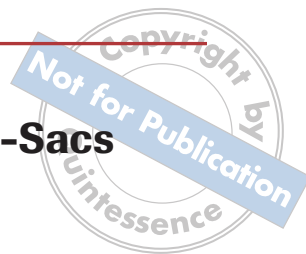


Why Do We Always End Up Here? Evidence-Based Medicine's Conceptual Cul-De-Sacs and Some Off-Road Alternative Routes



I work at Queen Mary, University of London, close to the 2012 Olympic Stadium and right in the heart of London's vibrant and ethnically diverse East End. I am Director of the Healthcare Innovation and Policy Unit at Queen Mary. Innovation: an idea, a technology, a research discovery, a way of working—anything that is perceived as new and which requires a change of hearts and minds and structures and systems to become business as usual.¹ Policy: perhaps best defined as 'the authoritative exposition of values'.² Most policy is about innovation: it seeks to justify why particular new ideas, technologies, research findings or ways of working should be taken up—and therein lies a research agenda.

Modern medicine, we are told, has become a victim of its own success. We have, allegedly, prolonged human life to the point at which the sick are demanding the right to die. Evidence-based decision support is so good, apparently, that patients no longer need a doctor, just a well-programmed computer. Indeed, we are approaching the time when the workings of our bodies will be programmed like a computer by technically trained doctors. Medicine, so they say, has lost its moral compass and sold out to tick-box appraisal toolkits. Is this paradox of progress all in the heads of the Luddites? Or are we experiencing a genuine and sinister erosion of medicine's core values and defining practices by new technologies in the hands of naive rationalists?³

Let me explain what I mean by 'conceptual cul-de-sacs'. Thomas Kuhn proposed that science progresses in paradigms—a paradigm being a set of assumptions and beliefs shared by a group of scientists about what the important questions are and how they should be tackled.⁴ Most scientists, most of the time, work within an existing paradigm and build rather doggedly on what has gone before. This is what Kuhn called 'systematic puzzle-solving', Wittgenstein called 'the railway tracks of science'⁵ and Einstein called '99% perspiration'.

Occasionally, someone (often a youngster new to the discipline or perhaps someone in a second career) questions the prevailing assumptions and methodological rules—Einstein's '1% inspiration'. A fight ensues, with the newcomer typically rejected by the old school as ignorant or not rigorous, and a breakaway group forms. The most famous example of this is Einstein himself, who

challenged the assumptions and methods of Newtonian physics and started playing to new rules, allowing new questions to be addressed in a whole new way.

Paradigms are not bad things. They don't just constrain our thinking, they enable us to think.⁶ Science could not progress without them. We learn the rules, apply them, argue about them, modify them. Indeed, Susan Leigh Star defined a discipline as 'a commitment to engage in disagreements'.⁷ If you're a geneticist and a historian challenges your work, you won't get very far. But with a fellow geneticist, you can have a good argument and make progress.

The pre-paradigmatic research of off-road breakaway groups is typically slow, messy and characterised by wrong turnings and periodic pile-ups.⁴ But eventually some tracks are laid and a clear direction of travel is pointed out. Yesterday's radicals become today's sticklers for procedure. Disagreement, and therefore progress, becomes possible. A new paradigm is born.

A few years ago, my colleagues and I developed a technique called 'meta-narrative review', designed to summarise the literature on topics that have been studied in very different ways by different groups of scientists.⁸ The meta-narrative reviewer asks 'what is the unfolding storyline of research that scientists tell themselves to make sense of their common endeavour; what are the assumptions underpinning that storyline—and what are the breakaway groups up to?'

The reason why we find research papers outside our own paradigm so impenetrable is that scientists consider their core assumptions to be self-evident so don't make them explicit. Core assumptions are to be found in undergraduate textbooks—or even better, school textbooks—which set out the 'normal science' of statistics, genetics and so on. New-paradigm ideas are slow getting into textbooks, since by definition they break the basic rules. This, incidentally, is why the paper you consider your greatest contribution to the field is also the one that is most likely to get rejected by all the leading journals.

