



COMMUNICATING RISKS AND BENEFITS:

An Evidence-Based User's Guide

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Communicating Risks and Benefits: An Evidence-Based User's Guide

Table of Contents

Introduction to Evidence-Based Communication	Page
Chapter 1: Introduction - <i>(Editors)</i>	1
Chapter 2: Goals - <i>Noel Brewer</i>	3
Chapter 3: Evaluation - <i>Julie Downs</i>	11
Chapter 4: Duty to Inform - <i>Baruch Fischhoff</i>	19
Chapter 5: Language - <i>Musa Mayer</i>	31
Evidence-Based Best Guesses at Best Practices	
<i>Basic Processes</i>	
Chapter 6: Definitions - <i>Baruch Fischhoff</i>	41
Chapter 7: Quantitative Information - <i>Angie Fagerlin, Ellen Peters</i>	53
Chapter 8: Qualitative Information - <i>Julie Downs, Baruch Fischhoff</i>	65
Chapter 9: Health Literacy - <i>Michael Wolf</i>	77
Chapter 10: Affect and Emotion - <i>Ellen Peters</i>	89
Chapter 11: Information and Persuasion - <i>Mary Brown, Christine Bruhn</i>	101
Chapter 12: Across the Life Span - <i>Valerie Reyna</i>	111
Chapter 13: Health Care Professionals - <i>Betsy Sleath, Michael Goldstein</i>	121
<i>Communication Design</i>	
Chapter 14: Readability, Comprehension, and Usability - <i>Linda Neuhauser, Kala Paul</i>	129
Chapter 15: Warnings and Disclosures - <i>J. Craig Andrews</i>	149
Chapter 16: Human Factors - <i>Gavin Huntley-Fenner</i>	163
Chapter 17: Shared Decision Making - <i>Nananda Col</i>	173
Chapter 18: News Coverage - <i>Gary Schwitzer</i>	185
Chapter 19: Inside the Organization - <i>Caron Chess</i>	195
Implementing Evidence-Based Communication	
Chapter 20: Practitioner Perspectives - <i>Lee Zwanziger</i>	205
Chapter 21: An Agency Perspective - <i>Nancy Ostrove</i>	215
Chapter 22: Strategic Planning - <i>(Editors)</i>	223

Chapter 1: Introduction

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Organizations bear economic, legal, and ethical obligations to provide useful information about the risks and benefits of their products, policies, and services. Failure to fulfill those obligations can be costly, as seen with Three Mile Island, Hurricane Katrina, Vioxx, and other cases when people believe that they have been denied vital information. Less dramatic versions of these problems arise with poorly handled produce recalls, badly labeled appliances, and confusing medication instructions. Financial analysts estimate that 70% of a typical private firm's assets are intangibles, like goodwill, that can be lost when communications fail. Public institutions' reputations often depend on their ability to communicate.

Risk communication is the term of art used for situations when people need good information to make sound choices. It is distinguished from public affairs (or public relations) communication by its commitment to accuracy and its avoidance of spin. Having been spun adds insult to injury for people who have been hurt because they were inadequately informed. Risk communications must deal with the benefits that risk decisions can produce (e.g., profits from investments, better health from medical procedures), as well as the risks — making the term something of a misnomer, although less clumsy than a more inclusive one.

The risk communication research literature is large and diverse, including results from many contributing disciplines (e.g., psychology, decision science, sociology, communications) and a wide range of applications. Unfortunately, the norms of academic research make it inaccessible to outsiders, filling it with jargon and technical details. Moreover, academic researchers' theoretical interests often lead to studying communication processes in isolation, leaving gaps as to how research results apply to complex, real-world situations. Unable to access the research literature, practitioners rely on their intuition, unproven *best practices*, and popular accounts of psychological research.

This guide seeks to fill that gap, making evidence-based communication possible. The chapters that follow cover key topics in risk communication,

focusing on three questions:

- (1) What does the science say about that aspect of human behavior?
- (2) What are the practical implications of those scientific results?
- (3) How can one evaluate communications based on that science?

