DISCUSSION PAPER

Medicine Is Not Science

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Abstract
Most modern knowledge is not science. The physical sciences have successfully validated theories to infer they can be used universally to predict in previously unexperienced circumstances. According to the conventional conception of science such inferences are falsified by a single irregular outcome. And verification is by the scientific method which requires strict regularity of outcome and establishes cause and effect.

Medicine, medical research and many "soft" sciences are concerned with individual people in complex heterogeneous populations. These populations cannot be tested to demonstrate strict regularity of outcome in every individual. Neither randomised controlled trials nor observational studies in medicine are science in the conventional conception. Establishing and using medical and other "soft science" theories cannot be scientific. It requires conceptually different means: requiring expert judgement applying all available evidence in the relevant available factual matrix.

The practice of medicine is observational. Prediction of outcomes for the individual requires professional expertise applying available medical knowledge and evidence. Expertise in any profession can only be acquired through experience. Prior cases are the fundament of knowledge and expertise in medicine. Case histories, studies and series can provide knowledge of extremely high reliability applicable to establishing reliable general theories and falsifying others. Their collation, study and analysis should be a priority in medicine. Their devaluation as evidence, the failure to apply their lessons, the devaluation of expert professional judgement and the attempt to emulate the scientific method are all historic errors in the theory and practice of modern medicine.

Keywords
Case reports, case series, Complementary and Alternative Medicine, evidence, evidence-based medicine, evidence-informed individualised care, medical experiment, medical practice, medical research, medical theory, non-scientific knowledge, observational studies, prediction, proof, randomised controlled trials, science, scientific knowledge, scientific method, unscientific knowledge

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Introduction

> "In recent years, ... a wide range of … major professional and patient societies of global clinical importance, have collectively articulated increasing and widespread concern at a deepening crisis within medicine – a crisis of knowledge, compassion, care and costs. ... alongside … an exponential rise in the incidence and prevalence of chronic and comorbid disease, we arrive at an astonishing picture of the current status of health services in our world today …" [1].

> "Putting medicine 'right again' will therefore necessitate an urgent and fundamental reappraisal of the nature of knowledge for clinical practice and an appreciation that by no means all of the knowledge centrally necessary for effective clinical practice is scientific in its nature. Such knowledge is not unscientific, but rather non-scientific" [2].

> "... we need more accurately to distinguish between scientific, unscientific and non-scientific forms of knowledge as they relate to the Profession of Medicine, otherwise old arguments will continue to escape resolution." [Personal communication Andrew Miles, December 2011].

> "As medicine has become more powerfully scientific, it has also become increasingly depersonalised, so that in some areas of clinical practice an over-reliance on science in the care of patients has led to the substitution of scientific medicine with scientistic medicine and an accompanying collapse of humanistic values in the profession of medicine" [3].

Is medical knowledge scientific and medical research science? If not, what information should we use in medicine, how should we obtain it and how should we apply it? What does it mean to speak of medicine as "*powerfully scientific*"? The terms "*science*" and "*scientific*" have ceased to have a useful meaning. In the academic world and in medical publishing, the terms "*science*" and "*scientific*" have, in fact, become so debased that it is no longer possible to know what they really mean. In the current paper, we aim to analyse, clarify and take frank issue with the notion that medicine is a science.

What does 'science' mean?

The conventional conception of science taught to generations of school children was one which, as U.S. President John F Kennedy put it:

> "... Science, technology, and education can be the ally of every nation. Never before has man had such capacity to control his own environment, ... We have the power to make this the best generation of mankind in the history of the world ..." [4].

Prime Minister Harold Wilson, in his famous 1963 "*White Heat of Technology*" speech put it this way:

> "The Britain that is going to be forged in the white heat of this [scientific] revolution will be no place for restrictive practices or for outdated methods on either side of industry" [5].

There are now many pretenders to the throne of the physical sciences, where "… the successes of the natura1 sciences have also tempted many to borrow the manners, the trappings, of these fields, in hopes of looking "scientific" [6]. The term "*science*" is employed in various fields to garner epistemic respectability for knowledge gained. The study of politics and political science is portrayed as science, as also is educational research [7].

