

Legal threats force corrections over scale measuring medication usage: A case study analysed by the method of Seven Steps

Introduction

This case study involves a controversial copyrighted questionnaire designed for measuring medication usage (Morisky et al. 2008). The creators of the questionnaire are reported to follow up on users who cite the questionnaire, presenting them with two painful options: 1) retract their article, 2) pay hefty licence fees.

Description

In what follows, the Seven Steps case analysis method is used to analyse a situation wherein some researchers have used a copyrighted questionnaire in a study (i.e., Hale et al. 2016) and are struggling to figure out the best course of action.¹

Creators of a copyrighted questionnaire called the Eight-Item Morisky Medication Adherence Scale (MMAS-8) attempt to charge users of their survey for a license or retract the article that used (and cited) the questionnaire. According to a Science Magazine news item, as a result of legal threats, some teams have paid a licence fee, and some decided to retract the article that used the scale (Marcus 2017). In deliberations regarding what the best course of action is, Hale and colleagues (hypothetically) use the Seven Step model (Davis 1999).

Analysis

1. State problem

- Should an article using an unlicensed measuring scale be retracted unless the authors pay for a costly retroactive license?

¹ This hypothetical analysis is inspired by true events as reported in the RetractionWatch blog: <https://retractionwatch.com/2019/02/15/legal-threats-once-again-force-corrections-over-a-scale-measuring-medication-usage/#more-86298>

- Is it morally right to use a licenced scale and to change it to a free scale?

2. *Check facts*

- The scale is used in a study published by Hale and his colleagues in the field of cardiology (Hale 2016). The scale is based on Morisky's copyrighted questionnaire:

Morisky's scale, copyrighted in 2006, is available for more than 110 health conditions and in more than 80 languages. It asks basic questions, such as: "Have you ever cut back or stopped taking your medication without telling your doctor[...]?" The survey became popular in health research after it was validated in a 2008 study by Morisky, but other similar tools are available (Marcus 2017).

- Hale et al.'s paper is cited 19 times in February 2019 (See Table 1). Some of the studies that cited Hale et al. are also cited by other studies. Therefore, retracting the paper will affect many parties.
- If the authors do not retract, the developers of the scale will sue them for not having paid a licence fee.
- Other articles that used this scale without a licence have been retracted:
 - For example, a study by Patel et al. into chronic kidney disease (Patel et al. 2016a). The Retraction notice reads:

"Due to an unintentional error, the MMAS-8 scale in our article, "Health and Nutrition Literacy and Adherence to Treatment in Children, Adolescents, and Young Adults with Chronic Kidney Disease and Hypertension, North Carolina, 2015", published on August 4, 2016, by Preventing Chronic Disease, was used without proper permission from Dr Donald E. Morisky and co-authors. We regret any problems our article may have caused, and we retract it from the literature (Patel et al. 2016b)

3. *Identify relevant factors*

- Title of the paper:

A Remote Medication Monitoring System for Chronic Heart Failure Patients to Reduce Readmissions: A Two-Arm Randomized Pilot Study

- Authors of the paper:

Timothy M Hale; Kamal Jethwani; Manjinder Singh Kandola; Fidencio Saldana; Joseph C Kvedar

- Authors are based in the following institutions:

- Partners Healthcare, Connected Health, Boston, MA, USA
- Massachusetts General Hospital, Boston, MA, USA
- Harvard Medical School, Boston, MA, USA
- Brigham and Women's Hospital, Internal Medicine, Boston, MA, USA

- Publishing journal:

Journal of Medical Internet Research (JMIR)

- Developers of the scale:

Steven Trubow (The Ohio State University, University of Wisconsin) and Donald Morisky (UCLA Fielding School of Public Health), co-founders of the company called MMAS Research LLC. The U.S. law encourages academic scientists and their institutions to protect and profit from their inventions, including those developed with public funds. According to the Bayh-Dole Act (BDA) passed in 1980, scientists are allowed to patent research that was developed with government funds (Resnik 2007, p.9).

