RELIABILITY MANAGEMENT IN RESEARCH STUDIES

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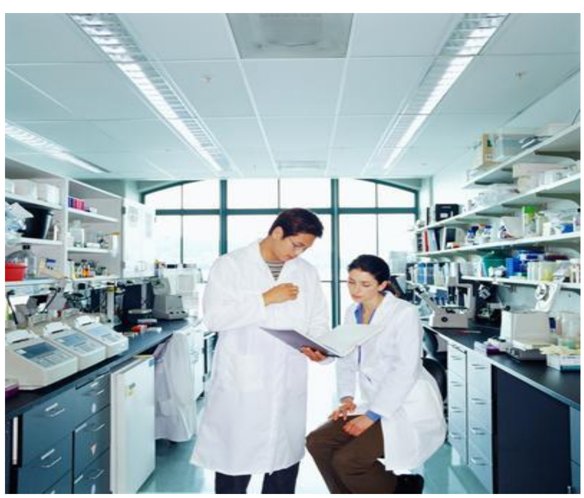
"The method of science is tried and true. It is not perfect, it's just the best we have. And to abandon it, with its skeptical protocols, is the pathway to a dark age." - Carl Sagan

ASTRACT

Scientific method is respected because of its truthfulness, dedication, reliability, reproducibility and honesty. Scientists are honoured for following the path of reason and rationality and for their inventions and discoveries benefitting the humanity. But scientists are also human and fallible. The lure of wealth, power, recognition and prestige may sometimes be overpowering and they may stray away. There may be political, economic and societal pressures to comply and compromise with and report fiction as fact. There have been several instances of persecution of scientists for their refusal to comply and abandon science. There may be acts of commission and omission, both intentional and unintentional, on their part, which are unscientific and prompted by short term gains, but leading to ultimate disgrace. Researchers should devise ways and means to resist such temptations and stick to the path of scientific method. It should be ensured that their observations are not clouded by biases, confounding factors, prejudices and preconceived notions to safeguard the reliability and validity of their findings. Scientific temper, honesty, dedication, openness, disinterest in material gains and fearlessness in revealing knowledge gained are the hallmarks of men of science and enhance the glory of science. The present study addresses the problems of managing reliability of scientific reports by addressing the factors that affect reliability and validity through an extensive review of literature on the subject. As per the ancient wisdom, "Protectors of righteousness are offered protection in return".

KEYWORDS: Bias, Confounding Factors, Reliability, Scientific Method, Validity

Fig.1. Research Laboratory



INTRODUCTION

Science is respected, because of its reliability and dependability, which are derived from its basis on research studies. By following a rigorous and honest protocol and eliminating the influences of short-term gains a research study confines itself to truthfulness and adds to the respectability of science. For achieving the above objective a research study should rid itself of biases and confounding factors. As the primary purpose of scientific publication is to share ideas and new results to foster further developments in the field, the increasing prevalence of fraudulent research and retractions is of concern to every scientist since it taints the whole profession and undermines the basic premise of publishing. While outright fraud by a small number of culprits is inherent in any human activity, there is a larger issue on the fringes of deception that is far more prevalent and of equal concern like adoption of certain practices blurring the distinction between valid research and distortions of "sloppy science" and "misrepresentation".

BIAS IN RESEARCH

Bias is any tendency which prevents unprejudiced consideration of a question and is an unknown or unacknowledged error created during the design, measurement, sampling, procedure, or choice of problem studied. It is a pervasive phenomenon, as one tries to confirm one's beliefs through research studies. Bias in research, where prejudice or selectivity introduces a deviation in outcome beyond chance, is a growing problem. A scientific method should be organized towards proving itself wrong, rather than right. A quantitative researcher should attempt to eliminate bias by resorting to various statistical tools and techniques, whereas a qualitative researcher should explicitly acknowledge the existence of bias.

Definition of Bias:
"Bias is a non-random error causing survey estimates to differ from population values."
"Bias is any systematic deviation from the truth that affects conclusions made from the data."

Causes of Bias: The factors probably amplifying research bias are:

1. Competitive aspects of professions with difficulties in obtaining funding
2. Pressures for maintaining laboratories and staff
3. Desire for career advancement (like 'first to publish' and 'publish or perish')
4. Monetization of science for personal gains

Rather than being "disinterested contributors to a shared common pool of knowledge", some scientists have become increasingly motivated to seek financial rewards for their work through industrial collaborations, consultancy agreements and venture-backed business opportunities, even to the exclusion of concerns regarding the accuracy, transparency and reproducibility in their science. As a result much of the publications have become "low input, high throughput, low output science".

Types of Bias:

1. Design Bias: It gets built in, when the study fails to identify validity problems and when the publicity about the research fails to incorporate the researcher's cautions. Unless the problems of regression and attrition are addressed, the study tends to be biased.
2. Measurement Bias: It exists, when the researcher fails to control for effects of data collection and measurement, like tendency for giving 'socially desirable' answers, to take into account 'self esteem' problem or using an invalid measure.
3. Sampling Bias: It exists, when certain groups are omitted from study, like women or minorities, and when most desirable or accessible groups alone are targeted.
4. Procedural Bias: It exists, when an interview or questionnaire is administered under adverse conditions, like use of students, payment to subjects, or brief and hurried administration of questionnaire to cut costs.
5. Problem Bias: It includes false positives (from erroneous incrimination of an independent variable having no effect), detection failure (from too small a sample, too gross measurement or no good statistical analysis) or solving a wrong problem (by wrong questions to wrong people, while trying to solve wrong problems).

