Approaches to reduce barriers that prevent individuals with ME/CFS from participating in research. For example, these might be logistical challenges, such as difficulty traveling to a study site, or might be because of an unwillingness to undergo certain types of research protocols
If there are hardly any places doing studies, it's hard for us to get to them due to the cost of plane travel, lodging, rental car, etc. Not to mention, many studies may be dubious in terms of whether or not it's actually applicable to our patient population. The Fukada criteria, pardon my French, is shit. It doesn't select for a homogenous group of patients. You could have major depression and still get (mis)diagnosed with "CFS," according to the Fukada criteria. You and the CDC have been completely botching the case definition and it's application in studies since the 80s. Look at people who did it better, study these: Ramsay International Consensus Criteria Canadian Consensus Criteria Dr. Leonard Jason has written extensive comparisons about the plethora of case definitions. Go talk to him. Read all his papers. Ditch the Fukada criteria. And the IOM criteria (2015), honestly, has a lot of problems. When you don't listen to the experts/stakeholders, you're going to keep messing it up like you have been for years. Many people rightly don't want to participate in studies that use dubious case definitions because the "results" will say they're results for "ME" people, but it's really just a mish-mosh. So don't require researchers to use a flawed case definition (Fukada) to be eligible for grant money! Can you imagine if NIH would only give grant money for cancer research if researchers used the Megan Case Definition (2019) that says cancer is identified by because people will have the name Megan. Understand my point?
Centralised symptom/patient databases could help identify appropriate patients without initial travel. Home based interventions - like blood testing or drug trials - may be needed for the severely affected.
Fund for travel / expense for patients if it requires travel. This is a huge burden financially and most of these patients do not work or have a positive cashflow. Have research opportunities in the Midwest, as research opportunities are mainly in the West, East, and South (Alabama).
I travelled to Stanford University from San Diego, CA to participate in two research studies. My community raised the money for me to be able to travel with my spouse & for someone to watch out children who stayed behind, as the trip was cost prohibitive to us on our own. There are more studies I qualify for, but I am unable to afford all the expenses we would incur to the there. I am also more severely effected then I was when I did the study. I would probably need medical transport to participate, and would not be able to participate in studies that might further worsen my condition, like exercise studies and spinal taps.

Ditto
$ to enable home visits by care providers who are trained to do rigorous assessments based on objective quantifiable criteria, and are up to date on therapeutic options including trials.
Exercise physiological data can be collected remotely without patients needing to travel. Surveys and questionaires are best done at home/before day to reduce exertional load. Travel is difficult and wheelchairs etc may be needed, somewhere to lie in the dark/quiet to rest on arrival. Recliner chairs/beds for patients to lie on while talking to researchers. Food water if provided needs to be preservative free, bland and low food chemical.
Exercise studies are hard on people with ME and can permanently worsen our condition. Must be sensitive to this issue.
In my case, I have 50 years experience in biology, and it is a therapy obtained by combining various fields such as pharmacology, medicine, oriental philosophy, alternative medicine, and feng shui. It would be good if the treatment was approved first and then the therapist was trained. There is no injection, medicine or surgery, so it is unlikely to be in modern medicine. As Jesus(God) heals a demon-possessed person, some psychic powers may enter and limit traditional research or papers
The system must learn how to deal with “Lazy Doctor Syndrome”
Clearly severely affected patients have difficulty participating in research, so accommodations must be made (e.g. driving patients to the research clinic, making their time there as stress free as possible, etc).
Have traveling phlebotemists to go into patients homes to collect blood. Have doctors/researchers do the same to gather histories, exams, etc
The ones that can get to you are the earliest in the disease to study. The homebound, bedridden - survey them, then if selected, skype them or zoom, we have the technology these days, students that know how to use it for gathering information. There is no excuse to find participants. Many of us that are borderline able to drive will make the trip for a study if you are for real about getting results. We want to help you help us.
Studies requiring hair samples could be mailed to the person with ME and mailed back.
As above: ME literate persons collecting/managing intake data from patients who could also provide emotional support and explanations, education if patient(s) feel uncertainty at any point of the process. And possible RN home visits for sufferers who are unable to get to research facility.
1) diagnoses are too late to participate in research sometimes, so have an initiative to diagnose early and quickly 2) reach out to diverse populations. Mostly white people are being diagnosed (I’m one) but I know that there are so many more out there who are being overlooked and are not white.

Utilize widespread technology that allows video chat (FaceTime, Skype, etc.) and develop online portal for the sharing of various medical testing (bloodwork, physician notes, etc.). Make sharing that information free and easy.
Work with clinicians in this field, such as Doctor Kaufman, and Paul Cheney, to find treatments that may help a little with PEM after study sessions, to help with the traveling and/or risk incurred by an exercise challenge. IV saline is one of these, but there are others.
all access to patients can be easily through the GP and hospitals and emergency rooms
MONEY! FUNDING! I LIVE IN LOS ANGELES; THERE ARE SEVERAL STUDIES I WISH TO PARTICIPATE IN BUT ARE EITHER 400 MILES AWAY FROM ME IN STANFORD OR 3000 MILES AWAY FROM ME IN ITHACA, NEW YORK OR BOSTON MASSACHUSETTS. I AM ON DISABILITY AND CANNOT AFFORD THE TRAVEL OR LODGING.
PLEASE SEE ABOVE!
A scientific study of the consequences of exercises studies might help me make a risk based decision. At the moment I won't as anecdotally I hear it permanently progresses the disease. Travel is the other main blocker I'm too ill. Technology can often overcome this, for comms or getting local clinic support eg attaching holsters taking bloods.
Hold Studies like the one at the NIH in various cities throughout the USA Or have researchers go to the patients house who are bedbound/ housebound
Patients are housebound & bedridden so tests & treatment should be done in home as they are too vulnerable to co-infections in doctors offices, research labs etc. ALSO ignorant doctors are forcing anti-depressants on swollen brain. Patients who refuse such regimes are labelled as psychiatric, institutionalized or sectioned.
Hacer una recogida de muestras biologicas, a nivel mundial. Facilitar los desplazamientos de los enfermos
Research protocols need to be designed with input from patients with various severity of the illness. The Workwell Foundation published a paper on their CPET testing protocol which includes many good considerations to help patients attend the testing and recover from it. In the UK the ME/CFS biobank team travel t patients' homes to conduct clinical exams and take samples, so as to minimise exacerbation of patient symptoms and reach housebound/bedbound patients. Where patients have to come in, help with travel, outside rush hour, quiet waiting area, space to lie down before and after testing, provision of fluids to stay hydrated, blankets to keep warm, minimise movement and chatter or noise in the area, minimise visual stimulation... Allow rest breaks, send forms to be completed several weeks in advance, don't overload with information - present it in a simple and accessible way and allow plenty of time for patient to process the information. Do not give rapid verbal instructions. Provide a bullet point summary of the protocol to the patient in advance, and any instructions in writing in advance.
-Bringing resources to the patient’s home - collecting data samples in the patient’s home (i.e., body fluids) at different time points (when the patient is having a relatively good vs. bad day) -Providing education to people who collect samples about the unique needs of ME/CFS patients

(having the person collecting the samples be scent-free, speaking in a soft voice/whisper, providing a low sensory experience. This includes recognizing these patients' needs to lie down etc. - to not over exert and therefore have Post Exertional Malaise)
Ya think? You suffer from the sickness, pain and devastation of this illness and see how much you want to travel of undergo research protocols. Why bother, this is all just to fool us yet again that you could actually want to do something for patients. You may be smooth at lying but we are better at detecting lies.
Well in many severe patients it is impossible to travel but samples can be collected in coordination with standards set by a central agency. Some of these obstacles are being handled in current disparate research efforts via sample databanks. We need more of this. The bigger issue is coalescing it all with a coordinated approach. And don't allow different case definitions to dissuade the effort. If enough samples show particular similarities using the same test, start there. ALSO we need a central database with anonymous generalized data provided by the PCP to the NIH or CDC or working group(s). AI will identify and corroborate what me/cfs practitioners already seem to know.
Consider partnerships with non-profit organizations to alleviate issues of transportation and accommodations.
NIH put up the biggest barrier to their own study when they excluded people with ME/CFS who had a more gradual, non "infectious" onset. That excludes about 40% of us, including me who met all the other criteria and were willing to participate. NIH chose to issue Collaborative Research Center grants all to Eastern US Centers, thereby narrowing the cohort, as most of us are too ill to travel far. Participating in research costs us, both in our health and wallets. For example, I spent $5000 on travel for a Phase 2 drug trial. This required 6 trips back and forth and about 24 hotel stays. The compensation for the study was only $1500. I felt that it was worth the risk to my health and the money, because the drug had the potential to be curative, and this was not a placebo controlled double blind study. Only because I knew for certain I would get the drug, was the risk worthwhile to me. CPETs are risky, and many people feel that they can be harmful, and cause permanent damage. Providing IV saline after the tests is very helpful in recovery, and may be enough of a consolation to some. Most research is investigational. People with ME are more likely to be motivated to participate in interventional studies, particularly drug research. NIH should be engaging Big Pharma to study off drugs already in use "off label" such as Ampligen, Low Dose Naltrexone, Mestinon, etc.
Often they cannot leave their homes so a doctor will need to visit them for samples but there are many of us who can go to a doctor office or lab for testing They must provide a bed and dark room for patients to lay down in if the test is long

