Research White Paper

Defining the Benefits of Stakeholder Engagement in Systematic Reviews

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The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information (i.e., in the context of available resources and circumstances presented by individual patients).

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies and strategies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To improve the scientific rigor of these evidence reports, AHRQ supports empiric research by the EPCs to help understand or improve complex methodologic issues in systematic reviews. These methods research projects are intended to contribute to the research base in and be used to improve the science of systematic reviews. They are not intended to be guidance to the EPC program, although they may be considered by EPCs along with other scientific research when determining EPC program methods guidance.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers and the health care system as a whole by providing important information to help improve health care quality. The reports undergo peer review prior to their release as a final report.

We welcome comments on this Methods Research Project. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by e-mail to epc@ahrq.hhs.gov.

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Defining the Benefits of Stakeholder Engagement in Systematic Reviews

Structured Abstract

Background. Stakeholder engagement efforts in the Evidence-based Practice Center (EPC) program initially focused on defining opportunities and developing materials to involve stakeholders in systematic reviews. Over time, the basic mechanics of working with stakeholders have become a routine part of the systematic review process, allowing the program to begin to explore how to improve stakeholder engagement and make it more effective

Purpose. The purpose of this research paper is to examine the benefits and challenges of engaging stakeholders in the process of developing and performing systematic reviews, drawing upon findings from the literature and Key Informant (KI) interviews with program leaders, systematic reviewers and stakeholders from within the EPC program and other international evidence-based programs.

Methods. We searched a range of databases, including Ovid MEDLINE, EBM Reviews, and Scopus. A gray literature search identified relevant guidance issued by internationally recognized organizations, and additional citations were identified both via research team members and by pearling of relevant article bibliographies. Abstracts and full text articles were reviewed for relevance by three investigators. In addition to the literature search we conducted a series of interviews with those who know the most about this process: 60 KIs were invited and one investigator facilitated all of the interviews. With permission from all participants we recorded and transcribed all calls; two investigators and two research assistants conducted analysis using NVivo to identify and synthesize recurring themes. In addition to identifying overarching themes, we conducted a more detailed exploratory analysis of the KI interviews with an eye towards articulating the benefits of engaging specific types of stakeholders at each phase of the systematic review.

Results. Of the 299 abstracts and 80 full-text articles reviewed, 24 addressed in some fashion the benefits, challenges, measurement or evaluation of stakeholder engagement. Benefits cited included identifying and prioritizing topics for research; providing pragmatic feedback on the research protocol; aiding in recruitment of research participants; helping the researchers understand the research subject's perspective; ensuring that findings are interpreted with the end user in mind and that final products are readable and accessible; and facilitating wider dissemination and uptake of research findings. There was almost no discussion of measurement or evaluation of the impact of stakeholder engagement. Of the 60 KIs we invited, 34 agreed to participate, we conducted 12 discussion sessions (60 to 90 minutes per session) with between one and four participants each. Indeed, it was not uncommon for stakeholders to represent more than one perspective. Overarching themes from our KI interviews were organized according to the three guiding questions of this white paper: (1) What are the potential or expected benefits of involving stakeholders in systematic reviews? (2) What are the challenges of involving stakeholders in systematic reviews? (3) How can we measure the impact of stakeholder engagement in systematic reviews?

Conclusions/Recommendations. Although it is recognized by many as an important next step, to date there have been few efforts to measure the benefits/tradeoffs of specific stakeholder engagement processes or differing approaches to selecting and engaging differing stakeholder types. In order to refine our processes for efficiently and effectively engaging stakeholders, we need to develop methods to evaluate the impact of stakeholder engagement based on a more concrete understanding of the specific benefits we are hoping to achieve. Toward this end, we reviewed the existing literature and conducted a series of KI interviews in an effort to more explicitly define the expected benefits of engaging stakeholders in systematic reviews.

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Introduction

Background and Rationale

Medical research has evolved over the years from the paradigm of the lone research scientist to a model that encompasses a broader range of clinical research activities, including multidisciplinary team science. One of the more recent developments in this evolution is the active engagement of stakeholders in the selection, design, funding, and conduct of research. Activities to ensure engagement range from relatively simple approaches, such as asking stakeholders to participate in research meetings or comment on research proposals, to more resource intensive, including the use of Delphi techniques to reach consensus about research priorities and involving stakeholders directly making funding decisions or conducting research.[1,2] The overarching goal of stakeholder engagement in medical research is to generate evidence that is more relevant and useful to those making real-world health care decisions, with the hope that this will increase the dissemination and uptake of research findings in clinical practice.[3, 4]

The move toward more explicit stakeholder engagement is consistent with the long tradition of applied research conducted to improve health and health care by the Agency for Healthcare Research and Quality (AHRQ). Along with other prominent institutions, such as the Patient-Centered Outcomes Research Institute, AHRQ Effective Health Care (EHC) Program firmly believes that stakeholder engagement is integral to its mission of providing evidence-based information to health care stakeholders that is timely, objective, scientifically rigorous, and developed and presented with transparency.[5] The EHC Program defines a "stakeholder" as a person or group with a vested interest in a particular clinical decision and the evidence that supports that decision, including:

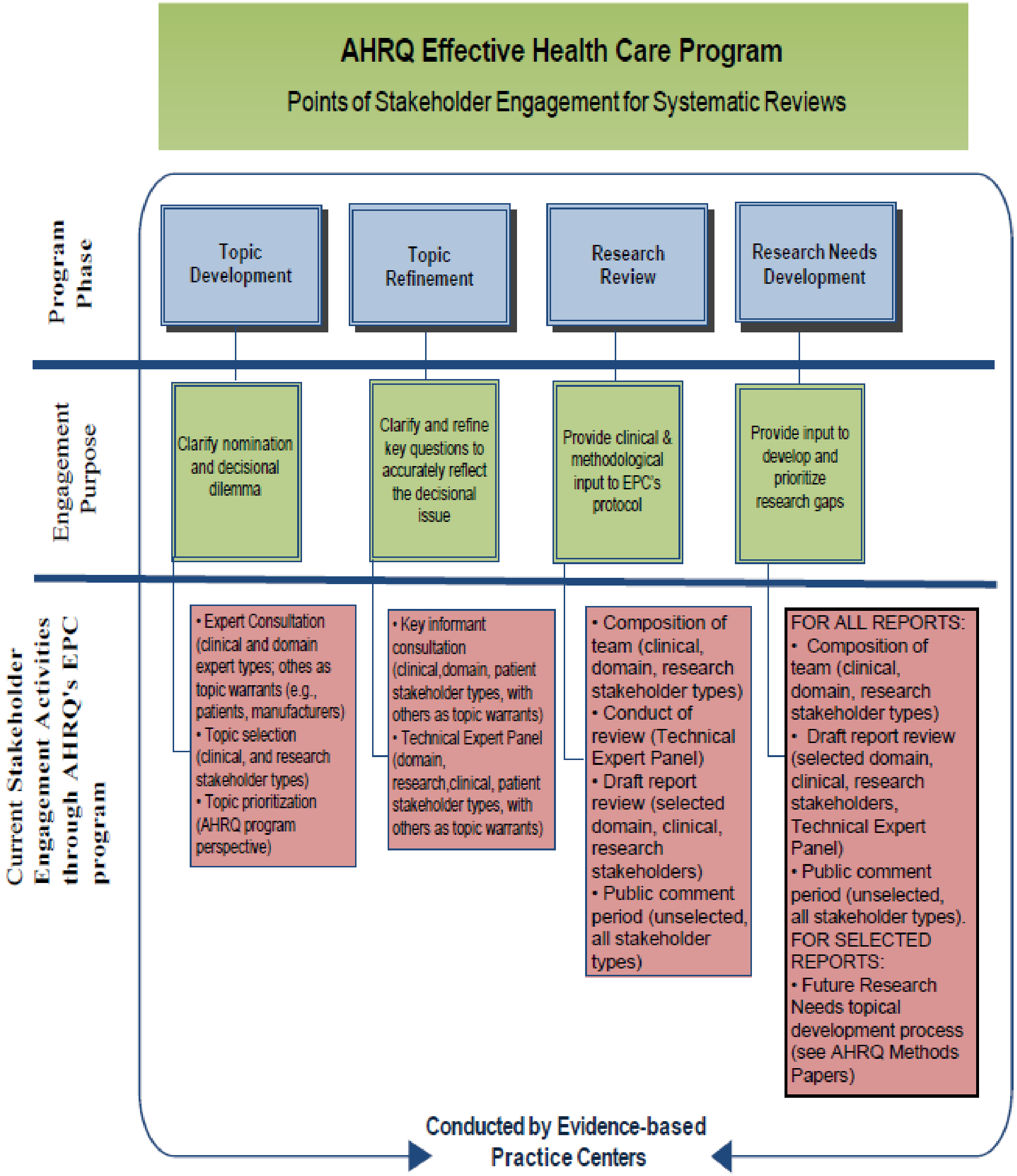
- Patients, caregivers, and patient advocacy organizations
- Clinicians and their professional associations
- Institutional health care providers, such as hospital systems and medical clinics
- Government agencies
- Purchasers and payers, such as employers and public and private insurers
- Health care industry representatives
- Health care policymakers at the Federal, State and local levels
- Health care researchers and research institutions.

A key component of the AHRQ EHC Program is to inform and facilitate medical decisions by producing systematic reviews that gather, evaluate, and synthesize the vast array of evidence on medical tests, treatments, and delivery systems.[6] At present, the Evidence-based Practice Centers (EPCs) engage stakeholders at several distinct points throughout the lifecycle of a systematic review—from topic refinement through report dissemination (see Figure 1 below). Stakeholder engagement efforts in the EPC program initially focused on defining opportunities and developing materials to involve stakeholders in systematic reviews. Over time, the basic mechanics of working with stakeholders have become a routine part of the systematic review process, allowing the program to begin to explore how to improve stakeholder engagement and make it more effective.

Although there is a growing literature on the process of engaging stakeholders in medical research, there are a lack of clearly defined measures for reporting and evaluation, which limits the ability learn from past experience, understand the effectiveness of engagement, or identify what approaches work best.[7] Indeed, knowing how to make an activity “more effective” presupposes an understanding of the desired outcome or expected benefit, and the ability to measure how effective the activity is to begin with. Moreover, understanding the challenges, tradeoffs, and adverse consequences of a particular activity is also integral to measuring overall impact and effectiveness.

Toward this end, this paper examines the benefits and challenges of engaging stakeholders in the process of developing and performing systematic reviews, drawing upon findings from the literature and Key Informant (KI) interviews with program leaders, systematic reviewers and stakeholders from within the EPC program and other international evidence-based programs. We define ***benefits*** as the expected positive changes to the quality and impact of the systematic review as a result of engaging stakeholders in the process. Additional positive externalities from engagement (i.e. positive consequences of the process that did not directly affect the quality and impact of the review such as building relationships, educating stakeholders about the research process, and personal benefits of involvement), were not included in the scope of this report. We define ***challenges*** as the costs and difficulties associated with engagement that need to be balanced against the benefits of involvement. Clearly defining the benefits and challenges involved in this process is an integral first step towards developing a process to measure and evaluate the impact of stakeholder engagement on the conduct, quality, and dissemination of the evidence reviews produced by AHRQ.

Figure 1. AHRQ Effective Health Care Program: Points of stakeholder engagement for systematic reviews



Methods

Literature Search

As a first step, we searched the published and gray literature to identify studies that address the benefits, challenges, and/or measurement of stakeholder engagement. The specific aims of this review were to: (1) understand the overall state of the field and whether there were existing efforts to explicitly define or evaluate the impact of stakeholder engagement in primary research or systematic reviews, and (2) better inform and focus the KI interviews.

We searched a range of databases, including Ovid MEDLINE, EBM Reviews (Cochrane Database of systematic Reviews, Cochrane Methodology Register, Database of Abstracts of Reviews of Effects, Health Technology Assessment) and Scopus (see Appendix A for the complete search strategy). A gray literature search identified relevant guidance issued by internationally recognized organizations, including the Cochrane Collaboration, National Institutes for Health and Clinical Excellence (NICE), Campbell Collaboration, U.S. Preventive Services Task Force, and others. Additional citations were identified both via research team members and by pearling of relevant article bibliographies. The final search strategy is listed in Appendix A.

Abstracts and full text articles were reviewed for relevance by three investigators. We included articles that described the benefits, challenges, and/or measurement of stakeholder engagement in systematic reviews or health research more generally, including primary research and health technology assessment. We excluded articles that were published prior to 2005,[a] those that primarily focused on *how* to engage stakeholders (instead of *why* or *when*), and those that were not relevant to health research or systematic reviews. Of the 299 abstracts and 80 full-text articles reviewed, 24 addressed in some fashion the benefits, challenges, measurement or evaluation of stakeholder engagement. Relevant information was extracted from each of these 24 articles (see Appendix B).

