IHS Behavioral Health Preventative Care Assessment Project

OMB Supporting Statement for Data Collection

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Background

The Indian Health Service (IHS), an agency within the Department of Health and Human Services, is responsible for the provision of health services to American Indians and Alaska Natives. The IHS currently funds health services for approximately 1.9 million American Indians and Alaska Natives who belong to more than 560 federally recognized tribes in 35 states.

The IHS goal is to raise the health status of the American Indian and Alaska Native people to the highest possible level by providing comprehensive health care and preventive health services. To support this mission, IHS uses the Government Performance and Results Act (GPRA) as one mechanism to assess quality of care among health programs in its network. IHS currently reports GPRA results for twenty-two clinical measures that fall into the categories of Diabetes, Dental, Immunizations, and Prevention. The prevention category includes three measures related to behavioral health preventive screenings: Alcohol Screening (to prevent Fetal Alcohol Syndrome), Depression Screening, and Domestic/Intimate Partner Violence Screening.

A. Justification

2. Need and Legal Basis

IHS is requesting clearance for data collection instruments to be used in conducting the study called the IHS Behavioral Health Preventative Care Assessment Project. The purpose of this data collection is to identify promising practices in behavioral health screening in the primary care setting, as well as barriers to high performance, as measured through GPRA. IHS will use this information to gain a better understanding of how tribal and IHS direct service programs provide high-quality preventive care in behavioral health, and to identify promising practices that can be adapted to the circumstances of both tribally-managed and IHS direct service programs. Approval of this request will allow IHS to conduct focus groups with employees of tribal health programs in accordance with the Intra-Agency Agreement between IHS and the Assistant Secretary for Planning and Evaluation (ASPE) (Appendix A).

The Government Performance and Results Act (GPRA) is a federal law that requires agencies to demonstrate that funds are being used effectively toward meeting their mission. GPRA goals serve as an important tool to focus performance initiatives on high-priority issues. IHS has reported GPRA data since 1999 and uses the results to assess annual and long-term performance in clinical care. The IHS has had some success in meeting its annual GPRA targets for selected clinical performance measures at the national level. However, there is significant variability in performance on GPRA measures among service units. The goal of this study is to identify quantitative and qualitative factors that contribute to high performance on a select number of behavioral health screening GPRA measures and to share this information with all service units, in an effort to improve preventive behavioral health care overall.

The IHS Director has identified three special health initiatives to address the highest priorities to the Agency and the Indian people it serves. One of these is a Behavioral Health Initiative (BHI). The BHI is intended to identify and support effective behavioral health techniques within the 12 IHS Areas, including identification of promising "models" of integration, and promote their adaptation and use throughout the Indian Health system. The proposed study will directly support the important goals of the Director's Behavioral Health Initiative. It will also provide relevant and practical information on behavioral health screening practices among Indian health programs, and will identify factors contributing to high performance on three behavioral health screening GPRA measures. These three measures are: Depression Screening in adults age 18 and over, Domestic/Intimate Partner Violence screening in women ages 15-40 and Alcohol Screening (to prevent Fetal Alcohol Syndrome) in women ages 15-44.

The study will include a sample of both direct, federally operated programs and tribally operated programs, identified as high or low performers on behavioral health GPRA measures. Because these particular sites were selected based on their GPRA performance and since the majority of IHS behavioral health funding is now administered by Tribes, it is important that the study also

include tribal sites, and this request is seeking approval to do so. Tribally-operated programs, which operated under the authority of the Indian Self-Determination and Education Assistance Act (Public Law 93-638, as amended), have the flexibility to design services and administer health care programs differently than federal sites. As a result, the experiences and perspectives of their staff are likely to differ from those at the federally-operated sites and can provide useful additional insights on how to improve the effectiveness of behavioral health screening. Overall, approximately half of the IHS budget authority appropriation is administered by these tribally-managed health programs; the remaining programs are primarily federally operated. Conducting focus groups solely with IHS direct services sites may not generate information and recommendations that could be adapted by tribal sites. Because Tribally-operated programs are not staffed with federal employees, OMB approval is needed to interview more than nine tribal program staff members.

This collection of data is authorized by the U.S. Public Health Service Act (42 U.S.C.241). A copy of this legislation can be found in Appendix D.

