Form Approved
OMB No.
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Attachment 5b

Provider Website Frequently Asked Questions (FAQs)

Registry of Unexplained Fatiguing Illnesses and Chronic Fatigue Syndrome (CFS)
Study Overview For Health Care Providers

CDC is conducting a pilot study of a new registry. A registry collects information on patients with certain illnesses. CDC's registry is a registry of unexplained fatiguing illnesses, including chronic fatigue syndrome (CFS).

This pilot study will teach us the best study design to use in order to have the most effective registry. This pilot registry is a one-year study limited to Bibb County, Georgia. If successful, the registry will be extended to include annual interviews to see if enrollees symptoms change. If extended, CDC is also planning to offer intervention trials to registry participants in the future. In these trials, CDC will try treatments that may lessen fatigue and other symptoms of CFS.

By conducting this registry, CDC hopes to find out:

1. How different are people with CFS from people with other fatiguing illnesses?
2. Among persons with CFS, how do their symptoms change over time?
3. What types of health care providers do people see for help with their fatigue?
4. What is the economic impact of CFS on individuals and families?
5. What do health care providers know about CFS and how to manage CFS?

We have asked health care providers who are likely to see patients (or clients) with unexplained fatigue to take part in the study. Many of these health care providers are doctors. We have asked other health care providers to take part, also. This group includes chiropractors, nutritionists, physical therapists, nurse practitioners, and physician assistants, registered massage therapists. To enroll in the registry, a person must have been referred by a participating heath care provider. To be referred, a person must meet these basic criteria:

- be between the ages of 12 – 59
- be referred by a participating health care provider in Bibb County
- have fatigue for 1 month or longer that is not explained by having another fatigue-causing illness
- have at least one other specific symptom

Once referred, a patient/client needs to complete 3 steps:

Step 1: Agree to be contacted by Abt Associates Inc. Abt Associates has been hired by CDC to run this study.

Step 2: Complete a phone interview. The interview will be used to find out how bad the fatigue makes the person feel, how long it has lasted, and to see if there is a reason for the fatigue.

Step 3: Complete a clinical evaluation. Qualified individuals will be invited for a free evaluation. It includes a physical examination, laboratory tests, and a mental health assessment. Clinical evaluations will take place at the CDC clinic in Macon.

Doctors at CDC will review evaluation data. A person will be enrolled in the registry if his or her fatigue cannot be explained by illness, disease, or a condition.

CDC will update registry members about the growth of the registry, and the latest findings from the registry study.

Taking part in this study is voluntary. People are free to take part in the study or not.

Health care providers who participate will receive provider-education about CFS, and will be assessed regarding their knowledge, attitudes and beliefs about CFS.

For answers to frequently asked questions, click on the links below.

Participation:

How can I participate?
What kinds of health care providers are participating in this study?
I don't treat patients for fatiguing illness or CFS. How does this registry apply to me?
I am a nutritionist, or physical therapist or acupuncturist or massage therapist, or dentist. To what extent can I be involved in the registry?
I see referrals only. I am not the primary care physician for my patients. Do you want me to participate?
Can I opt out once I have already agreed to participate?
Can patients opt out once they have already agreed to participate?
Will I be relieved of liability for participating in the registry?

Registry Referrals:

Is it necessary for me to complete a thorough work-up on the patient before I refer him or her to the registry?
I am unclear about the criteria a patient must meet for referral. With whom can I discuss these?
If I refer, can I continue to see/treat my patient?
Can I get a copy of my patient's lab results?
If the labs tests are abnormal, who is responsible for follow-up?

Registry Logistics:

What is my involvement?
How long does this study last?
Who will be conducting the survey?
Will there be training available for providers and office staff who agree to participate?
I am unfamiliar with provider-based registries, could you tell me about how these work?
Will I have to make any changes to the software or hardware my office currently uses or buy new products in order to participate?
I work in a solo practice/ small group practice and do not use electronic medical records, will I have to purchase this type of technology in order to participate?
Will patients have access to their records once they are enrolled?
How will the data be stored?

Who will be responsible for maintaining registry information?

Privacy and Confidentiality

I am concerned about insuring the privacy of my patient's medical information. Am I violating HIPAA regulations by giving out basic demographic information?

I am concerned that providing demographic information on individuals referred to the registry will jeopardize the trust my patients/clients have in me.

Will my office be required to create the consent forms or can I get copies from CDC?

How will the registry ensure patient confidentiality?

How will the data be stored?

Don't I need IRB approval to participate?

Registry of Unexplained Fatiguing Illnesses and CFS FAQs for Providers

Participation

How can I participate?

Abt Associates mailed invitational materials to certain health care providers in Bibb County, Georgia. If you do not recall receiving the materials, please call Kate Ballard of Abt Associates, toll-free, at xxx-xxx-xxxx.

What kinds of health care providers are participating in this study?

