Practice Guidelines and the Industrialization of Behavioral Healthcare Delivery

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INTRODUCTION

We have three major purposes in this chapter. First, we want to convince the readers that practice guidelines are not an arbitrary development in the field. Our logic, in outline form, will be that managed behavioral care marks the transition of this economic sector to full scale industrialization. Practice guidelines are a necessary component of an industrialized behavioral health care delivery system because they help ward off threats to successful industrialization. Second, we want to convince the readers that practice guidelines, done properly, hold out great hope for consumers, managers, payors, and providers alike, but only if they are properly done, with participation of all the major stakeholders. We will describe the Practice Guidelines Coalition process as a good example of what needs to be done. Finally, we will discuss where practice guidelines fit within an integrated system of evidence-based care.

The Non-Arbitrary Nature of Practice Guidelines

The Industrialization of Healthcare Delivery

There are not many times when you can see the future, but there is an exception when the speed of change is so fast that the present and the future are the same thing. You know you are in one of those times when you can say the same sentence in the present or the future tense and makes equal sense either way. The personal computer provides an example. At one point early in the development of personal computers you could say "personal computers will be big" or "personal computers are big" and it was just as sensible either way. People who fully realized what that meant easily made successful investments by betting on the future they could already see. Biotechnology or
the internet provide other recent example. The same applies, we would argue, to clinical practice guidelines.

In a span of less than a decade managed care has risen from a minor player to be the dominant force in private and public healthcare delivery (Frank, McGuire, Notman, & Woodward, 1996). The essence of managed care is not its form—there are many competing forms and new varieties are emerging every few months—but its nature. Managed care represents the industrialization of healthcare delivery (Cummings & Hayes, 1996).

Industrialization involves the systematized production of goods or services in large-scale enterprises that are responsive to the enterprise-wide bottom line. There are thus three defining characteristics of industrialization: large size, constant systematization, and the overall enterprise as the ultimate economic unit. These three characteristics put the productivity of an individual into the context of the productivity of an entire enterprise. The economic unit of interest goes beyond the worker, the family, the cottage, or the manor, to that of the firm. Technical efficiency and productivity generally rises during industrialization because tasks can become more systematized, worker skill and training can be better fitted to the tasks, mechanization and technical aids can amplify the skills and output of individuals, and efficiencies in the entire system are refined through innovation and competition.

If anyone doubts that industrialization is the process that is impacting healthcare delivery, consider this: the mental health needs of over 90 millions Americans are today controlled by two firms: Magellan and Value Options. In the year 2000 each of these firms expects to add one to eight million more consumers to their systems. There can be little doubt that we are already in an era where the delivery of behavioral health services resides in large-scale enterprises that are systematized to provide these services in a fashion designed to produce a positive, enterprise-wide bottom line. By definition, this means that healthcare delivery is industrializing.

Opponents of managed care, and there are many, need to distinguish specific forms of industrialization from the process itself. Specific managed care arrangements can and will change. Some will die out over time. But no one should think that this means that industrialization per se will be reversed. Never in human history has a major economic sector industrialized and then deindustrialized. It is unlikely to happen in healthcare delivery.

The reasons for industrialization are many, but the single biggest factor was the excess costs incurred by fee for service healthcare deliver. In fee for service healthcare, insurance was an industry, but healthcare delivery was not. Providers essentially ran their own "mom and pop" businesses. Healthcare delivery was very much like the small family farms so common in the first half of this century, prior to the era of the industrialization of agriculture.
Third party payers became increasingly subject to any escalation in costs that occurred. Cost escalation was relatively unconstrained since the contingencies operating in this system did not encourage efficiency or effectiveness. If patients stayed in therapy as long as provider felt it was necessary, providers would benefit since third party payers would usually reimburse for this amount without information on the need for treatment or its outcome. Providers learned to work the system. There was a rapid proliferation of private psychiatric hospitals and addiction treatment centers (Cummings, 1995; Trabin & Freeman, 1995). The number of behavioral healthcare training programs also increased.

Indemnity based health insurance companies faced with escalating costs were forced to maintain their profits by charging higher and higher premiums to businesses and individuals purchasing their policies. Costs for behavioral healthcare began skyrocketing. For example, during a five year period, from 1987 to 1992, the average yearly premium for mental health and substance abuse paid by employers increased from $163 per employee to $318, an increase of nearly 100% (Shoor, 1993; Strosahl, 1994). Both government payers (e.g., Medicare and Medicaid) as well as business and industry were unable to absorb any further increases in costs.

The industrialization of healthcare delivery has occurred so rapidly because large scale managed care enterprises were readily able to reduce cost while maintaining reasonable quality, primarily by driving down both unreasonable utilization and the fees charged by facilities and providers. Value Behavioral Health, for example, could reduce costs 40% while increasing access by 25% during first year after they took over an indemnity-based behavioral healthcare system simply by eliminating coverage for those who had been seeing a psychotherapist for years without clear justification, cutting therapists who tended to see the patients for years, and demand somewhat lower payment of clinicians (Shaffer, this volume).

These changes gave better overall value to payers and consumers. As time has gone on, however, the reduction in reimbursements has had serious consequences for some providers, who are working harder for less, and there is a broad perception that quality of care is beginning to suffer. In just a few years it seems that we have wrung out about all that we can using cost containment mechanisms. The rise of public support for legislation and regulation shows that MCOs are now cutting into the bone. Yet competition has reduced profit margins to a sliver.

With costs down, the next major area of improvement has to be value. In theory an emphasis on value can cut costs by reducing per incident costs and especially by reducing further demand for services through effective and efficient services. As the industry consolidates, this begins to make good
economic sense, since consumers stay with given firms for longer and longer periods.

**Stages in Industrialization**

Industrialization tends to go through four stages, and these stages are being followed quite closely in the industrialization of healthcare delivery systems (Hayes, Barlow, & Nelson-Gray, 1999).

1. In the early stages of industrialization, vendors proliferate and consumers are confused.
2. In the confusion, poor quality products succeed but then die out as the overall quality of products increases.
3. As products become better understood, vendors and product lines are consolidated and external review increases.
4. Finally, in a mature marketplace, known firms offer known commodities of known quality, cost, and value in a stable external review environment.

You can see these stages in a recent example: personal computers. In stage one, hundreds of software and hardware firms competed, each one claiming that their systems or programs were better. Customers were confused. Consumers had a hard time knowing if an 8 bit operating system was better than 16 bit, if Apple's system was better than IBM's; or if DOS was better than TRS-80. In stage two, computers began to get better and better. Some firms (e.g., Leading Edge) undercut the market with cheap clones but they later began to fail under the weight of returns, poor service, and the poor reputation these bred. In stage three, consolidation occurred. We went from dozens of popular word processors, to one giant and two also rans. Half a dozen computer makers survived with significant market share. Litigation and legislation began to be focused on the industry. People began to resent the hegemony of MicroSoft. We are now entering stage four. Variability in features, quality, and cost, occur within a known range and provide choice to the consumer who may, for example, choose slightly less sophisticated technology in exchange for a lower price. Changes in external review continue however (e.g., the antitrust suit against MicroSoft) which indicates that the marketplace is not yet fully mature.

The health care delivery industry is proceeding through this same developmental sequence and has recently reached stage three. Vendors did indeed proliferate chaotically and consumers were terribly confused. Even
three years ago a Louis Harris poll showed that a majority of US citizens did not know that “managed care” meant or what a “health maintenance organization” was (Gannett News Service, 1996). Quality was uneven and some vendors succeeded by cutting needed services (Manderscheid & Henderson, 1996). The industry has seen a tremendous degree of consolidation and a major increase in external review as any glance at the newspaper will show. Litigation, accreditation, legislation, and regulation are now an inherent part of the landscape of managed care. The healthcare delivery industry is trying to find ways to increase quality and efficiency through means other than mere cost reduction.

The Enemies of Industrialization

There are four big enemies of success in this stage. *Consumer confusion and fear* is one enemy. Fearful consumers are slow to buy and quick to complain. Confused consumers will make poor buying decisions that do not reflect the real value of competing products or services, and thus maintain inefficiencies in the system.

The second enemy is an *unpredictable context that too rapidly alters the playing field for competition*. This slows industrialization because investors become uncertain and because business errors are more likely. Challenging contexts per se are not necessarily bad because they tend to weed out strong and weak players. But unpredictability is another matter.

A third enemy is the *failure to demonstrate increased value*. Value is a measure of the quality and convenience of an item per unit of cost. Industrialization tends to occur when value leaps forward as a result of large scale, systematized enterprises, by reducing cost, or by increasing quality and convenience, or both. The personal computer industry, for example, has produced more and more powerful computers, for less and less. Value thus shot up. Mechanized production of shoes showed a different pattern. Quality did not necessarily increase over the shoes made by a good craftsperson, but the cost of shoes plummeted, and value rose. If value is not demonstrated, however, the main support for industrialization is removed.

A final barrier is *unexplained product variability*. Unexplained variability leads to an inability to improve quality and efficiency. Suppose a manufacturer is making a car and there is a poorly designed part. If the part varies too much in ways unknown to the maker (e.g., through manufacturing tolerances that are too large) the part might be fine in one car and a problem in others. If the part was made with good tolerances its bad design would be much more
easily detected. Any industrial entity must know what it is producing and selling, and unexplained variability interferes with that knowledge.

**Enemies of Behavioral Healthcare Industrialization**

Each of these four enemies of industrialization currently exists in the behavioral healthcare delivery sector. Consumer confusion and fear is exacerbated by the consumers perception of a loss of control. This is due in part to the complexity and rapidity of the changes in healthcare delivery. Plans themselves are confusing and difficult to understand. This perception is also due in part to an actual reduction in the range of plans offered by employers as they increasingly direct employees into lower cost options.

The context underlying managed care is relatively unpredictable due to rapidly evolving business and political events. Legislation such as the patients' bill of rights, lawsuits, or entirely new business models adopted by competitors provide a constant threat of rapid change. Ironically, however, some of these threats to predictability (e.g., suits over coverage practices) will increase the predictability of the business context in the long term because they will weed out excesses that the public does not support. That has been the experience in other sectors of the economy going through external market regulation and litigation.

There is indeed a widespread belief that the healthcare industry has failed to produce or to demonstrate value. Outcomes are unclear and consumers are increasingly beginning to believe the managed care reduces cost at the expense of quality.

Finally there is huge unexplained product variability in behavioral healthcare delivery. An enormous range of treatments exist for any disorder, and clinicians factors (e.g., theoretical orientation), not patient factors, seem to dominate as the source of variability in treatment decisions.

Thus, behavioral healthcare delivery faces every one of the major threats to successful industrialization. The industry has a built in bias toward any steps that will help solve these problems.

**The Role of Practice Guidelines in Reducing Barriers to Industrialization**

Clinical practice guidelines are statements of the best available evidence in specific practice domains for the purpose of advising practitioners in their
professional work. Unlike standards of practice, guidelines encourage but do not require that practitioners be guided by this evidence. Guidelines serve as summaries, reminders, prompts, and suggestions, not requirements.

Clinical practice guidelines have long existed in physical medicine, but their advent in behavioral healthcare is recent. Most of the activity in the area dates back only into the early 1990’s. Some examples of developments in this area include the development of a depression guideline by the Agency for Health Care Policy Research (published in 1994), the recommendation in support of clinical practice guidelines from the Second Summit of Applied Psychological Organizations (1992), the formation of the Task Force for Empirically Validated Treatment by Division 12 (Clinical Psychology) of the American Psychological Association (1995), the convening of a Conference on Scientific Standards of Psychological Practice (1994), the publication of the first practice guidelines from the American Psychiatric Association (1992), the formation of the Practice Guidelines Coalition (1996), or the requirement that at least two behavioral health practice guidelines be implemented in accredited behavioral healthcare organizations by the National Committee for Quality Assurance (1998). It is fair to say that at the present time clinical practice guidelines are only beginning to hit behavioral health in a meaningful way.

Despite their recency, it seems that clinical practice guidelines are bound to develop in managed care organizations for a simple reason: In each of the four areas that can slow industrialization, clinical practice guidelines are at least potentially helpful. It is for that reason that practice guidelines are a non-arbitrary aspect of the current healthcare scene. Unless industrialization per se stops in the healthcare delivery sector, the growth of practice guidelines will continue.

Consumer confusion and fear may be reduced by practice guidelines because in principle they can provide a quality floor and a more known product. If payers and consumers know that a system follows empirically-based practice guidelines, it is less likely that untested methods will be used before methods known to be successful are tried. If delivering these methods requires certain kinds of training or a certain number of sessions, payers and consumers know that it is more likely that such resources will be made available. Practice guidelines can reduce clinicians’ fear by providing more protection against arbitrary and capricious reimbursement decisions.

Contextual unpredictability may be reduced by practice guidelines for several reasons. Systems may be less subject to political battering if a credible practice guideline is being followed since it provides a kind of empirical shield against unwarranted criticisms and attacks. Practice guidelines can reduce contextual unpredictability by reducing and channeling the pressure of
regulation, legislation, accreditation, and litigation. If practice guidelines were broadly implemented, they would help level the playing field and prevent competitors from succeeding by reducing the quality of care in areas covered by guidelines.

The production and demonstration of value can be increased by practice guidelines because evidence of compliance with practice guideline provides evidence of quality of care. Further, if the guidelines produce better, faster, more long lasting desirable clinical outcomes, then they may produce cost savings through a reduction of the demand for services. At the system level, guidelines could provide a principled basis for the construction of mental health benefits as helping to direct the pre-certification and utilization review process on a case by case basis. Evidence-based practice guidelines could provide clinicians access to scientifically valid decision support tools that would help identify the procedures most likely to be effective. Finally, guidelines may help companies better allocate professional resources by providing a better match between the existing skills of clinicians and the types of core procedures recommended in guidelines. Costly doctoral professionals, for example, may be better suited to supervising a empirically supported protocol than in delivering most of the services themselves.

Probably the biggest issue for clinical practice guidelines, however, is whether they can reduce unexplained variability in treatment. In principle this seems likely, since following a practice guideline, by definition, should produce less variability than following nothing. It is not yet known, however, whether this theoretical expectation will be upheld. In all likelihood the answer will be complex, since probably some guidelines in some areas and in some formats will produce better outcomes than others. Focusing on a reduction in variability leads to the conclusion that penetration, not perfection, is most important. Even a highly flawed guideline, it widely read and followed, sets the stage for system improvement since these flaws can be detected and corrected. Among other things, this means that guideline acceptability to stakeholders is paramount, since resistance by any major sector will tend to reduce penetration and recycling and improvement.

