

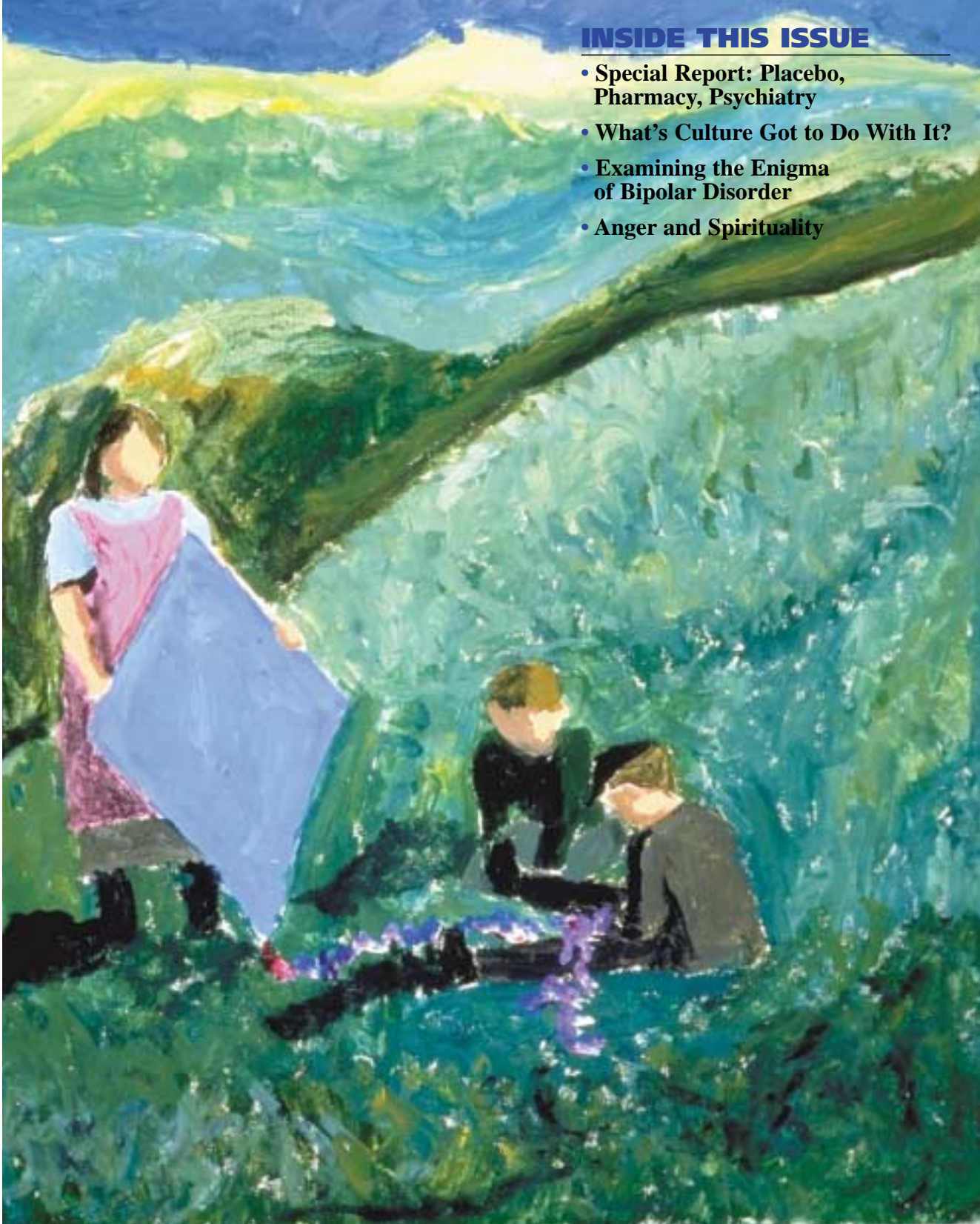
# PROGRESS

S U M M E R 2 0 0 0



## **INSIDE THIS ISSUE**

- **Special Report: Placebo, Pharmacy, Psychiatry**
- **What's Culture Got to Do With It?**
- **Examining the Enigma of Bipolar Disorder**
- **Anger and Spirituality**





**D**ear Readers of Progress:

In this issue, we tackle some controversial issues: how research on psychiatric medications is conducted, how HCPC responds to patient emergencies, how ethnicity and culture play a part in mental health treatment.

Stigma—misunderstanding and fear—is at the root of many of these issues, because it is stigma that keeps such questions from being properly discussed, scrutinized and, in many cases, resolved.

We believe it's important to address seclusion and restraint because they impact patient care and because we want to explain what really happens in an acute-care psychiatric hospital—as opposed to what is presented in the mass media.

We believe it's important to address the role of placebos in psychopharmacologic research because research in mental health is often misunderstood and undervalued. Yet, continuing the momentum of the Decade of the Brain is essential to finding causes and cures for mental illness.

We believe it's important to address the issues of ethnicity and culture because we know they are often overlooked in psychiatric treatment, but they are key to how patients respond to mental health interventions.

Research is one of HCPC's four missions and a very crucial one, I believe. That is why we were proud to sponsor last spring's Placebo Conference with the UT-Mental Sciences Institute, a groundbreaking event which brought together the major medical researchers, scientists, ethicists and physicians working in the field of psychiatric drug research.

I hope this and the other articles will enhance your understanding and even broaden your perspective about research and treatment in the field of mental health. I think you will find much that is encouraging and surprising about the role of HCPC in these efforts.

I want to especially thank the Houston Museum of Health and Medical Science for allowing **Progress** to use some of the wonderful artwork from their upcoming exhibit, "Childhood Revealed," a traveling exhibit organized by the New York University Child Study Center. These pieces by children with emotional problems are both fascinating and eloquent. I urge you to see them in person when they are in Houston, September 12 through October 15.

I consider **Progress** a key part of our community outreach efforts, and I was very pleased when a reader called me after receiving the last issue. He inquired whether **Progress** might address the co-occurrence of depression and cancer in a future issue. He felt there was a need to let cancer sufferers know that depression is common with their illness, but that it doesn't have to be debilitating. So, with the expertise of UT-Houston psychiatrists who work directly with cancer patients, we have put together an article we believe will be of interest to this population. (See page 7.)

I hope any of you who read this publication will respond as this reader did if there is an issue or concern you wish to see addressed. I cannot promise we can meet all your needs, but we will consider each of them and be open to all suggestions.

Sincerely,

Lois J. Moore, BSN, MEd, LHD, FACHE  
Administrator



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*On the cover: "Innocence of Youth" by a 15-year-old child with bipolar disorder. This (and all the art throughout this issue of **Progress**) is from "Childhood Revealed," and exhibition of art by children with mental health issues, to be on exhibit at the Houston Museum of Health and Medical Science, September 14 through October 15, 2000. Designed to raise awareness and eradicate the stigma of mental illness among children, this traveling exhibit was organized and curated by the New York University Child Study Center. The Center is a multidisciplinary team dedicated to advancing the field of mental health for children and their families through evidence-based practice, science and education. HCPC is grateful to the Houston Museum of Health and Medical Science and the Child Study Center for allowing us to feature these works in **Progress** (see Pages 15-16).*

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*"I Don't Know... I Do Know," 18-year-old female victim of abuse, 1997*



*EDITORIAL*

# Research Key to Early Identification and Prevention

by Robert Guynn, MD

**C**lassically, medical research has aimed at the better identification and treatment of disease. What type of infection is this? What procedures or interventions work best? Which medication is the most effective?

We figured out long ago, however, that diseases do not just happen. With the exception of a few uncommon genetic diseases, most illnesses arise out of a complicated mix of our genetic composition, the environment and our lifestyle.

It has also been long understood that it is better (and cheaper) to prevent disease than it is to treat it. It is better not to get cancer in the first place than to have the benefit of the most modern treatment interventions. It is better not to catch pneumonia than to have access to the most powerful antibiotics. A properly healed leg is not better than a leg that has never been broken.

If we do not yet know how to prevent an illness, the next best approach is early detection. It is far easier to treat tuberculosis found early by a skin test than once the clinical signs have become apparent.

The advantage is the same, of course, with the strategies of early-cancer detection.

As it becomes clearer and clearer that the goal of eradicating disease is slipping further and further into the future, it is apparent that a new medical research focus is needed in the meantime. In the 1970's scientists were talking about the imminent triumph of medicine over infectious diseases. (No one has to be reminded of the current problem of antibiotic resistant organisms or of

the AIDS pandemic.) Now prevention has become an extremely important strategy, even in infectious diseases. We can no longer sustain the fantasy that no matter what we catch, it will be cured.

The ideas of prevention and early intervention have taken hold in psychiatry as well and are shaping some of the research focus. We have come to suspect that how well one manages the first psychotic episode of an individual with schizophrenia affects the prognosis. We notice that prevention of recurrent manic episodes seems to help prevent development of the difficult to treat rapid cycling state. After several episodes of major depression, the current wisdom is to treat continuously with antidepressants.

Some investigators on the East Coast have taken the bold step of offering neuroleptic treatment to the siblings of schizophrenic patients, because these siblings have a 15- to 20-fold higher risk than the general population of developing schizophrenia themselves. Although this approach has raised some controversy, it is hard to argue against at least the idea that it is better to prevent than to treat the full blown syndrome.

What does that mean for us? A number of our faculty here at UT-Houston and HCPC are already interested and doing work in these areas. I would expect to see a natural expansion into prevention and early detection work, especially as our interest and focus on children and adolescents increase. Almost surely this is the way of the future. ★



*Dr. Guynn is Executive Director of HCPC, Chairman of the Department of Psychiatry and Behavioral Sciences in the UT-Houston Medical School and Director of the UT-Houston Mental Sciences Institute.*

# ... WITH Regard for Race, Color, Religion, National Origin ...

## *Ethnicity and Culture's Impact on Mental Health Care*

**W**hen Pedro Ruiz, MD, first began practicing psychiatry in New York City he was shocked one day by the sight of a secretary in his office falling to the floor with what he thought was a seizure. He feared epilepsy or a brain tumor. But in talking with her he learned that this was not an uncommon phenomenon among women like this secretary who were of Puerto Rican descent. He learned these events called "ataques," were not manifestations of a brain or psychiatric disorder, but usually cries for help from people overwhelmed by pressures or conflicts in their lives. When such conflicts are discussed and resolved, the "ataques" often go away.



Pedro Ruiz, MD

In his over 40 years as a psychiatrist, Ruiz, Medical Director of the UT-Houston Mental Sciences Institute (MSI), has discovered other such beliefs and behaviors

that, if not properly understood within a person's cultural framework, might look like and be diagnosed as psychiatric conditions. For example:

■ *Puerto Rican immigrants who are Pentecostals frequently reject the opinions of mental healthcare professionals who usually call their "visions" and "voices" psychotic disorders. For these people, these manifestations are religious practices.*

■ *A psychiatrist prescribes medications for a patient he has diagnosed with hallucinations, delusions or depression. But*

*the patient, who practices Spiritism, rejects that explanation and refuses the drugs. To him, these are not symptoms of illness, but very positive signs that he possesses a power called "mediumity," which allows one to help suffering people and predict the future. Because the psychiatrist did not understand the patient's culture, he or she has negatively impacted the patient's self esteem.*

■ *Nonverbal communication such as "talking" with one's hands or eyes and the use of mannerisms is very common in many cultures. Caregivers not of those cultures may misjudge the patient's verbal skills and label them as poor candidates for psychotherapy, thus depriving them of a very important therapeutic intervention, such as cognitive behavioral therapy.*

Obviously, concludes Ruiz, understanding a person's culture is paramount when providing mental health services.

It was a lesson that hit close to home for Ruiz, an immigrant from Cuba who studied medicine in France before emigrating to the U.S. Coming from an ethnic and cultural background different from the majority of North Americans, Ruiz was particularly impressed by these differences, and they have had a major impact upon his practice of psychiatry.

He has used his reputation as head of several important psychiatric organizations, including the American College of Psychiatrists and the American Association for Social Psychiatry, to promote the biopsychosocial diversity model among his fellow practitioners. It has become one of his main areas of professional focus, and much of his

own research has been in exploring the differences among ethnic groups in their response to psychiatric medications.

In the past few years, Ruiz has collaborated with Roy V. Varner, MD, HCPC Medical Director and Chief of Staff, on several published studies demonstrating that ethnicity and culture have important biological implications in the treatment of psychiatric illnesses.

Much of their work has centered around ethnopsychopharmacology—how persons of various ethnic and cultural groups respond to psychiatric medications—and they have demonstrated a number of differences between how certain medications for treating schizophrenia or major depression are tolerated differently by Caucasians, African Americans, Hispanics and Asians.

See "With Regard" on page 3



*Psychiatric technician Fatima Moreland in African dress celebrates Cultural Diversity Week at HCPC.*





## With Regard

Continued from page 2

“The fact that members of certain groups responded differently to medications based upon their ethnic background became an issue in psychiatry about 10 to 15 years ago, spurred on by advances in the field of neuroscience,” Ruiz says, “although such pharmacological differences were already known in other medical specialties.”

This spring the American Psychiatric Press published *Ethnicity and Psychopharmacology*, edited by Ruiz, as the latest volume in the *Review of Psychiatry 2000* series. The volume represents the first compilation in medical literature of current research on the topic.

The volume contains general comparative studies of pharmacokinetics and pharmacodynamics in the African American, Hispanic and Asian ethnic communities, including, “Ethnopsychopharmacology in the Public Sector,” by Varner in collaboration with Ruiz and HCPC’s David Small, MBA.

Based upon retrospective studies of data from the HCPC Pharmacy about dosages of medication given to patients when they were discharged, the group’s studies looked at dosage levels of both the older tricyclics and newer SSRI antidepressants given to patients diagnosed with major depression, and dosages of both the typical and atypical antipsychotics given to patients diagnosed with schizophrenia. Some of these findings had been reported earlier in *Psychiatric Quarterly*.

For patients with major depression, their

findings indicated that, adjusting for weight differences and length of stay among the patients, Caucasian patients required higher dosages of the tricyclic antidepressants than African Americans to obtain the same level of clinical response, corroborating earlier findings by other researchers. The same was found, although less conclusively, for the newer SSRIs, which had not been studied before in this population.

For psychiatric patients with schizophrenia, the study found that, while Caucasian and African American patients required about the same dosages of the typical (older) antipsychotic medications to obtain similar levels of clinical response (contradicting earlier published studies),

Hispanics required a much lower dosage than Caucasians or African Americans. At the time the study was conducted, these were the first findings reported regarding Hispanics in the medical literature.

With regard to the atypical antipsychotics, results for each ethnicity varied with the specific medications. African Americans seemed to need higher doses of clozapine than Caucasians. Both African Americans and Hispanics needed higher doses of olanzapine than Caucasians, while Asian Americans required a significantly lower dose of olanzapine than any of the other three ethnic groups.

Hispanics required less risperidone than

either African Americans or Caucasians.

HCPC attending physician, Nurun Shah, MD, herself an immigrant, adds to Varner’s findings. “In general, most Asian ethnic groups have slower metabolisms than Caucasians or Africans, and people of East Asian extraction (China, Japan) have a slower metabolism than people from South Asia, needing one-half to one-third the dosage of a medication to avoid severe side effects. Drug interactions are also a much more serious issue among this population.”

Varner says his group’s findings are very preliminary and he hopes to expand such studies. “They represent an important breakthrough in ethnopsychiatry because they are studies of a public sector population,” he says. “It is primarily in this sector, at places like HCPC, that multicultural and multiethnic populations tend to receive their psychiatric care.”

“The recent advances in ethnopsychopharmacology are beneficial to the U.S. as it becomes increasingly pluralistic and multiethnic,” agrees Ruiz in his Afterword to the volume.

But Ruiz stresses that ethnicity and biochemistry are only part of the equation. The impact of one’s culture—the customs, language, belief systems and social organization of any group of people—plays a significant role in the treatment of mental illness.

Culture also defines the way people think about such attributes as intelligence, competence, illness and health. As illustrated so well by the examples above, a manifestation one person sees as a symptom of illness, another person takes as a sign of total health.

