

Prevention and Primary Care Research for Children: The Need for Evidence to Precede "Evidence-Based"

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ABSTRACT: Medical care in the United States continues to face tremendous financial pressures. Public and private health policy claims to encourage primary care and preventive services, but also discourages services that have not been demonstrated to be effective and/or cost-effective. This article suggests a model to illustrate the conceptual relationship between traditional American medical care and "evidence-based" medicine. It further examines how the lack of an adequate research base makes a move to purely evidence-based care premature for primary care and prevention services. The paper defines a new conceptual statistic, the uncertainty index, as the proportion of non-refuted current practice that is also not corroborated by research evidence. The greater the uncertainty index, the less appropriate is a clinical model restricted to evidence-based care.

Specific theoretical barriers to outcomes research in prevention are discussed and simple criteria to determine the desirable components of care are suggested. The need for theoretical and empirical research into primary care and prevention, especially for children, is emphasized. Care that is of low risk, not of extremely high cost, and that is generally believed useful by the community of practitioners is particularly desirable in the absence of data refuting its value.

Medical Subject Headings (MeSH): evidence-based care, primary care, preventive services for children, prevention research, uncertainty index. (Am J Prev Med 1998;14:000-000)
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Background: A Revolution in American Medicine

Cost pressures are changing medicine in revolutionary ways. The mantra of these changes has included emphasis on the provision of services in primary care versus specialty care, an increased emphasis on the use of preventive services, and an increased awareness of limiting clinical services to those that have medically appropriate indications.¹⁻⁶ While these trends have the potential to improve the quality of care, the implementation of policies to bring about these trends has brought into focus the limited scientific basis for predicting the actual outcome of these changes, and indeed, the limited science underlying much of medical practice.^{7,8} A combination of traditional clinical trials and sophisticated health services research is necessary to answer the questions of which primary care and preventive services offer what benefits under what circumstances.

In the late 1980s and early 1990s, health services research was funded at unprecedented levels and was

moving from the esoteric into the mainstream of medical research. Outcomes, clinical effectiveness, and cost effectiveness studies were undertaken with new vigor and received much attention. Unfortunately, the press of financial concerns has moved at a pace more rapid than our understanding about the likely impact of policy and organizational changes. For-profit managed care organizations and delivery systems have emerged as powerful forces in shaping the delivery of health care. Limitations in the public funding of health services research, as well as threats against the very existence of the Agency for Health Care Policy and Research (in large measure due to their leading role in developing standards describing high quality health care), the lead funding agency for many of these studies, make it less likely that we will ever understand the full clinical impact of the many changes that are being pressed upon our health care delivery and financing systems. Such policy threatens to undermine the most constructive force that could move us towards a more cost-effective approach to medicine: the integration of clinical knowledge with an understanding of the effectiveness of health services interventions and organization.

Public policy and private sector initiatives have each sought to emphasize the role of primary care as first

Department of Pediatrics, UCLA School of Medicine, Los Angeles, California, Department of Maternal-Child Health, Harvard School of Public Health, ~~Massachusetts~~, *Quality matters, with a little bit*
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contact care in most clinical circumstances. With few exceptions, our current understanding does not link specific processes or combinations of processes in primary care with specific outcomes. This hampers the creation of specific definitions of quality of primary care. Quality is always an emerging construct. Its clinical and operational definitions represent snapshots of the state-of-the-art in both clinical knowledge and in our ability to conceptualize and measure clinical services and their impact. The state-of-the-art is continually evolving, and thus definitions of quality of care are dynamic. The lack of simple and stable operational definitions encourages managing care towards standards of economic productivity, which are more easily measured, rather than towards standards of quality clinical care. Such problems are magnified for primary care and preventive services because of the immature state of our conceptualizations: we have yet to operationalize the practice of primary care and many clinical preventive services (especially counseling interventions) into measurable components that are appropriate for assessment; and we are just beginning the process of conceptualizing the appropriate outcomes to measure, a step that must precede the actual development of good outcomes measures. Although attempts to summarize the state-of-the-art regarding primary care or clinical preventive services may be useful, attempts to restrict primary care and clinical preventive services to evidence-based care are problematic.