Practice guidelines so directly help with the major problems faced by industrial healthcare delivery systems that they will be developed. And, in fact, every large managed care firm is involved with guideline implementation. Many have been involved directly in developing them. But the guidelines being developed are not ideal.
POLITICAL PROBLEMS IN CURRENT CLINICAL PRACTICE GUIDELINES

Probably the biggest source of clinical practice guidelines right now is the industry itself. Unfortunately, those developed inside the industry tend to be proprietary and thus are not open to scrutiny and orderly change. They are often not based on the best available evidence, especially those developed by in-house staff. Industry guidelines also tend to overemphasize cost-reduction over quality outcomes and each firm has their own, which leads to a nightmare for clinicians working with several firms.

Those developed by specific disciplines or guilds tend not to have broad penetration, in part because they lead to professional in-fighting inside managed care firms as, say, social workers resist being directed by psychiatry guidelines. Guild guidelines tend also to be narrowly focused, and are biased by the values, goals, and roles of the specific guild or discipline. This is not a problem if they are applied only within specific disciplines, but even here guidelines not yet widely enough adopted that disciplines can reach their members.

Those developed by the government or private foundations tend to be dominated by professionals and scientists seeking comprehensive statements, and as a result they are long, complex, and clinician unfriendly. These guidelines are at a much level higher than that of the typical clinician, who often is a masters level provider with fairly general training in mental health treatments. Such guidelines tend to offer far too many recommendations to be practical, instead of focusing on the few clinical procedures that empirically are associated with good outcomes. They are also characterized by expensive and lengthy development cycles, taking a million dollars or more over a multiyear period. They have often been biased by political and professional in-fighting. Thus, almost all of the guidelines efforts now underway—industry, guild, and governmental—have problems.

There are other challenges faced by guidelines regardless of where they are developed. Many clinicians fear that these documents will be used as standards that specify cookbook-fashion what professionals must do. Properly implemented, guidelines provide a guide, but it is expected that often they may not fit. When they do not, the clinician need not follow them, but the clinicians may be asked whether the guide was considered. In essence, guidelines target unexplained variability, not absolute variability. The fear is nevertheless quite real.

And there are many other barriers to overcome. Our most popular diagnostic system is notoriously weak, especially in its treatment utility. We have a very large weakness in specification of technology. A related problem is that we often describe procedures in a way that makes theoretical orienta-
tion a major barrier and source of conflict. There is a major divide between psychosocial and biobehavioral approaches. And consumers will have to be given choice or guidelines will never be accepted. Most guidelines also have not meaningfully integrated consumer and clinician views about treatment acceptability and burden of receiving or delivering given services into recommended actions.

**Problems in the Science Base for Clinical Practice Guidelines**

The final group of problems is in our scientific culture. Guidelines are not purely scientific documents. They are meant to provide clinical guidance. They are not the place for scientific tomes and endless equivocation, and for guidelines purposes scientists need to learn to speak with a clear voice. Yet we have very few one-handed scientists: almost always scientists say “on the one hand this and on the other hand that.” That tendency is not helpful in guideline development.

An even more serious problem lies in the scientific literature itself. Our outcome research is also far too dominated by efficacy research. We have hardly begun to develop appropriate methods for effectiveness research and to implement them regularly. For that reason, data on clinician acceptability, client acceptability, and system applicability, among others, is usually not available. Evidence-based practice guidelines in the current environment usually will not include some of the kinds of data that may most predict whether the actual implementation of the guideline will lead to positive change.

Our current models of treatment development and dissemination are based on the FDA model of drug development. In this three-stage approach, pilot work is done by the pharmaceutical company, testing specific drugs with specific medical conditions. If the data are promising, large scale efficacy testing is then conducted, often with federal dollars. Dissemination research follows, especially to look for side effects, and continues following FDA approval as the delivery system itself continues to monitor impact and safety factors. Practice guidelines would be one form of “stage three” dissemination. The problems in transporting this model to mental health are considerable but the federal government forced the issue in the late 1970’s and early 1980’s as it began to fund only specific treatments for specific disorders. At the insistence of the leadership of the National Institute of Mental Health, federal funding was reorganized and proposals, reviews, and funding went through
sections that were organized in terms of particular diagnostic categories. Researchers were required to specify their interventions in a technologically precise manner. It is relatively easy to meet this requirement in pharmacotherapy, because it is easy to specify a pharmacological treatment, but psychosocial interventions are another matter. Treatment manuals and extensive adherence and competence measures became a virtual requirement for funding in the psychosocial area.

Compared to the state of the literature in the 1960’s and 1970’s, these changes have been positive in the main, at least as considered from a scientific point of view. It is now possible to conduct treatment outcome research in a fairly well controlled and replicable manner. This in turn has allowed us to begin to sort out to the most effective approaches for particular kinds of problems.

As more and more bells and whistles have been added to the typical clinical research study, the FDA model of treatment development has had the undesirable effect of increasing the distance between some aspects of the health care delivery system and our existing data. Let me give some examples.

Cost of Training

There is nothing in the current research system that demands that treatment technologies be simple to train. Researchers generally refuse to consider the cost of training as a significant component of their research program. One can understand the rationale. After all, the researcher is first attempting to determine whether a particular approach is effective. It seems almost unfair to treat the extraordinary means that researchers might use to make sure that therapists are well trained as a kind of “cost.” Efficacy is the first requirement of the FDA model—in this approach we can always get to cost in stage three dissemination research.

But the health care delivery system does not have this luxury. Use of a technology in their systems is inherently a matter of dissemination, and that immediately involves cost considerations. Dissemination research, furthermore, is both largely absent and often ill conceived when it does occur. Researchers think of dissemination research as proof of the transportability and generality of impact of specific technologies—clinical efficacy writ large. Health care administrators think instead of fit within their systems. Imagine the dismay of a clinical researcher who might realize that a favorite technology might have to be fundamentally altered to fit a system. By the rules of the FDA model, the whole process of treatment testing would then have to begin all over.
Broad Versus Narrow Focus

The FDA model calls for specific treatments for specific problems. If these “problems” were functional entities that might make a lot of sense, but practically everyone knows that syndromes are no such thing. Yet researchers can only secure funding if they claim that their treatment technologies apply to specific syndromes. Researchers become “experts” in these same narrow areas. They write books about them; they give workshops on them. They sit on review panels that are organized by these topographical entities.

The health care delivery system views it differently. Clinics cannot afford to have “experts” in every syndrome and empirically supported technology. They need broad approaches that are known to be effective, saving specific training for fairly costly disorders (e.g., borderline personality disorder; panic disorder). But to make the claim that an approach is broadly applicable is to fly in the face of both academic contingencies and the process of federal funding. And without federal funding, clinical outcome research is now basically impossible, since the FDA model has made it enormously expensive.

Technique Proliferation and Fractionation

Researchers need to make a name for themselves in particular areas in order to advance in the academy and to develop reputations that contribute to their success in obtaining research grant funds. One of the best ways to do this is to develop particular treatments that are “all your own”. This has led to a proliferation of manuals, the full impact of which we are only now beginning to feel. There are literally dozens of cognitive behavior therapy manuals now available covering almost every conceivable syndrome. Many of these manuals are quite similar and yet they go under different specific names. Each has their own particular training methods, adherence measures, competence measures and the like. New researchers are scrambling to get on the train. Unless something changes, the dozens of CBT manuals will be the hundreds in a short time.

Clinician Acceptability

Clinician acceptability is one of the most fundamental areas where there is a disconnect between your usual research methods and the health care industry. In the typical research study therapists are selected for their
willingness to be trained in the methods of interest. If a clinician has a problem with the underlying model in a particular technology, that person would be unlikely to be selected to be trained. Yet that very person—or other like persons—may need to be trained in the health care system as particular technologies are disseminated. Behavior therapy carries a particular burden in this regard because a behavioral model often flies in the face of the deeply held beliefs of some clinicians.

Adherence and Competence

Adherence and competence measures, while of great use in a research setting, are not necessarily directly applicable to the delivery system as we have developed them. They are just too costly, intrusive, and complex. Yet health care delivery systems must know what treatment is being delivered in order to improve their product. Researchers have to help provide simple means of assessing whether given treatment technologies are being implemented and properly used, but that need is not yet on the radar screen. As a result, in the current phase of development in the delivery system, clinicians merely need to learn to use the right words without necessarily changing what they do in actual practice. For example, an astounding number of clinicians claim to be “cognitive behavioral therapists” despite the fact that many have had no training in this approach and are not favorably disposed to it. A recent case in which psychoanalysts were using the term “relapse prevention” to describe their usual psychodynamic approach to addiction is an example.

How to Combine Technologies

Everything we know about clinical practice in physical medicine or behavioral health suggests that clinicians will modify and combine treatment technologies when they use them. However much the researcher might wish it were otherwise, it simply is not realistic to expect that this will not happen. The recent Phen-Fen case provides an interesting example both of the pervasiveness of this approach and of its problems. In this case, two medications that each worked separately and were approved for use in weight reduction turned out to have serious health side effects when combined.

The lessons from this case are twofold. First, combinations will be used. Second, they need to be examined empirically. In the behavioral health area, unlike the Phen-Fen case, toxic combinations would problem go on indefinitely because our means for detecting problems are so limited. There may not
be as many obvious examples of combinations that could be detrimental in behavioral health, but the possibility must be explored.

**Practice Guidelines and Effectiveness Research: Finding a Solution to the Scientific Problem**

Our current approach to effectiveness is a technique-oriented version. In this approach, the central goal of effectiveness research is the unambiguous statement of the relation between use of a technique or approach and clinical impact in the context of existing healthcare delivery systems. In this kind of effectiveness research, we try to learn whether clinicians can be trained to use a given technique properly, and if so whether it will be effective and cost-effective on defined populations in real world settings. This is a straightforward extension of efficacy research that seemingly takes advantage of all that we have learned to do there (e.g., defining technique and populations). The problem is that precious few systems and clinicians will play along. Few systems will demand that clinicians follow a given protocol with certain cases, and certainly not with non-volunteer clinicians. Few system administrators will want to face the political heat that would be needed to implement such a plan. Thus, perversely, the noisy real world context seemingly makes controlled effectiveness research impossible, even though the whole point is to examine work in that context empirically. That is the basis on which some have claimed that correlational research or even simply post-hoc surveys are the only alternative available (Seligman, 1995).

As this issue applies to practice guidelines, if we do not change our models of effectiveness research we will not get the real world data we would like to have as input to guidelines, nor will we have the ability to evaluate these guidelines in effectiveness research. There is another approach to effectiveness research, however (Strosahl, Hayes, Bergan, & Romano, 1998). This approach seems to fit the empirical needs in the area of guidelines rather well. In the "Manipulated Training Method" client outcomes are assessed in a large group of clinicians (say, pre-post measures on all clients starting treatment for a month or two by every clinician in the group), and then these clinicians are randomly assigned to training and no training conditions. If there is a reason to do so, there can also be comparison training or control training conditions, much as in efficacy research. Client referral continues as before (a key point), and outcomes are then assessed in the clients of subgroups of clinicians post-training, including clinical impact and system impact (e.g., cost-effectiveness). This method can be focused on specific populations (e.g., conduct it with...
clinicians in an anxiety disorders clinic, or prescreen clients and focus only of those with a given problem), but it can also be conducted with the kinds of general clinical populations many clinicians deal with daily. Ideally (for scientific reasons), some measures should be taken of what the clinicians actually do in treatment, but in principle even this is not necessary. After all, if clients get better faster after training we know that something important changed in the clinician’s behavior as a result of training. In practical terms, that is all we may absolutely need to know. Adherence and competence do apply to the trainers behaviors, however.

In our article (Strosahl et al., 1998), which was recently published in Behavior Therapy, we gave an actual example of this effectiveness research method. It did not have all of the bells and whistles of the method in the abstract, but it had most of them and the results were interesting. Eighteen clinicians participated—mostly master’s level with an average of 5.2 years experience—from the Group Health Cooperative of Puget Sound (a large regional HMO). Eight were trained in ACT, while 10 were not. All of their new clients were assessed for a month, pre-treatment and five months later (N=59). Training consisted of a 2-day workshop, a 3-day intensive clinical training, distribution of a detailed treatment manual, and 12 monthly 3-hour group supervision sessions. We told clinicians to use ACT methods only when they seemed appropriate (specific guidance was given about the things that might indicate usefulness of an ACT approach) and to feel free to combine ACT techniques with other methods. After one year of training, their new clients were once again assessed for a month, pre-treatment and five months later (N=67).

After training, ACT trained therapists were far more likely to be finished with therapy at five months in the eyes of the client, and were more likely to agree with the client’s assessment in that regard. Medication referrals were reduced significantly, and client ratings of the degree to which they could cope with the problem that brought them in were significantly enhanced. In short, clients got better faster, cheaper, and better following training.

This approach is relevant in two ways. First, it shows something of what should be done in the evaluation of practice guidelines. It is not enough to write them. They also have to be implemented, and done so in a way that will make a difference. Ultimately, that difference must reside in clinical outcome or the whole purpose of guidelines is unmet. The methods currently available for dissemination research, however, are a poor fit to the needs of the heath care
delivery system. Manipulated training studies provide a much better fit and one that could enhance the evaluation of clinical practice guidelines.

Second, if similar results were available in several areas, guideline development itself would be greatly enhanced, since the task then would be to describe the methods that had been shown to improve clinical outcomes when implemented in specified training programs. Clinical improvement from being guided by the literature would not merely be hoped for, but instead would be expected, since dissemination impact would already be known.

**Practice Guidelines Development**

*The Bottom Up Approach: Simplify, Simplify, Simplify*

When guidelines are thought of in industrial development terms, the perfection of initial guidelines is far less important than their penetration. Imagine that a fairly weak set of guidelines is developed, widely used, and is evaluated. The places where the guidelines are helpful or useless would quickly be known. This very information could feed into guideline improvement when the guidelines themselves were revised. Over time the guidelines should do a better job and the quality of the system itself will improve as a result. Now compare this situation to one in which a near perfect set of guidelines is developed and not widely used. The adequacy of the guidelines will not be known, and problems in implementation will have no impact on future draft of the guidelines. Even if future scientific progress leads to guideline modification, no positive long term effects can occur until the guidelines penetrate. Thus, while guideline quality is important, guideline penetration is much more so. Guidelines are themselves a quality improvement process that will be spread out over decades.

