Editorial

Is the HPCSA requirement for a research dissertation for specialist registration the best option?

> *"Instead of trying to make a prolific researcher of every physician, training physicians in understanding research methods and evidence-based medicine may also help improve the situation by instilling healthy skepticism and critical thinking skills…. It makes no sense to perform clinical research without ensuring clinical utility. Reform and improvement are overdue."*
>
> *John Ioannidis 2016*

In November 2010 the Subcommittee for Postgraduate Education and Training (Medical) under the auspices of the Health Professions Council of South Africa (HPCSA) decreed that for registrars who commenced training on or after 1 January 2011, *"Completion of a research component"* is a requirement for registration as a specialist.[1] The HPCSA does not prescribe the nature or the types of research to be undertaken, other than making the following statements:

"All specialist trainees will be required to complete a relevant research study, under the supervision of the Head of Department or nominee";

"The assessment criteria of the research study would be that appropriate theoretical knowledge is demonstrated; a research protocol is compiled according to required norms; and a progress report on the research project is given on a regular basis";

"Research results should be reported in a format of a dissertation according to acceptable scientific norms";"The research study, which will be assessed at university level, may be used as a credit for Part III of the MMed degree".

In 2005, John Ioannidis made the provocative claim that "It can be proven that most claimed research findings are false."[2] By "false" Ioannidis was not saying that the study was underpowered, incorrectly analysed, or difficult to reproduce. Instead, Ioannidis's claim was more profound: most studies reported findings that were untrue, claiming that "black" was "white" or "up" was "down". Outrageous? A 2015 paper in Science looked at 100 randomised controlled trials in the three most prestigious journals in psychological science.[3] As Ioannidis predicted, fewer than half of the studies *published in the most prestigious journals* could be reproduced. An accompanying editorial quotes Ioannidis as suggesting that the fraction of research results that are true in psychology research is "something like 25% ... [which] seems to be in the same ballpark as what we see in many biomedical disciplines."[4]

Since Ioannidis made his provocative claim, many critical assessments have validated his concerns. This deeply disturbing finding raises important questions about how physicians should practice medicine, and what we want to teach our registrars. First, we must teach, and we must affirm, that medicine is a scientific discipline. Physicians know a lot about truth. Cigarettes cause cancer. Hypertension causes strokes. Diabetes destroys the kidneys. Everything we know about health and disease, every intervention we make for our patients, is based on science. The fact that the medical literature is often wrong is an indictment of the literature, but it is also an affirmation of science. It is because truth exists that we can judge the medical literature as flawed.

Second, we must teach trainees that the medical literature is flawed not because science is untrustworthy, but because society rewards shoddy science. Everybody wants to be first. Each investigator wants to be the first to publish a new finding. Each journal wants to have the latest scoop on truth. If you are asking a question a second time, nobody wants to publish your finding. Let us say that you are the second investigator to show that cigarettes cause cancer, or that hypertension causes stroke – first, your study probably will not get funded, because someone else has already demonstrated this. Then, if your study does get funded, nobody will want to publish your result because it has already been shown in another study. Reproducibility is the cornerstone of science, but in our obsession with novelty, we favour shoddy first reports over solid demonstrations of reproducible science. We need to teach that science requires society to place a greater value on research which extends and confirms prior research.[5]

Given this background, what is the merit in teaching registrars how to conduct shoddy science? This Journal increasingly receives manuscript submissions from registrar projects. Many are inadequately powered to draw meaningful conclusions. They may address important clinical issues. However, lacking statistical power, selected for publication based on novelty, and given the likely false-positive rate of greater than 50% (which applies to the entire scientific literature, lest you think we are magically immune), the results are likely wrong. Are we advancing clinical care, or the academic prowess of our trainees, by requiring them to undertake and publish shoddy science? We believe that the volume of underpowered submissions is likely to increase, due to the current HPCSA specialist registration requirements.

The HPCSA devolves decisions regarding the nature of- and responsibility for the quality of the research component to the universities. Most South African universities currently accept case series, observational studies, audits, randomised trials and systematic reviews for the purposes of Master of Medicine (MMed) dissertations. Some universities also admit acceptance for publication in a peer-reviewed journal in lieu of a Master's dissertation.

