

VIII. Requirements for Clinical Guidelines

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Summary

The clinical guideline component of an integrated information system serves three primary functions: clinical decision support, treatment process tracking, and guideline variance tracking. Clinical decision support facilitates the selection of the most effective treatments for conditions and is useful to clinicians, consumers, families, and administrators. Treatment process tracking allows for a detailed and standardized record of clinical interventions. Guidelines variance tracking evaluates the congruence between guideline-recommended treatment and actual treatment delivered at the individual and aggregate levels.

While significant progress has been made in establishing the importance of clinical guidelines and determining standards for guideline development, a number of barriers to readiness remain:

- guidelines are unavailable for many disorders;
- there is no consensus on which guidelines are the best;
- few clinicians have been trained in the use of guidelines;
- clinical guidelines software is only recently available and has a short track record; and
- purchase or design of clinical guideline software and integration into existing organizational systems is costly.

Implementation of treatment process and guideline variance tracking systems also await further developments in the field. The greatest barrier to tracking the process of treatment is the absence of a formal system for reliably and validly describing both general treatment orientations and specific treatment interventions. The field will need to develop a standard terminology of treatments with associated definitions and codes. The taxonomy must then be integrated into other routinely used software. The ability to track guideline variance depends on further developments in both these areas.

Once the barriers in the areas of guidelines and treatment process description are resolved, the foundation for guideline variance tracking will be established. Interfaces must then be built between the clinical decision support software from which the clinical guideline recommendations are made, the treatment process tracking system which includes the data on treatment actually delivered, and consumer characteristics. This will require a relational database and/or a data warehouse to facilitate data analysis.

The success of all three aspects of the clinical guidelines component rests heavily on involvement of end-users in the development of tools such as guidelines, taxonomies, and software so that they are meaningful, reputable, and user-friendly. Widespread implementation will also require a substantial commitment to education and training, an emphasis on quality improvement, and flexible requirements that take into account the limitations to current knowledge in the field.

It is vitally important for the behavioral health care field to:

- develop user-friendly, evidence-based clinical guidelines that are effective for specific disorders and for co-occurring conditions;
- include key stakeholders in the guideline development and implementation process;
- develop decision support software;
- develop a standard terminology and taxonomy of treatment interventions with associated definitions and codes;
- integrate the terminology/taxonomy into other routinely used software;
- inform and educate clinicians, consumers, and managers in the value and use of clinical guidelines, tracking systems and data analysis and use;
- build interfaces between the clinical decision support software, the treatment process tracking system, and consumer characteristics;
- protect privacy and ensure confidentiality of consumer data; and
- protect intellectual property including clinical guidelines, software, treatment manuals, and coding systems.

VIII. Requirements for Clinical Guidelines

What is the Intended Purpose or Function of this Component?

The most important purpose of clinical guidelines is to promote quality behavioral health care. Guidelines are particularly valuable for problems and diagnoses where scientific evidence and/or clinical consensus suggest specific treatment approaches that are likely to produce better outcomes.

The effort by organized care systems to implement practice guidelines successfully will prompt the development of more exacting and standardized descriptions of treatment processes than are now available. This will, in turn, facilitate more broad-based treatment effectiveness research in real-world settings. Implementation of guidelines will also create incentives for more experimental and field studies to test the effectiveness of guideline-recommended practices.

Implementing guidelines will also increase the likelihood of a continuous quality improvement environment for clinical practice in general and a more applied national research agenda. Guidelines will focus stakeholder attention on the need to specify and improve the types of treatments provided for specific conditions. To contribute to quality improvement, it is critical that the implementation of clinical guidelines include measurement of treatment processes and outcomes.

As clinical practice increasingly adheres to guidelines with an evidentiary base, the scientific respectability of mental health services will be enhanced. Widespread implementation of clinical guidelines will advance treatment consistency and promote greater public confidence in mental health treatments. The combination of a clearer evidentiary base and greater treatment consistency will enable the behavioral healthcare field to address public prejudices about behavioral health services and promote the value of those services with a more compelling and unified voice.

The clinical guidelines component of an integrated information system serves three primary functions: clinical decision support, treatment process tracking, and guideline variance tracking.

