

Vaccine Trials Group Annual Review 2006



Introduction



The Vaccine Trials Group (VTG) was formed in March 1999 to provide a coordinated approach to the development, delivery, assessment and promotion of vaccines and allergy treatments in the community. It is a combined unit involving the Telethon Institute for Child Health Research, Princess Margaret Hospital for Children and the University of Western Australia School of Paediatrics and Child Health. The group has strong links with the Health Department of Western Australia and vaccine companies.

Our Mission

To improve the health of the community through immunisation and the prevention of infectious diseases

Our Aims

- to promote vaccine use in our community
- to study the safety and effectiveness of immunisation
- to conduct high quality clinical, epidemiological and laboratory research
- to prevent infection
- to improve the treatment of infection
- to provide training in clinical research and vaccinology

Key Research Areas

- Meningitis
- Respiratory Disease
- Human Papilloma Virus and the prevention of cervical cancer
- Ear, Nose and Throat Infections: Treatment and Prevention
- Other Immunisation Research

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From the Head of Department

The Vaccine Trials Group has had a very busy 2006 which has seen the research group attract national and international attention with a number of groundbreaking studies.

We have grown significantly to cope with the increased amount of clinical research (20 studies in the active clinical or laboratory phase) with more than 30 staff employed by VTG and an annual budget of over \$1million.

Importantly, our expertise in clinical research has been recognised by leading to a number of early phase studies that are critical in vaccine development. We were selected by the US vaccine manufacturer, Wyeth, as one of three sites to conduct a Phase I study of a new meningococcal B vaccine that is expected to provide protection against a broad variety of different group B strains which now cause almost all meningococcal disease in WA. The successful completion of this project has led to studies in toddlers and adolescents for this high priority vaccine. We are now involved in early phase studies in infants and toddlers of combination meningitis vaccines.

An effective avian influenza ("bird flu") vaccine is a critical part of preparing for an influenza pandemic. The VTG performed pivotal Phase I-II studies of an H5N1 bird flu vaccine manufactured by Australian company CSL Ltd. Funded by the National Health and Medical Research Council, the study involved more than 350 adults, elderly volunteers and young children in 2006. These studies were well supported by the Perth public and media and have led to the submission of the H5N1 vaccine for registration with the Therapeutics Goods Administration for use in the event of a pandemic.

In addition to clinical trials, we have also been active in other immunisation research. Understanding the epidemiology of infectious diseases is important in estimating the need for vaccines and determining likely impact and cost-effectiveness when new vaccines are introduced. Studies of human metapneumovirus in high-risk young infants and a study of hospitalisation of children with rotavirus gastroenteritis with other collaborators were completed in 2006, with the latter study being important in the decision to introduce rotavirus vaccine for all infants on the routine schedule in 2007.

Vaccines only work if children receive their immunisations in a timely manner and unfortunately WA has been lagging behind other States in our immunisation rates. Therefore, we undertook a study with the Health Department of WA of parents of children attending the Central Immunisation Clinic at Rheola Street to find out why they were choosing to be immunised at the clinic, and why some children had not completed their immunisations on time. Undertaking qualitative research of parental attitudes to immunisation and factors affecting uptake is likely to be critical in the future with the number of new vaccines being introduced for children and adolescents. One of our research nurses, Janet McBride, is reviewing the implementation of the HPV program in schools for her Masters thesis. Following this she will be examining parental perceptions of the new human papilloma virus vaccine for cervical cancer.

We continue to research why some young children are particularly prone to recurrent ear, nose and throat infections and why particular populations, such as babies in Aboriginal communities and in Papua New Guinea, are particularly prone to pneumonia and severe pneumococcal infections. These studies are looking at immune responses to common bacteria that cause these infections in collaboration with the Menzies School of Health Research in the Northern Territory, the Ear Nose and Throat and Microbiology Departments at Princess Margaret Hospital and the Papua New Guinea Institute for Medical Research. Preliminary results suggest that, in these populations, exposure to these bacteria in early infancy impacts on immune memory and long term protection against these common infections. In addition, the role of bacterial slime ("biofilm") in protecting the germs from the children's immune response, has been the subject of research by Ruth Thornton, a PhD student in the VTG. This research is changing our understanding of the process of recurrent and chronic infections in young children. It will hopefully lead to more effective treatments and possibly new vaccines for these important diseases.

