**TEMPLATE FOR CROSS-CENTER PROJECT PROPOSAL (1-2 pages)**

Ad Work Group Name or Project Title

Tobacco and Lung Cancer Working Group.

Project title: Primary care practice adoption and implementation of LDCT screening

Lead or Co-Lead Names: Steve Zeliadt, Sue Flocke

Background *(describe in a paragraph the gap/problem/need and its practical/scientific importance)*

Lung cancer remains the leading cause of cancer mortality in the U.S., responsible for more deaths than the 5 largest causes of cancer mortality combined including breast, prostate, colon, ovarian and pancreatic cancer.(Edwards et al., 2014) In 2011, the National Lung Screening Trial (NLST) was stopped early after it demonstrated that low-dose computed tomography (LDCT) screening among heavy smokers reduced lung cancer mortality by 20%.(Aberle et al., 2011) These results have led to a “B” recommendation by the U.S. Preventive Services Task Force (USPSTF) for annual screening with LDCT for high risk smokers and former smokers between ages 55-80.(Humphrey et al., 2013; Moyer, 2014) The recommendation has been controversial, as some decision makers consider the absolute benefit, which is a reduction in 3 deaths (from 21 to 18) among 1000 individuals screened, to be small relative to the potential burden and harms of interventions associated with indeterminate lung nodules and incidental findings. Among the 26,722 individuals screened in the NLST compared to the control group, there were 83 fewer lung cancer deaths; However, there were also16 deaths caused by iatrogenic complications associated with work-up of screening findings, 86 major complications, 142 minor complications, 713 surgical procedures, 671 bronchoscopies and 10,246 follow-up imaging tests.(Woolf, Harris, & Campos-Outcalt, 2014) The balance between benefits and harms of lung cancer screening is associated with considerable variation and is influenced by many factors include lung cancer risk, smoking history, gender, age, radiology performance, aggressiveness of recommendations, selection of population offered screening, and other factors.(Black et al., 2014; Field, Hansell, Duffy, & Baldwin, 2013; Pinsky, Gierada, Nath, Kazerooni, & Amorosa, 2013; Tammemägi et al., 2013)

The Centers of Medicare and Medicaid Services (CMS) convened a panel in early 2014 to review the evidence and consider the uncertainty around covering lung cancer screening for individuals over age 65. This panel concluded that there was considerable uncertainty that the benefits would outweigh the risks in this age group.(Woolf et al., 2014) CMS recently issued a preliminary coverage recommendation restricting payment for lung cancer screening contingent on imaging being offered only through certified screening centers who comply with CMS’s requirements. Health care systems and provider networks are in the process of developing approaches to offering lung cancer screening to patients in order to meet USPSTF’s “B” recommendation and Affordable Care Act’s requirement that all “B” level preventive services be provided without a co-pay.(Field et al., 2013; Kinsinger, Atkins, Provenzale, Anderson, & Petzel, 2014; Wender et al., 2013)

Because lung cancer screening is only recommended for current and former smokers, aged 55-74 who have at least a 30-pack year smoking history, the first step to offering screening is to identify eligible patients. These efforts overlap with “meaningful use” requirements of electronic medical records systems to identify smoking status, and many health systems’ efforts to document smoking status, smoking history and brief advice to quit involve linking to smoking cessation programs. The degree to which the new recommendation for lung cancer screening is facilitating or impeding the identification of tobacco users and the provision of cessation services is not known.

Another concern related to offering lung cancer screening is that smokers may perceive it as a substitute for cessation. The NLST did not observe differences in quit rates between those assigned to LDCT and the chest x-ray group.(Tammemägi, Berg, Riley, Cunningham, & Taylor, 2014) Preliminary evidence from an ongoing European screening trial observed that cessation rates at two-years were unexpectedly lower among patients offered screening (14.5%) compared to control group participants (19.1%; p<0.05).(Slatore, Baumann, Pappas, & Humphrey, 2014; van der Aalst, van den Bergh, Willemsen, de Koning, & van Klaveren, 2010) The Early Lung Cancer Action Program which offers LDCT screening, has observed that patients with non-suspicious findings have 28% lower abstinence rates compared to participants identified with suspicious findings, although multiple non-suspicious findings were not associated with long term relapse or absitence.(Anderson et al., 2009)

Aims or Research Questions

1. What is the current level of adoption of the USPSTF’s recommendation to offer lung cancer screening to high risk patients among safety-net clinics?
2. To what extent have community-based safety implemented this recommendation?
3. What are critical barriers faced by safety net clinics to implementing?
4. How are efforts to offer lung cancer screening enhancing or detracting from smoking cessation activities?
5. What are practices’ capacity for the following:

*tobacco use screening, advice and assistance*

* 1. identify tobacco users using EHR
  2. document of cessation advice
  3. document of assistance to quit;
  4. e-referral capacity to quitline or other cessation program
  5. documentation of the referral result (e.g. did the patient attend)

*lung cancer screening*

* 1. identify eligible tobacco users
  2. document patient education about screening was delivered
  3. document cessation advice integrated into screening discussion provided to current smokers
  4. process for notifying patients of suspicious results and/or incidental findings
  5. methods for tracking receipt of appropriate follow-up and repeat screening

