

EDITORIALS

Restricted availability of free anti-rabies vaccine in public health facilities in India: unethical and criminal

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More than 3 million cases of dog bite occur annually in India and hundreds of thousands of people are exposed to the risk of contracting rabies. But they are deprived of the free anti-rabies vaccine due to several unethical practices of the government and pharmaceutical companies.

Rabies is caused by the bite of animals, mostly dogs, who are themselves afflicted with rabies. The condition is fatal. An anti-rabies vaccine should be administered to people who have been bitten by a dog suspected to be rabid. The vaccine is one of the few medicines which was made available free of cost on a priority basis in public health facilities in India.

Until recently health centres used the obsolete Semple vaccine prepared from the brain of sheep. Other than the needless sacrifice of so many sheep, this vaccine had three problems. It was only 60-70 per cent effective. It usually required a course of up to 14 injections of 5 ml each. And about 1 in 5,000 persons injected with the vaccine would develop allergic encephalomyelitis, a serious brain condition.

The Semple vaccine was withdrawn in developed countries after the arrival of the more effective, safe and convenient cell culture vaccine. But its usage in India continued because it was much cheaper than the cell culture vaccine.

The Semple vaccine's cost advantage was lost when research showed that the cell culture vaccine was effective even when given through the intra-dermal route rather than the conventional intra-muscular route. This required one-fifth the dose and therefore the cost too became one-fifth. The World Health Organisation recommended the intra-dermal regimen as early as in 1992 (1). It has been extensively and successfully used in Thailand (2).

However, Indian authorities continued to use the obsolete Semple vaccine. This was partly because the manufacturers of the cell culture vaccine in India promoted it only for the intra-muscular route. None of the experts in the private medical sector was using the intra-dermal regimen. Their associations, studded with medical luminaries, have still not done anything to promote this route. This indicates the pervasive influence of vaccine manufacturers. It is a sad commentary on the ethics of the medical profession in India.

Unethical, callous neglect

In June 2005, the Semple vaccine was finally withdrawn from the Indian market as a result of a public interest litigation. When more than 3 million cases of dog bite occur annually in India, the authorities should have first ensured that adequate quantities of the cell culture vaccine were available. The budget of public health facilities should have been substantially increased to buy this comparatively more expensive anti-rabies vaccine. No such measures were taken. This was highly unethical neglect of what is, for poor patients, a matter of life and death.

The cell culture vaccine stocked now in public health centres is meant to be given free of charge to people with Below Poverty Line (BPL) cards. But the many poor people who do not possess a BPL card are asked to buy five injections of the vaccine, which costs Rs. 300 each. In some health centres all patients are charged Rs 50 per dose. Thousands of poor people cannot afford this expense and they go home without taking the injection.

Many amongst the poor have come to believe that people without a BPL card will have to spend Rs 1,500 in a government health centre for the vaccine. Several reports speak of poor people who were bitten by dogs staying at home rather than going to the health centre for treatment. This makes it difficult for doctors to use their discretion to waive charges for persons who do not have BPL cards.

Careful monitoring will show a rise in deaths due to rabies in India since June 2005, when the cell culture vaccine was introduced. This situation, which can be largely attributed to neglect by the authorities, persists despite protests by health groups. The Jan Aarogya Abhiyan (the Maharashtra unit of the nationwide Jan Swasthya Abhiyan) has lobbied with authorities in Maharashtra, including the health minister, to make the cell culture vaccine available free of cost to all victims of dog bites, not only to BPL card holders. Despite assurances, this measure has still not been implemented.

Double standards of multinationals

The most unethical players in this sordid story are the vaccine manufacturers, especially the multinationals. Internationally, they have registered their brands (Rabipur, manufactured by Chiron and marketed by Aventis, and Verorab by Leon) for both the intra-muscular and intra-dermal routes. In India, they have registered these brands only for intra-muscular use. Even the Indian National Dairy Development Board has registered its brand only for intra-muscular use. If these companies were to register and promote this vaccine for intra-dermal use, vaccine costs would drop to one-fifth of the current costs. Instead thousands of Indians are being denied the life- saving vaccine.

The Drugs Controller should, in public interest, ask these companies to register their brands for intra-dermal use as well. Or give official permission to doctors to use the intra-dermal route even if these companies refuse to register their brands for intra-dermal use. The intra-dermal route is scientifically well-established. Undergraduate textbooks include the Thailand Red Cross Society's intra-dermal regimen (3). Indian studies have shown the intra-dermal route to be as effective (4,5). The current WHO guidelines also recommend the intra-dermal regimen. (6).

The government could have long ago decided in favour of the intra-dermal route. Instead it set up a committee to study the feasibility of using the intra-dermal route in India. The Jain Committee, set up in September 2003, is yet to come out with its recommendations. A multi-centric trial has also been launched to study the intra-dermal route. These seem to be delaying tactics for the benefit of vaccine companies. As these companies focus on high sales per patient, poor Indians will keep dying because free cell culture vaccine is not available in government health facilities and cheaper treatment is not available in the private sector.

There is one more hitch. In the West the cell culture anti-rabies vaccine is available in 0.1 ml ampoules for intra-dermal use, but in India it is available only in 1 ml and 0.5 ml vials. If a doctor opens a one ml vial of Rabipur for the intra-dermal route, s/he must have five patients to inject, as the dose of Rabipur for the intra-dermal route is 0.1 to 0.2 ml. Although research in Thailand has shown that once opened the ampoule can be used for a week by keeping it refrigerated (7), the Indian government – as the largest buyer of the vaccine – should ask companies to manufacture 0.1 ml ampoules/vials for intra- dermal use at a reasonable price. This will enable doctors in primary health centres or small clinics to administer the anti-rabies vaccine even if there is only one patient and there is no reliable cold storage facility.

The Jan Swasthya Abhiyan has been lobbying for these changes with government officials. It has also lodged a complaint with the National Human Rights Commission. The health minister has announced that recent Indian studies of intra-dermal use have shown encouraging results and has said that this mode would “soon” be approved.

It is likely that the intra-dermal route will eventually be officially sanctioned in India. But will the government force drug companies to manufacture the smaller doses? We need strong public opinion to push for such changes. Any further delay means that thousands of poor patients will continue to die unnecessarily because the free cell culture vaccine is not available. Organisations working on medical ethics and human rights have not so far addressed this important issue. Will they take it up on a priority basis?

As this article goes to the press, the news is that the Drugs Controller has issued a circular permitting the intradermal route – but with the unreasonable clause that it can be given only at public hospitals getting more than 50 dog bite cases a day.

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