

Knowledge, Decisions And The Timing Of Policy Development: Creating A Strategic Framework For Science Policy

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Abstract

As an approach to linking patient outcomes research and nursing practice, the paper begins with a framework defined by three aims of science: building knowledge, making decisions and carrying out applications—and goes on to identify related, strategic questions about nursing research.

The National Center for Nursing Research (NCNR) is capable of bringing its resources and position to bear on those questions, which include: how are data about nursing practice related to the intellectual agenda of the initiative? How does nursing research contribute to evaluating decision-making based on the findings of the initiative? When would nursing research contribute to policies derived from the initiative; near term (practice and payment policies) and/or long term (health care system reform)?

NCNR's answers would establish a strategic framework about nursing practice and research in patient outcomes. The framework could guide science policy and bring decisions about design and methods to life. Those decisions are best made in light of both science and expected application, particularly when the applications include clinical decision-making, policies guiding practice, policies about health care financing, and policies affecting health care reform.

NCNR's strategic framework, and resulting science policy, would foster a portfolio of nursing research that meets the standards for patient outcomes research and falls within the authorization of NCNR.

Implications for some pivotal design and methods issues are discussed, followed by conclusions:

1. Improving the link to nursing practice requires specifying nursing data and inputs in relation to the samples, measures and analytic models used in outcomes research and creating simple ways of obtaining the pertinent data.
2. All studies of patient outcomes should address the limits of scope, rigor and generalizability. The field would benefit from a formal, but pragmatic, evaluation of the assets and liabilities of the knowledge base for clinical decisions and policy analysis.
3. Outcomes research must include some controlled experimental studies. Those studies should be multidisciplinary, of sterling quality, and focused on enduring policy questions.

As we discuss the topic for this session, design and methods and the link to nursing practice, it is important to remember the specific purpose of our discussion. We are here to try to contribute to the NCNR's deliberations over their science policy regarding patient outcomes research. The policy will reflect NCNR's definition of "science" in this field. If it affects how NCNR distributes its resources,

the policy will play a role in shaping knowledge about nursing practice and outcomes. By affecting the knowledge base for health policies, the science policy will eventually affect access to nursing care. In short, this is a science policy with substantial potential.

Our aim is to analyze the technical issues in a manner that helps to inform thinking about science policy. Here, I outline a strategic framework designed to support that analysis. It relates technical issues to the overarching purpose of conducting research in order to improve health services.

The framework is incomplete until NCNR's decisions are incorporated. Once completed, the framework should establish connections between science policy and three goals of science: to design a plan for building knowledge; to create the ability to make decisions; to prepare for the expected/desired applications. (See Figure 1) For patient outcomes research, those three general goals include many specific objectives. For example, research in the field addresses an agenda for building knowledge about what works and how to use it in health care. Studies also evaluate the quality of the knowledge base for decisions. Findings are, or will be, used to support policies guiding practice and payment now, and system reform later.

Related questions for science policy about nursing research include: how can data about nursing practice be linked to studies of what works and how to use it; how can the evaluation of the knowledge base as a premise for decisions be extended; and, how can the timing of nursing research be estimated so that studies can be articulated with the right policy activities? (See Figure 2)

Clearly, I am posing more questions than answers. Even so, each of the three goals is examined more closely in the following sections. The discussion focuses on the implications for linking data about nursing practice to

patient outcomes research. The paper outlines a strategic framework defined by the aims of building knowledge, making decisions and carrying out applications. This framework could be considered as part of the context for science policy.

I. National Center For Nursing Research

Major research efforts in patient outcomes are well underway, and will soon produce new premises for policies guiding both practice and payment systems. However, as the outcomes and effectiveness initiative gathers steam, it does so essentially without establishing positions for data about nursing practice. Notable as it is, the groundswell of related activities within organized nursing and by individual nurse scientists has not established those positions—in part because several strategic questions have not been answered. Yet.

The National Center for Nursing Research (NCNR) is capable of bringing its resources and position to bear on those questions, which include:

- how are data about nursing practice related to the intellectual agenda of the initiative?
- how does nursing research contribute to evaluating decision-making based on the findings of the initiative?
- when would nursing research contribute to policies derived from the initiative; near term (practice and payment policies) and/or long term (health care system reform policies)?

