

cal stump by oil, discarding the colostrums and breastfeeding their infants, regularly after initial delays, increases the risk of dying of the newborns. These indigenous practices coupled with their lesser utilization of Government health services are responsible for poor reproductive health of the mother. The basic aim of MCH services to ensure safe motherhood, which is one of the major components of Reproductive and Child Health Programme does not find acceptance among the tribal population. A gap between service utilizer and provider is visualized. But it is not a difficult task to bridge this gap and this has been proved by many underdeveloped countries. The tribal people have to be prepared to leave the above-mentioned traditional and indigenous beliefs and practices. They have to be educated to accept the MCH/RCH services provided to them through the network of Governmental

health posts by strengthening the IEC activities and its rigorous intervention in their areas, so as to decrease the early childhood mortality. Further, the reduction in childhood mortality is expected to bring about a sense of security among them for survival of their children to adulthood, which will develop an attitudinal change towards low fertility. To be more specific, the first important thrust has to encourage the people to get deliveries carried out under proper hygienic conditions, under supervision of trained health professionals. This can be achieved by strengthening the health delivery system in tribal areas of their residence. Since every tribal group has a different ethnic origin, there is need to adopt community-specific approach for achieving the health targets. Implementation of these programmes should be through better coordination and stronger interlinkages among health delivery sys-

tems, agencies, institutions and the tribal population for a healthy tomorrow.

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ARVIND VERMA\*  
KALYAN B. SAHA  
DINESH KUMAR

*Regional Medical Research Centre for Tribals (ICMR),  
Nagpur Road, Garha,  
Jabalpur 482 003, India  
\*e-mail: vermaarvind1@rediffmail.com*

## NEWS

### India, ideal destination for clinical trials

Drug trials, commonly known as clinical trials, are scientific tests made on human volunteers. Such trials are carried out in 3 phases. In the first phase, studies are carried out on volunteers to determine the safety of the drug. In the second phase, on persons having the disease or medical condition to determine whether the drug has some level of therapeutic effect. In the last phase, trials are long-term studies on patients to determine whether the drug will be truly effective in normal medical settings. India, a country with the largest pool of patients suffering from cancer, diabetes and other maladies, has become the global hub for carrying out clinical trials at random. Almost all the top pharmaceutical companies of the world have set up clinical trial facilities in major cities, like Ahmedabad, Hyderabad, etc.

According to the Confederation of Indian Industry (CII) study, clinical trials in India in 2002 generated \$70 million in revenues. The outsourcing of clinical trials is likely to go up as the patent regime has taken effect in January 2005. CII predicts that it would grow to \$200 million by 2007. The pace for drug trials in the country is so fast that the Clinical Data Interchange Standards Consortium (CDISC), USA, a non-profit organiza-

tion committed to the development of clinical research organisations' standards throughout the world, is looking for setting up its chapter in India.

The Government of India exercises control over the licensing and standards of imported and manufactured drugs, vaccines and medical devices through the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rule, 1945.

The Indian Council of Medical Research (ICMR) brought out a document in 1980 titled 'Policy statement on ethical considerations involved in research on human beings'. In 2001, the guidelines for 'Good clinical practices' or the GCP India were issued as an ethical and scientific quality standard for the design and conduct of trials involving human subjects.

The Government has noted that by participating in clinical trials, India will benefit scientifically; research on new drugs will be accelerated, new drugs will be made available to Indians at the same time it becomes available to the developed world. But a section of health experts are in total opposition to this. According to them, because India is a plethora of poor and uneducated people, the multinational com-

panies are interested in conducting clinical trials of newly discovered molecules. So opening up the sector by relaxing rules would subject the poor to more exploitation by the drug companies. These corporate sponsors have started using 'Contract Research Organizations' (CROs) and also dictate the terms of clinical trials which do not always work for the best interest of the participating patients. According to C. M. Gulati of Monthly Index of Medical Specialities, while in US animals enjoy protection from misuse, in India hardly any action is taken in case of violation of rules.

If the government wants to enact laws regarding the legitimate use of clinical trials, it should ensure that India gets total benefit – the drug in question should be available at cheaper cost in the Indian market than in other countries where trials do not occur. Another precautionary step to be taken is independent functioning of the ethical committees of the Institutes where the trials are conducted.

**Minakshi De** (*S. Ramaseshan Fellow*), lives at 35, Garpar Road, Kolkata 700 009, India. e-mail: amitkde@satyam.net.in