Skype. Funding for home visits.
Again = provide funds for travel/accomodation/a carer.... Provde appropriate environments - low noise, light. Somewhere to lie down. Also fund sending researchers to patients' homes
Remote monitoring eg use of heart rate monitors FaceTime consultations and use of online resources
- An international network of medical professionals assisting the collection of (blood?) samples.
First be kind and don't say it is all in head. If it was all in head then patient's symptoms wouldn't worsen only after exertion.
Although travel and exertion could be discouraging factors, this is a population so eager for research that I believe there will be many willing participants.
Allow participation from home eg via Redcap to collect data, or by paper submission Allow biological samples to be taken locally by local professionals and sent on Biomedical research attracts far more patient participation If the International Consensus Criteria or Candidian Consensus Criteria are not used some patients refuse to take part
None forseen, except monetary.
We are ill. Some of us can't afford to risk becoming sicker. BE GENTLE AND SUPPORTIVE - BELIEVE US IF WE SAY WE MUST STOP A TEST.
Many are too ill to travel and made much worse by travel etc...Do as much as possible online and via SKYPE/Zoom. Dark. quiet chemical free (no vinyl, perfumes, hand sanitisers) places for patients to rest on arrival. Remember that talking/listening can be onerous. Get patients to do as much as possible at home eg video themselves doing the lean test and provide the data...rather than do it in the lab. At home they don't have the stress/exertion of getting to the lab and can lie down afterwards and rest well. 2-day CPET tests can make people ill for many months and so less onerous tests are needed. Give people time to complete forms etc at home and upload the results rather than onerous in lab form filling.
Understanding the depth of illness we suffer & the fear of worsening our state is very real & justified. The risk of a moderate case becoming severe, house or bed bound is real. This support offered is tenuous at best. I would require a driver & accommodation to participate in research at a centre. Alternatively, collections could be done in the home. Aftercare follow up for post exertional crashes. Studying the disease at different stages. My experience is definitely of changes over the years where the disease shifts gear. It was very obvious to me right from the beginning that something was

seriously wrong, it would have been the ideal time to collect data. GP's should be able to recognise the possibility of ME from inception of sudden onset of viral cause, they simply need updated training. A holistic GP was able to recognise the seriousness of illness & provide symptom management where regular GPs did not. I am one of very few fortunate to have received care & compassion fairly early in the process. However, most doctors do not know the difference between ME & CFS, unfortunately GET was recommended to detrimental effect. Exertion is dangerous at certain disease stages & possibility limited forever.
If medical personnel could be trained (classrooms, or by Skype) to do the needed tests and follow through no matter where they lived, more patients who are very ill could participate in the research studies. As these patients are more severely ill, the anomalies might show up more readily.
Online, SKYPE,
1. Provide funding for people to travel to a study site as well as accommodation. 2. Conduct studies in multiple languages and/or provide translators. I suspect that many non-English-speaking background patients are far overlooked and reticent to participate due to cultural and linguistic barriers.
You need to allow older individuals to participate. If the individual has been ill with ME/CFS for ten years or more, you should not refuse to have them in a study because they are "too old" and have developed other diseases. If they have had ME/CFS a long time, chances are good that many of their problems stem from that illness. Also they may be developing chronic illnesses earlier than is usual. You need to know that. Ignoring this population doesn't help.
Need non-invasive 24/7/365 heart, breathing, movement tracking for very severe ME: you will be shock on immobile some like by son were for years, incl no leg movement. For severe light sensitivity, should have photometers that track level of room light that is unacceptable for patients. For my son, a starry nite w no moon would be excruciatingly bright, so had to make all walls, ceiling black, black curtains in hall window 100% blacked out inside and out will Al foil. His light tolerance was approx E-8 Candela/m2 for two years. Separately, please note Doxycyclin gave VERY severe eye pain for eye sockets, screaming for hours daily for month, went away overnight when Doxy stopped
-digitally accessible research opportunities -self-administered study designs with perhaps wearable tech or blood draws at local clinics -clear, direct questions on questionaire -flexible participation windows -transportation provided or transportation stipends
Create a network of universities, educational institutions and health facilities to participate collaboratively to collect samples and data from people Over a wide area to widen the net for More data.

Use Easily designed internet daily symptom tracking tools along with basic fees for patients to have blood drawn at the Red Cross, or have kits for us to submit other physical substances such as saliva, stool,etc, and also from family members for genetic studies. Also consider, hiring a company with nurses in large metropolitans who could be paid to take samples from a broad cohort there as opposed to a small city
Design studies that can be undertaken with more minimal challenges. If ME/CFS patients had ebola virus or amyotrophic lateral sclerosis, what could be done to include them in research?
For any ME/CFS personlife can be exhausting so the idea of hours and hours of questions is overwhelming, especially for a child who has a shorter attention span. Childhood research would likely require a different approach/reward. As a parent I would truthfully want to know how the research would help my daughter directly...I would want to see the research results and suggested ways it could us.
The researchers need to come to the patients, to draw blood or whatever. They are too fatigued!
The answer is obvious - these patients are too ill to travel. Most are fortunate if they can even leave their bedside to participate. If they do travel they require a serene setting, rest and sleep, saline IVs to help them overcome their electrolyte imbalance, proper nutrition and to be in a germ free environment free of environmental toxins.
Having volunteers got to their homes to collect lab samples, as they cant get out. Set up ride sharing. Lab sharing with Healthcare institutions. What are the barriers? identify them . Then brainstorm. Ask for volunteers, a lot of Seniors like to volunteer their time for worthy causes. For many patients taking meds makes it so we can not participate in trails etc, work around this. Most of us are on meds of some kind or other. For answers to this, we need to know what the exact barriers are. Do emails asking what these are to your base .Tell us what you need and let us tell you if we can make it happen.
One suggestion is to reduce the stigma of the disease or provide a platform that has some anonymity and more may come forward to participate. Many of us hide our suffering in the shadows and those fortunate enough to have options work jobs remotely from home but I personally would hesitate participating in research that could risk having my employer or colleagues learn of my illness. Also making the studies more accessible for bedridden patients by doing them remotely could create greater participation.
Modify a Fitbit-like home measurement device that sufferers can use to report data remotely from home in an automated way
Testing that can be done at home, local labs etc. It is critical to study the most severe patients to truly understand what is wrong.
The barriers mentioned are significant, but there are also barriers set by the research teams and clinical trials which are targeting young white people of young through middle age, when in fact there are older people who are healthy otherwise who suffer ME/CFS. Older people who have been ill for

