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Administrators in Academic Psychiatry

From the president's desk

by Pat Sanders Romano

I am in that limbo of being four weeks post-Italian-vacation and 45 weeks pre-Italian-vacation.

Why are those trips so vital to me?

· My trips are a welcome opportunity to concentrate on, and therefore recognize, the importance of relationships. With only a basic command of Italian and lots of smiles, I have made and maintained a large group of friends, with whom I now share major life events and simple pleasures.

· I am able to be a part of a community and experience the concept of "it takes a village." I watched the most adorable 16 month old use the cobblestone piazza as her playground. She is the most joyfully free child I know, because the eyes and arms of the entire village watch, embrace, and care for her.

· I can let down my guard, I can stop needing to be in control, and therefore I am more receptive to learning. How else can you explain the person who got D's in high school French speaking Italian?

Now that I have returned, a bit wiser, a bit relaxed and a whole lot happier, I have been trying to decide how I can and will replicate my Italian experience here in my work, in my affiliations and in my life.

And, in thinking about us, Administrators in Academic Psychiatry, I realize that we can also replicate this experience.

Relationships

As administrators, we have many relationships: with our chairs, our administration, our docs, our PIs, our students, residents and fellows, our colleagues, our staff and our patients. Yet, do we adequately concentrate and value those relationships, are they important to us?

I am currently working with a novice administrator. She is young, hard working and intelligent, with both book and "street" smarts, but she is feeling terribly frustrated trying to succeed in her job. It soon became apparent that the reason she is so frustrated is that she has been trying to do her job alone. I recounted a tale, cited in my Chair's most recent book by David J. Wolpe [*Teaching Your Children about God* (New York: Holt, 1993), p. 214]:

> *A boy and his father were walking along a road when they came across a large stone. The boy said to his father, "Do you think if I use all my strength, I can move this rock?" His father answered, "If you use all your strength, I am sure you can do it." The boy began to push the rock. Exerting himself as much as he could, he pushed*

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Fall educational conference

Psychiatry: Beyond clinical practice

The 2005 Fall Educational Conference will be held November 4-5 in New Orleans at the Chateau Sonesta Hotel in the French Quarter. The Education Committee has been working very hard planning an outstanding program. With the theme, "Psychiatry: Beyond Clinical Practice" we will be taking a look at furthering the psychiatry practice in nontraditional business models.

Geoff Nagle, PhD, MPH, MSW, LCSW will be our MacLeod Lecturer. Dr. Nagle is an Assistant Professor in the Department of Psychiatry and Neurology at Tulane University. He is the Director of the Tulane Institute of Infant and Early Childhood Mental Health, the Coordinator for Louisiana's State Maternal and Child Health Early Childhood Comprehensive Systems, Chairman of the Louisiana Governor's Children's Cabinet Advisory Board, and a member of the Louisiana Governor's Children's Cabinet. Dr. Nagle will discuss programs that have shifted focus from clinical practice to training and public policy initiatives.

Patricia Birkmeyer and **Doris Chimera** (U Texas - Galveston) and **Marti Sale** (U Kentucky) will discuss how they have implemented telemedicine projects to meet community and forensic needs. **Lee Fleisher** is scheduled to make a presentation entitled "Building effective teams: A group dynamics model". There will

be a presentation/ panel discussion regarding the effort to allow psychologists to prescribe medication. New Mexico was the first state to pass this legislation, and Louisiana was the second. This panel will take a look at the differences between the two states, and future legislative initiatives in other parts of the country. We are planning to have a presentation from the VA regarding Mental Illness Research, Education and Clinical Centers. MIRECC is a research arm of the VA. This presentation will provide an overview of MIRECC's network nationwide, and how academic medical centers can work in partnership with the VA. And of course, we will have the "Take Two Minutes" segment of our conference.

Our Fall conference will begin Friday evening, November 4, with a networking dinner at Michaul's Cajun Restaurant (www.michauls.com). Michaul's provides authentic Cajun food with live Cajun music and dance lessons. The Saturday networking dinner will be at Arnaud's restaurant (www.arnauds.com). Arnaud's is an old New Orleans restaurant with classic New Orleans Creole cuisine. This restaurant also houses a Mardi Gras museum. The attire for Saturday night is business casual (no coat/tie, but no blue jeans either).

Hotel reservations can be booked online at www.chateausonesta.com. Choose "Hotel Reservations", then choose "Group Block", enter 665320 in the "Group Block" box, and fill in the required information. Or call the hotel directly at (504) 586-0800. Please feel free to call **Jim Landry** at (504) 988-1975 if you need assistance in booking your room.

Finally, I would like to recognize our 2005-2006 Education Committee members. Tt takes the help of many of our members to put on a conference. One of things that make AAP such a strong organization is the willingness of its members to actively participate. This year thirteen of our colleagues volunteered to be part of the Education Committee: **Elaine Macintosh** (U Nebraska), **Hank Williams** (U Washington), **Christine Johnston** (Indiana U), **Doris Chimera** (U Texas - Galveston), **Radmila Bogdanich** (Southern Illinois U), **Cindy Smith** (Washington U), **Patricia Birkmeyer** (U Texas - Galveston), **Rich Erwin** (U Missouri), **Jim Puricelli** (Loyola U), **Pat Sanders Romano** (Albert Einstein COM), **Marti Sale** (U Kentucky), **Janice McAdam** (U Kansas), and **Steve Blanchard** (U Iowa). I sincerely thank each and every one of you for your efforts to ensure continued quality educational conferences for our members.

Continued from page 1

and pushed. The rock did not move. Discouraged, he said to his father, "You were wrong, I can't do it." His father placed his arm around the boy's shoulder and said, "No son. You didn't use all of your strength—you didn't ask me to help."

