30 June 2009

TO: Karen Matsuoka

FROM: Amanda Cash

SUBJECT: Patient Navigator Demonstration Program (PNDP) – Response to Comments

Background

This program is authorized under the Patient Navigator Outreach and Chronic Disease Prevention Act of 2005, P. L. 109-18, Section 340A of the Public Health Service Act (42 U.S.C. 256a). This Patient Navigator Outreach and Chronic Disease Prevention Demonstration Program (PNDP) authorizes funds for the development and operation of demonstration projects to recruit, assign, train and employ patient navigators who have direct knowledge of the communities they serve to facilitate access to health care for individuals who are at risk for or who have cancer or other chronic diseases, including conducting outreach to health disparity populations. Patient navigator services were pioneered by the Patient Navigation Program for improved early diagnosis and timely access to cancer care at The Harlem Hospital. The historic outcomes of this project were the first to show what a critical role patient navigation services can play in overcoming access barriers in the health care arena for underserved patients. This landmark model opened the door to having the Patient Navigator and Chronic Disease Prevention Act signed into law.

The PNDP is a pilot demonstration project for patient navigation. Its purpose is to develop programs that improve the quality of care for health disparities populations using recently-developed models of patient navigation. Navigation programs for the treatment of cancer are relatively well developed, and established programs are currently undergoing rigorous evaluation by NIH using confirmatory study designs involving specific hypotheses as well as pre/post and control group comparisons.

However, under PNDP, the navigation model is being expanded to new areas of clinical care - to preventive care and to chronic diseases other than cancer. PNDP programs are in development, so there is no expectation that the interventions will be stable over the course of the project. Because the programs are brand-new, and grantees are encouraged to improve (and change) program policies and procedures as experience is gained, the focus of the evaluation is exploratory and descriptive. The evaluation will describe whether there are indications that the programs are successful in meeting quality improvement goals across grantees and sites. While some comparisons to benchmarks and baselines will be made, these comparisons will be made within the context of qualitative data that explain how the programs were implemented, including the persons served, challenges encountered and lessons learned. The evaluation will provide information about what aspects of navigation are most resource-intensive and should provide guidance for development of future patient navigator programs.

Because the focus of the PNDP is development of program infrastructure and resources, and evaluation of the program is exploratory and descriptive, every attempt has been made to minimize the burden of data collection. This means that most if not all of the data are collected

as part of the clinical or administrative procedures already in practice at the sites. However, the sophistication of information technology and administrative oversight varies considerably among the sites. In sites where data collection procedures are new, implementation should provide valuable, direct information to the programs for their own monitoring of project goals and quality. The evaluation has not required implementation of standard measures across all sites because (1) some measures would duplicate existing procedures and would create additional burden; (2) some measures do not meet clinical or administrative needs, and (3) standardization is difficult because the sites differ considerably in the type and stage of disease or condition that is the focus of the program. For example, some sites are focusing on cancer prevention and treatment, while others focus on diabetes screening, prevention, and treatment.

OMB Comment: I think this study requires a part B but none is included.

HRSA Response: This is not a research or confirmatory study, and does not involve sampling. The PNDP is a pilot demonstration project and its evaluation will examine how the explicit duties of a navigator (provided in the statute) are translated at the community level. There was no statistical sampling used to determine how communities would receive funding; there was a competitive grant process through which six sites were chosen based on funding appropriated for the program.

OMB Comment: In order to assess the utility of this information collection, it would be important for us to know how the evaluation will proceed. For example, will the grantees be doing pre/post analyses?

HRSA Response: This pilot demonstration project is not a research study of a stable intervention. Some sites will be comparing limited information prior to having a patient navigator with the same information once the navigator is being used in practice, to see if there are fewer broken appointments, for example, but much of the information does not lend itself to pre/post analyses. HRSA will be describing data collected on the navigator activities, and characteristics, and on some patient health indicators as patients are navigated. The program will be compiling the data in a descriptive way to outline what the project achieved.

