Evidence-based Practice Center Systematic Review Protocol

Project Title: Decision support tools for screening and treatment decisions in early cancer

I. Background and Objectives for the Systematic Review

Complex Decisions and Decision Support Tools for Health Care Consumers

Some health care decisions do not have an obvious "optimal choice." For example, while it is clear that a person with a ruptured appendix must have immediate surgery or that someone with bacterial pneumonia must receive antibiotics, it is not clear whether a 55-year-old man with a localized low-grade prostatic malignancy should opt for treatments that remove or destroy the cancer, for active surveillance, or for watchful waiting. In the examples with a clear "optimal" choice, the likelihood of death or very serious complications is much smaller with the optimal treatment, and the benefits of the intervention outweigh the risks for most if not all patients. In the case of conditions for which there is not an optimal treatment choice, such as localized low-grade prostate cancer, the difference in the expected survival or other serious health outcomes between the available options is small enough for other considerations to take the forefront. For example, choosing to remove or destroy a low-grade prostatic malignancy can lead to complications, such as urinary or bowel incontinence and sexual dysfunction, while choosing active surveillance can cause anxiety about not treating the condition, inconvenience associated with regular testing, and a higher risk of disease progression. Individual patients and those close to them place different values on these outcomes and can therefore have different assessments of the balance of benefits and harms associated with each option. In other words, no universally "optimal" choice exists; the "optimal" choice is the one that best corresponds to the values of the health care consumer facing the decision.

Decision support tools (DSTs) are designed to *aid health care consumers facing complex decisions*. They are not meant to replace health care providers but to supplement the consumer-provider interaction and promote shared decisionmaking.[1, 2] DSTs may include brochures, audiovisual materials, educational sessions, counseling sessions, computer programs, interactive Web sites or media, or combinations thereof. They may be used to prepare the health care consumer for a consultation with the provider or during the consultation between the consumer and the provider. According to the International Patient Decision Aids Standards (IPDAS) Collaboration, a DST aims to *improve the quality of decisions*, that is, the extent to which the choices of health care consumers are *congruent with their informed and considered values in the presence of uncertainty*.

Premalignant and early stage malignant conditions and decision support tools

Clinical practice guidelines often recommend that health care consumers and their providers engage in shared decisionmaking when facing screening, other testing, or treatment decisions related to premalignancy or early stage cancer.[3-14] These conditions are therefore natural targets for the use of DSTs. In fact, many DSTs have been developed to support decisions on screening or treatment for premalignant or malignant conditions and have been evaluated in randomized controlled trials (RCTs).[15-18] Evidence on the effectiveness of DSTs for decisionmaking in premalignant and early stage malignant conditions has been summarized in systematic reviews,[19, 20] including in reviews focused on advanced cancers,[21, 22] and in the 2011 Cochrane review by Stacey et al.,[2] which covered DSTs for both cancer and noncancerous conditions.

Developing decision support tools

It is very important that DSTs are developed through a careful process and that they are implemented and broadly disseminated only when they have been fully developed and refined. The International Patient Decision Aids Standards (IPDAS) Collaboration has defined standards for the development process and outlined a development framework that builds upon several other developmental frameworks. Briefly, the key features of the developmental process include (1) scoping and design, (2) developing a prototype, (3) an iterative "alpha" testing phase with patients and clinicians, (4) "beta" testing in real-life conditions, and (5) production of the final version of the DST.[1]

Quantifying the effectiveness of decision support tools

Decision quality. DSTs are designed to improve decision quality, and it is natural to consider this dimension in measuring their effectiveness.[1] However, measuring decision quality is not straightforward.[23] Measurements relying on the reports of health care consumers about their satisfaction with the decisionmaking process, the quality of their interaction with their providers, their knowledge status, or their satisfaction with their final decisions are used often[2, 21, 24] but have limitations.[23] For example, evidence suggests that perceived satisfaction is driven primarily by patient expectations and that high satisfaction is often a result of very low expectations, rather than the high quality of the decisionmaking process.[25] In addition, how patients rate the quality of their interaction with their provider is difficult to interpret if the patients have no experience with a meaningful decisionmaking process. Similarly, self-reporting of knowledge status (as opposed to objective assessment of factual knowledge) is difficult to contextualize. Finally, some patients may report high satisfaction with their final choices because of their unwillingness to second-guess an anxiety-provoking decision.[23]

According to IPDAS,[1, 2] theoretically motivated measurements of decision quality should consider (1) attributes of the choice and (2) attributes of the decisionmaking process.

1. Attributes of the choice: The extent of the match between the values of health care consumers and their actual choices (or intended choices as a surrogate)
2. Attributes of the decisionmaking process include the following:
    a. Recognizing that a decision must be made
    b. Knowing all relevant and available options, including factual information about their characteristics and expected outcomes
    c. Understanding that values affect the decision
    d. Recognizing which outcomes or other features are valued more highly
    e. Discussing options with health care providers
    f. Engaging in shared decisionmaking in a preferred way

Clinical outcomes. Almost by definition, for most situations for which DSTs are proposed, the likelihood of mortality or other hard clinical outcomes across the compared options is either known to be similar or is substantially uncertain. Because there is no single optimal choice, hard clinical outcomes are probably not particularly relevant for measuring the effectiveness of DST-based interventions.[1] Intermediate health outcomes, such as quality of life, anxiety, depression, or decisional regret, are more relevant measures of the effects of DST-based interventions.

Health care–system outcomes. Finally, another set of outcomes can be measured at the system level, including changes in the variability of care (e.g., changes in the variability of surgery rates for localized prostate cancer across states); rates of surgery, radiotherapy, or other treatments; resource use; and rates and costs of litigation.

Interventions to Increase Provider Implementation of Shared Decision-making using DSTs

Provider willingness to engage in shared decisionmaking is a prerequisite for patient use of DSTs in real-life clinical practice outside the experimental setting of an RCT. Interventions have been specifically developed to increase the likelihood that providers will engage in meaningful shared-decisionmaking processes with consumers who face screening or treatment decisions for a premalignancy or early stage malignancy. Assessment of interventions to increase provider use of DSTs for implementation of shared decisionmaking is an essential complement to the assessment of DSTs designed for patient use.