I advised her that she didn't have to do everything herself, that a large part of being a proficient administrator was building relationships, and not going it alone. We, as administrators, learn to share the joy and the burden by relating to others. By the nature of our work we must assist others in reaching their goals, and that's our real satisfaction and our significant "core competency." How important was it to first inquire about our Purchasing Director's wife's heart surgery before I explained why we needed to purchase paint for a rat swimming pool? And how important was it to do several "riffs" on rats doing the back stroke before I got the PI to take the time to explain why he needed a rat swimming pool!

Community

Our departments can be like villages. We have elders, newcomers, neighbors, "haves and have-nots," and even the village "idiot." In many respects, we as administrators are the mayors. It is our job to make sure that the elders teach, the newcomers add vitality, the neighbors are friendly, the classes work cooperatively and the idiot is protected.

As my Chair, T. Byram Karasu, noted: [The Art of Serenity, (New York, Simon Schuster, 2003) p. 64]

The distribution of power and responsibility to one's team not only preserves the competent person's energy and wellbeing but also cultivates the competence of others, ultimately benefiting everyone. The one who has real power (personality, intelligence, judgment) will welcome all the help she needs even though doing so may seem to dilute her authority and significance. Ultimate authority and significance come not by holding on to the center of power and having others feel dispensable but making oneself relatively dispensable.

At this moment, as I write this, my staff is orienting a newly appointed Associate Executive Director in one our divisions. She will spend time with the person who handles Medical School education, the person who handles Graduate Medical Education, the person who handles faculty affairs and the budget manager. All were willing and excited to assist, allowing me to I finish this article as well as some other priority work. I know that they will watch, embrace and care for the new AED.

As mayor of my "village," I have developed my staff by treating them as individuals, by giving them their own distinct areas of responsibility, and by encouraging competence. At the same time, I demanded a workplace characterized by mutual respect and genuine compassion.

Letting Go

For me, as I suspect for many of us, this is the most difficulty skill to master. We were hired by our chairs because they accurately diagnosed us as "OC." So, while I recognize the value of letting go, it is still difficult for me to do in the workplace.

Where I have had success is with you, my colleagues in AAP. Certainly our educational meetings, with their relaxed and collegial environment, have encouraged skill building and knowledge development. Our listserv, as another means of stress-free learning, allows us the opportunity, in a non-threatening way, to seek guidance and learn from one another.

So, although I have 45 weeks to go, and I do miss the food, I am confident that I am working toward the spirit I so enjoy while on vacation.

Comings and goings

Please feel free to call new members and personally welcome them to our organization. One of the things that makes AAP special is its friendly members! The hospitality offered by a personal contact will surely be appreciated.

AAP wishes to extend a warm welcome to the following new members:

Lori Batkay
University of Pittsburgh
(412) 246-6772
batkaylj@upmc.edu

Georgia McCray
Vanderbilt University
(615) 936-5693
georgia.mccray@vanderbilt.edu

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Texas Children's Hospital
(832) 822-4771
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Susan Routburg
Children's Memorial Hospital (Chicago)
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sroutburg@childrensmemorial.org

The college corner

New MGMA/ACMPE study and reference tool available

by David Peterson, FACMPE

I have recently had the occasion to use a new study and general reference tool associated with the Medical Group Management Association (MGMA) and the American College of Medical Practice Executives (ACMPE). The book, **Physician Practice Management**, authored/edited by Lawrence F. Wolper, FACMPE, is described as a "seminal work" by MGMA President and CEO, William Jesse, MD, FACMPE, FACPM. In his Forward to the book, Dr. Jesse states that "this book is a comprehensive treatment of the breadth and depth of knowledge that must be mastered in order to effectively manage a medical group practice today."

Dr. Jesse continues: "At one time medical practice administration was primarily concerned with billing and collections and other aspects of financial management. Today, however, the practice administrator must be expert in human resources management, risk management, clinical and business operations management, governance, planning and marketing and a variety of other competencies, in addition to having extensive financial management skills."

It is probably no coincidence that the skill set Dr. Jesse describes is also contained in the eight domains of the ACMPE's **Body of Knowledge**. It is these domains that the medical practice executive must master to achieve ACMPE board certification and Certified Medical Practice Executive status in the College.

Coming in just shy of 700 pages, Mr. Wolper's book lives up to its subtitle, "Essential Operational and Financial Knowledge" and draws upon the expertise of 45 contributors. The topics covered in the book range, for example, from such medical practice staples as organizational management, financial management, labor law, and physician compensation (to name only four) to "Bioterrorism and the Physician's Office." Want to know about Stark law or the False Claims Act? - see Chapter 18. Facility planning and design? - see Chapter 23. Healthcare information technology? - see Chapter 13. Marketing? - see Chapter 7. How about medical practice in other countries? - see Chapter 1. It's all there and more in 24 different chapters.

Because of the broad range of topics covered, the book is a great primer on all facets of medical practice management and certainly relevant to the clinical administrator in an academic setting. Regardless of our practice setting, we all operate in a medico-legal environment and are extensively involved and, at one level or another, require expertise in all eight domains of the Body of Knowledge, as Dr. Jesse notes.

Mr. Wolper's book is an essential study tool when preparing for board certification and I highly recommend it. For those already certified or not seeking certification, the book is still a great reference tool and would be quite at home on every medical practice executive's office book shelf. It can be ordered through MGMA at www.mgma.com.

For more information on joining the ACMPE or the board certification and fellowship process, contact the ACMPE directly at (303) 397-7869 or contact David Peterson, FACMPE at (414) 456-8990, email at peterson@mcw.edu or at the Department of Psychiatry and Behavioral Medicine, Medical College of Wisconsin, 8701 Watertown Plank Road, Milwaukee, Wisconsin 53226.