For years the mental health profession in the United States has defined its diagnoses for mental illness based upon a certain baseline—mostly from the white European-American perspective. While differences in religious or ethical frameworks were taken into consideration, ethnic and other cultural differences that might keep a patient from reaping the benefits of therapeutic intervention were ignored.

The tendency was to say that all manifestations of mental illness are

Continued



Helen Café-Urtal, RN, models her native Philippine dress.

## With Regard

Continued

the same no matter the ethnicity or culture. However, as the National Institute of Mental Health noted in the 1995 report of the National Advisory Mental Health Council: "Several generations of research make it quite clear that however universal broad categories of mental illness may be, the patterns of onset and duration and even the nature and clustering of specific symptoms vary widely across cultures."

"When I came to this country and began the process of adapting to the culture here, I had some insights which initiated my interest in cross cultural psychiatry," says Ruiz. "I became very aware of how multiethnic and pluralistic U.S. society was." Practicing first in Miami, then 15 years in New York City, and for the last 19 years in Houston, Ruiz has worked with a "melting pot," including both immigrant populations and native-born Americans from a variety of ethnic backgrounds.

"In treating these patients," he says, "I began to see that when I didn't pay attention to the cultural aspects of the patients lives, it would often have negative results on the psychiatric

services I was trying to provide them. These realities helped me understand how cultural backgrounds have a major impact on the patients themselves as well as upon those trying to provide care for them.

"I'm not only talking about Hispanics, African Americans or Asians when I talk about cultural considerations and aspects of psychiatric diagnoses and treatment; I'm talking about all ethnic groups, like the Irish, Germans and Polish. Each of these ethnicities and cultures has its individual characteristics that go beyond the issue of healthcare."

UT-Houston colleague, Kathy Scott-Gurnell, MD, an African American psychiatrist who works with adolescents at HCPC, agrees completely, citing how vital it is when working with African American children to understand the culture and structure of their family systems.

"It's very important to pay attention to the African American family's hierarchy," she says, "especially the extended family." For example, she cites the importance of the matriarch in the black family. "The strong black grandmother is often the core of her family. Contrary

to the usual stereotype, she is not controlling or causing conflict. The other members of her family respect her as a wise counselor who is always there to protect the family. She is usually very open to any kind of help her children or grandchildren may need, but not for herself. Her whole purpose is to take care of people, so for her to seek help and look at her own problems is almost impossible," says Scott-Gurnell.

She cautions mental health caregivers not to accept stereotypes; for example, an unwed, teenage mother is not necessarily doomed to a troubled future. "We need to look further, into the extended family, and identify the strengths. Many times we will find a nurturing system of family and friends, which although it may not look like the 'traditional' family, is just as supportive of that young mother and her child."

It is also important to understand African American child rearing customs. "Many African Americans believe that a 'strong hand now will save heartache later,'" Scott-Gurnell says. "It's a biblically based principle which often means these parents may use more physical means of discipline.

See "With Regards" on page 23

For "A Taste of Nations" HCPC Psychiatry Residents Ateka Zaki, MD, Ajay Major, MD and Sreelatha Pulakhandam, MD, (2nd from right) joined Chandrika Vadagama, RN (center) and case manager Hasu Patel, MSW (right), in providing foods from South Asia.





# Maze of Discoveries

*On any given day Dr. Peggy Pazzaglia might be . . . overseeing a drug trial for a new anticonvulsant medication for use with psychiatric patients . . . tracking a family history of bipolar disorder over several generations . . . designing a research project to help victims of the street drug “fry” recover their language abilities . . . probing the physiology of nerve cells to understand how calcium affects brain functioning . . . studying the effects of stimulants and alcohol in animal subjects . . . working to define the differences between ADD (Attention Deficit Disorder) and other disorders with similar symptoms or the differences in populations with a dual diagnosis of mental illness and substance abuse . . . all in addition to treating her patients at HCPC.*

**H**er interests and the research which grows out of them are diverse but they are all connected by Pazzaglia’s curiosity about how the human brain works and her over 20 years experience in studying, treating and researching patients with bipolar disorder (manic depression).

Her work is complicated. “It’s difficult to explain what I’m doing because it’s all looped together,” she says.

Last fall, Pazzaglia brought one part of that loop full circle when she returned to her hometown and the institution that nurtured her, becoming an attending physician at HCPC and conducting research with her one-time mentor, Alan Swann, MD, a professor in the UT-Houston Medical School Department of Psychiatry and Behavioral Sciences and vice chair for research at HCPC and the Mental Sciences Institute (MSI).

“My background interests in medical school were in neurology and endocrinology and their relationship to the neuroimmune system,” says Pazzaglia, “but I was also drawn to the field of psychiatry, and then I figured out I could study these two areas with psychiatric patients.”

After graduation from the UT-Houston Medical School in 1978 and completing her residency at HCPC, Pazzaglia packed her bags and headed to the center of brain research in this country, the National Institute of Mental Health, outside Washington, D.C., where she worked in the field of neuropsychopharmacology (study of the effects of drugs on mental illness)



*Peggy Pazzaglia, MD*

and biological psychiatry. After several years there, she was invited to set up a research division combining the work of the psychiatric and pharmacology departments at the University of Mississippi Medical School.

But Texas was home and the chance to work with Swann, who has also specialized in researching the causes and treatment of bipolar disorder, lured her back.

Pazzaglia has always been involved in looking at the role of calcium in the functioning of nerve cells and has spent much of her career determining the effects of calcium in brain chemistry and psychiatric illness, specifically bipolar depression and substance abuse.

“My own personal bias, after hav-

ing worked with Dr. Swann” she continues, “was that secondary messengers in the brain, like calcium, were the key actors in cell communication, and if you really wanted to find out what was happening you had to go inside the cell machinery.”

Pazzaglia uses a simple example to explain how secondary messengers work: “When one nerve cell sends a message to another, via a neurotransmitter chemical, the cell receives the message when the chemical ‘parks’ on a neuroreceptor—like a plug in a socket. Once the neurotransmitter (plug) is connected to the neuroreceptor (socket), there is a completed ‘circuit’ that creates chemical molecules called secondary messengers. These secondary messengers produce additional changes to the cell by carrying a ‘chemical message’ of what the body needs.”

Pazzaglia’s curiosity about calcium stems from one of her chief scientific maxims: “If something in the human body is really important there will be a lot of mechanisms to regulate it. Calcium has a billion; it has a very complicated physiology. It communicates within and between cells; no neurotransmitters can get released into the next neuron without the action of calcium.

“All the currently approved medications used to treat bipolar disorder have calcium effects, and we know that people with diseases which cause a dysregulation of calcium, such as hypo- or hyper-parathyroidism, have symptoms resembling those of bipolar disorder,” she says.

“There are also rhythmic waves of calcium inside certain populations of brain cells which are used to communicate from one side of a cell to the other side of the same cell, and to generate rhythmic oscillations thought to be involved in certain hormonal release patterns.”

So, Pazzaglia has spent much of her career determining the effects of calcium in brain chemistry and psychiatric illness, specifically bipolar depression and substance abuse.

Beginning in the mid-1980’s, clinical reports and evidence from small,

*Continued*

randomized clinical trials suggested that calcium channel blockers (drugs usually used in treating high blood pressure) might have effects on mania in patients. Pazzaglia studied the effects of calcium channel blockers in patients with affective disorders, such as bipolar depression.

"We know from some of the studies I have done," she says "that these medications can block the high of alcohol consumption. However, the doses needed for psychiatric effects are much higher than typically used for hypertension. We also know that calcium is involved in cell death in the brain, for example, when a person receives a head injury or has a stroke, some of the damage is a direct effect of the blow or in the case of stroke, oxygen and nutrient starvation, but many of the surrounding cells are killed by increased amounts of surrounding calcium when the dying cells burst open and release their calcium into the surrounding tissue.

"My current plan is get permission to test two of these drugs—nimodipine (currently FDA-approved for treatment of certain kinds of strokes) and isradipine (FDA-approved for treatment of hypertension)—as novel treatments for adults who have bipolar disorder and their children.

"I want to determine if I can regulate the calcium in the cells of persons with bipolar disorder," she says, explaining that both of these medicines have very good anti-convulsant qualities and have been shown to prevent the overflow of dopamine (a neurotransmitter whose effects are increased by either cocaine or amphetamines when given to animals).

Two different phenomena she observed while treating patients gave Pazzaglia the impetus for testing these medications' effectiveness.

Although no specific gene for bipolar disorder has been found, most practitioners believe it is hereditary, based upon findings showing children with parents or siblings with bipolar disorder are 24 times more likely to develop bipolar illness, compared to the children of parents without the disease. "Research on bipolar disorder

See "Maze" on page 25

# DOUBLE TROUBLE: What is Dual Diagnosis?

*Dual diagnosis is the condition of one person having two major psychological/psychiatric diagnoses; most often it refers to a person who has a mental disorder, such as bipolar depression, and also a substance abuse disorder (drugs, alcohol, other addictive substances).*

*A person with a mental illness is three times more likely to have a substance abuse problem than a person with no mental illness; conversely, someone who has an addiction to substances is four times more likely to develop a mental disorder than someone who does not. At HCPC, over 30 percent of the patients are discharged with a dual diagnosis.*

*Well over 50 percent of those with bipolar disorder (manic-depressive illness) also have a substance abuse disorder; this is two to three times higher than the rate of substance abuse for those with depression.*

*It is believed that most mental and substance abuse disorders stem from certain biological and physiological risk factors that may arise from genetic or environmental causes. Heredity (genetics) plays a major part in the cause of several mental illnesses, such as bipolar disorder. Although it is highly suspected, no specific genetic link has been uncovered for substance abuse.*

*Sometimes the mental illness may precede the substance abuse; sometimes the substance abuse disorder precipitates mental disorders through alteration of the brain chemistry. Whichever occurs first, the outcome for patients who have a dual diagnosis is much worse than for those who suffer from either one or the other condition.*

*People with a dual diagnosis usually fit into one of these categories:*

1. Severe/major mental illness and a substance disorder.
2. Substance disorder and a personality disorder.

3. Substance disorder and personality disorder with substance induced acute symptoms that may require psychiatric care, i.e., hallucinations, depression, and other symptoms resulting from substance abuse or withdrawal.

4. Substance abuse, mental illness, and organic (such as brain damage) syndromes in various combinations. Organic syndromes may be a result of substance abuse, or independent of substance abuse.

*It is often difficult to separate the behaviors caused by a mental illness from those caused by substance abuse, but it is suspected that the presence of a mental disorder creates a physiological risk for development of a substance abuse problem.*

*Often, people will go undiagnosed for a mental disorder—it can look like a behavioral problem or a personality quirk—and when they are exposed to drugs (through "recreational" use) they find that the drugs make them feel better by relieving the anxiety or depression for the short term. Those who are already diagnosed with a mental disorder may abuse substances for the same reason or to alleviate the side effects of medication they may be taking for their mental illness. In all cases, substance abuse makes the psychiatric condition worse.*

*Like a psychiatric disorder, substance abuse is also a disease of the brain; addictive behavior is the manifestation of abnormal brain functioning. In addition, the use of substances like cocaine and alcohol can alter the brain's chemical functions and bring on psychiatric problems such as anxiety disorder, depression and even psychotic behaviors. ★*

*Excerpts above reprinted from Sciacca, K. "An Integrated Treatment Approach for Severely Mentally Ill Individuals with Substance Disorders," New Directions for Mental Health Services, No. 50, 1991, and the Dual Diagnosis Website at <http://users.erols.com/ksciacca>; search for programs at <http://cgibin.erols.com/ksciacca/cgi-bin/db.cgi>.*





# Cancer's Ill Will

Just 50 years ago, cancer was something to be whispered about. There were very few successful treatments and little hope for someone with the disease.

Today, many patients diagnosed with cancer can be optimistic; new discoveries and treatments have allowed people to live productive and long lives despite their disease. "The overall death rate for cancer has gone down and people are living much longer; it has become more of a chronic disease," says Alan Valentine, MD, associate professor of psychiatry in the Neuro-Oncology Department of UT-M. D. Anderson Cancer Center.

But a diagnosis of cancer can still be devastating—devastating enough to cause people to develop emotional difficulties, most often depression. Depression is also a common complication of certain kinds of cancer treatment and of the disease itself.

"The rate for diagnoses of depression in cancer patients, including adjustment disorder with depressed mood and major depression, is between 20 to 25 percent," says Valentine.

In most cases, Valentine and other experts agree, the depression can be successfully treated, but early intervention is important because depression adds to a patient's suffering and interferes with his or her motivation to engage in cancer treatment. "The problem is the mind-body connection," he says, "when a person's quality of life deteriorates they may lose the will to fight, physically and psychologically, the disease."

Unfortunately, too often the symptoms of depression in cancer patients are dismissed or overlooked by the patients themselves, who may be too ashamed to admit they have an emotional problem. And despite advances, the public remains fairly ignorant about cancer and myths abound: depression in a person with cancer is normal, treatment does not help, and everyone with cancer faces suffering and a painful death. The isolation and discrimination that cancer

patients suffer from family members and employers serves to exacerbate or possibly trigger feelings of worthlessness. Patients face a double stigma of cancer and mental illness.

No one would question the fact that a diagnosis of cancer dramatically alters one's life. It is common, therefore, for people who have been recently diagnosed with cancer (or any other catastrophic illness) to experience "reactive" depression, a period of a few weeks where they may go through some of the classic stages of grief, such as denial, anger, guilt, sadness and loss.



*"My Picture," 16-year-old female victim of cancer, physical illness, 1997.*

"A whole range of psychosocial stressors are attached to a diagnosis of cancer," Valentine says, "the first being the possibility that one is going to die, which in some cancers is a very real consideration.

"In addition, there are major lifestyle changes which cause special stress: the burden of being sick; dependency issues, such as loss of income or ability to care for one's family; loss of independence and becoming a 'burden' financially or physically; issues of body image and physical ability; and crises of faith and

spirituality, which are usually centered around issues of death and dying. These are normal parts of the adjustment process to a diagnosis of cancer.

But when the sadness and loss continue and develop into feelings of unworthiness, inadequacy and hopelessness, and the patient is unable to resume normal activities it has moved from the area of reactive to major depression.

"Some caregivers," says Robert Guynn, MD, HCPC Executive Director and an expert in the treatment of depression, "just see the depression as part of the cancer, or if they do recog-

nize it as something different, they dismiss the need for psychiatric care because it is 'normal' for people with cancer to feel bad. And there is also this rather bizarre belief that if you are depressed for a good reason, then it is a 'good depression' and you don't really need treatment."

"Nearly half of patients diagnosed with cancer," Valentine says, "will meet the criteria for at least one diagnosis of a psychological problem; some of these are much more serious than others. If the patient is coping

*Continued*

## Cancer

*Continued*

well, that's great; but when that emotional problem interferes with a patient's ability to participate in his or her cancer treatment, seriously impairing quality of life, family life or work, it should be treated. We can make it much more tolerable."

The symptoms of depression in cancer patients are the same as those for depression in the general public: excessive sadness and crying, loss of appetite, sleeplessness or sleeping too much, inability to concentrate, loss of interest in usual activities, feelings that life is not worth living. Sometimes the depression will manifest itself as anger or extreme irritability. In addition, depression and cancer have several symptoms in common such as weight loss, sleep problems and lack of energy.

Reaction to the diagnosis of cancer isn't the only trigger for depression; there are some cancers, most notably pancreatic cancer, in which depression is considered a function of the disease. Depression and other serious mental disorders are also by-products of cancer which has spread to the brain or nervous system.

"The field of psycho-oncology," Valentine says, "is only about 30 years old and because there are so many overlapping symptoms and conditions which can be attributed to the cancer, its treatment or the depression, it has been difficult to assess."

Often, the prescribed treatments—surgery, radiation, medications—for the disease, especially some of the chemotherapies, are also major causes of depression in cancer patients. Valentine's own research work is in this area, looking at Interferon, which is used to treat some cancerous tumors and Hepatitis C. "Interferon knocks out the body's thyroid function, which is very important in mood disorders," he says. "In addition, it disturbs the pituitary-adrenal axis and releases other cytokines (biologically active hormones that have positive and negative effects on cell reproduction), which have been linked to primary psychiatric disorders, especially schizophrenia."

