

# Highlights of the 2003 Institute on Psychiatric Services

The 2003 Institute on Psychiatric Services, held October 29 to November 2 in Boston, drew 1,875 participants to a varied program of more than 350 lectures, symposia, workshops, and poster sessions. Attendance was the fourth largest in the 55-year history of the American Psychiatric Association's (APA's) annual fall conference on clinical care and service systems. The strong attendance underscores psychiatrists' commitment to serving the most vulnerable populations.

In her address at the institute's opening session, Marcia Kraft Goin, M.D., Ph.D., president of APA, focused on the unifying theme of the meeting, "Access to Integrated Mental Health Care." The theme, she said, "underscores today's knowledge that biological, psychological, and social needs of all patients do not occur in isolation but form an integrated whole. The goal of our profession is to provide integrated mental health care that responds to these complex interactions, and to do so for all patients."

Dr. Goin said that psychiatrists should be heartened by the fact that we are closer than ever to a genuine understanding of the term "biopsychosocial." When mental illness is seen from this perspective, the usual nature-nurture questions about its origins become as irrelevant as asking, "What supports life—air or water?" The heavy focus on the biology of mental illness in recent years has led to an array of effective treatments, Dr. Goin noted. Then she invoked Theodore Reik's "third ear" to remind psychiatrists that when such treatments were not available, listening and trying to understand the personal meaning of each patient—the "psychological" part of "biopsychosocial"—was the primary approach to

treatment. She said that she was pleased to see the return of an emphasis on the psychological, especially in the work of Douglas Turkington and his colleagues, whose use of cognitive-behavioral therapy with psychotic patients might be called "Listening With the Third Ear 101."

Dr. Goin pointed out that the messages of the report of the President's New Freedom Commission on Mental Health and of APA's *A Vision for the Mental Health System* resonate with one another. The commission's report emphasizes that treatment should focus not just on managing symptoms but on increasing patients' ability to successfully cope with life's challenges and on facilitating recovery and building resilience. Both the report and APA's vision build on the principles that care should be patient and family centered, community based, culturally sensitive, and easily accessible, free of discriminatory barriers. Both documents recognize the harmful effects of stigma and the need for legislatively mandated parity. However, Dr. Goin noted, "in the midst of a commitment to outreach and integration with communities . . . it is important not to lose sight of the very first item in APA's *A Vision for the Mental Health System* that 'every American with psychiatric symptoms has the right to a comprehensive and an accurate diagnosis which leads to an appropriate, individualized plan of treatment.'"

Dr. Goin pointed out that even though the report of the President's New Freedom Commission presents a "comprehensive and honest acknowledgment of the problems" in mental health service delivery systems, it does not address the need for increased funding, which "is absolutely critical if changes are to be

implemented successfully." She described an effective program in California that targets homeless persons who are at imminent risk of being incarcerated. The program is relatively small and currently reaches only about one-tenth of the 50,000 homeless persons in California. However, \$55 million a year is needed to sustain such a program.

Finally, Dr. Goin praised APA members and other treatment professionals and advocates: "Although very gratifying, the work you are doing is not easy. This work, when done and done well, can be emotionally painful. You are to be complimented on your work, your stamina, and your great humanity."

## Alcoholics Anonymous: cult or cure?

George E. Vaillant, M.D., professor of psychiatry at Harvard Medical School and director of research in the department of psychiatry at Brigham and Women's Hospital in Boston, delivered a lecture titled "Alcoholics Anonymous: Cult or Cure?" For the past 30 years, Dr. Vaillant has directed Harvard's Study of Adult Development, which has prospectively charted the lives of 824 men and women for more than 60 years.

Dr. Vaillant pointed to the controversy surrounding AA and to some bad press the organization received several years ago, noting that this type of "wrestling match" hinders efforts to evaluate AA objectively. He believes that in evaluating AA it is important to apply the same type of analysis that would be applied to any other treatment: Is it effective? If so, what is its mechanism of action? Is it better than placebo? Is it better than or at least as good as other treatments? Finally, does it have any side

effects, and, if so, are they serious?

