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Throwing the Baby out with the Bath Water: The Need for Reviewing Ethics Requirements

No one questions the need for ethics in medical publishing. The current norm for credible journals is on insisting on patient consent for all clinical data published, whether prospective or retrospective. Clinicians are constantly learning, whether from published studies or their own experience, and it is appropriate that we "practise" medicine all our lives, not having approaches set in stone. Published guidelines frequently change; they also exhort us to individualize care. Thus, clinicians observe patterns, or try something not quite well spelt in guidelines, and when it works well, repeat it in later patients. It is this experience, sometimes accumulated over decades, that gives us the 'tricks of the trade.'

Many of us who maintain patient records find analyses of long-term data yield useful observations and evidence, which till very recently, were routinely published. But crucially, they cannot be predicted in advance. For example, with the same management approach, outcomes may differ because of demographic, economic or other factors. These intellectually satisfying exercises throw up hypotheses, which can be developed into formal studies. But having made an observation, how does one track down patients seen decades ago to take their consent? The easy answer: when you find something works well, plan a study, take approval from the Ethics Committee, obtain patients' consent: since prospective data is better than retrospective. However, this theoretically sound approach ensures losing wisdom gleaned from experience, and burying potentially meaningful data. Imagine Fuller Albright or Harvey Cushing's papers being rejected because patients' consent forms were not available!

At this point, it is important to distinguish two situations. Where routine management has been practised, if valuable patterns emerge, there should be no ethical dilemma in publishing aggregated data, which do not impinge on patients' anonymity. Where clinician/s deviated from then-standard practices, thus affecting patients' care, the need for consent is ethically imperative. Conflating these situations because of our recent increasingly obsessive concern about ethics discourages sharing learning, which is the very purpose of journals. Worrying, they could push clinicians reluctantly into the arms of predatory journals, which are an unfortunate reality.

Journals which have built up credibility the slow and hard way, must urgently find solutions. Credible journals must re-evaluate their policies, separating the groups where ethical clearance is redundant, and where it is indeed essential. Otherwise, all this worrying about consents and ethics clearances, would amount to throwing the baby out with the bath water.

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EXPERT'S REPLY

Ethical conduct of research is essential to safeguard research participants. All over the world, research is carried out only in accordance with the country's National ethical guidelines. The author is referred to the 2017 Indian Council of Medical Research (ICMR) National Ethical Guidelines for Biomedical Research Involving Children [1]; wherein it is clearly stated that waiver of consent may be obtained in retrospective studies, where the participants are de-identified or cannot be contacted. Hence there will not be an issue in conducting retrospective studies.

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