



**Centre for Health Economics
and Policy Analysis**

CHEPA WORKING PAPER SERIES

Paper 09-05

Complex Problems or Simple Solutions?

Enhancing Evidence-based Economics to Reflect Reality.

July 8, 2009

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The final version of this working paper will be published as a chapter in: Donaldson, Shemilt, Mugford, Vale & Marsh (eds) (2010) *Evidence-Based Decisions and Economics: Health care, social welfare, education and criminal justice*. Blackwell Publishing, Oxford.



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EVIDENCE-BASED HEALTH ECONOMICS: WHAT IS IT AND WHERE DOES IT COME FROM?

“For every complex problem there is a solution that is simple, neat and wrong.”

H.L. Mencken

As demands for new health care technologies¹ increase in environments of cost-containment, choices must be made about which interventions to fund. Similar problems arise in other sectors as decision-makers struggle to determine the most productive ways of deploying the resources available to them. The evidence-based approach has drawn on economics aimed at providing analytical frameworks to inform decision-making about effectiveness and efficiency of resource use. These frameworks increasingly form the basis for resource allocation decisions. For example, jurisdictions have adopted formal requirements and guidelines for economic evaluation in health care (1-4). Donaldson and colleagues (5) recognise the need for the application of evidence-based principles in the practice of economic evaluation. However, the importance of adopting evidence-based approaches in health economics is not confined to the economic evaluation of new technologies. Health economics encompasses a much broader range of influences and constraints on the production of health, illness and recovery in populations (6). Moreover, under an evidence-based approach, the methods and processes used, as well as the principles and assumptions on which they are based, must themselves be compatible with the concepts of economics (5).

The evidence-based approach to decision-making draws its foundations from clinical epidemiology. The focus of attention is establishing ‘evidence’ of effectiveness, i.e., providing information on whether a technology works or not (7). This has led to the development and use of research methods which devalue the complexity of social reality and exclude the consideration of context (8). As a result, the research answers questions about whether the intervention ‘works’ on average in the sample of the population selected for study. The addition of economics in the evidence-based approach has generally been constrained by the traditional confines of clinical epidemiology. Economic evaluations use health outcomes to compare the average additional (or incremental) costs and outcomes resulting from using a new intervention in place of the current treatment profile for a given patient population. In this way, the economic question remains ‘acontextual’ (6) and evaluations

¹ “Technology” refers to any health care intervention, programme or service, including, among other things: devices; drugs; instruments; genetic screening; equipment and facilities; genomics; medical and surgical procedures; professional practices; rehabilitation; alternative medicine; methods of organising services; and vaccination.

often overlook important aspects of patient relevant consequences as well as important modifying factors (9). The ‘science’ of controlling for ‘other factors’ undermines the ‘social’ nature of the problem. For research to be decision-informing, it must reflect decision-makers’ needs for information and knowledge about the problems they face and the contexts in which they are faced.

Current methods emerge from a scientific paradigm which is generally not compatible with either the economics discipline or the needs of decision-makers. The prevailing paradigm involves breaking down complex problems (e.g., what is the best way for this individual’s health problem to be addressed?) into smaller ones (e.g., what works best on average in a patient population with this health problem?) in order to analyze, understand and solve the problem by rational deduction. It assumes that associations between technologies and health outcomes demonstrated in ‘highly controlled environments’ (e.g., randomized controlled trials (RCTs), systematic reviews) are linear and causal in the real world, regardless of place, culture or other contextual circumstances (10). However, economic frameworks underpin the notion of the production of health, illness and recovery in populations (11;12). These frameworks identify the large range of health determinants and the complex pathways in which health is produced.

This working paper focuses attention on the importance of incorporating complexity in ‘evidence-based health economics’ or what might be more accurately described as applied economic evaluation. Complexity is increasingly identified as a priority for research in public health, health services research, and health policy (9;13-20). The concept of complexity refers to the difficulty associated with analysing and understanding a problem. So a complex problem may lie beyond the capacity of traditional analytic techniques (21). However complexity is not a dichotomous concept; that is, it is not simply a question of describing quantitatively the level of difficulty in a relative sense (where something is more or less complicated than something else). As an example, the Medical Research Council defines complex interventions as “interventions that contain several interacting components.” (22;23). Complexity science seeks to understand complex adaptive systems, i.e., systems characterized by a large number of agents interacting in open and dynamic environments, whose actions are interconnected among all agents in the system. The focus is on relations and interactions (i.e., interactive causality) and not on components and structures. Complexity emphasizes the importance of context, uncertainty, multiple objectives, multiple perspectives, and broader stakeholder involvement (9;24). This way of thinking focuses attention on explanation and understanding (why and how a technology works and under what conditions it works best) as opposed to simply whether an intervention works ‘on average’.

This working paper first describes the complexity in health and health care, and identifies the current approaches to dealing with complexity in evidence-based health economics. It then introduces the perspective of complexity as an alternative approach to conceptualising both the production of health, illness and recovery, and the system of planning, managing and delivering health care. This leads to a discussion of the implications of adopting a complexity perspective for the field of evidence-based health economics. Finally, the working paper concludes with the original contributions the complexity approach could make to evidence-based economics. Although this working paper focuses on health, the same principles would apply to education, social work, crime and criminal justice.

