

**Health Education and Health Promotion in Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS): Knowledge, Attitudes and Beliefs in the U.S. General Public**

**Generic Information Collection Request under OMB No. 0920-1154**

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**Supporting Statement A**

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#### A. JUSTIFICATION

##### 1. Circumstances Making the Collection of Information Necessary

Myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) is a complex and debilitating illness. It affects approximately 836,000 to 2.5 million Americans and costs US society about \$17 to \$24 billion annually in medical bills and lost wages (Jason et al, 1999; Reyes et al, 2003; Lin et al, 2011). ME/CFS is most common in aged 40-60 years but can affect all people including children, adolescents, and adults. While whites are diagnosed more often than other

racial and ethnic groups, some studies suggest that ME/CFS is equal or more common in minority racial and ethnic groups.

Functional impairment in ME/CFS is comparable to chronic conditions such as heart disease, multiple sclerosis, cancer, diabetes, rheumatoid arthritis, and lung disease, yet 84% to 91% of people with ME/CFS have not been diagnosed by a physician (Komaroff et al 1996; Nacul et al. 2011). In February 2015, ME/CFS was the subject of an Institute of Medicine (IOM) report whose primary message is that “ME/CFS is a serious, chronic, complex, and systemic disease that frequently and dramatically limits the activities of affected patients.”

Although there is no diagnostic test or cure for ME/CFS, management and treatment of symptoms can help people with ME/CFS. However, it can take up to 5 years for a patient to receive an ME/CFS diagnosis (CFIDS 2014; ProHealth 2008). Lack of a timely diagnosis delays treatment, which results in significant suffering and substantial economic burden. In addition, absence of symptom recognition by both patients and healthcare providers may play a role in diagnostic delays. In addition, misperceptions about the illness, such as the illness being of a psychological nature, can further prevent prompt diagnosis and cause greater mental anguish among patients.

Studies show that perception of a disease or illness along with knowledge, attitudes, and beliefs (KABs) influence behaviors of both healthcare providers and patients (Lin et al, 2009). For example, Brimmer et al. showed that physicians who reported making an ME/CFS diagnosis were less likely to harbor negative perceptions of the illness (2010). Dissatisfied ME/CFS patients were more likely to perceive their healthcare providers as dismissive and not knowledgeable (Deale and Wessley, 2001). Research has documented KABs in healthcare providers and patients, but there is limited information on how the general public views ME/CFS.

CDC proposes to conduct formative research designed to improve understanding of perceptions, knowledge, attitudes, and beliefs about ME/CFS. CDC has partnered with WebMD to develop a web-based assessment tool. Respondents will be adults at least 18 years of age who reside in the U.S. and visit the WebMD website for health information. The study goal is to obtain 3,500 completed surveys.

## **2. Purpose and Use of Information Collection**

The purpose of this project is to measure perceptions and KABs of ME/CFS in the general public. Information will be collected through an online screening process (Attachment 2) and an online survey (Attachment 3). The domains of information to be collected include:

- ME/CFS knowledge assessment [all participants]
- ME/CFS attitudes and perceptions [all participants]
- ME/CFS symptomatic experiences and behavior [participants who have symptoms]

- ME/CFS diagnosed experiences and behavior [participants who have a diagnosis]
- Demographics [all participants]

Subgroups of analytical interest include age, sex, race/ethnicity, and socio-economic status. CDC will use findings to inform strategic planning and stakeholder engagement for future health education, health promotion and future educational activities, to tailor communications for subgroups as needed, and to address disparities.

The results of this assessment tool will also help promote dialog among patients, healthcare providers, and the medical community with the outcome of closing gaps in health education and health promotion in KAB toward ME/CFS. Ultimately, this will help to improve ME/CFS diagnosis and healthcare quality.

Information gained from this formative research is important as it will inform the CDC on existing gaps in KABs about ME/CFS and how they may affect healthcare. For example, one segment of the population that is important to reach are those persons who may have early symptoms of ME/CFS but do not have the knowledge to recognize the symptoms or what actions should be taken. Education and communication to this group is important for early symptom awareness and follow-up. In turn, identification of public perception of ME/CFS will assist the CDC ME/CFS Program in how education and communication will evolve to meet these needs.

### **3. Use of Improved Information Technology and Burden Reduction**

Using the WebMD platform and its algorithm reduces burden as the system has been tested and used by the Federal Drug Administration (FDA) as well as public and private research universities. Additionally, the KAB survey uses the skip pattern to reduce the unnecessary questions based on respondents’ prior response. The collection mechanism is in place, and WebMD has demonstrated how its reach to the general public. An advantage of using this system is that recruitment is built into the platform, and additional outreach is not warranted. Further, personal identification information is not collected.

