

Newsletter

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National Vaccine Safety Workshop

A National Vaccine Safety Workshop was held in Sydney on 17 November 2005, sponsored by NCIRS, the Australian Government Department of Health and Ageing and the National Immunisation Committee. The workshop was attended by 40 invited representatives of federal, state and territory health departments, regulatory authorities, general practitioners, clinical immunisation specialists, industry and consumers. The workshop started with a presentation, by Dr Mike Gold (University of Adelaide), outlining recent WHO and USA initiatives in surveillance and clinical management of adverse events following immunisation (AEFI). This was followed by a series of presentations on current post-licensure vaccine safety practices in Australia at the national, jurisdictional and local levels, focussing mainly on AEFI surveillance and clinical management.

This formed the basis for the second part of the workshop where participants divided into three working

groups to discuss issues and formulate draft recommendations in the areas of surveillance, clinical management and research, and communication. A report summarising the workshop presentations will soon be available on the NCIRS website.



Participants from the National Vaccine Safety Workshop

Guest presentation

Dr Shelley Deeks

Dr Shelley Deeks, a public health physician from the Immunization and Respiratory Infections Division, Centre for Infectious Disease Prevention and Control, Public Health Agency of Canada, is secretary for the Canadian equivalent of ATAGI (NACI).

Dr Deeks outlined the processes and outcomes of a two day HPV vaccine research workshop held in Canada in November 2005. The goal of the workshop was to develop research priorities for HPV vaccine use in Canada by bringing together 55 invitees from the areas of immunisation, sexually transmitted infections, cancer, obstetrics and gynaecology, and industry. Following introductory presentations, workshop participants discussed research priorities in the areas of burden of

disease, vaccine research and program delivery, using an analytical framework, recently published in *Vaccine* 2005 Mar 31;23(19):2470-6. Participants voted on the importance and feasibility of potential research areas using a 5 point Likert scale. Program delivery was seen as most important, but challenging to fund. Recommendations arising included the need for a clear articulation of national goals for HPV vaccination programs and for a clear recognition that HPV vaccine must not come at the expense of cervical cancer screening programs. Proceedings of the workshop are being prepared for publication.

NCIRS Rotavirus symposium



Some of the Rotavirus Symposium speakers

On Saturday, April 8, 2006, NCIRS held a Rotavirus Symposium at the University of Sydney. The Symposium

was attended by 68 participants including a number of eminent invited speakers and representatives from many jurisdictions throughout Australia.

We were honoured to hear presentations from Professor Ruth Bishop, who first described rotavirus as a cause of infant gastroenteritis in 1973, and from leading rotavirus investigators, Professor Miguel O'Ryan from Chile and Professor Mathuram Santosham from the USA, who recently published phase III vaccine studies of the two upcoming rotavirus vaccines. Various Australian States and Territories presented information on the existing disease burden from rotavirus in Australia and discussion of surveillance options was chaired by Dr Vicki Krause (CDNA). Presentations are available on the NCIRS website <http://www.ncirs.usyd.edu.au/newsevents/index.html>

Recent NCIRS Publications

- ◆ Beard F, McIntyre P, Gidding H, Watson M. Influenza related hospitalisations in Sydney, New South Wales, Australia. *Archives of Disease in Childhood* 2006;91:20-5.
- ◆ Joseph TL. The implementation and evaluation of a program in Western Sydney to increase uptake of Prevenar™ vaccine in Indigenous babies (orated by Nola Brindell). *Aboriginal and Islander Health Worker Journal* 2006;30:22-3.
- ◆ Yohannes K, Roche PW, Roberts A, Liu C, Firestone SM, Bartlett M, East I, Hull BP, Kirk MD, Lawrence GL, McDonald A, McIntyre PB, Menzies RI, Quinn HE, Vadjic C. Australia's notifiable diseases status, 2004. Annual report of the National Notifiable Diseases Surveillance System. *Communicable Diseases Intelligence* 2006;30:1-79.
- ◆ Burgess DC, Burgess MA, Leask J. The MMR vaccination and autism controversy in United Kingdom 1998-2005: inevitable community outrage or a failure of risk communication? *Vaccine* 2006;24:3921-8.
- ◆ Hull BP, McIntyre PB. Timeliness of childhood immunisation in Australia. *Vaccine* 2006;24:4403-8.
- ◆ Wallace C, Leask J, Trevena L. A web-based decision aid pilot improves parental attitudes to MMR vaccination: a before and after study. *BMJ* 2006;332:146-9.
- ◆ Watson M, McIntyre P, Menzies R, Gilmour R. The association of respiratory viruses, temperature, and other climatic parameters with the incidence of invasive pneumococcal disease in Sydney, Australia. *Clinical Infectious Diseases* 2006;42:211-5

NCIRS Fact sheets related to vaccine safety

Available on the NCIRS website are relevant fact sheets related to vaccine safety. Recent fact sheets updated include *Hepatitis B vaccine* and *multiple sclerosis* and *Thiomersal*.

