Remodelling Medicine

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TRUTH, PROOF AND EVIDENCE

Summary

- Evidence Based Medicine is the current orthodoxy, but there are clinicians who distrust its influence, which may not reflect the intention of its pioneering authors.
- The chapter examines the principles of knowledge, truth and meaning that are the essence of all good science and that must underpin any system of evidence.
- In real life, the value of evidence from analytical and experimental scientific methods is complemented by a variety of other ways of knowing.

Attitudes to evidence

Evidence rules; O.K?

Well, yes and no. All medical treatments and procedures applied to individuals or populations are nowadays expected to be evidence based according to the rules of the scientific paradigm. This standard is applied rigorously to any new treatment or procedure that is up for adoption into the medical repertoire, though there are some to which it is difficult to apply, particularly surgical procedures.[1] Many that are more long established have not been so rigorously tested. The proportion that has been justified by such evidence is not as great as we might expect.

Evidence Based Medicine (EBM) – the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients[2] – is the current orthodoxy. But there are not a few clinicians and commentators who distrust its influence; certainly the influence that it has come to exert, and that may be somewhat removed from the original intention of the authors of the classic text that gave birth to it. Some of these critical comments will be presented later in the chapter. But the assumptions about the nature of evidence, and the concept of proof

may not be as robust as many like to think. And their coercive power for the validation or otherwise of what is being proposed or tested, and of its usefulness need to be reassessed.

The nature of paradigms and the problems associated with them were explained in part two of the Introduction, but to recapitulate briefly: Any medical treatment or procedure, and particularly any innovation, has to contend for acceptance within the prevailing medical paradigm, and bear the burden of proof. In science, the concept of the paradigm was developed most cogently by Thomas Kuhn (1922–96) as an explanation of the way that scientific attitudes and beliefs, and the research and development programmes that follow from them become established, and of the difficulties involved in changing them, and of the kind of revolution required to do so.[3] A paradigm can be thought of as a kind of mind set that determines, and restricts, the direction in which scientific thinking and investigation is allowed to progress. It determines the parameters of what Kuhn called 'normal science' and is defined in Box 10.1.

BOX 10.1 *Definition of paradigm*

A paradigm is a conceptual framework, adequate for its time but not eternally true, and essentially metaphysical because it is actually a framework of ideas and values, whatever 'objectivity' it may claim.

By contrast, Karl Popper (1902–94), does not trust the scientific community to define its playing fields and position its goal posts in this way. He insists, "A genuine commitment to the truth gives scientists the courage to challenge the truth of particular theories, including the ones associated with a scientific paradigm".[4] On this basis he introduces the concept of 'falsifyability' as the necessary test of any scientific proposition. It requires that a hypothesis be stated in such a way that it can be disproved by experiment.

Popper deprecates the somewhat totalitarian vision of science promoted by Kuhn, and favours a more open and democratic approach. Scientists should put their principles to the test of experiment in the same way that politicians put their policies to the test in elections.

Popper's approach is deliberately to challenge, and through the outcome of challenge to change the minds of the scientific community, when the evidence requires it. But his principles also required justice in their application. Tests should not be biased towards a dominant theory. There must

be a level playing field. "Tests must not be burdened with concerns about the costs and benefits of their outcomes, which would be tantamount to match fixing." In a book discussing the tension between the philosophies of Kuhn and Popper, Steve Fuller comments, "This metaphor reveals the remoteness of this normative ideal of science from actual scientific practice".[5] There is good reason for contemporary researchers in unorthodox fields of medicine to endorse this view.[6]

Reality, Truth and Knowledge

It is helpful to look behind the scenes of this debate at the principles of knowledge, truth and meaning that are the essence of *all* good science, and that must underpin any system of evidence.

Reality

First, some observations on 'reality', because any scientific endeavour is, surely, above all an exploration of reality, of our understanding of the way things really are. Two diametrically opposed views of the way things are will be held, for example, by a materialist like Richard Dawkins who sees no sense or value in any metaphysical interpretation of reality, and a theist like me for whom such an interpretation is inescapable. We both have 'motivated belief' for our understanding of reality,[7] but in the absence of falsifyable evidence I am willing to be guided by 'inference to the best explanation'. (See 'Ways of knowing', later in this chapter.)

Reality is the bigger picture that comprehends, makes sense of and gives value to every facet of human experience. It is intimations of reality that give meaning and direction and a passionate desire to the exploration of our experience; that arouse 'scientific passion'.[8] It is intimations of reality that give meaning and value to our individual lives.

Truth

Secondly, what do I mean by 'truth', and how is science implicated in the pursuit of truth? Scientist and Philosopher Michael Polanyi (1891–1976) offers a definition that I find helpful: "Truth lies in the achievement of a contact with reality – a contact destined to reveal itself by an indefinite range of yet unforeseen consequences."[8]

Truth reveals itself in those intimations of reality that persuade us that there is some coherent order and meaning in our experience and our

existence, and that at the same time inspire us to seek that true order and meaning. They are order and meaning that transcend the accumulation of facts. It is this kind of intimation of reality that leads mathematicians to judge the validity of an equation by its 'beauty'.[9]

Another author, Keith Ward, puts it like this: "When we apprehend a truth we . . . seek by intelligent enquiry to understand something of the nature of things, of how things really are in their characters and relationships. . . . Truth always lies beyond us, in its fullness. Yet we discern something of it".[10]

Writing as a doctor, and speaking, I hope, for other healthcare practitioners, I suggest that in clinical practice we seek, or should seek as complete an understanding of our patients as we can, in order that we may respond as faithfully as possible to the truth of their unique individuality and the unique problem that they present to us; a truth which in its fullness will always lie beyond us but which is the implicit goal of our work.

