

Cancer-Related Fatigue: Prevalence of Proposed Diagnostic Criteria in a United States Sample of Cancer Survivors

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Purpose: To evaluate the proposed cancer-related fatigue (CRF) diagnostic criteria in a sample of cancer survivors. More accurate prevalence estimates of CRF may result in improved diagnosis and management of one of the most common symptoms associated with cancer and its treatment.

Methods: Three hundred seventy-nine individuals who had been treated with chemotherapy, either alone or in combination with radiation therapy, were surveyed. Patients were asked background questions about their current condition, their medical history, and the frequency of fatigue during their chemotherapy. Additionally, patients who reported experiencing fatigue at least a few days each month during treatment were asked a series of questions about the impact of fatigue on their daily functioning.

Results: One hundred forty-one (37%) individuals reported at least 2 weeks of fatigue in the previous month. Of the respondents who had received their

last treatment more than 5 years ago, 33% still reported at least a 2-week period of fatigue in the month before the interview. Evaluation of the proposed criteria revealed that 17% of respondents met at least two criteria for CRF.

Conclusion: The prevalence of diagnosable CRF in the individuals in this sample, most of whom had completed treatment more than 1 year ago, was 17%—lower than expected based on previous reports that have used less-strict criteria. In a sizable number of people, CRF persists well beyond active treatment and should be a focus of intervention. Although they will require replication in other samples and clinical validation, these formal diagnostic criteria can be a step toward common language and a better understanding of the severity range and persistence of CRF.

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CANCER AND ITS treatment are associated with several symptoms, including pain, nausea, anorexia, and fatigue. Pain management has been a focus in oncology for many years, and significant progress has been made in its recognition¹⁻³ and management.^{4,5} Similarly, advances over the past decade have significantly improved the management of nausea and vomiting.⁶⁻⁹ This progress has had a significant positive impact on the quality of life of many people with cancer.¹⁰ However, progress in analgesic and antiemetic therapies has not been paralleled by comparable advances in the diagnosis and management of fatigue, providing the impetus for more recent attention to be directed toward the persisting problem of cancer-related fatigue (CRF).¹¹

Fatigue is now understood to be the most common symptom associated with cancer and its treatment.¹²⁻¹⁵ By altering a person's ability to engage in meaningful personal, work, and social activities, CRF can have a major negative impact on quality of life.^{12,14,16-18} Additionally, it poses physical, psychologic, and economic problems for patients.^{19,20} Fatigue is frequently one of the initial symptoms experienced by patients, and it tends to increase with the progression of cancer and cancer treatment.²¹ CRF differs from normal fatigue due to overexertion or lack of sleep. In contrast to everyday or normal fatigue, CRF is characterized by feelings of tiredness and weakness despite adequate amounts of sleep and rest. In addition to the direct impact from cancer, various treatment modalities, particularly che-

motherapy and radiation, are known to cause fatigue for many patients for an extended period of time. Although not based on formal diagnostic criteria, prevalence estimates of CRF vary from 60% to 90%.^{12-14,17,22} Typically, a patient need only say he or she is experiencing fatigue to be considered as having CRF. Therefore, existing prevalence estimates may be high and nondiscriminating. Current prevalence estimates may combine patients with everyday fatigue with those who have more clinically significant, definable CRF. Patients receiving chemotherapy have reported CRF, however defined, more frequently (80% to 96%)²²⁻²⁵ than patients receiving radiation therapy (60% to 93%).^{17,26,27} For this reason, we focused on cancer patients who had received chemotherapy.

Presently there are no established criteria for CRF. However, most practitioners would agree that a working set of diagnostic criteria is essential for research and treatment planning. To that end, the Fatigue Coalition, a multidisci-

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plinary group of medical practitioners, researchers, and patient advocates, drafted diagnostic criteria in 1998. These draft criteria have been published but have never been evaluated.¹¹

This article reports the first results available that provide information on the diagnostic criteria for CRF as proposed by the Fatigue Coalition. The parent survey from which this information was drawn was a population-based survey conducted by Wirthlin Worldwide Research on behalf of the Fatigue Coalition. Results presented in this article are from the second such survey of the Fatigue Coalition.²⁰ This second survey was aimed at confirming the conclusions of the first survey¹³ that characterized the incidence, prevalence, and functional impact of CRF. Other aims of the second survey included defining CRF and how patients experience it, exploring the impact of CRF on the daily functioning of patients and caregivers, and developing a means by which health care providers can improve their understanding of CRF. Information from this survey is intended to help establish guidelines for diagnosis and management of CRF.

