

# XMRV, CFS, and the Internet: How Patient Communities Are Changing Medicine

John Cmar, MD, FACP

Dragon\*Con 2011



disclosures



# disclosures







disclaimer





why this is  
important...

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## Chronic fatigue syndrome researchers face death threats from militants

Scientists are subjected to a campaign of abuse and violence

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**Robin McKie**

The Observer, Sunday 21 August 2011

[Article history](#)



Professor Simon Wessely has felt safer in Iraq than in Britain. Photograph: Laura Mtungwazi for the Observer



# agenda

- ✦ online patient advocacy groups
- ✦ effects on my own practice
- ✦ importance of the public interacting with the medical literature
- ✦ XMRV and CFS as a case study
  - ✦ what is CFS?
  - ✦ what is XMRV?



# online patient advocacy groups

- ✦ function of the Internet in bringing together communities
- ✦ basis:
  - ✦ shared experience
  - ✦ need for specific education/support
  - ✦ patient rights (legislation, access to care)



# online patient advocacy groups

- ✦ how could such a group possibly be negative from a physician standpoint?
  - ✦ population that feels marginalized
  - ✦ diagnosis that is “controversial”
  - ✦ dispute over evidence for treatment options
  - ✦ perpetuation of belief systems
  - ✦ buy-in with emotion and hope at the expense of the scientific process



# my own practice

- ✦ I love my job! ...but...
- ✦ most popular issue in my region: “chronic Lyme disease”
- ✦ advocacy group influence:
  - ✦ IDSA lawsuit
  - ✦ disclaimer on professional guidelines



# DISCLAIMER ALERT

- ✦ “It is important to realize that guidelines cannot always account for individual variation among patients. They are not intended to supplant physician judgment with respect to particular patients or special clinical situations. The IDSA considers adherence to these guidelines to be voluntary, with the ultimate determination regarding their application to be made by the physician in the light of each patient's individual circumstances.”



# groups and the process of science

- ✦ two issues working against them
  - ✦ the nature of medical studies
  - ✦ their consumption by the lay public, and their reporting by the lay media