MGMA academic practice compensation survey

If you are a member of the MGMA Academic Practice Assembly, you should have already received the questionnaire for the Academic Practice Compensation and Production Survey. You are asked to complete the questionnaire and return it by the due date. If you have previously participated in the survey you know how valuable the information is in managing academic practices. Members who have not participated in the past will find the survey an extremely useful tool for faculty recruitment, productivity, compensation and a variety of other data.

MGMA will be giving awards of $1,000, $750, and $500 to the top three ASIGs with the greatest participation percentage increase from last year. (Last year, Administrators in Academic Psychiatry received one of the awards - let's see if we can do it again!)

Another added bonus is the survey will be distributed in January 2006 just in time for budget preparations and anyone who returns a completed survey to MGMA receives a copy free.

So, please help yourself - and AAP - by filling out the survey and returning it by the due date.

Mental illness stigmas receding, misconceptions remain

New survey shows disconnect between understanding and treatment seeking

The diagnosis of a mental illness no longer carries the fear or shame it once did, according to a survey released recently by the American Psychiatric Association. Nearly 90 percent of Americans surveyed correctly believe that people with mental illness can live healthy lives and an overwhelming majority (80 percent) feels confident that mental health treatment works. Study findings also show that nearly 70 percent of people surveyed view going to a psychiatrist as a sign of strength.

Despite this very positive news, however, there are still some grave misconceptions to address. Each year in the United States, 1 in 5 adults are diagnosed with a mental illness, yet the same proportion of adults say they would not see a psychiatrist under any circumstances. In addition, a majority (57 percent) of those surveyed are not concerned about themselves or a family member ever having to deal with a mental illness. This is troubling news considering that a 1 in 5 incidence rate means that few American families are ever untouched by mental illness.

Although 75 percent of consumers believe that mental illnesses are usually caused by a chemical imbalance in the brain, those surveyed are almost twice as likely to seek help from a primary care physician rather than a psychiatrist - a specialist specifically trained to diagnose and treat chemical imbalances and other determinants of mental illness.

"Overall, the survey reports good news for understanding of mental health," said Steven S. Sharfstein, M.D., president-elect of the American Psychiatric Association. "However, the public needs to know that psychiatrists are medical doctors who are uniquely qualified to evaluate a person's physical and mental wellness and develop a comprehensive, individualized treatment plan."

Additional significant findings:

- More women than men think that seeing a psychiatrist is a sign of strength (78 percent vs. 61 percent)
- 75 percent of adults surveyed correctly understand that psychiatrists are medical doctors with medical degrees, while 38 percent mistakenly think that psychologists are medical doctors
- Younger adults are significantly more positive than older adults (65+) about mental illness issues, highlighting progress made in younger generations embracing the realities of mental illness.

According to recent studies, each year, more than 10 million antidepressant prescriptions are written by primary care doctors, with no mental health follow-up afterwards. While primary care doctors are often the first line of defense, for some patients, additional therapy is an important part of treatment.

"The most important step is to see a doctor if you are concerned about your mental health and we encourage people to seek someone with whom they feel comfortable. Our goal is to raise awareness so that patients know to ask specifics about mental illness and seek the treatment that will be right for them," said Dr. Sharfstein. "We seek to work closely with primary care providers to ensure comprehensive care, which may include medication, talk therapy or a combination of both."

American Psychiatric Association, Press release 05-24, May 4, 2005.

New APA Consumer Website -- Healthy Minds, Healthy Lives (www.healthyminds.org)

- Warning signs of mental disorders, treatment options, and prevention measures;
- A search function;
- The latest medical information from independent news sources;
- Links to other mental health resources;
- How to locate a psychiatrist; and
- Access to fact sheets and APA's *"Let's Talk Facts"* brochure series The brochures are free for the general public and can be purchased by health care providers, health care and academic institutions and businesses that seek to improve consumer understanding of mental health disorders.

Developing a compensation report card

How do you weigh the value of teaching, research and service?

By Claude E. Nichols, MD

Developing a report card to acknowledge the contributions of faculty in the three-legged stool of research, service and education is a difficult process. The rationales for developing this sort of reporting structure are to allow internal and external review of funds distribution and to allow informed salary decisions among faculty.

Whatever guidelines and metrics are used must reflect the character of the institution. The system must align faculty incentives with those of the institution. It also must ensure that all significant individual contributions are accounted for accurately and that there is a direct link between academic activities, recognition and reward.

Why bother? Arguments for developing this type of reporting system are many. First, it provides an objective way to assess each faculty member's contribution to the strategic goals of the department or institution. This allows for a reviewable, repeatable methodology for salary distribution. It also advances the strategic goals of the institution by guaranteeing a high degree of faculty buy-in. It explicitly states the criteria by which each faculty member is evaluated and, in turn, makes the faculty member aware of what is valuable to the institution. But there are also downsides to this type of assessment methodology. Productivity issues may arise with senior faculty members. The amount of financial reward available to recognize faculty contributions may be disappointing in proportion to the magnitude of the activity. Issues regarding the distinction of merit versus worth—with merit being how well one does one's work and worth being how important one's work is to the organization—also may arise. Expectations that the evaluation system will eliminate ambiguity surrounding teaching contributions may undermine the activity because these systems tend to be complex.

Basic elements

To be effective, a faculty evaluation system must include the following elements:

1. It must reflect the values and priorities of the institution.
2. Faculty must be involved in its design and construction.
3. The system must provide for feedback for individual faculty career goals, as well as personnel decisions.
4. Evaluation must be linked to faculty development opportunities.
5. Input must come from a variety of sources.
6. Data must be reliable.
7. Faculty concerns must be identified and addressed.
8. Both formative (career development) and summative (current performance) components of evaluations must be developed and differentiated.