Dr. Vaillant first explored the track records of other treatments—"interventions that should work but don't." Neither psychotherapy nor selective serotonin reuptake inhibitors are effective for treating alcoholism, he said. And detoxification, although desirable, does not change the natural history of the disease. He pointed out that although a study of at least five years' duration is necessary to demonstrate success, no studies of more than two years have been conducted to assess the efficacy of AA or other treatments for alcoholism. Until such studies are available, he said, one needs to think of these treatments as helpful in managing the acute phases of the disease but not as a cure. One advantage of AA, he noted, is that it "keeps on giving," whereas other treatment tend to provide benefit only while the patient is in the treatment setting.

One thing that is known, he said, is that four factors are associated with relapse prevention: external supervision; encouragement of a competing dependency, such as food; development of a new love relationship; and increased spirituality. Unlike most professional treatment programs, AA's approach combines all four of these factors, Dr. Vaillant said; the "spirituality" aspect of AA is not so much a form of religion as an enhancement of hope and self-esteem.

"But does AA work?" he asked. In his opinion, the best controlled study ever conducted of randomly matched patients was a study by Welch and colleagues published in the *New England Journal of Medicine*, which showed that hospitalization and education were equally as effective as AA in preventing relapse, although AA had the advantage of being less expensive. However, that study ended after two years, and other data show that the efficacy of AA increases over longer follow-up periods: "AA isn't a magic bullet," he said, "It's something like teeth flossing that you have to keep doing."

In addressing the question of side effects—of whether AA is a "cult"—he pointed out that although AA is characterized by a high level of social cohesion, an intensively held belief

system, and a profound influence on members' behavior, these are all things that could be said of a close family. AA is aimed at the well-being of the individual, not at "mind control," he said. And, unlike a cult, AA does not believe that its approach is the only way.

Dr. Vaillant also noted that AA's governing structure is different from that of cults. AA leadership positions rotate frequently, and the organization's leaders embrace anonymity. The organization espouses "corporate poverty." Finally, AA favors humor, as evidenced in its "rule 62": "Don't take yourself too damn seriously!"

### **Creating a culture of safety**

In December 1995, Betsy Lehman, a health columnist for the *Boston Globe*, had almost completed a course of chemotherapy at the Dana-Farber Cancer Institute in Boston when she died from a massive overdose of a powerful anticancer drug. In the aftermath of this highly publicized medical error, James B. Conway was hired by Dana-Farber to help the organization understand how the tragedy had occurred and to prevent such incidents from happening again.

In a lecture titled "Creating a Culture of Safety: Challenge Your Mental Models," Mr. Conway, senior vice-president and chief operations officer at Dana-Farber, recounted the story of "a journey leading change" that began by setting a goal: "In three years Dana-Farber will be a leader in patient safety." Throughout his story he emphasized the important role that psychiatrists can play in creating cultures of safety—the level of emotion surrounding medical errors is high, and psychiatrists have the skills that are needed not only to help patients and their families deal with the harm caused by errors but also to create a nonjudgmental environment in which individuals are encouraged to tell their stories and communicate with one another.

If an organization's culture is to change, the full support of its leadership must be clear from the start, Mr. Conway said. The next step was to listen to patients and family members. He found that many said the same things: "We're cancer patients, and we

know there are errors. We didn't know you did." "I wanted to talk and they gave me a lawyer." "I still don't know what happened to my brother." Most patients are understanding when errors occur, but their trust can be eroded by an organization's reaction.

Clinical staff at all levels have genuine concern about the safety of their practice, Mr. Conway pointed out. Most have a story about an error that they have made or have witnessed, a story that they have never shared and want to tell. Some fear they may have harmed a patient but are not sure. They feel ashamed and worried about their colleagues' judgment and about being "hung out to dry." At a meeting convened to listen to Dana-Farber frontline staff, Mr. Conway asked staff members to write on a card a brief description of an error that they had made. The cards were shuffled and redistributed, and each person read the card that he or she was given. The organization's leaders had worked hard to create a nonpunitive environment and had made it clear that the leaders were at the meeting to support staff members. As the cards were read by others, the people who had written the descriptions began to speak up themselves—to own the error and to tell their story.

