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PART B
STUDY DESCRIPTION

TITLE OF PROTOCOL	**Discussions of Prognosis and Stopping Cancer Screening in Older Adults**
Principal Investigator	**Mara A. Schonberg, MD, MPH**

B1. PURPOSE OF PROTOCOL

Adults >75 years are the fastest growing segment of the US population and cancer incidence increases with age.[1, 2] However, it is not known if cancer screening benefits adults >75 years since few have participated in cancer screening trials. For breast and colon cancer, it is estimated that 1,000 older adults need to be screened for these cancers for one to avoid breast or colon cancer death in 10 years.[3] Due to this 10-year lag-time to benefit, guidelines recommend that adults with <10 year life expectancy not be screened for these cancers.[4-7] The rationale is that these patients will not live long enough to experience the life-prolonging benefits of cancer screening. Instead, screening these patients only puts them at risk of the harms of cancer screening which include anxiety resulting from false positive tests, overdiagnosis (detection of tumors that are of no threat), and complications from work-up and/or treatment of cancer.[8] Despite these guidelines, 40-50% of US women ≥75 years with <10 year life expectancy undergo screening for breast cancer with mammography and 51% of US adults with <10 year life expectancy undergo colorectal cancer screening.[9-12] Reasons that so many older adults with short life expectancies are screened include habit, lack of knowledge or understanding of the risks of screening, and concerns about cancer.[13-17] Also, system-wide programs designed to boost screening rates in younger and healthier patients have been shown to lead to inappropriate screening of older adults in poor health.[18, 19] In our current system, older adults report that undergoing cancer screening is really not a decision but rather a moral obligation while deciding to stop being screened is a major health event.[20]

A physician's recommendation is one of the strongest drivers of whether or not an older adult is screened for cancer.[14, 21, 22] However, primary care physicians and/or nurse practitioners (herein referred to as primary care providers, PCPs) report feeling uncomfortable and ill prepared to talk to older adults about stopping cancer screening.[14, 20] Implicit in these discussions is an assessment of patient life expectancy. However, PCPs report discomfort estimating and discussing patient life expectancy and avoid these discussions.[14] By avoiding these discussions, PCPs may be undermining their patients' ability to make informed decisions around cancer screening.[23] As a result many older adults are being diagnosed and treated for cancers that never otherwise would have caused problems or symptoms in their lives. This is particularly concerning since the risks of work-up and treatment for cancer rise with age and increasing frailty.[24-26] To help PCPs estimate patient life expectancy, Dr. Schonberg (PI of this proposal) previously developed and validated an index to predict mortality within 10 years among adults ≥65 years.[27, 28] This index and other validated mortality indices are available at ePrognosis.org. However such tools do not give PCPs information on how to approach and discuss prognosis with older adults when recommending stopping cancer screening. Such discussions could provide a unique opportunity for PCPs to inform older adults of their prognosis and could trigger PCPs to begin the process of helping older adults think about their values and goals of care as they approach the end of life. However, this opportunity is often missed because PCPs find these conversations challenging. Therefore, we aim to use qualitative interviews to learn from PCPs and adults 76-89 years with approximately 5-10 year life expectancy their thoughts, preferences, and suggestions for how PCPs should discuss their overall prognosis when recommending stopping cancer screening. We will use these data to develop strategies and guiding principles for PCPs to use for having these discussions, and we will draft scripts to suggest language for PCPs to use to discuss prognosis when recommending stopping cancer screening. We will then provide 45 PCPs with the drafted scripts and prognostic information for 1-3 of their patients (goal to recruit 100 adults aged 76-89 years) before a clinic visit to learn if this information is useful to PCPs and older adults. Our specific aims are:

Aim 1: To learn from PCPs and older adults about how to discuss patient prognosis when recommending stopping cancer screening and to develop strategies for having these

discussions.

Aim 2: To study whether providing information on patient prognosis and scripts for discussing patient prognosis when recommending stopping cancer screening are useful to PCPs and older adults.

Impact: Due to a shift towards population management in health care, multi-level programs are increasingly being implemented to facilitate cancer screening for patients.[29] In addition, public health messages about cancer screening tend to be uniformly positive.[30, 31] Therefore, a PCP must often communicate to older adults with short life expectancy when it may be time to stop being screened for cancer to prevent these patients from being exposed to screening. Since weighing the benefits and risks of cancer screening with older adults requires consideration of patient life expectancy; ideally, PCPs would have sensitive tools for communicating patient life expectancy available for these discussions. Therefore, we will develop strategies for these discussions as part of this proposal. Providing older adults with information about their prognosis may allow older adults to make more informed decisions around cancer screening and possibly more informed medical decisions in general. Understanding their prognosis may help older adults with short life expectancy avoid medical interventions with a long lag-time to benefit that may only cause harm.

B2. SIGNIFICANCE AND BACKGROUND FOR THE STUDY

Overview: The American Cancer Society and the American Board of Internal Medicine Choosing Wisely Campaign recommend clinicians not screen older adults who have <10 year life expectancy for breast (specific to women) or colorectal cancer (CRC).[5-7] This is because these patients have little chance of experiencing the life prolonging benefits of cancer screening and instead may only experience harm from being screened. The most concerning harm of cancer screening is overdiagnosis - the diagnosis and treatment of cancers that otherwise would not have caused problems in an older adult's lifetime.[8] Despite this, around half of adults $\geq$75 years with <10 year life expectancy are regularly screened for cancer.[9-11, 32] One reason for the overuse of these tests is that PCPs feel uncomfortable discussing stopping screening with older adults since it requires estimating and discussing patient prognosis. Some PCPs admit to recommending cancer screening to older adults with short life expectancy simply to avoid talking to patients about prognosis.[14] However, by avoiding these discussions, PCPs may be impeding older adults' ability to make informed decisions about their care and may be putting patients at risk of the harms of cancer screening without any chance of benefit. Therefore, we aim to interview PCPs and older adults about their thoughts and feelings on how PCPs may discuss older adults' prognosis in the context of talking about stopping cancer screening. Based on our findings, we will develop strategies for PCPs to use to approach these discussions and we will draft scripts to suggest language for PCPs to use when communicating about prognosis when recommending stopping cancer screening. Then, we will study if providing PCPs with these scripts and information about their patients' prognosis is useful. Specifically, we will provide 45 PCPs with information about their patients' prognosis and the example scripts before a clinic visit for up to 3 of their patients (goal to recruit 100 patients with approximately 5-10 year life expectancy). We will then interview PCPs and older adults after these visits to learn how and/or if the prognostic information and the scripts were used. These data are essential for improving the quality of PCP discussions around stopping cancer screening and will ultimately improve the care of older adults.

