Ethical issues in immunisation seminar

IS IT UNETHICAL NOT TO HAVE A NO-FAULT COMPENSATION SCHEME FOR SERIOUS ADVERSE EVENTS ATTRIBUTED TO VACCINATION? IS THE CURRENT SYSTEM OF VACCINE POLICY MAKING IN AUSTRALIA SUFFICIENT? WHAT LEVEL OF VACCINE RISK IS ACCEPTABLE AND WHO SHOULD DECIDE? HOW FAR CAN WE GO IN PROMOTING VACCINATION?

Prepared by Kirsten Ward

These questions were addressed in a one-day seminar organised by NCIRS and the University of Sydney’s Centre for Values, Ethics and the Law in Medicine (VELiM), on 26 March 2012.

Following a Welcome to Country, the symposium was officially opened by Her Excellency Professor Marie Bashir, Chancellor of the University of Sydney. This was followed by a ‘this is your life’ account of Australia’s national immunisation program, jointly presented by Dr Julie Leask and Professor David Isaacs. The 85 attendees heard presentations from a range of interdisciplinary speakers and engaged in discussion on some of the major ethical issues facing immunisation programs in Australia today.

Is the current model of vaccine policy making in Australia sufficient?

Professor Terry Nolan, Chair of the Australian Technical Advisory Group on Immunisation (ATAGI), presented an overview of the mechanisms and principles of vaccine policy making in Australia, one pillar of the National Medicines Policy. Areas highlighted for improvement included enhancing direct/indirect community input into this process and increasing the
transparency of technical advisory information. The need to capture what citizens want in the national policy decision making process was further echoed by Professor Glenn Salkeld, former member of the Pharmaceutical Benefits Advisory Committee (PBAC) economic sub-committee. He highlighted that citizens came into the picture only through measurement of quality of life and disease outcomes, though could move beyond this to capture community values through standardised web-based tools.

Associate Professor Helen Marshall from the University of Adelaide used early findings from the Health Monitor Survey of South Australian adolescent females about HPV vaccine policy to highlight the value and potential methods of capturing community values to inform vaccine policy making.

What level of vaccine risk is acceptable and who should decide?

Associate Professor Kristine Macartney, Deputy Director at NCIRS and member of the Advisory Committee on the Safety of Medicines (ACSOM), stressed the challenge in defining what an ‘acceptable’ risk for vaccines is and the importance of assessing this from the clinical trials through to post-marketing surveillance. She emphasised that everyone has a role in deciding on acceptability though as experts it was important to communicate all potential risks before, during and after scientific assessment. ‘Acceptable risk is in the eye of the beholder’ was emphasised by Dr Claire Hooker, Senior Lecturer in Medical Humanities at the University of Sydney. When taking action on risks, actions speak louder than words (i.e. increase in disease rates, vaccine withdrawal). Based on case studies around the world, she advised that when faced with two ‘bad’ choices pick the one that preserves trust in your organisation, as this allows scope to negotiate later. Professor Roger Magnusson, Professor of Health Law and Governance, Sydney Law School, asked “where does good health start?” With populations or individuals? He drew on the example of testing blood donations for surrogate hepatitis B core antibody to illustrate how governments need to balance duties to the individual (e.g. prevention of blood-borne viruses) and to the population (e.g. reduced blood stocks).

Is it unethical not to have a no-fault compensation scheme for serious adverse events attributed to vaccination? Is this feasible?

Associate Professor Heath Kelly, head of the epidemiology unit at the Victorian Infectious Diseases Reference Laboratory (VIDRL), set the scene for this debate, painting an argument for such a scheme based on philosophical and ethical principles as well as redistributive justice. Currently 19 countries have accepted that society owes a duty of care, or gratitude, to the very few individuals damaged by a vaccine and have introduced no-fault vaccine compensation schemes.

There is evidence to suggest the existence of such a scheme actually improves confidence in publicly funded vaccination programs and has the potential to improve vaccine safety surveillance if adopted internationally. When asked why the Australian government does not support such a scheme, Associate Professor Kelly indicated that responses from various ministers and health department staff had thrown no light on this issue. Whatever these problems are, they need to be understood in order to address specific concerns.

Professor Cameron Stewart, Professor of Health, Law and Ethics at the University of Sydney provided the legal arguments in favour of such a scheme. As vaccination is a public good, individuals accept a very small risk; thus if that risk eventuates the public should accept responsibility, somewhat analogous to land title in the Torres system.