Additionally, the environment must support this type of activity. Characteristics of a supportive culture include:

- Stable, effective, continuous leadership
- Well-managed faculty support
- "Champions" who can weather the initial skepticism
- Periodic reviews of the system to ensure that it continues to evolve and clearly reflects the goals of the department

Whatever guidelines and metrics are used must reflect the character of the institution. The system must align faculty incentives with those of the institution. It also must ensure that all significant individual contributions are accounted for accurately and that there is a direct link between academic activities, recognition and reward.

Examples of evaluation systems

Several types of evaluation

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systems have been described in the educational literature. The Association of American Medical Colleges' (AAMC) Mission-based Management Program has proposed a system based on relative value units (RVUs). This group outlined several steps to develop this type of RVU system:

1. Establish a list of faculty activities in education. This could include lecture, laboratory, clinical and nonclinical activities, as well as participation in developing materials, directing or administering education, doing research and writing, etc.
2. Evaluate the quality of teaching and the individual's specific role. Did the person work alone or as part of a team?
3. Identify the type of educational work. These might range from teaching and administration to developing educational products (courses, teaching materials), publishing and participating in service/outreach programs.
4. Weight the activities (category and programs). How important is the activity to the school's educational mission?

An advantage to using the RVU system is that faculty effort and contributions are not solely determined by the time expended. Under the AAMC scheme, the number of RVUs credited to a faculty member would be calculated as the product of the activity weight, quality and role adjustment, type of work, and units of activity performed.

An RVU methodology can also be utilized for research activities. These metrics provide important management data and aids in departmental goal setting.

Another methodology is the evaluation system used at the University of Minnesota Department of Family Practice and Community Medicine. This merit-review system evolved through several iterations of historical methods.

Each faculty member gathers supporting materials documenting his or her performance into a portfolio. The areas include: education, research and related activities, patient care, administration, outreach, self-development and citizenship. Faculty members also outline their goals on an annual basis.

A peer-review committee reviews and rates the portfolios and forwards its assessment to the department head, who then meets with each faculty member and establishes the final merit rating for distribution of awards. This process has improved the individual faculty reviews, enhanced the department's ability to track faculty productivity and increased research productivity.

Another approach to mission-based reporting (not related to the RVU system) is being used by the University of California, Davis School of Medicine (UCDM) to track faculty activity in education, research and service. The UCDM reporting mechanism is used to evaluate departmental strengths and weaknesses as well as to enable department chairs to do career counseling and goal setting. Their experience is that mission-based reporting successfully quantifies individual, departmental and school-wide productivity in education. They acknowledge, however, that mechanisms must be in place to budget and reward faculty efforts.

For more information:

- Nutter DO, Bond JS, Coller BS, et al. Measuring Faculty Effort and Contributions in Medical Education. *Acad Med* 2000:75;200-207.
- Bland CJ, Wersal L, VanLoy W, Jacott W. Evaluating Faculty Performance: A Systematically Designed and Assessed Approach. *Acad Med* 2002: 77:15-30.
- Rimar S. Strategic Planning and the Balanced Scorecard for Faculty Practice Plans. *Acad Med* 2000: 75:1186-1188.
- Howell LP, Hogarth MA, Anders TF. Implementing a Mission-based Reporting System at an Academic Health Center: A Method for Mission Enhancement. *Acad Med* 2003: 78:645-651.

Claude E. Nichols, MD, is chair of the department of orthopaedics and rehabilitation of the University of Vermont and a member of the AAOS Academic Business and Practice Management Committee. He can be reached at claude.nichols@uvm.edu

Good leadership requires good conflict management

by Ronald Menaker, FACMPE

How does conflict management intersect with the role of leadership in the health care industry? The aging population, cost pressures, staff shortages, increased competition, reduced reimbursements and other factors place tremendous pressure on leaders. Conflicts emerge as stakeholders take positions. Leaders of health care organizations need excellent conflict management skills if they are to guide their organizations to success.

Embrace leadership paradoxes

As leaders, we must embrace three fundamental paradoxes.[1] Executives need to:

- Be more hands-on with the business, but less hands-on with employees;
- Seek diverse points of view, but drive for consensus in order to take action; and
- Encourage experimentation, showing tolerance for mistakes, but safeguarding the assets and reputation of the organization.

Leaders benefit from an ability to see things as they really are and level with their co-workers while maintaining optimism.[2] We must mobilize thoughtful discussions around challenges and develop a plan to galvanize action.

Leaders should identify strategies by looking outward at the organization, yet inward at their own leadership needs.[3] Leaders should:

- Maintain perspective and the capacity for reflection, acting as both observer and participant;
- Court the uncommitted and the undecided; and
- Monitor and manage the level of conflict or dissatisfaction to encourage healthy percolation of issues without a destructive eruption of emotionis and resistance.

We must keep a delicate balance between exerting pressure to change and offering reassurance that change is in capable hands.

Manage many challenges

Leaders also need to manage the intellectual, physical and emotional challenges they face.[4] We need to contain hunger for congtrol and importance, which can lead us to avoid contentious issues. It's important to maintain a distinction between the personal and professional self to minimize defensiveness. Personal attacks can unwittingly conspire to make an organizational issue a personal issue as the leader becomes the problem.

With whom do administrators have conflict?

Medical practice administration brings a high potential for conflect with physicians regarding role and identity. Who has the strongest voice in administrative matters, especially in physicina-led organizations? Physicians may want control but hold the administration accountable for getting results. A great deal of relationship-building is required to understand these roles. Furthermore, the lay administrator needs facilitation and mediation skills to work through issues that affect clinical processes.

As leaders, we must separate the people from the problem, focus on interests, not positions, and look for options to create win-win scenarios.[5] A probing technique can help determine what is important and why.[6]

Insights and application

I focus on three ways to improve my own conflict-resolution skills. First, I try to balance optimism with reality. Optimism needs to be coupled with strategies to monitor performance and address negative outcomes. I have been called a cheerleader, so I have to be careful not to let my enthusiasm blind me to reality.

