

1 Background letters and instructions related to the questionnaire

1.1 Letter to Stakeholder Organisations sent in May 2005

Dear

Consensus Development of the NICE Guideline for CFS/ME

As part of the CFS/ME guideline development process we intend to use formal consensus methodology. To support the Guideline Development Group (GDG's) in reaching their opinions, we intend to survey a wider group of patients and professionals who have an interest in CFS/ME.

We are contacting you to ask your help in identifying people who would be interested in assisting us by:

- 1 Reading the summary of evidence resulting from a systematic review of published research.
- 2 Rating their level of agreement or disagreement with the various options for investigation and treatment of CFS/ME, after reading the GDG's ratings.

The questionnaire will be sent to participants by email in December (the exact date will be confirmed directly with participants) and we estimate that it should take 2-3 hours to do this work. We recognise that this is a significant amount of time, but hope that some of your members would be willing to participate to assist the GDG in developing a robust guideline. To do so, it is important to have the experience and views of people with CFS/ME. Therefore it would be very helpful if you could identify at least 5 (or up to 50) people to participate.

We will also ask nominees who were not selected for the GDG to participate, therefore if you made any nominations, they, as well as GDG members, will be approached directly.

I would be grateful if you would complete the attached form identifying participants and return it to me **by 30th June**.

This survey is not part of standard NICE methodology and is being piloted on this guideline. NICE will be carrying out an evaluation of its effectiveness in supporting guidelines development where there is little firm published evidence. It would therefore be very useful to know how you selected members to take part.

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Thank you for your interest in this guideline and for taking the time to assist us in our enquiries. The list of GDG Members and further information about the guideline is available on the NICE website at <http://www.nice.org.uk/page.aspx?o=111636> .

Yours sincerely

Nicola Costin
Health Services Research Fellow
NCC-PC

CFS/ME Questionnaire

- 1 Organisation [Mail Merge name in]
- 2 The following people have agreed to contribute to the work of the Guideline Development Group by completing the questionnaire which will be emailed to them in December.

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1.2 Letter to participants sent December/January 2006

CFS/ME NICE Guideline

Dear CFS/ME Questionnaire volunteer,

Thank you for agreeing to complete a questionnaire about CFS/ME to assist the Guideline Development Group.

As you are aware NICE guidelines are based on research evidence, and before completing the questionnaire, we would therefore ask you to read the summary of evidence resulting from a systematic review (the Evidence Review) of published research. The review was carried out by the University of York and updates the earlier review which informed the CMO's report. The report of the research evidence is contained in the first 86 pages of the document. The background information, including the methods used, is included for completeness. I am sending it to you now so that you may read it prior to receiving the questionnaire.

The process so far has been that the Guideline Development Group (GDG) has reviewed the evidence presented in this review which is divided into four sub-sections. These being: Case identification; Diagnosis & Investigations; Interventions and Information & Support. For each sub-section they discussed the evidence and developed the statements which synthesised the evidence. From this, the GDG identified areas where there is uncertainty or variation in practice. These areas form the basis of the questionnaire which will be sent to you as an electronic document in February.

As you know, this questionnaire is not part of the standard NICE process, but is being piloted for this guideline as part of the formal consensus process. The GDG will take the results into consideration but, as with all NICE guidelines, the final content of the guideline is the responsibility of the GDG. You will have the

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opportunity to comment on the final document during the public consultation period.

Detailed instructions will be provided along with the questionnaire in February. After reading the attached, the questionnaire should take between 1 and 2 hours to complete in total. However, it will be divided into sections and, if it is more convenient for you to complete in four sessions, you are able to do so. The Guideline Development Group will be given the summarised results of the questionnaire but nothing will be presented to the GDG which will identify you individually.

The schedule for the questionnaire:

Date	Action
6 th February 2006	You will receive the questionnaire and instructions on how to complete it by email.
3 rd March 2006	<p>DEADLINE for you to return the questionnaire for analysis.</p> <p>Completed questionnaires should be returned to cfs_me@rcgp.org.uk by 12noon.</p> <p>Unfortunately, as deadlines are tight, we are unable to accept questionnaires that are submitted after the deadline.</p>

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More information on the guideline development and the timing of the consultation is on the NICE website – www.nice.org.uk

Once again, many thanks for your valuable contributions and I will contact you again in February with the questionnaire. Should you have any questions in the meantime, please contact me.

