Developing a Methodology for Establishing a Statement of Work for a Policy-Relevant Technical Analysis

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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. 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 bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review prior to their release.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

We welcome comments on this evidence report. 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.gov.**

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Structured Abstract

Context: The Duke Evidence-based Practice Center (EPC) initiated a project designed to improve the process of generating reports that synthesize and evaluate the scientific literature on topics of particular interest to health care policymakers, clinicians, and other decisionmakers. The project focused on two improvement opportunities: process efficiency and stakeholder satisfaction. We organized the analysis around the concept of a "statement of work (SOW)." As a contractual document, the SOW is the tangible manifestation of the objectives of each EPC project, serving as a foundation for interaction between involved parties, including technical details such as budget, timeline, and deliverables.

Objective: To identify potential solutions to the core constraints identified by the study.

Methods: The project proceeded in four steps: an interview of participants in the EPC process; a review of the technical contracting literature relating to formulating SOWs for the production of policy reports and similar intellectual products, and policy literature related to the determinants of a successful policy analysis; a synthesis of both the interview results and literature review utilizing tools suggested by the Theory of Constraints (TOC).

    TOC methods were applied to the initial results in order to identify a common undesirable effect (UDE) related to EPC reports: a *report that does not get used* is unsuccessful and is deemed fundamentally undesirable. A current reality tree (CRT) was constructed by working from this fundamental UDE at the top through proximate causes, and finally root causes identified during the process.

Conclusions: The analysis identified several problems that ultimately result in a report not meeting the partner's needs, and therefore not being used. The most significant problem, i.e. the *core constraint* (the most important target for improvement), identified was that the *partner does not know how to conceptualize and articulate needs, objectives, and specifications*. Several major potential change strategies for this core constraint were then explored. Two change strategies: *establish an ongoing relationship between partners, EPC, and AHRQ early in the process,* and *utilize a changes clause* were deemed to be the most practical means to exert impact on the SOW process by addressing this core constraint. In the final step, a Future Reality Tree was constructed representing an illustration of the impact of the proposed solutions on the EPC's SOW process.

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Executive Summary

In 1997, the Agency for Healthcare Research and Quality (AHRQ) created 12 Evidence-based Practice Centers (EPCs). The EPCs' mission is to "develop evidence reports and technology assessments on topics relevant to clinical, social science/behavioral, economic, and other health care organization and delivery issues." The principal products of the EPCs are called evidence reports. EPC evidence reports are evaluations of the scientific literature on topics of interest to policymakers, clinicians, and other decisionmakers. The reports are requested by organizations representing these interested parties. Like any process, the EPC process is subject to improvement. The importance of process improvement to the EPC program is reflected both in the existence and the content of the annual AHRQ meeting with EPCs and partner organizations.

Two areas have been evident targets for improvement: process efficiency and stakeholder satisfaction (where stakeholders are both direct participants in the EPC effort as well as other parties with an interest in EPC products). This report describes a project initiated by the Duke Evidence-based Practice Center to contribute to the improvement of the EPC process, focusing on specific actions that could serve to improve process efficiency and stakeholder satisfaction. We organized our efforts around the concept of a "statement of work (SOW)." As a contractual document, the SOW is the tangible manifestation of the objectives of each EPC project, serving as a foundation for interaction between involved parties, including technical details such as budget, timeline, and deliverables.

The project proceeded in four steps. In Step 1 we interviewed participants in the EPC process in order to establish a deeper understanding of the current process. In Step 2 we reviewed the technical contracting literature relating to formulating SOWs for the production of policy reports and similar intellectual products, and policy literature related to the determinants of a successful policy analysis. In Step 3 we applied the Current Reality Tree (CRT) technique from the Theory of Constraints (TOC) to synthesize the information provided in the first two steps in a way that highlights *core* constraints (i.e., constraints that are the most important targets for improvement.) In the final step (Step 4) we reviewed the information collected in the interviews and literature review in the context of the TOC exercise. The objective was to identify promising solutions for the core constraints, which may serve as input to an action plan by AHRQ in collaboration with EPCs and partners. With these solutions in mind, we constructed a Future Reality Tree, an illustration of the impact of the proposed solutions on the EPC's SOW process.

We utilized the Theory of Constraints for the next steps in the project. Our interviews with EPC researchers, partners, and AHRQ allowed us to identify a common undesirable effect (UDE) related to EPC reports: a *report that does not get used* is unsuccessful and is deemed fundamentally undesirable. We formulated a current reality tree (CRT) working from this fundamental UDE at the top through proximate causes, and finally root causes. In the next stage we extracted a list of root causes from our interviews.

Following TOC methods, we next explored the relationship between these root causes in order to identify one (or two) major problems that lead to the rest, and ultimately result in a report not meeting the partner's needs, and therefore not being used. Of these, the first (p*artner does not know how to conceptualize and articulate needs, objectives, and specifications*) rates as a core problem or the constraint that prevents an EPC from achieving its goal because it affects most other problems. This is the reason why specifications are insufficient in the first place,

which leads to an underestimation of the volume of work, results in new cost and time requirements that lead to delays in the report, and finally results in the report not being used.

The interviews, literature search, and input from an EPC directors' meeting identified several potential injections/change strategies: Two injections: *establish an ongoing relationship between partners, EPC, and AHRQ early in the process,* and *utilize a changes clause* were deemed to be the most practical means to exert impact on the SOW process by addressing the core constraint, *partner does not know how to conceptualize and articulate needs, objectives and specifications of the SOW.*

With these concepts of UDEs, root causes, and injections we constructed the Future Reality Tree for the SOW process; the ideal process that EPCs should follow in order to develop evidence reports that meet the needs of the partners.

Introduction

In 1997, the Agency for Healthcare Research and Quality (AHRQ) created 12 Evidence-based Practice Centers (EPCs). The objective of the EPC program was to provide a public service information resource for policymakers, clinicians, and other decisionmakers. According to AHRQ,[1] the EPCs' mission is to "develop evidence reports and technology assessments on topics relevant to clinical, social science/behavioral, economic, and other health care organization and delivery issues." In 2002, AHRQ announced a second 5-year cycle of funding for the program and expanded the total number of EPCs to 13.

The principal products of the EPCs are called evidence reports or technology assessments; for simplicity's sake, we refer to them here as evidence reports. EPC evidence reports are detailed evaluations of the scientific literature on specific clinical, behavioral, organizational, and financing topics of interest to policymakers, clinicians, and other decisionmakers. The reports are requested by organizations representing these interested parties. Termed "clients" in general management parlance, these organizations are called "partners" in the context of the EPC process.

