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Editorial

Medical research: The flop side

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ABSTRACT

Science in general and medical and allied sciences, in particular, have undergone a sea of change since its conception. In recent times it is experiencing exponential growth due to vast technological advances in the field of research. While some are on the right track others are in the wrong hands.

This editorial explores the latter part, which needs immediate global attention. If corrective measures are not honestly and immediately implemented the end product will brew more trouble than any good for mankind.

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Research is an integral part of the development of any subject including medicine. Committed researchers big and small; all have their contributions to the enrichment of this fraternity. Dedication, devotion, honesty and fearless unbiased reporting of their work have established the subject where we are at present. Though many of them have paid a heavy price for this. One of the blurring examples is the contribution made by Gregor Mendel, ‘the Father of Genetics’ whose work went unrecognized during and long after his lifetime.¹ But over time a sense of laxity, malpractice and biased reporting with conflict of interest have crept in.

Translational research, the mother set of research activities, deals with empirical exploration to find the answer to a pertinent, challenging or time contextual issue. As we move from the bench side activities to its final bedside delivery the research process has to pass through multiple stages.² Nonadherence to standard protocol at any stage of the research is bound to jeopardize the entire process.

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A closer look into this issue has many revelations. A basic systematic approach will help us understand the grey areas.

To start with bias can creep in at the stage of animal studies. Many times gender representation is ignored or heavily downplayed with the pretext of difficulties in sex determination among lower vertebrates and mammals. But committed researchers ridicule this and brand it as a lame excuse.³ This laxity at the formative stage of drug or interventional research can bring in many unforeseen issues in future days. A valiant check by competent authorities to ensure gender equity at the formative stage will lay the foundation for transparent research.⁴

The second area of concern is reporting bias. Where the researchers are desperate to prove their hypothesis and indulge in biased reporting. This includes data manipulation for a favourable outcome or result and reporting only the statistically significant findings and omitting the important observations which contradict their proposed hypothesis.^{5–7} This type of practice can be ameliorated by making the open data repository mandatory in the field of medical research. Where the researchers are required to submit their database for independent scrutiny. This will enable others,

especially the editors and reviewers of biomedical journals to cross-check the reported pieces of information for their harmony with the study objectives. Once this practice is made mandatory as in other fields of sciences, the quality of research in the field of medicine will see its golden era.

The third one is publication bias with over-emphasis on the p-value. Here the publication houses give priority to research articles that report statistically significant observations and sideline others even though they have an important message to deliver. This over-emphasis on the p-value has and still misleading medicine at an unparallel cost. Here the role of editors and reviewers is paramount. Their in-depth scrutiny of reported findings and emphasis on gender-based data analysis along with quality data reporting will act as a game-changer. We must remember that a p-value is just a number and a favourable reporting of p without other supporting parameters is misleading.^{8,9} The p-value must always be supported by information like a 95% confidence interval, odd's numbers, r^2 etc. A higher level and in-depth analytical findings should be sought from the authors, and it should be communicated in clear terms that the manuscript is not publication worthy unless they meet the established publication guidelines like STROBE, CONCERT and others that are recommended by regulators from time to time. Publication ethics is an important cross-check mechanism to ensure the real things are reported.¹⁰


Clinical trials particularly the triple-blind, placebo-controlled randomized ones are considered the gold standard in evidence synthesis.¹¹ The different phases of trials should adhere to gender equality in addition to an adequate number of participants. But it's been observed that recruitment is often less and phase one and two trials are heavily skewed for male participants.^{12–14} These two phases are conducted to study the efficacy and safety and to find the best dose for the components. When the study enters phase three trial recruitment is made from all genders to test its approval for general use. Here is where the gender-skewed trials are likely to face major challenges. Many medicals and intervening agents/methods flutter or behave differently as it was not been adequately studied for efficacy and safety on the opposite sex.^{12–14} As per the US General Accounting Office report out of the 10 drugs that were taken away from circulation 8 were due to notable side effects in the fair sex.¹⁵ It's a well-known fact that both sexes behave differently to different agents which the researchers can't afford to ignore.¹⁶ Here the role of funding agencies and ethical regulators becomes significant. Their policy for grant

approval for projects with gender equipoise will eliminate this wrongdoing. Many reputed agencies have amended their guideline that includes animal and human research and others should follow them.^{17,18}

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