A Cochrane review by Legare et al.,[26] published in 2010, summarizes the effectiveness of interventions for promoting health care provider implementation of shared decisionmaking in all health conditions, based on studies in which an independent observer ascertained the outcomes. It concluded that there is uncertainty about which types of intervention are most effective in promoting health care provider implementation of shared decisionmaking. The review searched for RCTs, quasi-experimental studies, controlled before and after studies, and interrupted time series analyses. However, only five studies met review inclusion criteria, and all of these studies

were RCTs. Additional studies have become available since the publication of the Legare review.

Rationale for an evidence review: clinical issues and availability of scientific data to support a review

A large number of people face decisions about cancer screening, treatment, or other testing for premalignant and early stage malignant conditions. By their very nature, these decisions are complex and amenable to the use of DSTs. There is substantial evidence that, on average, DSTs are more effective than non–DST-based usual care in improving decision quality overall,[2, 27] and in cancer conditions[21] in particular. Nevertheless, knowing the overall average effect is not enough to promote the use of these tools to their best effect. A series of questions can be posed, including, but not limited to, the following:

1. Which (categories of) DSTs are more effective? Little information exists on the comparative effectiveness of alternative types of DSTs in published systematic reviews. This may be because head-to-head comparisons of DST-based interventions are infrequent and because numerous DST-based interventions exist. This is a very important gap in the current assessments of the evidence.
2. What is the effectiveness of DSTs in populations with low literacy or low numeracy? The additional challenges in such subpopulations include the difficulty in communicating the notion of probability and risk or in appreciating very low probabilities.
3. What is the effectiveness of DSTs among ethnic minorities whose first language is not English?

Additional trials have been published since the dates of the last searches carried out for the large Cochrane systematic review by Stacey et al. of decision aids for people facing health treatment or screening decisions.[2] A systematic review that updates the evidence base and evaluates the comparative effectiveness of DSTs (or equivalently, aims to explore which "components" of a DST-based intervention are most effective) can help identify which, if any, DSTs are most effective and can thus inform the prioritization of future research efforts. The Cochrane systematic review of decision aids by Stacey et al.,[2] published in 2011, is currently being updated. Despite the apparent overlap, our review for the Agency for Healthcare Research and Quality will be more narrowly focused than the review by Stacey et al.,[2] because it will be limited to premalignant and early stage malignant conditions, thereby allowing a more detailed analysis. Further, it will emphasize comparisons of the effectiveness of various categories of DSTs, defined by degree of tailoring to patients and participants (e.g., no personalized risk prediction, personalized risk prediction, suggestion choice most congruent to values); whether elicitation of values is implicit or explicit; whether the DST is provided during a consultation session or not; and other categorizations described in the methods section.

DST-based interventions are unlikely to effective if health care providers are not amenable to adopting them. Thus it is important to assess interventions promoting provider

engagement with shared decisionmaking using DSTs. Although there is a much smaller evidence base in terms of the effectiveness of provider-specific interventions for promoting shared decisionmaking with DSTs, a systematic review of the evidence base can, at a minimum, help identify gaps in knowledge and direct future research efforts in this area. The aforementioned Cochrane review by Legare et al.[26] concludes that there is uncertainty about what type of interventions are more effective in promoting shared decisionmaking. New studies are available, however, especially for early cancer or premalignant conditions. Also, if the eligibility criteria are broadened to include studies in which outcomes have not been validated by an independent observer (e.g., studies with provider-reported outcomes), still more evidence will be available for analysis.

Other ongoing work in this area

To ensure that our efforts are complementary, members of the Cochrane Review team were involved in the Topic Refinement process and have agreed to participate in this review as consulting experts. The authors of the Cochrane reviews are noted methodologists in the field of DST development and evaluation and are members of the IPDAS Collaboration.

Potential audiences

Potential audiences include current or potential users of DSTs (patients and those close to them, general and family practitioners, clinical specialists, clinical psychologists, nurse practitioners, genetic councilors, and other health care providers), managers or policymakers interested in quality improvement of health care delivery, developers of DSTs, clinical researchers, and funders of research.

II. The Key Questions

On the basis of input from stakeholders during Topic Refinement, we have developed the following Key Questions and study eligibility criteria to clarify the focus of the proposed systematic review:

KQ 1: For health care consumers facing screening or treatment decisions on premalignant or early stage malignant conditions, how does use of a decision support tool (DST)-based intervention compare with no use, usual care, or use of another DST with respect to (1) measurements of decision quality, (2) characteristics of the decisionmaking process, (3) choices and adherence to choices, (4) health outcomes, and (5) health care–system outcomes?

a. As above, by subpopulations (e.g., by type of cancer, by health or numerical literacy)

b. As above, by factors that may modify the intervention effect (e.g., attributes of the DST, exact components of the DST, screening vs. treatment, attributes of the health system or setting in which the DST is used)

KQ 2:	For health care providers who care for health care consumers facing screening or treatment decisions on premalignant or early stage malignant conditions, how do interventions for promoting use of DSTs for shared decisionmaking compare with usual care or with other interventions for promoting use of DSTs for shared decisionmaking with respect to (1) likelihood of engaging in shared decisionmaking and also to (2) measurements of decision quality, (3) characteristics of the decisionmaking process, (4) choices and adherence to choices, (5) health outcomes, and (6) health care–system outcomes? a. As above, by subpopulations (e.g., by condition, by health or numerical literacy) a. As above, by factors that may modify the intervention effect (e.g., predisposition of the provider towards using DSTs, attributes of the DST, exact components of the DST, screening vs. treatment, attributes of the health system or setting in which the DST is used)

The PICOTS (**p**atients, **i**nterventions, **c**omparators, **o**utcomes, **t**iming, and **s**etting) elements have been developed based on stakeholder input, the PICOTS of the Stacey et al.[2] Cochrane review,[2] and Chapters A through K of the standards developed by the IPDAS Collaboration that elaborate on a framework for developing and evaluating DSTs,[1] and have been modified based on public review comments. The PICOTS for Question 1 are listed below and those for Question 2 follow them.

Key Question 1

- **Population(s)**
  - Health care consumers who are legally able to make decisions for themselves, for a minor (e.g., a child), or for another adult who is unable to make his/her own decisions (e.g., an incapacitated partner), as well as informal caregivers helping with decisions. Only adults are targeted because children are not legally able to make their own health care decisions.
    - Health care consumers from the general population facing screening decisions.
    - Health care consumers with a very strong predisposition to malignancy (e.g., high cancer risk genetic conditions) facing preventative treatment decisions.
      - Deleterious BRCA gene mutations (breast cancer)
      - Lynch syndrome or presence of deleterious mismatch repair gene mutations (colon cancer, endometrial cancer)
      - Familial Adenomatous Polyposis Coli (FAP; colon cancer)
      - Significant family history suggestive of the above genetic syndromes.
    - Health care consumers formally diagnosed with a premalignant condition (e.g. ductal carcinoma in situ) or with an early state malignancy who are facing treatment decisions.
  - Health care consumers facing screening or treatment decisions where there is no "clearly best" option for all people.

