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Tailoring Shared Decision Making for Lung Cancer Screening in Persons with HIV (PWH)
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1. Background and Rationale

1.1. Introduction

As the population of persons living with HIV ages in the United States, lung cancer is now the leading cause of cancer death, with risk related to both increased tobacco use as well as independent risk associated with chronic HIV infection. Lung cancer screening with annual low-dose chest CT has been demonstrated to reduce lung cancer mortality by up to 20% in a subset of high-risk smokers, though potential longitudinal benefits may be greatly reduced in those with comorbid illness. While lung cancer screening is both feasible and likely highly beneficial in many persons living with HIV, there are limited prospective data and no HIV-specific guidelines to support tailored lung cancer screening decision making in this population, who are at higher risk for multimorbidity associated with aging. This study will bridge this significant knowledge gap through the iterative development and evaluation of tools to guide the shared decision making process for lung cancer screening in persons living with HIV. The study will consist of the following specific aims and approach: 1) Conduct a formative evaluation using qualitative methods to guide adaption and implementation of shared decision making for lung cancer screening tailored to persons living with HIV incorporating lung cancer risk as well as HIV severity, comorbidity and life expectancy; and 2) Pilot and evaluate tailored shared decision making using mixed-methods to assess the impact on patient knowledge and decisional conflict, as well as intervention acceptability, appropriateness and fidelity. Aim 1 includes focus groups of persons living with HIV and interviews with their primary providers to determine key barriers and facilitators to tailored shared decision making. Measures of comorbidity and life expectancy are also incorporated into this process to develop a tailored shared decision making intervention. Aim 2 is a single-arm feasibility trial to determine both the preliminary effectiveness and implementation of the shared decision making approach. The results of this study will be used to develop and refine tools for shared decision making for lung cancer screening in persons living with HIV, allowing for subsequent scale-up of implementation and assessment of effectiveness, reach and sustainability in a multicenter trial. This study directly addresses NIH high priority research topics of malignancy and comorbidity associated with HIV.

1.2. Relevant Literature and Data

1.2.1. The burden of lung cancer is particularly high in aging persons with HIV (PWH). Non-AIDS defining cancers are increasing in aging PWH. Approximately 50% of PWH in the US are over the age of 50, and lung cancer is now the leading cause of cancer death.[1,2] The cumulative incidence of lung cancer by age 65 in this population is 2.2% vs. 1.3% in the non-infected population.[3] This is largely attributable to high rates of tobacco use in U.S. PWH; an estimated 60% are current or former smokers.[4] There is also evidence for an increased risk of lung cancer independent of smoking.[5,6] Among those who are diagnosed with lung cancer, PWH may also be less likely to receive appropriate treatment and have poorer survival than their uninfected counterparts, highlighting the potential benefits of early detection to overcome these disparities.[7-9]

1.2.2. LCS is an effective tool for early detection in high-risk populations. The National Lung Screening Trial (NLST) enrolled >50,000 current or former smokers (quit within 15 years) of ≥30 pack-years, aged 55-74, and randomized individuals to LDCT vs. chest radiograph. The LDCT arm had a 20% decrease in deaths from lung cancer and a 7% decrease in all-cause

mortality.[10] The benefits of LCS have been confirmed in a subsequent trial,[11] and the United States Preventive Services Task Force (USPSTF) recommends screening for a similar high-risk group.[12] Due to this recommendation, and similar guidelines from the Centers for Medicare and Medicaid services (CMS), LCS is provided to insured eligible individuals without cost-sharing.[13] This benefit is also extended to many who are age ≥50 with smoking history ≥20 pack-years with an additional lung cancer risk factor based on National Comprehensive Cancer Network (NCCN) guidelines.[14]