Training new researchers in vaccinology, immunology and infectious diseases research is an important aim of the VTG. We are fortunate to have two paediatricians in training as clinical research fellows at the VTG and in 2006 we had four PhD students and three Masters students enrolled through UWA working on VTG projects.

We have also extended our collaborations locally and with national and international research groups in Brisbane, Sydney, Melbourne, Adelaide, USA, Papua New Guinea and the Netherlands which will substantially impact our research output. Over the last 12 months two students from PNG, Willie Pomat and Jacinta Francis, have been working on projects related to pneumococcal disease, and a post doctoral scientist, Selma Wiertsema, from the Netherlands is working on our otitis media projects.

None of this important research would be able to be done without the volunteers from our community who enrol in the VTG studies and give up their time to help develop and assess new vaccines and other treatments that will protect future generations of Australians from infectious diseases. Thank you!

Finally I would like to thank all our hard-working staff and collaborators who have contributed to the running of all these studies particularly our VTG coordinator Jan Adams who oversees all our projects.

Dr Peter Richmond
Head, Vaccine Trials Group



Highlights



2006 was a very exciting and busy year for the Vaccine Trials Group.

Our highlights include:

- Our study investigators and researchers presented study results from Perth to Port Hedland, Albany to Alice Springs, Melbourne and Sydney, as well as at overseas conferences in the US and Europe.
- Recognition of our research capabilities at a national and international level with invitations to conduct and lead studies of a new vaccine for the prevention of bird flu as well as a Phase I, 'First in Man' study of a novel Meningococcal B vaccine in adults.
- Many of our clinical trials attracted an overwhelming response and interest from the community and the media. This enabled us to enrol above our expected study participant numbers in several trials. The VTG was the leading Australian site for a number of these studies. More than 1000 participants in our Perth studies helped make a difference in protecting themselves and future generations against infectious diseases.

- Completion of studies across the entire age range with study participants ranging from infants born four months premature at King Edward Memorial Hospital to the 65 years plus older volunteers in a bird flu vaccine study - our oldest volunteer was 86 years of age.



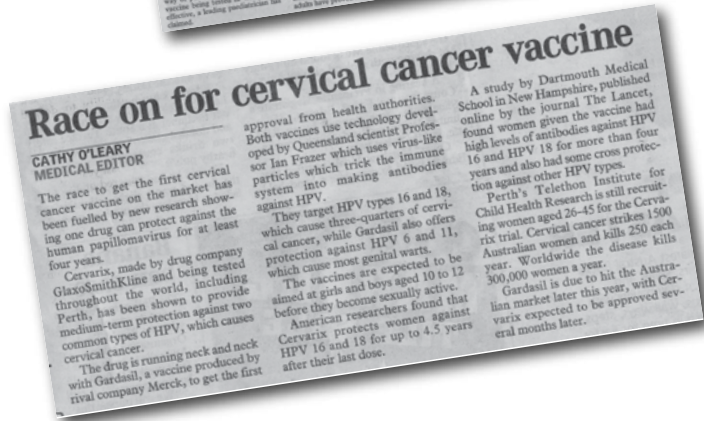
Lachlan Lees (left) is part of the meningococcal B vaccine study, which is hoped will prevent the disease that affected James Buchanan (right) when he was a toddler.

- Immunisation research and vaccine fridge cold-chain monitoring in WA. Research collaborations with the Health Department of WA.
- Collaboration with The Meningitis Centre and the Health Department of WA to help with the development of a WA Immunisation Alliance. This project will be underway in early 2007.
- Our first Strategic Plan was developed and now we are working towards a team structure that focuses on our key research areas.
- We had four PhD students and three Masters students involved in VTG research in 2006 and Jan Nelson completed her Honours degree on the immunology of otitis media in Indigenous children.
- The licensure of the Human Papilloma Virus vaccine, Gardasil, previously evaluated by the VTG. Gardasil has recently been included on the school immunisation program for young girls.



Study nurse Shalene Nandall vaccinates Olga against bird flu. They are watched by Olga's son Geoff, his niece Sarah and daughter Emily who are also part of the trial. Reproduced courtesy The West Australian.