A. Strategic Framework

NCNR's answers, essentially a strategic framework about nursing practice and research in patient outcomes, would guide science policy and bring decisions about design and methods to life. Those decisions are best made in light of both science and expected application, particularly when

the applications include clinical decision-making, policies guiding practice, policies about health care financing, and policies affecting health care reform.

NCNR's strategic framework, and resulting science policy, would foster a portfolio of nursing research that meets the standards for patient outcomes research and falls within the authorization of NCNR. Under the Health Care Research Extension Act of 1985, P.L. 99-158, NCNR was authorized at NIH for the "conduct and support of, and dissemination of information respecting, basic and clinical nursing research, training and other programs in patient care research".

ii. Agenda And Links

The first component of the framework focuses on knowledge; in this case, the patient outcomes research agenda of building knowledge about what works and how to use it—as well as the strategic question of what data about nursing practice would contribute.

A. Patient Outcomes Agenda

The roots of the patient outcomes research agenda are in quality of care and technology assessment. In the late 1980s, the Administrator of the Health Care Financing Administration (HCFA) discussed four areas of work that could support an initiative to improve effectiveness of care: database development, research on outcomes and clinical effectiveness, dissemination and assimilation of findings, and development of practice guidelines that are practical, based in science, explicit and revisable (Roper, et al, 1988; Roper, 1990).

The research agenda is enormous. For example, Berwick (1989a) outlined four components: efficacy (finding out what works), appropriateness (using what works), execution of care (doing well what works), and purposes of care (identify the values underlying actions). Even the

most pared-down empirical question becomes extraordinarily complex when it is placed in the domain of "usual" health care delivery.

Brook & McGlynn's (1990) definitions of "quality" illustrate such complexity. They identify two components of quality; the technical process of care and the art of care. The technical process refers to the amount, type and manner of resource utilization. It is measured by determining whether the service was appropriate. That is, was the right procedure done for the right reasons? It is also measured in terms of the outcomes; was the procedure done competently, and what were the outcomes for the patient? The art of care is measured in terms of patient satisfaction and compliance.

Elements of the patient outcomes agenda seem to fall within the purview of NCNR, and could plausibly draw on each of the branches (Nursing Systems, Health Promotion/Disease Prevention, Acute and Chronic Illness). Improving the links to data about nursing practice involves a number of actions, many of which have been discussed during this conference. Two categories of those actions are especially pertinent to this session:

- specify the nursing inputs for patient outcomes
- reconcile how we define and measure those inputs to the design and methods of patient outcomes research

B. Improving Knowledge About What Works

1. Specify Nursing Inputs

Although a large number of nursing inputs have the potential to contribute to outcomes research, I will focus on only two today: nursing data about the risks patients carry at admission; and, nursing services which are provided during hospitalization and affect the probability of receiving treatment and/or having various outcomes.

The first set of inputs, nursing data about risks, is indirect in the sense of providing additional data about patients. These are not data about nursing itself, but rather, unique data that nurses collect routinely. The second set of inputs, nursing services delivered during hospitalization, are direct in the sense of defining additional elements of clinical strategies in the context of the elements already under study.

These two sets of nursing inputs are significant because they could simultaneously improve the links to data about nursing practice and make unique contributions to the patient outcomes knowledge base. If the data were available, they would allow researchers to:

- use nursing data to enhance casemix measures, and
- use nursing data to refine definitions of clinical strategies, treatments, and outcomes.

2. Reconcile

A. Sampling

Sampling by outcome or clinical condition, sampling from “at risk” populations, and using power analyses to determine sample sizes for low incidence variables are important to outcomes research (Donabedian, 1988A, 1986, 1982; Siu et al, 1991; Luft & Hunt, 1986). Related research on quality assurance and dissemination aims to safeguard and improve the quality of care by changing providers’ behavior (Donabedian, 1991). The research focuses on increasing the systems’s capacity to implement an effective and comprehensive quality assurance program, and thus, the sample might draw upon providers, institutions, payors and agencies (Lohr & Schroeder, 1991). Nurse researchers have certainly developed a foun-

ation of experience in using the sampling techniques of patient outcomes research and research to guide dissemination (Lang & Merek, 1990; Moritz, 1991).

