

Request for Approval under the “Generic Clearance for the Collection of Routine Customer Feedback” (OMB Control Number: 0920-1071)

TITLE OF INFORMATION COLLECTION: Myalgic Encephalomyelitis (ME)/Chronic Fatigue Syndrome (CFS) Healthcare Provider Perspective Interview

PURPOSE:

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) is a complex illness affecting over one million U.S. adults [Jason et al. 1999; Reyes et al. 2003]. While severe and persistent fatigue is a key feature of the illness, patients also experience a number of other symptoms such as impaired concentration, muscle and joint pain, and post-exertional malaise (PEM). The multi-systemic and debilitating nature of the illness leads ME/CFS patients to experience functional impairment which is comparable to that associated with other chronic conditions, such as heart disease, multiple sclerosis, cancer, diabetes, lung disease and rheumatoid arthritis [Komaroff et al. 1996; Nacul et al. 2011].

Currently, there is neither a diagnostic biomarker nor a cure for ME/CFS. As such, patients can experience years of poor health and reduced functional ability, resulting in sizable economic costs to the individual, healthcare system, and society as a whole. For example, having ME/CFS or ME/CFS-related symptoms has been estimated to account for as much as \$19-51 billion in economic costs (including productive loss and medical costs) [Reynolds et al. 2004; Jason et al. 2008; Lin et al. 2011]. Despite their greater healthcare utilization, many individuals with ME/CFS also report experiencing system-level barriers to receiving high quality and effective healthcare [Lin et al., 2009].

In 2015, the Institute of Medicine (IOM) released its first report on ME/CFS and the primary message was that “ME/CFS is a serious, chronic, complex, and systemic disease that frequently and dramatically limits the activities of affected patients.” The IOM recommended revising diagnostic criteria and increasing medical education to improve the care that ME/CFS patients receive [IOM, 2015]. Further, the IOM stated that

“Many health care providers are skeptical about the seriousness of ME/CFS, mistake it for a mental health condition, or consider it a figment of the patient’s imagination. Misconceptions or dismissive attitudes on the part of health care providers make the path to diagnosis long and frustrating for many patients. The committee stresses that health care providers should acknowledge ME/CFS as a serious illness that requires timely diagnosis and appropriate care.” IOM, 2015

The Centers for Disease Control and Prevention (CDC) conducted focus groups and individual interviews with ME/CFS patients in 2015, in a project titled “Chronic Fatigue Syndrome: Symptoms from the Patient Perspective” (OMB Control No. 0920-1026). The purpose of the project was to collect feedback from patients with ME/CFS about their symptoms and the effects that the illness has on functioning in order to revise educational materials, provide more accurate diagnostic guidance to clinicians and update the CDC website. Lessons from this project informed educational and communication activities in several ways. First, when looking at the experiences of patients with ME/CFS, we need to pay more attention to broad personal experiences as well as the concrete, symptoms characterized by the illness. Moreover, participants articulated how they want to be approached by healthcare professionals and provided examples of what questions are important from the patient perspective when assessing ME/CFS.

CDC recently revised its website with information for patients and the general public, and found that results from the previous project were very helpful in explaining symptoms from the patient perspective. For example, when describing the “physical crash” (post-exertional malaise) that is sometimes associated with ME/CFS, many patients gave the example of having to pull over in their car after doing an errand and take a nap inside the car before continuing. We were able to capture patient descriptions for educational purposes and use them on the updated website. The feedback will also inform new materials and incorporate the patient view and description of symptoms for upcoming continuing medical education activities.

Building on this previous service delivery gen-IC submission with patients, this gen-IC proposes to carry out a very similar interview with healthcare professionals.

CDC is in the process of updating the section for healthcare professionals and engaging healthcare professionals to improve clinical education and communication. CDC wants to conduct interviews with healthcare providers, specifically physicians, physician assistants, and nurse practitioners to learn about their perceptions of (1) the ME/CFS diagnosis process, (2) managing ME/CFS patients, (3) patient-centered outcomes in office visits, and (4) preferred sources of educational materials. Results from the interviews would allow CDC to review current educational materials and inform new educational material for healthcare professionals, all of which would be incorporated into the healthcare provider section for future revisions of the CDC ME/CFS website. In addition, the results from the interviews will assist in the overall education efforts of healthcare professionals.

CDC seeks feedback from healthcare providers about the ME/CFS diagnosis process, managing ME/CFS patients, patient-centered outcomes in office visits, and preferred sources of educational materials. CDC will conduct 20 individual interviews (Appendix 1. Individual interview consent and guide) and 5 dyad interviews (Appendix 2. Dyadic interview consent and guide). The interviews will take place over the telephone. Dynamic Research will recruit healthcare providers nationally from their internal database, and they will screen potential participants using a screener developed for the project (Appendix 3. Screener for Eligibility).

DESCRIPTION OF RESPONDENTS:

Respondents are healthcare providers from the following physician disciplines: Family Practice, General Practice, Internal Medicine; and Physician Assistants and Nurse Practitioners.

TYPE OF COLLECTION: (Check one)

- | | |
|--|--|
| <input type="checkbox"/> Customer Comment Card/Complaint Form | <input type="checkbox"/> Customer Satisfaction Survey |
| <input type="checkbox"/> Usability Testing (e.g., Website or Software) | <input type="checkbox"/> Small Discussion Group |
| <input type="checkbox"/> Focus Group | <input checked="" type="checkbox"/> Other: <u>Interviews</u> |

CERTIFICATION:

I certify the following to be true:

1. The collection is voluntary.
2. The collection is low-burden for respondents and low-cost for the Federal Government.

3. The collection is non-controversial and does not raise issues of concern to other federal agencies.
4. The results are not intended to be disseminated to the public.
5. Information gathered will not be used for the purpose of substantially informing influential policy decisions.
6. The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the future.

