DOI: 10.1111/jcpt.13325

EDITORIAL

Journal of Clinical Pharmacy and Therapeutics WILEY

Drug compliance and the Morisky Adherence Scale: An expression of concern and a warning

Abstract

What is known and objective: Every prescriber knows that patients often do not take their medicines as prescribed. Hippocrates, the wise man of Kos, knew over two millennia ago. Our objective is to comment on the types of studies aimed at understanding and optimizing drug usage and to draw attention to the need to seek approval before using or citing the Morisky adherence scale.

Comment: The study of prescribing and how patients use their medicines is important. As part of this effort, the results of investigations of how patients adhere to drug prescriptions can be informative. However, the results are meaningful only if the methods used for doing the measurements are valid and made explicit. We were surprised when a team of our authors were threatened with legal action for citing the Morisky Adherence Scale and explaining how some authors had obtained their adherence scores. Adherence studies are but one facet of the study of prescribing aimed at improving clinical outcomes. Other aspects include investigating the quality of prescribing, and how unnecessary medicines can be deprescribed to improve the quality of care and reduce the risk of adverse effects.

What is new and conclusion: The study of optimal prescribing is an important endeavour and adherence studies are but one aspect. We report that using and citing the Morisky Adherence scale in any detail is a risky business. Prior approval is required unless one is prepared to pay up, retrospectively. We require all authors to certify they have no conflicts of interest with respect to the scale.

1 | WHAT IS KNOWN AND OBJECTIVE

Every prescriber knows that patients often do not take their medicines as prescribed. Hippocrates, the wise man of Kos, knew over two millennia ago.

"Keep a watch on the faults of the patients", he said. These "often make them lie about the taking of things prescribed". By not taking their medicines, patients "sometimes died" and "the blame" could then be "thrown upon the physician".[1]

Our objective is to observe that prescribed medication is not always helpful, and therefore, adherence is not always beneficial. We comment on the place of adherence studies in the pursuit of the optimization of drug usage and draw attention to the need to seek approval before using or citing the Morisky adherence scale.

2 | COMMENT

If one assumes that prescribed medicines work—although this assumption was more often wrong than right during Hippocrates' days, and is still often wrong as evidenced by the impact of recent prescriptions issued by high authority during the current COVID-19 pandemic—then measuring how well patients comply with prescribed treatments is a potentially useful endeavour.

Much effort has been aimed at a better understanding of the link between compliance and clinical outcomes, including adverse consequences, over the past decades. In a review of decades of research, Vermiere et al noted the difficulty in measuring compliance and noted the differential impacts of non-compliance in different settings.[2] Easy-to-use instruments for measuring compliance or adherence with self-report questionnaires are therefore welcomed by investigators. One of many such tools is the Morisky adherence scale, which is used in different variants.[3] Reviews of compliance studies therefore often identify primary studies in which the Morisky scales were used. A recent example is a study by Jia et al published in this Journal.[4]

During the review of the paper by Jia et al, our referee suggested that mentioning a measurement tool was not sufficient. Readers needed to know how poor adherence was defined. In response, the authors added the scoring reported by the authors of each study they were reviewing.[5] To us, as editors, appropriate citations to source material are important to inform those interested in investigating further and to give credit to the originators of the tools used, in this case Donald Morisky.

We were therefore surprised when we were copied onto an accusation of infringement of copyright of the Morisky scale sent to Jia and her colleagues, who were understandably distressed. They explained that they did not use the scale but simply reported and commented on its use, citing only material in the public domain. Their response did not satisfy Morisky who, via his business partner, a Steven Trubow, threatened legal action.

The threat by Morisky and his associates is not new.[6] Adam Marcus of *Retraction Watch* reported on a demand of $6500 for its use by a graduate student, and "tens of thousands of dollars each from hundreds of researchers". What seems new is that Morisky and his associates are now threatening legal action for not only using the scale, but simply citing the use of their work with the details

necessary to make sense of what is reported. It must be a lucrative business as there are Morisky offices in California, Paris and Vincenza.

It has also been reported that it can be very difficult to determine a licence fee from Morisky and Trubow; in a number of cases, they did not respond to email requests until the researcher gave up on using the scale or decided to use it anyway.[6–8]

As editors, we are still scratching our heads wondering what makes the tool so stressful to report on and so expensive to use, when there are many valid and free alternatives.[9] For Harrison Alter, a researcher at Highland Hospital in Oakland, California, the pricing of Morisky's scale was "absurd and predatory".[6] For Morisky, "the scale is an important tool for treating patients". "I am trying to save lives, and this is my legacy."[6] Some legacy.

Measuring adherence is just one, albeit important, way of probing how the impact of medications could be optimized, not only at the individual level but also at the population level.[10–13] A useful flipside of this has been the study of the extent to which medications are prescribed appropriately[14] and tools for measuring this are important.[15] Hippocrates' liberal prescription of laxatives was no doubt rarely justified. There is indeed much effort directed towards deprescribing unnecessary, inappropriate and dangerous medications[16] as numerous studies have shown that polypharmacy is one of the major predictors of hospitalizations and careless use of drugs, a cause of considerable morbidity and mortality.[17–20]

3 | WHAT IS NEW AND CONCLUSION

The study of optimal prescribing is an important endeavour. We report that citing the Morisky Adherence scale in any detail is a risky business. Prior approval is required from the originators unless one is prepared to pay up, with penalty, retrospectively. We now draw the attention of all submitting authors that mention the Morisky adherence scales to the paper by Marcus[6] and this editorial to ensure that they know exactly what they are in for and what payments may be required to Dr Morisky and his associates. We also require all authors to certify that they have no conflicts of interest with respect to the scale. As noted by Park and Lee,[7] researchers may be well-advised to avoid using the Morisky adherence scales and to seek out alternatives, and journal publishers likewise may well advise their authors not to use the scales. Ironically, Morisky and Trubow have become embroiled in their own lawsuit over the licensing of their business.[21]

CONFLICT OF INTEREST

The authors have no conflict of interest to declare.

