



**INFORMATION PACK  
FOR TD's, HSE and other interested  
parties**

**The situation of  
Myalgic Encephalomyelitis  
patients in Ireland 2017**

**#MillionsMissingDublin event  
Leinster House,  
May 11<sup>th</sup> 2017  
11.00am to 3.00pm**

## Quick Summary

- Worldwide there are Millions Missing from their previous active lives having acquired Myalgic Encephalomyelitis (M.E.)
- In Ireland there is estimated to be some 14,000<sup>1</sup> people living with M.E.
- M.E. is an acquired complex neurological disorder affecting multiple systems of the body
- The body's ability to generate and produce energy at a cellular level is seriously impaired meaning systems and organs cannot function properly causing progressive systemic deterioration
- Post Exertional Malaise (PEM) is the cardinal symptom of M.E. Essentially any action whether physical, cognitive, emotional, social etc drains available energy and if the ability to replace this energy is impaired this can lead to a worsening of all symptoms which can last for days, weeks or months – even causing a permanent, non-recoverable relapse
- Many people with M.E. are reliant on carers for their basic needs
- Deaths among the M.E. population are usually attributed to secondary causes such as cancers, cardiac issues and even suicide
- Life expectancy is shortened as deterioration becomes cumulative
- There are NO M.E. specialist hospital consultants in Ireland
- The HSE have failed abysmally to put in place proper diagnostic criteria and proper care plan pathways for people with M.E.
- The current 'treatments' listed on the HSE website have been demonstrated to be ineffective and to cause harm to people and children with M.E.
- There is no factual collation of data on numbers with the condition here in Ireland
- The Royal Academy of Medicine in Ireland concluded in a published paper on M.E. in Sept 2010 <sup>2</sup>*“There is a need for further education of the medical progression on this debilitating condition and there is clearly a need for further research into treatment which directly impacts upon the quality of sufferers”.*

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<sup>1</sup> Based on figures extrapolated from data in other countries

<sup>2</sup> A National cross-sectional survey of diagnosed sufferers of Myalgic Encephalomyelitis/chronic fatigue syndrome: pathways to diagnosis, changes in quality of life and service provision, C. Comiskey, F. Larkan, Sept 2016

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## 1. What is ME?

Myalgic Encephalomyelitis (M.E.) is an acquired complex neurological disorder affecting multiple systems of the body. Many cases are preceded by a viral infection with onset being usually rapid (acute). However gradual onsets have also been reported. Affected individuals do not recover from the infection and instead experience a wide variety of symptoms including the body's inability to produce energy.

Energy is needed to fuel the body's internal functions. Cells cannot survive on their own. They need power to stay alive. They need energy to perform functions such as growth, maintaining balance, repair, reproduction, movement, cognitive function and defence. All living organisms must obtain and use energy to live.

All body organs work through receiving an energy supply. If the energy supply is impaired in any way the body's organs deteriorate.

When the body receives energy it is converted into Adenosine triphosphate (ATP) which is considered to be the energy currency of life. It is the high-energy molecule that stores the energy we need to do just about everything we do.

Similar to Multiple Sclerosis, patients with Myalgic Encephalomyelitis share many similar pathologies including impaired ATP.

<http://bmcmmedicine.biomedcentral.com/articles/10.1186/1741-7015-11-205>

To give an example of the effect on one organ - the brain. Lack of cellular energy will start out by the patient showing symptoms of 'foggy brain' which could mean forgetting conversations, poor short term memory, inability to hold conversations, inability to absorb new information, difficulty reading a book or following a film, difficulty finding the right words, intermittent dyslexia, etc. However if energy disruption continues one will end up with dementia.

Therefore M.E. is a multi-system illness, negatively impacting on all systems of the body.

Marked debilitating fatigue and weakness, sickness, cognitive dysfunction and symptom flare-up follows any physical or cognitive exertion requiring energy. This aspect of M.E., referred to in literature as **Post Exertional Malaise (PEM)**, is a cardinal symptom of people with M.E. Essentially what it means is that any exertion, physical, cognitive or even emotional stress creates a prolonged reaction in the body where a relapse or worsening of all symptoms occur which can last for days, weeks, months or longer. Indeed many people who have pushed far too hard beyond their limits have become bedbound and carer dependent for years.

