Clinical evaluation: constructing a new model for post-normal medicine

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Abstract
The current paradigm in medicine is served by an explanatory model based on scientific positivism. We argue that there are inherent weaknesses in this model: its basis on reductionism, its reliance on linear thinking and its failure to incorporate human values invite a revision of our thinking about knowledge in medicine. We propose that a fresh explanatory model should be based on complexity theory, and argue that this better suits the new era of post-normal medicine, where analytical and predictive power are obtained by stepping back and looking at the relationships and overall context of a system rather than forcing reality into a preferred disciplinary framework. Better at times to be vaguely right, we argue, rather than precisely wrong.

Introduction
These are challenging times for science in medicine. It is less than a year since the genome project reported to a stunned world. Hailing its achievements, The Times described the project as ‘Unlocking the secret of creation, the greatest journey ever’, echoing the then United States President Bill Clinton’s comment, ‘Opening the book of life, the most important map ever produced by man’ (The Times 2000). Yet, within the same year we have seen the Chief Medical Officer failing to convince the nation about the safety of mumps, measles and rubella vaccination, whose link with childhood autism was introduced in a paper which had more authors than patients (Elliman & Bedford 2001; Wakefield et al. 1998). We have seen the National Institute for Clinical Excellence (NICE) being challenged by its prestigious counterpart the Drugs and Therapeutics Bulletin over the evidence describing the benefits of zanamivir, a new preparation to shorten morbidity from influenza (National Institute 2000; Drugs and Therapeutics Bulletin 2001). Simultaneously, we see science triumphantly securing the support of the public with its spectacular technical advances in DNA sequencing, and science struggling to secure the confidence and co-operation of individuals who appear obstinately disinclined to accept strong scientific evidence about childhood vaccination. Where do the origins of this conflict arise?

We propose that the origins of these problems lie within the scientific model itself. There are three generic problems. First, the scientific approach has been resolutely reductionist, fuelled by scientific positivism’s promises to understand systems by reducing to them to their component parts. Secondly, the scientific model relies on linearity to explain cause and effect. Linear thinking is the key ingredient of determinism that lies at the philosophical heart of the scientific model. Thirdly, the application of science to medicine has promoted a disingenuous notion of intellectual celibacy: the scientific experiment reports value-free information that incrementally and inductively builds up into a robust body of scientific knowledge.
We shall argue that neither reductionism nor linearity is sufficient to explain the nature of a world which is relentlessly non-linear and complex. Clinical scientists (and indeed the public) remain unclear about, or actively conceal, the values embedded in the scientific model (Dixon & Sweeney 2000) and the scientific model has always struggled with the paradox that science deals in generalities, while the focus of clinical medicine is the individual (Miles et al. 2000). The implications for the model are serious. The weaknesses exposed by recent events require a wholesale revision of the way we think about knowledge in medicine, and how it is constructed, promoted and distributed. We commend complexity theory as the basis of a new explanatory model for medicine, define its characteristics and illustrate its application with a series of examples.

The end of the line for linearity?

There can be no doubt that applying the principles of science to medical practice has resulted in spectacular advances for patients. Most current practitioners would point to the introduction of evidence-based medicine as a turning point for the profession (The Evidence-Based Medicine Working Group 1992). While it was, the origins of scientific thinking go back over 300 years to the work of Bacon, Newton, Harvey and above all Descartes. Assisted by parallel developments in maths and technology, the origins of hospital medicine probably can be traced back to the 19th century work of Bichat in his anatomy clinic in Paris. Koch’s postulates, published in 1891, firmly focused the scientific gaze on the germ theory of disease, heralding an expansion of science-based medicine (Greaves 1996). The scene was set: the approach reductionist, the key metaphor the body as machine. We all became disciples of Descartes.