This has comforting implications. Empirical clinicians do not need to wait forever to get perfect data (especially in the area of clinical effectiveness or utility) since guidelines themselves will help produce the needed data. It also means that two things are paramount: a) the acceptability of guidelines to clinicians, systems, and consumers, and b) the ability to recycle and improve guidelines over time.

We know only a little about how to improve acceptability, but it seems logical that the guidelines have to be simple, short, clinician friendly, and sensitive to client preferences and needs. In order to step around guild infighting they should be multi-disciplinary, but yet not interfere with more
focused discipline-oriented guidelines that specific disciplines are developing. That suggests that guidelines should focus on core clinical processes that everyone agrees upon. They have to be practical for systems to use, concrete, and be readily available. To avoid political in-fighting they should be based on a broad consensus about the best available evidence.

To a degree, acceptability and quality may conflict in practice guidelines. Guidelines of the sort just described focus on the floor, not the ceiling, and for that reason the improvements in outcome they are likely to produce will be incremental. Conversely, detailed guidelines that suggest a change in practice for most clinicians may have a greater likelihood of changing clinical outcomes (if they are high quality) but a much lower chance of being accepted. Managed care systems with a great deal of control over clinician behavior might think of “top down” guidelines for that reason, but in the vast majority of clinical settings a more “bottom up” approach seems indicated.

Frequent recycling carries other implications: guidelines have to be fast and inexpensive. A guideline that cannot be developed in six month and that costs much more than $100,000 is one you cannot revise every two years. Anything revised less frequently is old news. This precludes the gigantic tomes some guidelines efforts have produced. Recycling also suggests the value of a bottom up approach. Top down guidelines will almost certainly cost more to develop, maintain, and implement, than bottom up guidelines because the former is more detailed and intrusive. Bottom up guidelines aims for evolutionary not revolutionary change. Their simplicity makes them less expensive to develop and easier to implement.

**Producing Clinical Guidelines**

Who will produce evidence-based clinical practice guidelines and how? The most logical immediate answer is the government, but history has shown that government cannot do it. A federal agency designed to do just that (the Agency for Health Care policy Research) self-destructed in the attempt when back surgeons disagreed vehemently with a back pain guideline issued by AHCPR and took their objections to Congress. This was an object lesson for federal bureaucrats, and there is little chance that other federal agencies will now travel that same path.

Specific managed care companies have a hard time getting enough access to enough expertise, getting buy-in by diverse constituencies and stakeholders, and producing guidelines that are not biased by the economic motives of the company. Specific disciplines and guilds tend to produce guidelines that are just too narrow to be adopted by other disciplines.
Research scientists have a hard time being practical and succinct, and their literature review processes tend to be too broad and unfocused to be efficient. Consumer and advocacy groups tend to overemphasize the views of members and leaders, even if the literature does not agree with these biases. Furthermore, almost every development process currently available is either too inefficient, too narrow, too expensive, too top-heavy, too closed, or too lengthy. All of these problems increase as the number of guidelines increases. We simply do not yet know how to develop guidelines in a way that will work at full buildout.

**THE PRACTICE GUIDELINE COALITION EXPERIENCE**

The Practice Guidelines Coalition (PGC) experience provides a possible approach to guideline development that might help move the field in a positive direction. PGC is a developing organization launched by two national meetings called the *National Planning Summit on Scientifically-Based Behavioral Health Practice Guidelines*. The meetings, held in Orlando in November 1996 and Minneapolis in June 1997, gathered together over fifty representatives from managed care associations, other behavioral health care provider groups, behavioral science associations, professional groups, consumer groups, and the government. A list of organizations that participated in the National Planning Summits is shown in Table 1.

The representatives met to consider how best to work together to promote better behavioral health care delivery through evidence-based practice guidelines. The meetings were sponsored by the Association for Advancement of Behavior Therapy (AABT) and the American Association of Applied and Preventive Psychology (AAAPP), and were funded by grants from the Office of Behavioral and Social Sciences Research at the National Institutes of Health and by the Substance Abuse and Mental Health Services Administration. The meetings identified the central mission of a possible coalition, laid out the core interests of the various constituencies, and resulted in a unanimous decision to launch a development process that could lead to a membership-based Practice Guidelines Coalition.

Initially, attendees at the November meeting had a hard time being comfortable with each other. The atmosphere was respectful, but the tensions were palpable. One professionally oriented representative, for example, introduced herself by saying that she welcomed the opportunity to work together to fight managed care. The managed care representatives wondered aloud if the scientists were ivory tower eggheads and the professionals were
Table 1

Groups with Representatives Participating in the National Planning Summit Process (Either Meeting)
mere protectors of the guild. The hard core scientists sat back, arms folded, taking a skeptical eye on every statement.

But then something quite remarkable began to happen. First, the group began to listen. David Barlow gave a brilliant talk on the history of efforts to link science to practice. Clarissa C. Marques, then of the American Managed Behavioral Health Association (AMBHA), captured the attention of the group as she talked about how the industry was trying to link quality care to an empirical base.

Next, then the group began to talk to each other. A series of break out discussions put all the barriers the group would have to face on the table, along with the possible benefits of cooperation. The participants began to take each other more seriously. They began to let go of the cardboard cutout views they had of each other.

The group began to identify what they needed, and then what they needed of each other, and in so doing, they began to identify possible benefits of cooperation. For example, the flip chart that the group generated in the first meeting about the kinds of guidelines needed from an interdisciplinary group such as the one that was assembled said the following (edited only for reader understanding):

- Target high need areas.
- We need ultra-brief guidelines in some settings.
- Should identify consensus.
- Should be based on overlap between existing guidelines.
- Should include guidelines in clinical problem areas (e.g., suicide; compliance), not just syndromes.
- Some guidelines may need to be expansive, others not.
- Multidisciplinary guidelines should not interfere with disciplinary guidelines.
- Need both minatory and hortatory guidelines.
- Guidelines should be reverse engineered from outcomes.
- Should have goal of increase functionality and quality of life, but just symptom reduction.
- Should mesh with best available evidence.
- Should be user friendly.
- Must have significant input from practice base (field developed and tested).
- Should have criteria for entry and exit.
- Should have adherence tools.
- Should have indications for pharmacology.
- Should be revised continuously.
Connected to entire system (primary care, etc.).
Should address treatment failure options.
Should foster empowerment and self-help.
Should include psychoeducational and self-management.
Should include indicators for consultation.
Should be oriented toward community.
Should have validation program linked to it.
Should start with high priorities, such as (in adults)
  anxiety, depression, substance abuse; (in children)
  ADHD; (in adolescents) Substance abuse or eating
  disorders.
Should include prevention, v-codes, growth issues.
Dependent variables (processes, outcomes and
  measurements of them) should be attached
to guidelines.
Ethically, clinicians should inform patients of
guidelines-driven treatment plans and of the
evidence for it.

Guidelines that actually meet all of these requirements simply do not exist,
and the group realized this immediately as the list was generated. As the
groups began to discuss their hopes and fears, representative from opposing
groups began to see the issue is a new way. It is useful to examine the hopes
and fears of each group. What follows is that list, brainstormed at the first
meeting, and formally presented at the second, broken down by stakeholder.
Behavioral health systems and managers emphasized the following points:

Clinical practice guidelines developed via cooperation
  between the industry and key scientific, professional,
  and consumer associations is a very attractive
  product.
The development of clinical practice guidelines should
  involve the active participation of a variety of industry
  constituencies (AMBHA, THMOG, IBH, CentraLink, Council of Group Practices, Association
  of State Directors of Mental Health, Veteran’s Administration, etc.).
When target areas are identified, clinical practice
guidelines have to be developed quickly (within 3-6
  months) and renewed regularly to keep pace with
developments in the industry.
Practically useful clinical practice guidelines have to be simple and focus on the "critical few" core clinical processes.

Clinical practice guidelines need to focus on processes and procedures, not on the discipline of the provider.

Clinical practice guidelines must avoid any appearance of proprietary, discipline, profession, guild or self-serving interests.

Clinical practice guidelines should focus on the evidence and avoid any attempt to dictate health care policy per se at the industry level.

Professional associations and guild had a quite different list:

Clinical practice guidelines must be not be academic tomes, but products designed to help practitioners make decisions in the context of daily clinical practice.

Clinical practice guidelines must be user friendly in how they present core clinical concepts.

Clinical practice guidelines cannot become a "straight jacket" that supplants individual clinical decision making and the development of new and creative clinical approaches.

Clinical practice guidelines are the most applicable when they focus on the broad context of clinical assessment and decision making and leave the details of clinical implementation up to the practitioner.

Clinical practice guidelines cannot appear to reflect specific guild or association interests.

Clinical practice guidelines cannot favor any particular type of treatment (i.e., drugs versus psychotherapy, long term versus short term psychotherapy), unless there is a clear and agreed upon evidence basis for such a recommendation.

Scientific associations had a different set of concerns:

Scientifically based clinical practice guidelines must be grounded in a systematic and careful method of assessing and interpreting the existing research base.
Clinical practice guidelines should focus on effective assessment, treatment, and prevention processes and procedures, not on disciplinary interests.

Clinical practice guidelines should incorporate recommendations about how to assess clinical functional outcomes and over what time frames.

Clinical practice guidelines must be based in a coherent mechanism for describing the "strength" of a clinical practice recommendation, based upon the available evidence.

Clinical practice guidelines can include expert opinion, when the clinical topic is critical and the evidence is either scant or inconclusive, but these recommendations must be clearly distinguished from those based on scientific evidence and steps should be taken to subject such recommendations to empirical test as soon as possible.

Clinical practice guidelines should have a self-correcting function that is tied to research in the field.

Clinical practice guidelines should be updated periodically based upon changes in the evidence base or in expert opinion.

Consumer and advocacy groups had other concerns:

Clinical practice guidelines need to be built to attend to the best interests of the client and his or her immediate family members.

Consumers of behavioral health services must be a significant source of information about preferred outcomes of those services.

Clinical practice guidelines should not make treatment recommendations that place undue hardship on significant others as a part of treatment.

Clinical practice guidelines should not make recommendations that in effect deny a client access to care, even if there is no effective treatment available.

Clinical practice guidelines should state clear parameters for appropriate assessment of clinical and functional outcomes and recommend procedures for assessing those outcomes.

Federal and foundation entities added a few additional points:
Clinical practice guidelines must be built through a consensus process that includes all of the major constituencies in the behavioral health industry.

Clinical practice guidelines must be developed in a cost efficient way that includes the option of incorporating existing practice guidelines.

Clinical practice guidelines must help with the process of dissemination of science regarding effective behavioral health procedures.

Clinical practice guidelines should exist in some type of national center or clearinghouse, whose main goal is to coordinate development, refinement and dissemination.

Clinical practice guidelines should be developed by the behavioral health constituencies, not by governmental agencies per se.

What can be seen from these lists is that the concerns of stakeholders are legitimate and understandable. Furthermore, these imply enormous linkage between stakeholders. For example, the behavioral healthcare managers want cooperative, evidence-based guidelines, but they also want them to be developed in a cycle that takes no more than six months. The latter figure stunned the scientists in the room, who wanted evidence-based guidelines as well, but were not sure if such a short development cycle was possible. Between each pair of stakeholders there was a bi-directional set of interests, worries, needs, and a prod to change. To consider another example, the consumers wanted evidence-based care where possible, but wanted more attention to functionality, which was a bit of a challenge to the more purely syndromal thinking of many research scientists, practitioners, or funders.

By the end of the meetings, there was genuine enthusiasm for the idea that a bridge needed to be built between the industry, science, and the professions, with the active involvement of consumers, government, and other interested stakeholders. The PGC was born.

The central mission of the Practice Guidelines Coalition is the development of a multi-disciplinary, multi-organizational partnership that is dedicated to better behavioral health care through the dissemination and implementation of non-proprietary clinical practice guidelines for behavioral health providers that are based on a broad consensus about the best available evidence. Participants generally agreed that credible non-proprietary practice guidelines are best fostered through a broad, consensus building process based on a working partnership among all the key constituencies in behav-
ioral health, avoiding any hint of disciplinary, professional, corporate, or guild bias. It was broadly agreed among the participants that the Practice Guidelines Coalition will be open to all major organizations relevant to behavioral health care who wish to foster the goals of the Coalition. The Coalition intends to develop clinical practice guidelines that are brief, evidence-based, readily understandable by practitioners, focused on core clinical processes and measurable outcomes, nationally disseminated, multidisciplinary, and available in the public domain. The coalition is attempting to construct processes of review and development that are empirically sound, efficient, open, and participatory.

These PGC processes of guideline development are worth describing. The PGC guideline panel itself consists of eight members:

First, there are two respected scientists who are not strongly identified with a treatment or assessment model in the area of the guideline. They function more like "jurors" as in the NIH consensus conference model. Their role is to sort through the evidentiary summaries, articles and narrative summaries and organize their response to the core clinical and assessment questions, along with a statement of scientific confidence in each recommendation. Normally, one of these scientists will be non medically trained; the other will be medically trained. These scientists will expected to seek counsel from their colleagues in the event critical data is missing from the evidence reviews or when the evidence is hard to sort out and more expertise may be required.

Second, there are two behavioral health practitioners from different disciplines, whose role is to review and incorporate statements of expert opinion/best practice innovation into the guideline, to provide the panel with perspective about the likely practice impacts of scientific recommendations, to review their ease of application during a normal behavioral health service, and to review the user friendly attributes of the guideline format. These representatives do not represent an association point of view, but rather the practitioner point of view. Up to this time, each PGC panel has had one doctoral and one master's level practitioner.