many years may have insights to contribute and experiences that may add to the knowledge of whether this is one illness or many and what it affects long-term, not only short-term.
As a ME/CFS patient, I think traveling to the study site is the number one issue in participation. My suggestion for this would be having multiple off-site sites around the nation to increase participation and increase the study sample.
Connect with clinicians and use clinicians to collect samples and data, saving patients from having to travel. Funding would be needed to make this possible.
A mobile study- chronic virus testing, that is very quick and low key. Go down the list of most likely culprits. This could come up with some interesting stats. Never pressure a patient to do something-like exercise-when it would very likely do harm.
Increased funding.
Having a group of healthcare professionals assigned to visiting homes where homebound and bedbound patients reside, to gather information from caregiver if patient is unable to provide, develop mobile EKG's, vitals, blood work, etc..., and keep questionnaires as simple as possible as to not discourage people from participating in clinical trials. The mental and physical effort required often worsens symptoms of those with ME/CFS, so need to keep the research procedures very basic and simple as possible.
Expand the number of research facilities, possibly by working with universities in more cities. I NEVER see research studies in my area that I am able to participate in. I think everyone would be shocked by how many of us would be willing to participate in a study in the HOPE of finding any cure, or at the least, relief of some of our symptoms.
Too many of us live in abject poverty, have lost the ability to work, are unable to fill out forms or travel to places where our disability and needs might be recognized and met. This disease itself is a barrier to getting the help we require. We've lost jobs, family, friends and in too many cases, our homes. I suggest setting up another 15 or 20 non-profit Centers of Excellence all over the country, staffed by Specialists (perhaps newly minted, without the prejudices rampant today) in every medical specialty under which we might show symptoms - with safe, mold-free private or shared HOUSING (depending on the requirements of the individuals for sound and light controlled environments and in-house clinicians in every specialty for those of us who have become homeless. Perhaps a version of VISTA for Physicians - a year or two rotation in their post graduate training that might counter some of the debt they assumed during their original training. All Centers should share information with each other and the rest of the research community. Sensitive paid staff could help with bathing, housekeeping and delivery of wholesome individually appropriate sustenance. Respect for our privacy and individual needs should be a primary requirement. Currently there is nowhere for us to go when we've lost everything to this illness and the few organizations that might help in extreme circumstances (like AMMES.ORG) have very limited resources. Those of us with financial resources might be asked to pay rent. Individual Health Insurance for those who still have it, Medicare and Medicaid could cover some of the costs of our healthcare and centers where those of us who are not bed-bound might meet - or interact with

others there or outside the community on a shared network we all can access. This might provide whole communities of people living with ME, some of whom MIGHT be willing, even eager subjects for research, already in place. An on-site nurse could provide the regular IV saline drips that improve those of us with autonomic issues, nutritious hot food (with attention to each person's sensitivities) could be delivered to the people living in the community and the isolation that leads to so many suicides and deterioration because of inadequate nutrition could be addressed. It would be essential to honor the Helsinki Protocol to be certain that the people living in these communities have complete control of whether or not they want to participate in any research project and all research would have to be overseen by advocates to be certain no one in these communities is required to participate in any research at all - and all research should be as non-invasive as possible. Most of us want to help as much as we can - without risking our remaining health to do so.
A lot of patients are simply too sick to travel. I myself am bedridden, my life is crushed by this disease. Biobanks or nurses to visit patients for blood draws.
-
The use of activity trackers As ME/CFS patients experience post-exertional relapses, their activity pattern might offer valuable clues into the nature of this disease. Activity trackers such as fitbits or Apple watches have become reasonably affordable, making it possible to do large studies on the activity pattern of ME/CFS patients. Patients in the online community could be asked to use a device for a certain period of time and send the information to research teams to analyze the data.
1. Get one or more philanthropists to setup a sanitorium like facility for patient care, sharing, and learning. Conduct research studies as appropriate. 2. Collect data in the patient environment - see IBM Watson study of Parkinson's patients.
see comments above
-Bringing resources to the patient's home - collecting data samples in the patient's home (i.e., body fluids) at different time points (when the patient is having a relatively good vs. bad day) -Providing education to people who collect samples about the unique needs of ME patients (having the person collecting the samples be scent-free, speaking in a soft voice/whisper, providing a low sensory experience. This includes recognizing these patients' needs to lie down etc. - to not over exert and therefore have Post Exertional Malaise)
The researchers should go to the severely affected patients, as the UK Biobank does. Naturally, as exertion makes ME worse, severely affected patients would be crazy to agree to undertake it. Even in moderately affected patients it can cause a long term or permanent crash with the patient never recovering s/his previous level of functioning.

I suffer from all of these and have no suggestions as to how to reduce these barriers. I do want to relate that I often feel like a human guinea pig and I'm so fed up with that. I have given up on trying and so now am completely unwilling to participate in any research or protocols for treatment. When someone can tell me that they have found a definitive cure, I'll do it.
FUNDING so there are research sites in every state! That way more people would be able to go in for this. Also the fact we still keep getting asked to do exercise studies Is horrible because we are getting PERMANENTLY worse!
Travel must be provided with great sensitivity. It is the highest barrier to participating in research.
Providing transport to research facilities would be huge. If they're somewhat local to the facility this can be as simple as providing a car that takes them to the location. If not, perhaps there is a way the researchers can visit the patient to do blood work.
Patients have proven that they will do everything they can - they will go above and beyond what others will - to support research. Some ideas: Always make sure there is a comfortable place to sit or better yet lie down. If a procedure can be done sitting or lying down do that. Provide plenty of rest breaks. Ask the patient how they are doing. Provide plenty of liquids. Provide access to nutritious, low sugar, non-processed, gluten and dairy free foods. At the end of a study offer a saline IV if possible - particularly if exercise is included. The biggest problem, though, may be not having enough patients given the paucity of ME/CFS experts to fill research studies as the research field grows. Kill two birds with one stone - increase patient participation and low diagnostic rates by using the Bateman Horne Center's recent experience filling a large study to create a template or guide to other groups on how to find patients. Recognize the need to do that include the funding to do so in research grants. Find a way to support and emphasize the findings of the Clinician's Coalition
Biobanks of tissue samples. Use of wearable data gathering devices. Funding for researchers' travel to the homes of severely ill patients
I'm local to Stanford University, so I go there to help with studies, including blood draws. I wonder if people who do not live close to Stanford, could be tested locally with the results being sent to Stanford.
I would love to be a research subject and participate whenever I can. However, I live in northern Wisconsin and cannot afford travel to either coast where the research is being done. I am aware of a study in my state but I don't fit the criteria. I would gladly pedal into another PEM but where is testing like this in the Upper Midwest? I had to explain to my doctor about the type of testing reported in a recent MedScape CME article. She only knows what I tell her about ME. BTW, there are only 3 people diagnosed with ME in my small city and surrounding countryside. Think of how many are misdiagnosed!
Maybe there could be a way to donate blood to the cause regardless of location.

Offer local studies or in home / bed and / or online internet (Skype) participation if possible
Does the NIH not have some central database that alerts physicians to certain patient diagnoses that are undergoing studies so that they can inform their patients about them?
Gov't-mandated dissemination of info to GPS, ie. educate Dr's incl advising where, when and how patients can participate in research I ask my Dr 1/yr if she's aware of any studies - she's not aware of the ones I can find on the net (albeit they are not in our country [Canada])
We are one of the most disabled research populations. People who are quite ill have a great deal of difficulty traveling, or undergoing tests. I have not been able to participate in research because of those reasons. My energy is extraordinary limited and I wouldn't want to risk further deterioration in my health. It would make it easier for me would be to have transportation provided-i.e. someone to drive me to the research site, if necessary. And/or doing whatever would be helpful to advance research from home.
Require research on bedbound patients. Support research that can separate the mildly ill from the severely or very severely ill in terms of what they can and cannot do.
Creating a website where questionnaires from researcher can be posted and patients, physicians and researchers alike can participate in studies. Having a main website for such activities and making physicians and patients aware of it and encouraging them to participate in the research can overcome barriers of location and allow an international forum for participants and researchers.
Traveling is a big one so options for remote sites, phone interviews, etc. Also accommodations for time of day, etc.
I have ME from an infection after a procedure by a podiatrist. He knew I reacted to phenol and put it under bandage anyway. The hole never healed, got infection in the bone months later. I had surgery for that. I cannot understand these questions but I could not travel out of town. The fatigue and pain are severe. I cannot exert myself. Acupuncture has helped a lot but I'm broke after years of various treatments. All of my organs are damaged now and I can't have surgery. Oh, I got disability for somatoform disorder in 2008. I worked 30 years and doctors thought I was faking. Lost my job, husband and reputation. Now they believe me.
Find way to have tests/procedures done locally and the information sent to researchers
Blood draws can be sent on ice... I would just recommend you try not to do the types of tests on CFS patients that make them relapse. Exercise tests should be modified for us. I think if you provide a place for patients to recover after testing...like a hotel for a few days..with meal service...and IV therapy to help them recover after testing like normal saline that would help too.
The most difficult thing for patients would be the travelling to a study site. Most patients would prefer to remain local to them as travelling can be so tiring in itself.
Ask for participants through better means i.e televised news. I'm always looking for studies and trials to be part of and can never find any

