

## **Risk Evaluation and Mitigation Strategies (REMS): Building a Framework for Effective Patient Counseling on Medication Risks and Benefits**

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### **Introduction**

The Food and Drug Administration Amendments Act (FDAAA) of 2007 expanded the ability of the U.S. Food and Drug Administration (FDA) to ensure the safety of drugs and biologics on the market. Among the new authorities granted to the agency was the power to require sponsors to develop Risk Evaluation and Mitigation Strategies (REMS) for drugs or biologics that carry serious potential or known risks. The REMS program has since become an important tool in ensuring that the benefits of a given medical product outweigh the associated risks, and has enabled the Agency to approve a number of products that otherwise might not have been made available for patient use. Since the implementation of the REMS program, however, concerns have been raised regarding the effectiveness of the program, its potential to unnecessarily limit patient access to products, and the burden associated with its implementation.<sup>1</sup> In response to these concerns—and as part of FDA’s commitments under the Prescription Drug User Fee Act of 2012 (PDUFA V)—FDA has undertaken efforts to standardize and reform the way REMS are designed, implemented, and evaluated, and to better integrate REMS programs into existing health care systems.

Following extensive consultation with a range of stakeholders, in September 2014 the agency outlined four priority projects that it will pursue, one of which focuses on improving provider-patient benefit-risk counseling for drugs that have a REMS attached. Through this project, FDA aims to support the standardization of effective benefit-risk counseling between providers and patients, encourage providers to systemically educate patients about the benefits and risks of drugs with an attached REMS, and improve patient involvement in decisions regarding the initiation, management, and termination of the use of such drugs. To this end, and under a cooperative agreement with FDA, Brookings is working with the agency to develop an evidence-based framework of best practices and principles that can be used to inform the development and use of REMS tools.

### **Risk Evaluation and Mitigation Strategies**

Beyond the standard labeling and safety surveillance requirements that apply to all medical products on the market, FDA has a number of additional tools at its disposal to mitigate safety risks. Risk Minimization Action Plans (RiskMAPs) were designed for drugs that required safety measures above and beyond the approved labeling and routine reporting requirements, and included several tools designed to meet specific objectives in minimizing drug risks.<sup>2,3</sup> When FDAAA authorized FDA to require REMS for prescription drug and biological products in 2007, many of the principles used to develop RiskMAPs informed the development and implementation of REMS.

FDA can require a REMS for a particular drug prior to its initial approval or following approval if new information comes to light regarding the risk of serious adverse events associated with that drug. The drug's sponsor (i.e., its manufacturer) is responsible for designing, implementing, and evaluating the REMS. Sponsors develop and submit a REMS plan for their product, which is then reviewed and adapted in consultation with FDA. A given REMS program can include one or more elements as well as a diverse set of materials and processes (collectively referred to as 'tools') to help mitigate the risks of a particular drug:

- 1) Medication Guide or Patient Package Insert (PPI)
  - FDA-approved patient labeling.
- 2) Communication Plan
  - Risk communications (e.g., Dear Health Care Provider letters) to health care providers, such as physicians, pharmacists, nurses, and physician assistants.
- 3) Elements to Assure Safe Use (ETASU)
  - Prescribers have specific training/experience or special certifications;
  - Pharmacies, practitioners, or health care settings that dispense the drug be specially certified;
  - Drug be dispensed only in certain health care settings (e.g., infusion settings, hospitals);
  - Drug be dispensed with evidence of safe-use conditions such as laboratory test results;
  - Each patient using the drug be subject to monitoring; and
  - Each patient using the drug be enrolled in a registry.
- 4) Implementation system
  - System to monitor and evaluate implementation of ETASU.

Sponsors may be required to provide a range of resources to health care professionals as part of a REMS, including physical materials, online resources, or other support services. Sponsors may also provide information directly to patients through websites or printed handouts.

Sponsors must also designate certain outcomes against which the REMS program can be evaluated, and an assessment must be conducted at a minimum of 18 months, 3 years, and 7 years after the program has been approved. Drug sponsors can submit additional assessments outside of that timeline and may also request a modification or removal of the REMS at any point. If assessments show that the REMS is ineffective, or if new safety information on a drug comes to light that indicates the REMS is no longer necessary, FDA may decide to alter or discontinue the REMS altogether.

### **Patient Counseling as a Part of REMS**

Many REMS programs also include an element of patient counseling, which may take a variety of forms depending on the nature of the drug's risks, the provider in question, the timing, and the tools used to support the counseling. However, the goals are largely the same: to help providers educate the patient about the risk and the REMS program requirements and to help ensure the patient uses the drug safely. A number of types of REMS tools have been used to support provider counseling of patients about the risks of REMS drugs. (See Table 1 below) These have included Medication Guides (MedGuides), a patient counseling [document](#) (developed in particular for the extended-release and long-acting opioid analgesic

REMS), prescriber-directed counseling support tools, patient-prescriber agreements, and patient treatment continuation forms. A REMS may include one or more of these counseling support tools.

**Table 1: Available REMS Tools Counseling of Patients on Risks**

REMS TOOL	REMS TOOL DESCRIPTION
Medication Guide (MedGuide)	<ul style="list-style-type: none"> <li>• Part of a drug’s approved labeling</li> <li>• Describes all of the major risks of that drug, along with information on how to use it safely</li> </ul>
Patient Counseling Document	<ul style="list-style-type: none"> <li>• Single-page document developed for the extended-release/long-acting opioid analgesic REMS</li> <li>• Provides key points of information from the REMS MedGuide in summary form</li> <li>• Includes a blank space for a provider to write in information that is specific to his or her patient</li> </ul>
Prescriber-Directed Counseling Tools	<ul style="list-style-type: none"> <li>• Directed to the prescriber to help them prepare to counsel patients</li> <li>• Most frequently used for drugs that carry teratogenic risk; provides information on pregnancy prevention counseling</li> </ul>
Patient- Prescriber Agreement	<ul style="list-style-type: none"> <li>• Used to verify that counseling has taken place between a provider and patient and that certain required topics were discussed</li> <li>• May include patient-specific health information as part of the screening process to identify whether the treatment would be appropriate for a particular patient</li> <li>• Signed by both the patient and their health care provider before the initiation of treatment</li> </ul>
Patient Treatment Continuation Form	<ul style="list-style-type: none"> <li>• Must be signed by both the patient and provider to verify that the patient has benefited from the treatment and will continue to do so</li> <li>• May or may not require additional benefit-risk counseling to take place before the form is signed</li> </ul>

Though these tools are designed to help patients make better-informed decisions, evidence of their effectiveness is lacking. Concerns have also been raised about the fact that these tools have historically focused solely on the risks of a given treatment, which may hinder a patient’s ability to assess the potential benefits and be able to understand and balance both risks and benefits. Furthermore, most REMS tools focus only on the specific serious risk(s) targeted by the REMS rather than all of the risks associated with the drug. Others have noted that, with the exception of the patient treatment continuation form, these tools are largely designed to be used primarily at the initiation of a treatment, and have less of a role in decisions made after a period of exposure about maintaining or discontinuing a treatment. A REMS requirement that providers need to document and verify that counseling took place may also be overly burdensome and unnecessarily discourage providers from prescribing a drug with a REMS attached.

