REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 7-A-10

Subject: Shared Decision-Making

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Referred to: Reference Committee A
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As efforts to promote greater efficiency in the health care system intensify, more attention is being given to the role and responsibility of the patient in determining how health care resources should be used. Policymakers hope that a renewed focus on "patient-centered care" will help increase the value of health care spending in the United States, while also maximizing clinical quality. One concept that is gaining attention is the use of formal shared decision-making tools to help increase patient engagement in medical decisions when there are several clinically-appropriate options from which to choose. The Patient Protection and Affordable Care Act of 2010 (P.L. 111-148) includes provisions to facilitate and encourage the use of the shared decision-making process.

At the 2008 Interim Meeting, the House of Delegates established policy, directing the American Medical Association (AMA) to educate and communicate to physicians about the importance of shared decision-making guidance as a tool to advance patient-centered care (D-373.999, AMA Policy Database). This report was initiated by the Council to describe formal shared decision-making; discuss the design and development of patient decision aids; and summarize quality standards that have been developed to evaluate patient decision aids. The report also addresses potential benefits and limitations associated with the use of formal shared decision-making processes, and makes recommendations regarding future developments in this field.

BACKGROUND

According to the AMA *Code of Medical Ethics*, the principle of informed consent requires that physicians "present medical facts accurately to the patient…and make recommendations for management in accordance with good medical practice" (Opinion E-8.08). The concept of shared decision-making builds on this definition by fostering an environment in which patients have the opportunity to evaluate their medical options in accordance with personal preferences and values. The Foundation for Informed Medical Decision-Making, a non-profit organization based in Boston, Massachusetts, defines shared decision-making as "the process by which a health care provider communicates to the patient personalized information about the options, outcomes, probabilities, and scientific uncertainties of available treatment options and the patient communicates his or her values and the relative importance he or she places on benefits and harms." Although patients always have the right to participate in decisions about their medical treatment, using formal shared decision-making processes can be especially useful in cases where more than one treatment option is available, and no treatment is considered "best" according to clinical evidence.

SHARED DECISION-MAKING AND PATIENT DECISION AIDS

Formal shared decision-making processes are generally facilitated through the use of electronic or paper-based patient decision support aids, which are often developed by third parties and licensed for use by health plans, hospitals or physicians. Through tools such as booklets, videos, interactive computer programs, and structured personal coaching, patients receive evidence-based information about treatment options and outcomes that is specifically designed to help them evaluate tradeoffs in the context of their own feelings and preferences. Decision support aids supplement direct communication between the physician and patient by offering patients an opportunity to process complex – and possibly frightening – information at their own pace, using information that addresses the emotional as well as the clinical aspects of medical care.

Patient decision aids have three core elements: clinical information, "values clarification," and guidance to help patients make and communicate their treatment decisions (O'Connor, 2004). The clinical information component represents a synthesis of relevant evidence-based information about the patient's medical condition, available treatment options, and the potential risks, benefits, and outcomes associated with each option. The clinical information should reinforce what a patient has already learned from his or her physician, and give the patient the opportunity to consider the information in a different way, without being influenced by conscious or unconscious biases on the part of the physician.

The "values clarification" component of patient decision aids helps patients quantify the more subjective elements of addressing their medical condition and pursuing a course of treatment. The decision aids are designed to help patients learn about and identify with the physical, emotional and social aspects of each treatment option, so that they can visualize how their life might be affected by various treatments. Decision aids often use testimonials from actual patients to offer balanced examples of how and why different people made different treatment choices. Another element of values clarification could involve the use of questionnaire-type tools to help patients consider and articulate their priorities in evaluating their choices (e.g., maximize convenience, minimize pain, extend life expectancy).

The guidance and communication element of patient decision aids helps lead patients through the process of synthesizing the clinical and values information that they have obtained and making a decision that they are comfortable with. Entities that develop patient decision aids often market them similarly to disease management programs and may include personalized coaching by a nurse or other professional to help guide patients through the whole process. In some cases, especially in very sensitive areas such as decisions about end-of-life care, decision support aids have been designed to help structure and improve patient-physician conversations *per se*, with the physician taking the explicit role of professional guide.

In clinical practice, physicians determine what conditions and which patients could benefit from engaging in a formal shared decision-making process. In cases where evidence-based, best practice guidelines establish the preferred method of treatment, patients generally benefit from accepting the recommendation of their physician, and a formal shared decision-making process is not necessary. Similarly, some patients may be unwilling or unable to assume increased responsibility for their medical decision-making, and prefer to act on the recommendations of their physician, no matter what the circumstances. For these patients, the formal shared decision-making process could become overwhelming, and actually jeopardize rather than enhance the patient-physician relationship.