- Other parties:

The authors of papers that cite Hale et al.'s paper. According to Google Scholar (as per February 2019), 19 articles have cited Hale and his colleagues' paper. Retracting this paper will affect all the other papers that used it as a reference and add extra overhead to the journals that published these (see table. 1):

| Article | Publisher | Year |
|--|------------------------------------|------|
| Innovative Telemonitoring Enhanced Care Programme for Chronic Heart Failure (ITEC-CHF) to improve guideline compliance and collaborative care: protocol of a multicentre randomised controlled trial | BMJ Open | 2017 |
| Evaluating utility and compliance in a patient-based eHealth study using continuous-time heart rate and activity trackers | JAMIA | 2018 |
| Mobile Phone Apps to Support Heart Failure Self-Care Management: Integrative Review | JMIR Cardio | 2018 |
| Associations between Control of Glucose, Diabetes Support Services, New Insulin Initiation and 30 day Hospital Readmission in Diabetes Patients | ProQuest | 2017 |
| Extended, continuous measures of functional status in community dwelling persons with Alzheimer's and related dementia: Infrastructure, performance, tradeoffs, preliminary data, and promise | Journal of Neuroscience Methods | 2018 |
| Telemonitoring and hemodynamic monitoring to reduce hospitalization rates in heart failure: a systematic review and meta-analysis of randomized controlled trials and real-world studies | Journal of Geriatric Cardiology | 2018 |
| Updates in heart failure 30-day readmission prevention | Heart Failure Reviews | 2018 |
| Comparative Effectiveness of Disease Management With Information Communication Technology for Preventing Hospitalization and Readmission in Adults With Chronic Congestive Heart Failure | JAMDA | 2018 |
| Examining the implications of analytical and remote monitoring in pharmacy practice | The Pharmaceutical journal | 2017 |
| Extended, continuous measures of functional status in community dwelling persons with Alzheimer's and related dementia: Infrastructure, performance, tradeoffs, preliminary data, and promise | Journal of Neuroscience Methods | 2017 |
| Development of a Path to Home Mobile App for the Geriatric Rehabilitation Program at Bruyère Continuing Care: Protocol for User-Centered Design and Feasibility Testing Studies | JMIR Research Protocols | 2018 |
| A Novel Intelligent Two-Way Communication System for Remote Heart Failure Medication Uptitration (the CardioCoach Study): Randomized Controlled Feasibility Trial | JMIR Cardio | 2018 |
| The Therapist's Role in the Medical and Pharmacological Management of Heart Failure. Current Best Practices | Topics in Geriatric Rehabilitation | 2019 |

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|--|--------------------------------------|------|
| The effectiveness of telehealth on self-management for older adults with a chronic condition: A comprehensive narrative review of the literature | Journal of Telemedicine and Telecare | 2017 |
| Quality Improvement in Gastroenterology: A Systematic Review of Practical Interventions for Clinicians | Digestive Diseases and Sciences | 2018 |
| Timely Interventions for Children with ADHD through Web-Based Monitoring Algorithms | Diseases | 2019 |
| Improving the self-management of heart failure in low- and middle-income countries using a standalone mobile health intervention | TSpace | 2018 |
| A Guide for the Nurses in Care Management of Heart Failure | Journal of Cardiovascular Nursing | 2017 |
| Prevención de reingreso hospitalario del paciente crónico adulto | TAUJA | 2017 |

Table 1. List of articles that cited Hale et al.'s paper as per February 2019.

4. Develop list of options

- Option 1: Pay the retroactive fees for the licence
- Option 2: Retract the article
- Option 3: Find a similar model that is not licenced and correct the paper

5. Test options

Harm test: does this option do less harm than alternatives?

- Option 1: The money has to come from somewhere, and this could mean that the budget for an ongoing project should be reduced.
- Option 2: This is perhaps the most harmful option, not just for the group but also for the scientific community because the paper is cited 20 times. The results of this paper have been used by others.
- Option 3: This seems to be the least harmful, because it involves finding an alternative solution and updating the paper.

Publicity test: would I want my decision regarding this option published in the newspaper?