1.2.3. Lung cancer screening is feasible and likely beneficial in *most* eligible PWH. The NLST did not include PWH;[10] however, several single-arm feasibility trials of PWH demonstrate similar outcomes.[15,16] Our own group has demonstrated that false-positive findings and procedural complications do not appear to be more common in PWH with well-controlled HIV.[17,18] Given the lack of feasibility of a large-scale trial, our group modified the Lung Cancer Policy Model used by USPSTF for PWH using best estimates from the literature for a number of parameters unique to PWH including non-lung cancer mortality rate by age and CD4 strata and found that lung-cancer specific mortality reduction using standard eligibility criteria was 18.9% for PWH who are adherent to ART, similar to the 20.0% seen in NLST[19] (see preliminary work). Thus, LCS is likely to benefit PWH using similar criteria as the general population.

1.2.4. However, LCS may be less effective in persons with a high burden of comorbidity and competing health risks. To minimize harms and maximize benefits, patients who have conditions that substantially limit life expectancy or the ability to have lung surgery should not undergo LCS per USPSTF guidelines.[12] Evaluating comorbidities and accounting for competing risk of death from other causes is crucial in assessing the effect of LCS on mortality.[20] Aggregate benefits of screening may not be experienced for several years after cancer diagnosis ("pay-off" time).[21-23] Unfortunately, those at the highest risk for lung cancer may also be at the highest risk from related diagnostic or therapeutic complications, and/or competing causes of death, and thus unlikely to have sufficient "pay-off" time to derive benefits of screening.[24,25] Indeed, patients who met NLST criteria but had higher Charlson Comorbidity Index (CCI) scores (≥ 2 vs 0-1) showed significantly lower 5-year survival among patients with resectable stage I non-small cell lung cancer.[26]

1.2.5. Shared decision making (SDM) is used to guide patient-centered decisions regarding LCS; however, there are no tools tailored for PWH. SDM is defined as an "approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options to achieve informed preferences."[27,28] SDM is particularly important for LCS given comorbidities and competing risks in the eligible target population,[29] and is mandated by CMS and recommended by other guidelines.[13] Several tools, or decision aids, have been evaluated to guide and personalize SDM, but most focus on individual risk assessment of lung cancer rather than assessment for individualized competing risks or harms. While we do not intend that distinct thresholds for comorbidity or life-expectancy should definitively guide SDM, almost all guidelines recommend considering these elements in SDM. In those who have lower life expectancy, screening may be approached as more patient preference-sensitive.[12,29] Thus, an understanding of competing risk and life expectancy may be beneficial for clinicians and patients in deciding whether to screen, and particularly for PWH given their burden of multimorbidity.[25]

1.3. Compliance Statement

This study will be conducted with Fred Hutchinson Cancer Center (FHCC) policies and procedures and all applicable Federal and state laws and regulations including 45 CFR 46 and the HIPAA Privacy Rule. Any episode of noncompliance will be documented. Collecting,

recording, and reporting of data will be accurate and will ensure the privacy, health and welfare of research subjects during and after the study.

2. Study Objectives

2.1. Aims

Aim 1. Conduct a formative evaluation using qualitative methods to guide adaption and implementation of shared decision making (SDM) for LCS tailored to PWH incorporating lung cancer risk as well as HIV severity, comorbidity and life expectancy.
H1. Key themes will emerge from focus groups and interviews with PWH and providers that will help structure a SDM process for PWH and determine how best to incorporate measures of HIV severity, comorbidity and life expectancy, such as the Veterans Affairs Aging Cohort Study and Charlson Comorbidity risk indices.

Aim 2. Pilot and evaluate tailored SDM using mixed-methods to assess the impact on patient knowledge and decisional conflict, as well as intervention acceptability, appropriateness and fidelity.
H2. Tailored SDM will result in improvements in patient knowledge and result in low levels of decisional conflict. Surveys of patients and interviews of patients and stakeholders will be utilized to inform and subsequently iterate the intervention with regards to acceptability, appropriateness and fidelity.

2.2. General Schema of Study Design

The study will include: 1) a multilevel qualitative assessment of PWH and their providers to gather formative information to guide implementation of SDM for LCS and 2) A pilot SDM program tailored for PWH with a mixed-methods assessment.