B.1. The need to talk to older adults about discontinuing cancer screening: In an era of pay for performance and population management, PCPs must increasingly meet higher and higher targets for age-appropriate cancer screening to achieve payment incentives.[33, 34] As a result, healthcare systems are increasingly implementing programs to make getting screened for cancer as easy as possible (e.g., walk-in mammograms).[35, 36] In addition, ubiquitous pro-screening public health messaging campaigns have led to significant public enthusiasm for cancer screening and the Affordable Care Act provides coverage for breast and CRC screening for all older adults regardless of their health or life expectancy.[37] Therefore, to prevent older adults with <10 year life expectancy from being screened for cancer, PCPs must generally talk to older adults about the need to stop being screened. However, these conversations are notoriously difficult because they require consideration

and often discussion of patient life expectancy.[38] PCPs find prognostication difficult and feel poorly trained and ill-equipped to discuss prognosis with patients.[39-41] PCPs worry that communicating prognosis to older adults with <10 year life expectancy may result in a loss of trust and negatively affect the physician-patient relationship.[14, 20] Not surprisingly, few (<5%) older adults report that they have discussed stopping screening with their physicians.[42, 43] Also, few think about stopping screening on their own;[20, 44] only 8.2% of US adults >70 years reported that they had plans to stop undergoing CRC screening and only 5.7% of US women >70 years had plans to stop undergoing mammography screening.[45] Thus, there is significant need for strategies for PCPs to use to discuss patient prognosis when talking about stopping cancer screening.

B.2. Older adults' interest in prognosis: Studies of older adults with terminal illness have found that the majority want to discuss their life expectancy with their clinicians.[40, 44, 46, 47] However, less is known about preferences for prognostic information among older adults who have approximately 5-10 year life expectancy. In a study of 116 relatively healthy adults >70 years living in two North Carolina independent living facilities, 66% reported that they would want their physicians to discuss their life expectancy, even when they understood their physicians' estimates may be inaccurate.[48] However, fewer (52%) wanted their doctor to discuss their life expectancy when making cancer screening decisions, possibly because 62% did not see how their doctor's life expectancy estimate was important in this decision and many felt that they should be screened for cancer as long as they live.[13, 48] Three other studies asked older adults in a general setting (rather than in the context of a specific disease) whether they would want to discuss their prognosis with their clinicians. In these studies around 60% of older adults reported that they would like this information and the proportion increased as perceived life expectancy declined.[40, 44, 46] Older adults felt prognostic information would be helpful in planning for their future, for maintaining open communication with their physicians, and for medical decision-making.[44, 48] However, older adults who did not want prognostic information felt it could affect their will to live.[48] Therefore, we will develop strategies to discuss stopping cancer screening with older adults sensitive to their interest in prognostic information.[40] Reassuringly, studies of patients at the end-of-life, have found that patients are not harmed by talking with their physicians about their prognosis.[40, 49, 50]

B.3. Estimating prognosis: Several tools are available to help PCPs estimate older adults' prognosis. The Lee-Schonberg index (available at www.ePrognosis.org) considers a patient's age, sex, body mass index, function, mobility, history of cancer, diabetes, emphysema, heart failure and smoking, hospitalizations in the past year, and perceived health.[27, 28, 51, 52] Adults with >50% risk of mortality within 10 years based on their health score are considered to have an estimated life expectancy <10 years.[53] In addition, Walter and Covinsky used data from 1997 US life tables (recently updated using 2008 data)[8] to calculate the upper, middle and lower quartiles of life expectancy for US adults ≥70 year stratified by sex and age.[54] They recommended that clinicians estimate whether a patient is in the top, middle, or lower quartile of health for his/her age group and then refer to the stratified life tables to obtain an estimate of patient life expectancy. For example, for a 75 year old woman in poor health, her PCP would use the life expectancy information for 75 year old women in the lowest quartile). It is not known if PCPs are using these tools to estimate and/or discuss older adults' life expectancy when recommending stopping cancer screening. Drs. Schonberg and Smith (co-I) and their colleagues examined use of the prognostic indices on ePrognosis based on the website's first 4,426 visits.[55] The majority (86%) of visits were by clinicians; 91% reported that the calculator used was useful and 47% reported that the calculated prognosis affected decision-making.[55] No further data on how prognosis was helpful or affected decision-making were available. Therefore, as part of this proposal, we aim to learn whether PCPs find the prognostic indices useful when recommending stopping cancer screening to older adults.

B.4. Communication about Prognosis: In "Dying in America," the Institute of Medicine highlighted the need for patients to understand their prognosis for high quality medical decision-making.[56] However, discussing prognosis with patients is challenging and stressful.[41, 57] Communication about prognosis has been primarily studied between oncologists and patients with cancer[58-63] or among clinicians caring for adults with other terminal illnesses (e.g., congestive heart failure),[40] and not in scenarios typically encountered in primary care (e.g., when discussing stopping cancer screening). In oncology, clinicians are encouraged to prepare for end-of-life discussions by establishing what the

patient (and family) knows about their prognosis, determining how information is to be handled (e.g., how much the patient wants to know about their prognosis and readiness to engage in the discussion), delivering the information clearly, responding to emotion, establishing goals of care and treatment priorities, and establishing a plan.[58, 64-69] These same principles will likely be useful to PCPs when discussing prognosis when recommending discontinuing cancer screening; however, this has not been studied. Also, whether there may be differences in how prognosis should be discussed at the end-of-life versus when a patient has 5 to 10 year life expectancy is not known. With guidelines increasingly recommending PCPs consider patient life expectancy when deciding whether or not to recommend different medical interventions to older adults, data to inform PCP communication about older adults' prognosis are essential.[66]

