12 February 2019

Dr Masha Somi
Australian Technical Advisory Group on Immunisation (ATAGI)
Department of Health
GPO Box 9848 – MDP 13
Canberra ACT 2601
atagi.secretariat@health.gov.au

Dear Dr Somi,

Consultation: Proposed changes to the recommended use of pertussis vaccines in pregnant women

SHPA is the national, professional, for-purpose organisation for leading pharmacists and pharmacy technicians working across Australia's health system, advocating for their pivotal role improving the safety and quality of medicines use. Embedded in multidisciplinary medical teams and equipped with exceptional medicines management expertise, SHPA members are progressive advocates for clinical excellence, committed to evidence-based practice and passionate about patient care.

SHPA welcomes the opportunity to comment on and supports the proposed changes to the recommended use of pertussis vaccines in pregnant women. SHPA convenes a Women's & Newborn Health Leadership Committee who have provided responses to the consultation questions below.

Are there additional potential benefits, risks or unintended consequences which could arise from the proposed changes to the use of pertussis vaccines in pregnant women, not already outlined and how likely are they to occur?

In Australia, acellular pertussis immunisation is only available as part of a combined vaccine e.g. dTPa (diphtheria-tetanus-acellular pertussis) or dTPa-IPV (diphtheria-tetanus-acellular pertussis- inactivated polio). These are a mix of subunits (inactivated parts of the bacteria) and toxoid components. By the suggested broadening of recommended vaccination timing from mid second trimester to early third trimester (i.e. from 20 to 32 weeks gestation rather than the previous 28 to 32 weeks gestation), there is the potential extension of placental antibody transfer from mother to foetus by up to eight weeks.

Pertussis antibody levels do not peak until about two weeks after vaccination. While transplacental antibody transfer begins as early as 13 weeks gestation, maximum transfer occurs from 30 weeks gestation onwards[1]. There is recent evidence of vaccine efficacy when administered to mothers in second trimester, with comparable antibody levels in cord blood after maternal dTPa vaccine administration in either second or third trimester[1,2]. This provides reassurance that the proposed extended timing window will enhance the success of passive immunity being provided to the infant until they can receive their first dose of pertussis-containing vaccine (from six weeks of age). Earlier vaccination may also assist in protection if the infant is born preterm[3,4].

Are there additional clinical or implementation considerations which need to be outlined?

Pregnant women are concerned about the safety of medication use in pregnancy and a significant proportion overestimate risk.[5]. Pertussis vaccine administration after the initial 13 weeks' gestation period (i.e. after the critical period of organogenesis[6]), allows clinicians to confidently reassure pregnant women that pertussis vaccine can be considered safe for both mother and baby. Theoretical safety has been supported by the results from a large retrospective observational cohort study that compared the outcomes of 123,494

pregnant women vaccinated with dTPA versus 29,261 unvaccinated women, using administrative health care databases from two California Vaccine Safety Datalink sites[7]. The study concluded that vaccination was not associated with an increased risk of adverse birth outcomes in this cohort of women with singleton pregnancies that ended in a live birth.

If you have any queries, please do not hesitate to contact Johanna de Wever, General Manager, Advocacy and Leadership on jdewever@shpa.org.au or (03) 9486 0177.

Yours sincerely

Kristin Michaels
Chief Executive

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