The second part of Polanyi's definition is of absolute importance. It says that truth is creative. It is not simply accurate information about the situation that confronts us. In any field of enquiry or endeavour, whatever it is of the truth that we glimpse, if it is really true, makes possible consequences – new insights, opportunities, discoveries, departures – as yet unforeseen.

In clinical practice, if we respond faithfully, whether in the diagnostic process, in the management of the problem, or in the quality of the therapeutic relationship, to whatever is revealed to us of the truth of the patient's life, we are assisting a healing process whose essential nature is not just remedial but creative. It, too, involves new insight and understanding, new discovery, new growth, new ways of being; basic principles of healing, that apply on every level of experience from the physiological to the spiritual.[11]

Clinical practice requires truth of us in many senses and many ways. It does require accuracy of observation, and diligent enquiry. But ideally it also requires complete attentiveness to the patient as an individual, and to the patient's story, unprejudiced by our own well-being, attitudes, expectations, beliefs or desires. It consequently requires truthful self-knowledge, and a reflective approach to what we do. And that truth will lead in turn to new discoveries, insights and strengths in our own lives.

In evaluating our practice, clinical or scientific, exemplary truthfulness is required, in what we claim for it, in how we seek to explain it, and in the willingness and the methods with which we investigate it. And all this requires that we are motivated by the 'scientific passion' that Polanyi describes. In clinical medicine, as Conrad Harris points out, "Every patient

presents us, in a sense, with a research project".[12] The immediate goal of that search for truth, and the passion that motivates us, is the well-being of the individual patient. But the pursuit of that immediate goal is also a reaching out towards a greater and more universal truth about the human condition. I suggest that we have a responsibility to think critically and imaginatively about the truth of what is revealed to us in our patients' lives, and of our response to the problem they present, for the sake of what is to be learned about it, what is to be learned from it, and what is to be communicated about it. Because it is 'a contact with reality destined to reveal itself by an indefinite range of yet unforeseen consequences'.

Knowledge

> Knowledge is an extrovert element which a doctor acquires during his long and demanding education in order that he may direct it outwards upon the patient. But wisdom is an introverted element in the doctor's psyche; it has its origin within; and it is what makes him look not at the disease but at the bearer of the disease. It is what creates the link that unites the healer with his patient and the exercise of which makes him a true physician, a true healer. It is wisdom that tells the physician how to make the patient a partner in his own cure. Knowledge may enable you to memorise the whole of *Gray's Anatomy* or *Osler's Principles and Practice of Medicine* but only wisdom can tell you what to do with what you have learned. (Robertson Davies[13])

The pursuit of truth inevitably involves a pursuit of knowledge. You may be familiar with the quotation from TS Eliot's poem – *Choruses from 'The Rock'*:

> Where is the wisdom we have lost in knowledge? Where is the knowledge we have lost in information?[14]

Placing knowledge somewhere between wisdom and information like this puts it in a helpful perspective. It is not just information. It does not of itself confer wisdom. But it embraces information, and its proper function is to develop wisdom. The acquisition of knowledge goes hand in hand with intelligence, the power of the intellect. But like all great human attributes, intelligence can be well or ill-used. The reviewer of a book by biologist and theologian Celia Deane-Drummond, draws attention to a warning that echoes those words from Eliot, and that has real resonance for modern medicine. It is that our dependence on ever increasing technical wizardry points in the direction of what Deane-Drummond calls 'transhumanism', the triumph of intelligence over humanity, and a disastrous failure of wonder and wisdom.[15]

Figure 10.1 *The Caduceus*

The quotation at the beginning of this section is from a lecture by Robertson Davies called 'Can a doctor be a humanist?', which addresses the question – 'Can a doctor possibly be a humanist in a society that increasingly tempts him to be a scientist?' By 'humanist' he means a person with a deep interest in, insight into and care for human nature. He talks about the Caduceus, the familiar symbol of medicine and healing, and the identification of the two snakes coiled around the staff of Hermes with Knowledge and Wisdom (Figure 10.1). He discusses the tension between these two essential attributes of the physician's craft, the importance of keeping the right balance between the two, and the risk of allowing them to become opponents, of allowing knowledge to displace wisdom. He suggests "instead of calling them Knowledge and Wisdom let us call them Science and Humanism". I am indebted to a paper by Brendan Sweeney for introducing me to this most thought provoking lecture, and the delightful book in which it appears.[16]

So if wisdom is not to be lost in knowledge we have to treat knowledge with proper respect, but also with circumspection. All knowledge will not be true, but it must serve the truth, and must be willing to be displaced by new knowledge that is closer to the truth. It is within this perspective that we should regard the breadth of knowledge that a scientific community brings to the pursuit of truth and the exploration of reality. Popper himself writes: "The old scientific ideal of *episteme* – of absolutely certain, demonstrable knowledge – has proved to be an idol". The demand for scientific objectivity makes it inevitable that every statement must remain tentative for ever. It may indeed be corroborated, but every corroboration is relative to other statements which, again, are tentative. Only in our subjective experiences of conviction, in our subjective faith, can we be 'absolutely

certain'.[7] In *Personal Knowledge* Michael Polanyi only mentions Popper in passing, but his whole thesis invokes a kind of faith in what is known – the 'tacit knowledge' by which we perform so many functions and that is not susceptible to logical analysis, and the creative tension that exists between this and formal scientific method.