In preparation for this second survey, members of the Fatigue Coalition proposed a set of diagnostic criteria based on clinical experience, results from the first survey,¹³ and consensus-based discussions of significant issues. Diagnostic criteria for other fatigue conditions (eg, chronic fatigue syndrome) and potentially overlapping conditions (eg, major depression) were used as models from which the criteria were drafted and discussed. Sample criteria were drawn from both the *International Classification of Diseases Ninth Edition (ICD-9)*²⁸ and the fourth edition of the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*.²⁹ The final draft criteria, endorsed by all members of the Fatigue Coalition, are presented in Table 1.

METHODS

The telephone survey was a 25-minute quantitative assessment consisting of approximately 50 questions aimed at furthering the understanding of the effects of CRF during and after chemotherapy. The survey was conducted between July and August of 1998. Participants were recruited from a representative sample of 575,000 households across the United States. From this sample, 6,125 households were identified as having a cancer patient in the home. Households with a member who had undergone chemotherapy alone or both chemotherapy and radiation therapy were eligible to participate. Of the 2,319 who were deemed ineligible, 1,941 (84%) were ineligible due either to unconfirmed cancer or nonreceipt of chemotherapy, and 378 (16%) were ineligible because of a language/comprehension barrier. Of the remaining 3,806 potential contacts, 346 (9%) were never dialed, and 2,626 (69%) were called but not actually contacted. This resulted in a total of 834 people who were contacted, of whom 149 (18%) asked to be called back at a more convenient time, 279 (33%) immediately refused participation before screening for eligibility, and 27 (3%)

Table 1. Proposed (1998 draft) ICD-10 Criteria for Cancer-Related Fatigue

Six (or more) of the following symptoms have been present every day or nearly every day during the same 2-week period in the past month, and at least one of the symptoms is (A1) significant fatigue.
A1. Significant fatigue, diminished energy, or increased need to rest, disproportionate to any recent change in activity level
A2. Complaints of generalized weakness or limb heaviness
A3. Diminished concentration or attention
A4. Decreased motivation or interest to engage in usual activities
A5. Insomnia or hypersomnia
A6. Experience of sleep as unrefreshing or nonrestorative
A7. Perceived need to struggle to overcome inactivity
A8. Marked emotional reactivity (eg, sadness, frustration, or irritability) to feeling fatigued
A9. Difficulty completing daily tasks attributed to feeling fatigued
A10. Perceived problems with short-term memory
A11. Postexertional malaise lasting several hours
B. The symptoms cause clinically significant distress or impairment in social, occupational, or other important areas of functioning
C. There is evidence from the history, physical examination, or laboratory findings that the symptoms are a consequence of cancer or cancer therapy.
D. The symptoms are not primarily a consequence of comorbid psychiatric disorders such as major depression, somatization disorder, somatoform disorder, or delirium.

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refused participation after meeting inclusion criteria. Of the remaining 406 contacts, 379 (93%) agreed to participate and constitute the base of the sample for this study.

Sample

The mean age of respondents was 63 years old. Seventy-nine percent of the respondents were women, 50% had some college or higher education, and the mean household income was \$41,000. All respondents had cancer and had been treated with chemotherapy either alone or in combination with radiation therapy. The majority of participants (50%) had breast cancer (Table 2). Finally, approximately one quarter (26%) reported that they had suffered from anemia during or after their treatment regimen.

Procedure

Patients were asked background questions about their current condition, medical history, and frequency of fatigue during the time they received chemotherapy. Patients who responded "never" or "hardly ever" to a question about the frequency of fatigue they experienced during treatment were only asked a few additional demographic questions. Patients who reported experiencing fatigue at least a few days each month during treatment were asked a series of questions regarding the impact of fatigue on their daily functioning, including physical, emotional, behavioral, social, occupational, and economic factors. Questions about how patients coped with fatigue during and after treatment were supplemented by questions about their current level of fatigue. This was done specifically to estimate the prevalence of CRF as defined by the proposed ICD-10 criteria¹¹ (Table 1).

