

THE FOLLOWING ARTICLE ON THE SUBJECT OF VACCINE
HAS BEEN TAKEN FROM THE TIMES OF INDIA
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How many needle pricks can my baby take ?

India's human vaccine market – estimated at over Rs.680 crores – is viewed as a gold mine by multinational and national vaccine manufacturing companies. In recent years, a dizzying array of vaccines has been promoted for the prevention of chicken pox, hepatitis B, rubella, rabies and typhoid, apart from those already mandatorily included in the national child immunisation programme for the prevention of polio, tuberculosis, diphtheria, pertussis, tetanus and measles.

Advertising campaigns extolling these vaccines have warned of the 'dangerous consequences' to health should the public disregard immunisation for children. However, concerned parents have been left asking, "How many needle pricks can my baby take?" there are more questions. What are these vaccines made of ? What is the evidence of long-term immunity ? Are there long-term complications ? What are the contra-indications and side-effects ? Is there an alternative to vaccination ?

The Indian Academy of Pediatricians strongly supports the use of the four vaccines presently recommended in the government's child immunisation programme (BCG, Polio, DPT and Measles). In addition, it has recommended the inclusion of the rubella and Hepatitis B vaccines in the national programme. The academy now has a further list of vaccines which it has declared optional.

Justifying the academy's faith in these vaccines, its secretary general GS Hathi cites the disappearance of smallpox and the decline of polio as examples of the efficacy of immunisation. The burden of

illness and death due to these infectious diseases has been considerably reduced nationwide, he says.

Widespread faith in the 'magic wand' of vaccines has, however, come under increasing scrutiny from both a section of the public as well as the medical profession. At a recent meeting organised in Mumbai by The Health Awareness Centre, a local NGO, an audience of about 200 concerned parents was eager to debate the available evidence on vaccination and natural immunity. Many expressed concern about the safety and efficacy of the whole-cell pertussis vaccine (for whooping cough), as well as the vaccines in the child immunisation programme for rubella, hepatitis B and oral polio.

Vaccine scientist Jal Mehta says that incidents of vaccine failure have been largely responsible for the erosion of public confidence in immunisation programmes. Failures have been known to occur when the potency of the vaccine is not assured, leading to an outbreak of the disease in vaccinated children. In many parts of India, Mr. Mehta adds, the blame rests with the conditions under which these vaccines are stored.

Before conducting a vaccination programme, he says, a child's health record must be checked to ensure that there is no previous history of neurological disorders like convulsions, asthma, known allergies or evidence of immune suppression. In such cases, a vaccine should not be administered until the child's health has stabilised.

Field evidence has, however, revealed that such questions are not asked by government health staff. While the BMC has created a special cell to monitor

adverse vaccine reactions, such incidents are not appropriately investigated, admit senior government doctors. Nor is there a system for receiving regular reports from private medical practitioners.

Experts recommend judicious use of vaccines

A dizzying array of vaccines has been promoted for the prevention of chicken pox, hepatitis B, rubella, rabies and typhoid in the national child immunisation programme for the prevention of polio, tuberculosis, diphtheria, pertussis, tetanus and measles.

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Recommending a more judicious use of vaccines, health experts say that immunisation should be part of a total package that includes clean water, nutrition and environmental hygiene. In fact, according to some medical historians, several Western societies have seen a decline in many infectious diseases long before vaccines appeared on the scene largely because of improved standards of living.

Many illnesses like chicken pox are best allowed to run their natural course in childhood, says Mumbai-based general practitioner Dr. DM Dayal. According to him, chicken pox in childhood helps create immunity against severe attacks of shingles or herpes in adulthood. Evidence of long-term immunity provided by the newly developed chicken pox vaccine is still awaited, Dr. Dayal says, and, as of now, he has chosen not to recommend it to his patients.