However, nurse researchers have less of a foundation in studying patient groups as aggregates and assessing their status in relation to outcome variables. Linking outcomes research to nursing practice may require efforts to increase familiarity with the methods such as caseload analysis.

There are many models of caseload analysis. For example, using the basic dimensions of characteristics and policy associations, Meister (1989) illustrated an approach intended for research on families. The method includes assessment of four characteristics (demographic, health, economic, social) and four policy associations (family economics, health care systems, education and transition to work, services to young children and their families). This method, or any designed to array knowledge from practice so that it can be used in policy analyses, could generate a concise, practice-based set of parameters for describing groups of hospital patients. The parameters then contribute to developing sampling frames linking outcomes research and nursing practice.

B. Measurement

Measurement is more of a problem—for outcomes research as well as for creating links to nursing practice. Because the objectives of outcomes research include identifying the right interventions and how to use them to obtain the best outcome, the studies must go beyond the relationships between treatment and outcome to address variables such as provider competence, access (market level and beneficiary level), and acceptability of care (Brook & Kosecoff, 1988; Palmer, 1991).

Outcomes research must demonstrate the link between the processes of care and outcomes, and assess technology in ways that will explain the process of care, but the

link is obscured by the multiplicity of processes and providers embedded in care (Horn & Swain, 1988; Lohr, 1988). Research methods to untangle those effects are advancing rapidly, but remain limited by both databases and measures (Lohr, 1988; McNeil, 1990; Tarlov, et al, 1989; Ware, 1990). HCFA's administrative databases, often used in patient outcomes research, illustrate both the advances and the limits.

The administrative databases offer an unbiased, but partial, view of whole populations of patients and providers in the real world. They can be linked to mortality data, used to derive rates and variations in use of technology, and used to estimate costs of hospitalization (McNeil, 1990)

However, limits in data about how treatments were selected, how outcomes vary by provider, comorbidity and severity of illness make it difficult for researchers to define an inception cohort (Jenks, 1990; McNeil, 1990). Further, the risk adjustment variables are very limited—even the best account for less than 30% of the variance in mortality (Jenks, 1990). Therefore, the administrative databases are least useful for studying diagnostic entities, and have definite limitations in studies of therapies (Jenks, 1990; McNeil, 1990). Often, because research designs require risk adjustment and administrative databases don't fully address it, the outcomes included in those databases are viewed as relatively crude screening measures with uncertain sensitivity and specificity (Jenks, 1990, Jenks et al, 1988; McNeil, 1990; Schroeder, 1987).

Although most studies of patient outcomes make use of the HCFA administrative databases, they often use supplementary data as well (Agency for Health Care Policy and Research, [AHCPR] 1991). Similarly, researchers continue to examine ways of expanding the range of out-

comes beyond morbidity, mortality and disability (Brook & McGlynn, 1991; Greenfield, 1989; McCormick, 1991; Ware, 1990).

In general, nurse researchers have been conducting work related to the measures used in patient outcomes for 15 years. In 1978, Horn and Swain developed criterion measures of nursing care, followed by Hegyvary's measures of the quality of care, Strickland and Waltz work on nursing performance and standards, and Lang and Merck's (1990) discussion of frameworks to classify outcomes, to name a few. During those same 15 years, nursing has also conducted extensive work on patient classification and nursing resource consumption, as well as the conduct and utilization of research in nursing practice. This body of work is pertinent to patient outcomes, although the basis for articulation has not yet been fully specified (Lang & Clinton, 1983, 1984).

C. Analysis: Casemix

Patient outcome analyses usually aggregate data at the level of institutions (ie hospitals) or areas. The design often uses a measure of severity to reduce the confounding of degree of sickness with outcomes. For example, studies often adjust for "casemix", that is, the severity of illness of the group of patients admitted to each hospital. Methods for producing casemix indices have been studied extensively, and applied to various systems for hospital payment. Nursing has applied the principle, but not usually the same methods, to patient classification studies, by examining the relationships between acuity of illness and use of nursing resources.

Outcomes research uses casemix variables to quantify the effects on the probabilities of receiving the treatment or having the outcomes and thus, obtains a clearer picture of the probable role of the treatment in the outcome (Siu,

et al, 1991). Using nursing data in conjunction with casemix indices is an effort to improve the power of those indices. Casemix indices are already designed to move from the concept of a group with health outcomes to a more sensible, and powerful, view of a sample with health outcomes corrected for severity.

