Guildford ME/CFS Support Group
(& West Surrey)

Newsletter

December 2020

Future dates

Due to the Covid-19 Pandemic we are unable to offer monthly meetings until further notice. Contact us at Guildfordme@hotmail.co.uk if you would like to be added to our Whatsapp chat. We will require the mobile number to add.

NICE pulls the plug on graded-exercise-therapy and CBT as treatments for ME/CFS

Source: https://www.healthrising.org/blog/2020/11/13/nice-discards-graded-exercise-therapy-cbt-treatment-chronic-fatigue-syndrome
13th November 2020

Below is part of the full article which can be found at the source link above.

"There is no therapy based on physical activity or exercise that is effective as a treatment or cure for ME/CFS". NICE

Who would have thought? We knew that National Institute for Health and Care Excellence (NICE) – the executive branch in the U.K. responsible for producing treatment guidelines – was reconsidering its guidelines for M.E. (ME/CFS, chronic fatigue syndrome). Still, it came as a surprise when its draft guidance made explicit what people with ME/CFS have known for so long: that neither CBT nor exercise is "a treatment or cure for ME/CFS".

NICE went on to say GET "should not be presumed to be safe for those with this disabling and often neglected illness." (It also did not recommend the Lightning Process.)
Read the draft guidance here.
https://www.nice.org.uk/guidance/indevelopment/gid-ng10091/consultation/html-content-2

NICE does not recommend GET or CBT as treatments for ME/CFS
Plus it finally, finally, put CBT into the context it should have been offered all along – as a "supportive psychological therapy which aims to improve wellbeing and quality of life". That, CBT, when properly done, is certainly able to provide. Just don't pretend it's a treatment. (CBT was originally used in mood disorders but is now being used to assist with quality of life in many physiological disorders including heart disease, rheumatoid arthritis, multiple sclerosis, and cancer.)

One had the feeling that NICE was attempting to make up for past errors that have side-lined patients and their concerns and blunted their trust in the medical establishment. More severely ill patients have been particularly affected. The ME Association reported that Paul Barry, the Chair of the NICE group, singled out the more severely ill.

"This guideline reinforces the legitimacy of this biomedical disease and aims to reduce the disbelief and stigma felt by people with ME/CFS … It acknowledges the profound needs of people with severe ME/CFS and their carers whose lives are hugely impacted by ME/CFS, and states that this unique patient group should be treated with respect, dignity, and empathy."

It appears to be a repudiation of the wrong-sighted and even, at times, cruel practices that have been foisted on ME patients in the UK for years. The unremitting focus the UK and the Netherlands have had on GET has, of course, affected more than the patients in those countries. It's cast a pall over the entire ME/CFS community and the field itself. Even in the U.S., where research efforts have remained overwhelmingly biological, the taint remained in the form of popular medical websites espousing these practices.

Ironically, given that these programs were largely developed by psychologists – the psychological cost to the ME/CFS community has been huge. It's not just the disbelief that patients encountered amongst doctors and friends or the worsened health outcomes or lost opportunities.

There's also been a shattering loss of faith in the medical community itself. How is it that it could put so much emphasis for so long on a practice that is so at odds with patients' experience? Who among us, after all, did not wreck ourselves physically trying to maintain our careers and lifestyles? Who among us did has not tried again and again and again to "exercise"?

To their credit, the NICE authors acknowledged the harm that's been done:
"Health professionals should also recognise that people with ME/CFS may feel wary of trusting them if they have encountered doubt about their symptoms and condition.
ME/CFS can cause profound, long-term illness and disability, and much of the distress surrounding it is caused by difficulties in recognising, acknowledging, and accepting the condition and its impact.

(The) controversy over the use of graded exercise therapy and CBT that has served only to alienate many people with ME/CFS and in some cases undermine the confidence of those caring for them."

Beginnings
It's a big change for NICE in particular. GET for ME/CFS, after all, was basically borne in the UK. A search of PubMed indicated that London researcher Peter White lead the first GET M.E. trial in 1997. That first trial set the stage for the controversies that were going to embroil GET and ME/CFS for over 2 decades – and which finally culminated in NICE not recommending it as a treatment for M.E.

It provoked 4 published dissenting comments, including one by Charles Shepherd which began by stating that:

> "We remain firmly opposed to exercise programmes that encourage patients with the chronic fatigue syndrome to increase their levels of physical activity progressively without making allowance for fluctuating levels of disablement". Shepherd went on to comment why, if the program was such a success, no increases in either peak oxygen consumption or muscle strength were seen."

So it went for the next couple of decades. Biopsychosocial researchers presented sometimes garbled and misleading results, while patients, researchers and academics pushed back.

Large overviews of GET studies suggested it wasn't very helpful

There's always been a corrective to the graded exercise therapy (GET) mania that gripped institutional funders in the UK and the Netherlands for so long. It was called research. It's not that GET research has been particularly good. David Tuller, a thorn in the side of the CBT/GET crowd, has repeatedly exposed problems in the biopsychosocial (BPS) research done in Europe. Plus, there were the shenanigans that took place in the huge PACE CBT/GET trial. It was notable that even when the researchers lowered the bar to recovery so completely as to make it possible to enter the trial "already recovered" – even then – the best the PACE trial could conclude was that CBT/GET could "moderately improve" outcomes.

That was actually quite a overstatement. The trial was so poorly done that the Journal of Health Psychology – in what was surely a first for it – devoted an entire issue to problems found in the trial. A re-analysis of the trial data using the original criteria suggested that it completely failed. Later, the best the authors of the large 2017 GETSET trial could muster up was "it might reduce fatigue".

The vaunted Cochrane reports didn't have that much good to say about GET either. The 2019 review of GET studies (containing over 1,500 participants) concluded that exercise therapy "may slightly improve" physical functioning, depression and sleep compared to adaptive pacing (low-certainty evidence). The authors were also "uncertain if exercise therapy….reduces fatigue". An earlier Cochrane report stated that "little or no difference in physical functioning, depression, anxiety and sleep" was seen.

