

Optimising Immunisation in Special Risk Groups

Nigel Crawford



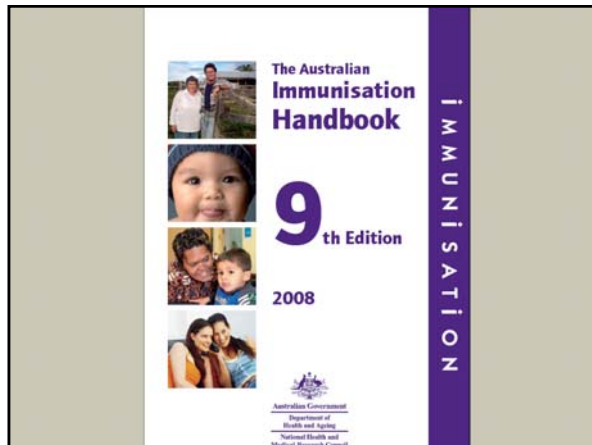
Special Risk 'Definition'

Patients who have:

- special immunisation requirements (e.g. children/ adolescents with a chronic medical condition)

and/or

- a suboptimal response to immunisation (e.g. due to impaired immunity)

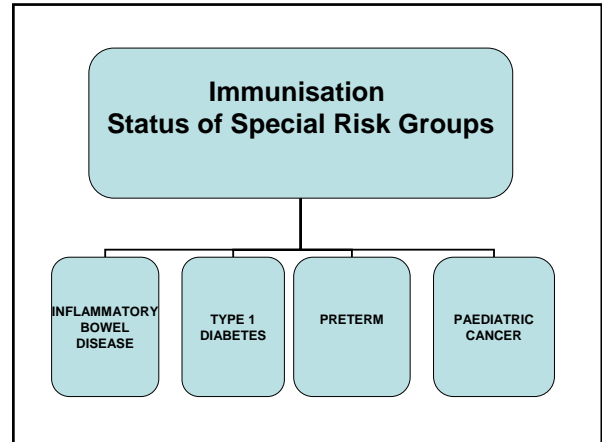
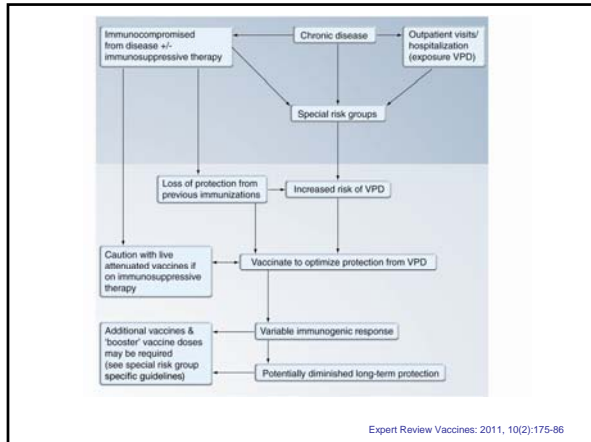


Thesis: questions to address

- What are the additional vaccine requirements in 'special risk' groups?
 - What is the evidence base for these recommendations?
 - What about new vaccines? Immunogenicity studies?
- Are these vaccines recommended by subspecialist physicians?
- Are the special risk groups receiving them?
- Optimising protection through translation of guidelines into clinical practice

Studies

- Current special risk guidelines
 - Specialists recommendations
 - Adherence to guidelines [audits]
- Improving the evidence base
 - novel vaccine immunogenicity studies
 - 10 valent pneumococcal vaccine
 - 4 valent HPV vaccine
- Systematic reminders
 - RCT postcard immunisation reminder



Preterm Infants

- Relative immunodeficiency
- **By 7 months**
 - B cell numbers term equivalent
 - Decreased $L\sigma$, total T cell and T_H persist
- Other risk factors
 - Prolonged hospitalisation
 - Medications: Steroids
 - Chronic lung disease

Bonhoeffer et al. Arch Dis Child 2006; 91:929-935
Crawford NW, Buttery JP. Paediatrics and Child Health. 2010; 20(6): 297-301.

Preterm risk VPD

- Pertussis
 - 50% cases in infants
 - LBW infants <2500 grams
 - RR 1.86 (95% CI 1.33-2.38)
- Invasive Pneumococcal Disease (IPD)
 - LBW c/w NBW infants RR 2.6 (P = 0.03)
 - PT c/w FT infants RR 1.6 (P = 0.06)

Langkamp et al. J Pediatr 1996; 128:654-9
Shinefield et al. Pediatr Infect Dis 2002; 21:182-6.