For example, a simple view of a patient group receiving/not receiving a treatment and then having outcomes (Figure 3) is greatly enhanced by including the concept of comorbidity and its role in expected outcomes (Figure 4).

Nurses routinely collect data, especially at the time of hospital admission, which could improve the empirical power of casemix indices. The research questions center on which data offer enough of an empirical boost to be worth retrieving, while the application questions center on how to best capture those data. The point is to find nursing data capable of contributing to the complex work of addressing the confounding of severity of illness with the probabilities of receiving treatment and having particular outcomes.

D. Analysis: Clinical Strategies

The purpose for including nursing inputs in the analysis is to have a more complete view of what actually happens, and works well, in treating a particular condition. Once nursing inputs are specified, their direct and indirect effects must be demonstrated in relation to the variables already used in patient outcomes research, such as treatment/procedure (occurs/does not) and outcome (mortality, morbidity, disability).

Data about nursing practice could increase the ability to explain variance in the patient outcomes. However, the data must be reconciled to the level of aggregation and measures used in outcomes research. Scales should be

concise, and indices must separate patients into distinct groups. Accuracy, sensitivity and specificity of measures should be quantified.

Using nursing data to refine definitions of clinical strategies, treatments and outcomes is an effort to define the nursing inputs into clinical strategies and to quantify their relative power in producing variations in treatments and outcomes.

For example, patients experience a number of events between admission and discharge. Some events, such as surgeries, are already factored into patient outcomes research. Some events, particularly temporary problems such as postoperative fever, have not yet been included. If those events are related to the probability of treatment and/or outcomes, then it may be necessary to include them in the analysis. Figure 5 continues the example of the groups with corrected mortality. Here, both subgroups are exposed to the risk of having a temporary diagnosis. Of those who have it, the ones who also receive a nursing input then go on to receive only half a dose of another treatment.

In this hypothetical example, analysis could determine the relationship between the dose of treatment and mortality. If the relationship is strong enough, the interim mechanisms—including the nursing input—merit closer analysis. Even if the results demonstrate that the nursing input is a significant mechanism, it may not be necessary to add that input to the database. If, as shown in this example, the input always occurs in the presence of a half dose of the treatment, then the treatment dosage may serve as a proxy measure for the nursing input.

Improving the links to data from and about nursing practice would allow a more complete view of hospital care. Procedures, morbidity and mortality would retain key roles, but they could also be related to other key elements

of care, such as risks at admission, recovery from admitting diagnoses, discharge planning and perhaps even well-being after discharge. There are nursing inputs into each of the elements (Figure 6). Improving the link between the outcomes agenda and data about nursing practice requires specifying the nursing inputs, and reconciling them to the sampling methods, measures and level of analysis used in patient outcomes research.

The effects of nursing inputs may be largest for outcomes that occur during the course of hospitalization or after discharge, in contrast to the medical diagnosis at admission or discharge (Lang & Merek, 1990). On the other hand, patient outcomes research often measures admission diagnosis, the occurrence of a treatment or procedure, the discharge diagnosis, and mortality at discharge. However, research focused on both direct and indirect effects of nursing inputs could link the two empirical tracks.

This places a particularly heavy empirical demand on hypotheses involving outcomes occurring after hospital discharge. Despite the sensibility of defining effectiveness in terms of the long term outcomes, most databases cannot fully support that framework—and few policy applications currently cross the boundary between hospital and home.

In summary, the existing body of work by nursing is significant for the agenda of patient outcomes research but does not yet answer the pivotal questions: what are the nursing inputs to patient outcomes? What really goes on? What works? How are nursing inputs related to the established variables in patient outcomes research? Sensitivity and specificity of patient outcomes measures have been identified as empirical problems for the field (Cleary, 1990; Institute of Medicine Core Committee, 1990, Jenks, 1990). The combination of nursing admission data about severity and data about the effects (direct and indirect) of

nursing inputs have the potential to reduce those problems. The potential can be realized if nursing admission data and nursing inputs are used as explanatory variables—they contribute less to understanding patient outcomes if they become a parallel field of study.