Other cancer treatments, such as those which suppress the immune system, reduce the body's ability to fight off disease and make the person weak and vulnerable to infections.

"Corticosteroids, which are ubiquitous in cancer treatment, are an occupational hazard for psychiatrists," Valentine says. "We have to use them, but they are notorious for neuropsychiatric side effects. While the final biological cause is still up for debate, we do know that cortisol metabolism is often altered in patients with depression and when you give people high doses of steroids, depression may follow."

Patients with a progressive form of cancer will often develop major depression as they become increasingly incapacitated and unable to care for their families or hold a job. "Patients come into the hospital and tell you they are sick of being sick," says Valentine.

There is another often-overlooked cause: unrelieved pain from both the illness and its treatments. "Many of these tumors hurt," Valentine says, "and we have studies that have shown that patients who rate their pain as very high, have a depression rate twice that of cancer patients who report low or moderate pain." Medicine is doing a better job of pain management now, he says, although some doctors are unwilling to prescribe medications for the pain and there are patients who falsely believe that they'll become addicted to the psychiatric medications.

In two of the most common and deadly adult cancers—breast and prostate cancer—there are secondary outcomes, concerning body image and sexuality, which may make these patients even more at risk for developing depression.

The loss of that part of a woman's anatomy which our culture has so closely associated with beauty, femininity and sexuality can be devastating; as is the potential loss of a man's sexual functioning or the possibility of infertility. For many men, the specter of urinary incontinence as a by-product of treatment can be as distressing as that of impotence and can cause

them to avoid any social situations.

Certain treatments for both these types of cancer can also be responsible for causing mental distress. Breast cancer treatments that disrupt estrogen levels—which includes the drug tamoxifen and other chemotherapies—have recently been discovered to increase a patient's risk of developing depression. In reducing the amount of the hormone estrogen, these treatments cause physical symptoms related to menopause and precipitate major depressive disorder.

In men diagnosed with prostate cancer, the depression is often triggered by loss of libido, impotence and urinary incontinence caused by surgical, radiation or chemical treatments. Even in newer treatments, where there is only temporary impotence, fear that one's sexual functioning will not return can cause depression. Valentine also says that depression is associated with certain hormonal therapies used in severe cases of prostate cancer.

Men who want to avoid surgery for their prostate cancer may become overly concerned about their PSA test. PSA, a protein found in prostate cells, can be measured and currently provides the most accurate test for the disease. Such patients may experience great anxiety while waiting for their PSA score and seek multiple tests to come out with a better reading.

Among the main difficulties in successfully treating the depression associated with prostate and breast cancers are societal and religious taboos about issues of sexuality, which make it difficult for many men and women to discuss the illness and its consequences with their loved ones or even with their physicians. This inability to communicate can distort patients' understanding about their illness and the treatments available, as well as isolate them emotionally from those who might provide support, thereby exacerbating the depression.

But if it goes untreated, the depression itself can create a downward spiral by producing behavior that reinforces the patient's negative self-image. The prostate cancer patient

*See "Cancer" on page 27*





*The Otter goes to the King* and says, "My children are dead and I demand vengeance." "Who killed them?" asks the King. "The Weasel!" the Otter replies.

So the King calls the Weasel before him and says, "You have been charged with the death of the Otter's children. How do you plead?" The Weasel replies, "I'm responsible, but it was an accident. The Woodpecker sounded the danger alarm and when I rushed to defend my land, I accidentally trampled the Otter's children."

The King calls the Woodpecker who says, "Yes, I did sound the danger alarm but I did it because I saw the Scorpion sharpening his dagger."

The King calls the Scorpion and says, "You realize, Scorpion, that sharpening your dagger is an act of war?" And the Scorpion says, "Yes, but I was only sharpening my dagger because I saw the Turtle polishing his armor."

"Yes," the Turtle says when called before the King, "I was polishing my armor, but I did it because I saw the Crab preparing his sword."

The King calls the Crab, who says, "Yes I was preparing my sword because I saw the Lobster slinging his javelin." And when the King calls the Lobster, the Lobster says, "Yes, I was slinging my javelin, but that was because I saw the Otter swimming after my children to devour them."

So the King turns back to the Otter and says to him, "You are the guilty party!"

*Illustration by Alycia Matthews*

**H** CPC Chaplain Swindell Hodges believes this old folktale has a lot to say to us as human beings living together, all seeking happiness and fulfillment.

That's why he uses it to help HCPC patients understand how spirituality can help them deal with anger and depression. In a new interdisciplinary approach, Hodges and HCPC counselors have added lessons on spirituality to their anger management therapy groups, with the ultimate goal of helping patients improve their behavior.

Patients who have problems controlling their anger are referred to HCPC anger management groups by their physicians or treatment teams. Anger is just one of several psychosocial issues addressed by members of HCPC's Patient Clinical Programming (PCP) staff of social workers and licensed counselors. In daily groups they provide coping skills, education, supportive therapy and group activities to help patients learn to handle their illnesses and make successful transitions from the Center back to the community.

In the anger management sessions, patients learn to understand anger as a natural human emotion that can often result in destructive behaviors. They are taught how to recognize their own anger patterns and how one's thoughts or interpretations influence feelings which cause behavior.

Bringing spirituality into a group with anger problems may seem a bit chancy, but Hodges says recognizing one's spirituality and using it to transform negative feelings and behaviors

*Continued*

## Amazing Grace

Continued

to a more positive resolution fits perfectly with the goals of anger management. "Spirituality," he says, "comes into play when a thought turns into a feeling and how one interprets that thought and makes the critical decision of how to act or respond to the event."

Hodges, an ordained minister of the Louisiana Conference of the United Methodist Church, joined HCPC last fall after finishing his residency as a certified hospital chaplain at The Methodist Hospital in the Texas Medical Center.

In addition to his Chaplain's duties, Hodges regularly provides group sessions on spirituality for all patients as a member of the Clinical Programming department. But he wanted to do more to assist his colleagues and provide treatment and education options for patients.

"We decided to join forces to see where the Chaplain's spirituality work might fit best into our programs," said HCPC social worker Randy Gold, LMSW. "That seemed to be in our anger and depression management sessions, where we use a cognitive behavioral approach and where his spiritual dimensions offered our patients alternatives to self-defeating behavior," says Gold. "Now they have a tool to use when they are deciding how they will react to an event."

Hodges defines spirituality as "making meaning," adding that "the spiritual part of a person is where he makes interpretations, sets his values, gets in contact with a Higher Power, has relationships with others, experiences creativity—in other words, makes meaning out of all those things that are not black-and-white in one's life."

"It is not just about religion or going to church," he adds. "Spirituality is a much broader concept, but hopefully one's religion is an aspect of it, and one that we try to help our patients focus on in a more therapeutic manner. Many of our patients can become troubled because of hyper-religiosity; we work to bring

their religious ideations into an area where they can actually help them."

While many mental health professionals have not been eager to embrace the concept of spirituality into their practices, Hodges says that is changing. He cites psychologist Kenneth Pargament's book, *The Psychology of Religious Coping*, as a major influence that has put spirituality into the language of psychology. "More and more psychological research has shown that part of our makeup as human beings is a spiritual dimension," Hodges says.

He has developed an easily adaptable learning module which he has been able to incorporate into the anger management therapy strategies used by Gold and his fellow HCPC counselors, one of whom is Priscilla Cleaveland, a Licensed Professional Counselor (LPC).

Each week, Hodges joins Cleaveland for the fourth day of her weeklong anger management sessions for patients on Unit 3C. "Adding the spiritual dimension helps patients experiencing painful feelings like anger, agitation, or upset," Cleaveland says, "showing them how they can choose behaviors with more positive long term consequences instead of just acting impulsively without regard to themselves or others."

Typically, during the first three days of her group, Cleaveland leads patients through lessons where they learn that anger has both negative and positive aspects. She teaches them how anger develops and gives them behavioral strategies they can use to calm down. They learn how changing their thinking patterns can alter their feelings and change their behavior.

In a recent session with Hodges, Cleaveland begins by explaining the "circle" of event-thought-feeling-behavior to help patients understand how thoughts influence behaviors. "First," she says, "there is the event; something happens in the environment (your boss chews you out). This event triggers thoughts or interpretations of the event (he is a rude bully). These thoughts cause feelings about the event (anger), and the feelings cause a behavior or action (yell back at the boss), which in turn begins the cycle again."

Hodges jumps into the discussion:



Chaplain Swindell Hodges listens as counselor Priscilla Cleaveland explains the cognitive behavioral cycle—in which an event triggers a thought, causing a feeling, finally facilitating a behavior—during her anger management group.



"It is at the crucial step," he tells the group, "where thoughts and feelings come together and we make critical interpretations of the things that happen to us, that we can use our spirituality." Spirituality, he tells them, includes their belief systems, morals and ethics, and is very important in how people decide to react and respond to different events in their lives.

"When I ask patients to talk about their own spirituality," Hodges says, "there is really no right or wrong answer. I want them to focus on where they are with their own spirituality and then realize that this is not just an auxiliary in their lives but an important part of themselves that they can tap into."

See "Amazing Grace" on page 28





# Handling with Care

*Mr. \_\_\_\_\_, a new patient at HCPC, is agitated and on edge. He's been pacing for several minutes, talking to himself. Suddenly, he wheels around and looks threateningly at Ms. \_\_\_\_\_, one of the psychiatric aides. "I don't need to be here!" he screams at her, calling her an uncomplimentary name.*

*Ms. \_\_\_\_\_ is neither surprised nor frightened by this patient's behavior. She has been watching him for several minutes, noticing his increasing agitation. She knows he was admitted non-voluntarily. She knows his diagnosis is paranoid schizophrenia. She knows that he is angry, afraid and alone.*

*And Ms. \_\_\_\_\_ also knows how to respond to this patient in ways that will prevent him from acting out any further. Her poise comes from her own knowledge about mental illnesses, her compassion for those who suffer from them and from a set of therapeutic patient management guidelines that she has learned in order to support the caregiving mission of the hospital.*

This patient management program is one of the main reasons UT-HCPC has maintained a model record among psychiatric facilities in patient safety and the safeguarding of patients' rights. Familiar to all staff who work directly with the patients, this program is designed to protect all concerned: other patients, staff and the acting-out patient. Based upon respect for the patient, its techniques allow a patient to maintain his dignity while not hampering any ongoing treatment progress.

## DIFFUSING DIFFICULTIES

When persons with acute mental illness, such as the patients at HCPC, are ill enough to need hospitalization they often lack the ability to reason correctly or control their impulses, and their behavior may become angry and aggressive. HCPC's psychiatric aides ("techs") and nurses are trained specifically to deescalate such situations before they become dangerous. They learn how to protect such patients from harming themselves or others.

"Specific verbal and behavioral strategies and 'milieu (environment) management' techniques are always the first line of response when a patient's actions threaten harm to themselves or others," says Arslee Mackey, RN, MEd, director of Nursing Operations at HCPC. "When the safety of the patient, other patients and

personnel is compromised, these personnel rely on specific nonviolent, physical intervention techniques."

All accredited behavioral healthcare facilities are required to have specific patient management guidelines. At HCPC, all new staff, whether they will work directly with patients or not, receive some patient management training in crisis intervention.

"Prevention," says HCPC Director of Nursing, Susan Grice, RN, DNSc, "is the whole purpose of this patient management program. That is why we train all staff, and provide intensive and ongoing training for our direct-care staff. We want our staff to be competent and confident in their roles and we want them to be pro-active and not reactive to patients in distress."

At least 12 hours of training in patient management a year is required of each HCPC staff member who is involved in direct patient care—nurses, techs, social workers and counselors. This includes instruction in "Crisis Prevention Intervention" (CPI), as well as "Handle With Care," a physical intervention program.

CPI is a blend of psychology, behavior management, safety procedures and verbal skills in which observation and intervention are both key.

"Observation," says psychiatric aid Horace Holness, an 11-year HCPC veteran, "is the chief part of the job of a psychiatric tech." Holness also serves as chief trainer for all HCPC staff,

working under the HCPC Department of Hospitalwide Education.

"In its simplest description, milieu management means watching what's going on—not unlike the mom who has eyes in the back of her head," he says. "If it is done correctly, this most crucial jobs goes virtually unseen."

But there is nothing simple about this work; each day presents a new challenge to create and maintain a healing environment, a place where there is support, where there is safety, where there is true caring and where restoration of one's self can begin.

It involves an almost seamless operation in which nurses and techs are constantly in touch with and maintaining the mood of the patient unit. Both nurses and techs monitor the milieu, and techs are strategically positioned in the day area to observe and interact with the patients. Each half-hour, a quick check with a patient or visit to a patient's room is made to assure that no one is in trouble.

The techs assigned to HCPC's patient care units (generally, three during the day shift, two in the evenings) must become expert at working with the nursing staff to keep the milieu on the patient unit calm, safe and therapeutic for all the patients. Depending upon where the patients are at any particular time—in their rooms, in the day area, off the unit at groups or recreation breaks—the techs position themselves physically so they can observe and therapeutically interact with the patients.

"The main part of our work involves watching," Holness says, "and being with the patients so that they come to know and trust us. Generally, we are the staff members who spend the most time with the patients. If we have done our jobs properly, when a patient leaves they will see us as a friend, even a family member."

When a tech or a nurse observes a patient who is becoming agitated or aggressive, they use the CPI techniques to intervene. CPI techniques teach that each crisis has levels of escalation and the appropriate responses to be taken at each level, including physical intervention, if needed. But the

*Continued*

## Handling with Care

Continued

underlying philosophy is that physical measures are used only as a last resort and that most situations can be deescalated through supportive and direct intervention.

In responding to patients, such as Mr. \_\_\_\_\_ for example, the caregiver's intent is to assure the patients that he or she is "on their side," to listen and to empathize. In approaching the patient, the nurse or tech must be aware that he or she is communicating nonverbally as well as verbally, be careful to respect the patient's personal space and check any gestures or facial expressions that might further upset the patient.



Members of HCPC's Special Team "special team" of trainers (left to right) Horace Holness, Renita Tillman and Jimmy Thomas, have a combined half-century of experience in working with psychiatric inpatients.

The caregiver will begin to calmly talk with the individual, making sure his or her tone is one that consoles rather than demands. The objective at this point is to gather information, listen to the patient and, finally, in a direct but non-punitive fashion, ask the patient to change his or her behavior.

The skill with which many techs practice this routine intervention does not minimize its profound importance—it is at this level that the situation can either be resolved or worsened.

When talking with a patient who is exhibiting "challenging" behavior, Holness says it is important to first clarify "why" they are exhibiting such

behavior and then try to help them reason to a less threatening stance.

"I have to caution new trainees," he says, "that the word 'rush' will get them in trouble when dealing with an angry patient. Listening is sometimes all a patient needs," he says, "because the verbal acting out is really the patient asking for help. They may realize that they are getting out of control and if we offer our ears and give them attention, it will help them change their behavior."

How something is communicated is often just as important as the message. Paraverbal communication includes the tone or inflection in the voice, the volume and the rate or rhythm of speech. "You want to be consoling and not demanding," says Holness, "because it conveys your

ization also have severely diminished capacities for reasoning, reality testing and impulse control, and are more likely to exhibit more threatening behavior."

"It's important at this point," says Holness, "for the tech or nurse to keep talking to the patient, explaining to him that we are on his side, that we respect him, but that we don't like his behavior."

The nurse or tech must create a situation in which the patient does not feel intimidated or threatened, he explains. Remaining as rational as possible, they should clearly explain to the patient why his or her behavior needs to be modified, and set reasonable limits to do that; the patient must realize that the consequences of his behavior are up to him.

"It's very important to practice 'rational detachment,'" Holness says, "because patients may say things to you that will really push your buttons but you can't take it personally. These people are ill and this is the manifestation of their illness. I always tell employees, 'You need two 'bags,' personal and professional, and when you come to work, you leave the personal bag at home.'

"But if the situation begins to escalate," Holness says, "the staff member will use certain nonverbal techniques to maintain contact with the patient while alerting other staff to what is going on." The caregiver assumes the "supportive stance," positioning himself in an L-shaped angle of about two to three feet from the patient. This gives the patient the non-verbal message that he is being paid attention to. "It communicates respect, but also alerts other staff and assures the safety for patient and staff if physical restraint is needed."