Preterm Infants

- Mount protective responses to most vaccines
- Vaccinate according to chronological not gestational age
 - **Timeliness**
- Where response is suboptimal
“additional” doses recommended

Routine schedule (2008)

Age	Vaccine								
Birth	Hep B								
2 months	Hep B	DTPa	Hib	Polio				7vPCV	Rotavirus
4 months	Hep B	DTPa	Hib	Polio				7vPCV	Rotavirus
6 months	Hep B	DTPa	Hib*	Polio				7vPCV	Rotavirus†
12 months			Hib		MMR		Hep A [‡]		Men C
18 months						VZV	Hep A [‡]	23vPPV [§]	
24 months							Hep A [‡]	23vPPV [§]	
4 years		DTPa		Polio	MMR				

* The 3rd dose of Hib vaccine at 6 months is dependent on the vaccine brand used in each state or territory.
† The 3rd dose of rotavirus vaccine at 6 months is dependent on the vaccine brand used in each state or territory.
‡ Aboriginal and Torres Strait Islander children in Western Australia and the Northern Territory.
§ Aboriginal and Torres Strait Islander children in Queensland and South Australia.

Hull et al. Commun Dis Intell. 2010;34(4):241-58.

Additional doses recommended

- Hep B vaccine (< 32 weeks or <2000g)
 - extra dose 12 months
- Pneumococcal (< 28 weeks or CLD)
 - 4th conjugate dose at 12 months
 - 23vPPV at 4-5 years
- Influenza vaccine (CLD, cardiac etc.)
 - > 6 months
 - 2 doses in 1st year / 1 month apart
 - ½ dose if < 3 years (0.25 ml)

Paediatric cancer



- Do childhood cancer survivors receive vaccination 'boosters' post chemotherapy ?
 - The following schedule was recommended (2007):
 - DTPa if <8 years of age (dTpa if ≥8 years of age)
 - IPV
 - MMR
 - Hepatitis B
 - 7vPCV
 - *Hib* (if <5 years or asplenia)
- [meningococcal C; varicella]

Patel et al. Clin Infect Dis 2007, 44:635-42

Paediatric cancer



- Immunosuppressed
 - primary disease
 - treatment (chemotherapy and/or radiotherapy)
- Heterogeneous group
 - solid tumours: short intensive therapy
 - ALL 2-3 years of treatment
 - post bone marrow transplant
 - [separate guidelines]

IBD and type 1 diabetes

Routine vaccines + additional:

1. Annual trivalent influenza vaccine
 - underlying chronic disease
2. Pneumococcal vaccines
 - IBD higher risk of IPD (immunosuppressed)
 - Type 1 diabetes

Neuzil et al. J Pediatr. 2000;137(6):856-64.
Hjuler et al. Pediatrics 2008, 122:e26-32

Special risk of IPD

Diseases compromising immune responses

- Haematological malignancies
- HIV infection
- Renal failure, or relapsing or persistent nephrotic syndrome
- Down syndrome.
- Congenital immune deficiency
- Immunosuppressive therapy (including corticosteroid therapy ≥2 mg/kg per day of prednisolone ≥2 weeks; or radiation therapy)
- Splenic function compromise due to sickle haemoglobinopathies, or congenital or acquired asplenia

Anatomical or metabolic abnormalities

- Cardiac disease associated with cyanosis or cardiac failure
- Insulin-dependent diabetes mellitus
- Proven or presumptive cerebrospinal fluid (CSF) leak
- Intracranial shunts and cochlear implants.
- Infant with chronic lung disease
- Cystic fibrosis
- ex-premature infants born at less than 28 weeks gestation

Australian Immunisation Handbook 9th edition p246

Special risk of IPD

If fall into one of these 'special risk' groups recommend:

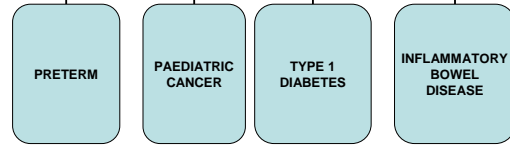
- 4th dose PCV (pneumococcal conjugate vaccine)
 - 12 months of age or at diagnosis
- &
- 23vPPV (polysaccharide vaccine)
 - @ 4-5 years of age

Physicians survey results

	Response rate	Recommendations as per guidelines		Personal immunisation	
		Influenza	Other	Influenza	Pertussis (whooping cough)
Neonatologists [Aust]	68% (76/111)	60%	58% additional pneumococcal	79%	71%
Paediatric Oncologists [Aust & NZ]	82% (37/45)	69%	8-month boosters* • 27% post high intensity chemotherapy • 48% after low intensity • 29% check serology		

Crawford et al. J Paed Child Health. 2009;45(10):602-9
Crawford et al. J Paed Child Health. 2007;43(9):593-6.