When applied to mechanical systems, such a reductionist approach was hugely rewarding. A jumbo jet is indeed a complicated system that can fully be understood by separating and reducing the system to each of its mechanical components and, more importantly, assuming that the interaction of those components is linear. Harvey’s description of the circulation of blood is one of the earliest and still most celebrated examples of this approach in medicine (Dixon & Sweeney 2000) and the molecular basis of genetics has undoubtedly helped explain the nature of certain conditions, like trisomy 21, where there is a direct connection between a structural abnormality and a characteristic pathology. However, in the first couple of decades in the last century, researchers in the life sciences realized that linear thinking repeatedly failed to explain the natural world, which, as their understanding grew, obstinately presented itself as non-linear.

Early 20th century biology floundered when it tried to explain the co-ordinating activities of cells, particularly their ability to differentiate. As genetic information is identical in each cell, how do cells specialize in these different ways? Biologists split into two camps: the vitalists suggested that some force or field must be added to the basic physics and chemistry to secure a complete understanding. The organismic biologists disagreed. Assisted by developments in systems theory, they argued that what was needed was an understanding of organizing relations (Haraway 1976). How things were connected was important: the metaphor of knowledge changed from the machine to the network.

Mathematicians too, were grappling with non-linearity. Up to the 1920s, when mathematicians came up against non-linear systems like the flow of water, they tended to minimize the intrusion of non-linearity, calling it small or insignificant. However, mathematicians could not escape the pervasive non-linearity in nature and when they began to explore non-linear equations, quite unforeseen developments were encountered. The application of maths to non-linear systems could not produce exact prediction: reinforcing feedbacks or iterations were fundamental to understanding how non-linearity worked. The mathematics of chaos had emerged.

In physics the seminal event was the publication of Heisenberg’s uncertainty principle, which defined the limits of a science’s ability to describe systems and predict events. Heisenberg argued that the very act of observation determined the observability of a system. Measurement could never be objective and observations merely reflected the mechanism of the observing instrument, rather than the nature of the system observed. The implications of Heisenberg’s contribution can’t be underestimated. ‘The foundations of physics have started moving’, he wrote in
the early 1970s, ‘this motion has caused the feeling that the ground would be cut from under science’ (Capra 1988; Heisenberg 1971). The paradigm of certainty, with its appeal that science would transcend not just physical but the social and cultural forces which had previously shaped world views, was challenged. Post-modern science had arrived.

**Intellectual celibacy and scientific knowledge**

The widely accepted version of the history of medicine promotes the view that knowledge developed through applying scientific principles to medicine is neutral, value free and completely objective. The truth is out there, waiting to be revealed. The randomized controlled trial has been developed as the key weapon for medicine to produce objective value-free knowledge. Agreed mathematical models of statistical and clinical significance weight the importance of the evidence in these trials. This model carries the crucial advantage of ensuring the reproducibility of findings.

No one can doubt that some of the advances in therapeutics are so robustly supported by scientific evidence as to be beyond dispute. One need only look at the vaccination campaign against poliomyelitis in the 1950s or the benefits of streptokinase in the 1970s and 1980s for evidence of unequivocal benefit of the application of science in medicine. Few commentators dispute this.

The philosopher David Greaves is one of the few dissenters. He argues that values were introduced into scientific medicine right at its inception, when Koch introduced his triad (Greaves 1996). Of the three elements in Koch’s model, the causal agent, pathological lesion and the clinical syndrome, it was the causal agent that attracted most of the attention. The pathological lesion came a close second, and interest in the clinical syndrome last by a long way. Koch’s triad wasn’t a triad: it was a hierarchy.

