Where's the Evidence?

Ahh, the promise of science and the secrets of life. Where else would a bright-eyed girl look but to medical school? How wonderful was the promise of science and the guidance by learned teachers into the world of molecules and breath. Science and medicine that had respectively proven the world was round and consumption was caused by a microbe named *Mycobacterium tuberculosis*.

The general public and health care practitioners are constantly told that health interventions should have scientific evidence of effect. This is a noble and justifiable position especially with regard to interventions which might cause harm (compare a sleep mask to a sleeping tablet for insomnia), but is difficult if not impossible to apply in real life. What? All medical practice should be based on sound scientific evidence, should it not? Why else attend medical school?

The Reading

It has been said that if a doctor reads two clinical papers per day, by the end of the year, he / she will be 55,000 years behind in their medical reading. Furthermore, most doctors have limited training in interpreting scientific papers, where trial teams often have their own statistician analyzing the vast amount of data collected. It is not always practical to review the analysis and resulting presentation.

Hence doctors generally take advice from guidelines and organized ongoing education. Guidelines and education are often compiled by professional organizations consisting of doctors themselves, who generally also rely on experts and specialists in a particular field to provide final approval. These specialists will also not be able to go through the vast amount of material in just their field and are reliant on other specialists, guidelines and meetings. While the days of the pharmaceutical rep are all but over, pharmaceutical (and supplement) companies spend billions of dollars on marketing through value-added online services, "facilitating links with clinical trials, journals and knowledge opinion leaders."

The Science

Science is "a system of knowledge covering general truths…as obtained and tested through scientific method." Scientific method is the "pursuit of knowledge involving the recognition and formulation of a problem, the collection of data through observation and experiment and the formulation and testing of hypotheses." The research is published in journals where it can be read by anyone, often for a fee.

In a utopian world, not only would the journal articles be free to everyone, but the scientist doing the science would be unencumbered. Unfortunately, I observe two problems with this. One is that humans are biased. To suggest that this bias is completely ignored in scientific methodology would be naïve. Even researchers acknowledge that "our talent for jumping to conclusions makes it all too easy to find false patterns in randomness, to ignore alternative explanations…to ceaselessly lead ourselves astray without realizing it." These

same researchers are looking at research and data analysis techniques to mitigate this problem and in a future world, humans may even be excluded from drawing conclusions from large data sets.

The second problem is twofold. That of a combination of direct funding by organizations with financial interest in the outcome of the research and the personal cost to those scientists who are brave enough to go against the prevailing understanding; think of Galileo – and yes, it is still happening today, albeit in a different guise.
https://www.thelancet.com/pdfs/journals/lancet/PIIS0140673605607611.pdf

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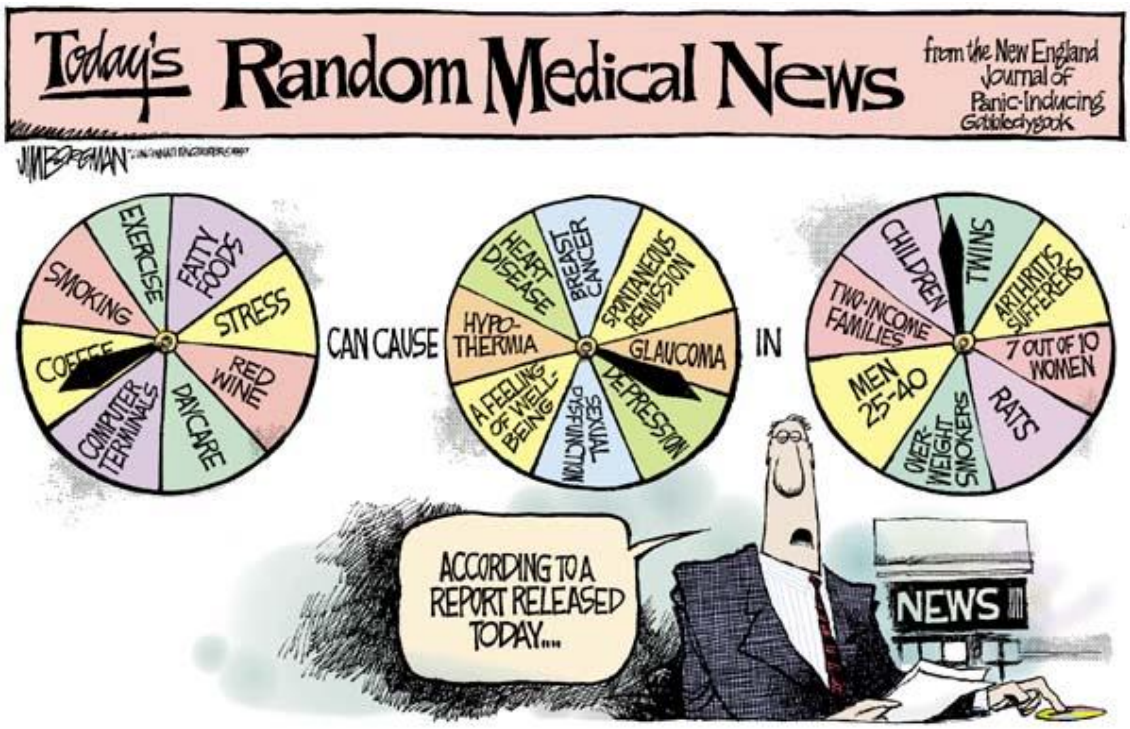
Richard Horton, editor of Lancet, one of the oldest and most prestigious medical journals has stated: "The case against science is straightforward: much of the scientific literature, perhaps half, may simply be untrue. Afflicted by studies with small sample sizes, tiny effects, invalid exploratory analyses, and flagrant conflicts of interest, together with an obsession for pursuing fashionable trends of dubious importance, science has taken a turn towards darkness."

