Information Collection Request
New

ASSESSMENT OF CANCER PREVENTION SERVICES AT COMMUNITY MENTAL HEALTH CENTERS

OMB Control No. #0920-XXXX

Supporting Statement: Part A

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Goal of the study: To assess barriers and facilitators to providing cancer prevention services at community mental health centers (CMHCS) in the United States, we will conduct two surveys of psychiatric clinicians and administrators at selected facilities.

Intended use of the resulting data: Study findings will be disseminated to target audiences such as National Comprehensive Cancer Control Program grantees and their state/local partners, other cancer prevention and control entities, CMHC staff, AHRQ, HRSA, NIH, and SAMSHA to help inform strategies that reduce cancer risk factors and improve cancer screening among persons with mental illness.

Methods to be used to collect data: Two internet-based surveys will be conducted among psychiatric clinicians and administrators from a sample of CMHCs, and a subsample of each group will be interviewed by telephone.

The subpopulation to be studied: The primary target audiences are psychiatric clinicians and administrators at CMHCs.

How data will be analyzed: Statistical analyses of quantitative and qualitative data.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Cancer Prevention and Control (DCPC), requests a two-year OMB approval for a new study titled "Assessment of Cancer Prevention Services at Community Mental Health Centers." The CDC proposes to survey psychiatric clinicians and administrators at selected CMHCs to assess the capacities of the centers to offer cancer prevention services (e.g., patient education about cancer risk factors, cancer screening or screening referrals, and tobacco cessation counseling or treatment). The objectives of the project are the following: (1) describe the capacity of CMHCs to provide cancer prevention services; (2) describe any written policies and procedures at CMHCs for providing these services; (3) describe any collaboration of CMHCs with health care providers or community health workers/organizations to provide these services; and (4) describe any barriers to providing cancer prevention services. If any CHMCs do offer these services, we will inquire about best practices and lessons learned.

In 2014, an estimated 43.6 million adults in the United States reported having any type of mental illness (MI) in the previous year, and 9.8 million had serious mental illness resulting in functional impairment.[1] Cancer incidence among persons with and without MI is similar; however, cancer mortality is higher among the former group.[2, 3] People with MI smoke at rates approximately twice that of adults without MI, which increases their risks of lung cancer and other tobacco-related cancers.[4, 5] Receipt of cancer screening among people with MI, however, is lower compared with the general population.[6, 7] Many people with MI receive care at CMHCs, which are the largest group of public-sector mental health providers in the US.[8] In 2012, nearly 25% of adults aged 18 years or older with any MI who received outpatient mental health services visited an outpatient mental health clinic or center.[9] Although clients at CMHCs often have multiple comorbidities, many of these facilities do not provide primary care services.[8, 10, 11] One solution to bridging this gap is integrated care, which is the systematic coordination of general and behavioral health care.

SAMHSA has fostered this approach through its Primary and Behavioral Health Care Integration Grants (PBHCI) program, with cardiovascular health being the primary care focus. Since 2009, SAMHSA has funded 187 PBHCI grantees to develop behavioral health homes for their enrollees.[9] Less is known about provision of cancer prevention-related services in these and similar settings. A recent study of clients at a publicly funded mental health program reported low levels of cancer screening referrals among eligible patients.[12] The proposed project, Assessment of Cancer Prevention Services at Community Mental Health Centers, would build on the integrated health care model by exploring the capacity of CMHCs to provide or make referrals to cancer prevention and screening services.

2. Purpose and Use of the Information Collection

The intended uses of the resulting data are to identify cancer prevention and screening/early detection services provided by CMHCs; existing/potential collaborations between CMHCs and local health care providers, community health workers, and community organizations to provide these services; barriers to providing these services; and awareness of cancer prevention resources.