### SECLUSION AND RESTRAINT

When a patient acts out in an assaultive manner and there is an immediate threat of harm, it may be necessary to use physical, non-violent means to keep the patient from hurting himself or others. Such techniques are designed to ensure the safety of the patient and the staff, constrain physical violence and help the individual regain control.

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## Handling with Care

*Continued from page 12*

Seclusion (isolation) and restraint (physical restriction of activity) are actions taken only as a last resort. The vast majority of psychiatrists, psychologists, nursing and other mental health personnel support their use for security and treatment—but never for discipline, coercion or staff convenience.

“The provision for seclusion and restraint to handle emergencies is necessary,” says Varner, “because, above all, we must protect all our patients. There have been reports of serious abuses of these procedures at other places, but they do not happen at HCPC.”

“Other means are always tried first,” Varner stresses. “In escalating cases some sort of verbal, non-violent mediation is attempted first and we try to calm a patient down. Sometimes a violent event unexpectedly occurs and in that case we seclude that patient to remove the danger to self or to other patients and staff.”

With society’s increasing—and proper—emphasis on protecting the civil rights of all vulnerable populations, especially as they relate to issues of safety of society as a whole, the use of seclusion and restraint has become a much-debated issue.

Over the past year, both the U.S. Congress and HCFA (Health Care Finance Administration), the government agency which administers Medicare and Medicaid, have introduced various legislative or regulatory proposals that would govern the use of seclusion and restraint. In addition, JCAHO (the Joint Commission for Accreditation of Healthcare Organizations), the nation’s independent accreditation agency for health-care institutions, is currently in the process of revising its standards for the use of seclusion and restraint. HCPC participated in the JCAHO national survey, which asked institutions their reactions to the inclusion of all the HCFA standards in the JCAHO standards.

All these regulatory bodies agree that seclusion and restraint are emergency safety measures to be used sparingly and with great prudence and

sensitivity.

They also demand that such restrictions be used only and after appropriate non-physical interventions have been tried and under the written order of licensed independent mental health practitioner, usually a physician, who must specify length and type of restraint.

Amidst this reform, HCPC finds itself not only in complete compliance with the proposed regulations, but actually “ahead of the curve.” It, too, has been busy revising its own standards (as required under the Texas Administrative Code) to ensure compliance and reflect the most current treatment methods.

“The main point of the new JCAHO recommendations is to limit the use of seclusion and restraint as much as possible in facilities such as ours,” says Mackey. “This is something we at UT-HCPC have already implemented. Although acutely ill patients, such as those treated at HCPC, may more readily require seclusion or restraint, HCPC requires such interventions with less than 10 percent of its patient population, most of them being time-limited seclusions.”

HCPC regulations stipulate that seclusion of a patient can only be instituted by a doctor (or registered nurse in an emergency) and only after other, less restrictive, alternatives have been tried, such as modifying the patient’s environment by suggesting he move to another part of the unit or removing sensory stimuli such as music or television, or talking with a patient to help redirect their focus or calm them verbally.

Texas state law mandates that while an appropriate mental health professional, such as a nurse, may begin the act of seclusion or restraint, only a “licensed physician” can actually write the order for such treatment.

HCPC also already meets the requirements of the proposed regulations by requiring a physician to actually see patient who has been secluded or restrained within one hour of the actual event. Because HCPC is a licensed public teaching facility, there are physicians present all day and this regulation can always be observed.

Patients in need of seclusion are always told why they are to be secluded, for how long, and what kind of

behavior they must display for release. They are escorted to a special seclusion room on the patient unit. “The idea is not to punish, but to provide a non-stimulating environment in which he or she can regain composure,” says Mackey.

“An order for the seclusion of an adult cannot go beyond four hours, but very rarely do we have an adult patient who is secluded longer than two hours,” she adds. Patients are observed every 15 minutes, and those who have been given medications have continuous observation by a specific staff member. Their need to use the bathroom or for food or drink are assessed at regular intervals.

“We use very little physical restraint at HCPC,” says Varner. “And if we administer a medication to a person who is being secluded or restrained, it is to help them gain control of their aggressive behavior. Such an emergency dosage is usually the same principal medication he or she is currently being treated with,” he adds.

All seclusion and restraint treatments used at HCPC are required to be thoroughly documented, reported and discussed by the patient’s treatment team. The team also considers alternative strategies needed to control the patient’s behavior and the implications of notifying the family or significant others. If a patient has three or more seclusions or restraints during their hospitalization, his or her case must be reviewed by Varner, the Medical Director.

“When patients are admitted, we try to inform and educate their families that while the individual is a patient seclusion and restraint may be used in emergencies to protect the patient and others from harm,” Mackey explains. “We want them to understand that seclusion and restraint are treatment options and not punishment or revenge for bad behavior.”

And always, following a seclusion or restraint, she adds, there is a debriefing session with the patient, allowing him or her the chance to talk with staff and other patients about what has happened and to understand why such intervention was warranted.

*Continued*

## Handling with Care

Continued

### SPECIAL TEAM

The Special Team program is one of the core features of HCPC's patient management program, and one that assures an outstanding safety and protection record at the Center.

Each day at HCPC, a new Special Team roster of psychiatric techs and nurses are assigned (one from each unit, in rotation) to respond to any call



(Top) Horace Holness, chief HCPC trainer, shows new employees the “supportive stance.” (Below) Holness and trainer David Haywood (back, center) demonstrate safety moves to new staff members.

for help in handling a difficult situation. The Special Team provides support and appropriate verbal or nonviolent physical intervention to resolve the situation. In addition, ten techs and nurses have been selected as permanent members and function as trainers for the entire staff.

Holness, who is one of the ten, says Special Team is a necessary part of our patient care program. “When a

See “Handling with Care” on page 29

The following are comments from members of the HCPC Special Team Training Unit about their work. All have been psychiatric aides/techs for over a decade, several for two decades.

*“The techs are the eyes and ears of the unit. This is why it is so important for all of the techs to be out on the unit interacting as well as observing. Restraining a patient is to be performed only when all means of verbal intervention have been exhausted.”*

**Charles D. Powell**

*“I think my strongest asset is patience, which is something you really can't train a person for, but it can be learned over time. Some people watch us and mistakenly say we have an ‘easy job.’ I believe the ‘Three Cs’— competence, confidence, comfortable—are necessary for someone to be a good psych tech. If you are competent then you have confidence and you are comfortable doing your job.”*

**Jimmy Thomas**

*“I agreed to be part of the Special Team trainers because I want to pass on to my peers what I've learned about how to treat our patients. Our patients are the reason we are here and we should always go that extra mile to serve them. There is no better feeling than being able to provide the care that helps someone increase their self esteem and makes it possible for them to go home.”*

**Foday Daramy**

*“We are liaisons, advocates, the five senses of the unit. Open communication between the patients and the staff and the treatment team is essential. When new patients arrive, I don't make snap judgments based on diagnoses; I talk with them and get to know them as individuals.”*

**Renita Tillman**

*“I seem to be able to deal successfully with patients who are combative and very angry. I have a gift for drawing people out, finding those who need some attention and getting them to participate. When I do training, I stress the importance of these verbal techniques. Because I work on the triage unit, I am one of the first people patients meet here and if there is a Special Team I know them already and have a rapport with them, so they'll listen to me.”*

**Carlton Lockwood**

*“I see my role as being here for the patients, especially orienting them and calming their fears when they first come in. I accepted the Special Team training assignment because it offered me a chance to grow in my job and help others grow in theirs. I'm good at talking with people: If you start a conversation, I'll finish it.”*

**Ted McKenzie**

*“A tech should be able to deescalate most situations even before the patient becomes agitated by looking for certain signs. The next step is to be supportive, to ask them what's wrong. Most of the time they'll be receptive because someone cares. Techs spend more time with the patients than anyone, so I stress communication skills in training. I want to train new employees because these are the people who will work beside me and I will depend upon.”*

**David Haywood**





# Childhood

Courtesy of the Houston Museum of Health and Medical Science (HMMS), HCPC is proud to present selections (on this page and throughout **Progress**) from "Childhood Revealed: Art Expression Pain, Discovery and Hope," an exhibition which will be featured at the museum September 15 through October 12, 1999.

This traveling exhibition, initiated as a public awareness campaign to call attention to the 10 million children in the U.S. who suffer with mental and emotional problems, is sponsored by the New York University Child Study Center. The national tour began in November 1999 at the Whitney Museum of American Art and will continue through 2002.

"Childhood Revealed" features 102 works by children ages 4 through 18 who are in the midst of, or have coped with mental health issues such as abuse, depression, learning disorders, divorce, substance abuse and violence. The art includes drawings, paintings and sculpture and was chosen nationwide by a jury of artists and educators from submissions by 10,000 clinicians nationwide.

The exhibition is the centerpiece of an awareness and anti-stigma campaign, the National



"Three girls and a dog," 13-year-old female, 1998.



Untitled, 14-year-old female suffering from depression, 1993.



"Camouflaged," 18-year-old female, 1996

# Revealed

Child Mental Health Initiative, organized by the NYU Child Study Center. The Center is a multi-disciplinary group of professionals who work to improve the practices of professionals serving children, influence public policy concerning children and be a major source of information for all those who care about children.

An opening reception for the exhibition will be held on September 15 at HHMS, hosted by the Houston Psychiatric Society. Harold Kopewicz, MD, director of the NYU Child Study Center and the Division of Child and Adolescent Psychiatry at NYU and Bellvue Hospital, will be the special guest.

During this exhibition, the HHMS will be presenting special parenting lectures each week, a display of works by local children and hands-on art activities for children. Each Thursday, when the museum offers free admission from 4 to 7 p.m., there will be information booths from local children's mental health agencies and on Saturday, September 23, Museum District Day, the HHMS will hold special events for children throughout the day.

For more information, or to schedule group tours, please call the HHMS at (713) 942-7054.



Unidentified.



"Breaking Through," 15-year-old victim of psychosis and bipolar disorder, 1998.



"Heroin," female 16-year-old with depression, 1997-98.





# Responding to Placebo

*So plain, so simple and seemingly benign—yet the placebo is a perplexing prescription at the root of a puzzle of medical principles and scientific progress.*

Since modern medicine began early in the twentieth century, the use of placebos has been a common part of the research for the treatments for illnesses of all kinds, especially in the search for more effective drugs for illnesses.

Perhaps one of the most notable occurred in 1954 and 1955, when the Salk vaccine for polio was tested for its effectiveness on thousands of American school children in a large clinical field trial. While a random number of children received the actual vaccine, an equal number received a shot of a harmless substance, and still another group received nothing.

Placebo (which is a Latin word meaning “I shall please”) is defined as “an inert or innocuous substance used esp. in controlled experiments testing the efficacy of another substance (as a medication).”

But a placebo can also be “a medication prescribed more for the mental relief of the patient than for its actual effect on a disorder”—which is “the placebo effect”. Remember the times you’ve given your child a “kiss” to make the hurt go away?

In the field of psychiatry and especially psychopharmacology (the development and study of drugs to treat psychiatric disorders), the placebo has become very prominent, because the placebo response to psychotropic medications is high. Much of the research in the development of new psychiatric medications involves evaluating their effectiveness by testing them with patients who have these disorders, and involves giving some patients real medications and others placebos.

These studies, called Clinical Drug Trials, are required by the Federal Drug Administration (FDA), the agency that approves all new drugs for public use in the U.S. Most new drugs tested in the U.S. are the products of drug companies who support the trials conducted at various institutions including UT-Houston and UT-HCPC.

In most of the clinical drug trials for



new psychiatric medications, the new unproven drug is given to a group of patient volunteers, who are the subjects of the research trial. Over a certain length of time, researchers observe and record how well the drug works or doesn’t work in alleviating the symptoms of the illness of these subjects and follow the side effects.

Another group of volunteer subjects are given placebos, so that researchers can compare what happens to the people taking the active drug to those who are getting placebo treatment. Sometimes,

the new drug is also compared to another, already approved medication given to a third group of subjects. All these studies are always “double-blind,” meaning that neither the research subjects nor the researcher knows who is getting a real medication and who is getting a placebo.

There is no doubt that the psychopharmacological revolution has improved the lives of thousands of those who suffer from mental illness. However, certain ethical dilemmas remain about how such drugs are developed, involving the need for scientists to conduct competent research, the pledge of a doctor to do no harm, and the right of the patient to have the best care possible.

Does the need to develop new medications that may help thousands justify the risks to those individuals receiving placebo treatment? Is scientific research ever more important than the right to treatment? Can a patient, especially one suffering from a psychiatric illness, truly give informed consent to participate in research? Can meaningful research be done without the use of placebos?

And then there’s that definition of “mental relief” or as it’s more commonly known, the “placebo effect”—when an ill patient gets better but not due to the action of the drug itself—a phenomenon that continues to confound scientists, physicians, psychologists, philosophers and ethicists alike.

Increasingly, the power of the placebo effect has brought the debate to a new level. While it has been generally accepted that 30 to 40 percent of patients respond to placebos, some researchers believe that for certain conditions—pain, depression, some heart and gastric problems—placebos work

for 50 to 60 percent of the patients. The “placebo effect” may be larger than that of the real drug being studied.

This was just one of the findings presented in “The Placebo Prescription” by reporter Margaret Talbot in the *New York Times Magazine* last January. Among other studies demonstrating how placebos are proving as or more effective at helping people as real medications, Talbot cited how Merck pharmaceuticals stopped the development of a new Prozac-like antidepressant because, during clinical trials, the placebo proved just as effective as the new compound.

Talbot also cites the findings of psychologists Irving Kirsch and Guy Sapirstein. Their analysis of 19 clinical trials of antidepressants showed that “the expectation of improvement” and not changes in brain chemistry caused by the drugs, accounted for 75 percent of the various drugs’ effectiveness. In other words, it was the belief that they were getting help that actually helped them.

Although psychiatry has come to the discussion about the “placebo issue” later than some other medical specialties, the issues of medical research with persons suffering from psychiatric disorders make the stakes higher. Clearly, it was time to get the perspective of all the stakeholder communities.

This awareness resulted in a groundbreaking two-day conclave last spring, “The Placebo in Mental Health Research: Science, Ethics and the Law,” sponsored by the University of Texas-Houston Department of Psychiatry and Behavioral Sciences and the UT-Houston Health Science Center’s Committee for the Protection of Human Subjects (CPHS).



*Placebo Conference hosts Daniel Creson, MD, PhD, and UT-Houston HSC IRB Coordinator, Paula Knudson.*

“We felt the time had come to address these kinds of issues within our disciplines and so we took a leadership role in bringing together experts\* from across the spectrum to debate them,” said Paula Knudson, Executive Coordinator for UT-Houston’s

*Continued*

# Placebo

Continued

CPHS, who along with Daniel Creson, MD, PhD, director of Continuing Education for the Department of Psychiatry, chaired the symposium. The CPHS is the Health Science Center's federally mandated Institutional Review Board (IRB) that oversees and approves all the Center's research programs involving human subjects, including those conducted at UT-HCPC and the UT Mental Sciences Institute (MSI).

"The conference was designed to be a sounding board and our goals were to uncover the vested interests of each of the groups impacted by the scientific use of the placebo," says Creson, "to evaluate the popular concerns related to psychiatric research, and finally, to find some ground for a consensus about their future use. To avoid any real or apparent bias, the conference received no support from the pharmaceutical industry."

At its most basic, the discussion over the justifiable use of the placebo is between two groups. The first is composed of physicians and scientific researchers who claim they cannot get meaningful results and create effective new medications without using placebos in their drug studies, asserting that risks are minimal. The second group includes those patient advocates and medical ethicists who question keeping people who are ill from receiving a medical treatment and exposing them to possible risk for the sake of medical advances that could benefit many future sufferers of the illness.

These are summations of the main points of each of the conference's eleven participants:

## THE SENIOR SCHOLAR

"We are faced with a number of critical paradoxes that weren't even considered until 50 years ago," said the conference's keynote speaker, Frederick Goodwin, MD, recognized as one of the pioneers of scientific psychiatry and a leader in the effort to integrate the science of psychiatry with ethical and community concerns.