- ***Clinical decision support.*** This function involves generating the appropriate guideline to provide clinical decision support for providers, care managers, and consumers to plan and undertake treatment.
- ***Treatment process tracking.*** After deciding whether or not to follow a particular guideline, the clinician inputs the type of treatment that is actually delivered and updates it periodically as necessary. This allows the system to track the type of treatment being delivered at the individual consumer level. The aspects to be tracked include level of care, modality, intensity, medication dosage, duration, theoretical orientation/global treatment approach, and components within a global treatment approach.
- ***Guideline variance tracking.*** The system is designed to evaluate the congruence between guideline-recommended treatment and actual treatment delivered at individual and aggregate levels.

Below we discuss the requirements for the clinical guideline component of the information system in regard to each of these three functions. Other components of the information system are closely related and essential to the effective functioning of the clinical guideline component, particularly outcomes measurement. Some of the linkages between outcomes and clinical guidelines will be addressed in this section.

What Information is Required to Accomplish this Purpose?

Clinical Decision Support

Generating the appropriate guideline for the user of the system involves both input of basic design information into the system itself and input of the decision support tool or guidelines by the user.

First, information must be put in to the system (input) to design the decision support tool's basic structure, define its fields and decision logic, and specify its content. Input information should include:

- fields for the types of consumer demographics that have relevance for determining preferred treatment approaches;
- lists of DSM-IV diagnoses, including diagnostic subtypes;
- decision rules for determining diagnoses based upon DSM-IV criteria;
- decision rules for determining diagnostic subtypes that have relevance for differentiating preferred treatment approaches;
- coded rating scales system/decision rules for determining severity of symptoms, level of functioning, level of social support, housing, and other consumer characteristics that might be relevant for determining type of treatment;
- lists of guideline-recommended treatments (e.g., setting/level of care, treatment modality, intensity of psychotherapy, dosage of medication, duration, theoretical orientation/general approach, and specific treatment interventions);
- decision rules for determining treatment approaches based on consumer demographics, diagnoses, diagnostic subtypes, and severity; and
- documentation of the evidence or other rationale supporting the decision rules.

Note that most decision rules will derive from diagnoses, although some may cover syndromes. Furthermore, not all diagnoses have sufficient supporting evidence to warrant a guideline-recommended treatment. Decision rules may be quite complex and involve non-linear algorithms that require longitudinal information on the clinical situation and treatment outcomes. Specifically, decisions about treatment must be based on information about a particular consumer including the consumer's phase of illness, prior treatment history, treatment preferences, response to specific treatments already provided, and length of time on treatment for the disorder in question. Information

must be input by the user of the decision support tool to determine an appropriate clinical guideline. Input information should include:

- consumer demographics, such as age, gender, race, ethnicity, and benefit coverage;
- consumer variables necessary for formulating a diagnosis, obtained from assessment measures, clinical interviews or by other means, and including symptoms (e.g., severity, chronicity, frequency of occurrence), problem behaviors, level of functioning, and type and severity of environmental stressors;
- diagnoses on all DSM-IV axes; and
- whether or not to follow the recommended guideline, with the rationale.

Even if a computerized decision support tool is programmed to produce diagnoses for a specific consumer, the final determination of diagnoses on all axes should be decided by and put into the system by the clinician.

Factors other than diagnoses can be crucial determinants of treatment planning. For instance, different guidelines may be recommended for consumers who have the same primary diagnosis but who have different comorbid diagnoses, diagnostic subtypes, life stressors, or other complicating factors. Also different guidelines might be followed depending on the phase of illness, response to previous treatments, length of time on treatment, and the consumer's preference. The decision support tool can help users input this additional information with question prompts for the clinician.

The clinician must decide whether or not to follow the recommended guideline and enter this decision into the system. Some decision support tools are designed with standard questions to be applied to all consumers; these are followed by suggested interventions with citations of supporting evidence. Other tools use a series of questions generated through algorithmic decision trees that require information about a particular consumer. These culminate in prescriptive guideline recommendations; supporting evidence is available if the user requests access to it. In either model, following the computer-generated treatment recommendation, the clinician user will input his or her decision as to whether or not to follow the recommendation.