### **4. Efforts to Identify Duplication and Use of Similar Information**

We reviewed currently funded programs and did not identify potential areas of duplication. We are not aware of any department or agency that collects or maintains data on KAB about ME/CFS.

### **5. Impact on Small Businesses or Other Small Entities**

This data collection will not involve small businesses. Participants will be the general public who visit the WebMD website.

### **6. Consequences of Collecting the Information Less Frequently**

This pilot project will conduct one-time information collection from the WebMD website visitors. All randomly selected visitors will only respond to this pilot survey once.

**7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

This request fully complies with the regulation 5 CFR 1320.5.

**8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agencies**

A. The Federal Register notice was published for this generic collection on August 23, 2019, Vol. 84, No. 164, pp. 44308. No public comments were received. No additional comment period is required for the proposed project.

B. The following survey experts were consulted for the development of this request:

Jin-Mann S. Lin, PhD, National Center for Emerging and Zoonotic Infectious Diseases, CDC  
Christina Louie, Executive Director, Market Research at WebMD; Email: [clouie@webmd.net](mailto:clouie@webmd.net)

**9. Explanation of Any Payment or Gift to Respondents**

Respondents will not receive payment or gifts for completing the assessment tool.

**10. Protection of the Privacy and Confidentiality of Information Provided by Respondents.**

This is one-time information collection on people visiting the WebMD website. No personally identifiable information will be collected, and so there will be no way to re-contact respondents or link the data to respondents. Additionally, IP address for the IT devices that internet browsers use to respond to the KAB assessment will NOT be tracked or saved in the data collection process.

**11. Institutional Review Board (IRB) and Justification for Sensitive Questions**

IRB approval is not required. This project was determined as Research non-engaged with the justification, “Not Research / Other, 45 CFR 46.102(1) Program Evaluation”. See Attachment 4.

**12. Estimates of Annualized Burden Hours and Costs**

This KAB pilot project includes information collection using a screener and KAB survey. It will take about one minute to complete the screener and approximately 8 minutes to complete the KAB survey.

**A. Estimated Annualized Burden Hours**

The estimate of annualized burden hours for this information collection is 530 hours; details are provided in Exhibit 12.A.

**Exhibit 12.A. Summary of Estimated Annualized Burden Hours**

Type of Respondents	Form Name	Number of Respondents	Number of Responses per	Average Burden per Response (in	Total Burden (in
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			Respondent	hours)	hours)
General public	Screener	3,800	1	1/60	63
General public	KAB survey	3,500	1	8/60	467
Total					530

### B. Estimated Annualized Burden Costs

The annualized cost to respondents for the burden hours is estimated to be \$13,250; details are provided in Exhibit 12.B.

The United States Department of Labor, Bureau of Labor Statistics, May 2019 ([http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm).) data were used to estimate the hourly wage rate for the general public and for private providers for the purpose of this generic request. Each project will have cost specific to the category of the respondents. Because it is not known what the wage rate category will be appropriate for the specific projects (or even whether they will be employed at all), the figure of \$25.00 per hour was used as an estimate of average hourly wage across the country.

#### Exhibit 12.B. Estimate of Annualized Burden Costs

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate Dept of Labor	Total Burden Costs
General Public	Screener	63	\$25.00	\$1,583
General Public	KAB survey	467	\$25.00	\$11,667
Total				\$13,250

### 13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no costs to respondents other than their time to participate.

### 14. Annualized Costs to the Government

The annualized cost of this project is estimated to be \$136,300. This includes the time of one GS-14 Mathematical Statistician. The source for salary is [fedsdatacenter.com](http://fedsdatacenter.com). Contract costs comprise the remainder of the estimated annualized cost to the government.

#### Exhibit 14.A Estimate of Annualized Cost to Government per Activity

Expense Type	Expense Explanation	Estimated Annualized Cost
Direct Costs to the Federal Government	CVDB: Personnel GS-14 Mathematical Statistician, 5% effort	\$7,000

Contract	Contract funds to Synergy/WebMD	\$129,300
TOTAL		\$136,300

**15. Explanation for Program Changes or Adjustments**

Not applicable – request is for a sub-collection under a generic approval.

**16. Plans for Tabulation and Publication and Project Time Schedule**

Statistical Analysis Plan

Descriptive statistics will be performed and percentages will be calculated for perception and KAB. For examining KAB differences between demographic subgroups such as age group, sex, race/ethnicity, and socio-economic status, we will perform proportions tests and report 95% confidence levels. The information will be collected January – May 2021, and data analysis will take place May – July, 2021.

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

The display of the OMB expiration date is not inappropriate.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.

## References

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