2.3. Study Duration, Enrollment and Number of Sites

2.3.1. Date Range of Study

This study will be conducted October 2020-September 2022. Estimate to complete Aim 1 in months 1-10 and Aim 2 in months 11-24.

2.3.2. Total Number of Study Sites/Total Number of Subjects Projected

There will be two sites for the study which perform separate tasks. The FHCRC will serve as the administrative home for the project and house the study Co-leader (Dr. Triplette) and the research coordinator. Will also be site of all data analysis.

The UW Madison Clinic will serve as the enrollment site and clinical visit site for Aim 1. UW Madison Clinic will serve as the enrollment site and both UW Madison Clinic and Fred Hutchinson Cancer Center will serve as the clinical visit sites for Aim 2. In Aim 1, Madison Clinic conference space will supplement online focus groups and interviews. In Aim 2, data collection will be concurrent with a clinical visit for LCS enrollment.

2.4. Study Population

2.4.1. Inclusion Criteria

Aim 1. We will recruit participants from two groups: PWH enrolled in the local UW HIV cohort and primary providers at Madison Clinic and other Seattle-based clinics serving PWH. Using proposed USPSTF guidelines, participants enrolled in the registry who are current or former smokers, ≥50 years old, and report ≥ 20 pack-years smoking history (n=165) will be eligible for recruitment. A purposive sample will be recruited, making every effort to include patients of diverse race/ethnicity, sex, income, and spanning the eligible age range for LCS. We will pay particular attention to recruiting women as well as men. Clinicians (medical doctors, physicians assistants, and nurse practitioners) who provide primary care for PWH (n=48) will be eligible.

Aim 2:
PWH who are eligible for LCS based on current USPSTF criteria[SMA1]. Plan to enroll approximately 50% who have never had a lung cancer screening exam, and 50% who are overdue (~12 months) for lung cancer screening exam.

2.4.2. Exclusion Criteria

Those found to be ineligible for LCS on coordinator review; or who are non-English speaking or have cognitive dysfunction that would prevent participation in SDM.

3. Study Procedures

3.1. Aim 1

3.1.1. Recruitment, enrollment and consent

PWH who are recruited for focus groups will be identified through the research registry (in which they have consent for contact for any future studies). Participants will be recruited from the registry who meet the following criteria: current or former smokers, ≥50 years old, and report ≥ 20 pack-years smoking history (n=165). The research coordinator (RC) will contact potential participants and confirm eligibility. An initial telephone script (Addendum 1) will be used to contact and briefly explain the study. Verbal consent (Addendum 2.1, Addendum 2.2) will be used prior to the focus groups. Participant clinicians will be recruited by Madison clinic provider Dr. Jehan with the assistance of the RC. Participant clinicians will also complete an electronic consent prior to the interviews (Addendum 2.3). An informational flyer will also be posted at UW Madison Clinic (Addendum 15.1) throughout Aim 1 enrollment.

3.1.2. Focus groups

All focus group participants will initially complete a brief survey of demographic information over the phone or through REDCap (Addendum 3 [PWH], Addendum 4, [providers]). The study team will use a focus group guide that addresses key constructs of the Tailored Implementation of Chronic Diseases (TICD) checklist, an implementation science framework that identifies potential barriers or facilitators of healthcare professional practice and intervention delivery.[30] Between 3-5 focus groups of 5-10 patients will be conducted and 10 clinicians will partake in one-on-one interviews, each lasting approximately 1-1.5 hours. Patient focus group size may be reduced in early recruitment or to accommodate participants. The facilitator (Dr. Brown) will then go through a widely used decision aid to guide screening, shouldiscreen.com (University of Michigan) which includes an estimate of personalized 6-year risk of lung cancer[31]. In provider interviews, two tools to measure competing risks, one to summarize comorbidity (the age-adjusted CCI) and the other to estimate 5-year mortality specifically in PWH (the VACS 2.0