Errors happen in the best of places with the best staff, Mr. Conway noted. Errors are overwhelmingly about bad systems, and they happen far more often than administrators imagine. Relying on incident reports is not enough. "You must go looking for errors, and there are endless opportunities when you do." Mr. Conway urged administrators to visit the American Hospital Association's Web site and download the leadership assessment *Strategies for Leadership: Hospital Executives and Their Role in Patient Safety*.

Administrators should be alert to "drivers" of errors, especially "normalization of deviance," which occurs when staff repeatedly encounter system barriers to reporting or talking about errors and begin to filter out the unsafe practices that they see around them. Mr. Conway urged administrators to create a system in which, at the end of every shift, each clinical staff member is asked, "Did anything get in

the way of good practice today?" The problems should be written down, and all staff should be asked to suggest solutions. When staff are working on a unit that doesn't feel safe that day, they should know whom to call and they should expect that the situation will be addressed immediately.

When Mr. Conway reflected on some of the lessons learned from Dana-Farber's journey, he emphasized the enormous benefit of telling stories. The near miss has particular power to leverage change, he said. In addition, all staff and administrators should be educated in the techniques of "root cause analysis," a structured approach to uncovering factors contributing to a "sentinel event." When such an event occurs, leaders should focus on three things: the impact on the patient and his or her family, on the organization, and on the staff member "at the sharp end of the error." The error should be disclosed to the patient and the family at once and support made available to them. The impact on the organization is likely to be high, and a press release should be disseminated quickly. Psychiatrists can provide invaluable support to clinicians who are involved in errors when the clinicians have the difficult task of meeting with patients and families who have been harmed and when they must confront the devastating emotions that may come later.

Mr. Conway acknowledged the complexity of searching for the errors that occur in institutions that patients go to so they can be helped, not harmed—and the pain of finding and facing those errors. "We are programmed not to go there. But we can go there, and we can be proud of the outcome."

### **Antisocial personality disorder**

Glen O. Gabbard, M.D., discussed the diagnosis and treatment of antisocial personality disorder. Dr. Gabbard is the Brown Foundation chair of psychoanalysis and professor of psychiatry at Baylor College of Medicine in Houston, Texas, as well as director of the Baylor psychiatry clinic and supervising analyst at the Houston-Galveston Psychoanalytic Institute.

Dr. Gabbard mentioned that for six years he worked in the prison system,

which is "the best place to learn about personality disorders." He noted that the language and definitions surrounding antisocial personality disorder are still evolving. For example, the term "psychopath" was the preferred term in the 1940s, subsequently went out of favor, and recently has come back into use for describing a subgroup of patients whose illness is refractory to treatment. An estimated 25 percent of prisoners have antisocial personality disorder; of these, one-third meet criteria for psychopathy.

Because persons who have this disorder are potentially dangerous, it is important to make the distinction between those who are treatable and those who are not, Dr. Gabbard said. For the purposes of diagnosis, he recommends the Psychopathy Checklist, Screening Version (PCL:SV). However, he believes that one item on the PCL:SV—"lacks empathy"—is not accurate, because some individuals with antisocial personality disorder possess very sophisticated empathy, which they can use to manipulate others. A more accurate descriptor, he said, would be that they lack the capacity for concern.

To give the audience a fuller appreciation of this type of patient, Dr. Gabbard screened a short videotape of a prisoner with antisocial personality disorder. This person was a good example of how affable people with this disorder can be and illustrated how aspects of their conversations often don't quite add up. In their desire to impress the person they are talking to, they can become blustery and narcissistic. They can also be charming to the point that women—including clinicians, journalists, and other professionals—fall in love with them. "Any of us can be conned, even the best clinician in the world," Dr. Gabbard warned. "For example, you agree to lend a patient \$200 and in retrospect think, 'That must have been a psychopath!'"

Dr. Gabbard explained that both biological and social factors are responsible for the development of antisocial personality disorder. Although genetic factors are predictive of the disorder, an adverse home environment has an additive effect in increasing a person's risk. Dr. Gabbard

pointed to studies suggesting that parental behavior can influence a child's tendency to develop the disorder and that a more optimal environment can mean that those who are predisposed to developing it do not.