Alain Li-Wan-Po PhD[1]
Gregory M. Peterson PhD[2]

[1]*Centre for Evidence-Based Practice, Nottingham, UK*
[2]*School of Pharmacy and Pharmacology, University of Tasmania, Hobart, TAS, Australia*

Correspondence
Alain Li-Wan-Po, PhD, Centre for Evidence-Based Practice, Nottingham NG9 3FD, UK.
Email: a.liwanpo@gmail.com

ORCID

Alain Li-Wan-Po https://orcid.org/0000-0003-1868-436X
Gregory M. Peterson https://orcid.org/0000-0002-6764-3882

REFERENCES

1. Hippocrates. Decorum. In: Jones WHS, ed. *Hippocrates Volume II*. William Heinemann; 1923:267-302.
2. Vermeire E, Hearnshaw H, Van Royen P, Denekens J. Patient adherence to treatment: three decades of research. A comprehensive review. *J Clin Pharm Ther*. 2001;26:331-342.
3. Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. *Med Care*. 1986;24:67-74.
4. Jia X, Zhou S, Luo D, Zhao X, Zhou Y, Cui YM. Effect of pharmacist-led interventions on medication adherence and inhalation technique in adult patients with asthma or COPD: a systematic review and meta-analysis. *J Clin Pharm Ther*. 2020;45:904-917.
5. Khdour MR, Kidney JC, Smyth BM, McElnay JC. Clinical pharmacy-led disease and medicine management programme for patients with COPD. *Br J Clin Pharmacol*. 2009;68:588-598.
6. Marcus A. Pay up or retract? Survey creator's demands for money rile some health researchers. *Science*. https://wwwsciencemagorg/news/2017/09/pay-or-retract-survey-creators-demands-money-rile-some-health-researchers. Accessed 19 October 2020; 2017.
7. Park SP, Lee EYJ. How should medical researchers respond to false copyright infringement claims? *Sci Ed*. 2019;6:137-141.
8. Marcus A. Legal threats once again force corrections over a scale measuring medication usage. *Retraction Watch*. 2019. https://retractionwatchcom/2019/02/15/legal-threats-once-again-force-corrections-over-a-scale-measuring-medication-usage. Accessed 21 October 2020.
9. Nguyen TM, La Caze A, Cottrell N. What are validated self-report adherence scales really measuring?: a systematic review. *Br J Clin Pharmacol*. 2014;77:427-445.
10. Lisowska A, Makarewicz-Wujec M, Dworakowska AM, Kozlowska-Wojciechowska M. Adherence to guidelines for pharmacological treatment of young adults with myocardial infarction in Poland: data from Polish Registry of Acute Coronary Syndromes (PL-ACS). *J Clin Pharm Ther*. 2019;44:471-478.
11. Khan S, Rupniewska E, Neighbors M, Singer D, Chiarappa J, Obando C. Real-world evidence on adherence, persistence, switching and dose escalation with biologics in adult inflammatory bowel disease in the United States: a systematic review. *J Clin Pharm Ther*. 2019;44:495-507.
12. Hartman L, Lems WF, Boers M. Outcome measures for adherence data from a medication event monitoring system: a literature review. *J Clin Pharm Ther*. 2019;44:1-5.
13. World Health Organization. *Adherence to long-term therapies : evidence for action*. In: Sabaté E, ed. World Health Organization; 2003.
14. Bitar S, Thilly N, Agrinier N. Sustained adherence to ESC guideline-recommended medications is associated with lower long-term mortality in heart failure and reduced ejection fraction: insights from the EPICAL2 cohort. *J Clin Pharm Ther*. 2020;45:793-803.
15. Aguiar JP, Brito AM, Martins AP, Leufkens HGM, Alves da Costa F. Potentially inappropriate medications with risk of cardiovascular adverse events in the elderly: a systematic review of

tools addressing inappropriate prescribing. *J Clin Pharm Ther*. 2019;44:349-360.
16. Baumgartner AD, Clark CM, LaValley SA, Monte SV, Wahler RG Jr, Singh R. Interventions to deprescribe potentially inappropriate medications in the elderly: lost in translation? *J Clin Pharm Ther*. 2020;45:453-461.
17. Jennings ELM, Murphy KD, Gallagher P, O'Mahony D. In-hospital adverse drug reactions in older adults; prevalence, presentation and associated drugs-a systematic review and meta-analysis. *Age Ageing*. 2020;49:948-958.
18. Farrell C, Brink J. The prevalence and factors associated with antipsychotic polypharmacy in a forensic psychiatric sample. *Front Psychiatry*. 2020;11:263.
19. Mabuchi T, Hosomi K, Yokoyama S, Takada M. Polypharmacy in elderly patients in Japan: analysis of Japanese real-world databases. *J Clin Pharm Ther*. 2020;45:991-996.
20. Iihara N, Bando Y, Ohara M, et al. Polypharmacy of medications and fall-related fractures in older people in Japan: a comparison between driving-prohibited and driving-cautioned medications. *J Clin Pharm Ther*. 2016;41:273-278.
21. Marcus A. Duo that used legal threats to force scientists to pay for a tool face off in court. *Retraction Watch*. 2020. https://retractionwatchcom/2020/10/02/duo-that-used-legal-threats-to-force-scientists-to-pay-for-a-tool-face-off-in-court. Accessed 21 October 2020.