

WHAT THE SOUTH AFRICAN DEPARTMENT OF HEALTH MUST DO AND PROVIDE FOR PUBLIC AWARENESS ON THE HPV VACCINE TO ENSURE INFORMED CONSENT:

Parents are not informed as to which HPV vaccine is to be used in South Africa, on the HPV invitation letter signed by Dr Aaron Motsoaledi, the Minister of Health and Ms Motshega, Minister of Basic Education for the vaccination rollout in March 2014.

On the Basic Education Health, Human Papillomavirus (HPV) Vaccination Consent* Form

It states that -

*“**Girls who are 12 years and older can assent by signing in the space provided. “*

Are we to understand that a child can make this medical decision without the consent of the parent and possible influence of the teacher or vaccine administrator?

According to medicalprotection.org

<https://www.medicalprotection.org/southafrica/factsheets/consent-the-basics>

“Correct as of December 2013

*In terms of s129(2) of the Children’s Act 38 (2005), a child may consent to his/her own medical treatment or the medical treatment of his/her child if he/she is over the age of 12 years and is of sufficient maturity **to understand the risks of the treatment** and the benefits associated with the treatment.*

Respect for patients’ autonomy is expressed in consent law; to impose care or treatment on people without respecting their wishes and right to self-determination is not only unethical, but illegal.

*Information. It is an offence to provide a health service to a user **without their informed consent, under the National Health Act 2003** (there are some exceptions to this, such as in cases of emergency or when there is a risk posed to public health). In addition, the National Patients Health Charter (2008) states: “Everyone **has a right to be given full and accurate information** about the nature of one’s illnesses, diagnostic procedures, the proposed treatment and the costs involved for one to make a decision that affects any one of these elements.”*

This form also states that the -

“1. The vaccine is safe with minimal risk to the girl. “

Below you will see that this statement is **false and that informed consent cannot be given** with the information that has been provided by the South African Department of Health.

This form also states that -

“8. If any of these problems get worse go to the nearest clinic or hospital and take the HPV immunisation card with you. “

What if the “problems” are too severe for the child to travel to the nearest clinic or the clinic is closed? Is an emergency number provided in this case?

This form also states that -

“Please note that the HPV vaccination cannot be given to girls who are under 9 years, or if they have had a recent severe illness, or are very ill on the day of the vaccination. The HPV vaccination will also not be given to girls who are pregnant or have already had the HPV vaccination. “

What if the child is not yet aware they are pregnant?

Due to the **misinformation** that has been sent out by the South African Department of Health on the subject of the HPV vaccine, we cannot see how any parent is able to give **informed consent**, let alone a minor.

We therefore ask the following questions regarding informed consent on the HPV vaccine roll-out and the parent's information pack:

A) Are the vaccine package inserts or a copy of these inserts provided to parents to read prior to obtaining consent?

B) Have South African government health officials required any modifications to the HPV vaccine package inserts such as the below requirements made by the Japanese Ministry of Health?

"Does the vaccine package inserts include stronger safety warnings to medical consumers regarding the possibility of Acute disseminated encephalomyelitis (ADEM), Guillain-Barre and neurological problems."

On March 26, 2013, the Japanese Ministry of Health, Labor and Welfare informed GlaxoSmithKline they had 30 days to alter the package insert for Cervarix by adding the following to the Precautions/Adverse Reactions section:

"Acute disseminated encephalomyelitis (ADEM): Acute disseminated encephalomyelitis (ADEM) may occur. In such cases, pyrexia, headache, convulsion, movement disorder, and disturbed consciousness, etc., generally occur within several days to 2 weeks after vaccination. If ADEM is suspected, diagnosis should be made by MRI etc., and appropriate measures should be taken.

Guillain-Barre syndrome: Guillain-Barre syndrome may occur. If any symptoms such as flaccid paralysis originating from the distal extremities, decreased or absent tendon reflexes, appropriate measures should be taken."

