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**OFFICE OF RESEARCH AND DEVELOPMENT
HEALTH SERVICES RESEARCH AND DEVELOPMENT SERVICE (HSR&D)**

PROGRAM ANNOUNCEMENT: SUBSTANCE ABUSE



Investigator-Initiated Research Priorities in Substance Abuse:

- **Implementation and Cost of Best Practices for Screening and Brief Interventions for Patients with Substance Use Disorders in Primary Care**
- **Evaluating the Outcomes and Costs of Smoking Cessation Initiated during Medical and Surgical Patient Hospitalization**
- **Evaluating the Effects and Costs of Guideline-Concordant Care for Patients with Comorbid Substance Use Disorders and Major Depression**
- **Effectiveness of Centralized Versus Referral Models of Care for Substance Abuse Patients with Medical Comorbidities**

1. Purpose. The Veterans Health Administration (VHA) is focusing major resources and energy to improve the quality of the health care it provides and to create improvements that are measurable, rapid and sustainable. With the inauguration of the Quality Enhancement Research Initiative (QUERI) in early 1998, special emphasis has been placed on improving the quality of care in ten clinical areas that are prevalent in VA: chronic heart failure, ischemic heart disease, diabetes, prostate disease, stroke, substance abuse, mental health (depression, schizophrenia), spinal cord injuries, HIV/AIDS, and cancer. For each of these areas, QUERI will identify gaps in science, practice, and information systems, and develop and evaluate methods for translating evidence of clinical effectiveness into practice. Additional information about QUERI is available on the VA web page at <http://www.va.gov/resdev>.

2. Synopsis. This Program Announcement invites research proposals to enhance the quality of care for veterans with substance abuse in four areas:

- (a) implementation and cost of best practices for screening and brief interventions for patients with substance use disorders in primary care;
- (b) evaluating the outcomes and costs of smoking cessation treatment for hospitalized medical and surgical patients;

(c) evaluating the effects and costs of guideline-concordant care for patients with comorbid substance use disorders and major depression; and

(d) effectiveness of centralized versus referral models of care for substance abuse patients with medical comorbidities.

Projects may not exceed four years or total costs of \$750,000. However, HSR&D is especially interested in projects that can demonstrate results in a shorter time frame. For example, descriptive studies or studies that do not include evaluation of a screening program or intervention would be expected to reach completion within two years, at a substantially lesser annual cost. For the initial round of review, a brief planning letter (see Attachment A) must be received by December 10, 1998 and full proposals must be received by February 5, 1999. The first opportunity for proposal review will be March 1999, with the earliest possible funding date of April 1999. Thereafter, projects will require a Letter of Intent consistent with regular IIR policy, and proposal due dates are May 1 and November 1, until further notice.

These investigator-initiated research projects comprise part of a broader, comprehensive and merit-approved strategic plan that also includes a targeted research solicitation for service directed research projects to implement and determine the cost-effectiveness of best practices in VA opiate substitution programs and to identify best practices and associated costs for continuing outpatient care for patients with substance use disorders. [See “Service Directed Research Regarding Best Practices in VA Opiate Substitution Programs and for Continuing Outpatient Care for Substance Abuse Disorders, at <http://www.va.gov/resdev/hsr-sols.htm>.] Investigators interested in substance abuse quality of care also should consider two solicitations for research that cuts across the conditions identified in paragraph one above. Specifically, HSR&D is issuing announcements entitled “QUERI: Common Issues in Implementation of Clinical Practice Guidelines” and “QUERI: Patient-Centered Outcomes,” both available in October 1998 on the VA web page at <http://www.va.gov/resdev/hsr-sols.htm>.

3. Background. Behavioral research studies of “sensitive behaviors” such as substance abuse (and its treatment or prevention) among diverse subgroups of veterans can impose a number of scientific challenges regarding the incorporation of multi-disciplinary frameworks and methods. For example, the efficacy and effectiveness of substance abuse treatment interventions may be affected by a host of confounding factors, including comorbidities (e.g., dual drug abuse, psychiatric diagnoses, HIV) and family or social dysfunctions (e.g., homelessness, disadvantaged cultural/ethnic minorities, transitions between alcohol and other drug use behavior over time).