Key Informant Interviews

To ensure a comprehensive understanding of the benefits and challenges of stakeholder engagement within a systematic review (or EPC) context and identify any existing formal or informal efforts to measure or evaluate the impact of engagement, we conducted a series of interviews with those who know the most about this process: ***systematic reviewers*** who engage stakeholders in their work, ***programmatic officials*** who commission systematic reviews, ***policy makers*** who use systematic reviews, and ***stakeholders*** who have been involved in the systematic review or research process.

Potential KIs from each of the above groups were identified by members of our working group and invited to take part in a 90-minute individual or group interview between April 2 and April 29, 2013. We invited 60 KIs from across the 4 perspectives highlighted above. One investigator facilitated all of the interviews. Each KI completed an "EPC Conflict of Interest Disclosure Form" prior to being interviewed and no conflicts were reported that prevented participation for any individual. We asked all KIs for their permission to audio record and

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[a] The AHRQ Effective Healthcare Program was established in 2005.

transcribe the discussions and acknowledge their participation in our final White Paper, also assuring them that no individually identifiable information would be included in our final report.

To guide the interviews, we developed a set of semi-structured interview questions designed to elicit a multi-faceted understanding of the value of engaging stakeholders in systematic reviews, including the expected benefits and challenges (see Appendix C). Our goal was not to test a specific hypothesis, but rather to understand KI perspective and experience regarding stakeholder engagement in systematic reviews. Although the nature of the discussions differed slightly according to the make-up of each interview group and the perspective and experiences of the KIs, each group reflected on the following overarching domains: (1) What did you expect/hope to achieve by engaging stakeholders? (2) What are some of the tangible benefits and challenges of stakeholder engagement (including points in the process when it is most/least valuable and particular types of stakeholders who have added the most/least value)? (3) How can we measure the value (i.e., the balance of benefits and challenges) of stakeholder engagement in systematic reviews?

Transcripts were entered into NVivo software for analysis. Two investigators and two research assistants read all of the transcripts to identify and synthesize recurring themes. Themes and findings were presented to the larger working group during biweekly calls to generate additional discussion and insights. In addition to identifying overarching themes, we conducted a more detailed exploratory analysis of the KI interviews with an eye towards articulating the benefits of engaging specific types of stakeholders at each phase of the systematic review. Finally, we noted any particular suggestions by KIs of how to measure the achievement of expected values or benefits.

Results

Literature Search

Overall we found 24 articles describing—in more or less detail—the benefits, challenges, or approaches to measuring and evaluating the impact of stakeholder engagement. The majority focused on stakeholder engagement in primary research, and only a few articles were specific to systematic reviews. In general, the articles described developing perspectives, recent experiences, and tools or best practices for conducting stakeholder engagement. See Appendix B Table B-1 to Table B-5 for a full listing of the relevant information extracted from each article.

Although the literature on stakeholder engagement in primary research touched on a wide range of benefits, most studies relied on observations and inferences, with very few directly measuring the impact of stakeholder engagement. Benefits cited included identifying and prioritizing topics for research; providing pragmatic feedback on the research protocol; aiding in recruitment of research participants; helping the researchers understand the research subject's perspective; ensuring that findings are interpreted with the end user in mind and that final products are readable and accessible; and facilitating wider dissemination and uptake of research findings. There was almost no discussion of measurement or evaluation of the impact of stakeholder engagement.

Of the handful of the studies we reviewed that reported on the effect of stakeholder engagement on the quality and impact of systematic reviews, the majority were specific to the UK. Several general benefits were articulated, including refining the scope and improving the quality of the review, suggesting and locating relevant literature, interpreting the review findings and putting them into perspective, improving the readability and clarity of the report, and contributing to wider dissemination and utilization of the findings. [8-12] However, as in the literature on stakeholder engagement in primary research, there was no effort to explicitly measure the impact of stakeholder engagement and/or evaluate whether, how, and through what means these suggested benefits were achieved.

The need for additional time and resources was cited as one of the primary challenges of engaging stakeholders in both primary research and systematic reviews.[8, 12, 13] Moreover, concerns about the representativeness of stakeholder perspectives, the ability of stakeholders to participate consistently throughout the review process,[8] and the potential of merely tokenistic involvement were also raised.[13]

Although the studies cited above articulate a general sense of the benefits and challenges of stakeholder engagement, the literature is silent on the topic of how to measure the impact of their involvement. Indeed, there has been little effort to explicitly evaluate impact or develop quality standards for stakeholder engagement in systematic reviews or even in health research more broadly. In a recent systematic review of the impact of patient and public involvement in health and social research, Brett, et al. concluded that the impact of public and stakeholder engagement is weak and poorly reported.[14] Specific to systematic reviews, Boote, et al. suggested that we need to find out more about what works best, for whom and in what circumstances.[8] Both authors (and a number of other articles reviewed for this paper), highlighted the need to evaluate the impact of stakeholder involvement on the systematic review process, to make explicit the contribution of stakeholders at different stages of the review, and to develop quality standards.[8, 14] In short, although the existing literature supports the EHC program's belief that stakeholder involvement provides important concrete benefits to systematic reviews (see summary in Table 1, for example), the discussions of specific benefits and challenges are broad and lack the refinement necessary to design a set of measures for evaluating the impact of stakeholder engagement on the systematic review process.

Table 1. Literature search: Potential benefits and challenges of engaging stakeholders in systematic reviews

Benefits
• Refine scope
• Improve quality
• Suggest and locate relevant literature
• Interpret findings/put findings in perspective
• Improve readability and clarity of report
• Increase dissemination and utilization of findings
Challenges
• Additional time and resources
• Selection of stakeholders/achieve representativeness
• Reliability/consistency in participation
• Maintain confidentiality
• Manage and support stakeholders
• Overcome tokenism

Key Informant Interviews

Of the 60 KIs we invited, 34 agreed to participate –15 ***systematic reviewers*** who engage stakeholders in their work, 10 ***programmatic officials*** who commission systematic reviews, and 9 ***stakeholders*** who have been involved in the systematic review or research process. In all, we conducted twelve 60 to 90 minute discussion sessions with between one and four participants each. All policymakers also represented another perspective, so their input could not be called out separately. Indeed, it was not uncommon for stakeholders to represent more than one perspective. Overarching themes from our KI interviews were organized according to the three guiding questions of this white paper: (1) What are the potential or expected benefits of involving stakeholders in systematic reviews? (2) What are the challenges of involving stakeholders in systematic reviews? (3) How can we measure the impact of stakeholder engagement in systematic reviews?

What Are the Primary Expected Benefits of Involving Stakeholders in Systematic Reviews?

Overall, the expected benefits described by KIs clustered into six overarching domains: (a) establishing credibility, (b) anticipating controversy, (c) ensuring transparency and accountability, (d) improving relevance, (e) enhancing quality, and (f) increasing dissemination and uptake of systematic review findings. Appendix D provides excerpts from KI interviews regarding the expected benefits of engaging stakeholder in reviews.

Establishing Credibility

Systematic reviewers and programmatic officials in particular commented on the importance of engaging stakeholders from the beginning of the systematic review process in order to establish credibility and gain stakeholder buy-in. When stakeholders are engaged from the beginning, they are more likely to understand the process and feel that their insights are incorporated into the design and conduct of the review. The very act of engagement helps to establish the credibility of both the systematic review process and the final report. KIs who had been engaged in a review as a stakeholder reported that it gave them a sense of investment in the process and findings, as opposed to feeling that the results were simply “announced” to them at the end.

Anticipating Controversy

Several KIs explained that a key benefit of engaging stakeholders is the ability to anticipate controversies and opposing views that could potentially derail a report’s relevance. Systematic reviewers and programmatic officials in particular underscored the imperative of understanding the context and history of a given topic, including areas of scientific uncertainty or debate and politically charged or “hot button” issues from a consumer or advocacy perspective. Moreover, they described instances when stakeholders were able to uncover “blind spots” including issues of current debate or concern that impacted what questions were asked or how the report’s findings were communicated. Although it isn’t always possible to completely prevent controversy, especially when reviewing important topics, there was a general consensus that having a comprehensive understanding of the potential issues in advance enabled systematic reviewers to be more prepared to respond to criticism or controversy should it arise.

Ensuring Transparency and Accountability

KIs described the benefit of engaging stakeholders in the review process as key to ensuring transparency and accountability, particularly in situations where systematic reviews directly determine policy. KIs from the stakeholder and policy/programmatic perspective suggested that engaging a broader community in the process is a democratic right. One stakeholder argued that engaging the public in making decisions about the direction of a systematic review and ensuring that the process is geared towards questions and issues that are relevant to them is a moral imperative. Systematic reviewers and program officials both noted that mandates to engage stakeholders are important aspects of displaying accountability, transparency, and ongoing support for systematic reviews.

Improving Relevance

KIs from all perspectives suggested that a primary motivation for engaging stakeholders is the belief that engaging the end users – patients, clinicians, policymakers, or guideline developers – is necessary to produce reports that are timely, relevant and address real-world dilemmas. There was general agreement that engaging those who would use the evidence was the best way to ensure that a systematic review addresses the right questions, includes the right outcomes, and that the review team does not miss a critical perspective. KIs repeatedly emphasized that stakeholders bring an understanding of the context that comes from having in-depth professional or personal experience with a topic and that without this input systematic reviews could miss the target and end up gathering dust on shelves rather than changing practice.

Enhancing Quality

In addition to improving relevance, systematic reviewers and program officials identified a number of specific areas where stakeholder input improved the scientific quality of the final report, including: framing the review and defining the key questions; helping the team to refine the scope of the review; and establishing appropriate parameters for the population, intervention, comparator, outcome, timing and settings (PICOTS) considered. Systematic reviewers credited stakeholder input with identifying nuances that were integral in helping to clearly define the PICOTS considered in a given review. Moreover, clinical experts were identified as instrumental in providing valuable context that may not be readily apparent from the published literature, including identifying tests and procedures that are obsolete, or highlighting dosing and side effect profiles of different classes of medications that may influence study findings.

The majority opinion was that engaging patients in the other technical aspects of the report, such as gathering, qualifying, analyzing, and reporting the findings, was not as valuable, unless they had research or clinical background and training. However, a number of systematic reviewers suggested that engaging clinical experts during the conduct of the review could add substantial value, ensuring that they hadn’t missed any critical or high-impact studies, further refining inclusion and exclusion criteria, and helping the team to “read between the lines” of the published studies and highlight issues that might not be readily apparent to those not so familiar with the clinical context. The value of contacting industry stakeholders to identify ongoing studies relevant to the review was also noted.

Increasing Dissemination and Uptake of Systematic Review Findings

All of our discussions touched in some fashion on the idea of engaging stakeholders as a route to improving the dissemination and uptake of systematic review findings. KIs from all perspectives agreed with the principle that involving stakeholders meaningfully in the process should, at least in theory, increase the likelihood that systematic reviews address the right questions; are relevant to the real-life decisions faced by patients, clinicians, and policymakers; and that the findings are actually used to guide and inform real-life medical decisions. Moreover, KIs expressed the hope that by involving stakeholders in the conduct of systematic reviews, they are likely to become advocates for the results, thereby facilitating more widespread dissemination and uptake of the final product. However, despite agreeing on the principle that engaging stakeholders can facilitate dissemination and uptake of reports, there was also consensus that we still have more work to do as a field to improve the dissemination and uptake of evidence.

What are the Challenges of Involving Stakeholders in Systematic Reviews?

Part of understanding the value of stakeholder engagement is recognizing the challenges and tradeoffs that are involved. KIs identified the following overarching challenges to involving stakeholders in systematic reviews: (a) time, (b) training and resources (for stakeholders as well as researchers who would engage them), (c) finding the right people, (d) balancing multiple often competing inputs, and (e) understanding when to engage specific types of stakeholders. Of the challenges, two are tradeoffs (time and resources), which have to be balanced against the benefits generated by stakeholder engagement or else minimized. The others are potential problems that, unless addressed by the engagement process, can prevent the benefits from being realized. Appendix D provides excerpts from the KI interviews to illustrate these themes.

Time

First and foremost, KIs from all perspectives agreed that engaging stakeholders requires a significant investment of time, especially if it is to be done well. Systematic reviewers repeatedly emphasized that engaging stakeholders in the systematic review process lengthens the project timeline, especially if stakeholders are engaged at more than one time point. Given how rapidly new research becomes available, this can be a significant problem for systematic reviews. There was disagreement as to whether the extra time involved resulted in an improved product, with some arguing that the time spent engaging stakeholders was at least partly recouped by avoiding missteps, and others arguing that getting the results out to stakeholders earlier was more important than engaging them in the systematic review process. This investment of time was cited as an issue for stakeholders as well. Meaningful involvement in a systematic review requires a great deal of time and energy, and by definition stakeholders usually have other professional or caregiving responsibilities.