The words "s*cience*" and "*scientific*" are now used in numerous and conflicting senses. On the one hand "*science*" is used to describe a process of investigation and study which generates information of exceptional reliability, like that in the physical sciences. But obtaining reliable knowledge is not science. Any knowledge, scientific or other, when proposed as evidence stands or falls on its own inherent reliability, which must be subjected to scrutiny and testing case-by-case [8]. Scientific knowledge when presented as evidence is no different from any other kinds of knowledge in this respect.

The terms "*science*" and "*scientific*" are also loosely used as labels for all kinds of empirical studies of varying reliability to heighten their status and foster acceptance.

What is Science?

Strictly defined, "*science*" means the physical sciences, the "hard" sciences such as physics and chemistry. These disciplines are the benchmarks for science, the biological sciences less so. Physics, for example, has been so successful in validating theories that many are used for universal application anywhere in time and space to predict the outcomes of previously unknown circumstances.

Lofty descriptions of science in general are misleading, such as "*the aims of science are ...*" European anti-trust law (i.e., competition law) addresses the economic "*object or effect*" of practices by those in a position of market dominance [9]. In science, irrespective of what the individual scientist's motivation may be for practicing science (the object), it is the outcomes which are definitional: the results and discoveries achieved from tireless, unshakeable scientific enquiry (the effects), which have given us cars, computers, smart phones, air travel and all manner of other devices and constructions.

The conventional conception of Science

The science taught to students over the past 60 years could be termed the "*conventional conception of science*" [10-12]. It is an idealised version which does not represent how all science is done in the real world, with its sometimes confused philosophy and external influences: addressed over centuries by leading thinkers including Francis Bacon, William Whewell, Karl Popper, Thomas Kuhn, Bertrand Russell, Ernst Mach, Pierre Duhem, Rudolf Carnap, W.V.O. Quine, Werner Heisenberg, Paul Feyerabend, Russell Hanson, David Bohm, Herbert Simon, Paul Thagard, Imre Lakatos, Carl Hempel and Larry Laudan [11,13-19]. With regard to this school-taught, faultless view of scientific inquiry, Haack, notes the New Cynicist view that "the supposed ideal of honest inquiry, respect for evidence, concern for truth, is a kind of illusion, a smokescreen disguising the operations of power, politics and rhetoric" [13]. Medical students are taught an idealised version, where scientists say "Let's assume there's no difference; now let's try to disprove that theory." ...Setting up falsifiable hypotheses which you then proceed to test is the very essence of the scientific method" [20].

"Soft" *vs.* "Hard" Science

"Soft" science fields cannot match the success that the physical, "hard" sciences, such as chemistry and physics have achieved. Psychology and political science, for example, are fields of inquiry which are properly called "soft science". It is not possible to test their theories by experiments, achieve strict regularity of outcomes or to validate them scientifically. The consequences are significant and can be seen from Box 1.

Box 1 Scientific Validation of Theories

A) Psychology:
In psychology experiments the participants are an heterogeneous group. Each is a singular irregular "experiment". The outcome may be that 70% respond in the expected manner but 30% do not. A theory cannot predict which participant will respond as expected or when but only what the probability might be in any case. A scientific theory will be falsified by any one of the 30% of irregular outcomes. Whether such a theory should be applied to any future case requires professional judgement, experience and all the evidence relevant to the case.

B) Space Exploration:
If theories were established as valid 70% of the time, the crew and funders of a space mission would have to accept that for nearly one launch in three the craft could fail to launch, complete its mission and return.
A successful mission also relies on numerous theories all being right and not just one. If each theory were right 70% of the time, for a combination of such theories the probability of their being right and hence the spacecraft completing its mission and returning safely could be an exceptionally small one and space exploration might be unlikely to be undertaken.

Strevens has written that 'The three cardinal aims of science are prediction, control and explanation; but the greatest of these is explanation. Also the most inscrutable: prediction aims at truth ... Explanation, by contrast, aims at scientific understanding ...' [21]. In dealing with fields of study which call themselves a "science", but which cannot predict as science can then clearly such subjects should not be described in such fashion. The alternative is we must teach schoolchildren, undergraduates, the media and the public more about what science is and that the knowledge we gain from it is far from the certain knowledge the public and many engaged in science believe it to be.