These questions assume that sound communications must be evidence-based in two related ways. One is that communications should be consistent with the science — and not do things known not to work nor ignore known problems. The second is communications should be evaluated — because even the best science cannot guarantee results. Rather, the best science produces the best-informed *best guesses* about how well communications will work. However, even these best guesses can miss the mark, meaning that they must be evaluated to determine how good they are and how they can be improved.

Each chapter in the guide is self-contained, so that its issues can be studied on their own. Each is written as simply as possible, consistent with fidelity to the science it reports. Each includes both the references documenting its claims and an annotated list of further readings. They offer evaluation methods suited to practitioners with no budget, a small budget, and a budget worthy of the stakes riding on the communication — so that evaluation can become part of every application.

Some chapters deal with the audience (e.g., how people interpret quantitative information, how emotions — and age — affect risk perceptions), others with communications (e.g., decision aids, mass media). Introductory chapters consider the goals of risk communications (Chapter 2), methods for evaluating them (Chapter 3), standards for assessing their adequacy (Chapter 4), and the language that they use (Chapter 5). The first of three concluding chapters reports the perspectives of the committee's practitioner members (Chapter 20). The second concluding chapter places the guide in the context of the strategic communication initiatives of the U.S. Food and Drug Administration (FDA), including the Risk Communication Advisory Committee, which created the guide (Chapter 21). The final chapter summarizes the state of the science and the steps that organizations can take toward evidence-based communication (Chapter 22).

FDA regulates some 20% of the U.S. consumer economy, including food, drugs, medical devices, and dietary supplements. This guide applies not only to all those products, but to any situation with a duty or desire to inform. We hope that it will help to foster a community of researchers and practitioners committed to evidence-based communications. We invite readers to join that community. Membership should not only aid their own work, but also help to protect the commons of public goodwill upon which all communications depend. Everyone benefits when individuals receive needed information in a timely, concise, comprehensible way, building warranted trust in their own decision-making abilities and in the institutions that support them.

Chapter 2: Goals

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Summary

This chapter reviews three goals for risk communication. Just presenting risk information is an inadequate goal. More ambitious and defensible is to change what people think, or possibly, to change their behavior. Aiming to change beliefs or behavior provides specific outcomes for evaluating whether the risk communication worked.

Introduction

Risk messages are so common that we often barely think about them: Smoking increases your risk for cancer. Don't drink and drive. The terrorism threat level is orange. But what's the point? Some risk messages seem to be merely about sharing information, or just getting it said. Others seem to be about changing what people believe or how they behave. As people charged with the task of communicating risk, we need to think carefully about what we can expect from specific risk messages and from broader risk communication efforts. The National Research Council emphasizes the need to link goals and outcomes: "A risk communication is successful to the extent that it contributes to the outcomes its sponsor desires."¹

Scarce resources raise the stakes for risk communication, because you may not get a second chance to have impact. A paradox is that you should think first about goals rather than resources. Experts in planning risk communication start with tools like logic models² that allow them to think first about what outcomes they want to achieve. These specific outcomes will suggest goals that you can refine to meet your resources. However, making available resources the starting point can limit creativity and shut down options before they can be explored.

This chapter presents three simple goals of risk communication (Figure).



They don't apply to all audiences, communicators, or problems. It will be up to you to decide what fits your risk communication needs. It comes down to Alice's dilemma in *Alice in Wonderland*³:

"Would you tell me, please, which way I ought to go from here?"

"That depends a good deal on where you want to get to," said the Cat.

"I don't much care where—" said Alice.

"Then it doesn't matter which way you go," said the Cat.

"—so long as I get somewhere," Alice added as an explanation.

"Oh, you're sure to do that," said the Cat, "if you only walk long enough."