Even that may have been an overstatement. Mark Vink and Alexandra Vink-Niese re-analysed the GET studies used in the Cochrane review, and concluded that the Cochrane conclusions were wrong and that studies actually suggested that GET was completely "ineffective".
Dr. Alastair Miller's take on the NICE's GET turnabout was that NICE had succumbed to political pressure – but maybe NICE was just following the science. Perhaps NICE thought one could reasonably expect that two decades of work and millions of dollars spent should result in something better than "may slightly improve" physical functioning and "little or no difference in physical functioning".

In the end, it's no wonder NICE is turning its back on GET – GET's return on investment has been atrocious. The wonder is what took it so long.

In truth, NICE is a bit late to the game. NICE's new recommendation is just the latest blow to the biopsychosocial approach to ME/CFS. The U.S. dropped the first bomb on CBT/GET when a re-analysis by the U.S. Agency for Healthcare Research and Quality (AHRQ) of CBT/GET studies left it unable to recommend them for ME/CFS. That prompted the Centres for Disease Control to remove its recommendations for CBT/GET from its website.

Then, the Dutch Health Council – hailing from one of the centres of the biopsychosocial movement – recommended that GET not be used to treat ME/CFS. Then, just this year after receiving a call from Vicki Whittemore of the NIH, and Elizabeth Unger of the CDC (and work from many advocates – read more here from MEAction), the Mayo Clinic removed recommendations for CBT/GET from their website.

Dr Myhill vs GMC (28th Sept to 1st Oct 2020)

Source: www.drmyhill.co.uk/wiki/Press_Release_re_my_Non_Compliance_Hearing_-_MPTS_-_Myhill_vs_GMC_Sept_28_to_Oct_1_2020

Dr Myhill faced a Non-Compliance Hearing at the Medical Practitioners' Tribunal Service [MPTS] from 28 September 2020 to 1 October 2020. Dr Myhill won the case - i.e. Non-Compliance was not found.

Dr Sarah Myhill is one of the leading doctors to stand up against the prevailing orthodoxy that ME is 'all in the patients' head'. She has recently demanded a Public Inquiry into the shameful and inadequate treatment of ME patients in the UK, and that the authors of the flawed PACE trial are held to account for their malign impact into the lives of hundreds of thousands of vulnerable, ill sufferers. Was this advocacy for an "undeserving" patient group which made Dr Myhill the target of GMC ire? And is this the best use of the time and resources of the GMC when the medical profession in the UK is facing the biggest public health challenge of our lifetimes? This is after all, a doctor about whom no patient has ever made a complaint; indeed many thousands of Dr Myhill's patients are fulsome in their testimonies that Dr Myhill's treatment got them back from the brink to full, or at least better, functioning.

LTBM is happy to report that the latest attempt to muzzle Dr Myhill in the GMC witch hunt against doctors of alternative and functional medicine has failed. Dr Myhill yesterday walked free after a four-day GMC hearing having won her case. This was GMC prosecution number thirty eight against Dr Myhill. Her advocate Mr Charles Taylor described this as "outrageous" behaviour by the GMC.

The GMC was represented by Ms Eleanor Grey, Queen's Counsellor, who jumped up and demanded that Mr Taylor retract that statement. He refused because "outrageous" was the only word that accurately described the unreasonableness of the GMC's actions over the past twenty years. He said,

> "Dr Myhill is the most prosecuted doctor in the history of the General Medical Council". Indeed, every GMC attack on Dr Myhill has involved patients who suffer from chronic fatigue syndrome or ME. Dr Myhill stated "CFS/ME is clearly a physical disorder with physical treatments which are proven to work. But doctors who recommend these treatments which involve benign intervention such as vitamin B 12 injections, magnesium, vitamins C and D and anti-viral medications are attacked by the Establishment. This is the ninth occasion that I have been investigated for the use of vitamin B12 injections and the fifth occasion for the use of magnesium".

Mr Charles Taylor, retired barrister, who is also a patron of his local ME group and represented Dr Myhill pro bono, commented "Dr Myhill must be the safest doctor in the country because despite no patient ever complaining about her she is the most investigated doctor – the current score is Myhill 37 GMC nil". He also repeated the advice given to the GMC by one of its own legal advisers Mr Tom Kark QC who stated

> "the problem with the Myhill cases is that all the patients are better and all refuse to give witness statements".

This latest case hinged on issues of patient confidentiality. In complaining to the GMC about Dr Myhill's recommendations for the use of a physical approach to treating CFS/ME the complainant GP sent the patient's entire NHS medical records to the General Medical Council without patient consent and without effective anonymisation. Dr Myhill immediately realised this was a clear breach of DPA legislation. So when the GMC demanded that Dr Myhill release her records to the GMC, she refused stating

> "even if I correctly anonymised my patient records, they would be juxtaposed in the same bundle as the NHS records and patient confidentiality breached".

This did not stop the GMC from continuing its persecution of her for the next two years having launched its case against her in October 2018. On numerous occasions Dr Myhill asked the GMC to supply her with the legal basis for its on-going prosecution but this was never forthcoming. Dr Myhill stuck to her guns. The Tribunal agreed with her in its summing up

> "whilst the GMC did provide some clarification within its letters to Dr Myhill, it was limited and did not address her full concerns. Several of Dr Myhill's clarification questions directed at the GMC had gone unanswered on numerous occasions and, when answered, the GMC's response was minimal".

Mr Charles Taylor took the GMC Tribunal through the General Medical Council's own Guidance on confidentiality and demonstrated multiple GMC breaches of its own advice. He then went on to underpin this with extensive references to the General Data Protection Act, The Human Rights Act, The National Health Service Act 2006, the Medical Act 1983 and Common Law and further illustrated this with case law. Dr Myhill commented "it was quite extraordinary to see how the GMC case against me fell apart. It made me wonder what malign influence lay behind this ridiculous and, for the GMC, unwinnable prosecution".

In its judgement of the case, the GMC Tribunal stated,

> "It considered that Dr Myhill's actions reflected well on how a doctor approaches their responsibility to their patients".

It went on to say,

> "The Tribunal considered that Dr Myhill's genuine concerns in respect of Patient B's privacy, confidentiality and duties as a doctor were at the heart of her reasoning for not providing the confidential Medical Records".