From the moment an EPC report is proposed, to its production and use by a partner, all parties are engaged in a process. Like any process, the EPC process is subject to improvement. The importance of process improvement to the EPC program is reflected both in the existence and the content of the annual AHRQ meeting with EPCs and partner organizations.

Two areas have been evident targets for improvement: process efficiency and stakeholder satisfaction (where stakeholders are both direct participants in the EPC effort as well as other parties with an interest in EPC products). Process efficiency assures that the immediate goals of any EPC project are accomplished without wasting public resources. Stakeholder satisfaction directly impacts the long-term sustainability of the EPC program; stakeholders who have a sense of satisfaction in the process and the products are more likely to value and support the public service provided by the EPC program.

This report describes a project initiated by the Duke Evidence-based Practice Center to contribute to the improvement of the EPC process, focusing on specific actions that could serve to improve process efficiency and stakeholder satisfaction. To maintain a level of concreteness, we organized our efforts around the concept of a "statement of work (SOW)." As a contractual document, the SOW is the tangible manifestation of the objectives of each EPC project, serving as a foundation for interaction between involved parties, including technical details such as budget, timeline, and deliverables. A well-constructed SOW is also the keystone for clear communication and effective interaction between naturally distinct parties. It should provide a level of guidance that maximizes the chance that the final product will serve the purposes of the partner or sponsor. When poorly constructed, the SOW can lead to significant delays and can ultimately result in an unsatisfactory report.

It should be noted that while the SOW document is of potential importance, it is the *concept* of the SOW that is fundamental. This project is aimed at identifying strategies for enhancing the success of the EPC program; some, if not all, of the enhancements should be reflected in an improved SOW document. (For a more detailed definition of the statement of work, see Appendix .)

Methodological Overview

The project proceeded in four steps:

- In Step 1 we interviewed participants in the EPC process in order to establish a deeper understanding of the current process, focusing on the definition and determinants of a successful report. Although the primary goal was to understand current processes, we also solicited ideas about solutions, including strategies for producing a more useful SOW.

- In Step 2 we reviewed the technical contracting literature relating to formulating SOWs for the production of policy reports and similar intellectual products, as well as the policy literature related to the determinants of a successful policy analysis. This step was intended to complement the interviews in Step 1 by placing the EPC activities in a broader context, and particularly to identify existing concrete solutions to problems noted in the interviews.

- In Step 3 we applied the Current Reality Tree (CRT) technique from the Theory of Constraints (TOC) to synthesize the information provided in the first two steps in a way that highlights *core* constraints (i.e., constraints that are the most important targets for improvement.) Again, in the spirit of maintaining concreteness, we were especially attentive to distinguishing constraints that were within the control of the EPC participants. As part of this step we presented the work from Step 1 and Step 2, as well as preliminary reflections on the core constraints, at the 2004 annual EPC meeting and solicited written feedback.

- In the final step (Step 4) we reviewed the information collected in the interviews and literature review in the context of the TOC exercise. The objective was to identify promising solutions for the core constraints, which may serve as input to an action plan by AHRQ in collaboration with EPCs and partners. With these solutions in mind, we constructed a Future Reality Tree, an illustration of the impact of the proposed solutions on the EPC's SOW process.

Step 1: Informant Interviews

Informant Interview Methods

Semi-structured interviews were conducted with the three groups involved in the EPC activities: EPC staff (research center directors and project managers), AHRQ staff, and representatives from partner organizations (both public and private). Interviews were conducted by telephone, were audio-taped, and lasted about 45 minutes each. The interviews were conducted over a 2-month period by a team of three researchers. An interview guide was followed. Questions were general in nature and focused on areas related to the establishment of appropriate processes for evidence-based reporting and health technology assessment. All topics in the interview guide were covered during each interview. Interviews were conducted with 11 EPC directors, one EPC project manager, three AHRQ representatives, two Federal partners, two non-federal partners, two academic experts, and one management expert.

All interview tapes were transcribed and then read several times to identify key issues. A structured coding scheme was devised based on a reading of the transcripts and the objectives of the project; sections of text were coded to the identified themes. Coded segments were then examined and compared, first to identify similarities and differences and later to produce a conceptual framework for analysis and interpretation.

Informant Interview Results

An analysis of the coded transcripts was organized by the three major interview topics:

1. The concept of a successful report.

2. Determinants of a successful report.

3. The role of AHRQ processes and procedures in promoting success.

Quotes presented here have been selected as typical of the perceptions and experiences recorded; they are not, however, statistically representative of a larger population.

The Concept of a Successful Report

For researchers, success is perceived to occur at different levels. Primarily, a report is considered successful when the partners use the report (either to produce guidelines or develop policy), confirm that the report met their requirements, and provide the researchers with feedback from end users. In addition, for researchers, a successful report must be a rigorous synthesis (in accordance with evidence-based principles), intellectually satisfying, conducted using a credible synthesis of data, and provide new insights. A few researchers noted that reports should allow junior faculty in pursuit of an academic career to publish, while others did not view publication as an important endpoint. The metric by which success is measured has not been firmly established; there are some reports that, regardless of whether they have technically been good analyses or not, have either not been used to implement policy or have not received "a lot of press." In addition to issues related to the nature of the application of the report, EPC directors generally agreed that a successful report must break even financially.

AHRQ staff also reflected on what constitutes a successful EPC report, one that blends the notions of excellence and usefulness. First, a good report has to "meet the needs" of the partners. It answers questions that the partners will find useful and have asked. It has to be an excellent, well-written synthesis of the qualitative issues related to the topic addressed, and the highest methodological standards must have been applied. A successful report shows how each piece of evidence fits together to answer a question. It has clear key questions, identifies all the relevant literature, utilizes a technical expert panel knowledgeable about the subject, incorporates clinical opinion, and demonstrates an understanding of evidence, while remaining non-normative. A successful report requires "clinical content expertise, knowledge of the technology and identification of the policy implications."

The concept that partners have of a successful report is one that meets their needs. A successful report "includes what we told you to do." In order to be a good report, it has to include the "universe of evidence," not just a subset, with tables that organize evidence in a manner that is easy enough to understand so that committees can weigh the evidence themselves. They understand that in order to have a successful report, they must "have an outcome in mind."

