

Evidence-based Medicine (EBM) Essay

September 2017

Once upon a time all of the evidence available pointed to the earth being flat, and that is was the centre of the universe, not the sun.

For some, evidence-based thinking is a static concept that appears to provide security and a platform from which to base beliefs and work from, no matter what the subject matter is. Whether you are a clergyman in the 1500s clinging to a belief that the world is flat, or a member of the EBM community in the 21st Century your standpoint appears rigid.

For others it is a barrier, and a barrier that is not just hindering innovation, preventing, for example, scientific growth, but also has a knock on effect to the careers of scientists and clinicians, and further to the choices available to the average person, and in this case, patient due to the work of those scientists and clinicians. A current example might be a pioneering scientific researcher in the 21st Century with evidence on autism, vaccines or mould who believes early evidence is available that could be more widely developed to push the evidence window wider.

The divide can become particularly apparent if the prevailing position, in this case EBM, is not willing to give space to allow the development of new ideas. If it subsequently does there may remain concerns from the initiating side that there could be influences from bias that can alter/manipulate the subject, such as academia or industry, both of which can be, in turn, heavily influenced by money and/or politics.

But, at their heart, it might be argued, both sides have the best interests of people at their heart, and that ultimately is a commonality that can be built on in due course.

The explorer Ferdinand Magellan completed the first global circumnavigation in 1521, but it wasn't until the 20th Century, initially via the Small Steps programme and then the Apollo programme that we actually saw our blue marble home in all its glory. Copernicus delivered his long-developed theory on the revolutions of the celestial spheres in 1530 stating that the earth (and the other planets) rotated daily on its axis and annually around the sun- some 80 years before the development of the telescope, which would then facilitate Galileo's pronouncements on heliocentricity. Galileo went on trial and was convicted for his theory, and has become a poster-boy for persecution of new science. New thinkers, it seems, can often face an uphill battle when they strive to add to existing evidence which may ultimately challenge beliefs.

It is beyond our comprehension, as it would have been to the lay person in the early 1500s, to think where our understanding of ourselves and the world(s) around will have lead us to 500 years from now. But advancements will happen and in the medical world EBM is just one part of the medical model that governs healthcare today. At this time in the evolution of medicine we seem to be at the brink of a paradigm shift that appears to want to evolve from a reductionist approach to one that is more integrative, and it will be interesting to see how that shift affects EBM. Driving this paradigm shift in no small part is the access to science and technology that is transforming our understanding of human physiology on a daily basis.

The Oxford dictionary definition for the word evidence is “*the available body of facts or information indicating whether a belief or proposition is true or valid*”¹. The key word here is ‘available’, which in light of the examples given above illuminates the dynamism of evidence. It evolves. Preconceptions, and strongly held convictions can all be changed with evidence (whether that evidence is robust or not!).

When we focus that light on evidence in medicine the implications are enormous, because it is our very own lives that may well be dependent upon it, it has to be robust. Medical evidence is also evolving, and in many areas of medicine, at pace thanks to the scientific and technological advancements we now have access to. A key question as the future of medicine unfurls might be to ask what the criteria is for that evolution, but we also need to consider who is not only defining the criteria, but also managing the message. To put that into a medical context, if we are thinking about the function of the thyroid gland and only consider the input to that gland via measuring Thyroid Stimulating Hormone(TSH) as evidence of gland function we are missing the output messages of T4 and then T3, and further, T3 uptake. At the same time we aren’t even considering the possibility of antibodies affecting gland health. Sure, there is a feedback loop that means eventually TSH levels will likely change, but by solely using that as evidence, even if the measured parameters were devised from using information gained via a double blind randomised control trial, so much more is missed. If we are only hearing from those that measure TSH (and perhaps even decided the reference ranges for TSH too), and not from the others then how reliable is their message?

Evidence is important, but to get the optimal evidence the right questions would have to be asked. The Students 4 Best Evidence group list four key question steps in Evidence Based Medicine (EBM); firstly, asking the right question(s), secondly, searching for the evidence, thirdly, appraising the evidence and fourthly, acting on the evidence. A fifth is also cited, which is evaluating your practice². When we interact with our patients it is crucial to ask them the right questions, but it is also critical that we also ask ourselves the

¹ <https://en.oxforddictionaries.com/definition/evidence>

² <http://www.thestudents4bestevidence.net/start-here/what-are-the-key-steps-in-ebm/>

question as to whether we have the ‘current, best evidence³’ available to support our work with that patient. Sackett, who co-authored probably the most cited journal piece to date on EBM, stated in 1996 that EBM is about ‘integrating individual clinical expertise and the best available external evidence⁴. But Sackett added an extra point towards the end of his 1996 article, which was that along with the integration of the best external evidence with individual clinical expertise the integration of patient choice is also required.