Immunisation Status of Special Risk Groups



Audits of immunisation status

	No. participants	Median age (years) [range]	Routine vaccines	Additional vaccines		Other vaccines
				Influenza	Pneumococcal	
Preterm	100 • 40 < 28 weeks • 60 28-32 weeks	> 13 months	90-92%	20%	35%	19% (extra Hep B)
Paediatric cancer	89 • 45 ALL • 5 AML • 39 solid tumour	5.3 [0.2-17.8]	55%*	47%		61% (boosters post chemo)
Type 1 diabetes	100	13.2 [3.8-19.2]	88%	25%		
IBD	101 • 74 Crohn's • 24 UC • 3 Indeterminate	15.3 [5.5 - 22.8]	90%	10%	5%	

* 40% had primary course interrupted

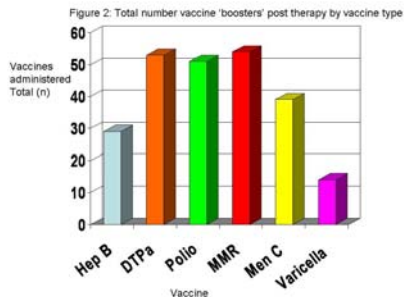
TABLE II. Characteristics of Participants Receiving Booster Immunisations

Variable	'Received booster' immunisations/total	Percent %	ORs ratio (95% CI)	P value
Sex				
Male	23/43	53	c	
Female	31/46	67	1.8 (0.7-4.6)	0.18
Diagnosis				
Leukaemia	35/50	74	c	
Solid tumour	19/39	43	0.4 (0.15-1.0)	0.04
Residence				
urban	30/53	57	c	
rural	23/33	70	1.8 (0.6-5.0)	0.22
Pearson Chi square for trend				
Age (years)				
<2 years	10/11	91		
2 to <5 years	21/25	84		
5-6 years	8/17	47		
>7 years	15/35	43		
			$\chi^2 = 16.0$	0.001

c, comparative group.

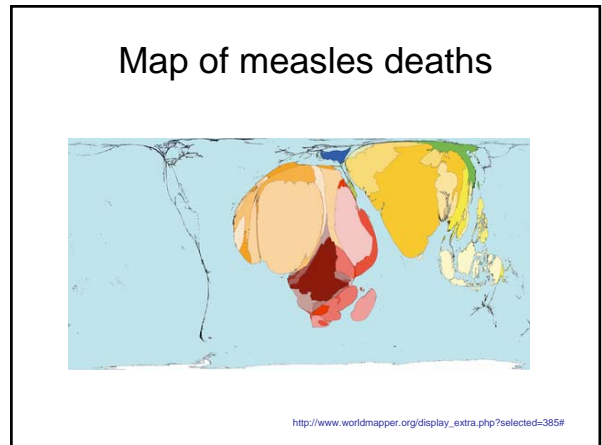
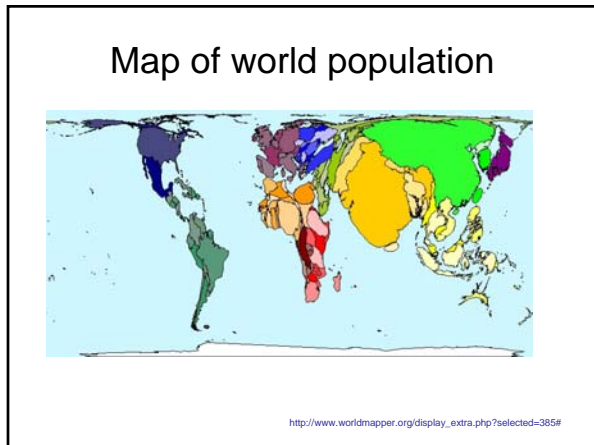
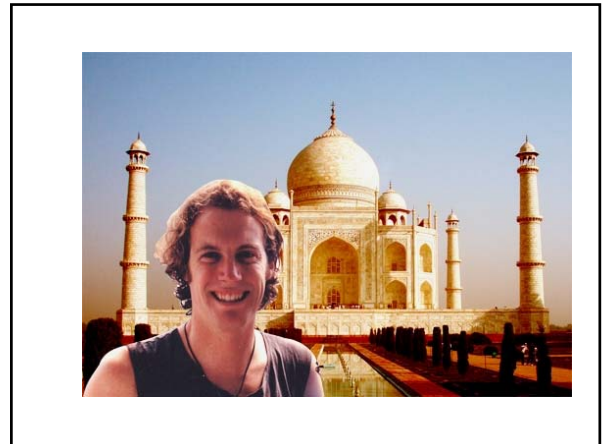
Crawford et al. Pediatr Blood Cancer. 2010;54(1):128-33.