Our non-EPC interviewees (two academic experts in technical analysis for policymaking and one management expert) confirmed the importance of a useful report as a prime measure of success. One academic expert suggested that one should not underestimate the potential value of academic products (e.g., manuscripts and technical reports) as they may influence the way people think about a problem; this effect may be slower but potentially more profound.

Determinants of a Successful Report

For researchers, the most important determinant for a successful report is having a well-defined scope of work. Narrow and clearly worded questions facilitate research work and make it feasible to complete the report with the available time and resources. Other major conditions are to understand the audience and the intent of the report. Researchers need explicit information to know "the context of what users are looking for." They also need to know more about the desired structure and tone of the report (scientific vs. lay tone).

There is an overall concern among researchers, however, that these requirements are often not explicit enough or not clearly established in the original statement of work. If reports have to meet partners' needs, those needs have to be identified. "Clear expectations need to be identified by the partner." "What they want" has to be well articulated to result in a credible product, and it has to be identified up front using relevant questions. "A crucial component is to define the scope of the project up front." Several problems have been identified with this process. In many instances, what EPCs are asked to do is completely "out of feasible bounds." Broad scopes and questions are the norm, not the exception. In many cases, EPCs have perceived that partners were not sure what they really wanted to do. "It took us a while to figure out what they actually wanted." When research questions have to be refined, not only is the scientific success of the report at risk, but there can be financial implications because "budget is the concrete manifestation of a statement of work." This problem is particularly relevant because of the strict time frame for completion of reports. Because the work with partners changes over time, some change is inevitable; researchers indicate "we need flexibility." However, when partners do not develop a clear conceptual framework up front, the result is that questions are not specific enough and researchers cannot define the type of analysis needed.

Researchers indicated that one factor that can influence a project's success is *consistency of role expectation*. Specifically, it is sometimes difficult to keep up with how partners define their

roles; a partner may be "hands-off" in the beginning, and then decide that it wants to be intimately involved in completing the project, or it may request that the EPC become deeply involved in dissemination and implementation aspects of the project that were beyond the initial project scope.

AHRQ recognizes that reports need to *start with a well-defined conceptual framework*, identifying what the problems are and where the complexities lie. Developing this conceptual framework requires time and commitment. In constructing the final report, the technical analysis often has to be adjusted to match the conceptual framework.

Partners have also identified that a major determinant of a successful report involves *asking focused questions*. They consider this to be their main responsibility. The partners also raised the point that this is a learning process and that they have come to recognize this through their participation. On the other hand, several partners said that they were disappointed with certain reports that were too detailed to support decisionmaking. Even if the reports were technically perfect, they did not meet the needs of the end users because they did not present information in a useful manner. Partners said it is necessary to "identify the audience for the report early," to "show how each piece of evidence fits together to answer a question," and to structure the evidence report so that it is facile for decisionmakers to weigh the evidence themselves.

Two other factors were generally agreed to be determinants of a successful report. The first is having an *abundance of communication*. All parties involved mentioned that establishing a "face-to-face relationship" is essential. Partners realize that it is crucial to have greater interaction with AHRQ and researchers in the very beginning stages of the project. "Our input can't come too late in the process." Establishing this relationship outlines the nature and content of the report in an interactive, refined process. For researchers there is an inherent tension: "the more we want the reports to have impact, the more we have to negotiate with the partners."

The second factor determining a successful report is the presence of *a formal process for creating a standard report*: establish a good working team with diverse and substantial expertise, develop collaborations with clinical and content experts, identify the literature, synthesize the evidence, and write a technically correct and readable report. The role of external experts is considered to be very helpful. The experts know who the leaders are in the field (professional societies, advocacy groups, industry), and can fill in the story behind the solicitation and agendas.

One academic expert mentioned the importance of establishing a process for dealing with especially contentious topics (e.g., independent oversight panels) in circumstances where potentially important information might otherwise be suppressed or enhanced for reasons other than good science. The management expert highlighted the importance of a well-constructed SOW; this was the only person who volunteered the SOW as a determinant of a successful report.

The Role of AHRQ in Promoting Success

Overall, both partners and researchers indicated a high level of satisfaction with AHRQ. Respondents also indicated that, in some areas, the role of AHRQ could be enhanced in order to improve the success of EPC reports.

There is a widespread perception, both among researchers and partners, that AHRQ should mediate—or at least facilitate—the interaction between analysts and partners. "AHRQ has to make sure that the project they select creates the greatest value." "I would be happy to see AHRQ take a stronger role in making partners prioritize questions, in order to avoid scope creep

when the partner suddenly discovers he wants to ask another question." There is a need to prioritize among all possible questions, focusing on those questions whose answers provide the greatest value. Partners have to understand that "they are going to receive what they need, but perhaps not what they want." Researchers would like AHRQ to "push the partner to define what they want." Partners should understand that they are receiving "an enormous gift," but they have to be prepared to collaborate on the project and be ready to use it. They need to have an understanding of evidence-based medicine and systematic reviews. "We need to educate them." Researchers advocate that AHRQ accomplish this work up front, "they could set the stage better with partners." This educational process would allow for aligned expectations and a focus on the "right questions."

From the researchers' perspective, AHRQ needs to minimize the gap between what partners want and what is expressed in the scope of work. Current mediation strategies were not seen as adequate. AHRQ has to identify "other ways of doing the intermediary work, other mechanisms." Partners also recommended establishing a formal process, with clearly established parameters, to ensure that all issues are addressed. "We need a consistent, routinely followed process."

All parties expressed that the process has improved over time. Earlier reports were more "painful." Both the EPCs and AHRQ commented that the more recent reports have been better. EPCs are more experienced doing things for the price, can better estimate the amount of literature they are going to have to review, and have developed more experienced teams. While "EPCs have learned by doing," EPCs expressed a strong desire to have more opportunity to benefit from the experience of others.

Three issues involving AHRQ were also mentioned. First among these was the existence of some variability among the different Task Order Officers overseeing the different reports in the way they conduct their work. Having a "fabulous project officer" is a key factor. A second issue was the role of the Coordinating Center. Although the establishment of the Coordinating Center raised a lot of expectations, the overall perception is that its impact is very limited at the moment. The third issue involves the budgets. The EPCs perceive that they are not receiving the funding they need to conduct their work. "This work is more than pulling together a few RCTs (randomized controlled trials)." Limited resources place a significant constraint on doing a quality job. "We need more money, more time." This is still a largely boutique industry model and it is, consequently, quite expensive. Each product has to be developed largely from scratch, by hand. Although some standardization can help, tailoring is one of the most attractive and useful features of the EPC reports. While academic institutions seem to be better suited to find solutions (junior faculty can sometimes augment the contributions of assigned staff); for other institutions this is not always possible.

