

AS A MATTER OF FACT: EVIDENCE-BASED DECISION-MAKING UNPLUGGED

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SUMMARY

The rationale of evidence-based decision-making is to inform the decision-making process with information relevant to the decisions being taken. In this paper the models of research and analytical approaches used to generate the evidence are shown to be generally not 'decision-informing'. The researcher's interest in health care interventions has led to the development and use of designs which strip the research of contextual issues and hence represent a major departure from both the underlying notions of the complex pathways to health and the empirical findings concerning the importance of population context. In this way, the evidence-based approach, dominated by a focus on health outcomes from health care interventions, overlooks the notion that society is not a 'level playing field'. Decisions based on research 'evidence' of this type risk redeploying resources inefficiently and in ways which systematically favour those groups with favourable 'prospects for health' (or non-health care determinants of health), and the conditions that those groups in society tend to suffer from, and away from those groups with less favourable prospects for health. Existing approaches to informing the decision-making process could be enhanced by broadening the scope of the research to incorporate relevant determinants of health in both the specification of the problem and the selection of methods of analysis that enable us to explore the complex pathways to health. © 1997 by John Wiley & Sons, Ltd.

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INTRODUCTION

Changes in the demographic profiles of populations and the expectations of health care systems by those populations together with developments in health care technologies impose increasing demands on health care resources. Although spending more money on health care was never a solution to this problem, the fiscal climate of the 1990s means it is no longer even an option.

Instead, decision-makers at all levels of the health care system are now challenged to deploy the health-care resources at their disposal in ways which do most good and are encouraged to base their decisions on the evidence of outcomes produced by alternative uses of resources.

Evidence-based approaches to decision-making have emerged as ways of improving the performance of health care providers¹ and health care systems.² Some proponents argue that at the individual patient level, physicians have always

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sought to base their decisions and actions on the best possible evidence.³ Others have shown that evidence alone is insufficient to change physician behaviour,⁴ and have suggested that evidence of effectiveness of interventions can be used in performance appraisal of individual physicians and also for determining at the system level which services physicians will be reimbursed for providing.⁵ Nonetheless, the normative position remains the same; decision-making in health care *should* be based on the research findings concerning the effectiveness of interventions.

Proponents of the evidence-based approach emphasize that the application of research findings to decision-making is a matter of judgement and not a recipe for 'cookbook' practice. 'External clinical evidence can inform, but can never replace, individual clinical expertise that decides whether the external evidence applies to the individual patient at all, and if so, how it should be integrated into a clinical decision'.⁶ Despite these exhortations, decision-making processes are becoming increasingly dominated by matters of research evidence in ways which restrict or prevent consideration being given to applicability of the 'external evidence'. For example, at the level of health care programmes, evidence-based approaches were used to inform a process for identifying services to be 'delisted' under the publicly funded Ontario Health Insurance Plan.⁷ Similarly evidence-based approaches underly the procedures used for admission to drug formularies in Australia and Canada.^{8,9} In these cases, decisions are taken centrally, which prevents providers considering the applicability of the evidence to the presenting problem. At the individual patient level, evidence-based clinical guidelines risk becoming clinical rules where providers of care are held increasingly accountable for their decisions.

Although the rationale of the evidence-based approach is to inform decision-making, in this paper the models of research and analytical approaches used to generate the evidence are shown to be generally not 'decision-informing'. In the next section, the contrasting frameworks of the researcher and the decision-maker are identified, showing that although both frameworks are 'problem-based', they are essentially 'based' on different problems. In particular, the researcher's interest in health care interventions has led to the development and use of designs which strip the research of contextual issues and hence represent

a major departure from both the underlying notions of the complex pathways to health and the empirical findings concerning the importance of population context. In the subsequent section the implications of this service-focused approach underlying evidence-based decision-making are considered.

SOCIAL CONTEXT AND HEALTH CHANGE

The basic premise of evidence-based decision-making is that the decision-making process should draw upon the best available evidence from research. The proponents of evidence-based approaches emphasize the importance of assessing both the quality of the evidence generated by research studies in addition to the appropriateness of the evidence for the problem being addressed.⁶ Nevertheless, there is an underlying premise that the findings produced by high-quality studies ought to be useful to, and hence used by, decision-makers. To this end, various approaches have been proposed or developed for the timely dissemination of research to decision-makers and the explicit accommodation of the research findings into the decision-making processes at both the individual patient level and the programme evaluation level.¹⁰⁻¹³ In this way, the evidence-based approach is 'research-led', with researchers providing information that decision makers 'should' use.

This underlying rationale assumes correspondence between the interests of the researcher that gave rise to the research, and the needs of the decision-maker. Although both the research activity and the decision-making process are both 'problem-based', the problems addressed in the research are often somewhat different from the problems faced by the decision maker. The research environment is characterized by interest in the relationship between exposure to a particular intervention and responsiveness in terms of the health status change among individuals with a particular clinical condition. Other possible explanations of patterns observed between exposure and outcome can confound or confuse the estimation of the intervention-outcome relationship. Researchers develop criteria for excluding particular types of individuals from the study sample to reduce 'noise' ('confusion') and randomize the

sample between the intervention and control groups to reduce bias ('confounding'). These procedures are used as means of reducing the probability of the observed changes in health of the study sample being explained by other factors (or determinants of change).