3. Information Users

This study will collect information about practices at selected higher and lower performing sites, in an effort to identify promising practices in behavioral health prevention in the primary care setting as well as barriers that may limit the provision of behavioral health screening. Gathering data directly from employees at IHS and tribal health programs will allow the project team to gain critical ground-level perspective on what specific work processes, policies, and priorities create the conditions for high-quality behavioral health preventive care.

The information will be collected by a contractor with extensive experience with tribal programs and behavioral health. The information collected will be analyzed by the IHS National GPRA Support Team (NGST): Ms. Elaine Brinn, Dr. Amy Patterson, Ms. Janae Price, Ms. Wendy Blocker, and Ms. Christine Brennan, with review and assistance from IHS HQ representatives Dr. Phil Smith, Ms. Lucie Vogel, and Mr. Francis Frazier, and ASPE representative Ms. Sue Clain. The NGST will use information gathered during focus group discussions at IHS and tribal site visits to draft national reports and other final project materials, which will include:

a) A description and analysis of the qualitative and quantitative factors that contribute to success or challenges in providing preventive care
b) A promising practices and recommendations guide
c) Recommendations for additional studies that would be useful in identifying other factors that contribute to success and overcoming challenges by Indian health programs in providing preventive care

Information that is published in the final report will not identify individual staff respondents, nor will it identify their program without permission from the program. The

report will be disseminated to tribally and federally operated programs as a "lessons learned and promising practices" guide with specific recommendations for improvements in behavioral health preventive care that clinics can adapt to their own circumstances.

4. Improved Information Technology

The information collection will take the form of in-person focus groups that generate qualitative data. The study does not intend to use automated information technology to collect and process information. The project team considered the use of telephone interviews to reduce burden, but concluded that the focus-group model was more conducive to clear, complete, and substantive qualitative responses. By combining several respondents into three focus groups, the overall time burden and amount of work disruption per clinic will be reduced, compared with conducting more numerous individual, in-person or telephone interviews. Most clinics have a period of time each week when they do not schedule appointments to allow for meetings, and the contractor will work to schedule the focus groups during that period of availability.

In-person focus groups will allow for greater sharing of information compared to telephone or individual interviews. It will allow the facilitator to gather qualitative information on the dynamics of high-performing sites and low-performing sites. It will also generate a build-up effect that allows participants to add to each others responses, provide multiple viewpoints, and generate more meaningful dialogue. Each focus group will be recorded and transcribed to ensure accurate data capture. Telephone interviews may be used as a cost-effective follow up mechanism in the rare instance where a key member of the administrative or provider staff must be absent from the scheduled focus group.

The focus group discussions conducted at each site will be summarized in a site report by the contractor. Qualitative software (NVivo 7.0) will be used to validate the accuracy of transcriptions and reports generated after each site visit. In-depth qualitative analysis of findings by the project team will identify common factors and best practices and determine the contributing factors to both high and low performance on behavioral health GPRA measures.

5. Duplication of Similar Information

After consulting with subject matter experts and program staff, the project team has not identified any similar qualitative information regarding the provision of preventive behavioral health services among its health programs. The project team has identified a current project dealing with domestic violence, the competitive cooperative agreement for Violence Against Women (VAW) Pilot Program (Funding Announcement Number: HHS-2008-IHS-IWHD-0001, Catalog of Federal Domestic Assistance Number: 93.933.) However, this project and the Preventive Care Assessment Project are very different in terms of content and purpose. The VAW Pilot Program primarily funds training for nurses to become Sexual Assault Nurse Examiners (SANEs) and travel to attend

meetings, and the development of culturally appropriate tools for assessment. It does not include an information-gathering component, nor is it a study intended to identify best practices in primary care behavioral health screening.

6. Small Businesses

This information collection will solicit information from tribally operated service units, which are either Tribal governmental or non-profit entities. Some of these service units may be small. However, the sample size has been kept to a minimum, participation is voluntary, and project team members are working with the service units to schedule visits to have the least impact on their operations.

7. Less Frequent Collection

This is a one-time collection of data.

8. Special Circumstances

There are no special circumstances for collecting this information. The data will be collected in a manner consistent with the guidelines in 5 CFR 1320.5.