Researchers in dominant paradigms tend to be very keen on procedure. They set up committees to define and police the rules of their paradigm, awarding grants and accolades to those who follow those rules. This entirely circular exercise works very well just after the establishment

This editorial was the keynote lecture presented via videolink at The Royal New Zealand College of General Practitioners' Conference, Auckland, September 2011.

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of a new paradigm, since building systematically on what has gone before is an efficient and effective route to scientific progress. But once new discoveries have stretched the paradigm to its limits, these same rules and procedures become counter-productive and constraining. That's what I mean by conceptual cul-de-sacs.

Here's an example. Remember when the cause of peptic ulcer was too much stomach acid, and all the treatments were oriented to reducing acid production? Remember when Barry Marshall proposed that peptic ulcer was actually caused by a bacterium?⁹ And he had to go as far as drinking a vial of the offending bacterium to prove his point? It took them 20 years to get around to giving him the Nobel Prize for Medicine and changing the textbooks.

Very occasionally, overt paradigm wars break out in the academic journals. Take the classic stand-off between Jeffrey Pfeffer and John Van Maanen—both professors of organisation science. Pfeffer published a paper in 1993 arguing that organisation science was a weakly developed paradigm in need of greater consensus.¹⁰ A hundred different flowers were blooming, he said, and the garden was growing wild. The rules of organisational science, he proposed, should be modelled on the high-paradigm discipline of economics and be focused on hypothesis-driven studies conducted to strict methodological rules. This should be linked to a tighter research governance structure, more focused funding allocation, selection of editorial board members, and the salaries of faculty members.

Van Maanen was the brilliant and unconventional new kid on the block.¹¹ 'I suspect,' he wrote in 1995, 'that I am a weed in Jeffrey's dreamtime garden. I am therefore a candidate for pruning, paring and discarding.' He declared Pfeffer's stance on rigid paradigm rules to be 'philosophically indefensible; naive as to how science actually works; [. . . and . . .] reflective of an out-of-date and discredited version of knowledge, rhetoric and the role [which] theory plays in the life of any intellectual community.'

Van Maanen's central argument was that there are two fundamental approaches to science. The first assumes a hard reality out there, ready to be measured and classified, with language taking the subservient role of describing and representing that fixed reality. In this objectivist approach, method is privileged over theory and hierarchies of evidence (that is, lists of preferred and non-preferred study designs) are all-important. The second approach holds that our representations come first, allowing us to see selectively what we have described. In this constructivist approach, conceptual and theoretical concerns dominate and methods may be flexible so long as they serve theory. It follows from objectivist assumptions that paradigms can be controlled

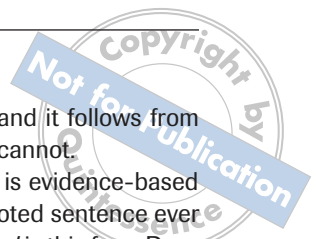
by enforcing methodological rules—and it follows from constructivist assumptions that they cannot.

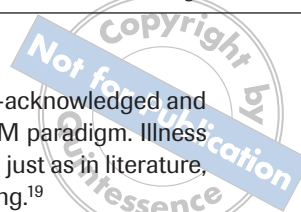
The paradigm I want to talk about is evidence-based medicine—EBM. The most widely quoted sentence ever published in the *British Medical Journal* is this from Dave Sackett in 1996: 'Evidence based medicine is the conscientious, judicious and explicit use of current best evidence in making decisions about the care of individual patients.'¹² This wasn't so much a definition of EBM as a skilful rhetorical move to position his new paradigm squarely on the moral high ground. Anyone disagreeing would have to argue that doctors should be using worse evidence or practising non-conscientiously, non-judiciously and so on.

A few years later, when EBM had built a reputation for itself as the only game in town, Anna Donald and I decided to propose a definition with which it was possible to disagree. We defined EBM as 'the use of mathematical estimates of the chance of benefit and the risk of harm, derived from high-quality research on population samples, to inform clinical decision-making'.¹³ Our definition exposed three underlying assumptions of the EBM paradigm: clinical practice equates more or less with clinical decisions; clinical decisions are best made using mathematical predictions; and evidence from population samples maps more or less directly to decisions on individual patients. In the circumstances for which EBM was originally conceptualised, these assumptions were entirely reasonable. Many people—my own mother included—owe their lives to the rigorous science of EBM that was built on these foundations.