Scientific Pretenders

In recent decades, systematic fields of study, recognized as such with the suffix "*ology*", such as gerontology, have become transformed into a "science", alongside the physical sciences. Some even go so far to say that marketing is a science [22].

The word "science" has been stripped of its true meaning. Susan Haack (in 2012) puts it this way:

> "And as the prestige of the sciences grew, words like "science," "scientifically," *etc*., took on an honorific tone: ….. Advertisers routinely boast that "science has shown" the superiority of their product, or that "scientific studies" support their claims. Traditional or unconventional medica1 treatments are often dismissed out of hand, not as ill-founded or untested, but as "unscientific." Skeptical of some claim, we may ask, not "is there any good evidence for that?" but "is there any scientific evidence for that?" ...... whether expert testimony is reliable enough to be admitted, the U.S. Supreme Court suggests that such testimony must be "scientific knowledge," arrived at by the "scientific method." The titles of conferences and books speak of "Science and Reason," as if the sciences had a monopoly on reason itself [6].

The adoption of "science" as a descriptive term is an attempt to achieve the same epistemic value that "science" is perceived to have in generating knowledge when the "soft sciences" cannot deliver that value. This is not to say that the soft sciences cannot generate reliable knowledge. They may, but their methods of inquiry are qualitatively quite different from those associated with the physical sciences.

Science and Pretenders - conceptually different modes of enquiry

In testing by experiment, "pure" or hard sciences exclude all information external to an experiment. Tests that the soft sciences conduct do not have that luxury. To decide whether their theories may have validity they deal with a broader range of information and are dependent upon culling evidence from a "factual matrix" [8]. This distinction is not the demarcation of Popper [16]. That has been described as "the fruitless preoccupation with the problem of demarcating real science from pretenders" [13]. How we should approach validation, acceptance and the application of theories in the soft sciences - their warrant or justification as knowledge - is conceptually fundamentally different from the conventional conception of science and from demarcation and that is irrespective of whether the physical sciences in all respects themselves always fulfil the strict application of the scientific method. Demarcation itself appears not an absolute. Russell wrote "I mean by 'hard' data those which resist the solvent influence of critical reflection and by 'soft' data those which, under the operation of this process, become to our minds more or less doubtful. The hardest of hard data are of two sorts: the particular facts of sense and the general truths of logic" [17]. That conception, however, puts physical sciences firmly at one end of any notional spectrum of "hardness". How we should approach the validation and acceptance of theories in the "soft sciences" appears a less well examined issue.

Medicine and medical research

The historic aim of medicine is to care, comfort and console in addition to ameliorating, attenuating and curing disease in the individual person [3]. It is a profession, or a vocation, but not science. The practice of medicine treats distinct individuals in heterogeneous populations. Indeed, as former *BMJ* Editor Richard Smith puts it, "Doctors are not scientists … Most doctors … [i]n their methods of working … are more like jazz musicians …" [23].

No two patients are the same. Diagnosis is not precise or often even right. Treatments vary widely in their effectiveness and efficacy. Medicine has its successes and failures in individual cases. As Osler said, "Medicine is an art of probabilities, or at best, a science of uncertainty"

[24]. In retrospect, it is unfortunate that he employed the word "*science*" in his description of medicine, as if medicine were some form of it.

Medical research focuses on the systematic collection of information about diseases in individual patients in order to gain knowledge and understanding of their pathophysiology and to formulate treatment. Such research does not seek to predict new or rare diseases. It is a practical and intellectual endeavour that is not and cannot be constrained by "the scientific method", as employed by the hard sciences.

Is there a scientific method?

Whilst the modern view is there is no single scientific method the conventional conception of science teaches that scientific enquiry seeks to establish theories which explain the natural world. The scientific method, used to conduct experiments, is an essential component of this endeavour. Investigators use it to test hypotheses and establish them as theories, or, depending on the experimental results, to falsify and discard them. It is the process by which theories are validated to create a reliable, consistent and non-arbitrary explanation for observed and predicted phenomena. The scientific method is the standard approach investigators employ in experiments to minimise bias and expunge prejudice. Used appropriately, this process generates specific information to a high degree of certainty.