In a challenging paper on 'Clinical medicine and the quest for certainty', Grant Gillett, a neurosurgeon in New Zealand, provides quotes from Hippocrates. "Even if it is not always accurate in every respect the fact that it is able to approach close to a standard of infallibility as a result of reasoning – should commend respect for the discoveries of medical science. Such discoveries are the product of good and true investigation, not chance happenings. But we also need to hearken to the critical voices that teach us about the provisional nature of knowledge when it is properly evaluated as *an evolving human endeavour* rather than an increasingly clear and bright map of biomedical reality."[1] (My italics.)

And we must remember that knowledge is more than an accumulation of facts. Eric Cassell again:

> Facts do not stand alone; they derive their meaning from their relationship to the other facts with which they form a whole; and also from that very whole of which they are a part. . . . This is of great importance to us as physicians. We elicit medical facts because of our need to understand, and what we want to understand are not isolated facts but wholes – whole kidneys, whole bodies, whole persons, and even whole communities.[17]

In other words: Knowledge = Facts + Understanding + Meaning.

Personal knowledge

My exploration of these themes has been greatly assisted by the book, *Personal Knowledge*, first published in 1958 by Michael Polanyi (1891–1976), from which I have quoted already.[8] It was introduced to me as essential reading if I was seriously interested in achieving a better understanding of the limitations of scientific proof.[18] Polanyi's working life overlapped that of Kuhn and Popper, but preceded them by some 20 years. It is an intellectually challenging but most exciting book, because it is about the kind of scientific passion that I believe is felt by many who work in medicine, whether in research or in direct patient care. Its Key themes of the book are summarised in Box 10.2.

BOX 10.2 *Key themes in Personal Knowledge*

- The ideal of detached scientific objectivity is a fiction.
- There is available to us a truer kind of objectivity that derives from our intimations of universal truth.
- This objectivity has an intuitive quality that has informed all great science.
- This glimpse of objective truth inspires 'scientific' passion'.
- Scientific passion is a heuristic passion – a passionate desire to find out or discover.
- BUT – The conclusions to which we are lead by our scientific passion are not infallible; they may be false but they are never meaningless.
- Personal knowledge is not license to speculate. It demands discipline, and rigorous discrimination of error, and discernment of its fruitfulness – the creative potential to yield unforeseen consequences.
- Scientific truth can be discovered, but not constructed.
- The methodology of proof, however, is constructed and contingent, and can never be absolute.
- Neglect of the principles of objective truth and personal knowledge will allow 'the tendency towards a universal mechanistic conception of things – completely to denature our image of man'.

Objectivity and intuition

Fifty years ago Polanyi challenged the ideal of detached scientific objectivity. He did not believe in it, and took great pains to demonstrate, by reference to various scientific methodologies, that it is a fiction. Firstly he insisted that all attempts to establish rules for scientific validity involve a measure of personal judgement, even though that judgement is collective and consensual within the scientific community. They are therefore contingent and provisional.

More radically perhaps, he proposed an altogether new meaning for the concept of objectivity. Not as a dispassionate, unbiased, value-free statement of observable fact, but as an intuition of universal truth, an intimation of reality. He writes, for example, of the theory of Relativity as, ". . . pure speculation, rationally intuited by Einstein . . ."

Insights of this kind are of the nature of scientific discovery. Polanyi quotes Pasteur, for example, who said of his conviction, against very strong opposition, that fermentation was a function of the living cells of yeast, "If anyone should say that my conclusions go beyond the established facts I would agree, in the sense that I have taken my stand unreservedly in an order of ideas which, strictly speaking, cannot be irrefutably demonstrated".

Personal knowledge as Polanyi defines it, is not therefore a kind of subjectivity, but an objectivity that wholly subordinates the subjective to an intimation of truth that lies beyond us; that is transcendent, if you like. It is not a construct of our intellect or imagination, but a glimpse of a greater truth.

For example, mathematical physicist John Polkinghorne has stated that it is generally agreed among mathematicians that mathematics is not a process of construction, but of discovery; that mathematicians are not playing complex games of their own contriving, but exploring a pre-existing reality.[9]

Scientific passion

Many readers of this book who are involved in medicine and the sciences will already have understood, and perhaps recalled from your own experience what is meant by scientific passion, but Polanyi vividly evokes the connection between scientific discovery and scientific passion. "Personal knowledge in science is not made but discovered, and as such it claims to establish contact with reality *beyond* the clues on which it relies. It commits us, passionately, and far beyond our comprehension, to a vision of reality. Of this responsibility we cannot divest ourselves by setting up objective criteria of verifiability. Like love, to which it is akin, this commitment is a 'shirt of flame', blazing with passion, and also like love, consumed by devotion to a universal demand."

Criteria of scientific proof

Polkinghorne and Polanyi both emphasis the circularity in the relationship between theory and experimental proof, which Polanyi describes in the following way. "The rules of scientific *procedure* which we adopt, and the scientific *beliefs* and valuations which we hold, are mutually determined. For we proceed according to what we *expect* to be the case and we shape our *anticipations* in accordance with the success which our methods of *procedure* have met with." (My italics).

This warning about seeing only what we have learned to expect is echoed by Conrad Harris in the paper quoted earlier in which he encourages general practitioners to be more attentive to the, so to speak, corroborative detail of patients' stories (he calls it pathography) that does not fit the familiar clinical picture; not only for the sake of good patient care, but for the sake of fruitful research: "The observation and description of what is before one's eyes, *unconditioned by preconceived ideas*, is the starting point of all scientific research" (my italics). It requires only a shift in perspective.[12]

John Polkinghorne states, "There is an inescapable circularity in scientific argument. I think we have come to learn that the vocabulary of proof, in that strict logically coercive and inescapable sense, is actually not a very interesting category. Most things elude it. Even mathematics".[19] Doctors and medical scientists must learn to avoid, or at least to be aware of the risk of this circularity in clinical case taking and analysis, and in research, and not to pre-empt the conclusions we reach. The circularity in scientific argument may be inescapable, to an extent, but awareness of the risk will likewise prevent a pre-emptive closing of the circle. Otherwise science would never advance. Unfortunately, some doctors' and medical scientists' attitudes particularly, to unorthodox ideas, do become pre-emptive in this way. Pre-existing expectations do produce a closed circle, even occasionally a surprisingly vicious circle. And the vocabulary of proof is used coercively.