We have asked health care professionals practicing in the following specialties in Bibb County, Georgia to participate in the study:

Acupuncture	Internal Medicine
Allergy & Immunology	Massage Therapy (Registered)
Chiropractic	Neurology
Clinical Psychology	Nutrition (Registered)
Dentistry	Obstetrics/Gynecology (Primary Care)
Endocrinology	Pediatric & Adolescent Medicine
Family Medicine	Physical Therapy
Gastroenterology	Psychiatry
General Medicine	Rheumatology
Infectious Diseases	

I don't treat patients for fatiguing illness or CFS. How does this registry apply to me?

We are looking for certain health care providers in Bibb County, Georgia who see patients between the ages of 12 and 59. These providers must not work exclusively with the military, correctional facilities, or with inpatient populations in psychiatric hospitals or nursing homes. If your practice is such that you do not meet these criteria, please let Abt Associates know by completing and returning the Provider Verification Form that we sent as part of an information packet about the registry.

I am a nutritionist, or physical therapist or chiropractor or massage therapist, or dentist. Making referrals is typically beyond the scope of my work; I generally coordinate with my client's primary care physician when making decisions of this nature. To what extent can I be involved in the registry?

If the primary care physician has not referred this patient, you can still refer him/her by taking a medical history to rule out conditions or illnesses that we specify. We will provide you with a one-page form that lists the criteria that non-physicians are to consider when making referrals.

I see referrals only. I am not the primary care physician for my patients. Do you want me to participate?

Yes, you do not have to be the primary care physician to make a referral. You need to practice in Bibb County, Georgia and agree to be part of the study.

Can I opt out once I have already agreed to participate?

Your participation is voluntary, you can choose to participate or withdraw at any time without penalty or loss of benefits to which you may otherwise be entitled. We request that you let Abt Associates know by calling Kate Ballard at $$$-$$$-$$$$

Can patients opt out once they have already agreed to participate?

Participation is voluntary; your patients can choose to participate or withdraw at any time without penalty or loss of benefits to which they may otherwise be entitled. If a patient wants to withdraw, he/she should let Abt Associates know. If your patient has not yet completed the telephone interview, please instruct him/her to call the toll free number in the Abt Associates Telephone Center: $$$-$$$-$$$$. If a patient has completed the telephone interview, he/she should call Abt Associates at $$$-$$$-$$$$ to withdraw. Patients may also inform the Abt Associates representative when he/she calls them.

Will I be relieved of liability for participating in the registry?

This research study will not interfere with your responsibilities for diagnosing and/or treating patients who you refer to this registry. We neither ask nor expect any change in the level of care you provide to your patients/clients.

Registry Referrals:

Is it necessary for me to complete a thorough work-up on the patient before I refer him or her to the registry?

No, we understand that it may take months to complete a differential diagnosis for fatiguing illness. If you are a medical doctor, we ask instead, that you rule out some basic causes of fatigue by conducting standard blood tests and taking a thorough medical history. If you are not a medical doctor, we ask that you take a thorough medical history.

We have identified specific medical history information and laboratory test results that would qualify as exclusionary in our provider referral materials. If your patient meets symptom referral criteria and you are having difficulty completing laboratory tests because of insurance limitations, please refer him/her. We will conduct laboratory testing

as part of our clinical evaluation and will provide the results to the patient (who may elect to have them sent to his/her health care provider).

I am unclear about the criteria a patient must meet for referral. With whom can I discuss these?

Please call James Jones, MD at CDC can be reached at (404) 639-1412. This may be a toll call.

If I refer, can I continue to see/treat my patient?

Yes, please continue to see/treat your patient. We do not want to interfere with your practice or alter your provider-patient relationship. We will not be providing treatment or management of the illness in the first year pilot of our study.

Can I get a copy of my patient's lab results?

Abt Associates will send results to you if your patient authorizes us to send results to you. Interpreted laboratory results will always be sent to participants, whether or not they authorized a copy to be sent to their health care providers.

If the labs come back abnormal, who is responsible for follow-up?

CDC physicians will review the laboratory results and notify Abt Associates of abnormalities. Abt Associates must send the laboratory results to the patients and point out clinically significant abnormal findings. A copy of the results will be sent to you if your patient authorizes Abt Associates to send them. Any follow-up care is the responsibility of your patient.

Registry Logistics:

What is my involvement?

Your involvement is limited to discerning eligibility and making the referral.

This is a one-year pilot study, starting in June 2007. Over this initial 12-month period, please refer your patients with unexplained fatiguing illnesses. Once you determine that a patient is eligible for referral, please give the patient the registry recruitment packet that we will provide, and notify Abt Associates of the referral. We would appreciate it if you provided assistance to your patient if he/she has questions and mailed the paper sign-up form in a pre-paid envelope if the patient chooses that medium to sign up. The patient may also choose to sign up via our website or by phone.