This letter required the manufacturers of Gardasil and Cervarix to add the following to the 'Precautions' section of their package inserts within the next 30 days:

"Although the mechanisms of pathogenesis are unclear, severe pain which is not localized at the injection site (e.g. muscle pain, arthralgia and skin pain, etc.), numbness, weakness, etc., may occur after vaccination and these symptoms may persist for long time. Vaccine recipients and their guardians should be instructed to consult a healthcare provider who can provide appropriate medical care including making neurological and immunological differential diagnosis if any abnormalities are observed after vaccination."

WHAT SA GOVERNMENT MUST DO AND PROVIDE FOR PUBLIC AWARENESS AND INFORMED CONSENT:

Other queries to Dr Motsoaledi, the South African Minister of Health

1) Do you, Dr Motsoaledi, believe in the right to informed consent?

South African parents have not been adequately informed of the serious potential risks involved, such as **death**, even if rare of the HPV to enable them to give informed consent.

(VAERS received 12 424 reports of AEFIs following qHPV distribution, a rate of 53.9 reports per 100,000 doses distributed. A total of 772 reports (6.2% of all reports) described serious AEFIs, including **32 reports of death**. The reporting rates per 100,000 qHPV doses distributed were 8.2 for syncope; 7.5 for local site reactions; 6.8 for dizziness; 5.0 for nausea; 4.1 for headache; 3.1 for hypersensitivity reactions; 2.6 for urticaria; 0.2 for venous thromboembolic events, autoimmune disorders, and Guillain-Barré syndrome; 0.1 for anaphylaxis and death; 0.04 for transverse myelitis and pancreatitis; and 0.009 for motor neuron disease. Disproportional reporting of syncope and venous thromboembolic events was noted with data mining methods.)

<http://www.ncbi.nlm.nih.gov/pubmed/19690307> and as stated and acknowledged on the American CDC (Centre of Disease Control) website

2) Are parents aware that data on the HPV efficacy against early stages of cervical cancer, are only available for females aged 15-17 years, not for 12-14 year-olds?

3) Are parents aware that a booster shot will be required since according to Dr. Diane Harper, the leading international developer of the HPV vaccines, *“if you vaccinate a child, she won’t keep immunity in puberty and you do nothing to prevent cervical cancer.”* Dr. Harper emphasized the need for Gardasil booster shots, because it is still unknown how long the vaccine immunity lasts. More booster shots mean more money for Merck, obviously and more risk for children.

4) Are parents made aware that the most effective prevention to reduce the incidence of cervical cancer is still the pap smear, which is by far the safer alternative and currently in the USA, one particular HPV blood test is starting to be recommended in place of the “Pap smear” test because it has been “shown” to give fewer false negatives than the “Pap smear” .

<http://consumer.healthday.com/women-s-health-information-34/misc-women-s-problem-news-707/fda-experts-debate-pap-smear-s-future-685746.html>

5) Will parents be notified of the possible effect on fertility (primary ovarian failure) and post-vaccination autoimmune phenomena, which are a major facet of the autoimmune/inflammatory syndrome induced by adjuvants (ASIA) and different vaccines, including HPV, have been identified as possible causes.

(Human Papilloma Virus Vaccine and Primary Ovarian Failure: Another Facet of the Autoimmune/Inflammatory Syndrome Induced by Adjuvants; American Journal of Reproductive Immunology; Colafrancesco S, Perricone C, Tomljenovic L, Shoenfeld Y; doi: 10.1111/aji.12151.) <http://www.ncbi.nlm.nih.gov/pubmed/23902317>

“We documented here the evidence of the potential of the HPV vaccine to trigger a life-disabling autoimmune condition. The increasing number of similar reports of post HPV vaccine-linked autoimmunity and the uncertainty of long-term clinical benefits of HPV vaccination are a matter of public health that warrants further rigorous inquiry.

Premature ovarian failure 3 years after menarche in a 16-year-old girl following human papillomavirus vaccination, BMJ Reports 2012, Deirdre Therese Little, Harvey Rodrick Grenville Ward, doi:10.1136/bcr-2012-006879.

