

THE VISN 5 MIRECC MATTERS

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IMPROVING CONSENT CAPACITY FOR RESEARCH IN SCHIZOPHRENIA

Submitted by Kristen J. Prentice, PhD

The thousands of veterans who generously volunteer to participate in clinical research studies are critical to the success of the VA's extensive research endeavors. The VA has made clear its commitment to protect these research participants and has taken exceptional measures to make its human research programs among the safest in the world. One of the most significant challenges to the VA's safety efforts is the prevalence of mental illness and other conditions that could interfere with the capacity of prospective research participants to fully appreciate their risks and responsibilities as subjects. In response to this challenge we are starting a new research study (funded by a VA Research Career Development Award to Dr. Prentice), aimed at maximizing prospective subjects' capacity to give fully informed consent. We hope to help VA researchers protect their most vulnerable charges and also extend access to those veterans who might otherwise be excluded from the research process.

While federal regulations specify the types of information that must be discussed during the consent process, truly informed consent depends on the potential subject's capacity to use the information to reach a logical decision regarding participation. There is broad consensus that this decisional capacity rests on an individual's skills

in four basic domains: 1) understanding the proposed study; 2) appreciation of the study's personal relevance and of how it might affect their treatment; 3) ability to reason logically to make a decision about participation; and 4) expressing a choice about whether to participate. As one of the top ten causes of disability in the world, afflicting more than 90,000 veterans, schizophrenia (SZ) is seen as a significant threat to an individual's capacity to give valid informed consent. Though schizophrenia patients typically perform poorly on assessments of decisional capacity for informed consent, most research has shown inconsistent relationships between patients' psychotic symptoms and capacity to provide informed consent. A better predictor of poor consent capacity is poor cognitive ability, a relationship found regardless of whether someone has a mental illness. Because of this relationship, and because the information discussed during an informed consent interview is often complex, individuals will vary in their capacity to process information for the purposes of understanding, appreciation, reasoning and expressing choice.

Despite the apparent deficits in SZ patients' decisional capacity for informed consent, the conclusion has not been that such a deficit should preclude SZ patients from participating in clinical research. Such a response would be too extreme in its consequences for the progress of research and for patients' autonomy in the decision-making process. We are left, therefore, with the question of how to proceed with research that includes these patients. In previous

work, we have shown that a standardized educational training program (Informed Consent Training, ICT) was superior to a control condition in improving some aspects of decisional capacity for informed consent. In our new study, Improving Consent Capacity for Research in Schizophrenia, we will evaluate the efficacy of a revised ICT (ICT-R) with extensive focus on the complex appreciation and reasoning domains of informed consent capacity. The intent is to provide prospective research subjects with the “tools” they need to think about research participation. In a highly interactive discussion, a trained interviewer “walks” the patient carefully through the steps involved in understanding, appreciating and reasoning about a decision to participate in research, and instructs the patient on how to interpret study design information. Using a battery of neurocognitive assessments and symptom ratings, we will also further address the roles of cognition and psychosis in decisional capacity for informed consent.

PERRY POINT PHP VETERANS VOLUNTEER AT LOCAL NURSING HOME

Submitted by Alicia Lucksted, PhD

Three veterans attending the Perry Point Partial Hospitalization Program (PHP) have been volunteering their time at a Havre de Grace nursing home with the help of a MIRECC Small Grant Program award to the PHP. "They are short staffed there at the home, so the staff need us; told us they really appreciate us coming. We help set up the bingo, help the residents play, help them get around and help clean up after, and offer them friendship and encouragement," said Mr. McHoul, one of the participating veterans.

Jane Manlove, LCSW, Program Coordinator for the PHP, applied to the Small Grant Program in December, 2005, with the idea of a Volunteer Mentoring Program. She requested the award to cover the transportation costs involved in getting the volunteers to and from the nursing home. At

the start of the volunteer program, a PHP staff person arranged for the taxi, rode with the veterans to the nursing home, helped them settle into their volunteer roles, and accompanied them back to the PHP. Now, the veterans carry out the logistical tasks themselves and are traveling and volunteering on their own. As one said, "After a few visits we knew our way around and really enjoyed it. We look forward to it". "It's a good thing, to do good for a person, to help a person. It gives me real satisfaction," added Mr. Burley, another of the participating veterans. All of the men concurred, adding that they can tell the nursing home residents like it when they show up. Mr. McHoul reflected further on the personal benefits, saying, "It also gives us, the vets, a chance to get out among people, to socialize more, rather than doing the same thing all the time". Finally, Mr. Jaques, the third participant, summed the experience up as "a good deed". When asked about the future, the volunteers agreed that the project should continue and even expand to involve more veterans. In fact, another veteran who overheard our conversation said he would like to try it!

Ms. Manlove is helping the participants find a way to continue their volunteering even after the MIRECC Small Grant Program award is spent. "I believe this experience has had a positive effect on their self esteem and given them more confidence," Ms. Manlove concluded.