The importance of experimental testing to science and the scientific method is notable in Thomas Kuhn's seminal 222-page essay, "*The Structure of Scientific Revolutions*" [11]. The work contains 146 instances of the term "experiment" and "experimental". This exemplifies that throughout the philosophy of science, scientific experiment is and has been an essential part of science for at least 400 years following Bacon [14].

Scientific enquiry is a specialised subset of decision-making. The conventional conception of the scientific method involves four main elements: 1) the observation and description of phenomena; 2) an hypothesis to explain the phenomena; 3) use of the hypothesis to predict either other phenomena or the qualitative results of new observations and 4) repeated experimental tests of predictions in properly performed experiments reproducibly carried out by other researchers independently of each other.

In physics and chemistry, the scientific method addresses narrow, closely defined questions (hypotheses) tested by carefully designed experiments to elicit a narrow range of evidence of high reliability. The method usually tests a single variable in closely controlled conditions to eliminate any confounding variables or factors. But in medicine, evidence employed for making diagnoses and determining treatment in individual patients is disparate and wide-ranging.

Consensus has no place in the scientific method for testing hypotheses. Repeatedly in the history of science and medicine, the scientific method is a singular tool which overthrows a widely accepted theory supported by a majority consensus of scientists or physicians and shows that the consensus is wrong. Marshall and Warren provide a salutary example in this context with their 1982 discovery demonstrating the role of the bacterium *Helicobacter pylori* in gastritis and peptic ulcer disease [25].

Without the high standards required of evidence in science it would be impossible to achieve the certainty and the success of the application of science to modern technologies. Each increment of scientific knowledge is based upon numerous prior theories holding good as the scientific base upon and from which new or improved knowledge and theories can be discovered and established. There is now a substantial established body of scientific knowledge. Some fields such as geometric optics have ceased to yield research problems and have instead become tools for engineering [11].

In carrying out a scientific experiment, those involved tacitly assume and must be sure they can assume that the myriad scientific theories unpinning every facet of the design and performance of the experiment hold good and which underlie the general physical environment within which the experiment is conducted. It is, for example, assumed the measuring apparatus used will work and will continue to work as designed in accordance with the predictions of each element of science underlying that design and construction. Thus, the experimenters assume, subject to routine calibration and recalibration, that they can, all else being equal, for the duration of the experiment always rely on the measurements recorded by that apparatus within known and stated bounds of accuracy of the instrumentation concerned. Duhem recognised that, as any experiment is theory-laden, falsification does not falsify the hypothesis under test, but all the assumptions and theories underlying the design and execution of the experiment in addition to the tested hypothesis: "Tests of models are not tests of theories" [18]. Quine propounded that this applies not only to confirmation of scientific theories, but to all knowledge claims whilst Laudan argued that the significance of such underdetermination has been greatly exaggerated [19].

Science and soft science part company

The success of science is grounded on two things: 1) its high standard of proof, requiring strict regularity of experimental outcomes and 2) each element of scientific knowledge underpinning the acquisition of new knowledge has been established to a high degree of certainty. No *GIGO* (garbage in equals garbage out) for science [26]. The ability to test by experiment under these two conditions is the defining point at which science and the soft sciences part company. We apply the theories and knowledge obtained by science. We combine each of a myriad of discrete items of such theories and knowledge. We apply them in technology with a high degree of confidence.

Another characteristic that distinguishes science from soft science is having theories that provide accurate and reliable prediction. Prediction must work in existing previously observed and unobserved cases and in wholly new cases (e.g., calculating what the force of gravity on the moon was before astronauts landed there). The inventor of the term “scientist”, William Whewell (1794–1866), a polymath, Master of Trinity College Cambridge, England and one of the most influential figures in nineteenth century Britain, specified tests scientific theories should pass in order to be accepted as empirical truth:

> “Our hypotheses ought to fortel [foretell] phenomena which have not yet been observed” …… They should “explain and determine cases of a kind different from those which were contemplated in the formation” of those hypotheses and hypotheses must “become more coherent” over time [15].

Science systematises *data* - raw facts and figures with no significance beyond its existence - and *information* - meaningful data, useful or not - into *knowledge* that has predictive ability and a high degree of certainty, followed by *understanding* - the process by which new knowledge can be derived from existing knowledge. (The fifth and ultimate stage, *wisdom*, is the ability to increase the effectiveness of existing knowledge and understanding, perceive outcomes and determine their value) [8].

