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TITLE: Development of Meharry Medical College Prostate Cancer Research Program

PRINCIPAL INVESTIGATOR: Flora A. M. Ukoli

CONTRACTING ORGANIZATION: Meharry Medical College
Nashville, TN 37208

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14. ABSTRACT There is substantial urology, oncology, epidemiology, nutrition and other expertise at Meharry and Vanderbilt addressing issues related to prostate cancer (PCa) disparity among African-American (AA) men, and the six program new/junior minority investigators have maintained partnerships with VU mentors, and established viable community network ties. Dr. Ukoli has recruited 105 participants into the lycopene study, sent 192 stored plasma samples for lycopene analysis, and received a DHHS 2-year funding for prostate cancer education intervention among low-income AAs. Dr. Washington recruited 200 participants into the PCa health care seeking behavior study, is now analyzing the data, and preparing a full grant proposal. Dr. Stewart completed her pilot project, received independent funding to continue her PCa cell line studies, two of her students received pre-doctoral awards, and will apply for a CTSA grant for DNA extraction/genotyping to investigate genetic polymorphisms in PCa risk using 300 AA and Nigerians samples storedby Dr. Ukoli. Dr. Ogunkua's work continues to grow; he has now dosed/sacrificed 60 mice recording data at all time-points, and submitted one R21. Dr. Taher is revising his DOD career development grant that scored 2.5, presented two posters, and currently working on a manuscript with the PI.					
15. SUBJECT TERMS Prostate cancer, Dietary risk factors, Lycopene, Genetic predisposition, African-Americans, Cancer research training, Quality of life, Community outreach, Recruiting study participants, Cell line inhibition, Animal studies, Prostate cancer screening.					
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INTRODUCTION:

[Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.]

The reason for African-Americans (AA) being disproportionately affected by prostate cancer (PCa) may include biologic tumor differences, genetic predisposition, differential exposures, limited utilization of preventive health care such as prostate specific antigen (PSA) testing, and inadequate access to health care. The paucity of minority PCa investigators and low accrual of AAs in clinical trials also contribute to the lack of progress in reducing this disparity. This proposal includes research initiatives to study the genetics, pathogenesis and epidemiology of PCa disparity among AA men. The genetic similarity between AAs and Africans, disparity in the degree of racial admixture, differences in dietary style and body fat patterns provide the unique opportunity to study genetic and environmental causes of PCa in black men. The PCRCP now has 9(75%) members of its initial membership at Meharry, all three collaborators at the University of Benin in Nigeria, and each of the pilot project PIs at Meharry continue to retain their mentors/collaborators at VUMC, working on overlapping PCa topics at the genetic, molecular, clinical and epidemiological levels.

The program goals are to:

- 1). Develop an Outreach Core to sustain communication network with AA communities in Nashville, address PCa needs and facilitate recruitment into PCa early detection programs and research studies.
- 2). Develop a PCa research training program for junior faculty, new PCa investigators, and graduate students.
- 3). Conduct pilot projects, accumulate preliminary data, submit independent proposals, and generate new research ideas to sustain the PCRCP at the completion of this DOD award.

The scientific aims of the program are to:

- 1). Conduct research of biomarkers and lifestyle risk factors of PCa development and progression in African-Americans and Africans.
- 2). Study the role of specific genes, gene-gene interactions, gene-environment interactions in PCa initiation and progression in these populations.
- 3). Conduct investigator-initiated clinical trials with emphases on nutritional interventions and molecular therapeutics.
- 4). Use mass spectrometry and proteomic-based approaches to identify predictive factors of PCa aggressiveness, treatment response and metastasis and develop molecular classifications and/or biomarkers of aggressive PCa.

BODY:

*[This section of the report shall describe the research accomplishments associated with each task outlined in the **approved** Statement Of Work. Data presentation shall be comprehensive in providing a complete record of the research findings for the period of the report. Appended publications and/or presentations **may** be substituted for detailed descriptions but **must** be referenced in the body of the report. If applicable, for each task outlined in the Statement of Work, reference appended publications and/or presentations for details of result findings and tables and/or figures. The report shall include negative as well as positive findings. Include problems in accomplishing any of the tasks. Statistical tests of significance shall be applied to all data whenever possible. Figures and graphs referenced in the text may be embedded in the text or appended. Figures and graphs can also be referenced in the text and appended to a publication. Recommended changes or future work to better address the research topic may also be included, although changes to the original Statement of Work **must** be approved by the Grants Officer. This approval must be obtained prior to initiating any change to the original Statement of Work.]*

Statement of Work:

Task 1 Start-Up Phase

The Program Executive Board is in place to oversee the scientific merit of the program. This committee is made up of senior faculty from MMC and VUMC.

MMC Faculty

Derrick Beech, MD.
Flora A. M. Ukoli, MD, MPH.
Margaret Hargreaves, Ph.D.
Billy Ballard, DDS, MD.

VUMC Faculty

Robert Matusik, Ph.D.
Rodney Davis, MD.
Susan Kasper, Ph.D.
Robert Dittus, MD, MPH.

The program Advisory Board continues to ensure the smooth running of the program, and is made up of senior and administrative faculty external to the program.

Lee E Limbird, PhD.	Vice President for Research, MMC. (Committee Chair)
John J. Murray, MD. PhD.	Associate Vice President for Clinical Research, MMC
Andrea Baruchin, PhD.	Assistant Vice Chancellor for Research, VUMC
Gordon Bernard, MD.	Assistant Vice Chancellor for Research, VUMC

The PI consults regularly with members of the Executive and Advisory Boards as needed. Both boards have been extremely supportive and their input has been very useful in moving this program to its present status and achievements.

Task 2. Development of Program Outreach Core (2 – 6 months)

The Outreach Core is operational and continues to expand its network within the community. The PI actively sources for and becomes a member of community groups so as to increase the visibility of the program as well as gain the friendship and trust of the community. It is understandable that the community requests that their demands be met right now, placing less emphasis on long-term goals of rigorous epidemiological studies. That is the main reason for seeking funds to immediately provided prostate cancer screening education within the community. This has been achieved with the grant received from the Department of Health and Human Services, Center for Medicare and Medicaid Services (CMS) Award “A prostate cancer education program for low-income African-Americans”.