Summary: Guidelines encouraging clinicians not to screen older adults with <10 year life expectancy for cancer may be unrealistic if PCPs cannot talk to older adults about the fact that they have <10 year life expectancy.[6] Therefore, it is essential that we learn from PCPs and older adults thoughtful strategies for PCPs to communicate prognosis in these settings. Although prognosis is a sensitive topic, we suspect that similar to oncology, PCPs that master the art of discussing prognosis with older adults will likely have more satisfied and trusting patients and may help their patients receive higher quality care and better outcomes.[70]

B3. DESCRIPTION OF RESEARCH PROTOCOL

A. Study Design – Overview, Methods, Procedures

APPROACH

Overview: In Aim 1, we will conduct at least five focus groups with PCPs and 8 individual interviews to learn their thoughts, attitudes, and experiences with discussing and estimating older adults' prognosis when recommending stopping cancer screening. In addition, we will conduct 30 semi-structured qualitative interviews with adults 76-89 years with approximately 5-10 year life expectancy to learn their thoughts, feelings, and experiences with respect to discussing their prognosis with their PCPs. In addition, we will attempt to interview 5 financial planners and 5 members of the clergy to learn their approach to talking about life expectancy with older adults and the language that they use. We will use data gleaned from these interviews to develop strategies and guiding principles for PCPs to discuss prognosis with their patients when discussing stopping cancer screening and we will draft scripts to suggest language for PCPs to use when having these discussions. Focus groups will be held in an available conference room at BIDMC. Individual interviews will be held in a place that is convenient for the individual, such as available conference room, private office, or private clinic space at BIDMC, or at the patient's home or other private space. In Aim 2, we will learn if PCPs find the scripts and information on their patients' prognosis useful. We will give 45 PCPs (23 community-based) the scripts and patient prognostic information (using the Lee/Schonberg index and the Walter et al. life expectancy tables) on 1-3 of their patients (goal to recruit 100 patients overall). We will interview PCPs after each patient visit to learn if they found the prognostic information helpful and for feedback on the scripts. We will interview patients after each visit to learn from their perspective if their PCP discussed their prognosis and/or stopping cancer screening and to learn patients' thoughts on these discussions. We will also review the PCP note from the visit to learn if any discussion about prognosis or cancer screening was documented. These data are needed to help PCPs feel prepared to discuss stopping cancer screening and patient prognosis with older adults with <10 year life expectancy.

Aim 1- To learn from PCPs and older adults about how to discuss patient prognosis when recommending stopping cancer screening and to develop strategies for having these discussions. Since qualitative research is well-suited to harvest personal perceptions regarding the complexities of a topic and to understand processes, we will conduct 5 focus groups with PCPs and 8 individual interviews to learn their thoughts, experiences, and suggestions for discussing older adults' prognosis when recommending stopping cancer screening. We will also conduct 30 (15 with women) individual interviews with adults aged 76-89 with approximately 5-10 year life expectancy on their thoughts, experiences, and attitudes about discussing prognosis with their PCP. We chose to conduct focus groups with PCPs because we are interested in the exchange of ideas that may be generated by PCPs in a focus group. We chose to conduct individual interviews with patients because this topic may be sensitive to patients and it may be difficult for some older adults with health problems to arrange to come to the medical center for a focus group.

We also plan to interview financial planners and members of the clergy to learn how they approach discussing life expectancy with older adults to see if their experiences may inform PCPs' approach to these discussions.

PCP Eligibility and Recruitment: We will recruit PCPs from Beth Israel Deaconess Medical Center's (BIDMC's) academic internal medicine practice HealthCare Associates (HCA), BIDMC Senior Health (BIDMC's geriatrics practice), and from up to 16 community Boston area primary care practices that are part of BIDMC's Affiliated Physicians Group (APG). Dr. Schonberg has previously recruited patients and PCPs from these practices. Non-resident physicians and nurse practitioners that care for a patient panel that includes adults $\geq$75 years will be eligible to participate. We plan to conduct 5 PCP focus groups with 6-8 PCPs per focus group (6-8 PCPs per focus group will allow for optimal group interaction while leaving enough time for all participants to express their views).[71]. We will attempt to conduct focus groups at a convenient time for PCPs (e.g., at a time that is periodically reserved for faculty meetings but when a faculty meeting is not scheduled). Although participants in PCP focus groups will likely know one another, group compatibility has been shown to promote cohesiveness and the group's effectiveness to discuss a topic.[72] We will provide a meal at each focus group and $50 incentive. Dr. Schonberg will invite PCPs to participate through individual emails and in person presentations. PCPs will complete written informed consent. We aim to recruit 50 of 253 possible PCPs to participate (see Table 1 for the number of patients and PCPs at each site).

Table 1: Sites (2014 numbers)	76-89 years male	76-89 years Female	Total (% non-Hispanic white)	MDs	Nurse Practitioners	Total
BIDMC HealthCare Associates -HCA)	739	941	**1680 (73%)**	64	7	**71**
BIDMC Senior Health	66	199	**265 (86%)**	5	1	**6**
Community practices (APG)[a]	1074	1483	**2557 (82%)**	62	12	**74**
Total	**1,879 (42%)**	**2,623 (58%)**	**4,502 (81%)**	**131**	**20**	**151**