Specific private sector initiatives are also hampered by a lack of scientific knowledge. One of the frequent tenets of private sector efforts to develop "disease management" programs is that educating and "empowering" patients to various degrees will help to increase the quality and reduce the costs of care.⁹ While there exists some evidence that patients who are better consumers have better health outcomes, fundamental questions remain as to how to effect changes in patient behavior to improve cost efficiency and clinical outcomes.¹⁰ Similarly, physician education plays prominently in private sector attempts to control costs and maintain quality,¹⁰ but limited data are available to suggest how this should be done. These concepts belong in the realm of clinical prevention, and may represent primary, secondary, or tertiary prevention activities. Competitive pressures make the private sector an unlikely source for open debate and discussion about what works and what doesn't, and thus an absence of public sector research into how patient and or physician education can promote desirable outcomes is likely to delay progress in this area. Private sector programs will be left to discover the wheel anew, and patients and efficiency will both suffer as a result.

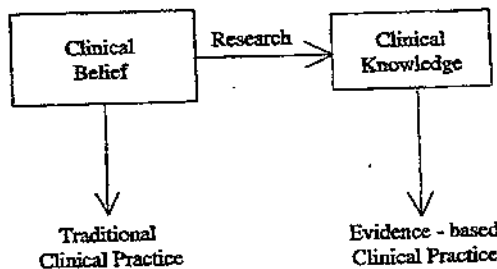


Figure 1. This schematic illustrates how traditional clinical practice stems from the belief of practitioners, while evidence-based practice stems from clinical knowledge. The model further demonstrates that clinical knowledge results from the action of research upon belief.

A Simple Model Linking Research and Evidence-Based Care

Research that focuses on primary care and preventive services is fundamental to a rational approach to the practice of medicine as we head to the twenty-first century. The need for evidence precedes the ability to move to evidence-based primary care.

This thesis follows from the model shown in Figures 1 and 2. Figure 1 illustrates how traditional medical practice results from physicians following through on their beliefs regarding best clinical practice. As research evidence accumulates, belief approaches knowledge,¹¹ and practice based on such knowledge is termed "evidence-based." Figure 2 demonstrates how clinical practices can be divided conceptually into 6 categories, based on clinical beliefs and research findings. The model assumes that clinicians deliver care according to their beliefs under the traditional model. At an operational level, the model concerns the behavior of a single clinician, but conceptually it represents an integration of all care. I will demonstrate how the model leads to a variety of conceptual indices that may be useful when considering the issue of evidence and of quality improvement. The index that is most relevant for this paper is the uncertainty index (UNI), which is an attempt to represent mathematically how much we know about what constitutes good clinical practice. The UNI can be considered globally, but is more likely to be useful when considering particular health services or management of specific diseases (e.g., well child care, treatment for asthma, etc.).

Using the definitions from Figure 2, evidence-based care consists of a + b (all care that is corroborated by research, regardless of clinician attitude towards it), traditional practice consists of a + c (all care that clinicians believe in, regardless of research evidence), and desirable care consists of a + b (research corrob-

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| | | Believed useful ? | |
| | | Yes | No |
| Research Corroborated ? | Yes | a | b |
| | No | c | d |

Evidenced based = a + b
Traditional practice = a + c

A

| | | | |
|--------------------|-----|-----------|-----------|
| | | Cell c | Cell d |
| | | | |
| Research Refuted ? | Yes | c 1 | d 1 |
| | No | pc2 + qc2 | rd2 + sd2 |

p = Proportion of c2 that is clinically useful
q = Proportion of c2 that is not useful
r = Proportion of d2 that is clinically useful
s = Proportion of d2 that is not useful

Desirable practice = a + b + pc2
Ideal practice = a + b + pc2 + rd2
Inappropriate care = c 1
Uncertainty index (UNI) = c2/a+c2
Improvability index (II) = a+b+pc2/a+pc2
Immediate improvability index (IMI) = a+b+c2/a+c2
Innovations improvability index (INI) = (a+b+pc2+rd2)/(a+b+pc2)

B

Figures 2a and b. The six components of care, based on clinical belief and research evidence. Practitioners and the research agree that care in cell a is desirable and that care in cell d1 is not. Cell b represents effective care that is not incorporated into practice and may reflect immature diffusion of new and effective clinical processes or technology (e.g., antibiotic therapy for peptic ulcers), or effective procedures that have not been incorporated into the culture of medical practice (e.g., certain adult immunizations). Cell c1 represents care demonstrated by research to be ineffective, but that is still incorporated into practice. Again, this may represent incomplete diffusion of new information, or a distance between research evidence and clinical culture. The greatest controversy in the current debate arises around cell c2: care that is believed to be effective, but that has neither been corroborated nor contradicted by research evidence. C2 includes traditional medical interventions and new interventions that are as yet not researched. This distance

may have policy implications. Cell d2 represents care that has neither been incorporated into practice, nor refuted by research. Opportunities for innovation and new clinical approaches fall in this cell.

erated care), plus some proportion p of c2 (representing care that is useful and that has neither been refuted nor supported by research evidence, and that is currently believed in by clinicians). Theoretically, there is an analogous component, proportion r of d2, that represents useful care that is neither supported nor refuted by research and that clinicians have not incorporated into clinical care. This component should be incorporated into a model for ideal care, but it represents care that is sufficiently beyond the clinical state-of-the-art not to consider it here. It represents the room for true innovation. The uncertainty index (UNI), $(c2/a + c2)$, is defined as the proportion of non-refuted current practice that is also not corroborated by research evidence. For simplicity's sake, I have not included here consideration of the uncertainty around potential interventions that have not been refuted or corroborated by research and that are not a part of current practice (cell d2).

