Risk Evaluation and Mitigation Strategies: Improving Benefit-Risk Counseling Between Providers and Patients
Benefit Risk Counseling in REMS
Concept Paper Review

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U.S. Food and Drug Administration
Goals for Today’s Meeting

- Obtain feedback on enhancing draft FDA concept paper (background and “ideal” counseling framework).
- Gain stakeholder input into how to translate high level framework into something practical and implementable.
- Identify barriers to implementation and potential solutions.
Background: Risk Evaluation and Mitigation Strategies (REMS)

- What is a REMS?
- What a “Medication Having a REMS” means for HCPs and patients
- Patient Counseling in REMS
- About the Benefit Risk Counseling in REMS Project (BRCP)
Why are We Here Today?

- REMS are safety programs that FDA can use for selected medications that have serious adverse events to help ensure benefits outweigh risks pre- or post-approval
  - Specific to mitigating serious medication risk(s); REMS do not address overall medication safety or medication benefits
  - All REMS have elements to inform/educate about risks; some also require additional actions to ensure safe use
- Medications with serious risks that have a REMS need an even higher level of patient understanding and involvement
  - When included, existing REMS counseling tools focus on risks only; patients want more balanced information to help them put risks in the context of potential benefits when such medications are being considered
- Providing balanced information, context, and comparative information is best conveyed during counseling tailored by the HCP to each patient’s specific profile of potential benefits and risks
- Project is about developing a framework for providing such counseling
Development of the “Ideal” Framework and Concept Paper: Project Timeline

- REMS integration initiative was established in 2011
- Public meeting: Standardizing and Evaluating REMS – 2013
- Draft workplan: Risk Communication Advisory Committee – 2013
  - Benefit-risk counseling in REMS was identified as a priority project
Development of the “Ideal” Framework and Concept Paper: Project Timeline II

- Development process: BR counseling framework and concept paper
  - Brookings white paper (literature and gaps) – 2015
  - Brookings expert meeting – July, 2015 → target HCPs
  - Draft framework development and expert outreach for input (2015/2016)
  - Draft concept paper development (1Q, 2016)
  - Duke/Brookings extended stakeholder meeting – April, 2016
  - FDA Drug Safety Board Meeting (implementation) – May, 2016
  - Final concept paper development and clearance

- Public comment
  - Publish Federal Register (FR) notice and concept paper
  - Incorporation of public comment

- Publish concept paper
Development Process for the Framework and Concept Paper

- Literature Review
- White Paper
- Expert Meeting

- BR Counseling Framework (draft)
- Expert Outreach
- Concept Paper (draft)

- Stakeholder Meeting
- Drug Safety Board
- Concept Paper (final)

- FR Notice & Post Concept Paper
- Public Comment
- Publish Concept Paper
What Have We Produced So Far?

• An “ideal” framework for counseling when a medication with a REMS is being considered or used
  • Started with set of desired outcomes and guiding principles
  • Elicited best practices based on literature and expert insights
  • Organized this information into a high level “table”:
    • Counseling that is aligned sequentially to phases of the counseling process: assessment, treatment decision and reinforcement
    • For each phase of counseling, identifies best practices: topics, techniques and tools

• A draft concept paper describing the background and the “ideal” framework
  • Acknowledge need for further translation and implementation
Concept Paper Structure (Current Draft)

- Introduction
- Background
  - What is a REMS?
  - What a “Medication Having a REMS” means for HCPs and patients
  - Patient Counseling in REMS
  - About the Benefit Risk Counseling in REMS Project (BRCP)
- Setting the Context
- The Benefit Risk Counseling Framework
  - Elements of the Framework
  - Framework: Key Principles and Best Practices
  - Phased Benefit Risk Counseling
  - Considerations When Implementing
- Conclusion

- References
- Appendices
  - REMS Description
  - REMS Counseling Tools
  - Desired Stakeholder Outcomes
  - Key Principles
  - Benefit Risk Counseling Checklist
Setting the Context

- Framework focused on supporting HCPs when counseling patients who are being considered for, or are treated with, a medication with a REMS
  - Principles and practices may be useful (even if REMS medication is not under consideration).