Achala Daga, associate professor of community and preventive medicine at the JJ Hospital, says that what needs to be urgently addressed is mal-nutrition, the underlying cause of many diseases among children under five. Immunisation by

itself cannot save these children from untimely deaths. Dr. Daga adds that while there has been a decline in the incidence of some vaccine-preventable diseases like polio, today's major culprits are pneumonia, diarrhoea and malaria.

What's being pumped into a baby's body, ask concerned parents

Do today's young, educated and aware parents buy into the immunisation mantra? No way. They now want information on what is being pumped into their baby's body. They demand an assurance on the safety of vaccines and evidence of long-term immunity against disease.

Explaining the logic of immunisation and the vaccine manufacturing process, Shankar War, who is in charge of the bacterial vaccine department at Mumbai's Haffkine Institute, explains it thus: When a disease-causing micro-organism enters the body, the immune system is stipulated to fight the invader. The fighter cells produce antibodies to neutralise the invasion. If the individual's immune mechanism is compromised by poor nutrition or environmental hygiene, or drug abuse, the body takes a longer time to marshal its response.

Vaccines, meanwhile, are injections that contain small amounts of bacteria or virus, with the harmful elements removed. Bacteria causes diseases such as diphtheria, pertussis and tetanus, while viruses lead to polio, hepatitis, rubella, measles, mumps, chicken pox and rabies. When vaccines are injected, they artificially stimulate the body to produce antibodies. Consequently, when the real invader enters, the system is already geared to recognise the enemy and antibodies are promptly released to do battle.

Vaccine manufacturing relies on the use of live organisms that are obtained from "internationally reputed institutions." These are 'cultured' (grown) in the

laboratory. For multiplication, the bacteria or virus depends on the presence of other micro-organisms that it can feed on – and these are provided by animal or human cells. By entering the cell and destroying it, the organism then finds the means to grow.

The organism is killed or kept alive, depending on the specific vaccine requirement. For instance, vaccines like oral polio, rubella, measles and mumps utilise the live but weakened (attenuated) virus. (Animals are repeatedly infected with the virus over a long period of time until the virus loses its virulence and is weakened.)

The rabies and the Salk polio vaccine (named after its inventor, Jonas Salk) utilise the 'killed' virus, which undergoes treatment with heat and drugs. Although dead, the parasite still stimulates an antibody response.

The tetanus vaccine utilises the toxin excreted from the bacteria. The hepatitis B vaccine uses a new technology called 'recombinant DNA technology.' Here, the genetic information of the virus that causes this disease is isolated. This reveals the mechanism by which the hepatitis B surface antigen is manufactured. When injected into someone, it produces antibodies that fight the virus.

Meanwhile, the animal or human cells, used to 'culture' the parasite are generally derived from three sources. They could be 'human diploid cells' derived, for instance, from the lung of a human foetus. Or they could be 'vero cells' from the kidneys of the African green monkey, or primary chick embryos cells. Once obtained from the original host, a 'cell line' is developed and maintained in the laboratory and there is no need to go back to the original host.

The only exception, however, is in the case of the live (oral) polio vaccine. Every bulk batch of the polio vaccine requires a

return to the monkey host for obtaining fresh cells, confirms KK Das, Manager, Oral Polio Vaccine. Haffkine Institute.

A vaccine has a shelf-life of upto three years, provided it is consistently maintained at a stable refrigeration temperature of two to eight degrees Centigrade.

The main concerns about the vaccine manufacturing process focus on the instability of the micro-organism, impurity in the 'cell line' and the toxicity of the purification and stabilising agents. The latter include chemicals and heavy metals like mercury.

Vaccine scientist Jal Mehta says there is a "far-fetched chance" that mutation can take place in vaccines when there is chemical, bacterial or radioactive contamination that enters the genomes of the virus and changes its chromosomal pattern. The live polio vaccine, for instance, is highly sensitive to unstable temperature and is exposed to contamination if the vial is opened and left unutilised for several hours by health workers.