Patient Eligibility: To target patients with 5-10 year life expectancy and for whom a discussion about stopping screening would be appropriate, we will recruit patients aged 76-79 with at least one Charlson Comorbidity (e.g., diabetes)[73] and all patients 80-89 years that meet eligibility criteria. Since the average life expectancy of a 75 year old man is 11.0 years and a 75 year old woman is 12.9 years,[74] by necessitating that a patient 76-79 years has a significant health condition we will increase the likelihood that study participants will have >50% chance of mortality in 10 years using the Schonberg-Lee index.[75] We chose to limit our sample to patients 76-89 years because regardless of life expectancy the USPSTF does not recommend breast or CRC screening for adults >75 years and a discussion about stopping cancer screening would be appropriate for these patients. Although approximately 20% of adults 65-75 years also have <10 year life expectancy, some PCPs may feel uncomfortable recommending stopping screening to these patients since guidelines vary for these patients.[4, 5, 76] However, we anticipate that the strategies we develop for PCPs to use with patients 76-89 years will extrapolate to younger patients with short life expectancy. To target patients who have been engaged in cancer screening, we will include women who have undergone mammography screening in the past 3 years and women and men that have undergone CRC screening in the past 10 years but for whom there is no documentation in the screening sheet or problem list that the patient has chosen to stop being screened for cancer. We will exclude patients with a history of breast and/or colon cancer; patients whose last colonoscopy showed adenomatous polyps; and women whose last mammogram was read as abnormal since screening decisions may differ for these individuals. To further exclude patients who have already decided to stop being screened, we will ask patients their intentions of being screened for breast (women only) or CRC cancer using a validated measure (scored from 1-15), and we will exclude those who score 11-15 (leaning towards not being screened) for both cancers (women) or CRC cancer (men).. We will also exclude patients who do not speak English, are in hospice, do not have capacity to participate, have a history of dementia or score $\geq$10 (indicative of dementia) on the Orientation-Memory-Concentration (OMC) test[77, 78](see Appendix A1-eligibility questionnaire). We are excluding patients with dementia because we are interested in learning from patients how their PCP may talk to them about their prognosis. In the future, we will use what we learn to develop strategies for PCPs to discuss prognosis with older adults with dementia and their proxies and among non-English speakers. Since on average adults $\geq$90 years have <5 year life expectancy[79] and since dementia is common (36%) we will exclude adults $\geq$90 years.[80] We will target a sample that is 50% female and socioeconomically diverse.

Patient Recruitment: Through a HIPAA waiver, we will have a data manager provide a list of all patients aged 76-89 seen at each site. We will randomize these lists stratified by race and sex. We will review patient records sequentially to find patients that meet our eligibility criteria. We will email the PCPs of potentially eligible patients to ask permission to contact their patients. We will send patients approved by their PCPs an informational letter about the study that will include a number to call if patients want to opt-out of being contacted (more details are in Human Subjects). After one week, we will call patients that do not opt-out to tell them more about the study and to see if they are willing to participate. If a patient is willing and eligible to participate, we will schedule to meet him/her at a time and place that is convenient for the patient. We will obtain written informed consent. If a patient would like a family member to be present at the individual interview, we will also obtain written informed consent from the family member. We will offer participants $25 incentive.

Financial Planner/Clergy Eligibility and Recruitment: Through email, we will reach out to financial planners and members of the clegy in the Boston area to see if they are interested and willing to participate. We will provide financial planners and members of the clergy a $50 incentive for participating. Financial planners/clergy will complete written informed consent. We aim to recruit 5 financial planners and 5clergy to participate.

Data collection (draft interview guides are in Appendix A4): A research assistant (RA) with graduate training and experience in qualitative research methods will conduct the focus groups and individual interviews. The RA will also record reasons patients or PCPs were excluded or chose not to participate in aims 1 or 2.

PCPs: After introducing the focus group/interview's purpose and structure, the RA will ask PCPs if they have talked to older adults about stopping cancer screening, how these conversations went, and whether they discussed patient prognosis during these discussions and if so what approach they used. The RA will ask PCPs about barriers and facilitators to these discussions. The RA will then show PCPs different methods for estimating prognosis (see Appendix 9a/b) to learn their thoughts on how they would like this information presented and how prognosis assessment could be implemented in practice. The RA will also give PCPs an example patient with <10 year life expectancy and will ask PCPs whether and how they would approach discussing stopping cancer screening and prognosis with the patient. Afterwards, the RA will show PCPs example scripts for discussing stopping mammography, CRC screening, and for explicitly discussing prognosis during these conversations. In preparation, we created outlines for these scripts (see Appendix B). Language for discussing stopping CRC screening may differ from discussing stopping mammography because risks of colonoscopy differ from mammography. We will revise the scripts iteratively throughout this study. We will also ask PCPs if they would recommend different strategies for discussing stopping other medical interventions and we will ask PCPs to complete a background questionnaire (Appendix A.3). At the end of each focus group, we will ask PCPs to let us know (through email or as part of an individual interview) if they have new thoughts or if they did not get to express a thought. In addition, we recognize physician presence could deter nurse practitioners (NPs) from speaking candidly. However, there are only 1-2 NPs at each community practice and it may be challenging to recruit NPs to an NP only focus group in the community. Therefore, we will conduct exit interviews with NPs where we will ask NPs their thoughts on these conversations specific to their role and we will ask NPs to share any thoughts that they did not get to express.

Financial Planners/Clergy:After introducing the interview's purpose and structure, the RA/Dr. Schonberg will ask these professionals if they have talked to older adults about their prognosis. If so, we will ask these professionals how they approach these discussions, what makes them easier and what makes them more challenging and what language that they use. We will specifically ask financial planners what tools they use to estimate older adults life expectancy.

Patients: After explaining the structure and purpose of the interview, the RA will first ask patients to describe whether their PCP has talked to them about stopping cancer screening and if so how the conversation went. The RA will also ask patients whether their PCP or another clinician has talked to them about their prognosis. The RA will then explain that there is a lag-time to benefitting from cancer screening; therefore, experts recommend PCPs consider patient prognosis when deciding on cancer screening for older adults (using simpler language). The RA will explain that researchers are interested in their thoughts on how they would want their PCP to talk to them about their prognosis in this setting. The RA will also ask patients for feedback on the example scripts for PCPs to use to discuss stopping cancer screening and long-term prognosis with older adults. In addition, the RA will also give each participant a background questionnaire (Appendix A.2) to complete. Data will be entered as it is collected via computer into REDCap (a secure web-based research tool for data collection).[81] The RA will arrange a time to complete the background questionnaire in private with participants that prefer to have it administered to them.

Developing Scripts: Based on the strategies identified and the specific language and framing of the issues provided by patients, PCPs, and financial planners/clergy we will develop at least 2 scripts (one for each cancer type) for PCPs to use when recommending stopping cancer screening to older adults. Similar to conversation guides developed for discussing prognosis at the end of life,[49] our scripts will provide guidance for framing the conversation and example language to use when discussing stopping cancer screening. We will create a first draft of the scripts after the first few focus groups and interviews so that we may ask subsequent participants to provide feedback.

