

Immunisation Program Update

Issue No. 2

June 2016

From the Manager:

Feedback received following the release of the first issue of this periodic newsletter has been positive. Thank you to all who sent Update #1 through your networks and contacts and to anyone who provided feedback.

We continue to see many changes in the program area and again in this edition, we seek to assist vaccine service providers with information that will assist them to understand the changes, new requirements and other impacts on services.

Please continue to send your suggestions and comments which can be emailed to:

immunisation@health.qld.gov.au

Karen Peterson

Manager, Immunisation Program

Alerts

Please make all practice/clinic staff aware of the following:

Providers are reminded that Seqirus (formerly bioCSL) Fluvax® brand trivalent influenza vaccine is NOT REGISTERED for use in children ≤5 years of age and is not recommended for use in children <9 years of age.

Fluvax® has been associated with unacceptably high rates of adverse events, particularly fevers and febrile convulsions in children of this age.

Fluarix Tetra® brand quadrivalent influenza vaccine is NOT REGISTERED for use in children <3 years of age.

The quadrivalent paediatric influenza vaccine Flu Quadri® Junior should be used for children <3 years of age.

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Make reporting immunisation data quicker and easier!

Send your immunisation data to registers electronically. Not sure how? Talk to your software vendor or Medicare's eBusiness team at:

p: 1800 700 199

e: ebusiness@humanservices.gov.au

- Are you using the latest software version? If not, your system may not be using the most up to date list of vaccines. Contact your software vendor for advice.
- If you send immunisation records by mail, do this at least weekly to make sure they are entered onto VIVAS as soon as possible.
- Not sure about the details of a child's previous vaccination history? Is a parent asking you why their child is overdue? Check the child's history on the ACIR secure site. Vaccine service providers can register for access to the ACIR secure site online at: <https://www.humanservices.gov.au/health-professionals/enablers/accessing-acir-using-hpos>

Vaccine reporting tips:

Menitorix® – report to ACIR as dose 1 of meningococcal C

This is the first dose of the meningococcal C component. ACIR will search for previously reported Hib doses for the child and automatically record the Hib component accordingly (routinely dose 4).

Priorix-Tetra® or **ProQuad®**

ACIR records **Priorix-Tetra®/ProQuad®** as the second dose of MMR and first dose of varicella vaccine.

18 month DTPa booster – This dose should be recorded as dose 4.

Regional updates

Public Health Units (PHUs) in Hospital and Health Services across Queensland periodically provide immunisation update sessions for vaccine service providers. These sessions provide an opportunity to ask questions about program changes and to raise and discuss professional issues amongst peers.

Information about scheduled updates for 2016 can be provided by your local PHU. Contact details for Queensland PHUs is available online at:

<https://www.health.qld.gov.au/system-governance/contact-us/contact/public-health-units/>



'No jab no pay'

Parents who are having issues with Australian Childhood Immunisation Register (ACIR) records need to make sure they register their child's Medicare number with Centrelink. The Australian Government Department of Human Services will check whether a child is assessed by ACIR as being up to date with their vaccinations (or has an approved exemption) when a family's payments are due. If the child's Medicare number is not registered with Centrelink, the child's ACIR records cannot be accessed and payments will be affected.

Families who are having issues with their payments should check with Centrelink to make sure their child's Medicare number is included in the information recorded by Centrelink.

Spotlight on HPV vaccination

Recently, there has been significant social media discussion about human papillomavirus (HPV) vaccine safety, particularly around premature ovarian failure (POF). It appears this was prompted by a statement from the American College of Pediatrics (ACP), a small group of clinicians who split from the esteemed American Academy of Pediatrics in 2002. In Queensland, these social media discussions may have affected parents' decisions about consent and some parents have withdrawn consent for HPV vaccination in the School Immunisation Program.