- **Interventions**

  - DST-based interventions are interventions designed to help health care consumers make specific choices between a well-described set of options.
    - *At a minimum*, an eligible DST provides (1) information on the options and the expected relevant outcomes and (2) implicit methods to clarify values.
    - *In addition***,** an eligible DST may include information on the health condition, personalized probability estimates, costs per option, explicit elicitation of values, information about others' opinions, coaching on decision theory concepts, personalized recommendations, a formal decision analysis, or other components.

  - Only fully-developed DSTs are eligible. Should a DST's developmental stage be unclear or fail to fulfill all the IPDAS criteria, the Ottawa Hospital Research Institute (OHRI) database and documentation requested from the DST developers will be consulted in order to establish the developmental status of the DST.

- **Comparators**

  - Another eligible DST-based intervention
  - Not using a DST, usual care, or "status quo" (this will be clarified per study)

- **Outcomes (Decision-specific)**

  - Measurements of decision quality (as per IPDAS criteria)
    - Congruence between actual or intended choice and the consumer's values
    - Change in factual knowledge, including health literacy (harms and risks, as well as benefits) and numerical literacy

  - Other characteristics of the decisionmaking process from the perspective of the *health care consumer*:
    - Decisional conflict
    - Perceived or objectively measured quality of health care consumer-provider communication
    - Perceived and objectively measured participation in decision-making
    - Proportion undecided
    - Health care consumer satisfaction

  - Other characteristics of the decision-making process from the perspective of the *provider*:
    - Perceived and objectively measured quality of communication
    - Perceived and objectively measured consumer participation in decision-making
    - Provider satisfaction

  - Actual or intended choices and adherence to choices

  - Intermediate health outcomes
    - Quality of life measured by condition-specific or generic instruments

        - Anxiety, emotional distress, depression, or decisional regret

    - Health care–system outcomes
        - Resource use including costs
        - Length of consultation
        - Litigation rates

- **Timing**

    - No restrictions

- **Setting**

    - No restrictions

Key Question 2

- **Population(s)**

  Providers who care for health care consumers, such as those described for KQ 1, including providers in training

- **Interventions**

    - Provider-targeting interventions designed to increase the adoption by providers of a DST for shared decisionmaking, a process whereby the provider and the consumer jointly decide on which actions to take.
    - Only fully-developed interventions are eligible. Clinical decision support algorithms or other tools that facilitate clinician decisionmaking but are not geared toward facilitating use of a DST for shared decisionmaking are not eligible. Further, DST-based interventions are consumer-mediated interventions and fall under the purview of KQ 1. They are not considered further in KQ 2.

- **Comparators**

    - Another intervention designed to promote provider use of DSTs for shared decisionmaking
    - No intervention

- **Outcomes (Decision-specific)**
    - Likelihood of engaging in shared decisionmaking. The outcome assessors may be a third observer or the providers or consumers who took part in the intervention.
    - Measurements of decision quality (as per IPDAS criteria)
        - Congruence between actual or intended choice and the consumer's values
        - Change in factual knowledge including health literacy (harms and risks as well as benefits) and numerical literacy

- Other characteristics of the decisionmaking process from the perspective of the *health care consumer*:
  - Decisional conflict
  - Perceived and objectively measured quality of health care consumer-provider communication
  - Perceived and objectively measured participation in decisionmaking
  - Proportion undecided
  - Health care consumer satisfaction

- Other characteristics of the decisionmaking process from the perspective of the *provider*:
  - Perceived and objectively measured quality of communication
  - Perceived and objectively measured consumer participation in decisionmaking
  - Provider satisfaction

- Actual or intended choices and adherence to choices

- Intermediate health outcomes
  - Quality of life measured by condition-specific or generic instruments
  - Anxiety, emotional distress, depression, or decisional regret

- Health care–system outcomes
  - Resource use, including costs
  - Length of consultation
  - Litigation rates

- **Timing**

  No restrictions

- **Setting**

  No restrictions

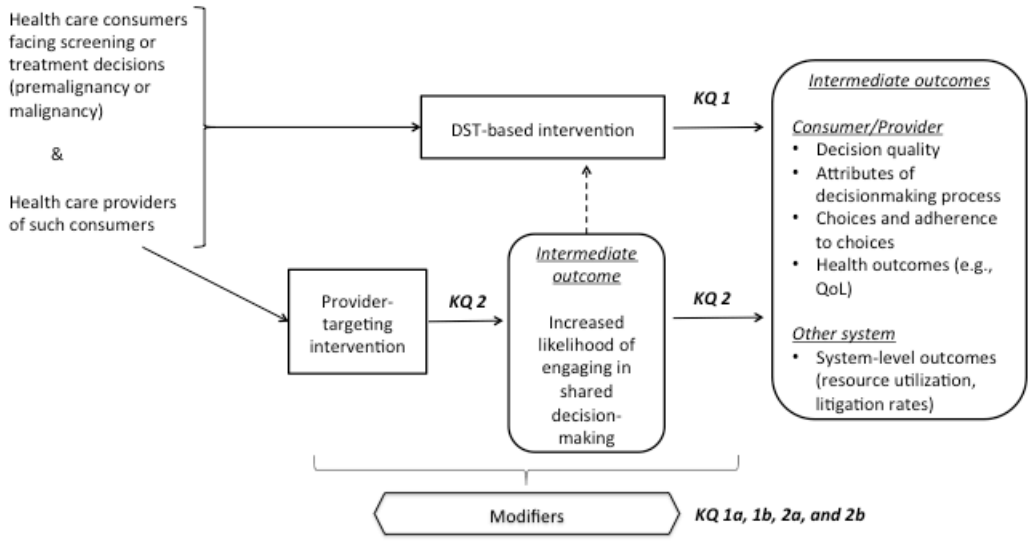
III. Analytic Framework

Figure 1 shows the analytic framework. Some outcomes can be perceived both as measurements of benefit (effectiveness) and as potential harms. For example, anxiety, decision regret, or costs can be perceived as harms when the DST-based intervention is not favored or as benefits when the DST intervention is favored. Harms are, therefore, not explicitly depicted in the framework.