Accordingly, an expert panel of VA scientists, clinicians, and administrators, found three factors that provided a “compelling rationale” for the development of a broad, comprehensive, and merit-approved strategic plan to help identify and implement best practices in VHA for improving the treatment of substance abuse disorders.

These factors were: (1) the high prevalence and cost of substance abuse disorders, both nationally and within VHA; (2) the increasing complexity of these disorders, coupled with declining VHA resources for treatment; and (3) a growing body of scientific knowledge pertaining to the effectiveness of substance abuse treatments and the development of evidence-based, clinical practice guidelines.

4. Research Priorities. Experts advising the VA have identified four distinct high priority areas for investigator-initiated research related to substance abuse. These areas are:

- a) implementation and cost of best practices for screening and brief interventions for patients with substance use disorders in primary care;
- b) evaluating the outcomes and costs of smoking cessation treatment for hospitalized medical and surgical patients;
- c) evaluating the effects and costs of guideline-concordant care for patients with comorbid substance use disorders and major depression; and
- d) effectiveness of centralized versus referral models of care for substance abuse patients with medical comorbidities.

a. Implementation and Cost of Best Practices for Screening and Brief Interventions for Patients with Substance Use Disorders in Primary Care

The heightened morbidity and mortality risks associated with hazardous alcohol use and smoking are well-documented (Babor et al., 1987; Chou et al., 1996; Heineman et al., 1994; Hurt et al., 1996; Mashberg et al., 1993; McLaughlin et al., 1995). Many VA primary care patients drink in a hazardous manner and/or smoke. Between 10 and 36% of patients seen in primary care settings meet criteria for alcohol abuse or dependence (Buchsbaum et al., 1992), and many more are at-risk or hazardous drinkers (Barry & Fleming, 1993). Veterans are more likely to smoke than non-veterans are, and the prevalence of smoking is even higher for veterans seeking health care at the VA (Klevens et al., 1995; McKinney et al., 1997).

Although prevalent among VA patients, these substance use disorders often remain undetected because they are not screened for by primary care providers (Connors, 1995; Robinson et al., 1995). Unlike screening for illicit drug use, reliable and valid self-report screening instruments (questionnaires and interviews) for alcohol abuse (Connors, 1995) and at-risk and hazardous drinking (Barry & Fleming, 1993; Schmidt et al., 1995) have been developed and tested in primary and other health care settings. Assessing whether or not a patient smokes and, if so, the frequency and amount of tobacco consumption, is a relatively straightforward process that takes, at most, one minute (Cromwell et al., 1997). Thus, effective methods for detecting hazardous drinking and tobacco use are available, but not consistently used (Robinson et al., 1995).

Brief interventions to reduce alcohol use have been evaluated in a wide range of health care settings and shown to be efficacious (e.g., Bien et al., 1993; Babor, 1994; Fleming et al., 1997; Wilk et al., 1997). Likewise, brief interventions to eliminate tobacco use among smokers seen in medical settings have been found to be cost-effective (Cummings et al., 1989; Cromwell et al., 1997).

As a result of the extensive data on the validity of screening and the efficacy of brief interventions for patients engaged in hazardous drinking or smoking, their use as a part of routine practice in primary care settings has been recommended by guidelines development panels (APA, 1995; Fiore et al., 1996; Hughes et al., 1996), and specified in VA directives (e.g., Department of Veterans Affairs, 1996). Overall, early identification and brief intervention or referral for alcohol or smoking problems in VA primary care has the potential to reach a large number of veterans and to have a significant positive impact on their health and quality of life.