Several Western scientists have expressed concern about the use of primate tissue in vaccine manufacturing, and have urged that a 'serious effort' be made to stop its use. Last year, Western newspapers had reported the possibility of an experimental oral polio vaccine used in Africa in the 1950s being contaminated with the HIV virus present in the monkey cells used in the manufacturing process. This, they said, could have led to the virus jumping species and finding a new host in humans.

Under-reporting of adverse vaccine reactions could jeopardise infants' safety

Seem, a Mumbai housewife, says her baby was a "bubbly, smiling, healthy and responsible child" – that was until the child was given her first shot of the DPT

(diphtheria, pertussis and tetanus) vaccine at three months. It was after that the baby started to 'rock herself'. The doctors Seema consulted assured her that this was 'normal'. When the baby was 15 months, she was administered the MMR (Measles, Mumps and Rubella) vaccine.

"Thereafter, my child completely withdrew. her babble disappeared, she would not come to us, she would only look at my feet. I strongly suspect that it was because of a defective vaccine that my baby developed features of autism (a neurological disorder)."

There are many Indian parents like Seema whose story has not come to public attention because of the social stigma attached to autism. In Mumbai, the health authorities have not heard of such vaccine-damaged children. This is because doctors who administer the vaccine usually do not report cases of adverse vaccine reactions to the municipal authorities.

In the developed countries, where there is greater public awareness, vociferous questioning has forced governments to look this issue squarely in the face. When some infants in the UK and Japan died after being administered the whole cell pertussis vaccine (the 'P' component in the DPT vaccine), a massive public outcry prompted the governments concerned to suspend use of that vaccine.

Harvard University's Dean of Public Health, Barry Bloom, states in a recent interview that while the whole cell pertussis vaccine has worked well, it does have some side-effects, with one in 30,000 children becoming neurologically damaged.

Suspension of the vaccine in the UK, however, led to an increase in the incidence of whooping cough, says Mr. Bloom. This triggered research leading to the development of the cellular pertussis vaccine, which Mr. Bloom says is more expensive and less toxic.

The cellular vaccine has been licensed for use in Japan since 1981 and in the US since 1996 for children two months and older, confirms Stanley Plotkin, a leading vaccine scientist, who recently visited Mumbai, India, however, continues to use the whole cell pertussis vaccine in its national child immunisation programme.

Cases of healthy babies being damaged by the whole cell pertussis vaccine in the West have been documented by H. Coulter, a medical historian, and B. Fisher, vice president of 'Dissatisfied Parents Together', in their book. 'A shot in the dark'. The adverse reactions include convulsions, shock, abnormal screaming episodes and 'sudden infant death syndrome' (stoppage of breathing). The long-term complications include learning disabilities and hyper-activism, among other forms of brain damage. Such incidents are under-reported by doctors, for fear of malpractices suits, the authors of the study say.

Babies who suffer progressive neurological disease should not be administered the pertussis vaccine, say manufacturers of the vaccine here. But is that condition apparent to parents when the first dose of DPT is mandatorily given at six weeks of age in India?

A spokesperson of The Indian Academy of Pediatrics says, "The whole cell vaccine does give more local reactions. Unless a control trial is done, it is difficult to talk about the long-term reactions. We have always taken the stand that the cellular vaccine is better than the whole cell, because of the complications that occur after vaccination. But it is not available in our country. We have not, however, advocated use of the cellular vaccine to the government."

A vaccine against rubella or German measles is now being advocated for inclusion in the child immunisation programme, to be followed by a booster shot for adolescent girls. While Indian

data on rubella incidence is inadequate, extrapolations based on worldwide data have resulted in the claim that the estimated irrevalence in India is 100-200 per 100,000 population.

A harmless childhood disease, rubella produces mild symptoms that can pass unnoticed. Children who contract the infection are likely to acquire lifelong immunity. Rubella is, however, dangerous for women in the first six weeks of pregnancy, causing congenital malformations, deafness and mental retardation in babies. If rubella occurs after the first trimester of pregnancy, the incidence of foetus abnormality is low, says Mr. Plotkin, who developed the rubella vaccine.