Reality and complexity in health care decision-making

Complexity in health and health care

Complexity in health embodies two elements: the production of health, illness and recovery and the system of planning, managing and delivering health care (a third element of complexity, the decision-making process lies beyond the scope of this working paper). The production of health, illness and recovery in populations occurs through multiple dynamic interacting systems. The human body is inherently complex while individuals are part of wider social systems made up of complex social relationships and institutions (20). Although the uncertainty associated with the outcomes and costs of health care interventions is already recognised in economic evaluation methodology, the influences on the expected distribution of outcomes and costs are limited to a small number of largely bio-medical markers (e.g., age and sex). This fails to acknowledge the wider range of social factors and their interactions that influence the distribution of outcomes. Without such careful consideration, the outcomes of health care at the individual level are much less predictable (20).

The system of planning, managing and delivering health care is embedded in the wider society and shaped by society's principles and values. The health care system involves a large variety of actors and activities interacting in diverse and complex settings that change over time (16). Social and professional networks have a key impact on health care professionals' behaviours, attitudes and practices (25). All of these factors influence the way problems are defined and analysed and solutions developed and delivered. As a result there is a system influence on the association between interventions and outcomes that lies beyond statistical variations. For example, social scientific and epidemiological researchers have observed that providers' diagnostic and management strategies are influenced by providers' personal and professional characteristics, patients' physical and psychosocial

characteristics, practice settings, and organisational and structural features of health care systems (26-31). All these factors are influential in determining costs (32) and health outcomes (31;33) of interventions. The implication for evidence-based health economics is that the efficiency of an intervention for identical patients might differ between the different providers. So what provider characteristics, either taken alone or when interacting with patient characteristics, are associated with greater levels of efficiency? Some might argue that these issues may be addressed by using modelling techniques or decision analysis tools; however, the next section will highlight the main limitations of the decision analytic modelling approach.

In addition to information generation, there is the problem of implementation that needs to recognise that health care decision-making spans different levels of the health care system: macro (policy), meso (administrative) and micro (clinical). Health care decisions often are interdependent both within and across levels of decisions. The evidence-based approach often assumes a linear, rational decision-making process (34-36). However decision-makers use a variety of processes, depending upon, inter alia, the nature of the problem (14;37). Health care decisions emerge from a complex, dynamic and often non-linear process, involving many stakeholders and the dynamic interactions among stakeholders have a significant impact on the outcome of a decision (14).

Complexity in evidence-based health economics

Systematic reviews have shown the limited influence of economic evaluations on health care decisions (38-43). Although, there is a trend towards greater use of economic evaluation, as jurisdictions introduce requirements for economic evaluations and guidelines for the methods and conduct of those evaluations at the macro level (39), the use of this 'economics evidence-base' at the meso and micro levels remains low. For example, in the National Health Service (NHS) in England and Wales, the National Institute for Health and Clinical Excellence (NICE) makes explicit use of economic evaluation for technology appraisal, but local decision-makers often follow different decision-making approaches (43-45).

Barriers to the use of economic evaluation in decision-making have been identified. As with any type of information, decision-makers may not have the time and other resources to understand the concepts on which the evaluations are based or the implications of the findings for the decisions they face. But even if the evaluations are understood by the decision-makers, the design of the economic evaluation may fail to reflect the nature of the decision-makers' problem. (39;43;46-49). Alternatively the methodology in many cases does not reflect the decision-makers' context of constrained

maximization (50-53). In other words, the simple questions being addressed by the economic evaluation are not the complex questions being faced by decision-makers. Patient groups are not homogeneous and neither are the providers who are responsible for their care. Moreover, decision-makers do not have an infinite stream of resources that can be used to implement 'cost-effective' interventions irrespective of their total additional cost but operate in a budget-constrained environment. The decision problem cannot be reduced to one of considering the incremental cost-effectiveness ratio (ICER) of different interventions and comparison with some arbitrary cost-effectiveness threshold.

Decision analytic modelling is being used in many economic evaluations to evaluate complex health care decisions under uncertainty (54-57). Proponents of this approach claim that it allows explicit representation of the 'real world' in a more simple and comprehensible structure (54). Mathematical and statistical models are often developed to synthesise information from different sources to determine the relative cost-effectiveness of alternative interventions (55;57-59). Modelling techniques are presented to: i) extrapolate primary data beyond a trial follow-up period; ii) link intermediate endpoints to final outcomes; iii) synthesise and compare interventions when no 'head-to-head' trials exist; iv) generalise from trial populations to specific target groups; v) generalise data gathered in one setting to other settings and countries; vi) investigate uncertainty in the knowledge base; vii) identify priorities and designs for future studies; and viii) provide more precise and reliable estimates of cost-effectiveness (54;55;58;60).