Sample Size: In qualitative research, sampling until the point of redundancy or thematic saturation is an accepted point to stop sampling subjects.[82, 83] Research suggests that on average thematic saturation is achieved after 25-30 individual interviews[44,45] and primary care based qualitative studies tend to include around 30 participants (in focus groups or individual interviews).[14, 84-88] Experts recommend a minimum of 4 focus groups with 6-8 participants each, with at least 2 focus groups per stratum, to reach saturation in studies where focus groups are the sole means of data collection.[71] Therefore, we plan to conduct 5 PCP focus groups (at least 2 at each practice setting [academic/community]) that include 6-8 PCPs each and we plan to conduct 8

individual interviews with PCPs unable to participate in a focus group. We plan to conduct 5 interviews with financial planners and 5 with members of the clergy. We also plan to conduct 30 individual patient interviews with adults aged 76-89 years (15 with women and 15 seen in the community).[89] If new themes emerge during the last scheduled interviews we will conduct additional interviews until no new themes emerge.[89] We aim to recruit 50 PCPs, 5 financial planners, 5 members of the clergy and 30 patients 76-89 years.

Aim 2- To study if providing information on patient prognosis and example scripts for discussing patient prognosis when recommending stopping cancer screening is useful to PCPs and older adults.
PCP recruitment: We will recruit PCPs from the same practices and using the same methods as in Aim 1. PCPs that participate in Aim 1 will be permitted to participate in Aim 2 since we will now be obtaining data from PCPs based on their experience at the point of care. We will explain to PCPs that we are interested in learning strategies for talking to older adults about stopping cancer screening and that we will attempt to recruit up to 5 of their patients to participate. Once one of their patients agrees to participate, we will send the PCP via secure email the patient's prognosis calculated by the Lee-Schonberg index three days before the patient visit. We will also send PCPs information on patient life expectancy from Cho et al.'s US life tables (see Appendix A9 for an example). [75]In addition, we will send PCPs the scripts we develop in Aim 1 on how to sensitively include information on patient prognosis when recommending patients stop being screened for cancer. After three of their patients have participated or once we meet our recruitment goals, we will ask PCPs to complete a 10 minute web-based questionnaire about their experience (details below).. We will also offer PCPs to complete questionnaires in person or over the phone if they prefer. We will provide PCPs a $75 incentive. We aim to have 45 PCPs (1/3 community-based) participate.

Patient recruitment: Patient eligibility criteria and recruitment methods are the same as in Aim 1 except we will only recruit patients with a routine visit scheduled in the next 3-12 weeks with a participating PCP. We will obtain verbal rather than written consent for Aim 2 because we do not plan to audiotape interviews. Also, we will exclude patients that participated in Aim 1. Briefly, we will send patients deemed eligible by their PCP an informational letter about the study. The RA will call patients that do not opt-out of being contacted to reassess patient eligibility and willingness to participate. For patients willing and eligible to participate, the RA will schedule a time to administer the background questionnaire (Table 2 below) before the patient sees his/her PCP. Within 3 days of the PCP visit, the RA will administer a follow-up questionnaire. Patients will receive $25 incentive for participating. More details on patient recruitment for Aim 2 are in Human Subjects, section E.2.a.

Table 2: Data Collection	When	Content
Patient Background Questionnaire (Appendix A2)	RA administers before visit	Assesses: race/ethnicity, education, sociodemographics,[90] function,[91] life expectancy (Lee-Schonberg index),[28, 92] comorbidity,[73] family history of cancer, and intentions to be screened for breast (women only) and CRC cancer (all),[93] patient perceived trust in their PCP
Patient Follow-up Questionnaire (Appendix A6)	RA administers within 3 days of the visit	- Whether PCP talked about stopping cancer screening and/or patient life expectancy If so were they satisfied with the information, how did it make them feel, feedback? If not, would they want this information and suggestions for presenting prognosis
PCP questionnaire (Appendix A7)	Email after the visit	- Each time: whether prognostic information was useful, helpful, & feedback on scripts - First time: assess facilitators and barriers to discussing prognosis when discussing stopping screening; PCP race/ethnicity, gender, practice characteristics
Chart abstraction (Appendix A8)	After note is signed in chart	- Abstract text from note that refers to cancer screening and/or patient prognosis - Research team will review text to assess if stopping screening/prognosis discussed

Impact: PCPs need strategies for communicating prognosis to older adults with <10 years life expectancy so that patients have the information they need and desire to make informed, valued-based medical decisions.

B. Statistical Considerations

Aim 1:
Analyses: We will use several methods for addressing rigor in qualitative research.[72, 94] All interviews will be audio taped (using 2 audio recorders) and transcribed verbatim. Using thematic analysis,[30,33] our inter-disciplinary team (Drs. Schonberg, Smith, Hamel, and Park) will independently review transcripts from the first PCP and patient focus groups and the first three patient interviews to identify important concepts that emerge and to create a common codebook that will be used to code

additional interviews. Drs. Schonberg, Hamel, and Smith will code the remaining interviews and will meet bi-monthly to discuss how different codes are being interpreted and applied. The codebook will be revised as necessary to clarify codes, to add additional codes as themes emerge, to combine codes that do not offer a useful distinction, and to eliminate codes that are not useful. Disagreements about the meaning of codes will be resolved by consensus. Based on our analyses, we will modify the interview guides as needed to explore new areas of inquiry. We will analyze our data to see if different themes are noted by PCPs or patients from different practice settings and for differences by patient sex. We will also examine if different themes arise from PCP focus groups compared to PCP individual interviews. Once our data are coded by theme, the codes and associated passages will be entered into an NVivo qualitative analysis software database to search for patterns among themes. The themes will be used to develop strategies and guiding principles for PCPs to use for communicating prognosis when discussing stopping screening with older adults. To validate our interpretation, we will send at least 6 participants (3 that are PCPs) the revised scripts and themes from the qualitative interviews to allow them to make additional comments.

Dr. Shivani Jindal will help with reviewing the qualitative interviews to identify themes in the data regarding older adults and PCPs preferences regarding whether or not PCPs should discuss long-term prognosis with older adults.