OMB Comment: Will there be randomized control groups? If not, how do we know whether any improvements we see are attributable to the intervention?

HRSA Response: There will be no randomized control groups as the programs evaluated are pilot demonstration programs. The navigator programs are still in development, and the evaluation is a proposed assessment of whether funded grantees were able to achieve the outcomes that were proposed in their grant applications. Findings from the PNDP evaluation may be applied to create stable programs in the future which would possibly be appropriate for a randomized control study. The legislation permitted grantees flexibility in that each application could outline how the grantee would measure and evaluate program outcomes. Each grantee developed benchmarks based on their community needs and their populations served.

OMB Comment: How will the patients be sampled?

HRSA Response: Patients will not be sampled for this project, not in the traditional sense of the word. Grantees will enroll patients in the navigator program based on criteria outlined in the application process. The grantees were funded based on a competitive grant process, and all patients identified as meeting certain clinical criteria (which differ across sites) will be asked to enroll in the program. The sites are using a combination of socio-demographic and clinical criteria to identify patients at-risk for adverse health outcomes. Each site, in their grant application, discussed the populations and needs of the communities they serve. One site may have a greater number of patients with diabetes, for example, and their focus will be to enroll diabetics in the PNDP, while another site may focus on the elderly.

Patients enrolling in the navigation program will be followed over time. Participation is completely voluntary and any patient may decide to terminate their involvement with the project at any time for any reason. While sites will track enrollment and drop out rates, obtaining follow up information on patients that meet clinical criteria but that do not enroll or that drop out is difficult in many sites given available data collection structures. Describing the challenges and solutions to obtaining relevant outcome data will be one of the important findings to come of out the evaluation.

OMB Comment: How will non-response be handled?

HRSA Response: Non-response for this project might be better described as non-participation, since the aim here is to enroll patients in a program. We will report information on rates of program non-participation, refusals, and drop-outs and will look for common factors across sites that could help to explain patient non-participation.

OMB Comment: It is also not clear what the "matrix" is.

HRSA Response: The matrix is a framework the contractor and the program office are using to guide evaluation of the program. The matrix includes a set of questions that are linked to the data collected across the sites. An updated version of the matrix is attached with revisions that provide greater clarity.

OMB Comment: And what does the italics and underlined text represent? What is the 3rd column, for example, and how were they developed? (e.g. is "8% participate in clinical trials" a baseline or a benchmark? How was the figure 8% picked? And is it practical to expect that PNs will be able to get 75% of their patients insured? What if >25% of their patients are not eligible for health care coverage or cannot afford what is available for them?)

HRSA Response: The italics and underlined text relate to the logic model and are not significant; they have been removed to prevent further confusion. The third column represents benchmarks and baseline indicators for the six sites conducting the program.

The benchmarks were developed from a review of the available literature, from grantee proposals, and the contractor's significant experience in this area. The contractor conducting this

evaluation conducted the initial Patient Navigator Program for NIH. The purpose of evaluation is to determine whether all six sites can meet the benchmarks, and what factors, if any, prevent the sites from meeting the benchmarks. In the case of insurance/health care coverage, most of the sites have found ways to obtain at least limited coverage for their patients though Federal, State, County, or private programs. The evaluation will examine what common factors determine success in meeting this benchmark across sites, and what challenges prevent successful attainment of the benchmark.

OMB Comment: It also seems a bit odd to assess the PNs against a benchmark: why not compare against a control site? How do we know that a particular site wouldn't have been able to reach the benchmark without the intervention? Also, for each benchmark, please provide information on what the numerator and denominators are.

HRSA Response: Comparisons with control sites are not part of this exploratory study because the programs are in development and the design is an exploratory one.

The benchmark had not been previously reached prior to the development of PNDP because improving benchmarks is a key goal of the navigation program at the site. In other words, navigation is the quality improvement activity that targets many of the benchmarks. The evaluation will not prove that the site could have achieved the benchmark with navigation. The benchmarks in the matrix came from clinical experts at the sites, a review of the literature, and the contractor's previous experience with a patient navigator program at NIH.