Polanyi writes, "No rule of scientific procedure is certain of finding truth and avoiding error". Perhaps the over-riding criterion should be integrity rather than proof; an integrity that accepts that the circle of knowledge is never closed, and that is always open to, and willing to give ground to the emergence of new insights, whatever we have hitherto believed or been lead to expect.

Destructive analysis

Integrity will insist that the operation of intuition, personal knowledge and scientific passion in science does not mean that anything goes. Personal knowledge is not license to speculate. It demands discipline, and rigorous discrimination of error. Despite the elusiveness of proof, rigorous experiment is necessary. As Polanyi says, "This method of criticism is indispensable – destructive analysis remains an indispensable weapon against superstition and specious practices".

But the rules and interpretation of experiment must be applied critically and with discernment. The 'mutually determining' nature of scientific theory and scientific procedures, and the risk of paradigm paralysis, must

not be allowed to suppress emergent truths that do not fit. As Polanyi also says, ". . . to deny the feasibility of something, merely because we cannot understand in terms of our hitherto accepted framework how it could have been done or could have happened, may often result in explaining away quite genuine practices or experiences".

Evidence

> Evidence is a very fluid concept. If something fits our worldview and our prior probabilities and concepts, we are very happy to accept some reasoning as evidence. If something does not fit into our way of thinking, then even the best experimental evidence can be easily dismissed. Evidence is a complex beast. It is a concoction of empirical data, sprinkled over a plausible theoretical model, and fitted into the framework of a plausible worldview. (Harald Walach[19])

As these observations and the discussion of paradigms and models in part 2 of the Introduction make clear, the nature and validity of evidence is pre-empted by the paradigm that sanctions it and the model that it serves. They will strike a chord with many who are uneasy about the demands of evidence in clinical practice, which are not only imposed in the name of science but in many instances by policy makers. And they will encourage those who explicitly question its coercive power.

Gillett, whom I quoted earlier says this (referring back to the work of Kuhn and Michel Foucault):[20] "The underlying thought is that validated knowledge in an area of human inquiry is a joint product of intellectual exploration and the power structures that legitimate certain conceptualisations and modes of exploration. For instance, power is exercised in medical scholarship by authoritative bodies enforcing positivist conceptions of argument and investigation which go under the name of evidence based medicine. – An atmosphere is created whereby any views that depart from statistical methodologies based in the natural sciences are regarded as inferior or suspect".[1]

Gillett's comment quoted earlier about the provisional nature of knowledge when it is properly evaluated as an evolving human endeavour, and the discussion of reality, truth and knowledge, are echoed by Iona Heath in *The Mystery of General Practice*. Commenting on the dissonance between the biomedical model and the general practice model, she quotes Carl Rudebeck: "According to (the requirements of scientific biomechanical medicine), an answer should be numerical or it is not an answer. If on the other hand, research is looked upon as an activity adding to or changing our prevailing comprehension of reality . . . then the range of issues may

be considerably widened. . . . The evaluation of the quality of research at one instant and according to strict formal criteria . . . is somewhat contradictory to the process of knowledge production itself."[21]

Controlled trials are the favoured methodology of evidence based medicine, designed to test the validity of a proposition about patient care by controlling the variables that might prevent a statistically valid answer to a specific question; usually a question about one specific intervention in one specific condition in a clearly defined population of patients. Gillett describes this methodology as "the current fundamentalism of the prospective randomised, controlled, double-blind trial". Toon, writing about the philosophy of general practice, comments, "It is a small but logically dubious jump from seeing the evidence from controlled trials as the soundest evidence on which to base clinical actions to the view that there is no other valid evidence for clinical activity".[22] Controlled trials generate evidence of interventions made under ideal test conditions. The limitations of this evidence are summarised simply and clearly in an article about the use of placebos in an edition of the *British Medical Journal* focusing on that theme: "Published evidence applies to a patient only if that patient has similar characteristics to patients in the study population. Even if this is the case, their response can rarely be accurately predicted. This is one of the problems with evidence based medicine: often its application to the individual is under less than ideal conditions."[23]

In other words, what actually happens – the *effectiveness* or clinical outcome in practice – may be different because the context is different. This effect of context on evidence is explained nicely, though in the course of examining a different issue, in a paper by Bernard Crump. He writes, "Experimental evaluation is based on an approach to the establishment of causation that can be described as successionist. The changes in outcome that occur in the experimental and control group are all that matters, and are observed externally. The context in which these changes occur is relevant only in so far as they can confirm the adequacy of the randomisation process. This failure to take account of context leads to at least two problems. Where evaluations lead to the conclusion that an intervention works, it is not known why it has worked. They are also prone to lead to the conclusion that an intervention does not work when another perspective is that the impact is place and context specific".[24] He goes on to describe by contrast 'generative' methods of evaluation used in social science that are rigorous and exacting but that emphasise the capture of evidence about the context in which interventions take place.