### The REMS Benefit-Risk Counseling Initiative

In response to these and other concerns related to the REMS program, FDA created the REMS Integration Initiative in 2011. Under this Initiative, FDA intends to standardize and improve the way that REMS are developed, evaluated, and implemented within the health care system. When PDUFA was re-

authorized under the Food and Drug Administration Safety and Innovation Act of 2012, the REMS Integration Initiative was folded into FDA's PDUFA V commitments. As part of this, FDA pledged to continue its work to evaluate and standardize REMS processes and to work with stakeholders to integrate REMS into the current health care system.

In pursuit of this broader goal, the agency also agreed to undertake projects within each of four priority areas, one of which is focused on improving the communication of benefit-risk information to patients. Stakeholder feedback to FDA indicated that patients would value receiving information that would help them to better understand both the benefits and the serious risks involved with using a drug with a REMS. Ideally, this information would be communicated to patients via their health care provider, and it would allow them to better participate in decision making about initiating, maintaining, and/or discontinuing that drug. Enabling patients to participate and make informed decisions about their course of treatment and ensuring their compliance with safe use conditions is particularly important with drugs that have potential or known risks that are serious enough to require a REMS, and both stakeholders and FDA saw opportunities to standardize and improve the procedures and tools providers use to counsel patients about initiating and safely using these products.

Through this project, FDA hopes to achieve four major goals:

- Support the standardization of effective health care provider to patient counseling to help improve informed therapeutic decision-making and risk management.
- Encourage health care providers to systematically discuss and educate patients about risks of medications with a REMS, and how those risks should be weighed against the potential benefits of the drug, using initial and follow-up counseling sessions both before prescribing and during treatment.
- Enhance patient involvement, knowledge, and understanding of the risks of products with REMS and how to manage them.
- Provide a basis for designing and demonstrating the impact of effective counseling instructions, techniques, and tools as part of risk mitigation programs.

In support of these broader goals, and under a cooperative agreement with the agency, Brookings is working with FDA to 1) obtain literature-based evidence as well as practical expert insights into effective processes, techniques, and principles to support effective counseling and informed decision-making between providers and patients; and 2) apply these to developing a framework of principles, best practices, or attributes that could ultimately be used by sponsors to design more effective REMS counseling tools. This framework will apply to the patient-provider counseling that is conducted when initiating, maintaining, and/or discontinuing medications with REMS, and will be developed in the context of FDA's REMS regulatory authority and limits, as well as to address the challenges to implementation posed by the healthcare delivery system.

As an initial step, Brookings partnered with FDA to conduct a scan of the existing literature on benefit-risk counseling to communicate benefits and risks, and to support informed decision-making between, and implementation by, providers and patients. The methodology and initial findings from this review

are described in further detail below. This white paper will serve as the starting point for subsequent work done through a series of stakeholder convening activities that include representatives from academia, industry, health systems, and patient advocacy groups, among others. These convening activities will provide an opportunity for Brookings and FDA to further develop and refine the framework that can be used to inform the improvement or development of REMS tools.

## **Methodology of the Literature Review**

This review of the literature involved a combination of structured searches using key terms identified through reviewing the transcript of a Risk Communication Advisory Committee meeting, as well as additional terms suggested through consultation with individual experts. Hand searches identified several additional pieces of the literature. In total, the team screened 210 publications and extracted findings from 112. However, this is not a systematic review, and relevant key pieces of literature may have been missed. An effort was made to concentrate on findings from systematic reviews and meta-analyses, as well as previous efforts to identify best practices in 1) risk communication in the clinical setting, 2) shared decision-making, and 3) motivational interviewing. This included a 2011 FDA [publication](#), “Communicating Risks and Benefits: An Evidence-Based User's Guide”, which contained several relevant chapters. In addition, the Brookings team received input and feedback on the development of this paper from two expert reviewers, Betsy Sleath and Nananda Col.

The initial set of best practices and principles listed here is not definitive, but is rather a starting point for further discussion, refinement, and improvement through additional consultation with experts and other key stakeholders.

## **Benefit and Risk Communication between Providers and Patients**

Effective risk communication is an essential component of risk management and is central to FDA’s mission to safeguard and promote public health.<sup>4</sup> It is also an integral component of high-quality medical practice. When delivered appropriately, effective benefit-risk communication can facilitate and support informed decision-making by providing individuals with objective facts, including information about the limitations on that knowledge.<sup>5</sup>

However, communicating risk is a complex process, and existing research indicates that there is substantial room for improvement in health professionals’ ability to employ effective risk communication strategies.<sup>5</sup> Studies of actual provider-patient interactions have found that health care professionals rarely provide adequate benefit-risk education or engage their patients in a way that facilitates informed decision-making.<sup>6,7</sup> In one study, for example, physicians provided information on medication-related adverse events to just 10% of patients, while another study found that physicians communicated benefit information to only 38% of patients.<sup>8,9</sup> Another survey found that, depending on the condition under discussion, there was significant variation in the proportion of provider-patient conversations that 1) included reasons not to take action, and 2) included the patient being asked about his or her preferences for the course of action.<sup>10</sup> Studies have shown similarly low levels of risk communication between pharmacists and patients, though pharmacists regularly interact with patients to share information about the medications they dispense.<sup>6,11</sup> Studies have also found that the written consumer medication information provided to patients is often not sufficient to enable patients to

understand their risks and benefits, and that patients do not want written information to replace verbal communication.<sup>12</sup>

Improving providers' skills will likely require specific training, although additional research is required to determine the most effective approaches to both improving skills and implementing those skills in practice.<sup>13</sup> Research also indicates that patients have a generally poor understanding of risks and benefits, both as it relates to their risk of developing a particular disease as well as the benefits and risks related to various treatment options.<sup>14,15</sup> They often lack the health literacy required to understand what their doctor is telling them and may struggle to understand the educational materials they receive, particularly if they are not provided in plain language.<sup>16</sup>

The manner in which benefits and risks are communicated (e.g., the format, language, timing, etc.) is critical in shaping a patient's understanding. Most studies evaluating the strengths and weaknesses of various approaches have focused on a treatment's effect on a single outcome over a single time horizon. However, patients often need to decide on treatments that affect multiple outcomes, both beneficial and harmful, over different time horizons.<sup>17</sup> Little information is available to guide clinicians about how to explain complex risk information to their patients. Though several groups have attempted to review this literature and provide a summary of best practices, it is likely that there is no single 'best' method of communicating probabilities across all contexts, but rather a range of good options that may be more or less suited to certain scenarios.<sup>5,18,19</sup>

### **Communicating Qualitative Risk and Benefit Information**

Qualitative (or semantic) risk information is often a feature of patient-provider communication, and in many cases can help patients contextualize the risks and benefits of a particular intervention. For example, providers may use words or phrases such as 'low risk', 'frequently', or 'strong likelihood' to describe risks associated with a treatment.<sup>20</sup> However, research has shown that both patients and physicians attach wide ranges of numerical estimates to words and phrases that denote frequency or likelihood, which indicates a significant lack of agreement about what various qualitative terms mean to different individuals.<sup>21,22,23</sup>

Studies have also examined the impact of verbal risk descriptors on patient knowledge and decision-making processes, and have generally found that patients exposed solely to qualitative information had a less accurate perception of risk when compared to those who received quantitative risk information.<sup>24,25,26,27</sup> Given the lack of precision in verbal risk descriptors and the probability that they will be interpreted differently by different patients, it is recommended that physicians supplement qualitative information with numerical risk estimates, and use evaluative remarks such as 'low' or 'poor' with caution when communicating with patients about risk.