If the clinician user decides not to follow the guideline recommended by the decision support tool, he or she should indicate his or her rationale. This may be due to consumer considerations, such as consumer preference for a different approach, or the consumer's demographic characteristics, treatment history, co-occurring disorders, or other clinical factors. It may be due to clinician considerations, such as the clinician's lack of training in and experience with the recommended treatment, or the clinician's decision to pursue an alternative treatment. The rationale may be due to organization or system considerations, such as lack of a treatment program that can meet the guideline recommendations for type of treatment; lack of staff or facilities to meet the recommendations for intensity of treatment; lack of adequate reimbursement from consumer, managed care company, or insurer to meet the recommendations for intensity or duration of treatment. Finally, the rationale may be due to other considerations that are user defined, uncoded, and require free text for explanation.

Treatment Process Tracking

After deciding whether or not to follow a particular guideline, the clinician user inputs the type of treatment that is actually delivered and updates it periodically as necessary. There are several aspects of treatment that should be put into the system and tracked, including:

- treatment setting/level of care, such as acute inpatient psychiatric unit, residential treatment center, partial hospital/day treatment, intensive outpatient program;
- treatment modality, such as group therapy, family therapy, couples therapy, and individual therapy;
- treatment intensity, such as hours per day, and/or days per week;
- medication usage, such as type, dosage, frequency, and duration;
- treatment duration, such as number of inpatient days, number of partial hospital/day treatment days, and/or number of outpatient visits;
- theoretical orientation/global treatment approach, such as cognitive/behavioral therapy, psychodynamic psychotherapy, medication, and other (user defined, uncoded with free text explanation);
- treatment intervention components within a global treatment approach, such as exposure to feared stimuli, relapse training, breathing retraining to counteract hyperventilation, daily record-keeping of situations/feelings/thoughts/behaviors, interpretation of dreams, type of medication with dosage and frequency of administration, etc.

Guideline Variance Tracking

All aspects of recommended treatment(s) should be provided by the guideline(s) including setting/level of care, treatment modality, intensity of psychotherapy treatment, frequency and dose of medication, duration of treatment regimen, theoretical orientation/general approach, and key components. This information is generated through specific decision rules within the decision support tool. To track variance from the recommended guideline, the clinician user (provider or case manager) must input the actual treatment provided at the same level of detail as the guideline(s).

If there is variance between the guideline-recommended treatment and the actual treatment that is due to a decision made by the clinician user, then the clinician user should also input the decision and his or her rationale. Otherwise, in an information system that is preprogrammed to note variances, the differences between guideline-recommended treatment and actual recommended treatment will appear as unplanned and not specified by the clinician user.

Who Provides the Information?

Clinical Decision Support

Those who design a clinical guideline for decision support are not usually the same people as those who use it to guide clinical decision-making. In the design phase, the most important issue is the quality of the guidelines that are input into the system. Quality depends upon the experts who develop the guidelines and the processes and methods they use. Of these methods, the most important is to use a sound evidentiary base consistent with standards and principles established by such highly regarded scientific and professional organizations as the Institute of Medicine, American Medical Association, American Psychological Association, and American Psychiatric Association.

It should be noted that currently available guidelines were developed primarily by scientific experts commissioned by government agencies, professional guild associations, managed care companies, and provider delivery organizations. These guidelines are of variable quality and lack broad-based consensus from major stakeholder groups. This state of affairs fragments rather than unifies the field. For this reason, input from the following stakeholders is recommended in the guideline development process:

- scientific experts in treatment research related to the specific disorder for which the guideline is targeted;
- scientific experts in guideline development who do not have special expertise or bias in treatment for the specific disorder for which the guideline is targeted;
- clinician experts in treatment of the specific disorder for which the guideline is targeted;
- industry experts (both public and private sector) who can address the practicality of implementing a guideline at organization and system levels; and
- representatives of consumers of treatment for the disorder being targeted for guideline development, and representatives of consumers' family members.

Once the guidelines are developed, they must be put into the computerized decision support system. If the stakeholders listed above are involved in the process of designing the decision logic and the screen flow, it will ensure a more user-friendly and practical application. At this point in the development process, it would also be useful to enlist an expert in learning technology. Finally, computer programmers would conduct the necessary programming to build the software application.

At the implementation stage, the people who use the system are different from the original designers. They are likely to include:

- clinicians responsible for direct care;
- clinical supervisors responsible for clinical oversight and case disposition;
- care managers responsible for treatment authorizations;

- care management supervisors responsible for care management oversight and resolution of complaints, appeals, and grievances;
- consumers interested in a better understanding of what constitutes state-of-the-art care for the problems they want treatment to address. Consumer involvement is particularly feasible when the software is available in a web-based version.