In this way, the 'problem' to the researcher is the health condition which defines the population to be studied. The focus of attention is the intervention and the objective for the researcher is to estimate the relationship between exposure to the intervention and the changes in health status among the study population. The analytical strategy followed is to exclude, as far as possible, all 'confounding' explanations of health changes in the study population. The research findings provide information about the effectiveness of the intervention on average among those individuals meeting the inclusion and exclusion criteria (the study sample) under the prevailing study circumstances. The evidence derived from the results of the study is then based on judgements about the probability of confounding explanations of the observed changes in health status. These judgements tend to be made by those performing the research in the context of conclusions drawn from the study.

An interesting feature of this model is the absence of explicit interest in other determinants of health. Within the context of a broad determinants of health model (see Fig. 1) the research goal is to estimate the link between health care and health. Both the study sample and the population from which that sample is selected are homogeneous with respect to the condition. It is not that the other determinants of health are ignored or overlooked. On the contrary, the potential heterogeneity of the study sample with respect to other health determinants, and hence possible causes of the condition, lies behind the importance of exclusion criteria and the randomization of subjects between intervention and control groups. This does not remove heterogeneity with respect to health determinants from the study sample, but randomization of the sample between intervention and control groups attempts to ensure that the two *groups* are homogeneous with respect to the mix of individuals' health determinants (i.e. the distribution of education levels, income levels, employment status, etc., within the two groups) and hence the mix of underlying possible causes of the condition.

Although the research model is problem-based,

the nature of the problem being addressed is somewhat different from the problem faced by the decision-maker at the level of either the individual patient or the health care programme. In particular, the decision-maker requires information about what might reasonably be expected to happen to the presenting individual (patient) or population group under the prevailing circumstances (i.e. the prevailing context). The decision-maker is therefore operating in the real world characterized by Fig. 1 as opposed to being confined to the single pathway between health care and health within that world. For example, among individuals with a particular condition, each has their own context or combination of health determinants (i.e. individual level characteristics in addition to characteristics of the physical, economic, social and cultural environments in which they live). Each individual's context represents potential contributing causes of the condition and hence potential confounding effects on the 'health care–health' relationship.

In this way, the problem facing the decision-maker, whether at the individual patient level or the health care programme level, is the health condition of interest in the prevailing context. The focus of attention is the expected response of the health condition to the intervention being considered in the particular individual or population group. The decision-maker therefore requires information on the relationship between exposure to different interventions and the changes in outcome for individuals or groups with similar contexts. Decision-informing research requires an analytical strategy that accommodates explanations that 'confound' estimates of the intervention's effectiveness *per se* and hence generates information about the relationship between health determinants and the intervention's outcomes among all individuals exposed to the intervention (i.e., the arrow leading from the determinants of health to the health care–health link in Fig. 1).

In practice, bureaucratic and institutional restrictions have tended to constrain health policy makers' responsibility to issues of health care (some might argue, even more narrowly, illness care) and the management of resources allocated to health care. However, the separation of the responsibility of health care from other health determinants has spread beyond responsibilities whereby the determinants are also treated as separable entities in estimating the relationship

between health (illness) care interventions and health outcomes. As a consequence, the context in which 'evidence' is both generated by the researcher and sought by the decision maker (does the procedure 'work?') differs from the context of the presenting problem.

In order that research be decision-informing, as distinct from simply addressing the perceived needs of the decision-maker, it needs to be designed in ways which address the prevailing problem. Problems are exogenous to the decision-maker and cannot be made to fit the research

evidence. To be decision-informing, the research must be informed by the underlying problem of the decision-maker, whether that be at the individual patient or health care policy level.

The concepts of multiple determinants of health and complex pathways to health¹⁴ have important implications for estimating the effectiveness of health care interventions and for interpreting such estimates for the purposes of decision-making at either the individual patient or health care programme level. In particular:

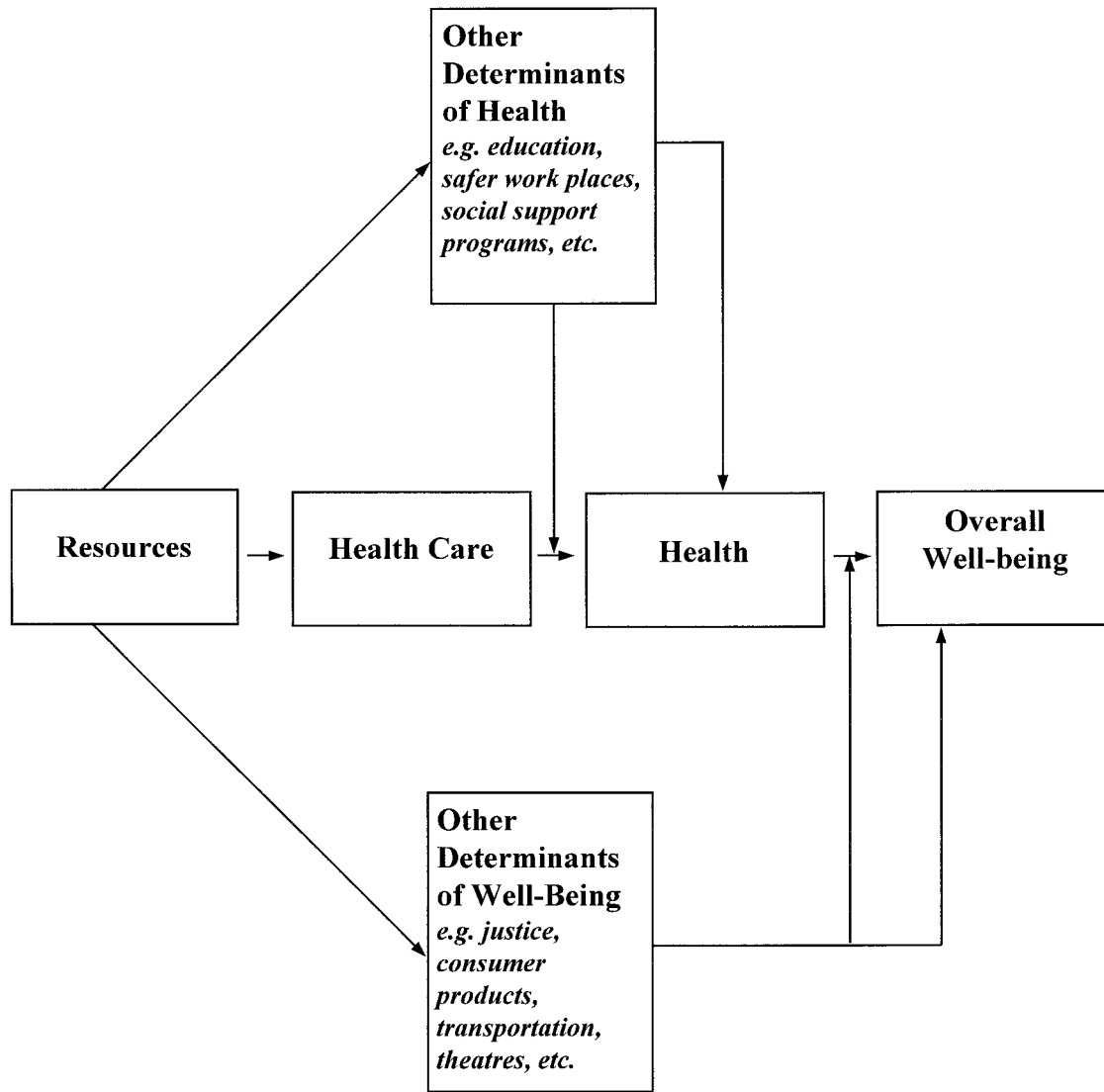


Figure 1. A model of determinants of health.

1. Among any group of subjects with a common health state or condition the causes of that condition may vary, i.e., different mixes of health determinants may be associated with the same health status.
2. The mix of determinants may be systematically related to various social, cultural, ethnic or economic variables, i.e., there may be systematic variations in the causes of conditions.
3. In the presence of systematic differences in the causes of conditions, we might expect systematic variation in the effectiveness of particular interventions aimed at changing conditions, i.e., social determinants of health may influence the effectiveness of health care interventions.

Consider the analogy of the gasoline in a car. The consumer is provided with research showing that higher grade gasoline improves the performance of cars. However, for cars with fuel ignition or carburettor problems the amount of performance improvement from the use of higher grade gasoline will be less. The research presented to the consumer is based on well maintained vehicles and hence excludes other possible determinants of a car's performance. As a consequence, the effectiveness of a particular intervention may be conditional on, or vary according to, the prevailing levels and mix of other determinants.

Over 10 years ago, Syme¹⁵ commented on the tendency for research designs to conceal potentially important determinants of health change:

'Everyone is aware of the fact that patterned irregularities in disease rates exist for socioeconomic status, race, sex, marital status, religious groups, geographic areas, and so on... most epidemiology research "holds constant" these "background" factors so that other more interesting variables can be studied. This is done because it is tacitly recognized that if the factors were not statistically removed from analysis they are so powerful that they would overwhelm everything else being studied. In consequence these factors are rarely studied in their own right'.

Although exceptions to this general trend existed at the time, interest in exploring the conditional relationships has increased considerably over the last decade. However, most of the research on social variations remains confined to epidemiological studies of social inequalities in health. For example, the Whitehall study found significant variations in smoking-related diseases

between occupational groups even after controlling for smoking behaviour.¹⁶ This might lead one to question messages about the adverse effects of smoking on health, and hence whether the effectiveness of smoking cessation on health is the same across social contexts. Similar concerns are expressed by Tatz¹⁷ in documenting the poor survival of members of championship aboriginal football teams in Australia, leading the author to question the wisdom that sport must be good for the body, at least among aboriginal populations.

The effects of unemployment on depression and subjective measures of health status were found to vary according to the level of unemployment in the area of residence of the individual,¹⁸ while the observed poorer health among elderly persons from lower social groups can be explained by both their greater exposure to psychosocial risk factors and the greater impact of these risk factors on health status compared with elderly persons from higher social groups.¹⁹

Examples from clinical epidemiological research tend to be less prevalent. Lipworth *et al.*²⁰ analysed outcomes from cancer treatment by income group of patient. Low-income persons were found to have substantially less favourable survival rates following treatment at identical tumour clinics and hospitals. These poorer outcomes were not accounted for by stage of cancer, age of patient or type of treatment. Leon and Wilkinson²¹ found that such systematic differences in prognosis by social group were common to many cancers and heart conditions after controlling for the staging of the condition, the type of service and the quality of care. Similarly, Carnon *et al.*²² found that recovery from various surgical procedures for cancer was poorer among deprived groups after adjusting for stage of disease and treatment type.

While Syme¹⁵ was primarily concerned with appropriate study designs in the analysis of determinants of *health*, these findings suggest that corresponding concerns are appropriate for the design of studies evaluating the effectiveness of health care interventions (i.e. the determinants of *effectiveness*). Where health is the outcome of a broad range of determinants, the consequences for health of changing any single determinant may depend on the context in which that change occurs, i.e. the levels of other determinants of health. Evans *et al.*²³ discuss possible linkages between social environments and biological effects. This implies that if health care resources

Table 1. Determinants of health change and the misallocation of resources

		Treatment A	Treatment B
Subjects	N	100	100
<i>of which</i>			
<i>group X</i>		50	50
<i>group Y</i>		50	50
Outcomes	QALYs	1000	800
<i>of which</i>			
<i>group X</i>		200	400
<i>group Y</i>		800	400
Effectiveness	QALYs/N	10	8
<i>of which</i>			
<i>group X</i>		4	8
<i>group Y</i>		16	8

are to be used in ways that do most good, the decision-making process needs to be informed by research which explores and reports on relationships between the outcomes of health care interventions and the prevalence and mix of other health determinants.