### **Communicating Quantitative Risk and Benefit Information**

There is substantial evidence to demonstrate that providing patients with quantitative information improves the accuracy of their risk and benefit perceptions, increases their understanding and knowledge of decision options, and promotes informed decision making.<sup>16,18</sup> However, presenting numerical information in an appropriate manner is challenging. Numeracy in the general population is

low, and many patients have difficulty in understanding, using, or attaching meaning to numbers.<sup>14</sup> Physicians may also struggle to understand and communicate statistical information effectively. This has important implications for the design and delivery of risk communication, as the lack of understanding can lead to under- or overestimation of risk, which often results in poor choices. The manner and format in which numerical data is presented can significantly influence patients' understanding of risks, their decision-making process, and the degree of risk they are willing to accept. It is therefore important to present risk data in a way that maximizes understanding and minimizes unintended bias.

### **Visual aids**

Visual aids—such as pictographs (also known as icon arrays), bar charts, Venn diagrams, and pie charts—are strongly recommended for presenting quantitative risk information, as they can increase accuracy of risk perception and improve comprehension.<sup>16,18,19,28</sup> However, patients vary in their ability to interpret visual displays, and the most effective type of visual aid will likely depend on the context.<sup>5,29</sup> Several reviews found pictographs and bar graphs to be accurately perceived and easily understood by patients, particularly those who are less numerate.<sup>30,31</sup> There is evidence to suggest that pictographs lead to better accuracy and are processed more quickly in cases where the numerators are small, while bar graphs lead to better accuracy with medium and large numerators.<sup>32</sup> Findings regarding patient preferences are mixed.<sup>17,33,34</sup>

Graphs can also influence behavior. For example, graphs that display only the number of individuals affected (i.e., the numerator) lead to greater risk aversion, while pictographs, which display both those affected and the entire population, decrease risk avoidance.<sup>20</sup>

There is also evidence that graph type can influence different levels of comprehension. Recent theories of how people make health-related decisions suggest that comprehension can be divided into two broad categories: 'gist' understanding and 'verbatim' understanding. Gist refers to the essential aspect or bottom-line meaning of the communication (e.g., smoking is bad for your health), while verbatim refers to precise and accurate reporting of quantitative information (e.g., smoking increases the lifetime risk of lung cancer by x%). There is some evidence to suggest that patients rely more on gist representations of information in reasoning and decision-making in contrast to representations of verbatim facts.<sup>35</sup> This has implications for the design and use of visual aids, and the selection of the appropriate visual aid will likely depend on the message that the provider wishes to communicate. For example, one study found that pie graphs and pictographs were better able to convey gist information; whereas, bar graphs and pictographs are better at communicating verbatim information.<sup>20</sup> However, the review did not identify any best practices or principles related to the optimal approach to conveying gist versus verbatim information. It is unclear, for example, whether focusing on gist is sufficient to adequately convey risks, nor is it clear how the gist of a message should be determined, or how to ensure that this information is presented accurately and with minimal bias.

### **Relative risk reduction (RRR), absolute risk reduction (ARR), and number needed to treat (NNT)**

RRR, ARR, and NNT are common approaches to describing risks associated with an intervention, particularly when presenting changes in numeric outcomes. For example, physicians could describe the risks and benefits of an intervention in the following ways: 1) the treatment reduces the risk of death by

x% (RRR), 2) the treatment reduces the risk of death from x% to y% (ARR) or, 3) x number of patients would need to be treated to prevent one additional death (NNT).<sup>20,36</sup>

These three methods of displaying numeric outcomes can significantly influence risk perception and comprehension. Of the three, NNT is the most difficult to understand and is not recommended by any of the studies reviewed for this white paper. RRR can be more persuasive than ARR (i.e., is more likely to influence decisions to initiate therapy) but can magnify risk perception and decrease understanding.

<sup>37,38,39</sup> Overall, ARR is considered to be the best method for communicating changes in numeric outcomes.<sup>19</sup> However, unlike the RRR, which is constant across different risk groups, the ARR can vary substantially according to the patient's risk factors. Thus, in order to communicate a patient's ARR, one must estimate their base risk (without the intervention) and then factor in the effect of the intervention.<sup>40</sup> Expressing a population-level ARR to a patient can potentially be misleading to patients whose risk profile differs from the average person, which may be the case for patients contemplating the initiation or discontinuation of a drug with a REMS. This introduces a level of complexity that is often beyond the skill set or available resources of practicing clinicians.

### **Incremental risk**

Incremental risk allows patients to distinguish between the baseline risk of an event (i.e., the risk that is present without intervention) and the risk associated with a treatment.<sup>20</sup> Visual aids can be particularly effective at communicating incremental risk, and there is significant evidence to suggest that incremental risk be included in any presentation of changes in numeric outcomes.<sup>18</sup>

### **Framing and Ordering**

The way that information is framed and the order in which benefits and risks are presented can also impact patient understanding and behavior.<sup>18</sup> Positive framing (e.g., referring to survival rates rather than mortality rates) can reduce perception of harm and increase acceptance of harmful interventions (such as surgery), while loss framing may be more effective in improving comprehension.<sup>41,42</sup> Similarly, when the risks of a treatment are presented after the benefits, those risks may be perceived as being more worrisome and common than if they were presented first. These sources of bias may be offset with the appropriate use of visual aids such as icon arrays or summary tables that list all relevant risks and benefits together.<sup>18</sup> Framing effects appear to be smaller when both the beneficial and harmful effects of a treatment are included.<sup>43</sup>

### **Event Rates vs. Natural Frequencies**

Presenting information as an event rate (x% chance) versus a natural frequency (x out of 100) can also impact how patients perceive risk and benefit, though the evidence is mixed in terms of the degree of impact or which format is preferable for communicating risk. In some studies, frequencies have been shown to improve understanding, but others have found that overall accuracy and comprehension were better for event rates. There is also some evidence to suggest that natural frequencies increase the perception of risk when compared to event rates.