Based on the results of multiple studies indicating the efficacy of screening and brief intervention or referral, these practices have been specified in guidelines developed by various panels, and in VA Directives for clinical care. However, it is not known to what extent these practices have been incorporated in VA primary care settings and to what extent time constraints and other logistical demands present barriers to implementation.

Screening and intervention/referral compete with other demands that providers have during time-limited health care encounters. If they are not obtained directly by the primary health care provider, the results of screening need to be compiled and communicated to the provider or other health care professional who will conduct the intervention or make a referral. Diagnostic assessment of alcohol/drug abuse, and data on the patient's history of prior smoking quit attempts and treatment may be needed to determine if a referral to specialized treatment is warranted. An efficient, practical system to screen patients for alcohol and tobacco use disorders, and then intervene briefly or refer them to specialized care, must be available if these activities are to be routinely incorporated into primary care providers' daily practices.

HSR&D Service is interested in one or more projects that are designed to:

- (1) Assess existing practice patterns in VA with respect to screening, brief intervention, and referral to specialized treatment for primary care patients with substance (alcohol and tobacco) use disorders, and determine the prevalence of and practices at specialized smoking cessation programs in VA.
- (2) Develop and evaluate the efficiency, level of implementation, outcome, and cost of alternative methods of incorporating guideline-concordant best practices for screening, brief interventions, and/or referral for patients with alcohol and/or tobacco use disorders in the varying settings within which VA primary care is offered.

The first component of the proposal should be to conduct a survey of VA primary care providers to determine practice variations in the use of screening, brief intervention and/or referral for patients with alcohol and tobacco use disorders, and to determine the prevalence of and practices at specialized smoking cessation programs to which appropriate primary care patients could be referred.

To place the use or nonuse of screening/intervention/referral practices in context, information should be gathered on the number of patients seen, staffing level and pattern, and the availability of space for screening and interventions at the primary care unit. The survey of smoking cessation programs should determine their prevalence and characteristics (e.g., length of waiting list, staffing, number of patients seen, and treatment practices, such as nicotine replacement therapy).

The second component of the proposal should be to specify and evaluate, at multiple sites, methods to implement alcohol and tobacco screening and brief intervention/referral in primary care settings. Practice guidelines for screening and brief interventions should shape implementation efforts. The proposed project should identify efficient, practical methods to:

- (a) screen patients for alcohol and tobacco use disorders (e.g., via on-site paper-and-pencil, computer-assisted, or interview-based methods, or via pre-visit mailed questionnaire);
- (b) conduct diagnostic assessments of alcohol abuse/dependence and level of nicotine dependence, and/or obtain data on prior history of smoking quit attempts and treatment, to determine if referral to a specialized program is needed;
- (c) conduct brief interventions and/or refer patients to specialized care;
- (d) identify the specific staff to conduct brief interventions (e.g., physicians, nurses, health educators);
- (e) specify the type of training needed for office and clinical personnel; and
- (f) determine the outcome and cost of implementing and running a practical screening, brief intervention, and referral system.

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b. Evaluating the Outcomes and Costs of Smoking Cessation Initiated During Medical and Surgical Patient Hospitalization.

Randomized clinical trials have demonstrated that hospital-based smoking cessation interventions can significantly increase the number of quit attempts and cessation rates among medical and surgical patients (Strecher et al., 1985; Stevens et al., 1993; Taylor et al., 1990; Ockene et al., 1992; Campbell et al.,

1991; Rigotti et al., 1994; Simon et al., 1997). However, current VA clinical practices in providing smoking cessation treatment for hospitalized patients have not been evaluated systematically.

Cigarette smoking is the major cause of preventable death in the United States (MMWR 42, 1993; MMWR 45, 1994; Herdman et al., 1993). In VA facilities, tobacco-related diseases together represent the single most expensive medical problem treated (U.S. Department of Veterans Affairs, 1996). At least 6.5 million adult smokers are hospitalized each year in the United States, providing health care professionals a window of opportunity for smoking cessation interventions (Orleans et al., 1993).