US studies show that 36 per cent of the young women vaccinated against rubella in infancy lose their immunity by the time they are adolescents (Neil Miller, 'Vaccines and natural health', Mothering, Spring, 1994). Those who have never acquired natural immunity because of the vaccinations in childhood, run the risk of contracting rubella while pregnant.

Mr. Plotkin says it is 'easier to vaccinate babies rather than adults'. Routine vaccinations of infants would reduce the circulation of rubella in the population, he adds. But for that to happen, governments must ensure that at least 80 percent of the child population is covered by their programmes.

A simple but expensive IgM antibody test already exists to detect whether a woman, on the verge of motherhood, has antibodies to rubella. No effort has, however, been made to develop a cheaper test. The vaccine manufacturers insist that it is easier to vaccinate the entire population of babies instead.

Storage problem, government laxity raise concern over oral vaccine

India's record in vaccinating 121 million children against polio over two days, December 6 and 7, 1997, has been cited as one of the "most staggering achievements in the history of public health" by Harvard University's Dean of Public Health, Barry Bloom.

Mr. Bloom, a staunch proponent of vaccines, has spoken glowing of the campaign in the US as well, saying that polio is now virtually extinct in that country. However, he admitted in the course of a recent interview to a medical journal, that there were still eight to 15 cases reported every year in the US, and that these were "all derived from a single mutation in one of the live polio vaccines that causes the virus to revert to virulence."

The US based Centers for Disease Control are on record to say that the oral polio vaccine using the live virus has become the dominant cause of polio in the US today. This, say health experts, raises cause for concern.

Polio is held to be a contagious disease caused by an intestinal virus that may attack the nerve cells of the brain and the spinal chord. In 1955, Jonak Salk, an American physician and microbiologist, developed a killed-virus vaccine against polio. In 1959, Albert Sabin, also an American physician and microbiologist, developed a live-virus (oral) vaccine against polio. Both vaccines are considered safe and effective.

The oral, live-virus polio vaccine is now widely used in India's child immunisation programme. In the absence of a monitoring system to detect cases of polio among those who have been vaccinated, there are no studies on the efficacy of the immunisation campaign. Nor, for that matter, have there been widespread complaints on record. However, there have been some voices of dissent.

In a recent interview, Pushpa Bhargava, founder director of the Centre for Cellular and Molecular Biology, Hyderabad, questioned use of the oral polio vaccine, stating that it provided unreliable immunity. "OPV has not worked in this country. All evidence available as of today supports this view."

Dr. Indira Nath of the All India Institute of Medical Sciences has stated that her hospital sees numerous polio victims who have had the mandatory drops.

Health professionals say that given the instability of the oral polio vaccine, the often improper storage facilities in this country and laxity in administration of the vaccine by health workers, it may end up being defective. Further more, children whose immunity has been depressed due to a variety of factors, may respond adversely to the vaccine.

In the US, the instability of the live virus polio vaccine has now caused its use to be restricted to the first dose. Subsequent booster shots use the killed virus, reports Mr. Bloom.

Some scientists have been gone so far as to question the use of the polio vaccine, saying that in the West, the decline in the incidence of polio occurred long before the appearance of the vaccines.

"Many people mistakenly believe that anyone who contracts polio either becomes partially paralyzed or dies. However, in most infections caused by polio, there are few distinctive symptoms," say W. Volk and M. Wheeler in their book, 'Basic Microbiology'.

"In fact, the natural polio virus produces no symptoms at all in over 90 percent of the people who are exposed to it, even under endemic conditions," add M. Burnet and D. White in 'The Natural History of Infectious Disease.'

This has led more than one scientific researcher to conclude that the small percentage of people who do develop paralytic polio may be "anatomically susceptible" to the disease. The vast remainder of the population may be naturally immune to the polio germ, says Richard Moskowitz, MD, ('Immunizations: The Other Side').