Members of the program attend several community events and activities (eg. Martin Luther King celebration at Tennessee State University). In collaboration with the Jefferson Street United Merchants Partnership (JUMP) the PI has started working on developing a Barbershop health program for all African-Americans in which she will focus on prostate cancer education dissemination.

Products:

Membership of numerous community organizations

Men’s Health Network (MHN)

Women Against Prostate Cancer (WAPC)

Prostate Cancer Support Group (USTOO)

Jefferson Street United Merchants Partnership (JUMP)

CMS Award # 110CMS030208/01.

Task 3 Initial Training: Investigators, Trainee-PIs, Post-Doc, GRA (2-8 months)

Training of the program staff was completed within two months of hire as planned. The trained program post-doctoral fellow (Abu K. Taher, M.D., MPH), is still in the program. The trained research assistant (Libnir Telusca, MSPH) moved on to another job and was replaced by part-time Mariam Abayomi-Cole, MSPH. This research assistant was again trained to collect data and to enter the food frequency information into the ACCESS program. She however had to relocate for personal reasons and has not been replaced. The trained graduate student (Fanesia Whitney) was replaced by a new graduate student (Mbeja Lomotey) who has since been trained and has become proficient in data management. The PI will personally mentor him and guide him into working on a related research project for his MSPH thesis.

Products:

Graduate students (3)

Post-doctoral fellow (1)

Deliverables:

Regular learning contact with respective mentors as needed.

Monthly tutorials within each pilot project team.

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Task 4: Continuing Medical Education in Prostate Cancer Research (Month 3 – 36)

CME is ongoing within and outside the program. Each pilot project PI attends the seminars relevant to their topic and area of study.

Seminar Series Attendance:

Vanderbilt University	
Epidemiology Seminar series	(Weekly)
Urological Workshop on Research	(Weekly)
Vanderbilt Ingram Cancer Center Seminar series	(Weekly)
Meharry Medical College	
Grand rounds in surgery/Prostate cancer seminar series	(Monthly)
Grand rounds in internal medicine/Family medicine	(Monthly)
Works-In-Progress Seminar Series	
Department of Cancer Biology	(Weekly)
Tennessee State University	
Center for Health Research TN State University	(Weekly)

Attendance at Workshops and Conferences:

- 2007 DOD IMPACT meeting, Atlanta GA. (September 2007)
- 2007 First AACR. The Science of Health Disparities in Racial/Ethnic Minorities and the Medically Underserved Conference. Atlanta GA. (November 2007)
- 2007 American Public Health Association Annual Meeting and Exposition Sunday, November 4-7, 2007.
Taking health into our own hands: Outcome of a prostate cancer project community-based peer navigator training and education tool for prostate cancer prevention decision-making in Black men.
Case-control study of prostate cancer: Diet and other risk factors.
- 2007 Sixth AORTIC conference. CTI Conference Center, Cape Town, South Africa. 24-28th October 2007.
- 2007 National Leadership Workshop on Mentoring Women in Biomedical Careers. Theme “Mentoring is Everybody’s Business”. NIH. Bethesda MD. November 27-28, 2007.
- 2007 Ninth HBCU and HIS Health Services Research Conference. “Improving Health Outcomes and Health Disparities: Research and Intervention Perspectives. New Orleans, LA. December 6 – 7, 2007.
- 2007 First Meeting of Women Against Prostate Cancer. Organized by the Dean & Betty Gallo Prostate Cancer Center and the Men’s Health Network. Baton Rouge, LA. December 8 – 9, 2007.
- 2007 Cancer Health Disparity Summit 2007. NIH/NCI. Bethesda MD. July 16-18.
- 2007 TN State Cancer Coalition quarterly meeting.
- 2007 TN Cancer Coalition Annual Summit

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- 2007 Ninth HBCU and HIS Health Services Research Conference. "Improving Health Outcomes and Health Disparities: Research and Intervention Perspectives. New Orleans, LA. December 6 – 7, 2007.
- 2007: American Public Health Association Annual Meeting and Exposition. Nov. 4-7, 2007.
- 2007 Grantmanship Training Seminar for Research Scientists, FASEB Career Resource, Bethesda, MD.
- 2007 Society of Toxicologist Annual Meeting and TOXEXPO 2007 Charlotte North Carolina.
- 2007 IMPaCT, Innovative Minds in Prostate Cancer Research today. DOP Sept 2007
- 2007 AMHPS Environmental Health Services and Toxicology Research program Colloquium Sept 2007 Atlanta, Georgia

Products & Deliverables:

Seminar / Pilot project reports and presentations

- 1 LaMonica Stewart:
"PPAR γ signaling in Human Prostate Cancer Cells", Works-in-Progress Seminar Series, Department of Cancer Biology, Meharry Medical College
- 2 Flora Ukoli:
"A prostate cancer screening program for low-income African-American men in Nashville". Ninth HBCU and HIS Health Services Research Conference. "Improving Health Outcomes and Health Disparities: Research and Intervention Perspectives. New Orleans, LA. December 6 – 7, 2007.
- 3 Ben Ogunkua:
"B(a)P and Progression of Prostatic Neoplasia in Transgenic Mouse Models". Department of Biological Sciences Work-in-Progress seminar, MMC
- 4 K.A. Taher & F. Ukoli:
"Screening for Prostate Cancer: Positive Attitude and Response by African-Americans". Grand Rounds. Department of Surgery, MMC. February 2007.
- 5 Flora Ukoli:
"Dietary fatty acids and prostate cancer risk in Nigerians. A case-control study: Sixth AORTIC conference. CTI Conference Center, Cape Town, South Africa. 24-28th October 2007.
- 6 Flora Ukoli:
"Dietary fat and prostate cancer risk among African-Americans and Africans: A case-control study". Department of Defense IMPaCT Meeting. Atlanta GA. September 2007.

