

# **Pennsylvania Department of Health Final Performance Summary Report Formula Grants**

## **Overview of the Health Research Project Performance Review Process and Criteria**

An applicant that receives a health research grant under Tobacco Settlement Act / Act 77 of 2001, Chapter 9, is subject to a performance review by the Department of Health upon completion of the research project. The performance review is based on requirements specified by Act 77 and criteria developed by the Department in consultation with the Health Research Advisory Committee.

As part of the performance review process, each research project contained in a grant is reviewed by at least three experts who are physicians, scientists or researchers. Reviewers are from the same or similar discipline as the research grant/project under review and are not from Pennsylvania. Reviewers use the applicant's proposed research plan (strategic plan), the annual progress report and final progress reports to conduct the review. A grant that receives an unfavorable performance review by the Department may be subject to a reduction in funding or become ineligible for health research funding in the future. The overall grant evaluation rating is based on the ratings for the individual research projects contained in the grant.

This performance review report contains the outcome of the review for the grant as a whole (outstanding, favorable, or unfavorable), strengths and weaknesses of each research project, as well as recommendations for future improvement.

The following criteria were applied to information submitted by research grant recipients:

- **Criterion 1 - How well did the project meet its stated objectives? If objectives were not completely met, was reasonable progress made?**
  - Did the project meet the stated objectives?
  - Were the research design and methods adequate in light of the project objectives?
  - Consider these questions about data and empirical results: Were the data developed sufficiently to answer the research questions posed? Were the data developed in line with the original research protocol?
  - If changes were made to the research protocol, was an explanation given, and, if so, is it reasonable?
  - Consider (only for clinical research projects) the extent of laboratory and clinical activities initiated and completed and the number of subjects relative to the target goal.
  - Were sufficient data and information provided to indicate or support the fact that the project met its objectives or made acceptable progress?
  - Were the data and information provided applicable to the project objectives listed in the strategic research plan?

- **Criterion 2 - What is the likely beneficial impact of this project? If the likely beneficial impact is small, is it judged reasonable in light of the dollars budgeted?**
  - What is the significance of this project for improving health?
  - Consider the value of the research completed towards eventual improvement in health outcomes.
  - Consider any changes in risk factors, services provided, incidence of disease, death from disease, stage of disease at time of diagnosis, or other relevant measures of impact and effectiveness of the research being conducted.
  - Consider any major discoveries, new drugs and new approaches for prevention, diagnosis and treatment, which are attributable to the completed research project.
  - What are the future plans for this research project?
  
- **Criterion 3 - Did the project leverage additional funds or were any additional grant applications submitted as a result of this project?**
  - If leveraging of funds were expected, did these materialize?
  - Are the researchers planning to apply for additional funding in the future to continue or expand the research?
  
- **Criterion 4 - Did the project result in any peer-reviewed publications, licenses, patents, or commercial development opportunities? Were any of these submitted/filed?**
  - If any of the above listed were expected, did these materialize?
  - Are the researchers planning to submit articles to peer-reviewed publications, file for any licenses, or patents or begin any commercial development opportunities in the future?
  - Consider the number/quality of each.
  
- **Criterion 5 - Did the project enhance the quality and capacity for research at the grantee's institution?**
  - Were there improvements made to infrastructure?
  - Were any new investigators added or were any researchers brought into the institution to help carry out this research?
  - Were funds used to pay for research performed by pre- or post-doctoral students?
  
- **Criterion 6 - Did the project lead to collaboration with research partners outside the institution, or new involvement with the community?**
  - Are the researchers planning to begin any collaborations as a result of the research?
  - For clinical research only: consider the number of hospitals and health care professionals involved and the extent of penetration of the studies throughout the region or the Commonwealth.