- *Counseling* encompasses the broad range of interactions between a patient and his/her HCP that occurs throughout the continuum of care

- Framework development envisioned three scenarios:
  - A patient diagnosed with a progressive condition. HCP believes that a REMS treatment may be the best option, but would consider other options.
  - A patient with a symptomatic condition who has tried multiple therapies and wants to consider other therapies. HCP is willing to consider REMS treatment.
  - A patient being treated with REMS medication who has difficulty with REMS requirements.
Setting the Context: The Phased Counseling Process

PHASE I:
Assessment of Treatment Needs and Goals

PHASE II:
Review of Treatment Options and Selection of Treatment

PHASE III:
Reinforcement of Safe Medication Use and Monitoring of Treatment Experience
Framework Schematic

- Desired Outcomes
- Guiding Principles
- Phased Counseling Best Practices (Topics, Techniques, Tools)

Translating Best Practices into Practice
Implementation Considerations
Desired Outcomes, at a Glance

**Patient**
- feels able to contribute to decision making,
- feels informed about his/her options,
- is confident in ability to do what is necessary to minimize risks and maximize benefits, and
- feels decisions are right for him/her.

**Provider**
- retains role as clinical expert and advisor,
- is able to elicit the information needed to assess and effectively counsel,
- is confident that the patient understands the B and R of the recommended and alternative treatments and could comply with the safer use conditions, and
- is confident that treatment decisions are appropriate for the patient.
Guiding Principles

Principle 1: It is essential for counseling discussions to take place between a HCP and patient about potential benefits and risks when considering medications that have potentially serious risks requiring a REMS.

Principle 2: Effective counseling is a dynamic process that needs to take place starting with the initial assessment of the patient and continuing over the lifecycle of treatment of a patient taking a medication with a REMS.

Principle 3: The counseling discussion about the potential benefits relative to risks of different treatments needs to be as individualized to the patient as possible.

Principle 4: Counseling should support making an informed treatment decision by a patient and HCP following a shared decision making process, whenever appropriate, based on potential benefits and risks, as well as a mutual understanding of patient obligations under the REMS for appropriate and safe use.

Principle 5: Efficiency and effectiveness of counseling about medications with REMS may be enhanced by adopting and implementing best practices in risk communication and healthcare counseling, supported by decision aids, resources, and other counseling support tools.
## Table: Phased Counseling Using Best Practices

<table>
<thead>
<tr>
<th>Counseling phase</th>
<th>A. Topics</th>
<th>B. Techniques</th>
<th>C. Tools</th>
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</thead>
<tbody>
<tr>
<td>I. Assessment of patient's treatment needs and goals</td>
<td>1. Patient's medical condition and history</td>
<td>5. Assess patient's literacy and numeracy, and tailor counseling</td>
<td>12. Evidence-based resources re: medical condition</td>
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<td></td>
<td>2. The need to make a treatment decision</td>
<td>6. Convey a desire for patient input</td>
<td>13. Patient value clarification tools</td>
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<td>3. Patient's involvement in decision</td>
<td>7. Assess patient’s preferred level of participation</td>
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<td>4. Patient's values and goals for treatment</td>
<td>8. Prepare patient for the shared decision making process</td>
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<td>9. Seek patient interaction early and often (e.g., open-ended questions)</td>
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<td>10. Elicit patient’s goals and values (no assumptions)</td>
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<td>11. Identify additional areas of interest to the patient</td>
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<tr>
<td>II. Review treatment options and make a decision</td>
<td>14. Key aspects of the REMS treatment option:</td>
<td>15. Evidence-based resources re: medical condition</td>
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<tr>
<td></td>
<td>• Potential benefit(s) of REMS product</td>
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<td>• Potential harms of REMS product</td>
<td>16. Other potentials factor into treatment decision (e.g., treatment admin, insurance)</td>
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<td></td>
<td>• Actions needed to mitigate REMS-related risk(s)</td>
<td>17. Patient’s initial assessment of options</td>
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<td>15. Key aspects of other treatment options under consideration (incl. no treatment)</td>
<td>18. HCP’s overall assessment and recommendation</td>
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<td>16. Other potentials factor into treatment decision (e.g., treatment admin, insurance)</td>
<td>19. Patient’s comfort with recommendation</td>
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<td>17. Patient’s initial assessment of options</td>
<td>20. Confirmation of decision (or its deferral)</td>
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<td>18. HCP’s overall assessment and recommendation</td>
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<td>20. Confirmation of decision (or its deferral)</td>
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<td>III. Reinforce safer use and monitor treatment</td>
<td>35. Next steps: REMS requirements, if applicable</td>
<td>30. Draw on best available evidence on options</td>
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<td>Next steps: monitoring and follow-up assessment</td>
<td>31. Focus discussion on the most relevant benefits and risks</td>
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<td>36. At follow-up: Patient experience with treatment benefits and harms</td>
<td>32. Use plain language</td>
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<td></td>
<td>At follow-up: Patient experience with REMS requirements</td>
<td>33. Convey simple, quantitative, evidence of benefit and risks, including likelihood, magnitude, and timeframe</td>
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<td>37. At follow-up: Patient experience with REMS requirements</td>
<td>34. Convey the degree of uncertainty about expected benefits and risks</td>
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<td>38. At follow-up: Whether need to revisit treatment decision</td>
<td>35. Complement evidence with bottom-line gist; make a direct link between the options and patient treatment goals</td>
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<td>39. At follow-up: Whether need to revisit treatment decision</td>
<td>36. Seek feedback to assess patient understanding of options (e.g., teach-back)</td>
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<td>37. Encourage questions</td>
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<td>38. Elicit patient’s preferences among options (no assumptions)</td>
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<td>39. Demonstrate safer use practices, when possible</td>
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<td>40. Seek feedback to assess understanding and attitudes on safe medication use</td>
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<td>41. Reinforce REMS requirements at every follow up</td>
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<td>42. Consider enhanced techniques (e.g., motivational interviewing)</td>
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<td>43. When compliance is an issue</td>
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<td>44. Provide opportunity to review treatment decisions at follow-up</td>
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<td>45. REMS materials and counseling tools</td>
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Framework Schematic

