Best Practices in Risk Communication and Communicating Uncertainty: Applications to FDA-Regulated Products

Presentation to FDA Risk Communication Advisory Committee
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Presentation Overview

Best Practices in Risk Communication

FDA Challenges to Implementation

Strategies for Overcoming Challenges

Measuring Success

Areas for Future Research
FDA’s Regulatory Mission

**Dietary supplements**
**Bottled water**
**Food additives**
**Infant formulas**
**Packaged foods**

**Prescription drugs (brand and generic)**
**Non-prescription drugs (over-the-counter)**

**Vaccines**
**Blood and blood products**
**Cellular and gene therapy products**
**Tissue and tissue products**

**Simple devices (tongue depressors, bedpans)**
**Complex technology (pacemakers, insulin pumps)**
**Dental devices**
**Surgical implants and prosthetics**
**Wearable technology**

**Biologics**

**Medical Devices**

**Food**

**Drugs**
FDA’s Regulatory Mission (continued)

Electronic Products
- Microwave ovens
- X-ray equipment
- Lasers
- Ultrasonic therapy equipment
- Sunlamps

Cosmetics
- Color additives (makeup, personal care products)
- Skin moisturizers and cleansers
- Nail polish and perfume

Veterinary Products
- Livestock feeds
- Pet foods
- Veterinary drugs and devices

Tobacco
- Cigarettes
- Roll-your-own tobacco
- Smokeless tobacco
HAMBURGER $2.35
CHEESEBURGER $2.95
TUNA SALAD $2.75
Egg Salad $2.65
OMELETTE $3.10
BEEF STEW $3.45
FISH FILI $3.10

RISKS

BENEFITS

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Challenge

How does FDA apply risk communication best practices given real-world limitations?
Best Practices in Risk Communication

Create and follow a strategic plan
The plan should be science-based and have clear implementation steps

Benefits
Being proactive with communications versus reactive
Promotes evidence-based decisions regarding what is communicated and how it is communicated

Actions
Hire or train staff with risk communication expertise and skills
Collaborate with the scientific community about messaging
Best Practices in Risk Communication

Use audience segmentation

Divide audience into discrete segments with similar beliefs, behaviors, and information needs.

Different beliefs underscore different barriers/facilitators to informed decision making.

Targeting “the public” as a whole will not work.
‘Unfortunately, many believe the “general public” is well suited for any test, survey, or focus group. The thing is that using the non-descript “general public” isn’t helpful because it doesn’t exist. So your critical task in recruiting for tests – and also in designing – is to get more specific and identify what your team really means when they say the “general public”.’
Example Persona: “Careful Users” of Prescription Drugs

Includes about half of the population

- Have somewhat higher levels of health literacy and view themselves as capable and moderately confident at using the Internet to find health information and information about prescription drugs.

- They usually read the directions and warnings they take with their prescription medicines – A large percent of them or someone in their household are likely to be currently taking at least one prescription medicine.

- Can read and understand FDA drug safety messages and intend to report any symptoms to their health care professional and look for more information.

Demographics

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>26% 30-44</td>
</tr>
<tr>
<td></td>
<td>31% 45-49</td>
</tr>
<tr>
<td>Gender</td>
<td>54% Female</td>
</tr>
<tr>
<td>Race</td>
<td>72% White</td>
</tr>
<tr>
<td>Education</td>
<td>33% Some College</td>
</tr>
<tr>
<td>Internet Access</td>
<td>84% Yes</td>
</tr>
</tbody>
</table>

Know that decisions are not always made rationally

Emotions can play a significant role in decision making

Reach individuals through trusted sources and ‘influencers’ (e.g., physicians, community leaders).

Understand that they are impacted by other sources—personal experience, media outlets including social media platforms.
Use clear communication and plain language principles

Simple, clear language = Greater audience understanding

Communicate to audiences in the same way they communicate

Complex

The Dietary Guidelines for Americans recommends a half hour or more of moderate physical activity on most days, preferably every day. The activity can include brisk walking, calisthenics, home care, gardening, moderate sports exercise, and dancing.