Posters:

- 1. P. Moss and L. Stewart:
"PPAR γ ligands regulate the invasion of androgen-independent human prostate cancer cells." AACR Science of Health Disparities in Racial/Ethnic Minorities and the Medically Underserved Conference, Atlanta, GA. November 2007.

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2. L. Stewart, P. Moss and B. Llyes:
“The PPAR γ ligand ciglitazone reduces androgen receptor activity in androgen-dependent, but not androgen-independent human prostate cancer cells. DOD IMPACT meeting. Atlanta GA. September 2007.
3. Khandaker A. Taher, Temple Oguike, Usifo Osime, Derrick Beech, Michael S. Cookson, Flora A.M. Ukoli.:
“A comparative evaluation of the fatty acid profiles of African-Americans and Africans: Implication for prostate cancer risk:. AORTIC 2007 OAREC. October 2007. Capetown, South Africa.
4. Khandaker A. Taher, Rodney Davis, Carlton Z. ADams, Philip Akumabor, Usifo Osime, Flora A. M. Ukoli: “A comparative study of serum linoleic acid in prostate cancer risk between African Americans and Africans”. American Association for Cancer Research. First AACR Conference: The Science of Cancer Health Disparities. Atlanta GA. November 2007.

Task 5. Subject Recruitment and Data Collection. (6 – 36 months)

A: Outreach:

Pilot projects 1 and 3 are involved in outreach activities and recruitment of study participants. Details of their outreach activities are reported under the individual pilot project sub-sections.

B: Research Projects:

Pilot Project 1: (Dr. Ukoli, PI / Dr. Robert Dittus, Mentor) HSRRB Log No. A-13323.0

“Lycopene in Prostate Cancer Risk among African-Americans and Nigerians: A Case-Control Study”

This study has a site in Nashville and a site in Nigeria, and will be a continuation of Dr. Ukoli’s ongoing prostate cancer dietary risk study funded by DOD, Award Number DAMD17-02-1-0068, titled Dietary Fat and Vitamin E in Prostate Cancer Risk among African Americans and Africans: A Case-Control Study. Identifying, contacting, and recruiting prostate cancer cases is a challenge. So far we have demographic and diet history information, and stored blood samples for a good number of controls from both study sites. Effort will be directed mainly to meet the recruitment goal of prostate cancer cases in the next year. Work has started in Dr. Gross’s laboratory for lycopene analysis on 192 stored samples of participants who consented to have their samples used in related studies. Dr. Gross has done a lot of work on lycopene analysis and after careful deliberations it was decided that we needed to measure both the cis- and the trans- forms of lycopene and not just the simple total lycopene. Their laboratory is currently setting up the system to measure the two fractions and total lycopene.

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Nashville Site: HSRRB Log No. A-13323.1a (Proposal No. PC041176)

Data collection is ongoing with a total of 38 new participants recruited in Nashville within this pilot project. Given that some participants in the parent study had agreed to have their samples utilized in future related studies we can boast of an overall participant count to 204 of which 186 completed the food frequency questionnaire. Of the entire participants available to this study 31 are confirmed prostate cancer cases. So we are still sourcing for prostate cancer cases to meet our recruitment goal of 50 cases for this pilot project. We have identified 11 men with elevated PSA who have since been referred to the urologist and are followed up to see their definitive diagnosis. Although we have met our recruitment goal for controls 25% of them are between the age of 40 – 49 years, one decade younger than the cases. We are therefore focusing attention on recruiting controls who are at least 50 years old, to make the cases and controls more age-comparable.

Community network activities needed to be boosted by the PI to maintain the desired study momentum in Nashville. Study flyers/brochures are displayed at appropriate locations and also distributed at public events such as the Martin Luther King's day parade at the Tennessee State University. The program continues to maintain the support of the Interdenominational Ministers Fellowship (IMF) in Nashville and several additional churches (more than 20) and associations (7). Collaboration with urologists will improve now that Meharry now has a professor of urology on faculty with a primary appointment at Vanderbilt.

The PI is an active member of the following community groups/associations:

- a. USTOO International
- b. USTOO Meharry Chapter
- c. Men's Health Network
- d. Interdenominational Ministers Fellowship
- e. Women Against Prostate Cancer (WAPC)
- f. TN Prostate Cancer Coalition
- g. NAACP, Nashville.
- h. United Nashville Partners Against Cancer (UN-PAC)
(Meharry-Vanderbilt-TSU Cancer Outreach partnership)
- i. Jefferson Street United Merchants Partnership (J.U.M.P.), Nashville.
In collaboration with JUMP a Barber's shop health education initiative is currently in its planning stage.

Nigeria Site: HSRRB Log No. A-13323.1b (Proposal No. PC041176)

67 new participants have been recruited at this site with all their completed questionnaires and biological samples received. In addition to participants recruited since 2005 within the parent study who consented to allowing their samples to be used in related future studies, the total study participants is now 153, 39 confirmed prostate cancer cases, 65 controls and 49 men with elevated PSA who have been referred to the urologist for adequate follow-up. We are therefore working harder to meet our recruitment goal of 50 prostate cancer cases and 100 controls with normal PSA and normal prostate on DRE.

The collaboration with our colleagues at the University of Benin remains strong. Only one new urology faculty was appointed in the institution last year, and he is interested in working with

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the PI as well as the two current project urologists who remain supportive and interested in collaborating with the PI on this project.

Products:

1. Collaborators at the Nigerian site continue to be supportive.
2. Collaborators in Nashville:
 - i. William Hughes, M.D. Urologist
 - ii. Rodney Davis, M.D. (Vanderbilt / Meharry faculty) Urologist
 - iii. Ram Dasari, M.D. (Urology Associates) Urologist
3. IRB periodic reviews and approvals from MMC and UBTH.

