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Bridging the Gap:
The Use of Research Evidence
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HTA Initiative #18
Bridging the Gap: the Use of Research Evidence in Policy Development

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EXECUTIVE SUMMARY

The idea and need for this paper arose from discussions that took place between the leaders, Duncan Saunders, Don Juzwishin and Seana Collins, with the participants during the teaching of the first annual Putting Evidence into Practice (PEP) workshops in Edmonton, Alberta in November 2003. The PEP workshops are a 3 day program delivered by the University of Alberta and Capital Health Evidence-based Practice Center to teach participants about:

- critical appraisal skills within different disciplines;

- the discovery of new approaches to teaching evidence-based practice;

- identifying strategies to incorporate evidence into decision-making; and

- networking with international leaders in evidence-based practice.

The leaders and participants of the Policy Small Group session were lamenting the fact that there appeared to be no framework or approach that was readily available to bring evidence into the policy discussion other than that which governed the scientific evidence. Often variables such as values, politics, ideology and customs would have a significant influence in policy discussions but there did not appear to be a standardized and consistent way in which to bring them into the policy discussion. Furthermore there did not appear to be a way to assess the relative merits of this form of "non-scientific" evidence. The PESTLE Analysis, a popular method of examining different external factors affecting an organization was adapted and used in the second annual workshops in November 2004, but it appeared to be lacking in its utility for dealing with questions surrounding the policy issues of the effectiveness of health care interventions. With the encouragement and participation of the Small Group Policy Making participants at PEP in 2003 and 2004 this project was launched and the results in the form of this paper will be used at the third PEP workshops in November 2005.

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INTRODUCTION

Public policy can be a messy business. Bismarck's famous observation about legislation—and what is legislation but public policy writ large—and sausage making is often quoted (one translation of Bismarck's observation: *"People who love the law or good sausage should never watch either being made"*) because it resonates with our beliefs and experiences. Policy decisions are difficult to evaluate at the best of times. Is a given decision good or bad? Is it effective or ineffective? What about unintended consequences? But if the outcomes are difficult to evaluate, consider how more difficult it is to evaluate the process used to arrive at a policy decision. Is it good or effective if based on good information? Is it bad or ineffective if based on poor or no information? Can a decision be based on good information yet be considered a bad decision? Can a decision be based on no information yet be considered a good decision?

Determining which policy decisions are good and which are not is a significant issue in public administration and political science but is beyond the scope of this paper, as is the creation of a model for policy development. We are much more modest in our goals. We simply want to explore the gap between the world of policy making and the creation and application of research and to suggest a framework for identifying potentially relevant information for making policy decisions. Our hope is that this framework may assist in at least narrowing the gap by increasing understanding in both communities of the full range of information that may be available or used in the policy process.

Therefore, this paper has two specific objectives:

- to describe some of the challenges of using research evidence to inform healthcare policy making; and

- to provide policy makers and researchers with a framework or tool that would identify and facilitate the use of research evidence and other information in healthcare policy making.

The paper first explores some of the themes found in the policy literature to establish a context for the presentation of the framework. This exploration is not intended to be a thorough analysis or even a complete survey of policy development models, nor is it intended to serve as the foundation for the framework. It may, however, serve to sensitize the user of the framework to the dynamics surrounding any policy-making activity. Following this brief exploration, we present and discuss the framework for categorizing policy-related information. Finally, a number of best practices for healthcare policy making are also identified in the hope of stimulating further discussion.

Throughout the paper, individuals who make policy decisions, usually but not only at the elected official level of government, are referred to as policy makers or decision

makers. Others involved in the policy-making process are referred to as researchers or analysts. It is usually the job of the researchers and analysts to prepare policy information and options that policy makers or decision makers use in their final determination of a policy.

POLICY MAKING AND RESEARCH EVIDENCE

Just as there is a wide range of contexts in which policy makers function, ranging from hostile to researcher friendly, there is also a wide range of the possible uses of research during policy development. Hanney S, Gonzalez-Block MA, Buxton JM, and Kogan M[1] conducted a detailed study of research and its influence or effect on healthcare policy. Their analysis of research inputs and decision contexts is particularly informative (see Table 1).

Table 1: Decision context, research inputs, and forms of research utilization in policy making

		CONTEXT OF DECISIONS			
		Explicit			Implicit
		Choice		Support	
		Technical	Political		
RESEARCH	Models	Conceptual modeling	Constrained frameworks	Symbolic payback	Paradigms
INPUT	Specific findings	Data-based policy	Strategic research	Symbolic argumentation	Practice wisdom

Source: [1]

Hanney et al.[1] describe the context of decisions as explicit and specific or implicit and diffuse. Decisions are explicit if they are open and transparent to the public and implicit if they are conducted behind closed doors. If decisions are implicit, they are more likely to be informed by the paradigms or common practices, which require a minimum, if any, of formal research. Decisions that are explicit and open to public view are likely to require some form of research to support the choice taken. Traditionally, political decisions tend to be justified in terms of values or ideology shaped in the political arena. Scientific efforts are often helpful in providing support of policy formulation—but often in reverse—providing justification for a policy action taken. Technical decisions are often justified with respect to the scientific enterprise. In the context of this study, explicit decision making, based on technical approaches with conceptual modeling and supported with clean data, would be synonymous with best practice. The model (Table 1) is characterized with discrete cells, but in reality the elements are known to be part of a continuum, not mutually exclusive, and they intermesh rather than exist in isolation. The use of research in "policy making should eventually lead to desired outcomes, including health gains."[1] If so, it would follow that best practice in policy making for achieving the best ends for improved population

health is more likely to be created from the technical category in which conceptual modeling and data-based policy is produced.

