

Editorial

Medical research in India: Fit and fine or frail and vulnerable?

Those who hope, by retiring from the world, to earn a holiday from human frailty, in themselves and others, are usually disappointed.

—Iris Murdoch

What is it that we call medical research? In 1953, Watson and Crick began their paper with ‘*We wish to suggest a structure for the salt of deoxyribose nucleic acid (D.N.A.). This structure has novel features which are of considerable biological interest*’.¹ The first randomized controlled trials (RCTs) with positive outcomes were published in the late 1940s.² The tumour-suppressor protein p53 discovered in 1979 continues to be studied.³ Medical research is thus a broad and vast tapestry that covers a wide range of disciplines that often intersect—biology, pharmacology, toxicology, physiology and pathology among others. Today, we also have an intersection with fields such as physics, radiation and even artificial intelligence as seen with baricitinib for Covid-19.⁴ The overarching goal though remains unwaveringly the same—a safe and better life for our patients. As a country, where do we stand in this regard? A study that evaluated research output from 579 Indian medical colleges from 2005 to 2014 showed that less than 5% institutions produced more than 100 papers annually but accounted for nearly 40% of the country’s research. A total of 332 of 579 (57.3%) medical colleges did not have a single publication during this time with states having the largest number of private medical colleges faring the worst.⁵ And then we have the problem of research fraud in India.⁶ Is this by any means just an Indian problem? Not at all.⁷ There are though at least a couple of problems that specifically impact India.

The first of these would be the Medical Council of India’s (and now the National Medical Commission or NMC) guidelines for promotions in medical colleges. One of the key criteria is publications which are different for each cadre (Professor, Associate Professor and Assistant Professor). These guidelines raised the hackles of the medical community for ill-chosen indexing policies regarding journals and position of the author in the publication.^{8–10} Perhaps the most challenging aspect of this was the linking of promotions to peer-reviewed publications. It is anyone’s guess as to the route those in medical colleges without publications or limited publications would have taken to ensure their promotions. The scourge of predatory journals with dubious indexing¹¹ is not lost on anyone and yet the MCI criteria (or at least the earlier ones) showed the road that could be easily travelled by some academics in medical colleges without fear of punitive action.

The second is the postgraduate (PG) training. At this level, a defensible thesis is a must and this needs some understanding of research methodology. One can safely assume that the first 6 months of any postgraduate course is *settling in* time while the next one to one-and-a-half years are devoted to the thesis while balancing clinical and teaching responsibilities. The joy of doing research turns into something onerous and that needs to be ‘checked off’ a long list. When postgraduation is completed, they slip into a long bond period and are frantic to ‘make a life’. They may never want to do research. I am a ‘clinician’ or I am a ‘surgeon’ and research is not my priority is a common refrain. My own life story mirrors this. As an undergraduate medical student and then an intern, I had no clue whatsoever about medical research. I worked hard, saw patients, read electrocardiograms, happily did intensive care unit (ICU) duties under a hawk-eyed cardiology professor and even the odd liver biopsy (under supervision) and went home sated and proud. I finished MBBS in a state of blissful research ignorance and

stepped into MD Pharmacology (not a calling of my choice) in the early 1990s only to be hit by a sledgehammer and a highly driven mentor. As a faculty position loomed on the horizon even before I finished my postgraduation, she said, 'you need a paper'.

My first paper, a narrative review was trashed by the interviewers and I didn't get the faculty position. I did eventually get it when I published my dissertation the origins of which came from a paper in the *Lancet*.¹² This was the mid-1990s and International Council for Harmonization Good Clinical Practice guidelines (ICH GCP) had begun to make inroads into India.¹³ The Indian Council of Medical Research (ICMR) published their second set of guidelines for human research in 2000¹⁴ and institutes began establishing ethics committees for research oversight and participant protection. A multinational corporation came to us with a randomized controlled trial (RCT) for a novel antimalarial¹⁵ as did the WHO with a drug combination for filariasis.¹⁶ I did not look back. But then this does not need to be and cannot be everyone's trajectory.