The Chief Medical Officer’s struggle to convince the public about the safety of MMR is the most recent in a series of examples that illustrate the view that scientific knowledge is not free of values, nor is it the sole commodity that contributes to decisions about health. Here, a report on 12 patients, eight of whose parents attributed their clinical problems to vaccination with MMR, has resulted in a substantial minority of nurses in general practice reporting themselves ambivalent about the vaccine (Petrovic et al. 2001). Conflicts of interest like these have been reported in medical journals for over 50 years. In the late 1950s, a classic paper by Walsh McDermot described morbidity among the Navaho Indians. Their resistance to accepting the notion that microbes could be responsible for some of the endemic diseases was the first illustration that medicine may have its cultural boundaries (Cassell 1991). Brooke’s classic paper 30 years later was the first to show that clinicians were similarly affected by cultural differences. The difference he observed when comparing the therapeutic approach by American and British cardiothoracic surgeons to the same clinical vignettes was attributed by the authors to ‘cultural differences difficult to quantify’ (Brook et al. 1988). In the mid-1990s, a comparison of prescribing across European countries, which arguably supported the same biomedical model, scientific principals and critical appraisal of the evidence, showed huge variations in the evidence base for the most prescribed medicines in the United Kingdom (UK), France, Germany and Italy (Garratini & Garratini 1993). In the UK the vast majority of medicines dispensed were supported by abundant research evidence, while in France and Italy about half the products prescribed lacked any rigorous evidence of efficacy. In countries effectively supporting the same paradigm, something else was influencing decisions.

These examples aren’t simply of esoteric interest. They illustrate a central theme that knowledge in medicine cannot be divorced from cultural context. Doctors are not immunized by their medical education from the aspirations, fears, prejudices and social commitment of the normal human condition. The point is important too because in the late 1990s we have seen the politicization of the assumed objectivity in science. The Secretary of State, describing the introduction of the National Institute for Clinical Excellence, promised the electorate that NICE would ‘provide the right evidence for the right treatment at the right time’ (Secretary of State for Health 1998). This is almost an unknowable proposition, the right person and the right time are retrospective accolades. Politics and science have become uneasy bedfellows.
Science, populations and people

The dramatic arrival of a model of evidence-based medicine in the early 1990s provided an uncomfortable reminder of the medical profession’s inglorious tradition of failing to apply good clinical evidence that was readily available. Developments in clinical evaluation, particularly refinements in meta-analysis, were presented as offering the potential to gain further insights into previously uncollated bodies of knowledge. Certainly, there are conspicuous examples of clinical practice where meta-analysis has dramatically clarified the evidence: the example of streptokinase referred to above is one of the most compelling examples. However, equally robust meta-analyses, for example of the value of anticoagulation in atrial fibrillation, attracted serious criticisms for extrapolating evidence derived from heterogeneous populations in randomized control trials to individuals living in open systems (Sweeney et al. 1995). The central dilemma was that while science in medicine dealt with generalities and populations, clinical practice centred on one-to-one consultations. Scientific information and sophisticated technology do not do the work of medical practice. Scientific knowledge constructs the means that are employed by human beings whose guiding principles are personal and moral as much as technical (Miles et al. 1999, 2000, 2001).

A sextet of paradoxes

We are thus left in contemporary medical practice with a set of paradoxes (see Table 1). The role of science is dominant, yet the hegemony of science and medicine is under threat. The scientific model, which we use, is based on linearity and informed by determinism, but it is clear that nature is non-linear and unpredictable. Thirdly, the application of science to clinical practice produces dichotomous evidence – either things are or are not significant – but we deal with conditions which fluctuate, emerge and differentiate at unpredictable rates. Fourthly, we use a reductionist model to try to explain systems. Here, the term system denotes the coming together of components, their interconnections and purpose. Thus a doctor’s surgery or consultations (microsystems) and the National Health Service (NHS) (macro-system) can be seen as systems. The problem for clinicians is the need to oscillate between the structure of that system and the pattern produced by the connections between its component parts.

While the medical profession has rightly espoused the model of evidence-based medicine, clinicians still struggle with the inescapable truth that individuals with an evidence-based diagnosis, receiving evidence-based treatment, will ultimately die of their evidence-based disease, or one of its long-term sequelae. Finally, doctors may be the field-workers of science and medicine but they cannot escape their own humanity. They constantly oscillate between a clinical and a human ‘gaze’ on the medical body (Good 1994; Evans 2001). If these paradoxes represent the weakness in the present model, how best can we proceed?