Deliverables:

1. Stored blood samples from 105 new participants
2. First batch of 192 of previously stored samples shipped out for lycopene analysis
3. Abstracts: 4 submitted and 2 accepted as posters.
4. One manuscript under preparation.
5. Grants Submitted:
 - ii. DHHS/CMS HBCU Research Network Grant Opportunity. A Prostate Cancer Screening Program for Low Income African. Funded, Sept. 2007.
 - iii. NIH CNP Pilot project Submitted in partnership with Margaret Hargreaves, Ph.D. "Integrated Prostate Health Program for Low-Income African-Americans: CBPR Approach", scored 214, but funding cut-off point was 210.
 - iv. DOD Clinical Trial Proposal submitted in 2007, but was not funded.
6. Community-based prostate cancer health education presentations 4
7. Community-based prostate cancer screening activities 2
8. MMC-based prostate cancer screening (available daily by appointment)
9. SPSS database: Data entered for 1011 participants.
 1. Personal information/Urology symptom history
 2. Diet assessment
 3. Food Frequency
 4. Fatty acid profile
 5. Lipid profile
10. ACCESS data collection software program for dietary assessment.
35 entries for all 4 questionnaires.

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Pilot Project 2: (Dr. Cui, PI / Dr. Robert Dittus, Mentor)

“Genetic Indices of Steroid Hormone Synthesis and Metabolism in Prostate Cancer: A Pilot Study.”

Dr. Cui is being supported extensively to conduct breast cancer and other research at this time. This pilot project is therefore going to be completed by the PI and Dr. LaMonica Stewart. Dana Marshall, Ph.D., director of research in the department of surgery at Meharry is supportive of this and we started DNA extraction in her laboratory at Meharry. The manual technique for DNA extraction is however cumbersome. Therefore we shall submit a proposal to the Meharry Clinical and Translational Science Award (CTSA) program to secure funding for completing DNA extraction and genotyping at the VUMC GCRC. The data we analyze from this work will then serve as preliminary data for NIH RO1 submission.

Pilot project progress:

Dr. Flora Ukoli's laboratory:	Stored samples:	680.
Dr. Dana Marshall's laboratory:	DNA extraction completed:	64.

Products:

1. Stored blood samples from 575 participants in the parent study (DAMD17-02-1-0068: “Dietary Fat and Vitamin E in Prostate Cancer Risk among African Americans and Africans: A Case-Control Study.) Ukoli's IDEA Award.
2. Stored blood samples from 105 participants from Dr. Ukoli's pilot project 1.

Pilot project 3: (Dr. Washington PI / Dr. Robert Dittus)

HSRRB Log No. A-13323.3

“Prostate Cancer Health Care Seeking Behavior of African American Men.”

The PI is also the Director of the Meharry MSPH Program. Community outreach and networking has been very successful, and study participants were recruited from a total of 13 community sites and churches. This pilot project met its goal to recruit 200 African-American men. Data collection has been completed and data analysis is in progress. Tables from interim data analysis is displayed in Appendix B. One of the questionnaire items highlighted the fact that just over 50% of the participants were at least satisfied about various aspects of their access to health care. This means that almost 50% are dissatisfied or neutral.

Products:

1. IRB periodic review and approvals.

Deliverables:

1. Data base of 200 study participants
2. Initial data analysis result. (Appendix B)
3. One grant submitted and awaiting review summary.

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Pilot project 4: (Dr. Stewart, PI / Dr. Matusik, Mentor)

“Inhibition of Prostate Cancer Growth by Thiazolidinediones”

All the experiments proposed within this pilot project have been completed, and the research goals have been accomplished.

- 1) Commercial siRNA reagents were used to demonstrate that thiazolidinediones (TZDs) use both PPAR gamma dependent and PPAR gamma independent signaling pathways to inhibit proliferation of the PC-3 human prostate cancer cell line.
- 2) Western blot analysis revealed that TZDs regulate several proteins that regulate cell cycle progression and apoptosis. TZDs reduce expression of cyclin D1, cyclin D3 and the proto-oncogene c-Myc and induce expression of the cyclin dependent kinase inhibitor p21.
- 3) Cell Death ELISAs indicated that the TZD ciglitazone does not induce apoptosis in human prostate cancer cells. However apoptosis is increased in prostate cancer cells treated with the TZD troglitazone.
- 4) Boyden chamber assays revealed several TZDs inhibit the invasion of the PC-3 prostate cancer cells. Microarray analysis suggests that this decrease in tumor cell invasion may be linked to increased expression of tissue inhibitors of matrix metalloproteinases.

Products:

1. Conferences attended: DOD IMPACT meeting (September 2007) and AACR Science of Health Disparities in Racial/Ethnic Minorities and the Medically Underserved Conference (November 2007)
2. Seminar presented: “PPAR γ signaling in Human Prostate Cancer Cells”, Works-In-Progress Seminar Series, Department of Cancer Biology, Meharry Medical College
3. Grants submitted: "PPAR gamma signaling in androgen-independent prostate cancer". Department of Defense Prostate Cancer Research Program IDEA Award, submitted May 2007.
4. Manuscript under development. The PPAR γ ligand ciglitazone reduces androgen receptor activity in androgen-dependent, but not androgen-independent human prostate cancer cells.

Deliverables:

Posters and Abstracts sent and accepted:

- 1) P. Moss and L. Stewart. PPAR γ ligands regulate the invasion of androgen-independent human prostate cancer cells. AACR Science of Health Disparities in Racial/Ethnic Minorities and the Medically Underserved Conference, Nov. 2007.
- 2) L. Stewart, P. Moss and B. Llyes. The PPAR γ ligand ciglitazone reduces androgen receptor activity in androgen-dependent, but not androgen-independent human prostate cancer cells. DOD IMPACT meeting, September 2007.
- 3) L. Stewart. DOD New Investigator Award funded.

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Pilot project 5: (Dr. Ogunkua, PI / Dr. Matusik, Mentor)

“Benzopyrene B(a)P Induced Activation of Prostatic Specific Genes”

A colony of mice has now been established and laboratory experiments are now ongoing, and the PI collected tail clip and DNA isolation to identify transgenic mice. He has established tissue collection procedures for gene expression and pathology assessment of the prostate, and assessed proliferation and apoptosis in the prostate. RNA isolation and qRT-PCR has been completed, immunohistochemistry for markers such as AR, PB, Foxa1, Foxa2, p63, Nkx3.1 established, and Western Blot Analysis has also been established.

