



Ethical classification of ME/CFS in the United Kingdom

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Abstract

Few conditions have sparked as much controversy as myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS). Professional consensus has long suggested that the condition should be classified as psychiatric, while patients and advocacy groups have insisted it is a serious biological disease that requires medical care and research to develop it. This longstanding debate shifted in 2015, when U.S. governmental health authorities fully embraced medical classification and management. Given that some globally respected health authorities now insist that ME/CFS is a serious biological disease, this paper asks whether it can be ethical for the U.K. practice guideline now in development to characterize the condition as a mental health disorder. Following a brief history of ME/CFS controversy, I offer three arguments to show that it would be unethical for the U.K. to now characterize ME/CFS as a mental health condition, considering the relevance of that conclusion for ME/CFS guidelines elsewhere and for other contested conditions.

KEYWORDS

informed consent, ME/CFS, philosophical ethics, policy guidelines, right to healthcare

1 | INTRODUCTION

Few conditions have sparked as much controversy, publicly or professionally, as myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS). Indeed the name itself reflects a dispute, as those who prefer the label from the International Classification of Diseases, 'myalgic encephalomyelitis' (ME),¹ continue to do battle with those who prefer the term 'chronic fatigue syndrome' (CFS), adopted by the U.S. Centers for Disease Control (CDC) in 1994.² This is not just a matter of choosing the best name. These two labels reflect sharply opposed perspectives on the nature and management of the condition.

The crux of the dispute is a matter of mind vs. body, uncomfortable as that may be for those of us who embrace a holistic approach to medical practice. Since the 1990s, medical and mental health professionals have shared a general consensus that ME/CFS is best categorized within psychiatry, and best managed with mental health strategies,

chiefly cognitive behavioral therapy (CBT) and graded exercise therapy (GET).³ Patients and advocacy groups, however, have vocally resisted that characterization, pointing to research that suggests the symptoms of ME/CFS – including disabling fatigue, pain, neurocognitive impairment, sleep disturbance, and gastric distress⁴ – arise from a biological disease that requires medical treatment, and research to develop it.⁵

³Harvey, S. B., & Wessely, S. (2009). Chronic fatigue syndrome: Identifying zebras amongst the horses. *BMC Medicine*, 7(58), <https://doi.org/10.1186/1741-7015-7-58>; Sohl, S. J., & Friedberg, F. (2008). Memory for fatigue in chronic fatigue syndrome: Relationships to fatigue variability, catastrophizing, and negative affect. *Behavioral Medicine*, 34(1), 29–38. Norwegian Institute of Public Health. (2006). *Systematic review executive summary: Diagnosis and treatment of chronic fatigue syndrome/myalgic encephalopathy (CFS/ME)*. Retrieved from: <https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0097697/>.

⁴Carruthers, B. M., van de Sande, M. I., De Meirleir, K. L., Klimas, N. G., Broderick, G., Mitchell, T., ... Stevens, S. (2011). Myalgic encephalomyelitis: International consensus criteria. *Journal of Internal Medicine*, 270, 327–338.

⁵Maes, M., & Twisk, F. N. (2010). Chronic fatigue syndrome: Harvey and Wessely's (bio) psychosocial model versus a bio(psychosocial) model based on inflammatory and oxidative and nitrosative stress pathways. *BMC Medicine*, 8(35), <https://doi.org/10.1186/1741-7015-8-35>; Hornig, M., Montoya, J. G., Klimas, N. G., Levine, S., Felsenstein, D., Bateman, L., ... Lipkin, W. I. (2015). Distinct plasma immune signatures in ME/CFS are present early in the course of the illness. *Science Advances*, 1(1), e1400121; Baraniuk, J. N., Casado, B., Maibach, H., Clauw, D. J., Pannell, L. K., & Hess, S. S. (2005). A chronic fatigue syndrome-related proteome in human cerebrospinal fluid. *BMC Neurology*, 5(22), <https://doi.org/10.1186/1471-2377-5-22>.

¹World Health Organization. (2016). *International classification of diseases, Tenth revision*. Retrieved from: <http://apps.who.int/classifications/icd10/browse/2016/en#/G93.0>.

²Centers for Disease Control and Prevention. (2012). *Chronic fatigue syndrome: 1994 case definition*. Retrieved from: <http://www.cdc.gov/cfs/case-definition/1994.html>.

The battle that has developed over ME/CFS holds valuable lessons for bioethics. We have witnessed a decades-long clash between patient and professional perspectives on the existence of disease. On one level it has been a struggle about patient credibility.⁶ On another level, it has been a battle about expertise, as ME/CFS advocates have demanded a place at the table when it comes to knowledge formation about this condition,⁷ taking cues from HIV/AIDS advocacy.⁸ But that is not the end of the story.