Index), will be introduced alongside a mock tool to aid in shared decision making (Addendum 16).[32,33] The facilitator will lead discussion of barriers and facilitators across TICD constructs of: 1) tailoring SDM to PWH, and 2) utilizing the measures of competing risk. For example, key TICD constructs for tailoring SDM include determining **patient needs** and **preferences**, and provider assessments of **feasibility** and **attitudes towards the guidelines**. When considering incorporating measures of competing risk, key constructs include the **cultural appropriateness of the recommendation** for both PWH and their providers as well as provider assessments of **consistency with other guidelines** and **relative strength of supporters and opponents**. Interviews with providers will follow patient focus groups and incorporate resultant themes in the discussion. The focus group and interview guide is addended here (Addendum 5.1 and 5.2). These guides will be adapted throughout Aim 1 to improve clarity and receive greater response by patients and providers.

3.1.3. Sample Size

Thematic saturation, the point at which no further theme are generated from subsequent groups, can often be achieved with 3-6 focus groups.[34] As we are conducting focus groups/interviews with providers and patients separately, we will allow up to 8 focus groups and 10 interviews, and will use iterative analysis to determine saturation.

3.1.4. Data Collection and Analysis

All focus groups will be recorded and transcribed. We will use a framework analysis approach which combines inductive and deductive methods to generate themes and map them onto an implementation framework; in this case we will map themes onto the constructs of the Tailored Implementation of Chronic Diseases (TICD) checklist.[30,35] Results will be entirely qualitative and key quotes and field notes will be used as evidence in analysis. Initial focus groups and interviews will be reviewed and coded individually by members of the analytic team (Dr. Triplette, Dr. Crothers, Dr. Brown and others as designated), who will then compare coding to reach consensus on a codebook to use in analysis of subsequent focus groups. Codes will then be analyzed through a constant comparison method to determine key themes, again using a framework approach of thematic analysis to map themes onto the specific constructs (such as “patient needs” or “guideline appropriateness”) of the TICD checklist. We will analyze all focus groups in real time to make iterative changes to the focus group guide based on feedback and refining potential methods of SDM.

3.1.5. Reimbursement

All patient participants will be provided with $40 for participation in the study and if in-person, parking reimbursement. Providers will receive a $10 gift card for completing the interview.

3.2.Aim 2

3.2.1.Recruitment, enrollment and consent

We will utilize the UW HIV Cohort registry, a subset of the HOPE research cohort who indicated interest in future contact, and provider referrals (see Addendum 17) to identify potentially eligible participants based on age and smoking status. The study coordinator will contact individuals to confirm their eligibility for LCS including assessment of smoking pack-years. Participants who confirm that they are interested in the study will complete verbal consent for a limited chart review to inform risk factors in the shared decision-making tool. This includes age, gender, BMI,

and most recent CD4 count, HIV RNA level, hepatitis C status, eGFR, AST, ALT, platelets, WBC count, hemoglobin and albumin. Individuals eligible for LCS will have a study and SDM visit scheduled, at which time informed consent will be obtained by the coordinator. Research coordinator (RC) will contact potential participants and confirm eligibility. An initial telephone script (Addendum 6) will be used to contact and briefly explain the study. In-person written consent (Addendum 7) will be used at the time of the patient visit. RC will also confirm insurance-coverage eligibility for participant at no cost to the participant through UW radiology scheduling partner.

