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Protocol Registration Receipt
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Understanding and Discouraging Overuse of Potentially Harmful Screening Tests

This study is not yet open for participant recruitment.

Verified by Stacey Sheridan, MD, University of North Carolina, Chapel Hill, September 2012

Sponsor:	University of North Carolina, Chapel Hill
Collaborators:	Agency for Healthcare Research and Quality (AHRQ) Duke University
Information provided by (Responsible Party):	Stacey Sheridan, MD, University of North Carolina, Chapel Hill
ClinicalTrials.gov Identifier:	

Purpose

Most prevention efforts focus on promoting services (e.g. vaccination, screening tests). While some of these services have clear net benefit, many instead have possible or clear net harm. Currently, three quarters of services graded by the U.S. Preventive Services Task Force (USPSTF) have possible or clear net harm (C, I, and D services). Many of these services are delivered in healthcare settings at higher rates than what might be expected based on their potential for harm. This leads to adverse outcomes, excess costs, and missed opportunities to deliver more quality care. An important issue in delivering prevention messages is how to shift toward a focus on the appropriateness of prevention: encouraging services with clear net benefit and either discouraging or reducing demand for services with possible or clear net harm. Unfortunately, little is known about what drives overuse of potentially harmful screening services or how to make harms relevant to patients.

This randomized controlled trial (RCT) of 775 patients at 4 primary care practices aims to 1) assess factors associated with intent to receive possibly or clearly harmful screening services and 2) determine whether and how patients' plans to get screened change with various presentations of information about harms (e.g. qualitative, quantitative, narrative, framed). The investigators will focus on three types of screening services: osteoporosis screening (previous C recommendation and now no recommendation for women < 65 years old with no fracture risk factors), prostate-specific antigen (PSA) screening (D recommendation for all men, regardless of age), and colorectal cancer (CRC) screening (C for ages 76-85).

Condition	Intervention	Phase
Preventive Screening Prostate Cancer Osteoporosis Colorectal Cancer	Behavioral: Quantitative Information Sheet Behavioral: Qualitative Information Sheet Behavioral: Narrative Information Sheet Behavioral: Framed Information Sheet	N/A

Study Type: Interventional
Study Design: Prevention, Parallel Assignment, Single Blind (Subject), Randomized, Efficacy Study
Official Title: Understanding and Discouraging Overuse of Potentially Harmful Screening Tests

Further study details as provided by Stacey Sheridan, MD, University of North Carolina, Chapel Hill:

Primary Outcome Measure:

- Change from Baseline in Intent to Accept Screening Immediately Post-intervention [Time Frame: Pre- and Post-Intervention (same visit)] [Designated as safety issue: No]

  Following the example of others, we will measure intent to accept screening services with possible or clear net harm with a single item "I plan to get screened for (name of screening test) in the next year." Because the recommended screening intervals for services under study are variable and not all participants will be due for screening in the next year, we will additionally query participants about plans for screening within the recommended screening interval (e.g. osteoporosis screening--5 years; CRC--10 years). Responses will range from "strongly disagree" to strongly agree". All outcomes will be measured before and after participants receive the information sheet. All data will be collected at the one study visit.

Secondary Outcome Measures:

- Change from Baseline in Perceived Disease Risk Immediately Post-Intervention [Time Frame: Pre and Post Intervention (same visit)] [Designated as safety issue: No]

  Perceived risk or susceptibility of disease will be measured for each disease state under study using one item that reads, "How likely is that you will get (insert prostate cancer, osteoporosis, or colon cancer) in the next 10 years?" Answers will be on a likert scale from "not at all likely" to "very likely."

- Change from Baseline in Perceived Disease Severity Immediately Post-Intervention [Time Frame: Pre and Post Intervention (same visit)] [Designated as safety issue: No]

  Perceived Disease Severity will be measured for each disease state under study using the Revised Illness Perceptions Questionnaire for Healthy People. It includes the following four questions: 1) x (insert prostate cancer, osteoporosis, or colon cancer) has serious financial consequences; 2) x strongly affects the way the patient sees himself as a person; 3) x causes difficulties to those close to the patient; 4) x is very serious. Answers will be on a 5-point scale from "strongly disagree" to "strongly agree."

- Change from Baseline in Disease Specific Knowledge Immediately Post-Intervention [Time Frame: Pre and Post Intervention (same visit)] [Designated as safety issue: No]

  Two questions central to understanding each exemplar service (i.e. prostate cancer screening, osteoporosis screening, colon cancer screening) were selected to assess specific knowledge. Response options include true, false, or don't know.

