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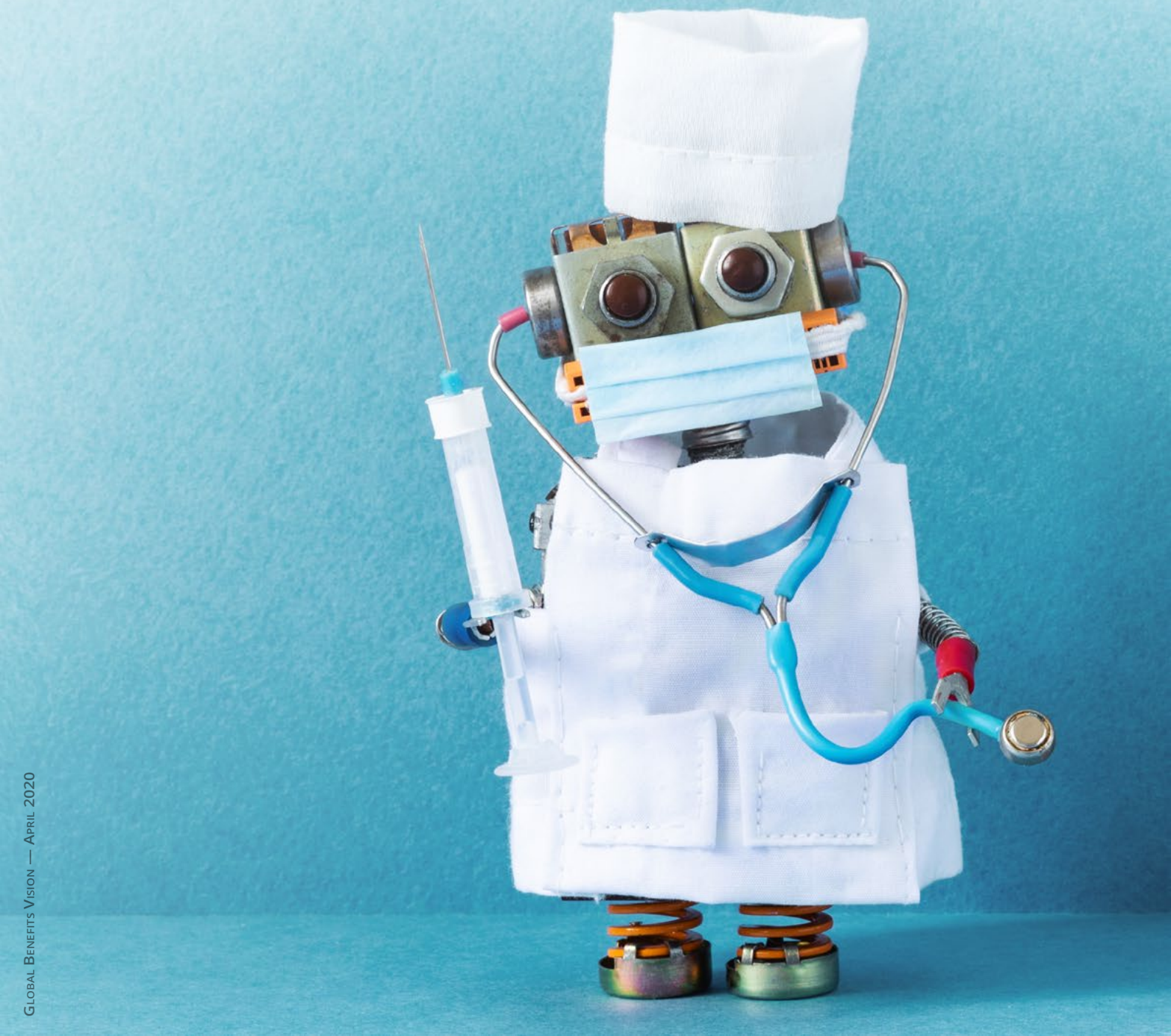
Knowledge & Wisdom for Global Employee Benefits Professionals



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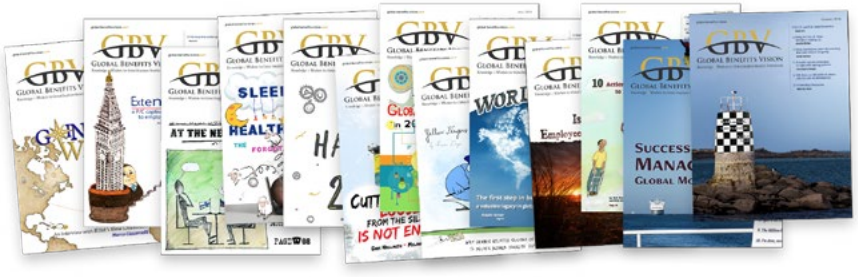

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GLOBAL BENEFITS VISION

Knowledge & Wisdom for Global Employee Benefits Professionals

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Manuel Géa

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BMSystems
Chief Executive Officer

Co-founder of BMSystems, CEO and VP R&D Information Systems – Information systems specialist. Played key roles in the development of BMS and of the computing firm Formitel. Scientific Engineering (operational research specialty) degree from Ecole Centrale Paris. Dregree in sociology (General semantic specialty) Paris IX Dauphine University. Former Chairman of the Supervisory board of Pherecydes-Pharma (anti-bacterial bio-agents pharmaceutical company). Former McKinsey executive, creator of Practice Pharma services in France. Former Division Managing Director with Boehringer-Ingelheim France. Former International business manager at Colgate-Palmolive. Manuel Gea contributed to the development of the CADI tools: CADI™ Search (data acquisition & mining); CADI™ Framework (data organization & structuring); CADI™ Fiber-N (integrative engine); CADI View (model representation & visualization); CADI™ knowledge Database.