Although clinicians should not be too hopeful about the success of treatment for the subgroup of patients with psychopathy, various prognostic factors are indicative of positive outcomes among patients with antisocial personality disorder who are not psychopathic. Dr. Gabbard said: depression, anxiety, the capacity to form a therapeutic alliance, and any superego development, such as a socially desirable need to rationalize antisocial acts, which indicates that the patient has some level of concern for others. However, again, clinicians can be fooled by the patient into incorrectly thinking that these criteria have been met, Dr. Gabbard cautioned. The most accurate assessment will be obtained by looking at the patient's past records, not by interviewing the patient, he said.

Dr. Gabbard noted that there is no body of controlled efficacy research on the treatment of antisocial personality disorder. The most positive statement that can be made about treatment is that some patients may be treatable under some circumstances. The therapist must be stable, persistent, and thoroughly incorruptible. He or she must be prepared to repeatedly confront the patient's denial or minimization of antisocial behavior. Although these patients "love to go back to their childhoods," Dr. Gabbard noted, confrontation of here-and-now behavior is more effective. He emphasized that clinicians should not begin treatment if they do not feel safe in the presence of the individual.

### **Psychiatrists and marketing representatives**

As in previous years, the American Association of Community Psychiatrists sponsored a debate that was held during the institute. This year the topic was "Resolved: It Is Unethical for Psychiatrists to Invite Sales Representatives to Market Products Through Such Methods as Educational Materials, Samples, and Gifts in Clinical Settings." The debate was

moderated by David A. Moltz, M.D., of Brunswick, Maine. The affirmative case was presented by Charles R. Goldman, M.D., professor of psychiatry at the University of South Carolina School of Medicine in Columbia, and the negative position was argued by Michael A. Silver, M.D., medical director at the Providence Center in Providence, Rhode Island.

Dr. Goldman opened by acknowledging that his position—that it is indeed unethical for psychiatrists to invite sales representatives to market products—is extreme and unpopular. He then reminded the audience of the Enron situation as an example of what can happen to a profession, even among people who are not “evil,” when the overall system is corrupt. Reform was needed to address the system, Dr. Goldman said.

He pointed out that physicians have a responsibility to maintain an objective, balanced viewpoint, especially in the areas of diagnosis and treatment. However, it is difficult to remain objective if everything one reads promotes medication as the best form of treatment, he said. He pointed out that increasingly there is a lack of objective data to support the pro-medication message. He emphasized that it was not his intention to criticize drug companies: the people who work for these companies are simply doing their jobs, doing what they are good at. However, he does not believe that psychiatrists should be participating in these activities: “We should not be working with drug company salespeople at all. . . . We need to stop playing their game and restore balance to the system.”

Dr. Silver opened his argument of the negative case—that it is not unethical for psychiatrists to invite sales representatives to market products—by acknowledging that the topic is an emotional one. He believes that drug companies have been stereotyped as greedy corporations interested only in profits—much like tobacco companies. However, pharmaceutical products are of huge benefit to millions of people, he noted. The people who work for drug companies are simply working within the capitalist system, which, although flawed, is superior to the alternative: communism.

Dr. Silver pointed out that, given the various other flaws of the U.S. health care system, U.S. psychiatrists “have no moral authority” to oppose marketing by sales representatives. For example, “What about the fact that there are so many people without health insurance?” he asked. He noted that drug company representative supply psychiatrists with product samples that can then be given to patients who can’t afford medications. “And if you’re going to ask these representatives for samples, you have to treat them decently,” he said.

Dr. Silver suggested that a better way of addressing the system’s current flaws might be to prepare physicians for the pressure of pharmaceutical marketing—for example, through medical school curricula. Physicians can and do make good medical decisions, he argued, and they should have access to as much information as possible when making those decisions, including information from pharmaceutical companies. Physicians simply need to ensure that they maintain their skepticism, which is a reasonable expectation given their training in critical thinking. The bottom line, Dr. Silver said, is that the positives of marketing by pharmaceutical company representatives outweigh the negatives.