Periodically, we will update you on the progress of the study through email updates.

How long does this study last?

Abt Associates will operate a CDC clinic in Macon for a one-year period, beginning in June 2007. During this one year period, the registry is open to referrals. This is a pilot study to determine if a registry is feasible. If it is successful, the registry will be reopened and extended to include annual follow-up of patients' symptoms via telephone.

Who will be conducting the survey?

Abt Associates is a social science research firm that has been contracted by CDC to conduct the telephone survey and clinical evaluations. Since 1988, Abt Associates has assisted CDC with a series of CFS studies. Abt Associates has telephone interviewers in Las Vegas, Nevada, and Hadley, Massachusetts, and field staff across the US.

Will there be training available for providers and office staff who agree to participate?

We will send you provider referral materials. Included will be a study description, eligibility criteria, referral instructions, patient recruitment packets and consent-to-contact forms. If you have any questions about these materials, you can call Kate Ballard of Abt Associates, toll free, for assistance at $$$-$$$-$$$$.

I am unfamiliar with provider-based registries, could you tell me about how these work?

Registries are used to collect information on patients with specific diagnoses to track the history and progression of illness in people with those diseases. Provider-based registries rely on health care providers to identify and refer patients to the registry. Registry staff then contact the patients periodically to question them about their symptoms.

I use an electronic billing/ medical records system to maintain patient data - will I have to make any changes to the software or hardware my office currently uses or buy new products in order to participate?

No, you do not need to make any changes to your systems, software or hardware. This is a prospective study; there is no need to search your databases for people you have seen in the past who might qualify. Please consider patients as they come in to see you, whether or not you have seen them in the past.

I work in a solo practice/ small group practice and do not use electronic medical records, will I have to purchase this type of technology in order to participate?

No, a special electronic record keeping system is not needed in order to participate. While having Internet access is helpful, you may also refer your patients via US mail or telephone.

Will patients have access to their records once they are enrolled?
Patients will receive their laboratory results. If a patient wants to see the questionnaire data, he/she may request copies from Abt Associates.

How will the data be stored?

Health care providers and their referred patients will be assigned unique identification numbers. Data contained in paper questionnaires will be converted to electronic data and identified by that identification number. Electronic data will be transferred to a secure website and storage at Abt Associates. Prior to delivering the study data files to CDC, Abt Associates will strip out identifiers, such as name, address and telephone number.

Who will be responsible for maintaining registry information?

Abt Associates, the contractor hired by CDC, will maintain the registry.

Privacy and Confidentiality:

I am concerned about insuring the privacy of my patient's medical information. Am I violating HIPAA regulations by giving out their basic demographic information?

You are being asked to provide basic, non-identifying information such as the patient's initials, sex, year of birth, gender, race, on all the patients you refer to the registry. This

information is considered "de-identified" in HIPAA regulations.[1] You will not be disclosing private health information (PHI) by providing this information.

[1] *Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule.* Department of Health and Human Services. http://privacyruleandresearch.nih.gov/pr_02.asp, p.10.

I am concerned that providing demographic information on individuals referred to the registry will jeopardize the trust my patients/clients have in me.

The referral information (patient's initials, year of birth, sex, race, and ethnicity) that you provide is considered "de-identified" according to HIPAA regulations.[1] Abt Associates will not be able to identify your patient using the data you provide. Abt Associates will not be able to contact your patient until your patient consents to be contacted and provides contact information. The demographic information you provide will serve to tell us descriptive information about which patients agree to participate and which patients are not represented in our registry.

[1] *Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule.* Department of Health and Human Services. http://privacyruleandresearch.nih.gov/pr_02.asp, p.10.

Will my office be required to create the consent forms or can I get copies from CDC?

Abt Associates will provide your practice with study materials that you can give your patients. Included in the materials will be the Consent-to-Contact Form.

How will the registry ensure patient confidentiality?

Patients and providers who participate in this study will be assigned unique identification (ID) numbers to identify their questionnaire data. The same ID number will be used to identify participants' specimens. Although no one can absolutely guarantee confidentiality, using an identification number greatly reduces the chance that someone other than the Contractor will ever be able to link a subject's name to his or her sample test results. Any identifiers, such as name, address and telephone will be stripped from all data files that are sent to CDC. All staff associated with the study receive training on confidentiality and sign an affidavit of non-disclosure. Violations of the affidavit are subject to fines and/or imprisonment.

Don’t I need IRB approval to participate?

Some institutions, such as hospitals, require Institutional Review Board (IRB) approval in order for their staff to participate in research studies.

A CDC IRB and the Abt Associates IRB have approved this study. If you require documentation of CDC IRB and/or Abt Associates IRB approval, or if your institution requires other documentation, please call Marjorie Morrissey, toll-free, at xxx-xxx-xxxx.