Trevena et al. suggest that event rates may be better in cases where two *independent* events are being compared (e.g., the chance that drug X will reduce risk of stroke when compared to placebo), while frequencies may be better in cases where the provider is presenting changes in numeric outcomes or



the frequency of joint occurrences of *dependent* events (e.g., the probability that someone with a positive test result actually has the disease). Regardless of which approach is taken, it is important to clearly define the denominator and to keep it consistent so that the patient understands the population that the estimate refers to.<sup>18</sup> When relevant, this should include the time frame over which the risk is being measured, as this can itself have significant effects on patient behavior and understanding. Patients often fail to adjust their risk perceptions to account for different time spans, and may misperceive risk that compounds over long periods of time. One suggested approach is for the provider to reinforce the time frame repeatedly to draw the patient's attention to it.<sup>20,44</sup>

### **Comparative risk and benefit information**

Comparative risk information may also be a helpful tool for contextualizing the likelihood of experiencing a particular outcome. This kind of context is particularly important when discussing preventive interventions or screening tests, as the benefit is a reduction in a disease-specific mortality rate. There are four broad approaches to comparative risk information: 1) the patient's personal level of risk is compared to the absolute risk for another population or the 'average' person; 2) the patient's risk of experiencing a particular outcome is compared to their risk of experiencing some other outcome (e.g., the risk of dying from prostate cancer in the next 10 years compared to the risk of dying from other major causes); 3) the risks associated with 'no intervention' are compared to those associated with an intervention or screening test; and 4) both the beneficial and harmful effects of a treatment are included as part of the discussion.

There is evidence to suggest that comparing an individual's risk to the average person's risk can lead to an inflated perception of risk, which has led some to counsel caution in using such data.<sup>44</sup> However, two reviews have suggested that providing information on the risk of conditions or outcomes other than the target condition can be helpful—if such data is available.<sup>16,18</sup>

### **Tailoring Risk Communication**

Tailored health communication refers to providing information to a patient based on characteristics that are unique to that patient.<sup>45</sup> This can include a range of factors, including comorbidities, education levels, health literacy, cultural background, and age. The risks and benefits of treatments are dependent on a patient's risk factors. Thus patients need tailored information on the effects of treatment on their health risks in order to understand the benefits and risks for their clinical circumstances. Given that risks and benefits are highly individualized, tailored messages that use an individual's specific risk factors can be more relevant to the person and thus potentially more effective in driving informed decision making.<sup>46</sup>

Several studies have found tailored risk communication leads to more active, informed decision-making in the uptake of screening tests, and several others have found that tailored risk information led to increased knowledge and more accurate risk perception when this information was included in a screening intervention.<sup>45</sup> Another meta-analytic review showed that tailored print messages about health have been effective in changing behavior related to screening uptake, but the effect size was small and dependent on the variable used for tailoring.<sup>47</sup>

Of the studies included in our review, the findings on the effects of tailored risk estimates appear to be mixed, and heterogeneity in both the interventions and the selected outcome measures makes it difficult to draw strong conclusions about effective strategies. Furthermore, much of the evidence to support tailored risk communication comes from the field of breast and colorectal cancer screening, and it is unclear whether those findings can be generalized to other contexts.<sup>18</sup> More research is required to determine whether and how best to tailor risk information in the context of benefit-risk counseling on medications.

### **The Role of Affect and Emotion**

Another important consideration in benefit-risk communication is the role of affect and emotion, which can significantly influence the way individuals perceive risk and arrive at decisions. Though feelings such as anger, fear, or grief can have a negative impact on the accuracy and efficiency of the decision-making process, some have argued that feelings are generally a helpful, even necessary, component in that process, and can be useful in influencing patient behavior towards a desirable goal. For example, graphic warnings about the health risks associated with smoking can invoke fear and heighten perception of risk, potentially leading more people to quit or avoid smoking in the first place.<sup>48</sup>

However, the appropriateness of altering a patient's affect or emotions towards a particular health decision is often less clear than in the case of smoking. This can make it challenging to develop appropriate communication strategies, and can also pose serious ethical concerns. (Conversely, failing to consider affect and emotion can pose its own set of ethical questions).<sup>48</sup> It is important for providers and communication tool developers to understand the effects of affect and emotion when making choices about the content and manner in which information will be presented.

Because providing risk information can potentially decrease benefit perception, it is generally recommended that patient be provided with information on both the risks and the benefits of a particular intervention, as well as what might happen in the absence of that intervention (i.e., the effects of not taking an action). Furthermore, the use of evaluative labels or symbols (similar to Consumer Reports) can help patients to identify and understand key or 'gist' messages, though as noted previously these should be used with caution. Providers should also include an opportunity for patients to reflect on the information that they have been given and how they may feel about it, particularly in cases where emotions are likely to run high (e.g., high-risk pregnancy screening or cancer treatment decisions). More broadly, it is important to consider the impact of advertising and other promotional efforts on a patient's baseline perception of the risks and benefits associated with a medication.<sup>48</sup>

Though these effects are not always clear or predictable, advertising exists to convey positive messages about a medication and thus may increase perceptions of benefit and decrease perceptions of risk.

### **Implementation Challenges: Making Decisions in Real-World Settings**

Though the recommendations listed here may seem straightforward, it is important to note that implementing best practices can be difficult when dealing with complex decisions in real-world settings. For instance, menopausal hormone therapy (MHT) has been the recommended regimen for over half a century for the prevention and treatment of osteoporosis among menopausal women, and there is strong evidence to support its benefits in preventing fractures.<sup>49</sup> However, findings from large

randomized trials have also found that MHT is associated with a host of potential risks, including an increased risk of breast cancer, venous thrombosis, stroke, and coronary heart disease.<sup>50,51</sup> Providers are thus tasked with determining whether the fracture-prevention benefits of MHT outweigh the risks for an individual patient.

This can be a very challenging proposition. A number of variables affect a patient's benefit-risk profile, including age, years since menopause, and baseline (pretreatment) risks.<sup>52</sup> The decision also requires assessing multiple treatment effects on multiple outcomes, and there is no widely accepted methodology for performing this type of assessment.<sup>53</sup> Informed decision-making requires providers to engage in a personalized discussion regarding the balance of potential risks and benefits as it relates to the patient's health circumstances. However, as noted above, more research is required to determine how to best implement this in practice.

### CURRENTS GAPS IN KNOWLEDGE

There are several gaps in the existing knowledge base on risk communication between providers and patients. These include, but are not limited to:

- The impact of benefit-risk communication approaches delivered by other members of the health care team (e.g., nurses, social workers, pharmacists)
- Evidence to support the design and delivery of tailored risk information
- How best to communicate changes in risk and benefit outcomes over time
- How best to communicate uncertainty about risk estimates at the population and individual level
- Whether and under what circumstances to include comparative risk information
- Developing visual aids that support the presentation of complex multidimensional quantitative data
- How best to communicate the *benefits* related to a medication (as opposed to simply communication about medication risks) in an objective and non-promotional manner
- How to practically provide ARR tailored to the individual's clinical risks
- How to narrow down the number of options/outcomes/risks to discuss (to avoid information overload)
- How best to account for/harness affect and emotion in communicating risks and benefits

## BEST PRACTICES IDENTIFIED IN THE LITERATURE

As noted above, there is likely no single best method for communicating risk. However, our review identified several high-level best practices that have been proposed and which have support in the literature:

