CORRESPONDENCE

Figure 1. *Ficus* spp. growing on Bhimbetka rock shelters.

frequently as epiphytes on tombs or old buildings, dry rocks and on stems of trees, often entirely covering their stem and killing them or causing mechanical damage to old buildings and rocks. The more common species are pipal (*F. religiosa*) and banyan (*F. benghalensis*, *F. mollis*, *F. rumphii* and *F. scandens*). The rock-shelters of Bhimbetka are heavily attacked by *F. mollis* (syn. *F. tomentosa*) thereby causing immense damage to rocks and ultimately to the rock paintings. Due to stress conditions prevailing on rock-sites of Bhimbetka their growth is much stunted but the roots are strong, copiously branched and widely spreading, causing breaks and fissures on rock-surfaces. Some of such trees seem to be over hundred years old (Figure 1).

These *Ficus* species, if allowed to encroach as epiphytes on ancient rock-shelters, would gradually ruin the age-old heritage. Although it is difficult to uproot old fig trees growing on huge rock-shelters, the managers of Bhimbetka world heritage site have to formulate strategies for checking their growth. Removal of juvenile plants as and when noticed would be of immense significance.


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Infant mortality in tribals of central India

The level of infant mortality is a sensitive index, not only of the health services of a country but also of its social and economic development. This vulnerable age is exposed to several exogenous and endogenous factors, which influence the health, growth and development of the child. Each year, 10.7 million children under the age of five years die – 4 million die during the first four weeks of life. In the less developed countries, this accounts for 98% of reported neonatal deaths. India is following the demographic transition pattern of all developing countries from initial levels of ‘high birth rate high death rate’ to the current intermediate transition stage of ‘high birth rate low death rate’ which leads to high rates of population growth, before graduating to levels of ‘low birth rate low death rate’. Fertility has a direct bearing on infant mortality; more the children born, more are likely to die. In India, the vital demographic parameters like crude birth rate (CBR-25.4), total fertility rate (TFR-3.1) including the infant mortality rate (IMR-61.47) has continued to remain high, as compared to those of all the developed and many of the developing countries. India is a country of diverse population in terms of culture, language, religion, level of development, etc. The CBR is highest in Bihar and lowest in Kerala, while for IMR, it is highest in Orissa and least in Kerala. Central India, i.e. undivided Madhya Pradesh has also reported high CBR (30.8), TFR (3.31) and the IMR (86.0). Similarly, the TFR in the state is also fifth highest in the country. Only Meghalaya, Uttarakhand and Bihar have TFRs higher than that of Madhya Pradesh. Further, in Madhya Pradesh, the CBR, according to type of residence, is 23.0 in urban areas as compared to 32.8 in rural areas. Similarly, the IMR and the neonatal mortality rate in urban areas are 53.0 and 41.9 respectively, considerably low as compared to those of rural areas, namely 92.0 and 64.6 respectively of the state. Under the age distribution of fertility, a rural woman (TFR-3.56) in Madhya Pradesh has, on an average, almost one child more than the urban woman (TFR-2.61).

The vital demographic parameter of scheduled tribe (ST) projects a miserable situation and needs special attention by understanding in-depth problems and formulation of decentralized programmes for their development. The TFR in ST population of Madhya Pradesh (3.06) is higher than the TFR for the ST population of the country (3.06) (ref. 4). This high level of birth and death statistics in the state implies presence of certain socio-cultural factors, which play an important role in determining the health status. Madhya Pradesh is one of the large states possessing 23.27% of its population as tribal. The major tribal groups are Gonds (44.61%), Bhils (20.93%) followed by Kawars, Sauris, Baigs, etc. Various primitive tribes of the state have reported high fertility and high infant mortality even in the undivided Madhya Pradesh (rural).

These aboriginal groups invariably lead an isolated life remote from the general system. They belong to different ethnic groups and are at low levels of education, and have poor social, cultural and political development. Backwardness of these people, their inherent inborn timidity, escapism and rigidity brings them to the state of utter penury. They are primitive in each and every aspect of life like agriculture, education and even in health matters. Low age at marriage (14–15 years) along with low age at first delivery (18–20 years) indicates the long reproductive period before maturity, which may be associated with infant mortality. Further, their benign and harmful traditional birth-related practices of having delivery at home, attended by untrained personnel, cutting the umbilical cord by unhygienic instruments, treatment of umbili-
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 organization 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 companies 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.

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