In the late 1970s, Goodwin was an advisor to the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research which established many of the current research standards. He was also a former head of the National Institute of Mental Health.

"Psychopharmacology came relatively late to psychiatry," he explained, "after the atrocities of the Nazi concentration camps and the findings of the Nuremberg Trials, in a climate where there were intrinsic ethi-



Frederick Goodwin, MD

cal concerns about doing medical research on human populations."

Goodwin believes there are philosophical issues regarding the interpretation of "best possible treatment," that can never be resolved because it states that all persons involved in medical research should get the best treatment possible—which many believe forbids the use of placebos. It was first outlined in the Declaration of Helsinki, a code of ethics for clinical medical research, adopted by the physicians of the World Health Organization in 1964.

While Goodwin believes that placebos are needed to assure correct results in clinical drug trials, he does see a consensus forming among mental health researchers against the use of placebos in some drug trials, such as those with subjects with severe mental disorders, where lack of treatment could cause serious consequences, or in prolonged drug trials.

"There should be more focus on using placebo-based drug trials with patient populations that have proven resistant to all other treatments, and for continued investigations to discover other ways to design drug studies that may reduce the risks to the participants," he said.

Beginning a theme that would weave throughout the conference, Goodwin emphasized the importance of informed consent in clinical research. For Goodwin, the informed consent process (in which the researcher tells the potential subject what will happen during the research and the subject agrees to participate) is key to ensuring that medical and professional ethics are not compromised when doing such research.

## THE HISTORIAN

"The placebo effect has been part of medicine for a long time," said HCPC Executive Director Robert Guynn, MD, Chairman of the Department of Psychiatry and Behavioral Sciences. "In fact, before the twentieth century the vast majority of medications were placebos."

From the time of the ancient Egyptians, he said, medications made from exotic, rare and even disgusting ingredients were deemed to be powerful; such "powerful" treatments were often effective.

Because little real treatment was avail-

able for chronic mental illness in the early part of the last century, Guynn said, certain procedures, such as inducing insulin comas in schizophrenics, were tried. "They worked", Guynn said, "but they were really placebos; patients improved because for the first time they were getting attention from the caregivers, not because of these so-called remedies.

"Only since the mid-1900s have placebos, as we understand them, been routinely involved in medical research, and, therefore, caught between two ethical standards of doing no harm to patients and ensuring effective and safe treatments." Like Goodwin, Guynn questioned interpretations of the Helsinki document that say the use of placebos is unethical when there is an effective treatment available. "There are instances in the history of medicine," Guynn pointed out, "where the 'active' treatment is inferior to the placebo and actually does harm."

To fully understand the placebo effect, he said, you also have to understand the opposite concept, the "nocebo" (I shall harm) effect. "Not everyone assumes that the treatment they are to be given will make them better, which is often the reason for the placebo effect, but they believe it will do them harm in some way, and develop into intolerable side effects."

The placebo effect is a factor in all areas of medicine and practitioners will always have to deal with it, Guynn said, because it is a phenomenon of human nature, dependent upon factors such as the doctor-patient relationship, a person's history with using medications, as well as personality variables. These factors also explain why researchers see such wide variances of responses to placebos from study to study.

## THE SCIENTIST

The placebo is not just part of medical history, said Peter B. Silverman, PhD, JD, it is an element of natural animal biology and learning behavior.

"The basic science of the placebo effect is the basic science of classical conditioning, and the response to placebo treatments can be conditioned very effectively in animals," asserted Silverman, head of the Behavioral Neuroscience Laboratory at UT-MSI. He described a number of experiments conducted in his laboratory, emphasizing the similarity between classical conditioning outcomes and the placebo effect. He also demonstrated that the placebo effect is not only psychological but also biological.

Classical conditioning is a simple form of learning in which animals or humans make a connection between two formerly unrelated events, resulting in a change in

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behavior. For example, a dog injected with morphine displays a specific behavior pattern. If injected daily for several days, just the approach of the researcher or the sight of the syringe will elicit the behaviors even without the injection being given. The dog has come to associate the researcher/syringe with the effects of morphine.

Silverman injected a substance toxic to certain cells into the brains of laboratory rats and it destroyed a motor pathway of cells on one side of the brain that affects the rats' motor response to dopamine, a neurotransmitter. The result was that a rat that ordinarily behaves normally, when given a drug that affects dopamine, ran rapidly in circles.

Silverman placed the rats in big plastic bowls where their motions were analyzed with computer software. When given the drug that affects the dopamine, the rats ran in circles; when given a saline solution, they did not.

Weeks or months later, when placed in the bowls without any drug treatment at all, the rats repeated the same behavior from before: those who ran before, ran this second time; those who did not run, still did not. The group that had a drug paired with the environment now responded to the environment alone as if they'd been given a drug. Those that had never had the drug-environment pairing, did not. "Here the placebo is seen not to be a pill, but a process," Silverman said. "A single pairing of drug and environment was shown to result in the environment eliciting drug-like effect over a year later."

Silverman said that it is far easier to control the relevant stimuli and determine the condition effects of treatments in basic research with animals. In humans, it is harder to ascribe placebo affects to classical conditioning alone, because researchers do not have control over the all the various stimuli (like verbal communication) that may become associated with treatments. "Nonetheless, seen in the context of classical conditioning, placebo effects in clinical studies are less mysterious," he added.

### THE RESEARCHER

"Placebo-controlled studies present a dilemma of balanced risk between individuals and populations," said Alan C. Swann, MD. "There is the risk to the individual subjects in the research, but placebo-based trials reduce the risk that ineffective treatments will be considered effective and used on populations. And because placebo-based trials require fewer subjects and require a shorter duration of time, effective treat-



*Alan Swann, MD*

ments can be made available sooner, reducing the number of individuals exposed to ineffective or toxic treatments."

Swann, who is the Vice Chair for Research at MSI and Director of Research at HCPC, has been involved in a number of national clinical trials and published widely, most recently on the cause and treatment of bipolar disorder.

He outlined the pros and cons of two common kinds of "parallel studies" used in clinical drug trials: one group of subjects receives the new drug, the other group gets an already proven effective drug; or one group of subjects receives the new drug and the other group gets a placebo.

The advantage of comparing the new drug to a standard medication ("equivalence" or "comparison" design) is that all participants in the study get something that has the potential to help them. But such studies require more subjects and produce no direct measure that the new drug really works.

And for scientists, said Swann, proof of change is paramount. "One of the major pitfalls for researchers designing drug studies," he said, "is determining the amount of change the study is looking for, which must determine the size of the group to be studied to insure that the findings are scientifically valid."

Thus the second, or "superiority trial" test, can usually demonstrate a drug's effectiveness with fewer subjects. However, medical ethicists find it troubling because it keeps those subjects taking the placebo from receiving a known and effective treatment, he said.

To get around many of the difficulties of "parallel" drug studies, Swann suggested researchers use "crossover" drug studies, in which one group of subjects gets placebo and the other gets active medication and then the groups switch. He agrees with Goodwin that "enrichment" studies with treatment-resistant patients reduce the risks, but they also limit the number of subjects, making the findings less reliable.

"Placebo-based trials should be used only when there is no generally accepted treatment available, the established treatments are toxic or are effective for only a limited group, there is a high placebo response for the illness or the course of ill-

ness varies widely," Swann concluded.

Again like Goodwin, Swann reiterated the importance of valid informed consent and the participation and oversight of the community. "I believe we can reasonably protect subjects from risk by insisting on a high standard of informed consent with independent monitoring of the consent."

### THE MEDICAL ETHICIST

Harold Vanderpool, PhD, ThM, who approaches medical ethics from a religious and historical perspective, believes the views of both sides in the placebo debate should be modified, and the use of the placebo to study drugs in psychiatric patients limited, but not forbidden. Vanderpool is a professor in the Institute of Medical Humanities at the University of Texas Medical Branch in Galveston.

Like Swann and Goodwin, he agreed



*Harold Vanderpool, PhD, ThM*

that placebo-controlled studies are usually very safe for moderately ill psychiatric patients and can be justified for use with treatment-resistant patients or those who cannot tolerate the side effects—but only if these patients are capable of giving informed consent and the harms are closely monitored.

Respecting the patient's autonomy, obtaining truly informed consent from research subjects and using large and diverse subject groups are key to conducting truly ethical research studies with the placebo, he said.

"Those who say the use of placebos is wrong are correct in their assertion that researchers should search for ways to benefit the patient-subjects themselves, and not use them as a means to an end to benefit others," he said. "But I believe not allowing patients to make the free will choice to participate in such a study both paternalistic and pessimistic. Patients should be allowed to participate if they are fully informed and consent."

He defined truly informed consent as telling patients what the research is all about in plain language they can understand, which includes explaining that they may get a placebo that has no effectiveness, that there are potential risks of taking an

## Placebo

Continued

untried active medication and that it is okay to say no and stay with their current medication.

But Vanderpool was also skeptical of scientists who say that “comparison” studies are not good enough, and of the need for placebo-based studies when so many effective medications already exist. He called for a new standard in drug research, involving large clinical comparison trials.

“Placebo-controlled drug studies, which by their very nature withhold benefits, must minimize the harm, uphold the rights of the patients, be limited in their use and be scientifically verified,” he said.

### THE FEDERAL REGULATOR

The use of placebos in research is considered scientifically and ethically acceptable—and almost essential—for approval of any new psychiatric medication by the Federal Drug Administration.

The FDA, said Thomas Laughren, MD, has never ruled that a placebo-controlled drug study was unsafe or couldn’t produce enough evidence to show the drug was effective. Laughren heads the group overseeing the testing of psychiatric medications and their final approval for the FDA.

He said in order for the FDA to approve a new drug, there must be “substantial evidence of effectiveness from adequate and multiple trials.” Because of the variability of psychiatric illnesses and the responses subjects have to psychiatric medications, researchers need to use placebos to demonstrate “substantial evidence” with psychiatric medications. “The ‘equivalence test’—demonstrating the new drug is just as effective as a current one—is not enough,” he said.

Thus, the FDA requires researchers to use ‘superiority’ drug trials showing difference, that the new drug is better than something else.

He cited data from a number of drug development programs illustrating the continuing problem of the high percentage of subjects who respond to the placebo (placebo effect) in drug trials—a number, he said, that is often as high as those who respond to the active medications.

This makes “assay sensitivity,” or the knowledge that the drug testing process has been designed properly (e.g., enough subjects, correct doses), very crucial, Laughren said. If the study concludes there is no difference between two active drugs it could mean that either both drugs work or that neither drug works, so each trial must show a difference.

Despite their high failure rate, placebo-

controlled trials are still the most efficient way to test new drugs, which is why drug companies use this design, Laughren said.

However, he added, the “three-arm” drug test, in which one group of subjects is given an active drug, another group is given a placebo, and the third group the new drug, is the kind of drug test study the FDA likes best.



Thomas  
Laughren, MD

To resolve the ethical question of whether patients assigned to placebos will suffer more harm than patients assigned to active medications, Laughren said it was necessary to distinguish between serious harm, such as death or severe relapse, and less serious harm.

If available treatments have been shown to prevent serious harm, it would not be ethical to use placebos he said. However, the FDA considers delaying effective treatment an acceptable risk, providing the patient has been told of the risks and has given his informed consent.

### THE PUBLIC HEALTH PROFESSIONAL

As a student of diseases and populations, Karin Michels, ScD, MSc, MPH, believes there is no hedging: serving the good of the majority by denying treatment to an individual is unethical—even if it means treatment that is more effective for future populations. “There is no justification for the use of placebos in drug studies when effective treatment exists” she said.

“Research has a greater obligation to the patients it has now than to those of the future,” said Michels, a clinical epidemiologist at Brigham and Women’s Hospital, affiliated with Harvard University’s Medical School.

She argued against the use of placebos based upon the medical research principle of “equipoise.” (Equipoise, or being equal, refers to the ethical fairness of conducting randomized clinical trials. If a trial therapy is known to be better than the current therapy, it is unethical to give a subject the older treatment. Before conducting a randomized clinical trial of a new medication, researchers must be able to state that there will be no difference in the outcome between subjects treated with a trial med-

ication and those treated with a control therapy, either a placebo or an active drug.)

Countering assertions by earlier speakers, Michels said that the legal justification for using placebos—informed consent—is a fiction. The forms are incomprehensible and incomplete, patients don’t understand the difference between treatment and research goals, and they have the “therapeutic misconception” that the doctor knows best.

The Declaration of Helsinki, she said, states that the responsibility for the human subject must always rest with the researcher and never with subject of research.

Michels also attacked the scientific arguments in favor of the use of placebos, asserting that a variety of drug trial designs, not just “superiority” tests using placebos, were effective. Besides, the FDA, she said, accepts “equivalency” drug tests as good enough to approve a drug effective to treat a life-threatening illness, such as cancer, AIDS or infectious diseases.

She denied that placebos must be used to provide a baseline reference point, citing the extreme variability of the placebo effect, and that the FDA’s “assay sensitivity” could be compromised even by active control medications used in drug studies because they are not always efficient or effective.

Michels bolstered her position with findings by the National Bioethics Advisory Commission and the World Health Organization, both of which prohibit the use of placebos if the risk is a return of symptoms or there is already a standard treatment approved.

Although she acknowledged that the dilemma over the use of placebos in psychiatry was especially difficult, Michels concluded “we can’t just say it doesn’t matter and use placebos in these studies because it seems to be the easiest and cleanest method for us to conduct research.”

### THE LAWYER

Although there is very little codified law that touches the use of placebos in research, said Jack Schwartz, JD, Assistant Attorney General for the state of Maryland, he believes it is just a matter of time.

Federal Regulations, he said, mandate that the drug approval process must include “well controlled studies” but they do not mention placebo controls specifically. Informed consent is also mandated in the laws that govern all research with human subjects funded by the U.S. Department of Health and Human Services.

The National Bioethics Advisory Commission issued new recommendations in the past year saying researchers must

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give heightened scrutiny to the use of placebos and that they require special justification, he said.

Schwartz presented cases showing how future courts might rule on the use of placebos, such as a federal appellate court ruling that a doctor can give a drug to a sedated inmate without his permission only for patient's medical benefit, but not just for research purposes. "Placebo control trials are not really for the benefit of the patients," Schwartz said, "because the overarching intent of this randomization is to gather scientific knowledge."

In another case eventually overturned by the New York Supreme Court, it was ruled a violation of Constitutional rights to involve voluntary patients in psychiatric hospitals in non-therapeutic research that created a greater than minimum risk for the subjects and where the informed consent process was inadequate.

In the next few years, Schwartz foresees more courts targeting rights abuses, inadequate disclosure and improper informed consent, holding researchers liable under malpractice statutes.

"In our litigious society, where debatable ethics soon become debated court cases, the law will evolve as fashioned by the courts, unless Congress or the state legislatures get involved. To avoid this, he said, researchers should "get their own ethics house in order. Good ethics is good law as well as good science."

### THE PHILOSOPHER

"Who has the proper understanding of a good society? There are many moral perspectives; everyone has biases." Physician-philosopher and medical ethicist, Tristram Engelhardt, PhD, MD, provided what he termed a "deconstructivist view" of why there is no central ethical principal for solving the ethical questions of placebo use in psychiatric drug testing.

Engelhardt, who teaches philosophy at Rice University and medical ethics at Baylor College of Medicine, said that in "post-modernity," the time we live in now, there is no one guiding principle.

Until the Enlightenment in the 1700s, he said, Western man believed in faith in Faith. Then there was a new collective faith in Reason; people assumed that a person could reason to what was right.

But in the post-modern society that approach doesn't work, Engelhardt said,

Continued



## From one who knows

The following essay is by HCPC Research Intermediary Janet Allen, who works with physicians and patients involved in research at HCPC, making sure that patients understand the research in which they have agreed to participate and conferring regularly with them as the research progresses (See **Progress**, March 1999).

