Guildford ME/CFS Support Group
(& West Surrey)

Newsletter

September 2016

Future dates

Open to all members and carers.

12th October 2016 (Wednesday) 7.30pm The White Lyon and Dragon
Perry Hill, Worplesdon, Guildford, GU3 3RE
www.whitelyonanddragon.com
(not far along from the Worplesdon Hotel)

14th November 2016 (Monday) 11.15am The Seahorse
The Street, Shalford, Guildford, GU4 8BU
www.theseahorseguildford.co.uk

8th December 2016 (Thursday) 7.30pm Weyside
Millbrook, Guildford, Surrey, GU1 3XJ
www.theweyside.co.uk

This year instead of a formal 'Christmas Dinner' which requires pre-booking, pre-ordering and deposits we are shooting for a more relaxed alternative in the form of a typical meeting. As per a typical meeting those who decide to have food can order when then they arrive.

The Huffington Post: 3 reasons why an invisible illness is more dangerous

Source: www.huffingtonpost.com/entry/3-reasons-why-an-invisible-illness-is-more-dangerous_us_5798d772e4b0e339c23fff38

By Cassandra Marcella Metzger 27th July 2016

Invisibility presents extraordinary obstacles and risks depending on who is blind to your illness.

When you get an invisible illness like fibromyalgia, or lupus, or MS, or chronic fatigue, your whole world alters. How you see yourself changes. But how the world sees you does not. Your illness is invisible to others, to doctors and to the government. The perils of not being seen can be life-threatening.

Nearly half of U.S. citizens live with some sort of chronic condition. Most do not use a cane or crutch or wheelchair, which would reveal their disability. Ninety-six percent of chronic conditions are invisible.

That invisibility presents extraordinary obstacles and risks, depending on who is blind to your illness.

Invisible to the eye

Ailments that are not visible to the naked eye wreak havoc in relationships. Spouses do not believe. Friends and family doubt. Doctors do not believe and send patients to psychiatrists.

Scepticism is not in itself pernicious; science advances through questions. But the human suffering is real, and questioning the integrity of someone who is searching for answers magnifies the pain.

In a recent report on Lyme disease research, Dr. Nevena Zubcevik told a gathering at Spaulding Rehabilitation Hospital in Massachusetts that:

> … many patients she sees have been suffering the physical, mental, and emotional effects of the disease for so long, they have lost the will to live. “I literally have patients who were just done,” she said. “They couldn’t go on. The first thing I do is validate their experience, and tell them, “I believe you.” Sometimes they start crying because somebody finally listened. Some patients show symptoms of post-traumatic stress disorder because they’ve been ignored for so long. Marriages dissolve all the time because one spouse thinks the other is being lazy. Many chronically ill patients end up alone.
>
> I would say alone and potentially suicidal. And the same could be said for those suffering from other invisible illnesses such as CFS/ME, fibromyalgia, lupus, MS, Crohn’s disease and others. Just because an illness is not obvious to you does not mean it is not real. To think that is ignorant.

Invisible to medical tests

Some of the most debilitating conditions are not only invisible to the naked eye, they are also invisible to the eye peering down the microscope. That, too, does not mean it does not exist. The only significance is that medical science has not figured it out yet.

When people have said to me that my illness is all in my head, my riposte is, “Yes it is in my head. My condition is a neurological disorder, and the brain is the largest organ of the nervous system. So it is in my head. It’s just not in the part of my head I can control.”

For centuries, as Susan Sontag aptly pointed out in her book Illness as Metaphor, illnesses have been blamed on the character of the afflicted rather than on the inadequacies of the medical field. Tuberculosis (TB) was deemed to be caused by the inward and suppressed passion of an excessive romantic. (1) “As cancer is now imagined to be the wages of repression, so TB was once explained as the ravages of frustration,” she wrote in 1978. (2)

No one today thinks either TB or cancer is the result of repression or frustration, because science has since figured out the physical cause of each. I daresay and hope that in another 40 years, people with Lyme, CFS/ME, fibromyalgia and other such illnesses will have been researched thoroughly so that those afflicted are not blamed for being too uptight, too perfectionist, too lazy. Or whatever. It is insulting.

Invisible to the government

But that (visibility) will not happen without the funding for research. We have to look deeper, and that costs time and money. Medical research in this country is not appropriated according to the number of those affected. Statistics appear not to matter at all. Instead, monies into medical research seem to go to those with the biggest megaphone.