People are extremely sick , they would need to become in patients to carry out proper research like a centre for excellence
Online community to discuss this matter and spread word on what this is to more individuals.
Make every study and research clearly about ME and PAINSS/PEM and that it is biological
Find a way to support and emphasize the findings of the Clinician's Coalition
I suggest you listen to the OMF foundation and the SMSCI organizations and listen to repected ME/CFS researchers, like Nancy Klimas, etc.
More local testing, if possible, through reliable collaborators. Keep in mind at all times the unique PEM of this disease, how easily it is brought on and how devastating it can be. Taylor pre and post testing protocols to these unique needs. Get input from patients about how to make your protocols more suitable for this patient population. The bottom line is, LISTEN TO PATIENTS! This field has been hugely set back by the lack of this, as you know.
Make testing portable.
How was this overcome for Parkinsons, HIV, MS.... Design studies that allow for remote participation / sample collection e.g., blood collection, MRI, et al. (incentivize Lab Corp, Quest, medical Universities)
I would change that question to say patients might have an INABILITY to undergo certain types of research protocols. I for one am not unwilling to travel afar and participate in a two day exercise challenge for the cause and to learn about myself, but I am completely UNABLE to do that because of the potentially devastating effects it could have on my health short term and possibly long term if my reaction is bad enough. That knowledge of my body and its limits does not represent an UNWILLINGNESS, it represents INABILITY. The use of the term â€œunwillingnessâ€ makes it sound like my decision is solely based on my will....If my will was the only factor, I would be healthy. Would you describe a person with only one hand unwilling to clap? It is just as impossible for people with moderate to severe ME/CFS to participate in some of the more strenuous thing like travel, and exercise and for some trying to maintain, they don't want to get worse. So please, don't call it unwilling.
Patients inability to travel to be included in studies would seem to be a huge barrier to advancement in studies.
ME/CFS patients are chronically exhausted and often crash from simple things like reading, accessing the internet, and going to doctors' appointments. It is nearly impossible for ME/CFS patients to seek out studies/trials even if they want to participate because they are inherently held back by their condition. If you need more research participants, make it easier for them to join up!
As I mentioned earlier, I have no answer for this, but it frustrates me as a patient that I can not be included in any of the studies because they are being conducted so far away. I'd be willing to travel and stay in a motel if I could afford it, just to be useful to furthering understanding of the disease. I have ALL the little symptoms that are discussed on the message boards - a host of oddities, really. Yet there's no way to impart what I've gone through to any of the researchers.

I am willing to do almost anything in the name of science and to cure this awful illness. However, please don't ask me to spend my money (since I can't work and make any) or travel long distances (since I can hardly make it to the mailbox) to do so. Also I have to be on antidepressants just to survive, please don't make me go off my meds in order to engage in a study. I do believe some guidelines are far too strict to be inclusive enough.
I wish I could fill this all out but I feel so sick. I didnt use to be like this. I just want to feel better.
finding ways to implement a lot of rest, ways to make research accessible without requiring travel that many cannot physically or financially handle.....I know there are a lot more, because I have read many studies that I'd love to participate in, but that have had too many barriers, but like I said in the question above, simply answering all these questions at once has done me in & my brain & body are now totally shutting down....maybe you should highlight questions that ME/CFS patients would be especially knowledgeable about & let them know before they start filling this out which ones those are so they can use their precious & extremely limited energy on those first (hint - this one in particular is one patients know better than anyone & I owuld have really liked to be able to better answer it)
Generate funding so that participants can be paid to participate. Get the insurance industry involved in funding research.
Clinics and safe islands free of toxins and microwaves. Grants to allow large areas to be microwave free.
I would gladly participate in studies but in my country of origin I have never been offered the opportunity to participate.
It seems we're willing to undergo pretty much anything you want us to in order to further ME research, so I don't believe that would be an issue. I would say it's important for most of us to be able to recline while we're waiting and during tests, if possible. A room that is not too bright and quiet, with water, snacks, pillows and light blankets would make us more comfortable. Funds for travel and hotel stays would help because many of us rely on Social Security or disability and our budgets are very tight.
Chicago area has no ME/CFS treatment center. I can't travel so I can get out to California or Boston. That is prohibitive.
Funding to help those that ARE able to get to certain study locations. Researcher home visits are the only way to include the sickest, and potentially most telling, among us.
Funding at home patient draws or local facility blood stool and saliva draws.

I've advised people to avoid FMT clinical trials due to low donor quality. The current quality is neither safe nor effective.
Anonymous participation if requested Outreach projects in CFS clinics
Keep a register of patients. Monitor them regularly. Bring the studies closer to patients rather than making patients travel (as travel and stress will OBVIOUSLY exacerbate symptoms and interfere with results). Warn patients of the risks of each trial and monitor them for at least 6 months afterwards, with additional monitoring yearly up to 5 years afterwards. This is a chronic condition and short-term results do not matter to patients as much as long-term results. Make sure that invasive or disruptive tests which MAY cause a worsening of symptoms is only used as a last resort. Take responsibility when a study causes harm to patients (don't try to cover it up or hide it).
?
This will be much stronger if you can include information in section 1 identifying what data sources are NOT included in the research. Not just "we used this", but "we did not include". People without internet access. People of low economic status. People from 3rd world countries. People who do not have access to medical professionals skilled in diagnosis of the condition. Minority populations. Undocumented immigrants. These are just a few that pop into my head with a minute's thought. A couple of strategic discussions should produce a more comprehensive list, which can then be prioritized. Even if it's included as an addendum, future research can and should be more inclusive of various populations. (I learned this in my doctoral research studies in music... now it can help us!)
Establish an international database of all patients willing or able to contribute in ME/CFS research. Many of us, including myself, would do whatever we can to help to contribute to the research. This database should be available to all researchers clinicians to access. Allow certain tests / studies to be used across multiple studies e.g. I undertook WES to be able to contribute to Dr Phair's metabolic trap research, and 23andMe analysis to contribute to Dr Klimas' study - I'd be happy to share this data (and more) with any other researcher if there was a simple way to do this, and I'm sure many other patients would too.
As i stated earlier, i have been denied as a participant because of BMI, hypothyroidism, and prednisone use. Let me be your lab rat!

Many of us cannot travel and are not in a healthy-enough state to submit to some of the rigorous testing currently required. Better (less exhausting) "gold standard" testing (no exercise to exhaustion situations - this just isn't possible) Researchers must come to us. Some of us are in rural or outlying areas and cannot travel to research centers.
It might be helpful to get special rates at a hotel near a site so that patients will have a place to recoup their energy.
See above
Open studies to older people who have been ill for decades, or study them in a separate research project. (I'm one) Do studies in more than one location to make travel time shorter.
Collection of med records from patients. All of us. Org
Many patients would love to participate in research but live too far from a research center and/or are (much) too ill to travel. Establishing a large biobank, maybe following the template of the UK ME-biobank, could help overcome some of these access problems.
Providing housing and physical support for several days before, during and after the research.
Many ME/CFS patients are not under active medical care from a primary care physician who supports their (necessarily often unverifiable) diagnosis, and many are "invisible" due to being housebound and minimally able to function, let alone advocate for themselves. Consider structuring studies in ways that account for the ongoing learning curve in making the disease more visible to the medical community, and that also accommodate individual needs regarding energy levels and ability to travel (visiting researchers, postal-mail or online participation options, travel vouchers or volunteer support networks for travel, outreach to educate doctors who may have patients presenting with ME/CFS). Consider spreading the word of research studies primarily via ME/CFS advocacy organizations, instead of primarily via healthcare providers and research hospitals. Communicate very clearly and upfront exactly what will be required of study participants.
- ensure availability of good data regarding patient limitations to researchers; make sure these data are vetted by ME/CFS patients - ethics review board committees that include established ME/CFS researchers and ME/CFS patients - grant money specifically for travel of research assistants with more severe patient populations - I have issue with the use of the phrase "an unwillingness to undergo certain types of research protocols." ME/CFS patlents are desperate for answers and willing to risk worsening of symptoms for research. Anyone who drops out or is "unwilling" to participate is doing so because they know their limitations and said protocol would likely take them above what they know they can tolerate.