Further, almost by definition, DSTs are designed for decisions without a clear "best" option. Thus, the impact of DST-based interventions on the clinical or long-term health outcomes is much less relevant than in, for example, the evaluation of drug

interventions.[1] Clinical or long-term outcomes (e.g., impact on mortality) are not depicted in the figure.

Figure 1. Analytic framework



Abbreviations: DST = decision support tool; KQ = key question; QoL = quality of life. Refer to the PICOTS for the description of the modifiers.

Figure 1: This figure depicts the key questions (KQs) within the context of the PICOTS described in the previous section. In general, the figure illustrates how DST-based interventions may result in such outcomes as decision quality, other attributes of the decision-making process, choices and adherence to choices, health outcomes, and health system-level outcomes, while provider-targeting interventions designed to increase the likelihood of engaging in shared decisionmaking may result in such outcomes as the likelihood of engaging in shared decisionmaking, as well as all other outcomes that may be a result of DST-based interventions.

IV. Methods

A. Additional criteria for Inclusion/Exclusion of Studies in the Review

We will use the eligibility criteria for populations, interventions, comparators, outcomes, timing, settings, and study designs and setting (PICOTS) as described for the Key Questions (Section II above). Here, we provide some additional details about the inclusion and exclusion criteria we plan to use for each Key Question. These criteria were chosen on the basis of a preliminary review of the literature and general principles of

study design. They have been modified slightly based on input from the TEP members.

- For Key Question 1, only randomized trials will be included. We will require that trials have enrolled at least 10 subjects (per arm); smaller sample sizes are unlikely to provide estimates of treatment effects that are adequately precise.

- For Key Question 2, in addition to randomized trials we will include non-randomized comparative studies, before-and-after studies, and interrupted time series. We will require that all studies have enrolled at least 10 subjects (per arm).

- For all Key Questions we will exclude editorials, commentaries, narrative reviews, letters to the editor, and other manuscripts not reporting primary research findings.

- For all Key Questions we will exclude studies in which the decision being made pertains to hypothetical (rather than actual) screening or treatment choices available to health care consumers

B. Searching for the Evidence: Literature Search Strategies for Identification of Relevant Studies to Answer the Key Questions

Appendix 1 describes our proposed literature search strategies, which are based on the searches from the Stacey and Legare reviews. These searches will be conducted in MEDLINE®, EMBASE®, the Cochrane Central Register of Controlled Trials, PsycINFO®, and the Cumulative Index to Nursing and Allied Health Literature (CINAHL®) databases . These databases were chosen after a preliminary review of existing systematic reviews on DSTs. The search for KQ1 uses a filter to limit it to only randomized controlled trials, while the search for KQ2 will make use of the Cochrane Effective Practice and Organization of Care (EPOC) Group methodological filter. We will use the searches conducted for the Stacey and Legare Cochrane reviews[2, 26] to cover literature through the last reported date for each search in each review. We will check the excluded studies list of the Legare review for trials excluded on the basis of outcomes not assessed by a third observer and screen those studies for inclusion in this review. We will update the searches of all databases through July 2013 and update the searches again following submission of the draft report.

We will also perform a focused search for more recent systematic reviews on the topic and use their reference lists of included studies to validate our search strategy and to make sure we can identify all relevant studies.

A common set of 200 abstracts (in 2 pilot rounds, each with 100 abstracts) will be screened by all reviewers and discrepancies will be discussed in order to standardize screening practices and ensure understanding of screening criteria by all team members. The remaining citations will be split into nonoverlapping sets, each screened by two

reviewers independently. Discrepancies will be resolved by consensus involving a third investigator.

Potentially eligible citations (i.e., abstracts considered potentially relevant by at least one reviewer) will be obtained in full text and reviewed for eligibility on the basis of the predefined inclusion criteria. Full-text articles will be screened independently by two reviewers for eligibility. Disagreements regarding article eligibility will be resolved by consensus involving a third reviewer.

We plan on including only English-language studies during full text review because our preliminary searches indicate that few non–English-language citations are retrieved (approximately 7% of references). We may reconsider this decision if a large number of potentially relevant studies are identified during abstract screening. To accommodate this potential modification of our inclusion criteria, we will not use language of publication as a criterion at the abstract screening stage (instead, we will evaluate the language of publication only at the full-text review stage). Through AHRQ's Scientific Resource Center we will request Scientific Information Packages (SIPs) from developers of DSTs that will be identified through the IPDAS collaboration's website and other sources. We will also do focused searches of ClinicalTrials.gov for registered ongoing studies that are expected to be published after the completion of the systematic review. However, we will not actively search the gray literature, and we will exclude studies published exclusively in abstract form (e.g., conference proceedings) because they are typically not peer reviewed, only partially report results, and may change substantially when fully published. We will generate a list of reasons for exclusion for all studies excluded at the full text screening stage.

We will ask the TEP to provide citations of potentially relevant articles. Additional studies will be identified through the perusal of reference lists of eligible studies, cancer-specific patient and professional organizations Web sites, published clinical practice guidelines, relevant narrative and systematic reviews, databases of DSTs (e.g., the OHRI database), and conference proceedings. All articles identified through these sources will be screened for eligibility against the same criteria as used for articles identified through literature searches. If necessary, we will revise the search strategy so that it can better identify articles similar to those missed by our current search strategy. We will ask the TEP to review the final list of included studies to ensure that no key publications have been missed, and we will consider any suggestions for included studies from the TEP, peer reviewers, or public reviewers against the inclusion/exclusion criteria to ensure no key publications have been missed.

Following submission of the draft report, an updated literature search (using the same search strategy) will be conducted. Abstract and full-text screening will be performed as described above. Any additional studies from the updated search or

suggested by peer or public reviewers will be added to the final report if they meet eligibility criteria.

C. Data Abstraction and Data Management

Data will be extracted into SRDR (http://srdr.ahrq.gov/).[28] The basic elements and design of these forms will be the similar to those we have used for other effectiveness reviews and will include elements that address population characteristics, sample size, study design, descriptions of the interventions and comparators of interest, analytic details, and outcome data. Prior to extraction, forms will be customized to capture all elements relevant to the Key Questions. We will use separate sections in the extraction forms for Key Questions related to intermediate outcomes, terminal outcomes, or adverse events, and for factors affecting (modifying) the treatment effect among subgroups of patients, as described below. We will pilot test the forms on several studies extracted by all team members to ensure consistency in operational definitions. If necessary, forms will be revised before full data extraction. We have consulted with the TEP to ensure that all items of clinical or research importance are captured; the final extraction form will be circulated to the TEP members for review prior to data extraction to ensure that all important items are captured appropriately.