In what can only be described as an astonishing sociomedical transformation, battle lines for the debate have now shifted. In December 2014, the U.S. National Institute of Health concluded, 'although psychological repercussions (i.e., depression) may accompany ME/CFS, it is not a primary psychological disease in etiology'.⁹ In January 2015, the U.S. Institute of Medicine (now National Academy of Medicine) published the results of its extensive investigation into the issue, concluding:

ME/CFS is a serious, chronic, complex systemic disease ... Many health care providers are skeptical about the seriousness of ME/CFS, mistake it for a mental health condition, or consider it a figment of the patient's imagination ... The committee stresses that health care providers should acknowledge ME/CFS as a serious illness that requires timely diagnosis and appropriate care.¹⁰

Finally, based on these reports, in August 2015 the U.S. Chronic Fatigue Syndrome Advisory Committee recommended that guidance for managing ME/CFS should include a 'declaration that the disease is not the result of fear-based avoidance of activity', and 'a clear indication that the disease is not a psychiatric or somatoform disorder'.¹¹

In effect, the U.S. reversal of opinion asserts that the patient perspective on ME/CFS was correct all along – so what used to be a chasm between patient and professional perspectives has now become a chasm between professionals who accept the biological

orientation to the condition and professionals who continue to embrace the former consensus on psychiatric etiology and management. This shift raises new ethical questions that are pressing.

This paper investigates ethical ramifications of the dissolution of professional consensus about ME/CFS as they bear on the new practice guideline in development in the U.K. by the National Institute for Health and Care Excellence (NICE). Given that some globally respected health authorities are now convinced about the presence of serious biological disease in patients with ME/CFS, can it be ethical for NICE to continue to characterize ME/CFS as a mental health disorder, directing patient care wholly down the mental health track?

The U.K.'s current NICE guideline for ME/CFS was implemented in 2007.¹² Though it carefully avoids a direct answer to the question of etiology, the guideline takes an unequivocal stance in favor of a mental health characterization and approach to management. The National Health Service puts NICE recommendations in context for patients with this current explanation:

CBT is a talking treatment that can help you manage CFS/ME by changing the way you think and behave ... It can help you to ... challenge feelings that could prevent your symptoms from improving ... and gain a better understanding of how your behaviour can affect the condition.¹³

Although the current UK approach was well aligned with global professional consensus in 2007, it now contradicts U.S. recommendations.¹⁴

Faced with public pressure to revise the guideline in light of the new U.S. approach, NICE initially decided against it,¹⁵ but reversed that decision in September 2017 to initiate the revision process.¹⁶ At this time it remains unclear what direction revisions will take. Is NICE free to do what it chooses with the new guideline? Would it be ethical to continue to characterize ME/CFS as a mental health condition or does the U.S. position mean that, in the words of the Chronic Fatigue Syndrome Advisory Committee, doing so would be 'an injustice to all concerned'?¹⁷

To begin, I briefly address conceptual confusions about mind and body as they pertain to ME/CFS, then I discuss the guideline in the

⁶Blease, C., Carel, H., & Geraghty, K. (2017). Epistemic injustice in healthcare encounters: Evidence from chronic fatigue syndrome. *Journal of Medical Ethics*, 43, 549–557.

⁷Ankeny, R. A., & Mackenzie, F. J. (2016). Three approaches to chronic fatigue syndrome in the United Kingdom, Australia, and Canada: Lessons for democratic policy. In S. Dodds & R. A. Ankeny (Eds.), *Big picture bioethics: Developing democratic policy in contested domains* (pp. 227–243). Cham, Switzerland: Springer; Calon, M. & Rabeharisoa, V. (2003). Research 'in the wild' and the shaping of new social identities. *Technology and Society*, 25(2), 193–204.

⁸Epstein, S. (1995). The construction of lay expertise: AIDS activism and the forging of credibility in the reform of clinical trials. *Science, Technology and Human Values*, 20(4), 408–437.

⁹Green, C. R., Cowan, P., Elk, R., O'Neil, K. M., & Rasmussen, A. L. (2015). National Institutes of Health Pathways to Prevention Workshop: Advancing the research on myalgic encephalomyelitis/chronic fatigue syndrome. *Annals of Internal Medicine*, 162(12), 860–865.

¹⁰Institute of Medicine. (2015). *Beyond myalgic encephalomyelitis/chronic fatigue syndrome: Redefining an illness, report brief*. Retrieved from: <http://www.nationalacademies.org/hmd/Reports/2015/ME-CFS.aspx>.

¹¹Chronic Fatigue Syndrome Advisory Committee. (2015). Recommendations from the HHS CFSAC. Retrieved from: <https://www.hhs.gov/sites/default/files/advcomcfs/recommendations/2015-08-18-19-recommendations.pdf>.

¹²National Institute for Health and Clinical Excellence Guideline Development Group. (2007). *Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy)*. Retrieved from: <https://www.nice.org.uk/guidance/cg53>.

¹³National Health Service. (2018). *NHS choices: Chronic fatigue syndrome*. Retrieved from: <https://www.nhs.uk/conditions/chronic-fatigue-syndrome-cfs/treatment/>.