Questions for prostate cancer screening are:

1. Some men can live long, normal lives with untreated prostate cancer.
2. Problems with sexual function and urination are common side effects of prostate cancer treatments.

Questions for colon cancer screening are:

1. Most polyps in the bowel never become cancer.
2. Bleeding and perforations are complications of a colonoscopy.

Questions for Osteoporosis screening are:

1. Broken hip bones are uncommon before age 65.
2. Treatments for osteoporosis can sometimes result in bone damage.

- Change from Baseline in Disease-Specific Screening Attitudes Immediately Post-Intervention [Time Frame: Pre and Post Intervention (same visit)] [Designated as safety issue: No]

  Six questions will assess participants' attitudes about each screening service under study.

  Questions include:

  1. Screening for x(insert prostate cancer, colon cancer, osteoporosis) in healthy persons my age is a good idea.
  2. There is little harm to screening for x.
  3. I owe it to people close to me to get screened for x.
  4. I owe it to my doctor to get screened for x.
  5. I would regret not being screened for x.
  6. I do not feel any special responsibility to get screened for x.

  Response options range from "strongly disagree" to "strongly agree".

- Change from Baseline in Decisional Balance Immediately Post-Intervention [Time Frame: Pre and Post Intervention (same visit)] [Designated as safety issue: No]

  Decisional balance will be measured by a single item for each screening service under study. Participants will be asked, "Which best describes how you feel right now?" Participants will select one of the following answers: 1) The benefits of X (insert prostate cancer, colon cancer, osteoporosis) screening greatly outweigh the harms; 2) The benefits of X screening somewhat outweigh the harms; 3) The benefits and harms of X screening are about the same; 4) The harms of X screening somewhat outweigh the benefits; and 5) The harms of X screening greatly outweigh the benefits.

- Change from Baseline in Values Clarity Immediately Post-Intervention [Time Frame: Pre and Post Intervention (same visit)] [Designated as safety issue: No]

  Values Clarity will be measured with three items for the values subscale of the decisional conflict scale.

  Items include:

  1. I am clear about which benefits matter most to me;
  2. I am clear about which harms and side effects matter most to me;
  3. I am clear about which is more important to me (the benefits or the harms);

  Response options rrange from strongly disagree to strongly agree.

- Change from Baseline in General Screening Knowledge Immediately Post-Intervention [Time Frame: Pre and Post Intervention (same visit)] [Designated as safety issue: No]

  General screening knowledge will be assessed using 8 items developed by investigators.

  Questions include:

  1. Screening means detecting disease before someone can see or feel any problem.
  2. Some diseases detected by screening won't cause any problems in a person's lifetime.
  3. In some cases, screening can lead to treatment that is not necessary.
  4. Screening never harms anyone.
  5. An abnormal screening test means I have the health condition for sure.
  6. A normal screening test means that I have am free of the health condition for sure.
  7. Screening can only decrease your chances of getting sick or dying if effective treatments are available.
  8. Screening can only decrease your chances of getting sick or dying if you live long enough for treatments to work.

  Response options are true, false, or don't know.

- Change from Baseline in General Screening Attitudes Immediately Post-Intervention [Time Frame: Pre and Post Intervention (same visit)] [Designated as safety issue: No]

  General Screening Attitudes will be assessed at baseline by 38 questions that were developed by investigators and assessed for content validity by panel of experts. Questions assess the following sub-constructs:

  General approach to screening, Value of Screening, Need to Know about Disease, Early Detection/Treatment, Benefits, Harms, Anticipated Regret in Choosing for/against screening, Duty/Responsibility to be screened, Effect on screening on MD/patient relationship.

  Response options range from "strongly disagree" to "strongly agree" on a 5-point scale.

  At post intervention, a subset of 12 of the 38 questions (1-2 from each subconstruct) will be used to assess changes in general screening attitudes.

Other Pre-specified Outcome Measures:

- Key moderating variables [Time Frame: pre-intervention] [Designated as safety issue: No]

  Multiple variables will be measured to examine whether they moderate the effect of the intervention on the primary outcome intent for screening.

