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Risk Communication in Regulatory Context:

Navigating Challenges and Embracing Future Directions

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Effective risk communication is crucial in public health decision-making. Failures in risk communication can have unintended consequences, including loss of life, financial burdens, and damaged reputations. Understanding risk communication fully means asking the right questions about the legal, ethical, and practical aspects that shape its implementation. In the pursuit of enhancing and evolving this field, we describe the relevance of risk communication to the U.S. Food and Drug Administration (FDA), outline some current challenges in risk communication, and propose a series of guiding questions and strategies aimed at steering regulatory agencies, researchers, and practitioners toward actionable and impactful future directions.

Why Is Risk Communication Important for the FDA?

The FDA plays a vital role in promoting the health of the public through surveillance, regulation, and communication, serving as intermediaries between scientific research and public policy. The FDA is not only a regulator but also an educator and facilitator of public discourse about immediate and long-term health risks.

The FDA's regulatory scope is extensive, encompassing food, drugs, biologics, medical devices, electronic products that emit radiation, cosmetics, veterinary products, and tobacco products, which includes cigarettes, tobacco, cigars, hookah, and e-cigarettes.[1]

As the FDA's "Communicating Risks and Benefits: An Evidence-Based User's Guide" emphasizes, it is not enough to merely convey information; it must be disseminated based on empirical evidence and tailored to an audience's needs, ensuring comprehension and actionability and leading to informed decision-making by the public and health professionals. Proper risk communication builds trust, encourages informed choices, and protects public health.

Current FDA Challenges in Risk Communication

Risk communication features several challenges that reflect the complexities inherent in today's multifaceted information landscape. These include:

1. Navigating the uncertainty in risk;
2. Ensuring information is truthful and not misleading;
3. Effectively communicating risk in a cluttered information ecosystem; and
4. Navigating the regulatory constraints that shape how the FDA can communicate risks.

To facilitate effective risk communication to the public, these challenges must be addressed and navigated.

Challenge 1:
Navigating the Uncertainty in Risk Communication

Navigating the uncertainty in risk is a foundational challenge, particularly when evidence about the health effects of a product is unclear or conflicting. Risk is not a static or universal concept; it is relative and can vary significantly depending on whose risk is being measured. Risk also exists on a continuum. It is often based on limited bodies of evidence and can be shrouded in uncertainty, particularly when evaluating short- versus long-term implications. Risk uncertainty—combined with the public's discomfort with ambiguous information—poses a significant challenge for those working to craft effective messages.

As science progresses, messages must evolve accordingly, which creates the challenge of maintaining public trust amidst changing advice. For instance, when communicating about tobacco product usage, understanding risk involves acknowledging a "Continuum of Harm" and the principle of harm reduction. From the perspective of harm reduction, the ultimate goal is to encourage individuals to quit the use of all tobacco products or to prevent the initiation of use given the absolute risk inherent to all tobacco products. However, suggesting less harmful alternatives for individuals who cannot or are not ready to quit might be the next best step. Crafting messages that accurately depict relative risks without endorsing the use of any tobacco products is a substantial challenge, complicated by uncertainties about absolute risks, continually evolving products in the marketplace, and mistrust of scientific data from government entities.

Strategy: Using Experimental Studies to Identify Evidence-Based Solutions

An effective strategy to overcome the challenge of navigating uncertainty in risk communication is to use experimental studies with controlled conditions and randomization. In support of the FDA, RTI International has conducted extensive research over the last two decades on effective communication about tobacco products, prescription drugs, and other regulated substances. These studies have systematically tested various messages to determine which features are helpful when communicators are navigating uncertainty and striving to clearly convey risk information.