9. *Federal Register* Notice/Outside Consultation

A 60-day Federal Register Notice was published in the Federal Register on April 29, 2008 (73 FR 23254) Vol. 73 No 83 pp 23254-23255 (see Appendix E). There were no public comments. There was no outside consultation with industry or other outside entities. ASPE (part of the Office of the Secretary of HHS) and IHS are collaborating on this study through an intra-agency agreement. A number of ASPE and IHS colleagues were consulted informally in the development of the study design and that practice continues as needed as the study progresses. There has been no consultation with other HHS agencies on these information collection requirements as the data is being collected solely from federal and tribal Indian Health programs.

10. Payment/Gift to Respondents

Participation in the focus groups is voluntary. No payment or gift will be provided to respondents.

11. Confidentiality

Site administrators and focus group respondents will be notified that no data collected will be identified by program site unless explicit permission is given by that healthcare program.

No Social Security numbers or other personal information will be collected during these

focus groups except for each respondent's name and job title. This information is only for the use of the contractor conducting the focus groups and IHS and ASPE project team members, to permit validation of site report information by comparison with transcripts. The identities of IHS and tribal employees participating in these focus groups will not be released in any public form.

The IHS Institutional Review Board determined that this project meets the criteria for appropriate evaluation exempted from the provision of 45 CFR 46 because it is a program evaluation and not research as defined by the common rule (a copy of the IRB exemption letter is attached- see Appendix C).

Prior to each site visit, the project team will send a letter to the CEO for that site and to the appropriate IHS Area director to request approval and solicit participation in the study. A letter will also be sent soliciting approval for the site visit from the tribal government(s) of the Tribe(s) served by that site.

12. Sensitive Questions

This study will ask employees to describe work processes relating to behavioral health screening and referrals for services generally. Individual patient information will not be collected. Questions of a sensitive nature will not be included in the data collection instrument.

13. Burden Estimate (Total Hours & Wages)

12A. Burden hour estimate: The project team will conduct up to three focus groups per site, each lasting 2 hours. The number and type of respondents will vary depending on program composition. The estimated burden hour over the life of this collection is 180 hours (see table below). The burden hour per health program is approximately 6 hours total. The burden hour per individual respondent is 2 hours total.

Type of Respondent	**No. of Respondents**	**No. of Responses per Respondent**	**Average Burden per Response (in hours)**	**Total Burden Hours**
Provider: Physician, PA, NP, RN, BH Specialist, Substance Abuse Counselor	3	10	2	**60**
Administrator: CEO, Clinic Director, etc.	3	10	2	**60**
Data Entry: Data Clerk,	3	10	2	**60**

IT staff, etc.				
Total				**180**

12B. Annualized hourly cost: Each focus group will last for 12 hours. The number and type of respondents will vary depending on program composition. The cost burden to respondents is equal to the hourly rate they earn during the time spent in the focus group. The following table provides a cost estimate based on average salary ranges for professional categories, as found on the IHS job vacancy database.

Type of Respondent	**Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Physician	60	$50.00	$3000.00
Physician Assistant/Nurse Practitioner	60	$35.00	$2100.00
Registered Nurse	60	$26.00	$1560.00
Behavioral Health Specialist	60	$30.00	$1800.00
Substance Abuse Counselor	60	$17.00	$1020.00
Data Entry Clerk	60	$17.00	$1020.00
Total			$10,500.00

14. Capital Costs (Maintenance of Capital Costs)

There are no capital, operating and/or maintenance costs to respondents or record keepers to report for this collection.

15. Cost to Federal Government

A one-time cost to the government of $200,000 has been provided for this project in the form of a transfer from ASPE to IHS via an amended Intra-Agency Agreement (Appendix A). Of these funds, more than half has been obligated for the contractor to conduct onsite focus groups and prepare site reports, with the remainder designated for contractor support to enable the IHS National GPRA Support Team at the California Area Office to prepare focus group guides, conduct contractor oversight, perform data analysis, and prepare national draft and final study reports, and to purchase NVivio software and study-related reference materials.

16. Program or Burden Changes

This is a new data collection.