Let's take a break. Consider my bicycle. Consider my route to work on the canal path, missing out the traffic jams. Consider the angry goose who knocked me off my bicycle on the towpath. Consider a scan of my right shoulder. Consider the steroid injection that didn't fix it, and the instrument that my orthopaedic surgeon was itching to use on me. In the language of EBM—which converts the unique individual narrative into abstracted population categories and Bayesian probabilities—the clinical question goes like this: 'In a 51-year-old otherwise healthy female with a 40% tear of the supraspinatus tendon and a negative response to triamcinolone, what is the chance of achieving functional recovery via arthroscopic repair compared to intensive physiotherapy, and what are the risks of each?'

In a perfect evidence-based world, the odds ratios of these choices would have been programmed into the clinical computer system, so that when the surgeon entered the diagnosis on my personal medical record, an algorithm would have popped up showing the benefit-harm ratios to inform a shared decision-making discussion with an empowered patient. Actually, this was evidence-based surgery, so the only thing programmed





into the computer was a waiting list. The surgeon put my name on the bottom of it and told me if I hadn't got better by the time I got to the top of it, he would operate. Anyway, it was lucky I bust my shoulder, because if I hadn't, I would have been stuck for a real-life example of evidence-based medicine. Most medical cases, especially in primary care, fit the clean, efficient, probabilistic language of EBM remarkably poorly.

Let me tell you of another case I saw in my surgery—a 59-year-old man complaining of a cough, whom I knew well. He was an asylum seeker from a war zone, living in damp rented accommodation. He and his family were awaiting rehousing, for which I had written to the relevant authority, but they were still many points short of the top of the waiting list. In this context, and taking account of intuitive cues built from 25 years of listening to patients coughing,¹⁴ I classified this patient's cough alongside the abdominal pain for which he had been fully investigated (no organic cause found) and his recurring headaches accompanied by flashbacks (post-traumatic stress disorder). I removed my doctor-as-diagnostician hat and turned away from the computer screen. Drawing on the work of my colleagues in narrative medicine, I listened to his troubles and, for a few brief minutes, bore witness to his suffering.^{15–18}

The medical student who was sitting in with me later called up a guideline on his personal digital assistant and challenged me. Why had I not listened to the patient's chest or asked him to blow into a meter? Why had I not completed the decision support algorithm? Why, he implicitly asked, had I not followed the rules? In justifying my actions, I offered my bold student four books with which to complicate his evidence-based world.

The first is *How Doctors Think* by Kathryn Montgomery, a Professor of English Literature at Northwestern University.¹⁹ Drawing on Aristotle, Montgomery argues that despite its own emphatic claims to the contrary, medicine is not a science at all—and nor, incidentally, is it an art. Medicine is a practice—specifically, an uncertain, paradox-laden, judgment-dependent, science-using, technology-supported practice. As such, and despite all the scientific knowledge that informs it, medicine is comparable to the practice of law or making of ethical judgments. In every case, the practitioner must reason not from the general to the particular but from the particular to the general—abduction rather than deduction. The question facing every practitioner, every time they encounter a case, is: 'What is it best to do, for this individual, at this time, given these circumstances?'

The good doctor must draw, as Sackett rightly said, conscientiously and judiciously on the best that science can offer and make optimal use of available technologies. But the skilled practice of medicine is not merely about knowing the rules, but about deciding which rule

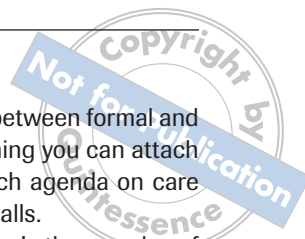
is most relevant. This remains under-acknowledged and under-theorised in the dominant EBM paradigm. Illness may be a narrative, but just as in law, just as in literature, there is no text that is self-interpreting.¹⁹

The British Thoracic Society has a rule that a patient presenting with a cough should have their chest examined and peak flow rate measured. The Medical Foundation for the Care of Victims of Torture has a rule that patients scarred by unimaginable abuse should not be subjected to procedures that they may experience as traumatic unless the reasons for doing so are over-riding. These competing rules must be weighed against each other with the patient's best interests in mind. The question of whether, on this occasion, the patient in front of me should be asked to strip to the waist and say 'ah' will not be answered by the evidence-based guideline which the A-grade student keeps at his or her finger tips.