As above: enough funding that research protocols can be conducted in our own homes, or else you're losing out on the most significantly impaired majority of the population with the illness. Given that it could be argued that the more severe and even extreme cases might shed the greatest clarity on the most crucial mechanisms of the disease, it's foolish to ignore the populations that have had this the longest, are the oldest, and are the most severely impaired.
Create a one stop shop website with an interactive map that all mecfs patients can check to see if a research trial is near them. There should also be an interactive calander which has dates and contact numbers. Possibly on-site links to Amtrak, Lyft, or Uber would speed the process along for patients enough to make a difference for a percentage which while small given the size of the mecfs population may have a great impact to individual research trials sample sizes. Also an online carpooling system to allow patients with rides from family members, or otherwise, to pick up enroute other patients heading to the same trials. This online carpooling section of the website could be used by volunteers as well. To prevent liability it may benefit from private web hosting and utilizing a list of â€˜trusted drivers' and â€˜trusted patients' to ensure safety; only drivers and patients approved by a list of accredited practitioners and researchers should be allowed to use the site's service.
Eliminate wireless and pesticide or herbicide spraying.
NOTE: This comment violates decency standards and has been removed. For more information please see, https://www.nih.gov/news-events/social-media-outreach/nih-comment-guidelines
Try to reach out to the most severely ill patients who can't leave their house. This can work through sending them tools like activity trackers or other tools that they can use themselves. When necessary, a nurse could visit them to explain protocols or to take blood samples.
It's perfectly possible to recruit severe ME if proper respect and care is shown as Stanford are currently doing. The current NIH study is very demanding, not all research has to be so demanding and you could reach many people if it wasn't.
I think people not wanting to change their lifestyles could be a problem however, when people feel lousy enough that often changes. I'd involved certified health coaches, again, try the Cleveland Clinic's Center for Functional Medicine, and the Functional Medicine Health Coaching Academy. They have the answers. I trained there and I have MCS and EMS and am having a much better outcome than most do. Its really not hard when you discover the benefits and how to do this both on a budget if needed (example- Dr Terry Wahls did this at the Veterans Administration with few resources) and learn practical ways to make it work. Its a gift to be healthy and strong again, able to do things you never imagined. For wireless you'd need to work on reducing near field exposures, perhaps using or wearing shielding to reduce far field exposures from cell towers, etc. A SHIELDED BED CANOPY - for research I'd use the

best you can get. That would be GREAT STUDY actually, since SLEEP is so critical for those with CFS. I cannot say enough about that bed canopy which I resisted getting because off cost, ,but it made a huge difference.

Conduct a vigorous campaign to educate primary care physicians and relevant specialists on the nature of the illness and how to diagnosis. Patients are still having trouble getting a ME/CFS diagnosis and without the diagnosis, patients can't participate in ME/CFS research. (This has been my son's experience: His doctor says that he fits the ME/CFS criteria but she says she absolutely will not diagnose without a diagnostic test.)

My own experience with participating in research -- and the experience of others I know who participated in a different study -- is that the researchers don't understand how ill ME/CFS patients are and don't not provide enough support to protect patients.

Expand opportunities for participation from patients who live far from ME/CFS clinicians and research labs (think of the many patients in rural areas); patients with low incomes; patients who are members of historically marginalized communities; and patients who lack the support of family and friends.

Contracting with local blood draw companies or with hematology, nursing, and medical schools to do home visits for tests. You provide specimen bags/containers for feces collection, hair samples, saliva samples, etc that a person can send in on their own, mailing from their home mailbox.

Surveying ME patients would be informative in designing future research. Prior to being diagnosed, many patients have been told that the illness was in their head. Genuine participation with patients should begin with an understanding of past treatment. On average, ME patients do not receive the ME diagnosis for over 5 years. The multiple organizations (Open Medicine Foundation, Solve ME/CFS, ME Action, etc) advocating for research, funding, and care developed because patient needs were not being/are not being addressed. People with ME are anxious for approaches to improve their health and an ability to resume premorbid functioning. As noted at the conference, the majority of people are not even diagnosed. Particular efforts to engage African Americans and Latinos who are under-represented should be central. Today, the identified ME patients have individually sought answers to their diminished health status and had the resources to do so. This suggests that current data is not representative of all ME patients.

Recently, there has been widespread support for participating in the various ME funded studies through the ME social media networks. My experience is that patients are not reluctant to participate in studies. Many of us are too ill or some of the interventions are too invasive to be worth the personal health risk. Additionally, travelling for care and/or research is costly financially, physically, and disruptive to daily life. Connecting research to patient education and care options would encourage people to participate.

I am writing this response at LaGuardia Airport waiting for my flight home to upstate after seeing my ME specialist in NYC. Since becoming ill in 2012, I have spent tens of thousands of dollars trying to preserve my current health with visits to specialists at Mass General, Brigham & Women’s, Mt. Sinai and the Mayo Clinic in addition to my local university medical center. I was not diagnosed until December 2018 and gratefully have experienced some improvement since then.

A major barrier to patient engagement is negative past experience with providers who dismiss either ME or the severe PEM many of us experience. I have seen neurologists, infectious disease specialists, and pulmonologists. The Mayo Clinic visit typifies an unhelpful consultation. As a health professional myself (and my husband is too), I was stunned when a neurologist said I did not have acquired neuromyotonia and he did not have a working diagnosis for the debilitating changes I was experiencing. I was advised to attend the Mayo Clinic week long course that included exercise and cognitive behavioral therapy. This despite the fact that I taught cognitive behavioral therapy. CBT may be helpful in dealing with the impact of ME and related diagnoses but it is not and should not be a primary intervention for ME. Until diagnosed with ME, I tried to maintain my very active lifestyle both personally and athletically which adversely affected my health. I am disabled and my physical activity is limited to 30â€ on a recumbent bike. I cannot walk any distance without exceeding my target heart rate.

Prior to and since being diagnosed in 2018, I have experienced multiple professionals who have said in effect, " I know nothing about ME". How is this an acceptable response to a patient? I now provide the CDC Fact Sheet or a research article or the Medscape review article of the NIH Conference to practitioners, who are not ME literate.

It is known that too much exertion exacerbates post exertional malaise (PEM) and places patients at risk of further incapacitation. We now know that pacing helps patients and all ME patients can benefit from this approach. The 2-day CPET is less invasive and considerably less costly than the iCPET. Serious consideration should be given to the cost/ benefits of using one approach over another. My dysautonomia was diagnosed by the iCPET and a subsequent 2-day CPET provided more clinically relevant data including a target heart rate for me at considerably less cost. A clinical intervention assessing the benefits/risks of conditioning could improve patients' health status. The current NIH study requires 2 prolonged stays with extensive testing. Unfortunately, this is not feasible for many.

Specific targeted recruitment of severe patients is warranted and gathering data from patients' homes are essential. Detailed training of research staff will be necessary as patients need interventions that address their multiple sensitivities e.g., light, sound, difficulty with blood volume that makes blood draws challenging.

Use ME subjects meeting the ICC and provide in-home collection of samples and testing. Many people with ME are house-bound and cannot reach a research site or tolerate multiple days of testing. If ME is to be researched, subjects with severe ME must be included to avoid biasing the sample towards less severe cases only.

Patients have proven that they will do everything they can - often at risk to their health - to support research. Some ideas:

Be aware that many patients with this disease might be unable to undergo certain types of research protocols, because of the potentially devastating effects it could have on their health. Acknowledge the level of functioning that must exist for patients to undergo various types of research.

-Always make sure there is a comfortable place to sit or better yet lie down. If a procedure can be done sitting or lying down, do that. Provide plenty of rest breaks and absolute quiet. Ask the patient how they are doing. At the end of a study offer a saline IV if possible - particularly if exercise is included.

-Increase patient participation and low diagnostic rates by using the Bateman Horne Center’s recent experience filling a large study to create a template or guide to other groups on how to find patients. Recognize the need to do that include the funding to do so in research grants.

-Find a way to support and emphasize the findings of the Clinician’s Coalition

-Pay patients for travel, and offer a quiet place to stay.

-Use the communities to spread the word when research subjects (and controls) are needed, with specific criteria.

-Engage the expert clinicians to help with enrollment.

There are no individuals with 'ME/CFS'.