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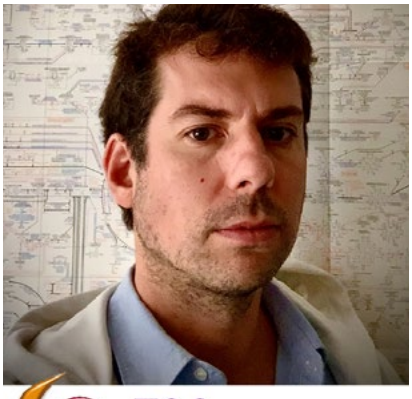
BMSystems
Integrative Biology Director



Integrative biologist Director- Biochemist with a PhD in Biotechnology from INA-PG, France. He worked for several years on the metabolic engineering of yeast and bacteria for the production of oleochemicals, pharmaceuticals and antibiotics at CNRS and INRA genetic engineering departments. After a short period in the R&D of AKK Sweden, he joined the Chemical Engineering Department at MIT (USA), where he worked on the generation of microbial fuel engines by rerouting yeasts metabolism towards lipid and hydrocarbon production. He joined Bio-Modeling Systems in 2016 where he develops predictive biological models with the aim of identifying potential therapeutic mechanisms for (auto) immune, neurological, metabolic and cancer related pathologies. He is the author of 17 publications in international journals, 4 patents and book chapters.

→ PAGE 30: *Life after COVID-19: dealing with Chronic Fatigue Syndrome?*

Profiles of Contributors

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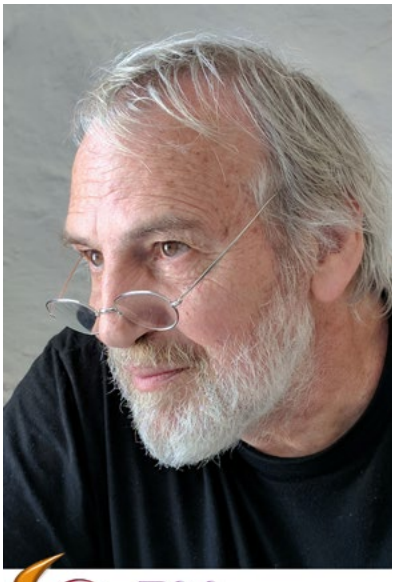

Founder of BMSystems; Chairman, CSO-CTO - Geneticist, physiologist & molecular biologist; Inventor of the CADI methodologies and tools. He holds a Ph.D. in Zoology and is in charge of all model-building activities within the company. Creator of Millennium Pharmaceuticals' (USA) high-throughput DNA sequencing unit. Former collaborator of Nobel Laureate Prof. Jean Dausset. Inventor of new technologies in molecular biology (6 issued patents). MRC Overseas fellow, Member of H.U.G.O., Wellcome Trust Systems Biology expert board. Member of the Cambridge Healthtech Institute Scientific Committee, Member of the Evaluation committee for the funding priorities in the "*Medical Systems Biology-MedSys*" program; German Federal ministry of Research. 16 original articles in international journals including Nature, Cell, Nature Genetics, Genomics, J Mol Endocrinol, J Comp Biochem Physiol. 7 international patents, 7 book chapters, numerous invited communications at international conferences

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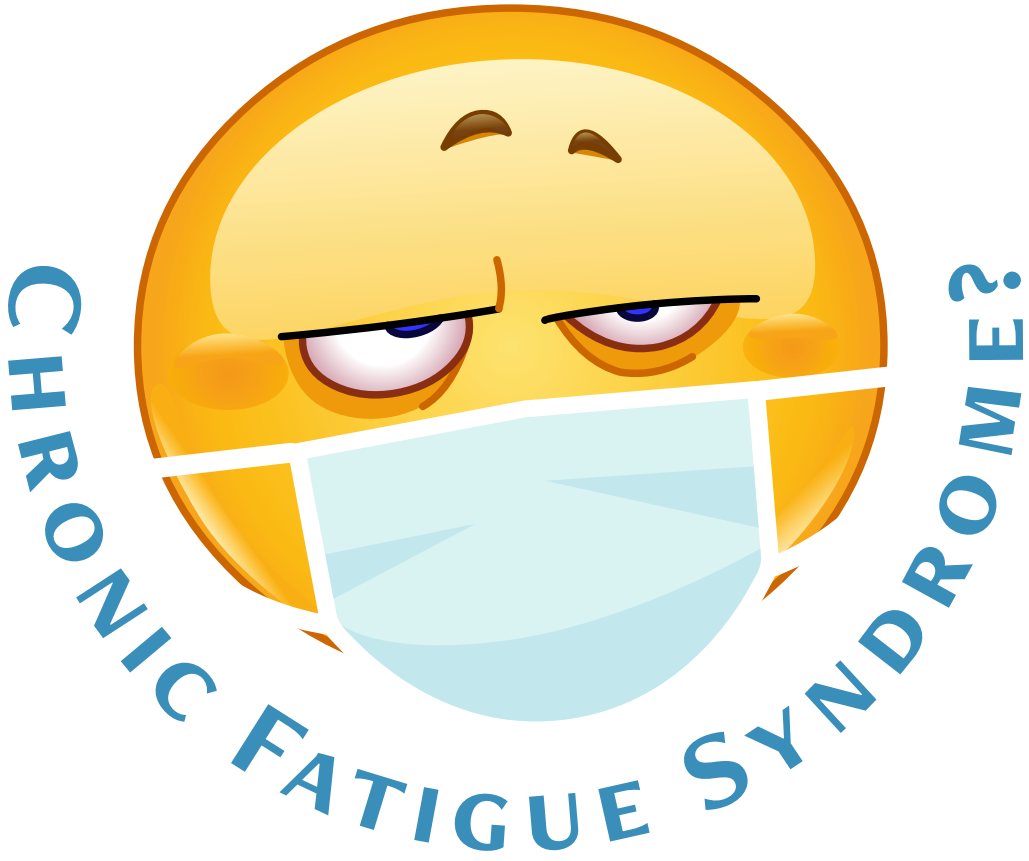
Life after COVID-19:

dealing with



Interview with **BMSystems** addressing the potential connections between recovered COVID-19 patients and Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (CFS/ME).

The links are compelling, as is the potential impact on employers and insurers.