For more engaged patients with medical conditions that have more ambiguous treatment protocols, shared decision-making can facilitate and promote the delivery of patient-centered care. Where appropriate, physicians may "prescribe" a decision support aid for a patient diagnosed with a clinical condition that can be treated in multiple ways. For example, if a patient is diagnosed with prostate cancer the doctor might recommend that the patient use a decision support aid to help clarify the patient's understanding of the condition and possible treatment options. Because there is no clinical consensus on the preferred treatment (or non-treatment) of prostate cancer, the shared decision-making process can be a valuable tool in helping patients understand and accept the course of treatment that is most appropriate for them. Ideally patients will use the decision support tool before their next medical visit, so that they are in a better position to discuss and choose treatment options with their doctors.

QUALITY STANDARDS FOR PATIENT DECISION AIDS

Patient decision aids or decision support tools are intended to be much more comprehensive than standard patient information materials that are widely available in health care settings or online. Typical patient flyers generally provide brief, easily understood, factual information about a medical condition or procedure. In contrast, patient decision aids are designed to engage patients in a process of learning about their health and treatment options. Assuring the clinical quality and ethical design of patient decision aids will become increasingly important as the concept of shared decision-making gains popularity.

The International Patient Decision Aids Standards (IPDAS) Collaboration is a multi-disciplinary effort to establish an internationally approved set of criteria for evaluating the quality of patient decision aids. Led by researchers from Canada and the United Kingdom, researchers, practitioners, patients and policymakers from 14 countries used online tools to establish a consensus on criteria that could be used to measure the reliability of a decision aid. The researchers identified evaluation criteria in three broad areas: content, development process, and effectiveness. Within each of those areas, the IPDAS instrument (IPDASi) identifies specific elements that should be evaluated to determine the comprehensiveness and integrity of the tool. Among these evaluation elements are whether the tool adequately describes the health condition and all treatment options (including no treatment); what methods are used to help patients clarify values; whether a systematic development process followed; how developer credentials are documented and scientific evidence verified; and how conflicts of interest are identified and handled.

The IPDAS Collaboration is currently piloting a service through which developers of patient decision aids can have their product evaluated using the IPDASi. The National Committee for Quality Assurance (NCQA) has communicated with the IPDAS Collaboration steering committee about the possibility of developing accreditation standards for decision aids or the process of using them. In 2009, the IPDAS Collaboration received funding from the Foundation for Informed Medical Decision Making to conduct research correlating the results of randomized trials against the IPDASi ratings, and to establish a "must have" set of quality criteria for patient decision aids.

The Ottawa Health Research Institute (OHRI) also has a research group dedicated to patient decision aids, led by Annette O'Connor, a leading IPDAS Collaboration researcher. The group designs and tests patient decision aids, and conducts research on the decision support needs of patients and physicians, tools that measure the quality of decision support services, and the cost-effectiveness of decision support-service models. OHRI's Web site is an excellent resource for information about the development and implementation of patient decision aids. The site includes detailed "toolkits" and tutorials to help integrate the use of decision aids into clinical practice. The

Web site also includes an "A – Z" listing of available decision aids by topic, along with results from IPDASi evaluations, if applicable.

The Council believes it is important to emphasize that shared decision-making protocols and patient decision support aids are to be used in conjunction with, not as a replacement for, physician consultation. Physician guidance regarding the appropriate use of decision support aids, and communication between patient and physician about the patient's values (as clarified through decision aids), are critical components of a comprehensive and effective shared decision-making process.

OPPORTUNITIES AND RISKS ASSOCIATED WITH FORMAL SHARED DECISION-MAKING

Formal shared decision-making processes and patient decision aids are potentially useful tools to help the US move toward more patient-centered care, which has the potential to improve the overall quality and efficiency of the health care system. Patients using formal decision support tools often report more comfort and satisfaction with their treatment decisions (O'Connor, 2004). Greater patient responsibility and engagement in developing their treatment plans might also lead to improved adherence and long term health outcomes, reducing wasteful spending associated with patient non-adherence.

Research also shows that patients using decision support tools tend to have more realistic expectations of the outcomes or results of their treatment choice. Formal shared decision-making programs might reduce tension between patients and physicians and limit a patient's feeling that his or her doctor may have made the wrong treatment choice, especially if the outcome is unexpected or disappointing. Accordingly, well designed and documented shared decision-making processes could help improve the medical liability climate for physicians and reduce the amount of waste associated with spending on defensive medicine.

Although there is some evidence to suggest that patients sometimes choose less invasive treatments when they evaluate their options using formal decision support tools, it is premature – and potentially dangerous – to suggest that the use of patient decision aids will reduce demand for medical services. The "efficiency" of the health care system can be improved through the use of shared decision-making processes to the extent that patients are better able to make decisions based on a full understanding of evidence and their individual preferences. The Council has previously emphasized the importance of pursuing policy initiatives that encourage better value for health care spending, rather than those with the primary goal of reducing costs. Effectively designed and implemented formal shared decision-making initiatives have the potential to yield better value for health care spending by creating a mechanism that incorporates patient preferences in health care resource use determinations.

