

Analysis of Chronic Fatigue Syndrome (CFS) Clinical Practice Guideline Development in Australia

pilot project 2003 end of year report to funding body

Project Summary

The University of Sydney has a unique opportunity to conduct a thorough study into the negotiations which produce clinical practice guidelines, using the recent case study of guidelines for chronic fatigue syndrome produced on behalf of the Royal Australasian College of Physicians. We have access to approximately 40,000 pages of documents on the deliberations of the working group which produced these guidelines.

The main outcomes of this pilot project will be an international research programme which we anticipate will be funded jointly by the ARC and overseas sources, and a methodology for the analysis of policy development based on a taxonomy of stakeholder characterisation and an examination of political processes employed.

Aims & Significance

Clinical practice guidelines are currently the primary mechanism for both the practice of medicine and the making of public policy related to research in medicine. Australia is unusual in having an explicit governmental framework for structuring such guidelines (NHMRC 1995): it is for this reason that we anticipate interest in this project from overseas funding sources in addition to the ARC. Guidelines are routinely presented to practitioners as best practice standards in areas with emerging or changing diagnostic and treatment standards. These consensus documents are produced through complex negotiations between healthcare providers, patients and the general public over both scientific and social issues. Public understanding of science becomes an integral part of the decision making underlying such guidelines. Australian clinical practice guidelines are written by working groups, typically chaired by a medical practitioner and composed of a mixture of medical practitioners, policymakers and lay people, and relying also on a process of submissions from the public. Ultimately a formal statement emerges which influences diagnosis, treatment and medical management, and which also has indirect effects on funding policy and public/private insurance coverage.

In 2002, a working group established under the auspices of the Royal Australasian College of Physicians (RACP) and funded by the Commonwealth Department of Health and Family Services issued a set of clinical practice guidelines on CFS. These guidelines had been researched and negotiated officially since 1996, and the need to develop appropriate and consistent guidelines for diagnosis and medical management of those with CFS in Australia had been recognised since the early 1990s (Loblay 1994). The RACP working group was composed primarily of medical practitioners representing a range of subspecialties typically associated with CFS, plus a representative from the Consumers' Health Forum. It produced draft guidelines as a result of an extensive scientific literature and policy review and consideration of public submissions from practitioners, consumer groups, CFS support groups and individuals, which were circulated for comment from 1998 onwards. These guidelines were controversial for a variety of reasons, and although the final document reflects modifications to the original draft guidelines, considerable dissent about the guidelines still exists both among practitioners and among lay/support groups.

The main significance of this pilot project is that it will lead to a major externally-funded programme examining the factors that contribute specifically to the production of clinical practice guidelines and more generally to the formalised public consultative processes which are increasingly popular and important in Australian policy development. It is essential to examine how various types of values interact with scientific information and the public understanding of science during these formal policy formation processes, and the impact of this interaction on decision outcomes.

Many influences on physicians' practice, medical and non-medical, are already recognised in the medical and ethical literature. There also is considerable theoretical literature in the philosophy of science and on the public understanding of science on the influence of values on scientific research and practice. However, there has been insufficient study of the actual interplay between these factors in concrete cases of the formation of formal public policy. (An exception is Thagard 1999, on the establishment of *H. pylori* as a causative factor for peptic ulcers.) Furthermore, there has been no comparison of such issues in countries with differing medical systems, values and healthcare funding schemes. Thus the larger project (for which this project serves as a pilot) will explain in detail how social values enter into the formation of clinical practice guidelines, including the framing of the questions to be addressed, the selection of individuals to represent various positions in response to those questions, and the way in which evidence is interpreted, as well as how these factors have historically evolved in Australia.

The topic of consensus formation is extremely timely, not only for health care but for controversial public policy decisions more generally (e.g., on the introduction of genetically-modified organisms, and the public funding of in-vitro fertilisation procedures). In an age in which the public is increasingly aware of controversies surrounding healthcare policy and eager to participate in the formulation of such policies, the impact of values as well as scientific information

on consensus decisions is critical to understanding the reasoning behind various specific recommendations, as well as the general structure of such decisions.

This project will serve as a pilot for a larger project to be coordinated by the investigators over a longer time period with outside grant funding. Co-investigators from a range of disciplines (for instance medicine, anthropology, sociology, linguistics, history, philosophy and bioethics) would be involved in a broader-based analysis of the debates over establishment of clinical practice guidelines for controversial disease categories. The goals would be to derive a more extensive analysis of the interplay between values and science, and to contribute to the understanding of specific areas of medical policy. Prominent scholars in these areas have expressed interest in taking part in such a project, once a pilot study has established the general categories and methodologies to be used.