Patients are often hospitalized for smoking-related illnesses and may not be able to smoke while hospitalized because of smoke-free environment policies. Consequently, they may be more open to receiving help in quitting smoking.

The Agency for Health Care Policy and Research (AHCPR) Guidelines for Smoking Cessation (Smoking Cessation Clinical Practice Guideline Panel and Staff, 1996) recommend that hospitalized smokers receive interventions that have been found to be most efficacious for adult smokers in a variety of settings. More specific guidelines for tailoring smoking cessation treatments for hospitalized smokers are not provided. The American Psychiatric Association (APA) has developed more specific guidelines for treating nicotine dependence in psychiatric and substance abuse patients (American Psychiatric Association, 1996). These guidelines include recommendations for conducting smoking cessation treatment among psychiatric patients on smoke-free wards.

HSR&D Service is interested in one or more projects that are designed to:

- (1) Compare specific sets of brief smoking cessation interventions for hospitalized smokers in VA medical and surgical settings.
- (2) Determine the association between these interventions and patients' outcomes, including abstinence from cigarettes, quality of life, health care utilization, and short-term tobacco-related morbidity/mortality.
- (3) Assess the cost-effectiveness of the best practice interventions.

Proposals should identify a cohort of smokers who have been hospitalized in VA medical and surgical facilities. AHCPR practice guidelines for smoking cessation should be used as a basis for identifying the probable best practices in this area. These may include multiple components, some of which may be combined in an intervention:

- (a) brief individual counseling sessions incorporating behavioral and relapse prevention coping skills training;

- (b) self-help educational materials, pamphlets, videotapes, and so forth;
- (c) nicotine replacement gum/patches; and
- (d) follow-up contacts with patients post-discharge.

Proposals should specify methods for defining and explicitly measuring existing clinical practices in providing smoking cessation treatment for hospitalized smokers. These methods may include use of national VA databases and supplementary survey procedures. Proposals should evaluate the variability in clinical practices in smoking cessation treatment for hospitalized smokers and the extent to which current clinical practices are consistent with AHCPR guidelines.

Proposals should compare specific interventions based on probable best practices (see above) with "usual care" in terms of whether specific interventions enhance proximal outcomes of care, such as adherence to treatment recommendations and smoking status, and ultimate or distal outcomes, such as maintenance of smoking abstinence, quality of life, and health care utilization.

The steps would include defining and measuring the concordance of VA practices with clinical best practices, examining whether guideline-concordant care is associated with better casemix-adjusted outcomes, and documenting that outcomes are associated with improved quality of life. Proposals should also evaluate whether there are subgroups of hospitalized medical and surgical patients (e.g., patients with specific tobacco-related morbidities) who can be provided with low-intensity treatment with no adverse effects on outcome. In addition, proposals should address the cost-effectiveness of smoking cessation treatment for hospitalized medical and surgical patients and whether there is an "offset effect" in terms of reducing subsequent use of health care services.

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c. Evaluating the Effects and Costs of Guideline-Concordant Care for Patients with Comorbid Substance Use Disorders and Major Depression

Substance abuse and depressive disorders frequently co-occur, often resulting in negative effects on treatment compliance and suicidal behavior and increasing the probability that patients will need to be hospitalized (Agency for Health Care Policy and Research, 1993; American Psychiatric Association, 1993; American Society of Addiction Medicine, 1996; American Psychiatric Association, 1995; Helzer and

Prybeck, 1988; Cornelius et al., 1995). Approximately 25 to 30 percent of VA mental health patients with a substance abuse disorder also suffer a depressive disorder (Piette et al., 1997; Moos et al., 1998). In response to this high comorbidity rate, the VA established clinical practice guidelines for the treatment of comorbid substance abuse/dependence and major depressive disorder (MDD).