perspective on the medical  
literature for the non-  
medically trained

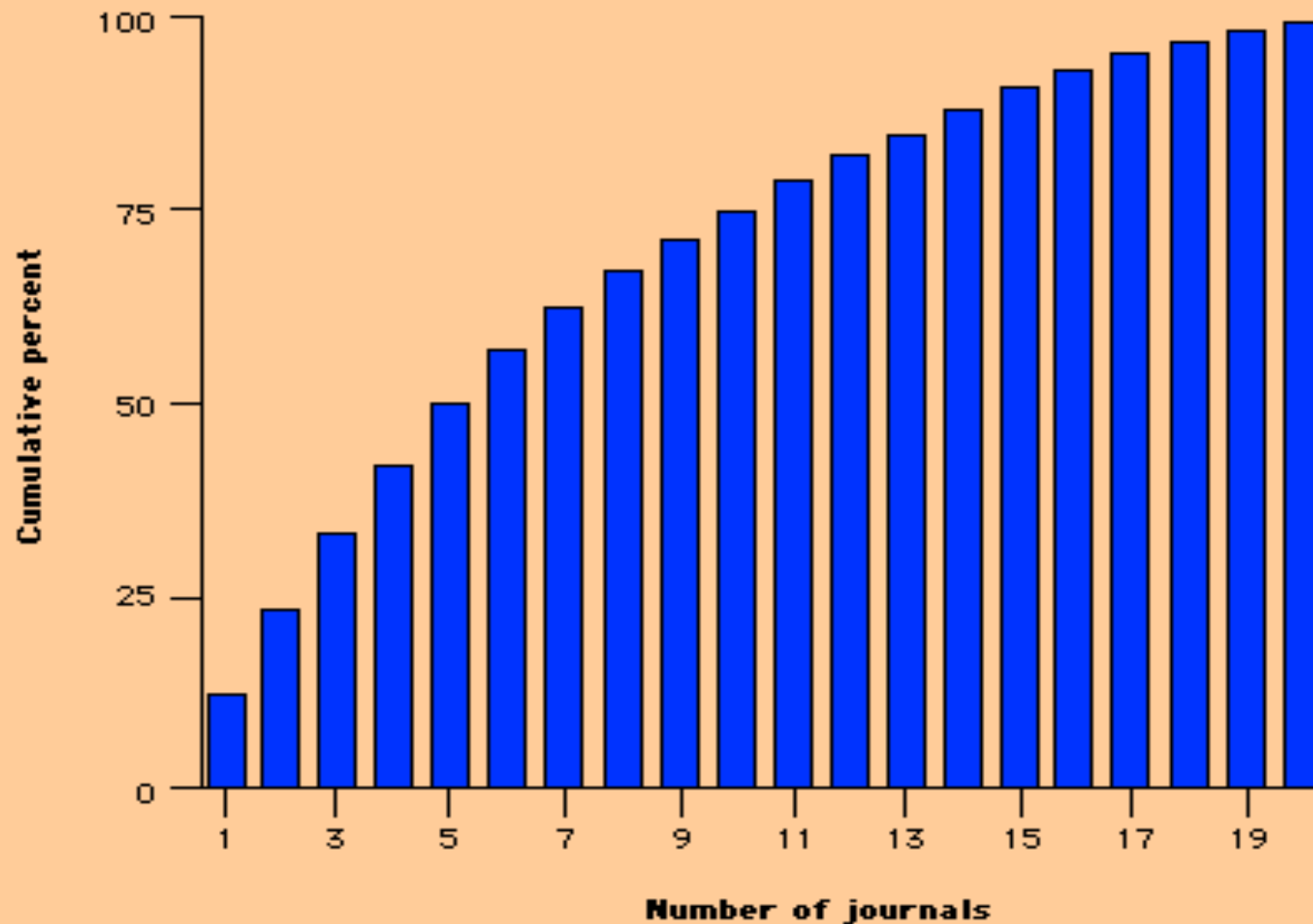


# why so bloody important?

- ✦ medical studies are both “easy” and “hard”
  - ✦ “easy” to read
  - ✦ “hard” to detect and overcome bias
- ✦ massive in number
- ✦ decreased physician time
- ✦ superficial and sensational media coverage



# sipping from a fire hydrant



**Yield of medical journals** The graph represents the cumulative percent of all scientifically strong, clinically relevant articles in internal medicine found in individual journals. An internist reading five of the most high-yield journals would encounter only one-half of such articles. Redrawn from Haynes, RB, ACP Journal Club 1993; 119(Suppl3):A22). Published in Fletcher, RH, Fletcher, SW. Evidence-based approach to the medical literature. J General Intern Med 1997; 12 Suppl 2:S5.



# science by press release

- ✦ authors promoting their studies in the media around the time of publication
  - ✦ biased coverage and incorrect conclusions
- ✦ examples:
  - ✦ Wakefield's original *Lancet* article on measles and autism
  - ✦ XMRV and chronic fatigue syndrome
  - ✦ arsenic-utilizing bacteria



# evidence-based medicine

- ✦ a bit more than us just not making things up
- ✦ term coined in 1991
  - ✦ “the integration of best research evidence with clinical expertise and patient values and circumstances”
  - ✦ “starts with the patient and ends with the patient”
- ✦ speaks to the core values of SCIENCE