17. <u>Publication and Tabulation Dates</u>

The tribal data collection portion of the project will commence from the date of OMB approval and end on the expiration date of the collection. Information gathered during this project will be used to prepare analyses and reports, including a summary report of "promising practices" for Indian health programs, to be distributed through the IHS network and by ASPE. Additional project summaries, suitable for publication, may also be developed.

Each participating program will receive a report of the focus group discussions conducted at its site. No individual focus-group participants will be identified in this study, either in the site reports or in the summary report. Furthermore, no sites will be identified in the summary report, unless a participating facility authorizes IHS and ASPE to do so. Finally, all site reports will be distributed only to the corresponding site via hard copy format. The summary report of "promising practices' and other project summaries will be prepared in formats suitable for possible publication and electronic distribution, though again, no identifiers will be included.

See the following table for data collection timeframe for proposed tribal sites:

Site name	Data Collection	Data Analysis and Draft Report
Cherokee Hospital	2 days	14 days
Nowata Primary Care Health Clinic	2 days	14 days
Cherokee Nation	2 days	14 days
Choctaw Nation (South)	2 days	14 days
Idabel Health Center	2 days	14 days
Chitimacha Tribe of LA	2 days	14 days
Tulalip Clinic	2 days	14 days
Snoqualmie Falls Tribe	2 days	14 days
Bartlesville Health Center	2 days	14 days
Stigler Health Center	2 days	14 days
Total	20 days	140 days

Following OMB approval the planned timetable would be:

Site name	Data Collection	Data Analysis and Final Report
Cherokee Hospital	Within 1 month of OMB approval	2-3 months following OMB approval
Nowata Primary Care Health Clinic	Within 1 month of OMB approval	2-3 months following OMB approval
Cherokee Nation	Within 1 month of OMB approval	2-3 months following OMB approval
Choctaw Nation (South)	Within 1 month of OMB approval	2-3 months following OMB approval
Idabel Health Center	Within 2 months of OMB approval	3-4 months following OMB approval
Chitimacha Tribe of LA	Within 2 months of OMB approval	3-4 months following OMB approval
Tulalip Clinic	Within 2 months of OMB approval	3-4 months following OMB approval
Snoqualmie Falls Tribe	Within 2 months of OMB approval	3-4 months following OMB approval
Bartlesville Health Center	Within 3 months of OMB approval	4-5 months following OMB approval
Stigler Health Center	Within 3 months of OMB approval	4-5 months following OMB approval

Activity	Expected Date of Completion
Data collection	1-4 months following OMB approval
Data analysis	4-5 months following OMB approval
Preparation of draft reports	3-4 months following OMB approval
Final report	5-7 months following OMB approval
Final briefing	8 months following OMB approval

The final work products generated from this study may also be prepared in form(s)

suitable for publication. IHS and HHS decision-making staff will also be briefed on the major findings of this study.

18. Expiration Date

The OMB number and expiration date will be displayed on the data collection instrument accordingly.

19. Certification Statement

There are no exceptions to the certification.

B. Collection of Information Employing Statistical Methods

In preparation for the study, quantitative performance data that had been reported through GPRA was reviewed by the IHS (NGST) and ASPE study team members. Quantitative data elements included national performance data (2005– 2007) on the three behavioral health GPRA measures: Depression Screening in adults age 18 and over, Domestic/Intimate Partner Violence screening in women ages 15-40 and Alcohol Screening (to prevent Fetal Alcohol Syndrome) in women ages 15-44. In addition, study team members will evaluate published and other available clinical prevalence data directly related to Depression, Domestic/Intimate Partner Violence, and Alcohol use among American Indians and Alaska Natives for context for data collected at site visits. Finally, existing quantitative and descriptive data available regarding structural features of clinics (e.g. staffing, funding levels, community demographics, and organizational structure) will be analyzed to provide context for data collected at site visits.

This study will collect qualitative information on behavioral health primary care screening from focus group participants. Qualitative data gathered by focus group discussion provides a rich resource for this study. The focus group interview format allows participants to provide responses related to their individual knowledge and experiences and fosters multi-level discussions between individual and/or group opinions. This interaction itself can provide key ideas and help participants identify characteristics of behavioral health screenings in the primary care setting. It can also uncover otherwise untapped knowledge that may not emerge in one-on-one interviews.