Summary of Step 1: Informant Interviews

Three salient themes emerge from the Step 1 interviews relating to the definition of a successful report, the determinants of a successful report, and the role of AHRQ in the EPC process. These themes relate to: (1) culture/education factors; (2) strategic factors; and (3) resource factors.

Cultural factors influence the definition of a successful report as one that is used productively. Researchers and users of evidence reports often have different values, goals, and perspectives about what constitutes productive use; these are shaped by their professional

cultures. The process of linking the work of researchers and users is especially challenging because it requires the meshing of two worlds. The differences relate to familiarity with the principles of evidence-based medicine on the one hand and the practical realities of clinical medicine or the exigencies of policymaking on the other. The process of identifying and synthesizing best medical evidence into policy is subject to the risk that participants do not share the same cultural foundation, experiences, and expectations. Cultural understanding must occur at an early point in the development of evidence reports—policymakers and researchers clinicians need to teach each other. Ideally, the process of mutual education should begin with a face-to-face meeting immediately after the evidence report is commissioned. Establishing trust and expectations early is essential to the success of an evidence report.

Regarding strategic issues, early development of a conceptual framework appears key to the development of a successful EPC report. A conceptual framework takes into account not only scientific evidence, but clinically relevant factors and stakeholder interests and serves as a vehicle for communication.

Finally, resource factors can strongly influence the success of any implementation effort. It has been a traditional practice for organizations seeking to develop various products (such as clinical guidelines) to rely on the goodwill of their academic grantees to provide expert input for dissemination and implementation efforts. Several EPC participants suggested that this unfortunate historical precedent caused partners to underestimate the true economic cost of an EPC evidence report. A more troubling concern raised by EPCs was scope creep—the tendency to expand the work required by the EPC—without due consideration of the costs and the implications for timely production.

Notably, the formulation or nature of the SOW was not perceived by EPC participants as an especially important aspect of a successful report, but rather seemed to be a necessary component of the EPC activity. The management expert was the only interviewee who independently noted the potentially vital importance of a well-crafted SOW in assuring a successful technical report.

Step 2: Literature Review

Literature Review Methods

MEDLINE® database searches were conducted in an iterative manner during April-July 2004 to retrieve articles related to technical contracting literature relating to formulating SOWs for the production of policy reports and similar intellectual products, as well as the policy literature related to the determinants of a successful policy analysis. Search terms included "statement of work," "policy and research," "translational research," "research transfer," and "dissemination and implementation." No specific key words were required as inclusion criteria; a relatively small number of studies exist on the topic, so a "bottom-up" search strategy was required. Journal articles were retrieved from diverse fields of study: policy analysis, organizational behavior, project management, health services research, environmental research, and Federal documents. The reference lists of each article were reviewed in detail to find additional articles.

Two reviewers independently read each article in full text (n = 51 articles, including 4 Federal documents), evaluated the relevance of retrieved articles, and recorded the main findings of each study in a table. Reviewers slated each article in the table for "inclusion" or "exclusion" based on the article's relevance to the topic. Included articles described problems and solutions associated with interactions between researchers and decisionmakers (38/51 articles were included). The main problems identified in each article and their proposed solutions were recorded. A set of 11 key themes emerged early, and key themes were recorded.

Key themes were:

1. Timing of the technical report

2. Communication between researchers and decisionmakers

3. Aligning goals

4. Managing expectations

5. Defining role/responsibility

6. Understanding cultural differences between researchers and decisionmakers

7. Using a knowledge transfer expert

8. Defining key questions

9. Ensuring non-normativity

10. Creating a useful product

11. Addressing ethical, legal, or social implications (ELSI) of a research report

The few initial articles that had been reviewed before the key themes emerged were re-reviewed to specifically identify key themes. A third reviewer read all of the articles deemed relevant by the two primary reviewers and resolved any disagreements about the relevance of a given article.

In addition, to address the goal of understanding the technical aspects of developing an SOW, a standard text entitled *Delivering Project Excellence with the Statement of Work* by Michael G. Martin[2] was read by one reviewer, who provided the other two reviewers with a written summary. This book describes the development of a successful statement of work from a management perspective. Information gathered from this text provided a foundation for thinking about statements of work. Other books from project management,[3-7] risk analysis,[8] business,[9] government contracting,[10-13] and qualitative analysis,[14-16] were used for background information, and written summaries of the relevant information were shared with all reviewers.

In reviewing the literature, we concluded that the major themes were conceptually similar to those uncovered in the informant interview, although they were perhaps articulated a bit differently. Indeed, we were able to regroup the 11 themes above into the three areas covered by the informant interview: cultural/educational factors (the problem of two cultures—analysts and decisionmakers), strategic factors (establishing mechanisms for facilitating a seamless link between the analysis and the ultimate application), and resource factors (effectively addressing resource issues initially and over time). Thus, for simplicity of exposition, we focus here on specific insights proposed in the literature linked to each of the three themes.

Literature Review Results

Culture/Education Factors

The differences between researchers and decisionmakers are manifest in multiple fundamental ways, ranging from the way they choose to craft questions (as researchable bites vs. broader policy questions),[17-19] to their attitudes towards time,[20] to their perceptions of success.[21] The literature suggests that these differences are firmly rooted in professional culture. This polarization is described frequently in the literature in terms of researchers valuing "excellence," while decisionmakers prize "relevance" most highly.[20,22] On the issue of attitudes towards time, researchers have been dubbed "chronophilic," while decisionmakers are "chronophobic."[20] Researchers are stimulated by key questions that may take years to answer, because answering compelling scientific questions is their life's work. Researchers are thus "chronophilic," always seeking more time to answer questions in greater depth. Decisionmakers, in contrast, are "chronophobic," chasing time against the next deadline. Decisionmakers have frequent, absolute deadlines; if a report is not available for a meeting at which a decision is made, it is useless.