EFFICIENCY, EQUITY AND EVIDENCE-BASED DECISION-MAKING: IMPLICATIONS OF RESEARCH-LED APPROACHES TO INFORMING DECISIONS

Evidence-based decision-making is presented as a means of doing most good with available resources. In this section we consider the implications of using 'research-led' and 'service-focused' information for the efficiency and equity of the use of scarce health care resources.

Evidence and the misallocation of health care resources

Consider a hypothetical randomized controlled trial of a new treatment A compared with an existing treatment B aimed at increasing survival time post myocardial infarction (see Table 1). For simplicity, the two treatments require the same quantity and mix of health resources. The 100 individuals randomized to receive treatment A are observed by the researcher to receive 1000 units of outcome (e.g. quality-adjusted life years

or QALYs) compared with 800 units received by the 100 individuals randomized to receive current treatment B. Faced with this information, a physician is likely to consider A to be the treatment of choice. At the level of clinical policy making, decision-makers may choose to recommend that A be preferred to B, in the form of either clinical guidelines or the determination of lists of 'approved' services. The italicized data represent information about the underlying distribution of subjects and conditions between two social groups in the sample. Because social groupings are not generally of primary interest in clinical epidemiological research, this information is not normally collected or analysed in research studies and hence usually remains unknown to both the researcher and the decision-maker.

Suppose the sample of individuals with the condition is split equally between two social groups X and Y (which might be, say, poor and rich), i.e. 100 X and 100 Y. Under randomization the distribution of social groups is expected to be the same for both treatment groups, i.e. both have 100 individuals of which 50 are rich and 50 poor. Suppose treatment B results in 400 QALYs for both X and Y subgroups (i.e. an average of eight QALYs per individual within each subgroup). However, suppose treatment A is much more effective in subgroup Y, producing 800 QALYs or an average of 16 QALYs per individual in Y, but only 200 QALYs, or four per individual, in subgroup X. This information is unknown to the researcher because the research studies are designed to produce similar mixes of social groups in each arm of the studies. In terms of the observed effectiveness, the average benefit per individual receiving treatment A is 10 QALYs.

The 'evidence' emerging from the trial is that treatment A produces 200 more QALYs than treatment B among groups of 100 individuals with the same condition (or an average of two additional QALYs per person). However, this information is inaccurate for both subgroups of the sample population. The estimated effectiveness of A overestimates the effectiveness of the treatment for subgroup X, for whom outcomes under treatment A are less than under treatment B. At the same time, the true benefits of treatment A to subgroup Y, 800 QALYs or an average of 16 QALYs per individual, are underestimated by the trial results. In this way 'evidence-based' decisions based on 'service focused' research would involve a misallocation of resources devoted to the

treatment of individuals post myocardial infarction.

Moving from the hypothetical to the real world, Roberts *et al.*²⁴ evaluated the costs and effects of two different health promotion strategies for chronically ill patients who were defined as 'poorly adjusted' to their medical conditions. Using randomized patient allocation, problem solving counselling and phone call support were used to augment conventional medical care and both were compared with the non-augmented medical care. No significant differences in the change in psychosocial adjustment over time were found between the two intervention groups. However, within treatment groups there was considerable variation in both outcomes and future health care costs. In other words, the treatment group 'averages' concealed within-group differences which otherwise could lead to resources being misallocated among health promotion programmes.

This supports the notion discussed above that study populations defined on the basis of clinical criteria, and hence homogeneous in conditions (in this case, poor psychosocial adjustment to a given illness), may be heterogeneous in relation to the causes of the condition. So, among a population with a particular condition but differing causes of the condition, the effect of changing one particular determinant, health care consumption, on the presence or severity of a condition might be expected to differ systematically by the level of other determinants. In this way, the efficiency of any particular intervention depends upon the context in which the intervention is considered. To ignore this context involves ignoring potentially important determinants of the efficient use of resources.

Overemphasis on the problems of non-deprived populations

If the effectiveness of interventions is enhanced by complementary mixes of other health determinants, evidence-based decision making informed by research that does not explore the role of individual and population contexts will lead to increasing emphasis being given to the problems of those groups with more favourable social determinants of health.

Consider separate interventions for two conditions, A and B, both evaluated by randomized

Table 2. Distribution of determinants of health change and treatment effectiveness