However current modelling techniques in economic evaluation are inadequate to address the many problems and decisions that decision-makers face. They suffer from a number of limitations, including structural assumptions made and the sources of data inputs (56;58;59). They depend on effectiveness estimates produced by systematic reviews and RCTs. Hence, although the model structure may initially reflect the decision-makers' needs, final models may be refined in accordance with the limitations of the data. In this way, the models risk being driven by the data rather than by the problem of the decision-makers. Many of these analyses are focused on narrowly defined populations, and driven by expertise and opinion (56). Many health care problems are complex, involving substantial uncertainty and ambiguity, and numerous interrelated systems, stakeholders and possible alternative solutions. Health care decisions are dynamic in the sense that their contexts change constantly, decisions are not independent, decisions have to be made in real time, and preferences do not remain constant over time. Most economic evaluation methods are presented as a series of neutral and decontextualised procedures, and thus as taking place in a social vacuum (9). Implicit assumptions about actors' interests and interactions ignore social reality. Understanding the preferences and behaviours of stakeholders requires serious attention to social reality (61;62). Because the nature of reality is relative and socially constructed, identical findings can lead to different interpretations.

Decision analysis cannot be used as a substitute for explanation and understanding of a problem. The method does not reduce uncertainty faced by the decision-makers (59). Modelling attempts to represent reality through use of mathematical and statistical relationships (60). For evidence-based health economics, the emphasis is on cause and effect (causal relationships). Applying mathematics to solve health care decision problems may grant a pseudoscientific aura of objectivity and truth around economic evaluation results (46). But decision analytic modelling may oversimplify complex decisions. Modelling techniques and decision analysis tools are based on the assumptions of the mechanistic paradigm. The response to the challenge of complex health problems has therefore been to emphasize more sophisticated analytical and technical tools (18), simply adding up the data of isolated parts without considering interactions between them (21). These ‘reduce and resolve’ approaches emphasize problem solving, prediction and control. The goal of the decision analysis is to find the optimum solution to a problem, assuming that predictions can be made. These research methods provide information on whether an intervention works or not, not on the conditions under which an intervention works best. This fails to reflect the complex pathways for the production of health, illness and recovery in populations, and the social contexts in which problems faced by decision-makers occur. Decisions based on the findings of the research generated under this narrow paradigm may be associated with reductions in efficiency of use of health care resources and increasing inequalities in health (63). This hints at the need and requirement for a broader scientific paradigm together with research methods to consider the complexity in the health field, and the contextual embeddedness of the decision-making process.

Changing research paradigms: reversing reductionist thinking to enhance problem solving

The term ‘evidence-based decision-making’ has been defined as “the systematic application of the best available evidence to the evaluation of options and to decision-making in clinical, management and policy settings” (64). The methods of the evidence-based approach are primarily epidemiological and statistical. The approach grades research findings according to the level of internal validity with results from systematic reviews and RCTs generally given precedence over information gathered from studies using other methods, such as observational studies, qualitative research, etc. (65;66). Although Coyle and colleagues (83) propose a hierarchy relating to the quality of data sources in economic models, while others are increasingly using Bayesian methods to combine information from heterogeneous sources, these developments remain within the same philosophical framework as the evidence-based approach, which has been criticized for promoting a positivist-empiricist conception of

the term 'evidence' (66). This reflects the underlying research paradigm on which the evidence-based approach is based.

Newtonian paradigm and the positivist perspective

The prevailing paradigm in evidence-based health economics is having problems both in its descriptive and prescriptive powers (62;67). Under the evidence-based approach, there is a predominant reliance on the Newtonian paradigm, which incorporates doctrines of reductionism and universality. The machine is the dominant metaphor of how the world works. Machines, although complicated, are characterised by high levels of control in the environment they operate and low levels of uncertainty in their performance. The Newtonian paradigm is based on reducing phenomena into smaller divisions, and considering parts in isolation in order to analyze and understand each part separately by rational deduction. The understanding of each part is aggregated to achieve an understanding of the whole phenomenon. These universal models of science are deterministic and objective, and consider researchers as independent observers. Relationships between causes (e.g., interventions) and effects are linear and causal in the real world, regardless of time, place or other context. A BMW car will perform the same whether it is in Canada or Mongolia and it will perform better than a Lada car in both settings.

This logical positivism however has extended to medical and biomedical sciences (68-70) with empirical observations (i.e., scientifically verifiable propositions) being the basis for evidentiary claims (66). The application of economic evaluation has been based on this form of positivism (67;71) with evidence-based health economics founded on empirical observations provided by experiments designed to maximise internal validity. Such empirical knowledge is considered more important, reliable and useful to decision-making than other kinds of knowledge and information (65). However, under contemporary theory of knowledge, all scientific knowledge is constructed and reflects the researchers' ontological and epistemological stances (i.e., their attitudes towards the nature of reality, truth, and knowledge), thus undermining the notion of a neutral observation (70;72). Decisions about research designs, implementation and interpretation are all value-influenced. For example, the choice of 5-year survival as an outcome measure may be made to ease the task of outcome measurement for researchers. But it implies that all survival durations less than 5 years are of equal value, and all survival durations exceeding 5 years are of equal value. But is anyone indifferent between surviving 5 years and surviving 10 years?

Complexity perspective

The perspective of complexity offers an alternative model for conceptualising the relationships between health care and health outcomes as complex processes composed of and operating within multiple dynamic and interacting systems.