During the rebuttal component, Dr. Goldman suggested that samples are the most effective marketing tool the drug companies have; these samples allow representatives to get “face time” with physicians, he said. He believes that psychiatry’s reliance on samples reflects a short-range view; in the longer term, he said, “we should be able to figure out other ways of getting samples.” Dr. Silver, on the other hand, believes that psychiatrists need to do whatever they can for their patients, which means obtaining resources offered by the drug companies. He believes that psychiatrists, not the drug companies, are responsible for the number of drugs they actually give to patients.

In summarizing his affirmative argument, Dr. Goldman stated that writing prescriptions on the basis of what is in the sample closet is not in patients’ best interests. Finally, Dr. Silver summarized by reminding the

audience that drugs help patients and are psychiatry’s major tools. Although they may sometimes be overused, it’s easy to overlook the big picture, “the huge advances we’ve made,” he said.

### **Body dysmorphic disorder**

Katharine A. Phillips, M.D., provided an update on the diagnosis and treatment of body dysmorphic disorder. Dr. Phillips is professor of psychiatry at Brown Medical School and director of the body dysmorphic disorder program at Butler Hospital in Providence, Rhode Island.

She began by pointing out that patients who have body dysmorphic disorder are typically secretive about it—clinicians have to specifically ask about symptoms. It is an unusually distressing condition associated with severe impairment—98 percent of sufferers have some social impairment, and 83 percent have occupational or academic impairment. Patients with this disorder have a high rate of suicide attempts.

Criterion A for body dysmorphic disorder in *DSM-IV* is as follows: “Preoccupation with an imagined defect in appearance. If a slight physical anomaly is present, the person’s concern is markedly excessive.” The three most common areas that patients are preoccupied with are the skin, the hair, and the nose. Ninety percent of patients with the disorder camouflage the perceived deformity—for example, with a wig, sunglasses, or a beard.

One challenge for clinicians is to distinguish this disorder from normal concerns about appearance. Thus criterion B is that the condition must cause clinically significant distress or impairment and must not be better described by another diagnosis, such as anorexia nervosa, although the two conditions often co-occur.

Dr. Phillips explained that although large-scale epidemiologic studies are lacking, the prevalence of body dysmorphic disorder in community samples ranges from .7 percent to .11 percent. In inpatient psychiatric settings, the prevalence is around 13 percent. She then posed the question, “But are clinicians making the diagnosis?” In every study that addressed this issue, none of the patients with



body dysmorphic disorder received this diagnosis from their clinician. However, most patients said that they wanted their doctor to know about their problem. Clinicians need to ask questions in response to any concerns a patient raises about appearance, Dr. Phillips said, and they need to be alert for clues such as delusions of reference, evidence of skin picking, and strange outfits possibly intended as camouflage.

Dr. Phillips described the clinical features of the disorder with reference to a sample of 234 patients. Most were single, and their average age was 31 years. The average age at onset of the disorder was 16 years. In most cases, the disorder begins gradually, although for 25 percent of patients it begins suddenly, often in response to something such as a remark from another person. For 85 percent of sufferers, the disorder is continuous, whereas for 15 percent it occurs only episodically.

The disorder is a form of obsession—thoughts about the imagined defect are difficult to resist or control, and they are time-consuming. Some patients with body dysmorphic disorder refuse to look in a mirror, whereas others are constantly looking in mirrors. Because staring into a mirror can produce a distorted view of one's appearance, it is very important for clinicians to get patients to stop doing it.

The disorder is characterized by lack of insight, sometimes to the point of delusion. Delusional patients with body dysmorphic disorder are more severely ill, and it is harder to persuade them to enter treatment programs. Dr. Phillips explained that in most cases surgery or other forms of nonpsychiatric medical treatment—for example, dental care—bring no change in distress levels. Some patients become acutely suicidal or violent when the surgery “doesn't work.”