## 2. Most Common Symptoms

There is a myriad of symptoms attached to M.E. The most reported ones are headaches, bone and muscle pain, swollen lymph nodes, muscle weakness, muscle spasms, seizures, neck pain, vision abnormalities (such as blurred vision), cognitive impairment, photo-sensitivity, noise sensitivity, paresthesia, bladder and bowel

dysfunction and sleep dysfunction. Cardiovascular abnormalities are also commonly reported.

Much like the disease Multiple Sclerosis, people can be affected in different ways. Severe cases often leave affected individuals bedridden, needing tube feeding and 24 hr care. Less severe cases are usually housebound with no basic energy to engage in ordinary simple self care and household activities like showering, washing hair, brushing teeth, making a meal, etc. Milder cases may be able to function at a higher level but energy is very limited and each task involves pacing and prolonged resting to restore enough energy for the next task.

Myalgic Encephalomyelitis may occur as an outbreak that affects a large group of people (epidemically) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2425309/> or may only affect an individual (non-epidemically).

The first outbreak of Myalgic Encephalomyelitis was recorded in 1934 but the term Myalgic Encephalomyelitis first appeared in the medical literature in 1956 when it was named by Dr. Melvin Ramsay.

<http://www.cfids-me.org/ramsay86.html>

Myalgic Encephalomyelitis is recognized as a distinct disorder and has been classified as a specific neurological disorder under G.93.3 by the World Health Organization (WHO) since 1969. See here question raised in the European parliament in 2013 calling on all member states to respect the WHO classification of Myalgic Encephalomyelitis.

<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+WQ+E-2013-003090+0+DOC+XML+V0//EN&language=lt>

### **3. What is CFS?**

Many people, including doctors, confuse the term M.E. with C.F.S. (Chronic Fatigue Syndrome).

The term CFS was first used in medical literature by the Centre for Disease Control, USA during the 1980s to describe an outbreak of an M.E. type illness in Lake Tahoe. The criteria used for this 'new' illness focused on the fatigue elements of patients symptoms and ignored the encephalitic (inflammation of the brain) features of the disorder. The name trivialised the seriousness of how ill these patients were and over time led to more and more people, with only fatigue as their primary symptom, to get a diagnosis of CFS. And so began the confusion between M.E. and CFS leading to a commonly used hybrid term MECFS.

Many CFS patients do not fulfil the criteria for ME and similarly many patients with M.E. have received a CFS diagnosis.

Over decades this conflation of the two illnesses has led to the severe neglect of people with M.E. - people who are suffering horrendous symptoms and who doctors simply see as a patient who has unexplained 'fatigue'.

The distinction between both illnesses has continued to cause problems for researchers, doctors, governments and patient organisations. Many began to use the terms interchangeably or with the combined acronym ME/CFS, creating a broad disease category that has no official classification.

This emphasis on fatigue unfortunately 'allowed' the disease of M.E. to become more and more disappeared and to be defined by some as a psychiatric illness, thus condemning some very seriously ill patients to a lack of proper diagnosis, lack of appropriate testing, lack of treatment and understanding of the symptoms and more importantly a lack of interest in pursuing biological research for the condition.

However in recent years much of this has changed and there are very reputable scientists now involved worldwide in M.E. research adopting appropriate and more stringent diagnostic criteria on trial participants.

Below is a summary of recent biological research findings in people with M.E.

<https://app.box.com/s/9s4coexxtys5bnz33i6qvqqyqu67ex5o>

#### **4. How is M.E. diagnosed?**

There is a myth that M.E. is difficult to diagnose because 'tests' don't show anything wrong with the patient. This is simply not true. Patients with M.E. are often given a diagnosis of CFS, or Post Viral Fatigue or, even worse simply Chronic Fatigue, making it look like they are just 'tired' people.

Many worldwide experts in the illness (including Ireland's Prof Darragh) came together and produced a comprehensive diagnosis criteria called the International Consensus Criteria (2011) – ICC-ME.