Internationally, there is increasing concern that most clinical research is not useful or ends up being untrue, resulting in vast wastage of resources.[2,6] Causes include studies that are underpowered and poorly designed. The perils and costs to society of research done for the sake of research are not trivial; indeed poorly conducted research does more harm than good. Consequences of poorly designed and conducted research include[7]:

1. *Harm to participants in research;* including wastage of participants' time, and futile exposure to discomfort and possible direct harm.
2. *Harm to science:* Published poor research with invalid results can influence other researchers to follow false trajectories thereby wasting time and resources. In addition, even when erroneous articles are completely retracted, they are not effectively purged from the literature, as many researchers continue to cite them in support of scientific concepts.[8]

3. *Harm to the public:* The general public tends to accept the results of poor research that is reported in the news media as being true and accurate. This can lead to widespread misconceptions and harm.

The nature of registrar-driven research lends itself to such problems as it encourages small studies that can be performed quickly. Furthermore, undergraduate medical curricula do not include research methodology and place little emphasis on evidence-based medicine. As a result, untaught and often unmotivated registrars are faced with the dilemma of having to fit a research project into an already overburdened academic curriculum and overstretched clinical load.[9] In Anaesthesia alone, we estimate the need for approximately 90 new clinical research projects annually to match the new anaesthesia registrar intakes in South Africa. To ensure that all these projects are scientifically sound and clinically valuable presents a large academic burden on the university departments in South Africa. We have reservations as to whether producing this volume of *clinically relevant* research is achievable.

Clinical research is an important component for ensuring that we provide better future health care; hence it is laudable to include a research component in clinical specialist training. However, research comes at a cost. It requires professional time spent on literature review, study concept and design, and ethics review and revision that is often followed by the need for broad participation by treating physicians, research coordinators, assistants, nurses, the patients and their families. It is therefore imperative that the benefit of the research justify this cost. A 'value-based' approach to research is necessary, where we focus on increasing the value of research conducted, while reducing associated waste.[10-12] In South Africa, we have started to address this problem, by identifying national perioperative research priorities.[10,13]

For research to be clinically meaningful, it should strive firstly to provide an answer as close to the 'truth' as possible, and secondly to ensure that the research findings are readily accessible globally, so that they can confirm or change clinical practice. For the results of clinical research to reflect the 'truth', investigators should first identify an important question in a field where there is equipoise, and seek to answer the question by proceeding to construct a well-designed study that avoids bias, is adequately powered and is pragmatic.[14] In addition, if a study improves understanding of some aspect of an underlying pharmacological or pathophysiological mechanism in the area of Anaesthesia and Perioperative Medicine, the research becomes all the more valuable. Finally, for research findings to have clinical impact, the research should be reproducible and implementable in clinical practice.[15]

Accessibility to research findings requires both peer and societal 'visibility'. To this end, research registration and subsequent publication in peer-reviewed journals, preferably with an open access policy is desirable. 'Grey-literature' publications such as university dissertations are difficult to access via search engines, decreasing their 'visibility'.[11] We have recently published two papers in this Journal, which provided a quandary for the editorial board.[16,17] Both of these studies addressed important clinical issues, but their inadequate sample sizes limited the interpretation and conclusions that could be drawn.[12] Hence, these studies cannot influence clinical practice. Following extensive deliberation, we chose to publish these research projects, as we believe that they address unresolved clinical controversies, and we would prefer that they be 'visible' in the peer-reviewed literature. However, publication of underpowered research is not sustainable, and has the potential to waste research resources. If future research projects do not satisfactorily address the two requirements listed above, it is likely that the majority of them will be committed to 'grey-literature'. 'Grey-literature' compromises the 'value-base' of research, as it is doomed to be repeated,[11] increasing the societal cost of the research.