Dr Myhill believes this attack on her by the GMC was prompted by her advocacy of CFS and ME being physical and NOT psychological conditions – indeed she has published three scientific papers establishing such followed by a British Medical Association Award winning book "Diagnosis and Treatment of Chronic Fatigue Syndrome and Mylagic Encephalitis - it mitochondria not hypochondria". Her treatments are all available free on her website Dr Myhill's website - which since 2010 has received well over 20 million hits. For those who prefer visual information, go to Life the Basic Manual YouTube Channel which gives short sharp and apposite information. As Dr Myhill stated to the Tribunal:

> "As members of the Panel are doubtless aware the CFS/ME world is split and many believe it has a psychiatric basis. The PACE trial of 2011 published in the Lancet seemed to support this hypothesis. However, it came under severe criticism and the conclusions of 40 international independent academics, as published in the Journal of Health Psychology August 2017 was that the study was scientifically unsound. Please do read this Journal – it shows, as just one example, how the goalposts for a 'defined recovery' were lowered, actually during the PACE trial, to a level so low that someone with that level would have been defined at the beginning of the PACE trial as being recovered.
>
> This is just one example of why the PACE trial is unsound. As I was the major exponent of CFS/ME being of physical origin it fell to me to flag this up. In consequence I was asked to report the PACE Authors to the GMC for scientific fraud. This I did in Jan 2018. I received much support from the world ME Community, with over 200 sufferers sending in detailed letters of support for my complaint to the GMC and in excess of 10,000 people signing a petition supporting my complaint. These patients told of how the PACE trial had harmed them physically, emotionally and financially.

Many wrote of being left bedridden for years after following the guidance in the PACE trial and others wrote of having lost their jobs and, sometimes their homes, after having been disabled by the treatments recommended in the PACE trial."

"Along with my complaint, the fact that the PACE trial had been proven to be scientifically unsound caught the public eye and this very subject was debated in the House of Commons June 2018 (ref MP Carol Monaghan). I know from a FoI search that the GMC followed this debate and was deeply interested in the outcome. However, in July 2018 the GMC wrote to me refusing to investigate the PACE authors."

"In complaining to the GMC about the PACE authors I had supplied the GMC with an extensive scientific evidence base and I expected the GMC to respond likewise. So, I asked the GMC to supply me with the scientific evidence base for such, but it refused. To be clear what I was asking for did not involve the release of any confidential or personal data whatsoever – I was requesting the published scientific literature, available in the Public Domain, upon which the GMC had relied in making its decision – internet links would have sufficed. On Friday 19 Oct 2018 I informed the GMC that I would take its refusal to the Information Commissioner (who in Sept 2019 agreed with me). However, next working day, Monday 22nd Oct 2018 the GMC launched its current investigation against me. I believe this was no co-incidence. I may be wrong, but I still believe to this day that the GMC deliberately launched this investigation to pressurise me into dropping my PACE complaint."

Dr Myhill commented today

"I now know how many of my CFS/ME patients have really felt over the years – ignored and belittled by doctors. I call this MAIMEs - Medical Abuse in ME sufferers. The GMC has dished out to me the same treatment that the medical establishment has dished out to them vis useless management plans and advice which have no evidence base and often make things worse. Now I have won, I want that winning streak to give my patients the strength and determination to continue with the physical treatments they know make them better and eschew the ridiculous psychiatric based therapies which do not address the root physical causes. My next battle is with the Information Commissioner to insist that the GMC release the evidence base for its refusal to investigate PACE authors. Help me to win that battle."

Note from Newsletter Editor

For ME/CFS people Dr Myhill's core approach has been to test energy systems and offer insights, supplements and dietary approaches to improve their health. She has published a number of scientific papers and associated books.

An overview of Dr Myhill's approach is in our Summer-2013 newsletter.

http://www.rescue.myzen.co.uk/2013%20Summer.pdf (pages 2 to 5)

Dr Myhill's focus is to empower patients to improve their own health. However, certain positions have drawn concern from the medical establishment. Historically Dr Myhill has discouraged women from using the oral contraceptive pill; has recommended an alternative method of breast cancer screening and has warned of a link between the MMR jab and autism.

Because this article brings up the history of contention with the GMC it would seem appropriate to mention that certain restrictions were applied to Dr Myhill in 2010 that were lifted in 2011. An article that talks about these restrictions was included in our 2010 newsletter as per the link below.

http://www.rescue.myzen.co.uk/2010%20Spring.pdf (pages 5 to 7)

Jennifer Brea steps down as Executive Director of #MEAction

Source: www.meaction.net/2020/11/12/important-news-from-jennifer-brea
12th November 2020

Dear Friends, I am writing today with some big news. After five years as co-founder and Executive Director of #MEAction, I plan to step down from that role sometime in the coming months, while continuing to serve as a member of our Board of Directors. Next week, we will officially launch our search for #MEAction's next Executive Director. I wanted to offer a small window into why now and what's next.

Making a film, building an organisation, and growing a movement, all while living with moderate to severe myalgic encephalomyelitis (ME), was challenging, to put it mildly. I did not do it alone. I had the support of my husband, and we had the support of so many friends and family. I also had the strength I drew from you and from our community. With the help of fellow patients and the passion and commitment of our #MEAction staff, I have been able to keep going and keep doing this work that I love, for longer than I ever imagined possible. I am incredibly grateful for that. Every time I was crashed, bed-bound, or facing a new health crisis, our staff, volunteers, and donors stepped up, the organisation grew and, together, the work thrived.

Over the last two years I have had to push through more personal crises than I care to count. I had surgery for thyroid cancer, which dramatically worsened my symptoms of craniocervical instability, atlantoaxial instability, and tethered cord syndrome. I then had multiple major neurosurgeries and a 40-day hospitalisation. The recovery and rehabilitation from these surgeries, hospitalisations, and eight years spent largely in bed or in a wheelchair due to ME was challenging and is ongoing. However, these diagnoses and the treatments for them afforded me the ability to move, think, and exercise without being crushed by the post-exertional malaise, sensory sensitivity, and dysautonomic flares that for so long had become the cost of living. I could walk, I could hike, I could close out the dance floor. It felt like a miracle.

