Human Vaccines
Publication details, including instructions for authors and subscription information:
http://www.tandfonline.com/loi/khvi19

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Published online: 01 Aug 2009.

To cite this article: Tamar Ben Yedidia (2009) The 3rd international conference on Influenza Vaccines for the World- IVW 2009, Human Vaccines, 5:8, 508-509, DOI: 10.4161/hv.5.8.9108
To link to this article: http://dx.doi.org/10.4161/hv.5.8.9108

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Meeting Report

The 3rd International Conference on Influenza Vaccines for the World (IVW 2009)

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Key words: vaccines, influenza, pandemic, swine flu, epitopes, peptides

The Influenza Vaccines for the World (IVW 2009) conference was held in Cannes, France on April 27-30. Scientists and Influenza experts from academia and industry joined to discuss influenza vaccines and related issues. They reported the latest data and trends associated with current and new influenza vaccines, their worldwide availability and delivery. Specific interest was in influenza vaccine effectiveness, surveillance, stockpiling and preparedness for pandemic outbreaks. Adjuvants and the development of novel vaccines for seasonal and pandemic influenza was also addressed.

The conference opened concurrently with the report of the swine flu outbreak and the World Health Organization declaration of a pandemic level 5 alert, indicating sustained human-to-human viral transmission in numerous geographic locations (infection cases were detected in at least two countries at this stage, in Mexico and in the United States). None of the participants presented data related to this new emerging threat but intensive discussions transpired on the need for global preparedness for the “next pandemic”.

“The swine flu outbreak, reminds us of the unpredictability of the timing and speed by which a pandemic situation can change,” said Dr. Klaus Stohr (Novartis Vaccines, Boston, MA). One option he suggested to confront the pandemic situation is the use of tetravalent vaccines (rather than the trivalent combination in seasonal vaccines). Previously only the avian influenza viruses were considered potentially pandemic strains; now, the swine flu must be considered when planning and preparing for the next pandemic.

Similar to the “Spanish flu” outbreak in 1918, that was responsible for the death of 50 to 100 million people worldwide, the current swine flu mortality cases occurred mainly in young adults rather than the elderly and toddlers that are the “at risk populations” for seasonal influenza. Younger adults have a much stronger immune response to invading viruses manifested by intensive cytokines secretion. Once out of control, this excessive “cytokine storm” response, may lead to death following flu infection, said Robert Webster, Ph.D., of St. Jude Children’s Research Hospital in Memphis. The “cytokine storm” theory may explain the similarity of death pattern in the 1918 pandemic and in the recent avian flu and swine flu infections of human.

We should target the body’s exaggerated immune response and try to control it in addition to the anti viral treatment and prevention (using vaccines) said David Fedson, M.D. (Independent, Sergy Haut, France). Since we cannot predict future mutations or what the next pandemic strain will be, drugs like statins, fibrates and glitazones, known for their anti-inflammatory effect, may be a useful treatment for young adults. However these drugs may also pose as a challenge in treating the virus. This approach may become the only mean of pandemic control in countries that are not vaccine producers and will not have enough vaccine doses when pandemic outbreaks. Controlling the overreacting immune response is inexpensive and can save many lives in case of pandemic. Nevertheless, we should keep in mind that no studies have yet evaluated the use of these drugs in influenza.

The Dilemma: Which Vaccine to Produce?

One major dilemma discussed in the conference was related to the limited production capacity of influenza vaccines. Influenza vaccines are manufactured by nine companies in five countries, with a total production capacity of 300–400 million doses annually. The limited production capacity will become a political issue as manufacturing countries will use their entire production to vaccinate their own populations. In such a scenario, vaccine producing countries will not supply other countries, leading to an international crisis.

Another dilemma is which vaccine should be manufactured; the seasonal vaccine or the pre-pandemic vaccines either for avian flu or for swine flu? The pre-pandemic vaccine as presented by Dr. Klaus Stohr (Novartis Vaccines, Boston, MA) and also by Dr. David Fedson (Independent, Sergy Haut, France), must have the following characteristics: it must be safe, should be administered in a single dose, contain multiple components to increase strain match, prime for different influenza strains, be antigen dose sparing (less than 15 microgram HA of each strain administered in a single immunization is preferred) and supported by public funding. Achieving population immunogenicity is more important in this case than individual efficacy.
Universal Vaccine: A Peptide-Based Approach

One solution for this dilemma is the early use of a pre-pandemic vaccine, followed by pandemic vaccines when available. An additional approach was suggested by Dr. Tamar Ben Yedidia (BiondVax Pharmaceuticals Ltd., Ness Ziona, Israel) who described the development of a multimeric epitope-based universal vaccine against influenza. This vaccine is a single formulation that is expected to be efficient against most influenza strains and therefore is not strain dependent as current influenza vaccines. It is based on conserved epitopes, common to the majority of influenza strains and hence confers cross strain immunity as shown in pre-clinical models. Immunizing with such a vaccine replaces the annual vaccination with a specific influenza strain that does not always match the circulating strain in the following season. This vaccine is a recombinant polyepitope, comprising several repetitions of linear influenza epitopes derived from different viral proteins that are present in various strains of influenza including H1N1 (both human and swine flu), H3N2 and Avian influenza H5N1. This vaccine elicits both cellular and humoral immune responses, leading to protection of mice from a lethal influenza infection with H1N1 and H3N2 strains, as well as HP H5N1 avian influenza.

This universal vaccine candidate, is now being evaluated in a Phase I/II clinical trial.

Increasing Production Capacity

Another way to overcome the limited production capacity is by increasing vaccine production using alternative manufacturing processes such as growing vaccines strains in cell cultures rather than in eggs. Cell culture systems offer great flexibility in production as compared to egg derived vaccines. Production can be initiated at any time, it is scalable according to changes in demand, it is not associated with hen-egg allergy and does not rely on egg supply which is especially important when strains for avian flu are grown (no need for strain adaptation to egg culture). Dr. Sharon Frey (St. Louis University Medical School, St. Louis, MO); demonstrated the comparable clinical efficacy of Novartis Vaccine’s Cell-derived subunit trivalent influenza vaccine Optaflu and the egg-derived subunit trivalent influenza vaccine, Agrippal® in a phase III clinical trial. Both Optaflu and Agrippal were well tolerated; the immunogenicity and efficacy of both vaccines were comparable, demonstrating a statistically significant protection against culture-confirmed influenza caused by vaccine-like strains, fulfilling and exceeding the required criterion according to CBER guidance. This however will not solve the need to predict which strain will circulate in the coming season or cause the next pandemic in order to prepare the matching vaccine in time.

Another approach that may increase production capacity significantly in shorter timeframe was presented by Dr. Vidadi Yusibov (Fraunhofer USA Center for Molecular Biotechnology, Newark, DE) who is using plant cells for production of viral proteins. Since pandemic influenza strain is unknown and unpredictable, the availability of a rapid engineering and production system is most beneficial in combating influenza pandemic he said. Plants (Nicotiana benthamiana) have been used to produce recombinant HA from A/Indonesia/5/2005 and other seasonal strains of influenza H1, H3 and B that are expressed in the plant cytoplasm. Immunization of mice with this recombinant protein induced serum hemagglutination inhibition and virus neutralizing antibody titers in mice and protected ferrets against homologous virus challenge.

Finally, the different speakers and presenters at the IVW 2009 drown a realistic and cautious optimistic picture of coordinate global confrontation against imminent pandemic threat.