We enjoyed excellent media coverage during 2006, with significant interest from radio, print and television. Here are examples of great support by the media.



**NOVA 93.7
CHANNEL 10
ABC RADIO
CHANNEL 9**



Vital trial: Nurse Shalene Nandall gives Ms Beale a vaccine against bird flu. Geoff Costello, his niece Sarah and daughter Emily are also in the trial. Picture: Lee Griffith

Grandmother joins hunt for bird flu vaccine

PETA RULE

Perth grandmother Olga Beale saw her childhood friends end up paralysed by polio and learnt early in life that new vaccines could change the world.

Now 71, Ms Beale is one of the first group of older people to take part in new research to find a foolproof vaccine for the bird flu H5N1.

A trial into the vaccine, developed by Melbourne-based CSL and being run by the Telethon Institute for Child Health Research and Princess Margaret Hospital, has been expanded after it proved safe for adults.

Volunteers aged over 65 and between six months and nine years old are being called for to have the two jobs which could save lives.



Multi-dose children's vaccines safe: doctor

CATHY O'LEARY MEDICAL EDITOR

There is no evidence that combined childhood immunisations, including the MMR vaccine, cause a so-called 'cocktail effect' or are more dangerous than separate injections, a Perth expert says.

Peter Richmond, from the vaccine trials group at the Telethon Institute for Child Health Research and Princess Margaret Hospital, said parents were regularly worried about overloading their children's immune systems but there was no scientific basis for their concerns.

He said research showed that combination vaccines were as safe as any others and that in some cases they produced a better response in terms of antibody levels.

Perth doctors hoped to publish soon the results of a study on MMR — which protects against measles, mumps and rubella — to strengthen the case against the vaccine overload theory.

MMR has been a controversial issue since researcher Andrew Wakefield claimed in 1998 that it caused autism.

Although his research has since been discredited, health officials, particularly in Britain, have had a particularly 'battle' to restore public confidence in the vaccine.

Dr Richmond said Perth researchers were part of an Australian trial to

Combined dose: Dr Peter Richmond with one-year-old Nicholas Williamson, the first child enrolled in the trial, and study co-ordinator Larissa Rhind with the new HibMenC vaccine. Picture: John Makrzycki

has killed about 150 humans in 2003, more this year, and more than 100 in the nearest neighbour to human, the pig. He warned the disease was deadly.

He said developing a strategy to manage the disease in the elderly was so our strategy was front line first, people considered deactivating so vaccine. He said his experience was that of her grandchild who had entered for the trial can

Newspaper clippings reproduced courtesy The West Australian

How many vaccines did we give in 2006?

- The nurses at the Vaccine Trials Group gave a total of 1893 vaccines.
- Of those vaccines:
- 1110 were given to adults
 - 438 were given to children 12 months and over
 - 345 were given to infants.

How many samples did we collect in 2006?

- There were a total of 7021 samples collected.
- 2834 blood samples
 - 794 saliva samples
 - 10 breast milk samples
 - 549 cervical samples (Pap smears).

The blood, saliva and breast milk samples were processed by the Vaccine Trials Group scientists, Immunology staff at Princess Margaret Hospital for Children and the Telethon Institute for Child Health Research laboratory staff. The cervical smears are transported to the United States for analysis.

Meningitis vaccine studies



Bacterial meningitis is a serious infection in children. The most common types of bacteria that cause meningitis are *Haemophilus influenzae* type B (Hib), meningococcal and pneumococcal bacteria.

In Australia group B and C strains of meningococcal cause the most disease with group B causing over 90% of meningitis cases in WA. Currently a meningococcal C vaccine is given at 12 months of age. Group Y is currently rare in Australia but causes one third of meningococcal cases in North America. Hib disease used to be the most common cause of meningitis but this is now prevented with routine vaccination of babies.

Antibiotics are the most effective treatment but death still occurs in 5% of cases and another 20% are left with permanent disabilities such as cerebral palsy, amputations, learning difficulties and deafness.

The Vaccine Trials Group is committed to working with other organisations toward helping raise awareness of meningococcal infection and looking at ways of preventing this devastating disease. The VTG is currently involved in a number of meningitis vaccine studies.

Several studies are trying to reduce the number of injections children receive while still protecting them against bacteria that cause meningitis.