<http://www.investinme.org/Documents/Guidelines/Myalgic%20Encephalomyelitis%20International%20Consensus%20Primer%20-2012-11-26.pdf>

The “Myalgic Encephalomyelitis – International Consensus Criteria (ME-ICC)” advocates for removing fatigue as a characteristic symptom and defines the disorder as an acquired neurological disease with complex global dysfunctions. The ME-ICC also defines specific symptom requirements: post-exertional neuroimmune exhaustion, neurological impairments, immune, gastrointestinal, and genitourinary impairments, and energy metabolism impairments.

The pre-runner to the ICC-ME was the Canadian Consensus Criteria (2003). CCC-ME

[http://www.ahmf.org/me\\_cfs\\_overview.pdf](http://www.ahmf.org/me_cfs_overview.pdf)

The Canadian Consensus Criteria defines ME/CFS as an acquired, organic, pathophysiological multi-systemic illness that occurs in both sporadic and epidemic forms and requires core symptoms including post-exertional malaise (PEM) and neurocognitive dysfunction, in contrast to the polythetic approach of the Fukuda case definition below.

The Fukuda et al. (1994) criteria was developed by the CDC in the USA after the outbreak at Lake Tahoe.

<https://www.cdc.gov/cfs/case-definition/1994.html>

This criteria is used to define Chronic Fatigue Syndrome. As Post Exertional Malaise is not a mandatory criteria under Fukuda you can begin to imagine the number of misdiagnosis and confusion that abounds. Research has indicated that individuals with a primary psychiatric illness (e.g. primary Major Depressive Disorder) may be misdiagnosed under the Fukuda criteria due to many overlapping symptoms including fatigue and sleep difficulties.

In the UK however another criteria was developed for and by a group of psychiatrists - called the Oxford Criteria.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1293107/pdf/jrsocmed00127-0072.pdf>

This criteria is far less rigorous and may include patients with fatigue as their only symptom. As you can imagine there are a myriad of illness which can have fatigue as a primary symptom, eg MS, Lupus, Fibromyalgia, cancer, heart disease, etc so the possibility for misdiagnosis is very high and the research criteria used results in a toxic mix of patients with a range of illnesses. The Oxford criteria is not used anywhere else in the world and yet the HSE have adopted them straight from the UK as if they are the best way to diagnose people with M.E.

To further explain how this criteria is viewed by international experts, in July 2016, the Agency for Healthcare, Research and Quality in the USA issued an addendum to it's Evidence Report recommending the retirement of the Oxford criteria for ME/CFS because it was the least specific of all the definitions and only included six months fatigue as a primary symptom and did not include Post Exertional Malaise which is considered a hallmark of the disease. See Introduction paragraph of this <https://effectivehealthcare.ahrq.gov/ehc/products/586/2004/chronic-fatigue-report-160728.pdf>

As you can glean from the above, the research criteria used can vary enormously from country to country and medical discipline to medical discipline. The Oxford criteria developed by the UK psychiatrists is unfit for use and cannot be reliably extrapolated to people with M.E. as the distinct neurological indicators of the disease are ignored and excluded.

**It is this criteria upon which the HSE diagnostic and treatment guidelines are based.**

The good news however is that in recent years there has been huge strides made in the understanding and appropriate categorisation of M.E.

In the USA for example the Institute of Medicine (IOM) produced a comprehensive report back in 2015 called "Beyond Myalgic Encephalomyelitis/chronic fatigue syndrome - Redefining an illness" which concluded "It is clear from the evidence compiled by the committee that ME/CFS is a serious, chronic, complex, and multisystem disease that frequently and dramatically limits the activities of affected patients". The report goes on to recommend a new diagnostic criteria very similar to the CCC-ME of 2003 mentioned above and lists Post Exertional Malaise as a mandatory criteria for diagnosis.

## 5. How is M.E. diagnosed in Ireland?

The HSE website is a cut and paste edit of the NHS guidelines in the UK which is based on the Oxford Criteria and does not require Post Exertional Malaise as a mandatory diagnostic symptom. How can a condition that has PEM as a CARDINAL symptom not require the same symptom to be present for diagnosis?

Given the stories of patients it seems pretty clear that people get an ME/CFS diagnosis here based loosely on the Oxford criteria which focuses primarily on fatigue which has lasted for more than six months and one of a selection of other symptoms which are generic to many other conditions. This 'criteria' means that the other common symptoms of M.E. often get ignored or disregarded or are treated as separate conditions with no one looking at the whole system and the whole illness. One can only imagine the number of misdiagnosis that this is creating. Patients with M.E. are often met with dismissal and denial of their condition due to the lack of knowledge within the HSE.