Assuming that researchers and policymakers articulate key questions in researchable form, and bridge misunderstandings during project development, cultural differences may still sabotage the final product. Lomas points out that researchers and decisionmakers tend to connect more frequently at the end of a research project, when trying to generate a final product.[23]

Different professional cultures generate different visions of the end product. Sorian and Baugh's survey of 292 State government decisionmakers revealed that aides to decisionmakers may read longer evidence reports, but decisionmakers often need shorter, simpler end products than researchers envision.[24] It has been suggested in that researchers should be prepared to do simple, quick evidence syntheses as well as detailed ones if that is what the partner truly needs.[25]

The literature supports the notion of approaching cultural differences through active education and integration. Many studies advocated communication between researchers and decisionmakers as early as possible, even during the proposal stage.[26] In addition to formal efforts at educating each other in their languages, tools and values, one recommendation in the

Canadian Health Services Research Foundation (CHSRF) conference report entitled *Knowledge Transfer: Looking Beyond Health* is that researchers should ask about the policy implications of the questions they are considering, if they are not explicitly told.[27,28] Many forms of interactive communication have been suggested to help break down cultural barriers: posting draft guidelines on a Web site for public comment, Internet discussion boards, and even "exchanges," in which researchers and policymakers actually trade jobs for a period of time.[29]

Strategic Factors

In addition to concerns raised in the Step 1 interviews, the literature provided additional insight into strategic concerns. Eight of the 38 articles we reviewed stressed the importance of a "knowledge transfer expert." Knowledge transfer experts are individuals who are trained to promote communication, reduce cultural tensions, guide the development of a conceptual framework, manage expectations, and otherwise bridge the gap that researchers and decisionmakers have neither time nor incentive to bridge. As a measure of what resources such work might require, a study of 265 applied research organizations in Canada revealed that on average, 14 percent of organizational budget went to knowledge transfer.[30]

One strategic determinant of a successful technical report is clear definition of roles and responsibilities. As described by Ross et al., there are several roles that partners can play in the research process.[31] First, a partner can be a "formal supporter" (financial support only); second, a partner can be a "responsive audience;" third, a partner can be an "integral partner."[31] Some studies suggest that role and responsibility definition is important because it encourages all parties to treat each other as equals.[21]

A related issue is the importance of establishing the operational definition of non-normativity. Typically, EPC reports are intended to inform, not direct, policy. Sorian and Baugh's survey of 292 State government decisionmakers revealed that decisionmakers want to see potential implications of various decisions within evidence reports, but not researcher opinion.[24] The importance of the researcher avoiding the role of policymaker is further reinforced by a review of the topic of technical policy analysis by Asher.[32]

Resource Factors

The general management/contracting literature is largely focused on balancing work and costs, and is an area in which the SOW is noted to be of particular relevance. Two crucial resource issues are accounting for project costs when the true costs are not known until work begins, and adjusting funding to account for changes in project scope, as when new issues become apparent.

One issue raised in the literature is the critical importance of the *due diligence phase*.[33,34] The due diligence phase allows the contractor to understand the objectives, problems, and constraints of the requesting organization. It is customary to pay contractors during the *due diligence phase*.

A contracting concept relevant to the production of policy reports is that of the *relational contract*. Relational contracts are "service contracts in which the contract performance requirements are continually evolving and accurately specifying the requirements in advance will be difficult, if not impossible; the relationship if the government and contractor…will evolve cooperatively."[33] Recent trends in Federal government contracting have moved away from a strict SOW process that must be followed at all costs. Relational contract theory suggests that current Federal contracting practices overemphasize fixed-pricing and bottom line price

competition.[33] Relational contracts are well suited to the concept of the Statement of Objectives (SOO), a variation of the SOW. The SOO formally *requires* parties to work together to define the contractual requirements. The five-step approach to using an SOO as described by Mather and Costello requires the requesting organization (in this case, the partners) to first "conduct market research," which would imply gathering information from all stakeholders who matter to the partner, including policymakers and patient groups, if relevant.[34] Second, the partner would develop an initial SOO and identify constraints that might affect the ultimate deliverable. Third, the partner (or knowledge broker) would conduct an initial competition. Fourth, the partner (or knowledge broker) would support contractors during the due diligence phase, which should take 6 weeks or more according to Mather and Costello.[34] Finally, a contract award would be made.

A major cause of resource problems is s*cope creep,* which occurs when the objectives of the partner organization change midway through the project. The literature supports the importance of controlling scope creep. The Federal government contracting literature addresses the issue of scope creep through the mechanism of *changes clause*.

Changes clauses constitute a formal process by which scope creep can be managed. As a reflection of their importance, the changes clause is one of the most litigated clauses in government contracts.[13] In fixed-price supply contracts, the changes clause provides that the contracting officer may at any time, by written order, "make changes, within the general scope" of the contract.[13] When a contractor receives a change order, he has 30 days to submit a "proposal for adjustment;" the term "equitable adjustment" is the process by which contractors recover "the reasonable value for the work under which no agreement was reached on price [in the fixed-price contract]."[13]

A *cardinal* change is a unique subset of changes to the initial contract, a modification "beyond the original scope" of the contract, which requires the contractor to perform "duties materially different from those originally bargained for." [13] The Court of Claims has ruled that a cardinal change is a breach of contract, entitling the contractor to damages. Cardinal changes are considered potential attempts at "unauthorized procurement," according to the theory of unjust enrichment,[13] meaning that the government (or requesting organization) is overstepping its legal bounds by attempting to derive extra benefits from the contractor.

Finally, a *constructive* change is a change that the contractor argues he has to make in order to meet project objectives, even though he has not received an official written change order. In other words, a constructive change is the formal process by which the contractor can change scope. It is important that a formal process for change orders be followed, because courts have not upheld oral change orders in recent years. If a contractor performs extra work without a written change order, he is considered a "volunteer."[13]

Research and development (R&D) contracting within the Federal government is not usually done according to fixed-price contracts. According to the Federal Acquisition Requisition (FAR) 35.005, the R&D SOW should allow contractors "freedom to exercise innovation and creativity," and be "individually tailored."[35] In R&D contracts, "the difficulties in estimating costs… normally precludes fixed-price contracting."[13]

A pragmatic approach for particularly complex projects, termed scope planning, is advocated in the PMBOK (*Project Management Body of Knowledge*).[3] Scope planning starts before the project charter is written and includes "the initial definition of constraints and assumptions." A project charter is a "document issued by the project initiator or sponsor that formally authorizes the existence of the project, and provides the project manager with the authority to apply organizational resources to project activities."[3] Scope definition also includes

consideration of constraints and assumptions and the development of a work breakdown structure (WBS). The WBS is defined as "a deliverable-oriented grouping of project elements that organizes and defines the total work scope of the project. Each descending level represents an increasingly detailed definition of the project work." The WBS helps enumerate tasks and sub-tasks needed to complete a project, and assigns responsibility for those tasks. It is then utilized to develop the SOW.[2] *Scope verification* is the process of "obtaining formal acceptance of the project scope by the stakeholders." *Scope change control* is a formalized method of monitoring changes in scope according to pre-defined criteria for documenting the change and ensuring adequate resources to support the change. Partner advantages gleaned from scope change control include performance measurement, which are necessary "to assess the magnitude of any variations [in scope] that do occur."[3]