To our knowledge, data have not been collected previously from CMHC clinicians and administrators about the capacities of these facilities to provide cancer prevention and screening/early detection services. Assessing whether cancer prevention education and other risk reduction strategies such as tobacco cessation counseling/treatment are available will identify gaps in access to these services. Inquiring about collaborations with health care providers, community health workers, and community health organizations could help identify promising practices and inform strategies to address gaps in services. Assessing awareness of cancer prevention and control resources will identify gaps in knowledge about evidence-based cancer prevention interventions (e.g., interventions in the Guide to Community Preventive Services) as well as government programs that provide free and low-cost cancer screening services. Cancer-related strategies in the Community Guide include interventions that help reduce out-of-pocket costs associated with screening; these costs limit access to health care services for some people with MI. Similarly, the National Breast and Cervical Cancer Early Detection Program and some Colorectal Cancer Control Program grantees provide services to underinsured and uninsured low-income adults. We will also inquire about respondents' awareness of National Comprehensive Cancer Control Program (NCCCP)-supported activities in their jurisdictions. NCCCP funds grantees to partner with health-care systems, health care providers, community organizations, and other entities to develop and implement cancer control plans (see **APP. 1**). These plans include goals and strategies to reduce disparities in access to cancer prevention, screening/early detection services, and treatment.

Findings from the proposed study will be disseminated and used by CDC researchers and administrators to understand the extent to which CMHCs provide cancer prevention services, as well as any barriers and facilitators to providing and making referrals for these services. Results will be shared with DCPC staff, CMHC psychiatric clinicians and administrators, cancer control programs and organizations, AHRQ, HRSA, NIH, SAMSHA, and policymakers. CDC's DCPC is responsible for investigating and promoting evidence-based, population-based cancer prevention and early detection activities.

3. Use of Improved Information Technology and Burden Reduction

The proposed study will use information technology to (1) identify and recruit eligible CMHC psychiatric clinicians and administrators, (2) to distribute the data collection instrument via online surveys, and (3) to send participants reminders to complete requested data collection activities. The online surveys will be

accessible by hyperlink on computers and mobile devices. The contractor will use their existing survey software tool. This tool allows for hosting and deploying surveys, as well as monitoring results. The instruments and interview guides will be pilot tested with a total of 9 CMHC psychiatric clinicians and administrators.

4. Efforts to Identify Duplication and Use of Similar Information

During development of the project, the CDC project team consulted with an advisory panel of researchers and public health professionals experienced in cancer prevention among persons with mental illness (see Section B). Their observations included but were not limited to the following: research on this topic is limited, some CMHC clinicians are becoming more interested in overall health outcomes and would welcome information from the proposed study, and some publicly funded mental health care facilities that plan to integrate cancer prevention services are interested in lessons learned by other programs. The CDC project team also reached out to staff at AHRQ, HRSA, NCI, NIMH, and SAMHSA to learn about any relevant data collection activities, as well as any interest in receiving and/or using findings from the study. The representatives confirmed that these agencies do not routinely collect information about cancer prevention and screening services at CMHCs (see summary of relevant data collections below). Agencies that work on identifying high-priority clinical preventive services and integrating primary and behavioral care services (e.g., AHRQ, SAMHSA) would like to receive the study results.

During the pre-development stage of the project, the lead investigator conducted a literature search of databases including PubMed, PsychInfo, Embase, CINAHL, Scopus, Google Scholar to describe the state of knowledge regarding the capacities of CMHCs to provide general medical services. Research on this topic has been limited, and largely focused on provision of screening for cardiovascular disease and diabetes.[8-11] Since the original literature search was conducted, at least four additional studies that address cancer prevention among persons with mental illness have been published. However, none captured the comprehensive information that will be collected in the proposed study. Two studies reported use of cancer screening; however, they were state specific (Oregon and California), reported receipt of a single type of screening test (cervical cancer and colorectal cancer), and used HMO and Medicaid claims data.[13, 14] Two other studies examined smoking cessation services for individuals with mental illness, but only one surveyed CMHC staff.[15, 16]

Relevant Data Collections by Other Agencies:

AHRQ conducts an annual survey of families, individuals, medical providers, and employers (Medical Expenditure Panel Survey); topics include perceived mental health status (not diagnosis of mental illness), cancer prevalence and expense.
https://meps.ahrq.gov/mepsweb/data_stats/MEPS_topics.jsp?topicid=4Z6
https://meps.ahrq.gov/mepsweb/data_stats/MEPS_topics.jsp?topicid=11Z-1

HRSA's Bureau of Primary Health Care funds and collects data from nearly 1400 health centers focused on integrating care; the data include preventive services delivered (e.g., cancer and mental health screening) and special populations (i.e., homeless, agricultural workers, public housing, school-based, and veterans).
https://bphc.hrsa.gov/uds/datacenter.aspx

NIMH reports the prevalence of specific mental illnesses, disability, and suicide. The Division of Services and Intervention Research supports intervention research (e.g., evaluates pharmacological, psychosocial,

and rehabilitative services) and mental health services research (e.g., clinical trials). When NIMH's database of grants was queried for cancer prevention activities, it yielded two results (smoking cessation intervention for depressed smokers; comparison of prevention education interventions for HIV/AIDS and cancer among Latino men).
https://www.nimh.nih.gov/about/organization/dsir/index.shtmlcompared

NCI – collects cancer surveillance data on different demographic groups (variables do not include diagnosis of mental illness); research areas includes cancer biology, genomics, etiology, diagnosis, prevention, early detection/screening, and treatment.
https://www.cancer.gov/research/areas/public-health
https://seer.cancer.gov/popdata/

SAMHSA – has funded more than 100 Primary and Behavioral Health Care Integration (PBHCI) grants since 2009. The grants support facilities that offer different levels of primary care (e.g., tobacco cessation counseling, screening for lipids, diabetes, and obesity) and behavioral health services onsite, or refer clients to primary care providers. An evaluation study revealed that some also offer immunizations and gynecological examinations; however, no data were reported on cancer screening. A majority of clients had risk factors for cancer (current smokers, obese, diabetic). A query of the grants database for cancer prevention/screening-related projects yielded no RFAs matching the search criteria.
https://www.integration.samhsa.gov/about-us/pbhci
https://www.integration.samhsa.gov/integrated-care-models/behavioral-health-in-primary-care
https://www.samhsa.gov/grants/grant-announcements-2018

5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently

Mental illness may be associated with behaviors such as cigarette smoking and physical inactivity that predispose individuals to an increased risk of some cancers as well as poorer cancer outcomes.[17, 18] In addition, lack of continuity of primary care may increase the likelihood of late-stage diagnosis. A number of recent studies have reported success in reducing smoking and improving diet, exercise, and weight in patients with serious mental illnessa.[19-23] Similar to people without disabilities, those with disabilities are more likely to be screened for cancer if they receive recommendations from their health care providers.[24-26] In a recent study of enrollees in community mental health programs, lack of physician recommendations for cancer screening emerged as the main cause of low screening rates.[12] Without a better understanding of the capacities of CMHCs to provide or connect their clients with cancer prevention and screening/early detection services, we lack a clear picture of barriers to cancer prevention among people with MI. The literature on interventions to encourage uptake of cancer screening among this population is scarce. A systematic review of randomized controlled trials to improve screening among patients with serious MI found no trials that met the review inclusion criteria.[27] Findings from the proposed study could be used to inform development of effective interventions to reduce disparities in cancer risk behaviors and screening among people with MI.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The request fully complies with regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

Part A: PUBLIC NOTICE

A 60-day Notice was published in the Federal Register on 11/08/2017 (Volume 82, Number 215, pages 51837-51838) (see **APP. 2**). CDC received four comments, two of which were duplicates. CDC did not provide responses to either of these comments, because they fell within the "outside of scope of project" category. The other two comments were letters from organizations (the Truth Initiative and the Academy of Nutrition and Dietetics), both of whom offered support for the project. The latter organization suggested enhancements to the proposed survey, which the CDC and its contractor had already addressed when the survey instruments and study methods were developed. CDC sent letters to both organizations, thanking them for their feedback. No changes to the project are required.