Work in comparative international healthcare reform can provide us with further insights into what a difficult area of public policy this is. In the preface of one comparative work, the editors remark on the experience of four countries. They state:

> In each of them, progress toward universal coverage for the whole population, the experience of these four countries offers a valuable fund of knowledge. In each of them, progress toward universal coverage was quite gradual, and each has continued to alter its structures and procedures to meet emerging circumstances. Their experience shows that the road to universally assured access to care is winding and often tortuous and that when this objective has been met, new and unforeseen obstacles appear. The journey of health care policymaking is not made without struggle and is not marked by clear signposts. The development of an effective and equitable health care system is arduous and never finalized, but it is one that nations undertake out of fear of a greater failure.[2]

The question is not whether evidence should influence policy decisions, but the degree to which high-quality evidence can do so. Policy decisions are at bottom political decisions and political decisions are at bottom a balancing act between competing interests. The rightness or wrongness of a policy decision does not depend on whether appropriate evidence was used, but on whether the policy can be supported by the majority of citizens. It is even possible to think of an example in which all the best evidence would suggest, for instance, that private health care is more effective in improving the health of all citizens than public health care, yet we may not like the reasonable policy conclusion. Values and ideology therefore play an important role in policy making and we can easily see that the way that values and ideology are held by policy makers will have a significant impact on resulting policies.

Despite this role of values and ideology, many commentators over many years have been concerned with the failure of decision makers to make the best use of the available evidence to achieve the public interest.

DEFINING THE GAP

This failure of take-up of high-quality research evidence by decision makers has been called the gap between research and policy. The research community has devoted much time and energy to talking about bridging the gap between research and decision making, but today significant chasms still exist between the two.

Why is there a gap between what evidence should be used to inform policy and what is being done? Stocking, in a commentary on why research findings are not used by commissions in the United Kingdom, for example, identifies four reasons: "…(1) the research is not there; (2) many managers are not 'knowledgeable'; (3) public health (and others) does not act as a product champion of knowledge; (4) change is more difficult than expected".[3] Stocking's experience is in the United Kingdom, but this literature review confirms her assertions for Canada.

In the Canadian context, Lomas[4] provides us with significant insights into why research evidence falls short of informing policy making. Lomas identifies four misunderstandings between the evidence production effort—research—and the policy-making effort. His first point is that researchers and policy makers consider each other's activity as generating products instead of engaging in processes; in other words, policy makers think of research and high-quality evidence as something that can be picked off a shelf like a carton of milk at the grocer. Second, researchers tend to not appreciate the distinction of a rational decision that is research driven and context free and a sensible decision that is pragmatically driven. Scientific research attempts to focus the question so that a clear and crisp answer can be provided. Policy making, on the other hand, tends to take other variables such as interests, ideology, values, or opinions into account. Third, decision makers are not sensitive to the incentives that drive researchers. Academic researchers receive their rewards through tenure by attracting grant money and publishing in peer-reviewed journals, not responding to a current issue before the government policy makers. Fourth, researchers rarely take into account the different audiences that would be audiences for their research. The culture in the research community is generally one of academic rigour that is measured by the complexity and nuance of language as well as ideas, and not its transparency and parsimony. The policy community has multiple audiences of differing levels of sophistication—multiple types of messages must be customized to their needs. These four misunderstandings in the cultures of the two communities and their lack of appreciation for one another contribute to the chasm between them.

THE POLICY DEVELOPMENT PROCESS

How are we to understand the policy development process? Howlett[5] provides a synthesis of how the policy-making process has been described and analyzed based on a historical overview of the sentinel policy development literature. Howlett begins with Lasswell, who, in 1956, advanced policy science when he first characterized the following items as comprising the policy development process:

- Intelligence gathering – collection, processing, and dissemination of information to participants in the policy development.

- Promotion of particular options.

- Course of action chosen by decision makers.

- Course of action implemented with sanctions identified for those who do not comply.

- Results evaluated relative to the goals established.[5]

Although the model was simple, it made a significant contribution to the policy sciences in that it extended the policy process beyond that of government and was characterized as an iterative process.

Howlett points out that during the 1960s and 1970s, studies in the policy sciences resulted in several "schools" of policy development. The pure rational model arose from studies that showed policy makers following systematic methods for arriving at logical, linear, efficient, and effective policies. Policy makers were characterized as neutral technocrats who identified a problem and then found the most effective or efficient way of solving it. This model was soon brought into question, as experience with policy making showed that it was hardly a linear affair. Recognizing the weaknesses of this approach, the limited rationality or incremental model was introduced by Lindblom in 1959. Lindblom discovered that policy makers often had vested interests or were not competent to deal with the issues as a result of the unavoidable complexity of the policy-making process. Howlett summarizes the elements of Lindblom's elements of the policy development model with the following characteristics of policy making:

- Analysis limited to a few somewhat familiar policy alternatives differing only marginally from the status quo.

- Analyses of policy goals intertwined with other values and the empirical aspects of the problem.

- A greater analytical preoccupation with the problems to be remedied than positive goals to be sought.

- A sequence of trials, errors, and revised trials.

- Analysis that explores only some, not all, of the important possible consequences of a considered alternative.

- Fragmentation of analytical work to many vested participants in policy making.[5]

According to Howlett, Lindblom identified that bureaucrats found it difficult to redistribute resources from the existing allocation (status quo) and that an inherent characteristic of bureaucracies is maintaining the status quo.

A second critic identified by Howlett of the rational model of policy making was Herbert Simon. Simon, like Lindblom, identified several elements that worked against rational policy making:

- Cognitive limitation of decision maker to consider all possible options.

- Inability to foresee all consequences of a policy decision.

- Comparisons of benefits and consequences often incommensurate.

- Unambiguous conclusions as to which alternatives are superior not always possible.[5]

This characterization of the "unmanageability" of the policy process led Simon to coin the "satisficing" criterion, which, given the "bounded rationality" of people, led decision makers to satisfy whatever criteria they set for themselves.[5]

Howlett also draws attention to the 1979 work of March and Olsen, who named their model the *"garbage can"* model of decision making to remove any mystique of science or rationality implied by earlier theorists, asserting that the rational and incremental approaches implied a greater level of intention, comprehension of problems, and predictability of relations among actors than they found in reality.[5]

Kingdon[6] and Kingdon and John[7] suggest that policy decisions are not made in a vacuum but in context and not at just any time but when the timing is right. The right time and context for policy decisions is called the policy window. A policy window opens when three streams—problems, proposals, and politics—come together. In other words, policy decisions are made when a problem is recognized, policy solutions are available, and the political conditions are right.