Desired Outcomes → Guiding Principles → Phased Counseling Best Practices (Topics, Techniques, Tools)

Translating Best Practices into Practice → Implementation Considerations

Validate

Today

Ideas
Questions and Discussion

- How would you improve approach to developing the high level framework?
- How could structure of the high level framework be improved (i.e. phased counseling each with related topics, techniques, and tools)?
- Do the framework and concept paper overlook any important elements or concepts that could make them more useful/implementable?
- How can we help HCPs translate the high level framework into something more implementable?
Working Session Logistics

- 3 work groups each with approximately 10 participants, an FDA moderator and a note taker
  - Group 1
  - Group 2
  - Group 3
- Groups will spend ~2 hours on the 3 phases of counseling
- Seek feedback to questions on topics, techniques and tools, as well as additional examples
- Report out
REMS

- Program to help ensure medication benefits outweigh (identified/potential serious adverse event) risks
- May be implemented pre- or post-approval
- Comprised of:
  - Goal(s)
  - Elements
    - +/- Medication Guide
    - Communication Plan for HCPs
    - +/- Elements to Ensure Safe Use (ETASU) that stakeholders need to execute
      - Prescribers have specific training/experience or be specially certified
      - Pharmacists or other dispensers be specially certified
      - Drug be dispensed only in certain healthcare settings (e.g., infusion centers, hospitals)
      - Drug be dispensed with evidence of safe-use conditions such as laboratory test results
      - Each patient using the drug be subject to monitoring
      - Each patient using the drug be enrolled in a registry
  - Timetable for submission of assessments
What “Medication Having a REMS” Means

- REM convey focused information about a specific, serious adverse event risk
- Vary in design: all REMS communicate, some also intervene to create/maintain safe use conditions
- FDA can require manufacturers to develop/implement
- HCP role
  - Understand the risk and the REMS
  - Assess and explain potential risks vs. benefits of different treatment alternatives for each patient
  - Executing the REMS to meet requirements and reinforce patient compliance
REMS Counseling Tools

- Not all REMS have counseling tools
- Designed to help HCPs communicate and educate patients about the serious risk(s) of a medication; not a broader, individualized discussion of benefits and risks among treatment alternatives