Yours sincerely

Nicola Costin

Health Services Research Fellow

NCC-PC

1.3 Letter sent to participants in April 2006 with instructions and questionnaire

Dear Participant,

RE: CFS/ME Questionnaire to inform the NICE Guideline

Thank you for agreeing to participate in the questionnaire to contribute to the development of the National Institute for Health and Clinical Excellence CFS/ME Guideline.

Please find enclosed:

- The questionnaire to follow on from the Evidence Review which you received in March.
- The Information and Instructions booklet for completing the questionnaire. It is essential that you read these instructions thoroughly before completing the questionnaire.
- A postage paid envelope to return the questionnaire.

The deadline for return of the questionnaire is: 5pm Friday 5th May 2006.

Please contact me if you have any questions concerning the questionnaire. In the meantime thank you for your co-operation and support with this important piece of work.

Yours sincerely

Nicola Costin
Project Manager / Research Fellow
NCC-PC

1.4 Information and Instructions for filling out the CFS/ME questionnaire

National Collaborating Centre for Primary Care

The NCC-PC is a collaboration between the Royal College of General Practitioners, Clinical Governance Research & Development Unit at University of Leicester, the Community Practitioners' and Health Visitors' Association and the Royal Pharmaceutical Society.

Funded to produce guidelines and audit advice for the NHS by the National Institute for Health and Clinical Excellence.

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1. Introduction

The purpose of the questionnaire is to inform the Guideline Development Group (GDG) on the diagnosis, referral, investigations and treatment for CFS/ME based upon the experience of a wide group of patients/carers and health care professionals. This questionnaire is not part of the standard NICE guideline development process, but is being piloted for this guideline as part of the formal consensus methods being used to develop the guideline. The GDG will take the results into consideration but as with all NICE guidelines, the final content of the guideline is the responsibility of the GDG.

The questionnaire and instruction document do not express what will be contained in the guideline or the individual views of the Guideline Development Group members, the National Collaborating Centre for Primary Care (NCC-PC) team or the National Institute for Health and Clinical Excellence (NICE).

The questionnaire consists of a series of statements on which you are asked to give your opinion. The GDG will receive the summarised totals for each statement. No information will be presented to the GDG or published in the guideline which will identify you individually.

Inclusions and Exclusions

The questionnaire consists of 90 multiple choice statements and should take between 1 and 2 hours to complete in total. We recognise it does not cover all potential areas of investigations, diagnosis or interventions for CFS/ME. It contains all of the statements on which the GDG did not reach consensus as well as a random sample of 20% of the statements where the GDG reached a consensus. There were originally over 500 questions or statements which were developed, discussed and rated by the GDG. As the full questionnaire was far

too long to ask you to complete, the attached questionnaire is a subset. It therefore does not cover all aspects of care or every possible situation. If you would like to see a full set of statements, please email cfs_me@nccpc.org.uk and they will be sent to you. However we cannot send these out by post.

You may wish to answer only the statements which are directly relevant to your expertise or profession. Follow the instructions below and rate the statements you feel are relevant to you. Your results will be processed for those you have answered and a rating of 'don't know' shall be assumed for all others.

2. General Instructions

2.1 The Content of the Questionnaire

Your details

We have asked for some information about you in order to analyse the questionnaire results. The results will be presented to the GDG in two ways. Firstly, the results from all respondents will be summarised. Secondly, they will be summarised separately for patient/carers and health professionals.

No information will be presented to the GDG or published in the guideline, which will identify you individually. We do need to know who you are in order to keep track of returned questionnaires, to send reminders and to calculate response rates. Therefore, each questionnaire has a unique number that identifies you and you do not need to put your name on the questionnaire when you return it.

We will be unable to process any questionnaire that does not have the identifying number on it.