A new fact sheet was added in January 2006 describing resources for addressing patient/parent concerns about immunisation. This fact sheet provides a list of resources available for health professionals and other immunisation providers to help discuss questions from patients/parents who have concerns about immunisation. This and all NCIRS fact sheets can be found at the following website address <http://www.ncirs.usyd.edu.au/facts/facts.html>

Recent Journal Club topics

Epidemiology of respiratory infections in young children - insights from the New Vaccine Surveillance Network. M.R.Griffin et al PIDJ Nov 2004;23(11 Suppl):S188-92 - Presented by Rob Menzies, Epidemiologist, NCIRS

This paper describes a surveillance network established in the US to provide data on diseases for which vaccines are soon to be, or have recently been, introduced for children. Funded by the CDC and established in 2000, three urban regions (Davidson, New York; Monroe, Tennessee; Hamilton, Ohio) provide data from their local hospital on in- and out-patients, and from local primary health clinics. Subject to parental consent, all presenting children aged <5 years with fever and/or acute respiratory symptoms have nose and throat swabs for viral culture and PCR testing, and a parental interview. In the first year, viruses were identified in 61% of admitted children, mostly RSV (20%), followed by parainfluenza (7%) and influenza (3%). PCR testing resulted in 1.5-2.6 fold increase in sensitivity, differing between viruses. Over four years, influenza was responsible for 9 / 10,000 hospitalisations, varying greatly between regions and years. This network provides population-based estimates of hospitalisation and consultation rates for disease due to respiratory viruses, before introduction of a vaccine, and impact after introduction. Data have already contributed to the development of vaccination recommendations by the Advisory Committee on Immunisation Practices, particularly for influenza. Some aspects of this network may be relevant to the evaluation of vaccination programs in Australia.

Modelling the effect of a booster vaccination on disease epidemiology. M.E. Alexander et. al. Journal of Mathematical Biology online - Presented by Dr James Wood, Postdoctoral Fellow, NCIRS

This paper looks at the effect of booster vaccination for infectious diseases with immunity that wanes over time. The model they use is a twist on the SIR models popularised by Anderson & May, and incorporates a seasonally varying risk of infection. Differences in transmission by age, and the timing of the booster shot are not considered, and thus their model still requires some development before it can be used as a guide to vaccination policy. This theoretical approach is also apparent in the content, which is heavy with formulae. Nonetheless, they reach some interesting conclusions about vaccine efficacy in the presence of waning immunity and illustrate their results by using vaccination against measles as an example.

Satellite Symposium, Vaccine Preventable Diseases in Indigenous Populations - International Perspectives, Alice Springs April 1-2, 2006

NCIRS jointly organised this Symposium with funding support provided by OATSIH. It was held as a satellite meeting of the 5th International Symposium on Pneumococci and Pneumococcal Disease. The aim of the meeting was to initiate collaboration between researchers in this field in Australia, Canada, New Zealand and the United States. The one-day meeting was preceded by a dinner and cultural exchange function. Presentations were made from each country on cultural perspectives, the general health and vaccine preventable disease burdens in indigenous populations, examples of indigenous participation in research projects and models for conducting ethical research in indigenous health. Presentations were made by representatives from the following Australian and international research and public health organisations: the Indian Health Service, Johns Hopkins Centre for American Indian Health, Centers for Disease Control Arctic Investigations Program, First Nations and Inuit Health Branch Health Canada, the University of Auckland, the Cooperative Research Centre on Aboriginal Health, Menzies School of Health Research, and NCIRS. Representatives with an interest in the area attended and presented from Australian Aboriginal and



Satellite Symposium dinner speakers

Torres Strait Islander, Maori, Navajo, White Mountain Apache, Canadian Inuit and Canadian First Nations communities.

The following suggestions are currently being pursued by NCIRS with other collaborators:

- Write a symposium summary for submission to a peer-reviewed journal,
- Establish an email interest group as a forum to discuss issues of common interest,
- Joint research projects providing greater numbers and therefore statistical power, eg. analysis of Hib surveillance data,
- Further face-to-face meetings, eg. another symposium on this issue at the next ISPPD in 2008.

Presentation slides from this meeting will be placed on the NCIRS website.

