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Damage to Immunisation Programmes from Misinformation on Contraceptive Vaccines

Julie Milstien, P David Griffin, and J-W Lee

Tetanus is responsible for 550,000 neonatal deaths globally each year. Tetanus toxoid vaccines are provided through the World Health Organization and the United Nations Children's Fund for national immunisation programmes to prevent infant deaths from tetanus. The vaccines are manufactured and controlled under strict standards. Rumours have circulated recently in Mexico, Tanzania, Nicaragua and the Philippines that WHO and UNICEF are using women as guinea-pigs to test a contraceptive vaccine given to them under the guise of tetanus toxoid vaccine. These rumours, apparently initiated by so-called 'pro-life' groups, are completely untrue. The vaccines do not contain contraceptive vaccines or any other substance which interferes with fertility or pregnancy and their labelling accurately describes their actual contents. The false claims made by these groups have had an adverse impact on immunisation programmes in all four countries.

NEONATAL tetanus is caused by a potent neurotoxin elaborated by the *Clostridium tetani* bacteria which flourish in wounds such as the healing umbilical stump. The stump is infected by the ubiquitous tetanus spores when unsterile instruments are used during delivery or when unsterile dressings are applied. Neonatal tetanus strikes babies, usually in their first week of life, with a mortality rate of up to 70 per cent. In the absence of preventive measures, this disease has killed 1.2 million infants each year and it has been responsible for 25 per cent of infant mortality and 50 per cent of neonatal deaths in areas of several developing countries.

Fortunately, the disease can be prevented by immunisation with tetanus toxoid vaccine (TT). About half the pregnant women in developing countries are immunised with TT. With the present immunisation coverage in women of childbearing age with at least two appropriately spaced doses of TT, about 700,000 infants are saved from neonatal tetanus every year. Additionally, about 15,000 mothers are saved from puerperal or post-abortion tetanus each year. The disease could be virtually eliminated if such immunisation reached more women.

STRATEGIES TO ELIMINATE NEONATAL TETANUS

In 1989, the Member States of the World Health Assembly resolved that neonatal tetanus should be eliminated¹ and the World Health Organization (WHO) developed a strategy for this purpose.² The strategy has three thrusts:

- delivery of tetanus toxoid vaccine in the manner most effective for protecting all newborns against neonatal tetanus;
- provision of clean delivery services to all pregnant women; and
- effective surveillance aimed at detecting and reacting to every case of neonatal tetanus.

In many countries, the most effective immunisation strategy is to give at least two doses of tetanus toxoid appropriately spaced during pregnancy to protect the mother and the unborn child at and following birth. In areas where infrastructure for delivering health services is better developed, the immunisation programme aims to give all women of childbearing age five doses of tetanus toxoid, properly spaced so as to provide immunity throughout their childbearing

life, and thus protect all their future children. It is the objective of routine childhood immunisation programmes to protect everyone, male and female, against tetanus and other diseases. However, prevention of neonatal tetanus must depend on the presence of protective immunity at the time of birth. This can be achieved by immunising women prior to or during pregnancy so that they can elaborate antibodies against tetanus. These antibodies can easily pass to the fetus across the placenta and protect the newborn from neonatal tetanus. Antibodies circulating in the mother's blood protect the mother from puerperal tetanus as well.

Immunisation strategies already evolved for WHO's global initiative for the eradication of poliomyelitis by the year 2000 involve polio-vaccine immunisation campaigns twice a year targeted at all children under five. The opportunity can be taken, if feasible during these National Immunisation Days, to immunise also those women who have not been reached by the routine TT immunisation services in places where neonatal tetanus cases still occur.

These two efforts, the acceleration of TT immunisation efforts for the elimination of neonatal tetanus, plus the use of National Immunisation Days to offer TT to women, have resulted in increased publicity about the TT vaccine and its immunisation schedule. This has led some people to claim that WHO has launched a new effort targeting women in mass campaigns in special areas, something which has not been done before. In fact, the immunisation strategies on which neonatal tetanus elimination is based are unchanged since 1980; only their acceleration and enhanced visibility are new.