The **Combined Meningitis (HibMenCY) Vaccine Study for Infants** is nearing completion and is looking at how well a combination HibMenCY vaccine works when given with routine vaccines at two, four, six and 12 months of age. Babies enrolled in this study have received either the combined vaccine (HibMenCY), or Hib and meningococcal C vaccine separately. Results from the first study of this vaccine performed by the VTG in 2003, were recently published and showed that the combined HibMenCY vaccine produced equivalent or better protection against the three meningitis-causing bacteria than when the vaccines are given as separate injections.

The **Combined Meningitis (HibMenC) Vaccine Study for Toddlers** who have not yet had their 12 month booster vaccine is still underway. The study is looking at how well a combined HibMenC vaccine protects children compared to when the Hib and Men C vaccine are given as separate

injections at their 12 months routine vaccine. The standard measles, mumps, rubella (MMR) vaccine is also given at this time.

The development of a meningococcal B vaccine to protect against all type B strains of meningitis has been elusive, however the VTG is very excited to be a part of studies of a new, world-first **Meningococcal B Vaccine**. The “first in man” adult study commenced in June 2006 and is nearing completion. Results thus far are looking very promising with no safety concerns and good immune responses.

We are currently recruiting toddlers and adolescents in the next phase of this study.



As part of the meningococcal B vaccine study for adults, participants received an electronic diary to record any side-effects such as redness and swelling at the injection site. Below, study coordinator Angela (right) shows participant Heidi how to use the electronic diary.

Respiratory disease

Influenza or the 'flu is caused by a highly contagious virus spread by coughing and sneezing. It is often considered a mild disease, slightly worse than a cold, but the 'flu kills millions of people, including children, around the world. Symptoms included chills, sweating, headache, cough and generalised muscle and joint pains. In rare cases, 'flu may lead to serious complications such as pneumonia or inflammation of the brain or heart. Children are two to three times more likely than adults to get sick with the 'flu and be hospitalised. Children are also thought to be very important in the spread of the 'flu virus in the community.

Children who enrolled in the **'Flu Vaccine Study for Kids** in 2005 returned in 2006 to receive their influenza booster vaccine for the coming 'flu season. This study looked at the safety and how well an Australian 'flu vaccine worked in children aged six months to eight years of age. They were given two doses of the influenza vaccine initially and then a booster the following year. Results from the study showed that the vaccine was safe and well tolerated and overall children developed a good immune response to protect against the influenza virus. Currently the influenza vaccine is not on the routine schedule and we hope that the information from studies such as these will help determine if 'flu vaccine should be considered for all young children.

Avian influenza or 'bird 'flu' is an infectious disease of animals (usually birds) caused by some strains of the influenza A virus. Human infection with these influenza A types is rare but in 2003, the largest and most severe bird 'flu outbreak in history began in South East Asia, caused by the H5N1 subtype of the influenza A virus. Of the 291 human cases of bird 'flu infection to date (11 April 2007, WHO) there have been 172 deaths. If this virus changes to spread easily from human-to-human, then it is likely that it will cause a pandemic where the whole population is at risk of getting the disease as no-one has any immunity to this strain of influenza virus.

International trials to develop an effective bird 'flu vaccine have shown that the vaccines are safe and no allergic

reactions have been seen. However, the immune response has been disappointing, with doses up to 6 times the normal 'flu vaccine needed to create an adequate immune response.

With funding from the National Health and Medical Research Council, CSL has developed a bird 'flu vaccine for use in Australia. The VTG has recently completed a study involving 200 adults in Perth (and a further 200 in Melbourne and Adelaide) who received two doses of the bird 'flu vaccine and had four blood tests to check their immune response to the vaccine. The vaccine was well tolerated and initial results suggest that both dose levels (two or three times the normal 'flu vaccine) produced antibody responses that neutralised the virus in the majority of adults. This data has been used to register the vaccine with the Therapeutic Goods Administration for use in the event of a pandemic. We are currently looking at how well the vaccine works in the elderly and in children. We have completed recruitment of 91 seniors aged 65 years and above, and 83 children aged 6 months to 8 years.

We still need children aged 6 months to 3 years for this important study.