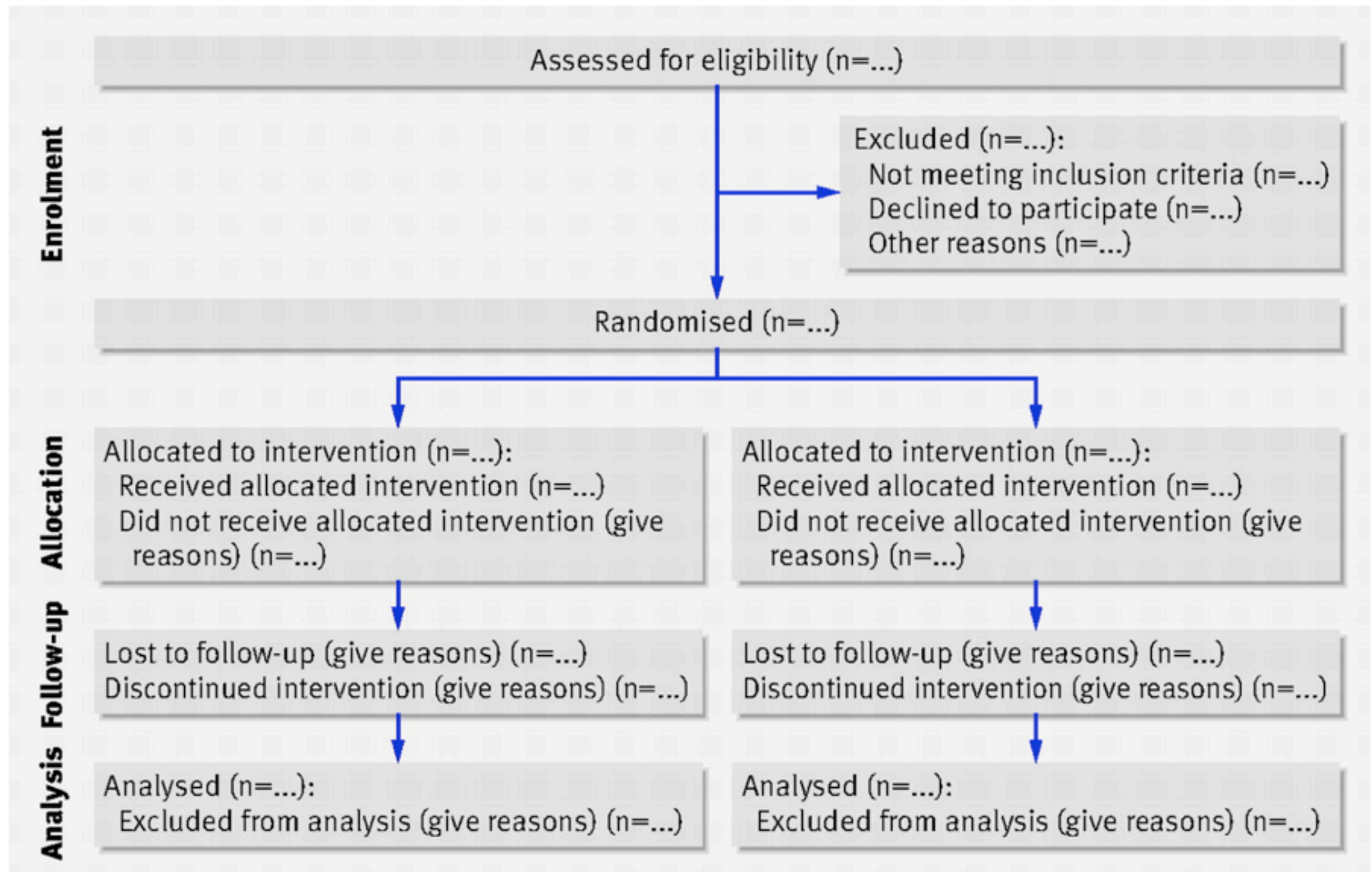


# EBM hierarchy of evidence

- ✦ all studies are not viewed equally
  - 1.randomized, double-blinded, placebo-controlled trial
  - 2.meta-analyses
  - 3.other less rigorous trials
  - 4.case reports and anecdotes
- ✦ different groups have different grading schemes for how “good” the evidence is for a particular topic