Examples

- Medication Guide (for patient)
  - Provided at dispensing/refill
  - If part of REMS, may be used by HCP to review with patient
- Patient Counseling Document
  - Facilitates interactive dialogue between HCP and patient
  - Key risk information plus space for tailored content
- Prescriber-Directed Counseling Tool
  - Prepares HCP to provide counseling at initiation of therapy
- Prescriber-Patient Agreement (PPA)
  - May include signature documenting counseling
  - May be provided to patient and/or retained in chart
- Patient Treatment Continuation Form
  - Documents at follow up that benefits continue to outweigh risks
  - Some may require providing ongoing counseling
Risk Evaluation and Mitigation Strategies: Improving Benefit-Risk Counseling Between Providers and Patients
Framework “Snapshot” to Counseling Practice Framework
(scenario of a new and untreated patient)

<table>
<thead>
<tr>
<th>Condition requires lifestyle or behavioral therapy but no meds</th>
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<tbody>
<tr>
<td><strong>Assess Patient Condition and Needs</strong></td>
<td><strong>Review options</strong></td>
<td><strong>Monitor and Reassess</strong></td>
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<tr>
<td>Condition requires medication(s) but none have a REMS</td>
<td>Proceed with routine counseling and treatment per labeling</td>
<td>Monitor and Reassess</td>
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<tr>
<td>Condition requires medication(s) and ≥ 1 has a REMS</td>
<td>Assess patient goals and values</td>
<td>Review treatment options &amp; make shared treatment decision</td>
<td>Consider a medication with no REMS</td>
<td>Proceed with routine treatment per labeling</td>
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</table>
What is Shared Decision Making?

“A decision-making process jointly shared by patients and their health care provider”

A collaborative process that allows patients and their providers to make health care decisions together, taking into account the best scientific evidence available, as well as the patient's values and preferences.

SDM is concerned with:

- **Protecting patients** from inappropriate paternalism and ‘one-size-fits all’ healthcare
- **Supporting patients** to exercise autonomy and participate in decisions about their health
When is SDM Appropriate?

- More than 1 reasonable treatment option
- Genuine uncertainty as to which is the most appropriate treatment
- The best choice depends on how an individual values different options
- It is possible to delay the decision to allow for time to deliberate
Talking about risks…

In the world, risk and benefit are **positively** correlated.

In people’s minds, they are **negatively** correlated.
Thinking about Benefits and Risks

Benefits

Risks

More benefits, fewer risks
Shared Decision Making

More benefits, fewer risks

Benefit: Risks

Classic SDM + REMS  Classic SDM+REMS  REMS SDM

A C A D A

B B
Is SDM required for all REMS drugs?

Is a REMS drug the dominant treatment option?

Yes
(explain why)

Discuss key risks

Risks
benefits
Monitoring

Ensure that patient understands risks (teach back)

→

Review risk mitigation strategies, monitoring for R and B of treatment

No
(explain that ≥ 1 plausible treatments, a decision must be made)

Identify plausible treatments for that patient (REMS, non-REMS)

Discuss pros and cons, compare:

REMS drug/s

Non-REMS treatment/s

Risks
benefits
Monitoring

Identify patient preferred role in decision making
**Sharing Decisions**

**General framework When Clinical Equipoise exists**

- **Patient**
  - Initial perception of condition, decision, choices, and preferences
  - Final perception of condition, decision, choices, and preferences

- **Clinician**
  - Frame condition
  - Frame decision
  - Review options
  - Assess patient’s desired role
  - Make (or defer) decision

- **How serious?**
- **How urgent?**
- **Set the tone**
- **There is a decision**
- **Preferences matter**
- **Pros**
- **Cons**
- **Uncertainty**
- **Offer support**
Sharing Decisions for REMS Drugs
(yellow=high priority)
‘REMS’ is shorthand for a REMS drug

General

Frame condition → Frame decision → Review options → Assess patient’s desired role → Make (or defer) decision

REMS

Review indication for REMS → Frame REMS decision → REMS* vs non-REMS → Assess patient’s desired role → Make (or defer) decision

• How serious?
• How urgent?
• Set the tone

• Why REMS drug is being considered
  • Preferences matter
  • Patient risk factors, impact on decision

• Assess preferred role
• Offer support

• Benefits of REMS**
• Risks of REMS*
• B&R of not using a REMS
• Monitoring requirement*
• Risk mitigation strategies*
• Key uncertainties

* Tie to patient’s personal risk factors
** If multiple REMS drugs are under consideration, then present information on other REMS options. If REMS drug is felt to be superior to
Skills that clinicians need to improve to facilitate SDM