The dangers of over-reliance on certain kinds of evidence is amusingly illustrated by David Haslam in his lecture 'Who Cares?' which in essence

is also about the limited appropriateness of the medical model to general practice.[25] He does this by quoting 'The McNamara fallacy':[26]

- The first step is to measure whatever can be easily measured. This is OK as far as it goes.
- The second step is to disregard that which can't be easily measured or to give it an arbitrary quantitative value. This is artificial and misleading.
- The third step is to presume that what can't be measured easily really isn't important. This is blindness.
- The fourth step is to say that what can't be easily measured really doesn't exist. This is suicide.

I have already referred to Iona Heath's reservations about the role of politicians and health service planners in misconstruing the nature of general practitioner care (Chapter 2). Others have regretted the use of evidence as a political tool. Evidence in the public health arena is a two edged weapon. Social structures and ideologies are interactive. Medicine and politics are no exception. Medical research fuels public health policy. Public health policy affects the organisation and delivery of health care. Medicine itself fuels 'the avalanche of public health rhetoric',[22] which in turn determines what happens in practice. The imposition of targets for clinical activity allied to financial incentives, for example, is an evidence based manipulation of both the medical profession and the patients – with the very best of intentions, but with consequences that are not necessarily always healthy, as we have seen. Nevertheless, the health gains resulting from public health policy are often beyond dispute. The banning of smoking in public places is an example of the public health triumph of good science (epidemiology) eventually driving policy. Epidemiology – the detailed observation and analysis of the march of events in the development of disease in order to understand the avoidable causes of the disease and to do something about them, has been one of the great advances of modern medicine; evidence in the service of health maintenance and disease prevention.

The trouble is that in this context, again as we have seen, the individual can become the herd. What is statistically good for the patient population detracts from the needs of individual patients, and may disregard social and cultural influences that bear heavily upon them. What is good practice for doctors in terms of performance targets may dictate and constrain the doctor–patient relationship, making care of the whole person more difficult to achieve.

Some critics see serious risks of the politicisation of evidence based medicine (EBM). Dixon and Sweeney spell this out clearly in the second

chapter of their book *The Human Effect in Medicine*.[27] They argue that EBM distorts health care, and indeed the proper nature of science; that the dominant medical scientific paradigm, cannot hold a position of unassailable centrality in clinical practice; that a rational appreciation and cognitive evaluation of information is only a part of the practice and understanding of medicine; and that (the EBM approach) is based on an inadequate explanatory model, inappropriate to the complexities and constantly evolving nature of the human condition. They conclude that "the view of science currently espoused by practitioners, demanded by managers and applauded by politicians has devalued an intellectual standpoint into an ideology".

Maya Goldenberg, writing in *Social Science and Medicine*, expresses perhaps the extreme pole of discontent with the EBM movement – "an antiquated understanding of 'facts' about the world in the assumption that scientific beliefs stand or fall in the light of the evidence".[28] She offers extensive criticism of the EBM approach, but the summary proposes that, "The appeal to the authority of evidence that characterises evidence-based practices does not increase objectivity but rather obscures the subjective elements that inescapably enter all forms of human enquiry. The seeming common sense of EBM only occurs because of its assumed removal from the social context of medical practice".

A nice summary of the prevailing discomfort at the imposition of EBM is given in Marshall Marinker's editorial résumé of the relevant chapter in a book called *Sense and Sensibility in Medicine*.[29] He asks, "Why (do) so many leading GPs react in this strongly ambivalent way to what must surely be regarded as a substantial contribution to the enhancement of clinical standards. What is going on?" He suggests the following answers:

- The language of EBM somehow misses the point of the clinical encounter in primary clinical general practice.
- Fear that what begins as 'best information' on which to base a decision can easily be transformed into contractual instruments disguised to control not simply facilitate the management of the patient.
- A suspicion that clinical judgment will be supplemented with protocols and algorithms of diagnosis and treatment that will constitute (perhaps legally) the accepted and mandated response to illness.

He comments, "These may well be quite unrealistic fears (the progenitors and proponents of EBM would certainly deny such dirigiste[i] ambitions), but they are quite widely felt and expressed".

i *Dirigisme*: Policy of state direction and control in economic and social matters. (*Concise Oxford Dictionary*).

Indeed they are still quite widely felt and expressed. Twelve years later, Des Spence, a 'dissident voice' from general practice writing regularly in the *British Medical Journal*, echoes these sentiments under the heading *Medicine's living death*. He says that when evidence began to be presented systematically in the early 1990s it left some room for discretion. "Then, however, came the march of the guideline machines, and by 2000 things were getting out of hand. . . . Since then guidelines have become ever more restrictive and prescriptive. . . . Evidence is treated like solid bricks rather than the shanty corrugated iron that it is. This is the slow garrotte of medical judgement. . . . So discretion, once the cornerstone of the medical profession, is dead. It has been replaced by mass production medicine with . . . patients all treated the same with no thought to individual views or need. . . . Our job is being reduced to a mere collection of algorithms."[30]

Ninety per cent of medical encounters in the UK take place in general practice where the problems that patients present do not conform to the tidy definitions of the EBM guidelines. Many of these illnesses still elude precise biomedical diagnosis when they are referred for specialist opinion, though they may be fitted into one. But general practitioners in particular are likely to have the sceptical attitude to EBM that has been described, though they may be obliged to implement its guidelines, as Spence regretfully remarks later in his piece.