Complex adaptive systems are characterized by large numbers of agents interacting and exchanging information in open and dynamic environments, and whose actions are interconnected among all agents in the system (13-16;73). The immune system and primary health care organisations are two examples of complex adaptive systems. The human body is composed of multiple inherently complex systems, including physiological, biochemical, molecular and psychological systems. Individuals are themselves nested in social systems (20;68). Complexity conceptualises a situation as a function of interacting and interdependent agents. Interactions occurring at a local level can have consequences for the whole system. At one level of analysis, an individual's emotional well-being will affect and be affected by changes at other levels (74). No single agent knows or controls the whole system so one cannot understand the system by examining individual components (13-16;73). The behaviour of an individual cannot be described simply by summing up the behavioural outcome of each constituent process (e.g., physiological, biochemical, etc.).

Interactions may be non-linear, meaning that small changes within, or external to, the system can lead to large changes to the system. Conversely, major changes can have little effect on overall system behaviour (13-16;73). For example, among type 2 diabetic patients with drug treatment failure, add-on drug therapy may have little effect on blood glucose levels, or cause a potentially dangerous reaction (75). There are often positive and negative feedback loops in the interactions (13-16;73). Complex adaptive systems are highly adaptive and resilient, attempting to balance seemingly opposing forces in ways that maintain system stability in response to perturbations (14;15). Feedback may help to maintain stability in the system or may lead to the amplification of perturbations moving the system away from its current state.

Modelling may accommodate aspects of non-linear relationships. However it fails to recognise the synergism of interactions (the whole is greater than the sum of its constituent parts), an emergent property of the complex system. For example, in palliative care, the patient's overall feeling of pain may be an emergent phenomenon, arising from the interactions of physical pain, emotional distress, anger, social isolation and other factors (76). So, for example, the effectiveness of an intervention will be influenced by these interactions.

Over time the overall behaviour of the system emerges through self-organisation (13-16;73) which arises under conditions of disequilibrium (14;73). Complex adaptive systems create or change their structures and behaviours, via the interactions of system elements, in order to meet the changing demands of internal and external environments (13-16;73). For example, variation in primary care practices is inevitable as each practice is a unique self-organized system that emerges through dynamic relationships and interactions among particular agents (e.g., family practitioners, office staff, patients and their families) with their unique preferences, interests, goals and priorities within the context of a particular community setting given specific regional and global influences (e.g., culture, regulations, health care systems) (77). In complex adaptive systems, individuals act and respond to the environment according to their own internal rules or mental models (14;15). For example, in their daily practice, primary care practitioners rarely directly accessed, appraised and made use of knowledge from research or other formal sources, relying instead on ‘mindlines’-“collectively reinforced, internalised, tacit guidelines” (78). Although there may be a lack of detailed predictability, complex adaptive systems can form specific types of behavioural patterns around ‘attractors’ and follow overall predictable paths (13-16;73). For example, professional traditions, values, and behavioural norms are attractors that determine and regulate medical practice (79). This suggests that a small number of rules may underpin the system behaviour (14).

Complex adaptive systems have fuzzy boundaries. System membership can change, and agents can be members of multiple systems at the same time (15). Complex adaptive systems are open systems characterized by agents interacting and exchanging information with others beyond the system boundaries. For example, individuals interact with other individuals in their social networks within social, cultural, economic and political systems which can influence behaviours and health outcomes (20). The systems, the agents within them, and their environments change and co-evolve through these interactions. Because complex adaptive systems are dependent on initial conditions, the system’s history is important to understand its current and future behaviour (13-16;73). For example, health care systems are embedded within and bounded by the broader (often country specific) societal contexts with which they co-evolve. Developments in contemporary health care systems cannot be understood without considering their historical context.

WHAT IT MEANS FOR THE FIELD OF EVIDENCE-BASED HEALTH ECONOMICS

Economics provides a set of principles for the exploration of efficiency in the use of scarce resources. However, the addition of economics in the evidence-based approach has been constrained by the traditional confines of clinical epidemiology – what has been described as ‘dolly economics’ (5). Thus, the questions about the efficient use of resources confronting decision-makers have remained acontextual (6). Nevertheless, the application of economics principles would suggest that the effectiveness and efficiency of a technology will depend on the preferences and circumstances of health care patients and providers as well as on the various contexts in which these actors operate (7).

Grossman’s model of the demand for health (11) and Evans and Stoddart’s framework for the determinants of health (12) are two economic approaches that accommodate the complexities and contexts discussed above. Both models particularly underpin the complex pathways to health, illness and recovery involving interactions among a large range of health determinants. The relation between intervention and health status is captured in the health production function. Grossman showed that social, economic, and environmental factors constitute inputs of the health production function (11). Evans and Stoddart proposed a dynamic framework for considering the factors that influence health in a community. The framework adopts a systems approach in which health outcomes are the products of complex dynamic interactions between health determinants. The framework’s feedback loops link the different components of health determinants (e.g., social environments, genetic endowments, etc.). These interactions are potentially as important as the actions of any single factor. What is not yet available is an understanding of how and why the interactions occur. This framework helps to: (i) refocus health improvement efforts towards the broad social determinants of health; (ii) emphasize the importance of considering both biological and behavioural responses to physical and social environments; (iii) underscore the interdisciplinarity of health production; and (iv) recognise and make explicit the possible trade-offs involved between different determinants of health (e.g., health care versus social support) (12). This multidimensional perspective reinforces the value of systems thinking and holistic approach to health, illness and recovery.