*Are placebo-controlled studies of medications for psychiatric disorders ethical? It's a simply stated question. But after a day and a half of conference I came away with a short but complicated answer—it depends.*

*It depends upon:*

- ...the illness being studied;*
- ...the scientific question to be answered and the math involved to answer the question with some level of certainty;*
- ...the possible risks of taking no medicine;*
- ...the possibility of taking an experimental agent that may cause its own problems;*
- ...the standard treatment that the doctors agree upon or if there is disagreement about the best care;*
- ...whether it is possible for a person to feel better while taking a placebo alone;*
- ...whether people with the condition can make sound decisions about their own lives and well-being with scientists and oversight agencies assuring that all of the right information is available to make such decisions.*

*The federally required Institutional Review Boards (at UT-H this is the Committee for the Protection of Human Subjects) made up of all types of professionals and non-professionals will scrutinize carefully whether it is right to ask people to volunteer to try the experiment. They will have to consider all the "depends."*

*Professional staff will have to assure preparation for the problems that may come up. What plans are there if a person*

*continues to feel bad?*

*People who have experienced the condition that is to be studied need to participate in the discussion about research as it is being developed. It should be in its very best form before the proposed experiment begins.*

*When it comes down to it, whether it is all right to conduct a placebo-controlled trial of an experimental medication for a psychiatric disorder depends upon the person being asked to try it.*

- The investigator must do all she can to make sure that the potential volunteer can think clearly before she asks the question. If the person is not thinking clearly, then we do not ask him about such research.*
- If he is thinking clearly and can be invited to volunteer, we must do all we can to assure that he has the information he needs and the unhurried time to make a decision. The language of scientists and the language of people who have spent years "on the outside" can be as foreign to one another as Greek and Vietnamese. We must make sure that we are communicating and not just talking to one another.*
- When a person makes a decision about whether or not to volunteer we respect the choice. And if the decision changes, we respect that as well, even when we disagree.*

*How would we know if a placebo-controlled trial of an experimental medication were ethical? It depends upon whether all the risks of research were in keeping with potential benefits, are carefully discussed, watched, and addressed and, most of all, whether the research volunteers are respected and cared for as contributors to the study. ★*

## Placebo

Continued

because there are many different philosophies or systems of “good” operative in the world and no “one” accepted moral philosophy or set of ethical rules, but many.

“The way we solve controversies is to draw our authority from the common consensus, not from God or from reason, because we no longer share a common understanding on faith or reason. We must create and discover our own rules,” he said.

With no one “right” anymore, society



H. Tristram Englehardt, MD, PhD

finds itself asking, “What do you believe in and what did you agree to?” to establish ethical standards. In order to get a final answer to any ethical question, such as whether or not to use a placebo in drug studies with psychiatric patients, Englehardt said, a person must have already subscribed to a certain belief system and a particular understanding of how to determine the right thing to do.

With no morality that gives us clear guidance, he said mankind is unlikely to ever come to a consensus that will endure forever, but it will create ways to come to terms with problems. These ways will not be connected to any rational, ethical system, but will rely on rules.

Whether or not we consider the use of placebos as “ethical,” Englehardt said, depends upon the particular situation, the kind of risks and whether people understand that risk, but, beyond telling subjects what will happen and getting their free consent, the ethics of placebo use in drug trials depends upon each situation.

## THE GUARDIAN

Many consider Robert Levine, MD, of Yale University, to be the “father” of the U.S. system of protection of the rights of human beings in medical research, specifically the development of the IRB system for oversight of all human subject research.

However, Levine, a pathologist by training who has an international reputation as a medical ethicist, believes the Declaration of Helsinki, considered by many the definitive

document in modern medical ethics, to be a badly flawed document in need of revision.

Drawn up to replicate the unscientific way drugs were tested in the 1950s, Levine said Helsinki has nothing to do with modern, controlled clinical trials, and is often ignored by researchers.

Levine asserted that “clinical” equipoise, a principle established in the 1960s and differing from Michels’ “theoretical” equipoise, argues that it is possible to use placebos when there is controversy among experts on the efficacy of the treatments available and no one knows for sure what is superior.

Until the late 1980s, he explained, a statement of “no difference” (equipoise) was always made in terms of the “primary outcome.” For example, physicians could report that there was no difference in the rate of return of breast cancer after five years with either a full mastectomy or a lumpectomy with radiation.

But, he said, it made a big difference to the patient, so the requirement of “no difference” was amended to consider both the risks and the benefits of a treatment. Levine believes that the “purpose of the randomized clinical trial is to resolve this dispute,” although he agreed with Michels “that the dispute must be resolved by making a therapeutic, not a just a statistical, difference.”

A patient’s right to self-determination, efficiency and the need to develop new, more effective medications justify the risks of using of placebos in carefully monitored clinical trials, he asserted. And informed consent can be obtained from a subject, he said, even one who is schizophrenic, when the disease is under control.



Robert J. Levine, MD

Like Vanderpool, Levine said that risks can be reduced in placebo-controlled trials by excluding seriously ill subjects and by shortening the duration of the trial. Gradual removal of patients from medications and psychosocial support should be routine, with the latter a justification that such studies do not deprive patients of all treatment.

“When we do justify placebo controls,” Levine concluded, “it’s important to think of the placebo as a non-therapeutic procedure that, in some cases, can present more than a minimal risk.”

## THE ADVOCATE

“Every human being has the inalienable right not to be experimented upon without giving his voluntary, informed, comprehending consent,” said rights advocate Vera Hassner Sharav. “That’s the critical issue, and Nuremberg and Helsinki are there to protect the individual from unwanted experimentation.” She said efficiency was the main consideration for those, like Levine, who approve loosening the Helsinki regulations.

“In clinical trials,” said Sharav, “the ethical imperative to protect patients is subordinated to testing new drugs rapidly and efficiently, but it poses risks of harm for the patients—who are not necessarily the beneficiaries of any new treatments.” She echoed Michels in asserting that “the common good cannot override the human rights of each person.”

Sharav, who has been one of the most effective public advocates for the protection of human subjects in psychiatric research, called for federal regulations involving psychiatric research with human subjects strengthened because they currently do not protect patients from researchers or IRBs whose moral compasses are skewed. These would include the establishment of a specific federal agency and regulations for medical research, a national human subject protection act, independent IRBs not affiliated with institutions, and independent witnesses to all informed consent proceedings.

Sharav said the ascendancy of biochemical psychiatry and the gilded age of research have taken away the independence of academic centers (where much new drug testing is done), and made them part of the industry. Market-driven experimental research and the money it generates, she said, have become more important than patient care.

Sharav was very critical of those who say some suffering is allowable if the result is treatments that are more effective. “Suffering is very real,” she said, “it is not only death that counts as a risk.”

At the conference’s end, Gerald Moeller, MD, Associate Professor in the Department of Psychiatry at UT Houston, outlined some of the points uncovered during the conference that warrant further consideration by all stakeholders.

“If the use of placebos is not acceptable in instances where safe and effective treatments are available,” he asked, “then what is the efficacy and safety of the commonly available pharmacologic treatments for psychiatric illness?” He cited FDA findings showing larger and extremely variable placebo response rates in studies on psychi-

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atric medications.

Researchers today, Moeller said, must focus on why the placebo response rate is so variable in psychiatric medications and why it has been increasing in recent drug studies. "There is a need," he said, "to find out if drug study designs can be modified so that the placebo response rate is less variable and can be more standard (such as the FDA reported in studies of new antibiotics). If this response could be standardized, researchers would not necessarily have to include placebos in future studies.

"While most of the presenters would agree," he said "that informed consent must be obtained in placebo-controlled studies, the data is lacking on how informed the consent is that is currently being obtained." He suggested the informed consent process needed to be assessed and improved, and that more research be done on developing tests to actually determine a person's capacity to consent.

Finally, Moeller urged researchers and IRBs to be proactive and open about these issues, within the field but also in informing the public on what they are doing to ensure these issues are being addressed. If ignored, Moeller warned, reiterating legal expert Schwartz, these issues would be decided by the courts or the government. ★

\*\*The participants were H. Tristram Engelhardt, Jr., PhD, MD, Baylor College of Medicine and Rice University; Frederick K. Goodwin, MD, George Washington University and former director of the National Institute of Mental Health; J. Ray Hays, PhD, JD, UT-HCPC Psychology Department; Thomas P. Laughren, MD, US Food and Drug Administration; Robert J. Levine, MD, Yale University School of Medicine; Karin B. Michels, ScD, MSc, MPH, of Harvard Medical School; F. Gerald Moeller, MD, Associate Professor, Department of Psychiatry and Behavioral Sciences, University of Texas Houston Health Science Center; Jack Schwartz, JD, Assistant Attorney General and director of Health Policy Development for the State of Maryland, where these issues have been particularly active; Vera Hassner Sharav of New York, vocal patient advocate and president of Citizens for Responsible Care and Research; Peter B. Silverman, PhD, JD, Behavioral Neuroscience Laboratory, UT-Mental Sciences Institute; Alan C. Swann, MD, Pat J. Rutherford Jr. Professor of Psychiatry, UT-Houston Medical School and MSI; Harold Y. Vanderpool, PhD, ThM, Institute for Medical Humanities at the UT Medical Branch in Galveston.

## With Regard

*Continued from page 4*

"The church, she continues, plays a very important role in the culture of African Americans. It's the place where they learn values, responsibility and leadership skills, and where young people identify their role models. It is the church family that gives people who may have a lower socioeconomic status in the community-at-large the chance to become leaders and express their intellectual and artistic gifts."

Surprisingly, Scott-Gurnell says younger African Americans have more stigma about mental illness than their elders. "There's a lot of embarrassment and denial. Sometimes they would rather blame their illness on a drug problem rather than accept the fact it's a true illness. The best thing that a professional can do for them is to help them realize that their disease can be controlled."

Once an African American adult decides to get help, he or she is most likely to look for a black psychiatrist, Scott-Gurnell says. "It's such a difficult decision to make that they don't want the added stress of having to explain their culture."

Just as in the Hispanic community, Scott-Gurnell says there are behaviors common to African Americans that are often misunderstood by mental health caregivers unfamiliar with the culture. "People who consider themselves devout Christians in the African American community, may talk about 'receiving spiritual messages' or 'communicating with God,' which can be misinterpreted. The manifestation of grief in the black community is often misunderstood," she says "because when there's a death people will say they feel the deceased's presence or that they are trying to communicate with them."

And of course, caregivers must realize the effects of racism and economic marginalization on the African American. Racism is the cause of many problems, from the executive who is worried about moving up the corporate ladder to children in school, whose hyperactivity and

acting out can be traced to feelings of discrimination.

"I have known individuals in conflict with their employer," says Scott-Gurnell, "who seem paranoid, when in reality they are afraid or suspicious of being discriminated against. I often see African American children who are in the juvenile justice system who grew up in a bad neighborhood and they seem to be paranoid. This paranoia is really a manifestation of the behavior of the streets; the child may be 'watching his back.'"

Ruiz adds that misunderstood cultural practices and beliefs occur in mainstream sub-cultures as well, for example the snake handlers of the Appalachian region of the U.S. "Even though I may not relate to those practices personally," he says, "I must remember that this is part of their culture and it is not for me to interfere with that."

Shah, who was born and educated in Bangladesh, shares Ruiz' and Scott-Gurnell's perspective an understanding of the culture is preeminent to providing effective care.

She says the stigma against mental illness is widespread throughout the entire Asian continent and is often linked closely to religious beliefs. "In South Asia," she says, "mental illness is not considered a real illness.

"Stigma," she says, "comes from the reaction to the behavior of those with a mental illness. They have been taught since childhood that this behavior is not a sign of any kind of illness, so they won't even consider medical intervention." In a culture which has very strict rules about every aspect of one's life (85 percent of the population are of the Muslim faith), the aberrant behavior of a person who is hallucinating or hearing voices is, Shah says, "beyond unacceptable; it is intolerable."

The mental health professional in this culture has to be very careful how he or she uses the term "mental illness," she says. "The practitioner must be very careful how he or she explains the diagnosis. It is very offensive to be called mentally ill. If you say mental illness, the family will shut the door on further help. The mind is so

*Continued*

## With Regard

Continued

powerful, if there is a problem with the mind, it's too threatening for them.

"For example," she says, "you wouldn't want to tell someone from this culture that the patient is schizophrenic; you have to use other words. And because the condition is often not accepted, the practitioner will face a lot of resistance if he or she prescribes medication."

She says there are also certain behavioral phenomena that occur in Asian cultures that may look like mental disorders but are accepted as perfectly normal cultural manifestations.

"Between the ages of 13 to 17, many young girls will suddenly become totally mute. They refuse to eat, they don't respond, they become almost catatonic. Most often, this condition is related to having a crush on a boy or some sexual issue. While this looks very much like what we in American psychiatry would call a 'conversion disorder,' these people would be very offended if you told them it was a mental disorder."

The place of the women in the culture, Shah believes, precipitates many problems. "In many rural areas, women aren't allowed to talk loud, they must walk behind the man. When a woman gets married her whole life and happiness relies on what her husband does or wishes for her.

"Sex is a great taboo; any kind of premarital sexual conduct is strictly forbidden. You very seldom hear about rape or incest or abortion; these are never talked about when they occur. An unwed mother is an out-cast."

On the flip side of the issue, Shah pointed out a number of non-traditional medical treatments utilized by Asians and considered very effective for relieving emotional distress, which, until recent years, were dismissed by Westerners. These include acupuncture, herbal medicines, massage, med-



*Psychiatric technician Ola Rojugokan in native African dress.*

itation and yoga. In general, Asians would turn to any of these methods to relieve a mental illness before they would seek the help of a psychiatrist, Shah said.

"The most crucial issue," says Ruiz, "regarding the provision of mental health services is to have programs that clearly respond to the particular social and ethical codes of the ethnic or cultural group being served, and to provide specific outreach efforts to meet their needs. It comes down to a question of what good is it—with the best of intentions and using all we have learned as psychiatrists—if we make a diagnosis and treatment plan for a person, and that individual will

not be compliant with our treatment recommendations?"

Outreach is essential for these people, he believes, because they will not come to seek services if that is not part of their own culture. "If I'm running a clinic and don't have staff that understands the language and the culture of the people that I'm providing services to, that's a mistake," he says. "When I was working in the Bronx I saw that the clinics in the neighborhoods did much better, so we set our clinic in the African American and Puerto Rican neighborhoods."

He laments that he is unable to provide certain cultural innovations in psychiatric education and care here, because the stigma is high and resources are limited. "Many Houstonians don't want to see Houston change, but the truth is that Houston is already a multiethnic metropolis and it continues to grow.

"When I came to Houston in 1981 as the head of psychiatric services at Ben Taub General Hospital, Texas ranked 44<sup>th</sup> in the nation in terms of the state's per capita contribution to mental health. I thought we had no where to go but up, but unfortunately we went down to 48<sup>th</sup>." [Texas rose last year to 43<sup>rd</sup>.]

We have fewer providers of all kinds, less opportunity for training and education, and less opportunity for us to learn about cultural issues."

Ruiz would especially like to replicate one program he provided in New York. "I had 'cultural brokers' on my therapeutic teams. These were non-professionals of the same cultural background as the patients who we trained in mental health care. They were also able to teach us a lot about patients who were from a culture we weren't familiar with."

There is a great need for such a program in Houston. "We treat a lot of Vietnamese, Cambodians and others from Southeast Asia and very often need translators; but the translators often are not familiar with the culture or about mental health, so

*See "With Regard" on page 25*





## With Regard

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they are not as helpful.”

[To meet part of this need, last year HCPC began a staff language competency program in allowing staff members to earn stipends for serving as interpreters for patients who speak Spanish, Vietnamese, or American Sign Language.]

Ruiz admits that the medical profession in general lags behind other sectors such as business and government in adapting to multiculturalism. But the psychiatric profession is now paying a lot of attention to requiring certain culturally related core competencies, such as knowing how a drug works in relation to its use with vari-

ous ethnic populations and how the mechanisms of psychotherapy should be applied to different cultures.

The impetus for this new interest, Ruiz believes, has come not only from the increasing presence of immigrants. It also stems from a new emphasis in healthcare on quality assessment, which has forced institutions to carefully study risk factors, and has uncovered errors that occurred because the practitioner was not familiar with his patient's language, ethnicity or cultural background.

