

FDA Risk Communication Research Needs

Purpose: The FDA identified a set of research questions, the answers to which the Agency expects will substantively support the FDA's Risk Communication Strategic Plan Strategy 1.1: "Identify gaps in key risk communication knowledge and implementation, and work toward filling those gaps." These questions were internally reviewed and prioritized by members of the FDA's internal Communication Council and by a small set of FDA social science researchers.

Generally, the questions fall into 5 broad topic areas and are categorized as such, with the full context in which the question was framed, on pages 3-4.

- When and what to communicate
- Reaching the audience (dissemination)
- Ensuring audience understanding
- Motivating audiences
- Evaluating effectiveness

Results: The results of the informal internal polling led to the following four breakdowns, in order of priority. Because feedback was fairly limited, we have not indicated levels of priority within these overall categories.

Strongest, consistent support:

- What is the impact of including quantitative information about risks and benefits in information to patients and consumers?
- How effective are various recall communications and activities on reaching, being attended to, being understood, and being acted on by targeted audiences?

Reasonably high and consistent support:

- What potential trusted information sources should FDA partner with?
- How can we most effectively communicate to different audiences that the information about a particular product or issue is continuing to accumulate and that circumstances could change, and that therefore they should not take hasty action but should "stay tuned" for updates?
- How effective are existing FDA tools used to communicate understandably "standing" and "emerging" product information? To what extent are people getting, or are they likely to get, "recall fatigue" or "emerging information fatigue"?
- How do medical professionals and consumers/patients integrate new information into their existing models of beliefs about the risks and benefits of medical products?

Highly important for at least one organization and at least moderately important for one other:

- How can we most effectively communicate to different audiences the uncertainties associated with emerging science so they can appropriately include this in their decision-making?

- How do different audiences perceive the meaning of “term of art” words, phrases, and disclaimers commonly used in FDA communications? If any are commonly misunderstood, what are alternatives?
- What constitutes a “balanced” picture of product benefits and risks?
- What is the potential value of social media tools for amplifying and disseminating critical information? What is the impact of using these tools?
- How “soon” do patients and consumers want to know about emerging risks of products they use? (e.g., as soon as there is a suspicion? Not until a link has been established? Not until there is a firm recommendation about how to manage the risk?)

Moderately or highly important for at least one organization.

- To what degree do medical professionals and industry understand statistical and other quantitative information in various product information tools?
- Under what circumstances is a risk-risk comparison likely to be more effective than a risk-benefit comparison for providing a “balanced” picture of a product’s riskiness (e.g., methylmercury in seafood)?
- What will motivate people to take action on different types of communications (e.g., recalls, warnings, problem suspicion, recommendations related to weight loss/maintenance)?

When and What to Communicate
<p>How “soon” do patients and consumers want to know about emerging risks of products they use? (e.g., as soon as there is a suspicion? Not until a link has been established? Not until there is a firm recommendation about how to manage the risk?)</p>
<p>How do medical professionals and consumers/patients integrate new information into their existing models of beliefs about the risks and benefits of medical products?</p> <ul style="list-style-type: none"> • What are their general mental models? • What are the gaps between expert (including HCPs?) and lay mental models and how can these gaps be plugged?
<p>What are patients’ needs for information to facilitate appropriate use of prescription drugs, and of medical devices necessary for maintaining their health? What are consumers’ needs for information to facilitate appropriate use of non-prescription drugs and medical devices?</p> <ul style="list-style-type: none"> • Caregivers’ needs? • Most effective information dissemination format for communicating risks and benefits? • How should information be most effectively tiered or layered?
Reaching the Audience (Dissemination)
<p>What potential trusted information sources should FDA partner with?</p> <ul style="list-style-type: none"> • Low tech • High tech
<p>What level of trust do different audiences have of different information FDA disseminates?</p> <ul style="list-style-type: none"> • HCPs, patients, consumers, caregivers, public health officials, media/press • Information about different products
<p>What is the potential value of social media tools for amplifying and disseminating critical information? What is the impact of using these tools?</p> <ul style="list-style-type: none"> • What audiences are best communicated with through these tools? • How can these tools be used to obtain ongoing feedback on the effectiveness of particular communications?
Audience Understanding
<p>What constitutes a “balanced” picture of product benefits and risks?</p>
<p>What is the impact of including quantitative information about risks and benefits in information to patients and consumers?</p>
<p>How can we most effectively communicate to different audiences that the information about a particular product or issue is continuing to accumulate and that circumstances could change, and that therefore they should not take hasty action but should “stay tuned” for updates?</p>
<p>How can we most effectively communicate to different audiences the uncertainties associated with emerging science so they can appropriately include this in their decision-making?</p> <ul style="list-style-type: none"> • Medical professionals, patients with varying health literacy and literacy skills, media/press, Congressional overseers <p>Narrative, graphic/pictorial, tabular, combination of methods – what are the circumstances under which particular presentations are most effective?</p>

<p>How do different audiences perceive the meaning of “term of art” words, phrases, and disclaimers commonly used in FDA communications? If any are commonly misunderstood, what are alternatives?</p> <ul style="list-style-type: none">• “safe and effective”• GRAS (generally recognized as safe) and GRAE (generally recognized as effective)• Product recall• Product correction• Dietary supplement disclaimer “These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.”• “Safety First”
<p>Under what circumstances is a risk-risk comparison likely to be more effective than a risk-benefit comparison for providing a “balanced” picture of a product’s riskiness (e.g., methylmercury in seafood)?</p>
<p>To what degree do medical professionals and industry understand statistical and other quantitative information in various product information tools?</p> <ul style="list-style-type: none">• Standing product information (e.g., labeling)• Emerging product information
<p style="text-align: center;">Motivating Audiences</p>
<p>What will motivate people to take action on different types of communications?</p> <ul style="list-style-type: none">• Product recalls• Product warnings• Suspicion of problems• Dietary recommendations related to weight loss/maintenance
<p style="text-align: center;">Evaluating Effectiveness</p>
<p>How effective are various recall communications and activities on:</p> <ul style="list-style-type: none">• Reaching targeted audiences?• Being attended to by targeted audiences?• Being understood by targeted audiences?• Being acted on by targeted audiences? <p>(For example, what factors of a communication strategy would lead to more recalled products being removed from public availability, both by retailers and in households? Would the use of specific words tied to the health impact or the food category make it more likely that the right people will pay attention to the message and act on it?)</p>
<p>How effective are existing FDA tools used to communicate understandably “standing” and “emerging” product information? To what extent are people getting, or are they likely to get, “recall fatigue” or “emerging information fatigue”?</p>
<p>What is the effect on ongoing perceptions of a food substance or product of recalls or warnings associated with a contamination episode?</p> <ul style="list-style-type: none">• Human versus pet foods; animal feed• Is product perceived as always problematic?
<p>What subgroups’ needs are most important to address given the value-added potential of improved understanding (i.e., bang for the buck)?</p> <ul style="list-style-type: none">• Low health literacy, numeracy• Spoken/written language and cultural differences in cognitive models associated with health/medicine