Although hundreds of biases have been recognized, they can be categorized into three groups:

A. Bias through ignorance reflects inadequate knowledge or scant supervision or mentoring.
B. Bias by design reflects critical features of experimental planning ranging from the design of an experiment to support rather than refute a hypothesis; lack of consideration of the null hypothesis; failure to incorporate appropriate control and reference standards; reliance on single data points (endpoint, time point or concentration/dose) and failure to perform experiments in blinded, randomized fashion.
C. Bias by misrepresentation, like tendency to over-statement, over-simplification, and the urge and rush to be first to publish a new 'high-profile' finding.

The research misconduct ranging from overt fraud and plagiarism (topics of high public visibility) to data manipulation, data selection and other forms of increasingly prevalent bias (though of less public visibility), all contribute to increasing concerns regarding scientific integrity and transparency.

CONFOUNDING IN RESEARCH

Definition of Confounding

"Confounding is a mixing of effects, which makes a relationship between two variables apparent, when there is none, or masks, when a true relationship exists."

"A confounding factor or variable is one, which although associated with the exposure under investigation, is itself independently of any such association is a risk factor for the outcome of interest."

Confronting the Problem

Confounding occurs when an observed association is due to three factors: the exposure, the outcome of interest, and a third factor which is independently associated with both the outcome of interest and the exposure. Examples of confounders: observed association between coffee drinking and heart attack confounded by smoking and income and health status confounded by access to health-care. Pre-trial study design is the preferred method to control for confounding. Prior to the study, matching patients for demographics (such as age or gender) and risk factors (such as body mass index or smoking) can create similar cohorts among identified confounders. However, the effect of unmeasured or unknown confounders may only be controlled by true randomization in a study with a large sample size. After a study's conclusion, identified confounders can be controlled by analyzing for an association between exposure and outcome only in cohorts similar for the identified confounding factor. For example, procedure type and timing (i.e., immediate versus delayed intervention) may both have significant and independent effects on breast reconstruction outcomes. One approach, termed a "stratified analysis", to this confounding would be to compare outcomes by procedure type separately for immediate and delayed interventions. The role of stratified analyses is limited, if multiple confounders are present or if the sample size is small. Multi-variable regression analysis can also be used to control for identified confounders during data analysis. The role of unidentified confounders cannot be controlled using statistical analysis.

INTERNAL VERSUS EXTERNAL VALIDITY

Internal validity refers to the reliability or accuracy of the study results. A study's internal validity reflects the author's and reviewer's confidence that study design, implementation, and data analysis have minimized or eliminated bias and that the findings are representative of the true association between exposure and outcome. However, high internal validity often comes at the expense of ability to be generalized.

External validity of research design deals with the degree to which findings are able to be generalized to other groups or populations. These studies usually include study populations generated using minimal exclusion criteria, making them very similar to the general population. The loose inclusion criteria may compromise the study's internal validity.

When designing trials, achieving balance between internal and external validity is difficult. An ideal trial design would randomize patients and blind those collecting and analyzing data (high internal validity), while keeping exclusion criteria to a minimum, thus making study and source populations closely related and allowing generalization of results (high external validity).

Descriptions of study methods should include details on the randomization process, method(s) of blinding, treatment of incomplete outcome data, funding source(s), and include data on statistically insignificant outcomes. Then readers can make independent judgments on the trial's internal and external validity.

STEPS TO

ENHANCE RELIABILITY OF STUDIES

Proper research is the cornerstone of business growth and development. Whether it's assessing potential markets, testing a new product or determining employee and customer demographics, finding answers to these problems requires unbiased research. Bias occurs when subjects, researchers or methodologies are influenced by external factors that alter results of a study.

Step 1
Choice of a neutral researcher or hiring an outside company, who have no motivation for achieving one result over another, eliminates the bias from pressuring the in-house research department for positive results. If internal researchers alone have to be used, impress on them the need for real, unbiased results.

Step 2
The format including determination of the question to be answered, construction of the null and alternative hypotheses, testing the alternative hypothesis first and acceptance of the null hypothesis, if the former is rejected, reduces research bias.

Step 3
Random selection of samples: Randomizing the sample prevents unfairly selecting one particular demographic, which may have different qualities or opinions, than the general population. If specifically researching a particular demographic, random choice of samples within that demographic avoids biased selection of a subset of the demographic.

Step 4
Assigning a random number to employees for in-house research prevents the researcher from inadvertently recognizing the employee, thereby introducing the familiarity bias.

Step 5
A research environment ensuring neutrality of researcher, neutrality of subject's emotional state, and privacy of questioning area enable the subject to offer his or her true opinions.

Step 6
Interview questions should be neutral without leading the subject. During a series of questions, general questions are asked before specific questions to avoid offering too much information too early. Questions should be simple and easy to understand to avoid misinterpretation.

Step 7
Results of a study should be tabulated with respect to the alternative hypothesis. Acceptance or rejection of the alternative hypothesis, rather than finding a specific answer, should be the

objective. If evidence is overwhelming with a probability figure higher than the researcher-determined cut-off, then the alternative hypothesis is accepted.

CONCLUSIONS

- Bias is ubiquitous and should be considered primarily a function of study design and execution, not of results, and be addressed early in the study planning stages.
- Not all bias can be controlled or eliminated; attempting to do so may limit usefulness and generalizability.
- Awareness of the presence of bias will allow more meaningful scrutiny of the results and conclusions.
- Terminology to describe bias is diverse, with some overlap in meanings and definitions.
- Scientists and researchers should fiercely defend their independence and objectivity and should resist temptations of short-term gains for the eternal glory of the scientific approach.

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