Manuel Géa *Dr. Athanasios Beopoulos* *Dr. François Iris*

As we are reaching near global consensus that business needs to resume, and countries ease lockdown, ***Global Benefits Vision*** explores the possibility of a link between COVID-19 and CFS/ME, highlighted by BM Systems of France led by Francois Iris and Manuel Gea, and how employers and insurers can prepare for such an outcome from an employee wellbeing perspective.

Data from patients clearly show that a significant proportion of those who have recovered from SARS/MERS subsequently show symptoms of, or have contracted CFS/ME within 6-9 months of recovery. The association is compelling and explored in more detail below. A recent study by Dr Mady Hornig of Columbia University Mailman School of Public Health ("*What does COVID-19 portend for ME/CFS?*," 17 April 2020), highlights this, "*Perhaps the most compelling reasons are the unusually high proportions of COVID-19 patients with neurological symptoms during acute infection – 36% in one study. Those with more severe acute COVID-19 illness had more neurological problems.*"

This leads us to look at the next step in computational modelling and research, as actuarial groups and researchers look beyond initial predictive models to longer-term recovery and post-COVID-19 treatment scenarios.

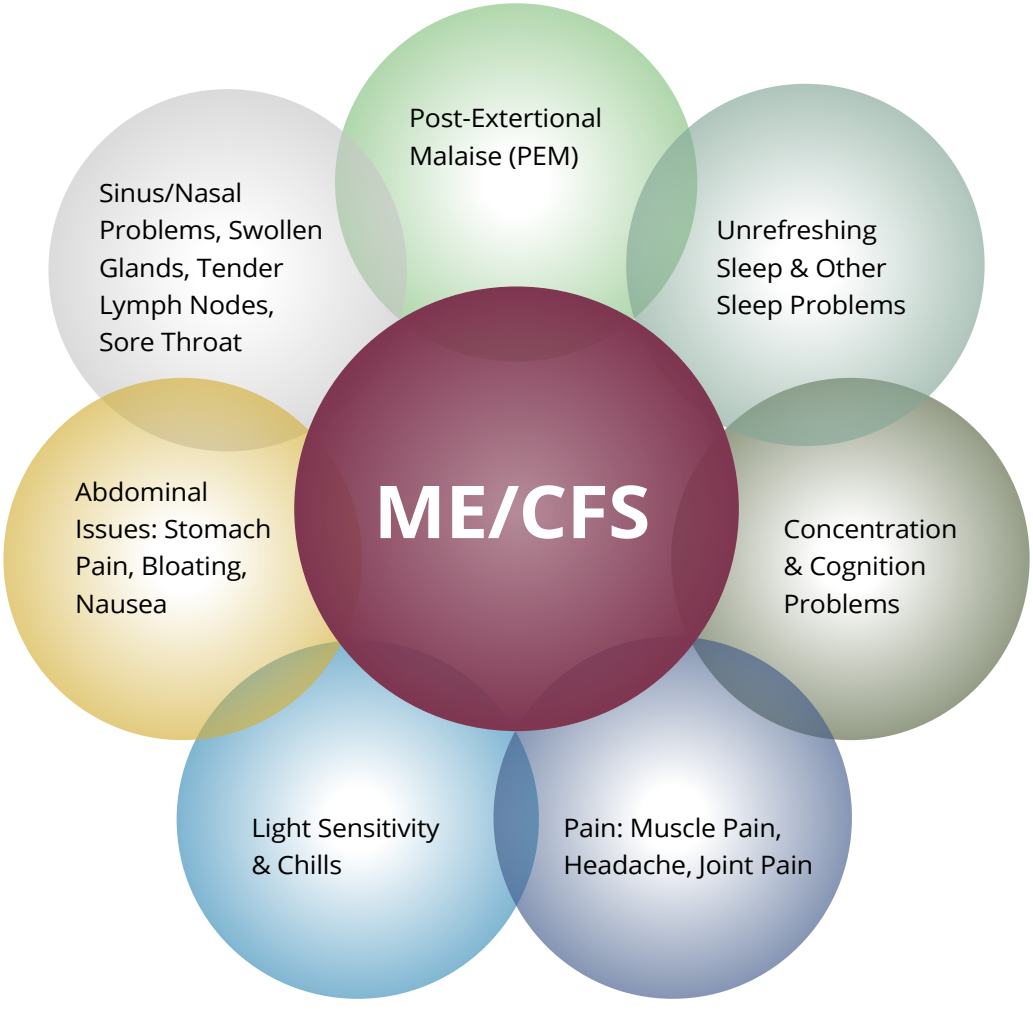
GBV has reached out to insurers' medical and actuarial departments for further comments on whether a link could be assigned, as with SARS/MERS; what impact this may possibly have on employers, employees, and insurers; and how can employee benefits solutions cater to this potential longer-term outcome of COVID-19.

WHAT IS CFS/ME EXACTLY AND HOW DOES IT AFFECT US?