Treatment Process Tracking

Clinicians responsible for direct care will probably have the primary responsibility within an organized care system for input of information necessary for treatment process tracking. In cases where the clinician submits the information on paper, administrative support staff at the treatment delivery site will be responsible for entering the data directly into the computer systems. In other cases, care management staff or their support staff in managed care companies will be responsible for entering treatment data submitted on paper by clinicians.

Guideline Variance Tracking

The information provided by the persons mentioned above input is essential for guideline variance tracking to work. To actually run the variance tracking reports, several additional people would likely be involved. Since this is largely a management reporting function, clinical administrators would probably be the primary people to initiate report runs. They would interact with programmers to input the parameters that define the reports.

What Information is Produced to Accomplish this Purpose?

Clinical Decision Support

The system must provide appropriate decision-treed questions and response option prompts to ensure that users input necessary and sufficient consumer information to generate diagnoses and guideline-recommended treatments. After the relevant information is input by the clinician user, the system should be able to:

- generate diagnostic recommendations for confirmation, rejection or revision;
- generate guideline-recommended treatments, framed in terms of core intervention strategies;
- provide supporting documentation of research evidence and other bases for the diagnostic and treatment guideline recommendations; and
- provide consumer education tools that support understanding of the guidelines and facilitate consumer collaboration with their refinement and implementation.

The system should be able to account for (and indicate as needed) the complexity of factors that contribute to a given guideline. This requires a non-linear approach to decisions and the capacity to

address such information as the phase of illness, treatment history, consumer preferences, response to previous treatments, and the length of time on treatment.

Treatment Process Tracking

For any given treatment episode, all aspects of treatment should be available for review, including treatment setting/level of care, treatment modality, treatment intensity, medication usage, treatment duration, primary theoretical orientation/global treatment approach, and components specific treatment interventions.

To provide meaningful and consistent information for each treatment episode, the system must have internally programmed rules for defining the beginning and end points of a treatment episode. These dates should be user defined (i.e. when the clinician and consumer decide to terminate treatment). However, when this is not possible, the default should be a specified period of time without treatment encounter data. Linkages to encounter data sets are essential for generating treatment episode information.

Additionally, the system should be able to aggregate treatment episode information across many consumers for data analysis. It should be able to provide both descriptive and inferential statistics regarding number of episodes and lengths of episodes (in terms of both days of treatment and number of visits). It should be able to perform these analyses for consumer groupings by selected demographic, diagnostic, and severity criteria and by provider, geographic setting, and benefit coverage groupings.

Guideline Variance Tracking

The system should be able to generate information on both individuals and groups regarding the variance between system-generated clinical guideline recommendations and actual treatments delivered. It should be able to do so at every level of treatment detail referred to above. It should be able to perform these analyses for individual consumers and providers and for consumer groupings by selected demographic, diagnostic, and severity criteria. It should also be able to perform these analyses by provider, geographic setting, and benefit coverage groupings.

The system should also be able to generate individual listings and aggregated data analyses regarding the rationale for guideline variances when they exist. It should be able to perform these analyses for consumer groupings by selected demographic, diagnostic, and severity criteria and by provider, geographic setting, and benefit coverage groupings.

Who Uses the Information that is Produced?

Clinical Decision Support

Several different stakeholders will want to use this clinical decision support system. Consumers will want to know which treatments are recommended for their particular problems and the rationale for the treatment recommended by the clinician responsible for their care. Clinicians and clinical supervisors will want to use the system for guidance regarding state-of-the-art therapeutic approaches for specific disorders they must treat. Care managers responsible for treatment authorization and their supervisors will want to use the system for making decisions to authorize particular treatments.

Treatment Process Tracking

Supervisors responsible for clinical oversight and case disposition may want to review the types of treatment delivered by the clinicians he or she supervises. Care managers responsible for treatment authorization and their supervisors will want to review treatment interventions already delivered before considering further authorizations; they may also want to see reports analyzing trends in types of treatments delivered for specific disorders.

Several other stakeholders will be interested in the patterns of treatment delivered based on analyses of aggregated data including consumers, their families, and consumer advocacy groups (unions, mental health associations, etc.). Another interested stakeholder group will be the organized care system that produced the data, particularly the account managers responsible for reporting trends in service delivery to payors and purchasers and the quality management executives and administrators responsible for overseeing and/or improving the quality of service delivery within their organizations. Other stakeholders interested in the data will be the payors and purchasers of behavioral health treatment services.