When asked about symptoms they experienced during treatment, 164 (43%) reported nausea, 70 (18%) reported depression, and 61 (16%)

Table 2. Sample Characteristics

Characteristic	No.	%
Mean age, years	63	
Sex		
Male	81	21
Female	298	79
Cancer diagnosis		
Breast	189	50
Genitourinary	35	9
Leukemia/lymphoma	33	9
Gynecologic	24	6
Gastrointestinal	24	6
Skin	8	2
Bone	8	2
Lung	6	2
Throat	6	2
Brain	3	1
Other	43	11
Education		
Some college or more	189	50
Mean income	\$41,000	
Previous cancer treatment		
Chemotherapy	154	
Chemotherapy and radiation	147	

reported pain. In contrast, 301 (79%) reported “debilitating fatigue.” The remaining 78 respondents (21%) said that they had “no fatigue” during or after their treatment. Because it was assumed that these people would have responded “no” to the survey questions about specific symptoms often associated with fatigue, this subset of individuals was not given the complete telephone interview. Therefore, for the purpose of determining the presence or absence of CRF as defined in Table 1, responses from this subset were recorded as “not present” for each of the Table 1 criteria.

RESULTS

Criterion A1¹¹ requires a person to report a minimum of 2 weeks of fatigue during the previous month. One hundred

forty-one individuals (37%) reported at least 2 weeks of fatigue in the previous month. Table 3 lists the number of respondents who reported a minimum of 2 weeks of fatigue at three different intervals since their last treatment (ie, < 1 year, 1 to 5 years, and > 5 years). Table 3 lists—individually by symptom—the number and percentage of symptoms from criteria A1 to A11. Percentages are also provided by time since last treatment to determine the extent to which there might be some reduction in each symptom over time. In general, although there is some lowering of prevalence estimates for symptoms after 5 years, the group of respondents less than 1 year since their last treatment is comparable with those 1 to 5 years after treatment. As time passes, there is at best a minimal decrease in reported fatigue, such that 33% of respondents who were more than 5 years since their last treatment at the time of the interview still reported at least a 2-week period of fatigue in the previous month (Table 3).

Criterion A specifies that six or more symptoms must have been present every day or nearly every day during the same 2-week period of time over the past month and at least one symptom must be significant fatigue. However, before determining the prevalence of patients who meet the proposed diagnostic criteria A and B, we determined the percentage of respondents who endorsed any number of criteria, regardless of whether criterion A1 (significant fatigue) was endorsed. Table 4 lists the prevalence of respondents who endorsed any number of symptoms without requiring that the fatigue criterion (A1) be one of them. This permits evaluation of the impact that a different criteria threshold would have on the percentage of respondents who meet category A of the CRF definition. For example, if any six endorsed criteria would constitute a CRF diagnosis, 25% of patients would meet criteria in category A. If any three

Table 3. Respondents Who Endorsed Category A Criteria

Individual Criterion Report*	Total Sample (N = 379)		Time Since Last Treatment					
			< 1 Year (n = 108)		1-5 Years (n = 139)		> 5 Years (n = 132)	
	No.	%	No.	%	No.	%	No.	%
A1 Two weeks of fatigue in past month	141	37	54	50	43	31	44	33
A2 General weakness	94	25	33	31	35	25	26	20
A3 Trouble concentrating	66	17	21	19	22	16	23	17
A4 Decreased motivation	90	24	32	30	31	22	27	20
A5 Insomnia/hypersomnia	118	31	43	40	43	31	32	24
A6 Nonrestorative sleep	119	31	42	39	43	31	34	26
A7 Having to push to do things	131	35	46	43	49	35	36	27
A8 Sadness or frustration	80	21	28	26	31	22	21	16
A9 Trouble completing daily tasks	96	25	34	31	38	27	24	18
A10 Short-term memory problems	72	19	16	15	26	19	30	23
A11 Postexertional malaise	66	17	19	18	24	17	23	17

*See Table 1 for complete descriptions.

Table 4. Respondents Who Endorsed Multiple Category A Criteria (N = 379)

	No.	%
Any one criterion	242	64
Any two criteria	192	51
Any three criteria	159	42
Any four criteria	137	36
Any five criteria	117	31
Any six criteria	96	25
Any seven criteria	72	19
Any eight criteria	49	13
Any nine criteria	34	9
Any ten criteria	21	6
Any eleven criteria	8	2

criteria were required, for example, 42% (rather than 25%) would meet diagnostic category A (Table 4).

Criterion B specifies that the fatigue symptoms must cause clinically significant distress or impairment in social, occupational, or other important areas of functioning. Ninety-seven participants (26%) responded that their fatigue (criterion A1) had caused significant disruption in their usual daily activities or responsibilities (Table 5). Although 36% of patients within 1 year of treatment reported disruption in their daily activities, fully 20% of patients more than 5 years after treatment reported persisting disruption (Table 5). Comparable percentages of respondents reported impairment 1 to 5 years after treatment (22%) and more than 5 years after treatment (20%). The bold-type font in Table 5 (A1 + any 5 + B) indicates that criteria A and B of the proposed ICD-10 diagnostic criteria for CRF were met by 66 (17%) of the respondents. Although it remains considerable, the prevalence was lower (14%) among patients

more than 5 years posttreatment than among patients who were less than 1 year posttreatment (20%). Presentation of the data in Table 5 allows one to consider the impact of changing the threshold required number of criteria. Except for the five percentage point change from 9% to 14% noted between A1 + any 7 + B and A1 + any 6 + B, all adjacent categories were within three percentage points of one another.