It is crucial to recognize that a problem is different from a condition. It may be true, for example, that perhaps as many as 40 million Americans are without health insurance. That is a simple condition of life. It is an entirely different matter for people to believe that it is wrong for 40 million Americans to be without health insurance. Only then does it become a problem to be solved. In fact, we could argue that the recurrent failures of health insurance reform in the United States is probably as much due to the inability to have the condition defined as a problem as to the lack of practical proposals or political will, although these latter two elements are probably also lacking. Only when the policy makers come to see a condition as a problem are they willing to do

anything about it. But only if the other two streams also come together at the same time can they do anything about it.

Policy solutions are usually generated in response to the recognition of a problem, but are generated from existing ideas and knowledge from existing proposals. Once the policy window opens, there is no time to generate new information or new evidence to create a new solution. Rather, successful policy solutions adopt or adapt proposals that have been floating around for some time within the specialist community involved with the condition or problem. Kingdon refers to this state as the policy primeval soup. The actual development of proposals that can serve as the basis for a policy solution must be done long before the policy window opens.

Finally, for an open policy window, the political conditions must be right. There must be political will to introduce a change and there must be strong community support for the change. Political will and community support depend on election cycles and outcomes, interest group campaigns, and backroom negotiations. These two conditions depend on the relative strengths of interest groups, as well as on the state of the economy and government budgets.

If the policy window is not open, all the high-quality evidence in the world will have no direct influence on a decision. On the other hand, it is before policy windows open that evidence can perhaps be its most effective, when it can be incorporated into the primeval soup of ideas and influence the development of proposals that can be recognized as the best solutions when the policy window opens.

What does all this mean for the relationship between researchers or analysts and policy makers? Simply, there is a natural limit to how much research evidence that researchers or analysts can expect to influence policy. No matter how hard researchers try to have decisions made based on the evidence, no matter how good the evidence produced, policy decisions will be made only when these influences come together. Not only is this combination of streams not directly influenced by evidence, but neither does the evidence play a determining role in any of the three streams.

But the fact that policy decisions are not determined by the evidence does not necessarily mean that there is a gap between research and policy; it simply means that in a democracy it is more important to achieve a balance of interests than to be scientifically correct. For researchers to directly influence policy decisions they would need to become decision makers; they would need to move from the professional domain to the management and governance domains. At that point, they are no longer professionals and no longer researchers.

NARROWING THE GAP

What is the evidence that might help inform the earlier question of how healthcare policy makers use scientific evidence to inform their policy questions? Responses to filling the gap between researchers and policy makers have arisen from the producer-push and user–pull models of knowledge transfer and uptake. These models have been supplemented by the interaction model of knowledge transfer and uptake [8]. Lavis et al.[9] conducted a study of the role of health services research in Ontario and Saskatchewan in which they studied whether, how, and under what circumstances health services research affects provincial policy making. From the traditional political science literature, Lavis et al. identified three categories of influences on the policy-making process: ideas, interests, and institutions. Ideas include research or high-quality evidence, whereas interests are the perceptions of actors about who will or will not benefit. Institutions are factors such as policy history, time pressures, and level of approval. Lavis found that the following factors favoured the use of research utilization: citable research, other forms of information (for example, results of pilot tests), and the policy makers themselves, particularly when they could pursue multiple objectives. Government interests and legacy policies were also factors. Stakeholders pursuing interests were an important influence as well.

The interaction between researchers and policy makers and the identification of an accountable "receptor" function in government departments[4] was confirmed by Lavis as being an important factor in the use of health services research or other information. Customizing research responses to policy makers needs was also identified as an important enabler. Other salient findings of the study were that just because a policy did not use research did not mean it was not well informed and that a poorly informed policy can use good research, leading researchers to discriminate between informed policies and those that are evidence based. In his concluding remarks, Lavis states, *"We need to look at more than the use (versus non-use) of research in isolated policy decisions and, ideally, at the way in which research is used and at its use in the context of other, competing influences on the policy making process"*.[9]

Innvaer et al.[10] corroborated the findings of Lavis through an extensive systematic review of current literature that they conducted and they found the following:

> Interview studies with health policy-makers provide only limited support for commonly held beliefs about facilitators of, and barriers to, their use of evidence, and raise questions about commonsense proposals for improving the use of research for policy decisions. Two-way personal communication, the most common suggestion, may improve the appropriate use of research evidence, but it might also promote selective (inappropriate) use of research evidence.[10]

Canadian researchers have undertaken serious study of the relationship of the research enterprise and the policy-making process. The Canadian Health Services Research Foundation's (CHSRF's) mission is "…*to sponsor and promote applied health systems research, to enhance its quality and relevance, and to facilitate its use in evidence-based decision making by policy makers and health system managers.*"[11] The CHSRF organized a national workshop on *Issues in Linkage and Exchange Between Researchers and Decision Makers* in February 1999.[12] Four themes emerged from the workshop:

- The environment for linkage and exchange between researchers and decision makers should be facilitated through leadership from the research funding agencies.

- The costs of linkage and exchange should be recognized.

- Time needs to be set aside by decision makers to prepare for and receive research for decision making.

- Linkage and exchange infrastructure should be supported through such positions as "knowledge brokers".[12]

The CHSRF published a report describing a comprehensive model that explicated the roles and relationships of the researcher, decision maker, knowledge purveyor, and research funders. The model explains the role of knowledge purveyors and where attention should be paid to improve the links between each of the groups.[11] Three suggestions were put forth:

- The process of getting evidence into decision making is more than simple linkage but involves multiples steps.

