Reducing Overscreening for Breast, Cervical, and Colorectal Cancers among Older Adults Frequently Asked Questions September 14, 2017

Cancer Type

Is a study required to address overscreening of all three cancers (i.e., breast, cervical, colorectal)? The funding announcement does not require inclusion of all three cancers. However, if one has the power and population to address overscreening in all three cancers, then we encourage applicants to consider this possibility. Additionally, we encourage applicants to email or speak with the scientific contact listed in the funding announcement to review your plan prior to submitting the application.

Study Design

Three aims were included in the program announcement, must all three aims be addressed or can applicants focus on one or two aims?

The purpose of the funding announcement is to stimulate interest in reducing overscreening for breast, cervical and colorectal cancers among older adults. As such we identified three areas of high interest to the NCI. Investigators may address one or more of the aims, or propose additional aims that address reducing overscreening.

You mentioned hypothesis-driven aims for this program announcement. Is a prediction of who provides unnecessary screening eligible?

This type of prediction is fine so long as the prediction is linked to two or more levels of the healthcare system, and improves healthcare delivery around overscreening within an older adult population. An important connection between the different levels are individuals who connect to different parts of the healthcare organization (i.e., such as *between*/ inter-level and *within*/ intra-level). Analyses need to consider these interactions, as reflected in an understanding of the mediators and moderators that result in timely and appropriate screening decisions, etc.

Study Outcomes

Must outcomes be tied to the United States Preventive Services Task Force (USPSTF) guidelines – i.e., overscreening for breast is routine mammography over 75 years regardless of expected life expectancy, or can alternate definitions of "older" adults be used (i.e., life expectancy) as an alternative to chronological age?

For the purposes of this funding announcement, the NCI defines overscreening according to the USPSTF age-based guidelines for breast, cervical and colorectal cancers, as follows:

- Routine breast cancer screening in average-risk women aged 75 years and older.
- Any cervical cancer screening in average-risk women aged 65 years and older.
- Routine colorectal cancer screening in men and women aged 75 years and older.
- Any colorectal screening in men and women aged 85 years or older.

That said, we recognize the shortcomings of using only age, and encourage the use of including other outcomes such as life expectancy, multiple morbidity, etc. in addition to age.

The focus of the program announcement is on overscreening in this older age group, that is that screening should be reduced. Can we use an outcome of better informed decision making regardless of whether someone decides to continue screening?

Primary outcomes should be a decrease in the proportion of older adults who are overscreened. Informed decision making could be a secondary outcome. A secondary outcome of a multilevel intervention focused on informed decision-making might emphasize the interrelationship between the individual, the healthcare team, their healthcare system and/or community setting.

Study Population

Are underserved populations a priority?

A significant percentage of the adult population has no access to screening, which creates variability in who receives or does not receive screening tests. If data support that older, medically underserved populations are overscreened, then they should be studied and are an NCI priority.

Intervention

A major problem with colonoscopy is bringing patients back for repeat exams prior to recommended date (i.e., 10 years). Would an intervention to address that be responsive?

Research has focused primarily on the use of screening colonoscopy which is performed every 10 years in *average* risk people *without* prior abnormal findings. The US Preventive Services Task Force recommends against *routine* colorectal screening in adults > 75 years. Much less attention has been given to colonoscopy performed at shorter intervals of 3 to 5 years in people with a *history* of adenomas and serrated polyps. This latter is secondary screening or surveillance colonoscopy. An intervention that addresses either situation, routine screening or surveillance colonoscopy would be a responsive application, particularly if two or more levels of the healthcare system are addressed.

R21 Mechanism

Do screening rates need to be one of the outcome measures for R21 submissions?

A goal of the funding announcement is to identify modifiable drivers of overscreening. Thus, retrospective studies that examine multilevel drivers of overscreening with screening rates as a primary outcome is possible. Alternatively, the R21 mechanism could be used to develop and pilot-test an intervention that aims to reduce overscreening.

How do you expect to see significant changes in overscreening in a 2-year period?

Screening rates could be looked at prospectively. If an individual who is over the age-limit but due for screening comes in for a primary care visit, receives the intervention, and leaves without being screened or being referred for screening, then this would be an immediately known change in screening rates.

Do you encourage the use of claims and/or electronic health record data for an R21?

The R21 mechanism is an appropriate use for secondary data, especially if it is linked to two or more levels of the healthcare system, then we encourage use of claims and/or electronic health record data.

Scientific Review Meeting

What standing review panels would be appropriate for this program announcement?

Applicants are encouraged to look at the Center for Scientific Review standing study sections (<u>https://public.csr.nih.gov/StudySections/Standing/Pages/default.aspx</u>) and review the general scientific area, and current roster of panel members and assess how the panel mission fits with your application. Some applications have been reviewed in Health Services Organization and Delivery Study Section (HSOD), other applications are being reviewed in Nursing and Related Clinical Services Study Section (NRCS), and Psychosocial Risk and Disease Prevention Study Section (PRDP). We encourage applicants to email or speak with the scientific contact listed in the funding announcement to review the focus of the study and how it aligns with the study section goals prior to submitting the application.

Is there guidance about how NOT-OD-17-050 (Reporting Preprints and Other Interim Research Products) will be implemented during review/study section?

The Center for Scientific Review (CSR) has not provided public guidance. However, more than likely, the Scientific Review Officer (SRO) will make an announcement to the panel at the beginning of the meeting guiding panel members on procedures for dealing with preprints and other interim research products.