It's probably not enough to try something and hope it will work. Doing so, may leave you in Alice's dilemma of just trying to get "somewhere."

Goal 1. Share information

The simplest form of risk communication has the goal of just putting risk information out there. It does not need to be easy to understand or have a clear message about what people need to do. Just say it. We see these messages all the time on consumer products. Many legal disclaimers have the flavor of just saying it. A company or agency relieves a legal responsibility by making the information available.

The goal of just saying it will rarely match the implicit goals of responsible and ethical risk communication. Indeed, ethics may require that people understand the risk message. Some risk communication materials seem almost willfully hard to understand. Package inserts for drugs are one example. Prescription drugs come with detailed information about how to take them, their side effects, and how they work in the body. However, package inserts often come in very small type, printed on paper that is folded over on itself a half dozen times. Taken as a whole, it fairly shouts: "Don't read me!"

This just-say-it approach can be well intended. Consent forms tell participants about risks and benefits of being in a research study. Scientific papers share the latest epidemiological evidence. Press releases recite specific scientific findings about a new hazard. If people are skilled and motivated, they can make sense of it. More often, I suspect, they are bored or confused by these long, technical documents written using complex language. Lawyers, editors, and scientists may insist on saying things precisely, but it does little to help everyday people.

Negative effects of unclear or confusing risk messages include that people may ignore the messages or even laugh at them. Everyone knows mattress warning labels say removing them can be illegal, but few people know why. One result is that mattress warning labels have become a familiar punch line for jokes. Labels that are just plain odd include labels on sleeping pills that say they cause drowsiness or labels on hair dryers that say they should not be used while asleep. Such silly warning labels have inspired web sites, contests, and even books (“Remove Child before Folding: The 101 Stupidest, Silliest, and Wackiest Warning Labels Ever”).⁴ These odd labels don’t create trust among consumers, and I suspect they have not saved lives.

A more positive form of this just-say-it approach is a community forum for sharing risk information. The community may benefit from the process of receiving the risk information, regardless of whether people truly understand what they heard. They may feel valued for having been chosen to receive the information, come to understand one another better, or interact in various ways that reinforce the fabric of their community. Thus, receiving and discussing the risk information can be a good enough outcome. However, even in such cases, risk communicators should always strive to do more than just say it.

Goal 2. Change beliefs

A more ambitious goal for risk communication is to change what people know and believe. They might come to know and understand new facts, or come to feel at risk for harm. Less helpfully, they might even accrue erroneous beliefs. I refer to knowledge, attitudes, and opinions simply as beliefs, though some social scientists make important distinctions among these things. In this chapter, I discuss the goal of changing beliefs in a general way, but later chapters discuss in more detail how to craft messages to persuade people they are at risk (Chapter 10) using accessible approaches (Chapters 11, 14).

Changing risk beliefs is a good goal for risk communication when we can’t recommend one course of action for everyone. Sometimes we know that a health behavior is right for everyone, or at least specific groups, but very often we are not sure. In this case, it is especially important to share risk and benefit information to allow people to make their own informed decisions. For example, doctors do not yet know the best treatment for men with elevated prostate specific antigen or PSA test results.⁵ Men could decide to have surgery,

a type of radiation therapy, or another treatment — or they may choose to do nothing at all. As none of these treatments is known to have the best outcome, these men’s choices will depend solely on their values. And making the choice well requires men to know the risks and benefits of each option. In contrast, the goal of changing beliefs (but not behavior) would be inappropriate for women contemplating cervical cancer screening. It saves lives, and for this reason guidelines clearly recommend most adult women get screened.