Under complexity thinking, the emphasis is on relations and networks between different determinants (interactive causality). This recognises that systems and individuals within them do not exist in isolation but interact and co-evolve with other systems. This does not imply that problems are too complex to be tackled but instead argues that problems should be approached differently.

For example, smoking represents a complex health problem; one which could be addressed by the application of complexity thinking. Individual behaviour is influenced by individual characteristics

(e.g., age, gender, occupation, socioeconomic status). But individuals are embedded in networks of relationships that have a significant impact on their beliefs, behaviours and choices (e.g., smoking in the family or among friends or colleagues). Environments in which individuals live may also influence behaviour (e.g., smoking behaviour may be facilitated or impeded by the tobacco tax policies and advertising laws). But these levels of influence need not be independent or separate. The relationship between gender and smoking might depend on family context and/or political environment. We might therefore expect that the effectiveness of smoking cessation interventions to be highly dependent on local and wider contexts. So the poor economic circumstances of unemployed single mothers might be an important part of exploring the effectiveness of particular interventions among women (e.g., smoking cessation programmes, drugs), not simply statistical 'noise' to be controlled for in intervention studies (7).

Similarly the interaction between the health professional and the individual may also affect smoking behaviour. Providers' choices of smoking cessation interventions are influenced by their personal and professional characteristics as well as the patients' physical and psychosocial characteristics and the contexts in which they work (e.g., practice organisation, remuneration policies, etc.). Hence what works best for a particular patient may depend on these supply-side factors and the efficient treatment for a given patient (or group of patients) may vary across different provider types and settings.

The proposed perspective would suggest consideration of a wide array of 'policy' targets. A better understanding of the 'smoking issue' would require a multidimensional approach focusing on various stakeholders' involvement. This would contribute to develop awareness of the issue of transdisciplinarity in evidence-based health economics. The transdisciplinary perspective is collaborative and inclusive, being open to incorporation of multiple perspectives, values, approaches and experiences in defining and solving complex problems (80). It allows creativity and innovative thinking in dealing with the challenges of producing and delivering contextually relevant knowledge. Because of uncertainty and ambiguity of complex health problems, one 'best' solution does not exist. For economic evaluation, this means creatively expanding the range of possible solutions, with a view to understanding why and how a technology works and under what conditions it works best as opposed to simply whether it works 'on average'.

The perspective suggests that, through observation over time, it may be possible to identify what factors were important in bringing about a change in a system. It points to the existence of recurring patterns and suggests that a small number of rules may underpin the system behaviour (14). Explanation and understanding is achieved through a contextual approach (observation or narrative

analysis) to study the dynamics of interactions and search for order in patterns over time, focusing on non-linear effects, unintended consequences, emergent and holistic properties, self-organisation and historical development of the system. Various analytical approaches to complexity science are being used or developed in many fields of research (13;61;81;82). The division of the determinants of behaviour into multiple levels would be of fundamental importance in this new model. For evidence-based health economics, viewing systems through multi-level models could accommodate the neoclassical economic framework while recognising that all action is socially situated and cannot be explained by individual motives alone (17).

Lastly, complexity thinking does not reject the Newtonian framework of modern science or its claim to reliable knowledge altogether. Rather it sees reductionist thinking in the context of a much broader framework. For simple problems where there is a high degree of certainty and agreement among stakeholders, reductionism and rational analysis are appropriate. In such situations, systems are close to equilibrium, displaying less emergent properties (14;15;17). However, few situations in health and health care have high levels of certainty and agreement. Systems change and evolve constantly and remain far from equilibrium (17). As problems become more complex with insufficient certainty and agreement, complexity thinking is more appropriate. For evidence-based health economics, this would alert researchers to the importance of considering the system as a whole and selecting the approach best suited to the complexities of the problem.

CONCLUDING REMARKS

Current economic evaluation approaches depart from the intellectual tradition of economics, and hence they provide simple solutions (e.g., ICERs) to inherently complex problems (52;53). A complex set of priorities, responsibilities, objectives, values and preferences drives national and local debates about health care resource allocation. In order to be useful for health care decision-making, the theory and practice of economic evaluation must expand to include different types of knowledge and methodologies, and must adapt to the practical realities and needs of patients, decision-makers, health care systems, and ultimately society.

New paradigms that incorporate a dynamic and emergent view of the world must replace reductionist approaches to health care. Complexity thinking offers an alternative model for conceptualising both (i) the production of health, illness and recovery in populations, and (ii) the system of planning, managing and delivering health care, as expressions of parts of complex, dynamics and interacting systems. It suggests that many types of knowledge are valid and useful for evaluation, not

just knowledge produced by traditional methodological approaches. For economic evaluation, this involves the acknowledgement of complex, interdependent relationships and broader contextual factors (24). An approach based on complexity, uncertainty and a plurality of legitimate perspectives, values, and interests would more firmly ground economic evaluations in the economic discipline as well as with the experiences of people engaging with health care systems (67). It provides a means of informing policy aimed at a more equitable and efficient use of health care resources because allocation decisions would be based on improved knowledge and understanding of health problems. Complexity thinking would thus expand the scope of economic evaluation, and increase its real world applicability (9). What is at issue is whether evidence-based health economics is ready to rise to the challenge.