For instance, while the risks associated with combustible tobacco products like cigarettes are well established, those associated with newer products like flavored disposable vaping devices and oral nicotine pouches are still unclear. An RTI study found that messages acknowledging this uncertainty led to decreased risk perceptions about vaping without affecting intentions to start or quit.[2]

Experimental designs can test different variables, such as including and excluding unnecessary information[3], distracting visuals[4], or integrating quantitative risk data[5] to improve public understanding. However, not every strategy is successful. For example, adding risk context led to cognitive overload in one study.[6] Revising the format or style of risk information presentation—through methods like bolding, text size or contrast, framing, plain language, dual modality presentations, and frequency of exposure—often improved information processing but had limited effects on downstream factors such as risk perceptions, trust, or behavioral intentions.[7] [8] [9] More research is needed to identify the most effective elements for clearly conveying risk information and addressing public discomfort with ambiguity.

Strategy: Rebuilding and Maintaining Public Trust

The erosion of trust in authoritative sources presents significant challenges to risk communication. A lack of trust in government, scientific institutions, or the media can lead to public skepticism and resistance to risk mitigation measures or messages. Designing studies and initiatives to rebuild and maintain public trust in scientific and governmental institutions and the scientific process overall can have important downstream effects.

In July 2019, RTI hosted an event called *Trust in Science* in Research Triangle Park, NC. The goal of the event was to foster collaborations and strengthen connections between nonprofit and funding organizations to address trust-related challenges affecting science and scientists. Key themes and ideas from this event emphasized the importance of transparency, consistent communication, and active engagement with the public to build trust.[10]

Clarifying how the FDA makes approval decisions can significantly enhance trust among both the public and health care professionals. It is not just consumers who need clear communication campaigns; health care professionals also benefit from better understanding regulatory pathways.

Recently, RTI and the FDA examined physicians' familiarity with the FDA's "Breakthrough Therapy" designation.[11] The study found that a third of physicians misunderstood the evidence required for this designation. It also revealed that many physicians preferred drugs described as "FDA-designated breakthrough drugs" over identical options. This indicates a need for targeted communication to ensure that both members of the public and health care professionals accurately interpret regulatory designations and trust the FDA's decision-making processes.

Challenge 2: Ensuring Information Is Truthful and Not Misleading

Ensuring that information is truthful and not misleading is another challenging aspect of risk communication. Communicators must strive to provide a holistic view that does not unduly alarm or reassure the public. The integrity of this balance is crucial for informed decision-making, where the benefits are appropriately weighed against potential harms. One critical challenge is understanding when something can be factually true but still misleading.

For example, an FDA-funded study showed that participants were deceived by implied claims in promotional materials, indicating that consumers often make inferences beyond what is explicitly stated.[12] RTI continues to collaborate with the FDA to better understand misleading terms and claims in the drug and tobacco space. Research collaborations between RTI and the FDA have demonstrated that consumer and physician perceptions of drug efficacy and risk can be influenced by extrinsic factors—such as comparative price cues[13 14 15]—and that both efficacy- and non-efficacy-related comparative claims can shape efficacy and risk perceptions.[16] Even claims that are not expressly false can be misleading through the inferences they imply.[12 17]

RTI and the FDA are building an evidence base to show that implicit marketing claims have the potential to affect perceptions of risks and benefits underpinning both consumer and physician treatment choices for prescription drug products. They are also exploring ways to mitigate misperceptions through the use of disclosures.

Strategy: Making Clear and Comprehensive Disclosures

To address the challenge of ensuring information is truthful and not misleading, it is essential to implement clear and comprehensive disclosures. Disclosures can provide context for the information presented, including any limitations of the data, potential risks, and uncertainties.

For instance, RTI's research has shown that disclosures can mitigate the effects of implicit claims by providing necessary context.[3 12 14] In one study, the FDA engaged RTI to evaluate how ingredient disclosure information—presented in six distinct formats—impacted the understanding of the health hazards of smoking among youth and adults.[18] The study found that —although all formats improved understanding—they also carried a risk of misleading participants. This highlights the need for disclosures to be tested through experimental studies to ensure they enhance comprehension without causing misconceptions.