Some patients however, particularly those who have the illness much longer, DID receive an M.E. diagnosis here, as many years ago there were experts in the field here in Ireland including our very own Prof Austin Darragh, RIP who was one of the authors of the ICC-ME of 2011.

Unfortunately that expertise no longer exists and has been allowed to disappear as experts here retired or passed away and were not replaced. M.E., for example, no longer features in education in medical schools.

## 6. What does the HSE say about ME?

If one googles the words 'HSE and Myalgic Encephalomyelitis' one is brought straight to the HSE information on Chronic Fatigue Syndrome. Go on. Try it.

The website then goes on to conflate the two conditions claiming that doctors 'prefer' to use the term CFS as opposed to M.E. This may well be the case of course as M.E. is not taught in our medical schools and many doctors are not aware of its existence or the fact that it is a distinct illness listed under neurological conditions in the WHO classifications completely separate from the entity CFS.

The entire website section needs to be re-written (and M.E. separated out from CFS) as it is riddled with inaccuracies and lacks any scientific basis. However we recognise that this may take some time so, as a starting point, the #MillionsMissing campaign want to immediately remove the current harm being caused to M.E. patients as a result of HSE treatment recommendations.

### **Urgent Recommendation:**

**We therefore recommend that the HSE immediately addresses the following interim change on their website about M.E.:**

Under the heading 'Treatment' the HSE currently recommend standard 'treatments' of psychological interventions and exercise - **Cognitive Behaviour Therapy and Graded Exercise Therapy (CBT and GET)**. These treatments have been proven to be both ineffectual and harmful to people with M.E. The current default position of



many doctors is to refer those diagnosed with the condition to psychiatry and physiotherapy. This referral sets up a pathway that is totally inappropriate and can end up blocking appropriate medical investigations and multi symptom management and treatment paths for people with the neurological condition of Myalgic Encephalomyelitis.

GET, as a treatment, has been proven to seriously harm and even kill people with M.E. as their bodies do not have the ability to reproduce energy and pushing their bodies beyond safe limits can end up pushing them into a severe case of their illness, often needing 24 hr care, bedbound, doubly incontinent, needing feeding tubes and having multi organ problems and even death. Other health agencies around the world have removed GET as a treatment on the basis that it is firstly ineffective and secondly likely to cause harm.

CBT as a treatment is not an effective tool. While it may be useful as an adjunct therapy (as with many chronic illnesses) it should not be recommended as a primary treatment. Many people with M.E. cannot get out of their beds or houses and to set them up with therapist appointments which they cannot possibly attend (or causes them severe crashes and relapses) amounts only to cruel and unusual punishment. If patients want to have psychological therapy to help them cope with their illness, then that should be their choice and something that they request for themselves, as is the case with any other illness.

**The removal of these treatment guidelines is imperative for the safety of people and children with M.E.**

#### **7. What is GET and why is it totally unsuitable for people with ME?**

GET means Graded Exercise Therapy, the principle of which is for the patient to increase their exercise over time even if they feel very unwell from doing so. The principle behind prescribing GET for those with ME is an underlying belief that the ongoing symptoms are due to false illness beliefs and deconditioning.

Graded Exercise Therapy became underpinned by the NHS after a large trial was conducted in the UK to establish whether CBT and GET were effective treatments for ME/CFS.

The study was known as the **PACE trial**. The authors were among a prominent group of British mental health professionals, and their associates, who had long argued that the devastating symptoms of M.E. were caused by false illness beliefs and severe physical deconditioning.

They recognized that many people experienced an acute viral infection or other illness as an initial trigger. However, they believed that the syndrome was perpetuated by patients' "unhelpful" and "dysfunctional" notion in that they continued to believe they suffered from an organic disease and that exertion would make them worse. According to these psychiatry 'experts', patients 'decisions' to remain sedentary for prolonged periods led to muscle atrophy and other negative systemic physiological impacts, which then caused even more fatigue and other symptoms in a self-perpetuating cycle.

