Vaccination records are paper-based in many countries and poorly standardized, if at all. Parents moving from one country to another may be facing difficulty in keeping vaccination records in place and up to date.[4]

Solution:

- The Vaccination App (VAccApp™) aims to change that. The VAccApp™ is our first mobile application specifically developed for patients and their families. In fact, it is one of the first successful applications of human centered design to global health.[1]
- Rather than representing a simple "to-do list" or an "appointment reminder", the VAccApp™ represents an educational tool to improve patient safety and the monitoring of the "real-world" effectiveness of vaccines at the same time.
- The VAccApp™ is designed to empower parents and caretakers to becoming active partners with regards to vaccine protection. Its user-friendly design invites lay people to take a closer look at their own vaccination record and the records of their children and family members. This allows individuals to gain clarity about their personal level of health protection and to keep track of immunization visits. If clarification is needed, the app will keep a list of questions, readily available via smartphone during upcoming doctor's visits.
- The VAccApp™ prototype was scientifically validated in busy emergency rooms in Berlin, Germany and was able to improve vaccine communication significantly.[10]

What areas or topics does your organization currently focus on?

- The Vienna Vaccine Safety Initiative is the first research organization that combines the disruptive quality of Design Thinking with the rigor of scientific research.[1]
- The Think Tank process takes time and patience, but allows us to take a fresh look at unresolved issues in health protection. Our ability to focus on any given topic from a variety of different perspectives is what generates new ideas and surprising insight.
- The ViVI Think Tank continues to grow while leveraging its unique set of expertise. We regularly launch joint research projects and publications highlighting important aspects of global health, infectious diseases epidemiology, and vaccine safety.
- We are also increasingly involved in scientific advisory functions, multi-disciplinary consultation and innovation. The lean launchpad approach provides stakeholders with swift access to a variety of perspectives and novel concepts addressing key challenges. The Think Tank's solution-driven yet science-informed approach combined with a significant level of expertise in implementation research deliver realistic results swiftly.
- There is no use in developing sophisticated vaccines and antivirals unless they are recognized as safe and effective by the end-user. Communicating different options for disease prevention and management requires a paradigm shift. Keeping the big picture is key.

- Current research and implementation projects by the Vienna Vaccine Safety Initiative focus on adjuvants and other non-active ingredients in vaccines, on pandemic preparedness, on the role of immunizations in migrant health, and on the impact of vaccine prevention on antibiotic stewardship.

What are your main goals for the next 5 years?

- We are planning to further build upon and consolidate the work we have done in recent years. Whatever we do, it will be designed to be useful in high *and* low resource settings. The very composition of the Think Tank reminds us to never lose sight of our fundamental drive and motivation.
- The next years will be dedicated to scaling our mobile health tools and to making them accessible to healthcare professionals and patients in different parts of the world. Multi-lateral projects are underway to take this innovation to the next level and to demonstrate cross-border feasibility of our innovative quality improvement efforts.
- A key focus will be the PEDSIDEA project helping us to better understand the disease impact of influenza and other acute respiratory viral infections on the individual.
- We have also developed additional digital tools for refugees to report health needs in a confidential and anonymous setting. Once again, this work is based on scientific research in close collaboration with stakeholder agencies. We are now working with international expert consortia to make this tool useful to migrants and refugees, who will have significant input on the design.
- International partnership projects will always include and support the training of young professionals. Last but not least, we will continue to work with parent and patient organizations towards an ongoing, active dialogue.

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