In this issue of The Update we provide you with information about HPV and vaccine safety that may help you in discussions with parents and patients to inform their decisions about vaccination. This information has been sourced from two National Centre for Immunisation Research and Surveillance (NCIRS) factsheets: Human papillomavirus (HPV) and Quadrivalent HPV Vaccine. These factsheets provide information on HPV disease; the current vaccines; and more detailed answers to frequently asked questions about vaccine safety, vaccine efficacy and impact.

Additionally, Associate Professor Julia Brotherton, Medical Director, National HPV Vaccination Program Register provides an update about the impact of HPV vaccination in Australia.



Image by Spirit Fire

HPV and vaccine safety

The National Immunisation Program (NIP) provides HPV vaccine for all children aged 11-13 years delivered through schools at no cost to parents and students. For those that miss this opportunity, a catch-up vaccination program is offered in the following year only.

Two HPV vaccines are available in Australia: the quadrivalent HPV vaccine, Gardasil®, which protects against four HPV types – 16, 18, 6 and 11; and the bivalent HPV vaccine, Cervarix®, which protects against two HPV types – 16 and 18. Gardasil is the only HPV vaccine currently registered in Australia for use in males. Gardasil® is provided through the Queensland School Immunisation Program.

Both vaccines provide 90–100% protection against persistent infection and cervical/genital disease due to HPV types 16 and 18 in females. Gardasil® also provides greater than 85% protection against persistent genital infection and disease due to vaccine HPV types in males.

Both Gardasil® and Cervarix® are safe and generally well tolerated. The most common side effect is a local reaction (pain, redness and swelling) at the site of the injection. No deaths reported in safety surveillance systems data in Australia or overseas, have been determined to be causally related to Gardasil® or Cervarix® vaccines.

The Global Advisory Committee on Vaccine Safety of the World Health Organization has reviewed the safety of HPV vaccines on six occasions and each of these reviews has concluded that the vaccines are safe.

There is no evidence from surveillance systems and follow up studies that syndromes such as premature ovarian failure (POF), postural tachycardia syndrome (POTS), or complex regional pain syndrome (CRPS) are occurring more frequently in vaccinated people than unvaccinated people. There is no scientific or epidemiological evidence that the HPV vaccines induce such illnesses.

Key Facts

- HPV infection rates are highest among young women, usually peaking soon after the age when most young women become sexually active. However, in men, HPV infection is evident at all ages and the risk of acquiring new HPV infection seems to remain stable over time.
- Cancers caused by HPV infection include cancer of the cervix, vagina, vulva, penis and anus. HPV infection is also associated with some cancers of the head and neck.
- The quadrivalent human papillomavirus (HPV) vaccine is now in its tenth year of use in Australia's National Immunisation Program. The impact on disease has been dramatic. Australia has been the first country in the world to document that HPV vaccination programs reduce the rates of HPV infection, genital warts and precancerous cervical lesions.
- Vaccination does not prevent infection from all HPV types. Therefore, Pap tests remain an important preventive strategy against cervical cancer for women.
- HPV vaccines are safe and generally well tolerated.
- No deaths reported in safety surveillance systems data in Australia or overseas, have been determined to be causally related to Gardasil® or Cervarix® vaccines.
- The Global Advisory Committee on Vaccine Safety of the World Health Organization has reviewed the safety of HPV vaccines on six occasions and each of these reviews has concluded that the vaccines are safe.

Impact of Human Papillomavirus (HPV) Vaccination in Australia

The following article has been provided by Associate Professor Julia Brotherton, Medical Director, National HPV Vaccination Program Register.

The quadrivalent human papillomavirus (HPV) vaccine is now in its tenth year of use in Australia's National Immunisation Program. HPV vaccines are now included in national programs in over 65 countries around the world and more than 200 million doses of the vaccine have been given.

The impact on disease has been dramatic. Australia has been the first country in the world to document that HPV vaccination programs reduce the rates of HPV infection, genital warts and precancerous cervical lesions.