According to some medical historians, long before the Salk killed-virus vaccine was introduced, the polio death rates in the US and the UK had already declined on their own by 47 percent and 55 per cent respectively. Statistics show a similar decline in other European countries as well (Michael Anderson, International Mortality Statistics, Washington DC, Facts on File, 1981).

These historians say that when the vaccine did become available, many European countries questioned its effectiveness and refused to inoculate their citizens systematically.

In 1948, at the height of the polio epidemic in the US, Dr. Benjamin Sandler, a nutritional expert at the Oteen Veteran's Hospital, detailed a relationship between polio and the excessive consumption of sugars and starches. He compiled records showing that countries with the highest per capita consumption of sugar had the greatest incidence of polio. He claimed that such 'foods' dehydrated the cells and leached calcium from the nerves, muscles, bones and teeth. A serious calcium deficiency, he said, precedes polio.

Building natural immunity can gear up body's response to future infections

Even as concerns remain about the safety and efficacy of certain vaccines used in the child immunisation programme is there a case to be made for the limited use of vaccines in children and adults ? Are vaccines the only means of building immunity against disease, or is there an alternative method ?

Medical professionals who endorse the use of vaccines point to their necessity in time of epidemics (outbreak of meningitis, Japanese encephalitis and influenza) and as therapeutic preventive treatment (anti-rabies vaccine). Dissenters argue against vaccinations on several counts.

For instance, some would argue that the use of the anti-rabies vaccine in India is a double-edged sword. Government hospitals in India continue to use a 'nervous tissue vaccine' against rabies. V. Srinivasan, a virologist and manufacturer of the modern tissue culture rabies vaccine, is of the view that the nervous tissue vaccine, which is cheaply available, tends to be administered in all dog bite cases, despite causing adverse reactions in some patients.

According to Mr. Srinivasan, those in high-risk groups, who routinely deal with animals, should be vaccinated against rabies. But, he adds, it is not recommended as a matter of routine for the general population. The vaccine also provides treatment against rabies after a dog-bite.

Experts in preventive and community medicine, meanwhile, recommend the use of preventive shots against meningitis or Japanese encephalitis at the start of its outbreak in any given area. They emphasise the importance of a 'disease surveillance mechanism' in districts that can serve as a timely warning and enable the health authorities to launch immunisation campaigns. While the

influenza virus is reputed to be highly unstable, anti-influenza shots are recommended for the old and the very young who are vulnerable to severe bronchial pneumonia.

Advocates of a natural health movement, on the other hand, say that building natural immunity against disease can be an alternative to vaccines. They argue that vaccines inject microbes directly into the blood-stream without censoring by the liver. Their view is that the persistent presence of viruses and other foreign proteins within the cells of the immune system leads to chronic and degenerative diseases.

These advocates add that childhood diseases are decisive experiences in the physiological maturation of the immune system and prepare the body for prompt and effective response to future infections. They should, therefore, not be suppressed.

They subscribe to the views of German bacteriologist Guenther Enderlein which hold that certain bacteria are able to take on multiple forms during a single life-cycle. When a person is healthy, these microbes live in a symbiotic relationship with other cells and play a helpful role in the body's immune system. Any severe deterioration of the body's internal environment, however, and they may change into disease-forming agents. Thus the germ is nothing but the "terrain is everything".

These researchers believe that a healthy "terrain" is dependent on a proper diet, particularly foods that are unrefined, organically grown and preservative-free. An improper diet tends to overwhelm the system and lead to disease, which is the cleansing effort of the body to rid itself of excess toxins and waste material.

The natural health movement believes that a healthy body requires adequate rest and sanitary living conditions. When all these requirements are met, many diseases will

pass an 'subclinical infections' without acute illness, or if there is illness, it will be relatively mild.

Alternative systems of medicine, such as homoeopathy, also question the basis of vaccinations. According to practitioner Zubin Marolia, homoeopathy believes that

some symptoms resulting in, say, ordinary fevers or abscess, are a part of the body's natural method of ejecting toxins and should not be suppressed.

The debate, for the moment, appears to be inconclusive.