Training and Resources

KIs also agreed that engaging stakeholders requires a significant investment of resources, and that lack of the appropriate training and resources can limit the benefits of the stakeholder engagement. Many investigators are unfamiliar with how to best utilize and engage stakeholders and lack the skills required for successful management of such a process. Moreover, stakeholders who do not have a clinical or research background may require additional training and ongoing support in order to make a meaningful contribution to the process. KIs from all perspectives, but especially systematic reviewers and those who had served as stakeholders, suggested that ensuring that both sides have the necessary background and training, and sufficient resources to support their role, would go a long way toward increasing the overall benefit of stakeholder engagement in systematic reviews. The training time and additional resource requirements were seen as very real and requiring acknowledgement by those commissioning and supporting stakeholder engagements in systematic reviews; these requirements also underscore the need for better specification in the activities of stakeholder engagement.

Finding the Right People

Identifying and inviting stakeholders to participate in the review process is not an exact science and figuring out whom to engage can be challenging. Moreover, because Federal regulations limit the number of stakeholders who can be engaged in a given review, the choice of who to engage carries a great deal of weight. Getting it wrong can limit or negate the value of the engagement. During one discussion among systematic reviewers, there was agreement that in many instances the benefit of engagement is highly correlated with which types of stakeholders are engaged and/or the make-up of the stakeholder group.

KIs who had been involved as stakeholders and systematic reviewers alike noted that not all stakeholders have the same level of commitment and/or ability to contribute significantly to the systematic review process. Engaging those with high commitment runs the risk of engaging those with the most conflicts of interest. Moreover, as highlighted above, stakeholders who are not intimately familiar with the scientific review process may need substantial background and training in order to make valuable contributions.

Both stakeholders and systematic reviewers also emphasized that beyond their clinical expertise or personal experience with the topic, less tangible (or readily apparent) individual characteristics often play a large role in shaping the value and impact of stakeholder engagement, including: personality traits, their level of social influence among their peers, their level of personal motivation and willingness to engage, comfort with sharing their opinions amongst a room full of “experts,” and comfort with group processes. Some even suggested developing a database of “good stakeholder” contacts so that those that are a proven asset to this type of work can be accessed for future work.

Balancing Multiple Inputs

Another challenge is defining the relative value of different stakeholders input. Only a limited number of stakeholders are engaged per review and it can be a challenge to determine whether a particular stakeholder is an outlier or has a personal or political agenda. As one systematic reviewer emphasized, not all stakeholder input is equal and it is often difficult to assess which points to incorporate. It is a delicate balance to make stakeholders feel that their insights are valued, while at the same time being mindful that not all ideas can be incorporated into the review as there are scientific as well as resource issues to also consider. Some systematic reviewers expressed concern about expectations associated with being able to respond to all opinions expressed through stakeholder engagement. On the other hand, KIs who had served as stakeholders reported feeling pressure to come up with new or interesting insights or contributions or raise issues that the systematic review team had not addressed. Stakeholders also reported feeling intimidated by the process or under pressure to serve as the representative voice for a large population of people.

Understanding How To Match the Right Type of Stakeholder to the Right Time in the Systematic Review Process

An overarching theme from many of the systematic reviewers was the concern that mandates for more extensive stakeholder engagement in systematic reviews seem to suggest that “more is better,” but there has been less attention to understanding when in the process it is most useful to engage a particular type of stakeholder. There was concern that we lump all stakeholders together into a homogenous group, without recognizing the different contributions that different types of stakeholders can bring at each point in the review. This increases the time and resources needed and risks frustrating or burning out the participants.

How Can We Measure the Impact of Stakeholder Engagement?

Because the practice of engaging stakeholders in systematic reviews is still relatively young, there has been almost no formal assessment of the impact of stakeholder engagement to date. The limited number of studies identified in our literature search focused primarily on measures of the engagement process (i.e., whether the process was transparent and stakeholders were engaged as partners), as opposed to the actual impact of the engagement on the design, conduct, or dissemination of the systematic review. With the exception of a small minority of KIs who felt that efforts at measurement in this area were futile and not the best use of scarce resources, there was general agreement that there is a need to further define what discrete benefits and impacts are expected from stakeholder engagement and to develop methods to measure and evaluate them.

Regardless of their perspective on the utility of this endeavor, we asked KIs to brainstorm and help think through strategies for evaluating the effectiveness of stakeholder engagement (see Appendix D for excerpts from KI interviews). Overall, there was consensus that it is important to build a better understanding of what we are trying to achieve and who and when we should engage to best achieve this goal. The most frequently cited method to capture the benefit and impact of stakeholder engagement was to evaluate the quality and validity of the review and how widely the review is used. For example, KIs suggested that tracking how a review is used to guide policy decisions or guideline development may be an important indicator of impact. Another suggestion was to evaluate whether a report resulted in the generation of new research or helped to spur the release of targeted requests for proposals. Moving beyond a simple assessment of the number of peer-reviewed articles and citations, and devising a way to assess the degree of dissemination and uptake in clinical practice by monitoring the number of page views or Internet downloads for a given report was also cited as another potential route for measuring impact.

Other KIs proposed very pragmatic measures of the effectiveness of stakeholder engagement, such as tracking the changes in key questions, inclusion and exclusion criteria, or other elements of the review. Consistent with findings from the published literature, efforts could also be made to survey or conduct informal briefings with the stakeholders who were engaged in the review to assess their perspective on the effectiveness of the process and the overall utility of the final report. Surveys to assess whether stakeholders involved in framing key questions could see any of their ideas incorporated could potentially measure this, although lack of incorporation could reflect competing input and scientific limitations as much as "failure" of engagement. This example illustrates the challenge of designing appropriate measures for engagement. One KI suggested that achieving "saturation" of new ideas before discontinuing stakeholder engagement at the research plan phase could be predictive of more useful reports. If this theory holds promise, it could be relatively easily evaluated qualitatively using recordings or transcripts of stakeholder engagement activities.

Empiric evaluation was also identified as a possible route to measuring effectiveness. AHRQ could assign a review to two different EPCs and ask one to engage stakeholders in the process, but not the other, and compare the overall quality of the reviews and perhaps evaluate their usefulness from the stakeholder perspective. A number of systematic reviewers mentioned the possibility of looking at this question retrospectively by comparing the quality and usefulness of past reports with varying degrees of stakeholder engagement. Another suggestion was to survey matched stakeholders who were or were not engaged regarding their perceptions of the utility of a systematic review, whether they actually used the review, and needed improvements. Alternatively, stakeholder input could be deliberately phased in to allow measurement of changes across a range of topics. One challenge in this approach would be in determining when change was just change and when it was "better."

Discussion

In general, findings from the KI interviews echoed the expected benefits of stakeholder engagement in systematic reviews highlighted in the small number of existing studies (see Table 1). For example, both the interviews and literature suggest that stakeholder engagement helps to improve the relevance and quality of the review and has the potential to increase dissemination and uptake of the report findings. However, KIs placed additional emphasis on the importance of stakeholder engagement for establishing credibility and buy-in, anticipating controversy, and ensuring programmatic and societal accountability. With respect to challenges, both the literature and the KI interviews emphasized the extra time and resources necessary to engage stakeholders and the need for appropriate training (on the part of stakeholders and researchers alike) in order to maximize the benefit of engagement.

Although the general themes highlighted in the literature and the KI interviews were similar, the interviews provided a more nuanced understanding of the tradeoffs involved, including the variation in relative benefits and challenges depending on *who* is engaged and *when* they are engaged. Systematic reviewers in particular highlighted the importance of engaging the right stakeholder at the right time and explained that in their experience the benefit of engagement often depends on the characteristics of the individual stakeholder, or combination of stakeholders, involved (e.g., training, personal experience, personality traits, level of connection with others). Many of the discussions also focused on the challenge of deciding what input to incorporate into the report, and the inability to respond to all stakeholder comments and/or concerns.

Moreover, a number of systematic reviewers clearly identified the need for more differentiated thinking about specific types of stakeholders (i.e., the general public is different than patients who are different from patient advocacy groups) as well as which stakeholders can contribute unique and valuable perspectives at specific points in the systematic review process. Overall, one of the strongest messages from the systematic reviewers we interviewed was the importance of linking the benefits of engaging specific types of stakeholders at different stages of the review process, rather than rotely engaging a broad range of stakeholders in all phases of the review as “insurance.”

While KI interviews conducted for this project were designed primarily to understand the overarching expected benefits of engaging stakeholders, in some cases they provided explicit examples of the benefits of particular stakeholders at specific points in the review. This enabled us to conduct a more refined exploratory analysis of the interviews, coding relevant comments from KIs about the specific benefits and challenges of engaging different types of stakeholders at different stages in the systematic review. Using a matrix (see Appendix E for example), we coded comments about the value of engaging the eight different categories of stakeholders (described on p.1 of the report) across three program phases for systematic reviews: topic refinement, research conduct, and research needs development. Of all phases of the systematic review we considered, the formative phase of refining the topic and developing the key questions was repeatedly identified as the most critical point for engaging stakeholders in general, and certain groups of stakeholders in particular. It was also the only phase where KIs felt engaging stakeholders produced all six benefits: credibility, anticipating controversy, transparency and accountability, relevance, quality, and dissemination and uptake of systematic review findings. In addition, KIs felt every category of stakeholder should be engaged at this stage. Future research could utilize such a matrix to explore in detail the expected benefits of engaging different types of stakeholders in each phase of the review.

Conclusions and Future Directions

Although it is recognized by many as an important next step, to date there have been few efforts to measure the benefits/tradeoffs of specific stakeholder engagement processes or differing approaches to selecting and engaging differing stakeholder types. In order to refine our processes for efficiently and effectively engaging stakeholders, we need to develop methods to evaluate the impact of stakeholder engagement based on a more concrete understanding of the specific benefits we are hoping to achieve. Towards this end, we reviewed the existing literature and conducted a series of KI interviews in an effort to more explicitly define the expected benefits of engaging stakeholders in systematic reviews.

Through our interviews, we identified six main expected benefits and five primary challenges of involving stakeholders in systematic reviews. Of note is that all benefits relate (either directly or indirectly) to the systematic review product, whereas most of the challenges relate to the process of eliciting meaningful stakeholder input. This suggests that attempts to measure stakeholder impact need to include both process and outcome measures.

Six main categories of expected benefits

1. Establishing credibility
2. Anticipating controversy
3. Ensuring transparency and accountability
4. Improving relevance
5. Enhancing quality
6. Increasing dissemination and uptake of systematic review findings.

Five primary challenges

1. Time and resources
2. Researcher skills for stakeholder engagement
3. Finding the right people
4. Balancing multiple inputs
5. Understanding the best/most appropriate time in the review process to engage different types of stakeholders.

Of all phases of the systematic review, the topic refinement and research development phase was repeatedly identified as the point where stakeholder engagement yielded the greatest benefit, with a preponderance of comments on the importance of stakeholder engagement at this phase in order to get buy-in and credibility for the process and product, to ensure the systematic review was scientifically valid, relevant, and useful, and to ensure uptake and use of the products. After verifying the appropriateness of this set of benefits to the EPC program, the next step in evaluating stakeholder engagement activities is to identify concrete measures for each of these benefits and challenges that can be used to assess the effectiveness of different methods, timing and intensity of stakeholder engagement.

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Appendix A. Search Strategy

Ovid MEDLINE(R) and Ovid OLDMEDLINE(R) 1946 to January Week 1 2013,
Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations January 14, 2013
Date searched: 01/15/2013

1	((stakeholder$ or consumer$ or community or user$ or public) adj2 (engag$ or involv$) adj5 (review$ or meta analys$ or metaanalys$)).ti,ab.	80
2	exp consumer participation/	29386
3	exp comparative effectiveness research/ or exp review literature as topic/ or exp meta-analysis as topic/	18744
4	2 and 3	74
5	1 or 4	153

EBM Reviews - Cochrane Database of Systematic Reviews 2005 to November 2012
Date searched: 01/15/2013

1	((stakeholder$ or consumer$ or community or user$ or public) adj2 (engag$ or involv$) adj5 (review* or meta analys$ or metaanalys$)).ti,ab.	0

EBM Reviews - Cochrane Methodology Register 3rd Quarter 2012
Date searched: 01/15/2013

1	((stakeholder$ or consumer$ or community or user$ or public) adj2 (engag$ or involv$) adj5 (review* or meta analys$ or metaanalys$)).ti,ab.	12

EBM Reviews - Database of Abstracts of Reviews of Effects 4th Quarter 2012
Date searched: 01/15/2013

1	((stakeholder$ or consumer$ or community or user$ or public) adj2 (engag$ or involv$) adj5 (review* or meta analys$ or metaanalys$)).ti,ab.	0

EBM Reviews - Health Technology Assessment 4th Quarter 2012
Date searched: 01/15/2013

1	((stakeholder$ or consumer$ or community or user$ or public) adj2 (engag$ or involv$)).ti.	3

Scopus
Date searched: 01/15/2013

1	(stakeholder* or consumer* or community or user* or public) W/5 (engag* or involve*) W/5 (review* or meta-analys* or metaanalys*)TITLE ABSTRACT	
2	Not participatory	139

