Offizielles Statement der TGA in Australien nach 2,2 Mio Dosen im australischen Impfprogramm

Human papilloma vaccine (GARDASIL®)

Advice from the Therapeutic Goods Administration

6 December 2007

- Australia is one of the first countries to roll out a massive cervical cancer immunisation campaign designed to protect young women from the strains of Human Papilloma Virus (HPV) that cause 70% of cervical cancers. Close to 20 million doses of the quadrivalent HPV vaccine (GARDASIL®) have been distributed world wide, including 2.2 million in Australia.
- The benefits of the vaccine will be substantial. Four out of five people will be exposed to HPV during their lifetime. Exposure from a single lifetime partner can still be enough to result in an infection that can lead to cervical cancer. Vaccination with HPV vaccine is most effective when it is given to females before they are likely to be exposed to HPV.
- There are over 700 new cases of cervical cancer reported each year in Australia (725 cases diagnosed in 2003), and by the age of 75, there is a risk of contracting this condition of 1 in 191. Cervical cancer resulted in the deaths of 216 people in 2005 and has a five year survival rate of around 74.6%.
- No vaccine is completely without side effects, but the diseases they prevent are far more harmful than the effects that can sometimes follow immunisation.
- Adverse events following immunisations are carefully monitored in Australia and regularly reviewed by expert advisory groups. A total of 496 suspected adverse events following injections of GARDASIL® have been reported in Australia to November 27, 2007. All have been assessed by an expert committee and in many cases also assessed by local authorities in States and Territories. The great majority are mild and common problems such as soreness, swelling or redness at the injection site (mentioned in 87 reports; 17.5% of reports). Other commonly reported reactions have included headache (96; 19.4%), dizziness (84; 16.9%), nausea (80 reports; 16.1%) and vomiting (30; 6.0%). A significant increase in reporting of adverse events is always seen after a new vaccine is introduced because of the higher level of awareness and lack of familiarity with a new product. Many of the events that are reported (such as headache, feeling dizzy or unwell) will be equally common in people of the same age who have not received the vaccine.
- In studies which compared the safety of the vaccine with placebo, large numbers of clinical study participants were given GARDASIL®. The results of these studies were considered in detail by the Therapeutic Goods Administration (TGA) before the vaccine was approved for use in Australia. This detailed information not unexpectedly showed some small increases in the rates of local and systemic adverse events with active vaccine compared with placebo and these are set out in the GARDASIL® product information document.

- The overall level of reporting for GARDASIL®, following the distribution of approximately 2.2 per million doses in Australia, is very low and consistent with that for other new vaccines and rates reported from other countries. Worldwide, almost 20 million doses have been given. With this number of people receiving the vaccine, even if all healthy and young, some serious events can be expected within days or hours of vaccination by chance alone but not related to vaccination. In Australia, adverse events reported following vaccines are all reviewed every 6 weeks by an expert committee, the Adverse Drug Reactions Advisory Committee (ADRAC), which advises the Therapeutic Goods Administration (TGA). Every six months, detailed reports of adverse events are published in Communicable Disease Intelligence, a quarterly publication of the Department of Health and Ageing, which is distributed to members of the Communicable Diseases Network Australia and other interested health and immunisation providers. No deaths occurring after GARDASIL® have been reported in Australia and no deaths directly linked to the vaccine have been reported in the USA.
- An important category of possible reactions to any vaccine or one of its components is allergy. Allergic reactions if severe may require adrenalin injections or other treatment, so the possibility of allergic reaction, although rare, is the reason why all persons providing vaccines must have the necessary drugs and equipment to treat them. To date, there have been 10 reports of anaphylaxis and 45 reports of urticarial reactions (or hives) in Australia following GARDASIL®. The current estimated rate of anaphylaxis based on doses given in Australia is 5.1 per million. Internationally this rate is 1.7 per million doses. The rates for other vaccines given to children and adolescents range from 0 to 3.5 per million doses in international studies.[1] Anaphylaxis is a rare event but healthcare professionals and patients should be aware of its possible occurrence. The occurrence of anaphylaxis and allergic reactions is not predictable and can occur in anyone regardless of whether they have a previous history of allergy or not. All such cases reported to the TGA to date have either been treated appropriately or have resolved without treatment. The rare occurrence of allergic reactions with GARDASIL® does not change any recommendations regarding the vaccine, but it is important that such reactions are reported promptly by the treating doctor to the State or Territory Health Department or direct to ADRAC, as set out in the Immunisation Handbook.
- If a patient does experience an allergic reaction or other significant adverse effect they should consult their doctor, who may consider referral to a State-based vaccination coordination clinic prior to the giving of further vaccinations with GARDASIL®. The TGA continues to be in contact with international authorities to monitor the occurrence of any serious events related to the use of GARDASIL® anywhere in the world. The United States Food and Drug Administration (FDA) and the European Medicines Evaluation Agency have also both assessed GARDASIL® as being safe and effective.
- The product information for GARDASIL® has been updated since the vaccine was first marketed to reflect the accumulating clinical experience, but neither the TGA nor other regulatory agencies have considered any further regulatory action is required at this time. The Australian Technical Advisory Group on Immunisation (ATAGI) reviewed the safety of GARDASIL® at its meeting on 4 October 2007 and, whilst continuing to monitor the situation,

agreed that no changes to the recommendations for the use of GARDASIL® were required.

1. Bohlke K, Davis RL, Marcy SM. Braun MM et al., Risk of anaphylaxis after vaccination of children and adolescents. Pediatrics 2003;112: 815-820.

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