Even within cancer research, the allocations make no sense. According to the American Cancer Society, as of March 1, 2016, grants awarded for breast cancer research is $102 million, while lung cancer is only $51 million. This, despite the fact that the Cancer Statistics Center estimates 158,080 deaths will be caused by lung cancer while breast cancer is estimated to kill 40,890. The entire month of October is devoted to breast cancer. Do you ever see any walks for lung cancer? No, because if you get lung cancer you do not live long or are strong enough to advocate for research.

Now imagine: if you have an invisible illness to the naked eye and to existing medical tests, just how dire funding for research must be. It is bad. Very bad.

And many invisible illnesses thwart our efforts to advocate for better because our energies are sapped by our daily existence. We are struggling just to function, never mind march with megaphones.

Nancy Klimas, a professor of microbiology and immunology, noted in a New York Times interview:

My H.I.V. patients for the most part are hale and hearty thanks to three decades of intense and excellent research and billions of dollars invested. Many of my ME/CFS patients, on the other hand, are terribly ill and unable to work or participate in the care of their families. I split my clinical time between the two illnesses, and I can tell you if I had to choose between the two illnesses (in 2009) I would rather have H.I.V. But C.F.S., which impacts a million people in the United States alone, has had a small fraction of the research dollars directed towards it.

In an interview with Al Jazeera, Prof. Klimas added that research into CFS/ME is small, especially when considering the number of people sick and how devastating it is. “I had looked up male pattern baldness … $18 million for male pattern baldness [but only] $3 million for chronic fatigue syndrome, an illness that affects 1 million people in this country that has at least 25 percent of them out of work and on disability.”

If only I were a man with baldness, I might be cured faster. I am sorry, but that’s just outrageous and must change.

If we do not see, we have to look. We, each of us, have to look beyond the obvious. Medical researchers must look deeper and more urgently for answers. Government needs to broaden its view, see needs, pinpoint gaps and allocate research funds more appropriately.

We have to be humble and consider that what we cannot see can still exist and still be true. No one in their right mind choses this, and by questioning their illness you are questioning their sanity. When truthfully, and as time will tell, ignorance is the insanity.

(1) Sontag, Susan. Illness as Metaphor and AIDS and Its Metaphors. New York: Picador, 1978, p. 20.

(2) Ibid., 21.

Tribunal orders release of data on controversial £5 million CFS PACE study

Source: www.relevantnow.com/stories/sneakbee/eGUoLsfAF5g

Thursday, 18th August 2016, London, UK - A tribunal has ruled that data from a treatment trial into Chronic Fatigue Syndrome (CFS) must be released, rejecting an appeal from Queen Mary University of London (QMUL).

PACE was a £5 million, publicly-funded clinical trial of exercise and cognitive behavioural therapy for CFS. It has been highly influential in determining treatment in the UK and abroad, but has been controversial. Academics and patients have both voiced concerns over “misleading” claims. Dr Richard Smith, former editor of the British Medical Journal, said in December 2015 of QMUL’s failure to release the data, “...the inevitable conclusion is that they have something to hide”.

QMUL spent over £200,000 on legal fees in this case, to appeal the Information Commissioner’s decision that they should release anonymised data from the trial. The request for data was made under the Freedom of Information Act by Mr Alem Matthees, to allow analysis of the data according to the study’s original published protocol.

QMUL made several arguments why the data should not be released, their main claims being that the data was personally identifiable information, and was not sufficiently anonymised. However, the tribunal rejected these arguments, noting that QMUL had already shared the data with a small selection of other scientists, stating, "In our view, they are tacitly acknowledging that anonymization is effective, or else they would be in breach of the consent agreement and the DPA principles."

The tribunal was satisfied that the data “...has been anonymised to the extent that the risk of identification is remote.” The tribunal also noted the "strong public interest in releasing the data given the continued academic interest" and "the seeming reluctance for Queen Mary University to engage with other academics they thought were seeking to challenge their findings."

In his correspondence with the court, Mr Matthees expressed “concerns that QMUL are restricting the registered researchers to whom they disclose the data upon request.” The tribunal said, “The evidence before us is not clear but if QMUL are cherry-picking who analyses their data from within the recognised scientific research sphere to only sympathetic researchers, there could be legitimate concerns that they wish to suppress criticism and proper scrutiny of their trial.”

In its submissions QMUL made a number of accusations of harassment from patients, while QMUL’s expert witness characterized PACE trial critics as "young men, borderline sociopathic or psychopathic", remarks the Information Commissioner dismissed as "wild speculations".