The natural approach to clinical decision making in general practice, the cornerstone as he puts it, was described to me by the late Robin Pinsent, a co-founder of the Royal College of General Practitioners Research Unit, as "informed empiricism".[31] This process of medical judgement is pragmatic, dealing with matters according to their practical significance or immediate importance, but based on a judicious blend of insight, experience, and formal evidence evaluated in the context of the individual problem. It is a harder task than the following of prescriptive guidelines and algorithms because it must take account of the variables that the analysis that provided the formal evidence excluded. It requires education and training. Informed empiricism is every bit as scientific as a strictly evidence based approach; rather more so in fact, because it acknowledges that every patient presents us, in a sense, with a research project, as Conrad Harris points out (Chapter 2).[12] It will occasionally misconstrue a problem when the metaorganic 'variables' confuse a necessary biomedical explanation, but no more so or more often than when the assumption of a biomedical explanation leads to neglect of the personal 'variables' that are the heart of the problem, and 'the disease is not the cause of the illness'; one of Alan Barbour's 'misconceptions and false starts that the clinical process can pursue'[32] (Chapter 6). This approach to clinical decision making is well recognised and respected,

but is increasingly difficult to apply as EBM becomes enshrined in biomedical dogmatism and health policy targets.

This problem is described trenchantly in a book by an American doctor, Jerome Groopman, reviewed in the *British Medical Journal*:

> Doctors need to think 'outside the box' much more often. . . . Failure to do so starts early in the medical training cycle, as medical students and junior doctors all too rarely question cogently, listen carefully, or observe keenly. . . . What's partly to blame for this is today's rigid reliance on evidence based medicine and even, to an increasing extent, on highly sophisticated technology that has taken us away from the patient's story.[33]

I am fascinated by the resonance, particularly in the second sentence, with the teaching of the 17th century physician Thomas Sydenham, who has been called the father of modern clinical medicine. His reputation is said to have rested on "his empiricism . . . his determination to observe and examine each individual patient with the open mind of a natural historian'. He taught us to 'listen intently and question the patient minutely about the march of events in the development of disease".[34]

The tension between the interpretive approach to diagnosis and treatment based on the individual experience of illness and the story, and the analytical evidence based approach, is explored by Tessa Greenhalgh in 'Narrative based medicine in an evidence based world', mentioned earlier.[35] This concluding chapter from a comprehensive study of the importance of the patient's story to the understanding and management of the illness, corrects a common misconception about the original intentions of the evidence based medicine (EBM) movement. The concept of EBM was not intended to preclude clinical judgement and the application of informed empiricism. The author, Trisha Greenhalgh, quotes its pioneers: "The practice of evidence based medicine means *integrating* individual clinical expertise with the best available external clinical evidence. . . . By individual clinical expertise, we mean the proficiency and judgement that individual clinicians acquire through clinical experience and clinical practice".[2] She argues, "Genuine evidence based practice actually *presupposes* an interpretive paradigm within which the patient experiences illness and the clinician-patient encounter is enacted". The belief that the EBM approach rests upon the assumption that clinical observation is totally objective and should, like all scientific measurements, be reproducible is incorrect. Its founding fathers made no such claim to objectivity. It seems it is the followers of the EBM movement who have turned their wisdom into a rigid doctrine they did not intend. As Greenhalgh concludes, "The irrevocably case based (i.e. narrative based) nature of clinical wisdom is precisely what enables us to contextualise and individualise the problem before us. Far

from obviating the need for subjectivity in the clinical encounter, the valid application of empirical evidence *requires* a solid grounding in the narrative based world".

Ways of knowing

Science is a way of knowing. The word derives from the Latin *scire*, to know. Epistemology is the theory of the method or grounds of knowledge (COD); the study of ways of knowing, we could say. One reason for distrusting the dominance of the biomedical model is that its particular analytical method restricts our ways of knowing, and there are other ways of knowing that must, and indeed in practice do belong to our medical epistemology (Box 10.3). Medicine has to deal with the reality of individual patients' lives, a reality that is expressed on different levels of experience, probably on several different levels of experience at the same time, from the molecular to the transcendental, in different individuals. "Different levels of reality may be expected to have their idiosyncratic characters, and there will not be a single epistemic rule for all." In other words, there will not be a single best way of knowing to meet all situations.

BOX 10.3 *Ways of knowing*

- Analytical/experimental scientific method.
- Motivated belief.
- Inference to the best explanation.
- Tacit knowledge.
- Intuition.
- 'Mindlines.'

Motivated belief

The quotation I have just used is from the physicist and priest John Polkinghorne, whose scientific credentials are impeccable.[7] In the same passage he writes,

> Scientists are not inclined to subscribe to an a priori concept of what is reasonable. They have found the physical world to be too surprising, too resistant to prior expectation. . . . Instead the actual character of our encounter with reality has to be allowed to shape our knowledge and thought. . . . The instinctive

> question for the scientist to ask is not 'Is it reasonable?', as if one knew beforehand the shape that rationality had to take, but 'What makes you think that might be the case?' Radical revision of expectation cannot be ruled out, but it will only be accepted if evidence is presented in support of the new point of view that is being proposed. *Science trades in motivated belief.* (My italics)

The cornerstone of much scientific research, and certainly of the science on which the biomedical model is based, is repeatable experimental confirmation, usually in controlled conditions. But many disciplines are not susceptible to this kind of investigation: many surgical procedures, for example; history; geology and the fossil record; the events recorded in astronomical observations; theories of the origin of life; many human predicaments that require a systematic solution. All these have a scientific component. In addition most other non-scientific explorations of reality also lack recourse to repeatable controlled investigation, including theology, whose relationship to science John Polkinghorne is exploring in the pages I have quoted.