3.2.2. Shared Decision Making visit

The coordinator will administer a pre-SDM survey that includes participant demographics, participant-reported risk factors, tobacco history, an assessment of LCS knowledge (the LKS) used in our prior study[36] and minimalist/maximalist approach to healthcare[40] (Addendum 8.1). Participants will then meet with the LCS nurse practitioner (NP), who will provide the SDM intervention and will supplement the discussion using language regarding comorbidity and life expectancy developed in Aim 1 to frame decisions; they will come to a mutual decision on whether to move forward with the screening process. To inform the tailored discussion, comorbidity burden and life expectancy will be estimated for each participant prior to the visit, using data from the UW HIV Information System (UWHIS) and EPIC to generate CCI, LCRAT, LCDRAT and VACS 2.0 Index from electronic-health records data (ICD-10 codes and most recent lab values within 1 year). A HIPAA waiver has been requested for this purpose. Prior to the visit, the participants lung cancer risk will be calculated using the LCRAT and the LCDRAT tools and mortality risk will be calculated using the VACS Index 2.0. The NP will receive an interpretation of these results, based on published literature and our preliminary work to guide discussion. The NP will complete SDM with the patient using the tailored SDM tool (Addendum 19) and guide (Addendum 20). The coordinator will observe the SDM discussions in order to complete an observational checklist assessing fidelity of the intervention (Addendum 9). Participants will then complete a post-SDM survey re-assessing LCS knowledge, resultant decisional conflict using the low literacy decisional conflict scale,[37] as well as validated quantitative 4-item scales of acceptability and appropriateness developed by Co-I Weiner, the Acceptability of Intervention Measure (AIM) and the Intervention Appropriateness Measure (IAM)(Addendum 8.2)[38] Participants who go on to LCS will be enrolled in the LCS program and linked to screening by a patient navigator.

3.2.3. Post-intervention interviews

Approx. 5 weeks post-SDM, 10-15 purposefully selected participants chosen to represent both broad demographics and maximum variation on AIM and IAM scores will be contacted for a 45-minute telephone or HIPAA-approved ZOOM interview to explore factors that might influence intervention acceptability and appropriateness. These will be conducted by the RC. Similar interviews will be conducted with the NP. Interview guides (Addenda 10, 11, 12) will be adapted throughout Aim 2 to better capture participant perspectives. The NP interview will also explore factors that might influence fidelity of intervention delivery. All interviews will be recorded and transcribed. This will have separate consent delivered over the phone by RC (Addendum 13.1 and 13.2).

3.2.4. Review of EHR.

Participants in Aim 2 will provide consent and HIPAA authorization (Addendum 14) for limited review of their medical records at the time of clinical visit. A HIPAA waiver has been requested

for review of EHR prior to clinical visit to determine comorbidity burden and life expectancy measures used in production of a tailored SDM tool. The EHR will be assessed for participants to determine the following information post-SDM visit: data of lung cancer screening scheduling, documentation of patient encounters around lung cancer screening, lung cancer screening results, lung cancer screening follow-up screening, procedures, and patient visits.

3.2.5. Sample Size

As this is a feasibility study and the majority of our outcomes are summarized, there is no appropriate power calculation to determine sample size. In our previous study of pre- and post-SDM knowledge, we found an improvement in overall understanding of possible harms of lung cancer screening from 69% to 93% in a group of 45 patients (p=0.002), and relatively few patients would need to be enrolled to demonstrate that magnitude of change. However, because we are interested in a robust sample to assess the other outcomes, we plan to enroll at least 50 patients into the SDM intervention. We will then sample patients for interviews until thematic saturation on acceptability and appropriateness are reached.

3.2.6. Data Collection and Analysis

Pre-/post-SDM survey data will be collected via tablet, with a paper option if desired. Participants will directly enter data into secure Research Electronic Data Capture (REDCap, Vanderbilt University) software. All interviews will be recorded and transcribed. Key outcomes are described above. Pre- and post-intervention LKS responses will be compared via Chochran-Mantel-Haenszel or Friedman test based on data type. A Chochran-Mantel-Haenszel test will be used with categorical data and a Friedman test will be used with non-categorical data. The DCS will be summarized as the median of scores for participants from 0 (extreme certainty) to 100 (extreme uncertainty). The IAM and AIM will also be summarized and presented as range of scores from 1 (low acceptability/appropriateness) to 5 (high acceptability/appropriateness). Fidelity will be summarized as median percent of checklist items completed. Joint displays consistent with a mixed-methods convergent design will be used to analyze and interpret the data, with themes mapped onto the TICD as in Aim 1.[39]

3.2.7. Reimbursement

Study participants in the shared decision making visit will receive $40 and parking reimbursement as needed. Patients participating in post- interviews will receive $20 and parking reimbursement as needed. Nurse practitioner(s) will receive a $10 gift card for completing the post- interview.