Simple

Do at least 30 minutes of exercise, like brisk walking, most days of the week.
President Obama signed the **Plain Writing Act** on October 13, 2010. The law **requires that federal agencies use "clear Government communication that the public can understand and use."**

On January 18, 2011, he issued a new Executive Order, "E.O. 13563 - Improving Regulation and Regulatory Review". It states that "[our regulatory system] must ensure that regulations are accessible, consistent, written in plain language, and easy to understand."

Two other executive orders (E.O. 12866 and E.O. 12988) cover the use of plain language in regulations.
### Version A: Control Group

**FDA Drug Safety Communication: Safety review update of Smoquit and risk of cardiovascular adverse events**

**What is Smoquit?**
- A prescription drug used to help adults quit smoking that works by blocking the effects of nicotine from smoking on the brain
- It increases the likelihood of abstinence from smoking for as long as one year compared to treatment with a placebo

The U.S. Food and Drug Administration (FDA) is informing the public about the results of a large, combined analysis, also called a meta-analysis, of clinical trials that compared patients who received the smoking cessation drug Smoquit to patients who received a placebo, which is a treatment with no drug in it. FDA required the manufacturer of Smoquit to conduct the meta-analysis to further evaluate the cardiovascular safety of the drug, and believes it is important to let health care professionals and patients know about the results of this study. FDA first notified the public about a possible increased risk of cardiovascular adverse events with Smoquit in its June 2011 Drug Safety Communication (DSC). A higher occurrence of major adverse cardiovascular events was observed in patients using Smoquit compared to placebo. Major adverse cardiovascular events were defined as a combined outcome of cardiovascular-related death, nonfatal heart attack, and nonfatal stroke. These events were uncommon in both the Smoquit and placebo groups, and the increased risk was not statistically significant, which means it is uncertain whether the excess risk for the Smoquit group was due to the drug or due to chance. However, the data were analyzed in many different ways and consistently showed a higher occurrence of events in patients using Smoquit, which makes it seem more likely that it is related to the drug and not purely a chance finding.

The meta-analysis findings of cardiovascular risk are similar to the findings in the smoking cessation clinical trial of patients with stable cardiovascular disease that was described in FDA's June 2011 DSC. The Warnings and Precautions section of the Smoquit label has been updated to include the results of the meta-analysis.

**Patients taking Smoquit should contact their health care professional if they experience new or worsening symptoms of cardiovascular disease, such as chest pain; shortness of breath; calf pain when walking; or sudden onset of weakness, numbness, or difficulty speaking.**

**Health care professionals are advised to weigh the risks of Smoquit against the benefits of its use.** It is important to note that smoking is a major risk factor for cardiovascular disease, and Smoquit is effective in helping patients quit smoking and abstain from it for as long as one year. The health benefits of quitting smoking are immediate and substantial. Report adverse events involving Smoquit to the FDA.

**Data Summary, Overall,** there was a low incidence of major adverse cardiovascular events occurring within 30 days of treatment discontinuation (Smoquit 0.31% [13/4190] vs. placebo 0.21% [6/2812]) in the trials included in the meta-analysis.

### Version B: Comparison Group

**Talk with your health care professional if you are taking Smoquit and have new or worsening symptoms of heart or blood-vessel disease**

**What is Smoquit?**
Smoquit is a non-nicotine prescription medicine that -- along with quit smoking materials and/or programs -- helps people 18 and older stop smoking.

**Looking at the best evidence**

The Food & Drug Administration (FDA) asked the drug company that makes Smoquit to review all of the large and well-done studies of Smoquit. FDA wanted to better understand the effect Smoquit has on heart and blood-vessel health, also called cardiovascular health. All of the studies compared people who were taking Smoquit to people who were taking a sugar pill that contains no drug, also known as a placebo.

**What did they find?**

Looking at the combined results of all the studies, people taking Smoquit were more likely than people taking placebos to have had one or more of the following heart-related problems:
- death related to cardiovascular problems;
- non-deadly heart attacks; and
- non-deadly stroke.

