

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:

Project	Title	Average Score
1087601	Outcomes of Disparate vs. Non-Disparate Cancer Patients Undergoing Patient Navigation	Favorable (2.00)

Project Number: 1087601
Project Title: Outcomes of Disparate vs. Non-Disparate Cancer Patients
Undergoing Patient Navigation
Investigator: Heron, Dwight

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:

The study proposed to review data collected on 542 navigated patients in three underserved communities between January 2005 and May 2008 relative to gender, race, age and stage of disease to identify possible indicators for the apparent excess mortality rates observed. Of the 542 records evaluated, only 395 had complete data. Of the 395 patients analyzed, successful treatment rates (alive without cancer) was 37.5, which was significantly lower than the national five-year survival rate of 65.4%. The investigators concluded that their patient population had lower survival rates than the national average and that race and socioeconomic status were associated with lower survival.

The research is important and provides preliminary data on treatment survival and potential targets for future intervention. The investigators completed the planned analyses, and results are consistent with the study hypotheses.

Weaknesses include the lack of clear definition of good outcome, the lack of sample size justification, and the inadequate description of the data analysis plan as well as the lack of case-mix adjustment. Nevertheless, the design and analyses are within the scope of a small pilot study.

Reviewer 2:

The research question for this project was not entirely clear; however, I believe it is to evaluate disparities among medically underserved patients who participated in a navigation program. Findings indicated that the percentage of Black/African American patients and those 65 years and older was higher in the study target areas compared to the Commonwealth of Pennsylvania and national averages. "Success rates," those who were alive without cancer, were stratified by age, insurance status, income, gender, race, and cancer type. Success rates were lower for younger individuals, uninsured, female, and Blacks. The success rates in this project were lower than national averages. The objectives of the research questions were met. Statistical analyses could have been more sophisticated, and it seems that potential reasons for these disparities could have been explored.

Reviewer 3:

The stated objectives of this project were to evaluate navigated patients in three community hospital sites in terms of age, race, and socioeconomic state, as well as to evaluate disease stage, disease site, and evaluate follow-up disposition.

The design and methods were adequate to meet these objectives. Unfortunately, the investigators were not able to review data for all 542 patients from the underserved community and could retrieve only 395 with complete results. It may have been interesting to note those they could not retrieve and if those patients were different from the 395 with regard to race, age, gender, insurance status or cancer type. Despite this, the investigators did an excellent job of describing the patients of interest and determining the successful treatment rate for all groups considered.

The descriptive statistics and proportions presented were excellent; however, the biostatistician could also have included some tests of statistical significance, for example, to test the difference in success rates by gender, race, etc. These would have been simple 2 x 2 chi-squared tests. It would also have been interesting to include an analysis of all patients, including those who died because of other causes. It is sometimes difficult to attribute cause of death, and an additional analysis may have been informative.

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:

The major benefit of the study is that it provides insight into how outcomes in the identified clinics compare to the national average and provides areas for future improvement. The overall lower survival rates and the significant differences by race and socioeconomic status suggest that future interventions are needed to address these gaps.

However, the investigators did not discuss future plans for the project, and it is unclear whether adequate information on explanatory variables was collected to adequately intervene in the future. It appears that an opportunity to make a difference in the study population was missed by not collecting key patient, provider and clinic/systems predictors of poor outcomes that would help guide future interventions.

Reviewer 2:

The beneficial impact of this project is likely to be small. Understanding health disparities in this region is important; however, just a documentation of these disparities is not moving the field forward. In addition to this, the potential reasons for these disparities need to be explored so that interventions to improve health can be developed. It seems the most beneficial impact was to create awareness of these problems for the staff and some linkages to the community.

Reviewer 3:

The significance of the project was identifying the lower-than-national rates of survival across gender, race, and cancer type. Perhaps this could be translated to suggest that patient navigation could be enhanced to improve survival rates. It would have been interesting to compare the three hospital sites' successes to those of the Commonwealth rather than to rates via the National Cancer Institute, since it is known that the risk factors for low survival are greater in Pennsylvania when compared to national averages. The average period of follow-up of patients should also have been included in the analyses.