Pretending that there is something like 'ME/CFS' or CFS is the main barrier that prevents individuals with ME from participating as patient selections will mostly consist of noise. That is, you are this barrier.

PEM is one of the most restricting symptoms in people with ME. PEM can lead to an irreversible worsening of symptoms and overall health state. Study participation will nearly always cause PEM. Possibilities: Organize a transport of participants to the study site, go to the participants, use communication on distance (telephone, internet) - this will enable the inclusion of international participants also - don't pack too much into one day, take enough breaks into account, stop when the participant needs to (flexibility).

Many people with ME are taking supplements or medication for symptom relief or out of desperation - excluding these as participants or having protocols that demand stop taking these supplements/meds (although often needed from a research point of view) will exclude a huge portion of people with ME.Â Theoretically, there are enough people with ME; the reason why factually there aren't is bad diagnostics, so diagnostics needs to be improved.

Money: finance the travel and the stay. Many people with ME are poor due to a neglect by the social system.

Consider working with GPs or other doctors that could take samples and send them in.

Consider strategies from rare diseases research.

Provide maximum support with travel and housing before and after the testing. Seek out patients with milder ME, who are less likely to participate in online groups.

First you have to decide what type of ME/CFS patient will be the subject of choice, meaning does the researcher want to target those with mild to moderate ME/CFS, or those who are completely bedridden. Some challenges apply to one group and not to others. Probably the biggest issue for any patient will be the physicality involved; getting dressed and leaving the house, travelling, being awake or seated upright for too long, before even arriving at a facility. By the time a patient is ready for the study, he/she will already be pretty physically drained and following direct instructions or having too

many conversations and questions to answer will exhaust the patient cognitively as well. Patients are not willing to make themselves sicker or endure PEM for any reason other than a real trial that offers real treatment possibilities. It will be very difficult to get a patient to go through all of this just to test biomarker theories or measure brain inflammation. As patients, we know these are necessary studies to conduct, however the suffering we endure is so great that it overrides the greater good in most cases (that's how bad it is). Ideally any study that does not directly involve trialing a specific treatment should be conducted in the home of the patient with all equipment brought to the home. Any patient would agree to help the ME/CFS cause in any capacity if it does not entail making them even sicker than they already are. Financial compensation also does not actually compensate for the risk of losing even more of one's life and functional ability even if just for a week. As I'm sure this goes without saying, absolutely no patient will engage in anything remotely like the PACE trial or GET. That should be off the table entirely in terms of research studies.
Contract with a national home healthcare service to collect samples from ME/CFS patients who are housebound. Enable researcher contact to be virtual.
Increase the number of locations of all studies. I live within 15 minutes from a major medical school and hospital, yet no one here is doing any research on ME/CFS. I can barely get to the grocery and pharmacy, never mind travel hours to a center in Boston.
The biggest difficulty is access. I could participate if there were mobile blood draws and local scans. I can't travel. Leaving my house for a couple of hours causes 5 days of PEM.
A diagnostic test (e.g. blood based test of mitochondrial functioning or other marker e.g. phenylalanine) e.g. currently the strenuous exercise tests may be included because there is no simple diagnostic test. Therefore, these strenuous tests could be removed and this would encourage participation.
Patient identification and diagnosis Physician and health care provider education
More collaboration enlisting labs, imaging, anonymity by assigning patient number to be used in all worldwide research. Patient only gives their information wants to a centralized agency and is assigned a number to be used in all a me CFS research. Utilize medical students Fort compilation and other items as heart of coursework
A huge issue. The studies are conducted on site. I can't travel.
Many studies of ME/CFS do not include patients with severe illness because it is prohibitively difficult or impossible for them to travel to a study site. This reduces the generalizability of research findings and may limit the signal:noise ratio of the data. Unfortunately, it is very expensive to include other pathways by which these individuals can participate in research, such as at-home study visits with phlebotomy or blood spot sampling kits. Perhaps supplemental funds could be offered to studies that proposed expansions into the homebound community so that their potentially massive contributions to research are not lost due to the funding required to address these logistical challenges.

Due to issues with physical activities, noise and sensitivity to light, a special environment would need to be created for research candidates. Research for other than a treatment could be done in the patient's homes.
Research funding should include travel funds for patients that are not charged against the grant ceiling.
use of the services that insurance companies use to obtain samples from homebound patients
In order to bring in more researchers and gain the attention of doctors/hospitals, we need the full commitment of the NIH toward finding a cure for ME/cfs by investing $200 million a year in research funding through RFA's. This is similar to what is spent on Parkinson's and MS. When the NIH sends this signal to the research/medical community such as they have done with AIDS, the medical community will surely respond. Recently, my friend asked her niece who graduated with a PHD in medical research what area she would focus on, the niece responded: Alzheimer's! My friend asked why, the niece responded... well that is where the funding is!!!
I suspect, for many people, lack of support and financial problems are a substantial barrier. When it takes everything you have to manage necessary living activities (such as preparing food), that's *all* you can do, and anything else is an extravagant luxury. Similarly, if you're constantly struggling with lack of financial support or health care, just trying to survive takes up all your focus. It would help tremendously if ME/CFS patients did not have to worry about getting or staying on disability benefits or getting in-home assistance. (Even those of us who are lucky enough to have relatives or friends to help know how overloaded our caretakers are, and are probably keeping our requests to a bare minimum while really needing more help than we ask for.) I realize this is not the NIH's job, but perhaps you could approach the SSA about setting up a program to assist massively underserved groups such as ME/CFS patients to get the benefits we desperately need but are routinely turned down for (and don't have the energy or comprehension to file appeals about or figure out how to prove our claims).
1. Admitting patients to the hospital where the research is carried out. 2. Explore if it could be feasible to carry out parts of the reseach at the patients' home. 3. More mouse models? 4. Explore if post mortem studies could be relevant. I have already donated my body to ME research, when I have passed away.
Travel

-Develop a mobile clinic that could take diagnostic and testing equipment into the homes of severely ill home-bound and bed-bound people with ME/CFS.
Chemical and scent free lodging. An understanding that many ME/CFS patients are very sensitive to even small amounts of medications and supplements and that these must be tried one at a time with a very small dosage.
Increase the number and geographic locations of researchers. Increase availability of home services.
Difficulty traveling is going to be an issue with the most relevant individuals - the most ill. Co-op with local labs and hospitals for data collection.
Back when I was a Clinical Research Coordinator before developing ME, my department (Center for Human Genetics at Duke University) would send phlebotomists, nurses, PA's on "field trips" to collect data. We would go to the patients.
If someone has ME, they are too sick to travel safely to any study. There is no safe way to participate. Some things that can be done is to accommodate at home whenever possible. Include giving IV fluids to offset the harm done by participating in studies. Home health care support before and after with specialized transport to minimize stimulation.
As you know many are too sick to travel. Those who can travel, like me, need extra days upon arrival at the study site to recover from traveling prior to any testing. And many live at or below the poverty level and don't have money for airfare and hotels, so funding for travel is necessary for many, including extra days stayed at a hotel in order to recover from PEM before any testing. And meals. Whenever possible, arrange for in-home testing. Have clinicians come to patients' homes to draw blood etc.
Dedicated centers of expertise are likely to be the only appropriate facilities for this. Most medical facilities are not equipped to deal with ME patients (which is a whole other problem in itself), they are simply not suited for the limitations, are far too noisy and uncomfortable. This problem thus becomes one of geography, as the scarcity of genuine experts make it difficult to provide adequate regional coverage. There has to be enough experts to be able to provide geographic coverage and reach as many patients as possible. This is clearly a long-term goal, but typical medical resources are clearly not equipped as of now.
* Logistically, it is probably most efficient to have the study site travel to the patient. Managing ME/CFS symptoms is a complex task that requires many and highly individual measures, e.g. having available special food, house remedies, pillows, curtains, other supportive substances or objects, and adhering to certain schedules. The patients' home is usually specifically outfitted to cater to his/her needs.