He also believes that cultural and ethnic issues must be built into the medical school curriculum, which he has already accomplished at the UT-Houston Medical School for psychiatric care directed at Hispanic Americans, and which psychiatric

training directors at other schools have established for the African American, Asian American and Gay and Lesbian populations.

Ultimately, Ruiz places his hopes for greater cultural awareness and acceptance in education. “Despite its diversity, this is what holds the U.S. together,” he says. “Education is mandatory in the U.S. and as the children of the immigrants become educated, they also become less defensive and more flexible and understanding. If they come from a country that was repressive, they learn how to live with others in a democratic society. Without education, people do not function well in either a democratic or a multicultural environment.” ★

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## Maze

*Continued from page 6*

is what I do, so when I saw patients with bipolar disorder, I asked them to bring in their children.

“I would observe the kids and make a mental note of which children I thought were most likely to develop bipolar disorder. The parents would stay in touch with me and tell me if and when their children showed signs of having the illness. I found out I was pretty good at picking them out.” During her research work in Mississippi, in fact, she uncovered four generations in ten different families with bipolar disorder.

“What’s happening now, however, is that we are seeing bipolar disorder manifested earlier and earlier in children and it’s a very malignant, late stage form of the illness. For example, you might see a four-year-old with symptoms you’d expect in someone who has had the illness for 40 years. These children experience the rapid cycling between manic highs and depressions that usually aren’t seen until a person is much older.

“We think the disease has developed ‘genetic anticipation,’” she says,

“a pattern in which it increases its penetration into the genetic pool and strengthens and manifests itself earlier and earlier with each generation. So, someone in the first generation may have a very mild form of bipolar disorder, but by the fourth generation the children have this severe form.

“I am hoping that the neural-protective components of these medications will keep children who carry the genetic risk of bipolar disorder from developing such a severe progression of the disease. Because the cycling pattern of mania and depression is so individual in people with bipolar disorder, I will use each patient as their own ‘control group,’ and design a study where they will be alternately exposed to the traditional medications for bipolar disorder (lithium, and two anticonvulsants, tegretol and valproic acid), a placebo or no medication, and then the calcium channel blockers. Through assessing the hormonal and neuropeptide (a class of molecules that form the basic building blocks of proteins and function as neurotransmitters) differences in spinal fluid, I hope to be able to understand how the physiology works when compared to people without the disease.”

This leads to a new “loop” or

facet of Pazzaglia’s research agenda, melding her interests in bipolar disorder and substance abuse with another phenomenon: the fact that more than half of young persons with a substance abuse diagnosis also have a diagnosable mental illness.

Dual diagnosis, a combination (comorbidity) of a mental illness and a substance abuse problem is a major public health problem, primarily because of the prevalence and earlier use of drugs among the population—61 percent of patients with a diagnosis of bipolar disorder also meet the criteria for substance abuse. Dual diagnosis may also be a contributing factor in the worsening of diseases such as bipolar disorder.

“First,” Pazzaglia says, “it’s necessary to understand that there are two different kinds of bipolar disorder. The first, primary bipolar disorder, precedes the substance abuse. People have a hereditary bipolar illness,” she explains, “but it’s in a mild form and they may not know it. Then they are exposed to drugs or alcohol recreationally and it makes them feel better so they begin to self-medicate themselves with the substances. Usually in these cases, it’s done in binge

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episodes that correspond to the manic and depressed cycles of the bipolar disease. So when they are manic they take alcohol to 'calm down,' and when they are depressed, they use cocaine, a stimulant. In reality, both drugs and alcohol worsen the bipolar disease and make it much more difficult to treat such patients."

Secondary bipolar disorder refers to permanent brain changes that are drug-induced and mimic bipolar illness. It is often seen in patients who have been using cocaine for a long period or began using it at an early age, Pazzaglia says.

"As someone who has spent her whole career studying bipolar disorder and its victims, I can tell the difference between a patient with primary bipolar mania or depression and one with secondary or cocaine-induced mania or depression," she says. "These are not the same disease and appear clinically distinct to me.

"My aim is to continue doing research with the calcium channel blockers on parents and children with 'pure' bipolar disease, and ultimately study people with bipolar illness complicated by drug abuse. By comparing some of the hormonal differences, brain wave activity and neuropeptide differences in all three groups, I hope to be able to find a better way to treat patients so they can function on their own, with few side effects and the least time spent being ill."

Expanding upon this research, Pazzaglia would like to collaborate with another investigator studying a population with substance abuse disorder-only and then pair her findings with the bipolar-only group with the substance abuse-only group to "tease out" the basics of dual diagnosis conditions.

This is a very difficult population to study, Pazzaglia says, because the diseases intertwine and the symptoms are mostly the same.

Is substance abuse a genetic disorder? "Drug abuse is so prevalent in this group," Pazzaglia says, "it is hard to separate what is drug abuse and what is bipolar disorder. We don't know what causes kids with bipolar

disorder to gravitate toward drug use, but we know that it occurs.

"There is some sort of causal relationship between substance abuse and an affective disorder," she confirms. "We know that there is a high prevalence of depression in families with a substance abuse history. Whenever I get family histories which show generation after generation of alcoholism or drug abuse, I always note that there may be an affective disorder involved too."

Once again, Pazzaglia's research in bipolar disorder and substance abuse propels her investigations in another direction, and creates a new "loop" in her investigations.

"The disease process in bipolar illness is different with each person, which makes it very difficult to diagnose. I think bipolar illness has been very much over diagnosed in the last few years; it's given to any patient who is impulsive or irritable.

"If it's diagnosed in a person who has no genetic history of it, you have to be careful because it could very well be something else," she says.

"In children," Pazzaglia says, "the diagnosis is even more difficult. Any child who acts hyperactive is given a diagnosis of ADD, but unfortunately, hyperactivity in children is no more specific than irritability and impulsiveness in adults.

"Several parents with bipolar disorder I've been following have come to me saying, 'My child was diagnosed with ADD (Attention Deficit Disorder), and the doctor prescribed Ritalin® (a stimulant used to increase attention and decrease restlessness in children and adults who are overactive), but do you think it may be bipolar disorder?'

"Children are manifesting bipolar symptoms earlier and earlier," Pazzaglia explains, "but the symptoms—physical over activity, problems with attention and concentration—closely resemble those of ADD, so the physicians put them on Ritalin®, which has been the traditional treatment for these symptoms.

"To me, they looked very different from children with ADD; they looked more like persons with bipolar disorder, only neurologically immature," she says. "And those children who had been exposed to Ritalin® were

much worse than other children with bipolar disorder; in fact, the older ones seemed to cycle as chaotically as the dually diagnosed bipolar kids who were strung out on cocaine."

Pazzaglia says something in stimulants, like Ritalin®, makes bipolar disorder worse. "It makes sense because researchers use cocaine in animals to simulate bipolar mania and depression as well as epilepsy. This more severe variant caused by exposure to Ritalin® is also harder to treat, sometimes requiring five or six medications, very much like bipolar/cocaine abuse or end-stage bipolar disorder.

"The physicians don't think there is a big distinction. As one mother said to me, 'The child psychiatrist told me it doesn't matter if my child has bipolar disorder or ADD, we'll just put him on Ritalin® and see if it works.' But those of us who work in bipolar disorder agree with those in child psychopharmacology that exposing these children with hereditary bipolar disorder to Ritalin® is very damaging."

There have been no controlled studies with children with bipolar disorder, Pazzaglia says, so she plans to develop a research project involving children with pure bipolar disorder and those with ADD to scientifically evaluate what she has discovered clinically—that many children are being misdiagnosed and treated with medications that may make their disease worse.

"I need to learn all I can in order to help. I'm not in any way an expert in child psychiatry, but because bipolar disorder is showing up at younger and younger ages, I want to quantify for child psychiatrists what I see and then teach other practitioners to be able to recognize the differences and diagnose these children properly."

And she will. And from that work, Dr. Peggy Pazzaglia, will no doubt find a new focus of interest, a new problem to attack as she continues to uncover new pathways in the search for the causes and treatment of mental illness. ★

\*Endocrinology is the study of the body's glands that produce hormones, neuroimmunology is the study of the interrelationship between the body's nervous system and the immune system.





## Cancer

*Continued from page 8*

may believe he is unworthy or that he is a financial burden—thoughts which lead him to act petty or unkind, fueling his self-pity and further depression.

Perhaps the first step in treating the depression that accompanies cancer is acknowledging that these feelings and moods are not “normal” just because a person has cancer, but that they are common, and they are treatable. “We do know that in the general population, depression can be successfully treated in 65 to 70 percent of the population, although we don’t have statistics for success rates in cancer patients,” Valentine says.

However, Valentine says socio-economic, religious or cultural attitudes toward drugs and psychiatry often keep people from seeking help for pain relief or mental distress. Practitioners understand that it is difficult enough for patients to face a diagnosis of a life-threatening disease without having the added burden of dealing with the possibility of mental illness.

In fact, Valentine says, the National Comprehensive Cancer Network, composed of 20 major cancer centers around the country, has developed guidelines for mental healthcare with cancer patients, which they call “distress” guidelines in order to de-stigmatize the issue of having a mental illness. “We try to make it as easy as possible for our patients to accept the fact that the cancer is causing them emotional upset. So, if a macho ‘good ole boy’ patient feels more comfortable saying he has problems with ‘stress,’ rather than saying depression or mental problems, it may allow him to seek psychological help.

“Whether it’s an adjustment disorder or major depression, psychotherapy is considered uniformly appropriate, especially supportive therapy,” says Valentine. Supportive psychotherapy is designed to help a patient get through a particularly difficult time, fortify his ego, facilitate problem solving and strengthen the patient’s abili-

ties to return to his usual level of functioning.

“I am a psychiatrist who by interest and training has focused more on a medical model of treatment for psychiatric disorders, but I soon learned when I came to M.D. Anderson that medication is not enough when you are dealing with cancer and the guilt, fear and stress that accompanies it.

“We end up doing quite a bit of general psychiatry,” Valentine says, “because cancer doesn’t occur in a vacuum, it happens in the context of what else is going on in somebody’s life. So, if you’re having family problems or trouble with your boss, the stress will probably be worsened by the illness. I tell patients when one member of a family has cancer, the whole family has cancer; there are lots of hidden casualties.”

Peter Levine, MD, of UT-Houston, who serves as head of Psychiatric Consultation Services at Memorial Hermann and has practiced psychiatry with cancer patients since coming to Houston in 1977, says that his work may range from managing a patient’s pain medicine or antidepressant/antipsychotic medications to psychotherapy with the patient and family.

“Our aim with psychotherapy and in working with the families of cancer patients,” he says, “is to get people to the place where they are realistic about their disease but remain hopeful that they will survive.”

Valentine says there have not been substantial studies to determine which kinds of antidepressant medications are best for treating the illness in cancer patients, although the newer SSRIs (Prozac®, Zoloft®, Paxil®) are used more often, usually because they have fewer side effects.

The ultimate threat of untreated depression is suicide, and cancer patients talk about suicide a fair amount, Valentine says. While usually the person does not really want to die, Valentine points out that the suicide rate among cancer patients is twice that of the general population. The major risk factors for suicide in this population, he says, are pain, end-stage disease, physical or emotional exhaustion, delirium and social

isolation.

“The two biggest fears of cancer patients are pain and abandonment,” concurs Levine. “Thus, it’s very important to have a supportive group of people or a mental health professional and not to shy away from talking to them about the issues.”

The worst thing a cancer patient with depression can do is to ignore these feelings. “We know,” says Valentine, “that psychiatric problems can increase the length and cost of cancer treatment, and there are many in the field who believe that untreated mood disorders can even cause the cancer to worsen.

“I tell my patients that when they are depressed or anxious they won’t tolerate their treatment or its side effects as well, they’ll lose their motivation and become non-compliant with the treatment, and with all the other things they should pay attention to, such as diet and exercise. Ultimately, they’ll impair their cancer treatment and the cancer will get worse.”

“It is crucial to get over the idea that significant depression in a cancer patient is normal,” says Guynn. “Depression, panic, stress and anxiety are physiologically no good for the cancer. Just as a patient’s oncologist will stress changes in lifestyle, such as or exercise to improve the ability to fight the disease, they also should consider that optimizing their patient’s mental state is just as important.”

“Most cancer patients wind up dealing with their cancer in a very courageous manner,” says Levine. “I feel it is a privilege to provide psychological support during what may be the last stage of a patient’s life cycle. It is important to help the medical caregivers, as well as the cancer patient, recognize emergent psychological and psychiatric problems which, left untreated, can only add to the medical problems and lead to further suffering. Finally, as many cancer patients are living with their illness for ever-increasing lengths of time, it’s quite rewarding to help patients re-establish themselves in their normal life patterns.” ★

## Amazing Grace

Continued from page 10

He tells Cleaveland's group the story of the Otter's Children, listens to their reactions and teases out lessons about judgment, revenge, mistrust and how such cycles of reaction can lead to tragedy. "Have you ever had cycles in your life," he says, "where one thing led to another and to another and it just steamrolled into something bad?"

He asks what might have happened if one of the characters had stopped the cycle.

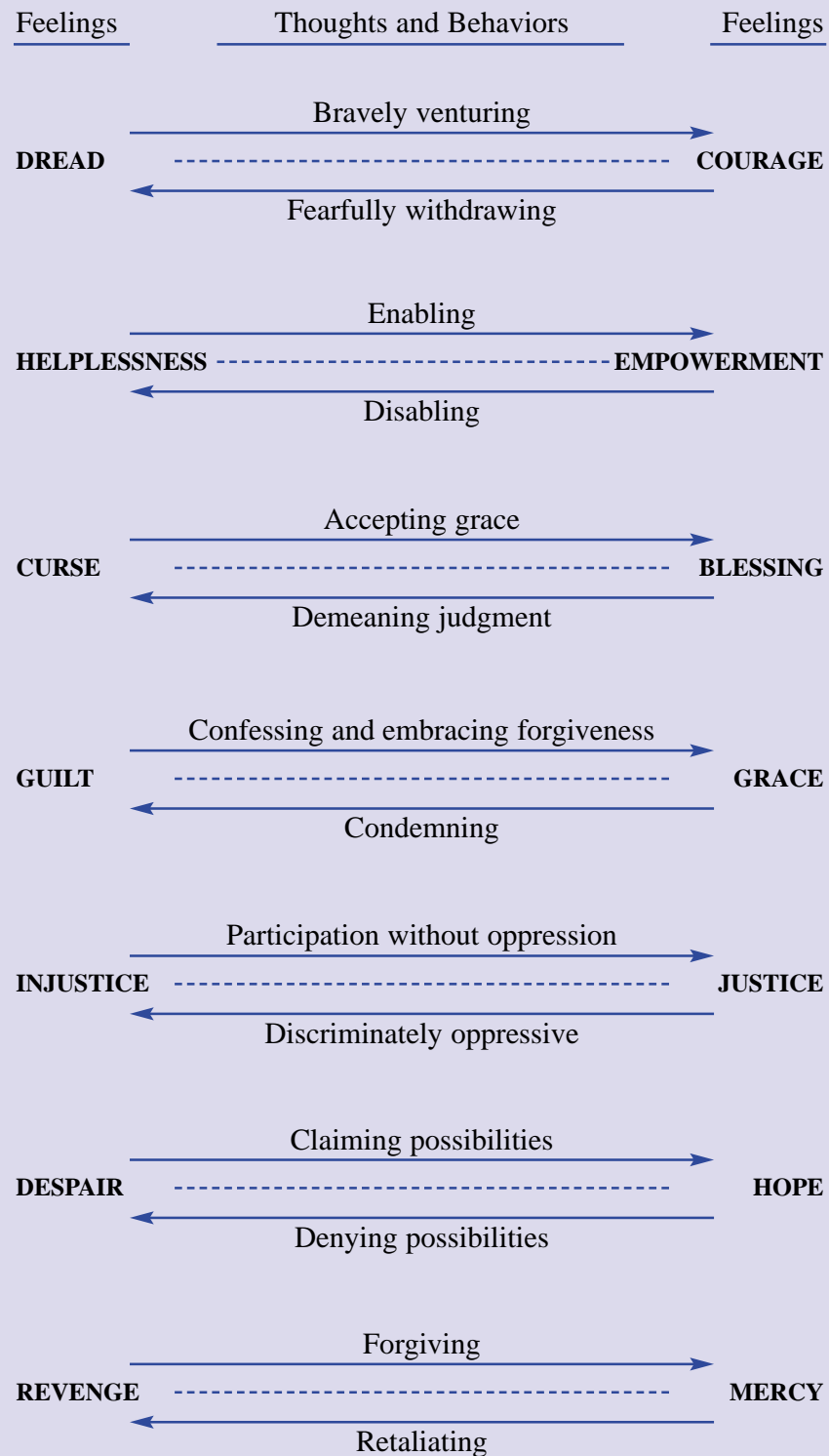
"Let's go one step further," he says. "What might have happened if someone had done something positive, for example the Scorpion decides he's been friends with the Turtle for a long time and he's going to go talk this over with him before he does anything? Then what would happen?"