The ability to make practical and moral judgments requires a quality that Aristotle called *phronesis* or practical wisdom: the ability to apply general rules to particular situations.^{20,21} It links to what Polanyi called tacit knowledge,²² Schon called reflection-in-action²³ and Conan Doyle (who trained as a doctor before he became a writer) called intuition.²⁴ *Phronesis* also explains why, as the Dreyfus brothers observed, experts reason differently from novices and humans reason differently from computers.²⁵

The second book I offered my student was *Complex Knowledge* by Professor Hari Tsoukas, an organisational sociologist from Cyprus who draws on Wittgenstein.^{26,27} Tsoukas defines knowledge as the capacity to exercise judgment, and suggests that it requires two things. First, the ability to draw distinctions: to distinguish between a dry cough and a wet cough, but also between a simple cough and an anguished cough. Second, location of the practitioner within a collectively generated and sustained domain of action. Knowledgeable individuals exercise judgment within their domain of action, because they have gone through a period of socialisation that enables them to appreciate and take account of subtle aspects of context when making distinctions. My own domain of action is primary health care, which places central importance on 'the hidden agenda': unspoken psychological needs which present as minor physical complaints.²⁸ My student, fresh from his evidence-based medicine lectures, was connecting with a different and (I contend) less relevant domain of action.

My third complicating text was *Upheavals of Thought: The Intelligence of Emotions*²⁹ by Martha Nussbaum, Professor of Philosophy at the University of Chicago, who encourages us to think of our emotions as part of our intelligence and allow it to inform our judgments. When ethics is reduced to the dispassionate application of principles, or when medicine is reduced to the



dispassionate application of scientific evidence, we will necessarily make worse judgments, not better ones. *Upheavals of Thought* runs to 751 pages. After demolishing the assumptions of behaviourism, Nussbaum takes us through Freud on desire; Aristotle on virtue; Rousseau on empathy; Proust on passion; Emily Bronte on romanticism; Mahler on the evocative power of music and Joyce on the hot striving of love. Medicine may not be an art, but if the arts are ignored, the moral imagination and the capacity for compassion will wither. As Rita Charon (a Professor of Medicine with a PhD in English literature) puts it, the competent clinician is not one who can beat the computer at reading ECGs but one who can connect emotionally with the stories and plights of their patients.³⁰ Evidence-based guidelines notwithstanding, those who cannot feel will not see.

Perhaps it was a touch unfair on my student, but I felt that his education would be incomplete without encountering one more giant of contemporary philosophy: Annemarie Mol, Professor of Philosophy at the University of Amsterdam, who draws eclectically on the work of Bruno Latour in actor-network theory. In her book *The Logic of Care*, Mol challenges the assumption that the essential task in clinical practice is to make a series of decisions and ensure that the patient is given a choice in these decisions.³¹ Whereas in the logic of choice, the focus is on particular decisions made at particular time points, Mol's proposed new paradigm—the logic of care—emphasises the ongoing, never-ending work from both patient and clinician that goes into the complex task of living with an illness.

The logic of choice has run unquestioned through at least the last 15 policy documents released from the UK Department of Health. The entrenched social determinants of health are readily overcome, so the rhetoric goes. All you have to do is choose the healthy option at every node in the decision tree. You may of course need a nudge to do it these days.³² The logic of choice is bounded, linear, predictive—and evidence-based: it relates to a set of defined options, each linked to a specific probability of success.