Guideline Variance Tracking

Supervisors responsible for clinical oversight and case disposition may want to review the variance between the guideline-recommended treatment and the type of treatment delivered by the clinicians he or she supervises. Care managers responsible for treatment authorizations and their supervisors will want to review variances between guideline-recommended treatments and actual treatment interventions delivered for particular consumers before considering further authorizations for them. Care management supervisors may also want to see reports analyzing variance trends in treatment for specific disorders. Other stakeholders C consumers, organized care delivery systems, payors and purchasers C will also be interested in aggregate trends in guideline variances.

How Ready is This Component for Inclusion in the Information System?

Clinical Decision Support

Clinical guidelines are available for many behavioral disorders, but there are even more disorders for which formal guidelines have never been developed. For the guidelines that are available, there are usually many versions, and they vary both in quality and in the degree to which they are accepted. No set of clinical guidelines has received widespread acceptance across all professional disciplines in the behavioral healthcare field. Furthermore, consumer groups maintain that interventions outside the traditional medical model such as consumer-run services and support groups are essential aspects of treatment for certain disorders; they note that these interventions are not mentioned in clinical guidelines developed by professionals.

There is also controversy regarding the type of evidence that should be used to develop clinical guidelines. Some question the sufficiency of scientific evidence to support clinical guidelines, the relevance of findings from efficacy studies for treatment of consumers seen in actual practice, and the potential usefulness of guidelines that are enforced punitively and with excessive rigidity. Others insist that scientific evidence, particularly when obtained from efficacy studies should serve as the primary basis for guideline development.

Training programs in medical and graduate schools, internship and residency programs, and continuing education programs seldom teach evidence-based treatments or use a clinical guideline framework. Consequently, few clinicians are prepared to use clinical guidelines on a routine basis.

Existing decision support engine software can incorporate any content, including that which is necessary for organizations to customize their own clinical guidelines. Although several clinical guideline software packages have been developed, very few are fully developed or available for purchase. Of these, even fewer are well established with a track record over several years.

Design or purchase of clinical guideline software and their integration into existing information systems is expensive. At a time when most organizations have slim margins, it is unlikely that they will implement a clinical guideline component of their information systems unless they perceive it to be a necessary cost of doing business. Requirements are expected to intensify soon for guideline-related treatments, however, at that point the market for adoption of clinical guideline and related software products will improve substantially.

Treatment Process Tracking

Most behavioral healthcare organizations can (and usually do) track the level, intensity, and duration of treatment. Very few provide tracking systems for the global orientation of treatment delivered, however, although this is beginning to change due to the National Committee on Quality Assurance (NCQA) accreditation requirements regarding clinical guidelines. Unfortunately, the field currently lacks methods for describing the global orientation of treatment in a reliable and valid manner, so the value of this type of tracking is low.

Of much greater value would be the tracking of specific treatment interventions, but it is very unusual to find an organization that does this. The exception are grant-funded research projects. We also lack a taxonomy for describing treatment interventions in a reliable and valid manner.

No formal coding system exists for general treatment orientations or for specific treatment interventions. Individual organizations may be able to develop such systems for their own internal purposes, however, this may only serve to fragment the field further. A standardized approach is needed that the entire field will adopt and which all organizations to use. Rudimentary systems are available through Health Care Financing Administration (HCFA), the American Medical Association (AMA), and a few other organizations, but they lack the detail the behavioral healthcare field needs. One more comprehensive effort currently underway to address this need is the Jossey Bass Treatment Definition and Coding System Project.

Guideline Variance Tracking

It is rare to find an organization that tracks the use of clinical guidelines in behavioral healthcare, much less the variance between guidelines and practice and the rationale for variance from guideline recommendations. A few managed care companies run periodic checks on adherence to guidelines for specific types of disorders and interventions. Examples are family therapy for children, medication evaluation for adults with major affective or psychotic disorders, and timely outpatient follow-up visits following discharge from hospital. However, these checks do not go to the level of

detail described in this paper and do not address treatment interventions such as systematic desensitization, interpretation of resistance, monitoring of dysfunctional thoughts, etc.

What Future Efforts are Required for Readiness?