Products:

1. MMC Institutional Animal Care and Use Committee (IACUC) approval received.
2. Additional 20 mice sacrificed, bringing total to 60 for experiment. Dosing of CD1 mice tissue collection and analysis in progress.
3. Data tabulated for all tissues and at all study time-points
4. Established Transgenic mice colony at Meharry Medical College.
5. R21 “B(a)P and Progression of Prostatic Neoplasia in Transgenic Mouse Models” submitted to NIEHS

Deliverables:

1. ARCH Pilot Project funded: “Benzo(a)Pyrene [B(a)P] and Prostate Cancer Progression in Transgenic LPB-Tag Mice.”
2. Abstract submitted for the 46th annual meeting of the society of toxicology March 25-29, 2007 Charlotte NC.
3. Work-Progress Seminar, Department of Cancer Biology, MMC. 2007.
4. Guest speaker presentation: “Environmental Toxicants and Prostate Cancer” Department of Environmental Family and Community Medicine, MMC. 2007.

Conferences and Workshop attended

1. Grantmanship Training Seminar for Research Scientists, FASEB Career Resource, Bethesda, MD
2. Society of Toxicologist Annual Meeting and TOXEXPO 2007 Charlotte, NC.
3. IMPaCT, Innovative Minds in Prostate Cancer Research today. DOD Sept 2007
4. AMHPS Environmental Health Services and Toxicology Research program Colloquium Sept 2007 Atlanta, Georgia

Abstracts Submitted/Accepted:

O. Ogunkua; R. Matusik; T.A. Ansah; A. Deutch; A. Ramesh; J. Morrow; M. Aschner and D. B. Hood. “Differential system Models [prostate, colorectal and CNS] of polycyclic Aromatic Hydrocarbon Toxicity”.

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Manuscript in preparation:

Benzo(a)Pyrene and 2, 3, 7, 8-tetrachlorodibenzo-p-dioxin Effects on *AhR-AR* Cross Talk in Neotag Cells.

Pilot Project 6: (Post-Doctoral Fellow Dr. Taher / Dr. Cookson & Dr. Ukoli, Mentor)

“Racial comparison of health related quality-of-life outcomes in early prostate cancer”.

Dr. Taher has gained clinical epidemiology experience working with the program PI on the prostate cancer dietary risk factor study. He is therefore competent, skilled, and confident in recruiting, consenting, interviewing, collecting and storing biological samples. He has also completed data analysis, developed and submitted abstracts and posters that have been presented at national conferences. He is currently working on a manuscript with Dr. Ukoli titled “Fatty-Acid profile differences between African-Americans and Africans”.

Dr. Taher opted to conduct a population (clinical) study that will involve men who have been treated for prostate cancer especially as the mentor, Dr. Ukoli, worked and published in this area of quality-of-life among African-American who had radical prostatectomy. Michael Cookson, MD., urology professor at Vanderbilt University, remains his primary mentor in addition to Dr. Ukoli (Community Medicine/Epidemiology), and Rodney Davis, M.D., urology professor at Vanderbilt University. He is working on revising his grant to be submitted this year.

Deliverables:

1. DOD Career development award grant to be resubmitted in June 2008.
“Racial comparison of health related quality-of-life outcomes in early prostate cancer”. Submitted in 2007 with a score of 2.5, but not funded.

Abstracts/Posters:

2. Khandaker A. Taher, Temple Oguike, Usifo Osime, Derrick Beech, Michael S. Cookson, Flora A.M. Ukoli. A comparative evaluation of the fatty acid profiles of African-Americans and Africans: Implication for prostate cancer risk. AORTIC 2007 OAREC. October 2007. Capetown, South Africa.
3. Khandaker A. Taher, Rodney Davis, Carlton Z. Aams, Philip Akumabor, Usifo Osime, Flora A. M. Ukoli. A comparative study of serum linoleic acid in prostate cancer risk between African Americans and Africans. American Association for Cancer Research. First AACR Conference: The Science of Cancer Health Disparities. November 2007. Atlanta GA. Recipient of AACR-Astra Zeneca Scholar-in-Training Award.

Task 6. On-going and Final Data Analysis (6 - 36 months)

Ongoing and final data analysis has been described within each pilot project sub-section.

Task 7. Report Writing and Presentations (12 - 36 months)

A summary of details within each pilot project sub-section:

- | | |
|------------------|---|
| Pilot project 1: | Awaiting laboratory analysis of lycopene to include in the data base. Personal information data has been analyzed. Abstracts and posters from the parent study have been completed and presented at national and international conferences. |
| Pilot project 2: | Not yet addressed. A CTSA proposal will be submitted to seek pilot funding to complete DNA extraction and genotyping to be conducted at the GCRC Vanderbilt |
| Pilot project 3: | Completed. Results presented at seminar and PI has now received independent funding to continue new experiments. She is therefore willing to take up pilot project number 2. |
| Pilot project 4: | Completed, and currently writing report and manuscript. |
| Pilot project 5: | Completed, and currently analyzing data to be used as pilot data in submitting an R21 for independent funding. |
| Pilot project 6: | Not yet initiated. Career development grant will be revised and resubmitted by June 2008. |

Deliverables: Publications to date:

1. Flora A. Ukoli, Eruke Egbagbe, Barbara B. Zhao, Efosa Iyamu, Dale Young, Philip Osime, Usifo Osime, Lucile L. Adams-Campbell. Anthropometric Body Fat Predictors of Elevated Prostate Specific Antigen among Rural and Urban Nigerians: A Population-Based Study. West Afr J Med. 2007 Jan-Mar;26(1):7-13.

2. F.A. Ukoli, E Egbagbe, F. Akereyeni, E. Iyamu, T. Oguike, P. Akumabor, and U. Osime. Response to Prostate Biopsy by Nigerian men: Community and Hospital Experience. Proceedings of the UICC World Cancer Congress, Washington D.C.(USA), July 8-12. 2006. Medimond. International Proceedings. 2006; Pgs 341- 347.