1. How are clinics measuring or planning to measure quality of care and performance related to lung cancer screening?

Approach *(describe the proposed study design, the more concrete the better)*

* 1. Formative work using interviews with primary care clinicians to develop survey
  + Klabunde national survey Ann Fam Med 2012 might be a good starting point re: current practice and knowledge re: lung cancer screening. Note that her sample included physicians with high rates of insured patients.
* 2: Observational study
  + Data collection involves survey.
  + Ideally assess at 2 time points approximately 12 months apart; anticipate change.
  + Setting -safety net practices; community health clinics
  + Sample – primary care clinicians; <who is knowledgable about the system>
  + Recruitment – potentially follow the strategy by Klabunde – mailed invitations and incentives, followed by phone call. Size and scope of that project is probably larger than we can do with CPCRN collaborative project.
  + Measures – <we need input here>
  + Analyses – descriptive analyses; test associations clinician and practice characteristics of those who have adopted implemented vs. not adopted / implemented.
* Timeline and initial steps
  + determine sampling frames – regional/ state of PRCs vs. national survey
  + refine research questions / hypotheses
  + select measures / items
  + refine protocols and IRBs
* Resource Considerations
  + cost of mailing lists / web vs. paper survey. Telephone interviews?
  + incentives for participants
  + staff and effort to achieve 50% response rate like Klabunde? Used Westat?
  + statistician for sampling and analysis

Cross-Center Project Criteria *(briefly describe how the proposed project responds to the review criteria)*

* Significance: could this project significantly accelerate the implementation of evidence-based cancer control?

This project will address several key domains of cancer control implementation science. While the NLST is one of the most well executed clinical trials ever conducted and it was stopped early due to the relative mortality benefit observed in the intervention group, the implementation of lung cancer screening into the real-world practice setting provides enormous challenges. First, population-level screening is expensive due to both the expense of screening with LDCT scans as well as the costs associated with follow-up imaging and procedures. This cost also is likely to compete with commitment of resources to smoking cessation, which has been shown to be a highly cost-effective (and even cost-saving) approach to reducing lung cancer mortality as well as morbidity and mortality associated with other smoking-related diseases.(Barnett, Wong, & Hall, 2008; Bolin, 2012; Curry, Grothaus, McAfee, & Pabiniak, 1998; Ruger & Lazar, 2012) Understanding how health systems and clinics navigate cancer control strategies under resource constraints is a critical priority for the field of implementation science. Additionally, identification of the target population and appropriate marketing and education of providers and patients will be critical to effective implementation. For example, only 7 million of the 94 million current and former smokers in the U.S. meet the eligibility criteria for USPSTF’s recommendation based on the NLST trial.(Gates, 2014) Extending screening to individuals who do not meet the risk criteria is expected to offer very little benefit in terms of reducing lung cancer mortality but will expose those individuals to the harms of working up indeterminate and incidental findings.(Tammemägi et al., 2013) The approaches that health systems and providers take to disseminating screening will be critical to ensuring offering screening leads to benefits observed in the NLST and does not inadvertently lead to unnecessary harms. Third, the requirements proposed by CMS for coverage of LDCT screening for patients over age 65 are groundbreaking in their attempt to ensure a new healthcare technology is leading to its expected benefit. This paradigm-changing requirement by CMS will receive considerable scrutiny as it is implemented into clinical practice, as the burden of these requirements are assessed and the impact they have on the dissemination and reach of the lung cancer screening. Additionally, ten implementation components of high quality cancer screening have been identified.(Tanner, Gould, & Silvestri, 2014)

* Feasibility: does CPCRN have the expertise, time, resources, and partnerships to carry out the project?

Dr. Zeliadt at the University of Washington has expertise in assessment of cancer screening programs in breast, prostate and lung cancer. He is currently leading a national effort to assess the performance of lung nodule follow-up care for 128 VA Medical Centers, and is on the Steering and Evaluation Committee for the VA’s Lung Cancer Screening Clinical Demonstration Project.

The CPCRN member organizations have extensive experience conducting formative qualitative work and surveys with primary care clinicians. Each CPCRN also has strong partnerships with FQHC or safety net practices which could aid in the design and conduct of this proposed project.

* Scalability: does the project have the potential to be scaled up if successful or lead to additional, competitively awarded funding?

While the project itself would not necessarily be scaled up for a larger project, the findings could inform both the barriers and the drivers of implementing LDCT scans. One reason CPCRN sites are excited about this project is its potential for capacity building and long-term foundation for conducting research with our community partners. The survey work will identify outliers that are on the forefront of implementation of lung cancer screening programs. By gathering more information from these individuals and fostering relationships we could help develop a network of collaborators to develop and examine best practices and future interventions optimizing lung cancer screening and improving how smoking cessation is integrated into screening.

* Scientific Merit: does the project make an important contribution to scientific knowledge of D&I?

The implementation of lung cancer screening may not reach the individuals for whom it could help, and has the potential for net harm through unnecessary surgical and biopsy procedures involving the lungs which carry considerable risk or by inadvertently diminishing smoking cessation efforts. It is one of the few preventive services recommended by USPSTF that carries such uncertainty and potential for harm, and how health systems and clinics approach its implementation will provide value contributions for other settings.

* Funder Priority: Is the project responsive CDC/NCI priorities for CPCRN?
* Member Interest: are enough CPRN members interested to lead/conduct the project?

Tobacco control is a critical priority for CDC and NCI.

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