

## Editorial

# Scales and questionnaires under copyright: additional barriers to health research

## Escalas e questionários sob copyright: novas barreiras à pesquisa em saúde

Thiago Botelho AZEREDO , Renata Dias REIS , Fernando FERNANDEZ-LLIMOS 

Reviewers RBFHSS 2020

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Psychometric and epidemiological measuring instruments, such as questionnaires, scales and classification algorithms, when appropriately developed, selected, adapted and validated, are extremely useful tools in health research. With these instruments one can measure patient reported outcomes and evaluate some clinical and all humanistic outcomes of health interventions. These instruments yield consistent, reliable and valid responses about the variable of interest, they allow the comparison of results among different populations and settings, and enable knowledge generation, diffusion and improvement.<sup>1,2</sup>

Despite the importance of these research instruments to study different settings and populations, either to validate them or to enhance data gathering and data interpretation quality, a current situation is raising concerns: the employment of copyright protection to enforce the request for payment in exchange for use authorization.<sup>1-4</sup>

A quite old and well-known instrument used in medication adherence research, the Morisky scale, had its newest versions MMAS-8 e MMAS-4 protected by copyright in the recent years.<sup>3,5,6</sup> Copyright holders have been selling licenses for using scale in research and even in clinical practice.<sup>3</sup> In 2017, *Retraction Watch*, an observatory of scientific scholarly publishing that monitors journal articles retractions, reported that these scales copyright holder had contacted hundreds of researchers that had used the scales "without permission".<sup>3</sup> These researchers should then ask for a retrospective license and demonstrate that they had used the scale "appropriately". Depending on the situation, license prices ranged from US\$100 to US\$40,000, reaching US\$100,000.<sup>3</sup> If authors decline the payment requirement, they could be forced to retract the article published or may be at risk of legal consequences.<sup>3</sup> One of the cases reached U.S. courts alleging inadequate fund claims, arguing that scale items were at the public domain.<sup>3</sup> Interestingly, time after, the partners holding the copyright sued mutually litigating for the copyright ownership and monetary benefits.<sup>7</sup>

A similar situation also happened with the Mini-Mental State Examination (MMSE) scale, highly used in mental health clinical practice and research to evaluate patients' cognitive status. Originally, the scale was published in 1975 freely available to institutions. In 2000, Mini-Mental intellectual property was transferred to MiniMental LLC (company created by the authors that registered the copyright of the instrument). In 2001, an agreement established with Psychological Assessment Resources transferred the exclusive intellectual property and the rights to this company. In 2010, the company released a second edition with a required payment of US\$ 1.23 per test. These restrictions led to the MiniMental oblivion in textbooks and clinical manuals.<sup>4,8-10</sup>

There are similarities between these two cases. Both implicate highly popular, commonly used, well-known scales, as well as the conversion of a public domain instrument to a licensure pay-walled regime. These changes result in important barrier to research by creating a monetary obstacle to disseminate research results.

Validated scales and questionnaires are created by researchers' work. Similarly, the results of a clinical trial or the development of a statistical test are created by researchers' work. The results of a clinical trial can make part of a meta-analysis without the mandatory request of permission to the trial authors. Likewise, authors of articles that used a given statistical test, like occurred in all the validation studies of the instruments previously

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mentioned, were not obliged to ask for permission to the mathematicians that created those tests. If so, why should exist a different intellectual property protection for those who publish the research that led them to the creation of a scale? This trend goes against movements in favor of free access to knowledge and open science, which argue that this excessive protection of intellectual property is a barrier to the dissemination and collective construction of knowledge, that excludes countries and populations from the benefits of scientific research that should move forward through an international, integrative and collaborative effort.<sup>3,4,7-12</sup>

In Brazil, copyright regulations do not support monetary rights for questionnaire developers, once “questionnaires to be filled with any type of information, scientific or not, as well as their instructions” are not amenable to protection as copyright.<sup>13</sup> However, given the international characteristic of scientific production dissemination and of the necessarily public characteristic of scientific publishing, authors and editors may be restrained or besieged (monetarily, morally or legally) if they select for their studies these research instruments under copyright restrictions.

It might not be uncommon that articles and recent guidelines with recommendations to develop, select and adapt research instruments had included among the initial stages of these processes contacting with original version authors and the ascertainment of formal permission of use – what represents in itself a given restriction to the freedom of knowledge production.<sup>14</sup> Different situation exists when authors of an instrument ask to be part of the research teams that aim to cross-culturally adapt and validate new version of the instrument they created. This safeguard, if fairly requested, aims to ensure that criteria and constructs that guided the development of the original instrument are also complied in the translated version.<sup>14</sup> Thus, this would be a way to further ensure that translated instrument possesses similar psychometric characteristics than the original instrument. New version’s validation team should see this participation as a method to keep the quality and ensure replicability of the two versions of the instrument.

We consider that the aforementioned way of exploring copyright, of abusing of intellectual property control, represents a barrier to knowledge and science. Researchers, authors, and editors should reflect about this topic, keeping in mind the interests that should be moved forward with scientific effort: the interest of science as a public good or the safeguard of financial interests.

In this first editorial, we reiterate our consideration to all the reviewers who, free of charge and for the development of science, devoted part of their time to review our articles in 2020. Your value is priceless for RBFHSS. There is no quality scientific production without every careful and critical look in the evaluation of the manuscripts. Dear 2020 article peer reviewers, thank you very much!

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Renata Dias REIS is a pharmacist, Master of Science and Pharmaceutical Technology (CTECFAR / FF-UFRJ) and post-graduated in Management of Health Care Networks (ENSP / FIOCRUZ).

Thiago Botelho AZEREDO is a pharmacist, PhD in Public Health, professor at the Faculty of Pharmacy at the Federal University of Rio de Janeiro, professor of the postgraduate program in Pharmaceutical Science and Technology (CTECFAR / FF-UFRJ) and researcher at the Observatory of Surveillance and Use of Medicines (Observium / FF-UFRJ).

Fernando FERNANDEZ-LLIMOS is a pharmacist, PhD in Pharmacy, professor at the Pharmacology Laboratory of the Faculty of Pharmacy at the University of Porto and associate editor of the Brazilian Journal of Hospital Pharmacy and Health Services.