The index offers a conceptual means to compare how satisfactorily researched are various clinical disciplines and domains. This paper argues both that the uncertainty index is relatively high for clinical preventive services in primary care and that the higher the uncertainty index, the less appropriate is a clinical model restricted to evidence-based care. Other concepts that come from the model that will not be discussed in this paper include the Immediate Improvability Index (IMI), $(a + b + c2/a + c2)$, which is defined as the incremental increase in desirable care that would occur by simultaneously incorporating unused but research-supported care into practice and eliminating research-refuted care from practice. Conceptually, the IMI represents the ratio of care that is improved to the full extent of our knowledge, compared to current practice, and ought to represent the goal for current quality improvement initiatives in health care systems. As research defined current practice as useful or not, this index would approach the Theoretical Improvability Index (II) $(a + b + pc2)/(a + b + pc2)$. Further research and innovation in areas currently not incorporated into practice lead to an index comparing ideal practice to current practice, the Innovations Improvability Index (INI), $(a + b + pc2 + rd2)/(a + pc2)$. As clinical care is managed increasingly by health care organizations and not by individual physicians, the plans' incorporation of the Uncertainty Index into their development of a benefits package, and their success in raising the Immediate Improvability Index may prove useful as conceptual guides to

tion may have policy implications. Cell d2 represents care that has neither been incorporated into practice, nor refuted by research. Opportunities for innovation and new clinical approaches fall in this cell.

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comparing the quality and comprehensiveness of competing systems of care.

In this paper, I suggest that it is appropriate to consider desirable those services in c2 that have not been demonstrated to be of particularly high cost or high clinical risk when balanced with the perceived benefit. I further propose that the greater the uncertainty (high UNI) for the topic, the less strict the evidentiary standards that are appropriate to impose, all else held equal. The high-risk/high-cost component ought to be placed high on the clinical research agenda so that it can be subject to formal evaluation by empirical data, or at least on the health services research agenda so that expert belief can formally assess the current risk/benefit and cost-effectiveness of such interventions.

Thesis: Increase the Research Base of Preventive Services for Children

The literature regarding adult preventive services has largely been driven by a perceived need to understand the number of lives saved or improved by a given clinical preventive service at some unit cost. This literature has often focused on evaluating expensive interventions, particularly those related to leading causes of death. It has contributed to our understanding, for example, of the impact of various intervals and methods for screening for diseases such as breast cancer and colorectal cancer. This still incomplete literature has largely been summarized by the U.S. Preventive Services Task Force in their widely distributed, *Guidelines for Health Prevention*.¹² The *Guide* has come to be regarded widely, although not universally, as authoritative, in the United States, as has a similar document in Canada.¹³ Unfortunately, the first edition of the *Guide* did not provide similar energy or focus on preventive services for children. Although the Task Force has subsequently increased its effort to evaluate child health services, such an effort does not compensate for the paucity of rigorous scientific evidence regarding most pediatric preventive services. Both the American Academy of Pediatrics and the Canadian Pediatric Society recommend well child care not recommended by the Task Force.¹⁴ In 1988, the Office of Technology Assessment (OTA) commissioned a background paper to examine the evidence that well child services were clinically effective.¹⁵ The background paper had reached the accurate conclusion that there was not a rich scientific basis for many of the practices that the field of pediatrics had incorporated into the prevention of disease and the promotion of wellness. The OTA concluded that, with the exception of immunizations, whose effectiveness was well established, the practice of well child care lacked demonstrated clinical effective-

ness.¹⁵ This conclusion was widely interpreted to mean that well child care was ineffective. In accepting a Distinguished Achievement award from the Ambulatory Pediatric Association, Barbara Korsch faulted this sort of logic that would, as a matter of policy, consider ineffective anything that had not been demonstrated to be effective. In appreciating the potential for this logic to disrupt the practice of medicine as we know it, as well as the ascendancy of a philosophy to demand evidence of effectiveness, Brook has argued for a paradigm shift that any new technology or new application of existing technology ought to be evaluated by rigorous trials before being reimbursed generally by third party or public funds.⁷ In fact, Brook has proposed that participation in clinical trials ought to be offered to potential candidates for these new technologies. In general, policy makers and health benefits designers are now considering the imposition of a standard of strong outcomes evidence of effectiveness and cost-effectiveness before including interventions in a health benefits plan.¹⁶ While such standards are intellectually admirable and may constitute an appropriate goal, they currently represent a precipitous shift in health care policy that requires public debate about both goals and possible outcomes. These standards antedate an adequate body of evidence, especially regarding preventive services in general and pediatric preventive services in particular.