¹⁴CFSAC, *op. cit.* note 11, p. 14.

¹⁵National Institute for Health and Clinical Excellence. (2017). *Surveillance proposal consultation document: Chronic fatigue syndrome/myalgic encephalomyelitis*. Retrieved from: <https://www.nice.org.uk/guidance/cg53/documents/surveillance-review-proposal>.

¹⁶National Institute for Health and Clinical Excellence. (2017). *Surveillance report 2017: Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): Diagnosis and management (2007) NICE guideline CG53*. Retrieved from: <https://www.nice.org.uk/guidance/cg53/resources/surveillance-report-2017-chronic-fatigue-syndromemyalgic-encephalomyelitis-or-encephalopathy-diagnosis-and-management-2007-nice-guideline-cg53-pdf-5964455783941>.

¹⁷CFSAC, *op. cit.* note 11, p. 2.

context of heated controversy over the U.K.'s 'PACE trial',¹⁸ which established the mental health approach as the gold standard across the globe. I turn then to support three reasons why it would be unethical for the new NICE guideline to classify ME/CFS as a mental health condition. Finally, I consider new guidelines for ME/CFS outside the U.K., and the broader issue of ethical guidelines for other contested conditions whose status as medical diseases is hotly debated.

2 | SETTING ASIDE QUESTIONS RELATED TO DUALISM

It is important to acknowledge, first, that this paper proceeds as if it is unproblematic to mark a clear distinction between the idea that ME/CFS is a biological medical condition and the idea that it is a mental health condition. I choose this approach with awareness that both bioethics and medicine often resist a crisp distinction between biological and mental etiology. Based on the biopsychosocial model, it seems we should do our best to avoid language that implies a Cartesian mind–body duality.¹⁹

I support this approach primarily by noting that, in the context of philosophy, eliminating dualism is not about eliminating dualistic language. Dualistic and non-dualistic philosophers both comfortably accept dualistic language as the phenomenon that needs explaining, then they advance ideas about how best to explain it. For example, we can understand mental, or psychosocial, etiology to be neurobiological in the end of the day, where the ultimate source of the problem is brain states that correlate with psychosocial distress.²⁰ In this sense, though the language of 'mental vs. biological etiology' sounds like Cartesian dualism, we have conceptual understanding in place that allows us to work with the distinction in a non-Cartesian way.

There are strong reasons for thinking it's better to maintain the distinction than to encourage vagueness about etiology.²¹ Whatever our conceptual goals might be, the practical difference between medical care and mental health care remains sharp – and patients in need of medical care continue to suffer when they do not receive it. Though patients on both sides of the divide can sometimes benefit from management on the other side, it will always be a mistake to

provide only mental health care to patients who need biological medical care. For these reasons, I will proceed as if it is unproblematic to distinguish between the idea that ME/CFS is a mental health condition and the idea that it is a biological medical disease.

Second, though the grey area where mind and body overlap is larger and more complex than medicine has traditionally appreciated, the U.S. position on ME/CFS means that it will not be necessary to explore that territory further in this paper. U.S. health authorities are not asserting that physicians and policy makers should take ME/CFS seriously as an illness even if it lacks the biological basis that supports construing a condition as a medical disease.²² They are not asserting, moreover, that ME/CFS should be construed as biological because in the end of the day all mental health conditions are correlated with biological pathologies in the brain.²³ What U.S. health authorities now assert is that ME/CFS needs to be pulled out of the grey conceptual area where mind and body overlap, and placed squarely in the territory of biological disease alongside conditions like cancer, heart disease, and diabetes. Given the strength and clarity of that claim, this paper is focused on the question of whether it can be ethical for the U.K. to characterize ME/CFS as a mental health condition, framing the context for care within mental health.

Third, I should acknowledge that in this paper I will accept a *prima facie* tie between the confirmed presence of disease and the need for general access to medical care, that is, general medical support and testing and treatment as needed. In doing so I do not imply that patients with biological medical conditions always do require biological testing and treatment. It is clear that disease is sometimes best managed with mental health solutions like talk therapy, mindfulness meditation, or stress reduction. It remains the case, however, that when patients with disease can benefit from a non-biological approach, physicians do not actually shift their orientation to the mental health track. When the presence of disease is confirmed, mental health approaches are offered within a framework that continues to recognize the biological bottom line and the resulting importance of ongoing access to medical care.

The *prima facie* tie between disease and the need for access to medical care arises not from bioethical principles or concepts, but from a primary, perhaps even primal understanding of medical practice that is shared in societies where a broad right to health is recognized.²⁴ This understanding remains in place in countries like the U.K., which provide universal healthcare, and countries like the United States, which do not.²⁵ It remains in place when we support a traditional biological model of medical practice, and when we reject it in favor of a holistic approach that integrates mind and body. In all

¹⁸White, P., Goldsmith, K., Johnson, A., Potts, L., Walwyn, R., DeCesare, J. C., ... Sharpe, M. (2011). PACE trial management group. Comparison of adaptive pacing therapy, cognitive behaviour therapy, graded exercise therapy, and specialist medical care for chronic fatigue syndrome (PACE): A randomised trial. *Lancet*, 377(9768), 823–836.