No medication has FDA approval for the treatment of body dysmorphic disorder, Dr. Phillips noted. Antidepressants appear to control the symptoms, but they are not a cure. Clinical studies have shown selective serotonin reuptake inhibitors (SSRIs) to be effective. Dr. Phillips recommends that SSRIs be used for all patients with body dysmorphic disorder,

including those who are delusional. The maximum dosage should be used and in some cases should be exceeded, she said—although fixed-dose studies are lacking, practical experience suggests that these patients require above-usual dosages. Dr. Phillips suggested that clinicians allow 12 to 16 weeks for a response. Augmentation of the SSRI should also be considered, possibly with buspirone, second-generation antipsychotics, venlafaxine, bupropion, or clomipramine.

Dr. Phillips also pointed to studies suggesting that cognitive-behavioral therapy may be helpful for patients with body dysmorphic disorder. No comparison or combination studies have been conducted to assess the superiority of SSRIs, cognitive-behavioral therapy, or both for the treatment of body dysmorphic disorder, she noted. Although either or both approach may be used with patients who have a mild to moderate form of the disorder, patients with a severe form should be treated with SSRIs alone, primarily because they are often too ill to leave their homes to participate in cognitive-behavioral therapy.

### **Pursuing perfection in depression care**

In 2001 the Robert Wood Johnson Foundation (RWJ) issued a challenge to health care administrators: “Convince us that in two years you can develop a system of perfect care, and we will fund it.” This is how C. Edward Coffey, M.D., embarked on the motivating story of how his behavioral health care system dared to aim for perfection. In his lecture “Pursuing Perfection in Depression Care,” Dr. Coffey explained that the foundation could issue such a challenge because the Institute of Medicine (IOM) had simultaneously published a book—*Crossing the Quality Chasm: A New Health System for the 21st Century*—that contained a blueprint for vastly improving the quality of health care. The Henry Ford Health System in Detroit, where Dr. Coffey is vice-president of the behavioral health carve-out, was one of 12 RWJ finalists and received \$2 million, along with a two-year mandate.

Use of the term “perfect care” was one of the ways that Dr. Coffey held the attention of his listeners. He described the “six dimensions of perfect care” outlined in the IOM report. Care should be safe, effective, patient centered, timely, efficient, and equitable. “Why perfection?” he asked. If 99.9 percent accuracy is good enough, each year 12 babies in the state of Michigan will be given to the wrong parents and each day two landings at Boston's Logan airport will be unsafe. He urged his listeners to visit the IOM Web site and learn the ten rules for redesigning the system that are presented in the report.

In the Henry Ford system, the first strategy for achieving perfection in depression care was to create a small implementation team—the “Bluesbusters”—and formally launch the program. The team then set “perfection goals” for the system, one of which was to completely eliminate suicide. When other clinicians recoiled at such an ambitious goal, the team challenged them: “If zero isn't the correct number, then you set a number. Four? Forty?” Dr. Coffey described this “stretch goal” as the “single most galvanizing issue” that “got people on board” with the concept of perfection and with the program. The next step was to “ensure the voice of the customer.” An advisory board that included patients and patient advocates was formed, from which the team obtained invaluable information.

The most critical step was to map the processes of depression care in order to pinpoint specific spots where one alteration would “leverage change for the whole system.” Process mapping is a technical undertaking that is used in many industries, and a consultant from Ford Motor Company was brought in to help. Because of the two-year RWJ timetable, changes had to be rapid and measures needed to be implemented quickly. On the basis of the care processes map, small changes were set in motion, and about five weeks later, tests measured the extent of success of each change. The result, said Dr. Coffey, was a process of continuous learning in which celebration of small wins was important.

The 12 RWJ grantees found that they made the most progress toward perfection when they implemented what has come to be known as the “planned care model.” The model’s goal is to “improve outcomes by producing productive interactions between informed activated patients and a prepared proactive clinical team.” Health systems must be redesigned to make this interaction possible—to create educated patients who are able to manage their illnesses, to ensure that clinicians have protocols at their fingertips for making evidence-based decisions at each patient encounter, and to develop clinical information systems to support these changes.