* Cave: In this setup, unnoticed differences in homes, e.g. mold, may become a confounder.
This is where I think app based pooled data collection would be very useful. Our specialists are already recommending that we monitor our heart rates to stay below our anaerobic thresholds and to monitor our steps for pacing. Skype sessions could also help with logistical challenges.
Have phlebotomists/staff travel to the patient's homes when needed. This sickest need the help the most and will likely show the greatest abnormalities. The sickest are unable to travel, or need an ambulance and sedatives to tolerate the travel. Videoconference, skype and facetime, etc.
With adequate funding, nurses can be sent to homes of housebound and bedbound patients to collect samples. But few projects have had adequate funds to pay for such services.
There definitely needs to be a way to bring it to the patient instead of the patient having to go to the researchers. A lot of us can't get out to participate in any aspect, although we are willing to partake in most any way to provide data to further research.
Logistical Challenges In terms of patients' difficulty travelling to research sites, perhaps satellite sites could be set up, that could then be connected virtually. I realize this would be painstaking and time-consuming, but it could be a start and also help in promoting awareness.
1. Reach out to health services providers who have experience with disabled/ homebound/ bedridden patients may reveal new technologies or methods that have not been considered in ME/CFS. For example, home-based blood draws, physical therapy visits, Skype physician follow-ups, and portable chest x-rays/ ultrasound/ EKGs have long been used in home health care. Funding to provide such services is essential to recruit severely ill subjects. 2. Encourage and provide funds for community-based recruitment efforts to reach undiagnosed subjects and/or underrepresented groups. For example, most research samples consist of middle-aged, middle class or high, well-educated, Caucasian women. However, we know this disease affects men, children/ teens, ethnic minorities, elderly people, and poor people also. Many people in these groups might be undiagnosed due to problems accessing healthcare or misconceptions by healthcare providers as to who is affected. Active screening and recruitment from a community may overcome such barriers. 3. Communicate early, transparently, clearly, consistently, and continuously with the patient and caregiver community about the purpose, implementation, results, and consequences of studies. The history of ME/ CFS means that the patient/ caregiver community is often suspicious of the mainstream medical and scientific community. Communication can build and retain trust. Involving members or representatives of the community in design, implementation, analysis, interpretation, and dissemination of studies may also be helpful. 4. For studies that involve multiple tests, having the subject be able to get all the testing done in one or consecutive days, provided their health can tolerate it, may be less cumbersome that having the subject travel back and forth for multiple visits. In some cases, having them stay as inpatients or near

the study site helps.

5. Schedule visits and provide funds, as needed, so that someone can accompany the subject. This is especially important for studies that may result in PEM, include interventions with side effects, or include severely ill subjects.

6. Use technology such as mobile devices (not just telephones but health tracking devices like FitBit) and online platforms which may automatically send information to researchers, remind cognitively challenged subjects to respond, or allow outcomes to be measured from patients' homes rather than at a research site.

Housecalls should be made to draw blood and to do other in-home testing so that the moderate and severe patients may be studied. Support studies that evaluate samples such as hair which Ron Davis is trying to do.

Stop wording that patients are unwilling to undergo certain research protocols. Just that wording implies patients are resistant to helping find a cure or treatments which is absurd. Better wording is that they are not physically or financially capable or certain protocols have too high of a risk to cause permanent harm or long term exacerbation that impedes functioning of the patient without providing support (such as homecare).

By providing means of palliative and home-care specifically for people diagnosed with ME, those patients would have a safety net if the research participation makes them worse. Currently most patients do not have enough (or any support) in order to risk participating in these studies.

Most patient cohorts are obtained from specialty ME/CFS clinics. Many of those clinics only serve patients that are capable of travel (financially/physically) and capable for paying for services/ testing not supported by most insurance companies and HHS run programs such as Medicare/Medicaid. Due to these limitations there is a high probability that the ME-ICC patients have not been included in studies.

Anecdotally ME/CFS patients who are not jaded are willing to volunteer for trials at a high percentage rate, most are desperate for anything that might help the field move forward.

The largest barriers are lack of diagnosis, lack of knowledge about studies that need volunteers and patients that are severe as in housebound or bedbound.

The lack of diagnosis may not seem particularly relevant but it is more difficult to find early stage patients because being undiagnosed they cannot be recruited for ME/CFS research studies and the undiagnosed rate for ME is estimated at 84-91%Â[1].

Many patients have spent years or decades without a diagnosis since doctors are not trained to diagnose ME using the Canadian Consensus Criteria or the International Consensus Criteria. Or if they are diagnosed they may be tried on SSRIs or prescribed CBT/GET and fail to improve or worsen leading them to shun further treatment or diagnostics into their condition and going it alone which would reduce contact with medical professionals who could steer them into research studies.

Often there is great difficulty in reaching patients to inform them about research opportunities

seeking patients. Having clinicians who see ME/CFS patients regularly and are in the loop about studies needing patients can of course guide patients to apply for them. Another possibility would be a central database for current ME/CFS trials that patients can register to get e-mail alerts for.

As for house or bedbound patients the energy involved, the logistical or financial costs and the fear of causing disease progression may prevent their participation in research. Some may be able to participate with assistance in getting to and from appointments in the form of a helper or transportation or wheelchair/motorized scooter and of course reimbursement for costs incurred including meals if applicable. Home visits for certain types of research or for bedbound patients who cannot get to the research facility may be suitable as well. Also stigma or fear of loss of medical coverage or premium spikes can prevent patients from pursuing treatments or research participation. Some patients prefer to keep the diagnosis private.

Finally many patients will not be in the geographical locations the research is being done, in some cases their local physician or research center into ME if there is one could do the tests necessary or collect the samples and forward them to the trial researchers.

Â¹ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6331450/

(need to rest now)

In order for severe M.E. patients to participate in research, it needs to be accessible easily and affordably by car or air. The criteria for recruiting patients needs to be clear and the international consensus criteria(ICC) is the best tool we have yet. ICC should be required to be used on all research so we don't misappropriate funds by testing people that are not clearly M.E. patients. Paying a stipend would be something that will entice many as funds are so limited for so many. Recognizing that many severe M.E. patients also suffer from sensitivities to pharmaceuticals, dyes, noise, light, smells, etc. the procedures should encourage efficient ways to make sure the patient and research are not subjected to invasive or severity increasing environments or testing that doesn't have the potential for quality of life improvements.

Patients have proven that they will do everything they can - they will go above and beyond what others will - to support research. Some ideas:

Always make sure there is a comfortable place to sit or better yet lie down. If a procedure can be done sitting or lying down, do that. Provide plenty of rest breaks. Ask the patient how they are doing. Provide plenty of liquids. Provide access to nutritious, low sugar, non-processed, gluten and dairy free foods. At the end of a study offer a saline IV if possible - particularly if exercise is included.

The biggest problem, though, may be not having enough patients, given the paucity of ME/CFS experts to fill research studies as the research field grows. Kill two birds with one stone - increase patient participation and low diagnostic rates by using the Bateman Horne Center’s recent experience filling a large study to create a template or guide to other groups on how to find patients. Recognize the need to do that include the funding to do so in research grants.

Find a way to support and emphasize the findings of the Clinician’s Coalition

Many patients are so physically incapacitated they must be accompanied by a caregiver in order to participate in studies. Cognitive resources also may be so scarce that a caregiver is essential. In order for patient to take part in studies, travel to study sites may need to take place several days beforehand and afterwards it may be several days before the patient is well enough to travel home. Input from caregivers should be used whenever possible as they are the ones who see the impact of ME on the patient. Inclusion in studies of severely ill people with ME - not studying the severely ill is like studying consumer spending patterns but not including those below the poverty limit. In other words, not an accurate representation of the disease. Provisions must be made to study people severely ill with ME. People with ME of all ages and races must also be included. Understand that many patients cannot undertake cognitive or physical activities back-to-back even over the course of several days. Facilitate as much study participation remotely (preferably in home) as possible to minimize the cognitive/physical exertion required of the patient. In terms of accommodationÂ - Researchers may get very short responses before, during, after testing. I think it is helpful to explain that the study participant probably isn't mad at them but rather is unable to verbalize much because of difficulty focusing on anything (let alone more than one thing), pain, PEM, exhaustion from testing, other. Patients may also be more able to respond if they lay down, or at least, recline. From our experience, I would also suggest that patients be given extra fluids before and after blood draws and that draws be done lying down (despite 3 vials of smelling salts one of my sons fainted during a blood draw at NIH). Note - see also the MEAction submission
- Digital health apps, devices, telemedicine and home testing - Patient/advocate involvement in designing patient centric studies and research protocols
Establish protocols for home visits, use of technology and IT to facilitate involvement.
MEICC criteria
- Using (and funding) international collaborations to have the those with the best expertise involved in current research. - Initiating and funding Centers of Excellence in the central and western United States.
Improve clinician education in localities for accurate diagnoses. We have found patients to be very cognizant of participation in studies. Engage a local phlebotomist and hospital to obtain blood samples in a minimum amount of time. This can be more expedient and more effective than a biobank if a standard protocol is strictly adhered to.