Appendix B. Relevant Information From Literature Search

Table B-1. Context of stakeholder engagement

Author, Year, Country	What is the context for s/h engagement in this article?	How will those engaged be impacted by the decisions they have input into?	What types of s/h are engaged?
COCHRANE			
Horey, 2010[1] New Zealand	Cochrane paper, the purpose is to gain agreement on s/h engagement in the strategic direction for the Cochrane collaboration.	Information not found	Consumer volunteers; consumer facilitators and consumer organizations partners
Nilsen et al., 2006[2] Norway	A SR looking at s/h engagement in health care policy and health care research	Information not found	"…patients; unpaid carers; parents/guardians; users of health services; disabled people; members of the public who are the potential recipients of health promotion/public health programmes; groups asking for research because they believe they have been exposed to potentially harmful circumstances, products or services; groups asking for research because they believe they have been denied products or services from which they believe they could have benefited; and organisations that represent service user and carers." "…'lay', 'non-expert', 'service user', 'survivor' or 'member of the general public'."
Wale et al., 2010[3] Australia	The Cochrane Consumer Network (CCNet) is comprised of over 500 members (volunteers) from over 55 countries . "Its core functions are to enable and support consumers in the work of the Collaboration and to enhance accessibility and relevance of reviews and evidence-based health care through consumer and community participation."	"Consumers provide a prepublication lay-user perspective to Cochrane protocols and reviews, potentially balancing the health and medical researcher view."	"Members come from many different countries and have differing backgrounds in terms of roles and levels of involvement in their health systems."
COMPARATIVE EFFECTIVENESS/PATIENT-CENTERED OUTCOMES RESEARCH (CER/PCOR)			

Author, Year, Country	What is the context for s/h engagement in this article?	How will those engaged be impacted by the decisions they have input into?	What types of s/h are engaged?
Curtis et al., 2012[4] United States	The Expert Interviews Project aims to identify effective methods and best practices in s/h engagement through interviews and facilitated discussions with national and international experts representing diverse stakeholder groups and various fields of expertise	Information not found	Patients; caregivers; and experts
Deverka et al., 2012[5] United States	"This paper aims to define stakeholder engagement and present a conceptual model for involving stakeholders in CER" Article looked at results of literature review as well as The Center for Comparative Effectiveness Research in Cancer Genomics (CANCERGEN) to develop a definition for s/h and s/h engagement	Information not found	CANCERGEN: 13 s/h (2 policymakers; 1 regulator; 2 patients/consumers; 3 payers; 3 practicing clinicians; 2 from pharmaceutical and diagnostic industry.
Domecq Garces et al., 2012[6] United States	This is a systematic review of evidence about patient engagement in health care research . "We aimed to identify who are the relevant patients for engagement and how to recruit them, how can they engage, and how can their engagement result in changes in research design, conduct, analysis and dissemination."	Information not found	"Overall, the available research suggests that patients could successfully play an active and engaged role in research, from participant, to collaborator, to partner." "Engagement was described through all study phases (preparatory, execution and translation phases)."
Hoffman et al., 2010[7] United States	This paper discusses five general principles for successful stakeholder engagement in comparative effectiveness research. They are based on best practices and lessons learned from five comparative effectiveness research projects that involved the substantial engagement of multidisciplinary groups of experts and stakeholders. These projects are currently under way at the Center for Medical Technology Policy, in Baltimore, Maryland.	Information not found	Information not found

Author, Year, Country	What is the context for s/h engagement in this article?	How will those engaged be impacted by the decisions they have input into?	What types of s/h are engaged?
Kreis et al., 2012[8] Germany	Capture current practices of s/h engagement across a range of organizations and groups….that either conduct SRs or commission them. Goal was to learn from different types of highly regarded organizations how s/h are currently involved, to obtain in-depth understanding about processes	"…increases the accountability of the research process."	Federal agencies; payer and provider organizations; private and university-based organizations; professional societies
HEALTH TECHNOLOGY ASSESSMENT			
Gagnon et al., 2011[9] Canada	In 14 studies, pts provided consultation or data about domain of research. Domains: 1. Selecting technologies to be assessed(2 studies) 2. Assessing selected technologies (5 studies) 3. Dissemination (1 study)	Information not found	Eligibility criteria for SR: patients, caregivers, consumers, members of public
Gauvin et al., 2010[10] Canada	Information not found	Information not found	Definition of "public" depends on time, technology, etc. Six publics (category 1: citizens, groups representing citizens, elected officials; category 2: individual affected by health condition, representatives, service users)
Hailey, 2005[11] Canada	Very high level narrative review of reviews on consumer engagement in HTA to inform Alberta HTA program . Not detailed enough to be terribly helpful.	Information not found	Consumers, defined as patients, caregivers, organizations representing patients, members of the public who may receive health care services.
Hailey et al., 2012[12] Australia	Updated Survey of INAHTA agencies (Nov 2010) on consumer involvement	Information not found	The term "consumers" was taken to include patients, carers, long-term users of services, organizations representing consumers' interests, and members of the public, following a definition developed by the English HTA program

Author, Year, Country	What is the context for s/h engagement in this article?	How will those engaged be impacted by the decisions they have input into?	What types of s/h are engaged?
Moran et al., 2011[13] United Kingdom	Reviewed involvement at the five stages of research management in HTA: 1. Identification 2. Prioritization 3. Commissioning 4. Monitoring 5. Publication and dissemination	Information not found	"public involvement"-potential recipients of programs. Encompasses consumers and patients
Nielsen et al., 2009[14] Denmark	Information not found	Information not found	Groups, not individuals, potentially affected by or with interest in, including policy makers, patient organizations, health care professions, and industry.
Oliver et al., 2004[15] United Kingdom	This is a review of different types of consumer involvement in topic identification and prioritization and includes a range of research designs, not only systematic review and not only health care . Therefore the context varies considerably from study to study . The purpose of the review is to inform s/h engagement for NICE HTAs.	Information not found	Consumers
PATIENT AND PUBLIC INVOLVEMENT			
Barber et al., 2011[16] United Kingdom	Delphi process to answer whether it is possible to measure the impact of public involvement on research (health and social, not SRs)	Information not found	"public"
Boote et al., 2006[17] United Kingdom	UK NHS, formal policy initiative by the Department of Health, which involves the provision of NHS guidance stating that 'consumer involvement should exist at every stage of research where appropriate'	No specific information on this is found Main Study: Discussion of the value of consensus research in this policy area, and a Delphi study to reach consensus on principles and indicators of successful consumer involvement in NHS research Scope of Research in Which Stakeholders are Engaged: Health service research, clinical trials, secondary research, behavioral research, and population-based research in a variety of health areas, including mental health, physical and learning disabilities, cancer, pregnancy, childbirth and childcare, and older adults.	Researchers, consumers ("patients, potential patients, informal (unpaid) carers, people who use health and social services, and organizations that represent the interests of people who use health and social services, and members of the public who may be the potential recipients of health promotion plans"), and consumer-researchers.

Author, Year, Country	What is the context for s/h engagement in this article?	How will those engaged be impacted by the decisions they have input into?	What types of s/h are engaged?
Boote et al., 2012[18] United Kingdom	Considers the range of public involvement in individual systematic reviews by reviewing the literature on public involvement in individual SRs. Includes 9 SRs that involved the public at some level during the review process.	Not reported	"patients and potential patients; people who use health and social services; informed carers; parents/guardians; disabled people; members of the public who are potential recipients of health promotion programs, public health programs and social service interventions; organizations that represent people who use services."
Brett et al., 2010[19] United Kingdom	"Patient and public involvement has become a central tenet of health care policy in the UK and internationally in shaping health services and policy"	No specific information on this is found. Main Study: SR of qualitative, case studies, or cross-sectional studies reporting individual or organizational views of PPI, as well as economic evaluations to provide a synthesis of the evidence base on the conceptualization, measurement, impact and outcomes of PPI on health and social care research Scope of Research in Which Stakeholders are Engaged: The studies included in the review report on views of PPI in health research that involves different types of studies (including SR) in a wide variety of health areas.	Patients and public ("those who use health and social care services, those who are involved at different levels in research, carers/ guardians, people with a disability and other members of the public")
Brett et al., 2012[20] United Kingdom	The focus of this systematic review was to examine the value and challenges of involving the public in health and social care research (focus on independent research and not SRs). Includes 66 research articles that describe to impact (or value) of public involvement at some level in the research process.	Not reported	"patients and potential patients; people who use health and social services; informed carers; parents/guardians; disabled people; members of the public who are potential recipients of health promotion programs, public health programs and social service interventions; organizations that represent people who use services."
Involve, 2012[21] United Kingdom	Provides high-level advice to individual systematic reviewers and organizations who do systematic reviews on involving the public in the systematic process.	Not reported	"patients and potential patients; people who use health and social services; informed carers; parents/guardians; disabled people; members of the public who are potential recipients of health promotion programs, public health programs and social service interventions; organizations that represent people who use services."

Author, Year, Country	What is the context for s/h engagement in this article?	How will those engaged be impacted by the decisions they have input into?	What types of s/h are engaged?
Keown et al., 2008[22] Canada	Reports experience of the Institute for Work and Health SR program's experience using s/h engagement in SR to increase utilization of SR findings	Information not found	Policy and practitioner decision makers (system level)
Vale et al., 2012[23] United Kingdom	UK NHS, formal policy initiative by the Department of Health, which involves the provision of NHS guidance stating that 'stating that patients and the public must be involved in all stages of the research process'.	No specific information on this is found. Main Study: Semi-structured interviews with lead members of staff at MRC CTU to formally assess both past and current levels involvement across all CTU research studies. Scope of Research in Which Stakeholders are Engaged: RCTs, SR (including meta-analysis) and other clinical studies in a variety of health care areas, primarily cancer, HIV and other infectious diseases.	Researchers and consumers ("patients, carers or family members, health service users, patient representatives or members of groups or organizations that represent those affected by the condition being researched").
Wright et al., 2010[24] United Kingdom	UK NHS, formal policy initiative by the Department of Health, which involves the provision of NHS guidance stating that 'consumer involvement should exist at every stage of research where appropriate' and requiring "all applicants [for research ethics applications] to detail their user involvement activities, regardless of methodological or disciplinary standpoint"	No specific information on this is found Main Study: Secondary analysis of research evidence from a UK wide research prioritization exercise to develop "a framework for assessing the quality and impact of user involvement in published research and funding applications," building off on the principles and indicators developed by Boote et al.[17] Scope of Research in Which Stakeholders are Engaged: Broad spectrum of NHS research activities, including psychosocial research, clinical trials, biomedical research, and surveys in a variety of health care areas, predominantly cancer and palliative care.	Researchers ("any individual engaged in undertaking research activity, whether they are users or professionals, unless stated otherwise") and "members of the general public, patients, care-givers, potential patients and public, community and voluntary organizations."

Note: CCNet=Cochrane Consumer Network; CER=comparative effectiveness research; CTU=Clinical Trials Unit; CEHP=Continuing Education in the Health Professions; EUnetHTA=European Network for Health Technology Assessment; HIV=Human immunodeficiency virus; HTA=Health Technology Assessment; INHATA=International Network of Agencies for Health Technology Assessment; IOM=Institute of Medicine; MRC=Medical Research Council; N/A=not applicable; NHS=National Health Service; NICE=National Institute for Health and Care Excellence; PPI=patient and public involvement; RCT=randomized controlled trial(s); s/h=stakeholder(s); SR=systematic review(s); UK=United Kingdom; INVOLVE definition of s/h = "patients and potential patients; people who use health and social services; informed carers.

Table B-2: Stakeholder identification

Author, Year, Country	How are most important s/h identified?	How are conflicts of interest managed?	When in the process are s/h typically engaged?
COCHRANE			
Horey, 2010[1] New Zealand	Information not found	Information not found	S/h are engaged through all processes from decision-making to the dissemination of review findings and promotion of evidence-based care and encouraging others to be involved.
Nilsen et al., 2006[2] Norway	Information not found	Information not found	CCNet was involved in making authors aware of unpublished studies; commenting on drafts; and on the decision to include only RCT
Wale et al., 2010[3] Australia	"A consumer is considered as a receiver or user of a health service, patient, citizen, carer/caregiver, or layperson." Members of CCNet are voted on.	Not reported	Throughout the process, from hand searching for trials to disseminating information about the reviews.
COMPARATIVE EFFECTIVENESS/PATIENT-CENTERED OUTCOMES RESEARCH (CER/PCOR)			
Curtis et al., 2012[4] United States	"outreach through community-based organizations such as faith-based organizations, community centers, and libraries . Other potential locations include faith-based organizations, community centers, and libraries . Other potential locations included barbershops, health fairs, health clubs, talks, schools, pars/picnics, conferences, meetings and medical clinics"	Information not found	S/h engagement is looked at throughout all points of the process.
Deverka et al., 2012[5] United States	Information not found	Information not found	Stakeholders are actively involved across phases of the research process, throughout the research continuum
Domecq Garces et al., 2012[6] United States	Information not found	Information not found	Many studies have successfully engaged patients in all research steps: preparation of research (agenda formulation, funding procurement), execution of research (study conduct, data analyses) and the translation of results into action.