- Option 1: Probably not. By cutting the budget for one of the current projects, we would be questioned about our commitments. For instance, we might not be able to meet deadlines or deliver the promised quality.
- Option 2: No. Although a retraction notice is, in principle, similar to a newspaper publication, choosing to retract would have a knock-on effect on the other studies that used the results. These studies have to update their references and find alternatives for backing up the claims that are currently backed up by Hale et al.
- Option 3: Yes. It shows that while authors are respecting the law, they are also capable of thinking outside the box.

Defensibility test: could I defend my choice before a committee?

- Option 1: Yes. On the basis that the fees for the licence are reasonable, and there are the means to pay for it.
- Option 2: Yes. On the basis that the fees are not reasonable and there is no alternative model.
- Option 3: Yes. On the basis that a legal dispute will not result and the journal will agree to publish a correction.

Reversibility test: would I make my choice if I were adversely affected by it?

- Option 1: Being adversely affected by this choice would entail paying the fees or sacrificing one of the current projects to cover the fees. None of these outcomes is desirable.
- Option 2: Authors will not be able to publish their article. Besides the authors, those who cited the article would be adversely affected by this choice.
- Option 3: The only one adversely affected by this choice would be the developers of the scale. This is a reasonable option on the basis that the developers had originally suggested others should pay the license fee or retract.

Colleague test: what do my colleagues say when I describe my problem and suggest this option as my solution?

- Option 1: Colleagues are likely to ask: 'Which project are you going to sacrifice and how are you going to defend this choice?', or 'Don't you think that if you use some of the money

that was dedicated for another project to this, your future financial decisions will be questioned?'.

- Option 2: Given the stigma around having a retracted article, colleagues are likely to be concerned with academic reputation.
- Option 3: Colleagues are likely to suggest this option if an alternative model delivered the same results.

Professional test: what might my profession's governing body or ethics committee say about this option?

- Option 1: The local research council or academy of sciences would generally aim to prevent controversies in the future in order to support society's trust in science. Hence, their reaction is likely to be: 'In the future, please make sure that when you use resources that are developed by other people, you check whether they are licenced or not. It seems like this time you had the necessary resources to pay for that, maybe this will not be an option next time'.
- Option 2: The local research council or academy of sciences would perhaps not be happy with this option as it has a negative effect on other publications as well as on society's trust in science. Their likely response could be: 'You should contact the corresponding-author of all the other papers that cited yours and inform them that this paper is retracted'.
- Option 3: The local research council or academy of sciences would likely support this choice. Not only does it not involve spending scarce resources on a finished project, it would not affect society's trust in science. They might request that the author publicise the details of the alternative model.

Organization test: what does the company's ethics officer or legal counsel say about this?

- Option 1: There would likely be a concern with institutional reputation. They might advise the author to check their other publications for the appropriation of licensed material and to create awareness of the problems with using licensed material.
- Option 2: There would likely be a concern with institutional reputation. They might even consider this to be negligence. They might advise the author to create awareness of the problems with using licensed material.
- Option 3: Such an option would be viewed positively.

6. *Make a choice based on steps 1–5*

After going through all the steps, Option 3 seems to be the most reasonable option for several reasons:

- It is the least harmful option;
- It is publicly defensible;
- It adversely affects the fewest number of stakeholders;
- It is likely to be the most plausible option from the perspective of other colleagues;
- It does not negatively affect society's trust in science;
- It does not negatively affect the university's reputation.

7. *Review steps 1–6. How could one avoid such a situation in the future?*

- Check all the previously published material for the use of licenced material;
- Make sure that licenced material is not used unless there is a budget for it.

Are there any precautions you can take?

- Publish a letter to the editors and explain to the scientific community what exactly happened in an open and transparent manner.

Is there a way to access more support in the future?

- Arrange a meeting with other researchers and create awareness.
- Participate in a relevant conference and spread the news in an oral presentation.

Is there any way to change the organization?

- Ask the department to create separate inventories of free-to-use resources and paid resources;
- Ask the department to create an emergency fund should similar issues arise in the future;
- Ask the department to apply for a legal protection insurance to minimize the effects of legal costs, litigations, and so on.

References

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