DISCUSSION

This is the first attempt to estimate the prevalence of CRF using consensus-developed diagnostic criteria and survey data from a national sample. Compared with currently reported prevalence estimates of CRF, which range from 60% to 90%, the present results demonstrate a significantly lower percentage (17%) of people who would meet criteria for CRF. However, unlike all other previous studies that provided the percentage of individuals who reported any degree of fatigue, regardless of its impact on functioning, this study required that there be a significant number of fatigue-related problems and disruption in daily functioning to assign a diagnosis. Thus, we distinguished between fatigue as a symptom reported by the vast majority of people with cancer and CRF as a diagnostic entity. This in no way is meant to discourage clinicians from intervening with individuals who have fatigue that does not meet formal diagnostic criteria. Rather, it is intended to help sharpen the clinical assessment of fatigue and its effects on people's lives.

The different prevalence estimates underscore the essential need to develop and promote accepted diagnostic criteria for CRF. Some of the reasons for our lower

Table 5. Respondents at Three Different Time Points Since Their Last Treatment Who Endorsed Multiple (category A) Symptoms and Claimed Impairment (category B) (n = 301)

Multiple Symptoms Reports	Total (N = 379)		Time Since Last Treatment					
	No.	%	< 1 Year (n = 108)		1-5 Years (n = 139)		> 5 Years (n = 132)	
			No.	%	No.	%	No.	%
A1 + B	97	26	39	36	31	22	27	20
A1 + any 1 + B	92	24	36	33	30	22	26	20
A1 + any 2 + B	85	22	30	28	30	22	25	19
A1 + any 3 + B	80	21	28	26	28	20	24	18
A1 + any 4 + B	73	19	25	23	26	19	22	17
A1 + any 5 + B*	66	17	22	20	25	18	19	14*
A1 + any 6 + B	53	14	16	15	23	17	14	11
A1 + any 7 + B	36	9	9	8	15	11	12	9
A1 + any 8 + B	27	7	6	6	12	9	9	7
A1 + any 9 + B	17	4	5	5	6	4	6	5
A1 + any 10 + B	8	2	1	1	4	3	3	2

NOTE. "Any X" refers to the number of A2 to A11 criteria from Table 1 that were met.

*Corresponds to current proposed ICD-10 criteria A and B from Table 1.

prevalence estimate may relate to the sample that we studied, which was a community-based sample of previously tested patients. Whereas most other estimates are derived from patients receiving treatment, individuals in our study had completed cancer therapy more than 1 year before the interview. Thus, our estimate of prevalence of CRF is likely to be conservative and points to the persistence of the problem in a sizable percentage of cancer survivors. At the time of the interview, many of these patients had completed treatment more than 5 years ago and were surveyed in their homes, not during clinical visits. Conversely, most prevalence estimates in the literature are based on clinical samples of patients who are interviewed during or surrounding treatment. As a result, our data may be more representative of the prevalence of CRF among off-treatment survivors. Our estimate is also conservative in that 78 people (21%) who stated that they did not experience debilitating fatigue during treatment were not interviewed further and, therefore, were assumed not to have CRF.

These explanations for our lower prevalence estimate are only partially satisfying, however, because time off treatment seems to have only a modest impact on our estimates. At present, different definitions and criteria are being used to estimate the prevalence of CRF. As a result, whereas CRF is increasingly being recognized as a significant problem for patients with cancer, the degree to which it affects patients remains unknown.

We believe that a more compelling reason for our relatively low prevalence estimate is the difference in our criteria compared with other studies. Whereas as most estimates of fatigue prevalence are drawn from the percentage of individuals who report experiencing any fatigue,^{12,30} these ICD-10 criteria are designed to be considerably more discriminating and demanding. Six of the 11 criteria, plus self-reported functional limitations, are prerequisites for diagnosis. One in six individuals in this sample had diagnosable CRF. Although this might seem low, it exceeds point-in-time cancer patient prevalence for major depression,^{31,32} another symptom that has comparably rigorous diagnostic criteria.