III. Evaluation And Extension

The field of patient outcomes research is concerned with creating the knowledge base for decisions, especially decisions about clinical practice and policies. Collecting outcome data is one of the simplest steps; the real challenge lies in establishing decision-making processes capable of using those data (Ware, 1990). Therefore, the caliber of the knowledge base as a premise for decisionmaking becomes a central issue.

A. Knowledge Base And Clinical Decisions

Applications to practice include guidelines and monitoring. In both instances, the purpose is to improve the general level of standard practice (Lohr & Schroeder, 1990; Roper, 1988). In fact, Ellwood (1988) envisioned a national system for outcomes management as a technology based on guidelines and patient outcomes information routinely collected and used by all providers. Brook & McGlynn (1991) sketched a system of toll-free telephone numbers to be used by beneficiaries to call HCFA and obtain the relative risks of procedures their providers have suggested.

Applications to clinical decision-making will include a range of activities. The aim is to inform providers and improve their ability to consider research findings when making individual treatment decisions. This aim invokes a number of issues related to applying knowledge from research aggregates to individuals. The issues are familiar to researchers, but may not be so to providers. Thus,

one of the essential steps in fostering application of the outcomes knowledge base is to help clinicians avoid errors in reasoning and logic (Mulley, 1990).

The scope of the knowledge base, and explicit analysis of it, can affect the dissemination of findings. Ambiguity in objectives and uncertainty about applications are significant sources of resistance, as are concerns that the rational basis for decision-making may be faulty (Berwick, 1989b; Epstein, 1990).

Clinical decisions would benefit from a knowledge base that included analyses of the strategies used by providers and patients, particularly if all elements of the strategies were examined. Whether or not the presence/absence of a procedure in the hospital discharge dataset can serve as a proxy for complete strategies is a research question. It is also important to find some way of assessing how well a successful clinical strategy is specified. Are all of the elements identified and tested? Data from nursing practice could offer a database about the elements of care, that is, the components of strategies for combining the processes, providers and recipients of care.

B. Knowledge Base And Policy Analyses

Exceptional as it is, outcomes research will produce knowledge with specific limits in terms of scope and generalizability. Decisions based on that knowledge will be better informed if they are made with a clear view of those limits and the implications for policy analysis. Whenever policy decisions are made at the interface of facts and values, those decisions are likely to be better if the societal aspects of them are given serious consideration early on (Nightingale & Meister, 1987).

Policies based on outcomes research could address the economic and institutional barriers to improving outcomes. They can reinforce or change delivery patterns, such as the balance of authority for managing health care;

they might also affect the incentives for investing in quality improvements (Giegel & Jones, 1990). In short, policies emerging from outcomes research can reach all levels of the care system and profoundly affect factors such as efficiency of clinical care, accountability, allocation of resources, internal policies, functional differentiation of institutions, pricing, payment and competition (Donabedian, 1989).

However, despite the scope of impact, outcomes research is an emerging field and some fundamental questions are as yet unresolved. For example, there is disagreement over the fundamental question of whether or not consumers are capable of reporting or rating the quality of their health care (Davies & Ware, 1988). There is no consensus regarding whether or not the constraints of resources should be considered in the analysis of the quality of health care (Lohr, 1991; Palmer, 1991). Experts differ in their assessments of the magnitude and direction of effects of outcomes research on health care costs (Aaron, 1990; Epstein, 1990; Fleming, 1991; Lohr & Schroeder, 1990).

A formal, but pragmatic, evaluation could relate the assets and liabilities of the knowledge base for clinical decisions to policy development. If viewed as a research issue by NCNR, evaluation studies could fit within the Nursing Systems branch. The strategic questions for nursing include whether the evaluation can, and should, be extended.

A number of models have been developed to assess the logical quality of a knowledge base. For example, Rossi and Freeman's (1989) Impact Model can be used to develop the evaluation criteria. The model is based on causal, intervention and action hypotheses. Those hypotheses could also be used to identify relationships that should be specified in the conceptual framework, design and measures of patient outcomes research. The quality of the definitions of those causal, intervention and action rela-

tionships could then be evaluated. The evaluation should go further than to identify shortcomings, i.e. places where nursing practice was not included. It should produce a scholarly definition of the nursing inputs, as well as empirical evidence of the utility to be gained by including them.