Complexity and healthcare

Six attributes of complex systems

Any new explanatory model for clinical practice cannot ignore the fundamental benefits of retaining the scientific approach, but it is clear that the scientific approach, while necessary, is in itself insufficient to act as the sole explanatory metaphor in clinical practice. Complexity offers a new field that has the potential to incorporate the scientific model with its reductionist linear approach with firmer understanding of non-linearity and unpredictability in complex systems. Complex systems have six key attributes.
They are unpredictable, sensitive to their initial starting conditions and irreversible with time. Non-linearity is fundamental: in complex systems small changes can have disproportionately large effects, and large changes unexpectedly small effects. Complex systems often demonstrate order at various levels within the system. Patterns can produce themselves at these different levels. Systems settle around particular states known as attractors, and levels of complexity can increase as the interaction of components becomes richer. This introduces the notion of emergent properties, that is properties or behaviour of a system that are evident only at higher levels of complexity. Emergent properties arise from the freedom with which the system’s components interact: the parts of a complex system can react to stimuli in quite different and essentially unpredictable ways, giving rise to behaviour that can be surprising, unexpected and creative. Complex systems can be viewed as multidimensional phase spaces, of which the observer is an inevitable contributing part.

Table 2 Six attributes of complex systems

| Complexity addresses unpredictability. |
| Complex systems are non-linear.       |
| They are sensitive to initial conditions. |
| Complex systems incorporate the researcher as part of the system. |
| Complex systems are understood by describing not just structure, but also the relations between structural components. |
| Complex systems demonstrate emergent properties or behaviour. |

An explanatory model based on complexity carries certain important advantages. It helps us understand how small changes can result in disproportionately large effects: consider the huge redistribution of funds in the United States of America (USA) into spinal injuries following the actor Christopher Reeves’ riding accident (Greenberg 1997) The opposite is also true. Retrospective analysis of the enormous effort put into publicizing and implementing the Health of the Nation programme confirmed it as a failure with little impact on the targets it sought to influence (Health of the Nation 1998). It reminds the observer that systems are inextricably linked to their history. Among others, Davies has warned of the dangers of comparing health systems when their historical contexts are different (Davies & Marshall 2000).

Table 3 Three eras of science in medicine

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<th>Normal science</th>
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<td>Based on logical positivism; there is a single universal condition that can be understood and validated; the paradigm of certainty.</td>
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<th>Post-modern science</th>
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<td>The process of knowing becomes important; truth is socially constructed, contingent, provisional, influenced by power and social context.</td>
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<th>Post-normal science</th>
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<td>Distinguishes complicated systems (like a jumbo jet) from complex adaptive systems (like a health service). Reductionism no longer a valuable tool for understanding the latter. The interaction of the parts of a system become crucial. Some systems are better understood by standing back and observing patterns of behaviour.</td>
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This analysis suggests that medicine has moved into a third new era (Table 3). The era of ‘normal’ science really began when Koch’s approach was accepted, and was epitomized by the explosion in technological medicine during the greater part of the 20th century. More recently, post-modernism has challenged the directives of science in medicine, arguing for the contingency of truth, and acknowledging social context, power and approximation in any version of ‘reality’. However, by the time Muir Gray’s article in the Lancet consolidated the position of post-modern medicine, things had already moved on (Muir Gray 1999). The era of post-normal medicine had arrived (Kernick & Sweeney 2001). Post-normal medicine does not seek to overturn modern medicine, but to compliment it by offering valuable insights into systems behaviour at every level. Post-normal medicine accepts that certain activities can be described by rules, when systems are highly structured. However, it also cautions that in many areas, analytical insight and prediction can only be obtained by stepping back and looking at relationships in the overall picture, rather than compressing
reality into a disciplinary framework. Better at times to be vaguely right rather than precisely wrong.