The fact that a phenomenon or proposition cannot be investigated so scrupulously does not mean that the evidence that 'makes you think that might be the case' is not just as important as evidence that can be so rigorously tested. Nor does it mean that the quality of evidence should not and cannot be assessed intellectually. The evidence is essential to the motivation, and well founded motivation is essential to the belief. But motivated belief acknowledges that judgments such as these, including "the quality of a painting, the beauty of a piece of music, or the character of a friend, depend upon powers of sympathetic discernment, rather than being open to empirical demonstration". Polkinghorne implies that they are by no means subordinate ways of knowing because in fact "no form of human truth-seeking enquiry can attain absolute certainty about its conclusions".

Inference to the best explanation (abduction)

This is not far removed from the process of motivated belief, but involves choice between alternative or competing theories. The evidence can be construed in various ways, one of which is the most intellectually coherent and satisfying. It involves weighing evidence and judging probability, not proof. In a medical context a good example is what is known as 'differential diagnosis'. A doctor weighs the evidence of the available symptoms and signs, and perhaps the results of tests, and judges the probability that a particular diagnosis best explains what is going on. The differential diagnosis of a headache could be a hangover, a migraine or a sub-arachnoid haemorrhage (bleeding in the brain). Any one of those could be a correct

diagnosis. But it might also be an incomplete explanation if it neglects the circumstances that predisposed to the physiological disorder; which is a possibility that is central to the problem, the healthcare dilemma that this book is exploring. On the human scale, inference to the best explanation is often the only path we can follow, but it is not unscientific. It is also a necessary path of enquiry on the largest scale. The fact of the rational intelligibility of the universe, and of the explanatory power of science to unfold it, are not themselves self-explanatory. Einstein famously commented that "The most incomprehensible thing about the universe is that it is comprehensible". This remarkable fact, "The bedrock belief upon which all intellectual enquiry is built . . . is one of the main considerations that have led thinkers of all generations to conclude that the universe itself must be the product of intelligence".[7] This is inference to the best explanation. It is also motivated belief. The evidence is clear, the reasoning logical, but the conclusion is not absolute, and in this instance never can be. Claims about evolution at the level of species (macroevolution) or molecules (microevolution) depend similarly on inference to the best explanation because they concern unrepeatable past events.

Informed Empiricism

This term, introduced to me, as mentioned, by Robin Pinsent, is his description of GPs' way of knowing. It comprises their education and training and the research evidence related to the task in hand. But it also comprises experience, and allows that the actual character of their encounter with the reality of the patient's life and predicament should shape their knowledge and their thought (to paraphrase John Polkinghorne). Informed empiricism develops clinical acumen and clinical judgement. It acknowledges targets and guidelines but is not a slave to them because it knows that they are a generalisation and an abstraction that may or may not need to be applied to the individual patient. It is true to the original spirit of evidence based medicine. Informed empiricism enables the process of inference to the best explanation, but allows that the explanation may be unique to the individual patient, and accepts, "Every patient presents us, in a sense, with a research project. Every time we intervene in patients' lives we are conducting experiments".[12] But these observations by Conrad Harris carry an injunction to the open-mindedness towards the data that should be the rule for all scientists and clinicians. We should never be content "to stop asking questions once (we) find a pattern (we) know how to deal with (for fear that) going on may lead us into uncharted waters. . . . There is always a gap between what we know and what we need to know, and if we are not

constantly exploring a little of it we are in danger of forgetting that it exists". Informed empiricism must be a dynamic way of knowing. Just as, indeed, all ways of knowing must be dynamic.

Tacit Knowledge

Tacit knowledge is a concept developed by Michael Polanyi as part of his exploration of *Personal Knowledge*.[8] It describes the things we know, and things we know how to do that we cannot be taught, or that we learn without being taught; activities that we cannot precisely describe or explain to others. It is knowledge or technique that we discover by doing. A child learning to speak discovers the grammatical construction necessary to make sentences without being told how to do it. Adults may correct mistakes, and the knowledge and the skill may be refined by rules taught in later life, but the knowledge by which coherent speech begins to emerge is tacit knowledge. Similarly, we cannot describe or explain precisely what is involved in learning to ride a bicycle or hammer in a nail. There is a whole repertoire of knowledge and skill that we acquire in this informal and tacit fashion that will influence our actions, our behaviour and our interpretation of experience in many areas of life, including science.

I have already mentioned this tacit knowledge by which we perform so many functions and that is not susceptible to logical analysis, and the creative tension that exists between this and formal scientific method. It is one of the attributes of the mind whose subjugation to rules, regulations and protocols, and subsequent neglect James Willis laments in my references to his work in Chapter 9 ('A crisis of morale'). He is describing much the same thing as tacit knowledge when he writes about the 'under-mind', borrowing the concept from a book by Guy Claxton, *Hare Brain Tortoise Mind: Why intelligence increases as you think less*.[36] The book documents the evidence that it is the under-mind, or subconscious, that enables us, in Willis's words, to "operate better if we take a side-step and switch off our focused, logical, analytical, conscious approach for some of the time. And not just a bit better – we operate a *lot* better".[37] To neglect its operation in making medical judgements, he argues, can actually do harm. Tacit knowledge, the under-mind, is fed by experience, the things we learn without knowing that we are learning, or how we are learning, because the human mind is subconsciously alert to the things it needs to know. It is enfeebled if it is undernourished by over-investment in logic and lack of interest in the diversity of human experience.