Clinical Decision Support

It is vitally important for the behavioral healthcare field to develop clinical guidelines that focus on the core interventions that are supported by strong evidence as effective for specific disorders. These guidelines should also conform to the standards and principles established by organizations such as the [Institute of Medicine](#), the [American Medical Association](#), the [American Psychiatric Association](#), and the [American Psychological Association](#). They should obtain broad-based input and support from scientific experts, the professional disciplines, consumers, and administrators in both public and private sectors.

Guidelines based on scientific evidence and developed with broad support will have the maximum likelihood of being widely implemented and the minimum likelihood of causing harm. They are most likely to ensure that the field provides services of demonstrably consistent value, and to create a dynamic environment of quality improvement. They are also likely to reduce the fragmentation, confusion, and practice inconsistencies that now exist.

There are several different sources for guideline development, each with its own strengths and limitations. These include professional associations, private sector companies, the Federal government, and the various groups specifically devoted to developing and implementing clinical guidelines.

Professional associations such as the [American Psychiatric Association](#), the [American Psychological Association](#), and the [American Academy of Child and Adolescent Psychiatry](#) use expert consensus in combination with review of scientific literature to develop their clinical guidelines. Many of the most well-respected guidelines currently available were developed this way. They are useful and vitally important for specific professional disciplines. Some large systems of organized care have adopted several of these guidelines. However, because of how and why they were developed, they tend to be too discipline-specific and too weighty to be adopted across the entire field.

Private sector companies specializing in pharmaceuticals, disease management, and software applications have developed guidelines using scientific expert panels and review of scientific literature. These companies are often the most efficient at developing guidelines and at converting them into effective software. Many have excellent guidelines and are pioneers in guideline and software decision support efforts. However, as individual companies they have difficulty in garnering broad-based support for their guideline products.

Several branches of the Federal government's [Department of Health and Human Services](#) have been involved in clinical guideline development. Some of these efforts have been perceived as Federal pronouncements of what *must* be done, and consequently, met considerable resistance. Others attempted such thoroughness that they were perceived to be too weighty for easy use. The Agency for Health Care Policy and Research terminated its efforts in this area and the National Institute of Mental Health does not have guideline development as part of its strategy. The Substance Abuse and

Mental Health Services Administration, however, is considering partially sponsoring guideline development efforts by others and has launched some efforts on its own.

Various research and workgroups are involved with clinical guidelines. The Texas Medical Algorithm Project (TMAP) is a collaborative effort by the Texas Department of Mental Health and Mental Health Retardation and investigators at University of Texas at Austin College of Pharmacy and the Department of Psychiatry, University of Texas Southwestern Medical Center, Dallas to design, test, and implement clinical guidelines across the state.

The Practice Guideline Coalition includes representatives of professional and trade associations, scientific associations, accrediting and government agencies, and consumer associations in efforts to develop and disseminate clinical guidelines that will be sufficiently credible and user-friendly to be widely adopted and used to improve care.

Development of clinical guidelines for treatment for persons with mental illness must take into account the high prevalence of co-occurring disorders such as substance abuse or dependence and/or physical health problems. Co-occurring disorders require flexible implementation of several different clinical guidelines and sound clinical judgement regarding how to order and pace them in the treatment plan.

Disorders vary in the degree to which there are treatment interventions that have been proven effective. For example, strong evidence exists for recommending specific treatments for panic disorder, while there are few evidence-based treatment approaches that can be recommended for adjustment disorders. The strength of the evidence for each clinical guideline should be stipulated, and the degree to which clinicians should be expected to adhere to it should follow correspondingly: less adherence would be expected for guidelines with weak evidentiary and consensual support. Some disorders should have no recommended clinical guidelines because there is no evidence for particular treatments. Alongside recommendations for medications, clinical guidelines should include recommended psychosocial interventions (e.g., psychotherapy, group therapy, and wraparound services for children and people with serious mental illness) and where appropriate, recommendations for consumer-run services (e.g., for persons suffering from schizophrenia).

Even if the field agrees upon a core set of clinical guidelines, there will remain many elements of the content and the implementation procedures to be decided at local levels. The process by which these decisions are made will determine the fidelity with which the guidelines are implemented. Negotiation with key stakeholders is critical so they feel ownership in the guidelines, but such a process is time-consuming. Furthermore, guidelines must be reevaluated at least every two years and should also involve stakeholders input; such an undertaking is obviously expensive and ensuring adequate funding is crucial.