While we commend the requirement for a clinical research component to training, we should re-consider the training objectives for registrar research in South Africa. In our opinion the main objective should be the production of competent clinicians who are not only technically skilled, but also have insight into the disease processes of their patients. This requires inter alia a thorough knowledge of physiology, pharmacology, clinical pathology and medicine, for which the present curriculum is adequately designed. However, the competent, well-rounded medical specialist is also expected to keep abreast of important new developments in his/her field. Apart from having to distill new knowledge from ever-increasing numbers of research publications, the medical profession is confronted with escalating numbers of predatory, open-access journals that publish dubious research often without peer-review.[18-20] We therefore agree that in order to empower future specialists with the ability to read the scientific literature discerningly, it is essential that their tutelage include a research and evidence-based medicine component. With the intention of achieving this purpose, we recommend the introduction of a national research *educational programme*, structured as a course work Master's programme. These programmes should cover the principles of basic statistics, trial design, scientific writing, critical appraisal of published research and evidence-based medicine. Interestingly, it is possible that adopting a structured research programme may increase registrar research productivity.[21,22] We would continue to advocate support for those highly motivated trainees who *will* want to complete meaningful research, over and above a research educational programme.

To fulfil the HPCSA requirement for 'hands on' experience of clinical research, the establishment of meaningful, large, collaborative registrar research projects[23] is preferable to multiple, small individual projects. This should serve to increase the proportion of 'true' research findings, and increase the number of PhD dissertations. We are not saying that there is no place for research with small sample sizes. Indeed, there are good examples of South African MMed research projects that are well designed, and adequately powered with relatively small sample sizes that have made an important contribution to the international literature.[24-26] There is also a place for outstanding hypothesis generating studies,[27] and audits which, provided the loop is closed, may greatly improve patient care.[28] However, the current circumstances surrounding registrar research projects, in which there is inadequate capacity or time to generate the adequate sample sizes necessary to address important clinical outcomes projects, only serve to increase the proportion of 'false' research findings.[14]

Not only do we not support this, but we believe it is counterproductive. As part of their training in medical science, trainees should understand the profound limitations of small, underpowered trials. They should recognise the inherent biases in novelty-driven publication. It is not clear how this aim is compatible with requiring trainees to perform such trials themselves, and then reward them for having undertaken shoddy research with certification as a specialist.

We conclude that implementation of the well-intended requirement by the HPCSA for a research component to registrar training, needs reform. In most cases, structured course work on research methodology, and critical appraisal of the medical literature, should replace the

requirement for original research. The latter should be an option for the true enthusiasts, but with a focus on adequately powered investigations that yield reproducible science. The challenge for South Africa is to develop sufficient researchers who amongst themselves can address original, meaningful questions. This could be facilitated by external expertise through attracting experienced overseas research fellows to our university centres.[29,30] We need to engage nationally in discussions on how further progress can be made with regard to registrar research in South Africa.[9,31]

Biccard BM,[1] Dyer RA,[1] Swanevelder JL,[1] Coetzee JF,[2] Shafer SL[3]

[1] Department of Anaesthesia and Perioperative Medicine, University of Cape Town, South Africa.
[2] Department of Anaesthesiology and Critical Care, Stellenbosch University, South Africa.
[3] Department of Anesthesiology, Perioperative and Pain Medicine, Stanford University, United States of America