DOES FAMILY MEMBER PROVIDER OUTREACH IMPROVE THE QUALITY OF CARE FOR PERSONS WITH SEVERE MENTAL ILLNESS ?

Submitted by Lisa Dixon, MD, MPH

Research has demonstrated that when families actively participate in the clinical care of veterans with severe mental illness (SMI), the veterans experience improved outcomes, including treatment retention, vocational services participation, and empowerment. Numerous

studies show that when family involvement includes family psychoeducation (FPE), relapse rates are cut in half and treatment adherence, clinical symptoms, and patient functioning are improved. However, despite these demonstrated benefits, rates of family involvement in the VA are low. Even minimal family-clinician contact occurs for only one third of VA SMI patients, a lower rate than in non-VA systems of care.

A new family-engagement approach that is gradual, patient-centered, and recovery-based, could improve the treatment of veterans with SMI. **Lisa Dixon, MD, MPH, Alicia Lucksted, PhD, Aaron Murray-Swank, PhD**, and others are conducting a study (funded by VA Health Services Research and Development Service) to test the effectiveness of a structured, innovative, manualized family engagement intervention. In the Family Member Provider Outreach (FMPO) model's first phase, the "patient phase," a trained outreach person (a Family Member Provider, or FMP) who has a relative with a serious psychiatric illness will work with the veteran to

clarify the benefits of family involvement and the veteran's feelings about such involvement. The goals are to resolve veteran-based barriers to family involvement, to empower veteran-consumers to encourage and facilitate their family's involvement and to encourage mental health providers to involve their families in appropriate ways. The second phase of FMPO is the "family phase," in which the FMP engages in education with the relatives to strengthen their ability to support the veteran and to interact effectively with the veteran's treatment team.

This brief FMPO intervention aims to empower and educate veterans with SMI in ways that will increase the likelihood that their families and caregivers will become constructive partners in their ongoing mental health care, ultimately improving veteran outcomes and promoting the veteran's mental health.

UPCOMING EVENTS

Family Support and Education Program

Thursday, February 15, 2007

Topic: Schizophrenia and its Impact on the Family

Thursday, March 22, 2007

Topic: Creating a Low-Stress Environment and Minimizing Crises

All sessions are held from 4:00 pm - 5:30 pm

Baltimore VA Medical Center

Wait in the 6th floor lobby

The Family Support and Education Program is a monthly program for family members of veterans with serious mental illnesses, including schizophrenia, bipolar disorder, and major depression. The program is designed to help families support veterans' treatment and recovery, as well as assist family members and other caregivers as they cope with the effects of mental illness on the family. Group meetings are held one Saturday a month at the Baltimore VA Medical Center, and involve presentation of information and discussion, which is adapted to the needs of family members and veterans who attend.

To register for the workshop, or if you have any questions about the program, please contact **Dr. Aaron Murray-Swank** by phone: (410) 605-7000, ext. 4756, or email: aaron.murray-swank@va.gov.

Monthly SGA Consultation Seminar

March 1, 2007 (first Thursday of every month)

1:00 - 2:00 PM

MIRECC conference room, BVA (6A-168)

or PPVA VTel conference room, Bldg 364

or call 800-767-1750, code 79846

There has been increasing concern, both within and outside of the VA, about the metabolic side effects of second generation antipsychotic medications (SGAs). VAMHCS clinicians are encouraged to bring their difficult or complicated SGA cases to this seminar for consultation and advice. All VA clinicians are invited to attend even if you don't have a case to present. Your consultants are **Robert Buchanan, MD**, from the MIRECC Psychopharmacology Clinic and Maryland Psychiatric Research Center, and **Julie Kreyenbuhl, PhD, PharmD** from the MIRECC.

Recovery-Oriented Small Grants Program

Application Deadline

March 1, 2007

The VISN 5 MIRECC offers a small grant mechanism to fund recovery-oriented clinical and educational innovations in response to the VA's Action Agenda to transform VA mental health services to a recovery model. This program especially encourages (but is not limited to) proposals such as: creating, adopting, or launching new recovery-oriented clinical, self-help, or related projects (or expanding existing ones to reach more veterans), new programs to educate staff, veterans, and/or family members of veterans about mental health recovery models, or specific recovery-oriented services/programs. The first round of applications were received September 1, 2005, and reflected a diversity of VA programs and innovative ideas.

For more information, or to receive an application, please contact Alicia Lucksted, PhD, MIRECC Recovery Coordinator, at Alicia.Lucksted@va.gov, 410-605-7451 or 410-706-3244.

Schizophrenia And Other Mental Illnesses: Involving The Family, Improving Care

This one hour, three-part (20 minutes each) DVD program highlights the importance of including families in the treatment of patients with schizophrenia and other mental illnesses. This program is highly recommended for families, patients, clinicians, policy makers and the general public. For a copy, contact Fran Broomall at fran.broomall@va.gov or 410-605-7000, x 4740.

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<http://www.va.gov/VISN5mirecc>