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Cost of commercial protectionism in child health research

As someone with a background in both public health research and homeless services, I was recently approached by a group of voluntary agencies working with homeless families to assist them in conducting a research project to investigate the mental and physical health status of children passing through their services. The personnel involved were alarmed by what they saw as the largely undiagnosed, unmeasured and unmet needs the children presented. As part of my public service obligation as an academic, and having an interest in the topic, I readily agreed to help on a pro bono basis.

Attempting to identify a useful health measure threw up the routine issues of a lack of standardisation in assessment, a lack of national normative data, and the dearth of child health measures covering both mental and physical health. However, after an extensive search, two potential measures were identified. The first was the 50-item Parent Form of the Child Health Questionnaire (the CHQ-PF50),[1] which is suitable for older children, and the second was the Infant/Toddler Quality of Life Questionnaire (ITQOL)[2] for younger children.

This project was launched in response to real children's needs in the Irish context of voluntary agencies operating on shoe-string budgets, in an era of tightening budgets, a reduction in a government expenditure of over €6 billion in the next financial year, and a bail out from the International Monetary Fund and European Union.

The next barrier was the fee for the use of the proposed measures. Although some may accept the need to charge fees as a commercial reality, it could equally be argued that a wider appraisal, incorporating good publicity, exposure, a worthy cause, and publications/citations may be equally valuable in the long term.

However, putting the issues of fees aside, two points in the proposed licence agreement with the licencing company, HealthActCHQ, were very disturbing. The first prohibited the development of the measures. HealthActCHQ stated that all 'developmental work is undertaken exclusively by our scientific team'. The second issue of concern was the prohibition on developing normative data for Ireland. This restriction was explicitly stated: 'HealthActCHQ does not allow anyone to undertake iterative work, such as the development of normative data'. It should be noted that no Irish normative data for either of these measures are available and, as far as can be ascertained, there is no 'work in progress'.

It could be conceivable that through this commercial protectionism quality may be sacrificed for profit in the field of child health research. Companies in the psychometric and child health field are possibly stifling developments and improvements for commercial reasons. Furthermore, attempts at precision to overcome geographical, national, cultural, linguistic and temporal differences in normative scores are ignored and sacrificed.

Academics and clinicians need to be wary of health measures that may be suboptimal as a result of blatant commercial protectionism. Peer review and continued development are quality hallmarks that should not be swept aside lightly. Academics and clinicians need to cooperate to develop open-access[3] standardised measures of child health status and matching normative data. Such a united focus would inevitably benefit all concerned, particularly those most in need.

1 Landgraf JM, Abetz L, Ware JE. *The CHQ: A User's Manual*. The Health Institute, 1996.

2 Landgraf JM, Abetz L. *The Infant/Toddler Quality of Life Questionnaire: Conceptual Framework, Logic, Content, and Preliminary Psychometric Results. Final Report to Schering-Plough Laboratories and Health Technology Associates*. New England Medical Center, 1994.

3 Evans C, Connell J, Barkham M, Margison F, McGrath G, Mellor-Clark J, et al. A copyleft (free) self-report measure for psychological therapies: psychometric properties and utility of the CORE-OM. *J Affect Disord* 2002; **68**: 109–110.

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Author's reply: HealthActCHQ business is the development and the licensing of functional outcomes and quality-of-life surveys. HealthActCHQ is a privately owned, for-profit, scientific business. Since 1995, the company has been providing limited-use licenses for researchers. For more than 18 years, HealthActCHQ has developed and scientifically enhanced their total body of survey measurement work – including the Child Health Questionnaire (CHQ) and the Infant/Toddler Quality of Life Questionnaire (ITQOL). The company's surveys have not been developed with government grants, educational endowments or any other public funds.

As a private company, we self-fund all survey development, continuing support and ongoing scientific research. All surveys, scoring and normative data are proprietary and confidential information of HealthActCHQ, and are protected under the US Copyright Act and are protected in Ireland under one or more international treatises or conventions. The surveys, scoring algorithms and normative data are not in the public domain. Further developmental work on the company's intellectual property assets is the fiduciary obligation, role and right of our company's internal scientific development staff.

The company's website (www.healthactchq.com) openly provides detailed information for review prior to inquiry for registration on its licensing model and the terms and conditions for licensure and use. Licenses are granted to academic researchers, public health organisations, medical practice settings, clinical trials and others on the terms as presented at the website.

There are more than 350 international peer-reviewed manuscripts on the CHQ and the ITQOL presented on our website bibliography.

Declaration of interest

HealthActCHQ is the developer, owner and licensor of the CHQ and ITQOL as well as other patient-reported outcomes surveys,

and has a pecuniary interest in protecting the copyrights, reputation, quality and further development of these surveys.