Another question that is often raised is why so many doses are needed. Protection of the woman and her unborn baby starts two weeks after the administration of the second dose, provided the second dose is spaced at least four weeks after the first dose. However, this protection will be for a limited period of time unless it is boosted by additional doses.³ WHO recommends a five dose series to protect women and through them, their babies, throughout their childbearing life.

WHO agrees that it is important to protect men and boys as well as women against tetanus disease. This is done through the routine administration of diphtheria and tetanus toxoids and pertussis vaccines (DTP) to all children. In many

countries, tetanus toxoid is used in routine immunisation of older children of both sexes in the form of combined diphtheria-tetanus vaccines. These strategies are important to protect all children eventually against diphtheria and pertussis as well as tetanus, but it will not have an immediate impact on neonatal tetanus.

INACCURATE INFORMATION

In the past year, WHO and its partner in immunisation, UNICEF, have become aware of campaigns in four countries, Mexico, Nicaragua, Philippines, and Tanzania, to discourage women from receiving TT vaccine. The campaigns charged that immunisation campaigns providing TT, supported by WHO and UNICEF, were using women in Third World countries as guinea-pigs in an experiment to test an anti-fertility vaccine, targeting countries where population growth was high. Health officials in these countries were accused of being used by WHO as tools to limit population growth.

The publicity campaign even reached the Internet, with accusations presented by Human Life International, a 'pro-life' group claiming support of the Vatican. Human Life International circulated this information to its affiliates in more than 60 countries throughout the world, according to the press release on the Internet. (See box)

This publicity campaign apparently stemmed from reports in the scientific literature of a clinical trial carried out to assess the effectiveness of a prototype antifertility vaccine designed to provide protection against unplanned pregnancies for a period of one to two years, carried out by a group in India led by Talwar.⁴ The active ingredient in this vaccine is a subunit of human chorionic gonadotrophin (hCG), a hormone necessary for the initiation of pregnancy and produced in large amounts throughout pregnancy. It is hCG which is detected by pregnancy tests. The hCG used in the clinical trial was coupled with a protein 'carrier' so that it would stimulate the production of antibodies against hCG and thus prevent pregnancy. In the case of the study in question, the protein carriers used were diphtheria and tetanus toxoids, which are available relatively cheaply and produced under conditions which make them acceptable for human use.

There is no connection between tetanus im-

'Pro-Lifers' Accuse UN Agencies Falsely

The following is an extract from a press release issued by Human Life International, on the Internet.

Washington, May 16 1995/PR Newswire/via NewsPage

'.... Fr Matthew Habiger, PhD OBS, president of Human Life International, today called for a congressional investigation of "reports that millions of women in Mexico and the Philippines have unknowingly received anti-fertility vaccinations under the guise of being inoculated against tetanus"....

"The first discovery that tetanus toxoid vaccines contained the hCG hormone was made in Mexico in the autumn of 1994, when members of the Comité Pro-Vida de Mexico (Pro-Life Committee of Mexico) became suspicious of the protocols for the Mexican campaign: All males were excluded from the program and only women of reproductive age (15-45) were to be vaccinated.

"The Committee obtained vials of the tetanus vaccine. When analyzed by chemists they were found to contain hCG hormones as well as the tetanus toxoid....

"Soon, additional reports of tetanus toxoid vaccines laced with hCG hormones began to trickle in from the Philippines, where more than 3.4 million women were recently vaccinated against tetanus. Similar reports of hCG hormones being found in tetanus vaccine came from Nicaragua, which conducted its own vaccination campaign in 1993....

"Only women are vaccinated, and only the women between the ages of 15 and 45. (In Nicaragua the age range was 12-49). "But aren't men at least as likely as young women to come into contact with tetanus? And what of the children, including females? Aren't they also at risk? Why are these groups excluded from the vaccination campaigns?," asked Fr Habiger....

"The vaccination protocols call for multiple injections - three within three months and a total of five altogether. "But, since tetanus vaccinations provide protection for 10 years or more, why are multiple inoculations called for?" Habiger asked....