¹⁹Duncan G. (2000). Mind-body dualism and the biopsychosocial model of pain: What did Descartes really say? *Journal of Medicine and Philosophy*, 25(4), 485–513.

²⁰Walitt, B., Ceko, M., Gracely, J. L., & Gracely, R. H. (2016). Neuroimaging of central sensitivity syndromes: Key insights from the scientific literature. *Current Rheumatology Reports*, 12(1), 55–87; Allendorfer, J. B., & Szaflarski, J. P. (2014). Contributions of fMRI toward our understanding of the response to psychosocial stress in epilepsy and psychogenic nonepileptic seizures. *Epilepsy and Behavior*, 35, 19–25; Aybek, S., & Vuilleumier, P. (2016). Imaging studies of functional neurologic disorders. *Handbook of Clinical Neurology*, 139, 73–84.

²¹O'Leary, D. (2018). Why bioethics should be concerned with medically unexplained symptoms. *American Journal of Bioethics*, 18(5), 6–15.

²²Stone, J., Carson, A., & Hallett, M. (2016). Explanation as treatment for functional neurologic disorders. *Handbook of Clinical Neurology*, 139, 542–553.

²³Sullivan, M. D. (2017). Psychogenic pain old and new. In J. Corns (Ed.), *The Routledge handbook of philosophy of pain* (pp. 165–174). New York, NY: Routledge.

²⁴Office of the United Nations High Commissioner for Human Rights and World Health Organization. (2018). *The right to health: Fact sheet No. 31*. Retrieved from: <http://www.ohchr.org/Documents/Publications/Factsheet31.pdf>.

²⁵U.S. Department of State. (2018). *Observations by the United States of America on 'The Right to Health'*. Retrieved from: <https://www.state.gov/documents/organization/138850.pdf>.

of these contexts the confirmed presence of disease continues to indicate a prima facie need for access to medical care. What remains unclear in the context of ME/CFS is how we should make sense of the need for access to medical care with conditions whose status as diseases is disputed.

3 | THE NICE GUIDELINE IN THE CONTEXT OF 'PACE-GATE'

Before we can consider how NICE's guideline revisions are constrained by the dissolution of consensus, it is important, first, to be clear about the organization's goals and foundations. The National Institute for Health and Clinical Excellence is 'an independent organisation responsible for providing national advice ('guidance') on promoting good health and preventing and treating ill health'.²⁶ NICE directly articulates its approach to guideline development for confusing conditions:

When developing guidance ... NICE bases its decisions on the best available evidence. This evidence is not always of good quality and is hardly ever complete. Those developing NICE's guidance are therefore inevitably required to make judgements ... of two types. Scientific value judgements are about interpreting the quality and significance of the evidence available; social value judgements relate to society rather than science.²⁷

ME/CFS is certainly a condition for which judgment will be required. Much of that judgment will involve available scientific evidence, and much of it will involve 'social value judgments'. It is important to note that in the document *Social value judgements*, NICE unequivocally grounds its value judgments in the basic bioethical principles of 'respect for autonomy, non-maleficence, beneficence and distributive justice'.²⁸

Second, it is important to note that the U.K. is not just another setting where national health authorities struggle with the dissolution of professional consensus on ME/CFS. It is the conceptual home of the mental health approach to the condition. Based on a 1996 report by the Royal Colleges of Physicians, Psychiatrists and General Practitioners,²⁹ in 2005 U.K. researchers began recruiting for the 'PACE' trial ('Pacing, graded Activity, and Cognitive behaviour therapy; a randomised Evaluation'), a government funded endeavor, and the largest ever study on the effectiveness of CBT and graded exercise therapy for ME/CFS. Since publication of that

study's results in the Lancet in 2011,³⁰ PACE has served as the foundation for public perception and professional management of ME/CFS across the globe. The 2007 NICE guideline is tightly aligned with PACE conclusions, so when we address the question of ethical guideline revision in this context, we address it in a setting where the mental health approach has had its most powerful support.

As far as U.S. health authorities are concerned, there are serious problems with the PACE trial, and these arise in part from the 'Oxford definition' of ME/CFS³¹ that determined the study's participants. The IOM concluded that the Oxford definition is far too broad to pin down the group of patients who actually suffer from the condition, insisting criteria should be restricted to include only those with serious exertion intolerance.³² The AHRQ then took the IOM's refined definition as a starting point for re-evaluation of the study's results, concluding that 'there is low strength evidence ... that CBT ... provides improvement in fatigue, function, quality of life, and employment in adult patients with ME/CFS'.³³ With respect to PACE's support for graded exercise therapy (GET), the AHRQ notes three distinct forms of bias, and evidence suggesting that GET can actually cause harm to ME/CFS patients.³⁴

None of this begins to characterize the storm of public and professional vitriol that continues to expand around 'PACE-gate'.³⁵ Public concern about the trials heated up in 2015 with detailed critical examination by health journalist David Tuller.³⁶ This led to an open letter to The Lancet that year, signed by six prominent scientific professionals, detailing charges of unscientific practices, and demanding 'an independent re-analysis of the individual-level PACE trial data'.³⁷ That was followed by another letter signed by three dozen prominent scientific professionals.³⁸ PACE researchers' resistance to releasing the data³⁹ was ultimately unsuccessful when courts failed to find evidence supporting their concern about likely harassment by patients and advocacy organizations.⁴⁰ Once re-

³⁰White et al., *op. cit.* note 18.