The chance of having a heart-related problem was rare in both groups. The chance of someone having a heart-related problem if they took Smoquit was 3 in 10,000 (0.03%). A person taking a placebo had a 2 in 10,000 chance (0.02%) of having a heart-related problem. This difference in having heart-related problems could be due to chance. But FDA suspects that these heart problems may be due to Smoquit.

**FDA believes this because people taking Smoquit were consistently more likely to have these heart problems than people taking placebos.**

The makers of Smoquit have updated the Warnings and Precautions on the medicine’s label to include this new information.

**How does this affect me?**

**Patients:** The health benefits of quitting smoking are immediate and substantial. Talk to your health care professional if you are taking Smoquit and have any new symptoms of heart and blood-vessel disease, or if your condition seems to be getting worse. These symptoms include:
- chest pain;
- shortness of breath;
- calf pain when walking; or
- suddenly feeling weak, numb, or having difficulty speaking.

## Knowledge Was Greater for Those who Received the Revised Drug Safety Message

### Correct Responses to Knowledge Questions by Message

<table>
<thead>
<tr>
<th>Item</th>
<th>Original Message % correct</th>
<th>Revised Message % correct</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall Knowledge Index Score*</td>
<td>52</td>
<td>63</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>How common are major cardiovascular or heart-related problems for people taking Smoquit?</td>
<td>48</td>
<td>59</td>
<td>0.003</td>
</tr>
<tr>
<td>Who is most likely to have heart related problems?</td>
<td>46</td>
<td>56</td>
<td>0.005</td>
</tr>
<tr>
<td>People taking Smoquit should contact their health care professional if they have… (Check all that apply)</td>
<td>59</td>
<td>56</td>
<td>0.343</td>
</tr>
<tr>
<td>The chance of someone having a heart-related problem if they took Smoquit was 0.31%. How people does this mean had heart-related problems after taking the medicine?</td>
<td>28</td>
<td>63</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>What is the recommendation for people taking Smoquit?</td>
<td>79</td>
<td>79</td>
<td>0.746</td>
</tr>
</tbody>
</table>

* Cronbach’s alpha for knowledge index is 0.70. **Multivariate model** = Those with Revised version scored, on average, 10 percentage points higher on Index, controlling for other factors.

Conduct research and evaluation of communications

Research is key to understanding audience beliefs and behaviors

Evaluation enables continuous improvement of communication
Challenges to Implementing Best Practices

FDAs Communication Challenges

- Multiple Audiences (with different interests and info needs)
- Legal Reviews and Language (precision vs. clarity)
- Regulatory vs. Educational Responsibilities
- Balanced Summary of Product Benefits/Risks Without Endorsement
- Research and Testing Restrictions (e.g., Paperwork Reduction Act)
Strategies for Adapting to Challenges

Strategy: Create Message Maps

Message maps are a roadmap for displaying detailed responses to anticipated questions from stakeholders.

Reference: [www.orau.gov/cdcynergy](http://www.orau.gov/cdcynergy)

Who are the stakeholders?
What are their questions or concerns?
Develop key messages at 6th grade reading level.
Strategies for Adapting to Challenges

Strategy: Engage in Social Media
Active Listening

Active listening = Acknowledging that FDA is aware of concerns and information needs

Ensure that people feel heard
(even if FDA can’t address concerns right now)
Strategies for Adapting to Challenges

Challenges

Strategy: Acknowledge Uncertainty

Clarify what is known vs. unknown at the time of the communication

Distinguish types of uncertainty and how it might be resolved—scientific (more research needed), market (pricing being negotiated), process (drug shortage cause investigated)

Transparency is critical.
Avoid legalese.
Score Messages for Usability

Use a research-based tool to help plan, develop, and assess public communication materials.