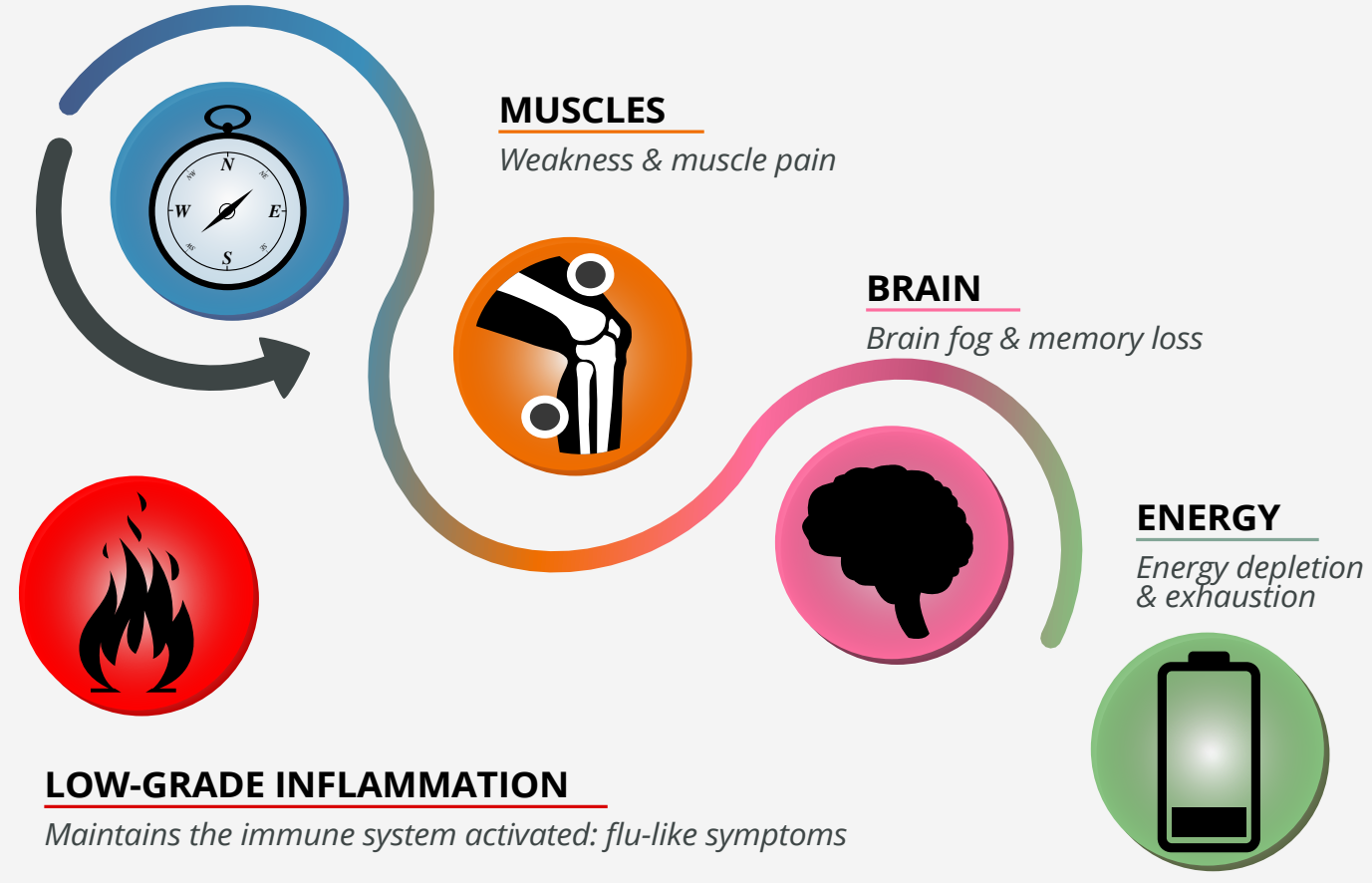
CFS/ME is a complex and devastating disease that imposes a burden of illness on millions of people around the world. It is a serious, chronic, and complex systemic disorder characterized by a state of deep exhaustion that is not due to intense physical or intellectual activity and nor is it relieved by rest. The pathology involves central nervous system and immune system disorders, characterized by extreme fatigue that severely limits the ability to perform ordinary daily activities. CFS/ME onset may occur suddenly, such as following a viral infection, or gradually.

CFS/ME pathophysiology has a multifactorial origin involving infectious (viral infections) and maintenance factors as well as the persistence of inflammatory (low-grade inflammation), immunologic (as abnormal cytokine production) and muscular (mitochondrial dysfunction and failure of bioenergetic performance) abnormalities at the origin of multiple dysfunctions (endocrine, neuromuscular, cardiovascular, digestive and others).

Symptoms include severe fatigue or exhaustion, unrefreshing sleep, weakness, muscle and joint pain, impaired memory or mental concentration, tender lymph nodes, sore throat, headaches, and sleep dysfunction.



The Five Mutually Reinforcing Drivers of CFS/ME



Source: BMSystems - www.bmsystems.net

Our research shows that CFS/ME is an inflammatory disease, caused by overlapping immune responses that misguide the actions of the immune system. When this occurs, the immune system tries to simultaneously resolve infection-like hazards that require opposing and often mutually cancelling strategies (known as humoral and cellular responses). The result is that the immune system getting 'stuck' in a constant, low potency, pro-inflammatory mode.

Now, challenges arise as the immune system, in addition to fighting infections, is responsible for the organism's housekeeping functions, in particular the constant monitoring and repair of tissues and organs. The abnormally tuned immune system of CFS/ME patients increases the permeability of tissue and muscle to immunological components, resembling the natural immune state that occurs after strenuous physical exercise, allowing the natural healing process to begin. However, in CFS/ME patients, this infiltration of tissue and muscle is triggered by the routine movements of daily life and, their immune system being stuck in a pro-inflammatory mode, instead of repairing the tissue creates even more damage.

At the systemic level, this constant low-grade inflammation causes muscular weakness and pain, flu-like and cognitive symptoms, depletes energy and sleep fails to be restorative.

WHAT CAUSES THE IMMUNE SYSTEM TO BE 'STUCK' BETWEEN THESE MUTUALLY UNRESOLVED RESPONSES AND KEEP IN THIS CONSTANT, LOW POTENCY, PRO-INFLAMMATORY MODE?

In a nutshell, this inflammatory condition can occur when a chronic, low-level, and often asymptomatic inflammatory reaction that biases the immune system towards cellular responses is superimposed on an acute infection that triggers a humoral response opposed to the first.

The first condition, which can drive a person's immune system to adopt a long-lasting strategy (or a polarized/biased response), is often due to a chronic viral infection with a double strand DNA virus such as are HHV, HSV, EBV, CMV, etc. More than 90% of people are exposed to these chronic dsDNA viruses by three years of age. The virus DNA can insert itself into a chromosome and remain latent in just a few cells for years, silently being copied each time the cell divides. Even if for most people this causes no problem, it can set the inflammatory background allowing the occurrence of CFS/ME for some others. This of course depends largely on the genetic and environment factors that shape an individual's immune system.