Applicability

Even if all problems in science were annulled, applying scientific conclusion to the individual is akin to Russian Roulette. The method of evaluating an intervention (e.g. an antibiotic) to treat a problem (e.g. pneumonia) is very specific and particularly useful when treating an immediate problem such as an infection. In this case, say ten people are given Penicillin and eight recover. This gives the individual good odds at recovery if they take the Penicillin with the alternative being the possibility of significant harm. However, studying for example whether magnesium is useful for sleep without assessing magnesium status (ignoring the difficulties of this) is almost laughable.

Applying this type of methodology to well-being and chronic conditions ignores the fact the humans are not genetically identical and present with a myriad of varying environmental factors affecting genetic expression. Population studies attempt to adjust for confounders such as smoking and exercise to overcome these problems. However, lifestyle and nutritional interventions remain complex to study, let alone draw usable conclusions from.

It is not unreasonable to suggest that a spinning a wheel would produce an intervention for the individual that is just as useful as a scientific study. As medicine moves from treating mainly acute illness and injury to that of "unexplained" chronic disease and unwellness, an alternative model of inquiry and research is needed.



Self-directed N-of-1 trials with Personal Data

If the science of health and well-being is so conflicted, how does an individual and their doctor move forward?

N-of-1 trials in which there is only one person being studied are gaining interest as possibly "the ultimate strategy for individualising medicine."

What if this was taken further? Consider a method whereby the individual is the scientist and the subject; apologies to all researchers who are shuddering at this heresy.

Technology might provide access to clinical acumen and data science, usefully progressing the health of an individual. Notwithstanding the Heisenberg uncertainty principle (observer effect), specific outcome measures are now trackable by available technology and can be analysed against user-defined interventions. Interventions would be based on clinical experience and known physiological pathways, as well as clinical trials and population studies. This is already being undertaken with recent examples including Swarthmore College (www.mementolabs.io) and Salk Institute (https://mycircadianclock.org/).

As a doctor I am looking to reclaim the promise of science and the exploration of life. Medicine is changing and innovative new solutions are promising to by-pass the roadblocks separating patients and doctors from their data and the outcomes they seek. Wearable medtech such as the Oura Ring are providing individuals with data on a level previously thought of as science-fiction. Health providers such as Heads Up (https://headsuphealth.com/) promise a means for individuals to collate and track their data including that from wearables and functional testing.

What is missing is guidance for the myriad of lifestyle, nutritional and supplemental interventions that an individual is faced with, and a means to track a specified intervention

against a sensible outcome metric. Health Function is developing software to help make it practical for individuals to track and treat their preferred metrics.

SleepPerformance is a diagnostic and treatment rules engine aimed at improving sleep, overall health, physical and mental performance. We are combining information from wearables (initially https://ouraring.com/) with a detailed user profile and symptom questionnaire to provide assessment and feedback. The user will be able to customize outcomes and interventions that are relevant to them, which are then then plotted along a visual timeline.

While not discounting the placebo effect, as so eloquently stated by Mathew Walker author of Why We Sleep, "One practice known to convert a healthy new habit into a permanent way of life is exposure to your own data."

Impression of SleepPerfomance timeline with metrics and interventions.

The intended outcome of SleepPerformance is health optimization through individualized interventions and life-style changes, reducing over- and under-treatment and improving outcomes through a low-cost and accessible platform. https://www.healthfunction.co.nz/sleepperformance

I invite you to join us in reclaiming science and exploration.

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