DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-24-24CB; Docket No. CDC-2024-0004]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Evaluation of an Online Prostate Cancer Decision Aid. This three-arm, randomized controlled trial (RCT) includes eight forms of data collection including surveys and interviews and will evaluate the impact of a virtual human decision aid to help improve the quality of prostate cancer screening and treatment decisions.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2024-0004 by either of the following methods:

- Federal eRulemaking Portal: www.regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to www.regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (www.regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other

technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

Evaluation of an Online Prostate Cancer Decision Aid – New - National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC), Division of Cancer Prevention and Control (DCPC) is requesting a new, three-year OMB approval to conduct a three-arm, randomized controlled trial (RCT) to evaluate the impact of a virtual human decision aid to help improve the quality of prostate cancer screening and treatment decisions.

Talk to Nathan About Prostate Cancer Screening (hereafter referred to as Nathan) is DCPC's online, interactive, human simulation decision aid designed to help men learn and make informed decisions about prostate cancer screening. A small, preliminary evaluation of Nathan showed promise in increasing men's knowledge about prostate cancer and likelihood of engaging in shared decision-making about prostate cancer screening with their health care providers. At this time, a larger, more systematic evaluation can help to understand whether Nathan is effective in areas such as improving knowledge, overcoming health literacy barriers, and resolving decisional conflict, especially among priority populations who are most likely to be affected by prostate cancer and least likely to be screened. Further, as some experts consider the digital divide to be the newest social determinant of health, it is important to explore how, where, and for which populations there may be disparities in accessing and using Nathan.

Broadly, the purpose of this information collection is to: 1) assess whether Nathan is more effective at helping men make decisions about prostate cancer screening than an established decision aid or standard educational materials; 2) determine if changes or

improvements to Nathan are warranted; and 3) identify ways to incorporate Nathan into primary care. We will select four primary care clinics to participate in this study. The RCT includes a three-group parallel design with one treatment arm and two control arms to test the effectiveness of Nathan for men aged 55-69. We will recruit 900 men aged 55-69 who have an upcoming general health exam at one of the four primary care clinics and randomize them to one of three arms: 1) Nathan (Intervention=300 men); 2) the Massachusetts Department of Public Health's (MDPH's) Patient Decision Aid, Get the Latest Facts about Screening for Prostate Cancer (Control 1=300 men); and (3) standard educational materials from the National Cancer Institute (NCI), Prostate Cancer Screening (PDQ®)–Patient Version (Control 2=300 men).

Eight information collection forms will be implemented to answer our evaluation questions. These include a provider survey; a patient eligibility screener; patient pre-exposure, post-exposure, and post-clinic visit surveys; a patient usability survey; patient user experience interviews; and clinic coordinator interviews. Each instrument will be administered once per respondent throughout the course of the study. The provider survey and clinic coordinator interviews will be conducted in English only. All other information collections will be conducted in English or Spanish. The total response burden is estimated to be 1,129 hours. There are no costs to respondents other than their time to participate in data collection activities.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Primary care providers	Provider survey	40	1	10/60	7
Men ages 55-69	Patient eligibility screener	900	1	8/60	120
Men ages 55-69	Pre-exposure survey	900	1	20/60	300
Men ages 55-69	Post-exposure survey	900	1	20/60	300
Men ages 55-69	Post-clinic	300	1	18/60	90

	survey				
Men ages 55-69	Usability survey	30	1	20/60	10
Men ages 55-69	User experience interview	900	1	20/60	300
Clinic coordinators	Clinic coordinator interview	4	1	30/60	2
Total					1,129

Jeffrey M. Zirger,

Lead,

Information Collection Review Office,

Office of Public Health Ethics and Regulations,

Office of Science,

Centers for Disease Control and Prevention.

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