Third, there are two behavioral health industry representatives, one public sector and one private sector, whose role is to address the implementation aspects of the guideline as it is being developed. This may involve questions around comparative costs of two treatments with equal efficacy, feedback when recommendations are becoming too esoteric or specialized to be feasible in a typical delivery system, etc. In their industry representation role, these individuals should interact with industry members in the Coalition to assure that all viewpoints are being considered.
Finally, there are two consumer advocates, one being a direct recipient of care and one representing the larger advocacy community such as significant others impacted by a behavioral health condition and the demands of treatment. These consumer advocates keep the panel focused on consumer and family needs and preferences, they help construct meaningful consumer information that would be attached to the guideline, and they look at feasibility in terms of personal cost, retention in treatment, burden of care placed on the family and so forth.

There are five possible sources of data input into the scientific review process:

1. The most published and most cited authors in the area over the last ten years (out of both PsychLit/MedLine) are asked to nominate what they consider to be the three most important articles in the area.
2. The top 25 highest citation impact articles over the last ten years in this area from the Science Citation Index and the Social Science Citation Index.
3. Limited numbers of raw articles submitted from participant organizations as representing important findings (limit of five).
4. Evidence tables, conclusions, and supporting articles from participant organizations. Existing guidelines may be part of this form of evidentiary material, provided that they are based on identifiable evidence tables and scientific review.
5. Articles suggested by the panels themselves.

Several articles are weeded out that come in through this process, namely, purely theoretical articles that do not review existing literature, animal studies without clear links to human concerns, and articles not focused primarily on the content area. If need be, the scientific subcommittee further weeds out articles on the basis of relevance or quality to limit the input to no more than approximately 50 articles. The goal of this process is to filter out relatively unimportant articles from ever being considered rather than doing a more comprehensive literature search and then using quality ratings as the filter.

These articles are examined by a scientific sub-committee, that is advisory to the scientists on the main panel. The scientific subcommittee is composed of 4-5 experts in the particular area. Each must have excellent credentials, and must represent a range of constituencies and competencies. The scientific subcommittee essentially combines the scientific input into evidence tables and conclusions, for use by the main panel.
Each member of the subcommittee reviews 10-20 articles, and completes an evidence evaluation form for each. The key section of the evidence evaluation form is the "Conclusions and impact" section. In this section the subcommittee scientists are asked to examine the list of questions being considered by the guideline panel, and to list conclusions that they draw from the article that speak to the guidelines questions. The subcommittee members try to state conclusions in terms of core clinical procedures and processes, where possible, and avoid phrasing statements in terms of discipline or orientation.

The guidelines questions addressed include the following:

What is the best established and most appropriate method of assessment for this condition? Are there assessment methods that should not be used?

Are there any age, sex, racial, ethnic, religious, economic, disability, social/familial or work setting factors that might mitigate how this problem presents or might influence treatment selection, likelihood of response or retention in treatment? Are there functional outcomes in any of these areas that should be measured?

What treatments have been shown to be effective with this problem? What core interventions in this treatment are most associated with positive clinical response? Is there evidence regarding the acceptability of recommended treatments with providers? What is the probability of positive treatment response based upon a review of "completers" data? Are there treatments with more variable or poorer outcomes that should not be employed? If there is more than one effective treatment, is there a significant cost differential between the two? Is this cost differential mitigated by other factors, for example, reduced relapse rates?

What are the consumer acceptance data like with the recommended treatment(s)? Are there differential drop out rates that might effect the population effectiveness of the treatments? What information should consumers receive regarding the risks and benefits of this treatment? Are there potential side effects that might affect treatment acceptability?
What is the estimated time frame for positive clinical response? What assessment procedure is recommended for measuring clinical response and when should it be used? What should be done if a patient is not responding as expected to the treatment? When should an alternative treatment be added or substituted for the existing treatment?

What are the most commonly occurring co-morbid conditions? How do they influence treatment selection and prognosis? Are there functionally distinct subgroups within this problem area, either diagnostically or in terms of underlying etiological or maintaining processes? Are there differential treatment considerations related to subgroups?

Is this a recurring problem that is subject to relapse? What is the relapse rate in patients who have responded to the preferred treatment(s)? What methods should be employed to prevent relapse?

Is there evidence that primary prevention or health promotion interventions can forestall the appearance and/or progression of this condition? If so, what are the core components of such effective interventions?

The main panel then works through this same list of questions, this time benefiting from the give and take from the different stakeholders they represent, and from the different data they bring to the table. The goal is to whittle down the input to the core clinical issues involved. The resulting product (and an associated consumer guideline) is shared among a broad range of constituent groups for input.

**An Example of the Results of the PGC Process**

Two demonstration guidelines projects, in panic disorder and the management of chronic back pain, have been conducted by PGC. The panic process is instructive and will be described here.

From the nominations submitted by participating organizations, the eight-member main panel was formed. The panel was composed of:

Two scientists, for whom panic disorder was not their main area of research: G. Terrence Wilson, PhD, a psychologist from Rutgers University and Gail Stuart, RN, PhD, from the Medical University of South Carolina;
Two industry representatives: Gary Mihalik, MD, MBA from the private sector (Greenspring of Illinois) and Wendy Wade, PhD from the public sector (South Central Community Mental Health Center in Bloomington, Indiana);

Two consumers: Cyma Siegel, RN, a consumer herself and founder, editor, and publisher of the National Panic/Anxiety Disorder Newsletter, and Jerilyn Ross, MSW, President of the Anxiety Disorders Association of America; and

Two clinicians: Cheryl Al-Mateen, a Virginia psychiatrist, and Deborah Jackson, MA, a counselor in the Washington DC area.

The next step involved in the development of the panic disorder guideline was the selection of the scientific subcommittee. Again relying on the recommendations of participating organizations and associations, a six-member scientific subcommittee was formed. This subcommittee consisted of the two scientists nominated to the main panic disorder panel, as well as Michele T. Laraia, PhD, RN, CS, Medical University of South Carolina, W. Stewart Agras, M.D., Department of Psychiatry, Stanford University, William Sanderson, Ph.D., Albert Einstein College of Medicine, and Kathy Shear, M.D., Department of Psychiatry, University of Pittsburgh. The articles gathered in the data collection process were then distributed to these subcommittee members, such that each article was independently reviewed by at least two of the panel members. The committee members then met for a one-day meeting in New York City, where they created a cohesive document of the state of the science, that was then passed on the main panel. The main panel met a short while later, and in just under two days, came to consensus.

By focusing only on the relatively black and white areas that are clearly known and are agreed to through a multi-disciplinary process emphasizing consensus and clear evidence, a remarkably brief and clinician-friendly guideline resulted. The draft guideline is shown in Table 2. In small type format the primary document can fit on both sides of a legal sized sheet of paper. The guideline lays out a working definition of panic disorder, issues relating to the assessment of panic disorder, as well as recommendations for psychosocial and pharmacological treatment, and the selection between, and combination of, the two types of treatment. Additionally, the guideline addresses issues of comorbidity, prevention, typical length of treatment. To be of use when there is not enough time even to read four bulleted pages, individual emboldened words in the guideline provide a quick overview. This overview version can be read in about a minute.

The guideline also has two appendices: a medication appendix delineating various pharmacotherapy types and dosages, and an appendix expanding on the psychosocial components laid out in the guideline. A consumer guideline was also developed, containing similar information as the main
WHAT IS PANIC DISORDER?

Recurrent, unexpected panic attacks—a discrete period of intense fear or discomfort, in which four (or more) of the following symptoms develop abruptly and peak within 10 minutes:

- Palpitations, pounding heart, or accelerated heart rate
- Sweating
- Trembling or shaking
- Sensations of shortness of breath or smothering
- Feeling of choking
- Chest pain or discomfort
- Nausea or abdominal distress
- Feeling dizzy, unsteady, light-headed, or faint
- Derealization (feelings of unreality) or depersonalization (being detached from oneself)
- Fear of losing control or going crazy
- Fear of dying
- Paresthesias (numbness or tingling sensations)
- Chills or hot flushes

1 month or more of persistent concern about having another attack or worry about the implications or consequences of panic (e.g., fear of loss or control, going crazy, or social humiliation).

or

A significant behavioral change related to the attacks (e.g., agoraphobic avoidance of panic producing situations).

What Should be Ruled Out?

- Direct physiological effects of a substance (e.g., Caffeine Intoxication).
- General medical conditions that can cause panic-like symptoms.
- Not better accounted for by another mental disorder (e.g., PTSD).

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Figure 1

Draft PGC Panic Disorder Guideline.
Basic Facts About Panic Disorder:

Tends to be chronic

Co-Morbidity is common. Usually at least one other disorder is present, including:
- Depression
- Substance abuse
- Other anxiety disorders
- Personality disorders

Associated with notable suffering, disability, and functional impairment (e.g., social withdrawal, employment or school difficulties).

Lifetime prevalence rates (With or Without Agoraphobia) between 1.5% and 3.5%. One-year prevalence rates between 1% and 2%.

Age:
- Occurs across the age range. Children may be as responsive to treatment as adults.
- In the elderly panic can be complicated by the normal aging process, medical co-morbidities, and concomitant pharmacological therapies, and thus may be misdiagnosed or left untreated.

Gender:
- More prevalent in women, particularly panic with extensive agoraphobia.
- Symptom severity worsens during the menstrual cycle and may improve during pregnancy in some women.

Racial differences:
- Seems associated with hypertension and with sleep paralysis in African Americans.

Belief systems:
- Incidence and prevalence seems consistent across ethnic/racial groups.
- Presentation and interpretation of symptoms is affected by ethnic, racial, religious, and family belief systems.

What Goes Into Effective Clinical Assessment?
- Consider using a screening questionnaire instrument for detection.
Conduct a thorough clinical interview assessing history and current symptoms—consider using a structured clinical interview to guide you.

Assess initially and on an on-going basis for:

- Number and severity of panic attacks
- Severity of anticipatory anxiety
- Severity of agoraphobic symptoms
- Suicidal ideation and attempts
- Panic attacks
- Missed work/school
- Underachievement at work or school
- Self-care
- Routine social behavior
- Quality of life

Assess for co-morbid conditions initially and on an on-going basis (particularly depression, substance abuse, agoraphobia, other anxiety disorders, and caffeine use). To rule out medical conditions that mimic panic, consider medical history with appropriate laboratory tests.

What Assessments Are Not Helpful?

The MMPI, projective tests, and neuropsychological testing have not been shown to be particularly useful in diagnosing panic disorder or measuring response to treatment.

There is no medical test that diagnoses panic disorder.

What Treatments Are Helpful?

**Effective Psychosocial Treatment**

The strongest evidence supports the effectiveness of a psychosocial interventions that include the following (see Appendix I):

- **Psychoeducation** about the symptoms, the disorder, and the specific role of fear of bodily sensations.
- **Exposure to the interoceptive reactions** that comprise and cue panic attacks.

Draft PGC Panic Disorder Guideline.
Cognitive restructuring to change maladaptive thought processes.

Training in proper breathing, to avoid hyperventilation, breath holding, shallow breathing, and other common breath problems occasioned by anxiety.

In vivo exposure to phobic situations.

Effective Pharmacological Treatment

The strongest evidence supports the effectiveness of SSRIs, TCAs, MAOIs, and high potency benzodiazepines (see Appendix II). There is comparable efficacy among these medications. The effectiveness of maintenance medication to prevent relapse has not been firmly established.

How Do Effective Treatments Compare?

The clear majority of patients show a positive response to either psychosocial or pharmacological treatment. Both are equally effective in acute phase (12 weeks) treatment.

Effective psychosocial treatment has greater durability than pharmacotherapy.

In studies comparing effective psychosocial treatment to a single form of effective pharmacological treatment (imipramine), dropout rates for pharmacotherapy are higher.

Are Combining These Two Forms of Treatment Best?

The data show that combining benzodiazepines with effective psychosocial treatment reduces treatment efficacy when compared to psychosocial treatment alone.

There aren’t sufficient data to evaluate the combination of psychosocial treatment with SSRIs, TCAs, and MAOIs.

Effective psychosocial treatment has been shown to reduce relapse following discontinuation of benzodiazepines.
Overall Clinical Management is Important

An essential component for either general form of effective treatment is **psychoeducation** for the patient and, when appropriate significant others, covering:

- An explanation of the **basis for panic** and anxiety.
- The **nature and course** of panic disorder.
- Rationale for the treatment, likelihood of a positive response, and expected time frame for response.
- **Likelihood of experiencing some residual anxiety** in the course of treatment.

If there is an **inadequate response** after an adequate trial of a first-line treatment, **switch** to another evidence-based treatment. At this time it may be important to **obtain a consultation** and/or refer the patient to a specialist or subspecialist.

If panic disorder is **more severe** than other co-occurring conditions (as determined by impairment or interference with daily living, and distress from symptoms), panic should be the **initial focus** of treatment, regardless of chronological onset.

The presence of severe agoraphobia and certain personality disorders is a negative prognostic indicator, while co-morbid depression has no consistent effect.

**Issues in Managing Psychosocial Treatment**

A positive response typically occurs within 6 to 8 weeks. A typical course of treatment in research protocols is about 12 sessions. However, in clinical practice, more or less time may be required.

- Some patients require only a few sessions to understand that panic is not dangerous, and improvement continues naturally from there.
- Others may require substantially longer than 12 sessions, especially if agoraphobia is severe.

**Issues in Managing Pharmacological Treatment**

A positive response typically occurs within 6 weeks (response to benzodiazepines occurs considerably

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**Figure 1 (continued)**

Draft PGC Panic Disorder Guideline.
faster) but additional time may be required to stabilize the response.

Because there is comparable efficacy, issues related to safety, tolerability, price, simplicity, and ease of discontinuation should guide clinician choice among effective medications.

Medications, especially benzodiazepines, should be discontinued gradually, as it may be difficult and may provoke relapse or even rebound panic.

If a patient has an inadequate response or is unable to tolerate the side effects of the medication, the potential difficulty in discontinuing the medication should be carefully considered.

Switching medications, using augmentation therapy, or treating medication side effects may be effective.

When used alone, SSRIs, TCAs, and MAOIs should be continued for at least 6 months following symptom remission, and longer if full remission does not occur.

Some clinicians advocate stopping medication only when the patient is in a stable life situation.

Longer use of medication may reduce the risk of relapse following discontinuation.

For patients with several episodes of panic, each responsive to medication, chronic medication use may be indicated.

Panic disorder patients may require lower beginning dose and slow titration of SSRIs, TCAs, and MAOIs compared to other patients receiving those medications.

How Do I Select Among Treatments?