Science seeks knowledge with which to understand the workings of nature. Laying the foundations of the modern scientific method for seeking knowledge, Francis Bacon recognized that it is only applicable to a small part of knowledge of the natural world and is not applicable to all knowledge of it. In 1620, he wrote in his *Novum Organum*, responding to the argument posed that nothing can be known:

> “XXXVII. Our method and that of the sceptics' agree in some respects at first setting out, but differ most widely, and are completely opposed to each other in their conclusion; for they roundly assert that nothing can be known; we, that but a small part of nature can be known, ...” [14].

Now we ask, 400 years later: “Is the scientific method the only route to reliable knowledge, particularly in medicine?”

Is medical research and its outcomes scientific?

Medicine focuses on causation and asks “does X cause Y?” If investigators establish that it does, then the next question they ask is “*why* does X cause Y?” But it is not as simple as that. A serious shortcoming of the “X causes Y” paradigm in medicine, in heterogeneous populations of complex organisms - individual patients and experimental laboratory animals - is that most biological effects do not have a single cause. In order for an “X” to cause outcome “Y”, other factors often need to be present. X might be observed to be the cause of Y *all else being equal*, meaning that all other factors necessary for this outcome must also be present and held invariant. A road traffic accident, for instance, might not have occurred if the road was not wet or a warning sign were present or the car was not driven quite so fast. An experiment reconstructing a road traffic accident would need to incorporate these features.

Medical research and experiment

Medical researchers are often not able to establish by observation or experiment that a given X causes outcome Y in individual patients or in animals in the laboratory. Intervening with X may generate outcome Y sometimes, but not every time and in some individuals, not at all. To further confound matters, outcome Y may occur when X is not present. Confronted with dissimilar results like this, it would be difficult to claim that medical experiments and resulting theories are scientific.

Replication and publication

Even without these hurdles, publishing a medical paper that claims its findings establish and validate (or falsify) a new hypothesis will not meet the strictures of the scientific method. Other investigators operating independently of each other need to be able to replicate the findings of the original study and in practice this is difficult if not impossible in medicine.

Pre-publication journal peer review, whatever its agenda may be, is not scientific peer review [27]. As Greenhalgh puts it in the *British Medical Journal* (of all places): “It usually comes as a surprise to students to learn that some (perhaps most) published articles belong in the bin and should certainly not be used to inform practice” [20].

Randomised controlled trials

Authorities consider randomised controlled trials (RCTs) to be the most reliable evidence in medicine and picture them as the “gold standard” of medical evidence. When properly done and blinded, researchers conduct these trials in a systematic, methodical and rigorous fashion. Nevertheless, randomised controlled trials are not science. This is especially the case with large scale RCTs claiming that a statistically significant treatment effect can be seen in an unidentifiable, small sub-group of a heterogeneous population, thus justifying treatment of that population with a particular drug [28]. This is wholly different from the successful application of science to technology. A senior executive of one of the world’s largest drug companies (GlaxoSmithKline) admits, “It is an open secret within the drugs industry that most of its products are ineffective in most patients” [29].

Although touted as being scientific, randomised controlled trials mostly generate just information and that of a statistical nature. RCTs are short on knowledge and understanding. Such trials frame their findings in terms of statistical significance and are subject to inappropriately bestowing causal relationships to statistical associations [28]. Furthermore, RCTs provide no knowledge to predict the outcome of treatment or its risks in an individual patient. RCTs do not tell us: when factor X can be predicted to cause outcome Y in a particular patient; that X is the only cause or factor in the cause of Y; when X does not cause Y; why or when Y will appear when X is not present. RCTs therefore cannot verify hypotheses about when or why X does or does not cause Y. RCTs also provide no information enabling us to predict new outcomes in addition to Y. RCTs provide no mechanism for prediction beyond a probability of how often we might expect X to cause Y. RCTs also provide no knowledge to predict the outcome of a treatment involving two or more drugs of unknown interactivity. Meta-analyses (systematic reviews) that combine RCTs addressing the same question have their own set of problems and biases [30].