Intuition

Intuition is the immediate apprehension of something. It is an attribute or faculty that enables us to grasp, to perceive, to be aware, to know something about our circumstances, our environment or another person, without conscious reasoning. It may be apprehended by the senses (we feel there is something wrong) or by the intellect (I know that person is lying). It is not the same as the process of picking up non-verbal cues that should be part of our repertoire of clinical and psychological skills in medicine, and in life for that matter. Howard Spiro discusses the role of intuition in medicine in his book *The Power of Hope*,[38] and quotes Henri Bergson's account of intuition as an inward and immediate vision of reality that contrasts with the knowledge gained by the systematic application of our intelligence in science.[39] But intuition has paved the way for the prodigious work of intelligence in science, of which Einstein's initial perception of the phenomenon of relativity is perhaps the best known example. It is an example that suggests that intuition is to an extent dependent on the openness of a prepared mind. On the other hand, psychologist Bruce Hood has argued recently in his book *Supersense* that intuition is an innate faculty that we all possess, which is perhaps our common belief.[40]

Mindlines

This diversity of ways of knowing is exemplified in clinical practice by a study of knowledge management in primary care whose objective was, "To explore in depth how primary care clinicians (general practitioners and practice nurses) derive their individual and collective healthcare decisions".[41] The authors found, "clinicians rarely accessed, appraised, and used explicit evidence directly from research or other formal sources. Instead, they relied on what we have called 'mindlines', collectively reinforced, internalised tacit guidelines, which were informed by brief reading, but mainly by their interactions with each other and with opinion leaders, patients, and pharmaceutical representatives and by other sources of largely tacit knowledge that built on their early training and their own and their colleagues' experience. The clinicians, in general, would refine their mindlines by acquiring tacit knowledge from trusted sources, mainly their colleagues". Mindlines "were grown from experience and from people who are trusted; they were 'stored in my head' but could be shared and tested and then internalised through discussion, while leaving room for individual flexibility. (They) might well be modified when applied to an individual patient after discussion and negotiation during the consultation;

at this stage patients' ideas of what is the appropriate evidence about their particular case (their own personal history, what their family has experienced, what they have read in the media, and so on) could influence the application or even the continuing development of the mindline. Further adjustment might subsequently happen during swapping stories with colleagues or in audit or critical incident meetings".

I would be very surprised if, in the midst of the inevitable uncertainty of medical practice, all clinicians do not employ these ways of managing knowledge, and the seven 'ways of knowing' that I have described, in medicine and indeed in life, and find them essential in making sense of their own and their patients' experience, and deciding what to do about it.

Conclusion

Evidence, like a paradigm, is an essential foundation for exploring reality, but it is not that reality. Evidence is information, an essential contribution to the acquisition of knowledge. But it must not be mistaken for knowledge, let alone truth. The scientific paradigm prescribes the information that fits the paradigm and the methodology that is appropriate to the research that will provide that information. The evidence acceptable to the paradigm sustains the paradigm. The relationship shows the circularity described by Polanyi and Polkinghorne, that is its danger. A paradigm that is open to information that does not fit will be a creative paradigm, open to that 'indefinite range of yet unforeseen consequences', new knowledge. One that is not will become an ideology, a victim of paradigm paralysis. Wisdom is the attribute we need to perceive both the value and the limitations of our paradigm.

The goal of our exploration of reality is truth. Evidence is an essential tool with which to dig for truth, but it is not truth. Truth is universal and indivisible. Evidence is contingent and conditional. Science, within its particular frame of reference – answering the questions 'What?' and 'How?' – is one of evolved humanity's glories, and a tributary pathway to truth. Evidence is the tool that it has fashioned and refined. But science is not the whole story. It does not, for instance, answer the question 'Why?'. There are other tributary pathways. The dialogue between science and theology, for example, although it is a dialogue of the deaf at its polarised extremes, is very fruitful where there is cross-border trade in intellectual goods between the two domains, the 'traffic in truth' that John Polkinghorne recommends.[42] In this context, the relationship between evidence and truth is nicely illustrated in an essay amongst the works of the

twentieth century theologian Austin Farrer. He is questioning the proposition that a truthful scholar is one who will not go an inch beyond the support of the evidence, and asks the question, "What is the supreme motive of the truth-seeking mind? Is it to explode shams, or to acknowledge realities? And (if) there are realities . . . too intangible to be proved, will intellectual honesty discount them, or will it embrace them?" (Echoes of the quotation from Schumacher in the Introduction). In Chapter 11 we will meet Thomas Kuhn's warning that "the man who embraces a new paradigm at an early stage (the 'paradigm pioneer' we will meet in the next chapter) must often do so in defiance of the evidence"; a decision that can only be based on faith.[3] Faith is the twin of love, says Farrer. (You will remember how Polanyi asserts that scientific passion is akin to love (p.171); and how Polkinghorne tells us that mathematical truth is recognisable by its beauty (p.166)) And love, Farrer continues, "with its inexhaustible appetite for what deserves loving, sees beyond evidence . . ."; when faith, the act of will by which we determine to accept or trust what draws our love, comes into play. "But though faith and love go beyond absolute evidence, they are not blind. If we *really* love and trust . . . we do not wish to entertain a fantastic image (of the object of our love)". (My italics.) And reflecting Polanyi's account of the role of personal knowledge he says, "After all the detection of shams, the clarification of argument, and the sifting of evidence – after all criticism, all analysis – a (truth-seeker) must make up his mind what there is most worthy of love, and most binding on conduct, in the world of real existence". Medicine operates in the world of real existence. Evidence is indispensable, but we must always be willing to see beyond the evidence and beyond the boundary of the paradigm that has hitherto sustained it. I suspect that the authors of *Follies and Fallacies in Medicine*, whom I quoted in the Chapter 2, would be unsympathetic to some of the propositions in this book, but really it has a similar aim, "to reach inquisitive minds, particularly those who are still young and uncorrupted by dogma". It addresses the same sort of errors that they were concerned with, "errors of doctrine, systematic errors which are part of dogma and accepted truth, distortions which set obstacles in the path of rational thought and enquiry".[43]

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