Post chemo immunisations



Case study

- CB- Diagnosed ALL 2003
 - completed treatment June 2005
 - i.e. 3-6 years of age
- Family completed immunisation audit
 - CB now 11 years
 - Influenza vaccine
 - No other immunisations since 1 year of age



- ### CB: Immunisation plan
- 6 vaccines @ clinic appointment
 - diphtheria-tetanus-pertussis-polio [dTap-IPV]
 - conjugate pneumococcal vaccine [PCV7]
 - Hep B [adult dose]
 - varicella
 - measles-mumps-rubella
 - meningococcal C
 - 2nd dose Hep B in 4/12; check MMR serology

Immunogenicity and safety of 10-valent pneumococcal vaccine in children and adolescents with leukaemia

Hjuler *et al. Pediatrics* 2008, 122:e26-32

Pediatrics | Hjuler *et al.* 122 (1) e26 Table 3. Microsoft Internet Explorer provided by MCR
<http://pediatrics.appublications.org/cgi/content/full/122/1/e26>

Table 3. aRR of IPD Among Children Aged 0 to 17 Years 10 Days After the First Hospital Contact for a Chronic Disease, According to Type of Disease, Compared With Children Without Chronic Disease or Reason

Type of disease	Cases ^a	Controls ^b	aRR (95% CI) of IPD Compared With Children Without Chronic Disease or Reason
Cancer			19.0 (8.7-41.5)
Hematologic cancer	44	3	52.1 (13.7-198.2)
Nonhematologic cancer	19	10	8.9 (3.1-26.1)
Renal disease			4.1 (1.5-11.1)
Chronic renal disease	6	2	18.9 (2.8-127.1)
Congenital renal malformation	7	10	1.6 (0.4-6.3)
Neurological disease			2.5 (1.7-3.6)
Congenital CNS malformation ^c	23	29	2.9 (1.4-6.2)
Epilepsy ^d	37	77	2.5 (1.5-4.2)
Cerebral palsy	18	23	1.2 (0.5-3.0)
Hydrocephalus	17	29	1.0 (0.4-2.4)
Heart disease			2.4 (1.6-3.4)
Chronic heart disease	14	12	3.6 (1.4-9.0)
Congenital heart disease ^e	67	142	2.0 (1.4-3.1)
Genetic disease			2.1 (1.1-4.1)
Chromosomal abnormalities	22	19	2.5 (1.1-5.6)
Inborn error of metabolism	5	9	1.1 (0.3-4.1)

National Immunisation Program

- PCV7 (Prevenar [Pfizer])
 - introduced NIP January 2005
 - catch-up to 2 years age (i.e. born Jan 2003)
- 3 + 0 dose regimen
 - 2, 4 and 6 months of age

Next generation vaccines

- PCV10 Synflorix® (GSK): [Protein D NTHi]

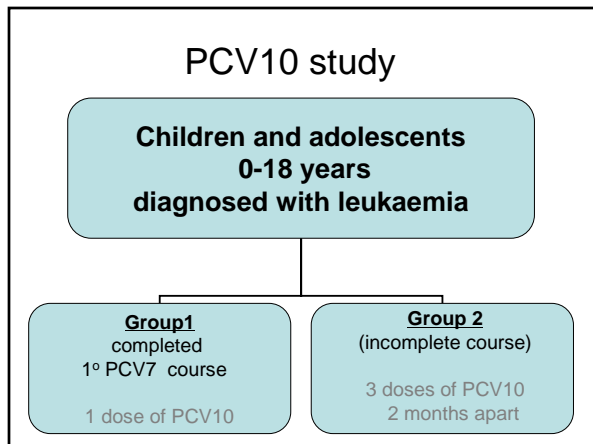
1	4	5	6B	7F	9V	14	18C	19F	23F
---	---	---	----	----	----	----	-----	-----	-----
- PCV13 Prevenar13™ [Pfizer (Wyeth)]

1	3	4	5	6A	6B	7F	9V	14	18C	19A	19F	23F
---	---	---	---	----	----	----	----	----	-----	-----	-----	-----


Oncology Guidelines

- At diagnosis haematological malignancy:
 - < 5 years of age completed 1^o course
 - single PCV7 booster
 - Aged 6-9 years recommended
 - 2 doses of PCV7: 2 months apart
 - dose of 23vPPV 2 months later
 - ≥10 years of age
 - single 23vPPV