We will store your names and addresses in a database separate from the questionnaire. Therefore, those who enter the data and analyse it will not know

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who you are. This database will be destroyed once the guideline is published.

The Statements

The questionnaire has been divided into four sections so that you can complete it in parts if it is more convenient for you to do so. The sections are as follows:

- Diagnosis, Investigations and Referral
- Pharmacological Interventions (**Please note that in this section the statements ask you to rate your agreement with how inappropriate something is.**)
- Behavioural Approaches
- Dietary and Complementary Approaches

There is a set of assumptions that are essential for you to read before completing each section of the questionnaire. These assumptions provide background information and context to the statements. These are located in section 4 of this document.

After reading the Evidence Review (which you have already received by post or electronically) and the assumptions, please read the statements, and rate the level of your agreement for each. Rate your agreement with the statement and **not** your agreement with the GDG rating.

The ratings are on a Likert scale which allows you to express a range of opinions numerically. The scale is as follows:

'Don't Know'	1	2	3	4	5	6	7	8	9
	<i>Disagree</i>			<i>Unsure</i>			<i>Agree</i>		

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If due to a lack of knowledge or no experience of the situation, you are unable to express an opinion, please select the 'don't know' option rather than rating the statement as unsure. Use the middle (4, 5, 6) ratings, if you are knowledgeable about the situation but are unsure whether you agree or disagree with the statement. Before opting for 'don't know' or unsure, please refer again to the assumptions detailed in section 4 of this document which may clarify things for you.

The GDG's ratings of each statement are included in the questionnaire for your information¹.

The Comments Section

If you would particularly like to briefly clarify one of your ratings for a specific statement please do so here.

¹ . The consensus rating is a summary calculation of the GDG's responses The definitions are based on the GDG participant's average rating and spread of ratings for a statement using a 9 point scale (from Strongly Disagree to Strongly Agree):

- 'agree' – the GDG agreed with the statement if the median (middle) rating of GDG participants was greater than 6
- 'disagree' - the GDG disagreed with the statement if the median (middle) rating of GDG participants was less than 4
- 'uncertain' – the GDG was uncertain if the median (middle) rating of GDG participants was between 4 and 6. If there was wide variation in the GDG participants' individual ratings (lack of consensus), then the GDG's view was also classified as uncertain.

This is a standard definition of consensus.

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Please do not use this section to comment on the content of the questionnaire, guideline (including the development process) or the evidence review. Any comments you have concerning these issues should be co-ordinated with your nominating stakeholder organisation and submitted at the public consultation phase later this summer. Further information about this process can be found at www.nice.org.uk.

2.2 Instructions specifically for completing the paper version of the questionnaire

- Place a tick in the appropriate boxes detailing your personal information on the front page.
- Place a tick in one box which represents your agreement with each statement (Note that the GDG rating is stated below the question).
- When complete, return the questionnaire in the pre-paid envelope provided.

2.3 Instructions specifically for completing the electronic version of the questionnaire

- Complete the electronic questionnaire in the Excel spreadsheet.
- Select the appropriate options in the personal information section at the top of the spreadsheet.
- The columns in the spreadsheet contain:
 - A. Statement number
 - B. The statement
 - C. The GDG's rating
 - D. The column for you to place your opinion rating (D –highlighted in yellow)

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To rate your agreement with a statement, click on the corresponding box to the right of the spreadsheet (column D, highlighted in yellow) and a drop down tab will appear to the right-hand side of the box. Click on this tab and select a numerical representation of your opinion.

- Repeat this process for all of the statements.
- Save your answers in the Excel spreadsheet. (Should you wish to complete the questionnaire in sections, Excel allows you to save the work you have done and return to it when ready)
- Attach the spreadsheet, with your ratings, to an email and send it to cfs_me@rcgp.org.uk.

3. Definitions of Age and Severity

While it is difficult to generalise about care for all patients with CFS/ME, to construct this questionnaire, a way of grouping statements was needed. The GDG decided that there were two important factors to consider:

1. whether that person is a child or adult
2. the severity of CFS/ME

Therefore, where appropriate this information is given in the statements. The definitions used within the questionnaire, of age and severity of CFS/ME are given below.