When pushed to provide evidence of these threats and harassment under cross examination, witnesses speaking for QMUL were unable to do so, and ultimately conceded that "no threats have been made either to researchers or participants."

The tribunal found QMUL's assessment of activist behaviour to be, “grossly exaggerated” stating that “the only actual evidence was that an individual at a seminar had heckled Professor Chalder.” [Professor Chalder is a leading researcher in the PACE trial and a key witness for QMUL.]

Continues with ‘Expert reaction to the decision’…

Expert reaction to the decision

Jonathan C.W. Edwards, MD
Emeritus Professor of Medicine
University College London
E-mail: jo.edwards@ucl.ac.uk

> “I think this is the right decision and I congratulate Mr Matthees on persevering with a very reasonable request. The report indicates that the Tribunal considered arguments from both sides very thoroughly. It has become clear that the reasons given for not providing the information requested are essentially groundless. It is also clearly appreciated that critics of the PACE trial are not young sociopaths - they include senior medical scientists like myself, concerned about poor science!”

Keith Geraghty, PhD
Honorary Research Fellow
University of Manchester
E-mail: keith.geraghty@manchester.ac.uk

> "I read the tribunal decision with great interest. I was surprised that the PACE authors declared in evidence that they had shared their trial data with other researchers. I contacted lead author Prof. Peter White to request access to PACE data to run an independent analysis, but my request was first ignored, then later refused. I now understand that the authors shared the data with a select few academics who they picked to co-write papers, but they have failed to share the data with the broader scientific community. Selectively sharing this publicly-funded data with collaborators but refusing to share data with anyone else, is not in the best interests of patients or science, and it creates a perception that the PACE team do not want independent critical analysis of this trial. I find it regrettable that the Medical Research Council, who partly funded this very expensive study, did not specify that the trial data be made available to other researchers.”

Alem Matthees
Patient and Second Respondent Australia

> I am very pleased with this outcome. Both the Tribunal’s decision and commentary are a long overdue victory for the patient community, as well as for advocates of clinical trial transparency and open data sharing. I want to thank everyone who gave support, advice or assistance, as well as anyone who engaged in debate over the PACE trial and the sharing of clinical trial data. This case ended up costing me greatly in time, energy, and health (currently bedridden).
>
> I utilised the FOIA to loosen the vice grip control over the data and allow truly independent and open analyses that do not rely on the approval of QMUL or the PACE trial investigators. All this came about largely because of their refusal to publish or release the protocol-specified outcomes, and their generally questionable and poorly or erroneously justified changes to the published trial protocol, i.e. outcome switching, after the trial was over and/or after seeing trial data. Claims of clinically significant improvement may be open to interpretation, but false or misleading claims of recovery or remission from debilitating illness simply have no place in the scientific literature.

QMUL releases the PACE data

Source: www.meaction.net/2016/09/09/qmul-releases-pace-data

Another article about the release of CFS PACE Study data…
Queen Mary University of London (QMUL) has released the PACE data to a patient who requested it under the Freedom of Information Act, as ordered by a recent tribunal, on the last possible day to lodge an appeal against the court's order.

The move follows the publication three days previously of an open letter from a group of scientists including Dr. Ron Davis, Vince Racaniello and Jonathan Edwards, urging QMUL's principal, Professor Simon Gaskell, not to appeal the tribunal's decision.

The data was requested in March 2014 by Alem Matthees, in order to allow the calculation of the trial's main outcomes and recovery rates according to the methods specified in the trial's original protocol. The original analysis methods were abandoned once the trial was underway and replaced by others, including an analysis in which patients could become more disabled and yet be classed as having "recovered".

Tom Kindlon, a patient whose criticism of PACE's analyses has been published in medical journals, said, "This is a great day for patients. We've waited years for this. Finally, it's going to be possible for independent parties to scrutinise the data and, in particular, find out what the results would have been without all the unjustified changes to the study protocol. Looking at how the objective data relate to the subjective outcomes will also be very interesting."

He added, "This was a publicly funded trial and cost £5 million in taxpayers' money — the data should never have been kept secret. It is very disappointing that both the PACE Trial investigators and QMUL fought the case so hard, forcing Alem Matthees to have to put in so much work when he is not well himself, and dismissing some other requests for basic information."