"At the moment, we only know the basic facts," said Fr Habiger, "but things look mighty suspicious that massive campaigns may be underway to vaccinate women against future pregnancies. If that is in fact the case the situation is absolutely unconscionable, with the women victims being treated as nothing more than uninformed, unwitting, unconsenting guinea pigs."

munisation programmes and this small clinical trial, carried out in India in 1994, and not sponsored, supported, nor executed by WHO. However, in order to discredit the development of anti-hCG vaccines, the information concerning these two separate activities has been erroneously linked and distorted to confuse people. Unfortunately this confusion can result in endangering the lives of infants and of their mothers by interfering with their access to immunisations.

After these rumours were spread, attempts were made to analyse TT vaccines for the presence of hCG. The vaccines were sent to hospital laboratories and tested using pregnancy test kits which are developed for use on serum and urine specimens, and are not appropriate for a vaccine such as TT, which contains a special preservative (merthiolate) and an adjuvant (aluminum salt). As a consequence of using these inappropriate tests, low levels of hCG-like activity were found in some samples of TT vaccine. The laboratories themselves recognised the insignificance of the results, which were below the reliable detection capability of the kits and were due to a nonspecific interaction between the adjuvant or other substances in the vaccine and the test kit. However, these results were misrepresented by the 'pro-life' groups with the resulting disruption of immunisation programmes.

When the vaccines were tested in laboratories which used properly validated test systems, the results clearly showed that the vaccines did not contain hCG. The results found in six laboratories in five countries on tetanus toxoid vaccines from seven manufacturers are available on request. The conclusion from all these studies was that the tetanus toxoid vaccines did not contain hCG. It was not found in the vaccines because it was not present. The low levels of hCG-like activity seen in some samples were the result of false positive reactions. In fact, in a laboratory in Hungary, it was shown that the sterile water supply from the local hospital gave a higher false positive level of hCG than did the TT vaccine.

Furthermore, laboratory specialists and experts in gynaecology consulted by WHO stated that the amounts of hCG, conjugated with protein, which would be necessary to elicit an immune response which could interfere with fertility or pregnancy would be hundreds or thousands of times higher than the biologically insignificant

amounts detected in the vaccine, even if these had been due to the presence of hCG.

TETANUS TOXOID VACCINES

As an organisation, UNICEF buys a large proportion of the vaccines which are being used for these immunisation programmes. The vaccines UNICEF buys are subject to a rigid system of inspection and control, not only by the national authorities in the countries where they are produced, but also through oversight by WHO. On behalf of UNICEF, WHO tests randomly selected samples of tetanus toxoid from those supplied by UNICEF to immunisation programmes, and conducts inspections of the manufacturers and of the national control authorities whose responsibility it is to release the vaccines.

These manufacturers and national control authorities have provided WHO with unequivocal statements that their vaccines contain only TT vaccine components and there is nothing in the vaccines which could interfere with fertility or pregnancy.

WHO has thus assured the governments in the countries involved that the manufacturing processes for tetanus toxoid are carefully and independently monitored and the process does not allow the final product to contain hCG. WHO and UNICEF consider it unethical for vaccine vials to contain active substances other than the vaccine itself and would strongly reject any vaccines that did not meet this criterion. Furthermore, the administration of tetanus toxoid vaccines has never produced either a fall in birth rate or an increased rate of spontaneous abortions in recipients, even in countries which have achieved high TT coverage levels and sustained this coverage over many years.

IMPACT OF RUMOURS ON IMMUNISATION COVERAGE

This publicity has had a strong negative impact on immunisation programmes in the four countries mentioned. In the Philippines, there was a court injunction, now lifted, against the use of tetanus toxoid in immunisation campaigns. According to Health Department personnel in the Philippines,⁵ the numbers of women getting tetanus vaccines dropped and immunisation against other childhood diseases such as measles

also dropped. Moreover, participation in the National Immunisation Day, essential in the polio eradication initiative, was diminished by this adverse publicity.

In Nicaragua, with the involvement of Cardinal Obando of the Catholic Church and the group Pro-Vida, immunisation with tetanus toxoid was stopped as well. The international organisations were accused of trying to sterilise women through use of tetanus toxoid, and the batches of vaccine in question were withdrawn by the Ministry of Health pending testing. Even when the vaccines were found to be negative for hCG, the Cardinal opposed continuing immunisation with TT until new vaccine could be used.