4. Study Administration

4.1. Data Collection and Management

Aim 1: All brief demographic surveys will be conducted over the phone and entered into REDCap software (UW ITHS) by RC. All focus groups will be audiotaped and then transcribed into word by Collaborative Data Services. These will be stored on the FH secure J: drive folder only accessible to study personnel.
Aim 2: As above, pre/post survey data will be collected via tablet and administered by RC. If directly patient entered into tablet will be on REDCap form. If preferred to be done by paper will be transcribed into REDCap by the RC. All interview transcriptions will be done in Word and

also maintained in J-drive folder. Data collected from the EHR will be transcribed by RC and maintained on REDCap.

4.2. Confidentiality

All data and records generated during the study will be kept confidential in accordance with FHCRC policies and HIPAA subject privacy. The investigator and other study team members will not use such data and records for any purpose other than conducting the study. All data will be maintained on secure REDCap software or J-drive as above.

4.3. Regulatory and Ethical Considerations

4.3.1. Risk Assessment

This study poses minimal risks to the subjects. The main risks are breach of privacy and confidentiality. This study involves: self-report of demographic data, participation in recorded focus groups, survey and interview data and limited permission to review EHR relevant to patient's comorbidity burden and life expectancy, and lung cancer screening. Data will be kept on password-protected REDCap or in secure location as above, and spreadsheets maintained in password-protected server on password-protected computer. All participants will be assigned a study ID and only a single linkage spreadsheet containing MRN and birthdate will be maintained in a separate location.

4.3.2. Potential Benefits of Study Participations

The main benefit to study participants will be in the form of quality improvement in the UW lung cancer screening program and improve the LCS process for PWH which can directly benefit these patients and providers. Participants in Aim 2 will also be enrolled into the LCS program should they agree and be eligible.

4.3.3. Risk-Benefit Assessment

The potential benefits to the screening program, the subjects and future patients being screening both within and outside of the UW outweighs the minimal risk.

4.4. Informed Consent and HIPAA Authorization

A waiver of documentation of consent has been approved, as of 2/3/2021, for patients and providers in Aim 1. As above, written informed consent will be obtained for each SDM study participant in Aim 2. A HIPAA authorization will be required for these subjects participating in Aim 2 SDM given limited review of the participants EHR. A HIPAA waiver has been requested for limited review of participants EHR, prior to formal consent/HIPAA authorization, specific to creation of tailored SDM tool. A waiver of documentation of consent has been requested for remote delivery of Aim 2 post- interview participants.

5. Safety Management

5.1. Clinical Adverse Events

Unanticipated problems involving risks to subjects and others will be monitored throughout the study, specifically breaches of confidentiality.

5.2. Adverse Events Reporting

No significant adverse events are expected as the study procedures are not greater than minimal risk. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of the study, these will be reported to the IRB.

6. Publication

The results from this investigation will be presented at national conferences and published in peer-reviewed medical journals.