Summary of Step 2: Literature Review

The literature review regarding the challenges to technical analysis for policymaking reinforced the general themes raised in the interviews in Step 1, and these themes fell into the categories of cultural/educational factors, strategic factors, and resource factors. The literature suggests that cultural differences are deeply rooted, are reflected in the polarizing distinction between "excellence" and "relevance," can persist throughout an entire project if not addressed, and, if allowed to persist, can sabotage the entire effort. Strategic factors highlight the importance of a conceptual framework, and specific, well understood and communicated processes for establishing that framework, as well as roles and responsibilities. Resource factors are noted to be crucial and are more extensively addressed in the management and contracting literature, stemming from the tendency for technical assessment projects to incur "scope creep."

Several potential solutions are offered, related to each category. To address cultural factors, approaches include education and integration, using various informal and formal techniques. To address strategic factors, suggestions include the identification and funding of a trained "knowledge transfer agent," formal assignment of roles and responsibilities, and establishment of the definition of "non-normativity." Problems related to resource factors can be approached with strategies such as institutionalizing a due diligence phase, and use of relational contracts, changes clauses, as well as more involved techniques such as scope planning.

Step 3: Synthesis—Development of the Current Reality Tree Based on the Theory of Constraints

Synthesis Methods

Primed with the insights provided in Step 1 and Step 2, we moved to synthesis—that is, to drawing up a representation of the current process, focusing on factors constraining the success of EPC products. We applied techniques described in the Theory of Constraints (TOC), a well-established, explicit, and reproducible means of identifying and addressing complex problems in a systematic and comprehensive manner.[4]

TOC is similar to traditional process improvement techniques, with the exception that it is designed to accommodate complex processes, such as provision of health services, which, unlike many industrial processes, are non-linear. TOC understands that processes do not function in isolation, but are part of a larger, intertwined system. Therefore addressing root causes at process levels does not result in sustainable solutions. Hence, as an alternative to investigating and addressing problems (or one root cause) at a process level, TOC demands a much more involved investigation into the *relationship* between several root causes of all the failures of processes in the system. It then forces the strategic thinker to explore the one root cause that leads to most undesirable effects (UDEs), and labels it as the core problem. TOC proposes to focus attention on this core problem. The core problem is called the "constraint" in TOC terminology. This constraint prevents an organization (e.g., an EPC) from reaching its goal (namely, developing a "useful" evidence report). Because the TOC thinking strategy has thought through other processes in a system that can affect the root causes of problems, its change strategies produce more sustainable results.

TOC proposes that this detailed investigation can be best performed through five systematic exercises. Each of these exercises requires construction of corresponding logic "trees." Most of these logic trees can be used as stand-alone tools, depending upon the nature of the questions under consideration.

We based our analysis for the current problem on the first of these logic trees, the Current Reality Tree (CRT). The CRT informs about the existing situation (what to change); this is followed by the design of new reality through the construction of a Future Reality Tree (what to change to). This involves introducing new ideas—strategies for change. These change strategies are called "injections" in TOC terminology. Identification of these injections and creating the Future Reality Tree were the objectives of Step 4.

Figure 1 illustrates a template of the CRT. It represents the various undesirable effects (UDEs) associated with the production and use of evidence reports, as well as a series of hypothesized causal relationships. At the top of the tree is the most important UDE, the UDE that is fundamental to the entire process. TOC proposes that strategic thinkers then explore other UDEs and their root causes, the relationship between them, and the core constraint (one root cause) that leads to the fundamental UDE.

We utilized the interview results, and the literature search to organize our thoughts to develop the CRT for the SOW process. For this purpose, we did the following:

- Identified the most relevant UDE.

- Explored other UDEs.

- Listed a set of root causes that led to the UDEs.

- Explored the relationship between the UDEs and the root causes, so that one (or two) core constraint (s) could be identified.

Figure 1. Template of a Current Reality Tree

Synthesis Results

Our interviews with EPC researchers, partners, and AHRQ allowed us to identify a common UDE, described from their perspectives:

- For researchers a report was considered "unsuccessful" when the partners failed to use the report and complained that the report did not meet their requirements.

- Partners considered a report successful if it met their needs.

- AHRQ staff believed that even a technically excellent EPC report was unsuccessful if it was not useful.

Therefore we concluded that that a *report that does not get used* is unsuccessful and among all UDEs, this effect is deemed fundamentally undesirable.

We formulated the CRT (Figure 2) working from this fundamental UDE at the top through proximate causes, and finally root causes. For this purpose we made several assumptions:

- The partner had some potential use for a report for which they could articulate needs. This precludes the possibility that a report is requested for no reason at all. This led to the principal reason a report would not get used—that the report does not meet those needs. We distinguish here between:

  o *Needs*—the ultimate goal of the information seeking activity

  o *Objectives*—how the partner articulates their understanding of their needs, e.g., in the form of key questions

  o *Specifications*—how the work is described for purposes of communicating with the contractor in the form of a Task Order or Statement of Work

- EPCs have expertise sufficient to produce a technically perfect report given adequate resources and specifications. This assumption derives from the vetting process used by the AHRQ in selecting EPCs for the program.

In the next stage we extracted a list of root causes from our interviews:

- Partner does not know how to conceptualize and articulate needs, objectives, and specifications required for the desired report.

- Specifications for a report are not initially sufficient.

- Specifications for a report change "mid-stream."

- Partner's initial objectives regarding the final report are clarified late in the process.

- Partner's *needs* change late in the process.

- Volume of anticipated work required for the completion of the report is initially underestimated by the EPCs.

- True cost and time requirement of the project are underestimated.

- Project cannot be accomplished within the timeframe allotted because new costs emerge later during the course of the project.

- Budget and timelines cannot be revised.

Following TOC methods, we explored the relationship between these root causes in order to identify one (or two) major problems that lead to the rest, and ultimately result in a report not meeting the partner's needs, and therefore not being used (Figure 1). This could be the result of causes in one of two categories: (1) resources (budget or time), and (2) specifications (stipulations of content or process for development of content).