A knowledge base may also be evaluated in terms of how well it supports its intended applications. In this case, the aims include enlightening policies to improve the general quality of care. Therefore, the knowledge base could be evaluated in terms of how well it incorporates societal aspects of health policy. Nightingale and Meister (1987) illustrated a model for this kind of evaluation, using prenatal screening as the example and well-being, autonomy, and equity as the societal aspects. They evaluated the quality of knowledge produced by cost-effectiveness analysis, decision analysis and technology assessment in terms of the caliber of the scientific findings and what those findings contributed to understanding the societal aspects of policies in the field.

Similar work could be done for patient outcomes. The scientific elements of the knowledge base could be evaluated in terms of meta-analysis, decision analysis/models, outcomes assessment, cost of care, dissemination and evaluation of dissemination, and use of administrative databases. In fact, AHCPR has six inter-PORT workgroups focused on these elements.

IV. Policy And Timing

Patient outcomes research has direct applicability to policies about practice and payment systems. Those policy effects are likely to occur in the near term, and research efforts would have to employ designs that could be launched and completed in a timely manner.

Work in this field can also contribute to health care reform. Since the development of system-level reforms is likely to take longer, research efforts could employ designs such as large randomized trials and still be completed in time.

If the links to data about nursing practice are improved, they will enable interactive and synergistic research and demonstration projects. Timing becomes important, and the strategic question for nursing becomes one of estimating when nursing research will be completed, as a way of identifying which policies can be affected.

A. Near-Term Policies

A substantial portion of the urgency surrounding patient outcomes research is related to the need for information to guide policies affecting practice and payment. Policies based on patient outcomes research and affecting practice and payment are likely to be incremental and emerge in the next few years (Griner, 1990; McCormick, 1991; O'Connor, 1990). Research efforts aimed at affecting those policies will have to operate on the same, relatively short, timeline.

The PORT projects funded by the Agency for Health Care Policy and Research illustrate designs intended to affect practice and policy. A PORT is designed to evaluate the effectiveness and cost-effectiveness of alternative services or procedures.

AHCPR identifies four components in the design for PORT projects: 1) review and formal synthesis/metanalysis of the literature to refine hypotheses, specify the data, and finalize instruments, measures and procedures, 2) collect and analyze data to explain variations in practice and outcomes; use secondary data and supplement with primary data, 3) disseminate findings and rec-

ommendations to providers and public, and 4) evaluate effects of dissemination on reducing unwarranted variations in clinical practice (AHCPR, 1990).

As of September 1990, the PORT projects focused on outcomes in back pain (surgical, nonsurgical treatment), arthritis (total knee replacement, nonsurgical treatment), acute myocardial infarction (variations in treatments), cataracts (variations in surgical treatment), therapies for benign prostatic hypertrophy and localized prostate cancer, chronic ischemic heart disease (diagnosis, treatment), biliary disease (surgical, nonsurgical treatment), hip fracture and osteoarthritis (treatment patterns), diabetes (treatment patterns), pneumonia (treatment patterns), cesarean section (diagnostic and practice patterns) (AHCPR, 1991).

Most of these projects are focused on conditions and treatments affecting a substantial percentage of significant populations, such as all adults or Medicare beneficiaries. Most make use of administrative data, primarily Medicare claims data. Some add specialized survey data, information from private insurance, chart reviews, vital statistics and hospital data. Two projects also add prospective data; acute myocardial infarction project has an inception cohort and pneumonia project has a prospective cohort. For the most part, the measures are selected to allow analysis of variations using at least hospitals, if not geographical areas, as the unit of analysis (see AHCPR, 1991).

Together, the PORT projects and the practice guidelines will have a major influence on clinical decision-making and policies guiding practice. Payors will be able to make use of the results as well, in establishing standards for services and payment—and thus, affecting access to care.

Data from and about nursing practice can improve the quantification of the risks patients bring to treatment, the elements in care that affect the probability of receiving

treatment or having outcomes. In sum, these data could provide unique, incisive information about the nursing inputs and the casemix. If timely, these findings could make a significant contribution to policy analyses of practice guidelines and payment systems.

The science policy questions include: how would nursing data help to quantify the risks patients bring to the treatment? How would nursing data help to quantify elements in the process of care that affect the probabilities of treatments and/or outcomes? Would data from nursing practice would offer unique and incisive information about inputs and casemix? If so, and if it could be marshalled within the topics and timeframes of the PORT projects, and other patient outcome projects, it would contribute to the knowledge base for policies affecting practice and payment.