³¹Sharpe, M. C., Archard, L. C., Banatvala, J. E., Borysiewicz, L. K., Clare, A. W., David, A., ... Lane, R. J. (1991). A report - chronic fatigue syndrome: Guidelines for research. *Journal of the Royal Society of Medicine*, 84(2), 118-121.

³²Institute of Medicine, *op. cit.* note 10, pp. 209-228.

³³Agency for Healthcare and Research Quality. (2016). *Diagnosis and treatment of myalgic encephalomyelitis/chronic fatigue syndrome, Addendum 2016*. Retrieved from: https://ahrq-ehc-application.s3.amazonaws.com/media/pdf/chronic-fatigue_research.pdf.

³⁴Ibid: 53.

³⁵Geraghty, K. J. (2017). Pace-gate: When clinical trial evidence meets open data access. *Journal of Health Psychology*, 22(9), 1106-1112.

³⁶Tuller, D. (2015). *Trial by error: The troubling case of the PACE chronic fatigue syndrome study*. Retrieved from: <http://www.virology.ws/2015/10/21/trial-by-error-ii/>.

³⁷Davis, R. W., Edwards, J. C. W., Jason, L. A., Levin, B., Racaniello, V. R., & Reingold, A. L. (2015). *An open letter to Dr. Richard Horton and the Lancet*. Retrieved from: <http://www.virology.ws/2015/11/13/an-open-letter-to-dr-richard-horton-and-the-lancet/>.

³⁸Davis, R. W., Edwards, J. C. W., Jason, L. A., Levin, B., Racaniello, V. R., Reingold, A. L., ... Zinn, M. (2016). *An open letter to the Lancet - again*. Retrieved from: <http://www.virology.ws/2016/02/10/open-letter-lancet-again/>.

³⁹White, P. D., Chalder, T., & Sharpe, M. (2016). *Releasing patient data from the PACE trial for chronic fatigue syndrome*. Retrieved from: <http://blogs.bmj.com/bmj/2016/09/22/peter-white-et-al-releasing-patient-data-from-the-pace-trial-for-chronic-fatigue-syndrome/>.

⁴⁰Tribunals Judiciary. (2016). *Queen Mary University of London v Information Commissioner, First-Tier Tribunal Appeal Number EA/2015/0269*. Retrieved from: <http://informationrights.decisions.tribunals.gov.uk/Public/searchresults.aspx>.

²⁶National Institute for Health and Clinical Excellence. (2008). *Social value judgements: Principles for the development of NICE guidance* (2nd ed.). Retrieved from: <https://www.nice.org.uk/media/default/about/what-we-do/research-and-development/social-value-judgements-principles-for-the-development-of-nice-guidance.pdf>.

²⁷Ibid: 4.

²⁸Ibid: 8.

²⁹Royal Colleges of Physicians, Psychiatrists and General Practitioners. (1996). *Chronic fatigue syndrome: Report of a joint working group of the Royal Colleges of Physicians, Psychiatrists and General Practitioners*. Retrieved from: https://me-pedia.org/images/7/71/1996_UK_Chronic_Fatigue_Syndrome_report.pdf.



leased, a preliminary re-analysis concluded, 'the claim that patients can recover as a result of CBT and GET is not justified by the data'.⁴¹ That led to a third⁴² and fourth⁴³ letter, this time to the *Journal of Psychological Medicine*, now with 140 professional signatures.

In July of 2017 the *Journal of Health Psychology* devoted a whole issue to PACE-gate, lamenting original researchers' refusal to fully participate.⁴⁴ By August 2017 debate about PACE among U.K. professionals had become so intense that the *Times* described it as 'an acrimonious scientific row': 'The dispute led to mass resignations and an exchange of insults so intense that in emails seen by *The Times* one scientist referred to another as a "disgusting old fart neo-liberal hypocrite".⁴⁵ That row is far from resolved. In August 2018, the *Times* reported that a new open letter demanding re-analysis by the *Lancet* has the backing of 'more than a hundred academics ... ten MPs, and scores of patient groups from around the world'.⁴⁶

Controversy about PACE raises pressing ethical questions. Given the magnitude and number of challenges to the science behind PACE, and the authoritative positions of its critics, why did this study pass peer review? If the United States is correct that ME/CFS patients are in need of medical care, and they are also correct that the recommendation to deny care has been based on compromised scientific standards, then PACE-gate presents us with an extraordinary phenomenon, where the research-to-guidelines system has actually obstructed access to medical care for millions of patients in need. No matter what conclusions we personally embrace about the PACE trial, it's clear this is an area where ethical discourse is sorely needed.