Guest presentation

Prof Bill Rawlinson - Congenital CMV

Prof Rawlinson, guest speaker from the Virology Division, in the Microbiology Department, South Eastern Area Laboratory Services (SEALS) at Prince of Wales Hospital, presented work from studies he, Lyndall Brennan, Sian Munro, Maria Craig, Cheryl Jones, Gillian Scott and others have been carrying out on congenital cytomegalovirus (CMV) - recently published in *J Clin Micro* 2005;43:5102-10; *J Paed Ch H* 2005;41:449-52, *J Clin Micro* 2005;43:4713-18.

CMV is the most common viral cause of congenital malformation in Australia, with an estimated 1500 infants being infected with CMV annually. Of these infections, 15% will be symptomatic at birth (30% fatally); of the remaining 1255 asymptomatic infants, an estimated 15% will develop CMV sequelae later in life.

CMV is a beta herpesvirus, and can be transmitted from mother to fetus either transplacentally, or possibly others such as intrapartum routes. CMV infection involves multiple organ systems, with particular preference for the reticuloendothelial and central nervous system (CNS).

Symptoms and signs including petechiae, jaundice, hepatosplenomegaly, microcephaly, intrauterine growth restriction, and seizures have been reported in studies. Ten to fifteen percent of asymptomatic infants may exhibit delayed clinical manifestations such as deafness, mental retardation and chorioretinitis, which can all appear during the first two years of life.

Congenital diagnosis is by clinical suspicion (although at least half of infected women are asymptomatic), CMV specific serology - particularly using IgM, and IgG avidity, and in some cases by amniocentesis (NAT, Q-NAT, culture). There are several candidate vaccines against CMV in various stages of preclinical and clinical testing, many are based upon multiple antigen presentation. Previous unsuccessful vaccines have included peptide subunit, live attenuated and multiple antigen vaccines. Vaccine strategies could include vaccinating all people, vaccinating anyone who is seronegative, vaccinating seronegative women prior to pregnancy, or vaccinating people before immunosuppressive treatments.

Commonly asked questions (and answers!)

Responding to vaccine doubters: a guide for providers

Dr Julie Leask

Many of us, particularly those who have cared for those with, or experienced, vaccine preventable diseases, can be dismayed when parents reject immunisation for their children.

In our eagerness to try & reassure vaccine doubters, it can be easy to leap in with information & advice. Before we do so, it's important to find out more. Is this person completely opposed to vaccination or just concerned? Where did their concerns originate? Was it from a bad experience such as unanticipated side effects or just a general approach to healthcare? Do they worry about one vaccine or all of them? Have they ever had any doubts about their vaccination decision?

Determining whether the parent is a fence sitter or completely opposed can help providers devote precious consultation time to where it's most likely to be effective. Fence sitters might be just seeking reassurance & will sometimes only be concerned about one vaccine such as the safety of MMR or the necessity of Hepatitis B vaccine. Health professionals have a profound influence on most parents' vaccination decisions. For fence sitters, it may only require a frank & unpatronising discussion, perhaps referring them to other resources such as the NCIRS website fact-sheets & MMR decision aid at <http://www.ncirs.usyd.edu.au/> or a point by point resource <http://immunise.health.gov.au/myths2.pdf>

For people whose bad experience has made them doubt vaccination, specialised immunisation clinics in most major capitals provide a venue where consultant paediatricians & nurses with immunisation expertise can assess the child,

provide advice & supervised vaccination.

From the research undertaken by NCIRS, parents who completely oppose all vaccines can be very hard to convince of the safety & importance of vaccination. Their views are attached to a wider approach that rejects conventional medicine & government intervention. Many such parents have the support of peers & health providers like a naturopath & so accepting vaccination might not just cause health concerns but also social ostracism. Given the lack of trust these parents tend to have in conventional medicine & government, written materials might not help either. Presented with pristine epidemiological evidence, many opponents say all vaccine research is funded by the pharmaceutical industry, hence untrustworthy. Providers might even find that such parents will try to convince them of their viewpoint, offering to loan books & research articles.

Some vaccine rejectors might agree to a compromise such as delayed or selective vaccination on the basis that something is better than nothing. For parents who clearly won't change their view, the best tactic might be in asking about their plans to help their child avoid some of these diseases which are around at present, eg, whooping cough & measles, perhaps even giving advice on other infection control measures. Refusal to sign a conscientious objector form or refusal to treat the child raises challenging ethical issues surrounding the rights of the child, parent & provider. While some might find this a successful strategy, it may also risk further alienating people already sceptical of orthodox medicine with the worst outcome being that parents are less forthcoming when the child requires urgent medical care. In rural areas, where access to health providers is already limited, treatment refusal based on vaccination rejection might further limit this access.