In spite of all these challenges, in May of last year, when I announced the remission of my ME symptoms, I committed to continuing in my role as Executive Director. I did so because I believe deeply in this organisation, in its vision that an empowered, connected, thriving community can change the world, and I knew that with my newfound, post-operative capacity, there was so much more that I could dream, build, do, contribute.

Then in March, my husband Omar and I both got COVID-19. While my ME symptoms did not come back, I became bedbound again, this time for different reasons. For three months, my lungs would burn with even minor movement. My mast cell activation syndrome (MCAS) flared and began to affect new organs/body systems that had never before been affected. This virus was and is so new, I had no idea if I would recover or how it might impact my health in the long run. It took me six months, but I have (nearly fully) recovered from COVID-19—albeit with much worsened MCAS. I did so in part because of the strategies I have learned being a part of this community. I stopped, rested, and then very carefully paced. In those months of uncertainty, I confronted what I had never really had the physical or emotional space to confront during my years living with ME: the truth that these last eight years, for all their gifts of friendship, purpose, and meaning, have also been deeply traumatic.

COVID-19 was the moment that I finally accepted my fragility. I know that is a strange thing to say, given how sick I have been. I've always encouraged others, especially patients involved in advocacy, to put their health first, to know when to step back, take a break, or pass the baton. It is an ethic we have worked hard to cultivate within our #MEAction community, but it is advice I have never given myself the permission to take.

I have a lot of work to do to heal emotionally and physically from all that I have been through, and I've reached a point where that has to be my primary focus. I have always put the work first. Now, it is time for me to pass the baton, to put my body first. The good news is, I have never felt better about doing so than I do at this moment.

Five years ago, co-founder Beth Mazur and I envisioned #MEAction as a platform to develop and support many leaders. We wanted a space where we could come together to fight for ourselves and fight for the people that we love. We believed deeply in the collective power of the ME community and the possibility of distributed leadership. Whether we are doing public outreach; agency, congressional, or parliamentary advocacy; medical education; or offering each other support in our 100+ local and affinity groups, #MEAction has always been a community of many leaders, committed to building capacity across our entire community. I'm very proud of the work that I've done, but it has never been about one person: it's always been about all of us doing what we can, big or small.

Together with our staff, volunteers, nine #MEAction USA State Chapters, #MEAction UK and Scotland affiliates, and all of you, we have accomplished so much in these first five years:

- We helped organise #MillionsMissing events in almost 100 locations, expanding the recognition of this disease around the world.
- We helped bring Unrest VR to Capitol Hill; sent the film to every congressional staffer; mobilised thousands of constituents; cultivated new allies in Washington; and ultimately helped to pass Senate Resolution 225.
- We screened Unrest in Parliament, mobilised over 3000 constituents across the UK, and collaborated with MPs to initiate a series of debates, culminating in an historic House of Commons motion.
- We put pressure on US federal agencies, resulting in an historic meeting with NIH Director Francis Collins.

In the face of COVID-19, we developed educational seminars for clinicians and long-haulers, organised new medical screenings of Unrest, and garnered press from numerous major outlets (like The Washington Post, Time, and The Atlantic) on the possible connections and lessons of COVID-19 and ME—and that doesn't even cover half of our COVID-19 work.

For years, we have campaigned against the harms caused by graded exercise therapy (GET) in the UK, organising petitions, educating MPs, and submitting public comment. Then on Tuesday, after decades of work by the entire UK ME community, NICE published its new draft guidelines, which have effectively scrapped GET as a treatment for ME.

Needless to say, I am so unbelievably proud of all we have achieved, together! I am also excited about this moment because of the work of our friends and partners in the ME community and beyond. Solve ME/CFS's ground-breaking You+ME registry and our Congressional advocacy collaborations; the massive research network the Open Medicine Foundation has built and funded, along with its new partnerships in Canada and with Emerge Australia; the work of Action for ME, Forward ME and others on Decode ME; PolyBio's vision to push the frontier of measurement, with their tissue analysis studies and high-resolution neuroimaging; and the emerging long COVID community's fierce advocacy and patient-led research. Our collective strength, capacity, and innovation have grown in ways I don't think any of us could have imagined five years ago.

The pandemic will forever change our world. Those changes will be felt profoundly by our ME community, presenting us with fresh challenges but also new opportunities to finally create the change we so desperately need. Our next Executive Director will have the daunting but exciting task of working with our board, staff, and volunteers to envision how #MEAction can best contribute to that new world, and collaborate with all of our partner organisations to fulfil our mission to fight for recognition, research, and compassionate, effective care for people with ME.

I am excited to work with our Board of Directors to find that leader, someone who can help propel #MEAction and our community toward an even better future for the millions who have been affected by ME.

While I am confident and hopeful about what lies ahead, this decision has been a weighty one for me, personally. There has been a lot of joy, marvelling at how far we have come, and a lot of tears. I want to be clear, though, that I am not going anywhere tomorrow—the search for our next Executive Director could take a few months, it could take up to a year. I also want to be clear that I am not leaving the larger fight. I plan to remain actively involved in #MEAction as a Board Member, and to support and contribute to the work of all our organisations, as I am able, for many years to come. I have no doubt that #MEAction, our community, and our work will continue to thrive, thanks to our thousands of volunteers, donors, staff, board, and every-day activists around the world. I look forward to supporting, advising, cheerleading, and amplifying all of that exciting work to come.

With a gratitude deeper than I will ever have the words or the art to convey,

Jen

Covid vaccine safety

The UK Government has secured early access to over 357 million vaccines doses through agreements with several separate vaccine developers at various stages of trials, including:

- 100 million doses of University of Oxford/AstraZeneca vaccine – phase 3 clinical trials
- 40 million doses of Pfizer/BioNTech vaccine – phase 3 clinical trials
- 7 million doses of Moderna vaccine – phase 3 clinical trials
- 60 million doses of Novavax vaccine – phase 3 clinical trials
- 60 million doses of Valneva vaccine – pre-clinical trials
- 60 million doses of GSK/Sanofi Pasteur vaccine – phase 1 clinical trials
- 30 million doses of Janssen vaccine – phase 2 clinical trials

The Medicines and Healthcare products Regulatory Agency (MHRA) will carefully and scientifically review the safety, quality and effectiveness data once it has all been submitted to determine how it protects people from COVID-19 and the level of protection it provides.