Second, I need to recognize when situations require technical change vs. adaptive (fundamental) change. How am I approaching the change process? Might I be the problem, resisting change to maintain my own comfortable status quo?

Third, I must guard against taking attacks personally, thus becoming an unwitting part of the problem. I resolve to separate the person from the issue and strive to see how my decisions will affect others.

Notes

1 Bates S. Corporate leaders face tough paradoxes. HR Magazine. 2003;48(7):12-13.
2 Bottles K. The good leader. Physician Executive. 2001;27(2):74-76.
3 Heifetz, RA, Linsky M. A survival guide for leaders. Harvard Business Review. 2002;80(6):65-73.
4 Ibid.
5 Fisher R, Ury W. Getting to yes: Negotiating agreement without giving in. 1991; New York: Penguin Books.
6 Shapiro RM, Jankowski MA. The power of nice. 1998;New York:John Wiley & Sons.

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Ronald Menaker is the administrator of the Department of Psychiatry and Psychology of the Mayo Clinic, Rochester, MN. He is also the vice chair of the American College of Medical Practice Executives (ACMPE).

NIMH policy for the recruitment of participants in clinical research

On June 1, 2005, NIMH instituted a new policy to monitor the recruitment of participants in NIMH-sponsored clinical research studies that expect to enroll 150 or more human subjects. The purpose of this policy is to ensure that realistic recruitment targets are established from the onset of a project, and that these targets are met throughout the course of the research.

Introduction

This policy relates to recruitment of participants in clinical research studies that expect to enroll 150 or more human subjects (in one institution or in a multi-institutional project) and are supported by NIMH grants, cooperative agreements, and contracts. This policy will not apply to research projects consisting of multiple independent studies that enroll fewer than 150 human subjects separately, yet may total 150 or more participants collectively.

NIH defines human clinical research as: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies. (2) Epidemiologic and behavioral studies. (3) Outcomes research and health services research. Note: Studies falling under Exemption 4 for human subjects research are not considered clinical research by this definition. This includes research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.)

In the past, some NIMH-sponsored research studies have not maintained an acceptable rate of recruitment, necessitating extensions in the time and funding needed to conduct the research. However, given the pressing need to support research that will reduce the burden of mental illness and behavioral disorders, in conjunction with declining fiscal growth, there is no longer the same flexibility to accommodate projects that exceed their proposed timeline and funding.

Purpose of Policy

The purpose of this policy is to ensure that realistic recruitment targets are established from the onset of a project, and that these targets are met throughout the course of the research. Mutually agreed-upon recruitment milestones (i.e., cumulative recruitment targets at set intervals) will be included in the terms and conditions of the award. If, at any time in the project period, the research design requires modification based on scientific results or other unpredicted events, the terms and conditions of the award may need to be modified. When developing milestones for recruitment, consideration must be given, as appropriate, to women and members of racial and ethnic minority groups and to children under the age of 21.

Responsibilities

The principal investigator/institution proposes the research project and its target population, including composition, and determines the preliminary recruitment targets.

The Scientific Review Administrator or contract officer, as appropriate, requests any additional information needed to review the proposed recruitment goals and strategies and the adequacy of the study population related to women, minorities, and children.

The peer review process assesses items such as relevance of the scientific question to the study population; acceptability of the relevant power calculations (including, as appropriate, calculations to detect gender, racial/ethnic, and age differences); and appropriateness of proposed recruitment strategies for total and for women, minority, and children study populations.

NIMH program staff review the research application/proposal and the summary statement/technical review for appropriateness and feasibility of recruitment strategies and targets. NIMH program staff contact the principal investigator/institution, when necessary, to obtain additional information.

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The National Advisory Mental Health Council reviews, as necessary, any issues related to proposed recruitment targets and strategies in grant applications.

NIMH program staff, prior to award, will request any additional information needed on milestones for recruitment targets (e.g., total, women, members of racial and ethnic minority groups) from the principal investigator/institution. Together with staff of the Grants Management Branch (GMB) or the Contracts Management Branch (CMB), program staff determine the terms and conditions of the award and discuss them with the potential grantee/contractor. The Grants Management Specialists or Contract Specialists review documents for inclusion in the official files and prepare special footnotes (i.e., terms and conditions) for the award statement. Awards will not be issued without appropriate documentation, i.e., one or more letters that define plans for meeting recruitment targets.

Terms and Conditions

NIMH program and GMB or CMB staff identify and review the following information from documents provided by the principal investigator/institution:

· Recruitment milestones that are expected to be met by the investigator/institution at specific time periods.

· Recruitment targets for women, members of racial and ethnic minority groups, and children as appropriate.

· Any other identified requirements for completion of the approved research project.

The GMB or CMB and program staff develop appropriate footnotes for the award that relate to recruitment milestones and the funds awarded. If, at any time, recruitment falls significantly below the milestones projected by the principal investigator/institution and agreed to by NIMH, NIMH will consider taking one or more actions, depending on the severity and duration of the recruitment shortfalls. NIMH generally will work with the grantee/contractor to correct the deficiencies before taking action, but in the case of continuing shortfalls, NIMH, in accordance with PHS policy, will consider suspending, terminating or withholding support and in some instances, may choose to negotiate a phase-out of the award.

Monitoring Award Performance

In accordance with the terms and conditions of the award, the investigator/institution provides NIMH program staff with progress reports on reaching recruitment milestones. Data and Safety Monitoring Boards may review the data and provide advice to NIMH, but this does not abrogate the responsibilities of NIMH program and GMB or CMB staff to monitor recruitment and determine whether the terms and conditions of the award are being met.

