

RESEARCH ETHICS

Unsafe abortions and experimental excesses

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Unsafe abortions, criminal or illegal, are a cause of excessive maternal morbidity, mortality and misery. Human experimentation with new methods of abortion in contravention of stipulations and guidelines fall in the same category.

Anybody who inflicts, encourages or condones unsafe abortion in contravention of the law commits a crime. Yet, articles in journals describe unsafe abortions and identify the person who conducted it, and the place where it was performed. The articles published in the *Journal of Obstetrics and Gynecology of India* (1–6) give graphic details of the horrors inflicted by criminal acts of illegal abortionists. None of these mention the steps taken against the culprits.

All cases of maternal mortality due to unsafe and unlicensed abortions are cases of double homicide (murder) and are required under law (CrPC. Section 39 and 174 read with IPC Sections 201, 299, 312 and 314) to be reported to the police, subjected to inquest, and criminal prosecutions launched. By not doing so, the authors are presumed to be siding with the criminals. The documentation of these murders should not be published as research articles. Such publications amount to documented defiance of law and criminal justice.

As regards the editor's responsibilities, they must be satisfied that authors reporting a crime through their journal have done all that they were legally required to do in that particular case.

Research in the cases of septic and unsafe abortion has to cover two aspects: injuries and their treatment, and the possible cause of the injury. A properly done medical termination of pregnancy (MTP) should not cause injury to the bladder or gut. If this occurs, there must be either some unrecognised abnormality in the patient or a lapse in the procedure. The researcher must try to elucidate it to prevent its occurrence in future.

However, illegal abortions are apparently not considered criminal and are not reported to the police, even when they prove fatal. This attitude is exemplified by the ob-

servations of the attending doctors in the report of an illegal abortion done by a 'dai' with a stick that resulted in gas gangrene. The abortion was done by an unauthorised person and it was an unnatural death with manifest evidence of foul play on the record. Exactly the same assertion has been made (1), when the authors state 'Autopsy was advised in all these cases, but refused by relatives', exemplifying the attitude of medical professionals not to report unnatural deaths in women.

Chemical abortifacient paste

As a result of an unhealthy enthusiasm to popularise abortions for population control, Fetex paste was licensed and publicised as an abortifacient. This paste has been reported to cause severe peritonitis, gangrene of organs and kidney failure in many patients. In a 1985 report of three cases (7), two died and the third survived renal failure but her 'whole vagina and cervix were sloughed and necrosed' after the illegal abortion with 'Fetex paste'. The authors pleaded 'Advertisements...should be stopped and the product should be withdrawn...'. The *Journal of Obstetrics and Gynecology of India* was one such journal advertising the Fetex paste. Following these reports, this preparation by Gambers Laboratory, was 'withdrawn' and 'banned'. However, in a recent report of the death of 34 women who died of septic abortion, in 25 'kutchi' was used by 'dai/quack', Fetex paste was used in 3 patients by general practitioners (GPs) (3).

What can be a worse reflection on the prevailing professional standards, ethics and the role of drugs control machinery than the fact that year after year of reports of severe adverse effects and fatal outcomes from the use of the chemical abortifacient paste, nobody questions how this obviously dangerous paste was permitted to be licensed as an abortifacient paste? Was it ethical for the practitioners of medicine to use this Ayurvedic preparation? Was it ethical to advertise it in the *Journal of Obstetrics and Gynecology of India*, the official organ of the Federation?

MTP: saga of inhuman experiments

Any form of physical or chemical interference with the fetus is potentially noxious enough to cause abortion up

to 20 weeks of pregnancy during which MTP is permitted. Even introduction of a fine needle for aspiration of amniotic fluid may result in abortion. But simply because MTP is permitted does not mean one can experiment with any substance or method. Yet, some studies (8–13) report the use of rubber catheters for intra- and extra-amniotic injection of distilled water, normal saline, hypertonic saline, boiling water, various chemicals including corrosive substances that formed 'Fetex paste'. These have been used to experiment and re-experiment upon thousands of women and have been reported as research publications.

All these are human experiments. No good journal today publishes a report unless the authors provide a proof of ethics committee clearance. Recruitment of patients has to be on the basis of informed and free consent. Any substance or device used in the human body is a drug. Even an approved drug when used for a different purpose or by a different route or different dose schedule or combination constitutes a new drug, the human trial of which needs prior approval of the drugs controller.

None of the aforesaid 'studies' appear to conform to the ethical standards for human experiments. How could instillation of distilled water (9), boiling water, a powdered tablet (13) or rubber catheter (12) be permitted? Imagine the indignity and discomfort of a Foley's catheter introduced in the uterus, its balloon inflated and left in a pregnant woman for 6–18 hours. How does it differ from the use of a sterile stick and cow's urine by quacks?

In my book '*Miscarriage of Medicine*' (Panchsheel Prakashan, Jaipur, 1993, chapter entitled 'Merciless assault on mother's womb' p. 34), I had quoted papers from the early 1980s which gave data on similar studies.

What is the rationale of repeating these experiments when the disadvantages of many of them have already been adequately evaluated? There is no evidence that any thought has been given to plan these trials to obviate biased inferences. As a result, most of the studies are exercises in futility. Why increase the risk to the women undergoing these trials? There is no evidence that clear-

ance of the ethics committee was taken before conducting the trials. No informed consent was taken. And worse, the Indian Council of Medical Research is a party to it all by commission and omission.

Anybody doing anything to terminate pregnancy is not only permitted to do so but the act goes unchallenged even if it kills or cripples the woman. It is no exaggeration to state that medical termination of pregnancy has come to be a 'pragmatic termination of maternity'.

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