		Treatment for condition A	Treatment for condition B
Subjects	N	200	200
<i>of which</i>			
<i>group X</i>		120	180
<i>group Y</i>		80	20
<i>randomized to intervention</i>			
<i>group X</i>		60	90
<i>group Y</i>		40	10
Outcomes	QALYs	700	550
<i>of which</i>			
<i>group X</i>		300	450
<i>group Y</i>		400	100
Effectiveness	QALYs/N	7	5.5
<i>of which</i>			
<i>group X</i>		5	5
<i>group Y</i>		10	10

control trials involving 200 individuals with the interventions in question randomly allocated among intervention and placebo groups. Table 2 records hypothetical data concerning the trials, with the italicized data again representing information concerning underlying distributions of the sample and outcomes usually unknown to either the researcher or decision-maker. In both samples the subgroup X outnumbers subgroup Y (e.g. more poor than rich), but the relative prevalence of Y types is greater in the sample for condition A, as might be the case if the relative prevalence of A exceeded that of B among the population of Y individuals. In terms of the effectiveness of the interventions, suppose the average additional benefits per individual (i.e. the difference in QALYs/N between treatment and control group within each trial) are greater in Y than in X although within each subgroup the average additional benefits per individual are the same in both trials, i.e. the effectiveness of the intervention compared with the control for either condition is 10 units per individual in subgroup Y and five units per individual in subgroup X. Randomization of samples of individuals with the conditions produces the scenario presented in Table 2. Although the underlying truth is that the effectiveness of both interventions is the same *within subgroups*, the intervention for condition A is observed to produce 700 QALYs, which exceeds the 550 QALYs observed in the trial for the intervention for condition B. In this case, the

Table 3. 'Effectiveness reversal': the 'more effective' is less beneficial for all

		Treatment for condition A	Treatment for condition B
Subjects	N	200	200
<i>of which</i>			
<i>group X</i>		40	160
<i>group Y</i>		160	40
<i>randomized to intervention</i>			
<i>group X</i>		20	80
<i>group Y</i>		80	20
Outcomes	QALYs	900	880
<i>of which</i>			
<i>group X</i>		100	640
<i>group Y</i>		800	240
Effectiveness	QALYs/N	9	8.8
<i>of which</i>			
<i>group X</i>		5	8
<i>group Y</i>		10	12

'evidence' of difference provided by the trials is simply an artefact of the distribution of the social determinants of health change among those individuals with the conditions.

Greater differences in relative proportions of different social groups in the samples produce greater discrepancies between the apparent differences in effectiveness estimated in the research studies and the underlying truth. The data in Table 3 provide an example of differences in relative proportions being so great that even where the average benefit (compared with controls) per individual for both X and Y subgroups, and hence the entire sample with the condition, is greater for the intervention for condition B, the trials' results provide the false impression that the intervention for A is more effective than the intervention for B. Faced with a decision of choosing between A and B, or at least establishing a priority ordering among them, decision-makers at the programme level would find it difficult to justify favouring B in the absence of the information on the social determinants of effectiveness.

These same data can be used to illustrate the potential for systematic error in choosing between treatments for a given condition. In this case A and B are the same but the samples used in the trials of two different interventions involve a different mix of other determinants of health. In the case of the data in Table 3, for both poor and rich patients B is better than A. However, the trials imply that A is better than B. A physician

faced with a patient with the condition and the 'evidence' from the trials would reasonably believe A to represent the treatment of choice.

Where effectiveness differs by social determinants of health, research based on methods that exclude or control for these influences provides a systematically biased estimate of the effectiveness of interventions. More generally, the bias in estimated effectiveness will favour interventions for conditions with greater relative prevalence among these groups with favourable determinants of health change, which tend to be the less deprived groups in society. Rankings of interventions according to outcomes, in terms of treatment effectiveness, are essentially rankings of the interventions in accordance with the levels of the non-health care determinants of the populations being treated. The problems of less-deprived groups dominate those of deprived groups precisely because less deprived groups are in a better position to benefit from health care. In this way the distribution of benefits favour the better-off groups and social inequalities in health increase.

Controlling confounders or concealing causes?

'It is insufficient to say that risk factors are related to social position and therefore risk factors account for social class differences. We should ask why are risk factors social class-based'. Marmot and Theorell²⁵

Given the recognition of the possible confounding role of social determinants of health in evaluating health care interventions, the argument presented by Marmot and Theorell²⁵ can be extended beyond the notion of differences in baseline risk to incorporate also the effectiveness of health interventions after controlling for baseline risk. However, to date the interest and attention of health services research remains focused narrowly on average effectiveness of interventions for particular conditions. The investment of scarce resources then becomes concentrated on disease-based programmes that may benefit disproportionately members of those groups already favoured by a more healthy mix of determinants.

Controlling for confounding explanations controls for possible causes of the condition. As Hertzman *et al.*²⁶ note, '...whatever people die of, poor people continue to die sooner'. However, these systematic patterns of illness and disease are

Table 4. Effectiveness of propranolol: findings of a randomized control trial (source: Ruberman *et al.*²⁸)

Outcome: 3 year mortality rate post myocardial infarction			
Clinical intervention:			
<i>Propranolol:</i>	9%	<i>Placebo:</i>	12%
Education level:			
<i>High:</i>	6%	<i>Low:</i>	13%
Social conditions (stress and isolation):			
<i>Low:</i>	2%	<i>High:</i>	14%

treated as coincidental as opposed to systematic in the research model. The use of randomized trials of condition-specific interventions for different conditions therefore risks concealing any *common* underlying causes of the greater prevalence of many *different* conditions among sub-groups of the population — what Syme and Berkman²⁷ call generalized susceptibility to diseases and generalized compromises of disease defence systems.

Consider the data presented in Table 4, taken from a randomized control trial of propranolol versus placebo in the treatment of patients following a myocardial infarction (MI).²⁸ Patients allocated to the treatment group (propranolol) were 3% less likely to die in the 3 year period following initial MI than those allocated to the control group (placebo). These findings were interpreted as evidence that the drug was an effective treatment post MI.

An interesting picture emerged, however, when the authors 'partitioned' the study subjects on the basis of which 'social' group they belonged to as opposed to which treatment group they were in. In particular, the difference in 3 year mortality rate post MI between groups defined by level of education was twice that observed between treatment and control groups. In discussing these findings, Pincus and Callahan²⁹ note that these differences in mortality '...could not be explained by an extensive array of biomedical variables available at baseline including laboratory tests, electrocardiograms and other specialized tests'. However, the differences were explained by variations in self-reported stress and isolation.