Solutions suggested here at http://me-ireland.com/structure.htm and http://www.me-ireland.com/research2.htm
-Specific funds for transportation costs and follow-up nursing home visits. In other words, we need to be able to convince severe patients that we will bring them to our brain imaging center and then make sure they get care during the likely post-visit crash. -Targeting recruitment to patient populations that aren't typically represented by advertising projects in clinics and community centers that target these under-represented groups (e.g. a clinic in a largely hispanic area, or a church in a largely Black area).
Travel compensation, follow up & aftercare. Testing will harm patients no matter what, so look after us.
1. Adopt Nancy Klimas' on-line patient interface and data gathering platform [used for her Genetics Project]to reach severe, homebound ME/CFS patients. 2. Use phones, Skype, telemedicine, etc. to communicate with severe patients. 3. Use visiting researchers, phlebotomists, nurses, etc. to gather data and specimens. 4. Establish protocols for severe and homebound patients to give researchers access to their medical records, diagnostic test reports, imaging films, etc. For example, at the NIH Conference April 5, 2019 Mike VanElzakker said he'd like to see patient's MRI films; how can patients give him access to them for his research?
Anything an ME person does costs us precious energy. One of our members cleans during commercials and then lies down again, so that she does not end up overdoing it and creating real trouble for her energy level. I have taken so much off of my to do list-primarily because I get unhappy when I can't even finish ONE project. And many of us have had tons of tests. Most do not mind it, but getting anywhere, even to a meeting with other ME people, takes extraordinary strength. Most can't travel by themselves as we would end up in Timbuktu-our minds, under stress, will override even Provigil. If I work too long at my desk I often can't work the next day at all and there is nothing my wonderful drugs can do about it. There would have to be centers for testing in most metros-perhaps one in one hospital that would be easy by bus or car?
This is a very difficult issue to address. I had a terrible response to an ME/CFS research protocol last year, the dose being used was far too high for me. There are some pretty good reasons patients resist some research protocols. I believe clinical treatment research with this population is dangerous to patients due to the lack of ability to address the underlying pathologies of individual patients. Again, we need a comprehensive systems biology approach to characterizing this illness, for individual patients, before broad scope treatments will be safe. In fact broad scope treatments may be strongly contraindicated for this population. We need customized medicine. Again, this should be a way to attract researcher and funding agency interest, as creating customized approaches today is in fact the leading edge of systems biology and bio-informatics. Also, when patients are too sick to come to research clinics, the answer is obvious, the research must come to them. And again, that should be easier today than ever before with tele-medicine, and the ability to utilize local labs for specimen collection.

Currently, most participants in ME research are patients of the dozen or so expert clinicians, most of whom don't take insurance. This greatly limits the diversity of patients being studied. To increase diversity, train doctors in underserved areas to diagnose people with ME and refer patients to studies. This can also help with the clinical care crisis.

Very severely ill and severely ill patients are rarely involved in research because they are completely or mostly unable to leave the house. Most studies are self-selecting for minor and minor-moderate patients. Perform in-home blood draws or other assessments whenever studying severe and very severe patients or patients during a crash.

It may also be possible to tap biorepositories of well-characterized patients to utilize samples that have already been collected or may be collected in the future.

Arrange for cabulance or taxi/rideshare transport to/from study site to reduce financial and cognitive burden to mild/moderate patients.

Consider satellite sites for larger studies to minimize travel. This need can be leveraged as an opportunity to partner with universities and larger medical centers and engage them in ME research.

Participating in research can be challenging for patients at all levels of severity since both physical and mental expenditures can lead to negative health effects. Make sure to allow for as much rest as possible between tests whenever doing so wouldn't affect research results. Wherever the study design allows, ask the person with ME whether they prefer to make one, intensive trip or several, shorter trips spaced out over a manageable period of time.

Minimize filling out of forms and/or allow participants to fill out forms at home days before or after the research.

Whenever possible, researchers should provide test results to patients' clinicians.

Provide flexibility in scheduling visit times would both make it easier for patients with delayed sleep schedules to participate and improve baseline data collection, as early start times can create extra physical stress by drastically reducing sleep.

Provide an environment equipped with ample comfortable upright and recumbent seating opportunities (chairs with stools, recliners, beds) and continually communicate with patients about their availability. Supply wheelchairs and escorts to transit patients between locations, including meeting them at the door for dropoff/pickup. Limit the number of steps required between location changes as much as possible, providing seating opportunities along the way and time between tests for stopping to rest.

Make efforts to limit the sensory stimuli within research environments (light, sounds, smells), including: dimming lights, supplying dark glasses; reducing ambient noise, adjusting machine volumes, asking staff persons to speak quietly and limit communication to minimum necessary if patients are experiencing sensory overload, and supply noise muffling ear muffs; asking staff persons to refrain from wearing fragrances, limiting odorous chemical uses in cleaning the research environment.

Before inviting patients to a study site, have staff transit the required route being especially attentive to visual, auditory and olfactory stimuli, and remedy any exposures wherever possible. Throughout study visits, be especially attentive to patients' body language and expressions, and ask patients often if anything can be done to make them more comfortable. They may be experiencing extreme sensory overwhelm but are unlikely to voluntarily communicate the fact, or may be so overloaded that they are unable to verbalize, but could nod if asked.

Offer nutritious snacks free of common allergens and hydration during study visits, especially before and following blood draws and exertion/postural challenges.

Administer post-procedure supportive measures such as IV saline to make stress testing less dangerous/frightening and aid in comfortably making the trip home to bed and in limiting the severity of PEM.

Many patients are intolerant to loss of even minimal amounts of blood. Limit blood draw volumes to the absolute minimum necessary. Provide extra fluids before and after draws. Perform blood draws while the patient is reclining or lying down. Be prepared for loss of consciousness, breathing or arrhythmia/arrest. Offer rehabilitating IV saline to mitigate crashes after blood loss.

Researchers may get very short responses before, during, after testing because of difficulty focusing, pain, or exhaustion from testing. Patients may be more able to respond if they can lie down or recline, and may become more responsive after being given time to recover.

Account for and accommodate a caregiver's essential role before, during and after studies.

Many research protocols involve exercise testing which can lead to long-term and even permanent worsening of symptoms for people with ME. Focus on finding ways to measure impairment without requiring multi-day exercise testing.

Ensure provocation studies incorporate disease-specific training and staffing of clinical support personnel present at all study visits in order to mitigate and navigate PEM subsequent to exertional or cognitive challenge (e.g. advance hydration, post-challenge IV saline, postural support, control of environmental stimuli, transport, cardiac resuscitation, seizure support, ER transfer, and post-visit follow up)

Develop standardized disease-specific informed consent protocols for use in provocation studies that adequately inform patients of potential long term iatrogenic harms and risks of undergoing CPET or other major exertional challenge. Recognize that rather than being unwilling, people with ME may be unable to perform certain activities without high risk of harm.

Support study designs which incorporate tiers of exertional risk in order to supply study participants with a choice in undergoing mild/moderate/extreme challenges rather than forcing an all-or-nothing decision. Participants may be uncomfortable with one extreme option, but eager to participate at a lower threshold.

Many patients face financial constraints due to their inability to work. Whenever possible, provide coverage for travel expenses to/from study site. Consider appropriate monetary compensation given the potentially deleterious physical effects on participants.

Overcome the sex, race, socioeconomic, age biases in existing data and research cohorts; account for males, minorities, poor, youth underrepresented (and underdiagnosed). Take steps to ensure that diversity is considered for researchers, clinicians and support staff participating in studies by liaising with the NIH's National Institute on Minority Health & Health Disparities Office.

Aim for study populations large enough to be able to support subgroup analysis and identification. Ensure that findings determined in narrowly defined cohorts are then replicated in populations that are more typical of the diversity of the disease seen in clinical care with its varied presentation, demographics, comorbidities, and concomitant medications.

Maintain a centralized website where enrolling studies funded by the NIH are listed, in which keeping content and contact information up to date is a required task for grant recipients