We cannot predict which individual will respond best to which treatment. The following factors should be considered:

- Suicide risk
- Availability of provider expertise
- Previous response
- Concomitant medical conditions

Figure 1 (continued)

Draft PGC Panic Disorder Guideline.
and pharmacological treatments
Psychiatric co-morbidities,
including substance use disorders
Patient preference
Chronic psychosocial problems
Risk/benefit ratio
Cost
Differential compliance to treatment modalities
Potential for pregnancy
Level of support from significant others

What About Prevention?

Early identification and treatment of the disorder is important in secondary prevention.

No known data exist on primary prevention of panic disorder.

Figure 1 (continued)

Draft PGC Panic Disorder Guideline.

guideline but with language designed for patients, and with a list of patient resources.

THE ROLE OF GUIDELINES IN ORGANIZED BEHAVIORAL HEALTHCARE

A self-amplifying loop between science and practice has never existed in behavioral health in the way that it has in some other areas of practical work. Behavioral health services are often delivered without significant regard for the nature and quality of the existing evidence. On the reimbursement and delivery systems side, sometimes cost containment has been more important in what services are paid for than clinical quality as defined by evidence of effectiveness and efficiency.

Practice guidelines, in combination with the industrialization of health service delivery across the spectrum of public and private agencies, hold out hope to change that picture. On the one hand, the combination of consolidation, accreditation, legislation, and regulation is increasingly linking the financial success of the health care industry to the production of quality outcomes. On the other, the behavioral sciences and professions seem finally
ready to cooperate in non-proprietary efforts to create evidence-based practice guidelines. For the first time the elements for an evidence-based revolution in quality of care is in place.

Integrating science with practice in organized behavioral healthcare delivery has two components: drawing on the existing science to contribute to the effectiveness and efficiency of healthcare delivery, and developing new scientific knowledge in the context of managed care. In both areas, practice guidelines could form the warp and woof of such an integration. The first area is obvious (using practice guidelines as a means of drawing on the existing science) but the second could be even more important. Properly done, practice guidelines could create this exciting loop:

1) Implementation of practice guidelines leads to both clinical success and clinical failure.
2) Clinical work with treatment resistant population leads to
3) Clinical innovation leads to
4) Preliminary intensive testing with individuals leads to
5) Development of formalized treatment protocols leads to
6) Formal testing in defined populations leads to
7) Inclusion of these innovations into practice guidelines leads to
8) Implementation by managed care leads to
9) Training in guidelines with the practitioner base lead to
10) Assessment of penetration of guidelines in delivery systems leads to
11) Assessment of outcomes produced by guidelines leads to
12) Accreditation and quality care standards based on successful training and implementation, which hopefully leads to
13) Better quality healthcare care overall, at lower cost, and thus to economic success of the industry, but also leads to
14) Success with some clients and failure with others, which leads to
15) #2 above

This is a remarkable possibility and one that could fundamentally change behavioral health care in this country. Yet it is easy to overstate the relevance
of practice guidelines. At present no one knows how to develop and implement them in a way that will produce changes in clinician behavior and, furthermore, it is not known if they will contribute to clinical outcome.

At present clinical practice guidelines in behavioral healthcare are more a focus of accreditation activity than of clinical excellence. But the possibility is there. Clinical practice guidelines, done well, could be a vital step toward a more empirical approach to behavioral healthcare delivery.

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Comment on Practice Guidelines

Duane L. Varble, Ph.D.
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Hayes and Gregg outline three major purposes in their chapter. Namely, "to convince the readers that practice guidelines are not an arbitrary development in the field"...to convince the readers that practice guidelines, done properly, hold out great hope for consumers, managers, payors and providers alike..." and "finally discuss where practice guidelines fit within an integrated system of evidence based care" (Hayes and Gregg page 1 of chapter 9).

This discussion will examine how well these three purposes are carried out. In addition specific issues of concern to behavioral healthcare providers will be highlighted.

THE NONARBITRARY NATURE OF PRACTICE GUIDELINES

Hayes and Gregg provide excellent examples of how industrialization works in manufacturing systems to produce cheaper costs and better quality. Their arguments that the industrialization of health care and especially behavioral healthcare, by means of managed care, will ultimately result in better quality for consumers is less convincing. Most of the empirical evidence to date indicates managed care has grown because of increased cost cutting measures not increased quality. In fact the perception that decreases in quality are occurring as a result of managed care has many consumers putting pressure on their congressional representatives to pass a patient's bill of rights.

Hayes and Gregg address this problem in their discussion of the industrialization process in terms of stages. Their contention is that managed health care delivery is not at a mature level yet but will reach maturity in the future. The fact that health care delivery is changing is certain but it is not so clear that practice guidelines or even managed care will be major components in the future.
Hayes and Gregg’s argument that practice guidelines will help ward off threats to successful industrialization makes sense if their scenario that consensually based guidelines can be developed that will actually guide practices across professional disciplines is achievable. Not only are there substantial problems with developing meaningful diagnostic systems that have treatment implications but the history of mistrust and poor cooperation among the major behavioral healthcare professional disciplines makes such consensus unlikely at the practice level. What seems more probable is a top down approach where the behavioral healthcare turf is carved up by legislation based on the desires of special interest groups and/or a few very large managed care organizations reaching an agreement about who will treat what problems and what the reimbursement rates will be. EAP programs and preauthorization requirements already serve some of these functions and could easily be expanded. No consensus building is required under this scenario and those providers who are in the medical fields with prescription privileges, such as nurse practitioners and physician’s assistants as well as physicians will be doing the lion's share of treatment. This saves money and has already started to occur in some settings such as Veteran’s Administration Medical Center Mental Health Clinics.

In concluding this section, Hayes and Gregg have made convincing arguments that practice guidelines are not an arbitrary development in the field if industrialization of behavioral healthcare occurs in the way they envision. Their assumptions that industrialization will occur in the relatively smooth straight forward fashion they would like are not convincing. Unfortunately, there are good reasons to predict that there will be precious little that will be behavioral in behavioral healthcare delivery. This point will be elaborated on in the next section.

**If Done Properly, Practice Guidelines Hold Out Great Hope for Consumers, Managers, Payors, and Providers Alike**

Hayes and Gregg let their idealism run wild in this regard. There is general agreement that the present behavioral healthcare delivery system is inefficient and only marginally effective. There is confusion among consumers, managers, payors and providers alike. Consumers do not know what benefits are available for what problems and have no rational idea who is best trained to deliver specific treatments. Managers are focused on keeping costs to a minimum by limiting the types and lengths of service. Payors have inadequate systems for handling changing benefits, variable benefits and
multiple options for different companies. Providers magically appear and disappear on provider lists as managed care companies buy and sell each other. Almost any change would be an improvement if it produced stability and predictability.

Hayes and Gregg persuasively argue that practice guidelines could help provide needed predictability if they are done properly. The first question is: if done properly by whose definition? The key concern here is whether it is realistic to assume that meaningful practice guidelines that incorporate more than pharmacological treatments can be developed and put into practice. Hayes and Gregg describe the enormous difficulties of achieving the necessary cooperation among a diverse group of stakeholders to arrive at some generic guidelines for two sets of symptoms, anxiety and back pain, in their discussion of the Practice Guidelines Coalition process. To achieve consensus these guidelines are so broad that they are minimally helpful to providers in addressing individual cases.

Consumers are not likely to consult behavioral healthcare providers for such symptoms because what they see advertised tells them otherwise. Open any magazine, but especially any magazine targeted to women and you will find advertisements for Prozac, Paxil, etc. "Having trouble sleeping? Just don’t enjoy your job anymore? Feel tired? This medication may help you get back on track" One of the advertisers for the NBC Today morning news show, the television industry leader, is the company that makes Buspar ..." feeling upset lately? maybe a little anxious? Ask your doctor about Buspar, research studies show that it is not addictive or habitforming..." They are not talking about seeing your psychiatrist. "Ask your doctor" means see your primary care physician or his/her nurse practitioner or physician’s assistant and they will likely prescribe Buspar if that is what you as the consumer patient requests. If you, as a consumer, requested that you be referred to a psychologist or a social worker the referral might be made but where are the advertisements for systematic desensitization or exposure and response prevention? The pharmacological companies have the money, the public acceptance of the biological model-based on “scientific evidence” and a huge headstart over any kind of behavioral healthcare. Furthermore, it is in the managed care companies cost cutting best interest to utilize pharmacological treatments whenever possible because it is faster and cheaper, at least in the short run.

In conclusion, I agree with Hayes and Gregg’s contention that practice guidelines, if done properly, could benefit everyone involved in the provision of behavioral healthcare eventually. However, it seems very unlikely that practice guidelines that have an important role for the behavioral in behavioral healthcare services will be developed and utilized in the foreseeable future.
The Fit of Practice Guidelines Within a System of Evidence Based Care

Just as in the last section the paramount questions here are what evidence and whose is it? Hayes and Gregg do an excellent job of pointing out the difficulties of obtaining agreement between scientifically oriented researchers who want to limit uncontrolled variables and providers who are faced daily with fuzzy diagnostic categories, overlapping symptoms and multiple influences of cultural and environmental factors. Researchers tend to frame the issues in terms of treatments for disorders while providers typically frame the same issues in terms of treatment of clients or patients. This variant of the debate about nomothetic versus idiographic emphasis has a long history and there are good arguments that the disorder treatment focus and the patient treatment focus are not mutually exclusive philosophically. The implications in practical terms are important, however. Hayes and Gregg present the dilemma well, i.e., in order to obtain the necessary money do the research the experimental model, including strict adherence to treatment manuals, is required but providers who are responding to the life event changes in their clients or patients find the inflexible treatment manuals to be inadequate or inappropriate and do not use them.

Hayes and Gregg provide some interesting strategies for dealing with this dilemma, namely, implement the practice guidelines in specific settings and evaluate client outcomes. Their example of the “manipulated training method” (Strosahl, Hayes, Bergan and Romano, 1998) offered a glimpse of how this could be done. Positive client outcome data from general clinical population studies would be the most convincing to the clinicians who are providing services today. Future generations of providers may be less influenced by theoretical orientation loyalties and more by the practicalities of pocket book issues based on what treatments are reimbursed. This trend is already underway. Evidence of effectiveness would help providers, payers and the managed care companies reach agreement about which practice guidelines to apply. Evidence of effectiveness does not yet seem to be that important to consumers based on their willingness to pay large sums of money for alternative treatments such as herbs, vitamins, extracts etc. Advertising and testimonials seem to drive these purchases not evidence of effectiveness.

The important point that Hayes and Gregg make, with regard to the evidence of effectiveness issue, is that practice guidelines that achieve sufficient penetration to be evaluated and modified in an ongoing improvement process could have much wider impact on evidenced based behavioral healthcare delivery than the more pure experimental models can ever achieve. I would argue that for such penetration to occur direct marketing including
Discussion of Hayes and Gregg

advertising to consumers has to be a part of the package. This means rethinking the ethical guidelines of the professional disciplines involved in behavioral healthcare delivery.

In conclusion, Hayes and Gregg make a good case for the role of practice guidelines in integrated evidence based behavioral healthcare. In fact, adoption of practice guidelines could make the evaluation of client outcomes in general clinical populations possible, which in turn, makes the acceptance of evidence based care by providers more likely.

**Specific Issues of Concern to Behavioral Healthcare Providers**

Behavioral healthcare providers did not receive much emphasis at this conference. They were not considered to be unimportant but the specific concerns of providers other than shrinking incomes as a result of managed care cost cutting did not get considered adequately in my opinion. Two managed care practices that are considered to be core issues for most of today's behavioral healthcare providers are non-clinicians making the decisions about the type and length of treatments through pre-authorization and re-authorization requirements and perceived interference in the relationship between the patient and the provider. Practice guidelines do not bear directly on these issues as long as they remain as guidelines and not standards of care. The fear of some providers is that practice guidelines will be portrayed as guidelines but acted upon as standards of care. In other words the provider who does not agree to follow the guidelines will be dropped from provider panels by the managed care companies. Most providers who deal with managed care companies on a regular basis have had some firsthand experience of disagreements between the company’s case management plan and the clinician’s. The pressure to comply with the company’s plan is not subtle and if compliance is not perceived to occur the provider may not be dropped from the panel but does not receive any further referrals. The client or patient is often caught in the middle of such conflicts.

In summary, Hayes and Gregg do an excellent presentation on the benefits of developing and adopting practice guidelines for behavioral healthcare. The task is a difficult one. This discussion has attempted to point out some of the more germane issues and pitfalls.

If practice guidelines based on consensus are developed and implemented everyone in behavioral healthcare will be better off. If a top down approach is used pharmacological treatments and not behavioral treatments are likely to be the result. Prescription privileges for psychologists would almost be a certainty.
Financial Risk and Structural Issues

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Why Integrate?
Integration of Medical and Behavioral Healthcare
Behavioral Healthcare Service System Pricing
Potential for Medical Cost Offsets
Reimbursement and Risk-Sharing Models for Integration
  Example 1
  Example 2
  Example 3
Psychotropic Drug Risk Issues
  Challenges with Integration
Summary
Managed care has brought about substantial change in the cost of healthcare, in the ways healthcare providers practice medicine, and how healthcare providers are reimbursed for their services. The growth rate and consolidation in managed behavioral healthcare in the 1990s has been remarkable in the United States. Managed behavioral healthcare organizations are now involved in the management of mental health and substance abuse coverage for over 176 million Americans. In most settings, behavioral healthcare services are provided "off-site" from primary medical care and are considered specialty services. However, there is an increasing trend towards the integration of behavioral healthcare services in primary care settings. This paper will examine some of the supporting reasons behind this integration, and explore some of the financial, risk and structural issues related to such integration under managed care.

**WHY INTEGRATE?**

Why even consider integrating behavioral healthcare services in primary care settings? After all, aren’t most behavioral healthcare services in managed care plans provided through managed behavioral healthcare companies on a "carve-out" basis? By design, doesn’t this structure separate the delivery of primary medical and behavioral healthcare services and make such integration extremely challenging, if not practically impossible?

One driving force behind integration initiatives is the return of a challenging issue for many employers and payers - healthcare costs are back on the rise! After several years of low or no increase in the cost of employers' health benefit plans, costs rose by over 7% in 1999, by over 8% in 2000, and are expected to rise by even larger percentages in the year 2001 (average increase expected at 11%). Perhaps most significant is that the cost of managed care plans may grow as fast or even faster than the cost of traditional indemnity medical plans as insurers try to recover from under-priced plans in previous years.