As the discussion ensues, Hodges points out that this discussion is really about spiritual dimensions. These dimensions, he says, have both positive and negative feelings attached to them, and both the positive and negative are within us at all times, most of the time in some sort of balance (see illustration).

"But when we're under stress, when there are difficulties or problems, they put pressure on these dimensions and we start coping. And when we cope we move one way or other, to the positive or the negative. Usually, when we are under stress and have problems, we move to the negative. I want to help you stop or change or move that towards a more positive feeling."

Hodges and Cleaveland then lead the group through a discussion of each of several dimensions, giving the patients concrete ways to think about the positive and negative aspects. In discussing guilt versus grace for example, Hodges explains that "grace is the act of forgiving self and others" while guilt is "condemning—the grudges we carry around against ourselves and others. I have a mental image of our guilt," he tells them, "as a big sack of rocks that we carry around and it

## SPIRITUAL DIMENSIONS



Hodges' "Spiritual Dimensions," illustrate for patients how each dimension has feelings that range from the negative to the positive.

See "Amazing Grace" on page 29



## Amazing Grace

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becomes bigger and heavier as we go along. Grace is our ability to take some of those rocks out of that sack. Maybe the guilt was deserved at one time, but we need to just let go of it.

"What I want you to remember is that when you feel the negative part of this dimension, whether it be guilt or despair or revenge, that instead of acting out rashly, from bad thought processes or incomplete information, you stop and discover how you can claim a possibility in this situation."

"Sometimes," adds Cleaveland, "when you have trouble seeing those possibilities, it's good to reach out to someone who can help you, such as a counselor, psychologist, chaplain or a friend. They can also reveal more possibilities."

The final spiritual dimension Hodges and the group discuss is that of mercy/revenge, relating it to the story of the Otter's Children. "Revenge can lead to a cycle of retaliation against others and against yourself," Hodges says. "When it is directed inward, we become depressed; when it is directed outward, it is aggression. Mercy is the quality that builds relationships; you can't have relationships with others unless you are forgiving of them and of yourself."

As they go back to their patient unit, the group thanks Hodges and Cleaveland and seems somewhat buoyed by the lesson. Hodges says this has been the general response from all the patients involved. "They like the fable, but they can also relate to the model and seem to be able to know how to use it."

Hodges' next step is to get the feedback of his fellow chaplains by

publishing a description of what he believes is a unique patient counseling collaborative. He's also planning to add his spirituality lessons to other PCP groups at HCPC, such as those dealing with depression, coping with illness and substance abuse.

Joy Breckenridge, PhD, Program Coordinator for Clinical Programming has already given her support. "Religion and spirituality are important to a majority of people in our culture, and they should be a part of mental health treatment," she says.

"Unfortunately, however, they are often neglected. Adding a spiritual component to our counseling groups is an effort to build on a valuable inner resource. Not only do they complement each other, but each extends the other in such a way that the content is more accessible and useful to patients." ★

## Handling with Care

*Continued from page 14*

patient is out of control there needs to be a systematic plan of action to not only help that patient gain control but also assure a safe environment for the other patients and staff."

"The determination of whether a Special Team's intervention is needed," says Mackey, "must be made by the Head Nurse or RNs on duty. As a situation develops they must assess possible scenarios and decide if extra trained people will be needed to help maintain a safe environment for the patients."

When a "Special Team" call is broadcast over the Center's public address system, all those assigned to the task force for that shift assemble as fast as possible, usually just inside the patient unit or wherever the help is needed.

This call, Grice says, is comparable to an emergency Code Blue situation in a medical hospital, signaling that a patient is in crisis and extra help is needed.

The nurse-in-charge explains the situation and what she wants the Team to accomplish. The Team chooses

a leader who assigns each of the members specific jobs and cues them when to act. While Team members engage the patient verbally, others keep the other patients away from harm. If a non-violent physical intervention is called for, certain members restrain the person and prepare the seclusion room.

"The group's primary responsibility," Mackey says, "is to make the situation safe and then work, first to de-

escalate the situation by talking to the patient, and if that should fail, using safe and appropriate physical restraint to keep the patient from harming himself or others. While time is of the essence, the process must be smooth, orderly and calming, not an intervention that would only serve to further excite a patient or disturb others."

"Special Team can sometimes be an alternative to seclusion and

*Continued*



*Haywood and Holness provide week-long verbal and physical intervention training to all new HCPC employees.*

## Handling with Care

*Continued*

restraint," says Varner, "a kind of preventive show-of-force, which often makes seclusions unnecessary."

Often, Holness agrees, just the presence of the 10-member Special Team on a unit is enough to change a patient's behavior and stop them from



*Paula McClintock, RN, refreshes her skills with the help of trainer Foday Daramy.*

acting out any further. "I try to think of myself as a peace officer when I am involved in a Special Team," he says, "My job is to keep people safe and preserve law and order. I am not looking for a fight. But if I must use more severe measures to do my job, I am ready. Above all, I try to do whatever I do gracefully, always keeping in mind that these people have an illness and deserve my respect and care.

"We always start with verbal intervention," says Holness, "even if it's been tried before. For example, the patient may believe that a certain unit staff member is against him or he distrusts the staff, but the Special Team members are new to him and may be able to establish a rapport with that patient."

If physical intervention is needed, the Team uses "Handle With Care" holds designed to control the patient in a manner that is therapeutic and allows the patient to regain his composure on his own. These maneuvers also are a safe way for the staff member to evade any further physical danger.

"The Handle with Care program is superior to other physical intervention models," says Holness, "because it is geared toward preserving the safety of

both the patient and the staff member. It has resulted in giving our staff members more confidence about their ability to keep themselves as well as the patients safe."

A very important part of any Special Team intervention is the debriefing. The unit staff and Special Team members will talk to the other patients about what has happened, allow them to express their feelings, explain the reasons behind the actions taken, reassure them, and work to return the unit atmosphere to a normal, calmer state.

The members of the Team then evaluate the incident and their responses, noting the strengths and weaknesses of that particular intervention and how safety measures were maintained. If weaknesses in the

process are uncovered, special attention to these areas will be including in the training curriculum.

"Special Team is a valuable program," says Mackey, "and in 95 per cent of the cases where a Special Team

is called, the situation is resolved just by the presence of the team or verbal deescalation."

The use of seclusion and restraint will continue to be carefully studied and monitored at mental healthcare facilities like HCPC. Meanwhile, the presence of a strong patient management program emphasizing patient respect, safety and confidence, coupled with a well organized Special Team program for emergencies, ensures that HCPC will maintain its superlative record for effective patient care among public psychiatric facilities. ★



*Haywood demonstrates to trainees the proper way to disengage when grabbed with fellow-tech Daramy.*



*"Sadness,"  
12-year-old  
child of  
divorce,  
1996.*





## Location! Location! Location!

Well, it's all true when it comes to the new NeuroPsychiatric Center (NPC), the county's mental health crisis clinic located in the Texas Medical Center. The NPC, operated by the Harris County Mental Health and Mental Retardation Authority (MHMRA) is located in the old Ben Taub Hospital emergency room complex, just east of Fannin off North MacGregor, between Hermann and Ben Taub hospitals.

Opening last October and replacing the former MHMRA crisis center in midtown Houston, the NPC's new location has produced a response rate that not even those who planned the new center anticipated: in October, 526 people used NPC's emergency services. By December the number was up to 1000, in March 1200 and in May over 1300 patients were served. These numbers are far larger than those served at the old crisis facility.

"We were truly amazed at the response," says Barbara Dawson, the NPC's Interim Deputy Director for Psychiatric Emergency and Hospital Services with MHMRA. "Surely it's the increased visibility in the Medical Center and the easier accessibility via mass transit," she explains, "but it's also because of our new program with the Houston Police Department and through word-of-mouth." She also notes that the number of children and adolescents brought in for services has increased dramatically.

"I think this improved crisis facility has also gone a long way toward meeting another main goal," Dawson adds, "which is helping to promote early identification and intervention of mental health problems, because we know that time can make a great deal of difference in treatment of these illnesses."

The Psychiatric Emergency Services (PES) at NPC function as a full-service, 24-hour, public psychiatric emergency room, with a staff of 100 psychiatrists, nurses, aides and counselors. Any person—with or without medical insurance—in Harris County who is experiencing a mental health or substance



MHMRA's NeuroPsychiatric Center housing the Psychiatric Emergency Services (PES), a new mental health crisis center, is located in the heart of the Texas Medical Center in the old Ben Taub emergency room.

abuse emergency can come to the PES for immediate evaluation.

Patients are assessed and stabilized or provided medication and then referred either to outpatient treatment through one of MHMRA's eleven clinics around the community or, if seriously ill, transferred to HCPC or another, private psychiatric inpatient facility. HCPC also receives all children and adolescents from the PES who need inpatient care.

For those patients who require a more thorough assessment before referral, the PES has a 23-hour observation area. "This gives us time to see if new medications are effective, have a family visit or just observe someone more closely when we cannot get a clear diagnosis of the problem."

The NPC, Dawson believes, is one of the few such psychiatric crisis centers around the country, but its new Medical Director, Dr. Avrim Fishkind, comes to Houston from a similar center in Washington, D.C.

By the end of the summer, NPC hopes to open its "second phase," a 39-bed inpatient facility for those patients diagnosed as needing very short stays, usually between three to five days, or further observation before they are transferred to HCPC, where the average length of patient stay is seven to ten days.

Currently, the NPC is sending about 250 to 300 patients per month to HCPC. Because MHMRA serves as the "portal authority" for HCPC and must approve all admissions to the Center, all patients who receive treatment either at the NPC or HCPC become part of the MHMRA system.

Funding for the NPC comes from MHMRA allocations provided by the Texas Department of Mental Health/Mental Retardation (TDMHMR), which is the state agency charged with providing these services. The Harris County MHMRA, along with the 40 other MHMR authorities located around the state, are all separate, non-profit agencies which contract with TDMHMR to provide mental health services in their areas.

Although HCPC is operated by the University of Texas-Houston and is not officially a part of the Harris County MHMRA, it is an affiliate of the Texas state hospital system and receives funding from the State Legislature through a contract with MHMRA, funded by TDMHMR. It also receives some funding from Harris County. Both HCPC and NPC/MHMRA also receive private funding for patient care through contracts with managed care companies sponsoring Medicaid.

*Continued*



“It can be very confusing to figure out all the players,” says Dawson, “but we hope the NPC’s increased visibility will make it easier for people to get help when they need it. We see the NPC as improving the communication between all the mental health providers and helping move people through the mental health system more efficiently.”

Despite the logistical problems of two different managing agencies, the interface between NPC and HCPC has worked out smoothly.

“The NPC fills an important niche in the continuum of care, making sure that truly those people without resources who need psychiatric care are prioritized and sent to our facility,” says Greg Gigax, RN, BSN, Coordinator of Patient Registration at HCPC, the department that oversees all admissions. “We continue to work hard at streamlining the admissions process for all agencies involved, which ultimately serves the patients and their families.”

“There is no doubt that inpatient hospitalization services for the mentally ill public will always be required,” says Dawson. “but the mission of NPC’s PES is to help those who do not need acute care avoid being hospitalized, promoting ‘least restrictive environment’ mandate and allowing them to remain in their communities.”

“Early intervention is also key. I believe when we see people soon enough and help divert them from more serious consequences, such as criminal behavior or violence, it improves the quality of life for the whole community.”

Dawson says that the increase in people needing mental health services generated by the opening of PES only shows how much a need there is in Harris County, but that access is greatly hampered because resources are limited. “In terms of funding for people with mental illness the Harris County MHMRA ranks 38th among the 40 Texas MHMR Authorities,” she says.

“There is talk that during the next session of the Texas Legislature, funding for all 40 authorities will be leveled to the ‘average’ amount of funding; in that case, Harris County would require an increase of \$9.8 million per year. To bring Harris County up to the national average would require \$50.9 million per year,” Dawson added. ★

## CROSSTALK Offers Unique Perspective

by Sylvia Villarreal

Talking things out is a time-honored method for articulating and resolving problems. And when those issues involve the destigmatization of those with severe, persistent mental illness, as well as providing advocacy and adequate funding for treating this most vulnerable group, clear communication is vital.

With this in mind, members of Houston’s mental health community have been meeting for the past year in a unique collaboration. Funded by a grant from Eli Lilly, the Key Influencer Project (KIP) is the brainchild of Harvard researcher and clinician William Glazer, MD. As a national consultant in the mental health arena, Glazer observed that the sea change in health care policy, with its increasing emphasis on cost containment, was demoralizing providers.

As a counteroffensive, he proposed “Key Influencers” be recruited to educate mental health providers about ways to be active participants in their own destiny. Glazer crafted a team teaching approach in which a triad of a consumer, a family member and a provider could join to protect quality of care as well as ensure access for severely ill psychiatric patients. KIP groups considered three specific questions in their initial discussions: Is there a revolution in the mental health system? Is there a new alliance among patients, providers and loved ones? What is the nature of recovery in the changing health care climate?

Their dialogues are summarized in a manual entitled “CROSSTALK, Developing the Mental Stakehold Alliance,” which has been used in presentations by KIP panelists at both UT-Houston Medical School and Baylor College of Medicine as well as the Veterans Affairs Medical Center, MHMRA-Harris County, and UTMB-Galveston.

Kathryn J. Kotrla, MD, a KIP panelist, is an Assistant Professor of Psychiatry at Baylor College of Medicine, Chief of Psychiatry at Ben Taub General Hospital and Co-Director of the Schizophrenia Diagnostic Group of the Veterans Affairs Mental Illness Research, Education, and Clinical

Center. Kotrla says being involved with CROSSTALK has been valuable on many levels.

“Sitting with consumers and families and hearing their stories, I was struck by the insensitivity providers had shown in some situations. Training medical students and other providers to respect the concerns of consumers and families is critical. The triad of consumer, family member and provider, which we used at the UT-Houston Department of Psychiatry Grand Rounds this past March, was very effective. Some colleagues commented on how moved they were by the presentation.”

Kotrla feels strongly about both the stigmas attached to severe, persistent mental illness and the gap in adequate funding for treatment. “We need more services where the neurobiological advances that are being translated into effective treatments can be utilized.” She also hopes programs like CROSSTALK can combat harmful myths that impact this group. “Particularly harmful is the idea that severe mental illness and violent behavior are inextricably linked. Bad behavior is not mental illness.”

Anu Matorin, MD, UT-Houston assistant professor of Psychiatry and Behavioral Sciences, also a KIP member, highlights the need to connect with colleagues, families and patients not just on a ‘clinical’ level but also on an advocacy level to influence change.

“As a field we are tremendously excited and optimistic—the challenge is to get these breakthroughs in treatment to those who need them most along with the necessary support services,” she says.

Linda Zwiefel, Education and Affiliate Coordinator for the National Alliance for the Mentally Ill (NAMI-Texas), manages the Houston KIP. Zwiefel hopes to expand the project statewide and currently plans to take CROSSTALK to judges and legislators. She has witnessed firsthand the personal growth of KIP consumer members as they develop coping and advocacy skills.

“These folks are the real experts,” Zwiefel notes. “They live and cope with mental illness on a day to day, minute to minute basis”

For all KIP members, helping this group to find a “voice” is both challenge and reward. ★



Untitled, 16-year-old female cancer victim, 1998

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