PACE-gate, and the U.S. conclusion about it, are the most substantial factors driving the need for NICE guideline revision, and this raises obvious ethical concerns. NICE has long maintained close ties to PACE researchers and advisors, who continue to hold authoritative positions with U.K. medical and mental health organizations. As an organization committed to evidence-based conclusions that meet bioethical standards, it is reasonable to hope that NICE can manage the challenge of an 'acrimonious scientific row' with a focus on patient safety and well-being. It is also reasonable to note, though, how difficult it would be for any professional to acknowledge error at the magnitude of PACE-gate.

⁴¹Wilshire, C., Kindlon, T., Mathees, A., & McGrath, S. (2017). Can patients with chronic fatigue syndrome really recover after graded exercise or cognitive behavioural therapy? A critical commentary and preliminary re-analysis of the PACE trial. *Fatigue: Biomedicine, Health & Behavior*, 5(1), 43–56.

⁴²Ablashi, D., Baraniuk, J., Barcellos, L., Bateman, L. Bested, A. C., Brown, M., ... Zinn, M. (2017). An open letter to *Psychological Medicine* about 'recovery' and the PACE trial. Retrieved from: <http://www.virology.ws/2017/03/13/an-open-letter-to-psychological-medicine-about-recovery-and-the-pace-trial/>.

⁴³Ablashi, D., Baraniuk, J., Barcellos, L., Bateman, L. Bested, A. C., Brown, M., ... Zinn, M. (2017). An open letter to *Psychological Medicine* again! Retrieved from: <http://www.virology.ws/2017/03/23/an-open-letter-to-psychological-medicine-again/>.

⁴⁴Marks, D. (2017). Special issue on the PACE Trial. *Journal of Health Psychology*, 22(9), 1103–1105.

⁴⁵Whipple, T. (2017, Aug 1). Scientists trade insults over myalgic encephalomyelitis (ME) study. *The Times*. Retrieved from: <https://www.thetimes.co.uk/article/scientists-trade-insults-over-myalgic-encephalomyelitis-me-study-slk0cv5lj>.

⁴⁶Whipple, T. (2018, Aug 21). Call for review of 'flawed' ME research in *Lancet* letter. *The Times*. Retrieved from: <https://www.thetimes.co.uk/article/call-for-review-of-flawed-me-research-in-lancet-letter-l75rvcpnrh>.

4 | ETHICAL CONSTRAINTS ON GUIDELINE REVISIONS

What constraints does the dissolution of professional consensus on ME/CFS create for NICE's revision of the ME/CFS guideline? First, it is important to clarify that physicians in one nation are not obligated to adopt the practices of physicians in another nation purely on the basis of the other nation's medical authority. In this sense, NICE professionals are free to make their own determinations about how best to approach classification and management of ME/CFS.

It is also important to point out, however, that NICE's mission does constrain the range of acceptable responses to the U.S. reversal of opinion.⁴⁷ NICE has an obligation to make sure guidelines reflect an unbiased, evidence-based picture of current understanding about how best to improve patients' health. Because current understanding of ME/CFS is sharply divided, it seems clear that if revisions do not embrace U.S. conclusions, they must at least remain neutral. They must present, in an accurate and neutral way, the current state of dispute about etiology and management.

Second, given the U.S. reversal of opinion, the current guideline raises concerns about informed consent, and these strongly constrain the nature of revisions.⁴⁸ In 2007, patients gave informed consent to CBT and GET when informed of NICE policy makers' conclusions about safety and effectiveness, because those conclusions reflected general medical consensus. In 2018, however, U.S. health authorities insist those recommendations are unsupported, with some concern that they might actually lead to harm. NICE's commitment to basic bioethical principles – including, specifically, informed consent⁴⁹ – demands that patients be informed about both sides of this debate, even if NICE professionals are themselves convinced about the value of CBT and GET. For this reason, again, if the guideline does not embrace the new U.S. position, it must at least convey, in a neutral, unbiased way, the current state of dispute about etiology and management.

Third, as I noted in Section 1, the confirmed presence of disease indicates a *prima facie* need for access to medical care, including general medical support and testing and treatment as needed. This is not a matter of debate. What is unclear in the context of ME/CFS is how we should understand the need for access to medical care with conditions whose status as diseases is deeply disputed. I suggest that, while the U.S. conclusion does not prove that ME/CFS patients suffer biological harms that require medical care, it does prove that there is a substantial possibility that they do – and this possibility is enough to establish patients' foundational right to access general biological medical care from their doctors.