Part B: CONSULTATION

Consultations were conducted prior to the development of the proposed study with researchers and public health professionals experienced in the field of cancer prevention among people with mental illness.

Expert Consultants

- Dennis Freeman, PhD Executive Director Cherokee Health Systems; Dennis.Freeman@cherokeehealth.com ; 865-934-6734
- Brian Hepburn, MD, Executive Director National Association of State Mental Health Program Directors; brian.hepburn@nasmhpd.org; 703-739-9333
- Margaret Swarbrick, PhD, Rutgers University, Director of the Wellness Institute at Collaborative Support Programs of New Jersey; pswarbrick@cspnj.org; 732-768-6909
- Peggy Hannon, PhD, MPH is an Associate Professor at the University of Washington School of Public Health and Director of the University of Washington Health Promotion Research Center (one of CDC's Prevention Research Centers); proflynx@gmail.com; 206-616-7859
- Ron Manderscheid, PhD is Executive Director of the National Association of County Behavioral Heath Directors and formerly Chief of the Surveys and Reports Branch at SAMHSA; rmanderscheid@nacbhd.org; 202-942-4296

9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive payments or gifts for providing information.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

CDC's Information Systems Security Officer has reviewed this submission, and has determined that the Privacy Act does not apply. While the Privacy Act is not applicable, given the sensitivity of the information collected, all appropriate security controls and rules of behavior will be incorporated to protect the confidentiality of information obtained. Personally identifying information (PII) will not be transmitted to

CDC. CDC will only include aggregate and summary information in reports and will not include information that may identify respondents.

Privacy will be maintained to the extent allowable by law. The contractor complies with the Privacy Act of 1974 (HIPAA) and the E-Government Act of 2002, including Title III: Federal Information Security Management Act, which covers site security, security control documentation, access control, change management, incident response, and risk management. The contractor has developed an Information System Security Plan and completed the Certification and Accreditation process with multiple Federal agencies to receive authorization to operate in their enterprise environments. In addition, the contractor has received authorizations to operate "low-to-moderate" risk category information systems in other environments. The contractor has also established an internal audit program to regularly review their information security program.

The contractor configures their computers with the applicable United States Government Configuration Baseline (USGCB) and ensures that they have and maintain the latest operating system patch level and anti-virus software level. Full disk encryption software has been implemented to protect the storage of data, as well as file transfer software for the secure, encrypted transmission of sensitive data to and from clients and subcontractors. The contractor has also implemented ASA Firewalls for boundary protection.

The contractor's web survey tool allows the integration of all survey consent information, including OMB and IRB information. Instructions for the survey and consent language will be embedded into the online survey as well as available in separate documents through hyperlinks in the introductory email. For the online survey, consent will be implied. For the telephone interviews, consent language will be included in the survey advance letter. Consent language will include but not be limited to the purpose of the survey, risks and benefits of participation, who will see the information collected, and how any personally identifiable information (PII) will be used.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

A. IRB Approval

The contractor's IRB has determined that the study protocol is exempt from IRB review per 45CFR46.101(b)(2) (see **APP. 3**). The survey includes questions that assess CMHC psychiatric clinicians' and administrators' perceptions about the capacities of the facilities where they work to provide cancer prevention and screening services to clients, as well as barriers to providing these services. To delve more deeply into the topics addressed in the survey, a subsample of respondents will be interviewed by telephone. All participants will be notified that participation is voluntary, any PII collected will be removed after data collection is complete, and individual survey and interview respondents will not be identified by name in any reports.

B. Sensitive Questions

The survey questions will assess the capacities of participating CMHCs to provide cancer preventive services, not clinical information about individual clients. Respondents will be notified that their participation is voluntary and their names will not be revealed in any reports. Findings from the study will be presented in aggregate and not as individual responses. Copies of the clinician and administrator survey instruments (**APP. 4**), clinician and administrator interview guides (**APP. 5**), recruitment and reminder

materials (**APP. 6**), survey web pages (**APP. 7**), consent materials (**APP. 8**), and clinician and administrator pilot feedback forms are attached (**APP. 9**).