The VTG completed a study at the end of winter 2006 into **human MetaPneumoVirus** (hMPV), a newly described virus that causes chest infections in children. By the age of five, nearly all children will have had a hMPV infection. In this study we investigated how frequently hMPV infection of the lungs occur in young children at high risk for severe disease. The study is being conducted in approximately 40 centres around the world and has recruited over 1500 children. The Perth site enrolled a total of 55 children into the study.

Respiratory Syncytial Virus or RSV is an important cause of chest infections and wheezing in young children, especially in preterm children with chronic lung problems. The VTG was involved in the 'Numax' study, a new preventative antibody treatment produced by Medimmune, designed to neutralise the virus. The antibody is given by regular injections over winter and it is hoped to be more effective than current treatments.

Human Papilloma Virus

Human Papilloma Virus (HPV) has been shown to be the main cause of cervical cancer in women. Over 75% of sexually-active women and men will be infected with HPV at some stage during their lives. Women may only know they have been infected with the virus when it shows up during a routine Pap test.

The 2006 Australian of the Year, Dr Ian Frazer, was jointly responsible for discovering the mechanism to develop a vaccine that would prevent infection of two types of HPV, 16 and 18, which cause up to 70% of cancer of the cervix worldwide.

Here at the VTG we have been involved in several HPV vaccine trials, including the recently licensed Gardasil and Cervarix, which is not yet registered for use at this time.

In early 2006 we saw the completion of the **HPV Adolescent Study**. This looked at the safety and tolerability of the

GlaxoSmithKline vaccine, Cervarix. There were 66 young girls aged 10 to 14 years enrolled in the Perth study. There were no safety concerns and the vaccine was well tolerated by all the girls. Participants who received the HPV vaccine have now been offered the control (Hepatitis A) vaccine. When Cervarix is registered for use the girls who received the control vaccine will be offered the HPV vaccine (or may choose to receive the CSL Gardasil vaccine through the school immunisation program).

We are currently in the third year of a 4-year **HPV Vaccine Study for Young Women aged 17 to 25 years** and in the second year of a 3-year **HPV Vaccine Study for Women aged over 26 years** to see if the vaccine also has any therapeutic benefits in women who may already have the virus. A total of two hundred and ninety five women enrolled in these studies. The studies will continue after the expected registration of Cervarix in 2007.

Ear, nose and throat infections

Many children suffer from chronic and/or recurrent **ear, nose and throat infections**. Even following numerous courses of antibiotics, infections often do not improve, or get better for only a short time before returning. Our research is focussed on why some children are particularly prone to these infections, particularly populations such as Aboriginal children who have very high rates of chronic ear disease and associated complications such as loss of hearing.

Biofilm in ENT disease

We believe that one reason for these chronic and recurrent infections in some children may be due to what is known as 'biofilm'. Biofilm occurs when bacteria stick to a surface and cover themselves in a layer of slime to protect themselves against a hostile environment. Most bacteria are present in this form including slime-covered rocks in streams and the plaque that is brushed off teeth in the morning. When the bacteria are in this slime they are well protected from antibiotics and the child's own immune system. In this slime, the protected bacteria form a reservoir of infection that is released from time to time causing some children to get the same infections over and over again.

Professor Harvey Coates, PhD student Ms Ruth Thornton and the ENT team have found preliminary evidence of 'biofilm' in children with chronic middle ear infections (otitis media) and recurrent tonsillitis. Ruth's work is trying to find out if this is the main reason for the chronic or recurrent nature of these diseases, which bacteria are the common ones in biofilm and whether these children have a weak immune response to the bacteria causing the infection. In addition, we have found for the first time, that those bacteria can also hide inside the middle ear cells which is another way they can escape detection by the child's immune system. This finding has important implications for the choice of antibiotics used in trying to clear up recurrent or chronic ear infections, as not all antibiotics can penetrate into cells to kill the bacteria.

Ruth has recruited two groups of children for these studies: the first being 150 children having surgery for glue ear, recurrent ear infections and perforated ear drums due to chronic infections. The second group consists of 100 children having their adenoids and/or tonsils taken out for otitis media, obstructive sleep apnoea and/or recurrent tonsillitis. So far, 85 children have been enrolled in this study and we are also enrolling 100 children who don't have ENT infections to see if they have a stronger immune response to these bacteria that protects them from the chronic biofilm infection. This information will be important for the design of new vaccines to prevent ENT infections.