Through sentinel surveillance at eight public sexual health clinics around Australia a large decline in the number of new patients with genital warts diagnosed over time has been observed. In young women diagnosis of warts declined quite rapidly following vaccination among women under 21 years of age, followed by women up to 30 years of age. Declines were also observed quite rapidly in same age heterosexual males showing the benefits of herd protection from vaccination. (Ali et al, BMJ 2013). Declines in genital warts are ongoing with most recent published data to mid-2014 from the Melbourne Sexual Health Clinic showing only 1.1% of women aged under 21 years present with genital warts compared to 18.8% prior to vaccine availability (Chow et al, STI 2014). Analysis of national hospitalization data for Australia also demonstrates declines in admissions coded as genital warts and shows declines of similar size for both Aboriginal and non-Aboriginal women and across social strata from those living in the poorest to wealthiest areas. These data support that the HPV vaccine was delivered equitably across the population (Smith et al, JID 2014; Smith et al, BMC Infect Dis 2016).



The prevalence of targeted type HPV infection of the cervix in young sexually active women has changed since the vaccine was introduced. In an assessment of 18-24 year old women attending for cervical screening in the pre-vaccine period 2005-2007 and in the post vaccine period 2011-2013, overall HPV prevalence declined, as did prevalence of any high risk type but this was overwhelmingly caused by a very large decline in the prevalence of those types targeted by vaccination from 28.7% (pre-vaccine period) to 6.5% prevalence (post-vaccine period) regardless of whether the individuals were vaccinated in the post vaccine sample. Prevalence ratios adjusted for age and hormonal contraceptive use showed that even unvaccinated women experienced a significant decline post vaccination in vaccine targeted HPV infection suggesting herd protection from vaccination. (Tabrizi & Brotherton et al, Lancet ID 2014). Similarly in a study where young Victorian women aged 18-25 years were recruited on Facebook to send in a self-collected vaginal swab, although 25% were HPV positive, with 15% having a high risk type, only 1.6% (95% CI 0.7-3.3%) had HPV6/11/16 or 18 detected. In all cases of HPV16 infection, the women were sexually active prior to vaccination. This remarkable reduction in HPV16 circulation in young sexually active women has been observed and reported (Osborne et al, Vaccine 2015).

Perhaps most significantly, cervical pre-cancer rates in young women in Australia have started declining since the vaccine was introduced (Brotherton et al, Lancet 2011). This is the strongest evidence to date that the vaccine is preventing lesions that may otherwise

develop into cancers in the coming years. Almost all results from cervical screening, which is currently recommended for all women aged 18 to 69 every two years, are recorded on Pap test registers in each state and territory. These data are collated nationally to monitor the performance of the cervical screening program. To the end of 2013, the rate of biopsy confirmed high grade cervical lesions (CIN2+) per 1000 women screened has fallen by nearly 60% in women < 20 years of age since vaccination became available and significant falls commenced somewhat later but are now highly significant in the 20-24 year old age group (25% decline) (AIHW 2015). This age group have had the highest rates of these lesions for many years but since 2010 they have become lower than the 25-29 year old rate due to ongoing declines. This is a complete change in the epidemiology due to vaccination and is increasing over time as women vaccinated prior to sexual debut commence screening. Two data linkage studies (one in Victoria and one in Queensland) have confirmed that disease rates are lower in vaccinated than unvaccinated women (Gertig et al, BMC Medicine 2013, Crowe et al, BMJ 2014). Recently published data from Victoria now show the decline in high grade lesions is extending up to the 25-29 year old age group (Brotherton et al MJA 2016).

Useful Links:

Brotherton JML, Gertig DM, Chappell G and Saville M, HPV vaccine impact in Australian women: ready for an HPV-based screening program. MJA 204 (5), 21 March 2016.

<https://www.mja.com.au/journal/2016/204/5/hpv-vaccine-impact-australian-women-ready-hpv-based-screening-program>

Watch a video with Dr Julia Brotherton discussing the HPV vaccine, its impact and its relationship to the renewal of recommendations for cervical screening in Australia.

