

## Transparency and integrity in research: from problems to potential solutions

Integrity embodies, above all, a commitment to intellectual honesty and personal responsibility for one's actions and to a range of practices that characterize responsible research conduct. In general, integrity can be characterized both at an individual level (i.e. researchers and others interested scholars) and a collective level (i.e. institutions engaged in research)<sup>1</sup>.

On an individual level, having a commitment to honesty and responsibility is fundamental, where these practices include: intellectual honesty in proposing, performing and reporting research; accuracy in representing contributions to research proposals and reports; clarity and fairness in the peer-review process; collegiality in scientific interactions; including communications and sharing of resources (e.g. physical materials, data sharing etc.); transparency in conflicts (or potential conflicts) of interest; protection of humans subjects and humane care of animals in the conduct of clinical trials; and adherence to the mutual responsibilities between investigators and their research team<sup>1</sup>.

On a group or institutional level, institutions should seek to create an environment that promotes responsible conduct by individuals and that fosters integrity by establishing and continuously monitoring structures, processes, policies, and procedures. To this end, it is important to: encourage respect for everyone involved in the research enterprise; promote productive interactions between trainees and mentors; advocate adherence to the rules regarding all aspects of the conduct of research, especially research involving human subjects and animals; reveal and manage individual and institutional conflicts of interest; arrange timely and thorough inquiries and investigations of allegations of scientific misconduct and apply appropriate administrative sanctions; offer educational opportunities pertaining to integrity and transparency in the conduct of research; and lastly, to monitor and evaluate the institutional environment supporting integrity in the conduct of research and use this knowledge for continuous improvement in research quality<sup>1</sup>.

## Why is a lack of transparency and integrity problematic?

As outlined above, scientific transparency and integrity, at both the individual and group/institutional level, are scientific aspects which seek, through a variety of tools, to improve the way projects are developed, data are collected and reporting is done<sup>2</sup>. Today, unfortunately, scientific output (e.g. scientific articles, particularly) is used for career promotion<sup>3,4</sup>, leading to a sharp rise in the number of articles produced, potentially causing a decline in quality<sup>5</sup>. In this respect, there appears to be a negative correlation between

scientific output and both transparency and integrity, where the higher the volume, the lower the scientific rigor. In other words, many researchers are more worried about increasing the quantity of publications, while increasingly eroding the quality of studies produced.

In a famous editorial written by Douglas Altman, in the British Medical Journal (BMJ) in 1994<sup>6</sup>, he discusses the problems underlying poor biomedical research and cites some of the reasons for low quality scientific research. He also questions, reflectively, the scientific community on an important issue: Why are errors so common? He then answers by stating:

"Put simply, much poor research arises because researchers feel compelled for career reasons to carry out research that they are ill equipped to perform, and nobody stops them." (1994; pg. 283)<sup>6.</sup>

Exemplifying this situation is the classic case of Tamiflu (Oseltamivir)<sup>7,8</sup>, in which a lack of transparency and integrity in science led to wasteful research, not only in terms of human resources, but also financially. Since the mid-2000s, governments have spent billions of pounds stockpiling two anti-influenza drugs, the neuraminidase inhibitors oseltamivir (Tamiflu) and zanamivir (Relenza). When the so-called "swine flu" H1N1 influenza emerged in 2009, the UK and Australian governments commissioned a rapid update of an existing Cochrane review of the drugs. Following this, the BMJ began one of the first campaigns on open data and pressured some companies to release data on several anti-influenza drugs, one of which was Tamiflu.

After reanalysis of data from around 107 studies conducted by numerous renowned institutions, the reviewers concluded that: "there was no convincing trial evidence that Tamiflu affected influenza complications (in treatment) or influenza infections (in prophylaxis)." Finally, the authors raised new questions about the drug's harms profile. The campaign lasted nearly 4 years and was considered a success, not least because it helped galvanize a movement toward increased transparency of clinical trial data.

In conclusion, the reviewers reported that the BMJ campaign: (a) facilitated the first ever Cochrane review based entirely on clinical study reports and regulatory data; led to changes in transparency by pharmaceutical companies and triggered inquiries at the national and international level; heightened awareness of the importance of independent access to underlying trial data, in particular highlighting important discrepancies between journal publications and underlying clinical study reports.

With the aim of improving the process of transparency and integrity in science, there are a number of key initiatives both in Brazil and internationally. The medical literature has historically played a leading role towards achieving this goal, most notably the ICMJE (International Committee of Medical Journal Editors) and ClinicalTrials.gov. As early as 2004, the ICMJE required pre-registration of clinical trials<sup>9,10</sup>, along with the other initiatives described below.

The ICMJE is a group of medical journal editors and stakeholders whose objective is to improve the quality of scientific publication and reporting of their manuscripts. Journals involved include the JAMA, BMJ, Annals of Internal Medicine and the Bulletin of the World Health Organization. With regard to reporting, the EQUATOR Network strives to enhance the trustworthiness and value of medical research bibliography, disclosing transparent reports on health research. To facilitate this goal, the network provides various reporting guidelines for different study designs<sup>11</sup>.

Reproducibility networks are being set up all over the world, the most pioneering of which is the United Kingdom Reproducibility Network (UKRN)<sup>12</sup>. This consists of a multi-disciplinary national consortium promoting reproducibility and transparency training initiatives, meta-research activities and disseminating best practices in research. Brazil has the Iniciativa Brasileira de Reproducibilidade (Brazilian Reproducibility Initiative)<sup>13</sup> comprising the ReproducibiliTea-Brasil<sup>14</sup> and the No-Budget Science Hackweek<sup>15</sup>, together

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making up a network of researchers engaged in research reproducibility. The Reproducibili-Teas hold regular regional meetings that bring together researchers of different levels to discuss articles related to transparency and integrity, both key elements of the Hong Kong Principles<sup>4</sup>.

One of the leading precursors of the open science movement is the Open Science Framework (OSF), a platform offering a range of functions fostering greater transparency and integrity, through a platform allowing pre-registration of study protocols, sharing of databases, and a host of related functions<sup>16</sup>. This can be defined as an open source software project which facilitates transparent collaboration in scientific research. This is associated with the Centre for Open Science (COS), a not-for-profit technology organization with the goal of increasing openness, integrity and reproducibility of scientific research. The organization started out with reproducibility of research in psychology and later included the biology of cancer, subsequently expanding its objectives, function and scope.

It is important to point out that some initiatives for improving these aspects of research are not exactly new, such as the Clinical Trials.gov<sup>10</sup>, allowing registration of clinical trials. In parallel, a number of meta-research projects have emerged for monitoring the compliance of researchers with the platform, such as European Union Trials Tracker<sup>17</sup> and the SEES (Strengthening the Evidence in Exercise Sciences) initiative<sup>18</sup>.

Transparency and integrity are widely considered the cornerstones of science, while transparent robust practices are invariably associated with quality. Therefore, it is fundamental that researchers (on an individual level) and institutions (on a collective level) endorse and practice responsible research conduct. Lastly, the creation of fresh initiatives, beyond those in place, is paramount in order to strengthen the movement of transparent, robust, open and reproducible science.

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