What can be done to improve medical research in India? Let us look at who 'guards' medical research. For regulatory studies done by the pharmaceutical industry, it would be the Central Licensing Authority and the institutional ethics committees (IECs). For academic studies, it would be the latter and institutional research boards/academic committees, should they exist. Ethics committees in medical colleges that oversee academic research are expected to be registered with the Department of Health Research. In a study of 494 medical colleges recognized by the erstwhile MCI, many states in the country had fewer IEC registrations relative to the number of IECs. For example, the state of Bihar had 13 medical colleges with only one having a registered IEC.¹⁷ Work done by IECs remains undervalued and unappreciated largely and they are often beleaguered by the quantum of work that is done *pro bono* and constant staff turnover. The quality of review by inexperienced IECs is also a matter of some concern. The next set of guardians are journal editors and reviewers who are plagued with the same issues as that of IECs. The system in India for research oversight is in place but a whole lot of poor research probably slips through the cracks.

Literature is replete with one singular advice that I can summate easily—establish a research culture early on, preferably at the undergraduate or postgraduate level and see good clinician researchers are produced. Is it that easy? The ICMR for instance has the short-term studentships (STS) for undergraduate medical students. The skew in the awardees with the dominance of undergraduates from the South and the West for the limited awards available relative to those from the North and the East has already been shown.¹⁸ So is there is problem of funds? It doesn't appear so though the problem of disbursement does exist and is a matter for another day. Adequate funding is available in India at both the postgraduate and faculty level. The Department of Biotechnology/Wellcome Trust India Alliance (India Alliance), for instance, funds research in health and biomedical sciences with emphasis on science that directly impacts society.¹⁹ Funding is also available all year round from premier organizations such as the ICMR, Department of Biotechnology (DBT) and the Department of Science and Technology (DST). Does the difficulty therefore lie with the teachers themselves who have limited or no experience in research and cannot inspire students? Can we learn from the L.V. Prasad Eye Institute (among a few others) that has managed excellent patient care along with research that serves society? In their paper on an integrated model of primary and secondary eye care for underserved areas, Rao and colleagues from this institute have identified key determinants for delivery of rural healthcare with their model.²⁰ Some of these include technology, funds, community outreach and cultural specificities. At the end of the paper, their source of funds is stated as nil, which is profound. This is a reflection of the most important determinant in this chain as stated by the authors themselves—the human in the pyramid who drives change.²⁰

The world of medical research in any country is only as fit or as frail and vulnerable as the human and policy vested in it. At the one end you will continue to see a list of Indian researchers who rub shoulders with the cream of scientists worldwide and bring joy and pride to the nation.²¹ We forget the word 'developing' added to our country for a few minutes. A publication by an Indian in the *New England Journal of Medicine* or the *Lancet* (even if the Indian is the *kth* author) makes us dewy eyed. At the other end, studies like those by Ray *et al* make us despair.⁵

Over the years, I have figured out the several *Ds* that are needed to do good research—determination, drive, being driven (by a mentor), dedication, doggedness and I would say even devoutness. Does everyone have it in them? A dear teacher of mine once told me that everyone will do their jobs well once we tap into their 'felt need'.

Policy-makers need to ask themselves this question. What is the 'felt need' of the average undergraduate or a postgraduate or even a teacher in a medical college? Is it research at all? If research is needed to be done by them, how can we make it easier? What are the variables that we need to address to make research joyous? How can we ignite the fire? If we remember Maslow, we need to ask as to where does research fit into an individual's *hierarchy of needs*? For clinicians, can we delink publications from promotions in medical colleges? Can we add another metric to this evaluation? How can we train some postgraduate teachers to be good mentors? As a country, if medical research were to be viewed well and something to aspire to, these questions will need to be addressed. The normal distribution curve of medical research in the country has frail and vulnerable at one end to fit and fine at the other with institutions and organizations falling somewhere along this curve. Shift the needle we must with all the 'Ds', a gap analysis to look for determinants, investment in infrastructure, funding that is sustained and a relook at the education and promotions policy with a thrust on the human in the chain. A determined focus on quality of the product be it the postgraduate student or the clinician researcher rather than quantity would also serve us well in the long run.