Whether a resource issue relates to budget or to time schedule, process failure can result from underestimation of resource requirements at the outset of the project, or because unanticipated requirements emerge later. Given the assumption about the capabilities of the EPCs, the proximate cause is insufficiency of the initial specifications.

The specifications can be insufficient because they do not provide an accurate guide to the ultimate volume or nature of work (e.g., number of studies to evaluate or specific techniques of synthesis to use) at the outset, or because the specifications change after the project is well underway. The latter problem (referred to in the interviews and literature as "scope creep") is the result of partners stating objectives at the outset that do not actually reflect their needs, or the partner's needs change due to external forces (e.g., new science, new political or other practical considerations). Insufficiency of initial specifications and scope creep are linked to the inability of the partners to conceptualize and articulate their needs, objectives and specifications (referred to as the "conceptual framework").
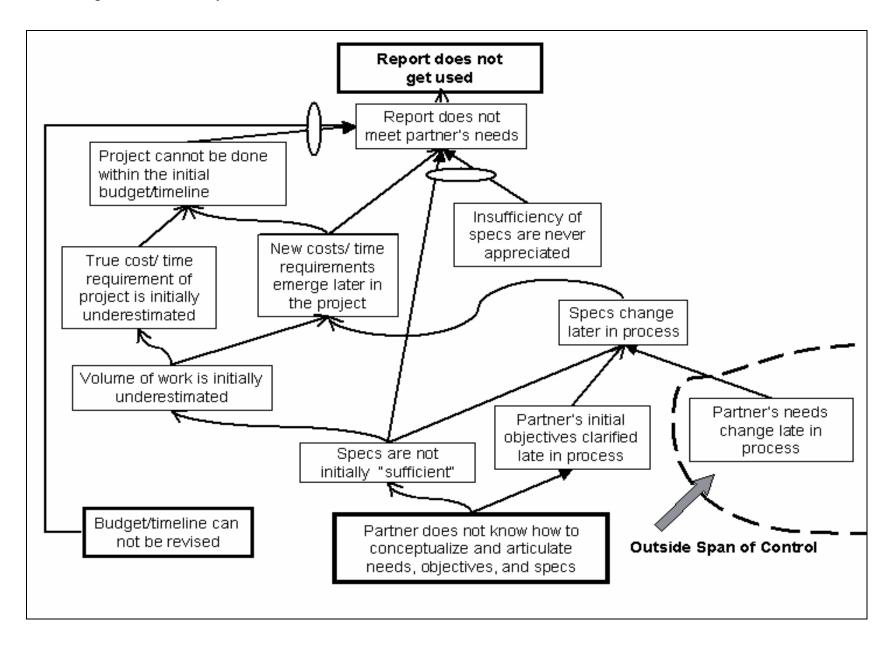
From this list and from Figure 2 we identified four basic "root causes":

1. Partner does not know how to conceptualize and articulate needs, objectives, and specifications (the SOW).

2. Partner's needs change late in the process.

3. Insufficiency of specifications is never appreciated.

4. Budget and timeline cannot be changed in response to down-line changes in project specifications.

Of these, the first (p*artner does not know how to conceptualize and articulate needs, objectives, and specifications*) rates as a core problem or the constraint that prevents an EPC from achieving its goal because it affects most other problems. This is the reason why specifications are insufficient in the first place, which leads to an underestimation of the volume of work, results in new cost and time requirements that lead to delays in the report, and finally results in the report not being used. If this one problem is solved, it is expected that most other issues can be resolved. Note that two other root causes that are not technically core constraints could also independently impact the success of the SOW. These causes are: 3. *insufficiency of specifications is never appreciated* and 4. *budget/timeline cannot be revised.*

The second root cause, *partner's needs change late in the process,* is isolated from the rest of the CRT because resolving this root cause is beyond the span of control of the EPC. TOC suggests that we eliminate it from our logical thinking process.

Figure 2. Current Reality Tree for the EPCs

Step 4: Identify Promising Solutions for the Core Constraints to Develop the Future Reality Tree Based on the Theory of Constraints

Solutions Methods

The objective here is to identify promising solutions/change strategies to address the root causes that lead to a report that is not used, and to depict a desired future through a Future Reality Tree. The Future Reality Tree is one of the five logic trees that TOC proposes. The UDE from the CRT (e.g. "Report is not used) is the desired effect (DE) of the Future Reality Tree ("Report *is* used"), and it results from one or more proposed injections (e.g. "establish on ongoing relationship between partner, EPC, and AHRQ starting early on").

Note that, as described in the Introduction, we are particularly interested in strategies that can be articulated in the SOW while including approaches that need not be incorporated into a SOW document. These approaches however must be consistent with the concept of SOW and can function as clear principles guiding the EPC process.

The result of the Step 3, the CRT exercise, was the identification of the core constraint (*partner does not know how to conceptualize and articulate needs, objectives, and specifications*). Our interviews and literature search allowed us to explore possible change strategies and promising solutions to address this core constraint. In addition, at the 2004 annual EPC directors meeting we presented the CRT and solicited solutions (injections in TOC terminology). We listed all these solutions, chose the most promising ones from our discussions with the EPC directors (and from Steps 1 and 2), and developed a Future Reality Tree (Figure 3).

Solutions Results

The interviews, literature search, and input from the directors' meeting identified several potential injections/change strategies:

- Establish a formally supported relationship between partners, researchers and the EPC early in the process.

- Involve a knowledge transfer expert. This expert will enable communication, reduce cultural tensions between researchers and partners, manage expectations, and guide the development of the SOW.

- Ensure frequent and ongoing communication, as well as the development of long-term partnerships between researchers and decisionmakers, in order to develop cultural sensitivity.

- Consider the current EPC SOW a "proposal SOW." This rough SOW would be utilized during the competitive bidding situation, while a revised SOW is created with input from the EPC, AHRQ, and partners within the first 30 days after contract award.

- Provide funding specifically for the EPCs to perform preliminary research in order to estimate the time and budgetary resources required for the stated scope of work (e.g. based on volume of literature, nature of expected end product).

- Utilize a changes clause in the SOW; in more complex tasks include formal Scope Change Control.