HSR&D Service is interested in one or more projects that are designed to:

- (1) Assess existing practice patterns for treating patients dually diagnosed with substance use disorders and major depression and assess these patients' outcomes.
- (2) Relate variations in current practices to casemix-adjusted outcomes and examine whether guideline-concordant care is associated with better casemix-adjusted symptom outcomes and improved quality of life than is non-concordant care.
- (3) Determine the cost-effectiveness of best practices in this area.

The proposed project should identify a cohort of patients with ICD-9 substance use disorder and major depression diagnoses. Practice guidelines should be used as a basis to identify the probable best practices for treating these comorbid patients. The project should specify a method for explicitly measuring existing clinical practices for treating comorbid patients. It should include a plan to obtain information about guideline-concordant aspects of care and patient outcomes, including alcohol and drug use, depressive symptoms, health care utilization, and indices of psychosocial functioning.

The project should follow the QUERI steps to determine whether probable best practices improve patients' outcomes and quality of life. These steps include defining guideline-concordant care, determining whether guideline-concordant care is associated with better casemix-adjusted outcomes, examining practice variations and outcomes for different patient subgroups, and documenting that outcomes are associated with improved quality of life. The project also should include a cost-effectiveness assessment of providing probable best practices.

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d. Effectiveness of Centralized Versus Referral Models of Care for Substance Abuse Patients with Medical Comorbidities

Veterans with substance use disorders (particularly those who inject drugs) currently have, or are at risk for having, a broad range of serious medical problems. These problems include viral hepatitis, sexually-transmitted diseases, endocarditis, a range of CNS infections, skin and soft tissue infections, tuberculosis, and HIV (Cherubin & Sapira, 1993; Cregler & Mark, 1986; Gourevitch et al., 1996; Haverkos & Lange, 1990; Metzger et al., 1993; O'Connor et al., 1994; Stein, 1990; O'Conner et al., 1994).

In addition to these high frequency medical conditions among patients with substance use disorders, these patients also experience problems common to the general population, such as diabetes, hypertension, chronic obstructive pulmonary disease, respiratory infections, and others. These medical problems, often combined with poor access to health care or poor compliance after referral and/or treatment initiation, contribute to the considerable morbidity and mortality among this population (Friedman et al., 1996; Gronbladh & Gunne, 1990; Hibbs et al., 1994).

Models of Care. These medical problems present great challenges to VA's health care system, particularly for substance abuse treatment programs that are often staffed by persons with little or no prior medical training (Woody et al., 1983; Ball et al., 1986). The result is that patients with comorbid medical problems, or who are at risk, are sometimes denied care, because the program cannot manage them, or they have fragmented care, where treatment for the substance abuse problem is delivered in one location and treatments or preventive services for other problems are delivered elsewhere.

Essentially, substance abuse treatment programs use two health care models:

- (1) **Centralized model**—in which medical services are available in the context of the substance abuse treatment program; and
- (2) **Referral model**—in which patients who need medical services are referred to a health care provider at another site, either in the same medical center or located elsewhere.

In a previous study on this issue, Umbricht-Schneiter et al. (1994) randomly assigned patients with current, untreated medical problems to receive treatment within their methadone program or to be referred to a nearby medical clinic that had no waiting list and where the patients' health insurance would cover treatment costs. Patients assigned to the in-clinic condition were seen for medical care more frequently than were patients assigned to the referral. These data documented superior compliance with medical treatment, when it is provided on-site. Because there is better compliance in the centralized model, initial costs of medical services may be higher. However, it remains to be determined if centralized services prevent more costly use of emergency or inpatient services and are thus less expensive over the long run.

HSR&D Service is interested in one or more projects that are designed to address:

- (1) how best to maximize compliance with and positive outcomes of preventive and therapeutic medical services for veterans receiving treatment for a substance use disorder; and
- (2) how to deliver such preventive and therapeutic medical services in a cost-effective manner.

Information obtained from well-designed studies could lead to identification of best practice guidelines for veterans who are receiving treatment for a substance use disorder. These veterans often need preventive services (for example, TB screening, hepatitis A and B vaccination), as well as treatment for acute or chronic medical disorders, such as cellulitis, pneumonia, HIV disease, diabetes, hypertension, and sexually transmitted diseases.