  These variables include:

  1. self-efficacy for screening (1 question)
  2. cues to action (6-questions on sources of health information)
  3. perceived ambiguity of recommendations for screening (1 question)
  4. personality traits (10-item personality index)
  5. optimism (3 question subscale of life orientation test)
  6. need for cognition (3 items from need for cognition scale)
  7. health numeracy (3 items from Schwarz and Woloshin numeracy score)
  8. prior screening status (1 item per service)
  9. study site

10. health insurance status

Estimated Enrollment: 775
Study Start Date: September 2012
Estimated Study Completion Date: September 2014
Estimated Primary Completion Date: September 2014

Arms	Assigned Interventions
Experimental: Quantitative In the quantitative arm, we will present harms as absolute risks in the Quantitative Information Sheet. Compared with other risk formats, absolute risks have been shown to improve understanding relative to other common risk formats.	Behavioral: Quantitative Information Sheet Patients will read an information sheet about one of the three exemplar services in one of four presentations: quantitative, qualitative, narrative, or framed. In the quantitative information sheet, harms will be communicated in absolute risks with accompanying fact box (i.e. box containing key facts and rates). In addition to information about harms, the information sheet will include the following information: a description of the disease to be detected and the screening test, a description of the possible benefits of the service, and a statement encouraging decision. As an adjunct to numerical information in paragraph form, fact boxes engage individuals to process information and improve understanding.
Active Comparator: Qualitative In the qualitative arm, we will describe harms using verbal descriptors (such as rare, uncommon, fairly common, and common) in the Qualitative Information Sheet.	Behavioral: Qualitative Information Sheet Patients will read an information sheet about one of the three exemplar services in one of four presentations: quantitative, qualitative, narrative, or framed. In the qualitative information sheet, harms will be communicated using verbal descriptors. In addition to information about harms, the information sheet will include the following information: a description of the disease to be detected and screening test, a description of the possible benefits of the service, and a statement encouraging decision.
Experimental: Narrative In the narrative arm, we will present harms using patient narratives (i.e. descriptions in which patients describe their experience with decision making about potentially harmful screening services)in the Narrative Information	Behavioral: Narrative Information Sheet Patients will read an information sheet about one of the three exemplar services in one of four presentations: quantitative, qualitative, narrative, or framed. In the narrative information sheet, harms will be communicated using patient narratives with accompanying fact box. In addition to information

Arms	Assigned Interventions
Sheet. To address concerns in the literature that characteristics of the narrator independently influence narrative effect, we will present narratives in paper format with a banner of culturally diverse age-appropriate pictures shown at the top.	about harms, the information sheet will include the following information: a description of the disease to be detected and screening test, a description of the possible benefits of the service, and a statement encouraging decision.
Experimental: Framed In the framed arm, we will frame not screening with potentially harmful services as beneficial (i.e. use a gain frame). In the Framed Information Sheet, we will highlight the harms that could be avoided by not getting screened.	Behavioral: Framed Information Sheet Patients will read an information sheet about one of the three exemplar services in one of four presentations: quantitative, qualitative, narrative, or framed. In the framed information sheet, harms will be communicated using a gain frame (as described in the arm section above) with accompanying fact box. In addition to information about harms, the information sheet will include the following information: a description of the disease to be detected and screening test, a description of the possible benefits of the service, and a statement encouraging decision.

Eligibility

Ages Eligible for Study: 50 Years to 85 Years
Genders Eligible for Study: Both
Accepts healthy volunteers.

Inclusion Criteria:

- Women between ages 50 to 85
- Men between ages 50 to 85
- Eligible for exemplar service of interest (see below for specifics of inclusion/exclusion for specific services)

Exclusion Criteria:

- Current treatment of psychosis
- History of alcohol or substance abuse within the last 2 years
- Dementia or other severe cognitive dysfunction
- serious medical illnesses with a life expectancy of less than 2 years (e.g., metastatic cancer)
- inability to speak and understand English
- blindness
- presentation for an acute medical visit
- no telephone number

Osteoporosis Screening (women aged 50-64)

Exclusion Criteria:

- a personal history of osteoporosis
- a personal history of moderate or severe osteopenia
- BMI (body mass index) < 18.5
- personal history of non-traumatic fracture
- family history of hip fracture
- current smoking
- current use of prednisone (>30 consecutive days)
- alcohol use of 3 or more drinks/day.

Prostate Cancer screening (men aged 50-69)

Exclusion Criteria:

- a prior history of prostate cancer

Colorectal Cancer Screening (men and women aged 76-85)

Exclusion Criteria:

- prior history of colorectal cancer
- adenomatous colon polyps > 6mm (or 2 or more < 6mm)
- symptoms referable to colorectal cancer

Contacts and Locations

Contacts

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Locations

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Investigators

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More Information

Responsible Party:	Stacey Sheridan, MD, Associate Professor of Medicine, University of North Carolina, Chapel Hill
Study ID Numbers:	12-1338
Health Authority:	United States: Federal Government United States: Institutional Review Board