Biological studies however have shown that the illness is characterized by immunological and neurological dysfunctions, and many academic and government scientists say that the search for organic causes, diagnostic tests and drug interventions is paramount.

In contrast, the British mental health experts focused on non-pharmacological rehabilitative therapies, aimed at improving patients' physical capacities and altering their perceptions of their condition through behavioural and psychological approaches. The PACE trial was designed to be a definitive test of two such treatments they had pioneered to help patients recover and get back to work. British government agencies, eager to stem health and disability costs related to the illness, had committed five million pounds to support the research.

There was a great fanfare when the results of the trial were published which showed that 22% of people in the two rehabilitative treatment arms had achieved 'recovery'. Headlines around the world trumpeted the story.

However since then the trial has been completely debunked by many scientists around the world. It turns out that the Principal Investigators of the trial had altered the primary outcomes in their original 'recovery' protocols halfway through the trial so much so that 13% of the trial participants could have simultaneously qualified as being disabled enough to enter the trial and recovered after the trial.

Suffice to say that when applying the original recovery outcomes the trial had a null effect. Despite that, however, the authors (who had considerable influence and power in media, government, insurance companies and the UK establishment) were able to control the media message and perpetuate the myth that the illness was fundamentally perpetuated by unhelpful illness beliefs.

There is much written about this trial and calls for its retraction and we can supply all the backup data necessary on demand. For now we are giving you two links. The first is to a recently published peer reviewed article which concludes:

*“The claim that patients can recover as a result of CBT and GET is not justified by the data, and is highly misleading to clinicians and patients considering these treatments”*

<http://www.tandfonline.com/doi/full/10.1080/21641846.2017.1259724>

The second link below is to an article just published on April 4<sup>th</sup> 2017 which explains, in an easy to understand way, the flaws of the PACE Trial and why it has been so damaging for people with M.E.. It concludes:

*“Studies like the PACE trial can have a strong impact on patient care, and flawed studies can result in harm to patients. Conventional peer review is obviously not enough; the effective peer review in this case came after publication. Numerous flaws were found that should have been addressed before publication. Critics called for the study to be retracted; so far it hasn't been. This unfortunate episode can serve as a wake-up call and it points out the value of freely sharing raw data with*

*other researchers. Good scientists want to know if they are wrong. They want to have their work scrutinized and should be willing to share their data without the requesters having to resort to a court order”.*

<https://sciencebasedmedicine.org/treating-chronic-fatigue-syndrome-with-cognitive-behavioral-therapy-and-graded-exercise-therapy-how-the-pace-trial-got-it-wrong/>

## **8. Current biological research**

The myth that M.E. is a self-perpetuating condition continues to this day in some quarters thanks to the control that the cabal of UK psychiatrists have of the Science Media Centre in the U.K. The SMC controls virtually all of the media message relating to M.E.

However thanks to a growing number of exceptional scientists, M.E. medical experts and patient advocates who have researched and delved into the biological dysfunctions caused by M.E., we are closer than ever to finding out the pathology of this illness. It is to those people that patients owe a debt of gratitude. Patients all around the world raise funds for research and have found online support through the establishment of many online groups. Below is a link to some of the peer reviewed biological research that exists

[https://m.box.com/shared\\_item/https%3A%2F%2Fapp.box.com%2Fs%2F9s4coexxtys5bnz33i6gvqqygu67ex5o](https://m.box.com/shared_item/https%3A%2F%2Fapp.box.com%2Fs%2F9s4coexxtys5bnz33i6gvqqygu67ex5o)

As you can see from the above link there are copious amounts of research already carried out that demonstrate that people with M.E. are harmed by exercise and therefore to provide this as a treatment is to compound that harm and possibly drive them into a situation of total and long-term severe disability. Again we can supply scientific evidence on demand but for now, one example from by Paul L et al is interesting "Demonstration of delayed recovery from fatiguing exercise in chronic fatigue syndrome". It should be noted that this paper was published almost 20 years ago.

<https://www.ncbi.nlm.nih.gov/pubmed/10209352>

## **9. How did the HSE get it so wrong?**

The problem with the HSE is that they simply just copied and pasted the UK NHS guidelines for this illness without any reference to the ever growing wealth of contemporary international research which supports a very different management pathway than that of the majority of the UK services. They have also not adopted a formal definition of M.E. which is sufficiently rigid to meet research standards.