Because information about criteria C and D cannot be collected reliably without trained clinical interviewing, only criteria A and B were evaluated. Table 5 depicts the number of individuals who met criteria A1, A2 to A11, and B, providing the best available estimate of the number of individuals in this study who would meet proposed ICD-10 diagnostic criteria for CRF. Specifically, 66 respondents (17%) met all three (A1, A2 to A11, and B) criteria. Similar to the results in Table 3, only a minimal decrease in numbers of patients meeting all three criteria was demon-

strated for those more than 5 years since treatment versus those within 1 year of treatment.

Thirty-seven percent of respondents reported experiencing fatigue for at least a 2-week period in the month before the interview. A similar percentage, 33%, who were more than 5 years since their last treatment still endorsed that they experienced fatigue. Similarly, proposed ICD-10 diagnostic criteria A and B were met by 17% of the entire sample, and fully 14% of respondents were more than 5 years posttreatment. This persistence of fatigue up to 5 years posttreatment suggests that a hallmark of CRF is that it can endure well beyond the end of a particular treatment regimen. Patients successfully treated for cancer may need to be prepared for the significant possibility that they will suffer chronic diagnosable CRF well into the survival period. This has been reported elsewhere.^{33,34} In addition, long-term survivor-specific interventions for persistent CRF are sorely needed. The required life and activity adjustments that individuals with CRF must make may, for a sizeable proportion, persist for several years, exerting a long-term financial and quality-of-life impact. Further studies will be needed to determine the nature, course, and management of long-term CRF.

Table 3 shows that for seven of the symptoms, respondents 5 or more years since their last treatment had the lowest percentages of individual criterion endorsements. The item about short-term memory problems (A10) was the only criterion for which the percentage of respondents who endorsed this symptom actually increased with time since last treatment. The two remaining items (A3, trouble concentrating, and A11, postexertional malaise) both demonstrated no evidence of significant decline as time-since-treatment increased. Although this could be supporting evidence for emergent cognitive impairment in cancer survivorship,³⁵ the noted increase may be a reflection of normal age-related decline in cognitive functioning. Either way, this points to an association of CRF with cognitive impairment.

The selection of six items under criterion A as the threshold for diagnosis, although based on expert input and consensus-building discussion, is arbitrary. We presented Table 5 to allow the reader to examine the impact of changing the threshold on prevalence estimates. For example, reducing the required number of A criteria by two (from A1 + any 5 + B to A1 + any 3 + B) increases estimated prevalence by 4%, from 17% to 21%. Increasing the required number by two (from A1 + any A5 + B to A1 + any 7 + B) reduces prevalence from 17% to 9%.

This study has some limitations. For example, it does not provide data to help determine the clinically accurate threshold number; this is a matter for future study. Rather,

the current data provide an understanding of the magnitude of the CRF problem when diagnosed according to these stricter-than-usual criteria. Another limitation is the possibility that the sample studied is not representative of the general population of United States cancer survivors. Although we started with a random sample of eligible participants distributed across the country, 70% of eligible patients were never contacted, and we cannot guarantee that they would have responded similarly. We considered weighting the data using available general population weights. However, to do so would introduce further potential for bias when extrapolating the data to all cancer survivors in the United States. It is important to acknowledge that although the prevalence of CRF as currently defined in this study is 17%, three methodologic factors suggest this is a conservative estimate. First, all patients surveyed had completed cancer treatment, so they were not likely to have experienced acute treatment-related effects (such as anemia) that would increase fatigue. Second, 21% of the sample was recorded as having no current symptoms of fatigue because they reported that fatigue was not a major problem during treatment. The decision not to interview these patients about their current fatigue essentially placed a

ceiling of 79% as the highest possible rate of occurrence of any of the diagnostic criteria. Finally, we note that although a relatively small percentage of patients met the criteria for the defined syndrome of CRF, clearly more patients reported some problems related to CRF. Specifically, 242 patients reported some fatigue-associated problem. This represents 64% of the total sample ($n = 379$) and 80% of those 301 patients interviewed specifically about their current fatigue symptoms. Many of these fatigue-related problems that are below the current diagnostic threshold will likely benefit from clinical attention and intervention, even if they fall below the formal criteria threshold for CRF diagnosis. Diagnostic verification studies comparing patients who meet the proposed criteria to those who do not and, more importantly, clinical management studies, are needed to determine the best ways to modify these criteria so as to maximize their ability to diagnosis CRF and to direct appropriate therapy and resources. Additionally, studies are needed comparing patients undergoing treatment to those posttreatment to determine whether differences exist using these proposed stricter criteria. It is our hope that the refining and use of these diagnostic criteria will help better support CRF research and clinical management.

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