Dr Marie Bismark, a dually trained doctor and lawyer and former director of the New Zealand (NZ) Accident Compensation Commission (ACC), described the successful operation of a no-fault compensation scheme for vaccine-related injuries in New Zealand. Based on the principles of community responsibility,
comprehensive entitlement, complete rehabilitation, real compensation and administrative efficiency this scheme has, since 2005, covered all accidents and ‘treatment injuries’. The ACC receives 1.5 million claims a year out of 4.5 million NZ population, though over half are declined. The scheme is funded by the public, primarily though a levy paid by all wage earners and general taxation. Claimants may receive one-off or ongoing compensation based on their needs, which are regularly re-assessed. Claims for vaccine-related compensation between 2005 and 2011 (n=493) had a total cash cost of $469,412 with 90% being under $500. Most of these were related to influenza, tetanus toxoid, meningococcal and ‘other’ vaccines and were mostly for less serious events, including cellulitis, infection, skin damage, allergic reactions and haematoma.

Overall, this session highlighted that a no-fault compensation scheme for vaccine-related injuries: is doable, affordable and ethical.

How far can the Government go in promoting vaccination?

The workshop concluded with a panel discussion chaired by Dr Stacy Carter and featuring Dr Robert Hall, public health physician who has held many senior positions in his 30-year career in public health; Associate Professor Ian Kerridge, internationally recognised scholar in bioethics and the philosophy of medicine and director at VELiM; Stephanie Newall, health consumer advocate and consumer representative on ATAGI; and Dr Peter Massey, program manager for health protection and a clinical nurse consultant with Hunter New England Population Health.

The discussion in this session highlighted that other strategies to promote immunisation should be considered over appeals to fear, which had the potential to unethically place someone in a state of distress. Furthermore, the need to ensure that all groups had adequate access to vaccination must not be forgotten amidst these discussions. Highlighting the inequities in healthcare delivery across the state Peter Massey said, “how far can we go? About 100kms, up to the sandstone curtain, up to the national parks that surround Sydney, that is about how far the government goes to promote vaccination”.

A number of presentations from the day are available online at http://ncirs.edu.au/news/archive.php. Many people also shared key messages live via Twitter. A summary of these can be found in the TweetReach report online at www.ncirs.edu.au.

Postscript

NCIRS would like to thank the organising committee, Dr Julie Leask, Professor David Issacs, Dr Andrea Forde, Associate Professor Ian Kerridge, as well as session chairs, presenters and attendees for their time and contribution to making this a successful event. In particular, Ms Kirsten Ward and Ms Joanne Perkins are to be congratulated on their organisation and administration, helping make this event such a success. Thanks also to the VELiM for their support and collaboration.
RESEARCH THAT MAY HELP TO PREVENT THE SPREAD OF INFECTIOUS DISEASES AMONG MUSLIM PILGRIMS AT MECCA IS BEING CONDUCTED AT THE UNIVERSITY OF SYDNEY.
Prepared by Sandra Margon, Regional Manager in the Office of the Deputy Vice-Chancellor International

Our very own Professor Robert Booy has led a pilot trial to determine the efficacy of face masks in preventing respiratory infections, including influenza, at the Hajj.

With more than two million people from 180 countries gathering for the Hajj pilgrimage, dense crowding leads to the rapid spread of infectious diseases.

Professor Robert Booy’s team ran a pilot study among Australian pilgrims at the 2011 Hajj to test the effectiveness of face masks in protecting against influenza.

Dr Osamah Barasheed, a Saudi medical doctor and PhD student under the supervision of Dr Harunor Rashid, conducted the trial using a group of local medical personnel.

Currently, respiratory samples from pilgrims who developed symptoms of influenza are being tested.
Summer scholar Sophie Hale awarded second prize in the Dean’s Competition


Australia is currently in the midst of a sustained pertussis epidemic. There are few data on comparisons over time to assess the impact of changes in diagnostic testing and whether there has been a change in the severity of pertussis infection. This study documented changes in pertussis hospitalisations in the last decade at The Children’s Hospital at Westmead and found that the use of PCR has enabled more cases previously clinically diagnosed to be laboratory confirmed, infants <6 months of age continue to be at high risk for hospitalisation and intensive care admission, and that most are too young to be protected by current vaccine schedules. Timely immunisation, particularly the first two doses, in infancy, is essential to protect these young infants.

SCHOLARSHIP AWARDED

Kerrie Wiley was awarded an NH&MRC postgraduate scholarship to complete her PhD, in which she is exploring uptake of influenza vaccine by pregnant women, and women’s attitudes toward vaccination during pregnancy. The study is also looking at women’s attitudes toward whooping cough vaccination post-partum. From the study she aims to develop an educational intervention to help women make an informed decision about having an influenza vaccine during pregnancy.

“I feel very fortunate to have my research supported like this. Ultimately this research will help pregnant women, in partnership with their health care providers, to make confident decisions about influenza vaccination during pregnancy.”