## **Overall Evaluation Rating**

An overall evaluation rating is assigned to each research project. The rating reflects the overall progress the project attained in meeting the stated goals and objectives. The rating is based on a scale of 1–3, with 1 being the highest. An average rating is obtained from all the reviews (minimum of 3) of each project and is the basis for the determination of the final overall rating for each project as follows:

1.00 – 1.33 = *Outstanding*

1.34 – 2.66 = *Favorable*

2.67 – 3.00 = *Unfavorable*

The grant level rating is an average rating from all projects as above. The numerical rating appears in parentheses for the grant and each project in the ***Overall Grant Performance Review Rating*** section of the report.

***Overall Grant Performance Review Rating***

**Grant Rating:** Favorable (2.00)

**Project Rating:**

<b>Project</b>	<b>Title</b>	<b>Average Score</b>
1085101	Determining Correlates of Hepatitis B Status Among High-Risk Asian and Pacific Islanders in Pennsylvania	Favorable (2.00)

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**Project Number:** 1085101  
**Project Title:** Determining Correlates of Hepatitis B Status Among  
High-Risk Asian and Pacific Islanders in Pennsylvania  
**Investigator:** Cohen, Chari

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## ***Section A. Project Evaluation Criteria***

***Criterion 1 - How well did the project meet its stated objectives? If objectives were not completely met, was reasonable progress made?***

### **STRENGTHS AND WEAKNESSES**

#### Reviewer 1:

This study represents an important effort to examine sociocultural and demographic factors associated with hepatitis B status among high-risk groups of Asian and Pacific Islanders (APIs) in Pennsylvania. Screening for hepatitis B virus (HBV) is an important (and relatively neglected) healthcare disparities topic, and the researchers should be commended for their important contributions to this field. Moreover, serological validation of the HBV infection (HbsAg, HbsAb) is more useful for health policy planning than self-reported HBV infection status.

This project has two specific aims to focus on two outcomes: HBV infection status (infected, not infected, and immune) and healthcare usage and access. During the study period, the aims and objectives were partially met. The study team has only worked on Specific Aim 1. They have not presented the results of Specific Aim 2 to examine the factors associated with limited access to health care.

With the cross-sectional study design using data collected from community-based HBV education and screening sessions between 2008 and 2010, the study team conducted data analysis among those self-identified APIs (n=639). For the first half of funding period, they planned to do data cleaning and data analysis for Specific Aim 1. They made reasonable progress toward answering research questions. For the second half of funding period, they planned to perform the data analysis for Specific Aim 2 and to disseminate the results in a scientific meeting and a peer-reviewed journal. This objective was not met. Based on their progress report and final report, they presented the results for Specific Aim 1.

Both Aims 1 and 2 explicitly indicate that their focus is on APIs. However, the measure of 'country of birth' shows that none of the participants was Native Hawaiian or Other Pacific Islander. They were all born in Asia: Korea, Vietnam, China, India, and others (Laos, Cambodia, Indonesia, Malaysia, and Hong Kong). The data from the non-Pacific Islanders will be inadequately addressed with respects to Aims 1 and 2.

Here, there were serious weaknesses in methodology and data analysis.

Measurement: There was no clear description of how they constructed the two outcomes (hepatitis B infection and hepatitis B immunity). They used either self-reported on the HBV screening survey or the blood sample from the screening test. Based on the HBV screening test, participants would have three groups: (1) HBV positive (HbsAg+); (2) HBV negative and immune (HbsAg-; HbsAb+); and (3) HBV negative and unprotected (HbsAg-; HbsAb-) who need a series of vaccinations. It is confusing to estimate the prevalence of HBV infection (n=40) and immunity (n=360). It is not clear that those remaining 239 were unprotected and needed vaccinations. Table 1 also shows the proportion of HBV vaccination (n=110). What is the denominator of the proportion of HBV vaccinations (16%)? They should clarify this prevalence.

As a proxy measure of acculturation, years in the U.S. was used with a mean of 17.2 years (10.9 standard deviation). In the analysis, they made three categories of this variable (28+, 17-28, <17). There was no scientific rationale to make such categories. In the previous study, foreign-born from the endemic countries (Asia and Africa) had higher HBV infection than those born in the United States (9.0% vs. 0.1%). They did not provide the proportion of U.S.-born. About 9% (n=57) reported that English was the primary language. Were they born in the United States? This is a very important issue when comparing the HBV infection prevalence in foreign-born and U.S.-born populations.