Author, Year, Country	How are most important s/h identified?	How are conflicts of interest managed?	When in the process are s/h typically engaged?
Hoffman et al., 2010[7] United States	We conducted a qualitative assessment of experience generated through five comparative effectiveness projects with substantial engagement of multidisciplinary groups of experts and stakeholders, conducted at the Center for Medical Technology Policy . We collected information through documents and semistructured interviews with one or more of the center's staff members as well as with stakeholder participants in each of the five studies.	Not Reported	"keep the stakeholders engaged throughout the research process."
Kreis et al., 2012[8] Germany	"Our choice of organizations was informed by the interest of the IOM Committee and also based on the authors' knowledge of organizations in the United States involved in systematic review production."	"We found considerable variation in how organizations deal with potential conflicts of interest . While all consumers who are involved in reviews carried out for AHRQ have to declare potential conflicts of interest, this was not reported by those we interviewed associated with the Campbell and the Cochrane Collaborations . At the latter, consumers have to declare potential conflicts of interest when they serve as review authors, but no clear guidance is available for those groups we spoken with for other forms if involvement (e.g. peer reviewers)."	Topic identification and prioritization; protocol development; review conduct; and translation of the results into a consumer friendly language and dissemination. Programmatic and individual level
HEALTH TECHNOLOGY ASSESSMENT			
Gagnon et al., 2011[9] Canada	Information not found	Information not found	Information not found
Gauvin et al., 2010[10] Canada	Information not found	Information not found	Information not found
Hailey, 2005[11] Canada	Not discussed	Not discussed	Includes examples from topic identification through dissemination.
Hailey et al., 2012[12] Australia	Invitation from participating agencies	Information not found	Formulation of topics; Preparation of assessments/ reviews; Dissemination
Moran et al., 2011[13] United Kingdom	Information not found	Information not found	Stages 1 to 4
Nielsen et al., 2009[14] Denmark	Information not found	Information not found	Information not found

Author, Year, Country	How are most important s/h identified?	How are conflicts of interest managed?	When in the process are s/h typically engaged?
Oliver et al., 2004[15] United Kingdom	Information not found	Information not found	Information not found
PATIENT AND PUBLIC INVOLVEMENT			
Barber et al., 2011[16] United Kingdom	Information not found	N/A	N/A
Boote et al., 2006[17] United Kingdom	No specific information on this is found	Consensus among researchers, consumers and consumer-researchers on the principles and indicators of successful involvement in NHS research.	The principles of successful consumer involvement in NHS research developed by study participants “address mainly research process as opposed to outcome issues in research”
Boote et al., 2012[18] United Kingdom	Not reported	Not reported	Identifies three different levels of public involvement among 8 different systematic reviews used as case examples—consultation, collaboration, and publically led—only 1 example of publically led, in the majority of case examples (n=6), the public were involved consultatively through a workshop to discuss the SR protocol or to review emergent findings.
Brett et al., 2010[19] United Kingdom	No specific information on this is found.	No specific information on this is found	Consultations with users were more likely to be used at just one stage of the research, the most common one being for setting research agenda. - user-led or collaborative studies with users were more likely to include users throughout the research project, from proposal, methodology through to writing up and dissemination of results
Brett et al., 2012[20] United Kingdom	Not reported	Not reported	Involvement was considered at the initial stages of research, undertaking research, during analysis and write-up stage, and dissemination.

Author, Year, Country	How are most important s/h identified?	How are conflicts of interest managed?	When in the process are s/h typically engaged?
Involve, 2012[21] United Kingdom	Not reported	Not reported	Considers involvement at 3 levels: Involvement in individual reviews—involving the public in a single review; Across a group of systematic reviews—involving the public in a series of reviews covering the same or similar topic (e.g., as with different Cochrane groups), and at a unit level—involving the public in organizations/departments that do systematic reviews and other research activities (e.g, NICE, AHRQ)
Keown et al., 2008[22] Canada	Not discussed	Not discussed	Identification of research question, feedback during review, member of review team for search/extraction/synthesis/drafting, comments on draft, and dissemination . Exact involvement varies from review to review based on topic and time.
Vale et al., 2012[23] United Kingdom	No specific information on this is found.	No specific information on this is found.	The consumers are involved in the entire research process from funding application to interpreting and disseminating the results of studies.

Author, Year, Country	How are most important s/h identified?	How are conflicts of interest managed?	When in the process are s/h typically engaged?
Wright et al., 2010[24] United Kingdom	No specific information on this is found	Consensus among researchers and service users on the principles and indicators of effective user involvement in published research and funding applications, and the application of tool for assessing the quality and impact of user involvement developed by Wright et al. [24], stating, e.g., that: - Research teams need to clear about why they wish to involve service users before approaching patients and carers, and to make this rationale clear in published papers and funding applications. - The level of user involvement needs to be appropriate for the aims of the research. - An appropriate strategy for recruiting service users need to be adopted, which involves the involvement of diverse service users - The nature of the training provided to service users needs to be appropriate - Sufficient attention needs to be given to the ethical considerations of user involvement and how these are managed. - Sufficient attention needs to be given to the methodological considerations of user involvement and how these are managed. - Research findings need to be appropriately disseminated to users involved in research as participants or collaborators - The 'added-value' of user involvement needs to be demonstrated - The effectiveness of how service users have been identified, trained and supported and the impact they had on the quality and outcomes of the research need to be an integral part of studies involving service users.	The service users are involved in the entire research process from funding application to publishing research findings.

Note: CCNet=Cochrane Consumer Network; CER=comparative effectiveness research; CTU=Clinical Trials Unit; CEHP=Continuing Education in the Health Professions; EUnetHTA=European Network for Health Technology Assessment; HIV=Human immunodeficiency virus; HTA=Health Technology Assessment; INHATA=International Network of Agencies for Health Technology Assessment; IOM=Institute of Medicine; MRC=Medical Research Council; N/A=not applicable; NHS=National Health Service; NICE=National Institute for Health and Care Excellence; PPI=patient and public involvement; RCT=randomized controlled trial(s); s/h=stakeholder(s); SR=systematic review(s); UK=United Kingdom; INVOLVE definition of s/h = “patients and potential patients; people who use health and social services; informed carers.

Table B-3. Tangible benefits of stakeholder engagement

Author, Year, Country	What were the key factors that prompted s/h engagement (i.e. mandates, research improvement, other)?	What did they expect/hope to achieve by engaging s/h	What are some of the tangible benefits?
COCHRANE			
Horey, 2010[1] New Zealand	"- Make information about evidence based health care more accessible. - Learn and keep up to date, either with research about a specific condition or with evidence base health care . - Contribute to the development of evidence based health care."	"improve the quality or accessibility of reviews and plain language summaries"	Improved readability and/or quality of reviews; improved usefulness of plain language summaries.
Nilsen et al., 2006[2] Norway	Information not found	Information not found	The potential benefits of consumer involvement in health care include: policy, research, practice and patient information that includes consumers' ideas or addresses their concerns; improved implementation of research findings; better care; and better health. Consumer participation can be viewed as a goal in itself by encouraging participative democracy, public accountability and transparency.
Wale et al., 2010[3] Australia	"Consumers have been part of the collaboration since its beginning and are formally represented on the steering committee." No other information is given.	Information not found	Explanation of terms; clearer language and comprehension of text
COMPARATIVE EFFECTIVENESS/PATIENT-CENTERED OUTCOMES RESEARCH (CER/PCOR)			
Curtis et al., 2012[4] United States	Information not found	Define project goals; understand patient and community needs; determine *why* to engage; determine points of engagement; create transparency; enable ease of participation & fair compensation;	Information not found
Deverka et al., 2012[5] United States	To align with the purpose of CERs in accordance with the IOM's definition; have s/h directly inform priority areas as opposed to the traditional s/h as a passive audience	Eliminate the divide between scientist and experts and real-world decision makers	Potential to share tangible benefits

Domecq Garces et al., 2012[6] United States	Questions remain on how to engage patients or their representatives (family members, caregivers, community representatives)	Our goal was to describe the practical steps needed to better engagepatients in research. We also asked a group of patients without medical orresearch training to provide their perspective on our results	"…improve study design (by choosing outcomes more meaningful to patients or designs that are more culturally sensitive or consistent with patients' context), execution (improving subject recruitment and retention) and translation (better implementation, dissemination and uptake)." "Patient engagement appears to enhance the quality of research (e.g., improving enrollment rates in studies, making studies more consistent with patients' values, goals, and preferences)."
Hoffman et al., 2010[7] United States	Evidence and knowledge gaps	This paper's main purpose is to describe and assess our experiences with engaging stakeholders in comparative effectiveness research, to provide useful insights for others doing similar work. We also hope that the paper will encourage more-systematic documentation and sharing of information about these activities.	From the interviews, our personal experience, and a review of documents from the Center for Medical Technology Policy, we identified five general principles that contribute to the successful engagement of stakeholders in comparative effectiveness research. The principles are as follows: ensure a balanced representation of all stakeholder groups; get stakeholders to "buy in" to the process and make sure that they clearly understand their roles; provide neutral, expert facilitation of the stakeholder discussions; establish connections among the stakeholders; and keep the stakeholders engaged throughout the research process.

Kreis et al., 2012[8] Germany	IOM recommendations	Information not found	Potential beneficial effect on the relevance and usefulness of the reviews; led to re-shaping the review questions; increased readability and/or quality of reviews, usefulness of summaries in a consumer-friendly language. Positive effects for consumers: acquiring knowledge and skills with the evidence-based approach, benefits from taking part in discussions with clinicians about the condition that affects them. Positive effects for researchers: feeling that their research actually makes a difference Positive effects for organizations: lending credibility and trust to the programme, establishment of a culture of knowledge exchange between researcher and consumers.
HEALTH TECHNOLOGY ASSESSMENTS			
Gagnon et al., 2011[9] Canada	Information not found	Information not found	Information not found
Gauvin et al., 2010[10] Canada	Information not found	Information not found	Information not found
Hailey, 2005[11] Canada	This is a review, so cites a range of views, mostly UK . Primary themes are: political imperative, morally correct, benefits the research by bringing in perspectives and information that might otherwise not be considered.	Ensure research is relevant to people, improve the legitimacy of the decision-making process.	Cites points for consideration from INHATA, including improving HTA products, increased visibility and uptake of products.
Hailey et al., 2012[12] Australia	Not stated	Transparency; reflects values of all users	Potential to broaden the perspective of assessments; broaden advice provided to decision makers
Moran et al., 2011[13] United Kingdom	Public involvement first piloted in 1997. Ethical obligation – public as part-owners of NHS	Information not found	Information not found
Nielsen et al., 2009[14] Denmark	Information not found	Information not found	Information not found

Oliver et al., 2004[15] United Kingdom	Pragmatism, in the face of consumer demand or non-cooperation, political principle and the pursuit of 'better' research.	Consumer involvement would improve the way in which research is prioritized, commissioned, undertaken and disseminated . Also result in 'better' research that has a higher methodological or ethical quality; produces findings which are more relevant to practical decisions made by consumers and those caring forthem; is presented in more accessible and widely disseminated reports; or more appropriately influences policy and practice.	Benefits firmly taken for granted – lack of benefit assumed due to lack of expertise or leadership in the process.
PATIENT AND PUBLIC INVOLVEMENT			
Barber et al., 2011[16] United Kingdom	N/A	Public involvement seen as an intrinsic value, but also able to improve the quality of the final product and make it more relevant to end users and increase implementation of findings.	Information not found
Boote et al., 2006[17] United Kingdom	UK NHS, formal policy initiative by the Department of Health, which involves the provision of NHS guidance stating that 'consumer involvement should exist at every stage of research where appropriate', no additional information on this is found	'Add synergy to the traditional disease focus of health research, and can facilitate the generation of more relevant research questions and outcomes measures that are grounded in the social realized of those being researched' 'Improve both the quality and relevance of health research'	(i.e., benefits of consensus): - To further assist researchers on issues of best practice relating to consumer involvement. - To provide consumers with criteria by which to assess their 'successful' involvement in research. - To provide funding bodies with guidance on consumer involvement that can be incorporated into applications for funding . - To provide policy analysts with a tool to monitor the extent of 'successful' consumer involvement in research.
Boote et al., 2012[18] United Kingdom	Not reported	Not reported	Refining scope of the review by helping SRs select outcomes, populations, or interventions to study (3 cases); set inclusion criteria or framework for analysis (1 case); Suggesting and locating relevant literature (3 cases) Appraising the literature (1 cases); Interpreting review findings or putting review findings into perspective (5 cases); Writing up the review by either directly authoring or providing input (3 cases)

Brett et al., 2010[19] United Kingdom	To democratize health and social care research - To ensure it has maximum health and social benefit	See answer to question 7, no additional information is found.	(Areas with Most Evidence of Impact) Impact on Research and Research Process: - PPI helps build important links with the community and can help with accessing participants, improving response rates, recruitment from seldom heard groups, development of greater empathy with research subjects and better informed consent based on a more informed participant. - PPI can help in the assessment and development of research instruments, improve the timing of interventions and ensure the instruments are more acceptable to the community. - Users can also collect deeper and more insightful data based on their rapport with the participant. Impact on data analysis with users providing a wider perspective, different insights and identifying knowledge gaps for future research. - PPI can also impact on dissemination and implementation due to the dedication of users, and in some cases through the development of a cohort of advocates who disseminate key findings. Impact on Users: - The beneficial impacts were divided into three main areas: personal benefits, impact on level of knowledge and impact on their level of skill, both positive and negative.