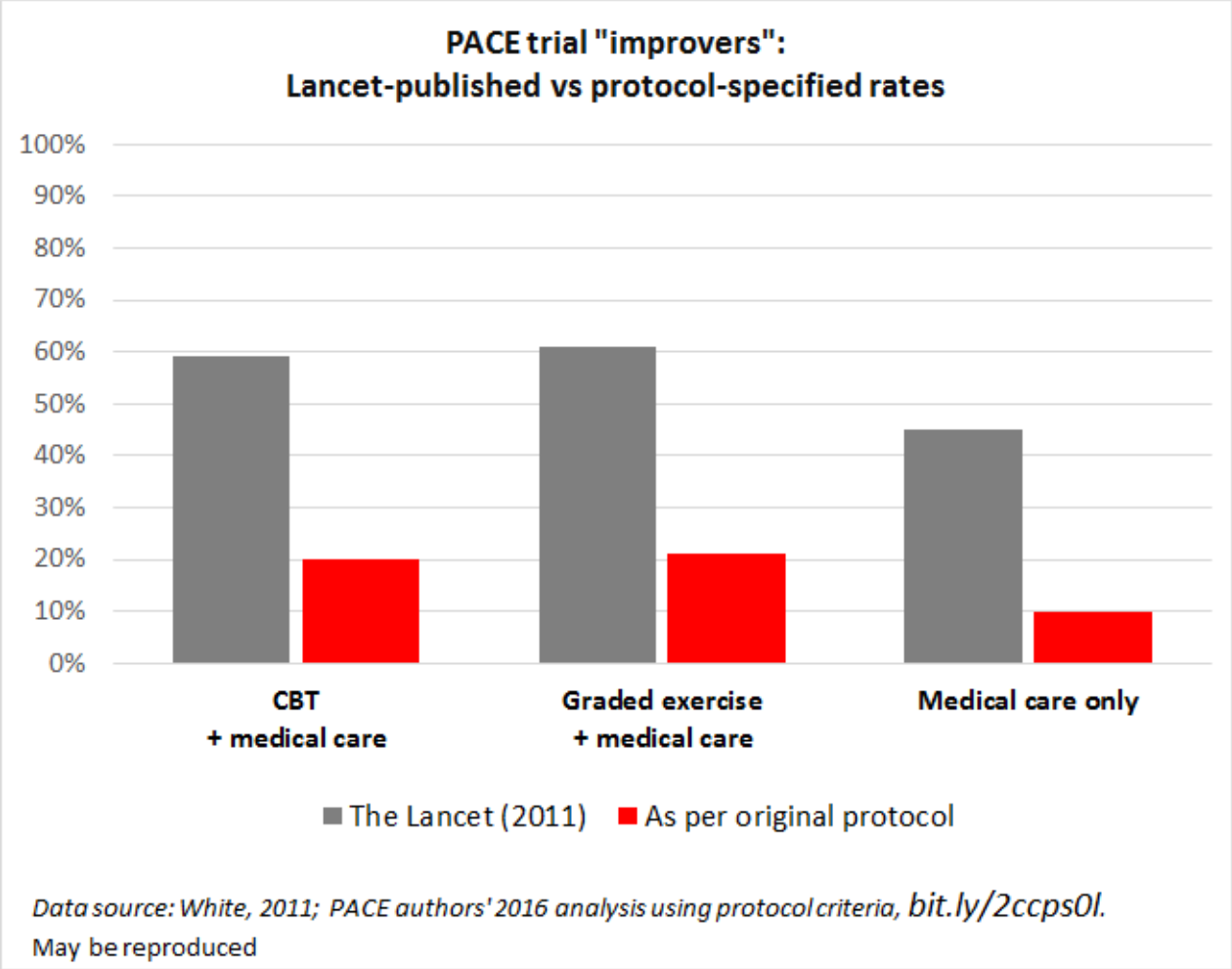
The day before the data was released, the PACE authors published online the main results for the trial using the original protocol-specified methods. The new results show that only a third as many patients improved according to the protocol-defined analysis, compared to the numbers reported in The Lancet in 2011.

The results confirm suspicions long-held by patients and scientists who have studied the trial critically that if the PACE investigators had stuck to their own original analysis protocol, PACE would have appeared to be a far less successful trial.

The new results show that only 21% of patients were classed as "improvers" in the graded exercise therapy group, compared to the 61% claimed in the Lancet paper using an analysis developed after the trial was under way. 10% of patients in the group that received no therapy were "improvers", indicating that, even with the subjective measures used, only one patient in ten reported improvement from the addition of graded exercise therapy. Results for the CBT group were similar to those for the graded exercise group.

