

Modification, translation and adaptation of questionnaires should copyright laws be observed?

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Abstract This commentary is intended to start a discussion about whether people should be allowed to modify, translate, adapt or sell copyrighted questionnaires without the permission of the developer (copyright-holder).

Keywords Copyright · Modification · Questionnaires · Translation

The validation study of the Greek version of our standardised Asthma Quality of Life Questionnaire [AQLQ(S)] [1] by Grammatopoulou et al. [2] has raised some important issues concerning health status questionnaires. The challenge for questionnaire developers is to ensure that the instrument really does measure what it says it measures (validity) and that it has strong measurement properties. It must be able to discriminate between patients of different levels of impairment and, in the case of clinical instruments, provide a diagnostic cut-point between normal and abnormal. It must also be sensitive to change in patients' status over time, and users need to know what change in score can be considered clinically important and justify a change in the patient's treatment. Confidence in the validity, measurement properties and interpretability cannot be obtained from just one 'validation study'. It has to be built up gradually over the years through additional

validation studies in different countries (like the one by Grammatopoulou et al. [2]) and through good performance in both clinical practice and research.

When questionnaires are adapted for other languages and cultures, the process is much more complicated than doing a simple translation. It has to be done by experts following recognised guidelines to ensure that the instrument has content validity for the local culture and climate, meets the original specifications for the instrument and retains its construct validity and that the measurement properties remain the same as those of the original. Quite a challenge!

Most developers copyright their questionnaires for one very simple reason. Any changes to the original instrument or inadequate translation can destroy the validity and alter both the measurement properties and interpretability. We have all heard horror stories caused by the use of rogue or poorly translated questionnaires. These include incorrect clinical decisions, loss of entire clinical trials, incorrect interpretation of clinical and research studies and confusions about which is the authorised translation.

For this reason, I am draconian and incredibly rigid and do not allow any changes to be made to my questionnaires. In addition, I only allow cultural adaptations to be performed by the MAPI Research Institute [3]. Not only does their translation follow recommended guidelines, they meet the requirements of all regulatory agencies. By using only one organisation, I can ensure international harmonisation (e.g. 14 countries use the Spanish AQLQ(S), each one is slightly different but all 14 Spanish versions have been harmonised).

These stringent requirements have been invaluable in ensuring that there is only one authorised version of each questionnaire in each language. Since our questionnaires are easily accessible, made available free of charge to all

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clinicians and academics and meet the requirements for pharmaceutical companies to take their products to the regulatory agencies, we have been able to help users avoid some of the disasters that have occurred with other, less rigidly controlled or accessible, questionnaires.

It was most unfortunate that the title of the paper by Grammatopoulou et al. and some of the text suggests that they have developed a new 18-item version of the AQLQ(S) whereas, they have assured me, this was never their intention, and the purpose of the manuscript was solely to show that the measurement properties of the authorised Greek version of the 32-item AQLQ(S) (cultural adaptation by MAPI) were consistent with those of the original North American English version. There is already the validated 15-item MiniAQLQ [4] in use in over 50 languages (including Greek) and so another shortened version was never required.

However, their paper has had an excellent effect. It has started an important discussion about the right to modify, translate or adapt questionnaires without the permission of the copyright holder. I am the first to acknowledge that when I read the title of their paper, I was enormously upset and distressed because of the confusion and problems it would create. In addition, it does not meet the original AQLQ(S) specifications and therefore lacks content validity. The items in the original AQLQ(S) were selected because they are the problems identified by asthma patients as being the most important in their daily lives and for which they want help (impact method) [5]. Some years ago, we too conducted a factor analysis [6] and found that a number of items, that were really important to patients, did not load on the main factors and would have been excluded if we had used factor analysis for the original development. Asthma is an enormously complex condition triggered by a huge range of stimuli (allergens, viruses, irritants, etc.) and these stimuli vary greatly between patients. Therefore, it is hardly surprising that the problems experienced by patients should not fit a nice mathematical model. For this reason, we rejected the factor analysis approach in favour of the more pragmatic and clinically sensible impact method; clinicians using quality of life questionnaires need to be able to identify patients' individual problems and they cannot do this if some of the most important problems have been omitted from the questionnaire. We believe strongly that one cannot omit problems that are important to patients just because they DO NOT fit a mathematical model. Hence these 18 items from the AQLQ(S) do not have the content validity of either the AQLQ(S) or the 15-item MiniAQLQ; the weighting of the individual domains will have been changed and therefore the clinical interpretation of overall and domain scores will have been altered.

Another issue, not directly connected with the current paper but one concerning developers, copyright-holders

and users is the adaptation of questionnaires for data collection by other media (e.g. electronic, phone, etc.). Two of our recent studies have shown significant bias and inadequate concordance between the original paper and Information Technology (IT) versions: the first used a specific Personal Digital Assistant, the second used two Interactive Voice Response systems [7, 8]. As a result, I have not allowed these particular IT versions to be used. These failures were developed with as much care and testing as we used for other devices that give valid data [9, 10]. The reason for some electronic versions performing poorly remains obscure and so there needs to be further discussion on this important issue. The copyright on all our questionnaires does not allow adaptation to other media without permission and so this is a further insurance that invalid electric versions do not get into circulation.

Some developers do not feel as strongly as I do about maintaining quality control and there are users who want to be able to modify, translate, adapt and even sell copyrighted questionnaires without permission (yes, people have tried to sell my questionnaires even though I send them out free of charge!). The question of upholding copyright law can only be answered with a simple 'yes' or 'no'. 'Yes'—permission must be sought from copyright holders, or 'no'—copyright can be ignored and people should be able to do whatever they like with anyone's questionnaire. There can be no middle ground because who would decide what modifications, translations, adaptations or selling would be acceptable—lawyers would have a field day and confusion would reign! It would be helpful to hear other peoples' points of views on this topic.

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