- Use plain language, and provide numeric data to support counseling
- Exercise caution in applying evaluative labels such as “low risk” or “high chance”
- Consider placing the targeted risks in context by comparing them to the risk of other outcomes, but exercise caution in comparing an individual patient’s risk to the risk faced by an ‘average’ person
- When communicating changes in numeric outcomes, use absolute risk rather than relative risk, and avoid using number needed to treat
- When using natural frequencies or event rates, clearly define the denominator and keep it constant across different risks
  - Event rates may be preferable when presenting the chance of a single event or the occurrence of two or more *independent* events
  - Natural frequencies may be preferable when comparing the chance of occurrence of two or more *dependent* events
- Keep time frames constant, and reinforce them repeatedly when describing risk over time
- Use visual aids to support the communication of quantitative risk information
  - When feasible, visual aids should depict the baseline risk separately from the treatment risk
  - Bar graphs and pictographs are perceived more accurately and easily and may be preferable
- Provide a summary table that lists benefits and risks of the intervention together so as to offset bias related to framing and ordering
- Consider providing information on the risks and benefits of taking no action
- Focus communication on key messages, and exclude non-critical information

## Shared-Decision Making

In recent years, shared-decision making (SDM) has been promoted as a potential approach to increasing patient engagement, improving communication between providers and patients, reducing inappropriate care, and controlling health care costs.<sup>54</sup> A range of health care stakeholders, including payers, health systems, and public policymakers (such as the Institute of Medicine and the Agency for Healthcare Research and Quality) have taken steps to encourage its practice, and a variety of research groups and companies have begun developing decision aids that can help to support the process.<sup>55,56</sup> The Affordable Care Act also authorized a number of programs that incentivize patient engagement and SDM, which could potentially support the development of decision aids and other decision support tools.<sup>57</sup> The

Center for Medicare and Medicaid Innovation, for example, recently awarded a \$26 million grant to a collaborative of 16 health systems, which will support a program to implement SDM for patients with diabetes or congestive heart failure, as well as patients who are facing hip, knee, or spinal surgery.<sup>58</sup>

There is also substantial evidence that patients are increasingly interested in greater participation in the health care decision-making process, though the degree of participation desired can vary across groups and between individuals within those groups.<sup>57</sup> Evaluations of SDM interventions have also shown that they are strongly linked to greater satisfaction among patients, though there is some evidence that patients and providers may have a different perception of what SDM entails when compared to published definitions.<sup>59,60</sup>

SDM interventions may be particularly relevant in the context of benefit-risk counseling, where there may be uncertainty around a patient's preferences or tolerance for risk, or in situations where there is conflicting or limited evidence of a particular drug's risks and benefits. SDM is broadly defined as a collaborative process by which physicians and patients consider the best scientific evidence available about a medical problem and attempt to reach a mutual decision about the care or treatment that will be pursued.<sup>61</sup> SDM is distinct from informed decision making, in that the latter describes the end goal (i.e. the patient's decision is based on appropriate information), while the former describes a process for reaching that end goal. It requires both physicians and patients to bring preferences, facts, and values into the decisional process and deliberate together in order to reach a decision.

## Overview of the Shared Decision-Making Process

Several different groups have developed models that outline the essential elements of SDM, though commonalities exist across those that were reviewed for this white paper.<sup>55,61,62,63</sup> In general, the process of SDM entails several steps:

- 1. Both parties agree that a decision needs to be made, and the patient agrees to participate in the process.**

SDM may not be appropriate for all clinical decisions, so providers must work with their patients to identify and prioritize decisions requiring a shared decision. Many patients may be unaware that they need to make a decision, may not appreciate how their preferences can factor into a decision (i.e., they may assume that the doctor knows best), or may have different preferences regarding the level of involvement they would like to have.

- 2. The patient is presented with the best available evidence related to the decision in a manner and format that is comprehensible and reflects their level of health literacy.**

Presenting the best available evidence related to a medical decision can be difficult, especially given the varying levels of health literacy among patients. As noted previously, communicating quantitative information can be particularly challenging, as both providers and patients can lack facility and confidence with numbers. It is also important to balance the amount of information presented, as providing information on all possible options and risks can be confusing for the patient.<sup>63</sup> SDM often includes the use of decision aids (DAs)—such as videos, interactive web programs, or printed materials—that are designed to help a person decide among treatment

options. DAs are often used to complement verbal dialogue in order to present the relevant evidence related to a decision.

**3. The patient's values, preferences, and ability to follow through with a treatment plan are elicited and incorporated into the decision-making process.**

Providers and patients can have a very different understanding of what is important, and in the context of preference-sensitive decisions (i.e., treatment decisions that have significant trade-offs in terms of risks and benefits for the patient) clinicians usually do not have all of the information that is necessary to make the 'best' decision without understanding a patient's values and preferences. The process of eliciting and clarifying these values and preferences is challenging, however, as these can change over time and can vary depending on how information is presented.<sup>64</sup>

**4. The provider arranges a follow-up to evaluate the outcome of the decision and make any necessary adjustments to the treatment plan.**

In many cases, particularly for the management of a chronic illness, decisions related to a particular treatment will need to be revisited and evaluated. The provider will need to assess the extent to which a patient has been able to implement the prescribed treatment and health management activities, and make any necessary adjustments or help the patient to address any barriers that are preventing them from taking the treatment safely.

### **Evidence to Support SDM in Benefit-Risk Counseling**

SDM has been measured in a variety of ways across studies. This may be due in part to differing perceptions about what SDM entails. A recent review of SDM examined the empirical evidence linking patient outcomes and SDM and attempted to identify the circumstances in which SDM is associated with different types of patient outcomes (affective/cognitive, behavioral, and health).<sup>65</sup> This review found that SDM can have a significant and positive impact on affective-cognitive outcomes such as patient satisfaction, decisional conflict, feelings of empowerment, and confidence in their decision. However, evidence is lacking for the association between empirical measures of SDM and patient behavioral and health outcomes such as medication adherence or quality of life.<sup>65</sup>

Most of what is currently known about the impact of SDM is based on clinical trials that compared outcomes among patients exposed to DAs versus standard of care.<sup>63</sup> As noted above, DAs may take a number of forms, including pamphlets, videos, or web-based tools.<sup>63</sup> Their purpose is to support decision-making by making explicit the decision, and provide evidence-based information about different treatment options and their associated outcomes compared to usual care and/or alternative treatments.<sup>66</sup> The main focus of decision aids is to impart knowledge to the patient about their condition and their treatment options, but a number of decision aids also include exercises to aid patients in clarifying how their values and preferences might impact their ultimate treatment choice.<sup>57</sup> They can be used before, during, or after a clinical encounter, but are not a replacement for counseling.

Both the Cochrane Collaboration and the UK's National Institute for Health Care and Excellence (NICE) have conducted large systematic reviews of the literature evaluating the impact of decision aids on a range of outcomes.<sup>67,68</sup> An overview of the results is provided below.