<https://youtu.be/pEDuaCpRpEo>

Hawkes D and BATTERY JP, Human papillomavirus vaccination and primary ovarian insufficiency: an association based on ideology rather than evidence, Current Opinion in Obstetrics & Gynecology: February 2016-Volume 28-Issue 1-p 70-72.

http://journals.lww.com/co-obgyn/Fulltext/2016/02000/Human_papillomavirus_vaccination_and_primary.11.aspx

Human papillomavirus, National Centre for Immunisation Research and Surveillance (NCIRS).

http://www.ncirs.edu.au/assets/provider_resources/fact-sheets/human-papillomavirus-hpv-fact-sheet.pdf

Human Papillomavirus (HPV) Fact Sheet, Queensland Health.

<http://conditions.health.qld.gov.au/HealthCondition/condition/14/217/80/human-papilloma-virus-hpv>

Cancer Council Australia, HPV Vaccine - Is the vaccine safe?

<http://www.hpvvaccine.org.au/parents/is-the-vaccine-safe-parents.aspx>

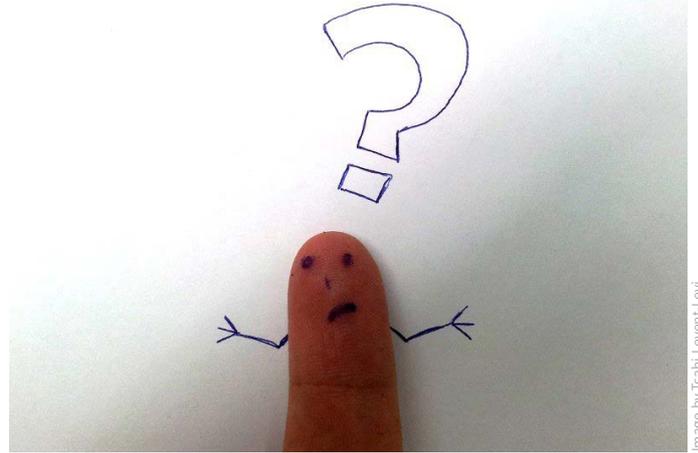
Influenza

Key points for influenza season

Please take care when recording influenza vaccine and ensure that the correct vaccine is recorded.

Vaccine storage

You need to ensure you have adequate storage space in your vaccine fridge to safely store your all your vaccines. It is not acceptable to store vaccines in a bar fridge, an unmonitored fridge or a fridge external to your practice/clinic.



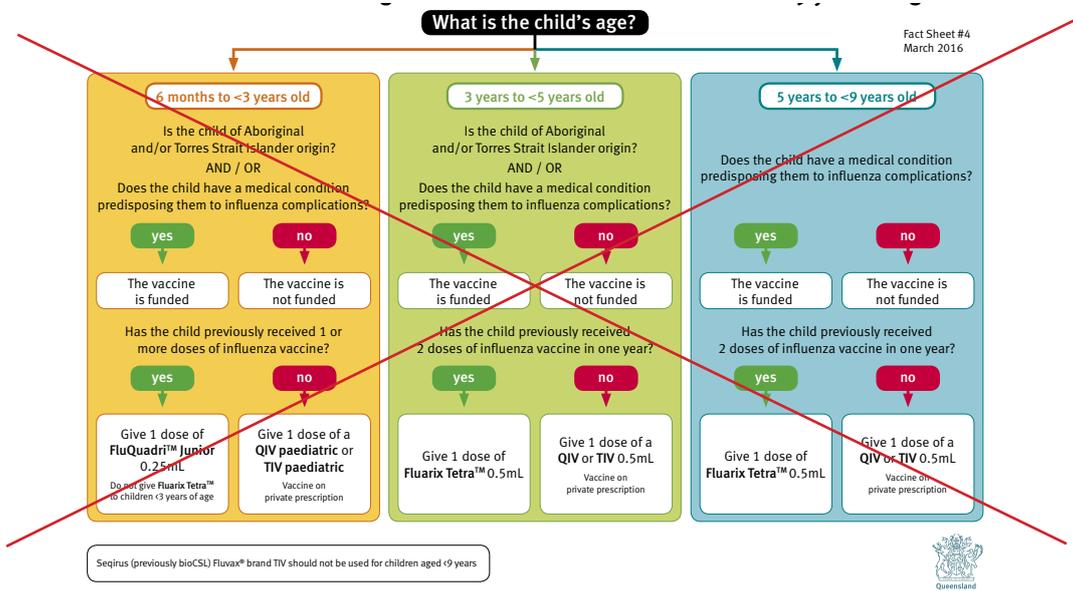
Which influenza vaccine do I use?