7. References

1. Engels EA, Yanik EL, Wheeler W, et al. Cancer-Attributable Mortality Among People With Treated Human Immunodeficiency Virus Infection in North America. Clin Infect Dis 2017;65:636-43.
2. Shiels MS, Islam JY, Rosenberg PS, Hall HI, Jacobson E, Engels EA. Projected Cancer Incidence Rates and Burden of Incident Cancer Cases in HIV-Infected Adults in the United States Through 2030. Ann Intern Med 2018;168:866-73.
3. Silverberg MJ, Lau B, Achenbach CJ, et al. Cumulative Incidence of Cancer Among Persons With HIV in North America: A Cohort Study. Ann Intern Med 2015;163:507-18.
4. Mdodo R, Frazier EL, Dube SR, et al. Cigarette smoking prevalence among adults with HIV compared with the general adult population in the United States: cross-sectional surveys. Ann Intern Med 2015;162:335-44.
5. Sigel K, Wisnivesky J, Gordon K, et al. HIV as an independent risk factor for incident lung cancer. AIDS (London, England) 2012;26:1017-25.
6. Kesselring A, Gras L, Smit C, et al. Immunodeficiency as a risk factor for non-AIDS-defining malignancies in HIV-1-infected patients receiving combination antiretroviral therapy. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America 2011;52:1458-65.
7. Marcus JL, Chao C, Leyden WA, et al. Survival among HIV-Infected and HIV-Uninfected Individuals with Common Non-AIDS-Defining Cancers. Cancer epidemiology, biomarkers & prevention : a publication of the American Association for Cancer Research, cosponsored by the American Society of Preventive Oncology 2015;24:1167-73.
8. Suneja G, Shiels MS, Angulo R, et al. Cancer treatment disparities in HIV-infected individuals in the United States. Journal of clinical oncology : official journal of the American Society of Clinical Oncology 2014;32:2344-50.
9. Coghill AE, Shiels MS, Suneja G, Engels EA. Elevated Cancer-Specific Mortality Among HIV-Infected Patients in the United States. Journal of clinical oncology : official journal of the American Society of Clinical Oncology 2015;33:2376-83.
10. National Lung Screening Trial Research T, Aberle DR, Adams AM, et al. Reduced lung-cancer mortality with low-dose computed tomographic screening. The New England journal of medicine 2011;365:395-409.
11. de Koning HJ, van der Aalst CM, de Jong PA, et al. Reduced Lung-Cancer Mortality with Volume CT Screening in a Randomized Trial. N Engl J Med 2020;382:503-13.

12. Moyer VA, Force USPST. Screening for lung cancer: U.S. Preventive Services Task Force recommendation statement. Annals of Internal Medicine 2014;160:330-8.
13. Centers for M, Medicaid S. Decision Memo for Screening for Lung Cancer with Low Dose Computer Tomography. 2016.
14. Wood DE, Kazerooni E, Baum SL, et al. Lung cancer screening, version 1.2015: featured updates to the NCCN guidelines. Journal of the National Comprehensive Cancer Network : JNCCN 2015;13:23-34; quiz
15. Hulbert A, Hooker CM, Keruly JC, et al. Prospective CT screening for lung cancer in a high-risk population: HIV-positive smokers. Journal of thoracic oncology : official publication of the International Association for the Study of Lung Cancer 2014;9:752-9.
16. Makinson A, Eymard-Duvernay S, Raffi F, et al. Feasibility and efficacy of early lung cancer diagnosis with chest computed tomography in HIV-infected smokers. AIDS (London, England) 2016;30:573-82.
17. Sigel K, Wisnivesky J, Shahrir S, et al. Findings in asymptomatic HIV-infected patients undergoing chest computed tomography testing: implications for lung cancer screening. AIDS (London, England) 2014;28:1007-14.
18. Sigel K, Wisnivesky J, Kong C, et al. Frequency of complications after lung biopsy in HIV-infected compared to HIV-uninfected patients: Implications for lung cancer screening. American Thoracic Society International Conference 2015.
19. Kong CY, Sigel K, Criss SD, et al. Benefits and harms of lung cancer screening in HIV-infected individuals with CD4+ cell count at least 500 cells/mul. Aids 2018;32:1333-42.
20. Rivera MP, Tanner NT, Silvestri GA, et al. Incorporating Coexisting Chronic Illness into Decisions about Patient Selection for Lung Cancer Screening. An Official American Thoracic Society Research Statement. Am J Respir Crit Care Med 2018;198:e3-e13.
21. Braithwaite RS, Concato J, Chang CC, Roberts MS, Justice AC. A framework for tailoring clinical guidelines to comorbidity at the point of care. Arch Intern Med 2007;167:2361-5.
22. Braithwaite RS, Fiellin D, Justice AC. The payoff time: a flexible framework to help clinicians decide when patients with comorbid disease are not likely to benefit from practice guidelines. Med Care 2009;47:610-7.
23. Gross CP, Soulos PR, Ross JS, et al. Assessing the impact of screening colonoscopy on mortality in the medicare population. J Gen Intern Med 2011;26:1441-9.
24. Kovalchik SA, Tammemagi M, Berg CD, et al. Targeting of low-dose CT screening according to the risk of lung-cancer death. N Engl J Med 2013;369:245-54.
25. Rivera MP, Tanner NT, Silvestri GA, et al. Incorporating Coexisting Chronic Illness into Decisions about Patient Selection for Lung Cancer Screening. An Official American Thoracic Society Research Statement. Am J Respir Crit Care Med 2018;198:e3-e13.
26. Tanner NT, Dai L, Bade BC, Gebregziabher M, Silvestri GA. Assessing the Generalizability of the National Lung Screening Trial: Comparison of Patients with Stage 1 Disease. Am J Respir Crit Care Med 2017;196:602-8.
27. Elwyn G, Frosch D, Thomson R, et al. Shared decision making: a model for clinical practice. J Gen Intern Med 2012;27:1361-7.
28. Elwyn G, Laitner S, Coulter A, Walker E, Watson P, Thomson R. Implementing shared decision making in the NHS. Bmj 2010;341:c5146.