3.1 Age

Adult: 16 and above.

Child: Under 16 -unless physical or emotional maturity requires that the individual be treated as an adult.

3.2 Severity

These definitions were agreed by the GDG and have been derived from definitions in the Royal College of Paediatrics and Child Health Guidelines² and the CMO report³.

- **Mild CFS/ME** –Individuals are mobile, can care for themselves and can do light domestic tasks with difficulty. The majority will still be working. However, in order to remain in work they will probably have stopped all leisure and social pursuits, often taking days off. Most will use the weekend to cope with the rest of the week.

- **Moderate CFS/ME** –Individuals have reduced mobility and are restricted in all activities of daily living, often having peaks and troughs of ability, dependent on the degree of symptoms. They have usually stopped work and require rest periods, often sleeping in the afternoon for one or two hours. Sleep quality at night is generally poor and disturbed.

² Royal College of Paediatrics and Child Health. Evidence based guideline for the management of CFS/ME (Chronic Fatigue Syndrome / Myalgic Encephalopathy in Children and Young People), December 2004.

³ Department of Health. A report of the CFS/ME working group: report to the chief medical officer of an independent working group. London: Department of health; 2002.

- **Severe / Very Severe CFS/ME** - Will be able to carry out minimal daily tasks only (e.g. face washing, cleaning teeth) or are unable to mobilise and do any of these for themselves. Have severe cognitive difficulties and be wheelchair dependent for mobility. These people are often unable to leave the house except on rare occasions with severe prolonged after-effect from effort. They may also be in bed for the majority of the time and are often unable to tolerate any noise, and are generally extremely sensitive to light.

4. Assumptions

When considering each statement you should assume that;

1. The person with the CFS/ME and health care professionals involved in their care will make decisions in partnership. These are directed by the patient's personal preferences and builds on the existing experience and skills of the professional.
2. All treatments are offered allowing the person with the CFS/ME to refuse without compromising the further therapeutic relationship.
3. There is a good rapport in which the patient and their families/carers feel believed and validated.
4. Treatment is provided by the NHS in the context of availability of adequate numbers of competent, appropriately trained health care professionals.
5. Minimal waiting times for good quality services are adhered to.
6. All vitamins and supplements taken are within the recommended daily allowance.

5. Summary

- Read the Evidence Review, if you have not already done so.
- Carefully read this information including the assumptions in section 4.
- Complete the questionnaire
- Return it by post in the SAE or email to ncostin@rcgp.org.uk
- If you have any questions contact Nicola Costin at the above email address

Note: **Please return the questionnaire either by post OR electronically. Please do not do both.**

1.5 Letter of thanks sent June 2006

Dear nominee/participant,

RE: Questionnaire to support the development of the NICE CFS/ME guideline.

I am writing to thank you for your returned questionnaires, comments, and the time and effort you dedicated to this work. We recognise the effort and personal sacrifice of time and energy you have made in order to help us answer some very difficult questions in complicated topic areas. I would also like to thank you for all of your valuable comments relating to these issues, which the guideline development group (GDG) have found to be very informative.

The results have now been statistically analysed and will be used as discussion aids for the GDG during the next stages of the development process which is writing the recommendations. The results will also be presented in the Appendices of the full guideline document which will be available, when published, on the NICE website (www.nice.org.uk).

Your feedback is very important to us and our process is designed to enable you to contribute throughout the development of the guideline at various, specific stages. Therefore, you will have the opportunity to comment, through your nominating organisation, on the draft guideline during the public consultation period. Details of this consultation will be published on the NICE website.

Comments received during the consultation period will be considered by the guideline development group so it would be very helpful if your nominating stakeholder organisation could submit any comments formally at that time. The

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GDG's response to comments received will then be published on the NICE website.

Further details of the development process, consultation and guideline timetable can be found on the NICE website.

Thank you again for volunteering your time to assist in this valuable work.

Yours sincerely,

Nicola Costin

Health Services Research Fellow / Project Manager