Seeing the Big Picture: Research Integrity

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Integrity in research is not a new topic. One of the first things we learn when we first became interested in doing research particularly among human subjects is how we should do it in an ethical manner even as we design these studies to be scientific. But is it just about ethics, as we "traditionally" talk about it? Or is there something bigger and deeper nowadays which should guide us?

I think all of us agree that there is a whole lot of opportunity out there to learn about ethical principles in doing research. We can always start with the local guidelines with its latest edition in 2017.[1] As highlighted in that document, insights and perspectives in research do not stay still. As we see different types of research activities, new issues emerge and policies revised. From the last time local ethical guidelines were provided in 2011, revision of the Declaration of Helsinki and the CIOMS International Ethical Guidelines for Health-Related Research Involving Humans, as well as promulgation of local laws such as the Philippine National Health Research System Act of 2013 (RA 10532), the Data Privacy Act of 2012 (RA 10173), and the National Commission on Indigenous Peoples AO No. 1-2012 and AO No. 3-2012 which gave details on procedures to be followed in doing research among indigenous people and their communities have all happened. These and other local circumstances such as natural disasters and public interest in stem cell therapy as examples have helped shape what we would now be allowed to do as clinical research. If anything, what is considered research involving human participants has been broadened extensively that not only direct involvement is covered but also includes use of identifiable human material and data.

It is probably not an overstatement to say that to be certain, one must always have a proper review of what one intends to do by having an accredited ethics review board (ERB) evaluate and give their approval – with revisions to mitigate ethical risks if needed. With the PCP requiring research among our trainees, such initiatives should likewise ensure that each of our Accredited Training Institutions has easy access to a properly accredited ERB. It may not even have to be within the same ATI. Short of having their own IRBs, there are now several alternatives which may be utilized whether at the regional and even national level through the Philippine Health Research Ethics portal.[2,3] There are likewise ongoing activities to ensure that new as well as established ERBs have proper continuing training.[4]

It remains challenging, but with much of the infrastructure for ethics review already in place in the local setting, it is a matter of awareness, political will and leadership among our ATIs to make sure our research undergoes and pass ethics review. In my mind, though, a greater challenge could be research or scientific misconduct. Although not a new phenomenon, research misconduct has certainly been receiving more attention lately in the global context. Since we do research to gather information that can be used to guide our decisions on patient care, such wrong information can be potentially harmful.

A list of Top 10 cited articles that have been retracted as of May 2019 is posted by Retraction Watch.[5] A quick glance down the list shows several articles of high relevance in the medical field, spanning various countries and even a few that are collaborative in nature; some of which were even published in high impact peer-reviewed medical journals. More importantly, even after the articles have been retracted, they continue to be cited perhaps indicating that the danger of propagating wrong information continues even after the articles have been withdrawn.

According to the US Office of Research Integrity, research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.[6] Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Similar to the ethical conduct of research, the broader area of research integrity requires the various stakeholders in the research activity to play a role. For example, the US National Institutes of Health requires all recipients and trainees of NIH grants to undergo training in conflict of interest, responsible authorship, policies for handling misconduct, data management, data sharing, and policies regarding the use of human and animal subjects.[7,8] A value based approach needs to be highlighted when talking about research integrity and misconduct. Not surprisingly, just like in other areas talking of integrity, honesty (defined as conveying information truthfully and honoring commitments) and accuracy (report findings precisely and take care to avoid errors) are on top of the list.[9] In the 2017 Philippine ethical guidelines, social value is emphasized. More specifically, it is stated that "social value can only be realized if the study is scientifically valid".[1]

However, efficiency (use resources wisely and avoid waste) and objectivity (let the facts speak for themselves) are there as well. In a country constrained by resources such as the Philippines, whether or not such research is conducted in a public

or private setting, use of resources wisely and avoiding waste has a particularly relevant and important meaning.

Understanding why research misconduct occurs can be important in helping prevent its occurrence. The US Office of Research Integrity mentions several factors: poor supervision, inadequate training, competitive pressures, personal circumstances and individual psychology.[10,11] All of these are certainly applicable in our country as well. For our young medical residents whom we require to do research as part of their training program, these factors may even be doubly important as many may feel that it is not their primary interest and it adds to the workload that they can be saddled with. It strongly highlights the role of a senior mentor to help guide rightful behavior. Most importantly, there is a need to have a senior physician supervising the research activity and ensuring that misrepresentations and falsification of data do not happen. The raw data, usually captured in Case Report Forms, should be easily available and scrutinized as part of these efforts. Again, similar to establishing an ethics framework to cover the conduct of research, ensuring research integrity also needs an institutional approach whereby all stakeholders are actively involved.[12]

As PCP continues to encourage and support the conduct of research, we need to complete the circle by starting to talk about research integrity. We started this journey by emphasizing the need for evidence-based medicine. We talk about principles which guide scrutiny of what constitutes a properly conducted scientific study. Then we went to generating ourselves those evidence in the local context, guided by similar principles in a properly designed scientific study. We also recognize that the ethical framework wherein we conduct these studies is just as important – and even more so in many situations. Thus, an ethical and independent ethical review is the only way to go. And finally, as we continue to push for more research, especially in a context that can be constrained by resources (time, money and infrastructure) ensuring integrity in the way we generate data should be a focus as well.

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