While the laboratory work remains to be conducted on the majority of samples, this study will hopefully unlock the causes of these diseases and lead to development of methods to prevent them occurring, or to treat them without the need for surgery.

The GROMIT Study

The GROMIT study is a new study that was funded in 2006 to investigate the Genetics of Recurrent Otitis Media and Immunology in Toddlers. The aim of this study is to get a better insight into why some young children suffer from recurrent ear infections. Investigators will study their immune function and genetic factors underlying this increased susceptibility to otitis

media. Grants from the UWA Research Grants Scheme and the TVW Telethon Trust were awarded to VTG staff for this project and the study will start in 2007.

Mucosal Immunity in Recurrent Ear Infections

Pneumococcal bacteria are the most common cause of childhood ear infections and mainly occur in children under 2 years of age. The pneumococcal bacteria are carried in the nose and throat of healthy adults and children, and can be passed by droplets in the air. Not all children who come in contact with this bacterium will get sick. We are interested in how the immune system responds to these bacteria at the mucosal surface which lines the ear, nose and throat.

With the help of collaborators in the Menzies School of Health Research in Darwin, a PhD student from PNG (Willie Pomat) and Honours student (Jan Nelson), have been looking at mucosal immunity to pneumococcal and Haemophilus bacteria in Aboriginal children from the Northern Territory. These are the first projects in Australia to study these mucosal immune responses in this high-risk population. Willie's results showed that the Aboriginal children were able to respond to the outside sugar capsule of the pneumococcus and these responses were enhanced by the new pneumococcal vaccine for babies, Prevenar. These results were presented at the International Symposium for Pneumococci and Pneumococcal diseases in 2006. Unfortunately, although these responses were able to eradicate those strains in the vaccine, new strains have emerged and are still causing ear disease.

New vaccines need to be developed that can protect across different strains and scientists are now using proteins from these bacteria to develop vaccines that appear to work in mice. More information is needed on how children respond to these proteins to choose the best one to make a vaccine. As part of her Honours thesis, Jan Nelson found that Aboriginal children do mount immune responses following exposure to and carriage of bacteria in early life. However, these immune responses do not appear to protect against subsequent carriage and ear disease. Also, there is a lack of cross-reactivity between antibodies to different versions of this protein, suggesting that representatives of both variations of the protein should be present in a future vaccine to protect against otitis media.

These new methods will be used for analysing samples collected in the study of the use of pneumococcal vaccine (Prevenar) in children with recurrent ear infection. The final sample collection was completed in 2006 and analysis is now underway and results should be reported in 2007. The study will also look at how well children's immune cells respond to the vaccine and bacterial proteins. This information will improve vaccine design and development. These assays are also being used in a study of pneumococcal conjugate vaccine being given to newborn babies in Papua New Guinea to try and prevent the very high rate of severe pneumococcal pneumonia and deaths in young infants. This study is in collaboration with the PNG Institute of Medical Research and colleagues in Populations Sciences and Cell Biology at the Telethon Institute for Child Health Research.

Other immunisation research



The **Vaccine Study of Postnatal Immune development in Neonates (VSpin) Study** is looking at the development of infants' immune responses to the routine vaccination schedule and how susceptible they are to infections. They will also be tested for allergies over the first two years of life.

The primary aims of this study are to evaluate vaccine specific antibody and cellular immune responses to routine infant immunisations given at two, four, six and 12 months of age and to evaluate the burden of infection and risk of allergic sensitisation in the first two years of life in preterm infants in comparison to term infants. The study comprises eight clinical visits from two months of age to two years of age.

We plan to enrol approximately 200 preterm and 100 term infants into the study. At this stage we have enrolled a total of 92 infants, 51 premature and 41 term from King Edward Memorial Hospital. Twenty subjects have completed the 2 year study and 27 will complete the study over the next 6 months. Recruitment for the study is currently on hold as we wish to analyse the samples we have for some preliminary data and results.