For a broader discussion on awareness of misinformation in health-related advertising, empirical ways to evaluate misinformation rejection and deception, and an experimental study examining consumer and physician audiences' ability to detect and report deceptive health messages, see:

- **Betts et al., 2021**
  https://pubmed.ncbi.nlm.nih.gov/33840305/
- **Boudewyns et al., 2018**
  https://www.researchgate.net/publication/323322533
- **Paquin et al., 2022**
  https://academic.oup.com/ct/article-abstract/32/1/25/6338420

Strategy: Leveraging New Advancements in Generative Artificial Intelligence (AI) Technology and Digital Modernization

Data analytics and emerging technologies can predict misinformation spread, analyze text and image data in real-time, and tailor risk communication messages for different audience segments at scale. Generative AI —widely adopted by the public—allows for rapid content generation and manipulation of images and videos, complicating the detection of false information. Regulatory agencies and researchers must embrace these technologies to understand their implications and applications for public health and risk communication. By using generative AI, agencies can enhance their ability to deliver accurate, timely, and targeted risk messages, effectively addressing misinformation.

RTI's data scientists and subject matter experts are exploring the effectiveness of generative AI tools in automating cumbersome and time-consuming tasks, including developing plain language content faster and coding of unstructured text, such as social media posts, blog posts, and more.

To counteract false claims, the speed of designing and testing messages across audience segments must be accelerated. Leveraging generative AI tools allows for rapid development and testing of messages while ensuring an equitable approach to meeting the diverse information needs of various audiences. Real-time testing can quickly refine messages to resonate with different subgroups.

Strategy: Active Science Monitoring

Continuous monitoring systems should be established to track scientific advancements and misinformation trends, ensuring timely updates to public messages. Although researchers and communicators can track scientific advancements through traditional systems like peer-reviewed publications, these methods are often slow. Meanwhile, the public is exposed to a constant barrage of information, which is constantly evolving and is often without context and sometimes false. The rapid scale at which information is shared online today necessitates a real-time monitoring of the information ecosystem. Efforts to design and implement real-time information surveillance systems should be a priority within the FDA's data modernization initiative.

For example, to help clients monitor the rapidly evolving vaping product marketplace, RTI has developed the Electronic Nicotine Delivery System (ENDS) Tracker, a dashboard that summarizes real-time data from social media and Google search trends, as well as quarterly product sales data and advertising expenditures. To learn more about the ENDS Tracker, contact endstracker@rti.org.

Challenge 3: Effectively Communicating Risk in a Cluttered Information Ecosystem

The modern information ecosystem is cluttered. This impacts communication, as the sheer volume and complexity of information available exceeds an individual's ability to process and understand it.[19] [20] [21] In today's media environment, risk messages must compete for attention amidst a deluge of information from credible and questionable sources alike, where sensationalism and simple heuristics often overshadow nuanced discussion. The challenge for risk communicators is to craft messages that stand out and resonate amidst the noise, all while remaining accurate and balanced.

Strategy: Using Formative Research to Shape Messaging

Conducting formative research is essential for effective risk communication because it provides a data-driven foundation for understanding the knowledge, attitudes, and beliefs of an intended audience (e.g., a specific cultural or age group).[22] This research helps isolate specific characteristics that shape perceptions and comprehension of risk messages, allowing for targeted and tailored communication strategies.[23] Although tailoring communication strategies may require significant resources, the investment can yield substantial returns.

For example, RTI's formative research for *The Real Cost* campaign was crucial to understanding youth perceptions about tobacco products and identifying key audience segments. [24] Additionally, formative research can help identify and prevent unintended messaging effects, ensuring that campaigns are both effective and responsible.

Strategy: Using Real-World Testing Environments

Creating testing environments that accurately reflect where the public encounters risk information—such as virtual realities or social simulations—is crucial. Although messages are often tested in controlled settings via focus groups or surveys, their real-world impact can differ significantly from the test setting. More studies are needed to examine risk communication in natural environments where evidence-based messages must compete with other content.

Challenge 4: Navigating Regulatory Constraints

The FDA's actions are often limited by legislative mandates, such as those set forth in the Family Smoking Prevention and Tobacco Control Act (TCA) of 2009. This Act stipulates that communication about harmful constituents in tobacco products must be comprehensible and not misleading to the average person. It also imposes specific limitations on the messages that can be disseminated. For example, the TCA restricts the extent to which the FDA can change the current text statements on cigarette warnings and requires evidence that new statements would promote greater public understanding of the risks of tobacco products. Therefore, the FDA must determine the best way to communicate the risks of tobacco products within the legal framework.