The focus group information will be analyzed using industry statistical software specifically designed for qualitative datasets (NVivo 7.0). It will also be evaluated through framework analysis. Framework analysis provides the flexibility for themes unique to each program to be captured, directly and indirectly, during the fieldwork (in this case, focus group discussion). This methodology allows for systematic interpretation and translation of the data by people other than the primary analyst. This approach is slightly more structured from the outset than most qualitative research, but has been increasingly used in healthcare research.

1. Respondent Universe

We are seeking approval for a respondent universe of tribal employees at tribal health programs. The participants will be identified by the tribal health program on the basis of their ability to provide relevant data. The expected response rate is 8-10 employees per tribally-operated program, or a total of 80-100 respondents. There is no statistical response rate associated with this type of data collection method.

2. Procedures for the Collection of Information

IHS study team members developed a methodology to identify programs with a record of

greater or lesser success on GPRA measure results for these three behavioral health measures at both Tribal and Federal sites using FY 2005, 2006, and 2007 GPRA performance results. Tribal programs voluntarily report their GPRA results quarterly and annually for national reporting. GPRA data collected for these three behavioral health measures includes: the number of patients eligible for a screening (denominator), number of eligible patients who receive a screening (numerator), and the resulting screening rate (percentage).

IHS project team members identified 17 sites (7 IHS and 10 Tribal) that were especially high or low performers on GPRA behavioral health screening measures in comparison to all sites. For the high performers, the project team selected sites that performed above average by 1 standard deviation of the mean. Further restrictions (beyond 1 standard deviation) were imposed on low performers to allow for a more representative (IHS and. Tribal) cross-section of participants.

The project team will convene focus groups on site with employees at all 17 Indian health programs in order to identify the factors contributing to (and possible barriers preventing) the provision of high quality behavioral health screening and care at the local level.

Focus group guides were developed by project team members at the start of the project. Two of the 7 IHS sites selected for inclusion served as "pilots" to test the focus group guides. The draft focus group guides were used by the contractor, with IHS NGST observers at the first federal pilot site, modified and refined based on the results, and then used again by the contractor with IHS NGST and HQ and ASPE observers at the second federal pilot site. The contractor has used the final focus group guides developed for the project (Appendix B) at the remaining 5 selected IHS sites, and will use the guide at the Tribal sites once approval is granted.

The procedures for collection of information through focus groups are such: a total of 2-3 focus groups, organized by occupational specialty, is convened at each program. These occupational specialties include providers (physician, registered nurse, behavioral health specialist, substance abuse counselor, physician assistant, or nurse practitioner), administrators (CEO, clinic directors, and other staff with decision-making capabilities); and data entry staff (registration clerk, site technician, clinical assistant, coding clerk, or billing clerk).

Focus group respondents are not randomly selected, but identified based on staff knowledge, experience, availability and other factors by the site Chief Executive Officer (CEO). A detailed description of the project purpose is fully disclosed to the CEO prior to any focus group sessions, to ensure the appropriate identification of participating staff. In the case of tribal programs, an introductory letter will be sent to each health program CEO as well as to the Tribe along with a request for appropriate tribal review and steps to be taken for approval of participation in this study.

Each group answers questions that relate to their role in the provision of behavioral health

screening. Providers deal with patients in a primary care setting and answer questions about identification, screening tools, documentation, and referrals and treatment. Administrators have decision making capacities that can affect a site's priorities and practices; they answer questions about policy, budgets, and initiatives.

Data Entry staff also play a role in this process when they enter clinical data into clinical information systems at clinics that have not yet implemented the Electronic Health Record (EHR). Accurate and timely data entry of clinical data allows providers to make informed decisions and allows sites to track their processes accurately. At sites that do not run the EHR, a focus group will be conducted with data entry staff, who will be asked to answer questions about information systems and data entry. (A copy of the focus group guides is in Appendix B). At such sites, behavioral health providers will participate in the provider focus group. At sites where the data entry staff has no responsibility for entering clinical data into the clinical information system, no data entry staff focus group will be conducted. Instead, the provider focus group will be split into two separate provider groups, one for primary care providers, and a second for behavioral health specialists. It is anticipated that most sites will have two provider focus groups. All focus group discussions will be conducted and recorded by a contractor with extensive experience with tribal programs and behavioral health.