The **DTaP (Pre-school booster) Vaccine Study** is looking at why some children develop redness and swelling at the injection site following their pre-school booster vaccination of diphtheria, tetanus, whooping cough and polio (DTPa-IPV). The study is being conducted by PhD student Olivia White. At the first visit, participants will receive their pre-school booster vaccines (DTPa-IPV and Measles, Mumps, Rubella) following a blood test and saliva sample. Parents will be asked to record on a diary card any local reactions at the injection sites and any general symptoms that occur over the next month.

We are still recruiting children due for their 4-year-old booster vaccinations.

Four-year-old Lily, pictured right with Sam from the VTG, is part of the pre-school booster study. Lily's father Christopher says the experience of being part of the study has been excellent for Lily as it has taught her to feel comfortable around doctors and health professionals and has given the family the opportunity to contribute back to healthcare in Western Australia.



Collaborations

Princess Margaret Hospital for Children

The Vaccine Trials Group is working in close collaboration with numerous departments at PMH. This includes the pharmacy where experienced clinical trials pharmacists, led by Margaret Shave, ensure that all clinical trials investigational products are stored, dispensed and accounted for according to good clinical practice. PMH Immunology department also assists in some of our studies with sample processing, storage and transportation. Prior to VTG employing two experienced children's phlebotomists, the PMH pathology service assisted us in venepuncture of infants and children.

We continue to work closely with wards and other departments to maintain links to inform them of the research studies in which we are involved.

The Meningitis Centre

VTG works closely with the Meningitis Centre, helping raise awareness about meningitis and promoting meningitis prevention through immunisation. We are members of their committee and the centre is extremely supportive in promoting our meningitis vaccine studies through their promotional activities.

The Divisions of General Practice

We maintain links with the Divisions of General Practice and have provided a range of information sessions and updates about our studies and immunisation.

The Health Department of WA

In 2006 VTG completed two research projects in collaboration with the Communicable Disease Directorate. These research projects reviewed the immunisation rates in children in central Perth and looked at why parents chose to immunise their children at the Central Immunisation Centre at Rheola St, West Perth.

The vaccine fridge research study reviewed the type of fridge immunisation providers in WA use to store their vaccines, and how they are monitored to ensure vaccines remain within the required temperature range.

We also continue to have strong links with the Population Health Areas and the Child and Adolescent Community Health Divisions of the Health Department of WA.

The Amanda Young Foundation

The Amanda Young Foundation was formed in 1998 following the tragic death of Amanda Young from meningococcal septicaemia at the age of 18 years. One of their missions is to raise awareness about meningococcal disease through fundraising and education in the community, schools and medical profession.

In 2006, the foundation held the first Meningitis Conference in WA. An audience of health professionals and consumers were provided with an excellent array of speakers, including Dr Peter Richmond from VTG. We maintain links with the foundation to assist with raising awareness about meningococcal disease through early detection and treatment and promotion of prevention through immunisation.

Community Involvement and Promotion

The VTG work closely with the community and have developed networks with a number of groups and organisations. These include child care centres, primary and high schools, community and child health centres, mothers' groups and sporting groups.

To ensure that our study information and promotional material are understood by community members we distribute our study information for consumer comment prior to its submission to ethics.

Through our consumer involvement, VTG have a representative on the Telethon Institute for Child Health Research Consumer Advisory Council, which was established in 2006 by Anne McKenzie.

Education and Training

Throughout the year VTG staff have presented over 35 information sessions about studies and immunisation to various groups and organisations. These have included GPs, nurses and other health staff and researchers and community organisations such as schools and childcare centres. Staff have travelled as far north as Karratha and Kalgoorlie, south to Busselton, Bunbury and Albany.

We held 3 seminars during the year. These seminars covered updates on immunisation, the Human Papilloma Virus Vaccine and results of the Influenza Vaccine study for children that was completed in 2006.

Ethics

All of our studies are approved by the Princess Margaret Hospital Ethics Committee and King Edward Memorial Hospital Ethics Committee. Approval has been obtained from other hospital or university ethics committees to allow us to promote our studies through their organisations.

Vaccine Trials Group staff



The Vaccine Trials Group has been fortunate to attract staff who bring a wide range of expertise and experience to the group. The following is a list of all VTG staff that contributed to our success in 2006.