A potential risk associated with the promotion of formal shared decision-making processes is that they could be used by insurers and others as a tool to reduce costs. Decision support tools could be created that are misleading or biased toward or against certain treatment choices, in an effort to encourage patients to choose less expensive options. Even in choosing what questions to ask, and how to ask them, it might be possible to subtly influence patient choices in an inappropriate manner. This risk makes the independence of groups creating these tools and the use of quality control measures especially important. In addition, implementation of mandatory or rigid decision-making protocols could create another administrative burden for physicians and another barrier to patient-centered care. Tools should be designed and implemented to aid physicians and patients,

rather than as a requirement for approval for insurance coverage, or as a means to steer patients toward a particular treatment option.

Successful use of patient decision aids and implementation of shared decision-making processes depends on the ability of physicians to effectively integrate the tools into their practices. Even if the decision aids are provided through a patient's health insurance, in many cases physicians will need to spend more time communicating with their patients and leading them through the decision processes. For some physicians, communicating with patients about values and preferences will involve new skills. Many practices may find it challenging to adopt shared decision-making protocols without additional funding and resources to support their use.

As noted, shared decision-making might not be an appropriate process for all patients. Some patients might not want to use decision aids and may feel overwhelmed by the extent of the information provided or confused by the process of clarifying their values. Physicians play a critical role in evaluating the appropriateness of offering or initiating a formal shared decision-making process based on the patient's clinical as well as personal needs.

DISCUSSION

The idea of incorporating formal shared decision-making processes into medical practice is attracting increasing attention from the health policy and medical communities. Efforts are being made to promote shared decision-making, while simultaneously enhancing the depth and breadth of research into the value of implementing shared decision-making processes on a larger scale. The Foundation for Medical Decision Making sponsors demonstration projects at 11 primary care and four specialty care sites to learn how decision support tools can be effectively integrated into medical practice, and how their use affects the decision-making process. In addition, hospitals and clinics in nine states are participating with the Foundation and HealthDialog (a non-profit organization that provides decision support tools) in a breast cancer initiative to support shared decision making at all major points in breast cancer treatment.

The 2010 Patient Protection and Affordable Care Act included provisions to support the use of shared decision-making specifically in the context of "preference sensitive care" (i.e., medical care for which the clinical evidence does not clearly support one treatment option). The Act gives the Secretary of Health and Human Services the authority to contract with an independent entity to endorse patient decision aids and establish standards for them. It also directs the Secretary to develop a program to award grants or contracts to entities to develop, test and educate providers on the use of patient decision aids. Additional grants will be available to establish Shared Decision-Making Resource Centers "to provide technical assistance to providers and to develop and disseminate best practices and other information to support and accelerate adoption, implementation and effective use of patient decision aids and shared decision-making by providers." Grants will also be available for health care providers to develop, implement and assess shared decision-making techniques.

In addition to federal support for the concept of shared decision-making, individual states have also been exploring its use. Washington state recently passed legislation authorizing the creation of a shared decision-making demonstration project, to be conducted at group practice sites providing health care through state-based contracts. The demonstration projects will include an evaluation of various aspects of the shared decision-making process and use of patient decision aids. These projects will assess patient understanding of treatment options, alignment between patient values and the care they receive, and the cost-effectiveness of shared decision-making in clinical practice. At the time this report was developed, other states were considering similar legislation.

The Council is encouraged by the potential of shared decision-making processes to further enhance the patient-physician relationship and to help improve the quality and overall value of health care in the United States. Data and information from demonstration projects and other targeted research will provide important guidance for physicians and the medical profession regarding the appropriate use of these tools and the most effective and efficient ways of integrating them into medical practice. The Council will continue to monitor developments in this field to ensure that implementation and application of shared decision-making processes remain voluntary for patients and physicians, and that effective and reliable evaluation processes are in place to ensure the integrity and utility of the information provided to patients.

RECOMMENDATIONS

The Council on Medical Service recommends that the following be adopted and that the remainder of the report be filed.

1. That our American Medical Association recognize the formal shared decision-making process as having three core elements to help patients become active partners in their health care:

    a. clinical information about health conditions, treatment options, and potential outcomes;

    b. tools to help patients identify and articulate their values and priorities when choosing medical treatment options; and

    c. structured guidance to help patients integrate clinical and values information to make an informed treatment choice. (New HOD Policy)

2. That our AMA support the concept of voluntary use of shared decision-making processes and patient decision aids as a way to strengthen the patient-physician relationship and facilitate informed patient engagement in health care decisions. (New HOD Policy)

3. That our AMA oppose any efforts to require the use of patient decision aids or shared decision-making processes as a condition of health insurance coverage or provider participation. (New HOD Policy)

4. That our AMA support the development of demonstration and pilot projects to help increase knowledge about integrating shared decision-making tools and processes into clinical practice. (New HOD Policy)

5. That our AMA support efforts to establish and promote quality standards for the development and use of patient decision aids, including standards for physician involvement in development and evaluation processes, clinical accuracy, and conflict of interest disclosures. (New HOD Policy)

6. That our AMA continue to study the concept of shared decision-making and report back to the House of Delegates regarding developments in this area. (Directive to Take Action)

Fiscal Note: Staff cost estimated to be less than $500 to implement.

References are available from the AMA Division of Socioeconomic Policy Development.