Brett et al., 2012[20] United Kingdom	Not reported	Not reported	Initial stages of research: helped identify relevant topics for research agenda, assisted in prioritizing topics, and provided pragmatic feedback on protocol Undertaking research: assisted in development of appropriate research instruments, helped recruit subjects, and helped researchers gain better insight on subject's perspectives Analysis and write-up: helped ensure that emerging themes and trends were interpreted from users perspective, helped identify research gaps, and helped to ensure that final research reports were readable and accessible Dissemination: helped to ensure that research was disseminated to wider audience and was user friendly.
Involve, 2012[21] United Kingdom	Not reported	Not reported	Not reported At the individual level: public involvement helps to ensure that questions and outcomes are relevant; deal with specific issues and questions as they arise. Across a group of SRs: public involvement helps to develop involvement across a coherent program of SRs, draw on experience and expertise of people who best understand the condition covered; ensure reviews address relevant questions and outcomes; ensure involvement throughout review process; provide opportunities for people to develop more strategic roles in review process. At the unit level: public involvement helps to ensure a consistent or strategic approach across a unit or department; develop public involvement in a broad range of review activities; coordinate the approach to involvement across reviews; lead to public involvement at the earliest stages of reviews; support researchers and public by ensuing they are not isolated; and facilitate quick response to specific issues.

Keown et al., 2008[22] Canada	Not clear, possibly to increase utilization of reviews.	Information not found	Information not found
Vale et al., 2012[23] United Kingdom	UK NHS, formal policy initiative by the Department of Health, which involves the provision of NHS guidance stating that 'stating that patients and the public must be involved in all stages of the research process', no additional information on this is found	"it was the right thing to do". - to learn more about the disease or population essential or necessary in - to ensure recruitment and - to ensure the appropriateness of research materials or giving guidance on issues - to meet the recommendations set by funding bodies to involve consumers, without it being a requirement - "Respondents did not know what reasons had lead to involvement in their studies."	- Improvements in study design and recruitment - Improvements in study promotion and dissemination - Improvements in study documentation, including protocol development, writing patient information, study papers - Improvements in decision making about the study or its findings - Increased confidence in the study, leading to better targeting and responding to consumer needs and to better understanding of the conditions or treatments being studied and the relevant research context
Wright et al., 2010[24] United Kingdom	A political imperative for the engagement of service users in research - the growth in patient and carer advocacy, advocating ethical and moral right for patients and carers to be informed about and engaged in research activity. - the dissemination of evidence of the benefits of service user engagement by the academic community	No specific information on this is found	(i.e., benefits of assessment tool) - To enable readers to assess the quality and impact of user involvement in published studies - To help researchers ensure effective strategies for user engagement are employed in research - To enable funding bodies to establish principles of effective user involvement in their own practice and to assess the quality of user involvement in applications

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Table B-4 Tangible challenges of stakeholder engagement

Author, Year, Country	Are there points in the review process when it is most beneficial to engage s/h?	What are some of the tangible challenges?	Are there points in the review process when engaging s/h is particularly challenging?
COCHRANE			
Horey, 2010[1] New Zealand	S/h engagement was beneficial throughout the process, from decision making to dissemination and beyond	Inconsistencies in the use of some terms and involvement of different s/h during different stages of the process; emotional burden; work overload media exposure; frustrations with limitations of engagement; lack of understanding of SR purpose and production processes; lack of s/h training; understand the difference of being critical without being offensive	Example given for different s/h engaged during different points: "some only involve consumers in development of plain language summaries; some do not have a specific policy for consumer involvement; and some have consumer input at every stage of the review development."
Nilsen et al., 2006[2] Norway	Information not found	Information not found	Information not found
Wale et al., 2010[3] Australia	Information not found	Lack of staff time	Information not found
COMPARATIVE EFFECTIVENESS/PATIENT-CENTERED OUTCOMES RESEARCH (CER/PCOR)			
Curtis et al., 2012[4] United States	Information not found	Patient training and support	Information not found
Deverka et al., 2012[5] United States	Information not found	Several in the operational level: - Varying expectations regarding 'engagement - lack of shared understanding regarding tools and methods available to conduct s/h engagement - absence of information to measure process	Information not found
Domecq Garces et al., 2012[6] United States	Information not found	Logistics (extra time needed to complete research, time constraints of patient or surrogates, incremental funding needed for patient engagement); worry of s/h engagement becoming tokenistic; scope creep, leading to the unfeasible research	Information not found
Hoffman et al., 2010[7] United States	Engaging s/h throughout the process would be most beneficial	Different s/h viewpoints; conflicting perspectives	Not reported
Kreis et al., 2012[8] Germany	Information not found	"…a Gap between the potential for impact and the actual evidence supporting impact, based on formal evaluations."	Information not found
HEALTH TECHNOLOGY ASSESSMENTS			
Gagnon et al., 2011[9] Canada	Information not found	Familiarity with HTA process; recruitment sensitive and time-consuming	Information not found
Gauvin et al., 2010[10] Canada	Information not found	Token involvement; disruption of HTA procedures	Information not found

Author, Year, Country	Are there points in the review process when it is most beneficial to engage s/h?	What are some of the tangible challenges?	Are there points in the review process when engaging s/h is particularly challenging?
Hailey, 2005[11] Canada	Concludes that consumer involvement makes more sense in long-term projects, not rapid reports.	Significant time and cost required to create a working relationship. Finding the right consumers (representativeness, capability) is difficult. Lack of knowledge and credentials on part of consumers, lack of education and skills for involving consumers on the part of HTA staff. Reports too long and technical for consumers to really review. Most interesting was that the difference in perceptions of what constitutes credible evidence and absence of evidence that consumer involvement makes a difference are two significant barriers.	Information not found
Hailey et al., 2012[12] Australia	Topic suggestions; topic prioritization process	Time and resource commitments	Rapid and horizon scanning reports/briefings
Moran et al., 2011[13] United Kingdom	Information not found	Information not found	Information not found
Nielsen et al., 2009[14] Denmark	Information not found	Information not found	Information not found
Oliver et al., 2004[15] United Kingdom	Focuses only on research agenda setting.	Poor representation of consumers; consumers' unfamiliarity with research and research programs' unfamiliarity with consumers; negative attitudes and poor working relationships; difficulties in communication; and time constraints.	These challenges can present themselves at any time during the review process
PATIENT AND PUBLIC INVOLVEMENT			
Barber et al., 2011[16] United Kingdom	Information not found	Time and money.	Information not found
Boote et al., 2006[17] United Kingdom	The principles of successful consumer involvement in NHS research developed by study participants "address mainly research process as opposed to outcome issues in research"additional information on this is found	- "Some people may argue that it is wrong to reach a consensus, as this may dilute the power gains that consumers have been trying to achieve in the research process"- "Consumers and researchers may have different or even conflicting ideas about what 'successful' consumer involvement in research means to them, and that consensus cannot be reached"	No specific information on this is found

Author, Year, Country	Are there points in the review process when it is most beneficial to engage s/h?	What are some of the tangible challenges?	Are there points in the review process when engaging s/h is particularly challenging?
Boote et al., 2012[18] United Kingdom	Refining scope of the review by helping SRs select outcomes, populations, or interventions to study (3 cases); set inclusion criteria or framework for analysis (1 case); Suggesting and locating relevant literature (3 cases) Appraising the literature (1 cases); Interpreting review findings or putting review findings into perspective (5 cases); Writing up the review by either directly authoring or providing input (3 cases)	Time and resources (specific to cases in which the public are paid for their involvement, 1 case mentioned); Concerns of involving members of the public who are affected by condition of interest and in poor health; Continuity issues, or inconsistency in public's ability to attend meetings, etc.; Group dynamics; Research ethic committee involvement; Concerns about the selection or representativeness of the public; Public's perceptions on the degree to which they had influence on the process	Not reported
Brett et al., 2010[19] United Kingdom	No specific information on this is found.	No specific information on this is found.	No specific information on this is found.
Brett et al., 2012[20] United Kingdom	Initial stages of research; undertaking research; analysis and write up, and dissemination	Initial stages: scientific and ethical conflict in protocol design, avoiding tokenistic involvement of public Data collection: difficulty in recruiting a diverse range of subjects, balancing academic criteria with public perspective, maintaining confidentiality, and managing public involvement Dissemination: research findings being disseminated before research published in academic journal Time and cost	Not reported

Author, Year, Country	Are there points in the review process when it is most beneficial to engage s/h?	What are some of the tangible challenges?	Are there points in the review process when engaging s/h is particularly challenging?
Involve, 2012[21] United Kingdom	At the individual level, public involvement is important at initial stages (key question development and selection of outcomes); at the group and unit level, involvement is important throughout the SR process	**At the individual level:** Identifying people, particularly in under researched areas where few patient groups or networks exist; making sure that the people's opinions are heard and valued; dealing with frustrations when studies included in the review don't include outcomes of interest; ensuring commitment for long reviews and ability to meet deadlines for rapid reviews; and dealing with concerns of the research team about involving the public. **Across a group of SRs:** Relying on the same group of members of the public; creating a large workload or burden for people to take on; and dealing with the possibility that members of the public involved may become professionalized and lose their ability to provide the "public's" prospective. **At the unit level:** Championing public involvement at a high/strategic level; losing the experience of specific disease or subject areas; relying on a small group of individuals for a wide variety of reviews; and expecting a large commitment of time and input.	Not reported
Keown et al., 2008[22] Canada	Increased relevance and clarity of the review itself and increased dissemination . Specifically, s/h choose research topics they are interested in, help identify missed literature, identify the most decision-relevant outcomes and keep the report practical, help team present key findings clearly in a way that is relevant, help identify dissemination targets and strategies . Describing s/h role in the report also increases credibility of findings during dissemination.	Time and resources, conflict between s/h desires and scientific rigor.	S/h rarely have time or expertise to act as members of the review team and actually participate in doing the review, so involvement is easiest at the beginning and end— topic identification, shaping key points, and dissemination.

Author, Year, Country	Are there points in the review process when it is most beneficial to engage s/h?	What are some of the tangible challenges?	Are there points in the review process when engaging s/h is particularly challenging?
Vale et al., 2012[23] United Kingdom	Information not found	- Researchers need additional resources and time to involve consumers - Consumers can become too unwell during the course of the research to continue their involvement or having difficulties attending meetings. - Researchers can find it difficult to know what to expect from the consumers and do not know where to go for help or advice	No specific information on this is found.
Wright et al., 2010[24] United Kingdom	Information not found	(Challenges of applying assessment tool)- The relative nature of the criteria demonstrates certain differences between applying the assessment tool to research proposals and applying the tool to published research- The critical appraisal criteria for assessing the quality and impact of user involvement on health research represent a particular ideological perspective that differs from the belief that user involvement is a moral and democratic right regardless of methodological impact	No specific information on this is found

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Table B-5. Measurement of stakeholder engagement

Author, Year, Country	How can we capture and measure the value of s/h engagement in systematic reviews?	Any other pertinent information?
COCHRANE		
Horey, 2010[1] New Zealand	Information not found	Information not found
Nilsen et al., 2006[2] Norway	Information not found	Information not found
Wale et al., 2010[3] Australia	"The Cochrane Consumer Network has surveyed its members and review group on a number of occasions, using the e-mail list for this purpose." Two evaluations were distributed: one that was CCNet-led and the other was led by an external consultant.	Information not found
COMPARATIVE EFFECTIVENESS/PATIENT-CENTERED OUTCOMES RESEARCH (CER/PCOR)		
Curtis et al., 2012[4] United States	Information not found	Information not found
Deverka et al., 2012[5] United States	"We mapped our experience with the CANCERGEN stakeholder engagement process to the proposed conceptual model to determine its utility and application to CER."	"In this article we propose definitions of the terms 'stakeholder' and 'stakeholder engagement' in the context of CER and offer a conceptual model for involving stakeholders in the CER process.
Domecq Garces et al., 2012[6] United States	Information not found	Information not found
Hoffman et al., 2010[7] United States	Information not found	Information not found
Kreis et al., 2012[8] Germany	Information not found	Information not found
HEALTH TECHNOLOGY ASSESSMENTS		
Gagnon et al., 2011[9] Canada	Information not found	Design notes: SR to examine involvement of patients/public in HTA (24 studies)
Gauvin et al., 2010[10] Canada	Information not found	Design notes: Qualitative concept analysis of public involvement in HTA process (lit review and interviews of HTA persons)
Hailey, 2005[11] Canada	Identified as an important concern . Suggests starting by summarizing involvement for each HTA and whether it benefited from the consumer involvement.	No.