Australian Immunisation Handbook 9th edition



PCV10 STUDY

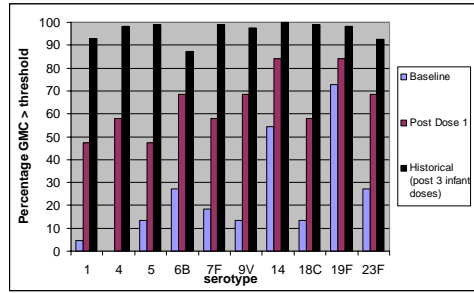


- Participants
 - 27 of 41 analysed [all ALL]
 - 23 RCH; 4 MMC
 - Age median 5.6 years [range 1.7-15.2 yrs]
 - 56% male 3 baseline serology only
- Groups
 - 22 Group 1 (previous PCV7)
 - 5 Group 2 (1 relapse post 2 doses)
- Treatment phase
 - 17/27 on maintenance therapy

Pneumococcal GMC pre & post

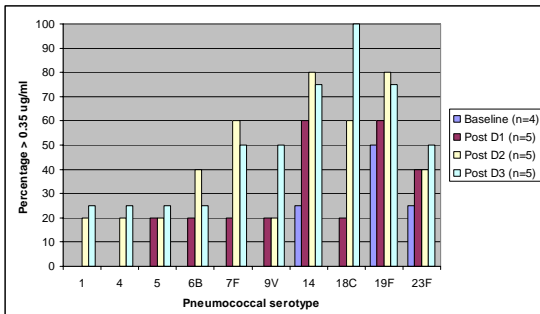
Serotype	Baseline	Post Dose 1	P value
1	0.13	0.28	0.01
4	0.08	0.49	0.0007
5	0.14	0.31	0.0063
6B	0.24	0.84	0.007
7F	0.09	0.31	0.001
9V	0.13	0.59	0.0008
14	0.38	2.5	0.0004
18C	0.10	0.64	0.003
19F	0.52	2.4	0.0012
23F	0.18	0.66	0.0014

PCV10: GMC above threshold (Group1)

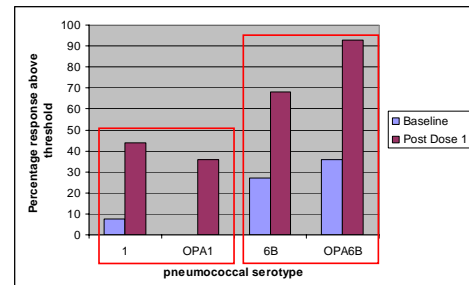


GMC= geometric mean concentration

PCV10: GMC above threshold (Group2)



PCV10: ELISA & OPA *



*OPA= opsonophagocytic antibody (subset n=14)

Vaccine safety



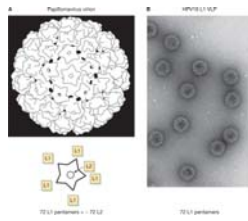
- 5 day diary
- Local reaction
 - 84% (21/25)
 - 19 tenderness; 2 induration/swelling
- Systemic
 - 44% (11/25)
 - 2 vomiting; 3 diarrhoea; 1 decreased appetite
 - 2 drowsiness; 2 irritability
 - only 1 fever > 38 degrees Celsius

Symptom	Type	SYNFLORIX		PCV7	
		N	%	N	%
Pain	All	2442	54.9	865	48.4
	Grade 3	2442	6.3	865	4.5
Redness (mm)	All	2442	64.8	865	65.4
	> 20	2442	10.6	865	9.1
	> 30	2442	4.1	865	3.7
Swelling (mm)	All	2442	53.8	865	49.5
	> 20	2442	15.2	865	11.8
	> 30	2442	6.8	865	5.7
Drowsiness	All	2442	71.7	865	68.2
	Grade 3	2442	2.9	865	3.2
Irritability	All	2442	80.5	865	78.0
	Grade 3	2442	10.1	865	8.6
Loss of appetite	All	2442	50.0	865	47.2
	Grade 3	2442	1.0	865	0.9
Fever (Rectal) (°C)	> 38	2442	60.1	865	59.5
	> 39	2442	7.2	865	6.2
	> 40	2442	0.2	865	0.2
	> 40	2442	0.2	865	0.2

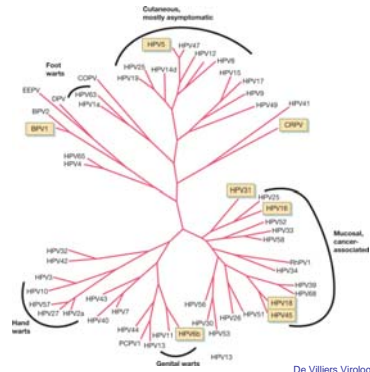
Both groups pooled from Studies 001, 003 and 011. N = Number of subjects with at least one documented dose. % = percentage of subjects reporting at least one specified symptom whatever the number of

