Special Articles

The process of producing a "NICE" guideline

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SUMMARY. This paper describes the process of preparing a Clinical Guideline for "NICE", the National Institute for Health and Clinical Excellence in the United Kingdom. The procedure involves the group appointed to prepare the guideline relating to the various "stakeholders" who have an interest on the one hand, and satisfying the fairly demanding standards set by NICE on the other. The strengths and limitations of the approach based on evidence based medicine are discussed.

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In the English language the word "nice" refers to a fine distinction, to an over-used adjective expressing approval, to a popular sugary biscuit, and to the acronym for the *National Institute for Health and Clinical Excellence*. This body was set up in response to the proliferation of clinical guidelines expressing the over-valued ideas of senior clinicians, sometimes influenced by the debt that they have to the drug industry. The aim is to produce guidelines paying attention only to evidence based medicine. At the beginning of 2010 there were about 100 clinical guidelines in existence, with another 60 or so in the process of development. To achieve this astonishing output the whole of medicine has been divided into 21 topic areas, of which "Mental health and behavioural conditions" are one, and there is a *National Collaborating Centre for Mental Health* (NCCMH) that produces most of those that concern mental disorder. Each guideline is initially produced by a *Guideline Development Group* (GDG) working in the collaborating centre, which is a shared collaboration between the *Royal College of Psychiatry and the British Psychological Society*, working in collaboration with the professional organisations involved in the field of mental health, national patient and carer organisations, a number of academic institutions and NICE. The purpose of this paper is to describe this process, as I have now chaired two GDG's - the original guideline on depression, and the more recent one on depression accompanying physical illness.

HOW THE GDG IS SET UP

A Director of the Collaborating Centre, together with a representative of NICE, has the task of appointing the Chairman. Once this has been done, the chairman and the director jointly choose the members of the GDG, and submit their suggestions to NICE. In the recent GDG there were 14 members, with an addition of 13 staff from the Collaborating Centre, including a systematic reviewer, health economist, a manager, an information scientist, an Editor and other research workers. There were two psychiatrists other than myself - a liaison psychiatrist and a psychogeriatrician, three physicians (a cardiologist, a

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geriatrician, and a rheumatologist), two clinical psychologists, two GPs, a pharmacist, a nurse, an occupational therapist and a service user. We had hoped for both a service user and a carer, but this turned out to be difficult as our potential carers could not take time off from their caring duties. Each person had to make a declaration of their interests before beginning their work.

STRUCTURE OF MEETINGS OF THE GDG

There were about 10 all day meetings of the group spread over 18 months, with a 2 day meeting when our work was almost complete. An early task was to produce a set of clinical questions that the staff of the Centre would be asked to address, in the event there were two general questions, three questions about the best service configuration to meet the needs of patients, four questions about the best psychological and psychosocial treatments, and 8 questions about the best pharmacological treatments. At this early stage NICE holds a meeting with "stakeholders" who have either expressed an interest in the topic the group is about to address, or are seen by NICE as being key experts in the field.

Once these questions were agreed, the staff of the research centre set about doing literature searches to identify the clinical trials that were relevant to each question. Sometimes this involved them in sifting through very large data-sets indeed: in the case of the original depression guideline, over 8,000 randomised controlled trials (RCTs) were identified. The first task was to do a quality control of each paper, rejecting those where the randomisation was defective and which did not meet a set of quality controls set up by NICE.

Each meeting began with the Chairman establishing that the service user had understood what was being said, and could make any comments she wished. During early meetings, it was the Chairman's task to prepare a "long version" of our final report dealing with general issues in the field - in the latter GDG, these included the possible relationships between physical and psychological morbidity. This report would be circulated before each meeting, and members were invited to comment upon it.