The HSE website information completely ignores the many thousand peer reviewed scientific papers that show the biological issues involved in M.E. Indeed the website appears to ignore the fact that it is a neurological disorder listed under the WHO G93.3.

The HSE have failed to ensure that its staff in acute and community settings are sufficiently aware of the illness and that patients can present from mild to severely disabled. As a result of this failure patients often experience ignorance of the condition or dismissal of the seriousness of their disability – indeed many patients are pressurised into agreeing to psychological interventions or to a physiotherapy regime undertaken by those not familiar with the disastrous consequences of PEM with a serious worsening of all symptoms.

### **10. What do Irish doctors know about ME?**

Many Irish doctors know very little about M.E. save what they read on the HSE website. The illness is not taught in medical schools here. It has virtually been disappeared or conflated with CFS.. There are no consultants specialising in the illness and therefore there is no clear medical care plan pathway for patients.

Many patients regularly report bad experiences where hospital staff have said they've either never heard of the illness or else they think that it means you have a 'mental health' problem. For an illness that has been categorised by the WHO as neurological this is beyond disgraceful.

It is also very difficult to find a GP who understands the illness or is willing to look up the current research. While they do exist here and there, they are doing so without any support or encouragement from their parent bodies or the HSE.

This inevitably leads to the neglect of people who are extremely ill. Whether the neglect is wilful or accidental is irrelevant in this situation. People are left to cope on their own seeking advice, testing and treatment abroad where they can afford it or left to rot in darkened bedrooms when they can't. Children also get M.E. and in the UK figures show it is the biggest contributor to school absences.

### **11. Recommendations**

The #MillionsMissing campaign requires the establishment of a Myalgic Encephalomyelitis (ME) Working Group with immediate effect.

The purpose of the M.E. Working Group will be to (not a definitive list):

1. Ensure that the harmful recommendations of CBT and GET are removed as treatment options from the HSE website (see above urgent recommendation)
2. Adopt an accepted internationally recognised set of diagnostic criteria (this group recommends the ICC-ME) which is sufficiently rigorous to identify research cohorts
3. Develop an M.E. policy to include
  - Diagnostic protocols
  - Treatment Options
  - Management Pathways

- Training programme for existing and new HSE personnel involved in all potential aspects of patient care e.g. Acute personnel, Community personnel, primary care personnel, hospital personnel, education personnel, social workers, etc
4. The advertisement and appointment of a Consultant with extensive experience of innovative practice in M.E. who will guide and inform the development of the HSE's M.E. practice in Ireland in line with the adopted International diagnostic criteria. Such practice to include informing all relevant groups of people responsible for ensuring that a person with M.E. is supported and managed in the most constructive and positive way possible.
  5. HSE website information to be in line with the policy and adopted diagnostic criteria

### **M.E. Working Group membership**

This M.E. Working Group should include representation from the following (this is not a definitive list):

- HSE Acute service professionals
- HSE community practitioners
- Education service
- Recognised international ME experts
- Those who have lived with and researched ME as sufferers and Carers
- Relevant patient organisations

### **Commitment:**

We require a statement from the CEO of the HSE to 'kickstart' Policy which directs this to be:

'an innovative project to address an existing need amongst a Patient cohort which the HSE has identified as urgent and in which the process of creating a Policy for Myalgic Encephalomyelitis, by including participants from all relevant parties, HSE Employees, and Patient/Client & Carer expertise, is to exemplify 'best practice' as outlined in the principles of the National Healthcare Charter'.

***Compiled on behalf of  
The #MillionsMissingDublin Event Campaign***

## Appendix 1

### Quick Glossary

M.E.	Myalgic Encephalomyelitis
CFS	Chronic Fatigue Syndrome
WHO	World Health Organisation
CBT	Cognitive Behaviour Therapy
GET	Graded Exercise Therapy
PEM	Post Exertional Malaise
HSE	Health Services Executive
ICC-ME	International Consensus Criteria for ME
CCC-ME	Canadian Consensus Criteria for ME
CDC	Centres for Disease Control & Prevention, USA
AHRQ	Agency for Healthcare Research & Quality, USA
IOM	Institute of Medicine, USA
NHS	National Health Service, UK