3. Fowke JH, Signorello LB, Underwood W 3rd, Ukoli FA, Blot WJ. Obesity and prostate cancer screening among African-American and Caucasian men. Prostate. 2006;66(13):1371-80.

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4. Fowke, J.H., Signorello, L., Chang, S, Matthews, C.E, Buchowski, M., Cookson, M., Ukoli, F., Blot, W. Effects of Obesity and Height on PSA and Percent Free PSA Levels Among African-American and Caucasian Men. *Cancer*. 2006; 107(10):2361-7.
5. Ukoli, F.A., Barlow Lynch, Lucile Adams-Campbell. The effect of radical prostatectomy on patient quality of life in African Americans. *Ethn Dis*. 2006;16:988-993.
6. Odedina FT, Ogunbiyi JO, Ukoli FA. Roots of prostate cancer in African American men. *J Natl Med Assoc*. 2006 Apr;98(4):539-43.
7. Fowke, J.H., Schlundt, D., Signorello, L.B., Ukoli, F.A.M., Blot, W.J. Prostate Cancer screening among low-income African-American and Caucasian men. *Urologic Oncology: Seminars and Original Investigation*. 2005;23:333-340.

Abstracts and Posters:

1. P. Moss and L. Stewart:
“PPAR γ ligands regulate the invasion of androgen-independent human prostate cancer cells.” AACR Science of Health Disparities in Racial/Ethnic Minorities and the Medically Underserved Conference, Atlanta, GA. November 2007.
2. L. Stewart, P. Moss and B. Llyes:
“The PPAR γ ligand ciglitazone reduces androgen receptor activity in androgen-dependent, but not androgen-independent human prostate cancer cells. DOD IMPACT meeting. Atlanta GA. September 2007.
3. Khandaker A. Taher, Temple Oguike, Usifo Osime, Derrick Beech, Michael S. Cookson, Flora A.M. Ukoli.:
“A comparative evaluation of the fatty acid profiles of African-Americans and Africans: Implication for prostate cancer risk:. AORTIC 2007 OAREC. October 2007. Capetown, South Africa.
4. Khandaker A. Taher, Rodney Davis, Carlton Z. ADams, Philip Akumabor, Usifo Osime, Flora A. M. Ukoli: “A comparative study of serum linoleic acid in prostate cancer risk between African Americans and Africans”. American Association for Cancer Research. First AACR Conference: The Science of Cancer Health Disparities. Atlanta GA. November 2007.
5. O. Ogunkua; R. Matusik; T.A. Ansah; A. Deutch; A. Ramesh; J. Morrow; M. Aschner and D. B. Hood. “Differential system Models [prostate, colorectal and CNS] of polycyclic Aromatic Hydrocarbon Toxicity”.
- 6.

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Task 8. Developing Grant Proposals for Independent Funding (24-36 months)

LaMonica Stewart, Ph.D.

DOD IDEA Award funded.

Flora Ukoli, MD., MPH.

DHHS CMS Grant funded.

NCI/CBPR Pilot Project award not funded.

DOD Clinical Trial Award not funded.

Submitting an HBCU Undergraduate Summer Training program grant, and preparing an RO1.

Ben Ogunkua, MD, Ph.D.

Submitting an R21 grant to NIEHS.

Khandaker Taher, MBBS, MPH.

Submitting a revised DOD Career Development Award not funded.

KEY RESEARCH ACCOMPLISHMENTS:

[Bulleted list of key research accomplishments emanating from this research.]

1. The prostate cancer research program (PCRP) has been established at Meharry Medical College, and prostate cancer research is being conducted actively both in the clinical, community, and basic science areas. The program investigators and mentors have established strong sustainable relationships.
2. Four strong research teams are in place in collaboration with investigators from Vanderbilt University, and a 5th team will now be formed to be headed by Dr. Rodney Davis of Vanderbilt University who holds a secondary faculty position at Meharry. This group will become very strong especially after the new Meharry urologist takes up her position at Meharry this year.
3. The international collaboration with the University of Benin, Nigeria, continues to be maintained in light of the very small budget allocation. A subsequent grant will budget adequately for urologists such that the study site will perform even better.
4. The program has full access to three research laboratories developed by Dr. Stewart, Dr. Ogunkua, and Dr. Marshall. Dr. Cui's laboratory will be accessible to this program once set up.
5. This program continues to maintain a very strong and visible community network with the full backing of Derrick Beech, M.D., professor and chair of surgery. Community trust has been gained especially now that we have initiated a Community-Based Participatory Research (CBPR) program to address prostate cancer education and prevention. Once we can offer free screenings to men who need our service that trust will be maintained, and the men will be in a position to consider participation in research projects that are of no immediate benefit.
6. Graduate student exposure:
 - a. Following the example of two doctoral students from Dr. Stewart's laboratory submitted pre-doctoral grants for funding, new students will now be able to choose the prostate cancer subject area for their thesis.
 - b. MSPH students in the first year, and any 2nd year student who selects to go into this area will be adequately exposed to prostate cancer research, community networking, participant recruitment, and data collection and management.
7. Pilot Projects:
 - Pilot project 1: 67 additional participants recruited, 192 blood samples sent for lycopene analysis.
 - Pilot project 2: 300 samples available for DNA extraction, of which 64 DNA extractions have been completed.
 - Pilot project 3: Completed. 200 participants recruited as planned.

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Pilot project 4: Experiment completed and program goal achieved since the PI has now secured independent funding.

Pilot project 5: Experiments in progress, as a total of 60 mice have been sacrificed, and their tissues harvested.

Pilot project 6: DOD career development award scored 2.5 and is in the process of revision for resubmission.