The data must include results from the lab and clinical trials; manufacturing and quality controls, product sampling, and testing of the final product.

Once they have thoroughly reviewed the data, the MHRA will seek advice from the government's independent advisory body, the Commission on Human Medicines. They will critically assess the data too before advising the government on the safety, quality and effectiveness of any potential vaccine.

The MHRA is globally recognised for requiring the highest standards of safety, quality and effectiveness for any vaccine.

Comment from Newsletter Editor
From the information above there are potentially 7 different vaccines that will be used on the UK population. At this time however, the UK Government has enough of the Pfizer/BioNTech vaccine to vaccinate 20 million people.

If it is approved, the UK have will have enough of the Moderna vaccine to vaccinate 3.5 million people by Spring 2021.

The Oxford/AstraZeneca vaccine has been approved for use in the UK, which will offer 50 million people vaccination.

So the Pfizer/BioNTech, Moderna and Oxford/AstraZeneca vaccines are of perhaps the most interest at the moment. So the reminder of this newsletter will include a few articles that offers further information about these vaccines.

The Pfizer/BioNTech and Moderna viruses are both mRNA type vaccines which is a newer approach to vaccination for Humans.

The Oxford-AstraZeneca's is different and a more traditional approach – it is an adenovirus-vectored vaccine taken from a common cold that normally infects chimpanzees. It has been genetically modified to avoid causing an infection in people and carries only a part of the coronavirus called the "spike protein". Once the vaccine is injected into human cells, it triggers an immune response against the spike proteins, producing antibodies and memory cells which will in the future destroy infected cells.

Covid Pfizer/BioNTech vaccine: What we know about jab's safety

Source: www.independent.co.uk/news/health/coronavirus-pfizer-vaccine-side-effects-safe-b1765035.html

By Health correspondent Shaun Lintern 2nd December 2020

The head of the UK's medicines regulator says "no corners have been cut" in checking the safety of the Pfizer coronavirus vaccine which could be injected into patients as soon as next week.

The announcement that the Medicines and Healthcare products Regulatory Agency (MHRA) had approved the vaccine for use was made by press release from the Department of Health and Social Care at 7am on Tuesday.

No detailed information was made available alongside it.

The full safety data and clinical trial results have still not been published by Pfizer and neither has any technical analysis by the MHRA. Its chief executive June Raine told a Downing Street press conference that the public could be confident there had been an "extremely thorough and scientifically rigorous review".

It would be far better if Pfizer, the government and the MHRA adopted more of a "show not tell" approach.

The Department of Health confirmed to The Independent it has given Pfizer an indemnity from being sued by patients and that the jab has been authorised under emergency regulations, specifically regulation 174 of the Human Medicine Regulations 2012.

This allows a rapid roll out of unlicensed medicines to tackle a public health emergency such as a pandemic. But ministers recently changed this law so that the regulations now, for the first time, protect pharmaceutical companies like Pfizer from civil liability in the event of any complications a result of their vaccine being used.

So what do we really know about the safety of the Pfizer/BioNTech vaccine?

In terms of the clinical trial results, we only have what Pfizer has announced in corporate press releases. It's important to note none of the safety data has been published.

It used around 43,000 people in its trials with more than 20,000 getting the vaccine and only mild side-effects were reported. It was 95 per cent effective at stopping the disease.

While this would suggest that any dangerous side effects that could impact large numbers of people who get the vaccine can be ruled out, it does not mean there won't be very rare side effects that emerge for a small number of people. Such side effects can only realistically emerge once a vaccine is used at population-level involving hundreds of thousands of people which can never be replicated through a smaller clinical trial.

The MHRA has said it will be actively monitoring the roll out of the vaccine through its yellow card reporting system that allows anyone, including the public, to report side effects they believe were caused by the vaccine. It will also be launching a random patient recall system to actively check on patients who have received the jab.

Vaccines are safe. They save millions of lives a year. But very rarely, complications do happen for some people and when they do, they can be devastating. During the swine flu pandemic in 2009 the UK rushed into use a vaccine created by GlaxoSmithKline (GSK), Pandemrix, which had not gone through the normal testing process unlike the Pfizer vaccine which has. The GSK drug was linked to a small number of patients developing the debilitating condition narcolepsy.

The then Labour government indemnified GSK and subsequent legal action by more than a hundred people is believed to have cost taxpayers millions of pounds in compensation. One of the issues was whether patients had been given enough information to give informed consent when being vaccinated.

For example, much of the literature about the swine flu vaccine was misleading and didn't inform people that the company had been given legal indemnity or tested in the usual way.
Should people suffer a permanent disability of harm as a result of a vaccine they can seek a one-off payment from the government under the Vaccine Damages Payments Act and the Department of Health has said ministers will add the Pfizer Covid vaccine to the list of vaccines covered by the law later this week.

That is a helpful step.

But the act only pays out £120,000 which could be of little help to someone who, as in the case of narcolepsy caused by the swine flu vaccine, loses their job and their livelihood. Public confidence is important and making it harder for the minority of people who may suffer a debilitating side effect of the Covid vaccine to get justice seems an odd way of tackling vaccine sceptics.

Peter Todd, a partner at Hodge Jones and Allen, which represented Pandemrix claimants, told The Independent: "I think it would be much fairer if society just stood behind everybody because the chances are actually that the level of adverse reactions will be very very low. Therefore, it really won't cost very much to make sure that everybody who has it is fully indemnified.

> "I think that would have been a better way for the government to promote the vaccination than simply say, 'You're all on your own, it's at your own risk.' That's a poor message really and encourages hesitancy which is not helpful in a pandemic."

He added that patients needed to be given enough information to be able to make informed consent.

> "I'd be interested to know why the government have given an indemnity [to Pfizer]. I can only assume it's because without it, the pharmaceutical company would have been reluctant to actually supply the vaccine.