Polysorbate 80 Causes Infertility, An Emulsifier That Can Damage Your Reproductive Health

Delayed effects of neonatal exposure to Tween 80 on female reproductive organs in rats. Gajdová M, Jakubovsky J, Války J., Food and Chemical Toxicology, 1993 Mar;31(3):183-90.

6) Will parents be notified that there was 200 events reported to the American Adverse affects VAERS detailing abnormal pap smears in girls who have had Merck’s HPV Vaccination Gardasil?

7) Will parents therefore be advised to have their children have pap smears after receiving the HPV vaccine.

8) Will parents be made aware that the rate of deaths as a result of cervical cancer were already in

decline in the developed world prior to the HPV vaccine? The American Cancer Society (ACS) notes that “between 1955 and 1992, the cervical cancer death rate declined by 74%” and adds that “the death rate from cervical cancer continues to decline by nearly 4% each year.

9) Are parents aware of the fast tracking of Gardasil (a mere six months of trial research) through the FDA without due scientific process and adequate research and conflicts of interest in how this vaccine came on the market? Merck was caught lobbying the 50 states for mandatory Gardasil vaccination before it had even secured FDA approval.

That the study was funded solely by Merck, which manufactures Gardasil, and all of the authors had financial ties to Merck. Most significantly, in every clinical trial evaluating safety for both Gardasil and Cervarix, the so-called placebo groups were given injections that included an active aluminum adjuvant. Though this is a common practice in vaccine trials, it is obviously a blatant means of biasing the results.

Human Papilloma Virus Vaccine and Primary Ovarian Failure: Another Facet of the Autoimmune/Inflammatory Syndrome Induced by Adjuvants; American Journal of Reproductive Immunology; Colafrancesco S, Perricone C, Tomljenovic L, Shoenfeld Y; doi: 10.1111/aji.12151.

Also, there are no restrictions with regard to conflicts of interest for the employees of the CDC or for those of the FDA (Kuehn, 2010). Each employee of either agency is allowed to own stock in drug companies. Dr. Julie Gerberding, former director of the U.S. Centers for Disease Control and Prevention, was named president of Merck & Co Inc’s vaccine division in 2009.

Gardasil Profit:

2012 sales: \$1.900 billion

2011 sales: \$1.2 billion.

When you factor in all the information unknown to the public. Does science really have anything to do with why this drug is even on the market?

Is there a cheaper alternative?

Researchers have been trying to find a cost-efficient method of detecting the cancer before it’s too late. “After years of work, a group of scientists have developed an alternative test to Pap smears. The vinegar test is inexpensive and can be carried out with very little training and not much need for equipment. It involves swabbing the cervix with vinegar, which makes any pre-cancerous tumors turn white. The results can be seen within just minutes.”

A total of 150,000 women living in the slums of Mumbai took part in the study. The results revealed that the vinegar test reduced cervical cancer deaths in the area by an overwhelming 31 percent. Experts predict that over 22,000 deaths in India and 72,600 deaths worldwide could be prevented as a result of this new method of screening.

<http://www.medicalnewstoday.com/articles/261381.php>

This can screen out those at risk from the 90-plus % of women who have no risk (and, in conjunction with a cryostatic (dry-ice cooled) probe, can also be used to treat the lesions found in those women with them), which should be used instead of either a “Pap smear” test or the recent FDA-approved blood test in developing countries as well as in those developed countries that wish to **minimize their healthcare costs** while maximizing the health of the people.

10) On the Basic Education Health, Guide for Educators, point 3.9 states,-

“All girls that were vaccinated will be observed for 15 minutes before they are returned to class.

Have doctors, nurses and other medical staff, especially those that are administering the vaccines

been issued with unified diagnostic criteria to help them recognize symptoms induced by the vaccine such as:

ADEM

GBS

Along with other symptoms as reported to VAERS such as:

blood pressure decreased

irregular heartbeat

heartbeat decrease

oxygen saturation decrease

blood sodium decrease which were all common with syncope and tonic-clonic episodes (formerly known as grand mal seizures)

loss of bladder control

Syncope (fainting)

Respiratory, thoracic and mediastinal disorders

Other symptoms of note are weakness and tingling of the extremities on one or both sides.