**Flow diagram of the progress through the phases of a parallel randomised trial of two groups (that is, enrolment, intervention allocation, follow-up, and data analysis).**



Schulz K F et al. *BMJ* 2010;340:bmj.c332



# which journals to read?

- ✦ based on the Impact Factor - calculated from the average number of citations journal articles get over the two years after publication
  - ✦ *New England Journal of Medicine*
  - ✦ *Lancet*
  - ✦ *Journal of the American Medical Association*
  - ✦ *Annals of Internal Medicine*
  - ✦ *British Medical Journal*



# purpose of medical studies

- ✦ examples

- ✦ look for risk factors for a disease
- ✦ evaluate a screening test for a disease
- ✦ examine a diagnostic test for a disease
- ✦ evaluate therapies for a disease
- ✦ examine the cost effectiveness of a test or treatment



# types of medical studies

- ✦ observational
  - ✦ retrospective v. prospective
  - ✦ cohort v. case control
- ✦ interventional
  - ✦ superiority v. non-inferiority
  - ✦ efficacy v. effectiveness (“pragmatic”)
- ✦ seeding trials



# weaknesses of EBM

- ✦ doesn't take into account plausibility
  - ✦ EBM is a methodology
  - ✦ not the same as Science-Based Medicine
- ✦ confusing and inadequate systems to describe the quality of evidence for a thing
- ✦ meta-analyses are challenging to do well



# structure of an article

- ✦ abstract
- ✦ introduction - logical framework for why we did the study
- ✦ methods - very specific
- ✦ results
- ✦ conclusions - informed by other data, but specifically limited to the study itself
- ✦ other



# structure of an article

- ✦ other
  - ✦ funding source and role
  - ✦ author affiliations and disclosures
  - ✦ references



# how physicians deal with medical articles

- 1.read/skim the abstract
- 2.read/skim the article
- 3.deep reading of the article



# how journalists deal with medical articles

- ✦ many focus reporting on:
  - ✦ out-of-context sound bites
  - ✦ things most likely to trigger public fear-reflex
  - ✦ false balance
- ✦ the good ones do, and limit the above
- ✦ mission of journalism as “reporting” v. “education”



# how drug/device companies deal with medical articles

- ✦ research and development v. marketing department
- ✦ goal is not to do science, but to make money
  - ✦ business agenda for nearly all industry-funded trials that are published
    - ✦ FDA approval for a new indication
    - ✦ enhance physician use of a drug
- ✦ monitoring physician behavior



# how I deal with medical articles

- ✦ read the abstract conclusion
- ✦ if interesting/relevant, read the “other”
- ✦ then read whole abstract, and article with a skeptical eye
  - ✦ any signs of bias?
  - ✦ does the conclusion come from the study?
  - ✦ do the statistics seem sensible?



# why do good journals publish crappy studies?

- ✦ topic is deemed important, despite flaws
- ✦ oversight
- ✦ reprint rights from drug and device manufacturers



# issues confronting the medical literature

- ✦ much of the money and things to be studied are supplied by biased sources
- ✦ authors are human
  - ✦ often make mistakes
  - ✦ sometimes lie



# issues confronting the medical literature

- ✦ public education about study results is primarily done by the media
  - ✦ badly
- ✦ snake oil salesmen co-opting the weak spots of EBM to sell magic beans
- ✦ non-standardized “grading” of evidence
- ✦ non-standardized reporting mechanisms for journal article retraction



# digital aspects of the medical literature

- ✦ subscription/paywall access
  - ✦ changing paradigms - PLoS ONE & publication fees
  - ✦ dealing with back issues - NEJM
- ✦ content delivery via RSS feeds
- ✦ increased reliance on online-only content



# chronic fatigue syndrome

- ✦ prototype medical condition for considering the effect of patient advocacy groups on medicine
  - ✦ uncertain prevalence due to case definitions
    - ✦ maybe 1,000,000 people in US, 250,000 in UK
  - ✦ subject symptomatology with few objective findings
  - ✦ poor clinical consensus, with disputing the existence as a clinical entity