These re-interpreted results were released without fanfare on QMUL's own website. Despite the dramatic fall in improvement rates, the study authors said that the outcomes were "very similar to those reported in the main PACE results paper" and supported their Lancet conclusion that CBT and graded exercise, added to standard medical care, "moderately improve" outcomes for CFS patients.

But journalist and public-health expert Dr. David Tuller, of the University of California, Berkeley, who has criticized the trial in detail, said, "Let's be clear. These findings are really much worse than those presented in published, 'peer-reviewed' papers. If these were the best findings for $8 million, then PACE really will not survive legitimate scrutiny."



But now, with the original, raw data going to Alem Matthees, a more independent review is sure to follow.

Over the past several months, following the first of Dr. Tuller's critical articles, patients and scientists have joined together all over the world to put pressure on QMUL to release the data. A petition led by #MEAction with over 12,000 signatures was featured in the Wall Street Journal, and was presented at the tribunal as evidence of the level of public interest in data release; and 24 ME/CFS organisations in 14 countries, representing tens of thousands of patients, wrote open letters to the university. L.A. Cooper, head of #MEAction Network UK said, "Our thanks go out to Alem Matthees, who worked incredibly hard to achieve the release of the PACE data at what was almost certainly enormous physical cost. Thank you, Alem!"

Is the biopsychosocial model responsible for patient dissatisfaction and harm?

Source: http://bjgp.org/content/66/649/437
By Keith J Geraghty, Aneez Esmail Published 1st August 2016

In 1977 George Engel wrote about the need for an 'integrated approach' in medicine that moved the focus beyond biological mechanisms of disease to include all pertinent aspects of illness presentation, setting out a 'biopsychosocial model'. Around the same time, McEvedy and Beard asserted that the disease 'benign myalgic encephalomyelitis', described by Ramsay at the Royal Free Hospital, London, was nothing more than a case of 'mass hysteria'. In the 1980s, doctors combined theories of neurasthenia, hysteria, and somatoform illness, to reconstitute ME as 'chronic fatigue syndrome'.

Psychiatrists argued that CFS was best understood using a biopsychosocial (BPS) framework, being perhaps triggered by viral illness (biology), but maintained by certain personality traits (psychology) and social conditions (sociology). Although the BPS model holds much utility in understanding 'illness' in a wider context, many sufferers of CFS reject the notion that their illness is psychologically or socially derived. Significant numbers of patients report difficult interactions with doctors that leave them feeling dissatisfied, disbelieved, and distressed. In this article, we question whether or not the BPS model generates 'harms' for CFS patients, and we ask if other, alternative approaches might be more preferable to both patients and GPs.

The potential for Iatrogenesis

GPs are increasingly encouraged to apply biopsychosocial principles in the clinical assessment of patients with medically unexplained symptoms, particularly CFS. There is a general argument put forward in the BPS literature that patients with CFS have higher rates of depression and anxiety, are combative, and seek unnecessary investigations in an effort to maintain sick role status and avail of social benefits. GPs are encouraged to challenge or reframe unexplained physical symptoms and to focus attention on issues such as potential somatisation. Patients calling for enhanced medical investigation are to be judged as seeking unnecessary tests and perhaps unnecessarily availing of scarce resources.

Raine and colleagues found that GPs often negatively stereotype patients with CFS as 'problematic' or 'hypochondriacs', with a view that these patients are not suffering from clear pathological illness, but are patients with complex psychological and social problems. However, is this narrative correct? There is increasing scientific evidence that confirms a range of physiological abnormalities in CFS. In 2011, a panel of experts published an International Consensus Criteria for CFS that promoted a neuro-immune model, rather than a psychogenic model, and in 2015 the US Institute of Medicine (IOM) suggested renaming CFS 'Systemic Exertion Intolerance Disease' (SEID), taking note of the multiple physical complaints patients endure. In contrast, GPs in the UK and elsewhere are encouraged to apply a biopsychosocial approach to CFS, including referring patients for psychological assessment and treatment within specialist centres. The BPS framework for CFS proposes that patients' abnormal psychopathology (essentially somatisation) may be treated with cognitive behavioural therapy (CBT) to alter patients' 'illness beliefs', and graded exercise therapy (GET) to change 'fear avoidance behaviours'. However, the 2015 IOM report stated that the symptoms most CFS patients present with — fatigue, pain, cognitive disturbances, or orthostatic intolerance — are unlikely to be 'dysfunctional illness beliefs'.