There were no major discoveries and no new approaches for prevention, diagnosis, or treatment as a result of this research project. There are no 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?

STRENGTHS AND WEAKNESSES

Reviewer 1:

Leveraging of funds was not a planned priority, and the investigators do not indicate that they intend to apply for future funding to continue or expand the project.

Reviewer 2:

No additional funds were leveraged through this project, and there seems to be no plan for applying for future funding. This project did, however, build on a disparities grant given to the institution from 2003-2010.

Reviewer 3:

The project did not leverage additional funds; no additional grant applications were submitted as a result of this project.

The researchers are not 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?

STRENGTHS AND WEAKNESSES

Reviewer 1:

No peer-reviewed publications are planned or were submitted.

Reviewer 2:

There was no publication that resulted from this project and no plans for publications in the future.

Reviewer 3:

The project did not result in any peer-reviewed publications, licenses, patents, or commercial development opportunities.

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

STRENGTHS AND WEAKNESSES

Reviewer 1:

There is no indication that the project enhanced the quality and capacity for research at the grantee's institution. However, this is not unexpected given the limited scope and funding for the project.

Reviewer 2:

As mentioned, this project built on a large NIH disparities grant that was funded to the institution from 2003-2010. The current project seemed to bring awareness of health disparities to these researchers and clinical staff at the hospital. The project also improved infrastructure for research and linkage to community resources.

Reviewer 3:

The project did not add any new investigators or students to the project. There were no out-of-state researchers who participated in this research. No funds were used to pay for research performed by pre- or post-doctoral students.

Improvements were made to the infrastructure by enhancing the skill set of the current UPMC McKeesport staff. The project also provided the chance to utilize community resources and other facilities in finalizing the findings.

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:

The project maintained ongoing involvement with community partners. No new linkages were formed.

Reviewer 2:

It does seem that linkage to additional community resources was achieved through this project. Furthermore, one of the sites was not in the area of the primary hospital, so this project further facilitated linkage to that clinical site.

Reviewer 3:

The project did not involve collaboration with research partners outside the institution.

Section B. Recommendations

SPECIFIC WEAKNESSES AND RECOMMENDATIONS

Reviewer 1:

1. The investigators should provide validated definitions for good outcome, provide sample size calculation/justification, provide better description of the data analysis plan and perform case-mix adjustment. This will improve the validity of their study findings.
2. The investigators should provide information on the explanatory variables that were collected as part of the study and provide more information on strategies to improve the disparate outcomes they found in the study clinics. Given the amount of time they spent working with these clinics, they should be able to provide some information on how to make improvement in outcomes.
3. The major benefit of the study is that it provides insight into how outcomes in the identified clinics compare to the national average and provides areas for future improvement. However, the investigators did not collect key patient, provider and clinic/systems predictors of poor outcomes that would help guide future interventions. It is important to collect these types of data and the investigators are encouraged to explore reasons for the observed disparities in outcomes.

Reviewer 2:

The statistical analyses for the project should have been more sophisticated. In addition to crude frequencies, regression models adjusting for all/many of the key factors could have been done. Also potential contributors to the disparities such as clinical care, adherence, etc. could have been explored.

Reviewer 3:

1. The descriptive statistics and proportions presented were excellent; however, the biostatistician could have also included some tests of statistical significance, for example, to test the difference in success rates by gender, race, etc. These would have been simple 2 x 2 chi-squared tests. It would also have been interesting to include an analysis of all patients, including those who died because of other causes. It is sometimes difficult to attribute cause of death, and an additional analysis may have been informative.
2. It would have been interesting to compare the three hospital sites' successes to those of the Commonwealth rather than to rates via the National Cancer Institute, since it is known that the risks factors for low survival are greater in Pennsylvania when compared to national averages. The average period of follow-up of patients should also have been included in the analyses.