GSK, Product Information: 2011

Immunogenicity of a prophylactic quadrivalent HPV vaccine in females with special risk conditions

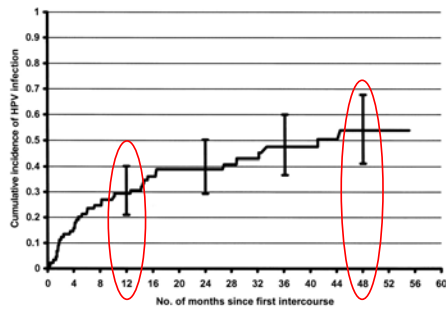


HPV Taxonomy



De Villiers Virology, 2004;324(1):17-27

Cumulative incidence of HPV infection from time of first sexual intercourse

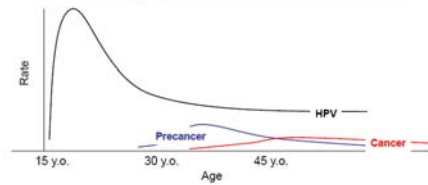


Winer R L et al. Am. J. Epidemiol. 2003;157:218-226

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American Journal of
EPIDEMIOLOGY

Time Line of Cervical HPV Infections And Progression to Cervical Cancer



Adapted from Schiffman & Castle NEJM 2005; 352:2101-05

Prophylactic HPV Vaccines Are L1 Virus Like Particles (VLPs)

L1 Insertion into a Baculovirus Expression Vector

Production in Insect Cells

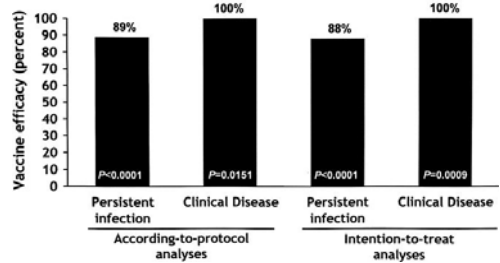
Spontaneous assembly of L1 into VLPs

Induce high titers of virion neutralizing antibodies

Non-infectious, Non-oncogenic

Reinhard Kirnbauer et al. PNAS 1992

Quadrivalent Vaccine Efficacy



Villa et al. Lancet Oncology, 2005;6(5):271-8.

National HPV Immunisation Program

- Commenced April 2007
 - funded catch-up for women 12-26 years ended Dec 2008
- School Program:
 - 2007
 - Years 7, 10-12
 - 2008
 - Years 7, 9 & 10
 - 2009-
 - Year 7 only

Evidence increased risk

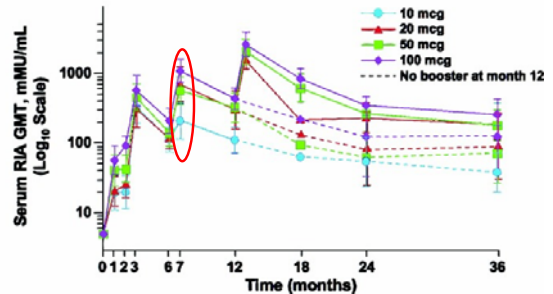
- Kane *et al.* Higher Incidence of Abnormal Pap Smears in Women With Inflammatory Bowel Disease. *Am J Gastroenterol.* 2008;103(3):631-6.
- Bhatia *et al.* Abnormalities of uterine cervix in women with inflammatory bowel disease. *World Journal of Gastroenterology.* 2006, 12:6167-71
- Tam Increased prevalence of squamous intraepithelial lesions in systemic lupus erythematosus: association with human papillomavirus infection. *Arthritis Rheum.* 2004;50(11):3619-25.
- Sasadeusz *et al.* Abnormal cervical cytology in bone marrow transplant recipients. *Bone Marrow Transplant.* 2001;28(4):393-7.

HPV exposure risk

- Paediatric cancer
 - female leukaemia survivors initiate sexual activity at the same age as healthy adolescents
- Rheumatology
 - 19.3 years (SD 3.9 years) higher than the general population at the time of the study (17 years)
 - 7.1% were sexually active before 16 years
 - 37.6% before transfer to adult care

Puikko *et al.* *Arch Dis Child.* 1997, 76:197-202
Packham *et al.* *Rheumatology.* 2002;41(12):1440-3

HPV 11 VLP Vaccine: Serologic Response



Frazer *et al.* PIDJ 2006

HPV study

Special Risk Group	Number of Participants
Paediatric Rheumatological Diseases (PRD)	38
Inflammatory Bowel Disease (IBD)	14
Paediatric cancer	10
Solid Organ Transplant Recipient (SOTR)	1
Chronic Renal Disease	1