In contrast to the world of rational choices, the logic of care is unbounded, non-linear and unpredictable; it's about everything that happens to a person as they live with illness. Self-care in diabetes, for example, is as much about retrieving your blood glucose meter from the jaws of the family dog as it is about being a good patient and writing down the readings to show the nurse. Care still includes the touchy-feely stuff. But it also includes the support groups and networks which people mobilise to help them live with illness. These networks are both social and technical; they grow organically and change dynamically; they are linked to people's identities and their hopes and dreams; they blur the boundaries between

professional and lay knowledge and between formal and informal care. But compared to anything you can attach a Bayesian probability to, the research agenda on care networks doesn't get many funding calls.

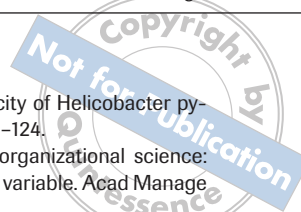
Let us return to my earlier question. Is the paradox of progress in medicine a black object invented by Luddites, or has evidence-based medicine, the bastard child, placed a rationalistic stranglehold on medicine's core values and defining practices—specifically: professional virtues, practical wisdom and the moral imagination?³³ I don't think there's a simple answer to that question. On the one hand, there is nothing inherently incommensurable about drawing on sound epidemiological research to support wise, practical, emotionally enriched clinical judgements. Dave Sackett is, by all accounts, a compassionate and caring clinician.

On the other hand, I think something sinister is happening, mainly because of the striking circumstantial resonance between the reductionism of EBM and the reductionism of contemporary policymaking. As Timmermans and Berg have shown, the protagonists of EBM, and the powerful complex of research funders, principal investigators, research governance and policy-making machinery have created such an unassailable set of rules and expectations that there is a tendency for all of medicine's questions either to be framed in the language of EBM and judged by its paradigmatic 'gold standard'—or be rejected as unimportant.³³ With its well-intentioned methodological fetishism and quantitative biases, EBM is well suited to producing abstracted generalisations based on population samples.

EBM isn't inherently wrong, but it plays to a vision of science that is characterised by predictive certainty—a vision that is taught to school-children and perpetuated in the media, a vision of simple logic with readily deduced details and rule-governed consequences.¹⁹ It is this logic, coupled with the values of consumerism, which appear to have prompted the coalition government to develop a one-dimensional metric of human happiness which will light up like a thermometer bulb when policy tickles the public G-spot.

Evidence-based medicine, and the rationalistic assumptions on which it is built, perpetuate the myth that, by reducing medicine's complexity to focused questions about populations, interventions, comparisons and outcomes, we will get rid of its uncertainties and ambiguities. In fact, as Ursus Wehrli has shown in *Art Tidied Up*,³⁴ you can't tame complexity without loss of meaning—sometimes very profound loss of meaning.

What is to be done? First and foremost, we medics need to get out more, and learn from other disciplines—especially (in my view) the social sciences and humanities. Far from being unfocused or watered down, interdisciplinary research is medicine's only hope of release



from a paradigm that has gone beyond its terms of reference and is beginning to do damage. It is only by grappling with unfamiliar paradigms that the limitations of our own will become evident.

Second, we need to encourage rather than suppress paradigm wars in our own journals. Here's one in *Public Library of Science*. Richard Lilford is undoubtedly one of the world's leading epidemiologists. He argued that the principles and methods of EBM should be rigorously applied to the evaluation of politically controversial e-Health programmes.³⁵ Jill Russell and I argued the opposite—that by privileging controlled experiments and refusing to engage with the personal, political and institutional context of technology programmes, e-Health evaluations are setting themselves up to fail.³⁶ Our paper was rejected four times on the grounds that it had been compared with an evidence-based checklist and found to be 'incorrect'. It is to the great credit of the editors that they finally accepted our 12-page rebuttal, which argued that challenges to the dominant paradigm will necessarily fail to meet established criteria for rigour.

Finally, let's not kid ourselves that paradigm wars in medicine will be politically neutral. As Nicolo Machiavelli put it in 1505:

... it ought to be remembered that there is nothing more difficult to take in hand, more perilous to conduct, or more uncertain in its success, than to take the lead in the introduction of a new order of things. Because the innovator has for enemies all those who have done well under the old conditions, and lukewarm defenders in those who may do well under the new.³⁷

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