Under the model, depression was reconceptualized as a chronic illness. Because most studies have shown that combining medication and therapy produce the best outcomes and because cognitive-behavioral therapy (CBT) has the most evidence of success, the Henry Ford System sent all of its psychotherapists to the Beck Institute to obtain certification in CBT. A detailed suicide-prevention protocol was disseminated, and high-risk patients were identified. In general, the rate of suicide in a psychiatric population is ten times that in the general population, Dr. Conway noted. Among patients in the Henry Ford system during the second year of the project, the suicide rate fell below the general population norm for three continuous quarters.

Other goals of the program addressed the dimensions of perfect care in the IOM report: patient centered, timely, efficient, and equitable. “All patients will be 100 percent satisfied” with each of these aspects of their care. A brief satisfaction questionnaire was developed, which patients now complete after each clinical encounter. Any rating of less than 100 is addressed before the patient leaves the facility.

Dr. Coffey reviewed some lessons learned. Leadership is key and must come from the system’s highest levels. Perfection must be the goal. Data are essential for monitoring the system’s vital signs. Information technology support is crucial to success. “Spreading the word” is important, and Dr.

Coffey referred his audience to the Web for information on the “new science of spread.” Finally, pursuing perfection can have “toxic effects” for certain people, and some Henry Ford clinicians had to leave the system because the goals and the changes felt too extreme.

### **Ethics and psychiatric research**

Laura Roberts, M.D., professor and chair in the department of psychiatry and behavioral medicine of the Medical College of Wisconsin in Milwaukee and editor of the journal *Academic Psychiatry*, gave a lecture called “Ethical Considerations in Psychiatric Research.” She opened by summarizing the concepts underlying ethically sound research: respect for persons (both society as a whole and the individual who is participating in a research study), beneficence, justice (a population should not be studied merely because it is a convenient sample), expertise (so as not to harm the participants), and integrity. She noted that science and ethics are inseparable: “Poor science is, by definition, poor ethics, although great science may still be unethical.”

Dr. Roberts then outlined the “necessity” criteria for ethical research. Researchers must use the least risky design and methodology necessary, as well as the least vulnerable population. The population under study must benefit from the research. Greater risk must be accompanied by more rigorous safeguards. Similarly, special safeguards should be used for special populations, such as children, prisoners, institutionalized persons, and persons who are terminally ill. Dr. Roberts noted that special populations are defined by their vulnerability to exploitation, with vulnerability defined as heightened barriers to fulfillment of the ideal of informed consent. She pointed out that any individual has the potential to be vulnerable.

Dr. Roberts gave various examples of safeguards for ensuring ethically sound research, including safeguards in the scientific design and methodology, safeguards in the selection and recruitment of study participants, research advance directives, exit criteria, scientific peer review, and au-

thorship standards, all of which are fully under the control of the researchers themselves. Additional safeguards—those that are not totally under the researchers’ control—include institutional review and oversight, conflict-of-interest management, and the informed consent process.

Dr. Roberts also summarized the results of some empirical research of informed consent and other ethically important aspects of research involving persons from special populations. Among the findings: when persons with schizophrenia were surveyed about aspects of participation in research and clinicians were asked to predict what their responses would be, there was a wide gap between predicted and actual responses. Patients with schizophrenia actually have very similar views on research to those of clinicians, Dr. Roberts noted, but clinicians do not expect the patients to have these views. In another study, patients with a mental illness, patients with a physical illness, and healthy participants had almost uniform responses to questions about the vulnerabilities of seriously ill people, the suffering associated with serious illnesses, and the importance of medical research. Studies have also shown that, among persons with schizophrenia, willingness to participate in research declines as the associated risk increases—that is, they do understand the issues involved in research participation. They also have a strong expectation of beneficence, and they understand that research is of more benefit to society as a whole than to the individual research participant, said Dr. Roberts.

In summarizing, Dr. Roberts suggested a number of “gifts” that mental health investigators can bring to the research process: compassion, attentiveness to ethics and human experience, attentiveness to the value and meaning of distinct perspectives, respectful awareness of issues facing special populations, rigorous self-observation and professionalism, and scientific excellence and empirical evidence.

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