- Ask about patients preferred role in decisions
- Assess support or undue pressure on patient
- **Assess patients’ values**
- Increase patients’ involvement in decision making

Légaré, Canadian Family Physician, 2006
The DECISIONS Survey

- Telephone survey of 3,010 Americans > 40 years of age, asked to recall the decision-making process about 9 common medical decisions
  - Rx meds, surgery, cancer screening
  - The majority reported a lack of involvement in decision making
  - Providers failed to solicit patient preferences and overwhelmingly recommended screenings.
  - Limitations: patient recall of events

The DECISIONS Survey

**Discussions of Pros vs Cons**

- **Medication Initiation:**
  - High blood pressure: 48% discussed pros, 91% discussed cons
  - High cholesterol: 55% discussed pros, 96% discussed cons
  - Depression: 54% discussed pros, 96% discussed cons

- **Cancer Screening:**
  - Colon cancer: 96% discussed pros, 96% discussed cons
  - Breast cancer (women): 20% discussed pros, 91% discussed cons
  - Prostate cancer (men): 32% discussed pros, 91% discussed cons

- **Elective Surgery:**
  - Knee/hip replacement: 97% discussed pros, 97% discussed cons
  - Cararact: 43% discussed pros, 96% discussed cons
  - Lower back pain: 80% discussed pros, 95% discussed cons

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Risk Evaluation and Mitigation Strategies: Improving Benefit-Risk Counseling Between Providers and Patients

Working Group Findings

4/14/2016
Breakout Session II: Questions to Address

• For each phase of counseling (I, II, and III):
  • Are the topics appropriate? What additional topics should be considered?
  • Are the techniques appropriate? What additional/alternative techniques can help to ensure effective counseling takes place?
  • Are there other existing resources and/or tools that could help support effective counseling?
## Phase I

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<th>Topics</th>
<th>Techniques</th>
<th>Tools</th>
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Duke MARGOLIS CENTER FOR HEALTH POLICY
# Phase II

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## Phase III

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Risk Evaluation and Mitigation Strategies:
Improving Benefit-Risk Counseling Between Providers and Patients
Counseling Scenario

• **Purpose:** To provide context for development of an FDA framework and supplemental tools for patient-provider interactive counseling on products with a Risk Evaluation and Mitigation Strategy (REMS).

• **Background:** Consider a patient newly diagnosed with a symptomatic and progressive chronic condition, such as multiple sclerosis, Huntington’s disease, or pulmonary hypertension. The patient was referred by her primary care physician to a specialist. Earlier this month, the specialist conducted a comprehensive evaluation of the patient, including a brief discussion with the patient on overarching treatment goals. There are multiple treatment options for patients with a similar form of disease and similar degree of severity. Based on the provider’s assessment of the patient and her understanding and experience with various treatments, the provider believes that a product with a REMS (Treatment A) may be the best treatment option for this patient; the provider would also consider another product (Treatment B), without a REMS, as an initial option for this patient.

• **Setting:** The patient and her spouse are meeting with the specialist in a 20 minute face-to-face consultation to determine the prescribed course of therapy.
Counseling Scenario, cont.

- **Provider introduction to the consultation session:**
  - Based on your medical history, the detailed assessment we conducted earlier this month, and our earlier discussion on your personal circumstances and goals for treatment, I have identified a course of treatment (A) that I will recommend that we start with. This treatment has to be considered carefully as it carries with it a risk of a particular serious side effect. Because of this risk, the treatment has what is called a Risk Evaluation and Mitigation Strategy (REMS), and I will briefly explain what this means in your situation.
  - As the person who has the most at stake in the outcomes of your treatment, your input into this decision is very important. I want to make sure that you are comfortable with our choice and that you fully understand the necessary steps to minimize the safety risks. If you decide that you are not comfortable with Treatment A, there is another option (B) that we can try. Treatment B is not believed to be quite as effective as Treatment A for patients similar to you, but it still should result in some improvements for you. Treatment B does have its own safety risks, but it has not been shown to cause the particular serious side effect that is associated with Treatment A.
  - The provider continues with the interactive counseling, in line with the Benefit-Risk Counseling Framework’s Best Practices and the sample algorithm (separate attachments)
Phase I. Assess patient’s treatment needs and goals

Q: Are there viable treatment options to manage your patient’s condition?

