

## Current scenario of clinical research exposure and practice in developing countries including India

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### Abstract

Research is essential for the growth and development of any medical science. The status of research in developing nations is very primitive mainly because of lack of funds and lack of motivation. India is doing good academic progress and the situation of clinical research in India is nowadays improving rapidly. Training programmes on research methodology are being conducted and multidisciplinary research units are being set up in several medical colleges in India. Several organizations have sponsored the development of short duration modules of mobile research workshops in India. Research publications are a desirable qualification nowadays, for promotion amongst faculty members. This has led to a great enthusiasm amongst faculty members to get their research studies published. This article describes the current status of clinical research in developing nations and discusses the measures undertaken to improve research activities in India.

**Keywords:** Attitude, Clinical Research, Practices, Researchers, Research Ethics

Access this article online	
Quick Response Code:	Website:
	www.innovativepublication.com
	DOI:
	10.5958/2394-4994.2016.00065.2

### Introduction

The British chemist William Harvey once said “What is research, but a blind date with knowledge?”<sup>[1]</sup> Global competitiveness among nations in the emerging knowledge economy of the world is often assessed from the research outputs originating from the country.<sup>[2]</sup> Research should be undertaken because it promotes basic knowledge, develops new tools like drugs and instruments, informs the public regarding health promotion and provides effective planning to guide health policies and actions.<sup>[3]</sup> Research is essential for the growth and development of any medical science.<sup>[4]</sup> Anaesthesia as a speciality interacts with many disciplines including surgery, obstetrics, neurology, pulmonology and critical care. This enables anaesthesiologists to collaborate in clinical research with many disciplines. A fundamental knowledge of clinical research would lead to a definite improvement in hospital infrastructure, facilitation of optimal drug utilization and active involvement of the anaesthesiologist in the drug development process. It will also help in improvement of the quality of prospective clinical trials in anaesthesia with specific attention to areas like trial methodology.<sup>[5]</sup>

### Current status of research in developing nations

In a survey of medical students and teachers in a tertiary care hospital at Mumbai in India, it was found that only a small percentage of the participants had taken any formal training in clinical research but many had participated in some form of clinical research.<sup>[6]</sup> In another study on trainee residents in south –eastern Nigeria, postgraduate research training, previous participation in research and previous research publication were significantly associated with current participation in health research.<sup>[7]</sup> A study conducted in Pakistan showed poor participation of doctors in clinical research.<sup>[8]</sup> In China, research scholars account for 0.08% of the total population compared to India’s 0.02%. One of the reasons for less number of research scholars in India is a much lower investment on resource and development as a percentage of the Gross Domestic Product (GDP) in comparison to China.<sup>[9]</sup>

An old proverb says “He who does not research has nothing to teach.”<sup>[10]</sup> The Medical Council of India (MCI) requires publications as a desirable qualification for promotions amongst faculty members in medical colleges. Such official policies have led to an increasing enthusiasm amongst medical teachers and students to submit scientific articles to journals for publication.<sup>[11]</sup> However, unfortunately, an increase in the quantity but deterioration in the quality of research literature has been observed.<sup>[12]</sup> There has been a dramatic increase in the number of medical journals published in the last two decades in tune with the increasing demand for the scientific articles.<sup>[13]</sup>

As said by some authors, most of the anaesthesiology research is oriented towards biological or quantitative methodology rather than based on a qualitative or psychological model.<sup>[14]</sup> A recent report stated that a large majority of potential investigators

lack knowledge of regulations, ethics and skills for clinical trial management.<sup>[6]</sup> Failure to follow ethical procedures includes research misconduct.<sup>[15]</sup> Only a small proportion of medical institutions in the third world countries have ethical committees. All the rest either have no committee or no functional committee.<sup>[16]</sup>

India is one of those Asian countries doing excellent academic progress.<sup>[2]</sup> Thomson Reuters predicts that India's research productivity will be on par with most G8 nations within 7 to 8 years and could overtake them;<sup>[3]</sup> nonetheless, the situation of clinical research in India is said to be fast improving and more and more medical, paramedical and science graduates are enrolling for clinical research training.<sup>[6]</sup> India is fast becoming a hub of clinical trials.<sup>[17]</sup> Foreign companies are opening clinical research organizations in all parts of our country and research work is being carried out in medical teaching institutes as well.<sup>[15]</sup> The major attraction to conduct clinical trials in Asia is attributed to the increasing prevalence of western diseases like diabetes mellitus, hypertension, dyslipidemia etc. with the changing dietary pattern and sedentary lifestyle.<sup>[17]</sup> India has the added benefits of a vast genetically diverse population, well equipped hospitals and highly qualified English speaking investigators making it one of the preferred destinations for conducting global clinical trials.<sup>[18,19]</sup> Anaesthesiology research in developing nations especially of Asia and Africa is almost touching newer heights in the last one decade.<sup>[14]</sup> The incremental increase in the number of poster presentations at the successive national conferences on medical education in India demonstrates that faculty capacity and interest in engaging in educational research is increasing in India;<sup>[20]</sup> nevertheless, although India shows a gradual increase in trials registered since the advent of CTRI (Clinical Trial Registry of India), it still continues to lag behind established countries in clinical research. One of the reasons for this setback could be the under registration of trials due to the lack of awareness among the researchers to register clinical trials in the registry.<sup>[17]</sup> Training in research procedures is not a part of medical education both at the undergraduate and postgraduate level in large parts of the world especially the developing nations. The only way through which post graduate (PG) students in most medical colleges of India get to know how to do research is by working on their dissertation.<sup>[21]</sup> In a predominantly electronic survey of faculty members and consultants in India, it was found that 42% respondents had never attended any workshop on scientific writing.<sup>[11]</sup> The state of science and education and research in India is not satisfactory on either of two counts: the benefits that have accrued to society at large have not been commensurate with the scale of investments, and comparisons with other countries can be very unfavorable.<sup>[22]</sup> Some authors have stated that research in our country is lacking