- Each of the steps involves improving relationships and communication across the four groups.

- Evidence-based decision making is a "virtuous cycle" and a weak link in the chain may interrupt the optimal flow of evidence into decision making.[11]

In an attempt to further advance this work the CHSRF sponsored a one day workshop in September 2005 reviewing a systematic review entitled "Conceptualizing and Combining Evidence For Health System Guidance"[13]. The purpose of the review was to ask the question "*what counts as evidence for health system guidance, and how can different types of evidence be combined to produce that guidance?* The output of the workshop will be a final report which will provide Canadian decision and policy makers with a generic framework of how deliberative processes in policy making can be used to advance the evidence to policy making cycle.

In another investigation, Lavis et al.[14] conducted a study of employment-related healthy public policy in Canada by examining the barriers to using the information that government departments and NGOs face. Lavis et al. looked at three dimensions of barriers: idea-related barriers, institutional-related barriers, and interest-related barriers.

From the study, the authors made three observations about building on the public policy process. First, health policy makers need to provide leadership by using appropriate values and language when framing information about the health consequences of decisions. Second, health policy makers should advocate for institutional innovations to ensure that health consequences of policy making are not ignored. Third, health policy makers should be prepared to scan and monitor the public, bureaucrats, and stakeholders who may be affected by the lack of support and be prepared to provide them with information.[14]

In a paper connecting research and policy making, Bogenschneider et al.[15] reviewed the four theories that have been postulated regarding the utilization of social science research in policy making. Although this project covers a broader span than the transfer and receipt of social science research, Bogenschneider et al.'s review is instructive. The first theory assumes that there is a causal relationship between social science research and policy making—although the literature reviewed earlier demonstrates that this is not the case, as competing factors, such as values, interests, and electability of politicians, among many others, come into play. The second theory takes into account the limitations of the social sciences, with social scientists being reluctant to share their findings because of the weaknesses of their methodologies. The third theory postulates that social science research is underutilized because the free market democratic forces prevent institutional structures from forming and integrating knowledge and power. The final theory explaining underutilization is based on a communication gap between the research community and policy makers.[15] In their work, Bogenschneider et al. use one technique—seminars to promote the use of research to inform policy making. Bogenschneider et al. focus *on encouraging researchers to be more policy sensitive in an attempt to entice policymakers to be more research sensitive*.[15]

Bryant[16] studied the role of various forms of knowledge in public health and health promotion policy creation. Bryant set out to develop a framework of policy development premised on the contention that public health and health promotion issues ought to be addressed within an analysis of policy change that takes into account concepts of interactive and critical knowledge, along with scientific knowledge. Bryant determined that anecdotal evidence can be a powerful political tool and ideology can influence the types of knowledge and evidence accepted into the political process. The use of interactive and critical knowledge is encouraged to be used with instrumental knowledge to advance the policy agenda. Bogenschneider et al.'s and Bryant's works underscore the important role that the social sciences can play in contributing to the policy-making process in health care.

In addition to the specific studies undertaken and noted about the gap from research to policy making, a comprehensive and systematic review of the literature on the utilization of health research in healthcare policy making was conducted by Hanney et

al.[1] Hanney et al. adapted a list of models of knowledge utilization first proposed by Carol Weiss[17]:

- The classic-/purist-/knowledge-driven model – knowledge is created, informing policy that impels action.

- The problem-solving-/engineering-/policy-driven model – a question arises from a client, stimulating a linear sequence of activities from problem identification to development and assessment of alternative solutions.

- The interactive/social interaction model – researchers and users share a common world in which the interactions result in creation of evidence.

- The enlightenment/percolation/limestone model – research is seen as an accumulation of insight, theories, concepts, and perspectives.

- The political model – research is motivated toward and provides ammunition in a contested environment of policy making.

- The tactical model – if in doubt about next steps in policy making, commission a research study; if perceived as a delaying tactic or a way of avoiding the issue, this can be a helpful technique.[1]

The attention being paid to the issue of increasing knowledge utilization in healthcare practice, decision making, and policy making is at a peak. The Canadian Health Services Research Foundation supports the evidence-based management of Canada's healthcare system by facilitating knowledge transfer and exchange—bridging the gap between research and healthcare management and policy. The CHSRF does this through several strategic initiatives,[11] including a brokering program that links decision makers and researchers, facilitating their interaction so that they are able to better understand each other's goals and professional cultures, influence each other's work, forge new partnerships, and promote the use of research-based evidence in decision making. These initiatives are at an early stage of development and have not yet been evaluated as to their utility or effectiveness for increasing the influence of research evidence. Knowledge brokering activities include finding the right players to influence research use in decision making, bringing these players together, creating and helping to sustain relationships among them, and helping them to engage in collaborative problem solving.

THE STEEPLE MODEL

Although evidence and information may not be the determining influence in policy decisions generally, there is value in exploring where evidence can make genuine contributions to policy debates. Researchers and analysts have much to offer the policy maker, often more than the policy maker recognizes. Davies,[18] in his analysis of whether evidence-based government is possible, also suggests, based on his experiences with the Strategy Unit of the United Kingdom's Cabinet Office, that several factors other than high-quality evidence influence the development of policy. These factors include the experience, expertise, and judgement of decision makers; resources; values; habit and tradition; lobbyists, pressure groups and consultants; and pragmatics and contingencies. The goal, as Davies writes, of evidence-based (or evidence-informed) policy is to ensure the best available evidence is integrated with these factors in the policy development and decision-making process.

To further this integration, the Strategy Unit has developed several tools to improve the policy development process. The *Strategy Survival Guide*[19] suggests a policy analysis model, **PESTLE**, to focus attention on six areas of analysis: political, economic, socio-cultural, technological, legal, and environmental. This model is defined broadly enough that, with appropriate specification, it can be applied to any policy area. The political analysis includes, for example, taxation policy and local government considerations. Economic analysis includes such things as business cycles, GNP trends, interest rates, inflation, unemployment, and disposable income. The legal analysis could include international/European Agreement law, employment law, competition law, health and safety law, and regional legislation. The environmental area of analysis could include environmental impact as well as environmental legislation, energy consumption, and waste disposal.