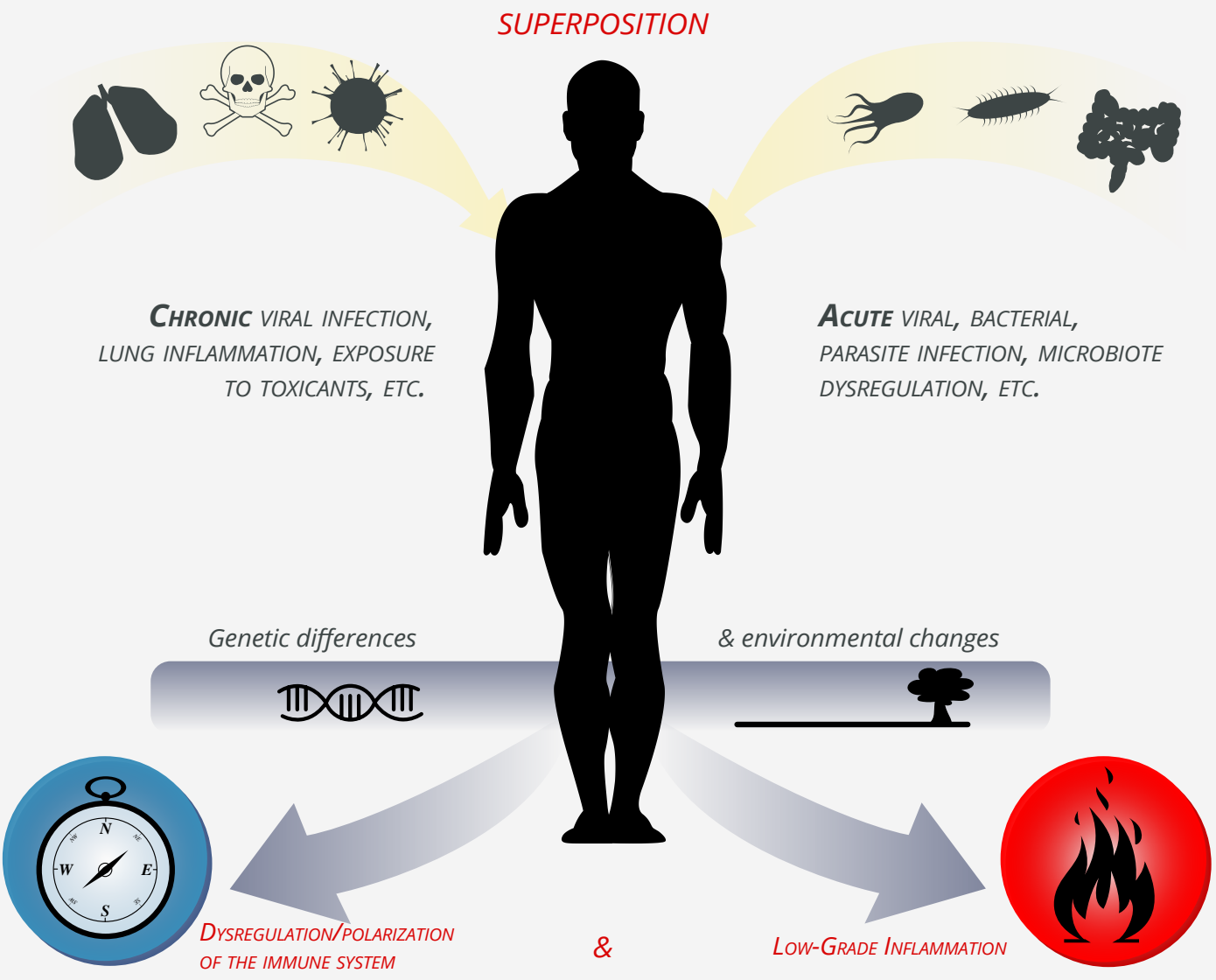
If one thing is made clear to everyone during the current coronavirus pandemic, it is that immune responses vary considerably from person to person.

The second condition, which could cause the immune system to adopt an opposing and conflicting strategy, leading to that particular low grade pro-inflammatory tuning, can be triggered by acute infections from positive-sense single-stranded RNA viruses (ssRNA). One of the most common triggers of CFS/ME is acute viral infections such as those provoked by the influenza ssRNA virus. As an example, a Norwegian national study showed that the percentage of CFS/ME occurrence doubled following the 2009 influenza A (H1N1) pandemic [1].

Coronaviruses are all positive sense ssRNA viruses, and among them, Sars-Cov-1, Mers-Cov and Sars-Cov-2 are known to cause very acute infections and inflammatory syndromes. From the previous 2003 SARS and 2015 MERS epidemics, we observe a strong correlation between the viral outbreaks and the increase in CFS/ME prevalence. Of 233 Hong Kong hospital SARS survivors assessed 4 years after the viral outbreak, over 40% had active psychiatric illnesses, 40.3% reported a chronic fatigue problem, and 27.1% were diagnosed with CFS/ME [2]. Similar data was obtained from 229 Toronto SARS survivors where, 3 years following infection, 10% presented CFS/ME symptoms[3]. For comparison, less than 1% of people worldwide meet chronic fatigue syndrome criteria. An equivalent relationship between chronic fatigue, depressive symptoms, and post-traumatic stress symptoms (PTSSs)- i.e. among the most prominent CFS/ME symptoms- is found among 2015 Middle East respiratory syndrome (MERS) survivors in South Korea. Of 148 survivors assessed at 12 and 18 months after the MERS outbreak, 72 (48.65%) presented chronic fatigue, depressive symptoms, and PTSSs [4].

It appears therefore quite probable that the current coronavirus epidemic, caused by the positive sense ssRNA SARS-CoV-2 virus, might trigger a worldwide spike in CFS/ME. However, it is far too early to estimate what proportion of the exposed populations may go on to develop CFS/ME as the formal diagnosis requires symptoms that last for at least six months.

CFS Triggering: Superposition of Humoral and Cellular Responses



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> *If one thing is made clear to everyone during the current coronavirus pandemic, it is that immune responses vary considerably from person to person.*

COULD WE DISCUSS THE CURRENT ENVIRONMENT FOR CFS/ ME THERAPY AND ITS FAILINGS, IN YOUR EXPERIENCE?