While this theory sounds esoteric, there is already evidence in medical literature of its application to clinical conditions, NHS organizations and primary care.

Applications of complexity to organizations, conditions and consultations

There is already abundant evidence of the application of complexity theory to commercial organizations. Wheatley (1999) has shown how Oticom, a Swedish company developing products for the deaf, re-fashioned its dynamics around the principle of self-organization. In complexity, self-organization describes the ability of a system to develop new structures, forms and relationships when pushed far from equilibrium. For this Swedish company, the response to pressures in the commercial market that were ‘pushing it far from equilibrium’ was to self-organize as it approached disequilibrium. For the employees, this meant redesigning their physical space and developing maximum flexible working conditions; they abandoned the office structure and indeed the normal furniture of their organization and ensured that their new flexibility allowed them to respond to the new conditions and the constant stream of commercial information that was affecting their company.

More recently, Peter Dick has described the National Health Service as a complex adaptive system (Dick 2001). Complex adaptive systems co-evolve with their environment and with each other. Complex adaptive systems have embedded hierarchies of learning systems that individuals, groups of individuals, organizations and groups of organizations develop, simply by learning what works and what doesn’t work. The complexity and the rapidity of change that face the National Health Services, Dick argues, are no longer well served from a conceptual framework based on the machine. The new diversity of the workforce and of its attitudes, of the expectations of patients and the public present new management problems that can only be solved by new organizational systems, attitudes and activities. In the USA the model of complex adaptive systems has influenced the plan to reform their healthcare system (Plesk 2001).

There is some literature describing the potential for complexity to help understand the workings of general practice. Miller et al. (1998) have described a primary care organization using complexity principles. Thus, the motivators or key values in the practice would be equivalent of the attractors in complexity theory. The practice itself could be seen as a complex adaptive system capable of self-organization and co-evolution. In the UK the move of general practices to Personal Medical Services (PMS) is an example of all organizational groups responding to changes in their environment, which, continuing the complexity metaphors, are destabilising or pushing their small systems further from equilibrium.

Finally, a new model for the consultation has been presented using complexity. Here, the consultation is represented by a multiple phase space in which five activities simultaneously take place in a system which interacts, feeds back, iterates and produces an emergent property, namely the outcome of the consultation. The phases include a biomedical phase (using the principles of evidence-based medicine), an economic phase (struggling with the issues of prescribing and rationing), a narrative phase (listening to and interpreting the patient’s story), a physical phase (facing up to the problems of nakedness and physical touching in the clinical examination) and finally the phase of philosophy (applying, however sub-consciously, philosophical principles of the preferred clinical system). These phases do not necessarily occur in that order: they can occur simultaneously, interact and co-evolve with the patient’s agenda to produce an outcome. They are to be considered as analogous to the phase spaces of mathematical topology (Sweeney 2001).

Table 4 shows the phases of the consultation based on complexity theory.

<table>
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<th>Table 4 Phases of the consultation based on complexity theory</th>
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<td>Biomedical phase</td>
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<td>Health economic phase</td>
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<td>Narrative phase</td>
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<tr>
<td>Physical phase</td>
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<td>Philosophical phase</td>
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Conclusion

In this article we have argued that there are inherent weaknesses in the scientific model of contemporary clinical practice. Exploring these weaknesses leads us to a sextet of paradoxes that require a new metaphor for knowledge and a new explanatory model for clinical practice. The network replaces the machine as the favoured explanatory metaphor. Principles of complexity, better elaborated in biology, physics and economics, constitute a more productive set of metaphors for post-normal medicine. Early examples of that application are beginning to show how this new set of metaphors for clinical practice can accommodate the tensions and paradoxes facing healthcare in a unitary model. Complexity theory offers a broader, potentially unifying, framework within which health care in the post-normal era can be understood.

References