11) Have doctors in targeted vaccine areas been alerted to the adverse effects and sometimes delayed symptoms of the HPV vaccine and provided with protocols on patient care and who to report adverse reactions to.

The updating of the labeling for Gardasil required by the FDA is an admission that these conditions do exist and are of concern.

12) Are parents and medical staff informed of VAERS and the reporting process of adverse HPV reactions.

13) How many reports of ADEM or GBS have been filed in South Africa after HPV vaccinations?

14) Who will be held accountable to any HPV vaccine adverse effects and is a policy in place to financially assist HPV vaccine damaged children for medical costs and other related costs?

a) Have you established treatment for HPV vaccine victims?

b) Set a policy in place to provide financial relief for HPV vaccine victims?

c) Set a policy in place to investigate all who have been inoculated with HPV vaccines?

d) Encouraged a protocol of South Africa's top neurological scientists obtaining information on adverse effects of the HPV vaccine with other countries such as Japan and Germany, amongst countries who have questioned the safety of the HPV vaccine?

15) Are black South African parents alerted to the study done by researchers from Duke University who found that although African-American women are twice as likely as Caucasian women to die from cervical cancer, HPV vaccines target strains of HPV that are far less likely to infect them? Are black South African girls being subjected to unnecessary risks even more so than white South African girls?

The available vaccines only protect against four strains of HPV, which, according to the study African American women are half as likely as White women to carry. Neither Merck nor GlaxoSmithKline has addressed the lack of coverage for HPV strains prevalent in African American women. Merck is currently testing an updated HPV vaccine that fights nine dangerous strains instead of four—6, 11, 16, 18, 31, 33, 45, 52 and 58. Although their preliminary study results are promising, the disparity will likely remain.

“The most disconcerting part of this new vaccine is it doesn’t include HPV 35, 66 and 68, three of the strains of HPV of which African-American women are getting the most,” said study co-author, Cathrine Hoyo. *“We may want to rethink how we develop these vaccines, given that African-Americans tend to be underrepresented in clinical trials.”*

Shouldn’t these studies and questions confirm that at the very least, black populations should refrain from HPV vaccines until further evidence is provided that they are safe and effective?

Ref: The findings, presented on Oct. 28, 2013, at the 12th annual International Conference on Frontiers in Cancer Prevention Research hosted by the American Association for Cancer Research. The research was supported by the National Cancer Institute (R01CA142983 and R01CA142983-02S1). The authors reported no conflicts of interest.
http://www.dukehealth.org/health_library/news/hpv-strains-affecting-african-american-women-differ-from-vaccines

16) Have other risks been explained to parents on vaccines? Such as the risk of autism and thimerosal-containing vaccines?

A two-phase study evaluating the relationship between Thimerosal-containing vaccine administration and the risk for an autism spectrum disorder diagnosis in the United States which provides new epidemiological evidence supporting an association between increasing organic-Hg exposure from Thimerosal-containing childhood vaccines and the subsequent risk of an ASD diagnosis. It also explains, in concrete terms with examples, why certain other articles “missed” this linkage.

Ref: David A Geier, Brian S Hooker, Janet K Kern, Paul G King, Lisa K Sykes and Mark R Geier. Corresponding author: Mark R Geier mgeier@comcast.net. Translational Neurodegeneration 2013, 2:25 doi:10.1186/2047-9158-2-25
<http://www.biomedcentral.com/content/pdf/2047-9158-2-25.pdf>

17) World Health Organization estimate which clearly states that only 0.15% of those infected with carcinogenic HPV (high-risk HPV) will ever develop cervical cancer – much less die from it. According to Dr. Diane Harper, the leading international developer of the HPV vaccines, 70% of HPV infections resolve themselves without treatment in one year. After two years, this rate climbs to 90%. Of the remaining 10% of HPV infections, only half coincide with the development of cervical cancer.