If you're unsure about which influenza vaccine to give to anyone eligible for vaccine supplied through the funded program, the table below should assist you:

Age	Vaccine	Dose	Number of doses required	
			In the first year of influenza vaccination	If previously received 1 or more doses of influenza vaccine
6 months to <3 years	FluQuadri™ Junior	0.25 mL	2 (4 weeks apart)	1
≥3 years to <9 years	Fluarix Tetra™	0.50 mL	2 (4 weeks apart)	1
≥9 years	Fluarix Tetra™	0.50 mL	1	1

The Australian Technical Advisory Group on Immunisation (ATAGI) advice for immunisation providers regarding the administration of seasonal influenza vaccine in 2016 is available at: <http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/ATAGI-advice-influenza-vaccines-providers>

Reminder: The 2016 influenza flowchart for children under 9 years (Fact Sheet #4) has been recalled as it contained an error. Please discard all copies.



Monitoring influenza vaccine safety

Active vaccine safety surveillance is conducted nationally in young children to monitor for the type and rate of reactions to each year's new influenza vaccine. This program is called AusVaxSafety*. As of mid-May 2016, the families of more than 1200 children aged 6 months to 5 years from more than 100 'sentinel' locations across Australia have responded to SMS or email messages to give us feedback on how their child felt days after vaccination.

This is the first year that the new quadrivalent vaccines (containing 2 influenza A and 2 influenza B strains) are being provided under the National Immunisation Program.

Results of this surveillance indicate that the safety profile of the 2016 influenza vaccines in children is excellent and the type and rate of vaccine reactions is within usual limits. Only 9% of participants have reported any reaction. Reactions recorded have been mild and resolved within 1-2 days. The most commonly reported symptoms include tiredness, irritability, and pain, swelling or redness at the injection site. A fever was reported in less than 3% of children. A small proportion of children (1%) have sought medical attention for symptoms following immunisation, and these have generally not been directly related to vaccination.

No vaccine-attributable serious adverse events have been recorded for the patients in this program. It is also important to note that safety demonstrated in children provides assurance that the vaccine is safe among all age groups.

Across Australia, health departments, clinicians and other researchers are conducting ongoing surveillance activities to monitor vaccine uptake, safety and effectiveness, and influenza activity. The success of AusVaxSafety surveillance is due to the active engagement of the public whose participation allows for real-time feedback on the safety of each year's influenza vaccine.

* AusVaxSafety surveillance is a collaborative initiative led by NCIRS and involves vaccine safety experts, state and territory public health systems, general practitioners and children's hospitals across Australia. It is funded by the Australian Government Department of Health. AusVaxSafety partners with and makes use of several computer-based surveillance systems, Vaxtracker, SmartVax, and STARSS, which send SMSs or web-based surveys to parents and carers seeking information on how their child felt after receiving the influenza vaccine.

Many Queensland GPs are participating in AusVaxSafety and their contribution is highly valued.

More information is available at: <http://www.ncirs.edu.au/surveillance/ausvaxsafety/>

Expiry date on vaccines

Vaccine expiry dates are applied to a vaccine to indicate the time up to which the vaccine is viable and can vary for different vaccines. For example the expiry date can appear as one of the following formats:

- mm/yyyy, or
- dd/mm/yyyy

If the expiry date appears as mm/yyyy then the vaccine does not expire till the end of the month of the expiry date ie if the month is 12/2016 then the vaccine does not need to be discarded till the 31 December 2016.