Other unscientific medical evidence: epidemiology and case studies

Epidemiology is concerned with the incidence of disease in populations and does not answer the question of what is the cause of an individual's disease [31]. Observational statistical studies tell us that X is seen in association with Y, not that it is the cause of Y. The assessment of causality is a matter of judgement, made with careful attention to the criteria identified for such purposes by the US Surgeon General, Bradford Hill and others in evaluating clinical information regarding the cases [32-34]. Beyond a probability of how often we might see X and Y together in a population, they tell us nothing to predict when X and Y will be seen in any particular individual.

Emphasising the importance of individual clinical information in epidemiologic studies, Sir Richard Doll took many years to establish smoking as a cause of cancer. He had difficulty in obtaining high quality data and thousands of subjects were needed. If 10% or more of cases had incomplete medical histories, the possibility of an unpredictable excess of cases of interest in those 10% meant the hypothesis could not be proven. His advice was that, since epidemiological studies could take years and still be wrong, reliable evidence in a shorter timeframe could be obtained from evaluating clinical data from detailed medical histories of as many affected cases as possible and basing conclusions on that [Personal communication Dr. A.P. Fletcher, April, 2012].

Basic observational research of well documented case studies provides information that doctors need to diagnose and treat patients appropriately. Today, patients are suffering because not enough basic observational case study clinical research is being done [35]. This is a consequence of following the philosophically, theoretically and empirically flawed theories of evidence-based medicine, which relegate such evidence to a low level in its flawed hierarchy of evidence [8].

Medicine is not searching the universe for evidence of "*black holes*" nor is in the business of building space shuttles. Not being a science, its hypotheses and theories cannot meet the scientific standard of proof that requires strict regularity of outcomes in all cases: a level of evidence that is irrefutable. For the practice of medicine, meeting such a standard is impossible, inappropriate and unnecessary. It does not need to meet the same high level of evidence and standard of proof as science. Case studies that provide a civil level of evidence that is "more likely than not", or, at best, a criminal level of evidence that is "beyond a reasonable doubt" will serve. Evidence from cases, case series and studies however can provide high certainty of knowledge even to the standard of beyond a reasonable doubt.

Other unscientific information and knowledge

Much of the information and knowledge doctors use to practise medicine comes from observation and experience, not medical research. Treatments in most of the medical specialties have not been proven safe and effective by RCTs, or by any other kind of experiment. Adverse drug reactions are poorly monitored. In many cases they are said to be reported only 2% of the time [36]. Indeed, as some observers note, "It is possible that some entire medical subspecialties are based on little evidence. Their disappearance probably would not harm patients ....." [37].

No requirements exist to prove with appropriate evidence the safety and efficacy of established practices in modern allopathic medicine. But with regard to complementary and alternative medicine (CAM), health authorities demand scientific proof of its safety and efficacy, despite the fact that most of modern medicine fails to meet that standard. The pharmaceutical industry has its origins in herbal medicine and these treatments remain of continuing commercial importance to it. And in China, with its sophisticated culture and long history, physicians use herbal treatments and acupuncture routinely in their medical practice.

CAM research is grossly underfunded in First World nations. The U.S. National Institutes of Health devotes 90% of its annual budget for medical research, US$ 30.9 billion, to pharmaceutically-oriented Western medicine and just 0.004% (US$ 132 million) to CAM research [38,39]. (And it did not start supporting any kind of CAM research until 1992).

Absence of predictive certainty

The practice of medicine functions without the level of certainty essential to science, recognizing the inherent uncertainties involved in researching, treating and making theories about complex heterogeneous biological organisms.

Andrew Miles and Michael Loughlin, in their editorial "Models in the balance: evidence-based medicine *versus* evidence-informed individualised care" for the *Journal of Evaluation in Clinical Practice*, make this observation: "Exponential increases in technological and biomedical advance over the last 100 years or so have radically transformed the scope, possibility and power of clinical practice, driving enormous shifts in individual and population health" [40].

As biomedical advances occur, medical theories are followed and applied, exactly correct or not. Albeit imperfect, they provide a framework for understanding. The germ theory of disease is one example. There are a large number of asymptomatic people infected with the bacterium *Helicobacter pylori*, but who do not have peptic ulcers [41]. Most diseases are multifactorial and pathogens are just one, perhaps necessary, but alone insufficient, factor for disease causes to be present. Failure to recognise this stifles attempts to identify other necessary factors causing a particular disease that requires treatment. With evidence-informed individualised care replacing flawed evidence-based medicine, perhaps this new and better way of practicing medicine will produce, alongside existing theories of immunity, a more certain and operative germ - and - nutritional deficiency theory of disease [8,40].