Author, Year, Country	How can we capture and measure the value of s/h engagement in systematic reviews?	Any other pertinent information?
Hailey et al., 2012[12] Australia	Information not found	Two-thirds (67%) of agencies involved consumers in aspects of their HTA programs; Compared with the 2005 survey, the 2010 survey reported an increase in the proportion of agencies that provide summaries of HTA reports for consumers (84%), and increased involvement of consumers in dissemination (42%).
Moran et al., 2011[13] United Kingdom	“evidence demonstrating efficacy slowly emerging”	Discussed how public involved in each stage Design notes: At end of 10-year period (to end of 2009), review of internal HTA documentation, interviews of staff, rapid review
Nielsen et al., 2009[14] Denmark	Information not found	Design notes: Engaged stakeholders about stakeholder involvement in EUnetHTA - developed draft stakeholder policy (Stakeholder open form, ref 3)

Author, Year, Country	How can we capture and measure the value of s/h engagement in systematic reviews?	Any other pertinent information?
Oliver et al., 2004[15] United Kingdom	Box 3 of the Exec Sum proposes intermediate and final measures for both benefits and harms/costs, but is rather general. **Benefits–intermediate** More informed discussion between consumers and professionals Greater understanding by consumers of technical issues Improved sensitivity to consumer concerns in planning research. Reduced barriers to broad participation. Improved public profile of research. Increased credibility of consumers. Increased enthusiasm amongst consumers and professionals for working together. Consumer and manager descriptions of success in involving consumers in R&D. **Harms and costs–intermediate** Increased work load Diverting consumers' efforts from services and campaigning Decreased enthusiasm amongst consumers and professionals for working together Greater confusion about the purpose of research. Damaged public profile of research. Reduced credibility of consumers. Lack of reporting of consumer involvement. **Benefits–Final** Research incorporating consumers' ideas and addressing consumers' concerns and needs. Greater uptake of research findings. Improved care. Improved health. **Harms and costs–final** Delayed research. More expensive research. Disappointment in limitations of research. Reduced uptake of research findings. Also has some discussion of how poorly records are kept so that it is not possible to evaluate if consumer involvement changed the research.	Proposes framework for examining the different ways consumers can be involved in research by creating a table with intensity of researcher control across the top and intensity of consumer control along the left margin . The EHC program is probably Type A (committee membership, like Cochrane). Not immediately relevant, but interesting.

Author, Year, Country	How can we capture and measure the value of s/h engagement in systematic reviews?	Any other pertinent information?
PATIENT AND PUBLIC INVOLVEMENT		
Barber et al., 2011[16] United Kingdom	Consensus on feasibility of evaluating 5 areas of impact: 1- identification of topics (can monitor source of topics) 2 - prioritization of topics, 3- dissemination of findings, 4 - impact of public involved, 5 - impact on researchers . Impact on research quality was generally not considered to be feasible.	Consensus among panelists that public involvement is of value but also that it should be evaluated.
Boote et al., 2006[17] United Kingdom	The development of consensus-derived principles of successful consumer involvement in NHS research and associated indicators, w which are defined as "a precise measure of a principle".	Implications for s/h:- "There are likely to be appreciable time and resource implications of implementing the principles, which will need to be acknowledged by all stakeholders." - "The principles raise issues of training (for both researchers and consumers), funding, documentation, and decision-making within the research process."Limitations to consensus measurement rather than consensus development:- Little acknowledgement of the increasing amount of high quality user-led research that has developed- The applicability or transferability of the principles and indicators to the different levels of consumer involvement (e.g., consultation, collaboration and consumer-control) in the research process that have been identified remains to be seen Directions for Future Research:- Baseline assessment of the extent to which the principles are being met in individual NHS research projects would provide policy analysts with the means to monitor the successful involvement of consumers in NHS research Reference to Specific Activities to Reach Out to and Engage Stakeholders in the Research Process: No specific information on this is found
Boote et al., 2012[18] United Kingdom	Need to find out more about what works best, for whom and in what circumstances. Thus, organizations need to evaluate the impact of public involvement in the systematic review process at the organization level. Make public involvement explicit throughout the SR (abstract and body of text) and develop quality standards for the involvement of the public.	Facilitating Strategies and Recommendations for Good Practices (Best Practices): Funding and payment to public for their involvement (maybe covering out of pocket travel expenses; identifying experts in recruiting and involving the public; recruiting the public through relevant networks; training, briefing and information provision; use structured methods of involvement (e.g., Delphi method through email).

Author, Year, Country	How can we capture and measure the value of s/h engagement in systematic reviews?	Any other pertinent information?
Brett et al., 2010[19] United Kingdom	" … the field of PPI is an area where there has been little, if any, attempt to develop instruments to measure impact. Two studies have attempted to measure the impact of PPI by RCT methodology to assess the difference in informed choice, and by assessing the difference in recruitment to a trial using information developed by users versus information developed by academic researchers [25, 26]."	Understanding of the impact and outcomes of PPI on health and social care research:- Studies do not report impact in enough detail and fewer still mention impact in relation to context and process in a consistent way.- PPI could be described as a 'complex intervention', where impact needs to be evaluated alongside broader factors to identify what works, for whom and in what circumstances.- There is a need to develop methods and instruments for capturing and measuring PPI impact and outcomes that ideally would include both qualitative and quantitative components.Measurement and Valuation of Resources Use and Costs of Stakeholder Engagement in the Research Process:- No evidence of economic analysis that considers the costs of implementing PPI, such as staff time and resources, reflecting a lack of appraisal of the impact of PPI more generally.Reference to Specific Activities to Reach Out to and/or Engage Stakeholders in the Research Process: - Two broad categories of activities to engage stakeholders are identified: 1) consultations with users; and 2) user-led or collaborative studies, no additional information on this is found.
Brett et al., 2012[20] United Kingdom	Indicates that evidence of impact of public involvement in the included studies was weak and poorly reported.	Not reported
Involve, 2012[21] United Kingdom	Not reported	Not reported
Keown et al., 2008[22] Canada	Not clearly discussed, but does mention s/h flagging missing search terms or articles, helping clarify conclusions, and actively disseminating findings . Also notes that involvements helps s/h "build capacity" of the s/h to seek out and use high quality evidence and to advocate for evidence in their organizations.	This program has a much closer relationship with a discrete group of s/h than does the CEHP . One challenge is that they have a smaller, more homogenous, and more stable pool of s/h, who are more directly interested in the results of the research . However it sounds like it could be an effective model.
Vale et al., 2012[23] United Kingdom	Difficulties were found to assess the direct impact of consumer involvement on either the research or the researchers, with no comparisons of consumer involvement with no consumer involvement being identified and carried out within CTU research studies (as in Nilsen et al., 2006[2]). - One such study is underway. [27]	**Reference to Specific Activities to Reach Out to and/or Engage Stakeholders in the Research Process:** - Consumer involvement was most commonly as part of a trial management group or similar study advisory or steering group, with consumers undertaking a variety of activities, for example, writing or commenting on patient information sheets; trial promotion activities; aspects of protocol development; and interpreting and disseminating the results of studies
Wright et al., 2010[24] United Kingdom	No specific information in this is found	Reference to Specific Activities to Reach Out to and Engage Stakeholders in the Research Process: No specific information on this is found

Note: CCNet=Cochrane Consumer Network; CER=comparative effectiveness research; CTU=Clinical Trials Unit; CEHP=Continuing Education in the Health Professions; EUnetHTA=European Network for Health Technology Assessment; HIV=Human immunodeficiency virus; HTA=Health Technology Assessment; INHATA=International Network of Agencies for Health Technology Assessment; IOM=Institute of Medicine; MRC=Medical Research Council; N/A=not applicable; NHS=National Health Service; NICE=National Institute for Health and Care Excellence; PPI=patient and public involvement; RCT=randomized controlled trial(s); s/h=stakeholder(s); SR=systematic review(s); UK=United Kingdom; INVOLVE definition of s/h = "patients and potential patients; people who use health and social services; informed carers.parents/guardians; disabled people; members of the public who are potential recipients of health promotion programs, public health programs and social service interventions; organizations that represent people who use services.

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Appendix C. Interview Guides

Introduction

- The mission of the Agency for Healthcare Research and Quality's (AHRQ) Effective Health Care (EHC) Program is to provide evidence-based information for health care stakeholders.
- The EHC seeks to produce information that is relevant to stakeholder needs, timely, objective, scientifically rigorous in construct, and developed and presented with transparency.
- AHRQ engages stakeholders in all facets of their research enterprise, including the production of systematic reviews, with the goal of ensuring that research findings reflect the needs of diverse users, are relevant to their unique challenges, and are applicable in real-world situations.

Purpose of discussion sessions

- The objective of our project is to better understand the value of stakeholder engagement in the production of quality systematic reviews so that we can evaluate and improve how we work with stakeholders in the future .
- Our primary goals are to:
  1) articulate the expected societal benefits of engaging stakeholders in systematic reviews;
  2) understand *how* we would measure the effectiveness of stakeholder engagement; and
  3) understand *when* we would measure the effectiveness of stakeholder engagement .
- We are very interested in learning from your experience engaging stakeholders or being engaged as a stakeholder in a systematic review .
- There are no right or wrong answers, so please feel free to share your thoughts openly . We strive for a balanced opportunity for everyone to express their thoughts during the discussion session call .
- We would welcome any materials that you would like to share with us either before or after the discussion session. Please send any materials to Johanna.anderson2@va.gov.

Ground rules for discussion sessions

- The discussion session proceedings will be tape recorded, transcribed, and analyzed for themes .
- Although the final report may list individuals who were interviewed, your individual responses will remain anonymous . Any material from the discussion session that is used in the final report will be de-identified so that it cannot be linked to specific individuals or organizations .
- You may refrain from answering any questions and are welcome to leave the discussion at any time .
- Any questions before we begin?

Discussion Session Guide (Systematic Review/Programmatic Perspective)

Introductory/framing questions

1. What types of stakeholders (e.g., clinical experts, patients, patient representatives) do you typically engage in the systematic review (SR) process?
2. In what aspects of the SR process have you typically involved stakeholders (e.g., developing key questions, providing feedback on protocol, etc.)? Does the type of stakeholder vary depending on the stage of the review process?

Understanding the value of engaging stakeholders in systematic reviews

3. What were the key factors that prompted you to include stakeholders (i.e. mandates, research improvement, other)?
4. What were your expectations about engaging stakeholders? What did you expect to get from engaging them in your systematic reviews?
5. In your experience, how does the review process differ when stakeholders are actively engaged?
6. Can you describe the tangible benefits you've seen from engaging stakeholders?
    a. Are there points in the review process when it is most beneficial to engage stakeholders?
        i. If yes, what are the tangible benefits?
    b. Is there a certain type of stakeholder that is most appropriate for engagement in systematic reviews? (Are there certain types of stakeholders that you have deliberately included or excluded?)
        i. If yes, when in the process do you get the most benefit from engaging this type of stakeholder?
7. What are the primary challenges or costs of engaging stakeholders?
    a. Is there a point in the review process when engagement is particularly challenging?
    b. Are there certain types of stakeholders that are harder to engage than others?
8. Have you conducted any type of formal or informal assessment of the benefits and costs of engaging stakeholders?
    a. If yes, can you tell us what that looked like?

Closing questions/wrap-up

9. What (in your experience) is lost by not engaging stakeholders?
    a. Are you aware of any publications that address this issue?
10. Are there any additional issues we didn't cover today that you think are important in understanding the value of involving stakeholders in the systematic review process?

Discussion Session Guide (Stakeholder Perspective)

Introductory/framing questions

1. Have you been involved as a stakeholder in the systematic review process? If so, please describe your experience, including what role you played and who was part of the team (including other stakeholders).

Understanding the value of engaging stakeholders in systematic reviews

2. What were the key factors that prompted you to participate? What were your expectations of your role in the systematic review process? What did you expect to get out of this process?
3. Do you feel that you made a contribution to the systematic review process? If so, how?
4. In your experience, is the review process different when stakeholders are actively engaged? Can you give me some specific examples of how it is different?
5. Do you think you were involved at the right stage? Do you think your input would have been more useful if you had been involved either earlier or later in the research process?
6. Did you encounter any challenges or barriers? If yes, can you tell me what was challenging?
7. What type of stakeholder do you think is most important to engage in systematic reviews?
    a. When in the systematic review process should this type of stakeholder be involved?

Closing questions/wrap-up

8. What (in your experience) is lost by not engaging stakeholders?
    a. Are you aware of any publications that address this issue?
9. Are there any additional issues we didn't cover today that you think are important in understanding the value of involving stakeholders in the systematic review process?

