

A. COVER PAGE

Project Title: Informed/Shared Decision Making for Prostate Cancer Screening Among Members of the World Trade Center Health Program	
Grant Number: 6 U01OH011690-03-02	Project/Grant Period: Final
Reporting Period: 2021	Date Submitted: 04-26-2022
Program Director/ Principal Investigator Michael A. Diefenbach, PhD	Administrative Official Information Ms. Diane M Marbury, CRA Senior Director, Grants Management Office dmarbury@northwell.edu 516-849-2321
Change of Contact PD/PI: N/A	
Human Subjects: N/A	Vertebrate Animals: N/A
hESC: N/A	Inventions/Patents: N/A

B. ACCOMPLISHMENTS

B.1. What are the major goals of the project?

Aim 1: a) To adapt a stepped decision making approach for PCa screening among WTCHP members, a psychosocially, vulnerable population with multiple comorbidities; and b) to train physicians in shared decision making. To achieve Aim 1a, we will conduct focus groups with WTCHP members and with physicians working with this population to obtain their feedback on PCa disease, screening knowledge and barriers to screening, as well as barriers to implementing a SDM approach in the clinic. Results from the patient focus group will be incorporated in the existing brochure on PCa screening by the American Cancer Society. To achieve Aim 1b, physicians will be trained in the adapted SDM protocol that will place a specific focus on the elicitation of patient preferences. *As of 1/24/2019 Aim 1 has been completed. All 4 focus groups were conducted and completed as of 11/6/2018. Results from the first 2 focus groups resulted in the decision to not use the ACS prostate cancer screening brochure and to create our own brochure that is tailored to the needs of the WTCHP members. Two more focus groups were conducted to obtain feedback on the newly developed brochure.*

For Aim 1b, we developed a summary sheet outlining the steps of shared decision making including communication best practices with regard to risk communication. *The on-site clinician SDM training took place on 1/24/2019. Providers were very receptive to the information we provided.*

Aim 2: To implement the stepped decision making approach in the clinic and to identify: a) the proportion of WTCHP members who agree to be screened; b) the psychosocial and demographic factors affect participants' screening decision; and c) the psychosocial and clinical outcomes of accepting/rejecting PCa screening. For Aim 2a, we will record the proportion of WTCHP members' uptake of screening after reviewing the screening brochure, and record the proportion of members who request further information from physicians and thus will utilize the SDM approach. For Aim 2b, WTCHP members' medical/psychiatric history and baseline data will be analyzed to predict screening acceptance/ rejection. We hypothesize that psychiatric morbidity is associated with lower screening utilization. WTCHP members will be followed longitudinally at 3-4 days and at 3 months post-monitoring visit to assess psychosocial/clinical outcomes, assessed via telephone (Aim 2c). We hypothesize that in the short-term screening is associated with an elevated stress response that will dissipate over time. Significant time has been spent with the staff at the Queens WTCHP to determine the most effective way to begin recruiting and enrolling patients into the 2nd phase of the study

Aim 3: To record the cost of implementing prostate cancer screening among members of the WTCHP

Cost associated with developing and implementing the PCa screening program, including patient support materials, physician training in SDM, cost of PSA testing, and physician time of shared decision counseling have been recorded and will be shared through our analysis paper.

B.2. What did you accomplish under these goals?

During this reporting period we have completed aims 2 and 3. We have successfully enrolled 666 through phase 2 of this study and have closed our follow up window. For aim 2, we enrolled 666 patients

B.3. Competitive Revisions/Administrative Supplements

N/A

B.4. What opportunities for training and professional development did the project provide?

In April 2021, Dr. Marziliano presented an oral presentation to the Society of Behavioral Medicine for the annual 2021 meeting regarding the changes that the study protocol had underwent in the previous year to continue enrollment and retention throughout the COVID-19 pandemic. This has been a great opportunity for Dr. Marziliano and the rest of our research team to share recruitment adaptation strategies to the broader scientific community.

Additionally, Thomas Mistretta, our study coordinator was able to present a poster and abstract of our phase 2 results to the Society of Medical Decision Making at their virtual conference in 2021. This was his first opportunity to present at a national conference and develop as a professional researcher.

B.5. How did you disseminate the results to communities of interest?

We have submitted abstracts to the Society of Behavioral Medicine's Annual meeting in 2021 and the Society for Medical Decision Making in 2021. We have shared our results and adaptation methods for aim 2.

B.6 - What do you plan to do during the next reporting period to accomplish the goals?

This is the last reporting period for this grant. We are currently drafting manuscripts for our results to publish.

C. PRODUCTS

C.1. Publications, conference papers, and presentations

Marziliano, A., Yacoub, A., Mistretta, T., Diefenbach, M. (2021 October 18-20). *Informed/Shared Decision Making for Prostate Cancer Screening Among Members of the World Trade Center Health Program* [Poster Presentation]. SMDM 2021 Virtual

Marziliano, A., Sookchan, A., Mistretta, T., Pfister, H., Benedict, C., Tagai, E., Miller, S., Diefenbach, M. (2021 April 12-16). *The Challenges of Conducting Clinical Research in the Times of COVID-19* [Conference Presentation]. SBM2021 Virtual

C.2. Website(s) or other Internet site(s) – include URL(s)

N/A

C.3. Technologies or techniques

N/A

C.4. Inventions, patent applications, and/or licenses

N/A

C.5. Other products and resource sharing

N/A

D. PARTICIPANTS

D.1. What individuals have worked on the project? Please include calendar, academic, and summer months.