National Institute of Mental Health. Terms and Conditions for Recruitment of Participants in Clinical Research. Bethesda (MD): National Institute of Mental Health, National Institutes of Health, US Department of Health and Human Services; 2005; updated 6/1/2005. Available from: http://www.nimh.nih.gov/researchfunding/policyforrecruitment.cfm..

Coming Attractions

American Medical Group Association
September 12-15, 2005
Chicago, IL
www.amga.org

Medical Group Management Association Annual Conference
October 22-23, 2005 (Academic Practice Assembly Preconference)
October 23-26, 2005
Nashville, TN
www.mgma.com

Administrators in Academic Psychiatry Fall Conference
November 4-5, 2005
New Orleans, LA
www.adminpsych.org

Administrators in Academic Psychiatry Spring Conference
May 6, 2006
Chicago, IL
www.adminpsych.org

Academic Practice Assembly Annual Conference
May 7-9, 2006
Chicago, IL
www.mgma.com

NIH Regional Seminars in Program Funding and Grants Administration
March 30-31, 2006
Boston, MA

May 30-June 1, 2006
Riverside, CA
grants.nih.gov/grants/seminars.htm

The GrAAPvine provides information about educational opportunities of interest to its members. It does not necessarily endorse these programs (except, of course, our own!)

Medical journals require registration of clinical trials

In the coming weeks and months, publishers of many, if not most, medical journals will begin to require prospective public registration of certain clinical trials as a prerequisite for publication.

Any research project that prospectively assigns human subjects to intervention and comparison groups in order to study the cause-and-effect relationship between a medical intervention and a health outcome must be registered..

Studies designed for other purposes (retrospective records review, pharmacokinetics, major toxicity, other phase 1 trials, etc.) are exempt from this requirement.

For more information about which clinical trials should be registered, see paragraphs three, four, and five of "*Is This Clinical Trial Fully Registered?: A Statement from the International Committee of Medical Journal Editors*" at http://www.icmje.org/clin_trialup.htm.

At present, the most prominent public trial registry that meets all ICMJE criteria is ClinicalTrials.gov, sponsored by the United States National Library of Medicine.

By July 1, 2005, you must register before beginning subject enrollment. Beginning September 13, 2005, register trials that began subject enrollment before July 1, 2005.

Sponsored clinical trials are likely to be registered on ClinicalTrials.gov (http://www.clinicaltrials.gov/) by the lead sponsor. Clinical trials conducted under an FDA IND or IDE are likely to be registered by the IND or IDE holder. Otherwise, trial registration falls to the study investigator. Before investigators register a sponsored trial, they should search the ClinicalTrials.gov website to be sure that the trial has not already been registered.

To register a trial, go to www.ClinicalTrials.gov and follow the navigational instructions.

Step 1 - Open an organizational or individual account. If your research department or group already has an organization account, contact the account's "Protocol Registration System (PRS) Administrator" and skip to Step 2.

If your research department or group does not already have an organization account, identify the person(s) who will serve as the PRS Administrator(s) and have them set up an account. Be sure that the name of the organization account is specific to your research department or group. All future trial registrations for that organizational account will have to be entered by the account's PRS Administrator(s).

Alternatively, investigators who do not belong to a research department or group that has an organization account (or the potential for establishing one with a centralized PRS administrator) may open an individual account by following the instructions on the ClinicalTrials.gov web site.

Completion of the account application takes only minutes, but allow 1-2 days for ClinicalTrials.gov to respond with an account number for use in Step 2.

Step 2 - Register the trial. The required information will include variations on the following:

- Unique trial number
- Trial registration date
- Secondary trial IDs
- Funding source(s)
- Primary sponsor
- Secondary sponsor(s)
- Responsible contact person
- Research contact person
- Title of the study
- Official scientific title of the study
- Research ethics review
- Medical condition studied
- Intervention(s)
- Key inclusion and exclusion criteria
- Study design type
- Anticipated trial start date
- Target sample size
- Recruitment status
- Primary outcome
- Key secondary outcomes

With required information at hand (the protocol, informed consent document, and IRB application will be helpful), expect entry of each registration to take approximately 1-2 hours.

While the ClinicalTrials.gov registration form may prompt for entry of information regarding a trial's IRB approval, it is not necessary at this time to obtain additional IRB approval of the content of the registration information itself. ClinicalTrials.gov has yet to determine if and how IRB validation of the registration information will be sought.

Unregistered or improperly registered trials risk not being accepted for consideration by ICMJE member and other journals.

For more information, see ICMJE editorial statements at

- http://www.icmje.org/clin_trial.pdf
- http://www.icmje.org/icmje_response.pdf
- http://www.icmje.org/clin_trialup.htm

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Small grant program for conference support

Announcement: PAR-05-123
Reissue of PAR-00-141
Agency for Healthcare Research and Quality (AHRQ)

Note: The policies, guidelines, terms, and conditions stated in this announcement may differ from those used by the NIH.

The Agency for Healthcare Research and Quality (AHRQ), announces its continued interest in supporting conferences through its Small Grant Program for Conference Support. AHRQ seeks to support conferences that help to further its mission to improve the quality, safety, efficiency, and effectiveness of health care for all Americans. The types of conferences eligible for support include: 1) Research development - conferences where issues or problems in the delivery of health services are defined and a research agenda or strategy for studying them is developed; 2) Design and methodology - conferences where methodological and technical issues of major importance in the field of health services research are addressed or new designs and methodologies are developed; 3) Dissemination conferences - where research findings are summarized and communicated broadly to organizations and individuals that have the capability to use the information to improve the outcomes, quality, access to, and cost and utilization of health care services; and/or, 4) Research Training, Infrastructure and Career Development-conferences where research faculty and students are brought together with users of research to develop, share and disseminate research products, experiences, curricula, syllabi, approaches or core competencies required to train individuals from multi- and interdisciplinary backgrounds or prepare developing or emerging research institutions to conduct and translate research related to fostering improvements in health care delivery in the US.