A second work that recently turned its attention to identifying ways to close the evidence to policy making gap is the work of Erickson, De Wals and Farand[20] in which they present an analytical framework to assist in the analysis and comparison of potential immunization programs. The analytical framework is comprised of 13 categories, including the burden of disease, vaccine characteristics and immunization strategy, cost-effectiveness, acceptability, feasibility, and evaluability of program, research questions, equity, ethical, legal and political considerations. Their model has been used to structure presentations and reports as well as establish priorities in policy making settings.

Like the PESTLE model from which it is developed, the policy model suggested here is a way to conceptualize doing policy analysis that helps the researcher and analyst provide a more complete set of evidence and information for the decision maker. The model also helps the decision maker conceptualize the type and quality of evidence that

is appropriate for the decision. The model contains elements or areas of information, as well as broad perspectives that are not normally explored by policy analysts.

The model uses seven major categories to describe the kinds of questions or information that policy decision makers tend to use, formally or casually, admitted or not, as well as a couple of categories that perhaps should be used more frequently. The seven categories indicated by the mnemonic **STEEPLE** are social and system demographics, technology, environment, economics, politics, legislation, and ethics (see Appendix A: Checklist). The mnemonic does not imply an order within which an analysis would proceed, although that may be the case in some aspects, nor does it imply the way the analysis should be reported. It does allow useful combinations and permutations of categories for the analysis where these would be useful. For example, technology and environment could be combined in an analysis, as could politics, legislation, and ethics. In other policy studies, all categories may best be kept separate. Regardless of how an analysis is approached, no category can be completely dealt with on its own. Analysis in one category can often influence the analysis in another.

STEEPLE differs from PESTLE in two significant ways: the inclusion of politics in the political component and the addition of an ethical analysis. The inclusion of politics focuses the analyst on some key issues faced by the decision maker, such as balancing the interests of competing interest groups. The ethical analysis component enables the analyst and decision maker to bring the articulation of values into the decision analysis in a conscious, self-aware manner. In all other ways, STEEPLE and PESTLE are essentially equivalent, with only nuances of differences in the other categories.

Although these major categories, with appropriate adjustments, apply to all public policy, whether it be environmental; business or economic; or social, cultural, or health policy, in this paper, we will apply the model to health policy issues, and most particularly to questions of health technology. In this application, the decisions required are usually whether to add a new technology or service—a treatment, diagnostic, or other procedure—to the list of insured or publicly funded services.

In the past few years, the nature of evidence that either is used or should be used in policy decisions has been the subject of debate. The STEEPLE model, however, is based on the premise that multiple types of evidence and methods are necessary to produce a rounded understanding of the problem, the proposal, and the politics of the situation. Evidence is taken here to have its usual definition as a thing or things helpful in forming a conclusion or judgement. A hierarchy of evidence, which assigns a different value to different types of evidence, simply is not a useful conceptualization for the STEEPLE model as a whole, although such hierarchies may have value within the components of the model. In the following sections, some of the types of evidence that could be brought to bear will be mentioned.

As mentioned earlier, in any given decision, not all parts of the STEEPLE model would be relevant. Part of the craft of policy analysis is in determining what information or

evidence for which elements is central to making the decision, what evidence is peripheral, and what evidence is not needed. The STEEPLE model simply allows policy researchers, analysts, and decision makers to conceptualize the different categories of information that may be useful to a decision.

Social and system demographics

Social and system demographics is intended to present the decision maker with an understanding of who is affected by the identified problem or who is affected by the conditions that have been defined as a problem, the extent or distribution of the problem, and what society is presently doing about it. This last element includes the operation of whatever services and service systems have been established to deal with the problem.

Using the application to health technology policy as an example, the social and system demographics element would primarily take the population health approach of examining the patterns of illness and the current patterns of care.

Patterns of illness, the description of who is affected along with the extent of the problem, deals with the population dynamics of affected patients. What are the trends in prevalence and incidence of the identified condition(s)? What is the age/gender structure of the affected population? What is the ethnic/cultural mix? What is the socio-economic status (education and income)? The answers to some of these questions, for example, socio-economic status, may simply show that identifiable subpopulations are not involved, that the problem crosses social and cultural boundaries. The involvement of identifiable subpopulations raises questions such as access to appropriate services and the ethics involved in responding or not responding to the problem.

Another area of interest is the burden that the problem has on the individual affected, in this application, the burden of illness. This area of information includes a description of the condition or illness; the usual progress of the condition or the natural history of the illness; the psycho-social effects of the condition on the individual; the economic effects such as the additional costs due to the condition, the ability to earn a living, and the income supports that may be necessary; and the effects of the condition on physical activity and lifestyle.

The system demographics for a health technology policy issue would be related to the patterns of care. System demographics analysis overlaps economic evaluation analysis only slightly. Systems demographics looks at typical utilization patterns (where evidence exists) but not costs, whereas economic evaluation looks specifically at the costs (based on utilization) of the technology in question and the specific comparator. Systems demographics might include a brief history and development of treatments or other services used for the condition or illness. It would definitely include an analysis of the current treatment options and identification of the present standard treatment or

services, an overview and trends of use of different treatment options, and description of the affect of patient or population characteristics on access to current treatment options and especially the standard treatment.

System demographics would also include the analysis of the capacity of the system to provide care. What are the trends in the number and distribution of practitioners and support staff capable of providing service, both for the current standard treatment and the proposed treatment or services? What is an appropriate patient/practitioner ratio? What is the affect of these system constraints on access to service?

The evidence for social and system demographics ranges from population surveys to case studies to program evaluations. Experimental or controlled studies of any nature are rarely done in this area and when they are done, they rarely answer the questions posed here.