Sample Size: In qualitative research, sampling until the point of redundancy or thematic saturation is an accepted point to stop sampling subjects.[82, 83] Research suggests that on average thematic saturation is achieved after 25-30 individual interviews[44,45] and primary care based qualitative studies tend to include around 30 participants (in focus groups or individual interviews).[14, 84-88] Experts recommend a minimum of 4 focus groups with 6-8 participants each, with at least 2 focus groups per stratum, to reach saturation in studies where focus groups are the sole means of data collection.[71] Therefore, we plan to conduct 5 PCP focus groups (at least 2 at each practice setting [academic/community]) that include 6-8 PCPs each and we plan to conduct 8 individual interviews with PCPs unable to participate in a focus group. We also plan to conduct 30 individual patient interviews with adults aged 76-89 years (15 with women and 15 seen in the community).[89] If new themes emerge during the last scheduled interviews we will conduct additional interviews until no new themes emerge.[89] We aim to recruit 50 PCPs, 5 financial planners/clerygy and 30 patients 76-89 years.

Aim 2:

Data analyses: Our study is descriptive and exploratory. Since we recruited 94 women ≥75 years from 46 PCPs in the first year of our DA trial, we feel our recruitment goals are feasible. We will report how many PCPs found prognostic information useful and helpful, and facilitators and barriers to using prognostic information when discussing stopping cancer screening. Using chi-square tests, we will examine if PCP experiences differ by their sex or practice site (BIDMC/APG). With 45 PCPs we will have limited power for these analyses; however, we will explore if there is a direction of effect. We will also report how many patients reported that their PCP discussed stopping cancer screening and/or their prognosis and patients' perceptions of these discussions. We will use chi-square statistics to examine if there are differences in patient preferences or experiences by their sex, age, or practice site. For example, with 100 patients and assuming that 50% are female (n=45), at an alpha of 0.05, we will have 0.81 power to detect a 28% difference in preferences for prognostic discussions by patient sex. While we will have limited power to detect small differences in patient characteristics around preferences for prognostic information, we will examine if there is a direction of effect. We will also examine if patients' intentions to be screened (measured on a validated 15 point scale)[95] change after seeing their PCP using the Wilcoxon Signed Rank Test. In our decision aid trial, we have recruited 196 women ≥75 years with <10 year life expectancy. At baseline, their mean intentions to be screened with mammography on the 15 point scale was 3.7 (+/-4.9), indicating that on average they were strongly leaning towards being screened. Therefore, if we assume in this study that we will have at least 40 female participants with compete data (accounts for 5 women missing data) and that the within pair correlation is as low as 0.1 (however, we expect a higher degree of correlation and therefore higher power), we will have 0.87 power to tell a difference in a mean score of 3.7 before the PCP visit and a mean score of 7 (being unsure about screening among participants on average) after

the PCP visit if the standard deviation is also 4.9. In sensitivity analyses, we will examine if there is a clustering effect by PCP. We anticipate greater power to examine differences in intentions to be screened for CRC since both sexes are screened for CRC.

C. Subject Selection

Patient Eligibility: To target patients with 5-10 year life expectancy and for whom a discussion about stopping screening would be appropriate, we will recruit patients aged 76-79 with at least one Charlson Comorbidity[73] and all patients 80-89 years that meet eligibility criteria. Charlson comorbidities include: myocardial infarction, congestive heart failure, peripheral vascular disease, cerebrovascular disease, emphysema/COPD, connective tissue disease, peptic ulcer disease, diabetes, hemiplegia, leukemia, malignant lymphoma, solid tumors, liver disease, chronic kidney disease, and HIV or AIDs.[73] Since the average life expectancy of a 75 year old man is 11.0 years and a 75 year old woman is 12.9 years,[74] by necessitating that a patient 76-79 years has a Charlson comorbidity we will increase the likelihood that study participants will have <10 year life expectancy.[75] The average life expectancy of an 80 year old man is 8.2 years and is 9.7 years for an 80 year old woman.[74] We chose to limit our sample to patients 76-89 years because regardless of life expectancy the USPSTF does not recommend breast or CRC screening for adults >75 years and a discussion about stopping cancer screening would be appropriate for these patients. Although approximately 20% of adults 65-75 years have <10 year life expectancy, some PCPs may feel uncomfortable recommending stopping screening to these patients since guidelines recommend screening these patients based on their age.[4, 76] To target patients who have been engaged in cancer screening, we will include women who have undergone mammography screening in the past 3 years and women and men that have undergone CRC screening in the past 10 years but for whom there is no documentation in the screening sheet or problem list that the patient has chosen to stop being screened for cancer. We will exclude patients with a history of breast and/or colon cancer; patients whose last colonoscopy showed adenomatous polyps; and women whose last mammogram was read as abnormal since screening decisions may differ for these patients. To further exclude patients who have already decided to stop being screened, we will ask patients their intentions of being screened for breast (women only) or CRC cancer using a validated measure (scored from 1-15), and we will exclude those who score 11-15 (leaning towards not being screened) for both cancers (women) or CRC cancer (men). We will also exclude patients who do not speak English, are in hospice, do not have capacity to participate, have a history of dementia or score $\geq$10 (indicative of dementia) on the Orientation-Memory-Concentration (OMC) test.[77, 78] To determine capacity, we will ask patients 7 institutional review board (IRB) approved questions (see Appendix A1 for the eligibility questionnaire) about their understanding of the study, the benefits and harms, and their role. We will exclude patients who answer 3 out of 7 questions incorrectly. We plan to include adults with capacity for informed consent but with mild cognitive impairment (MCI, suggested by scores of 5-9 on OMC test) since: 1) ~20% of US adults $\geq$75 years have MCI;[96-98] 2) many are screened without discussion of the risks of cancer screening and/or the lag-time to benefit;[99] 3) MCI increases with age and is associated with comorbidity and shorter life expectancy;[100] and 4) adults with MCI have successfully participated in our previous studies.[101] We are excluding patients with dementia because we are interested in learning from patients how their PCP may discuss their prognosis when talking about stopping cancer screening. As a next step, we plan to develop strategies for PCPs to discuss prognosis with older adults with dementia and their proxies. Since on average adults $\geq$90 years have <5 year life expectancy[79] and since dementia is common (36%) we will exclude adults $\geq$90 years.[80] We will target a sample that is 50% female and socioeconomically diverse.

In addition, if a patient would like a family member aged $\geq$21 years to be present during individual interviews, we will welcome the family member to consent and participate in the interview. Patients that participate in Aim 1 will not be eligible to participate in Aim 2.

PCP Eligibility: We plan to recruit PCPs to this study from HCA, Senior Health, and from up to 16 Boston area community primary care practices that make-up BIDMC's Affiliated Physician Group

(APG). Non-resident physicians and nurse practitioners that care for a patient panel that includes adults >75 years will be eligible. We will exclude clinicians that only see patients for urgent care.