Employers drive what happens in healthcare through their purchasing decisions. They are beginning to demand that healthcare providers focus on maintaining the health of their employees rather than on simply treating diseases. Interest is rising on how much health plans spend on disease treatment vs. early detection of disease and identification of people at risk for early symptoms. To be closely aligned with employers' desires and objectives is not only a business opportunity for healthcare providers, but an opportunity to influence benefit design and purchasing decisions for the good of consumers.
Consider the following statistics relating to medical and behavioral healthcare treatment in primary and specialty care settings:

- 60% to 70% of all medical visits have no medical or biological diagnosis which can be confirmed.
- An estimated 25% of patients seeking primary care treatment have anxiety and depressive disorders.
- HMO mental health specialty providers (in non-integrated settings) see only 3% to 6% of covered members in any given year, whereas at least 15% of all covered members are known to suffer from some type of psychological disorder during the year.
- More than 50% of patients with mental health problems are seen only in the general medical sector.
- Approximately 67% of all psychotropic medications are written by nonpsychiatric physicians.
- Primary care patients are non-compliant with behavioral healthcare referrals by anywhere from 50% to 90% of the time.
- Undiagnosed and untreated anxiety and depressive disorders result in significantly greater (up to 2 times) medical costs and greater social and vocational disability.
- Diagnosis and detection of behavioral disorders is missed in 33 to 50% of PCP outpatient cases.

Common symptoms of patients in primary care settings include:

- Chest Pain
- Fatigue
- Dizziness
- Headaches
- Edema
- Back Pain
- Dyspnea
- Insomnia
- Numbness
- Abdominal Pain

The University of Wisconsin School of Medicine reports the following statistics related to the percent of certain symptoms that initially had no medical or biological explanation, but were subsequently found to be related to depressive or anxiety disorders (See Table 1).

These data clearly indicate that somatization (the translation of emotional problems into physical symptoms, or the exacerbation of a disease by emotional factors or stress) is prevalent in primary care settings. Such somatization inevitably results in overutilization of healthcare services, potentially even overloading the system.
Besides the prevalence of psychological disorders among somatizing patients, there are observed levels of psychological illnesses among patients with chronic physical disease. Epidemiologic and other studies have reported the following age-sex adjusted (normalized) prevalence rates of comorbidity between psychological illness and chronic physical disease (See Table 2).

These data and observations provide supporting evidence that integration of behavioral healthcare services in primary care settings, where structurally possible, may have great potential for reaching and treating more patients with behavioral disorders, providing more appropriate healthcare services for the underlying illness or disorder, increasing awareness of behavioral disorders, increasing both medical and psychological wellness, and reducing medical, vocational and social costs.

**What Could the Integration of Medical and Behavioral Healthcare Include?**

The integration of behavioral healthcare services in primary medical settings could include or involve a fairly wide range of potential objectives and structures. The following list provides examples of what an organization could include in their integration of behavioral and primary medical care services:

- Mental health professionals are just “one of the docs”, as on-site members of the medical care teams within the medical care plan.
- Use of behavioral professionals as on-site consultants to PCPs.
Smooth transition between the medical and behavioral health portions of care.

Coordination of separate but related behavioral health and medical agendas and care (inter-departmental and inter-clinic care planning, case management, and program development).

Behavioral health therapy groups run in primary care settings (e.g., adolescent psychotherapy groups run in pediatric as opposed to mental health settings; newly pregnant, substance abusing women treated and educated in OB clinics).

Creation of innovative care programs to increase patient self-management and awareness (e.g., hypertension management, asthma self-management, “skills not pills” and reconditioning exercise programs).

Multi-departmental treatment of chronic pain or ADHD, allowing providers to see a more global approach to care of patients, decreasing the possibility of certain treatment elements being overlooked.

Case-finding programs - the process by which certain cases or illnesses are sought out, with the idea that early intervention will prevent more costly care down the road (e.g., inpatient medical and surgical patients with evidence of alcohol or drug problems; ER patients seen for symptoms of panic disorder).

Joint staff meetings between medical and behavioral healthcare professionals.

Increased use of technology and online medical information.

Video conferencing teaching sessions related to behavioral healthcare for PCPs.

Integration need not involve the primary behavioral healthcare providers on a full-time basis. However, there is a need for flexibility on their part in order to "capture the moment" when a medical PCP needs the behavioral provider. Many of the behavioral providers may spend only part of their day in the primary integrated care offices and the rest in their own personal behavioral healthcare practices. The behavioral healthcare provider would normally have a professional degree, state licensure, and be a member of important provider panels.
Behavioral Healthcare Service System Pricing: Traditional vs. Integration

The pricing of behavioral healthcare services in an integrated setting involves many new considerations beyond those typically found in pricing traditional carve-out services. The traditional way of providing segregated behavioral healthcare services primarily has an illness treatment focus. The development of expected costs related to these services include using historical utilization rates and referral patterns of PCPs and, at times, specialists to behavioral healthcare providers. Expected utilization rates of the various alternative modalities along the continuum of available behavioral healthcare services are also developed (i.e., inpatient acute, residential, day treatment, intensive outpatient, outpatient therapies, medication management, etc.). Demographic adjustments are considered, as well as considerations for the potential impact of Employee Assistance Programs.

Reimbursement rates for facilities are developed for the various inpatient and acute alternative services (per diems, case rates, program rates, or discounts to fee-for-service levels), and professional fee levels are also developed. Professional rates commonly vary by type of behavioral healthcare professional. Occasionally, professionals accept case rates for therapy or specialized treatment programs, but some type of fee-for-service reimbursement structure is the norm.

Risk-sharing arrangements are not common among behavioral healthcare providers, between behavioral healthcare providers and the managed care organization, or between the behavioral providers and the medical providers. The behavioral providers themselves have had little financial incentive (other than being removed from managed care provider panels) to manage utilization, develop wellness and prevention programs, and reduce medical or other costs through their healthcare and other activities. Risk-sharing considerations in traditional pricing are essentially nonexistent.

In an integrated behavioral and primary medical structure, there are many new considerations for the development of expected costs, including:

- The existence of primary behavioral healthcare providers
- An increased prevention and wellness focus
- Treatment pattern and service shifts from historical levels
- Potential medical cost offsets
- Financial risk-sharing and other revenue sharing arrangements
Primary behavioral healthcare providers could be teamed with medical PCPs and be responsible for a selected predetermined profile of services, which could include diagnosis, brief testing, brief therapies, patient and PCP education, and referrals to other behavioral specialists. Behavioral healthcare PhDs and, in some cases, MSWs could serve in this capacity, with service profiles appropriate for their training and expertise. They would be actively involved with the early identification and treatment of behavioral healthcare disorders in the primary care setting alongside the medical PCPs. They could be considered as "partners" to the primary care providers in the treatment of all patients receiving care.

The integrated system has a greater focus on behavioral wellness and illness prevention. Education programs and materials are more proactively developed to inform covered members on various topics, including stress, depression, anxiety, alcoholism, chronic illness, and workplace and family relationships. Intervention and case-finding programs could be developed in emergency rooms, acute inpatient settings, schools, and OB/Gyn clinics.

Treatment pattern and service delivery shifts from historical levels must be considered in the pricing process. There will likely be changes in the following pricing factors:

- Diagnosis rates of behavioral disorders
- Average lengths-of-stay for inpatient and acute alternative services
- Average lengths-of-treatment for outpatient services
- Rx vs. therapy service shifts
- Case management
- Referral patterns and patient flow among providers
- Overhead costs
- Case-finding results
- Professional provider mix in service delivery
- Education and prevention costs

The contract period is also a very important consideration in pricing. There will likely be start-up costs, which could be considerable in size, resulting from the integration process. The contract period needs to be long enough for the potential savings in medical costs to materialize and offset the start-up costs.
Potential for Medical Cost Offsets

Various studies related to the potential for medical cost offsets of effective behavioral healthcare service delivery and interventions continue to emerge. These studies on the effects of mental health and substance abuse treatment on medical and surgical utilization date back to the 1960s and can readily be found in the behavioral and medical journals and literature.

One particular recent study by Ron Z. Goetzel and colleagues examined how health risks affect medical costs and whether behavioral modification can produce savings. The study found that the two risk measures that had the largest percentage differences in mean annual medical expenditures between high and low risk levels were depression and stress level. Employees determined to be at high risk for depression had mean medical expenditure that were 70% higher than those of the employees that were determined to be at low risk for depression. In 1996 dollars, this translated to an annual difference of about $1,200 per employee after adjustments for group differences. Employees confronting high levels of stress had mean medical expenditures that were 46% higher than those of the employees that had low levels of stress. This translated to an annual difference of more than $700 per employee.

The study also found that multiple risk factors were extremely significant for cost levels. Individuals at high risk for psychosocial problems (high stress and depression) had predicted annual medical expenditures that were 147% higher than individuals without these risk factors.

The data from this study suggest that potential exists for reducing healthcare costs by implementing programs which address these two psychosocial factors which accounted for the greatest difference in healthcare costs between the high and low risk individuals.

<table>
<thead>
<tr>
<th>Treatment Category</th>
<th>Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total ambulatory care visits</td>
<td>17%</td>
</tr>
<tr>
<td>Office visits - minor illness</td>
<td>35%</td>
</tr>
<tr>
<td>Office visits - acute asthma</td>
<td>25%</td>
</tr>
<tr>
<td>Office visits - arthritic patients</td>
<td>49%</td>
</tr>
<tr>
<td>Pediatric acute illness visits</td>
<td>40%</td>
</tr>
<tr>
<td>Average inpatient surgical length of stay</td>
<td>1.5 days</td>
</tr>
<tr>
<td>Cesarean section delivery rates</td>
<td>56%</td>
</tr>
<tr>
<td>Epidural Anesthesia</td>
<td>85%</td>
</tr>
</tbody>
</table>

Table 3

Regressions seen in various medical costs and utilization rates.

Medical cost offsets are emerging and being reported through integrated programs that have been recently developed. The achieved reductions in various medical costs and utilization rates for one particular aggressive program for a large employer are summarized in Table 3.

These offsets or reductions were developed from the differences in actual utilization rates of various medical and surgical
services for a given group of covered lives after the integration of behavioral healthcare services as compared to rates prior to such integration. These medical/surgical utilization reductions translate to the following per member per month cost reductions for a typical managed care plan under relatively conservative actuarial assumptions (See Table 4).

The total savings for these medical and surgical service reductions amount to $3.45 per member per month. This is larger than the total amount of expected behavioral healthcare costs of between $2.00 - $3.00 for the typical managed care carve-out plan.

However, medical cost offsets through increased or integrated behavioral healthcare interventions are by no means guaranteed. The HCFA Hawaii Medicaid Project reported remarkably different impacts of increased mental health treatments on medical care costs. When such increased mental health treatments were unmanaged, nontargeted and unstructured, medical costs increased by 17%. However, when these increased mental health treatments were targeted, focused and brief, and delivered in a managed care setting, the cost of creating the managed behavioral healthcare system was recovered by medical-surgical savings within 18 months, and the significant reduction in medical interjection continued thereafter with no additional behavioral care required to maintain the cost savings.

The keys to obtaining real medical cost offset savings have been proven to include:

- High specificity and focus in psychological interventions
- Proper training of behavioral healthcare professionals
- Organized settings for healthcare delivery
- Collaboration with primary care providers

**Reimbursement and Risk-Sharing Models for Integration**

These levels of potential medical and surgical cost savings for integrated programs suggest that new models for reimbursement and risk-sharing
arrangements will be needed for successful integrated systems of care to better align the incentives between the behavioral and medical healthcare providers.

The reimbursement and risk-sharing arrangements for the behavioral and medical providers under an integrated scenario should be designed to motivate all providers to deliver cost-effective and efficient healthcare. They should also encourage early diagnosis and appropriate treatment of behavioral disorders in the primary care setting, provide for educational and prevention programs related to behavioral and medical wellness, and be fair to all participants. A few examples of potential integrated reimbursement and risk-sharing models for various provider risk arrangements are described below.

**Example 1 - Integrating Full-Time Behavioral Healthcare Into a Heavily Capitated PCP Group that Participates in Risk Pools in a Mature Managed Care Marketplace**

A medical PCP group receives a capitation for all covered members within their group and participates in risk-sharing of surpluses and deficits of external facility, nonbehavioral physician specialty, and prescription drug pools. There are 20 PCPs in the group. They receive capitation revenues of $5,000,000 per year covering 30,000 commercially-insured and Medicare members based on actuarially calculated rates from health plans. The medical PCPs are all salaried, receive payment adjustments for certain high member risk (via risk adjusters) as well as productivity-related adjustments, and participate in the risk-pool sharing.

Two full-time primary behavioral healthcare providers (PBCPs) join the primary care team, each with their own service profiles for behavioral healthcare services. The integrated group receives $300,000 per year in additional capitation payments from the health plans for these primary behavioral healthcare services for their existing capitated members. The primary behavioral providers are given a salary consistent with their service responsibilities and the new capitation revenues. They also participate in member risk adjustments, productivity adjustments, and risk-pool sharing in the same way as the medical PCPs. They will each have service responsibilities for the covered members of 10 medical PCPs in the group. Referrals to other behavioral providers outside of the primary care group are treated like any other professional specialty cost. Funding for new educational and prevention programs and materials may be taken from the joint revenues received by the
integrated group, or may be negotiated with the managed care plan or payer under the premise of future medical and behavioral cost savings.

In this example, both the medical PCPs and the primary behavioral providers participate in all healthcare cost results through the risk pools and through their own capitation structure. Any medical cost offsets savings would naturally flow through these pools. Additionally, “saved” medical PCP services would free up the PCPs to potentially take on more covered lives under the per member per month capitation arrangements, which would also increase the capitated revenue for the primary behavioral healthcare services. An actuarial analysis produces the following summarized business model for the integrated group (See Table 5).

The business model that was developed projected that the PCP group would receive nearly $665,000 in the first year and nearly $1.2 million in additional revenues in the second year after the primary behavioral healthcare integration. This amount, arising from additional covered capitated lives and risk-sharing revenues from medical cost offsets paid through the risk pools, would be available to fund the start-up costs of the integration, educational and prevention programs and materials, compensation to the primary behavioral healthcare providers, and additional profits for the entire integrated group.