AHRQ is especially interested in supporting conferences that demonstrate strategies which include plans for disseminating conference materials and products beyond the participants attending the event. Such strategies might include, but are not limited to, submitting articles for publication, posting information on a Web site, and seeking formal opportunities to discuss conference information with others.

This PA will use the conference grant (R13) award mechanism. AHRQ small conference grants are those with direct costs of $50,000 or less over the project period. Applicants may request full or partial support for conferences. Partial support is encouraged and the peer review will consider the overall structure and design of the conference as well as the subcomponent for which support is being requested. As an applicant, you will be solely responsible for planning, directing, and executing the proposed project.

Applications may be submitted by domestic (U.S.) public and private nonprofit organizations, including universities, clinics, units of State and local governments, tribes, foundations, and scientific or professional societies. An individual is not eligible to receive a grant in support of a conference. In the case of an international conference, the U.S. representative organization of an established international scientific or professional society is the eligible grantee. Grant funds may not be used to provide general support for international conferences held outside the United States or Canada. However, grant funds may be awarded to support specific aspects of an international conference held outside the United States or Canada.

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 9/04). The PHS 398 is available at http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format.

Key Dates

Application Receipt Date(s): August 20, October 20, December 20, February 20, April 20, June 20 annually (beginning August 20, 2005 and ending June 20, 2008)
Peer Review Date(s): October, December , February, April, June, August
Earliest Anticipated Start Date: January 1, March 1, May 1, July 1, September 1, November 1
***Date of conference*:** Within 12 months of start date of award
Conference Summary: Within 90 days after the conference dates
***Expiration Date*:** June 21, 2008

The complete program announcement can be found at http://grants1.nih.gov/grants/guide/pa-files/PAR-05-123.html.

Discontinuation of the NIMH behavioral science track award for rapid transition (B/START)

Notice: NOT-MH-05-015
National Institute of Mental Health (NIMH)

The National Institute of Mental Health began the B/START Program in October 1993 with the aim of facilitating the entry of new investigators into the field of behavioral science research. Since then, the program has successfully given rapid funding to new investigators in many areas of behavioral science research. The B/START R03 mechanism, however, has gradually evolved to resemble the regular small research grant program R03 (PA-03-108). Therefore, when the B/START program announcement (PAR-04-010) expires in October 2006, the NIMH will not renew this announcement. Please note that the last receipt date for the B/START program will be 10/1/2006 for both new and revised applications.

Initial projects from new investigators will continue to be accepted, but they should be submitted for the regular small grant R03 program (PA-03-108) or the Exploratory/Developmental Research Grant program (R21, PA-03-107). The regular R03 and R21 grant applications will be reviewed in content appropriate study sections at CSR and the NIMH, rather than through the mail-review method that did not afford discussion among the reviewers.

New investigators are also encouraged to check the NIMH webpage for other opportunities available to them at: http://www.nimh.nih.gov/grants/pamenu.cfm, where NIMH program announcements are listed in order of publication date, and at http://www.nimh.nih.gov/researchfunding/training.cfm, the NIMH Training page. Investigators may also sign up to be members of the NIMH Funding Opportunities (NIMHFUNDINGOPPS) listserv, which sends out emails announcing the publication of NIMH initiatives and notices. See http://www.nimh.nih.gov/tools/researchlistserv.cfm.

Inquiries regarding this notice may be directed to:
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New modifier For HPSA bonuses

Starting next year, you won't need to attach the QB or QU modifiers to your Medicare claims to identify your facility as rural or urban.

The Centers for Medicare & Medicaid Services (CMS) cannot distinguish between rural and urban health professional shortage areas (HPSAs) anymore, because of the automated bonus payment implementation, according to a July 22 transmittal. Therefore, CMS has end-dated the QB modifier (Physician providing service in a rural HPSA) and QU modifier (...an urban HPSA) and created a new modifier to take their places.

You can append modifier AQ (Physician providing a service in a Health Professional Shortage Area (HPSA)) to your claims with service dates on or after Jan. 1, 2006.

To read CMS' transmittal, go to http://www.cms.hhs.gov/manuals/pm—trans/R608CP.pdf.

FDA approves Cyberonics' VNS Therapy System™ for treatment resistent depression (TRD)

First FDA-approved treatment specifically for TRD
First implantable device-based treatment for depression

HOUSTON, Texas, July 15, 2005 — Cyberonics, Inc. (NASDAQ:CYBX) today announced that the United States Food and Drug Administration (FDA) approved the Vagus Nerve Stimulation (VNS) Therapy System™ "for the adjunctive long-term treatment of chronic or recurrent depression for patients 18 years of age or older who are experiencing a major depressive episode and have not had an adequate response to four or more adequate antidepressant treatments." VNS Therapy is delivered from a small pacemaker-like generator implanted in the chest that sends preprogrammed, intermittent, mild electrical pulses through the vagus nerve in the neck to the brain. The VNS Therapy System is the first FDA-approved implantable device-based treatment for depression and the first treatment developed, studied, approved and labeled specifically for patients with treatment-resistant depression (TRD). The VNS Therapy System was approved as a treatment for medically refractory epilepsy in Europe in 1994 and in the United States and Canada in 1997 and as a treatment for TRD in Europe and Canada in 2001. Over 32,000 patients worldwide have accumulated over 94,000 patient years of experience with the VNS Therapy System. The VNS Therapy System is now commercially available for the treatment-resistant depression and refractory epilepsy approved uses in the United States, European Union and Canada. For more information on VNS Therapy for treatment-resistant depression, including the contraindications, warnings and precautions, see the Physician's and Patient's Manuals and other information at www.cyberonics.com or www.vnstherapy.com or call 1-877-NOW 4 VNS.