No participant will be excluded based on race, ethnicity, or sex. Participants of all races and ethnicities will be sought. We plan to study English-speaking patients since we are exploring a novel topic- how PCPs should approach discussions about patient prognosis when recommending older adults stop being screened for cancer. Once we develop strategies for PCPs to use when talking to older adults about their prognosis in English, we will translate these strategies to other languages to learn if they are acceptable to non-English speaking older adults.

B4. POSSIBLE BENEFITS

All patient participants will receive $25 compensation for participating and PCPs will receive $50 compensation for participating. More generally, we will learn from patients and PCPs how PCPs may approach the topic of patient prognosis when discussing stopping cancer screening with older adults. If PCPs and patients become more comfortable talking about prognosis, older adults may be provided with the information they need to make higher quality decisions about whether or not to undergo cancer screening and other medical tests and interventions. Also, if PCPs learn to discuss prognosis with older adults when patients have close to 10-year life expectancy it could lead to earlier discussions between PCPs and older adults about advanced care planning and goals of care that may lead to improved care of older adults near the end of life. Although guidelines recommend that PCPs not screen older adults with <10 year life expectancy for breast or colon cancer, many older adults with short life expectancy are screened and few understand that the benefits of screening take years to occur while the chance of harm is immediate.[9, 10] Making information about patient prognosis accessible to PCPs and providing PCPs with guiding principles and language on how to discuss prognosis with older adults will hopefully lead to better clinical decision-making and improved care of older adults. Ideally, by better understanding their prognosis, older adults with short life expectancy may avoid tests from which they are unlikely to benefit and may only cause harm. Since the research proposal only involves interviewing older adults and PCPs, providing PCPs with patient prognostic information, and reviewing patient medical records, this study poses minimal risks to participants. The risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

B5. POSSIBLE RISKS AND ANALYSIS OF RISK/BENEFIT RATIO

This study involves reviewing patient medical records, conducting individual interviews and focus groups with patients and interviewing their PCPs, recording interviews, and providing PCPs with information on their patients' prognosis. It poses very little risk to participants. Some participants may develop feelings of anxiety, distress, or fatigue when answering interview questions. We will inform participants that they may stop interviews at any time, skip any question that makes them feel uncomfortable, and/or withdraw their participation. PCPs who prefer not to talk in front of other individuals will be offered the opportunity to participate in an individual interview instead of a focus group. Questionnaires for Aim 2 are shorter in length than questionnaires that we have used successfully in prior studies.[102-104] The information we are giving PCPs on patient prognosis may be estimated using calculators available on the web; however, we are making the information easily accessible to PCPs. If a PCP chooses to discuss prognosis with a patient, it is possible the patient may get upset; however, this is what we are trying to learn in this study- how to talk to older adults about their prognosis in a patient-centered non-threatening way that improves the patient-doctor relationship. Studies conducted with patients with serious illnesses near the end-of-life find that patients want the truth about their prognosis and that patients are not harmed when their clinicians talk to them about their prognosis.[40, 49, 50] The utmost respect will be paid to participant privacy and interviews and focus groups will be conducted in private. Data will be entered as it is collected into REDCap, so there will not be paper records. Each participant will be given a unique study ID not associated with personal identifiers to link with their data. Data used in analyses will be de-identified. All audio tapes will be coded so that no personally identifying information is visible on them; they will

be kept in a locked file cabinet in the investigator's office; they will be heard only for research purposes; and they will be destroyed in compliance with NIH policy. Each participant will have usual access to their PCP and Dr. Schonberg will also be available to talk with participants if they feel anxious.

B6. RECRUITMENT AND CONSENT PROCEDURES

Patient Recruitment and consent: Recruitment of patients to this study is similar for Aims 1 and 2. Through a HIPAA waiver, in Aim 1, we will have a data manager provide a list of all patients aged 76-89 seen at each site in the past year stratified by patient race and sex. In Aim 2, we will ask the data manager to produce a similar list; however, we will ask that the list only include patients aged 76-89 that are scheduled to be seen by a PCP participating in Aim 2 in the next 4-12 weeks. Also, in Aim 2, we will ask the data manager to send us an updated patient list every two weeks so that we will continuously have new patients that we may screen for eligibility that are scheduled to see their PCP. After obtaining the list of patient names, we will review patient records sequentially to find patients that meet our eligibility criteria. We will email the PCP of potentially eligible patients to ask permission to contact their patients and attach the opt out letter (Appendix C.3) that we plan to send to patients to this email. We will inform PCPs that our study aims to understand how patients would like their PCP to discuss their prognosis when discussing stopping cancer screening. We will ask PCPs to exclude patients with dementia or that are non-English speaking. We will send patients deemed eligible by their PCP an informational letter about the study (see section E.2.a below for more information about the contents of the Aim 1 and Aim 2 informational letters). The informational letter will include a number to call if patients want to opt-out of being contacted. After one week, the research assistant (RA) will call patients who have not opted-out to further describe the study and to see if they are willing to participate. For patients willing to participate, the RA will re-establish eligibility. Once a patient is willing and eligible to patient, the RA will follow the procedures described below specific to each aim.

Aim 1: In Aim 1, the RA will ask patients willing and eligible to participate in an individual interview. If the patient is willing to participate we will schedule to meet him/her at a time and place that is convenient for the patient (e.g., clinic, the patient's home). We will obtain written informed consent. If a patient would like a family member to be present at the individual interview, we will also obtain written informed consent from the patient's family member. We will offer participants $25 incentive.

Aim 2: For Aim 2, if a patient is willing and eligible to participate, the RA will schedule a time convenient to the patient to complete the background questionnaire over the telephone. The RA will obtain verbal informed consent in Aim 2 rather than written informed consent because this is a minimal risk study and we do not plan to audio-record interviews in Aim 2.