# 1994 CDC case definition

- Have severe chronic fatigue for at least 6 months or longer that is not relieved by rest and not due to medical or psychiatric conditions associated with fatigue as excluded by clinical diagnosis; and
- Concurrently have four or more of the following symptoms:
  - self-reported impairment in short-term memory or concentration severe enough to cause substantial reduction in previous levels of occupational, educational, social, or personal activities
  - sore throat that's frequent or recurring
  - tender cervical or axillary lymph nodes
  - muscle pain
  - multi-joint pain without swelling or redness
  - headaches of a new type, pattern, or severity
  - unrefreshing sleep and
  - post-exertional malaise (extreme, prolonged exhaustion and sickness following physical or mental activity) lasting more than 24 hours.

The fatigue and impaired memory or concentration must have impaired normal daily activities, along with other symptoms that must have persisted or recurred during 6 or more consecutive months of illness and must not have predated the fatigue.



a note about “It’s All In Your  
Head”



to the Googles!





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Chronic fatigue syndrome



www.ncbi.nlm.nih.gov

**Chronic fatigue syndrome** is a condition of prolonged and severe tiredness or weariness (**fatigue**) that is not relieved by rest and is not directly caused by other conditions. Symptoms of CFS are similar to those of most common...

Causes - Symptoms - Tests - Treatment - Prognosis - Complications

CDC - Chronic Fatigue Syndrome (CFS)

www.cdc.gov/cfs/ - Cached #2 in Chronic Fatigue Syndrome

Mar 24, 2011 – Offers information on diagnosis, treatment, support groups, and research publications. A U.S. Centers for Disease Control and Prevention site.

Symptoms - Diagnosis - Treatment - Causes

Chronic fatigue syndrome - Wikipedia, the free encyclopedia

en.wikipedia.org/wiki/Chronic\_fatigue\_syndrome - Cached #3 in Chronic Fatigue

**Chronic fatigue syndrome (CFS)** is the most common name used to designate a significantly debilitating medical disorder or group of disorders generally defined ...

Alternative names for chronic fatigue ... - List of people with chronic fatigue ...

Chronic fatigue syndrome - MayoClinic.com

www.mayoclinic.com/health/chronic-fatigue-syndrome

/DS00395 - Cached #5 in Chronic Fatigue Syndrome

**Chronic fatigue syndrome** — Comprehensive overview covers symptoms, causes, prevention, treatment of this complex disorder.

Symptoms - Treatments and drugs - Causes - Tests and diagnosis

Chronic Fatigue Syndrome - CFS - Center: Symptoms, Causes ...

www.webmd.com/chronic-fatigue-syndrome/default.htm - Cached

Find in-depth information on **chronic fatigue syndrome** including causes, symptoms, diagnosis, and treatments.

The CFIDS Association of America

www.cfids.org/ - Cached #1 in Chronic Fatigue ★★★★★

The CFIDS Association of America is the nation's leading charitable organization dedicated to conquering **chronic fatigue** and immune dysfunction **syndrome** ...

Chronic Fatigue Syndrome Causes, Diagnosis, Symptoms and CFS ...

www.emedicinehealth.com > home > arthritis center > arthritis az list - Cached ★★★★★

**Chronic fatigue syndrome (CFS)** is a disorder that causes symptoms like depression, weakness, headaches, muscle pain, having no energy and being ...

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**Chronic fatigue syndrome**



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[www.cdc.gov/cfs/](http://www.cdc.gov/cfs/) - Cached  in [Chronic Fatigue Syndrome](#)

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**Chronic fatigue syndrome - Wikipedia, the free encyclopedia**

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**Chronic fatigue syndrome (CFS)** is the most common name used to designate a significantly debilitating medical disorder or group of disorders generally defined ...