B. Long-term Policies

Patient outcomes research can identify what works. Using policy to leverage successful strategies will also require decisions about the organization and financing of services.

Extensions to policy are difficult in patient outcomes research because it is necessary to be confident that changes in health status are related to antecedent care (Donabedian, 1988b). Randomized clinical trials, while certainly the “gold standard”, cannot be conducted for every test, procedure and therapy. If the scope of observational studies is expanded to include large numbers of patients and providers, those studies can offer substantial information (Greenfield, 1989). However, some questions require controlled experiments—and, the timing of health care reform will accommodate some of them.

Newhouse (1990) discusses the critical role of rigor in longitudinal, controlled experiments to support policies and system reforms. For example, the experiment must

meet the standards of randomized trials so that the findings can be used with confidence even if they differ from observational studies.

Newhouse also points out the advantages and drawbacks of controlled experiments. They are costly, although not necessarily much more so than prospective observational studies. They take time, because they are prospective. Therefore, they require the funding agency to concentrate significant resources within a single project, and if that project is large enough to produce major advances in knowledge, to invest those resources for significant amount of time. On the other hand, if the design and execution are done well (with an interdisciplinary team) and the project is focused on an enduring questions, then the benefits in terms of the caliber of knowledge far outweigh the costs.

Blumenthal's (1991) analysis of the timing and course of health care reform establishes comprehensive reform as being at least 10 years away. Reform is not likely until a substantial portion of the middle class finds it impossible to obtain health insurance and health care costs become a palpable threat to economic well-being of the country. Blumenthal estimates that a decade or so will pass while the crisis builds, and meanwhile, health care costs will increase to about 15% of the gross national product. In that timeframe, research for policies related to health care reform could make use of a wider range of designs. This is an important opportunity, particularly in light of the difficulties associated with designing health services research that goes beyond analytic description to policy prescriptions (Ginzberg, 1991a, 1991b). At the same time, with the adoption of FASB 106 scheduled in 1993, the business community may well see a shorter timeframe for some reforms.

In either case, outcomes research can affect the nature of policies, particularly if it addresses the three components of policy development: knowledge base, political will, and social strategy (Richmond & Kotelchuck, 1983). Obviously, research contributes to the knowledge base. Linking the knowledge base to nursing practice can also contribute unique information to the other two components. The nature of nursing practice lends unique expertise in how policies work or don't work in the real world (strategies), as well as in what people need and want from health care, and for whom (political will).

If one of the aims of nursing research is to affect health system reform, then there are several science policy issues to address. First, does nursing have a cadre of researchers with the experience to design and conduct a large controlled experiment—or would it be wiser to work on developing an interdisciplinary team that includes nurse researchers? In their reviews of studies of the quality of nursing care, Lang and Clinton (1983, 1984) found that the field needed more rigor, more comparative analyses, more study of the relationships between intervention and outcome, and more study of the effect of structure on those relationships. More recently, Fetter et al (1989) addressed nursing's relative unfamiliarity with the methodological and feasibility issues of randomized clinical trials. Science policy, for example, could foster the use of interdisciplinary teams as an expedient choice.

Second, which enduring questions involve patient outcomes, nursing data and nursing inputs—and what are the policy applications of the answers? This complex issue is especially difficult when gaps occur between perspectives and technical ability. For example, a conference of nursing experts recently failed to reach a consensus about whether the quality of nursing care is a national issue (Aiken, 1989). On the other hand, they recommended more emphasis on multisite work as well as more

studies of the use of clinical and nursing intensity data as the basis for payment (Hegyvary, 1989). Science policy could bring empirical questions into focus and clarify their articulations with methods issues.

The implications of research designed to affect health care reform include the costs outlined by Newhouse, as well as the benefits. The magnitude and duration of controlled experiments can affect the whole portfolio of the funding agency. If NCNR determined that this kind of design fit within its science policy, the implications for its portfolio could be significant.

V. Developmental Perspective

Some highlights of the development of outcomes research are listed here, as part of the context for NCNR's science policy.