For both Aims 1 and 2, we will offer patient participants $25 incentive for participating. Dr. Schonberg has successfully used these recruitment methods and incentives in prior studies.[14, 104]

PCP Recruitment and Consent: Dr. Schonberg will invite PCPs to participate in Aims 1 and 2 through individual emails and through in person presentations at faculty meetings. PCPs that participate in Aim 1 will be permitted and invited to participate in Aim 2 since in Aim 2 we will be collecting information from PCPs at the point of care about their experience with a patient. We will provide PCPs a $50 incentive for participating. Table 1 shows the number of PCPs at each practice. We aim to recruit 48 eligible PCPs to participate in Aim 1 and 45 eligible PCPs to participate in Aim 2.

Aim 1: For Aim 1, we will explain to PCPs that we are conducting focus groups and individual interviews to learn from PCPs how best to approach talking to older adults about stopping cancer screening and their long-term prognosis. We will explain that we anticipate that the focus group will take one hour and that we will provide a meal. We will ask focus group PCPs to come 15 minutes early to complete written informed consent, to complete a questionnaire on their background characteristics, and to enjoy the meal. The email will also inform PCPs that we will provide $50 incentive for participating. The written informed consent form will explain that we aim to better

understand how to discuss prognosis with older adults when discussing stopping cancer screening, that we anticipate 48 PCPs will participate in 5 focus groups, that the study involves participating in a focus group or individual interview and completing questions about their background characteristics, and that participants will receive $50 in appreciation of their time. If a PCP responds that they would like to participate but cannot attend or would prefer not to participate in a focus group then we will offer that PCP to participate in an individual interview. If a nurse practitioner (NP) responds that s/he would like to participate in a focus group then we will let the NP know that we plan to ask him/her to stay for a few minutes after the focus group for an exit interview focused specifically on the NP role in discussing stopping cancer screening and long-term prognosis with older adults. The consent form will also explain that the interview will be recorded and how recordings will be stored and protected. It will also explain that participation is voluntary, that they may withdraw their participation at any time, and that their decision to participate will not affect their relationship with any member of the research team or any other individuals at BIDMC.

Aim 2: For Aim 2, we will present the study at faculty meetings and we will email PCPs individually to inform them of the study and to ask them to participate. The email will inform PCPs that we are interested in learning if information on their patients' prognosis is useful to them when discussing cancer screening with adults >75 years. We will explain that we will attempt to recruit up to 5 of their patients to participate . Each time one of their patients chooses to participate, we will email the PCP (through secure email) their patient's prognosis calculated by the Lee-Schonberg index and we will send a copy of Cho et al.'s US life tables that provides information on older adults' life expectancy by age stratified into quartiles (see Appendix A.9. for a draft of the information we will provide).[8] After their 5th patient participates or at the end of the study, depending on which comes first, we will ask PCPs to complete a 10 minute web-based questionnaire about their experience. We will inform PCPs that they will receive $50 in appreciation for their time for participating in this study. The email will also explain to PCPs that their participation is completely voluntary; that they can withdraw their participation at any time; and that if they decide not to participate in the study their decision will not affect their relationship with the research team or any other individual at BIDMC or APG. The email will also inform PCPs that their responses to questionnaires will be confidential and will be analyzed using a unique study ID.

Financial Planner/Clergy Recruitment and Consent: Dr. Schonberg will invite financial planners/clergy to participate in Aim 1 through individual emails. We will provide financial planners/clergy a $50 incentive for participating. We aim to recruit 5 financial planners and 5 members of the clergy to participate in Aim 1.

Aim 1: For Aim 1, we will explain to financial planners/clergy that we are conducting individual interviews to learn from financial planners/clergy how best to approach talking to older adults about their long-term prognosis. We will explain that we anticipate that the interview will take 30 minutes. We will ask financial planners/clergy to complete written informed consent and to complete a questionnaire on their background characteristics. The email will also inform financial planners/clergy that we will provide $50 incentive for participating. The written informed consent form will explain that we aim to better understand how to discuss prognosis with older adults that we anticipate 5 financial planners/clergy will participate in interviews, that the study involves participating in an individual interview and completing questions about their background characteristics, and that participants will receive $50 in appreciation of their time. The consent form will also explain that the interview will be recorded and how recordings will be stored and protected. It will also explain that participation is voluntary, that they may withdraw their participation at any time, and that their decision to participate will not affect their relationship with any member of the research team or any other individuals at BIDMC.

B7. STUDY LOCATION

Privacy

The utmost respect will be paid to participant privacy. Participant responses and data will be directly and securely stored and password protected via REDCap. Interview recordings will be stored in a locked cabinet in Dr. Schonberg's office. All interviews will be conducted in private office space or clinical space, or at the patient's home.

Physical Setting

For Aim 1, the RA will schedule to meet the patient at a time and location (e.g., clinic, the patient's home) that is convenient to the patient to conduct the semi-structured qualitative interview. For PCPs, we will attempt to conduct focus groups at a convenient time (e.g., at a time that is periodically reserved for faculty meetings but when a faculty meeting is not scheduled) or an individual interview at the convenience of the PCP.

Aim 2 will be completed over the phone with patients and through email with PCPs; information obtained from these calls and emails will be stored directly on REDCap.

B8. DATA SECURITY

All participants will be given a study identification number (ID). Only the study ID and not participant names or personal identifiers will be downloaded from REDCap with participant data. The ID code will be stored in secure REDCap files that will not be downloaded. Each computer device used to collect human subjects data will be password protected and encrypted. No personal identifiers will be entered using wireless connectivity. Data will be collected specifically for the proposed research project. The utmost respect will be paid to participant privacy and interviews will be conducted in private. Data will be entered as it is collected into REDCap, so there will not be paper records. Each participant will be given a unique study ID not associated with personal identifiers to link with their data. Data used in analyses will be de-identified. All audio tapes will be coded so that no personally identifying information is visible on them; they will be kept in a locked file cabinet in the investigator's office; they will be heard only for research purposes; and they will be destroyed in compliance with NIH policy. Each participant will have usual access to their PCP and Dr. Schonberg will also be available to talk with participants if they feel anxious.

B9 Multi-Site Studies

Is the BIDMC the coordinating site? ☐ Yes ☐ No

Is the BIDMC PI the lead investigator of the multi-site study? ☐ Yes ☐ No

B10 Dissemination of Research Results

At the end of the follow-up interview, we will ask participants if they are interested in receiving the final results from this study. We will explain that it may be several years before the results are available. We will keep record of participants interested in learning the results and will mail those patients a summary of our findings. In the letter, we will reference any publications resulting from the study.

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