This all suggests that the scientific method, the types of evidence it admits and that which it rejects and the standard of proof applied in science are less relevant to and in any event unattainable in medicine, but that improvements can be identified and should be implemented. The foregoing also raises the question: to achieve this goal what methods, evidence and standards of proof should be applied in medicine? And since it is not a science, what kind of knowledge should be brought to bear in medical theory and practice?

Can unscientific knowledge provide certainty?

A single well documented, spontaneous case report of "rechallenge" or three such cases of "dechallenge" prove beyond a reasonable doubt, if not irrefutably, that intervention X causes disease (outcome) Y [42]. Rechallenge (e.g., a drug causes an adverse effect when given a second time exactly the same way it did when given the first time) and dechallenge (where the adverse effect goes away when the drug is metabolised and removed from the body) are special examples where a case report and case series prove causality.

In law, three cases of a well documented "challenge" series (in the cases concerned where the subjects did not recover from the challenge and died) provides a level of evidence that is "beyond a reasonable doubt", the criminal standard of proof required in capital cases, like *R v* Smith [43]. (A sentence of death by hanging was imposed on Smith, who took a different name each time he married and pre-meditatedly murdered each of his three new brides in the bath, in a manner which looked like they had drowned accidentally, obtaining substantial inheritance sums on each death.)

In case series, researchers need to evaluate the fullest factual matrix possible for each case to compare cases and assess them. This is not "science" in its conventional sense, but a wholly different form of investigation freed of experiments and blinded controls, where none of the various disparate independent pieces of evidence alone can found a conclusion but together they can. This form of investigation, on a day-to-day basis, provides knowledge, of high certainty and understanding.

Vandenbroucke shows that case reports and case series "…Permit discovery of new diseases and unexpected effects (adverse or beneficial) as well as the study of mechanisms, and they play an important role in medical education" [44]. Although EBM relegates them to second-class status, case reports and case series are a means of obtaining valuable and reliable information of potentially exceptionally high certainty. And as Flyvbjerg demonstrates, all experts operate on the basis of intimate knowledge of several thousand cases in their areas of expertise. It is experience with these cases, particularly the paradigmatic and extreme ones, that transforms a beginner into an expert. Reliable rapid expert intuitive decision-making can be developed "after thousands of hours of practice" [45].

Flyvbjerg notes, citing Kuhn, that scientific activity is acknowledged or rejected as good science by how closely it relates to one or more paradigmatic cases or exemplars - cases that highlight more general characteristics. He argues and demonstrates, that whilst case study methods are widely used in social science they are held in low regard - and wrongly so. He attributes this to their being poorly understood and contrary to common conception: 1) general, theoretical knowledge is not more valuable than knowledge of individual cases; 2) generalisation on the basis of individual cases is possible and the case studies can contribute to scientific development ("scientific" in the sense of "soft" and "hard" sciences); 3) case studies are suitable for hypothesis testing and theory building; 4) case studies can be used for verification and falsification and do not merely tend to confirm a researcher's preconceived notions and 5) case studies can be used to summarize and develop general propositions and theories [45].

Medicine is fundamentally observational and dependent upon its practice for knowledge of prior cases and their outcomes coupled with the exercise of professional judgement. Acknowledging the role of case reports and case series in pharmacology (rechallenge and dechallenge adverse drug reactions), similar fact (challenge) case series in law, the vital importance of case studies in the social sciences and the development of human intuitive expert decision-making based on long practical experience with individual cases, it is clear that the primary and most essential source of information in medicine is well documented cases.

Non-scientific information

Professionals have knowledge, skill and experience. They do not acquire these qualities through science, nor do they make assessments and judgements in a scientific manner [46].

Describing the practice of medicine as an art is as unfortunate as is calling it science. The term "art" used this way is vague and fosters clouded thinking on the subject. As applied to medicine, it denotes the application of knowledge, understanding and wisdom in making medical decisions [8]. That some physicians are more successful at this than others and make better decisions with better outcomes is what makes medicine an "art". Different musicians may perform the same works, but some are considered to perform them better than others.