References

1. New requirements for the registration of specialists in South Africa: Health Professions Council of South Africa, Subcommittee for Postgraduate Education and Training, 2010.
2. Ioannidis JP. Why most published research findings are false. PLoS Med. 2005;2(8):e124.
3. Psychology. Estimating the reproducibility of psychological science. Science (New York, NY) 2015;349(6251):aac4716.
4. Bohannon J. Reproducibility. Many psychology papers fail replication test. Science (New York, NY) 2015;349(6251):910-1.
5. Kern S. Analytic model for academic research productivity having factors, interactions and implications. Cancer Biol Ther. 2011;12(11):949-56.
6. Ioannidis JP. Why Most Clinical Research Is Not Useful. PLoS Med. 2016;13(6):e1002049.
7. Whitley BE, Kite ME. The professional and social responsibilities of scientists. Principles of research in behavioural science. 3rd ed. New York: Routledge (Taylor & Francis Group), 2013:92-3.
8. Pfeifer MP, Snodgrass GL. The continued use of retracted, invalid scientific literature. JAMA. 1990;263(10):1420-3.
9. Aldous C, Clarke D, van Wyk J, Rout C. Avoiding the distant elephant: a model to approach the research component of specialization. BMC Med Educ. 2016;16:147.
10. Chalmers I, Bracken MB, Djulbegovic B, Garattini S, Grant J, Gulmezoglu AM, et al. How to increase value and reduce waste when research priorities are set. Lancet. 2014;383(9912):156-65.
11. Chan AW, Song F, Vickers A, Jefferson T, Dickersin K, Gotzsche PC, et al. Increasing value and reducing waste: addressing inaccessible research. Lancet. 2014;383(9913):257-66.
12. Ioannidis JP, Greenland S, Hlatky MA, Khoury MJ, Macleod MR, Moher D, et al. Increasing value and reducing waste in research design, conduct, and analysis. Lancet. 2014;383(9912):166-75.
13. Biccard BM, Alphonsus CS, Bishop DG, Cronje L, Kluyts HL, Kusel B, et al. National priorities for perioperative research in South Africa. S Afr Med J. 2016;106(5):58-9.
14. Ioannidis JP. How to make more published research true. PLoS Med. 2014;11(10):e1001747.
15. Ford I, Norrie J. Pragmatic Trials. N Engl J Med. 2016;375(5):454-63.
16. Davids JG, Turton EW, Raubenheimer JE. Comparison of lung ultrasound with transpulmonary thermodilution in assessing extra-vascular lung water. South Afr J Anaesth Analg. 2016;22(6):170-4.
17. van den Heever A, Schribante J, Perrie H, Lowman W. Microbial contamination and labelling of self-prepared, multi-dose phenylephrine solutions used at a teaching hospital. South Afr J Anaesth Analg. 2016;22(6):175-9.
18. Beall J. Predatory publishers are corrupting open access. Nature. 2012;489(7415):179.
19. Beall J. Predatory journals: Ban predators from the scientific record. Nature. 2016;534(7607):326.
20. Beall J. Best practices for scholarly authors in the age of predatory journals. Ann R Coll Surg Engl. 2016;98(2):77-9.
21. Ahmad S, De Oliveira GS, Jr., McCarthy RJ. Status of anesthesiology resident research education in the United States: structured education programs increase resident research productivity. Anesth Analg. 2013;116(1):205-10.
22. Wood M. Maintaining and fostering the future success of academic anesthesia: recruiting and training the next generation of academic anesthesiologists. Anesth Analg. 2013;116(1):1-3.
23. Moonesinghe SR, Walker EM, Bell M. Design and methodology of SNAP-1: a Sprint National Anaesthesia Project to measure patient reported outcome after anaesthesia. Perioper Med (Lond). 2015;4:4.
24. Rodseth RN, Gopalan PD, Cassimjee HM, Goga S. Reduced incidence of postoperative nausea and vomiting in black South Africans and its utility for a modified risk scoring system. Anesth Analg. 2010;110(6):1591-4.
25. Rumboll CK, Dyer RA, Lombard CJ. The use of phenylephrine to obtund oxytocin-induced hypotension and tachycardia during caesarean section. Int J Obstet Anesth. 2015;24(4):297-302.
26. Ngaka TC, Coetzee JF, Dyer RA. The Influence of Body Mass Index on Sensorimotor Block and Vasopressor Requirement During Spinal Anesthesia for Elective Cesarean Delivery. Anesth Analg. 2016;123(6):1527-34.
27. Zieleskiewicz L, Contargyris C, Brun C, Touret M, Vellin A, Antonini F, et al. Lung ultrasound predicts interstitial syndrome and hemodynamic profile in parturients with severe preeclampsia. Anesthesiology. 2014;120(4):906-14.
28. Hauser N, Dyer RA, Pepler PT, et al. An observational audit of pain scores post-orthopaedic surgery at a level two state hospital in Cape Town. South Afr J Anaesth Analg. 2014;20(2):110-16.
29. Dennis AT, Dyer RA, Gibbs M, Nel L, Castro JM, Swanevelder JL. Transthoracic echocardiographic assessment of haemodynamics in severe pre-eclampsia and HIV in South Africa. Anaesthesia. 2015;70(9):1028-38.
30. Ortner CM, Combrinck B, Allie S, Story D, Landau R, Cain K, et al. Strong ion and weak acid analysis in severe preeclampsia: potential clinical significance. Br J Anaesth. 2015;115(2):275-84.
31. Rout C, Sommerville T, Aldous C. MMed cohort supervision: A path out of the swamp? S Afr Med J. 2015;105(4):275-6.