This raises an important point. For the patient, EBM has agreed upon a criteria of diagnosis of Irritable Bowel Syndrome (IBS), but this is little more than an umbrella term that defines a broad issue, but doesn’t actually give a root cause resolution to the matter at hand. It is the best on offer at this time, but it clearly doesn’t do enough to fully satisfy the patient and resolve their symptoms. Where is the choice for the patient if the GP/MD they visit can only prescribe them a stool softener because they haven’t the capacity to evaluate studies on gluten pathologies, small intestinal bacterial imbalance, large intestinal dysbiosis or the other potential key triggers for IBS? EBM could then be reduced to little more than a post/zip code lottery for the patient depending on how able their GP/MD is to stay abreast of current research, or whether they can then refer on to a Consultant Gastroenterologist who is similarly willing/able to seek the root cause. We have so much further to go to give our patients optimal choices.

These choices and those of the GP/MD can be further mediated by national guidelines. In the UK these are divined by the National Institute for Health and Care Excellence (NICE), and then endorsed by Health England. The NICE strapline is “Improving health and care through evidence based guidance”. Their information is aimed at patients so they know what to expect after a diagnosis (so they can make choices and become partners in their own care), and for organisations to use so that they are working from EBM information on that condition. As a side benefit it is noted by NICE that using their guidelines can also reduce risk of litigious actions. Their information on IBS does acknowledge possible causes of IBS such as gut hypersensitivity, disturbed colonic motility, bowel dysfunction after an infection, microbial imbalance in the gut, low-grade inflammation or a defective antinociceptive system (but no framework is offered for looking into these things). Their care steps involve excluding inflammatory causes, reviewing red flag indicators and following that nutritional management (which typically involves a low FODMAP approach). Their primary role is clearly to set a quality standard.

Similarly, the European Food Safety Authority now considers evidence for health claims, and as of August 2017 there are none yet for probiotics! The claim process is a lengthy

³ Sackett, David et al. Evidence based medicine: what it is and what it isn’t. BMJ; 13 January 1996. available from <http://www.bmj.com/content/312/7023/71>

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one, and questions remain about bias. However, as we see with NICE, EFSA are also seeking to create an EBM framework, this time for health claims.

It is this standard that becomes a framework for both physicians and patients alike, in three key areas; patient safety, patient experience and clinical effectiveness. So, whilst patients might not be able to access *individualised root cause care* from every physician they see, they have the reassurance that they will be kept as safe as possible within the EBM framework.

So, the EBM framework should work in patient's best interest- that is unless the science they are working from is flawed. One is left to hope then that examples of large-scale flawed science that become dogma are few and far between, but a timely reminder raised its head in spring 2016 when the dismantling of work by Ancel Keys on the correlation between dietary fat and heart disease hit global headlines, thanks in part to work done by Nina Teicholz. This is where we see the explosion in science and technology developments in medicine is also translating across to information technology. Would Nina Teicholz have been able to lead the charge in changing perceptions on fat and heart disease in a world that did not have the internet and the ability to reach globally? Perhaps John Yudkin would not have been quite so vilified in 1972 if the internet had been around then!

This is where the individual experience becomes so important. Can EBM ever hope to cover all the bases when it comes to individualised care/medicine? Would a democracy of information rather than a dictatorship work better? We are certainly moving more towards a democracy of information thanks to communications technology advances. The medical situation at the moment is one where patients have choice within a framework or they can choose to seek 'complementary' care outside of the framework (from information they have likely found outside of their physician's office). The draw of complementary care is that it can be personalised to a greater extent, and if patients are seeking it, then they are exercising true choice, and attempting to take a greater responsibility for their own health. Whilst the medical model claims to pass responsibility of health to the individual, a 'managed care pathway' does little, some might argue, to instil a feeling of personal responsibility.

This exposes a further flaw in EBM as it relates to health (not the presence of disease which is the mainstay of EB 'Medicine'). The Medical definition of health (being the absence of disease or abnormality) has long-governed the medical model and as such has slowly evolved to become an even stronger legislative model. Although the medical model is supposed to pass responsibility of health to the individual, what kind of model is it that majority of the time they interact is because the individual has 'failed' to keep themselves 'healthy'....they have crossed the border from health to illness and apparently need the support of a medical practitioner to get back there. Where is the positive side of 'medicine' that actively promotes the good health state in the first place? Disease is a process and

pre-pathological changes are key to this. The question of health becomes even more complex when you take into account pre-pathological changes, and a person's genetics- where then does good health truly start and end?

As a species we are evolving and so is our understanding of ourselves and the world around us. We choose what we want to believe, as patients and as clinicians, and flat-earthers exist on both sides of the EBM argument. Whilst evidence is undeniably important, there has to be a channel for that evidence to be challenged and developed, and EBM may have to become even more dynamic to keep pace (and perhaps even remain relevant) so that there is less of a time lag between valid new theories and their acceptance. Finding common ground in how to manage translational gaps (the time between new scientific discoveries and patient benefit), whether they truly average seventeen years or not, may perhaps hold the key.