The definition of HBV knowledge is not clear. Prior HBV screening or HBV treatment seems to mean previous behavior (not knowledge). Knowledge of HBV infection can be measured by the knowledge of transmission mode, sequelae, and high-risk group. Future intervention will be developed to increase HBV awareness and knowledge, which may lead to later screening behavior.

#### Analysis/Tables:

The results were presented in the tables in a confusing manner, including some information that appeared to be ambiguous and even contradictory. Different denominators were noted in bivariate analysis.

#### Table 1:

Multiple miscalculations of percentages were noted with different denominators (n=555 to n=639). For example, about 13% (n=84) did not report their education. If there were a lot missing, they should include missing categories.

#### Table 6:

Information was lacking on how they measured vaccination status. Based on the screening result, those who are unprotected have a series of three vaccinations within six months. When did they ask about the vaccinations? Is this self-reported? Did they complete three vaccinations? The researchers need to provide a clear description.

The overall prevalence of HBV infection was 5.8%. There were subgroup differences in prevalence of HBV infection. About 12% comprised foreign-born from India who did not have any HBV infection, while 23% were born in China with 66% prevalence (Table 2). The results

will be important for further policy implications to consider diverse aspects of Asian Americans in terms of language, culture, and acculturation.

In model building, multivariate analysis (Tables 8 and 9) showed that country of birth was the only predictor for HBV infection and immunity after adjusted for age and gender. They could not find any other factors associated with these two outcomes. However, they seemed to overstate their conclusions based on the findings of bivariate analysis. In addition, they should consider some multicollinearity problems of living situation by adding three similar variables in the final model (e.g., family history of HBV, family history of liver cancer, and living with anyone with HBV). Conceptually, these variables of living situation are measuring the same things.

Reviewer 2:

The milestones that were met, based on the funding level and percent of effort allocated, were reasonable.

The main objective was to conduct analyses that would lead to a manuscript submission to a peer-reviewed academic journal. Their plan was to submit a manuscript by March 1, 2012. The Word document included (assumed to be their draft manuscript), unfortunately, is not prepared well enough in its current form for publication. The research team will benefit by seeking a biostatistician to help correctly write/interpret their results. For example:

1. An odds ratio represents the change in the “odds” of an event not the likelihood; reviewers will not like this nomenclature.
2. Why is “other” the reference group for the country of origin variable, especially since this is the main predictor the team is looking at for inference.
3. No p-values are reported for the multi-variable (not “multivariate”) analysis although 95% of confidence intervals are.
4. Results are discussed as if they were significant (based on  $p < 0.05$ ) when the confidence interval (CI) includes 1.0. If I were reviewing the manuscript, I would suggest major revisions and possibly rejection.

The research team did submit two non-federal grant applications. One grant was awarded, and they are awaiting a decision on the second.

The research team did not report that they met their objective of presenting their report(s) at a national conference or at the Pennsylvania Viral Hepatitis Conference in 2012, so we must assume these objectives were not met.

Overall, for the amount of funding and percent of effort allocated the milestones met were reasonable. A number of re-writes are warranted prior to publication.

The research design and methods were appropriate for Aim 1. For Aim 2, however, logistic regression is not appropriate. The research team will need to use either linear regression (if assumptions hold), negative binomial regression or generalized linear models (GLM) techniques. Again, the team may benefit by including a biostatistician on their team. If possible, the research team should include data from matched, U.S.-born patients to strengthen their argument that

country of origin affects the outcomes studied. I think this is a weakness that limits the reach of their results.

The data are present to answer the first research question, however the manuscript needs revisions. The research team will need to run additional analysis (discussed above) to be able to answer their second question (concerning number of physician visits). The team will need to strengthen their analytic plan to achieve answers to all their questions, but the data is present. It seems Specific Aim 2 is still being addressed in detail; but again, given the annual funding level it seems reasonable. The research team may benefit by including a biostatistician and “paying” the individual with authorship to expedite the process.