REPORTABLE OUTCOMES:

[Provide a list of reportable outcomes that have resulted from this research to include:]

1. Partnership established with several organizations and community groups in Nashville:
 - Interdenominational Ministers Forum (IMF)
 - 20 church communities
 - 3 local prostate cancer non-profit organizations
 - Two local African-American fraternities
 - Several community groups and organizations including
 - 100 Black Men of America.
 - NAACP
 - World Baptist Center
 - Academy for Educational Development (AED)
2. Partnership with the clinical research centers at Meharry and Vanderbilt:
 - i) CRC at Meharry is actively involved
 - ii) GCRC at VU ready to support program with DNA extraction and genotyping.
3. Maintained partnership with the Nigerian research collaborators: Usifo Osime, (Director), Philip Akumabor and Temple Oguike (urologists), Patrick Okoro, and Obarisiagbon (junior investigators in general surgery and urologist) have indicated interest to start training.
4. Maintained very strong collaborative partnerships with mentors and other collaborators at Vanderbilt.
5. Five pilot project PIs are still actively involved in prostate cancer research.

CHALLENGES:

PCRP Membership:

This is indeed a very ambitious and optimistic program and our inability to secure funding to include adequate salary support of at least 10% for every trainee PI impacted the program performance. That trainee PIs were able to achieve this level of performance at such limited salary support shows the type of commitment and interest they have for this topic. Dr. Cui had to concentrate more on projects that provided adequate funding support for his work and was unable to find time for his pilot project. Dr. Ogunkua and Dr. Washington needed more time to accomplish their project objectives and although they completed data collection, they are still working on their data analysis. Dr. Ukoli did not have funds to develop her own laboratory, planning to pay fee-for-service for the measurement of lycopene. This means that work can be delayed by a third party who does not have as much vested interest in this program.

Participant Incentive:

Potential participants do not seem to have the time for the study because their job comes first. \$40 incentive encourages, but is not sufficient to bring in participants at 8:00am on a work-day, especially for people who are on-the-clock, as many of our participants are.

Outreach Core:

Locating community leaders is by word-of-mouth, one identified community leader helping to inform those that he knows. Then contacting and convincing these leaders to arrange for a forum to meet with members of their community is a very slow process, but in the long run is very efficient and useful because each person that agrees to support the program really does so. Church leaders are a reasonable starting point, but there is need to expand into the rest of the community proper as only a proportion of African-American men attend church, and fewer still attend church health fairs.

Urologist at Meharry, Vanderbilt, and Urology Associates:

Meharry now has an urologist with primary appointment at Vanderbilt, which is indeed a very useful addition to our team. Starting a practice will certainly be very tedious and time consuming. The PI therefore has to wait patiently for Dr. Davis to settle down in Nashville and build a urology practice here in Nashville. It may not be wise at this time for a new urologist in town to introduce research topics and requests patients to consider participation as this might scare some people off, and they may choose to find another urologist who does not mention 'research'.

Development of Laboratories:

Dr. Ogunkua and Dr. Cui continue to work on developing their own laboratories and this is not easy. So far they have succeeded but they require funding to support at least one laboratory

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technician such that experiments can run more smoothly, freeing their time to carry out other responsibilities of a PI.

Dr. Ukoli certainly needs to develop her own laboratory for the measurement of nutrient biomarkers. Depending on the fee-for-service mechanism can be frustrating especially when the other laboratory has too much work and does not see other people's request as their priority. The other alternative is to secure interested and active collaborators here at Meharry Medical College who are willing to join this team and run immunoassays in their laboratory. Unfortunately there is not enough funds in this budget to support a laboratory technician for this purpose.

Program Coordinator/Research Assistant:

This program needs a full-time experienced program coordinator to take over all program administrative responsibilities, and free the PI to meet her responsibilities of achieving the program scientific study goals. Currently the PI is overloaded with these additional administrative responsibilities, making the effort allocated for the PI is inadequate. The salary that could be allocated for a research assistant in a small grant such as this can only attract new graduates who are looking for experience, are in transition, and can readily move on once they find a better paying job. Inability to retain a committed and dedicated research assistant leads to difficulty in continuity, duplication of effort in training a new person, and periods of a vacant position while going through the process of a new hire. An institutional grant such as this will need to maintain these two positions at the full-time level. In addition this type of grant will require funds to support a part-time graduate research assistant on each of the pilot projects.

Study Participant Recruitment:

Nashville Site:

1. Recruiting cases: It may be necessary to budget some administrative fee for physician office staff to process patients in their practice, identify potential participants, and process them for possible recruitment. Cancer register cases are two years in arrears, and so new cases continue to be difficult to recruit without the full support of the office administrators in local urologists, physicians, and oncologists.
2. Recruiting controls: Increase the incentive to \$80 will probably encourage minority men who earn wages to miss a day's job for this activity.

Nigerian Site:

Prostate biopsy in Nigeria: This site continues to requests an ultrasound equipment to facilitate adequate prostate biopsy by ultrasound guided technique rather than the 'blind' technique where the biopsy needle is 'digitally-guided' by the index finger. There is also a strong need to find money to increase the budget at this site to maintain full-time coordinator, research assistant and laboratory assistant. Also adequate salary effort support need to be budgeted to sustain the interest of faculty participating as collaborators.

CONCLUSIONS:

[Summarize the results to include the Importance and/or implications of the completed research and when necessary, recommend changes on future work to better address the problem. A "so what section" which evaluates the knowledge as a scientific or medical product shall also be included in the conclusion of the report.]

The collaboration between Meharry and Vanderbilt investigators continues to grow strong, and respective mentors continue to provide guidance as expected. The Executive and Advisory Boards are very important in providing the needed guidance, advice and solutions to program challenges outside budgetary requirements. Two PIs on this program did receive two other awards, while a third PI submitted a proposal, and the post-doc has also submitted a career development award. The goals of this program have been met, and the scientific objectives of the individual pilot projects are all feasible, two having been completed.

The underlying causes for lack of operational support from urologists need to be studied so as to find lasting solution for recruiting prostate cancer patients diagnosed within a few months and recruited before treatment. This program has received a one-year non-cost extension but will also need supplemental funds to meet its optimistic objectives but over-ambitious goals. There is need to maintain the interest of potential participants, community leaders, and health providers by continuous networking and education to eliminate the real challenges of recruiting study participants.