CBT
Cognitive Behavioural Therapies

The cause, or causes, of CFS/ME remain largely puzzling to the scientific community. This makes CFS/ME a confusing condition for the physicians, echoing the existing diagnostic difficulties and poorly codified management. No clear diagnostic criteria exist. From 1986 to 2020 at least 13 definitions and guidelines have been interchangeably used worldwide. Therefore, in the absence of a standard clinical recognition, physicians are frequently misinformed or even uninformed about the disease, and assigning a diagnosis of CFS/ME in the current clinical setting may take years.

Despite several attempts to describe the clinical features of the disease within the existing diagnostic criteria, findings indicate that many individuals, from major depressive disorder illness groups and other such illnesses to burnout cases, were categorized as having CFS/ME and vice-versa. The diagnosis of ME/CFS is still based on exclusion, meaning that other medical conditions must first be ruled out.

The lack of diagnostic biomarkers, of agreed reproducible case definitions together with selection bias in CFS/ME are well reflected in the attempts to estimate the burden of the disease. Form an analysis of epidemiologic studies, health and insurance databases, it is estimated that the disease predominantly affects adults, with a peak age of onset between 20 and 45 years and a female to male ratio around 3:1 [5]. The frequency of CFS/ME worldwide is estimated somewhere between 0.1–1% of the general population.

> ***No clear diagnostic criteria exist. From 1986 to 2020 at least 13 definitions and guidelines have been interchangeably used worldwide.***

According to the latest CDC estimates, between 836 000 to 2.5 million Americans suffer from the disease, whereas Euromene (EU official CFS/ME program) estimates that between 730 000 to 4.1 million Europeans could be affected by the disease.

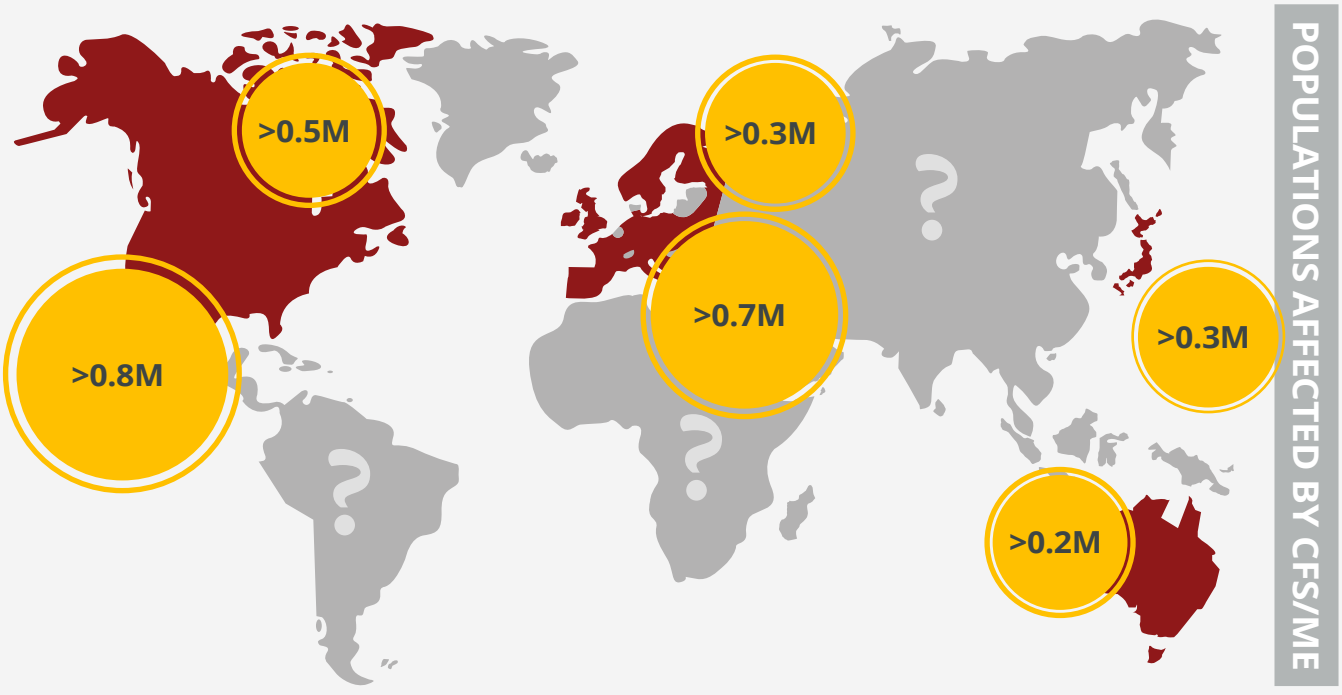
There currently are no pharmacological therapies to treat the disease, despite numerous studies aiming to understand the pathology and therapeutic attempts to, relieve the symptomatology or re-instate patients' pre-existing function. The clinical trials conducted so far have had poor validity, have proven to be inconsistent and inconclusive, while none of the pharmacological management strategies demonstrated any significant results.

Moreover, the lack of standard pharmacological guidelines or approved drugs has led to a lot of experimentation between groups of patients and health practitioners, using drug combinations intended to alleviate the symptoms of the pathology, , with often perilous results.

Alternatively, unconventional medical therapies, counselling and cognitive behavioural therapies (CBT) are frequently implemented, although with little or no evidence of improved symptomatology. These often reflect the misconception that CFS/ME is a psychological condition, when in reality it has a clear pathologic immunological basis.

CFS/ME Demographics & Market

- The frequency of CFS/ME is estimated at 0.1–1% of the general population.
- CDC estimates that between 0.8–2.5M Americans suffer from the disease.
- Euromene estimates that between 0.7–4.1M Europeans could be affected by the disease.