#### Reviewer 3:

There were two overall objectives to this project. The first goal was to determine the sociocultural and demographic factors associated with HBV infection among the Asian and Pacific Islander communities in southeastern Pennsylvania. The second goal was to determine whether these factors are also associated with healthcare access in the same populations. The first objective was very thoroughly addressed. However, the second was not, and no explanation is provided as to why this objective was apparently not pursued. The original research design and methods were generally adequate to address the project objectives, and the data were sufficient to answer the first objective. No data were provided on the second objective.

***Criterion 2 - What is the likely beneficial impact of this project? If the likely beneficial impact is small, is it judged reasonable in light of the dollars budgeted?***

### ***STRENGTHS AND WEAKNESSES***

#### Reviewer 1:

This study may have the potential impact of reducing health disparities of liver cancer in a high-risk population. HBV screening may be of benefit to identify HBV infected persons; and even more importantly, providing antiviral therapy to reduce risk for progression.

#### Reviewer 2:

It is limited to a small population and may not address a large burden of disease for Pennsylvania or the nation; however, this is an area that merits further research and will produce fruitful results. The project warranted a smaller funding level than was allocated. In light of the funds allocated, the significance of the findings is reasonable.

The results of the current study should be able to be incorporated into a larger study that includes an interventional piece. As such, the project may indirectly lead to improvements in health for a small population, but it was a needed step in the evolution of this knowledge base. The results generated led to an increase in the technical capability to conduct an interventional study. The subsequent study should help increase the clinical capacity and infrastructure to assist this limited population.

Future plans are to seek federal funds to support an intervention study to decrease the health disparity experienced by the population being studied.

Reviewer 3:

A better understanding of the cultural and demographic factors that are associated with HBV infection is very important, since this will allow more precise targeting of at-risk or affected populations for educational or prevention purposes. While the results of this study were not entirely surprising, and a number of methodological limitations further lessen the impact of the findings, the impact is still judged to be very large in relation to the project's very small budget (< \$1000).

***Criterion 3 - Did the project leverage additional funds or were any additional grant applications submitted as a result of this project?***

***STRENGTHS AND WEAKNESSES***

Reviewer 1:

The researchers received one non-federal grant and are planning to submit to federal and non-federal sources of funding to eliminate hepatitis B disparities in APIs in the future.

Reviewer 2:

Two non-federal grant applications were submitted, and one was awarded for \$125,000. The evidence provided by the team was weak to support the claims that funds were leveraged to train graduate students and incorporated researchers not in the original application. The expected leveraging of funds did materialize. The researchers are planning to seek federal funds.

Reviewer 3:

Two grant applications were submitted, and one was awarded from the Barra Foundation in the amount of \$125,000. This represents an outstanding leveraging of funds.

***Criterion 4 - Did the project result in any peer-reviewed publications, licenses, patents, or commercial development opportunities? Were any of these submitted/filed?***

***STRENGTHS AND WEAKNESSES***

Reviewer 1:

During the funding period, they have not submitted any manuscripts in peer-reviewed journals. They are working on the preparation of a manuscript focusing on the vaccine self-reported findings to submit to a journal.

Reviewer 2:

The team planned to submit a manuscript by March 1, 2012. The draft manuscript provided will need major revisions prior to publication but should eventually be published in a peer-reviewed academic journal.

The team does not report plans to file for any licenses or patents, or begin any commercial development opportunities in the future.

Reviewer 3:

At the time of the progress report, submission of an article to a peer-reviewed journal was planned. This is reasonable in relation to the limited scope of the project. Based on the amount of data provided in the progress report, there is a reasonable expectation that a publication will materialize.

There were no licenses, patents, or commercial development, but these would not be expected from this type of project, which primarily addressed an epidemiological public health question. Therefore, this is not a significant weakness.