Clinical guidelines should be presented in a user-friendly format. They should be brief **C** 2-4 pages per guideline **C** with a more extensive backup document of 8-10 pages. To achieve such brevity, the guidelines must be restricted to the core, most important considerations and interventions. Brevity and focus will increase the likelihood that the guidelines will be perceived as useful and will actually be used.

Computerized decision support software make it easy to access treatment definitions and codes and recommended clinical guidelines and are crucial for widespread adoption. To facilitate this process,

we should conduct a survey of the decision support software that is available for clinical guidelines, and then determine which software designs are most user-friendly. Elements such as screen design, level of detail, and degree of algorithm-driven directions should be addressed. Experts in learning technology should assist in this undertaking. It is not enough to develop good clinical guidelines: they must be presented in a format the people will use.

Several steps should be taken to provide potential developers and purchasers of clinical guideline software with information and recommendations to guide design, selection, and use. At the most general level, information should be disseminated regarding artificial intelligence, expert systems, and other related technologies that would maximize the user-friendliness of the software. At a more specific level, it would be helpful to provide a model, using one or two guidelines as examples, to demonstrate how a particular type of software might be used to create clinical guidelines. Several excellent examples are already available.

The value of clinical guideline decision support software will be judged in field settings by the ease with which it can be integrated into routine assessment, diagnosis, and treatment planning process. Decision support software for clinical guidelines should therefore be designed for easy integration into as wide a range of practice management and managed care information systems as possible. For easy access, a web-based product should also be considered. Behavioral health software vendors are already aware of the importance of easily integrating their software products with others to address the market demand for comprehensive functionality; the ease with which software products can be interfaced and integrated will become increasingly important. National and international informatics standards will help facilitate this integrability of different software packages. Behavioral health organizations should participate in the national committees that set standards for healthcare informatics.

For clinical guidelines to be widely implemented, they must be phased in gradually and involve collaborative planning with key stakeholders; education and training; flexible requirements that take into account the limitations to our field's current knowledge base; and an emphasis on continuous quality improvement. Without this, resistance (particularly from clinicians) will be enormous. National and regional forums for discussion and information-sharing regarding implementation challenges will help accelerate the learning curve; these can be facilitated through conferences, publications, and electronic networking. On a more fundamental level, for implementation to succeed, a radical shift must take place in clinical training programs to provide clinicians with the skills they need to select and deliver guideline-based treatment interventions.

Many research programs should emerge in response to implementation of clinical guidelines. First and foremost, implementation must include ongoing measurement of treatment effectiveness in field settings to regularly evaluate the guidelines and guide revisions and improvements. This is essential for the guidelines to remain credible and useful. In addition, research will help understand the extent to which, and how, guidelines are modified at local levels, and determine the factors that maximize clinician adherence to guidelines.

Treatment Process Tracking

To track the actual treatments delivered, the behavioral healthcare field needs a standard terminology of treatment interventions with associated definitions and codes. The intervention terms should be cross-indexed by the disorders for which they most commonly are used, the therapeutic schools with

which they are most commonly associated, and the interventions within other therapeutic schools that are labeled differently but which are basically synonymous. The intervention a taxonomy should have broad-based support from scientist-practitioners across the various behavioral healthcare disciplines and be tested for reliability, validity, and administrative feasibility. It must also have an implementation commitment from many types of behavioral healthcare organizations.

For such a taxonomy to be widely adopted, it should be integrated into other software that is used routinely, particularly at the provider level where treatment tracking data are initially entered. Use will be easier and maximized if the taxonomy is part of more complete treatment planning software integrated into the provider organization's overall practice management information system. The software should include a tutorial on how to use the taxonomy; help screens; and keywords to assist the user in identifying the treatments desired. Users could include clinicians, consumers, care managers, and administrators.

For implementation to be effective, those who enter the data **C** the clinicians who provide the care must cooperate. To obtain cooperation, implementation efforts should gradually phase-in the new system and provide plentiful opportunities for education and training in using new treatment definition and coding systems. Clinicians will want to be compensated for the additional work required. Without attention to methods to address, clinician resistance implementation will not be effective.