Country	CDS/ME patient estimation	Year of last survey
Great Britain	*250,000*	*2011*
Netherlands	*320,000*	*2004*
Germany	*250,000*	*2014*
Sweden	*260,000*	*2005*
Australia	*180,000*	*2002*
New Zealand	*20,000*	*2018*
Japan	*300,000*	*2011*
Canada	*560,000*	*2005*
United States	*0.8M–2.5M*	*2018*
Europe	*0.7–4M*	*2020*
Worldwide	*0.2–1%*	

- About 50% CFS/ME patients quit employment
- ME/CFS costs the U.S. economy about $17 to $24 billion annually in medical bills and lost incomes

Source: BMSystems - www.bmsystems.net

TREATMENT: WHAT IS CADI-T1031 – COULD YOU DESCRIBE THE POTENTIAL THERAPEUTIC STRATEGY?

CADI-T1031 is a "*disease-centric repositioning*" of existing molecules. The first personalized treatment for CFS/ME that address the mechanisms of the disease.

We have deciphered the mechanisms and modelled the pathologic basis of CFS/ME, allowing us to propose an innovative therapeutic strategy that has already successfully completed the proof of concept stage and is ready to enter clinical trials with our confidential partner. Our goal is to transform CFS/ME from a syndrome that lacks concrete diagnostic criteria and treatment, into a universally recognizable, diagnosticated and treatable organic disease. The treatment aims to significantly improve patients' lives, while the diagnostic tools, consisting of a combination of specific serological biomarkers and questionnaires, developed through our continuous collaboration with the *French CFS/ME patients association*, intend to become the golden standard for diagnosing the disease. These steps will hopefully provide along the way, the currently entirely lacking, but so much necessary recognition and social acceptability of people affected by CFS/ME in both medical and social contexts.

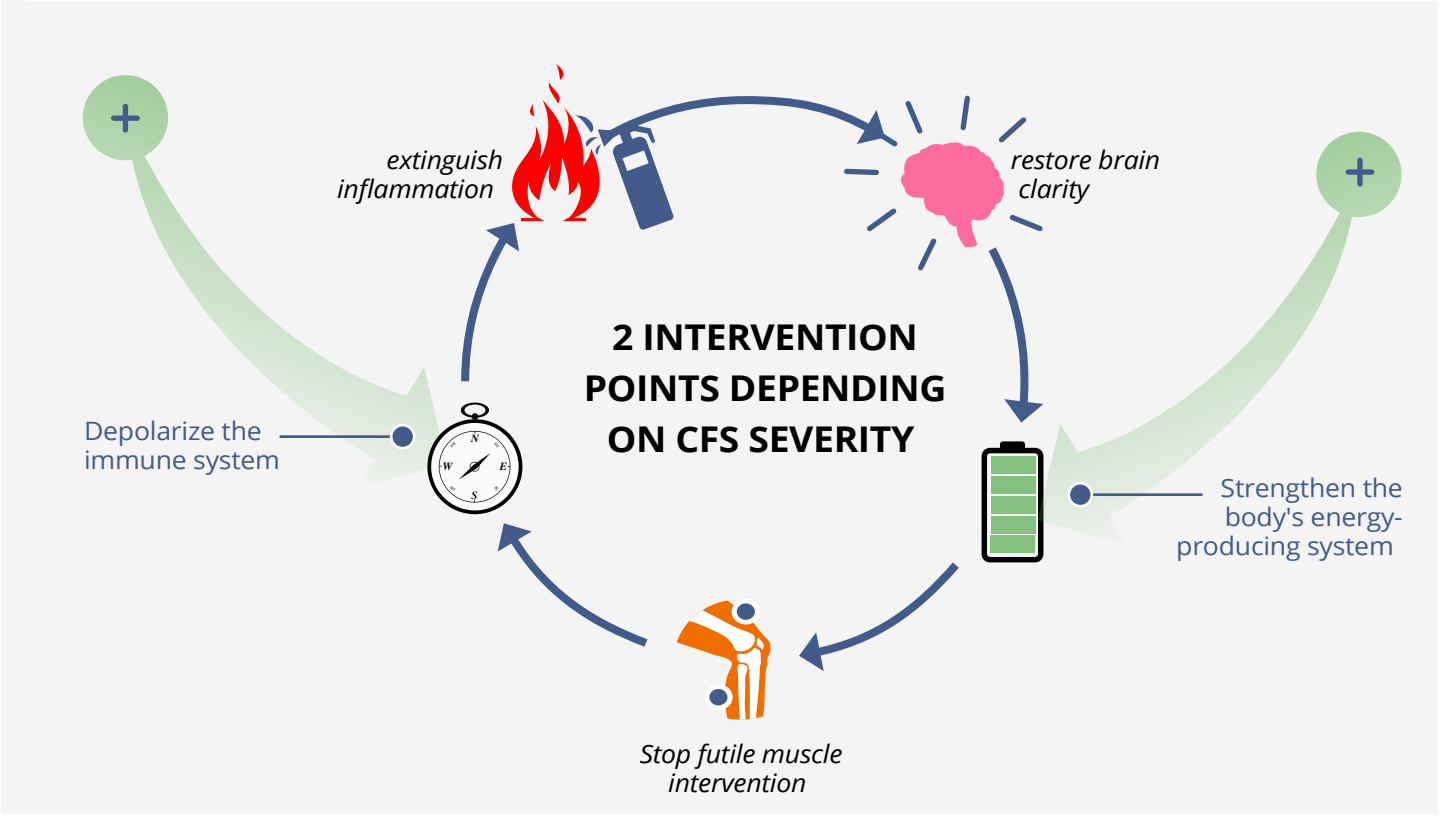
BMSystems' lengthy experience in immunology/inflammation suggests that there may not be a universal treatment for all CFS/ME patients, as immune function varies from person to person depending on genetic, pathologic and environmental backgrounds. Our diagnostic tools are therefore designed to monitor the patient's immune status, and the treatment is then tailored, using standardized pharmaceutical combinations, much like assembling Lego bricks, to match the patient's actual condition.