REFERENCES

1. American Managed Care Pharmacy (AMCP). The AMCP Format for formulary submissions. A format for submission of clinical and economic data in support of formulary consideration by health care systems in the United States (version 2.1). Alexandria, VA: Foundation for Managed Care Pharmacy; 2005.
2. Canadian Agency for Drugs and Technologies in Health (CADTH). Guidelines for the economic evaluation of health technologies: Canada. 3rd ed. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2006.
3. Commonwealth Department of Health and Aging (CDHA). Guidelines for the pharmaceutical industry on preparation of submissions to the Pharmaceutical Benefits Advisory Committee, including major submissions involving economic analyses. Canberra: Commonwealth of Australia; 2002.
4. National Institute for Health and Clinical Excellence (NICE). Guide to the methods of technology appraisal. London: National Institute for Health and Clinical Excellence; 2008.
5. Donaldson C, Mugford M, Vale L, editors. Evidence-based health economics: from effectiveness to efficiency in systematic review. London: BMJ Books; 2002.
6. Birch S, Gafni A. Evidence-based health economics. Answers in search of questions? In: Kristiansen IS, Mooney G, editors. Evidence-based medicine in its place. Adington, Oxfordshire: Routledge; 2004:50-61.
7. Birch S. As a matter of fact: evidence-based decision-making unplugged. *Health Econ* 1997;6(6):547-59.
8. Carr-Hill R. Welcome? To the brave new world of evidence based medicine. *Soc Sci Med* 1995;41(11):1467-8.
9. Lessard C. Complexity and reflexivity: two important issues for economic evaluation in health care. *Soc Sci Med* 2007;64(8):1754-65.
10. Biswas R, Umakanth S, Strumberg J, Martin CM, Hande M, Nagra JS. The process of evidence-based medicine and the search for meaning. *J Eval Clin Pract* 2007;13(4):529-32.

11. Grossman M. On the concept of health capital and the demand for health. *J Polit Econ* 1972;80(2):223-55.
12. Evans RG, Stoddart GL. Producing health, consuming health care. *Soc Sci Med* 1990;31(12):1347-63.
13. Holt TA, editor. *Complexity for clinicians*. Abingdon, Oxfordshire: Radcliffe Medical Press; 2004.
14. Kernick D, editor. *Complexity and healthcare organisation: a view from the street*. Abingdon, Oxfordshire: Radcliffe Medical Press; 2004.
15. Plsek PE, Greenhalgh T. Complexity science: the challenge of complexity in health care. *BMJ* 2001;323(7313):625-8.
16. Sweeney K, Griffiths F, editors. *Complexity and healthcare: an introduction*. Abingdon, Oxfordshire: Radcliffe Medical Press; 2002.
17. Kernick D. Health economics and insights from complexity theory. In: Kernick D, editor. *Getting health economics into practice*. Adington, Oxfordshire: Routledge; 2002:307-18.
18. Sanderson I. Complexity, 'practical rationality' and evidence-based policy making. *Policy Polit* 2006;34(1):115-32.
19. Shiell A, Hawe P, Gold L. Complex interventions or complex systems? Implications for health economic evaluations. *BMJ* 2008;336(7656):1281-3.
20. Wilson T, Holt T, Greenhalgh T. Complexity science: complexity and clinical care. *BMJ* 2001;323(7314):685-8.
21. Standish RK. Concept and definition of complexity. In: Yang A, Shan Y, editors. *Intelligent Complex Adaptive Systems*. Hershey, PA: IGI Publishing; 2008:105-24.
22. Medical Research Council (MRC). *Developing and evaluating complex interventions: a new guidance*. London: Medical Research Council; 2008.
23. Craig P, Dieppe P, Macintyre S, Mitchie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;337;a1635.
24. Healy SA. Changing science and ensuring our future. *Futures* 1997;29(6):505-17.

25. Ferlie E, Fitzgerald L, Wood M. Getting evidence into clinical practice: an organisational behaviour perspective. *J Health Serv Res Policy* 2000;5(2):96-102.
26. Aber S, McKinlay J, Adams A, Marceau L, Link C, O'Donnell A. Patient characteristics and inequalities in doctors' diagnostic and management strategies relating to CHD; a video-simulation experiment. *Soc Sci Med* 2006;62(1):103-15.
27. Landon BE, Reschovsky J, Reed M, Blumental D. Personal, organizational, and market level influences on physicians' practice patterns: results of a national survey of primary care physicians. *Med Care* 2001;39(8):889-905.
28. Lutfey KE, Campbell SM, Renfrew MR, Marceau LD, Roland M, McKinlay JB. How patient characteristics relevant for physicians' clinical decision making in diabetes? An analysis of qualitative results from a cross-national factorial experiment. *Soc Sci Med* 2008;67(9):1391-9.
29. McKinlay J, Link C, Arber S, Marceau L, O'Donnell A, Adams A. How do doctors in different countries manage the same patient? Results of a factorial experiment. *Health Serv Res* 2006;41(6):2182-2200.
30. Von dem Knesebeck O, Bönnte M, Siegrist J, Marceau L, Link C, Arber S, Adams A, McKinlay J. Country differences in the diagnosis and management of coronary heart disease – a comparison between the US, the UK and Germany. *BMC Health Serv Res* 2008;8:198.
31. Harris MI. Health care and health status and outcomes for patients with type 2 diabetes. *Diabetes Care* 2000;23(6):754-8.
32. Watkins C, Harvey I, Carthy P, Moore L, Robinson E, Brawn R. Attitudes and behaviour of general practitioners and their prescribing costs: a national cross sectional survey. *Qual Saf Health Care* 2003;12(1):29-34.
33. Rubin RR, Peyrot M, Siminerio LM. Health care and patient-reported outcomes: results of the cross-national Diabetes Attitudes, Wishes and Needs (DAWN) study. *Diabetes Care* 2006;29(6):1249-55.
34. Coyle D. Increasing the impact of economic evaluations on health-care decision-making. Discussion paper 108. York: Centre for Health Economics; 1993.