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**Chronic fatigue syndrome - MayoClinic.com**

[www.mayoclinic.com/health/chronic-fatigue-syndrome](http://www.mayoclinic.com/health/chronic-fatigue-syndrome)

/DS00395 - Cached  in [Chronic Fatigue Syndrome](#)

**Chronic fatigue syndrome** — Comprehensive overview covers symptoms, causes, prevention, treatment of this complex disorder.

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**Chronic Fatigue Syndrome - CFS - Center: Symptoms, Causes ...**

[www.webmd.com/chronic-fatigue-syndrome/default.htm](http://www.webmd.com/chronic-fatigue-syndrome/default.htm) - Cached

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**Chronic Fatigue Syndrome**

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CFS: Total guide to research proven natural & prescribed treatments.

**Chronic Fatigue in Women**

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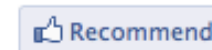
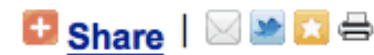
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Updated: June 29, 2011  
104 Pages

### What is Chronic Fatigue Syndrome?

Fatigue is a very common symptom all over the world. However, chronic fatigue syndrome (CFS) is more than just fatigue, it is a complex of symptoms that is both **prolonged** (persisting longer than 6 months) and **severe** (associated with substantial disability).

The term "chronic fatigue syndrome" was originally proposed by the U.S. Centers for Disease Control and Prevention in 1988 to replace numerous other names that had been used to describe the common set of symptoms for this syndrome (including "febricula" in 1750 and "neurasthenia" in 1869). The term "myalgic encephalomyelitis" is more commonly used in the United Kingdom to describe chronic fatigue syndrome.

It has been estimated that chronic fatigue syndrome affects about 0.3% of the adult U.S. population. The syndrome is much more common in women than in men with women representing about 75% of all cases. The mean age of onset is between 30 and 40. Without treatment, the overwhelming majority of patients (95%) fail to recover and continue to suffer with the effects of the syndrome.

In the past, chronic fatigue syndrome was associated with significant controversy among doctors, researchers, and patients. The major areas of disagreement were attributed to the lack of a standard definition for the disorder; the unknown etiology (cause) of the disorder; the absence of specific criteria to establish the diagnosis; and the lack of effective treatments for the disorder. In fact, until recently many health care providers believed that chronic fatigue syndrome was a "psychological" rather than a "physiological" (organic) disorder.

In 1994, an expert panel convened by the U.S. Centers for Disease Control and Prevention (CDCP) proposed a case definition for chronic fatigue syndrome that since has become widely accepted as the "standard". According to the CDCP, the primary feature of chronic fatigue syndrome is persistent or relapsing fatigue which is characterized by the following:

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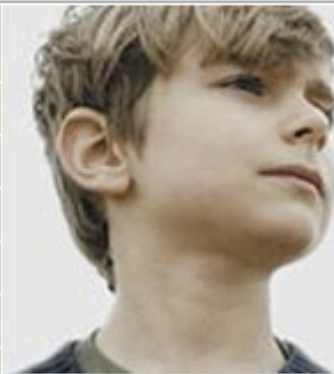
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Tune in to **NPR on Mon., Sept. 5**, for 2 separate CFS reports for "[Morning Edition](#)." You can also listen to the podcast or program archive posted later in the day at <http://n.pr/ox6DH4>.

**Institute of Medicine** released a new [report on pain](#) on June 29, 2011. [31 organizations joined to hail IOM's focus on pain](#).

It's summer and **orthostatic intolerance** can make you feel much worse. [Learn more about OI](#).

**24 Hours in the Enchanted Forest: A Race to Solve CFS** raised \$10,000 for the Association's research program. Watch this [action-packed video](#).

Author **Laura Hillenbrand's** book

### Research & Policy

The Association launched a **new blog/website** on May 24. Visit [Research1st](#) and join the conversation about research!