If the expiry date appears as dd/mm/yyyy then the vaccine expires on the actual date.



Diphtheria, tetanus and pertussis containing vaccines – DTPa and dTpa: which one do I give?

We know, it's complicated!

There are a number of different DTPa and dTpa vaccines (and different brands) in the schedule.

- DTPa – paediatric formulation for children under 10 years of age. Three different DTPa vaccines are used in the schedule. Funded vaccine is available for routine scheduled vaccinations and for catch up to 10 years of age.
- dTpa – adult/adolescent formulation for individuals over 10 years which contains reduced dosage of the diphtheria and pertussis vaccines. Funded vaccine is for adolescents eligible under the National Immunisation Program schedule, and for pregnant women (in their third trimester).

Which one do I give?

The table below will assist your decision making when choosing which funded vaccine to use for which age:

Schedule point	Diphtheria, tetanus, pertussis containing vaccines	Notes
2, 4 & 6 months	Infanrix hexa <i>DTPa-IPV-HepB-Hib</i>	
18 months	Infanrix or Tripacel <i>DTPa</i>	
Year 7 & 8 (School Immunisation Program)	Boostrix <i>dTpa</i>	
From 10 to 19 years	Boostrix <i>dTpa</i> Boostrix IPV or Adacel IPV <i>dTpa-IPV</i>	First dose of a catch-up schedule (either used as appropriate) No Jab No Pay
From 10 to 19 years	Tetanus and diphtheria toxoids absorbed	2nd and 3rd dose of a catch-up schedule No Jab No Pay
Pregnant women in their third trimester (from 28 weeks onwards)	Adacel <i>dTpa</i>	From 28 weeks At each pregnancy

Adults who wish to be vaccinated against diphtheria, tetanus, pertussis (dTpa) will need to obtain vaccine with a prescription from their GP.

Recording DTPa at 18 months and 4 years:

- The DTPa 18 month vaccination for children should be **recorded as dose 4.**
- DTPa-IPV at 4 years should be **recorded as dose 5.**

DTPa vaccine for children at 18 months

Infanrix® (GSK) and Tripacel® brand DTPa vaccines will both be supplied for vaccination of children at 18 months. For a time limited period, Sanofi will be supplying a DTPa vaccine which is labelled Daptacel® on the vial, with the outer box labelled Tripacel®.

Tripacel® and Daptacel® are the same, and the vaccine has been approved by the Therapeutic Goods Administration (TGA) for use in Australia.

Please be aware that you may start receiving Tripacel®/Daptacel® vaccine in your deliveries within the next month.

How to record this vaccine for ACIR and VIVAS:

Record as Tripacel® and include the batch number from the vial. Check that your medical software includes Tripacel® in its vaccine list. If it does not, contact your software provider to ask for the update. In the interim, record as generic DTPa with batch number.



Pertussis vaccination program for pregnant women

A range of new initiatives have been undertaken to promote the Queensland Government funded dTpa vaccine for pregnant women.

The popular VacciDate App, which has had over 38,500 downloads, has been updated to include a specific section on pregnancy. The Vaccination Matters website is now live with the new 'Whooping cough vaccine for pregnant women' content, including the 'Pregnancy' page and an additional slide on the Queensland Health homepage carousel. Check it out at: <http://vaccinate.initiatives.qld.gov.au/pregnancy/>. A range of new print resources promoting the funded dTpa vaccine for pregnant women with information and advice about pertussis can be found at <http://www.qld.gov.au/health/conditions/immunisation/increased-risk/pregnant-breastfeed/>.

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page 3 **Spirit Fire** <https://www.flickr.com/photos/spirit-fire/> "girls with heads together"

page 6 **Tsahi Levent-Levi** <https://www.flickr.com/photos/86979666@Noo/> "Finger face with a question"