### **Knowledge**

The Cochrane Collaboration review\* of 115 randomized trials of decision aids found high-quality evidence that decision aids improved patients' knowledge of treatment options and outcomes, and that patients who used a decision aid had more accurate expectations of the benefits and harms of the different options. More detailed DAs were found to improve knowledge when compared to simple DAs, but the incremental benefit was only marginal. The NICE review examined 29 randomized trials of patient decision aids and found similar high-quality evidence that the use of a decision aid in a consultation about medicines improved patient knowledge.

### **Decision processes**

The Cochrane review found that decision aids improve the overall processes for decision-making for patients. There was moderate-quality evidence that decision aids stimulated patients to take a more active role in the decision-making process, and that they reduced decisional conflict related to feeling uninformed. DAs also reduced the proportion of people who remained undecided after an intervention, and enabled patients to make health decisions that were consistent with their values and preferences. The review found no evidence that decision aids had a statistically significant effect on a patient's levels of anxiety, depression, or regret related to their decision.

The NICE review reported additional evidence that decision aids improve patient decision-making processes. The authors found moderate-quality evidence that decision aids reduced the number of patients who wanted their health care provider to make their decision for them, increased patient involvement in the medicine consultation process, and led to improvements in overall decisional conflict.

### **Adherence to treatment**

The Cochrane review found inconclusive evidence regarding decision aids' effect on treatment adherence, citing incomplete data, varying lengths of follow-up, and insufficient variation in choices in the studies examining treatment adherence. The NICE review found only low-quality evidence that decision aids do not improve adherence to medication.

### **Treatment decisions**

The Cochrane review found decision aids' effects on treatment decisions to be variable. The number of patients opting in favor of major elective surgery generally decreased when a decision aid was used, along with the number of patients choosing to undergo hormone replacement therapy and prostate-specific antigen testing. However, in many of the studies examined by the Cochrane review, no statistically significant difference in treatment choices was found between patients who used a DA and those who did not.

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\* The Cochrane Collaboration recently updated this review, but the results were not published in time to be included in this white paper.

### **Limitations of the Evidence**

Both reviews had some limitations. In the Cochrane review, several of the selected outcomes demonstrated statistically significant heterogeneity due to the inability to detect differences across diverse studies. These differences included variability in decision contexts, differing elements within the patient decision aid, the type of interventions, and the targeted outcomes. A sub-analysis of the Cochrane review explored three potential sources of heterogeneity: the type of control intervention, decision aid quality, and patients' baseline knowledge of probabilities.<sup>66</sup> The authors determined that the accuracy of the patient's baseline risk perception was an important variable for explaining heterogeneity. Decision aids generally had a greater effect when the baseline scores for accurate risk perception were lower, and were more effective in patient populations with a lower level of knowledge. In the NICE review, the included studies focused solely on adults; it is unclear whether the authors' conclusions about the effects of decision aids would also be applicable to children. Additionally, 14 of the 28 studies examined by the NICE review were conducted outside of the United States, and therefore may lack transferability.

More broadly, there is debate about how to measure a 'good' decision when there is no clear right choice between treatment options. In such cases, for example, is it more important that the patients reach their decision through a good process, regardless of the outcome? Some have also questioned the relevance and significance of the outcomes typically used to measure DA effectiveness, and have argued that more evidence is required to determine their effects on longer-term health outcomes or health system processes.<sup>63</sup>

### **Resources for DA Developers and Health Care Providers**

As noted above, there are several initiatives underway to promote SDM and develop high-quality DAs that can be used to support the counseling process between providers and patients. Three of these are highlighted below.

#### **International Patient Decision Aids Standards**

The International Patient Decision Aid Standards (IPDAS) Collaboration is an international group of researchers, practitioners, and stakeholders who developed a set of criteria to evaluate the quality of patient decision aids.<sup>69</sup> The criteria contains 64 items that can be rated either present or absent from a given decision aid, and cover a number of aspects related to a decision aid's content, development process, and effectiveness.<sup>70</sup> This set of criteria was updated in 2012 to reflect the emergence of new evidence around DAs. In addition to the checklist, the collaboration also developed an instrument known as IPDASi, which can be used to quantitatively assess a DA's quality across 10 broad dimensions.<sup>71</sup>

In recent years, the collaboration has been working to develop a set of minimum standards that could be used to certify DAs for use in the clinical setting. A subset of 44 criteria has been proposed for this purpose, but has not yet been formally adopted by the IPDAS Collaboration.<sup>72</sup> While recent research conducted by the collaboration indicates that developing such criteria is feasible, it remains unclear whether and how the minimum standards can be applied in practice to interventions that are designed for use within clinical encounters.<sup>73</sup> Some have also noted that, while the IPDAS criteria may be useful in



developing DAs and in reducing variations in their quality, the checklist should not be applied uncritically as the evidence underpinning it will likely evolve over time.<sup>74</sup>

### **Ottawa Hospital Research Institute**

An affiliate of the University of Ottawa, the Ottawa Hospital Research Institute has developed a number of DAs and related resources for instrument developers, health care providers, and patients. These include an inventory of DAs that have been developed by the Institute as well as by other groups. In order to be included in the inventory, the decision aid must be publicly available, supported by scientific evidence, be not more than five years old, and meet the Institute's definition of a decision aid.<sup>75</sup>

Additional resources from the Institute include online tutorials, overviews of the conceptual framework and research used by the Institute to guide the development and evaluation of DAs, and toolkits for people who are developing their own DAs or attempting to implement SDM into the practice setting. The Institute also leads an ongoing effort to systematically review clinical trials of DAs for treatment or screening decisions.

### **Agency for Health Care Research and Quality: SHARE Framework**

The Agency for Health Care Research and Quality (AHRQ) has developed a five-step process called the SHARE approach for shared decision-making that allows providers to engage in a meaningful dialogue about the benefits and risks of treatment options.<sup>55</sup> The five steps in the process are:

- 1: **Seek** the patient's participation.
- 2: **Help** the patient explore and compare treatment options.
- 3: **Assess** the patient's values and preferences.
- 4: **Reach** a decision with the patient.
- 5: **Evaluate** the patient's decision.

AHRQ offers an online shared decision-making toolkit for providers, which is aimed at supporting the implementation of the SHARE approach. These resources include webinars on topics such as overcoming barriers to SDM, the use of decision aids and other tools including reference guides for SDM, health literacy and numeracy, and techniques for communicating with patients.<sup>76,77</sup> AHRQ has also made available the educational modules from their SHARE approach workshop, a one-day, accredited train-the-trainer program for health care professionals.<sup>78</sup>

### **Barriers to Implementing SDM**

Multiple studies have also shown that physicians often fail to include patients in the decision-making process, owing to barriers that exist at both the patient and provider level. As noted above, patient barriers include lack of interest or awareness that a decision needs to be made and that their participation in the decision is important. Some patients—particularly those who are older, less educated, or otherwise marginalized—may lack the skills, confidence, knowledge, or tools to engage in SDM.<sup>63</sup>

The most often-cited physician barrier to implementing SDM is physician time constraints, though there is no robust evidence that more time is required to perform SDM.<sup>64</sup> Other physician barriers included lack of training and lack of awareness or agreement that SDM may be appropriate for a particular decision or clinical situation.<sup>79</sup> Physicians may also misjudge and determine that patients are not willing to be involved in the decision-making process. Some have also noted that SDM practices and principles are not well-integrated with evidence-based medicine guidelines, though there are attempts underway to address this through groups such as IPDAS.<sup>80</sup>