> "I think that people ought to be aware of that because people have got to make a choice about whether they're vaccinated, or not, they ought to be given good advice and good information in order that they can make the right choices.
>
> "It undermines giving informed consent if you're not given all the relevant information to make a decision at the time."

Doubts and questions about the vaccine remain. It appears safe for the majority of people based on the information that has been published to date from the clinical trials and the MHRA's assessment.

The UK death toll from coronavirus now exceeds 60,000 deaths. (76,305 as of 6th Jan 2021) With those sorts of numbers it is clear the risk-benefit analysis of having the vaccine is hugely in favour of getting the jab.

It is essential to save lives and get the country back to normal.

Five things you need to know about: mRNA vaccine safety

(Both the Pfizer/BioNTech vaccine and Moderna vaccine are mRNA type vaccines)
Source: https://horizon-magazine.eu/article/five-things-you-need-know-about-mrna-vaccine-safety.html

by Alex Whiting 11th December 2020

The world's first mRNA vaccine has begun its rollout after being produced at unprecedented speed as part of the global effort to end the Covid-19 pandemic. A second one is hot on its heels. The two – one made by Pfizer/BioNTech and the other by Moderna – mark the first time this vaccine technology has been approved for use.

In trials these vaccines have shown to be at least 94% effective at preventing people from falling ill with Covid-19. But how safe is this new technology? We spoke to Michel Goldman, a professor of immunology and founder of the I3h Institute for Interdisciplinary Innovation in healthcare at the Université Libre de Bruxelles in Belgium. Here are five things to know.

mRNA vaccine technology is not entirely new
Vaccines such as the inactivated polio vaccine, or most flu vaccines, use inactivated viruses to trigger a person's immune system to respond to that disease-causing organism. In other vaccines, such as the hepatitis B vaccine, an individual protein made by that organism is injected instead to trigger a similar response.

mRNA vaccines, however, trick the body into making the viral protein itself which, in turn, triggers an immune response.

Although the COVID-19 vaccines made by Pfizer/BioNTech are the first mRNA vaccines to complete all clinical trial stages and be licensed for use, the technology has been around for a while. Human trials of cancer vaccines using the same mRNA technology have been taking place since at least 2011.

"If there was a real problem with the technology, we'd have seen it before now for sure," said Prof. Goldman. Because the technology can be deployed extremely rapidly, and clinical trials have been so successful, mRNA platforms will be an important means of preparing for future epidemics, he says.

mRNA vaccines do not alter your DNA
A concern that some have had about the mRNA vaccines is that they could change people's DNA. But that idea is 'completely false' and has 'no scientific basis', says Prof. Goldman.

'The (vaccine) mRNA will not enter the nucleus of the cells, where our DNA is.'

Once the injected mRNA enters a human cell, it degrades quickly and only stays in the body for a couple of days. This is why people need two injections to develop the best immune response, he says.

"The highest risk right now (especially for vulnerable people) is not to be vaccinated."
Prof. Michel Goldman, Université Libre de Bruxelles, Belgium

mRNA vaccines are very specific
The novel coronavirus, or SARS-CoV-2, has a complex structure, and different parts of the virus trigger the immune system to produce different antibodies to neutralise the virus.

If an unvaccinated person catches the virus, they will produce antibodies that prevent the virus from entering human cells. They may also generate antibodies that do not have much impact. And in some cases, a person may produce antibodies which actually help the virus enter cells.

mRNA vaccines are much more specific. They are designed to only trigger an immune response to the virus's spike protein, which is just one component of the viral membrane and enables the virus to invade our cells.

To be sure this is the case, researchers are carefully monitoring that the vaccine does not trigger an unwanted immune response.

"So far this has not been shown for the (Covid-19) vaccines." But it "will remain important to ensure the immune response triggered by the vaccine is focused on the viral spike protein," said Prof. Goldman.

Corners were not cut in the clinical trials and approvals process
Vaccine trials take place in stages, starting with trials on animals, and then three trials on people – Phase 1, Phase 2 and finally Phase 3.

The Pfizer/BioNTech vaccine Phase 3 trial involved more than 40,000 people. It began in July and will continue to collect efficacy and safety data for another two years.

Safety issues that would affect significant numbers of vaccines mostly appear within two months, Prof. Goldman says.

However, after a vaccine is given to millions of people, very rare side effects that cannot be anticipated from clinical trials might develop, so researchers and regulators will be keeping a close eye on how the vaccine rollout goes. This will be especially important for Covid-19 vaccines based on innovative technology.

Regulatory agencies reviewed the data from Covid-19 vaccine trials more quickly than usual by looking at it on a rolling basis rather than only once the trials were complete, but they did not fundamentally change their rules. 'I really don't think that corners were cut in terms of safety,' said Prof. Goldman.

The process was faster than usual because researchers had already built an mRNA platform – a way of getting viral mRNA into the body – for cancer and other vaccines under trial. It meant this could be put into action as soon as the genomic sequence of the virus was shared.

Companies and governments also took the risk of producing large numbers of vaccines even before the the first stages of experimentation had been completed, which meant they were ready to begin large human trials as soon as the results were in.

‘It’s a financial risk, because if you were wrong all this is lost. That’s why the risk is shared between the private companies and the governments,’ said Prof. Goldman.

The vaccine triggers an inflammatory response
The vaccine partly works by inducing local inflammatory reactions to trigger the immune system. This means that it’s normal for many people to experience pain at the site of the injection and sometimes fever and discomfort for one or two days after the vaccine.

‘This is something that has not been advertised enough,’ says Prof. Goldman.

A November survey in 15 countries found 54% of people were worried about possible side effects from a Covid-19 vaccine.

One unwanted response to the Pfizer-BioNTech mRNA vaccine came to light during the first day of mass vaccination in the UK after two people with a history of significant allergies reacted to the injection. The UK regulatory authority updated its advice to specify that people with a history of anaphylaxis to medicine or food should not get the shot.

In the clinical trials, allergic reactions occurred in 0.63% of people given the Pfizer-BioNTech vaccine, and in 0.5% of people given a placebo.

‘My main concern is that people will use (possible side-effects) as an argument not to be vaccinated,’ said Prof. Goldman ‘The highest risk right now (especially for vulnerable people) is not to be vaccinated.’