The focus groups are run in an informal but structured style, to allow respondents to expand on their answers rather than just providing factual data, and to allow for follow up questions as necessary. Employees provide detailed information regarding program practices, screening and documentation procedures, initiatives, resources, and other factors relating to the provision of behavioral health preventive care at their health program. Each focus group discussion is recorded, and participants notified that the session is being taped. Respondents' confidentiality will be maintained and information collected will be limited to behavioral health screening and preventive care, referral for services, and follow up. Each focus group discussion is transcribed using the recordings.

Data Sources

Focus group results will be summarized by the contractor using the transcripts from the recorded focus groups. Data validation will be performed using written transcripts as well as original audio recordings. Data validation of recordings from 1-2 selected Federal sites has been undertaken to ensure the accurate transcription from the audio recordings. A draft site report is provided to IHS project team members by the contractor shortly after completion of the site visit and receipt of the transcript. The project team reviews the draft site reports, make recommendations for clarifications, and help the contractor finalize the site reports. The site report summarizes findings from all groups, using direct examples and quotes from the focus group participants, although individuals will not be identified. The site reports also summarize promising practice recommendations made by employees at each site. These reports will form the basis of a final report that summarizes recommendations and findings across sites.

Tabulations and Statistical Analysis

Because the focus group portion of this study is generating qualitative data, no specific tabulation or quantitative statistical analysis will be performed. Qualitative analysis of the focus group discussions will focus on identifying themes that emerge from the focus group discussions, using the Chronic Care Model and Institute of Medicine recommendations on Behavioral Health preventive care as a framework. The analysis will also compare responses from various sites, and identify characteristics of high and low performers. The NGST will also use existing data available to IHS on other qualitative and quantitative features of individual programs, such as staffing and funding levels, community demographics, and organizational structure, to identify factors contributing to greater successes and challenges in providing high quality preventive behavioral health care as measured by the GPRA screening indicators. This analysis will assist the project team in identifying which behavioral health screening practices are most effective in the primary care setting and could be adapted to varying local circumstances and implemented more broadly. The information and significant findings generated from this study may also be used to prepare one or more articles in a form suitable for publication. Key IHS and HHS research and policy staff will also be briefed on the major findings of this study.

3. Methods to Maximize Response Rates and Deal with Nonresponse

The IHS project team, working with the contractor, will work closely with each tribal program to maximize participation in the project, while retaining the voluntary nature of the effort.

4. Tests of Procedures or Methods to be Undertaken

The data collection instruments (focus group guides) were tested by the IHS contractor and IHS project team using federal employees at two pilot IHS-operated health programs and revised accordingly to improve their clarity, specificity and usefulness. At each pilot site, focus groups were convened and a draft collection instrument was used. Pilot focus group participants were given a short, anonymous questionnaire that allowed them to rate the effectiveness of both the focus group moderator and the questions. IHS project team and contracting staff used this feedback, along with their notes taken during the pilot site focus groups, to modify the questions to make them clearer and more precise, and to eliminate redundant questions.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The National GPRA Support Team members Ms. Elaine Brinn, Dr. Amy Patterson, and Ms. Janae Price will serve as the lead investigators on this study. The NGST consulted with Behavioral health staff at the IHS headquarters and Area level to design the focus group guides and oversee the project. The ASPE technical liaison, Sue Clain, and IHS

HQ staff members Dr. Phil Smith, Francis Frazier, and Lucie Vogel were consulted at every stage of the process for review and guidance in the development of the work plan, information collection instruments, data analysis plans, and liaison with Tribes. Ms. Clain and Ms. Vogel also conducted onsite observation and evaluation during the pilot at one Federal site. IHS has contracted with JL Ward Associates to conduct the focus groups; Mr. Ward has extensive experience with tribal health programs and behavioral health program design and analysis. Mr. Frazier has clinical experience and knowledge of IHS GPRA measures, Ms. Clain has experience in evaluation at the HHS Departmental level, and Ms. Vogel has experience in evaluation at the state and federal levels, including qualitative and quantitative studies.

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