Addressing these barriers will likely require interventions at multiple levels. Though there is evidence to support the effectiveness of SDM in clinical studies in a range of clinical situations, there is limited evidence to show which strategies are effective for implementing SDM in practice.<sup>64,81</sup> Some possible strategies might include financial incentives, provider training programs, and patient education efforts that can help to build health literacy and encourage engagement.<sup>82</sup> More research on the impact of SDM on health care processes and patient outcomes can also help to build support among clinicians. A 2013 review also noted that interventions to implement SDM were more likely to be successful if they included the introduction of a system where eligible patients were systematically identified or supported to use DAs ahead of the clinical consultation. In other words, SDM was more likely to take place in cases where the process did not rely on clinicians to initiate access to the tools.<sup>81</sup>

## CURRENTS GAPS IN KNOWLEDGE

There are a number of gaps in knowledge related to SDM and the use of DAs to support it. These include, but are not limited to:

- How to integrate SDM into clinical practice, identifying practice models and characteristics of interventions that promote integration.
- How to measure and define good decision-making, particularly in cases where there is no 'best' option.
- The effect of SDM interventions on health care delivery, resource use, unwarranted variation, and clinical outcomes.
- How to ensure quality control of DAs in order to minimize bias and conflicts of interest in their development.
- How to develop tools that target and facilitate communication among patients and their health care providers in a way that reflects the inter-professional nature of health care delivery.
- How best to tailor the health information being provided to a particular patient so as to reflect their clinical risks (which change over time), information needs (which can change over time), preferences, and their level of health literacy.
- How different approaches to SDM impact its outcomes, and which approaches are most effective in supporting good decision-making.
- The cost-effectiveness of different SDM approaches, including the use of decision aids.
- The effectiveness of various formats of DAs, such as computer-based aids.
- The impact of DAs on different cultural groups and on patients who have lower health literacy and numeracy.
- When during a patient-provider interaction DAs are most effective.
- How best to involve patients in the development of patient DAs.
- How to best elicit patient goals and preferences for treatment and communicate these goals to the health care provider
- How to ensure that a patient understands the benefits, not just components, of knowledge

## BEST PRACTICES IDENTIFIED IN THE LITERATURE

Although additional work must be done to more fully implement shared decision making into the health care system, there is some evidence that SDM is a useful method of increasing patient engagement in decisions related to their health care. Our review identified several high-level best practices and principles that have been proposed and are supported by the literature:

- Providers should work with patients to identify and prioritize which decisions are appropriate for SDM.
- Providers should inform patients that a decision needs to be made and elicit their preferred level of involvement in that decision.
- Providers should use the best-available evidence and apply the principles of evidence-based medicine to the SDM process.
- The SDM process should be interactive; for example, providers should ask patients to explain how they frame the decision, and use the teach-back technique to ensure that the patient has understood the information presented.
- Providers should elicit their patient's values and preferences and avoid making assumptions regarding them.
- Providers should acquire the necessary knowledge and skills before using a decision aid in their practice, including:
  - The relevant clinical knowledge
  - Effective communication and consultation skills, particularly in regard to eliciting a patient's values and preferences
  - Effective numeracy skills
  - Ability to effectively explain the tradeoff between a treatment's risks and benefits
- Organizations should consider supporting training and education of providers in developing the skills and expertise needed to use decision aids effectively, and should consider prioritizing and disseminating the decision aids needed by their target patient population to all relevant health care providers and stakeholder groups.
- Providers should read and understand the content of a decision aid before using it with their patients.
- Providers should not use a decision aid to replace face-to-face discussions between providers and patients.
- Providers should ensure that decision aids have followed a robust and transparent development process (such as the process outlined by IPDAS and the Ottawa Hospital Research Institute).
- Providers need to recognize that it may take more than one interaction with a patient to ensure that they can make an informed decision.
- Patients should be given the opportunity to review their decision at a follow-up appointment as their circumstances, values, and preferences may change over time.

## Motivational Interviewing

Motivational interviewing is a particular approach to counseling that seeks to change behavior, usually when a patient feels ambivalent about that behavior. It is focused on helping patients identify and resolve their ambivalence, often by helping the patient to explore their perspectives and the perceived barriers to the behavior change. The practice was originally developed for the treatment of substance abuse, but has since been expanded to include a range of health-related behaviors, such as in cases where the patient is not adhering to a prescribed treatment.<sup>83</sup> As described by Elwyn et al, MI involves four overlapping concepts:

1. Engaging: building a helpful working relationship with the patient
2. Focusing: the process of developing and maintaining a specific behavior change
3. Evoking: gaining the patient's perspective and input to ensure that their feelings are recognized, explored, and reinforced
4. Planning: developing a concrete plan of action and seeking patient's commitment to change

Much like SDM, motivational interviewing focuses on engaging patients in their own health care decisions. However, whereas SDM is considered more relevant when there is more than one reasonable treatment option and the patient needs to understand how to choose the best course by valuing the outcomes associated with different treatments, motivational interviewing is focused more on directing patient behavior towards a particular goal.<sup>84</sup> Motivational interviewing has been proposed recently as a complementary technique that can be used to help support patient-centered care, and which can be integrated with SDM practices in certain cases.<sup>83</sup>

## Evidence to support the use of MI in Benefit-Risk Counseling

There is strong evidence to support the use of MI in addiction treatment.<sup>85,86</sup> However, outside of this context the evidence is mixed, and it is unclear whether and under what circumstances MI techniques are appropriate in the context of counseling patients on initiating or using medications. There is evidence that MI can be used to improve client communication and counseling concerning lifestyle-related issues, and that it can be effective in cases where a patient is not adhering to a prescribed medication. A meta-analysis of cognitive-based behavior change techniques (such as motivational interviewing) found that they are more effective in improving medication adherence when compared to standard educational and behavioral interventions.<sup>84</sup>

### CURRENTS GAPS IN KNOWLEDGE

There are several gaps in knowledge identified relating to the use of MI in the context of patient counseling, including:

1. Which MI methods are most effective in driving behavior change
2. The most effective approaches to training health care professionals in MI techniques
3. Under what circumstances MI techniques might be integrated into benefit-risk counseling around medications

### **BEST PRACTICES IDENTIFIED IN THE LITERATURE**

While MI techniques may be valuable in the context of counseling on medications with serious risks, the available evidence found in this review did not contain best practices or principles for this particular context. As noted in one meta-analysis, there may be value in applying MI techniques in cases where a patient is intentionally non-compliant with a recommended treatment. However, these techniques were not well-described, which makes it challenging to identify relevant best practices.