A [6-page article](#) about CFS in **Nature Reviews Neuroscience** is freely available until Sept. 8

A large **international panel of experts** published a [new definition](#) of myalgic encephalomyelitis in the *Journal of Internal Medicine*, recommending it replace CFS - the name and definition.

**Promising biomarker revealed** after modest exercise challenge. Read about the [latest study](#) from Univ. of Utah. Journal highlights updated regularly on [Research1st](#).

CFS has been linked to a family of **murine leukemia virus-related viruses**, including XMRV, but there is conflicting data. An update on studies and media coverage provides the [latest news](#). Find other resources [here](#).

### We're Transforming

The CFIDS Association is transforming from a patient support and advocacy organization to one laser-focused on stimulating and supporting research. Read our [CEO's message](#) and about our [Scientific Advisory Board](#).

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This web page is provided by [Roger Burns](#), the publisher of [CFS-NEWS](#). See also the [introductory essays about CFS](#).  
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[CFS FAQ](#) (answers to frequently asked questions)  
[Doctors CFS page](#)  
[CDC Definition article](#), 1994; Fukuda et al.  
[American Journal of Medicine Symposium on CFS](#), Sept 1998  
[Myalgic encephalomyelitis](#)  
[ME-NET Research Papers](#)  
[Royal Colleges Report](#), 1996



# XMRV

- ✦ xenotropic murine leukemia virus-related virus
- ✦ discovered in 2006
- ✦ initially linked to prostate cancer prior to CFS
  - ✦ two further positive studies
  - ✦ numerous studies have refuted this link, including retesting of the original tissue samples in the positive study



# XMRV in the literature

- ✦ Lombardi et al. in *Science*, 2009
  - ✦ found evidence in 67% of 101 patients with CFS
  - ✦ present in 4% of healthy controls
  - ✦ rationale lacking to begin with
  - ✦ conclusions too strong for results
  - ✦ “science by press release”



# XMRV in the literature

- ✦ since then, one further positive study
- ✦ numerous negative ones, most recently in the *Journal of Infectious Diseases*
- ✦ included retesting prior samples, using the same viral primers and supplies
- ✦ lab and technique comparisons suggest lab contamination
- ✦ evidence virus arose in-lab in 2006



# science-based conclusions

- ✦ NO significant evidence that XMRV is a human pathogen
- ✦ singling out XMRV made little sense to begin with
- ✦ not 100% conclusive, but very compelling
- ✦ prior probability seems very low



# advocacy group reactions

- ✦ despite the current state of the evidence, continue to include the possibility of XMRV as a causative agent
- ✦ some patients demanding antiviral medications from their doctors
- ✦ sense that people doing good science are biased if they are not supportive of XMRV in CFS
  - ✦ threatening legal action
  - ✦ splintering of physician groups, buy-in with “CAM”
  - ✦ hostility and not open to physician opinion



a note on being “open-  
minded”



# engaging with Internet patient groups

- ✦ physicians need to actively, patiently, persistently engage
  - ✦ better discussion of literature with patients
    - ✦ constraints of time, understanding of EBM
- ✦ lay public needs to be skeptical of how the lay media reports on new studies
  - ✦ lay media = wikipedia
  - ✦ not be intimidated about going to the primary literature



# websites of note

- ✦ Retraction Watch - **[retractionwatch.wordpress.com](http://retractionwatch.wordpress.com)**
- ✦ Science-Based Medicine - **[sciencebasedmedicine.org](http://sciencebasedmedicine.org)**
- ✦ Bad Science - **[badscience.net](http://badscience.net)**
- ✦ Centre for Evidence Based Medicine - **[cebm.net](http://cebm.net)**
- ✦ Cochrane Colaboration - **[cochrane.org](http://cochrane.org)**



# vaccine clinic at Dragon\*Con!

- ✦ Marriott 109
- ✦ HIV testing
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- ✦ free!



# discussion

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