REFERENCES

- 1 Watson JD, Crick FH. Molecular structure of nucleic acids: A structure for deoxyribose nucleic acid. *Nature* 1953;**171**:737–8.
- 2 Craft AW. The first randomised controlled trial. *Arch Dis Child* 1998;**79**:410.
- 3 Soussi T. The history of p53. A perfect example of the drawbacks of scientific paradigms. *EMBO Rep* 2010;**11**:822–6.
- 4 Richardson P, Griffin I, Tucker C, Smith D, Oechsle O, Phelan A, *et al.* Baricitinib as potential treatment for 2019-nCoV acute respiratory disease. *Lancet* 2020;**395**:e30–e31. Erratum in: *Lancet* 2020;**395**:1906.
- 5 Ray S, Shah I, Nundy S. The research output from Indian medical institutions between 2005 and 2014. *Curr Med Res* 2016;**6**:49–58.
- 6 Jayaraman KS. Growing scientific misconduct causes concern. Available at www.nature.com/articles/nindia.2011.120 (accessed on 7 Jun 2022).
- 7 Smith R. Research misconduct: The poisoning of the well. *J R Soc Med* 2006;**99**:232–7.
- 8 Aggarwal R, Gogtay N, Kumar R, Sahni P. The revised guidelines of the Medical Council of India for academic promotions: Need for a rethink. *Natl Med J India* 2016;**29**:1–5.
- 9 Bandewar SVS, Aggarwal A, Kumar R, Aggarwal R, Sahni P, Pai SA. Medical Council of India's amended qualifications for Indian medical teachers: Well intended, yet half-hearted. *Natl Med J India* 2018;**31**:1–4.
- 10 Bandewar SVS, Pai SA. Regressive trend: MCI's approach to assessment of medical teachers' performance. *Indian J Med Ethics* 2015;**12**:192–5.
- 11 Gogtay NJ, Bavdekar SB. Predatory journals—Can we stem the rot? *J Postgrad Med* 2019;**65**:129–31.
- 12 Gopinathan N, Potkar CN, Barve AS, Kshirsagar NA. Effect of quinolones on skeletal muscle function. *Indian J Pharmacol* 1995;**27**:234–40.
- 13 International Council for Harmonisation. History. Available at www.ich.org/page/history (accessed on 7 Jun 2022).
- 14 Mathur R, Swaminathan S. National ethical guidelines for biomedical and health research involving human participants, 2017: A commentary. *Indian J Med Res* 2018;**148**:279–83.
- 15 Kshirsagar NA, Gogtay NJ, Moorthy NS, Garg MR, Dalvi SS, Chogle AR, *et al.* A randomized, double-blind, parallel-group, comparative safety, and efficacy trial of oral co-artemether versus oral chloroquine in the treatment of acute uncomplicated *Plasmodium falciparum* malaria in adults in India. *Am J Trop Med Hyg* 2000;**62**:402–8.
- 16 Kshirsagar NA, Gogtay NJ, Garg BS, Deshmukh PR, Rajgor DD, Kadam VS, *et al.* Safety, tolerability, efficacy and plasma concentrations of diethylcarbamazine and albendazole co-administration in a field study in an area endemic for lymphatic filariasis in India. *Trans R Soc Trop Med Hyg* 2004;**98**:205–17.
- 17 Nishandar TB, Birajdar AR, Gogtay NJ, Thatte UM. Current status of standardized, quality and ethical oversight of clinical research in the country: An audit of the Central Drugs Standard Control Organization (registration of ethics committees) and national accreditation board for hospital and healthcare providers (accreditation) databases. *Perspect Clin Res* 2019;**10**:84–90.
- 18 Thatte UM, Marathe PA. Ethics committees in India: Past, present and future. *Perspect Clin Res* 2017;**8**:22–30.
- 19 Deo MG. Undergraduate medical students' research in India. *J Postgrad Med* 2008;**54**:176–9.
- 20 Rao GN, Khanna RC, Athota SM, Rajshekar V, Rani PK. Integrated model of primary and secondary eye care for underserved rural areas: The L.V. Prasad Eye Institute experience. *Indian J Ophthalmol* 2012;**60**:396–400.
- 21 Ioannidis JPA, Boyack KW, Baas J. Updated science-wide author databases of standardized citation indicators. *PLoS Biol* 2020;**18**:e3000918.

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