The 3 year mortality rate was highest in the groups with high levels of stress and social isolation at onset in all education groups and similar for each education group. Differences in mortality among education groups reflected the lower prevalence of high stress and social isola-

tion in the group of higher educated individuals. Pincus and Callahan²⁹ conclude that, '...the data provide further evidence that biomedical risk factors and limited access to medical care explain only in small part associations between cardiovascular mortality and socioeconomic status'.

The relationship between social status and health within populations has been found to be common to many different conditions. In this case, effective interventions for those health determinants associated with social position (e.g. stressful life, social isolation) could potentially have a much broader impact on the health status of lower social status groups than narrowly focused disease-specific health care interventions.

Moreover, where the effectiveness of health care interventions is systematically related to social status, effective interventions to change the underlying determinants of health associated with social status (e.g. stress and social isolation) would potentially increase the effectiveness of health care interventions. In other words, health care and non-health care interventions may be complementary. In this way, health care providers would have a vested interest in improving the social determinants of health since this would increase outcomes associated with the services they provide.

DISCUSSION

'Success is measured not by the heights you achieve but by the obstacles you overcome.' Anon.

The increasing prominence given to evidence-based decision-making has sparked much interest and debate in the health research literature. The main challenges to the evidence-based approach have tended to centre upon the criteria for the quality of the evidence of effectiveness and in particular the designs on which studies are based,³⁰ the lack of consideration of issues of patient preference and cost effectiveness³¹ and the default strategy where the available research fails to meet these criteria.³² To date, little attention has been paid to the interface between health care effectiveness and the determinants of health within populations.³³ The purpose of this paper was more concerned with the 'service-focus' of the evidence-based approach and some

implications for its use in addressing real-world problems. The preoccupation with establishing 'evidence' of service effectiveness and the models of research developed to satisfy the preoccupation represent departures from both the underlying concept of the multiple determinants of health and illness and the population context in which decision-making takes place.

This difference in context does not reflect failure on the part of researchers to recognize that systematic variations in health exist or that health is produced by a wide range of factors with health care being one, potentially important, determinant. On the contrary, it is the response to this recognition of the multiple determinants of health in the way studies are designed and the implications for the information generated by the research that are the problem. In other words, the evidence-based approach, dominated by a focus on health outcomes from health care interventions, overlooks the notion that society is not a 'level playing field'. Policies aimed at maximizing health outcomes from health care interventions by basing decisions on this research 'evidence' risk redeploying resources inefficiently and in ways which systematically favour those groups with favourable 'prospects for health' (or non-health care determinants of health), and the conditions that those groups in society tend to suffer from, and away from those groups with less favourable prospects for health.

It is not the purpose of this paper to challenge the normative position that decisions should be based on the best available information, or that resources should be devoted to the generation of valid information. On the contrary, the discussion in the previous sections implies that the information emerging from current research is more concerned with satisfying the interests of the researcher and decision-makers operating in environments of bureaucratic constraints and institutional rigidities than with informing the decision-making about improving the health of populations.

It is worth noting that the importance of context in the evaluation of policies is not confined to issues of evaluations of health care interventions. For example attempts to study the effects of different payment methods on health care provider behaviour would generally attempt to exclude or control for all other possible explanations (or 'determinants') of behaviour change. Yet in practice these confounding factors

are part of the problem facing the decision maker. In Canada, the Deputy Ministers of Health sought to determine the most appropriate approach for remunerating physicians by reference to the evidence on the effects of alternative forms of physician payment. A review of the evidence commissioned by the committee³⁴ noted that existing research provided little information useful to the decision-makers' since the information generated by the research differed in context from the problem at hand. In particular:

- The alternative physician payment methods studied were often part of a broader package of structural changes in the delivery of services, i.e. observed patterns of behaviour might be a response to, or conditional on, other items in the package of changes.
- Studies tend to be based on a particular level of payment. Little attention is paid to variation in physician behaviour associated with different levels of payment under any of the methods.
- Studies are performed in the context of different systems of health care organization, funding and delivery. Hence the observed effects of particular methods of payment may be associated with the structural features of the system being studied.
- Studies often focus on the differences between physicians under different payment methods when the policy problem is concerned with the effect of changes in methods of payment on physician behaviour.

Irrespective of the quality of the research in these studies, the information provided does not inform the decision-maker about the effects on physician behaviour of changing to a particular type and level of payment as part of a broader conditions of service package from a particular type and level of payment method in the context of the particular health care system under consideration. Even for research performed within the problem context, the value of the research findings is compromised by the research model. For example, the change in physician hospitalization rates over time was similar between primary care physicians choosing to switch from fee for service payment to capitation and a matched sample of primary care physicians paid fee for service in Ontario.³⁵ However, that does not necessarily mean that the introduction of capitation payment on a wider scale would not

lead to a change in behaviour. Because those physicians choosing to change to capitation are not a representative sample of all primary care physicians, in terms of their practice characteristics (e.g., the average rate of hospitalization was well below the average for all primary care physicians), we have no information on how the imposition of capitation on other types of physician would affect behaviour, if at all.