Yes

Q: Assess patient’s literacy and numeracy, and tailor counseling
Q: Discuss need to make treatment decision with patient
Q: Elicit patient’s values and goals for treatment
Q: Elicit patient’s preferred involvement in treatment decision making

No

Monitor and reassess need for treatment over time.

Phase II. Review treatment options and make a decision. Based on your clinical assessment and the patient’s values and treatment goals:

Q: Is one or more products with a REMS among the viable treatment options?

Yes (The algorithm below assumes that a REMS product is clinically preferred)

Review and counsel about REMS treatment option with patient

Q: Review product’s indication and potential benefits to this patient
Q: Review the product’s risks, including REMS-related risks and REMS requirements, as instructed by REMS materials
Q: Discuss why treatment is a viable option, taking into account the benefits, risks, and REMS requirements, within the context of the patient’s health profile and treatment goals
Q: Elicit feedback on patient’s understanding and answer any questions

Discuss and counsel about other viable treatment options

Q: Review benefits and risks of other treatments, relative to the REMS treatment, within context of patient’s health profile and treatment goals
Q: Discuss other potential factors into the treatment decision (e.g., treatment administration, insurance coverage, etc.)

Determine and counsel patient on treatment recommendation

Q: Elicit patient preferences among options
Q: Discuss your overall recommendation in light of your assessment and patient’s treatment goals and preferences

Confirm treatment decision (or deferral of treatment decision, if you and your patient determine that additional information is needed)

Q: Are you comfortable that your patient understands the product benefits and risks, in their individual context?
Q: Are you comfortable that your patient would be able to comply with the necessary steps to mitigate the REMS-related risks?
Q: What is patient’s initial assessment of this option?

No

Review treatment options and make treatment decision, informed by FDA-approved labeling, treatment guidelines and standard practice

Phase III. Reinforce safer use and monitor treatment experience. If treatment involves a product with a REMS:

AT INITIATION OF TREATMENT:

Q: Review, reinforce, and implement relevant REMS requirements
Q: Confirm patient’s understanding of REMS requirements

AT EVERY FOLLOW-UP VISIT:

Q: Reinforce importance of maintaining safe use conditions per REMS
Q: Review treatment experience and assess need to revisit decision

Q: Is your patient comfortable with your overall recommendation?
Q: What is patient’s initial assessment of this option?
Q: Are you comfortable that your patient understands all options?
Risk Evaluation and Mitigation Strategies: Improving Benefit-Risk Counseling Between Providers and Patients
American Chronic Pain Association

Offering help & hope for people living with pain.

www.theacpa.org  800.533.3231
Facilitating Implementation of Benefit-Risk Counseling in a Real-World Setting

Risk Evaluation & Mitigation Strategies:
Improving Benefit-Risk Counseling Between Providers and Patients
Fear of the unknown
Don’t tell me, teach me!

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Question 1: What are the main challenges for different stakeholders to the implementation of the contained within the benefit-risk counseling framework?

- Their expectations of treatment
- Culture limitations
- Agreements put patients on the defense
Question 1: What are the main challenges for different stakeholders to the implementation of the concepts contained within the benefit-risk counseling framework?

- Time commitment
- Reimbursement
- Ability to explain in a meaningful way to the patient
- Tool box
Question 2: How might those challenges be addressed by different stakeholders?

- Need to overcome their symptoms and/or condition
- What is the role of the patient
- Use of graphical tools
- Two way partnership with HCP
- Ability to track progress via internet or app portal
Question 2: How might those challenges be addressed by different stakeholders?

- Schedule time to have conversation
- Better understanding of REMS requirements
- Don’t make assumptions
- Use of interactive tools to track progress of patients
Question 3: Are there any recommended enhancements to the counseling guide/checklist that will enhance its value/utility, given discussions of the framework structure, additional best practices and implementation challenges?

- **Format of materials**
- **Communication skills of HCP**
Communication is key
Question 4: How can FDA improve the usefulness of the checklist as a counseling tool?

- Use graphics that are tested whenever possible
- Keep it short, less words and more conversation
- Require CME to keep current on REMS
- Within the EMR the tool for discussion could pop up each time a prescription is written.
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Risk Evaluation and Mitigation Strategies: Improving Benefit-Risk Counseling Between Providers and Patients