because of two main reasons – first is lack of funding and second is lack of motivation among young scholars to take up research.<sup>[23]</sup> India has a large number of universities and medical institutes but they are somehow not able to produce good quality research work and publications.<sup>[15]</sup> The striking weakness of research in India is that research happens by and large only in a few elite institutions.<sup>[24]</sup> Medical colleges in India do not have a robust research tradition.<sup>[15]</sup> Over the years, it has been noticed that majority of the medical colleges in India have confined themselves to routine patient care and teaching based on conventional methods. The standard of papers published/ research projects undertaken by the students of post graduate courses in most of the medical colleges is not inspiring. This can be attributed to the lack of appropriate facilities for conducting research and a lack of motivation and knowledge on the part of the faculty and students in medical colleges for conducting research.<sup>[25]</sup> Lack of infrastructure and good laboratory facility for doing good research has been a problem faced by researchers both clinical and epidemiological.<sup>[21]</sup> As said by some authors, over the last decades, the price of traditional scientific journals has grown and this has made it difficult for many libraries to renew their subscriptions or start new ones and has prevented many researchers from consulting a large part of scientific literature.<sup>[26]</sup> The sense of frustration and helplessness where time, facilities and opportunities needed for engaging in discipline-based scholarship of discovery that is valued by the Medical Council of India (MCI) is not available to all faculty is reflected in the number of e-mails in the Health Professionals Education Google group passionately debating this issue.<sup>[20]</sup> Another issue is that most of the dissertations done by post graduate medical students are published as original research articles in journals. Most of these studies are conducted in patients less than 60 years old with no co-morbidities. However, our population is slowly ageing. So, the point is that how clinically useful are the results of these non-pragmatic trials? The clinician has to add his clinical judgment when making decisions based on the results of these trials.<sup>[27]</sup>

### **Measures undertaken to improve research activities in India**

The Medical Council of India, in a sincere attempt to encourage research activities has made research publications mandatory for teaching faculty members aspiring to gain promotion.

Learning research methodology is very important because a poorly designed and conducted research can never yield a worthwhile research paper.<sup>[3]</sup> Editors of various reputed journals have taken the initiative to bridge the gap in research by conducting comprehensive workshops on "Medical Research" all over India. These workshops deal with various segments of research from initiation of a research idea,

thorough literature search, and formulation of a research question, proper study design and conduction of research.<sup>[28,29,30]</sup> Organizations like the Indian Council Of Medical Research (ICMR) have sponsored the successful development of “in study” highly cost – effective short duration modules of mobile research oriented medical workshops in India which take research training to students doorsteps and motivate students for research.

The Government of India has taken various measures to encourage scientific research. These measures include successive increase in plan allocations for scientific departments, setting up of new institutions for science education and research, creation of centers of excellence and facilities in emerging and frontline areas in academic and national institutes, induction of new and attractive fellowships and strengthening research and development infrastructure in universities.<sup>[9]</sup>

The government of India had given sops like exempting service tax for clinical trials for new drugs. However, recently it withdrew this exemption. This has increased the cost of conducting clinical trials and research oriented pharmaceutical companies have started eyeing places abroad to shift clinical trials. Nevertheless clinical research in India has already been facing a difficult and unpredictable regulatory environment for the last few years and India has been struggling with regulations regarding research in the last few years.<sup>[31,32]</sup> The FIST programme (Fund for Improvement of science and technology) infrastructure in Universities and Higher Educational Institutions of the Ministry of Science and Technology of the Government of India has provided support for research facilities in many prestigious medical institutions in the country.<sup>[2]</sup> One of the programmes of the World Federation Society of Anaesthesia (WFSA)- ‘Innovation and Research’ aims to promote and support innovation and research in anesthesia with a focus on resource poor settings.<sup>[33]</sup> In order to promote and encourage quality medical research in India and to provide assistance to medical colleges in conducting research, a scheme of setting up of 80 Multi-Disciplinary Research Units (35 in 2013-14 and 45 in 2014-15) in the government medical institutions during the 12<sup>th</sup> plan period has been rolled out. According to this scheme, the faculty of medical colleges in India will be encouraged to carry out research projects on national and regional priorities. The total estimated cost of the project is Rs. 503 crores.<sup>[25]</sup>

To conclude, conducting good quality clinical research in several institutions in developing countries is currently difficult. However, many sincere measures have been adopted to give impetus to research activities especially in India. We recommend further strengthening of these measures in the near future.

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