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Failure in patient safety common in U.S. clinical trials

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Failure to protect patient safety and poor record keeping were among the most common violations picked up by the US regulator in the running of clinical trials over a period of seven years, reveals a study published online in the *Journal of Medical Ethics*.

The two Indian study authors reviewed the content of 84 first warning letters issued by the United States Food and Drug Administration (USFDA) following site visits to 46 trial sponsors, 20 lead researchers, and 18 institutional review boards, which assess and monitor safety, between 2005 and 2012.

Common concern

The analysis revealed that the most common concern raised among clinical trial sponsors was a failure to monitor progress according to the stated schedule (58 per cent), followed by a failure to obtain the agreement of the principal investigator (35 per cent). One in four of these warnings concerned new drug studies; the rest related to devices.

The study has been done by Yashashri Shetty, and Aafreen Saiyed, both from the Department of Pharmacology and Therapeutics, Seth GS Medical College, KEM Hospital, Mumbai. The most common concerns raised by the FDA to lead researchers were failure to adhere to the stated plan for the investigation (95 per cent) and failure to protect the safety of trial participants, including the reporting of side effects (55 per cent). Some 40 per cent of warnings additionally concerned poor record keeping. Almost 80 per cent of the warnings related to drug trials.

The most common reason for warning institutional review boards (61 per cent) was a failure to follow standard operating procedures and inadequate record keeping (55 per cent).

The researchers compared their findings with previously published research in the same arena, dating back as far as 1997. They found that while regulatory compliance had generally improved, supervision had worsened.

Work to be done

"Fair and appropriate procedures for handling violations during clinical trials need to be developed and implemented globally in order to protect human rights, wellbeing and safety, and to raise awareness of ethical behaviour," they conclude.

Clinical trials.