FROM THE UNITED NATIONS

Reproducibility, Replication and Fraud in Scientific Research

Reproducibility is the foundation of all scientific research. It is the standard by which scientific claims are evaluated. Biomedical research in the US is a 100 billion dollar a year business. Yet, much of the current published data, cannot be replicated/repeated by others even if it is published in so-called top flight peer-reviewed journals. We know that modern medicine has improved and extended life; however, monitoring research is vital. The UN/ World Health Organization (WHO) is active in over-seeing this area. The safety of drugs/medicine is a global and moral responsibility and there is a bi-annual meeting of the WHO Expert Committee on Selection and Use of Essential Medicines to review the latest scientific evidence on the efficacy, safety, and cost effectiveness of medicines in order to revise and update the WHO Model List of Essential Medicine for both children and adults. Members selected for the Expert Advisory Panel are chosen from a wide range of geographical locations, different approaches and professional experience with gender balance. The most recent meeting of the Expert Committee meeting was held in Accra, Ghana in March 2011.

Despite expert oversight, it is not unusual for scientists to be unable to replicate published scientific studies and there are numerous cases of fraud. Lack of reproducibility, replication and fraud in the scientific community has now reached the newspapers. (See Wall Street Journal, Dec. 2, 2010 and the New Yorker, December 13, 2010). The public is becoming more and more wary of believing any scientific reports (including global warming). The high level of skepticism in both the public and the scientific community has led to a special issue of the journal **Science** (December 2, 2011) devoted to the examination of data replication and reproducibility.

Well known and respected scientists have admitted to making up data: psychologist Dr. Diederick Staple, admitted fabricating data in dozens of studies and Dr. Jan Hendrick Schon, working at Bell Labs, New Jersey admitted to widespread fabrication and manipulation of data. In a case of faking with serious consequences

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is the British researcher, Dr. Andrew Wakefield, who falsified data linking childhood vaccinations to autism.

Competition for dwindling funding contributes to fraud when researchers, working globally across all scientific fields, rush their findings into publication before completing a stringent examination of their data. For example, in the five year span from 2002 to 2007, there was a 25% increase in the number of scientists competing for research funding and publication in journals. A fundamental issue is the requirement of journals for positive results; they will not publish negative results.

Many reasons are proposed for lack of replication including methodology for data analysis. Methodology of data analysis is of increasing importance as technologies are rapidly developing for making measurements. The methodology used for clinical trials is an important example. For a clear picture of results the crucial issues at stake include selection of the population for the clinical trial and how much and/or little information about the clinical trial should be given to patients and controls. The issue of replication and reproducibility is especially important when bringing a drug to market.

Before a drug can pass approval, pharmaceutical companies are required to test each drug on healthy and patients volunteers with a specific disease for which the drug was developed i.e. they select a population with as little variability in patient health as possible. Thus, these trials do not provide sufficient information for a wider and larger untested population with greater biological variability.

A historic example of the importance of how people are selected is revealed in a 1936 Literary Digest poll concerning the presidential election between Landon (the Republican candidate) and Roosevelt (the Democratic candidate). Ten million telephone owners were sampled. The journal predicted victory for Landon. Roosevelt won. The poll was inaccurate because Republicans were over represented amongst the ten million people who could afford to own a telephone. Furthermore, expectations and suggestions can influence the clinical response. This was demonstrated in a study for the treatment of migraines and tension headaches

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in which a “dummy pill"/placebo was as effective in the control group of patients as the drug being tested.

It has been said that Nature is tricky, but she is not out to trick us. Einstein’s belief was “God is subtle, but he is not malicious". The difficulties of scientific research are not to be underestimated and should not be manipulated for ideological purposes. Experiments must be carried out with rigor and honesty. When possible, all data must be coded so that it can be analyzed and evaluated in the absence of preconception.. Scientific research is time consuming and requires great patience, and the highest of ethical standards since the ultimate goal of drug safety is at stake.

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