Attempts by researchers to support better informed decisions need to consider ways of developing the methods of research to better reflect the contextual nature of the problems facing decision-makers. At this stage there would seem to be two broad approaches to enhancing the information base for decision makers:

1. *Enhancing current research approaches to explore the role of social variables*

Service-focused research could be extended to include the collection and analysis of data on non-clinical determinants of health as potential correlates of effectiveness. Traditional approaches of exploring variations in outcomes within study populations such as subgroup analyses are based on relatively simple models of health production and on assumptions of separable determinants which fail to reflect the complex structure of populations. Moreover, the variables used to define subgroups tend to reflect researchers' interest in variations in disease severity or staging as opposed to non-clinical determinants of health. Instead, more broadly based data sets could be analysed using advanced analytical techniques, such as multi-level modelling,³⁶ that better reflect the underlying concepts of the determinants of health and the complex structures in society. In particular, multi-level approaches go beyond determining whether a procedure or intervention works to consider simultaneously the conditions or characteristics of individuals and environments under which the probability of success is greater. This approach reveals any conditional nature of the effectiveness of health care interventions which is valuable information for the decision-making process. Nonetheless, it remains focused around the effectiveness of particular services and is therefore less able to find the 'right' solutions for the health problems of populations, and hence

addressing the causes of sickness or risks to health and is more suited to finding the 'right' members of the population for the interventions of interest.

2. *Shifting the focus from providers and their services to population groups and their problems*

The approach outlined above, although providing context-specific information, remains focused on interventions as the subjects of analyses. However, suppose the analyses identify systematic variations in effectiveness in favour of less deprived populations. For the purposes of illustration, suppose there is no evidence of effectiveness among the most deprived group as might be expected if the underlying causes of the condition differed by social group or social factors inhibited the biological processes underlying the condition. Efficient use of scarce resources *for this intervention* would imply the intervention not be given to these individuals with the anticipated increase in social inequalities in health. The resources of a health care system would become increasingly concentrated on less deprived populations. This results not necessarily because the problems of the more deprived groups are insoluble, but because the mechanisms we choose to evaluate for dealing with the observed problems are particularly suited to the less deprived groups, i.e. it is a feature of the 'service focus'. Suppose, instead, we choose to look at some social intervention such as income supplements, or social support strategies, for example. It may be that among all individuals with a particular health condition the social intervention is effective but the effect is confined to (or concentrated among) more deprived groups, if only because the intervention may be more in line with the cause of the condition in these groups. Essentially the distribution of benefits from interventions are likely to be closely associated with the distribution of the underlying causes of the condition.

Switching the focus of attention away from interventions and towards populations and their health problems could help avoid the 'paradox' of evidence-based decision making leading to increased inequalities in health

status. Consider the case of smoking. In many countries, 'interventions' aimed at reducing the prevalence of smoking in the population have been associated with marked reductions in the levels of smoking—what some have referred to as the 'spectacular success of smoking control policies'.³⁷ However the reductions in smoking observed in these countries have been largely confined to the higher social groups while in the lower social groups the levels of smoking remain roughly the same or in some cases may even have increased. Interestingly, this systematic difference in outcomes is inversely related to the size of the 'problem' of smoking prevalence with 'baseline' prevalence being higher in the lower social groups. Instead of focusing on interventions for smoking *per se*, an alternative approach would be to consider smoking prevalence as a set of different problems according to the causes of the behaviour. The main focus of attention for researchers and decision-makers would then be determined by the size of the problem, e.g. finding 'interventions' to reduce smoking in lower social groups becomes the priority smoking problem to be addressed. Under this approach, the search for 'evidence' occurs in the context of the problem, and in particular in the context of population groups for whom the prevalence is greatest (e.g. native populations, the homeless, single mothers, the long-term unemployed). Alternative uses of resources would then be compared on a more 'level playing field' (i.e. in the context of achieving health improvements among population groups with similar causes).

The success of the way in which scarce health care resources are allocated cannot be judged simply in terms of how much is produced, but must take account of the barriers that have had to be scaled to produce that improvement in health. Failure to incorporate the complex pathways to health in the design of research used to inform decision-making processes risks wasting resources while increasing the 'health divide'.³⁸

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REFERENCES

1. Sackett, D. and Rosenberg, W. On the need for evidence-based medicine. *Health Economics* 1995; **4**: 249–254.
2. Ham, C., Hunter, D. and Robinson, R. Evidence based policy making. *British Medical Journal* 1995; **310**: 71–72.
3. Sackett, D. and Rosenberg, W. On the need for evidence-based medicine. *Journal of Public Health Medicine* 1995; **17**: 330–334.
4. Lomas, J. and Haynes, B. A taxonomy and critical review of tested strategies for the application of clinical practice recommendations from official to individual clinical policy. *American Journal of Preventive Medicine* 1988; **1**: 77–94.
5. Lomas, J. Promoting clinical policy change: using the art to promote the science in medicine. In Anderson, T. and Mooney, G. (eds) *The Challenges of Medical Practice Variations*, pp. 174–191. London: Macmillan, 1990.
6. Sackett, D., Rosenberg, W., Muir Gray, J., Haynes, R. and Richardson, W. Evidence-based medicine: what it is and what it isn't. *British Medical Journal* 1996; **312**: 71–72.
7. Pringle, D. Deinsuring medical services: practical or perverse. Paper presented at the 6th Conference of the Canadian Health Economics Research Association, Waterloo, Ontario, 1995.
8. Henry, D. Economic analysis as an aid to subsidization decisions: the development of the Australian guidelines for pharmaceuticals. *Pharmacoeconomics* 1992; **1**: 54–67.
9. Canadian Co-ordinating Office for Health Technology Assessment. *Guidelines for Economic Evaluation of Pharmaceuticals: Canada*. Ottawa: CCOHTA, 1994.
10. Evidence Based Care Resource Group. Evidence-based care: 1. Setting priorities: how important is the problem? *Canadian Medical Association Journal* 1994; **150**: 1249–1254.
11. Evidence Based Care Resource Group. Evidence-based care: 3. Measuring performance: how are we managing the problem? *Canadian Medical Association Journal* 1994; **150**: 1575–1582.