Medical professionals have to make causal judgements in individual cases whilst addressing broad real world day-to-day questions. "If in all the known circumstances including Mrs Smith's clinical history to date can we achieve outcome X if we apply treatment Y?" This patient's doctor cannot answer this question in a scientific manner. The approach evidence-based medicine takes to medical decision-making is flawed and, fortunately, is now being replaced by evidence-informed individualised care. [40] Real world medical decision-making is based upon a variety of evidence in the factual matrix relevant to any clinical case [8].

In medicine, experienced physicians can acquire sufficient intuitive knowledge and skill to be able to make expert and reliable intuitive decisions. Kahneman and Klein show that intuitive decisions can be trusted "[i]f the environment is sufficiently regular and if the judge has a chance to learn its regularities, the associative machinery will recognize situations and generate quick and accurate predictions and decisions." …. "If an anesthesiologist says, 'I have a feeling something is wrong,' everyone in the operating room should be prepared for an emergency" … "Anesthesiologists are …. in a better position to develop useful intuitive skills" … "because the effects of their actions are likely to be quickly evident", whereas "…. radiologists obtain little information about the accuracy of the diagnoses they make and about the pathologies they fail to detect" [47]. Indeed, the intuitive knowledge and skill and diagnostic reliability of radiologists (and physicians in other specialities), might be improved by using online libraries of well documented medical cases for reference and study as a substitute for missing immediate feedback. Libraries of well documented medical cases should be used (in place of multiple choice questions) in Maintenance of Certification examinations in the various specialities.

Law, Medicine and Science

Law has an existing sound, practical, working and tried and tested framework for making evidence-based decisions. Lawyers learn that legal knowledge comes from centuries of trial (literally and in all its meanings) and error - and from the thinking of some of the finest legal minds. Legal issues can involve both life and liberty. In law, like medicine, outcomes of trials can involve life and death. Evidential inference combines facts with generalisations to produce networks of inferences [48].

In medicine, physicians lack knowledge on how to approach evidence and its assessment. Physicians would do well in making medical decisions to emulate law (and science) and be aware of the level of evidence used for making a particular decision - "more likely than not" or "beyond a reasonable doubt" (from law), or "irrefutable" (in science). Medicine would do well to take into account and apply by analogy the knowledge and lessons of law. The same observation can be applied throughout the "soft" sciences.

Science is a "one trick pony". It has one main approach to proving an hypothesis: testing by experiment. In testing hypotheses, science excludes all relevant evidence other than that gained by experiment, carried out within the framework of existing knowledge.

A diagnosis in medicine is like an hypothesis in science. But given the probabilistic nature of medical knowledge, physicians must use their professional judgement to arrive at a diagnosis; which is tested through treatment. Making a diagnosis is not a scientific process. It is, however, a systematic and methodical one, aided by experience, intuition and appropriate evidence (like X-rays and blood cultures).

In law, new approaches to the study of evidence, proof and fact finding are being explored to improve methods of decision-making in complex cases [48-50]. Such studies are not specific to the calling of lawyers. "Medicine needs to develop a better understanding of the nature of evidence and of evidential proof, by emulating law's approach to evidence" [42]. Medicine is not science and it and other "soft" sciences can learn more from law than from trying to copy science.

Conclusion

Medicine is not science and can learn more from fields like law and the way law handles evidence, than by trying to copy science. Science, in the sense of the conventional conception of the scientific method applied in chemistry and physics, is not the only route to and is limited in the extent to which and the fields in which it and it alone can deliver, reliable knowledge. There is an urgent need for a fundamental reappraisal of the nature of knowledge and how it is and can better be obtained. The terms "science" and "scientific" are used today in medicine and other "soft" sciences like sociology and "political science" in numerous and conflicting senses that have ceased to give these terms a useful meaning.

The practice of medicine is largely observational and functions without the level of certainty essential to science. As the reign of "evidence-based medicine" with its crippling flaws is replaced with evidence-informed individualized care, healthcare providers, physicians and surgeons will appropriately and once again better appreciate the importance of and application of non-scientifically obtained evidence. Case reports and case series are examples fundamental to medical practice and education.

Conflicts of interest

The authors report no conflicts of interest.

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