The treatment is divided into 2 main therapeutic phases. The immune equilibration treatment aims to resolve the on-going conflicting immune strategies and phase out the self-propagating inflammatory reaction. This phase is expected to last from 2-6 months depending on patient's follow-up and evaluation. The second phase is an energetic rehabilitation treatment, which aims to restore the patient's energy metabolism that is severely deregulated in CFS/ME, while simultaneously supporting the newly reached immune equilibrium.

This phase is expected to last anywhere from 6 months to 2 years, depending on patient's evaluation. Back and forth between Immune and Energetic treatments is not excluded in cases where the patient's immune system is dysregulated during rehabilitation, due to occurring infections or underlying pathologies. Finally, a maintenance treatment could be administered at will to cover the patient's fluctuating metabolic needs. It is important to note that all the components in each phases of the CFS/ME treatment have no toxicity and no known side effects, either individually or in combination.

> ***"CADI-T1031 is a "disease-centric repositioning" of existing molecules. The first personalized treatment for CFS/ME that address the mechanisms of the disease."***

Intervention paints against CFS



Source: BMSystems - www.bmsystems.net

INSURERS WOULD LIKE TO KNOW THE NUMBER OF INSURED WHO MAY EXHIBIT CFS IN A FEW MONTHS – HOW COULD THEY BUILD A MODEL TO ARRIVE AT ANESTIMATE? WHAT WOULD BE THE PARAMETERS? IS IT ENOUGH TO KNOW THE NUMBER OF INSURED WHO WERE HOSPITALIZED IN ICU FOR COVID-19 AND SURVIVED?

Today CFS/ME patients are not correctly identified and treated by the healthcare systems. The post-COVID response is a real issue for insurers and a clear challenge for healthcare professionals and systems since the usual response of "*it's all in your head*" may not run true.

Again, because of the individual-specific configuration of the immune systems, underlying comorbidities, and varying outcomes of Covid-19 infections, it is difficult to predict the prevalence of CFS/ME. It is even trickier to extrapolate data from previous pandemics caused by ssRNA viruses since, until recently, awareness of CFS/ME was limited, either because it was overlooked or treated as psychological problem, mainly due to limited understanding of the disease and confounding diagnostic criteria. So far, we only have access to sporadic epidemiological studies, which, although establishing a clear increase in the development of CFS/ME post SARS and MERS pandemics, are incomplete as a basis for the construction of a predictive model. Unfortunately, it appears likely that it is the current pandemic that would provide a measure of the real impact of the Sars-CoV-2 virus in the development of CFS/ME during the coming months.

This is also reflected by the rising concern of both scientific and popular media about an eventual spike of CFS/ME after the Covid-19 epidemic.

PVF
Post Viral Fatigue

PVFS
Post Viral Fatigue Syndrome

April 15th, 2020, NEW SCIENTIST

COULD the coronavirus sweeping around the world have a second illness following in its wake? We may expect to see an outbreak of post-viral fatigue syndromes in some people who have had covid-19, according to some researchers.

April, 30, 2020, ME ASSOCIATION, PRESS RELEASE

'We are starting to receive reports about previously healthy people who have had (or probably had) coronavirus infection and have not been able to return to their normal level of health and energy levels in the weeks following the onset of symptoms. These reports are largely from people who have managed at home and not had a more serious infection that required hospital admission. Some reports are from health professionals. It seems likely that some of them are experiencing what is called post viral fatigue (PVF), or a post viral fatigue syndrome (PVFS).

We are also receiving reports from people with ME/CFS (myalgic encephalomyelitis/ chronic fatigue syndrome) who have had this infection and now have a significant exacerbation of their ME/CFS symptoms – especially a further reduction in energy levels.

We are now expecting to see a number of new cases of ME/CFS that follow coronavirus infection fatigue '.

May, 1st, 2020, THE GUARDIAN

Dr James Gill [honorary clinical lecturer at the University of Warwick and a locum GP]*, said data from the Sars outbreak revealed that almost a third of those who had had that particular coronavirus still had a reduced tolerance to exercise many months later, despite having normal lung function. While Gill stressed that Covid-19 was a different disease, he said it could be that a similar proportion of about a fifth or a third of those with Covid-19 had lengthy recovery time [...] He continued. "We are learning on a daily, weekly basis, things about how people are recovering from this, and we can't know about the long-term impacts until we are in the long term."*

"There are a lot of people wondering whether or not we are going to see an uptick in cases of chronic fatigue going forwards as a result [of Covid-19]," he said. "We don't know that, but it is something that we are thinking may be possible." Carmine Pariante, a professor of biological psychiatry at King's College London, agreed there could be a rise in people experiencing a CFS-like syndrome.

May, 2nd, 2020, THE TELEGRAPH

"Based on my experience with SARS, I am deeply concerned that our definition of 'recovered' [...from Covid-19] is far too narrow. It's likely that some patients will experience chronic fatigue syndromes for months or even years after an initial infection," Dr Moldofsky told The Telegraph. A study led by Dr Moldofsky following the Sars outbreak in Canada in 2002 to 2003 found that some patients continued to have symptoms similar to CFS/ME for years after they were diagnosed with the coronavirus, which is closely related to Sars-Cov-2.

Another study published in the Journal of the American Medical Association in 2009 found that 40 per cent of 369 Sars survivors studied in China reported a "chronic fatigue problem", while 27 per cent met the US Centers for Disease Control and Prevention definition for CFS/ME.

CONCLUSION

While it may be too early to reach a realistic assessment on this issue, it is highly probable that a lack of correct diagnosis and subsequent treatment for CFS/ME, especially in the post-COVID-19 scenario, will bring this issue to the forefront. Questions need to be answered and responses to the virus need to be examined in more detail. BMSystems is attempting to answer these, to a great extent, through its research.

The lack of consensus in diagnosis is being addressed. However, the impact on the insurance industry will need to be assessed in more detail, models constructed, with deep delving focusing on recovery and treatment for employees, as an understanding of the links between COVID-19 and CFS/ME become clearer.

Global Benefits Vision will explore these in more detail in our Q&A with a variety of insurers, actuaries, and medical professionals as we see that there are a number of important and impacting questions raised that affect the workplace and employee wellbeing.∞

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