Technology effects and effectiveness

In its broadest definition, the technology component would cover all the technology that is involved in the problem, either affecting the condition itself or used to deal with the condition. When applied to health technology policy, the technology component becomes technology effects and effectiveness and deals primarily with the new technologies or services being proposed to deal with the condition.

Information that could be required in this area includes a basic understanding of what the technology has been approved for within Canada, that is, the condition(s) for which the technology has been approved by regulatory agencies such as Health Canada; the etiology of the condition(s) that the technology is meant to treat; the clinical indicators for the use of the new technology; the acceptance of the technology in professional practice in Canada; and what the best practice for condition(s) is currently thought to be.

The analysis of effects includes the action and effect of technology on the condition(s) it is meant to treat, symptoms, or etiology; the difference from the standard treatment(s); the expected benefits, both medical and the reduction of the burden of illness or the patient's improvement in quality of life; the risks, side effects, and safety issues for patients and providers; and the measurement and indicators of outcomes (benefits, risks, side effects).

Another area of information that may be needed deals with the program context. Is there a need for a wider program of intervention for the proper use of the technology? What would this program look like? Is there a requirement for other technologies for appropriate use of target technology or ability to use equipment already in use for publicly funded procedures? What follow up or related care would be required to maintain the outcomes? What would be the effect on related or follow-up treatments or care that would be required by current treatments?

Finally, the question of effectiveness needs to be examined. What is the available evidence of benefit or effectiveness? Are the outcomes achieved dependent on patient characteristics, specific training or experience of the providers (the learning curve), equipment used, or any other factors?

Assessing the effects and effectiveness of a technology or service requires different kinds of evidence depending on the technology or service being assessed. For medical technologies, a systematic review of a hierarchy of evidence, giving randomized controlled trials (RCTs) a prominent place, may well provide the best evidence. For behavioural interventions or similar services, program evaluations that do not include RCTs may still be useful.

Environment

Except in environmental policy itself, questions about environmental impacts are not usually asked. Nevertheless, as the United Kingdom's Strategy Unit recognizes, given the recent prominence of environmental issues, all public policy should probably have an environmental assessment performed. Of course, the nature and extent of an environmental assessment would vary considerably depending on the policy issue concerned. For health technology policy, the primary environmental concerns would be whether, in comparison to standard treatments, the new technology would result in any increases in medical waste or other pollutants; whether there would be environmental safety issues for workers, such as radiation risks; or whether, more generally, significant energy consumption effects exist. In an actual health technology analysis, environmental effects can be dealt with as part of the technology effects and effectiveness.

Again, systematic reviews of natural and physical science studies would likely provide the best evidence.

Economics

Virtually all public policy has an economic component, usually involving the provision of funding within government budgets, to cover the costs of service, the costs of providing a program, or the costs of regulating. Much public policy also affects the economy of the jurisdiction; for example, taxation policy influences the growth or evolution of certain types of enterprises. Hence, the economic component of public policy analysis can cover a great deal of ground, even when the model is applied to health technology policy.

Economic evaluation of the technology may include an analysis of the distribution and concentration of rewards and costs or the economic incentives and disincentives for using the technology. If direct government funding is involved, will the adoption of the technology influence government's revenue stream; that is, what is the multiplier effect

of adopting the new technology? What is the effect on employment of the new technology? Is this a net positive effect or a net negative effect?

Will introducing new technologies have effects on the market for the old technologies or related technologies and services? What effects or shifts may occur? What external economies or diseconomies (individual as well as social) will adoption of the new technology generate? How do these factors affect the real costs of the technology?

A large part of the economic evaluation of new health technologies deals with the questions of cost and utilization. The analysis would need to include, for example, the unit and capital costs of the technology and associated services, the cost-effectiveness or cost-benefit of the technology, utilization trends, and cost trends and cost transfers from displaced services.

The evidence used here is primarily economic in nature but may also involve quality-of-life measurements and other softer evidence of benefits in the cost-benefit analyses.

Politics

Commonly, politics—the means and ways that people in groups interact in the pursuit of their goals—is not consciously included in policy analysis or development. Policy analysts tend to work within a political environment and take that environment for granted. In fact, modern policy science has tended to go further and believe that politics has no place in policy science. But even 20 years ago, this notion was considered naïve:

> … the policy science movement and its literature naïvely cling to a number of outdated assumptions. One is the overly simplistic assumption that better policy knowledge will lead to improved policy decisions. Another is the idea that good policy science is "value neutral." There is little in the contemporary experience that demonstrates the reliability of either assumption, although both remained firmly grounded in the discipline. Taken together, they perpetuate one of the discipline's most powerful myths: mainly, that the concerns of policy science, if not all policy experts, transcend the play of politics.[21]

In keeping with the concept of policy windows, it is the premise of the STEEPLE approach that politics, conscious or not, is very much a part of policy analysis and development.

Although it may not always be a conscious element in a policy decision, elected officials are usually quite aware of the political support or resistance to any given decision. But the more controversial a policy may be, the more conscious everyone is of the politics involved. In almost every case though, stepping back from that taken-for-granted

environment and exploring how that environment affects a policy decision can be valuable.

A good starting point for any analysis of the politics of a situation is current government policy. What does the government see its role as or what is its political philosophy? Does the government see itself as activist or interventionist? Or does it see itself as primarily concerned with maintaining the existing structures and values of society? This preconception of its role usually persists over time, changing only when new parties are elected to govern. Nevertheless, it is useful for policy analysts and developers to reflect on this role from time to time. Ways of doing this include an analysis of recent government decisions, especially on similar policy issues, as well as government business plans or published goals.

Aspects of government policy that can and do change in shorter time frames include the social and/or economic goals and priorities for the jurisdiction. These factors would be pertinent in any application of the STEEPLE model. In the case of health technology policy, similar questions need to be asked about health system goals and priorities, health funding policy—the balance between full public funding, partial public funding, or wholly private funding—and cross-jurisdictional alignment and issues.