The integration will likely result in more behavioral services being provided per member in the initial stages due to increased awareness, diagnosis, education, etc. Care should be exercised to properly reimburse the behavioral providers for this productivity, as well as any associated reduction in medical services per member provided by the medical PCPs.

<table>
<thead>
<tr>
<th>Item Description</th>
<th>Before Year Integration</th>
<th>After Year 1 Integration</th>
<th>After Year 2 Integration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of PCPs</td>
<td>20</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Number of Full Time PBCPs</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Capitated Lives</td>
<td>30,000</td>
<td>31,500</td>
<td>33,000</td>
</tr>
<tr>
<td>PCP Capitated Revenue</td>
<td>$5,000,000</td>
<td>$5,250,000</td>
<td>$5,500,000</td>
</tr>
<tr>
<td>PBCP Capitated Revenue</td>
<td>$0</td>
<td>$315,000</td>
<td>$330,000</td>
</tr>
<tr>
<td>Risk Pool Sharing:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facility Pool</td>
<td>$250,000</td>
<td>$300,000</td>
<td>$500,000</td>
</tr>
<tr>
<td>Specialty Physician Pool</td>
<td>$250,000</td>
<td>$275,000</td>
<td>$300,000</td>
</tr>
<tr>
<td>Prescription Drug Pool</td>
<td>$0</td>
<td>$25,000</td>
<td>$50,000</td>
</tr>
<tr>
<td>Total Revenues</td>
<td>$5,500,000</td>
<td>$6,165,000</td>
<td>$6,680,000</td>
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<tr>
<td>Increase in Revenues</td>
<td>$0</td>
<td>$665,000</td>
<td>$1,180,000</td>
</tr>
</tbody>
</table>

Table 5

A summarized business model for the integrated group.
Example 2 - Integrating Part-Time Behavioral Healthcare Into a Mixed Capitation and Fee-For-Service PCP Group Without Existing Risk-Sharing Arrangements in a Less Mature Managed Care Marketplace

In this example, the 20 medical PCP group receives a straight capitation per member per month for their managed care business, and does not participate in any other risk-sharing arrangements. They also have a substantial amount of fee-for-service (FFS) business. They are salaried and receive high member risk adjustments and productivity-related adjustments within their group.

Four part-time behavioral healthcare providers join the PCP group and the group’s capitation payment for their managed care business is adjusted by the health plan (payer) for the service profile responsibilities of the behavioral providers. They are paid salaries by the PCP group for these services based on the new capitated revenues and their part-time nature. The integrated group negotiates with the managed care plan (payer) for a new risk-sharing arrangement related to specific medical and surgical utilization and cost targets. Instead of broad-based risk pools, specific targets are agreed to for selected services such as inpatient surgical days, C-section rates, ER visits or psychotropic prescription drugs. They will then share in any savings that result from these specific services, presumably partly, or even substantially, due to their efforts and interventions. They will also share in any losses that arise due to cost increases in these service areas.

The behavioral providers also negotiate an arrangement with the medical PCPs in the group related to reduced office visits for primary medical care services to the managed care members. If such reductions result and the medical PCPs can take on more covered members, the behavioral providers will share in the additional capitated income to the group from these new members. Additionally, if the behavioral providers bring in fee-for-service medical business for the PCPs arising from their own private behavioral practice patients, they will share in the additional medical fee-for-service income of the integrated group from these referrals. Expenses for educational and prevention programs would likely be shared within the new group.

An actuarial analysis produces the following summarized business model for the integrated group (See Table 6).

The business model that was developed projected that the PCP group would receive nearly $240,000 in additional revenues in the first year and nearly $500,000 in the second year after the primary behavioral healthcare integration. This amount, arising from additional covered capitated lives, fee-for-service revenues and risk-sharing revenues from medical cost offsets.
### Table 6

A summarized business model for the integrated group.

<table>
<thead>
<tr>
<th>Item Description</th>
<th>Before Integration</th>
<th>Year 1 After Integration</th>
<th>Year 2 After Integration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of PCPs</td>
<td>20</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td>Number of Part Time PBCPs</td>
<td>0</td>
<td>4</td>
<td>4</td>
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<tr>
<td>Capitated Lives</td>
<td>6,000</td>
<td>6,300</td>
<td>6,600</td>
</tr>
<tr>
<td>PCP Capitated Revenue</td>
<td>$1,000,000</td>
<td>$1,050,000</td>
<td>$1,100,000</td>
</tr>
<tr>
<td>PCP FFS Capitated Revenue</td>
<td>$5,000,000</td>
<td>$5,100,000</td>
<td>$5,250,000</td>
</tr>
<tr>
<td>PBCP Capitated Revenue</td>
<td>$0</td>
<td>$315,000</td>
<td>$330,000</td>
</tr>
<tr>
<td>Inpatient Targets</td>
<td>$0</td>
<td>$20,000</td>
<td>$50,000</td>
</tr>
<tr>
<td>Specialty Physician Targets</td>
<td>$0</td>
<td>$5,000</td>
<td>$10,000</td>
</tr>
<tr>
<td>Prescription Drug Targets</td>
<td>$0</td>
<td>$2,000</td>
<td>$10,000</td>
</tr>
<tr>
<td>Total Revenues</td>
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<td>$6,240,000</td>
<td>$6,486,000</td>
</tr>
<tr>
<td>Increase in Revenues</td>
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<td>$240,000</td>
<td>$486,000</td>
</tr>
</tbody>
</table>

Paid through the specific risk-sharing targets, would be available to fund the start-up costs of the integration, educational and preventive programs and materials, compensation to the primary behavioral healthcare providers, and additional profits for the entire integrated group.

**Example 3 - Integrating Full-Time Behavioral Healthcare Into a Multi-Specialty Group With a Global Cap in a Moderately Mature Managed Care Market**

Here, full-time primary behavioral healthcare providers join a multi-specialty group and work alongside the medical PCPs. The entire multi-specialty group receives a global capitation payment for all professional services as well as all Rx costs. They also participate in an external risk pool for facility costs. The medical PCPs and primary behavioral providers are salaried and have their own service profile responsibilities. Other specialists are salaried or paid on a discounted fee-for-service basis. Like in example 1, the PCPs and the primary behavioral providers participate in all of the risk pools, with the difference being that the specialty and Rx risk pools are internal within the group, rather than external. This provides more flexibility for the group to determine the specific details of the risk-sharing arrangements. Expenses for new educational and preventive behavioral programs may be funded out of the global capitation amounts.
Psychotropic Drug Risk Issues

The risks related to the assumption of risk responsibilities for psychotropic drugs among the medical PCPs and the primary behavioral providers in an integrated setting should be carefully considered. The integrated group may believe that they may be in a good position to control appropriate utilization and costs related to these drugs with more hands-on input from the behavioral providers. They would be well-served to analyze the expected impact of several factors on historical cost and utilization levels:

- The high cost of new and improved drugs with reduced side effects (e.g., generic drugs for treating depression may cost as little as a few dollars per month... to a few dollars per day for Prozac, Paxil, Zoloft or Wellbutrin... to even more for new drugs like Luvox, Celexa, Effexor or Serzone).
- The impact on consumer education and self-selection of drugs from increased activities of direct-to-consumer advertising from pharmaceutical companies.
- The impact of managed care plan activities to limit access to newer drugs.
- The trade-off of medical (medication) vs. therapeutic treatment approaches to behavioral disorders.
- Benefit plan specifications related to drug co pay differentials, and benefit limits on generic, brand and mail order scripts.

Trends have continued to increase regarding psychotropic drug use. Costs typically exceed $1.00 pmpm in a managed commercial population group, and in many loosely managed groups may approach or even exceed $2.00 pmpm. This may be related to the prescribing patterns of non-behavioral physicians, the desire among the user population for “feel good” enhancers, and the exclusion of psychotropic drug costs in most behavioral healthcare carve-outs (managed and reduced therapy services typically leads to higher medical/psychotropic treatment costs). Consideration should be given to such ongoing trends in any analysis of psychotropic drug risk responsibilities.

Challenges with Integration

While there is ample evidence that the integration of behavioral healthcare into primary medical settings may have significant potential, as de-
scribed above, many challenges may exist which could make such integration very difficult to achieve. These challenges could include the following:

**Start-up costs.** Who will provide the funding for the implementation expenses associated with the integration? Even if the model does pay for itself "down the road", if the managed care plan or payer will not provide capital for implementation costs with the anticipation that it will lead to lower future healthcare costs, do the behavioral and/or medical providers have the resources to handle these expenses?

**Aligning physician incentives.** It is usually not easy to implement financial incentive structures which will be perceived to be win-win among all the participants.

**Changing management thinking.** Integration typically has to overcome a few, if not many, hurdles in the thought and management processes of managed care plan executives, payers, and providers.

**Marginalization of behavioral healthcare.** There is still a prevalent tendency among managed care plans, payers, and medical providers to want to marginalize and separate the cost and delivery of behavioral healthcare.

**Mental health vs. substance abuse fragmentation.** There is still disagreement and friction within the behavioral healthcare community between these two segments.

**Need for integrated technologies.** The current technological capabilities of the medical and behavioral providers will likely be quite different, yet the need for common, integrated technological systems exists.

**Need for co-location.** Will it be easy to move primary behavioral providers into the bricks and mortar environment of the medical PCP group (even if it is not on a full time basis)? Are high front-end overhead costs associated with the co-location, and who will handle any such costs? Two different departments, two different organizations. Can you successfully bring together members of two entirely different organizations or departments for the sake of the common good?

**Provider credentialing.** Medical PCPs may have difficulty determining the skill levels needed by behavioral healthcare professionals. They may be uncertain on how to identify and select behavioral healthcare professionals who would have the capabilities to make the integration effort successful.

**Outcomes tracking.** This necessary capability is still not present in many behavioral healthcare practices.

**Summary**

While the focus of this paper has been on managed care plans and capitated PCP structures, many of the issues also apply, with some variation,
to fee-for-service systems. For example, psychoeducational programs and public stress screenings may be provided direct to consumers by the integrated providers at very low or no cost to the public in order to increase awareness and potentially lead to more fee-for-service business in the integrated setting. While many challenges may exist that may make the integration of behavioral healthcare services in primary medical settings a difficult and, perhaps, seemingly impossible task, such proactive activities may lead to much higher degrees of medical and behavioral healthcare wellness in our population than exists today. A more seamless system of meeting both primary medical and behavioral healthcare needs may be just what the some employers and patients are seeking. Motorola, for example, has been going straight to healthcare providers for these services, bypassing the health plans. Patients seem to like the “one-stop shopping” aspect of the integrated programs.

Behavioral health prevention programs that integrate medical and behavioral health are on the rise. Quaker Oats has launched their “Live Well Be Well” program, a risk appraisal program, and integrated behavioral and physical health prevention efforts. Group Health Cooperative is integrating behavioral and general health prevention by identifying high-risk populations and by merging depression and anxiety screening/treatment with general health maintenance. Digital Equipment has mandated that prevention and early intervention services be included in the behavioral health services it purchases. And Kaiser is implementing a major redesign project to integrate behavioral care in primary care settings. These are but a few examples of the trend towards increased attention to prevention, early treatment and integrated behavioral healthcare in primary care settings.
Discussion of Melek:

Integrated Care: Potential Disaster or Golden Opportunity?

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Stephen Melek examines the implications of the trend toward increased integration of behavioral health care and primary care services and addresses the question, does this trend present potential disaster or a golden opportunity for behavioral health care providers?

Melek begins by noting that some innovative providers have produced good patient outcomes by integrating behavioral health care into a primary care setting. To the extent that behavioral health care providers can successfully reduce patient medical expenditures via improved mental health, improved compliance with medical care instructions, and improved management of chronic diseases, behavioral health care providers may offer the solution to the fundamental dilemma posed by managed care: how can medical costs be managed and reduced without reducing the quality of patient health outcomes?

WILL INTEGRATED CARE SUCCEED IN EFFICIENT DELIVERY OF HIGH QUALITY CARE?

The potential role for integrated care in the nation's health care system will be defined gradually as providers, managed care organizations and researchers begin to answer detailed questions about the impact of integrated care. Which types of patients benefit sufficiently from behavioral health care to experience sizeable medical cost offsets? What treatment programs impact patient behavior consistently and effectively? Whose costs will be reduced by behavioral interventions? Is the time between delivery of the behavioral health
care service and the medical cost reduction short enough to justify provision of these services by managed care companies or employers with high turnover rates? How should risk be shared among providers, insurers, employers, and households? How should incentives be structured to induce optimal actions by members of these groups?

Melek assumes that continued exploration of integrated care will yield positive results. He assumes that providers and insurers will develop treatment patterns, organizational structures, and risk-sharing arrangements to develop the potential for quality and efficiency offered by the concept of integrated care. These assumptions raise a broad range of questions. If the trend to integrated care continues, how should providers respond? What public policy issues must be addressed in response to this trend? How should educational institutions adjust their programs to prepare new providers and veteran providers for the emerging market?

**How Should Providers Respond to this Trend?**

Successful integration of behavioral health and primary care will require business acumen as well as innovative clinical approaches. Managed care companies and providers are increasingly utilizing contracts that shift risk to the provider. This presents a spectrum of opportunities to providers ranging from traditional fee-for-service to case reimbursement, in which the provider is paid a given amount per case treated, and further to capitation, in which the provider is paid a given amount per enrolled member. Providers may contract with managed care companies directly, or as members of integrated primary and behavioral health care groups. Providers facing this broad spectrum of contract options, or - in the short term – facing a decision of whether to sign a given contract, must assess whether the specified services can be delivered at the contract price. Thoughtful analysis of this question requires in-depth understanding of the contract population, the distribution of potential service utilization rates, and service delivery costs.

Since actuarial analysis of these issues typically relies on historical cost and utilization patterns, cost and pricing analysis is problematic during periods of rapid innovation. Providers currently face an environment of ongoing shifts in treatment patterns that may affect diagnoses rates, average length of inpatient stays, and tradeoffs between alternate treatment approaches. Assessing the potential impacts of new risk-sharing arrangements is also hindered by the sizeable gaps that exist in the body of scientific knowledge about the relationships between patient characteristics, provider
interventions, and patient health outcomes. Analysis of price, risk, and contract terms in this environment requires particular care.