The biopsychosocial framework is contested by CFS patient advocacy groups, with claims that the BPS model is biased to the 'psychological', including reliance on CBT and GET. The evidence for the success of psychotherapies in CFS treatment is mixed. A 2011 psychiatry-led randomised control trial of CBT and GET for CFS reported a 22% improvement in subjective outcomes (wellbeing). However, this was not mirrored by objective measures of improvement (physical functioning), and at follow-up return to employment did not increase, healthcare usage remained the same, and patients reported a similar level of social welfare benefits.

Although CBT and GET may help some patients, these treatments are not universally welcomed by all patients with CFS and there is some evidence that graded exercise may exacerbate symptoms. In a 2010 ME Association survey of 4217 members, 57% of responders reported graded exercise therapy as being unacceptable as a treatment. Other patient surveys report similar findings of patient dissatisfaction and distress following engagement with CBT or GET. In addition, a study of referrals to CFS clinics found that 37% were rejected as inappropriate and 61% had a likely alternative diagnosis.

For patients assessed in-clinic, 43% had alternative medical/psychiatric diagnoses, commonly sleep disorders or depressive illness. In a separate study, two-thirds of patients with CFS referred to CFS clinics reported being dissatisfied with the quality of medical care they received. Dissatisfaction was associated with delays and disputes over diagnosis, rejection of a psychiatric diagnosis, as well as doctors being dismissive, sceptical, and lacking in knowledge about the condition.

Within the BPS framework, GPs may be inappropriately encouraged to view physical symptoms, such as pain, as being 'somatised', rather than complaints that require intervention, such as analgesia or referral to a pain clinic. If CFS patients perceive that GPs do not view their symptoms as 'legitimate' and 'physical' (that is, aberrations), patients may withdraw from seeking medical support. There is some concern that, if a patient with CFS rejects the BPS rationale for the illness and/or interventions of CBT/GET, this may be viewed negatively by a GP. In a patient advocacy group survey, 22% of CFS sufferers reported that they received no medical care, while the average rating given by those who did receive care was just 24%.

Across a number of studies, sufferers of CFS reported doctors being hostile and dismissive, leaving many patients feeling 'stigmatised' and 'marginalised'. Low levels of satisfaction around provision of care is a concern, as CFS is often a debilitating condition that greatly impacts on patients' quality of life, leaving many vulnerable to secondary depression and suicide.

Conclusion: involving patients and empowering GPs

Many CFS patients report that they wish to be cared for by GPs in primary care, rather than psychiatrists in specialist centres. CFS patients ranked the professionals they want to manage their condition, putting GPs as first choice (1502 votes), with psychiatrists last choice (15 votes).

However, in a survey of attitudes to CFS among English GPs, Bowen and colleagues found that many GPs lack confidence in making a diagnosis (48%) or in treating patients (41%). Scepticism and a lack of awareness and training among GPs concerning CFS may well explain some of the patient dissatisfaction highlighted in patient surveys, as well as explain delays and error in diagnosis. However, it is also arguable that the biopsychosocial approach of challenging the nature of the illness, and seeking to intervene with psychotherapy to challenge patients' illness beliefs may also play a part in generating distress for patients with CFS. In order to minimise iatrogenesis, GPs require better training in how to diagnose CFS and communicate with patients with CFS; GPs should not seek to impose a biopsychosocial model of illness on a patient.

Models of illness should not supplant the 'lived experience of illness' or subjugate the expert status of the patient as 'witness to their condition'. Nassir Ghaemi, critical of the biopsychosocial model, suggests doctors should consider alternative clinical approaches, such as Karl Jaspers' 'method-based' or William Olsen's 'medical humanist' model'.

Such models might be used by GPs to:

- inform patients of the absence of known aetiology in CFS (rather than speculating around psychogenic causes);
- inform patients that there are explanations for some CFS symptoms (for example, the IOM report of biomedical evidence);
- offer patients treatments such as CBT, but inform patients that these therapies do not work for all (rather than suggesting the patient controls outcomes);
- offer alternative interventions and support, such as counselling and community care (rather than just referral to CFS clinics); and
- accept the legitimacy of the patient account (rather than seeking to challenge patients' illness beliefs).