A more overt political analysis would deal with the degree to which any given condition has been defined as a problem by the decision makers, as well the degree to which they see the proposed technology, as opposed to alternatives, as a solution. It would also consider other processes or events that are influencing the decision.

Some understanding of the stakeholders and others affected by the decision is also needed. In the case of health technology, what would be the effect of the decision on manufacturers and suppliers of the new technology and of the current technologies? What would be the effect on providers and support staff? Will benefits accrue differently to those who adopt the new technology early than to those who adopt it late or not at all? How are patients, their families, and other caregivers affected? Are there any specific groups or identified subpopulations affected? How? What is the effect, if any, on the general public? In performing a stakeholder analysis, it is often useful to consider the four Rs[22]: the rights, responsibilities, and expected rewards or gains for each of the stakeholder groups and the relationships between the groups.

Little of the information specified in this section could be considered to be research evidence, even in the broadest sense of the term. Much of it is surmise and guesswork; some is anecdotal and some is simply documentary. Although wide-ranging in quality, opinion polls can sometimes provide useful information on public concerns and effects, and recent developments in the use of citizen juries, deliberative processes, and polling may bring some additional rigour to collection of stakeholder and public input.

Legislation/regulatory framework

Not all policy issues involve legislation, which is usually taken to include any regulations made pursuant to the statute involved. Many government programs or other initiatives are simply covered by enabling legislation. In these cases, the value in investigating the legislative framework is small. In some areas, though, the legislation and regulations affecting the policy decision are both enabling and restricting. It is in these latter cases that a thorough understanding of the effect of the legislation on the options being considered is required.

In addition to the legislation of the jurisdiction considering the policy decision, sometimes an understanding of the applicability of legislation or agreements in a superior, parallel, or subordinate jurisdiction is needed. Recently, many policy initiatives had to consider the potential effects of the NAFTA agreement and the Kyoto Accord. In the case of health technology policy, federal legislation that may have an effect includes the Canada Health Act and the Food and Drugs Act. In some cases, there may also be pending legislation or regulation that may apply to the issue. This situation may be more difficult to deal with because of the confidentiality that often surrounds new legislation until it is introduced in the legislature.

Again, the information contemplated by this area of analysis is probably not susceptible to scientific rigour, although there are specific principles of interpretation applicable to the legislation and regulation that need to be considered.

Ethics

Ethical analysis of a policy decision is something that is not commonly undertaken. Some commentators believe that ethics has no part in policy decisions, arguing that policy is a balance of competing interests and interest groups, with no right or wrong choices, and that ethical considerations simply interfere with the bargaining process. The STEEPLE model is predicated on the contrary position that the identification of the ends sought in a policy decision, the examination and articulation of the values embodied in those ends, and the assessment of the extent to which these ends are in keeping with the values of society is an important part of a complete policy analysis. This analysis also needs to be broadened to examine each of the proposed alternatives for the ends and values embedded in them. The ethical analysis suggested by the STEEPLE model does not imply an ethical position nor does it attempt to sell a particular solution or option on an ethical basis; STEEPLE's ethical analysis is simply an articulation and comparative analysis of the values inherent in the policy issue and proposed solutions.

When attempting to assess the ends against societal values, consideration needs to be given to the extent that values are shared across stakeholders. Where do they conflict; where are they neutral, and where does a consensus exist? In addition to assessing options against the identified values of stakeholders, an ethical analysis also assesses

options against typical ethical models: the common good, fairness and equity, benefit/harm ratios, and individual choice. None of these ethical models holds a complete answer, but it is useful to understand the different options from the different perspectives.

Once again, research evidence cannot be brought directly to bear on these issues, but the evidence offered of social impacts and technological effectiveness, for example, is certainly useful as a foundation for the ethical analysis.

STEEPLE and best practice in healthcare policy making

Although the application of the STEEPLE model does not require particular sets of skills, naturally the result of its application will depend in large part on the skills and expertise of the researchers, policy analysts, and decision makers. It may also provide an opportunity to develop a foundation for what might be tested in the future as a "best practice" in healthcare policy making. To date, little work has been done on best practice in policy making in Canada. But whether policy making is a science, or a craft, or both in turns, there is ground for best practices to be defined. The STEEPLE model could help begin the articulation of some of those requirements. Drawing partly from Pal[23] and Seale,[24] some suggestions for the further development of a best practices model for healthcare policy making can be put forward.

First, for policy staff to effectively integrate emerging research findings in the health policy arena into the policy agenda setting, development, design, implementation, and evaluation processes require the staff to stay current in the developments in those areas through training and education. Some knowledge and experience in the healthcare system, with policy analysis relying on the multitude of quantitative and qualitative methods to inform issues, as well as administration, is essential preparation for policy makers. There is currently no agreed upon professional competency identified for the practice of healthcare policy making in Canada. The STEEPLE model may be one source for defining the range of knowledge and skills that policy makers need, but these skills need to be further developed, validated, and field tested to ensure a consistent standard of practice.

Second, having access to data (in its many forms), library and competent information specialists who are familiar with the multitude of resources is essential. The amount of information being published each day in the health sciences is of such a magnitude that it is impossible for anyone person to stay abreast of daily developments, even in each of the subspecialties. Knowledge management skills and competencies are necessary so that the information that is available can be harnessed effectively.

Last, best practice in policy work needs openness to the kind of evidence that should be brought in to inform the question. Double-blind randomized control trials may well be the highest form of scientific evidence, but it is hardly the best method to answer a question about effective methods of encouraging appropriate means of palliative care.

The social sciences may furnish a more appropriate model of inquiry. An appropriate research design to match the problem or question being raised needs to be identified. There may well be several complementary approaches that need to be taken in any one case. The task of mediating in the policy making environment is not an easy one; however, being clear about what constitutes the credible evidence in each case makes the task easier.