Research Plan, Methods, and Techniques

Dr Rob Loblay (Immunology, Sydney), one of the RACP working group's co-convenors, has made available to us all documents collected by the working group, including all submissions and correspondence, working group meeting notes and summaries and an extensive scientific literature review conducted by the group. The printed documents number around 40,000 pages and occupy approximately 8 linear metres; in addition, some submissions are so far available in soft copy only. We will not be examining submissions in terms of identifiable individuals, but rather in terms of categories or types of submission (e.g., from individuals with CFS versus from support groups).

The primary method to be utilised for this pilot project is that of stakeholder analysis, which is an established methodology in public policy (e.g., in community consultation about government policy on illicit drug use). Stakeholder analysis is a formalised methodology for analysing the participants in policy processes in a way that allows the production of an explanatory framework for examining the outcomes of such processes. It focuses on how the characteristics of stakeholders (including individuals, groups and organisations) influence decision-making processes. This pilot project will produce preliminary analyses of the documents submitted to the group which produced the guidelines, and of the consultative and political processes that were deliberately and/or informally involved in the formation of the guidelines. The pilot project will develop a taxonomy of relevant stakeholders and factors (scientific, social and otherwise) that contributed to the guideline document, and will develop methodologies and hypotheses for a broader-based, cross-national comparison of development of such guidelines. The taxonomy and specific methodology developed will be published in a peer-reviewed journal of public health or public policy in order to disseminate the new methods produced as a model for other researchers working in related areas.

The Research

Summary

- The project experienced delays in obtaining access to archives and delays in obtaining ethics clearance. Subsequently, the project has been going extremely well.
- We have organised and analysed part of the archive of research materials which forms the basis of this project, we have made good progress on the theoretical side of the project, and we have begun to disseminate our results.
- Our use of funds has been as originally expected, except: we have spent less than projected on computer equipment as a result of combining resources with other projects; we have spent correspondingly more than projected on salary costs, to good effect.
- On the basis of the work done on this grant, we have an excellent chance of receiving a large ARC grant in 2005 (decision pending) or 2006.

Summary of methodology

Time dimension of interest: the policy process which we are studying took place over an extended period of time (about 8 years), and so it has been necessary to break our analysis up into several separate smaller analyses to be drawn together at the end, and to consider the stakeholders changing attitudes and influence/status over the course of the policy process.

Initial stakeholder analysis: Each document in the archived material to which we have access has been methodically assessed for stakeholder relevance and categorised according to:

- consumer type (or working group [WG] documentation)
- stage of policy referred to
- format of correspondence/submission
- main points of concern
- nature of input (whether it be supplying evidence, complaining about the process of policy making or working group formation, submitting a testimonial or petition, etc.)

This process was carried out in a qualitative manner according to stakeholder methodology (see Varvasovszky and Brugha, 2000) allowing new aspects of the stakeholders to emerge and the focus of categorisation to shift accordingly.

Comparative analysis: The Compilation of Submissions (CS) document, a compilation of consumer views, was summarized into 62 main points. The Draft Guidelines (DG) document then was thoroughly analysed for statements in support of or in opposition to suggestions and views expressed in these 62 main points. Future stages of this project will involve comparative analyses involving revised draft guidelines and final guidelines documents.

Critical analysis: A thorough assessment of our results against theories associated with democratic governance is planned as an arm of a larger project awaiting funding through an ARC Discovery Project application; some preliminary stages of this assessment have been carried out in the course of this current project. Our primary focus in the pilot project has been aspects of the CFS Working Group (WG)'s use of evidence and democratic principles in their procedures and actions as presented in our analysis of the archived material. This information will be interpreted in the process of a more detailed examination of democratic theory particularly with reference to the NHMRC guidelines, and those results will be compared to other instances of Australian and overseas policy formation as part of the future larger-scale project.

Results- initial stakeholder analysis

Developing an understanding of stakeholders to explain their interest, influence and intentions: The main stakeholders in this policy process have been separated into four major categories: CFS sufferers, carers and support groups (collectively referred to here as 'consumers'), medical practitioners, other healthcare professionals and researchers. Throughout the analysis process, various factors have come to light about each group which can be summarised as follows: consumers- emotional perspective, limited 'western' scientific knowledge-base, policymakers perception of this leading to lower credibility, and a resultant low level of influence in policy process; alternative practitioners (the major group that were categorized under the label of 'other healthcare professionals')- as for consumers, except for the emotional element; researchers and general practitioners- perhaps perceived by policymakers as an aspect of scientific research already incorporated using 'evidence-based' investigation, resulting also in a limited level of influence.

The relevance of consumers to policy formation: According to the WG and their DG, the clinical definition of CFS is very vague and the scientific basis of its diagnosis, prognosis and management has not yet been established by medical research. Therefore in the absence of higher levels of evidence, clinical guidelines on this illness cannot rely on scientific evidence. Those dealing with CFS on a daily basis, and particularly their experiences and views on its diagnosis and management which are level 4 evidence, must be relied upon to form a large part of the recommendations and their evidence base, as there simply is no traditional 'scientific' evidence. Therefore, the consumers and their contributions become highly important and relevant to the content of the document, its recommendations and its evidence base.