Such differences of approach may seem subtle, but arguably represent a more pragmatic approach, which we recommend for general practice. It is probable that harm could be minimised by adopting a more concordant model that includes patients' preferences in treatment and management.

Notes

Provenance - Freely submitted; externally peer reviewed.
Competing interests - The authors have declared no competing interests.

Metabolic features of ME/CFS

Source: http://m.pnas.org/content/early/2016/08/24/1607571113.abstract

31st August 2016

Although a highly bio-technical article, the following recent study results add to thousands of studies showing significant biological abnormalities in ME/CFS patients using the Canadian/Fukuda criteria. Specifically "Patients with CFS showed abnormalities in 20 metabolic pathways. Eighty percent of the diagnostic metabolites were decreased, consistent with a hypometabolic syndrome."

Significance

Chronic fatigue syndrome is a multisystem disease that causes long-term pain and disability. It is difficult to diagnose because of its protean symptoms and the lack of a diagnostic laboratory test. We report that targeted, broad-spectrum metabolomics of plasma not only revealed a characteristic chemical signature but also revealed an unexpected underlying biology.

Metabolomics showed that chronic fatigue syndrome is a highly concerted hypometabolic response to environmental stress that traces to mitochondria and was similar to the classically studied developmental state of dauer. This discovery opens a fresh path for the rational development of new therapeutics and identifies metabolomics as a powerful tool to identify the chemical differences that contribute to health and disease.

Abstract

More than 2 million people in the United States have myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS). We performed targeted, broad-spectrum metabolomics to gain insights into the biology of CFS. We studied a total of 84 subjects using these methods.

Forty-five subjects (n = 22 men and 23 women) met diagnostic criteria for ME/CFS by Institute of Medicine, Canadian, and Fukuda criteria. Thirty-nine subjects (n = 18 men and 21 women) were age- and sex-matched normal controls. Males with CFS were 53 (±2.8) y old (mean ± SEM; range, 21–67 y). Females were 52 (±2.5) y old (range, 20–67 y). The Karnofsky performance scores were 62 (±3.2) for males and 54 (±3.3) for females.

We targeted 612 metabolites in plasma from 63 biochemical pathways by hydrophilic interaction liquid chromatography, electrospray ionization, and tandem mass spectrometry in a single-injection method.

Patients with CFS showed abnormalities in 20 metabolic pathways. Eighty percent of the diagnostic metabolites were decreased, consistent with a hypometabolic syndrome. Pathway abnormalities included sphingolipid, phospholipid, purine, cholesterol, microbiome, pyrroline-5-carboxylate, riboflavin, branch chain amino acid, peroxisomal, and mitochondrial metabolism.

Area under the receiver operator characteristic curve analysis showed diagnostic accuracies of 94% [95% confidence interval (CI), 84–100%] in males using eight metabolites and 96% (95% CI, 86–100%) in females using 13 metabolites. Our data show that despite the heterogeneity of factors leading to CFS, the cellular metabolic response in patients was homogeneous, statistically robust, and chemically similar to the evolutionarily conserved persistence response to environmental stress known as dauer.

Ampligen - first drug approved anywhere for CFS

Source: www.healthrising.org/forums/threads/ampligen-takes-big-step-forward-becomes-first-drug-approved-anywhere-for-chronic-fatigue-syndrome.4815

Ampligen became the first drug approved for chronic fatigue syndrome (ME/CFS) anywhere in the world this week when ANMAT, the Argentine FDA, approved the drug for use in people with severe ME/CFS. Why should we get excited about Ampligen's approval in Argentina? Because Argentina has a modern medical system which includes having a rigorous drug approval process. Hopefully this will be a harbinger of things to come for Ampligen.

Argentina was the first Latin American country Hemispherx Biopharma (HB) - the maker of the drug - tried to get Ampligen approval in. The process, which took four years, began when HB teamed up with GP Pharm, an Argentine pharmaceutical company. GP Pharm used the same studies to shepherd the approval through ANMAT, the Argentine form of the FDA, that HB used in its FDA application for Ampligen two years ago.

Ampligen was approved for use in people with "severe ME/CFS" - a designation that was based on the type of ME/CFS patients that took part in the company's original U.S. studies. A person with severe ME/CFS in Argentina needs to meet the new IOM and the (old) Holmes criteria, and have a Karnovsky score between 40 and 60 in order to get access to the drug.

40: Disabled; requires special care and assistance.
50: Requires considerable assistance and frequent medical care.
60: Requires occasional assistance, but is able to care for most of his personal needs.