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To assist review, please provide answers to the following question:

Personally Identifiable Information:

1. Is personally identifiable information (PII) collected? [X] Yes [] No
2. If Yes, is the information that will be collected included in records that are subject to the Privacy Act of 1974? [] Yes [X] No
3. If Applicable, has a System or Records Notice been published? [] Yes [X] No

Gifts or Payments:

Is an incentive (e.g., money or reimbursement of expenses, token of appreciation) provided to participants? [X] Yes [] No

\$20 will be provided to participants who participate in the phone interview. While study participation is by telephone, family practice and internal medicine physicians can be hard to reach. The recruitment challenges include a busy clinical practice, which offers a narrow window for interviews and many physicians can only participate after hours or during lunch time. The typical incentive has been reduced to the lowest amount feasible to recruit an adequate number of respondents. The incentive helps to ensure both successful recruitment and commitment to participation as the providers will be contacted twice: once at recruitment and again for the interview.

BURDEN HOURS

Category of Respondent	No. of Respondents	Participation Time	Burden
Healthcare Provider - Screener	40	5 minutes	3.3
Healthcare Provider - Interviews	30	40 minutes	20
Totals			23.3

FEDERAL COST: The estimated annual cost to the Federal government is \$63,270. The cost is based on cost of one CDC employee and contractors to complete the project, which includes recruiting respondents, conducting interviews, and analyzing the qualitative data.

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents

1. Do you have a customer list or something similar that defines the universe of potential respondents and do you have a sampling plan for selecting from this universe?

[] Yes [X] No

If the answer is yes, please provide a description of both below (or attach the sampling plan)? If the answer is no, please provide a description of how you plan to identify your potential group of respondents and how you will select them?

The respondents will be selected from a nonprobability purposeful sample. A marketing research firm will recruit healthcare providers from a national database. Healthcare providers must be board certified and currently practicing to be eligible for participation. Personal identifying information (PII) is only being collected by the contractor and will not be provided to CDC. The contractor is collecting PII for the purposes of recruitment and to set up interviews. All data collection from interviews will be anonymous and final raw data and reports will contain no PII.

Administration of the Instrument

1. How will you collect the information? (Check all that apply)
 - [] Web-based or other forms of Social Media
 - [X] Telephone
 - [] In-person
 - [] Mail
 - [] Other, Explain
2. Will interviewers or facilitators be used? [X] Yes [] No

Please make sure that all instruments, instructions, and scripts are submitted with the request.

Appendix 1. Individual interview consent and guide

Appendix 2. Dyadic interview consent and guide

Appendix 3. Screener for eligibility

Appendix 4. Human subjects determination

References

Institute of Medicine, Brief Report, February 2015. https://www.iom.edu/~media/Files/Report%20Files/2015/MECFS/MECFS_ReportBrief.pdf

Institute of Medicine, Beyond myalgic encephalomyelitis/chronic fatigue syndrome: Redefining an Illness. The National Academies Press, 2015.

Jason, LA, et al., A community-based study of chronic fatigue syndrome. Arch Intern Med, 1999. 159(18): p. 2129-37.

Komaroff, AL, et al., Health status in patients with chronic fatigue syndrome and in general population and disease comparison groups. American Journal of Medicine, 1996. 101(3): p. 281-290.

Nacul, LC, et al., The functional status and well being of people with myalgic encephalomyelitis/chronic fatigue syndrome and their carers. BMC Public Health, 2011. 11: p. 402.

Reyes, M, et al., Prevalence and incidence of chronic fatigue syndrome in Wichita, Kansas. Arch Intern Med, 2003. 163(13): p. 1530-6.

Instructions for completing Request for Approval under the “Generic Clearance for the Collection of Routine Customer Feedback”

TITLE OF INFORMATION COLLECTION: Provide the name of the collection that is the subject of the request. (e.g. Comment card for soliciting feedback on xxxx)

PURPOSE: Provide a brief description of the purpose of this collection and how it will be used. If this is part of a larger study or effort, please include this in your explanation.

DESCRIPTION OF RESPONDENTS: Provide a brief description of the targeted group or groups for this collection of information. These groups must have experience with the program.

TYPE OF COLLECTION: Check one box. If you are requesting approval of other instruments under the generic, you must complete a form for each instrument.

CERTIFICATION: Please read the certification carefully. If you incorrectly certify, the collection will be returned as improperly submitted or it will be disapproved.

Personally Identifiable Information: Provide answers to the questions.

Gifts or Payments: If you answer yes to the question, please describe the incentive and provide a justification for the amount.

BURDEN HOURS:

Category of Respondents: Identify who you expect the respondents to be in terms of the following categories: (1) Individuals or Households; (2) Private Sector; (3) State, local, or tribal governments; or (4) Federal Government. Only one type of respondent can be selected.

No. of Respondents: Provide an estimate of the Number of respondents.

Participation Time: Provide an estimate of the amount of time required for a respondent to participate (e.g. fill out a survey or participate in a focus group)

Burden: Provide the Annual burden hours: Multiply the Number of responses and the participation time and divide by 60.

FEDERAL COST: Provide an estimate of the annual cost to the Federal government.

If you are conducting a focus group, survey, or plan to employ statistical methods, please provide answers to the following questions:

The selection of your targeted respondents. Please provide a description of how you plan to identify your potential group of respondents and how you will select them. If the answer is yes, to the first question, you may provide the sampling plan in an attachment.

Administration of the Instrument: Identify how the information will be collected. More than one box may be checked. Indicate whether there will be interviewers (e.g. for surveys) or facilitators (e.g., for focus groups) used.

Please make sure that all instruments, instructions, and scripts are submitted with the request.