Much of the debate about ME/CFS has been centered on the question of whether research has proven a need for biological

⁴⁷National Institute for Health and Clinical Excellence. (2017). *Charter*. Retrieved from: https://www.nice.org.uk/Media/Default/About/Who-we-are/NICE_Charter.pdf.

⁴⁸Geraghty, K. J. (2016). Cognitive behavioural therapy in the treatment of chronic fatigue syndrome: A narrative review on efficacy and informed consent. *Journal of Health Psychology*, 23(1), 127–138.

⁴⁹NICE, *op. cit.* note 26, p. 8.

medical care. Patients and advocacy organizations have insisted that research has reached that bar, while medical and mental health professionals have insisted that it has not. U.S. health authorities finally agreed with patients and advocacy organizations in 2015, but some professionals continue to believe that medical need remains unproven, and this conclusion is generally understood to justify a mental health approach to diagnosis and management.⁵⁰ That reasoning is confused, and in fact the debate itself is misplaced, because the bar that typically establishes a patient's basic right to access medical care from her doctor is not as high as proof of need.

Outside the contested terrain of ME/CFS, physicians, bioethicists, and policy makers unanimously recognize that patients have a basic right to access medical care from their doctors, not only when their need for it has been proven, but in every case where medical need is a substantial possibility. Indeed, it is hard to imagine what everyday medical care would involve if physicians provided medical support, testing, and treatment only to patients whose need for them had been proven. It is unreasonable, and indeed unethical, to set the bar for general access to biological medical care uniquely high for patients with ME/CFS.

At the level of policy we can see this clearly with a hypothetical example related to irritable bowel syndrome (IBS), which is biologically unexplained and very often classified in psychiatry rather than medicine.⁵¹ Suppose U.S. governmental health organizations had concluded that IBS is caused by a bacterial infection that poses serious, previously unrecognized health risks, revising recommendations to ensure that patients receive medical care. In countries then considering the issue, would it be ethical to adopt guidelines that classify IBS in psychiatry, framing the context for care in mental health?

When we consider this issue outside the contested terrain of ME/CFS it is easier to recognize the ethical imperative to address risk of harm in cases of deep diagnostic dispute. A conclusion by U.S. health authorities about disease in IBS would establish a substantial possibility of medical harm, and so it would establish a substantial possibility of medical need. That possibility, all on its own, would mean that practice guidelines elsewhere have an obligation to avoid systematic obstruction of patients' access to medical care. Similarly, no matter what conclusions NICE professionals reach about medical harm with ME/CFS, the possibility of medical harm will remain, and that will establish that it is unethical to obstruct patients' access to medical care.

It is important to note that, because many diseases do benefit from mental health care, there is nothing unethical about the suggestion that mental health approaches could improve the

biological disease, or possible biological disease, of ME/CFS – as long as access to general medical support is simultaneously protected. The possibility of disease means it would not be ethical to characterize ME/CFS as a mental health condition. It does not mean that mental health care cannot be as productive for ME/CFS patients as it can be for patients with any other form of disease or possible disease.

Finally, it is helpful to clarify that, while 'obstructed access to medical care' can be complicated when symptoms might have psychosocial etiology, those complications do not mitigate the seriousness of denying medical care to patients who might need it. It is possible, for example, to provide care for symptoms along the medical track and the mental health track simultaneously, and when that's the case, access to medical care is not obstructed. It is also possible to provide medical care for some symptoms and not others,⁵² or for symptoms at a lower level of pain or bodily distress and not a higher level.⁵³ In that case, access to care for some symptoms, or for a higher level of pain or bodily distress, would be obstructed, perhaps correctly. No matter where we prefer to draw the line between symptoms that need medical care and symptoms that need mental health care, it will continue to be a medical mistake and an ethical problem to fail to provide medical care to patients who need it.

While NICE has no obligation to adopt U.S. conclusions about ME/CFS, I have argued that, based first on NICE's mission, and second on its commitment to informed consent, if the new guideline does not do so, it must fully convey, without bias, the reality of professional debate about etiology and management. Third, based on the principle that patients' foundational right to access medical care from their doctors depends not on proof of need but on a substantial possibility of need, I have argued that it would be unethical for the guideline to characterize ME/CFS as a mental health condition. If NICE does choose to remain neutral on the debate, it must resist the very common temptation to obscure the boundaries between medical uncertainty and mental health diagnosis. A neutral NICE guideline must meticulously avoid language that encourages practitioners and patients to construe ME/CFS as a psychiatric disorder.

5 | CONCLUSIONS

The first two points I've raised about ethical constraints on NICE guideline revisions for ME/CFS might not apply outside the U.K. in other countries now grappling with the dissolution of professional consensus. First, in some nations practice guidelines might be

⁵⁰NICE, *op. cit.* note 15.