## SUMMARY TABLE OF BEST PRACTICES IDENTIFIED

### Benefit and Risk Communication

- Use plain language, and provide numeric data to support counseling;
- Exercise caution in applying evaluative labels such as ‘low risk’ or ‘high chance’;
- Consider placing the targeted risks in context by comparing them to the risk of other outcomes, but exercise caution in comparing an individual patient’s risk to the risk faced by an ‘average’ person;
- When communicating changes in numeric outcomes, use absolute risk rather than relative risk, and avoid using number needed to treat;
- When using natural frequencies or event rates, clearly define the denominator and keep it constant across different risks;
  - Event rates may be preferable when presenting the chance of a single event or the occurrence of two or more *independent* events.
  - Natural frequencies may be preferable when comparing the chance of occurrence of two or more *dependent* events.
- Keep time frames constant, and reinforce them repeatedly when describing risk over time;
- Use visual aids to support the communication of quantitative risk information;
  - When feasible, visual aids should depict the baseline risk separately from the treatment risk.
  - Bar graphs and pictographs are perceived more accurately and easily, and may be preferable
- Provide a summary table that lists benefits and risks of the intervention together, so as to offset bias related to framing and ordering;
- Focus communication on key messages, and exclude non-critical information

### Shared Decision-Making

- Providers should work with patients to identify and prioritize which decisions are appropriate for SDM.
- Providers should inform patients that a decision needs to be made, and elicit their preferred level of involvement in that decision.
- Providers should use the best-available evidence and apply the principles of evidence-based medicine to the SDM process.
- The SDM process should be interactive; for example, providers should ask patients to explain how they frame the decision, and use the teach-back technique to ensure that the patient has understood the information presented.
- Providers should elicit their patient’s values and preferences, and avoid making assumptions regarding them.

### Shared Decision-Making (Cont).

- Providers should acquire the necessary knowledge and skills before using a decision aid in their practice, including:
  - The relevant clinical knowledge
  - Effective communication and consultation skills, particularly in regard to eliciting a patient's values and preferences
  - Effective numeracy skills
  - Ability to effectively explain the tradeoff between a treatment's risks and benefits
- Organizations should consider supporting training and education of providers in developing the skills and expertise needed to use decision aids effectively, and should consider prioritizing and disseminating the decision aids needed by their target patient population to all relevant health care providers and stakeholder groups.
- Providers should read and understand the content of a decision aid before using it with their patients.
- Providers should not use a decision aid to replace face-to-face discussions between providers and patients.
- Providers should ensure that decision aids have followed a robust and transparent development process (such as the process outlined by IPDAS and the Ottawa Hospital Research Institute).
- Providers need to recognize that it may take more than one interaction with a patient to ensure that they can make an informed decision.
- Patients should be given the opportunity to review their decision at a follow-up appointment, as their circumstances, values, and preferences may change over time.

## Meeting Objectives

The Center for Health Policy at the Brookings Institution through a collaborative agreement with FDA is convening a workshop to solicit input into the development of a draft framework of benefit-risk counseling practices, methods, techniques and tools for medications with a REMS. This framework will be based upon a review of best practices drawn from the existing literature as well as the academic knowledge and practical insights from practitioners in the various fields, and is being developed in consultation with a range of stakeholders. This workshop will provide an initial opportunity for stakeholders with extensive knowledge of and experience with effective patient counseling methods to provide input into this framework and guidance as to its further development.

### **Session I: Principles and Best Practices for Effective Patient Benefit-Risk Counseling and Shared Decision-making**

*Objective:* Using the white paper as a starting point, identify additional/alternative principles, best practices, and/or tools that should be considered as part of a benefit-risk counseling process that involves shared decision-making. This includes:



- The desired outcomes of benefit-risk counselling to patients:
  - a. From the patient’s perspective
  - b. From the provider’s perspective
- The key principles that should guide FDA’s development of provider-to-patient benefit-risk counseling
- The best benefit-risk counseling and shared decision-making methods, practices, or techniques that should be considered
- The extent to which benefit-risk information can and should be tailored to the individual patient
- The essential information and skills that patients and providers need in order to participate effectively in a counseling process that includes shared decision-making.
- Key steps for a prescriber to take when initiating/maintaining a shared decision-making process
- The most effective supporting tools to facilitate effective counseling practices
- Best practices and principles that should be applied 1) in the development of decision aids or 2) in selecting/adapting existing decision aids.
- Possible approaches for embedding these best practices within the current care environment
  - a. The potential role of other members of the health care team in supporting benefit-risk counseling.

## **Session II: Translating Best Practices into a Benefit-Risk Counseling Framework: Key Challenges and Facilitators**

*Objective:* Discuss the critical aspects of an effective counseling process involving shared decision making that can be practically implemented within the REMS context, the main barriers to implementing best practices by stakeholders, and possible strategies to help to address those barriers within the REMS patient benefit-risk counselling process.

- Implications of the REMS context and current health care practice on FDA’s ability to effectively guide the adoption of the principles and best practices discussed in Session I.
  - a. What are some aspects of FDA’s REMS authority that may limit its ability to design, develop, and implement an effective benefit risk counseling framework?
  - b. What has FDA heard from sponsors and health care providers about some of the challenges they have had implementing REMS processes and tools to date?
  - c. What is FDA’s thinking about how a benefit-risk counseling framework could overcome these challenges?
  - d. What is the panelists’ reaction to FDA’s thinking?
- Considerations for developing a benefit-risk counseling framework that can be generated by FDA, implemented by sponsors, and be useful in practice given the REMS context and healthcare delivery challenges. Specifically:
  - a. Since FDA is able to discuss risks in detailed terms but benefits only in terms of treatment indication, how can a framework best guide physicians to talk about other patient specific benefits and benefit/risks without being specific?
  - b. How can a general framework address what patients need to know about both medications’ benefits and risks without being specific and directive about what to say in an interactive counseling process that includes SDM?

- c. What are some potential strategies for incorporating SDM principles and practices into the design and implementation of REMS programs?
- d. What are the best methods to encourage physicians to engage in SDM with their patients?
- Are there existing health care intervention or counseling effectiveness evaluation methods, measures, or tools that could serve as a model?

**Session III: Translating Best Practices into a Benefit-Risk Counseling Framework (Cont).**

*Objective:* Reflect on the morning's discussion, identify major takeaways and emerging themes, as well as discuss any additional challenges or strategies that have not yet been addressed.

**Session IV: Applying Best Practices to the Design and Implementation of a Benefit-Risk Counseling Support Tool(s) in REMS.**

*Objective:* Explore how evidence-based principles and best practices could be applied to the design of a tool supporting benefit risk counseling in REMS.

- Suggestions regarding optimal processes, techniques, language, timing, repetition, stakeholders, interactivity, and technologies that should be considered in the design and implementation of an effective benefit and risk counseling tool (e.g., decision aid) within REMS
- Aspects of shared decision aids or other benefit risk counseling support tools that would/would not be feasible to incorporate into a REMS counseling discussion.
- Recommendations for how to best implement decision aids or other benefit risk counseling support tools in REMS
- How to best measure and assess the effectiveness of a decision aid or other benefit risk counseling support tool in REMS (e.g., pilot testing, metrics of performance, etc.)
- Existing resources, initiatives, and models that can possibly be adapted or referenced in designing a tool

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