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6. Application Process.

a. Eligibility. Investigators who hold a VA appointment of at least 5/8 time are eligible to apply for research support. Co-investigators, consultants, and support staff may be non-VA employees. Refer questions about eligibility to Robert Small at 202/273-8256 or robert.small@mail.va.gov.

b. Planning Letter. A planning letter is the first step in preparing a proposal. It will be used only for administrative purposes (for format, see Attachment A). The usual Letter of Intent (LOI) process required for HSR&D's Investigator-Initiated Research projects, whereby a detailed description of the project must be approved prior to submitting a full proposal, **does not apply** to this round of review. Planning letters are due to HSR&D Service (124I), VA Headquarters, 810 Vermont Avenue, NW, Washington, DC, 20420, by the close of business on December 10, 1998. Facsimile and electronic mail copies will be accepted; address these to John Francis, HSR&D Service, at FAX number 202/273-9007 or john.francis@mail.va.gov.

c. Proposal Preparation and Submission. For detailed instructions regarding preparation and submission of a full proposal, and general review criteria, applicants should refer to HSR&D's "Instructions for Preparing Investigator-Initiated Research Proposals" (available at all VA research offices and on VA's research home page at <http://www.va.gov/resdev>). Full proposals must be received by February 5, 1999.

d. Review Schedule. Proposals received by February 5, 1999 will be reviewed at the Scientific Review and Evaluation Board subcommittee meeting in March 1999. Subsequently, and until further notice, proposals responsive to this announcement, based on an approved LOI, will be reviewed at regularly scheduled meetings of the Board, along with other IIR projects. Proposals received by May 1 are reviewed in June; proposals received by Nov. 1 are reviewed in January.

7. Review Criteria. IIR review is rigorous and standards very high; both scientific merit and expected contribution to improving VA health services are considered. Investigators are expected to develop and describe their research plan completely and in detail. Proposals recommended for approval will be considered for funding.

8. Funding. Studies submitted in response to this solicitation may not exceed four years or total costs of \$750,000. Both short-term and long-term projects may be proposed, but HSR&D is particularly interested in projects that can demonstrate results in the shortest possible time. For projects that require more than two years, investigators are *strongly encouraged* to identify major milestones or project components for which interim results can be reported and published. In planning project budgets, applicants are reminded to adhere to R&D guidelines regarding

allowable use of research funds for specific items. HSR&D expects to fund the first projects under this program in April 1999.

9. Coordination with QUERI. Principal investigators will submit regular annual progress reports and requested updates to the Director, HSR&D, who will provide these to the appropriate QUERI Coordinating Center, through the Associate Director for QUERI.

10. Inquiries. For further information about this solicitation, contact:

Charles E. Welch, III, PhD (124C)
Assistant Director, HSR&D Field and Core Support Programs
Health Services Research and Development Service
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420
202/273-8253

John R. Feussner, M.D.
Chief Research and Development Officer

Attachment

ATTACHMENT A

SAMPLE FORMAT FOR HSR&D PLANNING LETTERS

Provide a one-page letter addressed to the Review Program Manager (124F) that includes the following information:

1. Principal Investigator's name, affiliation, address, phone number, e-mail, and FAX number.
2. Name and affiliation of co-principal investigator, if applicable, and other key project participants.
3. Title and date of the solicitation to which you are responding.
4. Section of solicitation to which you are responding (e.g., paragraph number such as "4a").
5. Proposal title.
6. Specific focus of the proposed study.
7. Major methods to be used and type(s) of analyses to be performed.
8. (Optional) Name two or more scientists who are qualified to review the proposal; include name, degree, title, academic affiliation, complete address, telephone number, and e-mail address, if available.
9. Signature of the ACOS for R&D.

<<<END OF SOLICITATION>>>