SASGO position statement on the safety of cervical cancer vaccines

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A recent report in a local newspaper implied that 2 learners who had received the vaccines against Human Papillomavirus (HPV) were adversely affected by the vaccines and that the damage was caused by the vaccines themselves. This information was not put into context and was attributed to the vaccines without any evidence. It is essential that the public understand that cervical cancer is the second most common cause of death from cancer in women living in low resource countries (second only to breast cancer) and the fourth most common cancer cause of death in women globally after breast, colorectal and lung cancer. It is estimated that there are over 6000 new cases of cervix cancer diagnosed in South African women every year, of whom over 50% will die from the disease. Of those women acquiring and dying from cervical cancer in SA over 80% are black women, due to the lack of access to cervical cancer prevention through Pap smears.

Cervical cancer is caused by infection of the cervix by certain strains of the human papillomavirus (HPV), of which there are over 200 types described. In most cases the virus is transmitted through skin to skin sexual contact, which is why it is recommended for young girls and boys i.e. before sexual contact is initiated. The most common types of HPV associated with cancer of the cervix (and other organs) are types 16 and 18, which are the types targeted for prevention in the two commercially available vaccines. The one type only targets types 16 and 18 (Cervarix and is the type offered to girls in South Africa), and the other prevents infection with types 16, 18, 6 and 11(Gardasil) (the latter two types cause genital warts). Globally over 600 000 cancers in men and women are associated with infection by HPV types 16, 18 and it is important to know that these types of HPV also cause cancer at other sites, such as the vagina, the vulva, the anus, the penis and the mouth and throat. Preventing infection with HPV is likely to provide major public health benefits to millions of men and women globally over the next decades.

Since 2006, the two vaccines that prevent infection with HPV 16 and 18 have been developed and extensively studied in very sophisticated clinical trials, involving thousands of girls and boys. These studies have compared the active vaccine with what is known as placebo – that is inactive fluid that cannot stimulate the immune system. Extensive study of the adverse or negative complications in the active versus inactive groups has shown no difference in occurrence of complications.

The most common complaint in both groups was pain at the injection site, dizziness/fainting and headache. There were no differences in serious medical events, new onset autoimmune and chronic diseases, or deaths in the active and inactive groups recorded. There were a number of deaths from rare diseases that were not judged to be active vaccine related. By the end of 2013 more than 144
million doses of the Gardasil vaccine and about 41 million doses of Cervarix had been distributed worldwide with very few side-effects recorded.

Since 2014, the Department of Health of the South African Government has rolled out HPV vaccination in the public sector to all grade 4 school girls and to date over 1.2 million girls aged 9 – 13 years have been vaccinated. This vaccination prevents the infection by HPV in girls and protects them against developing cancer-causing HPV in adulthood. The vaccination is administered by injection in two doses and all grade 4 girls from 9 years and older in public and special education schools are vaccinated via the school-health system. Once resources increase, the vaccine will be rolled out to boys. The greatest burden of disease associated with HPV is in girls, hence the decision to begin the program by administering the vaccine to girls before doing so to boys.

The vaccine has been extensively tested and has been in use in many other countries, including, Australia, UK, USA and low resource countries such as Rwanda, Bhutan, Uganda, Vietnam, Peru to name a few: of critical importance is that there have been very few major adverse events reported and the vaccines have both been shown to be safe, acceptable, feasible to administer and effective.

As with all vaccinations, some children may experience some bruising or redness at the vaccination site. In very few cases, due to nervousness and anxiety, some girls have reported vomiting and nausea, although this seems to be at the thought of being injected rather than a response to the vaccine. It is estimated by the World Health Organisation (WHO) that more than 3 million lives are saved through the use of vaccines to prevent many other diseases. In addition the WHO recommends that all girls aged 9 – 13 receive either of the two HPV vaccines intramuscularly, twice, 6 months apart. Over the age of 13 or if HIV positive, three doses are recommended for both vaccines.

Facts about cancer of the cervix in South Africa:

- Cancer of the cervix is the second most prevalent cancer in women in South Africa.
- Approximately 3000 women die annually due to cervical cancer.
- HPV is 100% responsible for cervical cancer – the most virulent strains of HPV are 16 and 18, and it accounts for 70% of all cervical cancers.
- Cervarix® is the vaccination that will be used. To provide optimal cover, two doses needs to be administered preferably 6 months apart
- Girls must receive BOTH dosages to ensure efficacy. If a girl did not receive the first dose during the first round, she may receive the vaccination during the second round.
- The vaccine is most effective if administered at 9 – 13 years of age.
- There are almost no or only very mild side effects.
- The safety of the vaccination has been verified by numerous international health associations, particularly by the World Health Organisation (WHO) which recommends that all girls aged 9 – 13 years are vaccinated.