As our systematic reviewers produced their forest plots of the RCTs they had examined, it was necessary to divide the work of the group between service configurations, psychological interventions and drug treatments. After lunch the groups came together and presented their conclusions to the entire group. Towards the end of the series of meetings, health economists began to cost the various findings and to present data in terms of costs and benefits if each procedure. At this stage we began to draft and discuss our findings about the various treatments we were considering, and to prepare drafts of our various forms of output. These were the long version of the report, the report for health care professions, the report for the lay public and the brief report. The version for the lay public is particularly useful, as it gives the main recommendations without getting bogged down in the technicalities of relative risks, forest plots or Quality Adjusted Life-Years. (All of the versions are available over the internet, including the full guideline (Guideline Development group members, 2009), other versions and other guidelines (*NICE Website*, 2010) and even the forest plots (Depression in Chronic Physical Health Problems, Forest Plots, 2010) which formed the basis of our recommendations).

THE CHAIRMAN'S ROLE

The chairman's role during meetings is straightforward: ensuring that meeting start and finish on time, that service users participate and feel part of what is going on, and that members of the group have opportunity to freely express their opinions on all matters discussed. Between meetings the task is more complex - chasing up and reading papers relevant to the current work, writing drafts of the "long version" and serially revising them in the light of feedback sent by group members.

NICE'S ROLE

NICE has their own representative in the Collaborating Centre, who acts as a liaison officer between the GDG and the parent organisation. As each Guideline nears completion, collaboration with NICE becomes more noticeable, and we receive detailed comments upon our drafts. Once the whole Guideline is in draft two important things happen: with collaboration of a science writer from NICE a version of the Guideline in simple English is prepared, and discussed in details with the service users, and the draft is sent to all the stakeholders who have been identified to obtain their critical comments. With the first Guideline there were well over 1,000 such comments received, each of which had to receive a response from the GDG. Inevitably, this task is shared and largely occurs between meetings.

The whole rather complex procedure is governed by a detailed manual running to some 360 pages, if the Appendices are included. This is regularly updated, and can also be downloaded (Guideline Manual, 2009).

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LIMITATIONS AND STRENGTHS OF NICE GUIDELINES

When NICE began its work, heavy reliance was placed on RCTs, with a simple hierarchy of evidence ranging from multiple well conducted RCTs supporting the treatment in question, to uncontrolled studies, and resulting in a rating ranging from A to D. We were even allowed to include "good practice points", where no objective evidence could be gathered, thus stretching the limits of evidence based medicine.

In his Harveian Oration the Chairman of NICE (Rawlins, 2008; Guyatt et al., 2008) argued that the notion that evidence can be reliably or usefully placed in 'hierarchies' is illusory. There are cases where a treatment is so evidently effective that no RCTs have ever been done, or would be thought necessary. Rather, decision makers need to exercise judgement about whether (and when) evidence gathered from experimental or observational sources is fit for purpose. The system which effectively replaces the old ABCD system is the Grade system described by Guyatt et al. (2008). This system takes account of both the strength and quality of the evidence for supporting an intervention, and combines an assessment of the quality of the evidence (forest plots of multiple, well conducted treatment trials, for example) with judgements of strength, by showing that the desirable effects are greater than the undesirable effects.

The limitations of relying too heavily on RCTs include non-representative samples, selective publication of positive trials by journals, over-reliance on small differences which although statistically significant are clinically worthless, and the difficulty of designing control treatments for non-pharmacological interventions.

All our treatments can be thought of as having specific as well as non-specific effects. It is customary, but rather unhelpful, to refer to non-specific effects as "placebo effects", whereas they should perhaps be thought of as "case management effects" and attempts made to discriminate between such effects and no treatment or waiting list effects. In drug trials, the active drug/placebo difference does indeed give us the specific contribution of the drug, but well conducted trials give very impressive responses to the placebo, which are largely due to the case management regime, which has to be identical with that for the index group. This cannot be used as the case management effect however, since many disorders will resolve spontaneously with time, even without treatment.

With severely ill patients, it is unethical to deny them treatment, and in practice we mainly know about case management effects by studies of milder disorders - where case management effects are very strong (Thomas, 1987).

There are also limitations on what problems can really be studied by evidence based medicine. For example, in our first depression guideline we recommended that clinicians should remember social & inter-personal causes of chronic depression - yet there was no objective evidence supporting this statement, it just seemed to the GDG that this was good practice. Despite this limitation, if there are any better clinical guidelines in existence, please lead me to them.

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