Communicating to be understood is consistent with the National Research Council’s recommended approach to risk communication: “Risk communication is successful only if it adequately informs the decision maker.”¹ It also meets what some argue are the ethical requirements for informed decision making.⁶

One challenge is that not all people wish to make decisions about low- or even high-stakes issues or be informed of the various risks and benefits. In a recent study, one in eight women with breast cancer wanted minimal or no involvement with decisions about whether to get chemotherapy.⁷ Indeed, delegating decisions to experts or other trustworthy sources can be efficient, even when the decision is as important as getting treated for cancer. Life would quickly become impossible if all of one’s daily activities required a careful cost-benefit analysis of all the options to find the best one to choose.⁸ For this reason, people routinely take mental shortcuts to make decisions easier. Thus, risk communicators need to know that not all people will want all possible information.

Although making sure that people understand risk information can be an important goal, sometimes people mistakenly aim to change risk beliefs when they really want to change behavior.

Goal 3. Change behavior

Another goal for risk communication is to change people’s behavior. We might want them to stop smoking, get a flu shot, or not eat eggs subject to a food recall due to salmonella contamination. In other words, having people think about it and make a careful decision is not a primary goal. We just want them to act.

During a recent voluntary recall of eggs, FDA wanted people not to eat eggs from certain contaminated facilities. The idea of consumers thinking about the pros and cons of eating these eggs was not on the table by the time the recall happened. There was one message: Don’t eat these eggs.

Changing behavior as a goal for risk communication requires that we know what the best course of action is. Ideas about what people ought to do can come from many places. They might come from research: Most sexually active women should get cervical cancer screening, unless they have had their cervix

removed in a total hysterectomy. They might come from expert advice: Older adults should get an annual flu shot as it is likely to save lives (even though no one can say for sure how well each year's shots will work). They might come from an abundance of caution: The government routinely discourages people from visiting countries that are at war. The common element is that we want people to do a specific thing. Helping them understand the risks and benefits may be a secondary goal or perhaps not a goal at all.

Contrast the decision to get prostate cancer screening (which medical studies offer conflicting advice about) with the decision to get cervical cancer screening. We know that cervical cancer is preventable with regular screening and early treatment. More than half of cervical cancer deaths are among women who never or rarely get screened.⁹ The public health imperative for adult women is clear: Get screened. Indeed, many doctors feel so strongly about this that they withhold birth control pills until women get their annual Pap screening. This is very different from merely informing women about risks to change their beliefs and then just letting them decide about screening. It is still important to make sure women understand why they will be screened, and an individual woman and her doctor may come to their own decision about screening, but experts charged with the health of populations should send eligible women a clear message to get screened.

Communicating to change behavior need not be for the public's benefit. Much advertising has a goal of getting consumers to buy products. Cigarette ads promote a deadly product and in doing so make a lot of money for tobacco companies. They do this by promoting cigarettes as slimming, cool, and sexy. As a counterweight, the FDA's cigarette warning labels take the same highly visual and high-impact approach to show that smoking is ugly, disgusting, and lethal.

Our thinking about changing health and risk behaviors has a long history. Many scientific theories suggest that feeling at risk leads people to protect themselves.^{10,11} Ample evidence supports this idea.¹² Indeed, people who feel at risk for harm are somewhat more likely to try to protect themselves by taking actions like getting a flu shot or taking their medication. However, getting people to believe they are at risk and then to change their behavior turns out to be a tough task.

If behavior change is the goal, risk communication may not be the only, or even the best, solution. We have this idea that merely sharing risk information will change what people do. But does this match what we know to be true in our own lives? Just telling a friend that trans-fats are bad for him or that seat belts save lives is unlikely to make him put down the donuts or buckle up. Many, many studies document failed risk communication campaigns that were designed using state of the art methods by well meaning people.^{13,14} This is one

of the paradoxes of risk communication. People who feel at risk are more likely to take action, but it can be hard to get them to believe they are at risk and then to follow through.

A take home message is that if the main goal is to change behavior, risk communication alone can be a weak way to do that. Public health successes often rely on policy changes, like banning trans-fats in food as New York City did in 2006 or in mandating that cars include seat belts and that people use them as the United States did decades ago. The FDA already adopts this approach with food scares. When possible, they prompt a recall of the questionable product. They also communicate with the public about the risk, but this is a stopgap measure meant to deal with supplies of the food already in people's homes.

