Lacking quality in research: Is behavioral science affected more than other areas of biomedical science?

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When a clinical Phase II trial fails to meet its primary predicted endpoints, the preclinical data upon which the prediction was made is one area in the development chain that is often called into question. The reasons for translational failures are undoubtedly multifactorial but recent discussions increasingly focus on robustness of the preclinical data. Indeed, extensive analyses in several fields such as stroke, multiple sclerosis and amyotrophic lateral sclerosis confirm that preclinical efficacy data are not always as robust as claimed in the literature. These problems are not limited to any specific therapeutic area, academic or industrial research and are due to several generic factors influencing research quality (i.e. related to definition of pre-specified endpoints, principles of study design and analysis, biased reporting, and lack of proper training). Yet, partly driven by the fact that many current examples stem from neuroscience drug discovery, it is sometimes assumed that this area is affected more than others. Furthermore, there are concerns expressed about behavioral studies at risk of being poorly designed, underpowered and misreported. While there is no solid justification for such claims, it is important to review and analyze sources of bias and limited robustness that may be unique for behavioral pharmacology: multitude of environmental conditions that are difficult to control and that are often not reported (from housing conditions to subclinical infection); ethical concerns about *in vivo* research and the 3R pressure (as one of the major causes of studies being often under-powered); complexity of study design and analysis creating too much room for *post hoc* data „massaging“ and selective reporting; logistics of the study design and conduct (impact on blinding and randomization procedures); blood-brain barrier as a frequently neglected research tool quality factor; peculiar dose-effect functions („inverted U shape“) that are seldom viewed as a sign of poor study robustness. It is important to recognize all of these factors and take them into account when planning and conducting a study using behavioral methods in preclinical Neuroscience. It is argued that these basic improvements will greatly improve our ability to bring new innovative CNS medicines to patients.

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