Research conducted by RTI has highlighted the difficulties the FDA faces in meeting these requirements.[18 25] Such studies demonstrate the intricacies involved in presenting information on cigarette ingredients in a way that enhances understanding without being deceptive. RTI has conducted several FDA-funded studies that explored whether pictorial warnings improve the understanding of smoking risks compared to conventional text warnings.[26 27] The findings indicate that most pictorial warnings do indeed improve risk awareness. These insights have been instrumental in shaping the FDA's rulemaking regarding pictorial warning labels, enabling the agency to meet its obligations under the TCA, while effectively communicating risks.

Strategy: Actively Collaborating with a Network of Credible Stakeholders

Scholars argue that risk communications' interdisciplinary tradition should be further nurtured to drive the next evolutionary phase of risk communication research.[28] To effectively navigate regulatory constraints and improve public understanding of risks, the federal government must actively collaborate with nonprofits, academic institutions, and industry. These partnerships can support collaborative research on new communication techniques, message framing, and dissemination channels that comply with regulatory constraints.

For example, the ever-changing social media environment presents unique regulatory challenges.[29 30] New platforms regularly emerge, making it difficult for regulators to monitor content adequately due to privacy settings and access issues. Additionally, constraints on some platforms make it difficult for regulators to even see what communication is disseminated. For example, if prescription drugs are promoted on TikTok but federal employees are banned from accessing the platform, they cannot adequately monitor and regulate the content.

Furthermore, although the FDA can regulate industry claims, it lacks the authority to control misleading claims made by individuals. Social media algorithms—designed to customize content for users—further complicate the assessment of message exposure. Overcoming these challenges requires active collaboration with state health departments, health care providers, and technology companies. Such partners can help monitor the social media ecosystem, identify disinformation using advanced AI tools, and amplify credible sources by redesigning algorithms and search results.

For over 20 years, RTI has partnered with FDA offices —including the Center for Tobacco Products and the Office of Prescription Drug Promotion, within the Center for Drug Evaluation and Research—to improve communication about risky products. This partnership has generated an expansive body of research dedicated to addressing challenges in risk communication and has informed evidence-based, clear communication strategies to help the public make informed decisions about their health. Continual evaluation of these initiatives is crucial for shaping more effective strategies in this domain.

Key Takeaways

- **Multifaceted Challenges:** Addressing the complex challenges in risk communication requires clear, concise, and accurate messaging strategies. Communicators must understand how to convey uncertainty, provide comprehensive yet manageable risk information, and use audience segmentation to enhance message impact. An agile approach that embraces technological complexity and data modernization is increasingly necessary.

- **Collaborative Approach:** The evolving technology and information landscape requires a collaborative approach with public and private sector partners. These efforts are essential to creating a balanced public information ecosystem and fostering a collective understanding of science and its advancements, protecting public health.

- **Advanced Monitoring Systems:** There is a need for cutting-edge information systems, AI-assisted technologies, and digital platforms to monitor the information environment and identify sources of misinformation. These resources can help ensure that accurate information prevails in a cluttered information ecosystem.

- **Rebuilding Public Trust:** Efforts to rebuild public trust in government and health institutions are crucial. Intended audiences must have trust in the institution disseminating a message to act upon it effectively.

- **Effective Messaging:** Effective risk communication requires clear messaging that considers the audience and the credibility of the source. Using plain language and actively countering misinformation are key strategies to improve communication and ensure public understanding.

- **Emphasis on Diverse Research Methods:** A continued emphasis on a variety of research methods—including experimental studies, formative work, and real-world testing environments—is vital. These approaches help understand intended audiences better and ensure that risk communication strategies are both effective and responsible.

These key takeaways underscore the importance of strategic, research-driven approaches to risk communication, emphasizing the need for collaboration, advanced technology, public trust, clear messaging, and ongoing research. By incorporating these elements, risk communication can be more effective in conveying vital information to individuals, whether about everyday risks or crises.

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