If you have any additional comments or materials you wish to share, such as examples of reviews, please let us know via telephone at 503-220-8262 x52384 or via email at Johanna.anderson2@va.gov. We appreciate any and all information you can provide us with.

Appendix D. Select Quotes From Key Informant Discussions

Expected Benefits of Engaging Stakeholder in Systematic Reviews
Establishing credibility and buy-in to the systematic review process
“*I think that we were looking for buy-in from the beginning, the sense that the stakeholders felt that they were involved in a process, not just being announced to at the end what the result was, that they at least had an opportunity to review and provide input into the way the review was being done.*”
“*It's partly buy-in to the process itself . Although the goals of the reporting is to be as transparent as possible there can always be questioning of the reporting . So if people have been involved from the beginning in conference calls and reviewing various documents and we're able to document that that’s at least been addressed, that can, again, maybe not totally prevent any subsequent controversy that was mitigated.*”
Producing reports that are scientifically valid, relevant, and useful
“*So I think framing of the issue and the questions at the beginning is one of the absolutely most important things the patients can do for us . It makes it more relevant.*”
“*We have certainly seen stakeholders fundamentally change our key questions based on their input, and so clearly they’re having an impact, particularly in that process of framing what the true important questions are . We talk to them about decisional dilemmas and helping us understand where the points are in a medical care process that they truly are at sort of a crossroads and would benefit from specific information.*”
“*They are incredibly important for understanding how a report needs to be set up and to make sure that it isn’t sort of an ivory tower exercise but is useful and usable at the end of the day.*”
“*We need to know in advance what the most important questions and issues are to people who are in the field who are actually going to be using the results; whether it's parents trying to decide what the best interventions are for their kids; whether it's surgeons trying to decide what procedures...*”
“*[Stakeholder input was valuable in elucidating]…some of the nuances around those key questions, and I guess the example I’m thinking of was in perhaps a more clear definition of the population, and then certainly discussions around some of the outcomes.*”
“*We’ve certainly heard examples in cardiovascular disease of a research team that was very focused on laboratory value outcomes, and the patient says, “You know that’s not the issue…the issue s I that I am really tired . I am just so exhausted.” You’ve got to get these sorts of quality of life outcomes . And that’s critical . It is absolutely critical.*”
“*I have seen the inclusion of patients and patient advocates in the formulation of the questions be critically important in shaping, in very nuanced ways, the questions and the sub-questions, the overall quality of the review and also the utility of the review when it is actually completed.*”
“*…when thinking of how stakeholders have really changed the direction of projects the first examples that popped into my mind are examples where they’ve helped us understand where tests and devices and imaging protocols that were potentially within the scope of the review were absolutely obsolete and so did not need to be evaluated.*”
Anticipating and mitigating controversy/political issues
“*… [F]or some topics that we knew in advance were going to be somewhat controversial… I think there's a benefit in having some of the anticipated critical voices . The voices will be critical after the report ... at least have some say or some stake in the report itself . So getting them involved upfront hasavoided all controversy but it certainly has helped us be prepared for what's to come.*”
“*We just did a large report for an area that was quite controversial and that only became clear to us really at the end, and it was unfortunate because I thought, gee, if I’d known this or had this context or background at the outset, and I think that ... could have provided that and maybe we just weren’t asking the right questions because we didn’t know what questions to ask, or how to involve them best.*”
“*I think the only thing I would add is that involving them earlier on helps them being people that we feel might have conflicting views or controversial views . Including them earlier on might get some sense of, ownership is probably too strong a word, but sense of involvement early on that they provided input . Also at the end, I think, for us there's often the sense of the peer review process of let's make sure we get people involved, or at least a couple of people involved that we think might have issues with this report . I'd rather hear of those issues and controversies during the peer review process then after.*”
“*The mammography recommendation accelerated what was, to be perfectly honest, almost a backburner movement. We aspired to increasing the transparency of the process and we were considering ways to do so, but after mammography we said, “Okay, this now has to be a high priority*.”
Facilitating dissemination and uptake of report findings
“*The main thing is to make sure that the report is being used at the end and not just sitting on a shelf.*”
“*Perhaps [stakeholders] not being there in the same way I’d sort of feel nervous about the impact it would have in the outer world, because it’s not something that’s been developed with the insights of people out in the big wide world . It would be a bit like working in a laboratory in a very isolated way, which I certainly would like because I wouldn’t have the sort of touch point for the relevance of this piece of work, or its acceptability, or its appropriateness.*”

“*I think with the involvement of the public can actually direct our research in much more useful ways, that you’re doing something that benefits society as a whole and that is going to be more useful to people out there.*”
“*We’re not seeing a whole lot of evidence that systematic reviews are actually being used in a way that actually makes a difference in terms of our health care…*”
“*Transparency facilitating dissemination and uptake and impact are critical in terms of ensuring that we have the key perspectives on the report and providing feedback on the review . At the end of the day by having the key perspectives present to ensure that we will disseminate the report to an appropriate audience and the key audiences, and that will also ensure that we have uptake and impact.*”
“*We think about including them in the reviews because of the implementation aspect afterwards . So are we including people that will actually be able to help us disseminate the research once the research has been done? So I think that’s another aspect of why we’d want to be engaging stakeholder in the process.*”
“*Even the scientific community, I think, needs to be more aware of the EPC program, the reviews that are being conducted, the way they are conducted, the output from those reviews . So I think that by engaging a broader array of people at the beginning of the process, I’m imagining that that could have important impact on consumption of that evidence when it comes out . I think that people don’t even know about this EPC program.*”
Ensuring programmatic and societal accountability
“*Research is often funded by taxpayers and as a taxpayer I would prefer research to be undertaken that has a relevance to my life.*”
“*…with finite resources there is an argument for democratic accountability for that money…I think for me it is not just the money, it’s feeling that you’re doing something that benefits society as a whole.*”
Challenges of Engaging Stakeholder in Systematic Reviews
Time and resources
“It is time consuming.”
“There is a lot of commitment required from stakeholders.”
“Engaging stakeholders uses resources.”
“Time . I think more than anything else, time . You basically add 1 to 3 months at every step in which you choose to engage in outside resources and call them stakeholders. “
Lack of training
“Stakeholders need to be educated before they can effectively participate.”
“The scope of the review can be broadened by stakeholders.”
Finding the right people
“*I think it is not only who the stakeholders represent, for example if you’re thinking about your needs for various clinical experts to have the right experts whether it’s a surgeon or a hospitalist, or an oncologist, or radiologist, but it’s also about who those individuals actually are….do they have the right personal characteristics where they are responsive, professional, diplomatic….and then do they have the right connections? Are they part of important societies or in leadership roles in various societies and can spread the word? One radiologist is not the same as another radiologist, although that might be a starting point.*”
“*…also individuals may choose to join such a process because they have their own personal agenda, and when that’s present many of us have found that that can totally derail the group process and the ability to really look at things objectively.*”
“*We patients are a very varied bunch and I know it takes a lot of guts and a lot of commitment to actually invite us to participate meaningfully in the development; both of the question that the systematic review is going to ask or the questions, and also, to participate as a working member of the group assuming that our work will not rise to the quality of someone who really has the methodological rigor and background to apply the rigor that’s needed.*”
“*And some of those characteristics are training, which probably is highly associated with how effective you’re going to be . So you know do they have a good foundation of clinical epi(demiology) and critical appraisal and the development of research questions, you know relevant outcomes as opposed to not so relevant outcomes.*”
“*I would say that I think particularly now there’s a lot more interest in the part of a small group of patients partly stimulated by the query to be willing to participate in the development of systematic reviews, but I think that the preparation of investigators and the preparedness of investigators to put the time and effort in to making that participation meaningful is sadly lacking.*”
Knowing who to engage when
“*I think this has been sort of a challenge here in the US . In particular I think we went on, in recent, years, sort of a rampage of all stakeholders all the time should be engaged at the table as investigators in every research project . That was sort of the message that was coming from some of the funding agencies, and I think the feeling among some of the researchers was that not only is that not always true or helpful but it devalues the particular roles of the stakeholders.*”
“*The topic of this project, the value of stakeholder engagement, as if they’re all one group of people who all represent the same thing and they’re certainly not . I think we are really at a point in understanding this process that we need to move in to something that’s much more nuanced.*”
Balancing multiple inputs

“*The other issue is that once they express an opinion you have to deal with it . It depends very much on the skills and the personality of the people running the project . I did a number of projects where we had incredibly accepting project leaders who basically because somebody said it they decided they would go off and do it even though it wasn’t the best idea in the world . Part of my role is to try and rein in, not chasing down every alleyway that somebody recommends.*”
“*The flip side of that, which I think is quite problematic, is it can put an individual patient in a position where they feel massively uncomfortable . That they feel somehow that the approval or disapproval of the treatment is going to be down to them and how well they speak and how good a case they put . I think that’s really troubling that people go away with that feeling or enter with that feeling when in fact they’re much more peripheral to the decision process than that.*”
“*There are other cases where the patient who is present….says what they think the committee needs to hear…and not what they are genuinely are experiencing.*”
“*You also get patients coming to speak who are complete outliers to the general experience of patients on that treatment . For instance, you might have a 7-month average life expectancy but the patient speaking to you is the person who has actually lived 5years on the treatment . The benefit of their voice is a little bit lost because they don’t fairly characterize that particular stakeholder group.*”
Evaluate against real world outcomes
“*I think that, once again, we do need to evaluate the value of stakeholder participation in systematic reviews against some real world outcomes, even if it’s just page views on articles . Just saying that, like I did before, oh the questions are improved, it’s just going to cut it . It’s too self-preferential, too proximal.*”
“*…and that’s just not good enough to say, oh well, we met with the chair six times and the stakeholders were satisfied . No, no, no, no – I mean it really is the quality of the product that’s produced and the impact that that has; whether it’s just the number of people who’ve read it, where it gets picked up . I know that you can’t trace whether it gets implemented into practice, God forbid, but it’s got to be bigger than that kind of self-serving, easy to score an A on evaluation participation.*”
Changes in key questions and other aspects of the report
“*When I think about it, we’re not very good about tracking the changes in the questions, for example, which could help us address that question I think . That’s actually tedious to do.*”
“*For those EPCs that would have the records; I would think that you could at least look at what the initial PICOTs and key questions may be . How did the protocol change from the one originally written by the EPC to the one that was finally in the report?*”
“*I wonder if there’d be a way to take a particular report where there have been some drastic changes and look at, say, how many papers would have been included—did it improve the efficiency of the search, or would certain situations have been left out if there hadn’t been input from the stakeholders . I think you’d have to look at things like number citations, type of studies, particular patient populations.*”
“*Really, the outcomes would be many things, what the key questions were, what the PICOTs were, what the inclusions criteria were, what the results of—just the count of how many studies were accepted one way versus the other, and what the final conclusions were and how they differed.*”
Qualitative evaluation/survey of stakeholders
“*I would say you would go back and interview . Probably the ones that are used for guidelines aren’t the best example of this, but you could go back and talk to your initial stakeholders and ask them if they used it for anything, and if so, for what.*”
“*I was going to say in addition to looking at the conclusions differed or the results differed, you could have policymakers or that sort of person review and see which one was actually more informative.*”
“*Another thing I think that would really help you judge whether the key informant or stakeholder input was important was longitudinally the end use of the report and how many groups used it and what they used it for . That would involve some interviews or focus groups well after the final report.*”

Note: EPC=Evidence-based Practice Center; PICOTS=Population, Intervention, Comparator, Outcome, Timing, Setting

Appendix E. Key Information Perspectives on Benefits of Specific Types of Stakeholder Engagement in the Topic Refinement Phase

			Expected Benefit of Stakeholder Engagement in Systematic Reviews		
	Buy-in Process / Credibility	**Systematic Review (Relevant and Useful)**	**Uptake and Use of Product**	**Political - Controversy Mitigation**	**Programmatic Needs/Social Accountability**
SYSTEMATIC REVIEW PHASES					
Topic Refinement; Research Plan (PICOTS, I/E Criteria)	Patients, caregivers and patient advocacy organizations, Clinicians and their professional associations, Institutional health care providers, such as hospital systems and medical clinics, Government agencies, Purchasers and payers, such as employers and public and private insurers, Health care industry representatives, Health care policy makers at Federal, State and local levels	Clinicians and their professional associations, Government agencies, Health care policymakers at the Federal, State and local levels, Health care researchers and research institutions	Patients, caregivers and advocacy organizations, Clinicians and their professional associations, Government agencies, Purchasers and payers, such as employers and public and private insurers, Health care policy makers at Federal, State and local levels	Patients, caregivers, and patient advocacy organizations, Clinicians and their professional associations, Government agencies, Health care industry representatives, Health care policymakers at the Federal, State and local levels, Health care researchers and research institutions	Patients, caregivers, and patient advocacy organizations, Clinicians and their professional associations, Government agencies, Health care policymakers at the Federal, State and local levels, Health care researchers and research institutions

Note: I/E=Inclusion/exclusion; PICOTS=Population, Intervention, Comparator, Outcome, Timing, Setting

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