12. Guyatt, G., Jaeschke, R. and Cook, D. Applying the findings of clinical trials to individual patients. *American College of Physicians Journal Club* 1995; **122**: A12–A13.
13. Browman, G. Levine, M., Mohide, A., Hayward, R., Pritchard, K., Gafni, A. and Laupacis, A. The practice guidelines development cycle: a conceptual tool for practice guidelines development and implementation. *Journal of Clinical Oncology* 1995; **13**: 502–512.
14. Evans, R., Barer, M. and Marmor, T. (eds) *Why are Some People Healthy and Others Not? The Determinants of Health of Populations*. New York: Aldine de Gruyter, 1994.
15. Syme, S. L. Strategies for health promotion. *Preventive Medicine* 1986; **15**: 492–507.
16. Marmot, M., Rose, G., Shipley, M. and Hamilton, P. Employment grade and coronary heart disease in British civil servants. *Journal of Epidemiology and Community Health* 1978; **32**: 244–249.
17. Tatz, C. *Obstacle Race: Aborigines in Sport*. Sydney: University of New South Wales Press, 1995.
18. Turner, J. Economic context and the health effects of unemployment. *Journal of Health and Social Behaviour* 1995; **36**: 213–229.
19. House, J., Lepkowski, J., Kinney, A., Mero, R., Kessler, R. and Herzog, A. The social stratification of aging and health. *Journal of Health and Social Behaviour* 1994; **35**: 213–234.
20. Lipworth, J., Abelin, T. and Connelly, R. Socio-economic factors in the prognosis of cancer patients. *Journal of Chronic Diseases* 1970; **23**: 105–116.
21. Leon, D. and Wilkinson, R. Social inequalities in prognosis. In Fox, J. and Carr-Hill, R. (eds) *Health Inequalities in European Countries*, pp. 280–300. Aldershot: Gower, 1989.
22. Carnon, A., Ssemwogerere, A., Lamont, D., Hole, D., Mallon, E., George, W. and Gillis, C. Relation between socioeconomic deprivation and pathological prognostic factors in women with breast cancer. *British Medical Journal* 1994; **309**: 1054–1057.
23. Evans, R., Hodge, M. and Pless, I. If not genetics then what? Biological pathways and population health. In Evans, R., Barer, M. and Marmor, T. (eds) *Why are Some People Healthy and Others Not? The Determinants of Health of Populations*, pp. 161–188. New York: Aldine de Gruyter, 1994.
24. Roberts, J., Browne, G., Streiner, D., Gafni, A., Pallister, R., Hoxby, H., Jamieson, E. and Meichenbaum, D. The effectiveness and efficiency of health promotion is specially clinic care. *Medical Care* 1995; **33**: 892–905.
25. Marmot, M. and Theorell, T. Social class and cardiovascular disease: the contribution of work. *International Journal of Health Services* 1988; **18**: 659–674.
26. Hertzman, C., Frank, J. and Evans, R. Heterogeneities in health status and the determinants of population health. In Evans, R., Barer, M. and Marmor, T. (eds) *Why are Some People Healthy and Others Not? The Determinants of Health of Populations*, p. 80. New York: Aldine de Gruyter, 1994.
27. Syme, S. L. and Berkman, L. Social class, susceptibility and sickness. *American Journal of Epidemiology* 1976; **104**: 1–8.
28. Ruberman, W., Weinblatt, E., Goldberg, J. and Chaudhary, B. Psychosocial influences on mortality after myocardial infarction. *New England Journal of Medicine* 1984; **311**: 552–559.
29. Pincus, T. and Callahan, L. What explains the association between socioeconomic status and health: primarily access to medical care and mind-body variables? *Advances* 1995; **11**: 4–36.
30. Black, N. Why we need observational studies to evaluate the effectiveness of health care. *British Medical Journal* 1996; **312**: 1215–1218.
31. Dowie, J. 'Evidence-based', 'cost-effective' and 'preference-driven' medicine: decision analysis based medical decision-making is the prerequisite. *Journal of Health Services Research and Policy* 1996; **1**: 104–113.
32. Naylor, D. Grey zones of clinical practice: some limits to evidence-based medicine. *Lancet* 1995; **345**: 840–842.
33. Evans, R. and Stoddart, G. Producing health, consuming health care. *Social Science and Medicine* 1990; **31**: 1347–1363.
34. Birch, S., Goldsmith, L. and Makkela, M. *Paying the Piper and Calling the Tune: Principles and Prospects for Reforming Physician Payment Methods in Canada*. Report to the Federal/Provincial/Territorial Conference of Deputy Ministers of Health., Hamilton, Ontario: McMaster University, 1994.
35. Hutchison, B., Birch, S., Hurley, J., Lomas, J. and Stratford-Devai, F. Effect of a financial incentive to reduce hospital utilization in capitated primary care practice. *Canadian Medical Association Journal* 1996; **154**: 653–661.
36. Duncan, C., Jones, K. and Moon, G. Health-related behaviour in context: a multi-level modelling approach. *Social Science and Medicine* 1996; **42**: 817–830.
37. National Health and Medical Research Council of Australia. *Health Australia: Promoting Health in Australia*. NHMRC: Canberra, 1995.
38. Whitehead, M. *The Health Divide*. Harmondsworth: Penguin, 1988.