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Clinical trials of drug and behaviour therapies: methodological issues

Shimazu *et al*[1] designed a randomised controlled trial highlighting the efficacy of family psychoeducation compared with treatment as usual in the maintenance treatment of major depression. By definition, the index trial was a pragmatic trial. The authors did not use behavioural 'placebo' control groups, although in such a trial they are not necessarily needed. However, this study has faced bias with regard to recruitment and selection procedures, such as the exclusion of previous non-responders. Sample homogeneity is one of the ways to enhance the power of the study. The authors excluded patients who received electroconvulsive therapy, which improved the homogeneity. The bipolarity status, number of previous episodes, duration of untreated psychosis (DUP) and associated specifier (e.g. melancholic, atypical and psychotic features) might have been taken as inclusion criteria to improve it further. Alternatively, as clinical relevance is the primary consideration in pragmatic trials, differences in treatment structure (e.g. number of antidepressants, doses and length of treatment/follow-up sessions) may be ignored if they reflect clinical practice.

Participants might have a preference for only antidepressant or combined therapy, and this preference might undermine adherence (which is not addressed in this study), influence drop-out rate, and even affect treatment response.[2] This could be avoided with a two-level randomisation design: first, randomised to two different treatment protocols; and second, randomised to receive preferred treatment. The participants' expectation, which might be a confounding factor, was not a concern in this trial.

The frequently raised question 'Does combining family psychoeducation therapy with antidepressant treatment enhance the maintenance of treatment effects following drug withdrawal?' can only be addressed following drug withdrawal.[3]

Allegiance effects could have been minimised if the drug and family psychoeducation were each administered by professionals who did not have primary allegiance to the type of therapy they were administering and expertise in its administration. This issue is not addressed clearly by Shimazu *et al*.[1]

In this pragmatic trial, the goal was to duplicate clinical practice, including practitioners' clinical judgements in tailoring treatments to patients. However, therapy protocols need to be clearly specified (especially whether receiving antidepressant or antipsychotic drugs) and fidelity to treatment protocols maintained if a clearly defined therapy is to be evaluated and the therapy is to be duplicated by others. Information obtained from this drug–behaviour therapy trial might be maximised if measures of the putative therapeutic mechanisms of behavioural treatment (e.g. self-efficacy, symptoms-related coping) were obtained.

Adherence data can provide useful information about treatment acceptability in pragmatic trials. Adherence appears to be more easily assessed with drug therapy. Measures of adherence with behaviour therapy are often limited to self-report, although completion of in-therapy tasks and/or homework assignments and tape recorders capable of monitoring the use of relaxation tapes have been used as 'objective' measures of adherence.[4] Had the authors taken some of these measures, the confounding due to adherence would have been reduced.

The authors could have entered some additional factors into the Cox proportional hazards analysis, such as adherence, DUP, type of antidepressant, predominant side-effect and psychotic status of current episode, which may have made the analysis better powered.

The methodological issues we discuss here are not considered immutable, but are expected to evolve as investigators creatively tackle design issues when conducting drug–behaviour trials.

1 Shimazu K, Shimodera S, Mino Y, Nishida A, Kamimura N, Sawada K, et al. Family psychoeducation for major depression: randomised controlled trial. *Br J Psychiatry* 2011; **198**: 385–90.

2 Elkin I, Pilkonis PA, Docherty JP, Sotsky SM. Conceptual and methodological issues in comparative studies of psychotherapy and pharmacotherapy. I. Active ingredients and mechanisms of change. *Am J Psychiatry* 1988; **145**: 909–17.

3 Holroyd K. Integrating pharmacologic and nonpharmacologic treatments. In *Headache Diagnosis and Interdisciplinary Treatment* (eds CD Tolison, RS Kunkel): 309–20. Williams & Wilkins, 1993.

4 Epstein LH. The direct effects of compliance of health outcomes. *Health Psychol* 1984; **3**: 385–93.

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Authors' reply: Biswas *et al* are correct that our study was a pragmatic trial, but beyond that there seem to be many misunderstandings and we are happy to respond to the points they raise.

First, we did not compare family psychoeducation with treatment as usual (TAU). The comparison was between psychoeducation plus TAU *v.* TAU alone. We asked the pragmatic question whether adding psychoeducation to TAU alone was any better than TAU and were able to answer it positively. The strengths and weaknesses of this type of comparison are fully discussed in our paper.

Second, we did not exclude previous non-responders. We did focus on responders to pharmacotherapy in the index episode because this was a trial of maintenance treatment, and it is very hard for us to logically imagine such a trial without focusing on responders. In addition, it appears meaningless to us that Biswas *et al* would like to assess bipolarity in a trial of major depression.

Third, Biswas *et al* seem to insinuate that we ignored 'differences in treatment structure (e.g. number of antidepressants, doses and length of treatment/follow-up sessions)'. Our Table 1 shows that they were comparable between the two arms, where the doctors in charge of TAU were kept unaware whether their patients had their family participating in family psychoeducation or not. We strictly abided by the principle of ceteris paribus.

Fourth, we agree that adherence and allegiance are important but often ignored aspects in clinical trials. Adherence to the family psychoeducation by the family members was maximised because there was no missed session. Adherence to TAU by the patients may have been optimal or suboptimal but this is not a valid concern in our context because we minimised performance bias (i.e. differential TAU intensity between the two arms) by masking the doctors. Adherence to family psychoeducation by staff was ensured through videotaping and supervision. All these are explained in the paper. On the other hand, we admit we failed