

systematic literature reviews and meta-analysis to assess the safety and efficacy questions that remain unstudied. The twelve drugs are:

Amoxicillin
Amoxicillin clavulanate potassium
Cefixime
Chloral Hydrate
Dexamethasone
Epinephrine
Fluconazole
Mebendazole
Methylprednisolone
Prednisolone
Prednisone
Trimethoprim

The Foundation for the NIH, Inc., has referred four on-patent drugs to NIH. The feasibility and public health importance of studying these drugs will be reviewed at the scientific meeting on October 25 and 26, 2004. The four on-patent drugs that have been referred by the Foundation for the NIH, Inc., for consideration for study are:

Bupropion
Morphine
Sevelamer
Zonisamide

Individuals or organizations with comments, information, and current data regarding these drugs are requested to contact Dr. Tamar Lasky at NICHD (contact information above).

Dated: July 28, 2004.

Elias A. Zerhouni,

Director, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443-7978.

National Outcomes Performance Assessment of the Collaborative Initiative to Help End Chronic Homelessness—(OMB No. 0930-0247; Revision)—This Initiative is coordinated by the U.S. Interagency Council on the Homeless and involves the participation of three Council members: the Department of Housing and Urban

Development (HUD), the Department of Health and Human Services (HHS), and the Department of Veterans Affairs (VA). Within HHS, SAMHSA's Center for Mental Health Services is the lead agency.

This project will monitor the implementation and effectiveness of the Initiative. A national assessment of client outcomes is needed to assure a high level of accountability and to identify which models work best for which people, using the same methods for all sites. To this end, this project will provide a site-by-site description of program implementation, as well as descriptive information on clients served; services received; housing quality, stability, and satisfaction; and, client outcomes in health and functional domains. The VA Northeast Program Evaluation Center (NEPEC), based at the VA Connecticut Healthcare System in West Haven, Connecticut, is responsible for conducting this project.

Data collection will be conducted over a 36-month period. At each site, a series of measures will be used to assess (1) program implementation (e.g., number and types of housing units produced and intensity and type of treatment and supportive services provided), (2) client descriptive information (e.g., demographic and clinical characteristics, and housing and treatment services received) and, (3) client outcomes.

Client outcomes will be measured using a series of structured instruments administered by evaluation personnel employed and funded by the local VA medical center or outpatient clinic involved at each Initiative site who will work closely with central NEPEC staff. Assessment will be conducted through face-to-face interviews and, when needed, telephone interviews. Interviews (approximately one hour in length) will be conducted at baseline, defined as the date of entry into the clinical treatment program leading to placement into permanent housing, and quarterly (every 3 months) thereafter for up to three years. Discharge data will be collected from program staff at the time of official discharge from the program, or when the client has not had any clinical contact from members of the program staff for at least 6 months. In addition to client interviews, key informant interviews with program managers at each site will be conducted annually.

At most Initiative sites, it is expected that more people will be screened and or evaluated for participation in the program than receive the full range of core housing and treatment services. Entry into the Initiative is

conceptualized as a two-phase process involving an Outreach/Screening/Assessment Phase (Phase I), and an Active Housing Placement/Treatment Phase (Phase II) that is expected to lead to exit from homelessness; in some programs these two phases may be described as the Outreach and Case Management Phases. It will be important to have at least some minimal information on all clients so as to be able to compare those who enter Housing/Treatment with those who do not.

Client-level data at the time of first contact with the program (i.e., before the client receives more intensive treatment or housing services) will be collected using a screener form. The screener form will be completed by a member of the clinical staff when prospective clients are first told about the program, and express interest in participating in the program (i.e., when they enter Phase I). The purpose of this form is to identify the sampling frame of the evaluation at each site, or the pool of potential clients from which clients are then selected. Program implementation will be measured using a series of progress summaries.