29. Caverly TJ, Cao P, Hayward RA, Meza R. Identifying Patients for Whom Lung Cancer Screening Is Preference-Sensitive: A Microsimulation Study. Ann Intern Med 2018;169:1-9.
30. Flottorp SA, Oxman AD, Krause J, et al. A checklist for identifying determinants of practice: a systematic review and synthesis of frameworks and taxonomies of factors that prevent or enable improvements in healthcare professional practice. Implement Sci 2013;8:35.
31. Lau YK, Caverly TJ, Cao P, et al. Evaluation of a Personalized, Web-Based Decision Aid for Lung Cancer Screening. Am J Prev Med 2015;49:e125-9.
32. Tate JP, Sterne JAC, Justice AC. Albumin, white blood cell count, and body mass index improve discrimination of mortality in HIV-positive individuals. Aids 2019;33:903-12.
33. Simard M, Sirois C, Candas B. Validation of the Combined Comorbidity Index of Charlson and Elixhauser to Predict 30-Day Mortality Across ICD-9 and ICD-10. Med Care 2018;56:441-7.
34. Morgan D. Focus groups as qualitative research (2nd ed.). Thousand Oaks, CA: Sage; 1997.
35. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Med Res Methodol 2013;13:117.
36. Crothers K, Kross EK, Reisch LM, et al. Patients' Attitudes Regarding Lung Cancer Screening and Decision Aids. A Survey and Focus Group Study. Ann Am Thorac Soc 2016;13:1992-2001.
37. User manual decisional conflict scale. 2005. (Accessed March 1, 2020, at https://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Decisional_Conflict.pdf.)
38. Weiner BJ, Lewis CC, Stanick C, et al. Psychometric assessment of three newly developed implementation outcome measures. Implement Sci 2017;12:108.
39. Guetterman TC, Fetters MD, Creswell JW. Integrating Quantitative and Qualitative Results in Health Science Mixed Methods Research Through Joint Displays. Ann Fam Med 2015;13:554-61.
40. Scherer LD, Caverly TJ, Burke J, Zikmund-Fisher BJ, Kullgren JT, Steinley D, McCarthy DM, Roney M, Fagerlin A. Development of the Medical Maximizer-Minimizer Scale. Health Psychol. 2016 Nov;35(11):1276-1287.