Organized systems of care will need to inform and educate their staff and network clinicians regarding the purpose of the new tracking system, its potential benefits, and how the data will be analyzed and used. Clinicians will be particularly sensitive about the latter, and will want to know the extent to which the tracking will be used to punish noncompliant providers. They will be somewhat reassured, however, if managers adopt a flexible position, allow exceptions to guidelines with adequate rationale, and look only for extreme outliers. Clinicians will also want to know how the tracking system is used to evaluate the effectiveness of guidelines and to feed back useful information for improving the quality of care. Finally, organized care systems will need to provide information and training in how clinicians should use the system for accurate data entry. Eventually, training in this area should also be provided by medical and graduate schools, internships, residencies, and continuing education programs.

Guideline Variance Tracking

The steps outlined in the preceding section will lay the necessary foundation for guideline variance tracking. Interfaces must be built between the clinical decision support software from which the clinical guideline recommendations are made, the treatment process tracking system which includes the data on treatment actually delivered, and consumer characteristics. This may require a relational database and/or a data warehouse to facilitate the necessary data analyses.

What are the Hardware and Software Requirements for Linkage with Other Components and Information Systems?

Clinical Decision Support

Although a computerized clinical decision support module can stand alone, it should be integrated with a consumer's comprehensive (i.e., multi-sourced) computer-based record. Immediate access to

enrollment and encounter data sets that contain consumer demographics and diagnostic information, as well as benefit coverage, will prevent duplicated input; linkages between these data sets, guideline implementation, and performance and outcome data will facilitate clinical decision making and quality management. Clinical guideline recommendations should become part of the consumer's record to enable analyses of variances from recommended guidelines and assessment of the effectiveness of guideline-variant treatments.

Treatment Process Tracking

Data on the types of treatments and related services delivered should also be part of the consumer record. This will enable more sophisticated reporting to accreditors and purchasers regarding type of treatment delivered for specific types of problems, and the effectiveness of those treatments. Treatment process data should be integrated with treatment outcome and consumer satisfaction variables to evaluate the impact of differing treatments on consumer outcomes and satisfaction, and with data on consumer demographics to determine predictors of outcomes for specific treatments for particular conditions.

Guideline Variance Tracking

Variances between guideline-recommended treatment and actual treatment delivered should be recorded in the consumer's record, along with the rationale for the variance, to enable comparisons of guideline-recommended treatments and treatments delivered at variance with those guidelines. Guideline variance data should be reviewed for rationales as part of quality improvement efforts. They should also be linked with system guidelines to determine whether consumers are experiencing difficulty accessing necessary treatments because of system inadequacies.

What are the Requirements for Protecting Privacy and Maintaining Confidentiality and Ensuring Cultural Competence?

To the extent that clinical guidelines decision trees, definitions of treatment, and related coding rules are developed with private sector funding, there will be issues of intellectual property to address.

What ever information is input by the user (whether the consumer, the clinician, the clinical supervisor, the case manager, or the case management supervisor) regarding the consumer's demographic and clinical data, becomes part of the computerized consumer record, and as such, all policies and regulations pertaining to privacy of the consumer record would apply.

Analyses of aggregated data will generate reports used internally to manage care and improve quality and externally for accountability to purchasers, regulators, and accrediting organizations. Policies and regulations regarding the privacy of consumer data are least well defined for this type of information, but they are needed. Currently, there are varying regulations promulgated by states, institutional research review boards, and some Federal regulations that govern the exchange of information between benefit purchasers, health plans, treatment providers, and consumers.

Obviously, the most sensitive information requiring safeguards for privacy is contained in the consumer record. Both hardware and software technologies are available to protect the record against unauthorized access and include information certification servers, encryption, firewalls, and passwords with varying degrees of sophistication.

In addition, a record, or audit trail, should be kept of people who access a consumer's clinical record. The audit trail should include the person's name, position title, name of company, reason for reviewing the record, and any action taken. This audit trail should be made available to the consumer upon his or her request.

Clinical guidelines should be developed with attention to cultural variables. Where research indicates that race, ethnicity or religion warrant modification of the guideline, that should be included in the decision tree and have supporting documentation. Panels that develop guidelines should include people from diverse racial and ethnic groups and experts on the influence of racial and ethnic variables on treatment effectiveness.

When a clinical guideline indicates that the recommended treatment should be modified due to racial or ethnic factors, or recommends that the provider should be of the same racial or ethnic group, the process should be tracked to determine whether the guideline recommendation was implemented. The data should also be analyzed to assess consumer satisfaction and outcome.