Aside from immunizations, whose risks and benefits have been well studied, preventive services for children are generally low technology and of minimal risk for children. I propose that services with such characteristics ought to be considered as part of the desirable component of c2 in Figure 2. Preventive services for children fall in two major categories: community or public health interventions and clinical preventive services. Community interventions include such services as school lunch, Head Start, and injury prevention programs. Evaluation of the effectiveness of community interventions may involve straightforward assessments of process outcomes, such as the number of children receiving a hot lunch or served by Head Start, or the proportion of children wearing bicycle helmets. Unfortunately, those who oppose a specific program may criticize the use of process outcomes as not relevant to demonstrate effect. The evaluation of the programs with later outcomes may require more sophisticated conceptualization, data capture and measurement, and years of observation. Almost always such studies are more expensive to conduct. So the desired outcome of a school lunch program may be less hunger (which can be assessed by pre- and post-intervention surveys), better grades (which requires a review of records), or an increase in the high school graduation rate or ultimate earnings (which may be a dozen or more years hence). The "correct" outcome depends on the pur-

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poses and the judgment of the researcher. I propose that for low-technology interventions that are unlikely to be otherwise harmful, such as a school lunch or injury prevention programs, that we accept as useful for policy purposes the intermediate "process" outcomes that are more easily obtained. Otherwise, reduced availability of research funds, the uncertain completion of long-term studies, and the need for large sample sizes¹⁷ to avoid beta error combined with the policy irrelevance of process outcomes squelch such research. In turn, this threatens to create a false knowledge that such programs are ineffective or unable to be proven effective.

Analogous to arguments regarding the opportunity costs of providing care that is not in fact beneficial to patients, is the recognition of the opportunity costs of research. Common sense must intervene for us to determine as a community of scientists and practitioners how much research corroboration is "good enough" to base various practices on. Good enough to recommend a short counseling intervention during a health maintenance visit is very different from good enough to recommend the use of a highly toxic compound to treat a malignancy. Researchers must be confident that studies that use process or other intermediate outcomes will be considered "policy relevant." Otherwise, research into important clinical, health care delivery, and health services topics will not be undertaken because of the high cost and low feasibility of completing large prospective outcomes studies on topics such as comparing various schedules of periodicity for well child care.

Clinical preventive services in pediatrics include counseling based on child development and the age of the child (anticipatory guidance) as well as immunizations and screening for anemia, tuberculosis, and lead poisoning. Many pediatric and family practitioners consider the relationship between the clinician, the child, and the parent or family to be of therapeutic and preventive benefit. The impact of a continuing relationship with the pediatrician or family physician, and the effect of periodicity of visits, has never been well established, although continuity of care is considered a fundamental component of primary care, and there is evidence that the existence of a medical home improves the quality of care for children.¹⁸ Instruments to measure behavioral and social outcomes, and other measures of well-being in the pediatric and adolescent populations are in early stages or non-existent. There has been remarkably little theoretical groundwork laid for the choice of outcomes that are appropriate for assessing the impact of the range of preventive services in children. Clearly, the traditional assessments of morbidity and mortality are not sufficient for this population. Fatal events are thankfully rare, except in some adolescent subpopulations in which violent

deaths are all too frequent. Yet, there are cascades of events that may result from the preventive services contact. Although a brief conversation between a clinician and an eight-year-old about the health risks of smoking may be overwhelmed by external forces, so may it be leveraged by a child who accepts the information and shares it with friends. Similarly, the adolescent who takes the car keys away from an intoxicated friend provides leadership for his or her peers. There has been almost no conceptual groundwork laid to assess outcomes measurement for these sorts of services on either an individual or a population level. This constitutes a critical research agenda that needs to precede the creation of health policy based on the assumption of no effect.