Initiative sites will be responsible for screening potential participants, assessing homeless and disabling condition eligibility criteria for the program, and documenting eligibility as part of the national performance assessment. Each site will identify a limited number of portals of entry into the program in a relatively small geographic area, so that the evaluator can practically and systematically contact clients about participating in the evaluation. VA evaluation staff, clinical program staff, and NEPEC will work together to establish systematic procedures for assessing eligibility, enrolling clients into the Housing/Treatment Activity of the Initiative, obtaining written informed consent to participate in the national performance assessment, and other evaluation activities.

The revisions being made are the addition of a comparison group to be recruited from all participating sites. A relatively small number (N = 61, on average) of individuals can be served at each site due to the considerable cost of providing persons who are chronically homeless with permanent housing and a comprehensive array of supportive services needed to sustain housing tenure and to promote self-sufficiency among the target population and limited federal funds available for the program. Those in the comparison group (N = 39, on average) will be enrolled after client recruitment/enrollment for program

services is complete. Comparison group participants will receive referral/access to housing resources usually available in the community or case management and other supportive services routinely available in the community for persons who are chronically homeless. The same data collection instruments and

procedures will be used with both groups. In addition, in order to examine the association of program client choice in attending mental health services, a "Consumer Choice" set of six additional items is being added to the client baseline and follow-up interviews. These questions are of great importance

in determining the overall style of the housing first program, whether it in fact enhances choice, or in fact constrains choice by forcing people to comply with the service system's requirements in order to obtain their funds.

The estimated response burden to collect this information is as follows:

Respondents form name	No. of respondents	Responses per respondent	Hours per response	Total hour burden
Clients:				
Baseline assessment	1,100	1	1.50	1,650
Follow-up assessment	880	18	1.25	8,800
Sub-total				10,450
Clinicians:				
Screening	² 22	100	0.25	550
Discharge	³ 22	63	0.40	114
Sub-total				664
Administrators:				
Network definition	44	1	0.25	11
Network participation	77	4	0.75	231
Sub-total				242
Total	1,243			11,356 hrs.
3-yr. Annual Avg.	1,243			3,785 hrs.

¹ Assumes average follow-up period of 2 yrs. due to delayed recruitment at some sites & 20% attrition overall.
² Assumes an average of 2 screening clinicians per site, and twice the number of persons screened as enrolled.
³ Assumes an average of 2 discharge clinicians per site, and discharge rate of 25%.

Written comments and recommendations concerning the proposed information collection should be sent by September 3, 2004 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202-395-6974.

Dated: July 28, 2004.
Anna Marsh,
Executive Officer, SAMHSA.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Substance Abuse and Mental Health Services Administration
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Proposed Project: Participant Feedback on Training Under the Cooperative Agreement for Mental Health Care Provider Education in HIV/AIDS Program (OMB No. 0930-0195; Revision)—The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Mental Health Services (CMHS) intends to continue to conduct a multi-site assessment for the Mental Health Care Provider Education in HIV/AIDS Program. The education programs funded under this cooperative agreement are designed to disseminate knowledge of the psychological and neuropsychiatric sequelae of HIV/AIDS to both traditional (e.g., psychiatrists, psychologists, nurses, primary care physicians, medical students, and social workers) and non traditional (e.g., clergy, and alternative health care workers) first-line providers of mental health services, in particular to providers in minority communities.

The multi-site assessment is designed to assess the effectiveness of particular training curricula, document the integrity of training delivery formats, and assess the effectiveness of the various training delivery formats. Analyses will assist CMHS in documenting the numbers and types of traditional and non-traditional mental health providers accessing training; the content, nature and types of training participants receive; and the extent to which trainees experience knowledge, skill and attitude gains/changes as a result of training attendance. The multi-site data collection design uses a two-tiered data collection and analytic strategy to collect information on (1) the organization and delivery of training, and (2) the impact of training on participants' knowledge, skills and abilities. Information about the organization and delivery of training will be collected from trainers and staff who are funded by these cooperative agreements/contracts, hence there is no respondent burden. All training participants will be asked to complete a brief feedback form at the end of the training session. CMHS anticipates funding 10 education sites for the Mental Health Care Provider Education