35. Haines A, Donald A, editors. Getting research findings into practice. 2nd ed. London: BMJ Publishing Group; 2004.
36. Straus SE, Richardson WS, Glasziou P, Haynes RB. Evidence-based medicine: how to practice and teach EBM. 3rd ed. Edinburgh: Churchill Livingstone; 2005.
37. Greenhalgh T. Intuition and evidence-uneasy bedfellows? *Br J Gen Pract* 2002;52(478):395-400.
38. Drummond M, Brown R, Fendrick AM, Fullerton P, Neumann P, Taylor R, et al. Use of pharmacoeconomics information-Report of the ISPOR Task Force on Use of Pharmacoeconomic/Health Economic Information in Health-Care Decision Making. *Value Health* 2003;6(4):407-16.
39. Eddama O, Coast J. A systematic review of the use of economic evaluation in local decision-making. *Health Policy* 2008;86(2-3):129-41.
40. Späth HM, Allenet B, Carrère MO. L'utilisation de l'information économique dans le secteur de la santé : le choix des médicaments à inclure dans les livrets thérapeutiques hospitaliers. *Journal d'Economie Médicale* 2000;18(3-4):147-61.
41. van Velden ME, Severens JL, Novak A. Economic evaluations of health care programmes and decision making: the influence of economic evaluations on different healthcare decision-making levels. *Pharmacoeconomics* 2005;23(11):1075-82.
42. Walkom E, Robertson J, Newby D, Pillay T. The role of pharmacoeconomics in formulary decision-making. *Formulary* 2006;41(8):374-86.
43. Williams I, McIver S, Moore D, Bryan S. The use of economic evaluations in NHS decision-making: a review and empirical investigation. *Health Technol Assess* 2008;12(7).
44. Buxton MJ. Economic evaluation and decision making in the UK. *Pharmacoeconomics* 2006;24(11):1133-42.
45. Eddama O, Coast J. Use of economic evaluation in local health care decision-making in England: a qualitative investigation. *Health Policy* 2009;89(3):261-70.
46. Coast J. Is economic evaluation in touch with society's health values? *BMJ* 2004;329(7476):1233-6.

47. Menzel P, Gold MR, Nord E, Pinto-Prades JL, Richardson J, Ubel P. Toward a broader view of values in cost-effectiveness analysis of health. *Hastings Cent Rep* 1999;29(3):7-15.
48. Nord E, Pinto JL, Richardson J, Menzel P, Ubel P. Incorporating societal concerns for fairness in numerical valuations of health programmes. *Health Economics* 1999;8(1):25-39.
49. Stolk EA, van Donselaar G, Brouwer WBF, Busschbach JJV. Reconciliation of economic concerns and health policy. Illustration of an equity adjustment procedure using proportional shortfall. *Pharmacoeconomics* 2004;22(17):1097-107.
50. Birch S, Gafni A. Information created to evade reality (ICER): things we should not look to for answers. *Pharmacoeconomics* 2006;24(11):1121-31.
51. Birch S, Gafni A. The biggest bang for the buck or bigger bucks for the bang: the fallacy of the cost-effectiveness threshold. *J Health Serv Res Pol* 2006b;11(1):46-51.
52. Gafni A, Birch S. Inclusion of drugs in provincial drug benefit programs: should “reasonable decision” lead to uncontrolled growth in expenditures? *CMAJ* 2003;168(7):849-51.
53. Gafni A, Birch S. Incremental cost-effectiveness ratios (ICERs): the silence of the lambda. *Soc Sci Med* 2006;62(9):2091-2100.
54. Buxton MJ, Drummond MF, Van Hout BA, Prince RL, Sheldon TA, Szucs T, Vray M. Modelling in economic evaluation: an unavoidable fact of life. *Health Econ* 1997;6(3):221-7.
55. Soto J. Health economic evaluations using decision analytic modeling. Principles and practices- utilization of a checklist to their development and appraisal. *Int J Technol Assess Health Care* 2002;18(1):94-111.
56. Lee RC, Donaldson C, Cook LS. The need for evolution in healthcare decision modeling. *Med Care* 2003;41(9):1024-33.
57. Philips Z, Ginnelly L, Sculpher M, Claxton K, Golder S, Riemsma R, et al. Review of guidelines for good practice in decision-analytic modelling in health technology assessment. *Health Technol Assess* 2004;8(36).
58. Cooper NJ, Coyle D, Abrams K, Mugford M, Sutton A. Use of evidence in decision models: an appraisal of health technology assessments in the UK since 1997. *J Health Serv Res Pol* 2005;10(4):245-50.