Prof. Goldman was the first executive director of the Innovative Medicines Initiative, a partnership between the EU and the European pharmaceutical industry to speed up the development of, and access to, innovative medicines.

Oxford Covid vaccine 'safe and effective' study shows

Source: www.bbc.co.uk/news/health-55228422
By Michelle Roberts 8th Dec 2020

The Oxford/AstraZeneca Covid vaccine is safe and effective, giving good protection, researchers have confirmed in The Lancet journal.

Most in the study were younger than 55, but the results so far indicate it does work well in older people too. The data also suggest it can reduce spread of Covid, as well as protect against illness and death.

The paper, assessed by independent scientists, sets out full results from advanced trials of over 20,000 people. Regulators, who will have seen the same data, are considering the jab for emergency use. But there are still important questions about what dose to give, as well as who it will protect.

When the interim trial results were made public in a press release about a fortnight ago, the researchers reported three efficacy levels for the vaccine - an overall effectiveness of 70%, a lower one of 62% and a high of 90%.

That's because different doses of the vaccine were used in one part of the trial. Some volunteers were given shots that were half the strength than originally planned. Yet that "wrong" dose turned out to be a winner - giving 90% protection - while two standard doses gave 62%.

The Lancet report reveals 1,367 people - out of many thousands in the trial - received the half dose followed by a full dose, which gave them 90% protection against getting ill with Covid-19. The relatively small numbers in this group mean it is hard to draw firm conclusions. None of that group were over the age of 55 though - and experts know it is older people who are most at risk of severe Covid illness.

In terms of safety, there was one severe adverse event potentially related to the vaccine and another one - a high temperature - that is still being investigated. Both these participants are recovering and are still in the trial.

The study also measured protection against asymptomatic infection by asking volunteers to do regular swabs to check if they had Covid without feeling unwell. More of these cases were seen in the group that did not receive the vaccine.

Pascal Soriot, chief executive officer for AstraZeneca said: "The results show that the vaccine is effective against Covid-19, with in particular no severe infections and no hospitalisations in the vaccine group, as well as safe and well tolerated.

"We have begun submitting data to regulatory authorities around the world for early approval and our global supply chains are up and running, ready to quickly begin delivering hundreds of millions of doses on a global scale at no profit."

Dr Charlie Weller, head of vaccines at Wellcome, said: "Today marks another key milestone in the Covid-19 vaccine journey.

"Although we await the trial completion and full data, it is highly encouraging to see the data behind the interim results announced last month, including an analysis of the different dosing regimens. This suggests that this vaccine could prevent asymptomatic disease."

But some experts said the data could present regulators with a dilemma, with a relatively small cohort in the trial - which didn't contain any over-55s - getting a half-dose, which produced the best results.

Dr Michael Head, senior research fellow in global health, from the University of Southampton, said the researchers "were not yet able to fully assess how effective this vaccine is in elderly populations" and this could have implications for the roll-out in older age groups.
AstraZeneca executive vice-president Sir Mene Pangalos said adults of all ages needed to be vaccinated to make a "dent" in the pandemic.

"I realise the people that are most severely impacted by disease are the over-65s, over-75s, over-85s, but the reality is we need to actually have vaccines that immunise everyone from adolescence to the oldest adults to really dent the pandemic around the world," he said.

Meanwhile, the UK has started a mass vaccination campaign with another Covid jab made by Pfizer/BioNTech. On Tuesday Margaret Keenan, a 90-year-old grandmother, became the first person in the world to get the Pfizer Covid-19 jab as part of a mass vaccination programme..

The Oxford/AstraZeneca vaccine could also play a major role in fighting the pandemic if it is approved soon. It is cheaper than some of the other Covid vaccines and easier to store and distribute.The UK government has pre-ordered 100 million doses of the Oxford vaccine, which uses a harmless virus altered to look a lot more like the virus that causes Covid-19.

AstraZeneca says it will make three billion doses for the world next year.

Covid19 vaccine rollout and ME/CFS

Sources: www.bbc.co.uk/news/health-55228422
www.meresearch.org.uk/the-vaccination-question

This article contains answers to some of the basic questions about the Covid19 Vaccine rollout, which you will likely have already seen in the news. But also a small section about vaccinations in general for ME/CFS people.

Who will get the vaccine first?
Broadly, vaccines are being given to the most vulnerable first, as set out in a list of nine high-priority groups, covering about a quarter of the UK population. They are thought to represent 90-99% of those at risk of dying from Covid-19.

1. Residents in care homes for older adults and their carers
2. 80-year-olds and over and frontline health and social care workers
3. 75-year-olds and over
4. 70-year-olds and over and clinically extremely vulnerable individuals
5. 65-year-olds and over
6. 16- to 64-year-olds with serious underlying health conditions

   As ME/CFS is classified by both NHS England and WHO (World Health Organisation) as a neurological condition it should fall into this category according to Dr Charles Shepherd, Medical Adviser, ME Association. Because chronic neurological conditions are part of the 'serious underlying health conditions' list. And COVID-19 will almost certainly exacerbate pre-existing ME/CFS symptoms or cause a relapse of ME/CFS.

   Source: https://meassociation.org.uk/2020/12/covid-19-vaccine-eligibility-safety-and-me-cfs-what-we-know-so-far

   It is currently unclear if ME people will indeed be treated in the 'serious underlying health conditions' category, or who is deciding. It may well be above GP practices though they have been given some level of flexibility within categories to prioritise certain patients. Current advice is not to try to phone your GP practice as the lines are already very busy, but perhaps write to your doctor if necessary.

7. 60-year-olds and over
8. 55-year-olds and over
9. 50-year-olds and over

People aged over 80 in hospital, frontline health staff and care home workers have been the first to get the Pfizer jab at 70 designated hospitals hubs across the UK. Vaccination has now begun in care homes, which the government announced on 23 December. The second phase of vaccination will focus on the rest of the population, mainly the under-50s, who are much less likely to be ill with Covid-19. Teachers, transport workers and the military could be prioritised at that point, but more data on how well the vaccines are working will be needed before that decision is made. It could be well into 2021 before this phase begins.