PhD THESIS RECENTLY SUBMITTED

J. Kevin Yin recently submitted his PhD thesis, “The epidemiological and economic impacts of healthcare interventions to control influenza: implications for policy”. He was supervised by Prof Robert Booy, Prof Glenn Salkeld and Prof Kathryn North. His PhD projects included two Australian Research Council Linkage grants (assessing the social, economic and health impacts of oseltamivir use in aged care facilities [ACFs] and influenza vaccination in day care centres). His research mainly evaluated the clinical and cost effectiveness of influenza control measures, taking into account both health and economic perspectives. His work showed that treatment and prophylaxis with oseltamivir had clinical and cost effectiveness advantages over treatment only, and excellent safety supports the guideline statements advocating such a policy for management of influenza outbreaks in ACFs. His research also provided evidence about the efficacy of seasonal trivalent influenza vaccine in young children and assessed the burden of influenza-like illnesses in children. In addition, Kevin’s PhD provided answers to some important questions related to the control of the 2009 H1N1 pandemic. His research found a pre-existing influenza A antibody reserve in older Australians that was cross-reactive to the new pandemic (H1N1) 2009 virus. He has also systematically examined the safety, immunogenicity and effectiveness of the pandemic vaccines.

Kevin’s research has contributed to the epidemiological and economic impacts of healthcare interventions to control seasonal and pandemic influenza. He suggests that fully assessing the impacts of a control measure for an infectious disease like influenza is complex and we have much to learn and apply. Close to finishing his PhD, Kevin won the prestigious “Chinese Government Award for Outstanding Self-Financed Students Abroad.”
This review describes the different considerations relevant to decision making around the introduction of universal adolescent male HPV vaccination in Australia, the evidence that currently exists and the remaining uncertainties.

One HPV vaccine is registered for use in males in Australia, but only females are currently included in nationally funded HPV vaccination programs around the world. Late last year, both the US and Canadian authorities recommended vaccination of adolescent boys and young men with the quadrivalent vaccine. Recently, the Australian Pharmaceutical Benefits Advisory Committee recommended that the quadrivalent vaccine would be cost-effective if given to boys aged 12–13 years via the National Immunisation Program (NIP) with a catch-up program over 2 years for boys aged 14–15 years. This proposed change to the NIP is under consideration by the Australian Government.

In light of this, the Review article discusses the Australian burden of HPV-associated diseases in males, current evidence of vaccine efficacy against these diseases and published estimates of the cost-effectiveness of alternative male vaccination strategies. The paper also highlights the social and ethical factors that are important in HPV vaccination decisions. Although the body of evidence surrounding HPV disease and its prevention in men has increased, the existing uncertainties need to be kept in mind. The features discussed in this Review are applicable, with caveats, to policy making in other developed countries.

“Melina’s review in Lancet ID is definitely a career highlight for me. It was great to see the work that we do within the policy team progress into a manuscript that shares the research with the wider immunisation policy community.”

- Melina Georgousakis
INTERNATIONAL VISITORS

Chinese CDC staff visit NCIRS

A DELEGATION FROM THE CHINESE CENTER FOR DISEASE CONTROL AND PREVENTION (CDC) IN BEIJING VISITED NCIRS IN APRIL AS PART OF THE CHINESE CDC FUNDING AGREEMENT FOR THE PROJECT “DEVELOPMENT AND IMPLEMENTATION OF A POST-MARKETING EVALUATION SYSTEM OF VACCINES AND DEVELOPING NATIONAL IMMUNIZATION STRATEGY FOR NEW VACCINES.” THIS PROJECT IS A COLLABORATIVE PROJECT BETWEEN NCIRS; THE SCHOOL OF PUBLIC HEALTH AND COMMUNITY MEDICINE, UNSW; THE SCHOOL OF POPULATION HEALTH, UNIVERSITY OF QUEENSLAND AND THE CHINESE CDC.

Prepared by Dr Aditi Dey

The delegation included Dr Huaqing Wang, Deputy Director of National Immunisation Program (NIP); Dr Jingshan Zheng, Director of Immunization Service Division of NIP; Dr Keli Li, Deputy Director of AEFI Surveillance Division of NIP; and Ms Disha Xu, staff of AEFI surveillance division of NIP. The delegation visited the NSW Ministry of Health where they were warmly welcomed by Dr Jeremy McAnulty and Sue Campbell-Lloyd. An overview of immunisation service delivery in NSW and a brief orientation to the Australian National Immunisation Program was presented to the delegation on this day. The delegation also visited the TGA in Canberra to get further insights on the AEFI surveillance system in Australia. At NCIRS, they had an opportunity to interact with several staff members including Mandarin-speaking staff. Several potential collaborative projects were discussed and Dr Wang provided an overview of China’s national immunisation program. The delegation also visited Granville high school to observe a school-based immunisation service. On the last day of their visit to Australia, the delegation had the opportunity to visit a state Vaccine Centre and the School of Public Health and Community Medicine at UNSW to further discuss potential collaborative research projects. Overall, it was a very successful visit by the Chinese CDC delegation, which was only possible because of the good will and support of our key stakeholders.

