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Video consent of patients: Are the concerns overhyped?

11 April 2014 | News | By Rahul Koul Koul

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Much has been said about the non-maintenance of the required level of transparency in clinical trials in the country. While the civil society has been crying foul over long rope given to the clinical trials companies, the industry always claimed being victimized. However, now the union health ministry has made mandatory the audio-visual recording of informed consent process of each subject who participates in the clinical trials in the country. This is in addition to the requirement of obtaining written informed consent from the participating subjects.

The action in this regard comes after the Supreme Court's recent directive to the government while delivering its order in a writ petition filed by the NGO, Swasthya Adhikar Manch, Indore against the ministry of health and family welfare regarding lack of transparency in clinical trials. As per the apex court order dated on October 21, 2013, in respect of five global clinical trials for which approval has been given by the DCGI office from January 1, 2013 to August 31, 2013, before the clinical trials are conducted, appropriate provision should be made or administrative direction should be issued which ensures that audio-visual recording of the informed consent process of the participants is done and the documentation preserved, adhering to the principles of confidentially.

"In view of the above, it has been decided with the approval of the ministry of health and family welfare, that in all clinical trials, in addition to the requirement of obtaining written informed consent, audio-visual recording of the informed consent process of each trial subject, including the procedure of providing information to the subject and his/her understanding on such consent is required to be done while adhering to the principles of confidentially. Such audio-visual recording and related documentation would be preserved. This is applicable to the new subjects to be enrolled in all clinical trials including global clinical trials," Drugs Controller General of India (DCGI) Dr GN Singh in his order said, and added further that "All the sponsors/investigators/institutes/organisations and other stakeholders involved in conduct of clinical trials in the country are hereby directed to adhere to the above requirement of audio-visual recording of informed consent process of trial subjects with immediate. The order of course has brought cheer to activists who call it judicial help."

But that is hardly the end of the story. There is lack of clarity about what studies the health ministry order is applicable to. 'All

clinical trials' is a term that includes all kinds of studies, including field studies, where there are practical challenges in audio-visual recording. What if a patient due to religious and socio-cultural reasons, may not want to be videographed which is a reality in a country like India? How confidentiality of patients should be protected and maintained in an 'audio-visual' context and what processes need to be followed in then? These are few questions that seem to be genuine in nature.

Most importantly, the order states that audio-visual recording of informed consent will be applicable with immediate effect to all clinical trials where new patients are recruited which implies that it is mandated for ongoing trials as well. This will be a setback to ongoing trials as sites require time to procure equipment, train their teams in using them and provide storage areas for the recordings. Providing a window for implementation would have ensured that ongoing trials are not impacted even as sites invest in the requisite infrastructure to implement the new order.

Although it supports the need for a more robust and regulated environment for the conduct of clinical trials in India, the Indian Society for Clinical Research (ISCR) representing the interests of clinical research professionals in the country, has expressed concern over the haste with which the union health ministry has introduced the audio-visual recording of informed consent in clinical trials without the requisite clarity and an appreciation of the logistical issues in its implementation.

ISCR asked the regulators to provide more clarity and address concerns of stakeholders to ensure that an important step taken to safeguard the interests of patients does not act as a deterrent to stakeholders. ISCR spokesperson said that lack of guidance and direction on operational and logistical issues of managing the audio-visual recording process like kind of equipment to be used, where and how information should be stored, etc could leave room for ambiguity and inconsistencies in execution.

Over the last few years, three areas where there have been issues raised about the conduct of clinical research and which have been most misunderstood amongst the public at large are the informed consent process; making the distinction between death of a patient in a clinical trial and death of a patient due to a clinical trial; and compensation payouts.

The decision if looked at closely has silver lining for everybody. While the patients cannot claim to be ignorant about any possible side-effects later, the audio-visual recording of informed consent will go a long way in providing documented proof of informed consent, particularly where contested.