We ask then, why is the South African Department of Health so single-minded on rolling this as yet, unproven to be safe, HPV vaccine?

MERCK Pharmaceuticals was found guilty by a court of law for having caused 27,000 heart attacks because of VIOXX. This same company now brings us GARDASIL for our children, claiming it will prevent cancer, but this HPV vaccine has now proven to bring about infertility in some, and autism-like symptoms and birth defects in the offspring of other.

Shouldn’t the burden of proof of safety and efficacy be upon those manufacturing, selling, and regulating the product and not the exposed populations who increasingly are being told that these vaccines are safe? Will there be a cancer epidemic in the future because of these vaccines?

Dr. Meryl Nass, board certified internal medicine practitioner and vaccine specialist, who agrees that Gardasil was rushed to market without adequate safety testing. Three years after approval for girls, the company likewise received approval to vaccinate boys age 9 and above with no new studies and very little data to justify this action.

Dr Meryl Nass is a physician in private practice who is known for uncovering the use of anthrax as a biological weapon in Rhodesia. MOUNT DESERT ISLAND HOSPITAL, 10 Wayman Ln, Bar Harbor, ME 04609, (207) 288-5081 (Office)

Regarding Gardasil’s adverse effects, Dr. Nass said,

“Children don’t usually die suddenly when they are healthy but there are certainly lots of teenage girls who have died relatively suddenly after Gardasil or developed severe neurologic reactions.

Therefore, if you are going to try to balance safety and efficacy when you prescribe something like a vaccine, you have to know how effective it's going to be. Does this really prevent cervical cancer in young women? And does it prevent it in women who have already been exposed to these viruses? ... So I don't know how other doctors prescribe something like Gardasil ... Basically, they make an assumption that since the FDA has licensed it ... the manufacturer would only market something that's safe, doctors go ahead and prescribe. And what they may not be aware of is that it is extremely hard to link a side effect to a vaccine, for many reasons. Getting a judgment against a manufacturer is very difficult and it has become more difficult due to some recent litigation that reduced manufacturer liability for vaccines in general."

Haug CJ, Human Papillomavirus Vaccination – Reasons for Caution, New England Journal of Medicine, August 21, 2008, 359; 861-862.

Conclusions

From the start, a vaccine against the human papillomavirus was completely unnecessary. Aside from the unreasonable health risks that come with this vaccine, Gardasil is also the most expensive recommended vaccine on the market and in South Africa cost over 10 times more than what the government pays for a typical vaccine against childhood diseases – depending on the brand, one HPV shot could cost between R595 and R896 although the government will negotiate significantly lower prices than those in the private sector, it will still remain an expensive vaccine. The high vaccine cost can be linked to the monopoly pricing power of vaccine manufacturers seeking to recover high development costs. Their retention of exclusive patent rights and their power to keep vaccine prices high are aided by the absence of compulsory licenses, which could authorize the competitive development of cheaper biogenerics through developing country manufacturers.

<http://mg.co.za/article/2013-06-07-life-saving-cancer-vaccine-will-be-difficult-to-implement>

Maybarduk P, Rimmington S: Compulsory Licenses: A Tool to Improve Global Access to the HPV Vaccine? Am J Law Med 2009, 35:323-350. PubMed Abstract

Andrus JK, Sherris J, Fitzsimmons JW, Kane MA, Aguado MT: Introduction of human papillomavirus vaccines into developing countries - international strategies for funding and procurement. Vaccine 2008, 26(Suppl 10):K87-92. PubMed Abstract | Publisher Full Text

Padmanabhan S, Amin T, Sampat B, Cook-Deegan R, Chandrasekharan S: Intellectual property, technology transfer and manufacture of low-cost HPV vaccines in India. Nat Biotechnol 2010, 28:671-8. PubMed Abstract | Publisher Full Text | PubMed Central Full Text

If HPV vaccines are as good as they should be, all of these questions should be easy to answer.

South African citizens have a right to know. It is called the right to **informed consent**.

What is more important to you, Dr Aaron Motsoaledi, – vaccine safety, or vaccine uptake?