Nightingale's severity-adjusted mortality tables for the Queen of England locate the history of patient outcomes and effectiveness research well over a century ago—followed by the work of Groves, an English surgeon who used standardized mortality data in the early 1900s (Brook & McGlynn, 1991). Codman, a surgeon at Massachusetts General Hospital, devoted his work to “the end result” and convincing hospitals to begin routine surveillance of every patient's post-discharge course, and reporting to the public (Berwick, 1989b; Donabedian, 1989; Mulley, 1989). Donabedian's explication of the concept of quality of care infused evaluation with renewed purpose in the late 1960s. At the same time, the era of expansion in health care was winding down, and the era of cost containment was dawning (Relman, 1988). In the late 1970s, the concept of “sentinel events” in public health was defined in relation to unnecessary disease, disability, and untimely death (Rutstein, et al, 1976). The revival of

interest in the field has made use of those negative indexes for the aggregate, while attempting to develop positive indexes as well.

Relman (1988) observed the beginnings of the effectiveness initiative and noted that it marked the dawning of the age of “assessment and accountability”. This initiative has been framed as “simply, what works?” (Clinton, 1990). Since then, a substantial handful of PORT projects and nearly 50 effectiveness studies have been launched. Ambitious projects in measurement and design continue. This is an international field. For example, the Royal College of Nursing in England is operating a multifaceted standards of care project designed to improve quality. Major controlled experiments for policy, such as Newhouse's Health Insurance Experiment, stand in the midst of these developments.

Looking ahead, features of the American health care system are likely to include: expansions in workplace-based private insurance to cover most employed Americans and their dependants, a strong role for fee-for-service practice and free choice of providers, a reliance on the States to administer both private and public insurance, and some discretion for the States in cost containment and establishing standards of care (Blumenthal, 1991). Pressure for reform may rise sharply with the implementation of FASB 106 in 1993, and the direct effects of retiree medical benefits on corporate earnings and net worth, as well as stock values to shareholders.

Nurse researchers have already created and tested some links between outcomes and nursing practice. The question is how to improve the link. Several strategic actions have been discussed here, and the implications for individual researchers, academic nursing, clinical nursing, and NCNR may be different.

VI. Conclusions

1. Improving the link to nursing practice requires specifying nursing data and inputs in relation to the samples, measures and analytic models used in outcomes research and creating simple ways of obtaining the pertinent data.
2. All studies of patient outcomes should address the limits of scope, rigor and generalizability. The field would benefit from a formal, but pragmatic, evaluation of the assets and liabilities of the knowledge base for clinical decisions and policy analysis.
3. Outcomes research must include some controlled experimental studies. Those studies should be multidisciplinary, of sterling quality, and focused on enduring policy questions.

This research will go on for decades and results will accrue slowly. The research will lead, in some cases, to less care or more care, and probably in a large number of cases, to different care that may be roughly as costly as what we have now. Thus, rather than saving money, this field first promises to improve quality. (Aaron, 1990) The government's role is to call the public's attention to this work, set priorities, commit unique resources (databases), fund research, develop partnerships to carry out this work (Roper, 1990). The challenge to scientists includes setting priorities to advise Congress (Rockefeller, 1990), as well as sharpening the focus of the knowledge base and expanding the basis for policy development.

Linking patient outcomes research to nursing practice could contribute to both aims by creating an incisive database about severity and casemix, and by establishing the methods for relating specific nursing inputs to the field of outcomes research. Eventually, those links would affect decisions about policies, which in turn, affect patient outcomes and access to nursing care. Other important

effects might also occur—this paper focuses primarily on those that would affect the knowledge base for practice and policy.

This paper described a strategic framework defined by aims for knowledge, decisions and applications. Today, the focus is on implications for NCNR science policy and perspective is important. Outcomes research is not a silver bullet for our health care dilemmas. In fact, some argue that the strength of outcomes research lies as much in the pre-existing vacuum as in its science (Mulley, 1990). Nursing has some experience with this field, although probably not enough and too much of it in parallel. There is some real risk of failure in entering this field, although tolerating the risk of failure is necessary to success in science (Shapiro, 1990). Beginning with where we are, sound science policy—designed to shape science and guide decisions affecting access to nursing care—seems vital. Berwick (1989a) points out that issues of leadership, financing and conduct of health services research vary with the aggregate to be affected by the work. NCNR has a leadership role of national significance, particularly in relation to the community of nurse researchers.

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