⁵¹Community and Mental Health Team, NHS Digital. (2018). *Improving access to psychological therapies (IAPT): Report on integrated IAPT services pilot*. Retrieved from <https://files.digital.nhs.uk/27/D28972/iapt-int-rep-jan-2018-exec-sum.pdf>; Goldberg, D. P., Reed, G. M., & Robles, R. (2016). Multiple somatic symptoms in primary care: A field study for ICD-11 PHC. WHO's revised classification of mental disorders in primary care settings. *Journal of Psychosomatic Research*, 91, 48–54.

⁵²American Psychiatric Association. (2013). *Somatic symptom and related disorders*. In *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.). Arlington, VA: American Psychiatric Publishing.

⁵³Rosendal, M., Olde Hartman, T. C., Aamland, A., van der Horst, H., Lucassen, P., Budtz-Lilly, A., & Burton, B. (2017). 'Medically unexplained' symptoms and symptom disorders in primary care: Prognosis-based recognition and classification. *BMC Family Practice*, 18(18), <https://doi.org/10.1186/s12875-017-0592-6>.

developed by organizations that do not share NICE's basic mission, which demands an accurate, unbiased picture of current professional understanding. Second, guideline development in some nations carries a lesser commitment to informed consent, so NICE's obligation to inform patients and professionals about the new U.S. position might not have the same force outside the U.K.

My third point, however, poses an ethical problem for every country with a guideline that now characterizes ME/CFS as a mental health condition. I have suggested that, as a general rule, patients who face a substantial possibility of harm from disease have a foundational right to access biological medical care from their doctors. The new U.S. position establishes that patients with ME/CFS do face that possibility of harm: so as long as we accept this foundational right, we must also accept that it is unethical to classify ME/CFS as a mental health condition.

Conclusions about ethical guidelines for ME/CFS have ramifications for many other conditions whose status as diseases is now debated. Scientific support for the biological reality of long-term Lyme disease, for example, has reached a level that is impossible to ignore,⁵⁴ and the World Health Organization has recognized this with new medical diagnostic codes for long-term Lyme in the International Classification of Diseases. Ironically, the U.S. CDC led the way in opposing medical classification of long-term Lyme. Because the WHO has established a substantial possibility of medical harm from long-term Lyme disease, it seems the CDC now faces an ethical problem with its practice recommendations.⁵⁵

Similar challenges loom on the horizon based on disputes about the biological reality of chronic pain syndrome,⁵⁶ fibromyalgia,⁵⁷ irritable bowel syndrome,⁵⁸ and mitochondrial disorders.⁵⁹ As NICE points out, when conditions lack definitive scientific consensus, policy decisions must rely largely on ethical judgments. For this reason, it is immensely important for bioethicists to finally weigh in on public debate about the right to biological medical care for contested conditions. Few issues in

medicine have generated more insistent public concern, and as professional support for medical construal of these conditions gathers momentum, the need for ethical clarity becomes increasingly pressing.

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CONFLICT OF INTEREST

The author declares no conflict of interest.

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⁵⁴Maccalini, P., Bonin, S., & Trevisan, G. (2018). Autoimmunity against a glycolytic enzyme as a possible cause for persistent symptoms in Lyme disease. *Medical Hypotheses*, 110, 1-8; Feng, J., Wang, T., Shi, W., Zhang, S., Sullivan, D., Auwaerter, P. G., & Zhang, Y. (2014). Identification of novel activity against *Borrelia burgdorferi* persists using an FDA approved drug library. *Emerging Microbes and Infections*, 3, e49.

⁵⁵Centers for Disease Control. (2018). *Lyme disease*. Retrieved from: <https://www.cdc.gov/lyme/index.html>.

⁵⁶Pustilnik, A. (2017). Legal evidence of subjective states: A brain-based model of chronic pain increases accuracy and fairness in law. *Harvard Review of Psychiatry*, 25(6), 279-288.

⁵⁷Hauser, W., Burgmer, M., Killner, V., Schaefer, R., Eich, W., Hausteiner-Wiehle, C., & Henningsen, P. (2013). [Fibromyalgia syndrome as a psychosomatic disorder: Diagnosis and therapy according to current evidence-based guidelines]. *Zeitschrift für Psychosomatische Medizin und Psychotherapie*, 59(2), 132-152; Rice, D. A., Parker, R. S., Lewis, G. N., Kluger, M. T., & McNair, P. J. (2017). Pain catastrophizing is not associated with spinal nociceptive processing in people with chronic widespread pain. *Clinical Journal of Pain*, 33(9), 804-810.

⁵⁸Eriksson, E. M., Andren, K. I., Kurlberg, G. K., & Eriksson, T. (2015). Aspects of the non-pharmacological treatment of irritable bowel syndrome. *World Journal of Gastroenterology*, 21(40), 11439-11449.

⁵⁹Eichner, M. (2015, July 11). The new child abuse panic. *The New York Times*. Retrieved from: <https://www.nytimes.com/2015/07/12/opinion/sunday/the-new-child-abuse-panic.html>; Eichner, M. (2016). Bad Medicine: Parents, the state, and the charge of 'medical child abuse'. *University of California Davis Law Review*, 50(1), 205-320.