Hemispherx believes that at least 100,000 and perhaps as many as 500,000 patients in the 42 million person country will meet the criteria.

Equel's has been making the rounds of media outlets to discuss Ampligen. A financial analyst with Crystal Research agreed in an interview at Small Cap Nation - a financial media outlet focused on small companies - that the potential for Ampligen in the ME/CFS market alone was huge.

With Ampligen the sole drug even being considered at this point for ME/CFS it would have the market to itself. He called the Argentine approval "very significant" and put the potential valuation of the drug in the multi-billion dollar range.He also agreed the Argentine approval will make getting approval elsewhere easier.

The FDA question

I talked with Nancy McGrory at Hemispherx about the recent approval. She believes the approval could help HB in other countries with similar regulatory drug processes. The fact that Ampligen passed muster in a country with a modern medical system with a rigorous drug approval process will likely, McGrory thought, prompt other countries to take a much closer look at the drug.

Ten years ago, she noted, most pharmaceutical drug companies concentrated on getting drug approval at the FDA first in the belief that making it through the FDA's notoriously tough regulatory process would give other countries confidence that the drug was safe and effective. The FDA - which is focused first on protecting the public health - has proved so risk averse lately, though, that some drug companies are choosing to get drug approval outside the U.S. first.

That brought up the question, though, what's going with FDA approval for Ampligen? When I asked McGrory about the reception Ampligen was getting at the FDA these days, she sounded hopeful. She said she believed that the work of patients, advocates and ME/CFS experts to educate the FDA about ME/CFS had paid off. The FDA Workshop and other meetings, she believed, really got the message across about how serious disease is, and that produced a sea-change in the agencies attitude towards ME/CFS. The FDA she thought, would like very much to approve a drug for this illness.

Thomas Equels, HB's new President has made Ampligen approval the companies top priority and has stated that he will to do whatever is necessary to get it done. McGrory said HB officials have meet with the FDA and the NIH several times, and will soon meet to finalize the protocol for what will hopefully be the final phase III study on ME/CFS.

The FDA wants, and is going to get a several hundred person trial. Equel's job now is to find partners to fund it. The companies new stance - that it's committed to reach out and either license its technology or find a major pharmaceutical company or investor to assist it - is a distinct change of pace at HB.

In another hopeful note, Hemispherx reported it's at long last identified a subset of high responders to Ampligen and will present a paper to that effect at the IACFS/ME conference in October. Finding high responders to Ampligen would, of course, greatly help HB be successful in a phase III trial.

When asked in an extensive interview with Wall Street Transcript about what a potential investor should know about Ampligen Equels said:

It is very important to me that they know that we have worked diligently, over a long period of time, to develop this experimental drug, Ampligen, because we believe it has a multifaceted important role to play in the future of medicine in ME/CFS, immunooncology, as a viral-vaccine enhancer, and as a broad-spectrum prophylactic and early-onset viral therapy.

At Hemispherx, our team has the dedication to accomplishing those goals in large part based upon the fact that we have a strong and unrelenting belief that we are doing something that is very important for people who suffer from these diseases, many with clearly unmet medical needs. We are going to do our best to work, with what we have, to accelerate the process — in part by acquiring partners — so that we accomplish those goals.

Ampligen soon available in the European Union

Source: www.meaction.net/2015/08/10/ampligen-price-increases-substantially-available-soon-in-europe

Ampligen is a treatment for Chronic Fatigue Syndrome that has not yet been approved by the FDA. It is currently available to some patients at a limited number of sites around the US under a cost recovery program previously known as "compassionate care." It is delivered at a doctor's office via a twice weekly intravenous infusion.

Hemispherx also announced today that a Netherlands-based company called myTomorrows will be supplying Ampligen to some Chronic Fatigue Syndrome patients with "unmet medical need" through the Early Access Program (EAP).

Thomas K. Equels, Executive Vice Chairman and CFO of Hemispherx said

> "We are very pleased to be collaborating with myTomorrows to provide rintatolimod under these unique Early Access Programs. Not only will this collaboration create the possibility for physicians to use rintatolimod under certain circumstances, myTomorrows will collaborate with these physicians to capture data on patients treated and such data may add to our other efforts to gain full regulatory approval in Europe, Latin America, Australia, New Zealand as well as the U.S. and elsewhere."

The Guildford & West Surrey ME/CFS Group newsletters aim to inform members of relevant news and treatment options. Use of the treatments is done at your own risk.