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

Table A.12-1 displays the estimated annualized burden hours for this data collection. To calculate the total burden, we estimated 500 respondents for the surveys and 50 for the interviews, multiplied by one response per respondent, multiplied by the average burden per response. The average burden varied from 15-20 minutes for the surveys and an hour for the interviews.

Table A.12-1. Estimated Annualized Burden to Respondents

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Psychiatrists Psychiatric nurse practitioners Psychologists Registered nurses Physicians' assistants Licensed certified social workers Licensed independent clinical social workers Licensed mental health counselors	Clinician Survey Instrument	500	1	15/60	125
Administrators	Administrator Survey Instrument	500	1	20/60	167
Psychiatrists Psychiatric nurse practitioners Psychologists Registered nurses Physicians' assistants Licensed certified social workers Licensed independent clinical social workers Licensed mental	Clinician Interviews	50	1	1	50

health counselors					
Administrators	Administrator Interviews	50	1	1	50
				Total	392

Table B.12-1 displays the estimated annualized cost to respondents for reporting program progress information.

Table B.12-1. Estimated Annualized Cost to Respondents

Type of Respondents	Form Name	No. of Respondents	Total Burden (in hrs.)	Average Hourly Wage[1]	Total Cost
Psychiatrists Psychiatric nurse practitioners Psychologists Registered nurses Physicians' assistants Licensed certified social workers Licensed independent clinical social workers Licensed mental health counselors	Clinician survey	500	125	$87.82	$10,977.50
Administrators	Administrator survey	500	167	$50.99	$8,515.33
Psychiatrists Psychiatric nurse practitioners Psychologists Registered nurses Physicians' assistants Licensed certified social workers Licensed independent clinical social workers Licensed mental health counselors	Clinician interview	50	50	$87.82	$4,391.00
Administrators	Administrator	50	50	$50.99	$2,549.50

[1] Hourly wage information is from the U.S. Department of Labor, Bureau of Labor Statistics website (www.data.bls.gov/cgi-bin/print.pl/oes/current/oes_nat.htm).

	interview				
				Total	$26,433.33

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

The contractor will use their own survey software system for data collection and monitoring of survey completion. No capital or maintenance costs will be required. Additionally, there will be no start-up, hardware or software costs.

14. Estimates of Annualized Cost to the Federal Government

Table A.14.1 provides a detailed breakdowns of the estimated annualized cost to the government.

Table A.14.1 Estimated Annualized Cost for Data Collection

Expense Type		
Contractor and other expenses (Funding contract #: 200-2014-61267)	Salary/wages, supplies/materials, and other contractual services (Abt Associates)	$284,336
Total annualized cost to the government		**$284,336**

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

A. Time schedule for the entire project

Data collection will commence within one week of OMB approval and be conducted over a 3-month period.

Table 16-1 Deliverable Description		
Task #	Task	Time Schedule
2	Develop online survey instrument	1/31/2017
3	Prepare survey materials	12/29/2016
4	Develop draft and final study protocols	12/29/2016, 1/31/2017
5	IRB and OMB approvals • Submit protocol to Abt IRB for review	Within one week of approval of

	• Submit all OMB package materials to COR	completion of the final survey instrument, survey materials, and study protocol Within one week of IRB approval
6	Pilot test survey instrument and telephone interview guides with 9 respondents	Within 4 weeks of all IRB approvals
7	Implement online survey and telephone interviews • Initiate online surveys • Complete online surveys and telephone interviews	 Within one week of OMB approval 5/30/2018
8	Develop and submit dissemination plan	3/30/2018
9	Draft and submit final report	8/29/2018, 9/29/2018

B. Publication Plan

Strategies to disseminate the study findings may include peer-review publications, meetings/ conferences, and social media.

C. Analysis Plan

Descriptive, bivariate, and multivariate analyses will be conducted. All information will be aggregated and reported with no program identifiers present in external documents.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate for this data collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification for Paperwork Reduction Act Submissions.

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