Data from each eligible study will be extracted by a single reviewer. The extracted data will be reviewed and confirmed by at least one other team member (data verification). Disagreements will be resolved by consensus including a third reviewer. We will contact authors (a) to clarify information reported in the papers that is hard to interpret (e.g., inconsistencies between tables and text); (b) to obtain missing data on key subgroups of interest when not available in the published reports; and (c) to verify suspected overlap between study populations in publications from the same group of investigators. Author contact will be by email (to the corresponding author of each study), with a primary contact attempt (once all eligible studies have been identified) and up to two reminder emails (approximately 2 and 4 weeks after the first attempt).

D. Assessment of Methodological Risk of Bias of Individual Studies

We will assess the risk of bias for each individual study using the assessment instrument detailed by the Agency for Healthcare Research and Quality in its Methods Guide for Effectiveness and Comparative Effectiveness Review hereafter referred to as the Methods Guide. For randomized comparative studies, we will base our assessment on items from the Cochrane risk of bias tool for randomized controlled trials.[29]

We will not merge items into “composite” quality scores. Instead, we will assess and report each methodological quality item (as Yes, No, or Unclear/Not Reported) for each eligible study. We will rate each study as being of low, intermediate, or high risk of bias on the basis of adherence to accepted methodological principles. Generally, studies with low risk of bias have the following features: lowest likelihood of confounding due to comparison to a randomized controlled group, a clear description of the population, setting, interventions, and comparison groups; appropriate measurement of outcomes;

appropriate statistical and analytic methods and reporting; no reporting errors; clear reporting of dropouts and a dropout rate less than 20 percent; and no apparent bias. Studies with moderate risk of bias are susceptible to some bias, but not sufficiently to invalidate results. They do not meet all the criteria for low risk of bias, owing to some deficiencies, but none are likely to introduce major bias. Studies with moderate risk of bias may not be randomized or may be missing information, making it difficult to assess limitations and potential problems. Studies with high risk of bias are those with indications of bias that may invalidate the reported findings (e.g., observational studies not adjusting for any confounders, studies using historical controls, or studies with very high dropout rates). These studies have serious errors in design, analysis, or reporting and contain discrepancies in reporting or have large amounts of missing information.

In quantitative analyses, we will consider performing subgroup analyses to assess the impact of each quality item on the meta-analysis results. The grading will be outcome specific, such that a given study that reports its primary outcome well but did an incomplete analysis of a secondary outcome would be graded of different quality for the two outcomes.

E. Data Synthesis

We will summarize included studies qualitatively and present important features of the study populations, designs, interventions, outcomes, and results in summary tables. Population characteristics of interest include age, sex, the level of risk (with a diagnosis of early cancer; without a cancer diagnosis, but at high risk; screening in the population); health or numerical literacy, mismatch of native language and language of the DST, and cultural background (of which ethnic decent or racial group may be a proxy). Design characteristics include methods of population selection and sampling and followup duration. Intervention characteristics include whether the consumer is actively engaged by or passively exposed to the intervention, the intensity of the DST-based intervention (noninteractive material; interactive materials, such as computer software, but no counseling; counseling), and whether the DST is used by the consumer only or by both the consumer and the provider; whether the DST is integrated with institutional processes or is an add-on intervention; whether the DST has the potential to be realistically incorporated in routine clinical practice; and whether the DST is tailored to the needs of the target populations (e.g., in terms of language, literacy and numeracy level or cultural background. Outcomes of interest include decision quality, other attributes of the decision-making process, choices and adherence to choices, health outcomes, and health system-level outcomes.

For each comparison of interest, we will judge whether the eligible studies are sufficiently similar to be combined in a meta-analysis on the basis of clinical heterogeneity of patient populations and interventions, as well as methodological heterogeneity of study designs and reported outcomes. Discussions with the TEP indicate that in addition to pooling trials across medical conditions, as previous reviews have

done, we should analyze trials grouped according to the four major cancers (breast, colon, lung and prostate), and according to high prevalence versus rare cancers. The rationale for this is the differences in the nature of the choices or the perception of the choices among these groups.

DST-based interventions are quite heterogeneous. Below are several options for organizing them.

The summary effect from a meta-analysis of "any DST vs. control" is arguably meaningful and informative as a first approach, but it does not necessarily apply to individual DST-based interventions. All systematic reviews have focused primarily on this high-level comparison. An opportunity for advancing the state of the knowledge is by examining the comparative effectiveness of specific (categories of) DSTs (as described in Key Question 1 and subquestion 1b, for example). One potential categorization of DST-based interventions is according to their "components". It is likely that most comparisons are versus "usual care", and most evidence on comparisons between DSTs will be indirect (using usual care as a common reference). One can get information on specific DSTs through (i) subgroup analyses; (ii) a meta-regression analysis that focuses on the relationship between the intervention effectiveness and characteristics of the intervention: by DST comprehensiveness, whether the DST is given only to the patient or used during the consultation, or by levels of tailoring a DST to individual participants; (iii) a network meta-analysis comparing distinct DST-based strategies. Subgroup analyses are straightforward, but they do not inform on the comparative effectiveness of DSTs that have not been studied in head to head trials. Some subgroup explorations have been carried out in existing systematic reviews. Meta-regression analyses or network meta-analyses are more complex, but provide an opportunity to address comparative effectiveness. Example categories of increasing "comprehensiveness" may be simple interventions, such as distribution of educational materials without explicit elicitation of values versus interventions that include explicit elicitation of values. Example categories for tailoring of DSTs to participants include suggesting a decision in the end, based on the patient's information, providing personalized predictions of outcomes but not suggesting a decision, or not making suggestions and predictions. More comprehensive or highly tailored DST-based interventions take more time and resources to develop, and it is unclear whether they are more effective than less comprehensive ones.

On the basis of discussions with the KI during the topic refinement and our own review of several trials of DST-based strategy, we expect great variation in the interventions and in the definitions of outcomes. To address this we will seek input from TEP members to define groups of "sufficiently similar" interventions and outcomes for synthesis (including meta-analysis) during later stages of the review. TEP members' input will be solicited by providing a list of DST-based strategies or interventions and a list of outcomes (along with outcome definitions, when available) from the eligible studies. Of note, the material used to solicit input will not include any data on outcome

results extracted from the studies (to limit the potential for bias).