The numerator and denominator are site-dependent. Some sites are seeking to improve mammogram rates in their clinic population of eligible women; other sites are seeking to improve the percentage of diagnosed diabetics with HbA1c in a healthy range.

The diversity of communities and variety of settings in which similar programs have been managed successfully at the local level suggests that a "one size fits all" standardized approach for this program does not work. A hallmark of the program is the guiding principle of a significant degree of local control over the development and implementation of the PNDP grant. Each of the grantees is developing its own protocol for the patient navigator to fit the needs of the community and utilize and build on the available resources. Because no standardized competency training or evaluation exists, each site has developed their own standards for evaluating their patient navigator's performance. Each grantee site is enhancing or building on existing programs in their PNDP.

OMB Comment: Are there ICs missing? For example, the matrix talks about a "patient interview by navigator." I can't seem to find this in ROCIS.

HRSA Response: There are no information collection requests missing. Information collected about the patient is collected as part of the site's routine clinical practice, such as intake forms and administrative records, and this information will be abstracted from these existing records. The wording of the matrix regarding some of the data sources was somewhat unclear, and has been revised. The intake forms and other patient records are unique to the clinical practice of each program.

OMB Comment: Who collects the data in the "common data elements data dictionary" and when? Are these data collected every time a patient sees a PN? Why is health care coverage questions asked twice (once in table 1 and another time in table 8)? How do these data elements fit together to arrive at the measures specified in the matrix? (e.g. how do you measure # of broken appointments)? How were the conditions and comorbidities selected? For example, why is hypertension not listed as a possible comorbidity and why is mental illness only comorbidity? What is the "comorbidity interference degree"?

HRSA Response: Data will be collected through multiple procedures at the sites. Most of the data will be collected by the patient navigator in the course of providing navigation for services. Data sources tapped during these activities include the patient, health care provider, medical records, or other administrative data sources. In some sites, some information will be collected from central administrative data bases. Many of the data elements are only collected once (e.g. patient intake, PN demographics, utilization data). One data table (patient tracking log) is collected by the navigator on each PN contact with or on behalf of any particular patient.

Health care coverage is asked multiple times because for many patients in these populations it is a fluid variable and changes over time. Procedures for collecting the data elements differ at each site, although the data elements are standardized. For example, broken appointments will be tracked as part of navigator's clinical duties involving patient self-report, a review of medical or administrative records, or communication between PNs and health care providers. Some sites have administrative systems that are able to track missed appointments.

The conditions being navigated were identified by each site in their grant application based on their own assessment of their specific population. The comorbidity list is based on a standardized set of comorbidities from the Charlson Comorbidity Scale[1], modified to lessen the burden for the navigator and to include comorbidities known to complicate disease management some of which were added by the clinical experts at the sites. The Charlson Comorbidity Index was originally designed as a measure of the risk of 1-year mortality attributable to comorbidity in a longitudinal study of general hospitalized patients. It was then validated for the same outcome in a cohort of breast cancer patients. It was subsequently adapted so that *International Classification of Diseases*, Ninth Revision (ICD-9), codes could be used to calculate the Charlson Comorbidity Index with existing administrative data.[2]

Hypertension and depression are both comorbidities we are tracking. The degree of interference related to comorbidities is operationalized as a count of the number of comorbid conditions.

OMB Comment: According to the supporting statement this study appears like it will go on for 1.25 years (i.e. you're collecting 5 quarters of data). However, the logic model says that it will take at least 2 years to get some of the outcomes you are testing for (e.g. decreased time from screening to diagnosis, participation in clinical trials). This seems to mean that you will not be

[1] Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: Development and validation. Journal of Chronic disease 1987; 40: 373-383.
[2] Deyo RA, Cherkin DC, Ciol MA. Adapting a clinical comorbidity index for use with ICD-9-CM administrative databases. J Clin Epidemiol 1992;45:613–19.

able to obtain valid results on those measures unless the study was extended out to 2 years. Please explain.