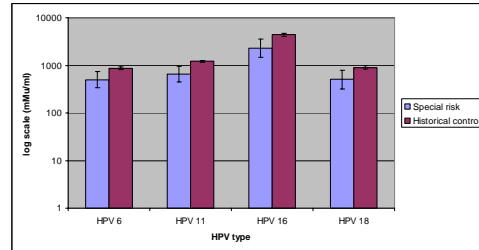
4vHPV [6,11,16,18] vaccine study

- median age
 - 14.7 years [range 11.8 to 24.7]
- median time for 3 dose administration
 - 6.1 months [3.9 to 16.5 months]
- median time post serology
 - 1.4 months [0.9 to 23.2 months]

Post hoc analysis

Immune category		No. participants
Level 0	nil or NSAIDs only	15
Level 1	corticosteroids only or <u>Immunomodulator</u> •Methotrexate •6-MP •azathioprine •cyclosporine •tacrolimus	22
Level 2	<u>Biologic therapies</u> (TNF blockers) •etanercept •infliximab or combination therapy of any level 1 medications	27

Immunogenicity GMT by HPV type compared with historical healthy controls*

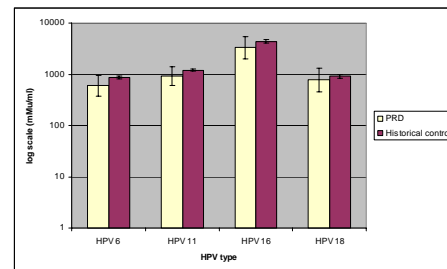


*CSL PI Gardasil (Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant vaccine)

JIA (n=28): combination therapies

	Medication [+ combination]	No. participants
Level 0	None	2
	NSAIDs	1
Level 1	methotrexate	8
	sulphasalazine	1
Level 2	Biologic alone	4
	Biologic + methotrexate	3
	Biologic + methotrexate + prednisolone	4
	Biologic + sulphasalazine	1
	methotrexate + prednisolone	3
	sulphasalazine + prednisolone	1

PRD immunogenicity



CSL Product Information Gardasil (Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant vaccine)

Diminished response

- 1 non-responder
 - SOTR (renal)
 - Tacrolimus, mycophenolate; prednisolone
- 4 incomplete responders
 - Type 6 (PRD)
 - Type 18 (IBD x2; Paed cancer x1)
 - 3 of 4 > 16 years of age

Vaccine Safety

- Unsolicited
- One reported flare
 - 3 days post dose 3 4vHPV vaccine
 - lasted 6 weeks
 - very active background disease
 - on biologic and immunomodulator therapy
 - Nil change in medications

Is your child up-to-date with their immunisations?

Our records show that your child may not be up-to-date with all the recommended immunisations.

Perhaps...

- You have immunisation questions
- Your child is over-due an immunisation
- Your child's immunisation record needs up-dating*

Who can help you?

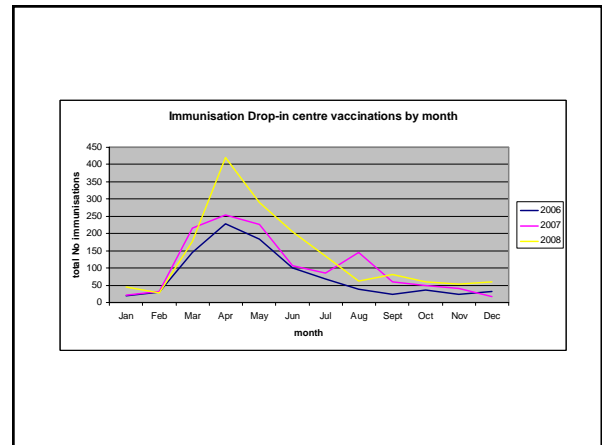
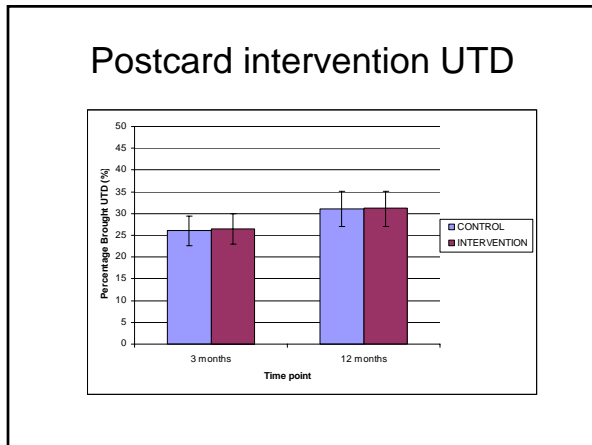
- RCH immunisation nurses at the drop-in centre:
 - Front Entrance (yellow box)
 - Open 9am-5pm weekdays
 - Tell them if your records need updating
- Your out-patient clinic doctor
- Local doctor or paediatrician
- Maternal & child health nurse
- Immunisation council clinic