The determination on the appropriateness of meta-analysis will be made *before* any data analysis; we will not base the decision to perform meta-analysis on statistical criteria for heterogeneity. Such criteria are often inadequate (e.g., low power when the number of studies is small) and do not account for the ability to explore and explain heterogeneity by examining study-level characteristics. Main analyses will include all relevant studies; subgroup analyses by clinical diversity (e.g., at high risk of cancer versus a diagnosis of early cancer) and other potentially important consumer characteristics (e.g., numerical literacy, cultural background) will also be performed. The concordance of findings across subgroup analyses will be evaluated qualitatively (in all instances) and quantitatively (using meta-regression when the data allow). In cases when only a subset of the available studies can be quantitatively combined (e.g., when some studies are judged to be so clinically different from others as to be excluded from meta-analysis) we will synthesize findings across all studies qualitatively by taking into account the magnitude and direction of effects.

We anticipate using methods that combine direct and indirect evidence (network meta-analysis and mixed treatment comparisons).[30-32]

Pairwise meta-analyses

Direct pairwise meta-analyses will be undertaken when there are more than three unique studies evaluating the same intervention and comparator and reporting the same outcomes. All meta-analyses will be based on random effects models.[33] Sensitivity analyses (including leave-one-out analyses, analyses assuming a fixed effects model, and reanalyses after excluding a group of studies) may be undertaken if considered appropriate (e.g., in the presence of studies with outlying effect sizes or evidence of temporal changes in effect sizes). For all statistical tests, except those for heterogeneity, statistical significance will be defined as two-sided $P<0.05$. Heterogeneity will be considered statistically significant when the p-value of the Q statistic is $P < 0.1$ to account for the low statistical power of the test.[34] We will attempt to explore between-study heterogeneity using subgroup and meta-regression analyses; the decision to quantitatively synthesize studies will not be based on statistical tests for heterogeneity.[35]

Network meta-analysis

The grouping of alternative interventions into categories will be decided on the basis of the information provided in the published studies and input from the TEP (see below); as such, we cannot provide details about the network structure (e.g. number of nodes) at this time. Based on the final grouping we will examine the network architecture and specify the analysis model. In general, we expect that we will use a generalized linear model with an appropriate variance structure (e.g., binomial for binary outcomes; normal for continuous outcomes) and link function (e.g., logit for binomial outcomes; identity for continuous outcomes) for each outcome of interest.[36] Models will account for between-study heterogeneity for each comparison of interest; if the data are sufficient, we will also

evaluate the consistency of direct and indirect effects using established methods. All models will be fit using Bayesian methods because they offer additional modeling flexibility (compared to maximum likelihood approaches) and because they allow direct probabilistic statements to be made regarding the magnitude and direction of the treatment effect.

We will obtain estimates of the treatment effects of interest, as well as the rank probabilities for each treatment strategy (e.g. probability that a type of DST is the "best treatment"). We will also report probabilities that the difference in the effects comparing pairs of treatments is larger than, e.g., 1, 1.25, 1.5, 2.0, 3.0, and 5.0 (these cutoffs may change, if for example all effects are too small, it is meaningless to keep the higher cutoffs). We will also evaluate the consistency of direct and indirect effects, whenever possible (i.e. for comparisons where both direct and indirect estimates are available).

Integrating data from RCTs and nonrandomized studies (KQ 2)

For KQ 2 we will review both randomized and nonrandomized studies. We will integrate information from these two design categories qualitatively, through a narrative synthesis with tabular or graphical presentation of information. We will also examine the feasibility of a sensitivity analysis, where we would allow the randomized data to 'borrow information' from the nonrandomized data in increasing degree: in one extreme the borrowing of information will be zero, reflecting only the results of the randomized evidence. In the other extreme, the 'borrowing of information' will be maximal, with randomized and non-randomized studies effectively considered together in the same meta-analysis. Between these two extremes, a range of intermediate degrees of borrowing of strength will be examined as a sensitivity analysis, to inform the interpretation of the systematic review findings. Technically, this controlled 'borrowing of information' can be performed using a meta-analysis of RCT data in a Bayesian framework, where the prior distribution for the true effect comes from a synthesis of non-randomized data. Multiplying the precision of the prior estimate with a factor $0 < a \leq 1$ allows exploration of the whole spectrum of borrowing strength: Very low values correspond to effectively using data only from the RCTs, and a value of 1 corresponds to using data from nonrandomized and randomized studies in the same meta-analysis. Formally, this is known as the power prior approach.[37]

F. Grading the Strength of Evidence (SOE) for Individual Outcomes

We will follow the Methods Guide to evaluate the strength of the body of evidence for each Key Question with respect to the following domains: risk of bias, consistency, directness, precision, and reporting bias.[38]

Briefly, we will define the *risk of bias* (low, medium, or high) on the basis of the study design and the methodological quality of the studies. We will rate the *consistency* of the data as no inconsistency, inconsistency present, or not applicable (if there is only one study available). We do not plan to use rigid counts of studies as standards of

evaluation (e.g., four of five studies agree, therefore the data are consistent); instead, we will assess the direction, magnitude, and statistical significance of all studies and make a determination. We will describe our logic where studies are not unanimous. We will assess *directness* of the evidence ("direct" vs. "indirect") on the basis of the use of surrogate outcomes or the need for indirect comparisons (e.g. when interventions have not been directly compared and inference is based on observations across studies). We will assess the *precision* of the evidence as precise or imprecise on the basis of the degree of certainty surrounding each effect estimate. A precise estimate is one that allows for a clinically useful conclusion. An imprecise estimate is one for which the confidence interval is wide enough to include clinically distinct conclusions and that therefore precludes a conclusion.