***Criterion 5 - Did the project enhance the quality and capacity for research at the grantee's institution?***

***STRENGTHS AND WEAKNESSES***

Reviewer 1:

One Asian master's student was involved in the project. It is not clear whether they supported her financially. They expected that the results of the project will enhance future intervention programs and program planning.

Reviewer 2:

The team did increase the capacity of their institution. The data they compiled and results obtained will increase the capacity of their institution, since Hepatitis is disproportionately higher in the population which the team studied. Evidence provided for additional researchers added or training provided to students was weak/stretched.

Reviewer 3:

This project supported in part the work of a master's degree student at the institution. Furthermore, the results generated by this project will enhance the research at this institution by targeting future HBV intervention strategies and educational programs to specific populations.

***Criterion 6 - Did the project lead to collaboration with research partners outside of the institution or new involvement with the community?***

***STRENGTHS AND WEAKNESSES***

Reviewer 1:

They will build some partnerships with the API community and researchers in Philadelphia. However, they do not have specific plans for how to collaborate. They also do not have specific plans for which API subgroups and which research groups will have partnerships.

Reviewer 2:

While they report it, the evidence is weak; although, the team should only need biostatistical support to complete this phase of their research. It is assumed they have included other

researchers for the funded grant and the submitted grant, but evidence was not provided. The team will need others to help with the intervention piece; otherwise, the current members of the team should be able to conduct/complete a majority of the work.

Reviewer 3:

In a general sense, public health studies such as this do help to build partnerships with specific community groups, such as the Asian and Pacific Islander population in southeastern Pennsylvania. The information generated by this study will be of interest to clinicians and other healthcare professionals in the community.

## ***Section B. Recommendations***

### **SPECIFIC WEAKNESSES AND RECOMMENDATIONS**

Reviewer 1:

1. Provide a clear definition of the study population of APIs.
2. The researchers need to clarify how they constructed their outcome measures (e.g., infection, immunity, not protected).
3. They need to provide the rationale for how they made categories of the predictors from a previous study (e.g., years in the U.S. and knowledge of HBV infection).
4. I recommend doing more refined data analysis in consideration of “missingness” and multicollinearity. In the tables, they could provide the crude odds ratio and the adjusted odds ratio to compare changes after adjustment.

Reviewer 2:

1. Seek biostatistical support for writing and interpreting the results of the analyses performed. The current version of the results section of the manuscript and the associated tables are weak and contain numerous minor interpretation errors.
  - An odds ratio represents the change in the “odds” of an event not the likelihood; reviewers will not like this nomenclature.
  - Why is “other” the reference group for the country of origin variable, especially since this is the main predictor the team is looking at for inference?
  - No p-values are reported for the multi-variable (not “multivariate”) analysis, although 95% of CIs are reported.
  - Results are discussed as if they were significant (based on  $p < 0.05$ ) when the CI includes 1.0.
2. Plan to use either linear regression (if assumptions hold), negative binomial regression or GLM techniques for Specific Aim 2. Logistic regression techniques are not correct for number of physician visits.

3. Include/obtain data from a matched cohort of U.S.-born patients to strengthen the argument that country of origin affects the outcomes studied. I think this is a weakness that limits the reach of the current results. Restricting the analysis to only foreign-born individuals weakens the investigation.

Reviewer 3:

A stated aim of this application was to address the hypothesis that limited healthcare access will correlate with age, country of origin, year of entry into the U.S., annual income, understanding of the U.S. health care system, and English proficiency in the Asian and Pacific Islander population in southeastern Pennsylvania. However, no details on the progress of this aim were provided, and it is not clear why this is so. Was it not possible to obtain these results for some unanticipated reason? Were the results simply uninformative?

**Additional Comments for Hepatitis B Foundation**

Reviewer 1:

The Hepatitis B Foundation is a long-standing organization that is working to reduce health disparities of hepatitis B infection by providing screening activities and education. They will continue to focus on liver cancer prevention and control in high-risk Asian Americans.