*Your child's immunisation records are kept on the Australian Childhood Immunisation Register (ACIR). This card is from RCH Immunisation Service staff. Dr Nigel Crawford, Ms Soraja Eka, Dr Jenny Royle. Tel: 9345 6399

Postcard reminder RCT

	Control	Intervention
Participants	648	466
Gender (% male)	62.8	56.9
Age	2.9 (+/- 1.8)	2.8 (+/- 1.8)
Proportion < 5yrs	81.5%	80.7%
No. appt (mean +/- SD)	1.4 +/- 0.7	2.3 +/- 1.8**
Clinic (% medical)	62%	60.1%

**p < 0.0001



Minimising missed opportunities to vaccinate

- Immunisation status assessed at each healthcare contact
- Needs to be easily available to HCWs if parents unsure
- Only true medical contraindications should delay immunisations

Crawford NW, Buttery JP [Editorial] J Paediatr Child Health 2008 Jun; 44(6):315-6.

Minimising missed opportunities to vaccinate

- 'Window of opportunity' before commencing immunosuppression
- Required vaccines should be administered simultaneously
 - avoid confusion and further missed opportunities
- All vaccinations should be recorded in the personal health record & ACIR

Publications

- Crawford NW, Heath JA, Buttery JP. Immunisation practices of paediatric oncologists: An Australasian survey. *J Paed Child Health.* 2007;43(9):593-6.
- Crawford NW, Buttery JP. Minimising missed opportunities to vaccinate. *J Paed Child Health.* 2008;44(6):315-6.
- Crawford NW, Vivien Y, Hunt RW, Barfield C, Gelbart B, Buttery JP. Immunisation practices in infants born prematurely: Neonatologists' survey and clinical audit. *J Paed Child Health.* 2009;45(10):602-9.
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- Crawford NW, Heath JA, Ashley D, Downie P, Buttery JP. Survivors of childhood cancer: An Australian audit of vaccination status after treatment. *Pediatr Blood Cancer.* 2010;54(1):128-33.
- Crawford NW, Buttery JP. Immunizations in an adolescent with inflammatory bowel disease. *Paediatrics and Child Health* 2011; 21(3):146-47
- Crawford NW, Bines JE, Royle J, Buttery JP. Optimizing immunization in pediatric special risk groups. *Expert Rev Vaccines.* 2011;10(2):175-86.

EXPERT REVIEWS
Optimizing immunization in pediatric special risk groups
Expert Rev. Vaccines 10(2), 175-186 (2011)

Research

IMMUNISATIONS IN IBD

People with IBD can be more susceptible to infection than the general population. Here paediatrician Nigel Crawford explains how you can minimise the risk of illness.

THERE is an increased risk of infections in all individuals who have a chronic illness such as inflammatory bowel disease (IBD). This is related to a number of factors, including the effect of the underlying IBD itself and the immune suppressive medications (e.g. prednisolone, azathioprine, methotrexate, infliximab) that are often needed to treat it. There is also a risk of infections through frequent attendance at healthcare facilities, including both outpatient visits and hospitalization. Unfortunately, not all of these so-called "opportunistic" infections are preventable. Individuals with IBD, particularly those being treated with immune suppressants, should ensure they present early for a medical review if they have a high fever or other signs of illness.



The aim is to see if they respond as well to the vaccine

Extra recommended free vaccines for babies born:

- **<28 weeks gestation:** Pneumococcal conjugate vaccine and hepatitis B vaccine at 12 months and pneumococcal polysaccharide vaccine at 4 years
- **<32 weeks gestation and/or**
- **<2000g birth weight:** Hepatitis B at 12 months of age
- **underlying medical condition:** Influenza vaccine annually, pneumococcal conjugate vaccine at 12 months and pneumococcal polysaccharide vaccine at 4 years

'e' health records

- Recommendations on discharge summary
 - Parents and GP
- Flag at outpatient appointments
 - Need resources to make sure immunisations can be administered
 - RCH Drop-in Centre
 - Monash Children's Hospital
- Long term follow-up: transition to adult care
 - HPV vaccination: persistence and protection?
 - Adult physicians
 - All of life immunisation register

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CHALLENGE

How can you best optimise immunisations in your patients?