What about the two dose policy?
Both the Pfizer and Oxford-AstraZeneca vaccines require two doses to provide the best possible protection. Initially, the strategy for the Pfizer vaccine was to offer people the second dose 21 days after their initial jab - full immunity starts seven days after the second dose. But when approval was announced for the Oxford-AstraZeneca vaccine on 30 December, it was also announced that the policy would now change - the new priority would be to give as many people a first shot of either vaccine, rather than providing the required two doses in as short a time as possible. Everyone will still receive their second dose, but this will now be within 12 weeks of their first. The Oxford-AstraZeneca second dose should be given between four and 12 weeks after the first, while the interval between the first and second Pfizer doses should be three to 12 weeks.

Can different vaccines be mixed and matched?
The official guidance states that every person should get the same vaccine for both doses. Dr Mary Ramsay, Head of Immunisations at PHE, said: "We do not recommend mixing the Covid-19 vaccines - if your first dose is the Pfizer vaccine you should not be given the AstraZeneca vaccine for your second dose and vice versa."

However, in the very rare circumstance in which only one vaccine is available at a vaccination site or it's unknown which product an individual received for their first dose, Public Health England says a different vaccine could be administered. But this advice does stress "this option is preferred if the individual is likely to be at immediate high risk or is considered unlikely to attend again".

"There may be extremely rare occasions where the same vaccine is not available, or where it is not known what vaccine the patient received," Dr Ramsay said. "Every effort should be made to give them the same vaccine, but where this is not possible it is better to give a second dose of another vaccine than not at all."

Where will I get a vaccine?
You'll be invited to book an appointment to get a vaccine as soon as it's your turn, probably by letter. Vaccinations will take place:

- in hospital hubs - about 70 have been set up across the UK so far
- in care homes, when the logistics are confirmed
- in thousands of GP surgeries as stocks become available
- in sports stadiums and conference centres acting as major vaccination hubs next year

The NHS is recruiting 30,000 volunteers to help with the rollout, including lifeguards, airline staff and students. It is a little unclear but perhaps only those with a medical background will be trained to give the jabs, the rest ushering for example. About 200 GP surgeries will offer vaccinations to the over-80s first. The programme will then be expanded out to more than 1,000 surgeries - with each local area having a designated site.

Vaccines in general and ME/CFS
We can only look at other vaccines such as the flu vaccine to see how ME/CFS people might be affected because the Covid19 vaccines and ME/CFS have not yet been studied. Some patients say that vaccinations, including for flu, significantly worsen their condition – and the numbers affected might be higher than we think. For instance, in Action for ME's very interesting article in 2006, "To Jab or not to Jab" – which drew together patients' experiences of vaccinations and the views of some clinicians and charities including ME Research UK – 4/20 (20%) patients said that the flu jab provoked a marked flare-up in their symptoms while other respondents reported a variety of reactions to other vaccines, though most respondents reported little or no adverse effects.

Given the importance of the Covid19 vaccination a flare-up from vaccination is likely preferable to a flair-up or more serious consequence of having Covid19.

Although mercury has long generally been withdrawn from use in vaccines, in both the UK and USA (to reduce the overall burden/exposure to mercury) there are exceptions such as the Swine flu vaccine for H1N1 in 2009. None of the Pfizer, Moderna or Oxford vaccines contain mercury.

> **Mercury**
> The ingredients used in the mRNA vaccines developed by Pfizer and Moderna are simple. They contain mRNA, as well as lipids to ensure safe delivery of the mRNA that will initiate an immune response. Although FDA approved adjuvants (aluminium salts) and preservatives (ethlymercury) have a history of safe use in vaccines, they were not used by Pfizer and Moderna in this vaccine technology.

Source: https://covidvaccine.mo.gov/facts/

The Pfizer vaccine BNT162b2 is highly purified single-stranded, 5'-capped messenger RNA (mRNA) produced by cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2. And includes the following excipients (stabiliser/therapeutic-enhancer such as drug absorption):

- polyethylene glycol/macrogol (PEG) as part of ALC-0159.
- ALC-0315 = (4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate)
- ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide
- 1,2-Distearoyl-sn-glycero-3-phosphocholine
- cholesterol
- potassium chloride
- potassium dihydrogen phosphate
- sodium chloride
- disodium hydrogen phosphate dihydrate
- sucrose
- water for injections

Source:https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca

The Oxford vaccine also appears to not include any Mercury. It includes the weakened adenovirus encoding the SARS CoV 2 Spike glycoprotein, as well as the following excipients:

- L-histidine
- L-histidine hydrochloride monohydrate
- magnesium chloride hexahydrate
- polysorbate 80
- ethanol
- sucrose
- sodium chloride
- disodium edetate dihydrate
- water for injections

Source:https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca

Allergic reactions

It has already been in UK news some time ago but people with significant allergies have been advised to avoid having the Pfizer vaccine specifically. But will likely equally apply to the Moderna vaccine.

Severe allergy-like reactions in a number of people who received the Pfizer vaccine may be due to a compound in the packaging of the messenger RNA (mRNA) that forms the vaccine's main ingredient, scientists say. A similar mRNA vaccine developed by Moderna, which was authorised for emergency use in the United States also contains the compound, polyethylene glycol (PEG).

PEG has never been used before in an approved vaccine, but it is found in many drugs that have occasionally triggered anaphylaxis — a potentially life-threatening reaction that can cause rashes, a plummeting blood pressure, shortness of breath, and a fast heartbeat. Some allergists and immunologists believe a small number of people previously exposed to PEG may have high levels of antibodies against PEG, putting them at risk of an anaphylactic reaction to the vaccine.

Others are skeptical of the link. Still, the U.S. National Institute of Allergy and Infectious Diseases (NIAID) was concerned enough to convene several meetings to discuss the allergic reactions with representatives of Pfizer and Moderna, independent scientists and physicians, and the Food and Drug Administration (FDA).

Source: www.sciencemag.org/news/2020/12/suspicions-grow-nanoparticles-pfizer-s-covid-19-vaccine-trigger-rare-allergic-reactions

If anyone turned out to be in the limited number of people to have an allergic reaction, thoroughly trained medical staff will be on-site to treat any problems.