The relation between the injections, and the root causes they could potentially attack are illustrated in the following table:
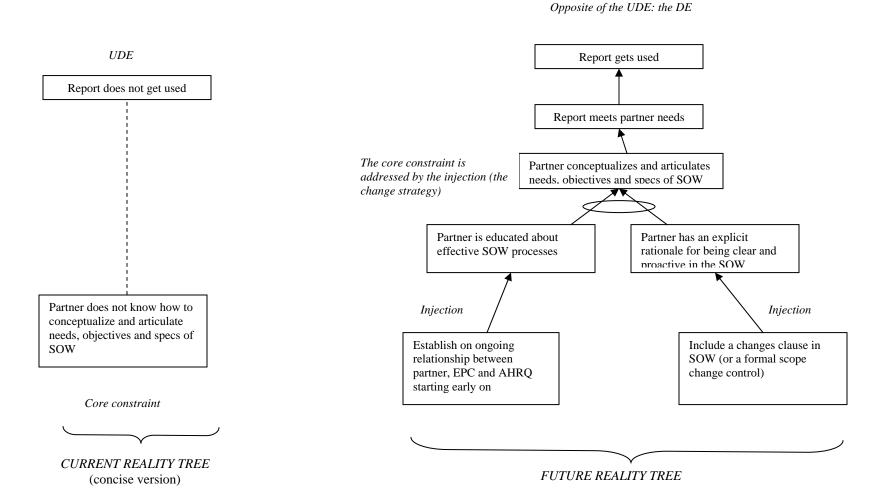
Solutions (injections) that can address root causes of EPC-SOW problems

Injection	Root causes that the injection can address
Establish an ongoing relationship between partners, EPC, and AHRQ early in the process	1. Partner does not know how to conceptualize a SOW 2. Specifications for a report are not initially sufficient
Involve a knowledge transfer expert	1. Partner does not know how to conceptualize a SOW 2. Specifications for a report are not initially sufficient
Concept of "proposal SOW" that is revised with EPC-input	1. Partner does not know how to conceptualize a SOW 2. Specifications for a report are not initially sufficient
Provide funding for EPCs to perform preliminary research	1. Volume of anticipated work is under-estimated by the EPCs 2. True cost and time requirement of the project are underestimated
Utilize a changes clause	1. Specifications for a report change mid-stream 2. Partners needs change late in the process 3. Budget and timeline cannot be changed in response to changes in project specifications

With these concepts of UDEs, root causes, and injections that lead to converting a UDE to a DE, we constructed the Future Reality Tree for the EPC-SOW process (Figure 3).

- The two injections (*establish an ongoing relationship between partners, EPC, and AHRQ early in the process,* and *utilize a changes clause*) were deemed to be the most practical means to exert impact on the SOW process by addressing the core constraint, *partner does not know how to conceptualize and articulate needs, objectives and specifications of the SOW.*

- The injections (change strategies) lead to *the ability of a partner to conceptualize and articulate needs, objectives and specifications of the SOW* (the core constraint is addressed by the injection).

- This ultimately results in the production of a successful EPC report *that meets partner needs* and therefore *will be used* (opposite of the UDE, the DE).

Figure 3. Future Reality Tree of the SOW process for EPCs

Opposite of the UDE: the DE

UDE

Report does not get used

Report gets used

Report meets partner needs

The core constraint is addressed by the injection (the change strategy)

Partner conceptualizes and articulates needs. objectives and specs of SOW

Partner does not know how to conceptualize and articulate needs, objectives and specs of SOW

Partner is educated about effective SOW processes

Partner has an explicit rationale for being clear and proactive in the SOW

Injection

Injection

Establish on ongoing relationship between partner, EPC and AHRQ starting early on

Include a changes clause in SOW (or a formal scope change control)

Core constraint

CURRENT REALITY TREE
(concise version)

FUTURE REALITY TREE

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Appendix

Technical Description of the Statement of Work

The Statement of Work (SOW) is most fundamentally a contractual agreement stipulating how a job, in this case a research study, will be done. The Statement of Work establishes expectations and mediates the relationship between contractor and sponsor (in the case of the EPC program, between research team and AHRQ, which contracts on behalf of a "partner"). According to Michael G. Martin, author of *Delivering Project Excellence with the Statement of Work,*[1] "the single most significant cause of project failure is the lack of a clearly defined and detailed statement of work." Martin identifies the first formal SOW written in modern history as the 1908 Army Signal Corps document entitled "Agreement and Specification for the Wright Brothers' Heavier-than-Air Flying Machine," (though he admits that Noah's biblical instructions for building the ark essentially constituted a Statement of Work). The Department of Defense and the National Aeronautics and Space Administration (NASA) have published handbooks that describe the step-by-step process of writing a Statement of Work.[2-4] NASA[4] defines the SOW as a document that:

> . . . . describes the work to be performed or the services rendered; defines the respective responsibilities of the Government and the contractor; serves as a basis for contractor response, evaluation of proposals and source selection; and ultimately provides an objective measure so that both the Government and the contractor will know when the work is satisfactorily completed and payment is justified.

Definitions from the Department of Defense and the project management literature have much in common with NASA's definition, but NASA's definition was selected for repetition here because NASA specifically addresses the responsibilities of both the contractor and the client (the Government). The SOW is not just a work plan detailing the services that the contractor (or researcher) will offer; rather, it lays the groundwork for a *relationship* between contractor and client.

All Federal agencies use the Federal Acquisition Regulation (FAR) to acquire needed supplies and services, and the FAR defines the SOW. One subsection of the FAR, subsection 37.602-1-Statements of Work, is given below (FAC 24, effective July 19, 2004).

FAR Subsection 37.602-1: Statements of work.[5]

(a) Generally, statements of work shall define requirements in clear, concise language identifying specific work to be accomplished. Statements of work must be individually tailored to consider the period of performance, deliverable items, if any, and the desired degree of performance flexibility (see 11.106). In the case of task order contracts, the statement of work for the basic contract need only define the scope of the overall contract (see 16.504[a][4][iii]). The statement of work for each task issued under a task order contract shall comply with paragraph (b) of this subsection. To achieve

the maximum benefits of performance-based contracting, task order contracts should be awarded on a multiple award basis (see 16.504[c] and 16.505[b]).

(b) When preparing statements of work, agencies shall, to the maximum extent practicable—

    (1) Describe the work in terms of "what" is to be the required output rather than either "how" the work is to be accomplished or the number of hours to be provided (see 11.002[a][2] and 11.101);

    (2) Enable assessment of work performance against measurable performance standards;

    (3) Rely on the use of measurable performance standards and financial incentives in a competitive environment to encourage competitors to develop and institute innovative and cost-effective methods of performing the work; and

    (4) Avoid combining requirements into a single acquisition that is too broad for the agency or a prospective contractor to manage effectively.[5]

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