HRSA Response: The logic model provides a broad picture of the program and its goals, and is a generalized statement of the timeframe. A timeline is attached for clarification. The projects themselves are funded for two years. Data collection will take place for 1.25 years which is scheduled to begin in August or September of this year. HSRA is required to conduct an evaluation as mandated by the legislation, but this will not preclude measuring some outcomes even though the grantees will not be funded past the end of September 2010. The evaluation will report on what outcome data are available, and will explain why and to what degree the information may be generalizable to future programs. Short-term outcomes, such as decreased time screening to diagnosis and clinical trials participation, will be measured.

OMB Comment: Finally, it seems that the grants have been awarded and the entities picked: however, there is no information on those sites and how they were picked.

HRSA Response: This is correct. The funding mechanism for this program was a competitive grant opportunity for two-years of support. The program was authorized in FY 2005 with appropriations for FY 2006 through FY 2010, and ends September 30, 2010. Federal funds were available beginning in FY 2008, thereby limiting the PNDP to a two-year grant period with the period of support for approved and funded projects beginning September 30, 2008 and ending August 31, 2010. FY 2008 funding was $2.948 million and awarded to six patient navigator grants.

Eligible applications were peer reviewed by an objective review committee, and the six awardees are from across the country (CA, FL, GA, NY, SC and TX) representing a diverse range of eligible organizations: academic health center, Federally qualified health center (FQHC), hospital district, free clinic and community non-profit organization. Per the legislation, eligible applicants included public or nonprofit private health centers (including a FQHC as defined in section 1861(aa)(4) of the Social Security Act), health facilities operated by or pursuant to a contract with the Indian Health Service, hospitals, cancer centers, rural health clinics, or academic health centers. Nonprofit entities that enter into partnerships with or coordinate referrals with such centers, clinics, facilities, or hospitals to provide patient navigator services were also eligible. All awardees applied for and received a funding preference by indicating how they will use patient navigator services to overcome barriers to improve healthcare outcomes in their communities. Barriers cited by awardees related to residing in a MUA or HPSA, geographic isolation, transportation, poverty (200% FPL), limited English proficiency, cultural barriers, lack of health insurance and epidemic chronic disease levels.

OMB Comment: These seem like huge questions to me, which will probably take the program/contractor several weeks to answer. If it will take more than 2 weeks, I would prefer HRSA to withdraw this ICR, work on it, and resubmit it.

HRSA Response: We believe that the questions you have raised were a result of unclear and perhaps inconsistent wording in some of the materials provided with this ICR, and that the revised materials will resolve the major issues noted in the questions. Due to the short time-

frame of this project and the legislative requirement to conduct the evaluation, HRSA requests that the ICR not be withdrawn. We apologize for the confusion with this ICR and would be glad to discuss any outstanding questions at your discretion.

Patient Navigator Demonstration Program Timeline

Date	Description
2005	
June 7	Program Authorized by Congress
2008	
FY 08	Funds appropriated to PNDP
Sept. 1	Grantees awarded funds
2009	
July 15	Grantee Quarterly Report (Quarter 2 2009) due
August	Target OMB approval
October 15	Grantee Quarterly Report (Quarter 3 2009) due
October	First data collected through Sept 2009 to HRSA (assumes OMB approval in September)
2010	
Jan 15	Grantee Quarterly Report (Quarter 4 2009) due
April 15	Grantee Quarterly Report (Quarter 1 2010) due
July 15	Grantee Quarterly Report (Quarter 2 2010) due
August 15	Grantee Final Report due
August 31	End Grantee Funding pursuant to authorizing legislation
Sep 1	Second Congressional Report Draft to HRSA
Sept 28	End of contract/Final Congressional Report to HRSA
2011	
March 30	Final report due to Congress