The potential for *reporting bias* ("suspected" vs. "not suspected") will be evaluated with respect to publication bias, selective outcome reporting bias, and selective analysis reporting bias. For reporting bias, we will make qualitative dispositions based on the results of the SIP requests, rather than perform formal statistical tests to evaluate differences in the effect sizes between more precise (larger) and less precise (smaller) studies. Although these tests are often referred to as tests for publication bias; reasons other than publication bias can lead to a statistically significant result, including "true" heterogeneity between smaller and larger studies, other biases, and chance, rendering the interpretation of the tests non-specific and the tests noninformative.[39, 40] Therefore, instead of relying on statistical tests, we will evaluate the reported results across studies qualitatively, on the basis of completeness of reporting (separately for each outcome of interest), number of enrolled patients, and numbers of observed events. Judgment on the potential for selective outcome reporting bias will be based on reporting patterns for each outcome of interest, across studies. We acknowledge that both types of reporting bias are difficult to reliably detect on the basis of data available in published research studies (i.e., without access to study protocols and detailed analysis plans). Although some degree of subjectivity is unavoidable in this assessment, we will explicitly present all operational decisions and the rationale for our judgment on reporting bias in the Draft Report.

Finally, we will rate the body of evidence using four strength of evidence levels: high, moderate, low, and insufficient.[38] These will describe our level of confidence that the evidence reflects the true effect for the major comparisons of interest.

G. Assessing Applicability

We will follow the Methods Guide to evaluate the applicability of included studies to patient populations of interest, which include U.S. settings, populations with low literacy or numeracy, and populations for whom English is not a first language.[38]

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VI. Definition of Terms

Not applicable.

VII. Summary of Protocol Amendments

No amendments have been made. In the event of protocol amendments, the date of each amendment will be accompanied by a description of the change and the rationale.

VIII. Review of Key Questions

For all EPC reviews, key questions were reviewed and refined as needed by the EPC with input from Key Informants and the TEP to assure that the questions are specific and explicit about what information is being reviewed. In addition, for Comparative Effectiveness reviews, the key questions were posted for public comment and finalized by the EPC after review of the comments.

IX. Key Informants

Key Informants are the end users of research, including patients and caregivers, practicing clinicians, relevant professional and consumer organizations, purchasers of health care, and others with experience in making health care decisions. Within the EPC program, the Key Informant role is to provide input into identifying the Key Questions for research that will inform health care decisions. The EPC solicits input from Key Informants when developing questions for systematic review or when identifying high priority research gaps and needed new research. Key Informants are not involved in analyzing the evidence or writing the report and have not reviewed the report, except as given the opportunity to do so through the peer or public review mechanism.

Key Informants must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals are invited to serve as Key Informants and those who present with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

X. Technical Experts

Technical Experts comprise a multi-disciplinary group of clinical, content, and methodological experts who provide input in defining populations, interventions, comparisons, outcomes, timing or settings as well as identifying particular studies or databases to search. They are selected to provide broad expertise and perspectives specific to the topic under development. Divergent and conflicting opinions are common

and perceived as producing health scientific discourse that results in a thoughtful, relevant systematic review. Therefore study questions, design, and/or methodological approaches do not necessarily represent the views of individual technical and content experts. Technical Experts provide information to the EPC to identify literature search strategies and recommend approaches to specific issues as requested by the EPC. Technical Experts do not do analysis of any kind nor do they contribute to the writing of the report or review the report, except as given the opportunity to do so through the public review mechanism

Technical Experts must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals are invited to serve as Technical Experts, and those who present with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

XI. Peer Reviewers

Peer reviewers are invited to provide written comments on the draft report based on their clinical, content, or methodologic expertise. Peer review comments on the preliminary draft of the report are considered by the EPC in preparation of the final draft of the report. Peer reviewers do not participate in writing or editing of the final report or other products. The synthesis of the scientific literature presented in the final report does not necessarily represent the views of individual reviewers. The dispositions of the peer review comments are documented and will, for CERs and Technical Briefs, be published three months after the publication of the Evidence report.

Potential Reviewers must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Invited Peer Reviewers may not have any financial conflict of interest greater than $10,000. Peer reviewers who disclose potential business or professional conflicts of interest may submit comments on draft reports through the public comment mechanism.

XII. EPC Team Disclosures

The following team members will be involved:

- The EPC director
- The EPC co-director
- 1 Project Lead
- 1 Co-project lead/Research Associate
- 1 Local Clinical Expert
- 1 Project manager

- 1 Program Assistant

All EPC team members have no financial or other conflicts of interest to disclose.

XIII. Role of the Funder

This project was funded under Contract No. HHSA-290-2012-0012-I from the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services. The Task Order Officer reviewed contract deliverables for adherence to contract requirements and quality. The authors of this report are responsible for its content. Statements in the report should not be construed as endorsement by the Agency for Healthcare Research and Quality or the U.S. Department of Health and Human Services.

Appendix 1: Search Strategy

Strategy for KQ1:

This strategy was developed for PubMed. It will be modified to the correct terminology for CINAHL, PsycINFO, EMBASE, and any other databases searched:

("Neoplasms"[Mesh] OR cancer OR cancers OR neoplasm* OR malignan* OR premalignan* OR precancerous OR hypertrophy) AND (((choice behavior[MeSH:noexp] OR decision making[MeSH:noexp] OR decision support techniques[MeSH] OR educational technology [MeSH:noexp] OR (decision[tw] OR decisions[tw]) OR (choic*[tw] OR preference*[tw]) OR communication package[tw]) AND (health education[MeSH] OR Health Knowledge, Attitudes, Practice [MeSH:noexp] OR informed consent[tw] OR patient[tw] OR consumer[tw])) OR ((consumer* OR parent OR parents OR woman OR women OR man OR men OR personal OR interpersonal OR patient OR patients OR consumer OR personal OR individual OR nurse OR physician* OR clinician OR doctor OR “general practitioner” Or “gp”) AND (participat* OR decision OR choice* OR preference)) OR “Decision Theory”[Mesh] OR "Decision Support Systems, Clinical"[Mesh] OR "Decision Making, Computer-Assisted"[Mesh] OR "shared decision" OR (("professional-patient" OR "provider-patient") AND (relation* OR communication)) OR ((“health care” OR healthcare) AND (providers OR professional)) OR “informed decision” OR “informed choice” OR “decision support” OR choice OR ((patient OR consumer) AND involvement) OR "option grids") AND (clinical trial[pt] OR randomized controlled trial[pt] OR random*[tw] OR (double[tw] AND blind*[tw]) OR double-blind method [MeSH:noexp])
Filters: Publication date from 2008/01/01

Strategy for KQ2:

(((((((shared decision*[tiab] or sharing decision*[tiab] or informed decision*[tiab] or informed choice*[tiab] or decision aid*[tiab] or ((share*[ti] or sharing*[ti] or informed*[ti]) and (decision*[ti] or deciding*[ti] or choice*[ti]))))) OR (((decision making[mh:noexp] or decision support techniques[mh:noexp] or decision support systems, clinical[mh] or choice behaviour[mh:noexp] or decision making*[tiab] or decision support*[tiab] or choice behaviour*[tiab] or ((decision*[ti] or choice*[ti]) and (making*[ti] or support*[ti] or behaviour*[ti])))) AND (patient participation[mh] or patient participation*[tiab] or consumer participation*[tiab] or patient involvement*[tiab] or consumer involvement*[tiab] or “training intervention”[tw] or ((patient[ti] or patients[ti] or consumer*[ti]) and (involvement*[ti] or involving*[ti] or participation*[ti] or participating*[ti])))))) OR (((decision making[mh:noexp] or decision support techniques[mh:noexp] or decision support systems, clinical[mh] or choice behaviour[mh:noexp] or decision making*[tiab] or decision support*[tiab] or choice behaviour*[tiab] or ((decision*[ti] or choice*[ti]) and (making*[ti] or support*[ti] or behaviour*[ti])))) AND (professional-patient relations[mh] or ((nurses[mh] or physicians[mh] or nurse*[ti] or physician*[ti] or clinician*[ti] or doctor*[ti] or general practitioner*[ti] or gps[ti] or health care professional*[ti] or healthcare professional*[ti] or health care provider*[ti] or healthcare provider*[ti] or resident*[ti]) and (patients[mh] or patient[ti] or consumer*[ti] or people*[ti])))))) OR (((patient participation[mh] or patient participation*[tiab] or consumer participation*[tiab] or patient involvement*[tiab] or consumer involvement*[tiab] or “training intervention”[tw] or ((patient[ti] or patients[ti] or consumer*[ti]) and (involvement*[ti] or involving*[ti] or participation*[ti] or participating*[ti])))) AND (professional-patient relations[mh] or ((nurses[mh] or physicians[mh] or nurse*[ti] or physician*[ti] or clinician*[ti] or doctor*[ti] or general practitioner*[ti] or gps[ti] or health care professional*[ti] or healthcare professional*[ti] or health care provider*[ti] or healthcare provider*[ti] or resident*[ti]) and (patients[mh] or patient[ti] or consumer*[ti] or people*[ti])))))) AND ((((((((((((((((((((((((intervention*[tw] or (intervention*[tw] and (clinician*[tw] or collaborat*[tw] or community[tw] or complex[tw] or DESIGN*[tw] or doctor*[tw] or

educational[tw] or family doctor*[tw] or family physician*[tw] or family practitioner*[tw] or financial[tw] or GP or general practice*[tw] or hospital[tw] or hospitals[tw] or impact*[tw] or improv*[tw] or individualize*[tw] or individualizing[tw] or interdisciplin*[tw] or multicomponent or multi-component or multidisciplin*[tw] or multi-disciplin*[tw] or multifacet*[tw] or multi-facet*[tw] or multimodal*[tw] or multi-modal*[tw] or personalize*[tw] or personalizing or pharmacies or pharmacist* or pharmacy or physician* or practitioner* or prescrib* or prescription*[tw] or primary care[tw] or professional*[tw] or provider*[tw] or regulatory[tw] or regulatory[tw] or tailor*[tw] or target*[tw] or team*[tw] or usual care[tw]))))) OR ((pre-intervention*[tw] or preintervention*[tw] or "pre intervention*"[tw] or post-intervention*[tw] or postintervention*[tw] or "post intervention*"[tw])))) OR ((hospital or patient) and (study or studies or care or health or practitioner* or provider* or physician* or nurse* or nursing or doctor))) OR demonstration project*[tw]) OR ((pre-post[tw] or "pre test*"[tw] or pretest*[tw] or posttest*[tw] or "post test*"[tw] or (pre[tw] and post[tw])))) OR ((pre-workshop[tw] or post-workshop[tw] or (before[tw] and workshop[tw]) or (after[tw] and workshop[tw])))) OR (trial[tw] or ((study[tw] and aim*[tw]) or "our study"[tw]))) OR ((before[tw] and (after[tw] or during[tw])))) OR (("quasi-experiment*" or quasiexperiment* or "quasi random*" or quasirandom* or "quasi control*" or quasicontrol* or ((quasi or experimental) and (method or study or trial or design*))))) OR (("time series" and interrupt*))) OR ((time points[tw] and (over[tw] or multiple[tw] or three[tw] or four[tw] or five[tw] or six[tw] or seven[tw] or eight[tw] or nine[tw] or ten[tw] or eleven[tw] or twelve[tw] or month*[tw] or hour*[tw] or day[tw] or days[tw] or "more than"[tw])))) OR pilot[tw]) OR "Pilot Projects"[Mesh]) OR ((clinical trial[pt] or controlled clinical trial[pt] or multicenter study[pt]))) OR ((multicentre[tw] or multicenter[tw] or multi-centre[tw] or multi-center[tw]))) OR (random*[tw] or controlled[tw])) OR ((control[tw] and (area[tw] or cohort*[tw] or compare*[tw] or condition[tw] or design[tw] or group[tw] or groups[tw] or grouping[tw] or intervention*[tw] or participant*[tw] or study[tw])) not (controlled clinical trial[pt] or randomized controlled trial[pt])))) NOT ((((("comment on" or review[tw] or review [pt])) OR (("Animals"[Mesh] NOT "Humans"[Mesh]))) OR ((rat[tw] or rats[tw] or cow[tw] or cows[tw] or chicken*[tw] or horse[tw] or horses[tw] or mice[tw] or mouse[tw] or bovine[tw] or animal*[tw])))))) OR (clinical trial[pt:noexp] or randomized controlled trial[pt] or controlled clinical trial[pt] or evaluation studies[pt] or comparative study[pt] or intervention studies[mh] or evaluation studies[mh:noexp] or program evaluation[mh:noexp] or random allocation[mh] or random*[tiab] or double blind*[tiab] or controlled trial*[tiab] or clinical trial*[tiab] or pretest*[tiab] or pre test*[tiab] or posttest*[tiab] or post test*[tiab] or prepost*[tiab] or pre post*[tiab] or controlled before*[tiab] or “before and after”[tiab] or interrupted time*[tiab] or time serie*[tiab] or intervention*[tiab]))) AND (("Neoplasms"[Mesh] OR cancer OR cancers OR neoplasm* OR malignan* OR premalignan* OR precancerous))
Filters:Publication date from 2009/01/01