Post PHAA Immunisation Conference Seminar Day
IMMUNISATION – REACHING FOR THE TOP
Time: 7:00 am – 2:00 pm
Date: 22 June 2012
Location: Darwin Convention Centre
Cost: $195

A number of NCIRS staff will be participating on the day.

Download programs and register at: https://www4.eventsinteractive.com/pha/getdemo.i?id=407016&s=_AQO0PZ8HK
SUMMARIES FROM OUR RECENT JOURNAL CLUB SESSIONS

A vaccine for malaria

First results of phase 3 trial of RTS,S/AS01 malaria vaccine in African children

**THERE ARE CURRENTLY EFFECTIVE INTERVENTIONS TO REDUCE MORBIDITY AND MORTALITY FROM MALARIA USING INSECTICIDE-TREATED BED NETS, INSECTICIDES AND ARTEMISININ-COMBINATION TREATMENTS.**

Prepared by Dr Aditi Dey

There are also several potential malaria vaccines that are in various stages of development. The RTS,S/AS01 vaccine is considerably further along the path to registration and potential deployment than other potential malaria vaccines. The vaccine has been developed in a public-private partnership with GlaxoSmithKline; Program for Appropriate Technology in Health (PATH) Malaria Vaccine Initiative; and the Bill and Melinda Gates Foundation. The RTS,S/AS01 malarial vaccine is a hybrid construct of the HBsAg fused with a recombinant antigen. The phase 3 trial of this vaccine started in May 2009 and has completed enrolment in seven countries in sub-Saharan Africa: Burkina Faso, Gabon, Ghana, Kenya, Malawi, Mozambique and the United Republic of Tanzania. There are 15,460 children in two age categories (6 to 12 weeks and 5 to 17 months) enrolled in this study. The full phase 3 trial results will become available in 2014. The interim results of the trial include vaccine efficacy against *P. falciparum* malaria in the first 6000 of 8923 children in the older age category (5 to 17 months) and an evaluation of the first 250 cases of severe malaria. The protective efficacy against all *P. falciparum* malaria episodes is 55% and the protection against severe malaria is 35%. There was a higher risk of febrile seizures and meningitis among RTS,S/AS01 recipients than among those receiving the comparator vaccine. The implications of these findings include active surveillance for safety and effectiveness, if this vaccine is deployed.

Reduced intradermal test dose of yellow fever vaccine induces protective immunity in individuals with egg allergy

**THIS STUDY FOLLOWS ON FROM A PREVIOUS STUDY* BY THE SAME AUTHORS WHO FOUND THAT AN INTRADERMAL DOSE OF YELLOW FEVER VACCINE PRODUCED PROTECTIVE IMMUNITY IN HEALTHY, NON-ALLERGIC SUBJECTS.**

Prepared by Kath Cannings

The yellow fever 17D (YF-17D) vaccine strain is propagated on embryonated chicken eggs and consequently the vaccine contains a small amount of egg protein. In Holland, where this study was conducted, the protocol for yellow fever vaccination in a person with history of egg allergy involves giving a test dose, 0.1mL of the vaccine administered intradermally. The test is read after 30 minutes. If there is a positive reaction (i.e. wheal greater than twice the size of the control), further vaccination is abandoned. The authors obtained serum from 7 out of 11 patients who had received the test dose and developed positive reactions at the outpatient travel clinic of the Leiden University Medical Center.

Neutralising antibodies were measured by constant virus-varying serum dilution Plaque Reduction Neutralisation Test. The sera from all 7 patients showed levels of neutralising antibody indicative of protection. There were no adverse reactions to the test dose in the 7 patients in addition to the local wheal formation. The authors conclude that a test dose of 0.1mL of YF-17D vaccine appears to be sufficient for production of protective antibodies in non-allergic as well as allergic persons. However, they admit that the sample size of this study was too small to conclude that post-vaccination testing would no longer be necessary after an intradermal test dose.

RECENT PUBLICATIONS


Hooker C, King C, Leask J. Journalists’ views about reporting avian influenza and a potential pandemic: a qualitative study. Influenza and Other Respiratory Viruses [Epub ahead of print]

Mehr S, Wood N. Streptococcus pneumoniae – a review of carriage, infection, serotype replacement and vaccination. Paediatric Respiratory Reviews [Epub ahead of print]

Rashid H, Khandaker G, Booy R. Vaccination and herd immunity: what more do we know? Current Opinion in Infectious Diseases [Epub ahead of print]


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