Another area in which pediatric prevention research lags behind is the measurement and interpretation of quality of life. Childhood functional status is frequently conceived of as the ability to perform such appropriate role functions as attending school and playing with friends. Parents have been used as proxies to represent how well the children were doing. Only recently have instruments begun to measure how children feel about themselves or their own well-being and the divergence of parent and child views are being documented.¹⁹ Even more disconcerting is that, in an era of cost-effectiveness analyses, no value has been assigned to temporary improvements in the quality of children's lives. In other words, an intervention that improves school performance for a period of 4 years, but that is ultimately overwhelmed by the pressure of external forces, is interpreted as ineffective because it has been "washed out" at the end of that time, rather than as having made a contribution to that child's life. In the adult health services literature, such an effect could be validated as having improved the "quality adjusted life years" even though it did not prolong life. In the pediatric population, because the measurement tools to integrate these improvements do not exist, the effects themselves are misinterpreted and perceived as non-existent or not valuable.

Conclusion: Prematurity of a Purely Evidence-Based Paradigm for Primary Care and Prevention

Financial pressures are radically changing the nature of the U.S. health care system. Attempts to limit costs have led to the seemingly attractive idea of limiting clinical services (or the third party payment of such services) to care that has been demonstrated to be effective. This paper has introduced a schematic model that relates the "traditional," autonomous practice of medicine to the practice of evidence-based medicine. The model suggests a statistic (the UNI) that may be useful to physicians, patients, benefits designers, purchasers, pay-

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ers, and health policy makers for comparing explicitly the degree of uncertainty among clinical areas. Given the context outlined above, I propose:

1. It is worthwhile to strive for the continuous improvement of health care. Primary care and prevention research are fundamental components of such improvement. Fundamental to primary care and prevention research are both a theoretical framework for considering quality and its measurement, and the development of tools to accurately measure the putative processes and outcomes of care.
2. There is an urgent need for clinical and health services research to address issues relevant to primary care and prevention. Potential benefits of such research include more appropriate and efficient services for patients; improved understanding about what constitutes quality health care and how it should be delivered; a reduction in uncertainty for clinicians, patients, and policy makers when deciding among potential services (i.e., decreased uncertainty index); increased satisfaction with medical care by those parties as well as by the purchasers of health care; and better insight into the relevant processes of health care. These circumstances promote competition in that they allow consumers, policy makers, and purchasers of health care to make explicit choices about what constitutes the best system to deliver the necessary processes of care and, when choosing among systems, to make explicit trade-offs of resources or costs for processes that may offer marginal benefit but not be necessary components of quality care. From a societal perspective, the potential downside to increasing funding for this research includes the potential diversion of funds away from patient service and towards research (only if we assume level funding for health care); and the potential to codify methodologically non-rigorous research if standards for research (such as adequate statistical power) are not maintained adequately. The latter can lead, in turn, to the decreased use of effective interventions or the increased use of ineffective or inefficient ones.
3. It is critical that a substantial proportion of this research be devoted specifically to the needs of children. Market forces have focused health services research, quality of care research, and prevention research towards adults, leaving a very high UNI for well child practice. Although the largest potential for benefit may rest with discoveries about the management of pediatric patients, the long time needed to reap those benefits and the difficulty in measuring them may discourage research on this population. Specific policy ought to encourage child health services research in these areas.

4. In the absence of convincing evidence to the contrary, clinical preventive services that are of low technological intensity, are broadly believed efficacious by the community of primary care clinicians, and have yet to be rigorously evaluated (i.e., have a high UNI) ought to be considered part of a standard health benefits package, especially for children. These constitute the most highly desirable services within the non-corroborated component of potentially useful care.
5. Particularly high standards of methodological rigor, including creative approaches to measuring complex and difficult-to-quantify outcomes, are necessary when evaluating the effectiveness of many clinical preventive services, especially in children, and particularly when evaluating the impact of the relationship between families and providers. Investment needs to be made both to develop and to enhance theoretical models about how these complex interactions affect clinical outcomes and to develop excellent measurement tools. High levels of rigor may be accomplished in non-experimental designs and using process or intermediate outcomes so long as the conclusions are consonant with the data and the methods.
6. Both process and outcomes research are important components of a primary care and prevention research agenda. Not only does outcomes research depend on the models and the measurement instruments mentioned above, but the marginal expense of an outcomes study over a process study should be justified by the anticipated marginal benefit of the outcomes data.

In conclusion, recent trends in the U.S. health care system are moving the practice of medicine towards evidence-based care. This trend has the potential to be progressive or restrictive depending on how it is implemented. Early evidence suggests that particularly with regard to prevention and primary care services, restrictive elements currently dominate. This paper presents a model that should prove useful in organizing the debates about which health care services ought to be delivered and where clinical and health services research funds ought to be directed. Building the evidence basis of primary care and preventive health services through a commitment to research can lead to more progressive change.

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