Policy makers and policy analysts, though, also need to recognize that there is a trade-off among time, cost, and quality—one can usually have two of the elements, but rarely all three. When timeliness is important, policy makers need to balance the quality of research they are seeking with the amount of risk they are willing to take for getting the wrong advice. Researchers need to balance the quality of the research they undertake against the time they are given. How much risk a policy maker is willing to take is the dilemma he or she faces. How much quality the researcher is willing to sacrifice is the dilemma he or she faces. The proper mix of risk to be taken by the policy maker and researcher should not be negotiated in isolation—all the cards need to be laid on the table and the consequences of getting it wrong need to be identified upfront. Nevertheless, the existence of policy windows suggests that timeliness often outweighs quality of the evidence. Politics, as well as management, is often considered the art of making decisions without sufficient information.

CONCLUSION

Public policy is a messy business, yet it can be influenced by evidence of all kinds. When evidence is artificially narrowed to mean only the results of systematic investigations toward increasing the sum of knowledge, or research evidence, the perceived role of evidence in decision making shrinks. Yet even in this much reduced role, research evidence can ultimately have significant effects. The problem is that it has to be mediated through the stock of knowledge generally held by the population before it can be part of a policy solution.

The STEEPLE model is an attempt to conceptualize all the kinds of information that go into a policy decision and point out where research evidence can play a role. But even where high-quality research evidence does not play a role, other evidence and information can. Like the justice system, testimony and anecdote can be useful sources of information for decision makers. The challenge is to ensure that all information used in a decision is given appropriate weight. Insofar as decision makers can often make good policy decisions, the process works. Therefore, the model is useful, but it is not the whole answer.

In the end, evidence and information cannot be the determining factor in policy decisions. There will always be world views and values, which will help to determine when a condition becomes a problem and when the political situation is such that a decision can be made.

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APPENDIX A:

THE STEEPLE MODEL

A Checklist for Health Technology Policy Decisions

Social and System Demographics

- Patterns of illness
    - o Population dynamics of affected patients
        - Trends in prevalence and incidence of the identified condition(s)
        - Age/gender structure
        - Ethnic/cultural mix
        - Socio-economic status
            - Education
            - Income
    - o Burden of illness (on individual)
        - Description of condition
        - Usual progress of condition
        - Psycho-social effects
        - Economic effects
            - Addition costs due to condition
            - Ability to earn a living
            - Income supports
        - Physical activity/lifestyle effects
- Patterns of care
    - o Brief history and development of treatments for condition
    - o Current treatment options/standard treatment
    - o Overview and trends of use of different treatment options
    - o Affect of patient or population characteristics on access to current treatment options/standard treatment
    - o Capacity of system to provide care
        - Trends in the number and distribution of practitioners and support staff capable of providing service
            - Standard treatment
            - Proposed treatment

- Appropriate patient/practitioner ratio

Technology Effects and Effectiveness

- Condition(s)
    - Condition(s) for which the technology has been approved by Health Canada and other regulatory agencies
    - The etiology of the condition(s) that the technology is meant to treat
    - Acceptance of the technology in professional practice in Canada
    - Alternative treatments and therapies, best practice for condition(s)
- Effects
    - Action and effect of technology on the condition(s) it is meant to treat
    - Difference from standard treatment(s)
    - Expected benefits
        - Medical
        - Reduction of burden of illness or improvement in quality of life
    - Risks and side effects
    - Measurement and indicators of outcomes (benefits, risks, side effects)
- Program context
    - Need for wider program of intervention for proper use of technology
    - Follow-up or related care required to maintain the outcomes
    - Requirement for other technologies for appropriate use of target technology
    - Effect on related or follow-up treatments or care that would be required by current treatments
- Effectiveness
    - Available evidence of benefit or effectiveness
    - Dependence of outcomes achieved on:
        - Patient characteristics
        - Training or experience of the providers (learning curve)
        - Other factors

Environment

- In comparison to standard treatment
    - Increases medical waste or other pollutants
    - Raises safety issues for workers

- o Increases radiation risks
- o Produces significant energy consumption effects

Economics

- Distribution and concentration of rewards/costs

- Incentives and disincentives

- Multiplier effect
  - o How much
  - o Effect on employment
  - o Forward and backward linkages

- Market effects/shifts

- Externalities (social and individual)

- Cost and utilization
  - o Unit costs of technology and associated services
  - o Cost-effectiveness/cost-benefit
  - o Utilization trends
  - o Cost trends and cost transfers from displaced services

Politics

- Government policy
  - o Perceived role of government (political philosophy)
  - o Social and/or economic goals and priorities for the province
  - o Health system goals and priorities
  - o Health funding policy
    - ▪ Full public funding
    - ▪ Partial public funding (e.g., field trials)
    - ▪ Wholly private funding
  - o Cross-jurisdictional (F/P/T) alignment and issues

- Political analysis
  - o Degree condition has been defined as a problem
  - o Degree technology is seen as a solution
  - o Other processes/events influencing decision

- Stakeholder analysis
  - o Effect of decision on

- - - Manufacturers/suppliers
      - of new
      - of current
    - Providers and support staff
      - early adopters
      - late adopters
      - nonadopters
    - Patients, family, and caregivers
    - Other specific groups
    - Public
  - Four R analysis
    - Rights, responsibilities, rewards for each of the key stakeholder groups
    - Relationships between stakeholder groups

Legislation/Regulatory Framework

- Applicable health legislation/regulation
  - Enabling effects
  - Constraining effects
- Potentially applicable legislation/regulation/international agreements (e.g., NAFTA, Kyoto)
- Emerging legislative and regulatory constraints or facilitators

Ethics

- Values, assumptions underlying the definition of the problem and the decision options
- Value conflict, neutrality, or consensus across stakeholders
- Evaluation of alternatives against
  - Identified values
  - Common good
  - Fairness and equity
  - Benefit/harm ratio
  - Patient choice