This program has successfully produced minority prostate cancer investigators who are submitting competitive research grant proposals, received additional funding, attracted one post-doc, and four graduate students to the field. Adequate salary support for all members of this program is a necessity bearing in mind that there might not be other grants to part-support them at this time in their young research careers. The enthusiasm of program members and mentors, and particularly of the first time program PI, must not be allowed to taper off in the absence renewal of the program or the provision of supplemental funds to meet the existing budget gaps. This request has been submitted to the program grants manager.

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REFERENCES: *[List all references pertinent to the report using a standard journal format (i.e. format used in Science, Military Medicine, etc.).]*

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List of Appendix:

Appendix A: Supplemental Fund Rationale and Needs: Summary of the Meeting with the Advisory Board and Executive Committee

Appendix B: Descriptive Analysis: Pilot Project 3.

Appendix C: Status Report on Laboratory Analysis of Lycopene: Pilot Project 1.

APPENDIX A: Supplemental Fund Rationale and Needs: Summary of the Meeting with the Advisory Board and Executive Committee

The main points from the 2nd PCRP Advisory Board/Executive Committee Meeting: Presentations by each pilot project PI was followed by very fruitful and exhaustive deliberations, with lots of useful comments, observations and advice from members. The main observation was that PIs have made appreciable progress since the DOD site visit, and that the program did not have enough funds to meet all its goals.

It was suggested that the DOD be approached for possible supplemental funds.

1

- a) The program did not have salary support for the basic science members of the group. Each PI will need at least 10% salary support to protect their time for this program. \$40,000
- b) One full-time laboratory technician to support Dr. Ogunkua and Dr. Cui. \$45,000
- c) Funds required for pilot project 3 DNA extraction and Genotyping= \$20,000*

3 Epidemiology Projects: (3 pilot projects)

- a) Dr. Ukoli's project:
 - i. 200 additional lycopene analysis @ \$40 = \$ 8,000*
 - ii. 50% increase for 100 case participant incentive @ \$80 = \$ 8,000*
 - iii. Physician/urology office staff time-effort for processing records for potential participant eligibility. 300 @ \$10 = \$ 3,000*
- b) Dr. Washington's project:
 - iv. Increase salary support to 10% = \$10,000
 - v. 200 participant @ \$30 cash incentive = \$ 6,000*
- c) Special strategy to improve participation of prostate cancer survivors
 - vi. Full-time recruiter, Prostate cancer survivor = \$35,000
 - vii. UsTOO Meharry (support group start off funds) = \$ 3,000*

* Supplement by 2007/2008 of \$48,000

APPENDIX B

Pilot Project 3:

Results of Selected Demographic characteristics of 200 African-American men recruited.

Highest grade of school completed

- | | |
|-----------------------------------|-------|
| • 8 th Grade or less | 3.5 % |
| • High School Graduate of GED | 11.7% |
| • Some College/Technical Training | 31.3% |
| • College Graduate | 26.1% |
| • Post Graduate | 12.6% |

Job Status

- | | |
|-----------------|-------|
| • Full-time | 40.0% |
| • Part-time | 8.8% |
| • Retired | 13.5% |
| • Unemployed | 24.7% |
| • Disability | 4.2% |
| • Self-employed | 8.8% |

Marital Status

- | | |
|---------------------------|-------|
| • Married/Living Together | 41.3% |
| • Single | 28.4% |
| • Widowed | 4.0% |
| • Separated | 4.0% |
| • Divorced | 14.7% |
| • Other | 7.6% |

Total Family Income (before taxes) in the last year

- | | |
|-----------------------|-------|
| • Less than 10 -49.9K | 52.1% |
| • 50-74.9K | 16.3% |
| • 75 – 99.9K | 10.0% |
| • 100K + | 5.4% |
| • Don't know | 21.7% |

The largest number of subjects received health care from their private doctor (42.9%) followed by clinics in hospital (22.3%) and community health centers (21.0%), and other health sources.

Selected Prostate Cancer Health Care Behavior

- | | |
|--|-------|
| • The majority of men have had a physical examination | 79.5% |
| • Have had a test for prostate cancer | 46.0% |
| • Have asked their physician to examine their prostate | 39.6% |

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- Forgot to ask their doctor to examine their prostate 20.0%
- Was afraid to ask their doctor to examine them 16.7%
- When in doctors office patient put off exam until next time 42.9%
- Will ask for prostate exam at next visit 78.3%

Selected Family and Friend Support in Seeking Prostate Cancer Access to Health Care

- In seeking health care, subject indicated that their family and friends help them:
 - Very often (26.9%)
 - Fairly often (29.3%)
 - Not too often (21.6%)
 - Never (22.1 %)
- When asked how much help their family and friends to are them, the subjects indicated:
 - A great deal (27.2%)
 - A lot of help (28.6%)
 - Little help (23.8%)
 - No help (20.4%)
- When asked if their family and friends will help them if the subjects really needed help:
 - Yes (80.3%)
- When asked if they had friends they felt free to talk with about their problems:
 - Many (16.9%)
 - Some (22.1%)
 - Few (45.5%)
 - None (15.5%)

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APPENDIX C:

Pilot Project 1: Status Report of Lycopene Measurement: From the Research Laboratory of Myron Gross, Ph.D. at the University of Minnesota.

From: diebes@gmail.com [mailto:diebes@gmail.com] **On Behalf Of** Anthony Diebes

Sent: Monday, March 24, 2008 10:29 AM

To: Ukoli, Flora

Subject: description

Hi Flora,

Here is a brief description of the assay. Let me know if you need more information.

Anthony

The Molecular Epidemiology and Biomarkers Research Laboratory at the University of Minnesota is currently validating a HPLC method that will allow the simultaneous determination of several carotenoids. Included in this panel of carotenoids are trans-lycopene and three cis isomers of lycopene. The cis isomers of lycopene included in the panel are 15-cis, 13-cis, and 9-cis. This analytical method will also give the total concentration of lycopene.

Anthony Diebes

Scientist

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