Major depressive disorder is one of the most prevalent and serious illnesses in the U.S., affecting nearly 19 million Americans every year. According to the National Institute of Mental Health, depression is the leading cause of disability in the United States and worldwide. Approximately 20 percent of depressed Americans, or approximately four million people, experience chronic or recurrent TRD that has failed to respond to multiple antidepressant treatments including antidepressant medications, talk therapy and in some cases, ECT (electroconvulsive therapy).

"Today for the first time, Americans with treatment-resistant depression have an FDA-approved, informatively-labeled, long-term treatment option for their lifelong and life-threatening illness," commented Robert P. ("Skip") Cummins, Cyberonics' Chairman of the Board and Chief Executive Officer. "Cyberonics is much better prepared to accomplish its mission today than it was in 1997 at the time of epilepsy approval," continued Mr. Cummins. "In 1997 when the VNS Therapy System was first approved by FDA, the device was a new device, the therapy was a revolutionary new therapy and Cyberonics was a new device company with no U.S. commercial experience. Today, the Company, the therapy and the VNS device that was approved as a treatment for TRD have not only survived, but also thrived in eight years of commercial use and in seven years of rigorous TRD studies. VNS is today a proven, safe, effective and cost-effective therapy with good coverage, coding and reimbursement, whose approved use, like so many anti-epileptic drug precedents, is expanding to another indication. Studies and epilepsy commercial experience confirm that VNS offers patients and their families, prescribing physicians, surgeons, hospitals and payers a unique value proposition and benefit to risk ratio that for many is sustained or improves over time. Furthermore, Cyberonics has proven its unwavering commitment to people with chronic, treatment-resistant illnesses through long-term clinical studies. Today, approximately 330 well-trained customer support personnel are beginning to satisfy the very specific needs of patients with TRD, their families, psychiatrists and payers as well as the needs of our existing epilepsy customers.

Excerpted from press release July 15, 2005, Cyberonics, Inc.

Billing for VNS services

Coverage for VNS Therapy for the adjunctive long-term treatment of chronic or recurrent depression for patients over the age of 18 who are experiencing a major depressive episode and have not had an adequate response to four or more adequate antidepressant treatments is likely to be based on each individual's unique clinical circumstances until payers have an opportunity to implement formal policy. Medical policy documents are designed for informational purposes and receipt of benefits is subject to satisfaction of all terms and conditions of the coverage.

Medicare

Medicare covers hospital inpatient and outpatient services that are medically necessary and appropriate. Contact the patient's local Medicare Carrier Medical Director for further coverage information.

Medicaid

Medicaid programs cover hospital inpatient and outpatient services that are medically necessary and appropriate. Most state Medicaid agencies have yet to develop their own coverage policy for VNS Therapy for depression. In many cases, prior authorization may be required. Reimbursement mechanisms vary state by state.

Private Payers

Private payers also cover hospital inpatient and outpatient services that are considered to be medically necessary. Many private payers have not yet developed clinical guidelines for coverage of the VNS Therapy System for depression. In some cases written prior authorization may be required. Reimbursement mechanisms will also vary from plan to plan.

ICD-9 PROCEDURE CODES —IMPLANTATION, REPLACEMENT OR REMOVAL

04.92 Implantation or replacement of peripheral neurostimulator lead(s)
86.94 Insertion or replacement of single array neurostimulator pulse generator
04.93 Removal of peripheral neurostimulator lead(s)
86.05 Incision with removal of foreign body or device from skin and subcutaneous tissue; Removal of neurostimulator pulse generator (single array, dual array)

PHYSICIAN AND OUTPATIENT FACILITY CPT-4 CODES

Implant

64573 Incision for implantation of neurostimulator electrodes; cranial nerve
61885 Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array

Revision or Removal

64585 Revision or removal of peripheral neurostimulator electrodes
61888 Revision or removal of cranial neurostimulator pulse generator or receiver

ANALYSIS-PROGRAMMING—ALL SETTINGS

95970 Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse, amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (ie, cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/ transmitter, without reprogramming
95974 Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse, amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse enerator/ transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour
95975 Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse, amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/ transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)

For futher information, see the VNS/Cyberonics website at http://www.vnstherapy.com/default.aspx. Reprinted with permission.

The back page

Save the whales. Collect the whole set.
A day without sunshine is like, night.
On the other hand, you have different fingers.
I just got lost in thought. It wasn't familiar territory.
42.7 percent of all statistics are made up on the spot.
99 percent of lawyers give the rest a bad name.
I feel like I'm diagonally parked in a parallel universe.
Honk if you love peace and quiet.
Remember, half the people you know are below average.
He who laughs last, thinks slowest.
The early bird may get the worm, but the second mouse gets the cheese in the trap.
Support bacteria. They're the only culture some people have.
Monday is an awful way to spend 1/7 of your week.
Change is inevitable, except from vending machines.
Get a new car for your spouse. It'll be a great trade!

Plan to be spontaneous tomorrow.
Always try to be modest, and be proud of it!
If you think nobody cares, try missing a couple of payments.
How many of you believe in psychokinesis? Raise my hand...
How do you tell when you're out of invisible ink?
When everything is coming your way, you're in the wrong lane.
Hard work pays off in the future. Laziness pays off now.
If Barbie is so popular, why do you have to buy her friends?
How much deeper would the ocean be without sponges?
Eagles may soar, but weasels don't get sucked into jet engines.
What happens if you get scared half to death twice?
I used to have an open mind but my brains kept falling out.
I couldn't repair your brakes, so I made your horn louder.

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Publication deadlines
Publication deadlines are on the 5th of February, May, August and November. News items and articles are welcome and should be sent to:

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