Commons ID	S/K	Name	Degrees(s)	Role	Cal	Aca	Sum	Foreign	Country	SS
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MADIEFENBACH		Diefenbach, Michael A	PhD	PI	2			NO	N/A
JMOLINE		Moline, Jacqueline	MD, MSc	PI	2			NO	N/A
MARZILIANO		Marziliano, Allison	PhD	Co-I	10			NO	N/A
MBELLEHSEN		Bellehsen, Mayer H	PhD	Co-I	0			NO	N/A
JKORNTRICH		Kornrich, Jason M	PhD	Co-I	0			NO	N/A
SHALL		Hall, Simon	MD	Physician	1			NO	N/A
N/A		Mistretta, Thomas	MPH	Coord, Research	9			NO	N/A
N/A		Yacoub [Sookchan], Andrea M	MPH	Sr Coord, Research	4			NO	N/A
jwang11		Wang, Jason J	PhD	Assoc Investigator	1			NO	N/A

D.2 Personnel updates

- a. Level of Effort: N/A
- b. New Senior/Key Personnel: N/A
- c. Changes in Other Support:
- d. New Other Significant Contributors: N/A

E. IMPACT

E.1 - What is the impact on the development of human resources, if applicable?

N/A

E.2 - What is the impact the Public Health Relevance and Impact? The investigator should address how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, legislation, policy, or use of technology in public health.

The ultimate public health impact of this research would be the adoption of prostate cancer (PCa) screening in conjunction with an informed/shared decision making paradigm that would ultimately shape future protocols and procedures for all members of the WTCHP looking to discuss PCa screening.

Furthermore, our study shows that Informed Decision-Making is sufficient in this population, saves resources, is effective and does not cause additional burden to staff or members. This can be translated to implement this approach for other complex health decisions facing patients.

F. CHANGES

F.1 – Changes in approach and reasons for change, including changes that have a significant impact on expenditures

In 2020 and through 2021, we transitioned to remote recruitment of subjects in response to the COVID-19 pandemic. While hurting our recruitment rate per month, we saved on parking fees and conference travel.

F.2 - Actual or anticipated challenges or delays and actions or plans to resolve them

N/A

F.3 - Significant changes to human subjects, vertebrate animals, biohazards, and/or select agents

N/A

G. Special Reporting Requirements**G.1 Special Notice of Award Terms and Funding Opportunities Announcement Reporting Requirements****G.2 Responsible Conduct of Research****G.3 Mentor's Research Report or Sponsor Comments****G.4 Human Subjects**

G.4.a Does the project involve human subjects?

Yes

G.4.b Inclusion Enrollment Data

Race (all males)	Hispanic	Non-Hispanic	Unknown	Grand Total
American Indian/Alaska Native	4	3		7
Asian		19	7	26
Black or African American	2	72	0	74
Native Hawaiian or Other Pacific Islander		1		1
Other	48	15	3	66
White	60	348	25	433
Unknown	21	3	35	59
Grand Total	135	461	70	666

G.4.c ClinicalTrials.gov

N/A

Does this project include one or more applicable clinical trials that must be registered in ClinicalTrials.gov under FDAAA?

No

G.5 Human Subject Education Requirement

Are there personnel on this project who are newly involved in the design or conduct of human subject's research?

No

G.6 Human Embryonic Stem Cells (HESCS)

Does this project involve human embryonic stem cells (only hESC lines listed as approved in the NIH Registry may be used in NIH funded research)?

No

G.7 Vertebrate Animals

Does this project involve vertebrate animals?

No

G.8 Project/Performance Sites

N/A

G.9 Foreign Component

N/A

G.10 Estimated Unobligated Balance

There is no unobligated balance. The funds at the end of the reporting period were less than 25%. The fund has been spent down.

G.10.a Is it anticipated that an estimated unobligated balance (including prior year carryover) will be greater than 25% of the current year's total approved budget?

No

G.11 Program Income

Is program income anticipated during the next budget period?

No

G.12 F&A Costs

Is there a change in performance sites that will affect F&A costs?

No

I. OUTCOMES

I. Provide a concise summary of the outcomes or findings of the award, written for the general public in clear and comprehensible language, without including any proprietary, confidential information or trade secrets

Note: project outcome information will be made public in NIH RePORTER

(N = 666) members of the WTCHP enrolled in our study from a pool of 2546 members. Patients were on average 55.21 years old (7.66 SD). Men were uniformly interested in screening, with an uptake of 97.4% without further physician consultation. Screening led to a small number of follow-up biopsies and to 5 discovered early stage prostate cancers. 3-4 days after their decision was made and at 3 month post baseline, men did not report any high levels of decisional regret, or elevated levels of prostate cancer-related anxiety. Providers rated the program highly as it did not add a significant amount of time to their patient visits. Patient interest in the screening program was high, integrated well into the clinic and with the help of the screening brochure facilitated patient screening decision making. There were no short or long-term psychosocial consequences for being screened.