In addition, Melek advises providers to give careful consideration to the non-price contract specifications such as the length of the contract. A contract period of several years may be needed to recoup the program’s setup costs, but a lengthy period of contractually-fixed price increases the risk posed by uncertainty about pricing and utilization.

To build the capability to assess new programs and understand cost, risk and price, providers (who traditionally treat one patient at a time and record the results of that treatment in individual patient files) must develop new methods for efficient analysis populations of patients. While such analysis has traditionally been conducted by researchers, innovative risk-bearing providers will find it useful as well.

Developing a computerized infrastructure for collecting and analyzing outcomes data is essential for such analyses. Without computerized medical records, collecting sufficient data on ongoing outcomes tracking is problematic: information about large groups of patients that is stored in individual patient charts is only accessible at high cost, while electronic information can be retrieved readily if an appropriate system has been set up. Designing such a system requires thoughtful consideration of the types of information that may be useful.

First, if the expected benefit of behavioral health care includes reduced utilization of physician office visits, medications, and hospital services, for example, the data tracking system must be sufficiently comprehensive to encompass care obtained at all of these sources.

Second, effective programs reduce utilization of medical services while improving patient health outcomes or, at minimum, without impacting patient health outcomes. The outcomes tracking system must therefore be sufficiently comprehensive to include data on relevant dimensions of patient health status, both medical and psychological, to assess the quality of innovative programs.

Third, meaningful outcomes assessment must include consideration of variations in initial health status among different patient groups. If patients participating in a weight-loss program, for example, make fewer appointments with primary care physicians, it is important to assess whether the program effectively improved their overall health status or whether we are simply observing fortuitous selection of relatively healthy patients. This raises the complex issue of risk-adjustment. Development of meaningful risk-adjustment systems is not inexpensive, and use of partial risk-adjustment mechanisms creates opportunities to earn profits via clever patient selection rather than delivery of quality health care.
Finally, if variations in patient characteristics exert significant impacts on program outcomes, large samples may be needed to understand the impacts of alternate treatment protocols on patient outcomes. In such cases, it may be difficult to assess program innovations undertaken by small organizations or innovations that target small patient groups. Program assessments in these cases may require analysis by an independent researcher who collects comparable data from several cooperating integrated care groups.

The Federal Trade Commission (FTC) has explicitly recognized the importance of computer information system infrastructure as a key strategy for increasing efficiency in physician networks. The FTC's fundamental antitrust question regarding physician networks is: will the network succeed as a profitable business venture because the network structure facilitates efficient delivery of quality health care or because it increases the physicians' bargaining power as they deal with employers, insurers, hospitals, and other health care entities? Networks whose profit-potential stems from increased bargaining power may be challenged as unlawful mergers, while networks whose profitability stems from increased efficiency will not be challenged. The FTC horizontal merger guidelines for physician networks identify investment in computer infrastructure as evidence that the network is working to improve coordination and efficiency among providers.

How Should Policy Makers Respond to the Trend Toward Integrated Care?

Policy makers will face at least two issues as managed care plays an increasing role in the provision of behavioral health care. How will cost-based competition among providers and managed care organizations affect the quality of patient care? Will providers have sufficient information and resources to negotiate reasonable contracts with managed care organizations?

How Will Cost-Based Competition Among Providers and Managed Care Organizations Affect the Quality of Patient Care?

Several conference participants expressed deep concern that cost-based competition in the health care industry is driving high-quality care from the market. If hourly reimbursement rates continue to decline for behavioral health care providers, traditional one-on-one care may be substantially replaced by group treatment programs. This concern raises two questions.
First, how can high quality products survive in markets dominated by price competition? Second, how are the reimbursement rates set? Do managed care companies enjoy sufficient market power to dictate reimbursement rates that are insufficient to cover providers’ costs?

The potential trade-off between cost and quality is not unique to behavioral health care or to the broader health care industry. Consumers face this trade-off in a wide array of markets. More powerful computers cost more than less powerful models. Expensive new cars may be safer than cheaper used vehicles. Airline passengers can buy higher-price first-class tickets if they value the extra leg-room enough to pay the higher price. In competitive markets in which buyers can accurately assess product quality, firms frequently offer a variety of models, with higher quality models tagged with higher prices. Each buyer is free to decide whether the additional quality offered by the luxury model is worth the higher price. While some firms offer a full range of price/quality combinations, other firms fill specialized niches, offering only luxury products or serving only the bargain-hunter market. Competitors are free to test whether consumers would prefer new combinations of price and quality. For example, the Wall Street Journal reported recently on a new chain store that plans to target customers who prefer to buy products that are cheaper and lower quality than the products typically sold in existing discount stores. One potential customer of the new chain reportedly explained that she does not want to pay for long-wearing fabrics for children’s clothes that will be outgrown in a few months.

Government policy dictates the level of quality for some goods. Prior to 1977, federal regulation of airline pricing and routes essentially required interstate airlines to provide high cost/high quality service. The success of Southwest Airlines in the interstate market in Texas during the 1970’s offers an interesting example of consumers choosing, instead, to forego some convenience in order to obtain lower prices.

Concern about price/quality choices made by consumers generally focuses on markets in which buyers cannot readily assess the quality of the goods offered for sale. Economists use the term, search goods, to denote goods that can be inspected and assessed before purchase. Buyers can easily make informed decisions about price/quality trade-offs for these goods. Buyers cannot assess the quality of experience goods, in contrast, until they purchase the item and experience its use. Restaurant meals, used cars, and hair cuts are experience goods because the buyer cannot inspect the quality of these goods until they have been purchased and experienced. Some goods, such as vitamins, are even more difficult to assess. Buyers are still unsure about the quality and impact of these goods after they purchase and use them.
Despite the difficulty of assessing product quality, high quality products frequently compete successfully against cheaper/lower quality competitors. The key to success for the higher quality products is that the extra quality must be valued by consumers enough to induce some of them to pay the higher price. Consumers assess product quality with a variety of market-based and regulatory consumer information and consumer protection strategies. Buyers obtain additional information from second opinion experts, from quality reporting services such as Consumer Reports, and informal word-of-mouth sources. Buyers reduce their risk of purchasing a low quality item via product warranties, department store return policies, and repeat purchases from known suppliers. Government policies assist purchasers via legal liability, safety standards, and regulations requiring government approval for items such as prescription drugs.

Applying this combination of market and government strategies to health care is problematic for several reasons. First, the employers who purchase health insurance and the employees' households who utilize the health care may not agree on the optimal level of quality to be purchased. (In assessing this problem, we should not rush to conclude that employers have no interest in providing quality health insurance and quality health care. Since employers offer health insurance as one component of a total compensation package, they have a profit incentive to consider household satisfaction and employee willingness to forego wage increases in order to obtain more comprehensive health insurance coverage.) Second, provision of multiple levels of health care quality present complex ethical issues. On the one hand, consumer selection of a low price/low quality option raises concerns about equity, the degree to which the choice was informed and voluntary, and the impacts of this choice on the consumers' family members. On the other hand, insistence on provision of only one level of quality may price some consumers out of the market entirely. For employees with automatic employer-provided coverage, mandating a single (high)level of quality will reduce employee wages. Some low-wage workers might be better off if they could reallocate some of their total compensation to wages by accepting lower quality health care. Third, it is difficult for employers or households to assess the quality of alternate treatment programs.

We will focus here on the third concern: can employers or households assess the quality of care offered by competing managed care companies? If quality cannot be assessed, buyers will not be willing to pay higher prices for higher quality services, and high quality providers will disappear from the market. More costly/higher price services will only be offered in a competitive market if providers, provider organizations, researchers, or government
agencies demonstrate and/or guarantee the value of these services. How can providers help consumers and employers assess the quality of care?

The computerized data needed by providers to assess program quality and assume and price risk may also provide the basis for demonstrating program quality to employers and households. Since it is difficult for buyers to compare idiosyncratic pieces of information produced by individual behavioral health care providers, standardized "report cards" that provide comparable audited data for all providers may help buyers compare alternate plans. The difficulty in developing useful report cards lies in determining exactly what pieces of information are both available and useful to buyers. For example, it is relatively easy to report the proportion of HMO patients who receive anti-smoking counseling, but it might be more meaningful and more difficult to report the proportion of smokers who actually quit smoking in response to the counseling.

Development of meaningful and useful report cards will require a two-pronged effort. Providers and managed care companies must strengthen the infrastructure to support better data collection and analysis. Providers, consumer groups, and employers must also give thoughtful consideration to the dimensions of quality that are valued by consumers and the measurement of health outcomes.

Psychologists may make a particularly valuable contribution in developing an understanding of consumer perception and valuation of health care. One example of the stumbling blocks inhibiting development of meaningful quality measures is that consumer attitude surveys seem to indicate that consumers value the warmth and friendliness of the providers' office staff. If a consumer selects a physician whose office staff seems caring and supportive, without considering the physician's performance in producing health outcomes, is this consumer necessarily making a "wrong" choice? If a smoker understands the health impacts of smoking, but does not want to give up the pleasure of smoking, is a "quality" provider one who respects this choice or one who continually works to induce the smoker to quit? It will be difficult to assess the impact of innovative healthcare delivery programs until we have a better understanding of the consumers' concept of "quality healthcare".

Will Providers Have Sufficient Information and Resources to Negotiate with Managed Care Organizations?

Some conference participants expressed two concerns about the relative bargaining power of providers vs. managed care companies. First, providers may negotiate with managed care companies from weak positions if
managed care companies have greater resources for collecting and analyzing outcomes, risk, and financial data. Second, managed care companies may present contracts to providers on a "take it or leave it" basis, rather than negotiating a mutually-beneficial contract if providers must compete vigorously to obtain managed care contracts.

The first concern raises two issues: Do managed care companies have access to better information than providers? Can the larger managed care organizations analyze data at lower cost per enrollee than the smaller provider organizations? Large size may confer significant efficiency advantages for two reasons: developing computerized medical records systems will require significant capital investment and larger organizations are more likely to have large enough patient samples to obtain statistically significant conclusions. The viability of small provider groups in the managed care marketplace may depend on their ability to obtain data collection and data analysis services at competitive prices.

The second concern focuses on the impact of cost-based competition, which places providers under intense financial pressure. As in any industry with excess capacity, competitive bidding pushes price down near average variable cost, which implies reimbursement rates that are not sufficient to cover average total cost. This type of intense competition is often described with the terms, "destructive competition" or "cutthroat pricing".

Should providers expect reimbursement rates to continue to decline? This vigorous competition, with reimbursement rates below providers' traditional average cost, resulted from decreased demand for behavioral health care services. With prices below traditional average cost, fewer students will earn the degrees necessary to enter the field and some providers will exit via early retirement or career changes. For areas in which traditional treatments continue to be the norm, this decrease in the supply of behavioral health care services will permit reimbursement rates to stabilize at levels that cover average cost.

This process is expected to occur in any industry in which demand for the product decreases; it is the normal process by which supply adjusts to the new level of demand. Destructive competition and cutthroat competition pose particular problems, however, in industries characterized by high fixed costs, large infrequent contracts, and fluctuating demand. Behavioral health care does not appear to meet the first or third criterion of high fixed costs and fluctuating demand, but increasing penetration of managed care may introduce the second characteristic to this industry. If providers feel pressured to successfully bid for one of a few large contracts, they are likely to feel pressured to ensure that the bid is low enough to obtain the contract. In this situation,
they may bid at prices that are sufficient to cover variable costs (i.e. direct costs of providing patient care), but not total costs.

For areas of behavioral health care in which group treatment or integrated behavioral and primary care are successful in reducing cost, the introduction of a newer lower-cost production technology will lead to prices that approximate the average cost of delivering care via these new methods. Traditional methods will only be marketable in these areas if the providers can demonstrate that the extra cost is justified by higher quality outcomes. The burden of proof, in this case, will lie on the shoulders of providers who wish to continue using traditional treatment patterns.

How Should Educational Institutions Respond?

As managed care plays a growing role in the behavioral health care industry and primary and behavioral health care develop new models of integrated delivery, provider organizations will need to assess the results of innovative programs, develop computer infrastructures to support data collection and analysis, decide how much risk to bear, and evaluate alternate pricing methods. New graduates and continuing practitioners may require increased financial, business, and computer literacy. They may need additional quantitative and research methods skills to develop systems for analyzing outcomes data and cost data for populations of patients.

Educational institutions therefore face the age-old dilemma: if new topics are added to the curriculum, the institution must either reduce the time devoted to traditional topics or lengthen the course of study. Graduate schools may explore the possibility that students might study business, computer information systems, and quantitative methods as undergraduates. Alternatively, it may not be efficient or effective for every behavioral health care provider to undertake outcomes studies, risk assessment, and cost analysis. Some providers may opt for overview summaries of these fields, and contract with consultants or hire business managers to provide these services. Conference participants, however, repeatedly returned to the question of how providers can exert more control over industry pricing and patterns of care. Providers in leadership roles area may require in-depth understanding of these additional subjects. Educational institutions may respond to the variety of provider preferences by offering specialized study tracks.
CONCLUSION

Do the increasing roles of managed care and integrated primary and behavioral health care present health care providers with potential disaster or a golden opportunity? Answers to this question depend on many factors, including the future evolution of the health care industry and the extent to which behavioral healthcare providers step into leadership roles.

Conference participants focused largely on the potential to exercise leadership in developing integrated primary and behavioral health care. If integrated care can consistently generate sufficient medical cost offsets to fund the cost of providing the behavioral care, these programs will help managed care organizations solve the fundamental problem of delivering cost effective plans to employers without sacrificing health outcomes.

In addition, behavioral health care providers may offer the expertise needed by managed care companies to understand consumer perceptions of health care and consumer values. It is clear that automobile manufacturers understand consumer demand in great detail. One manufacturer recently announced that it believes its target consumers are now more concerned about safety than style. It is designing its new cars to specify deliver higher levels of safety. This firm is responding to its customers' definition of "automotive quality". Current discussions of health care report cards indicate that health care providers do not have this type of sophisticated understanding of their customers' values. Behavioral healthcare providers may be ideally positioned to help managed care companies develop this understanding.