<table>
<thead>
<tr>
<th>Main Message and Call to Action</th>
<th>Score</th>
</tr>
</thead>
</table>
| **1. Does the material contain one main message statement?**<br>
A main message is the one thing you want to communicate to a person or group that they must remember. A topic, such as heart disease or seasonal flu, isn’t a main message statement. If the material contains several messages and no main message, answer no. (User Guide page 5)<br>
NOTE: If you answered No to Question 1, score 0 for Question 2 and continue to Question 3. | Yes = 1<br>No = 0 |
| **2. Is the main message at the top, beginning, or front of the material?**<br>
The main message must be in the first paragraph or section. A section is a block of text between headings. (User Guide page 6)<br>
NOTE: This item isn’t applicable to 1-3 sentence messages, such as tweets. | Yes = 1<br>No = 0<br>NA |
| **3. Does the material include one or more calls to action for the primary audience?**<br>
If the material includes a specific behavioral recommendation, a prompt to get more information, a request to share information with someone else, or a broad call for program or policy change, answer yes. If the call to action is for someone other than the primary audience, answer no. (User Guide page 10) | Yes = 1<br>No = 0 |

Strategies for Adapting to Challenges

**Strategy: Conduct Rapid Prototyping**

Rapid generation, iterative testing, and refinement of messages and materials (rather than perfecting materials before testing resulting in delays)

Shift FDA infrastructure to support alternative testing approaches
Strategies for Adapting to Challenges

Strategy: Employ User-centered Design (UCD) Approaches

Factors that affect the user experience:

RTI iShoppe® allows researchers to immerse participants into a simulated environment and study their behavioral responses to changes that are difficult to assess in real-world settings.

Customized versions can address specific applications or research questions.
Strategies for Adapting to Challenges

Strategy: Use Search Engine and Web Page Optimization

Drive online traffic to information you want them to see. Monitor how easily people can find content they are looking forward.

Enhance existing digital strategy, channels, and partnerships. Promote these resources to increase awareness.
Building new digital services or improving old ones can be risky, complex, and expensive. Doing it well can solve real problems, improve lives, save taxpayer money, and improve the government.

18F Consulting helps federal agencies adopt modern approaches to managing and delivering digital services. We're federal employees, like you. But we're also a team of designers, product strategists, architects, and acquisition specialists, with wide-ranging experience inside and outside the federal government.

https://18f.gsa.gov/dashboard/
Strategy: Test Messages with Federal Employees

Federal government employs almost **2.5 million** civilians (most not scientists)

Research with federal employees not subject to PRA

Include those likely to represent most audience segments—patients, smokers, consumers of a certain product
Strategies for Adapting to Challenges

**Strategy: Expand Expedited OMB Review Process**

FDA Centers have access to expedited OMB review process for research.

Expand number of studies that can use this at one time as it is currently limited.

**Typical timeframe:** 4-8 weeks
How Do We Measure Success?

**Risk Communication Goals**
Share information, Change beliefs, Change behavior

**Locate, Understand, and Use Information**
Audiences must be able to locate information, find key points within messages, and comprehend key information

**Informed Decision Making**
- Aware of choices available
- Understand pros/cons of each choice
- Identify personal values and preferences
- Make decision consistent with values/preferences
- Participate in decision at desired level
How Do We Measure Success?

Healthy eating
Allergen avoidance

Food

Cessation
(current users)
Non-uptake
(non-users)
Non-purchase
(youth, etc.)
Legal display and sales (retailers)

Tobacco

Safety (avoid contraindications)
Medication adherence
Patient-provider discussions
Prescribing guideline adherence

Drugs

Medical Devices

Safety (appropriate use)
Privacy / Limited data sharing
Behavior change (wearables)
Areas for Future Investigation

**Translation**
What are the best methods for translating new communication research into FDA practices?

**Social Media**
How can FDA best utilize social media given its limitations? What do audiences expect and desire from FDA on social media platforms?

**Audiences**
Who are FDA's primary audiences? What are the best strategies for reaching each of them?

**Consensus Building**
How can FDA establish a process for quickly developing cross-agency consensus during outbreaks and emergent issues?
Resources

Plain Language.gov
http://www.plainlanguage.gov/

Usability.gov
http://www.usability.gov/

CDC Clear Communication Index
www.cdc.gov/ccindex/

Health Literacy Tool Shed
http://healthliteracy.bu.edu/

FDA Guide: Communicating Risks and Benefits
http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm268078.htm
Thank you

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