In Mexico, three groups, including the *Comité Pro-Vida de México* (Pro-Life Committee of Mexico), charged the Secretary of Health with genocide because of alleged use of TT vaccines containing an 'abortive and sterilising substance', even while noting that this could cause heads of families to lose confidence in immunisation campaigns resulting in children remaining unvaccinated against other diseases such as poliomyelitis. National legislators supported this charge of the Secretary of Health.

Tanzania requested assistance from WHO in combating the misinformation, which reportedly was a barrier to reaching their target to immunise mothers with tetanus toxoid. A local newspaper in Dar-es-Salaam quoted a German woman representative of a 'pro-life' group as charging that Mexico and the Philippines had been made the target of the World Health Organization-sponsored vaccine because of their high population growth.

WHO has in fact targeted 12 countries for enhanced activities to eliminate neonatal tetanus. These countries, which have contributed over 80 per cent to the global total of estimated neonatal tetanus deaths in 1994, are Angola, Bangladesh, China, Ethiopia, Ghana, India, Indonesia, Nigeria, Pakistan, Somalia, Sudan, and Zaire.

CONCLUSIONS

Experts in gynaecology and in immunisation agree that the charges that tetanus toxoid vaccines contain an anti-fertility or anti-pregnancy agent are without any foundation. Nevertheless, the charges, with tacit support from 'pro-life' and church groups, persist. The deliberate campaign to discredit immunisation programmes in several countries could result in deaths of newborn babies because they or their

mothers did not receive immunisations which would protect them from diseases of early childhood. It is too early to calculate the impact of such misinformation campaigns in terms of lives lost; WHO information systems are currently accumulating such data. The actions already taken by these groups and individuals have almost certainly cost the lives of infants, and possibly also of mothers, in the countries concerned.

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RÉSUMÉ

Le tétanos néonatal est responsable d'une grande partie (jusqu'à un quart) de la mortalité des nouveau-nés dans de nombreux pays en développement. L'anatoxine tétanique fournie par l'OMS et l'UNICEF aux programmes de vaccination visant à prévenir ces décès est préparée et contrôlée selon des normes très strictes. Au Mexique, en Tanzanie, au Nicaragua, aux Philippines, on a fait récemment courir le bruit que l'OMS et l'UNICEF prenaient les femmes comme cobayes pour tester un vaccin contraceptif, administré sous l'étiquette de vaccin antitétanique. Ces rumeurs, qui émanent apparemment de groupes se qualifiant de "pour la vie", sont totalement fausses. Les vaccins antitétaniques ne contiennent aucune substance contraceptive ou ayant un effet quelconque sur la fécondité ou la grossesse, et leur étiquette correspond exactement à leur contenu. Les fausses assertions de ces groupes ont exercé un effet nocif sur des programmes de vaccination destinés à protéger les bébés du tétanos néonatal.

RESUMEN

El tétano neonatal es el causante de hasta un 25 por ciento de la mortalidad infantil en muchos países en desarrollo. Las vacunas de toxoide tetánico, suministradas a través de la OMS y de UNICEF para programas nacionales de inmunización dirigidos a evitar dichas muertes, son elaboradas y controladas bajo estrictas normas. Según rumores circulados en México, Tanzania, Nicaragua y las Filipinas, dichas organizaciones estarían utilizando a las mujeres como conejillos de indias para probar una vacuna anticonceptiva, administrada veladamente en lugar de la vacuna de toxoide tetánico. Estos rumores, creados aparentemente por las llamadas agrupaciones "pro-vida", son completamente falsos. Las vacunas de toxoide tetánico no contienen vacunas anticonceptivas ni otras sustancias que interfirieran con la fertilidad o el embarazo, y sus etiquetas describen fielmente su verdadero contenido. Las falsas acusaciones de esos grupos han tenido un impacto negativo en los programas de inmunización creados para proteger a los niños contra el tétano neonatal.