Head of Department

Dr Peter Richmond

Coordinator

Jan Adams

Clinical Research Fellows

Dr Karen Prosser

Dr Tanya Stoney

Study Investigators

Dr Rachel Skinner

Dr Richard Loh

Prof Peter Sly

Prof Pat Holt

A/Prof Harvey Coates

Dr Karen Moller

Dr Alison Stubbs

Dr Robyn Leake

Dr Louise Farrell

Dr Julie Rowe

Dr Andrew Wilson

Dr Tony Keil

Mr Shyan Vijayasekeran

Research Nurses and Assistants

Kylie Rooney

Grania O'Connor (until Mar 07)

Kim Moyes (until Aug 06)

Karen Collins (until Aug 06)

Amanda Morcom (until Dec 06)

Phlebotomists/Scientists

Samantha Curtis

Olivia White (until Oct 06, now PhD student)

Sharon Ringrose

Lisa Montgomery

Sam Brophy-Williams (until Dec 06)

Angela Fuery

Tania Smith (until Dec 06)

Administration Staff

Danielle Everett (until Feb 06)

Krishny Ponen (until Oct 06)

Sonali Gunasekera

Samuel Gray

Honours Student

Jan Nelson

PhD Students

Willie Pomat

Ruth Thornton

Holly Clifford

Olivia White

Masters Students

Janet McBride

Jacinta Francis

Neville Shine

Karen Prosser

Post Doctoral Scientist

Dr Selma Wiertsema

Respiratory Study Coordinators

Sanela Bilic

Shalene Nandlall

Jo Harvey (until Aug 06)

Angela Caskey (until Jan 07)

Meningitis Study Coordinators

Jennifer Kent

Larissa Rhind

Angela Fuery

Immunisation Research Study Coordinators

Samantha Curtis

Sam Brophy-Williams (until Dec 06)

Human Papilloma Virus Study Coordinators

Janet McBride

Dayle Kirchner (until Jan 07)

Sally Willmot (until Sep 06)

Ear, Nose and Throat Researchers

Selma Wiertsema

Ruth Thornton

Willie Pomat

Jacinta Francis

Financial report

Total income for 2006 was **\$1,303,477.26**.

Expenses:

Salary including on costs	762,187.63
Research Expenses	137,538.75
Study Participant Expenses	36,146.18
Clinical Trial Equipment	16,648.71
Total expenses	\$ 952,517.27

Our Funding Sponsors

CSL Limited, Garnett Passe and Rodney Williams Foundation, GlaxoSmithKline, Health Department of Western Australia, MedImmune, National Health and Medical Research Council and Wellcome Trust, PMH Foundation, Royal Australasian College of Physicians, TVW Telethon Trust, University of Western Australia, Wyeth Pharmaceuticals.

2006 Publications

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2. Skinner SR, Kang M., Rosenthal SL. Vaccinating young adults against HPV: the importance of understanding health decision-making and behaviour. *Sexual Health* (in press, accepted Mar 2007)
3. Safety and immunogenicity of Human Papilloma Virus 16/18 L1 vaccine in 10-14 year old girls. Australian Sexual Health Conference, Melbourne, October 2006.
4. Safety and immunogenicity of Human Papilloma Virus 16/18 L1 vaccine in 10-14 year old girls. ANZ Adolescent Health Conference, Sydney, November 2006
5. Immunisation of adolescents. Immunology meets Gynecology, GSK Satellite Symposium. International Federation of Gynecology and Obstetrics, Kuala Lumpur, November 2006 (fully funded)
6. Implementation and impact of HPV vaccines; an evolving story. Keynote lecture, Immunisation Advisory Centre (IMAC) Vision for Vaccines Symposium, School of Population Health, Tamaki Campus, University of Auckland, September 2006 (fully funded)
7. HPV vaccines, adolescents and vaccination programs. Australasian Chapter of Sexual Health Medicine, NSW Scientific Meeting March 2006
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Telethon Institute for Child Health Research
Corner Hamilton Street and Roberts Road, Subiaco
(on the Princess Margaret Hospital site)
PO Box 855, West Perth WA 6872
Telephone 9340 8542 Fax 9340 7429 Email vtg@icr.uwa.edu.au

The Vaccine Trials Group is a collaboration between Telethon Institute for Child Health Research, Princess Margaret Hospital for Children and the University of Western Australia School of Paediatrics and Child Health.



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