59. Sheldon TA. Problems of using modelling in the economic evaluation of health care. *Health Econ* 1996;5(1):1-11.
60. Brennan A, Akehurst, R. Modelling in health economic evaluation. What is its place? What is its value? *Pharmacoeconomics* 2006;24(11):1043-53.
61. Bourdieu P. *The social structures of the economy*. Oxford: Polity Press; 2005.
62. Small N, Mannion R. A hermeneutic science: health economics and Habermas. *J Health Organ Manag* 2005;19(3):219-35.
63. Hall J, Birch S, Haas M. Creating health gains or widening gaps: The role of health outcomes. *Health Promot J Austr* 1996;6(1):4-6.
64. National Forum on Health. *Canada health action: Building on the legacy – Final Report Volume II: Creating a culture of evidence-based decision making* [Web document]. Ottawa: Health Canada; 1997.
65. Cohen AM, Stavri PZ, Hersh WR. A categorization and analysis of the criticisms of evidence-based medicine. *Int J Med Inform* 2004;73(1):35-43.
66. Goldenberg MJ. On evidence and evidence-based medicine: lessons from the philosophy of science. *Soc Sci Med* 2006;62(11):2621-32.
67. Mannion R, Small N. Postmodern health economics. *Health Care Analysis* 1999;7(3):255-72.
68. Herman J. Beyond positivism: a metaphysical basis for clinical practice? *Med Hypotheses* 1992;39(1):63-6.
69. Kneebone R. Total internal reflection: an essay on paradigms. *Med Educ* 2002;36(6):514-8.
70. Malterud K. Reflexivity and metapositions: strategies for appraisal of clinical evidence. *J Eval Clin Pract* 2002;8(2):121-6.
71. Richardson J, McKie J. Empiricism, ethics and orthodox economic theory: what is the appropriate basis for decision-making in the health sector? *Soc Sci Med* 2005;60(2):265-75.
72. Latour B, Woolgar S. *Laboratory life: the construction of scientific facts*. Princeton: Princeton University Press; 1986.

73. Cilliers P. Complexity and postmodernism: understanding complex systems. London: Routledge; 1998.
74. Frijda NH. The laws of emotions. *Am Psychol* 1988;43(5):349-58.
75. Vinik A. Advancing therapy in type 2 diabetes mellitus with early, comprehensive progression from oral agents to insulin therapy. *Clin Ther* 2007;29(6, part 1):1236-57.
76. Munday DF, Johnson SA, Griffiths FE. Complexity theory and palliative care. *Palliat Med* 2003;17(4):308-9.
77. Miller WL, McDaniel RR Jr, Crabtree BF, Stange KC. Practice jazz: Understanding variation in family practices using complexity science. *J Fam Pract* 2001;50(10):872-8.
78. Gabbay J, le May A. Evidence based guidelines or collectively constructed "mindlines?" Ethnographic study of knowledge management in primary care. *BMJ* 2004;329(7473):1013.
79. Freidson E. Profession of medicine: a study of sociology of applied knowledge. Chicago: The University of Chicago Press: 1988.
80. Albrecht G, Freeman S, Higginbotham N. Complexity and human health: the case for a transdisciplinary paradigm. *Cult Med Psychiatry* 1998;22(1):55-92.
81. Moss S. Policy analysis from first principles. *Proc Natl Acad Sci USA* 2002;99(suppl 3):7267-74.
82. Seely AJ, Macklem PT. Complex systems and the technology of variability analysis. *Crit Care* 2004;8(6):R367-84.
83. Coyle D. Use of evidence in economic models. In: Donaldson C, Shemilt I, Mugford M, Vale L, Marsh K, editors. Evidence-based decisions and economics: Health care, social welfare, education and criminal justice. Oxford: Blackwell Publishing; Forthcoming 2010.

WORD COUNT

Main text: 5,061 words
References: 1,862 words
Full word count: 6,937 words

Tables: 204 words

Summary points

- The production of health, illness and recovery in populations is a complex process that embodies a wide range of influences and interactions between influences
 - Economic evaluation approaches oversimplify the decision-makers' problem by adopting inappropriate research paradigm that ignores the contexts in which health problems are experienced and health care is delivered
 - Complexity theory provides a basis for studying problems in their contexts and addressing questions about the circumstances under which interventions work best and what works in specific circumstances
 - Broad-based economic models already exist with the capacity to incorporate complexity
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Implications for practice

- Efficiency of health care interventions needs to be evaluated in the contexts in which problems are experienced
 - Outcomes will depend on the interactions of patient and provider characteristics and settings
 - Economic models should inform as opposed to be constrained by clinical epidemiology approaches
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Implications for research

- Broad economic models of health production should provide the basis for economic analyses
 - The focus of analyses should be the health problem and its distribution as opposed to an intervention and its consequences
 - More attention should be given to analysing the variations in the population distributions of costs and effects across different interventions
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