Results- comparative & critical analyses

The DG contains at least one (and often several) comments in support of 30/62 of the CS main points, and in opposition of 11/62. Only 5 instances were found of so-called "perspectives" that illustrated the CS main points. For 8/62 main points, the DG made *both* opposing and supporting statements. This analysis has not yet produced sufficient data to draw any definitive conclusions due to the fact that a major aspect of our stakeholder analysis which serves as the background for our comparative analysis is still to be completed, owing to the level of disorganisation and the sheer volume of the archives. One hypothesis still under consideration in light of these difficulties is the that the consumer content that appeared in DG was not included in response to consumer submissions, but due to other factors considered by the WG. As part of the next stage of this study, we plan to examine in detail chapter drafts and correspondence amongst the WG leading up to and following the release of the CS.

Lack of consensus among consumer submissions: This creates a difficulty for policymakers and must be considered as a complication in the process of formulating guidelines based on pluralistic principles. For example, the section in CS on "Diagnosis" contains firm recommendations from some that the guidelines should not outline any diagnostic tests for CFS as this would only create confusion since there is no definitive diagnostic test, whereas many submissions were adamant that particular tests should be listed as diagnostically valuable.

Inconsistent evidence evaluation: The DG's section on treatment recommendations contains some points of concern regarding this issue, the details of which include two separate tables giving conflicting information, dubious claims about conclusions reached in studies, and confusing statements about levels of evidence- all of which tend to permit a bias toward an exclusive recommendation for cognitive behavioural therapy (CBT).

Contradictory use of levels of evidence:

Levels III-3 and IV are supposedly regularly accepted in the DG as sufficient evidence to support statements made, as indicated by boxes with summaries of diagnosis and the nature of illness and recovery; however, this position seems to be selectively altered by the WG at various times:

- At one point it is stated that evaluating proposed treatments requires "randomized, double-blinded and placebo-controlled trials," a comment which in its context could be interpreted as being included primarily in order to be able to only "recommend" the use of CBT.
- The consumer representative revealed his suspicions to fellow consumers in July 1998 (in a summary of the progression of the guidelines) that the WG had failed, up to this point (and most likely would repeat this failure

in the future), to incorporate any consumer perspectives into the document because it was only considered level IV evidence.

A paper to be submitted soon (Mackenzie and Grossman in preparation) will look at theoretical (statistical and economic) aspects of these sorts of decisions about levels of evidence.

We plan to examine these issues regarding the WG's use of evidence levels in terms of how the NHMRC's "guidelines for guidelines" instructs policymakers to assign and utilize evidence hierarchies, and also the implications of these procedures in terms of the demands of democratic theory for citizen participation in healthcare decision-making within a pluralistic democracy. Relevant to this examination, Mackenzie and Grossman have made considerable progress on a separate, more theoretical paper discussing the inappropriateness of implementing strict hierarchies of evidence; this paper as well as one based on this CFS work will be presented at the AAHPSSS conference in early July. The CFS research also will be presented at part of a special symposium based on our larger project (of which the CFS project forms one branch) at the International Association of Bioethics (IAB) to be held in November 2004 in Sydney.

General comments, including comments on any difficulties encountered.

The volume of the material and its relative disorganisation, plus the need to seek ethics committee clearance and to consult materials at the convenience of the archive, has meant that the initial analysis did not proceed as quickly as hoped in the first half of 2003. However, in the second half of 2003, we were able to proceed as hoped. We did use all of the funds for salary costs, as more RA time was needed than originally anticipated, and computer equipment was made available through alternative means.

Academic Output

Publications

- Rachel A. Ankeny and Fiona Mackenzie, "Commentary on Better Than Numbers: A Gentle Critique of Evidence-Based Medicine," in Ian Kerridge, Chris Jordens, and Emma-Jane Sayers (eds.), *Restoring Humane Values to Medicine: A Miles Little Reader* (Sydney: Federation Press, 2003), pp. 118-121

Papers in progress

Conference presentations

- 2 presentations at the Australasian Association for the History, Philosophy and Social Studies of Science Conference in Newcastle, July 2004 - "The Evidence of Bureaucracy: Why EBM's Strict Hierarchies of Evidence are Detrimental to Health Research and Medicine" and "How Liberal Democracies Make Health Policy: The Case of Guidelines Development for Chronic Fatigue Syndrome."
- Presentation at the International Association of Bioethics Conference in Sydney, November 2004, plus a special symposium supported by a workshop preceding the conference which will include international commentators, funded by the University of Wollongong Near Miss funding. The conference session is titled "Stem Cells and Big Picture Bioethics: Comparing Policy Making in Liberal Democracies."