Other policy approaches to changing behavior rely on increasing taxes on unhealthy products. Tobacco taxes are the single most effective way to decrease smoking,¹⁵ which is the leading killer of Americans due to its many ill health effects that include stroke, heart disease, and a long list of cancers.¹⁶ An increasingly popular and flexible policy change is to make healthier options the default.¹⁷ In my own work, we find that asking parents to consent to all teen vaccines increases consent for HPV vaccine above asking about just that vaccine on its own.¹⁸ Policies can supplement or even replace risk communication efforts as a way to benefit the public's health and meet program goals.

Evaluation

Each of these goals should lead us to think about evaluation. Just saying it means you have no expectation of impact, and thus you do not need to evaluate the impact. Communicating to change risk beliefs, however, clearly suggests assessing whether risk beliefs actually changed. And communicating to change behavior suggests assessing whether behavior did indeed change. Evaluation is not always needed: One can intervene but not evaluate. This will require using already tested methods and tools with few changes to them. Chapter 3 addresses evaluation in greater depth.

One challenge is that risk messages can have unexpected effects on what people believe. Sometimes they work just fine. In some cases, however, people resist believing they are at risk. In other cases, merely mentioning risks, even very small ones, can cause people to overestimate potential harms and undervalue the benefits. These unexpected effects should not discourage us, but they mean that evaluation of the impact of messages can be important.

Another challenge is that people may tune out risk messages. We exhaust consumers by talking about every possible hazard. Consumers expect us to share information that passes some minimum level of import and relevance. The complexity arises in deciding whether risk and benefit communication meets that need, and evaluation can help.

Conclusions

Choosing a goal for risk communication is fundamentally important. It affects what activities you choose, and what results you can expect. Choose the just-say-it approach if you want to make your lawyers happy, and then say it in language that is as hard to understand as possible. Choose the risk-belief-change approach if you're not sure what the best course of action is for the whole population, but you have credible information about risks and benefits. Choose the behavior-change approach if you know what is best for the population, and then use belief change as a back-up or reinforcement. Whatever you do, make sure you don't join Alice in asking which way to go as long as you get somewhere.

Additional resources

1. <http://www.re-aim.org/tools/Planning%20Tool.pdf>. This helpful website has a checklist for planning interventions, but it can also be applied to risk communication campaign planning.
2. Logic models. For a nice graphical way to show program inputs, outputs and outcomes, search the web for "logic models" or look at the paper by Millar, A., Simeone, R.S., & Carnevale, J.T. (2001). Logic models: A systems tool for performance management. *Evaluation and Program Planning*, 24:73-81.

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Chapter 3: Evaluation

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Summary

Risk communications are all around us, but rarely evaluated. Formal evaluations can improve communications and separate those that work from those that don't, making best use of scarce resources of time and money. This chapter discusses the role of formative, process, and outcome evaluation in avoiding common pitfalls that might undermine a communication's effectiveness

Introduction

Risk communications pervade our daily lives. Public service announcements educate us about early signs of a stroke. Cars beep at us to fasten our safety belts. Television shows how our brains will look on drugs. Cigarette packs warn of the hazards of using the products they contain. Such communications typically operate on the assumption that providing a little information – or motivation – about a risk will help people to avoid it.

However, these messages don't always produce optimal behavior change. The sheer omnipresence of warnings may undermine any single warning's effectiveness.¹ We are accustomed to warnings even for risks that are minimal or self-evident, like a fishing lure that is "harmful if swallowed."² So perhaps it is not surprising that we react to new communications with inattention, rather than heightened alertness. When a computer message pops up, we swat it away without even reading it.³ When credibility is low or ulterior motives are suspected, such as concern for liability, messages may be discredited.⁴ A brazen example comes from the game Pass-Out, which has *Pink Elephant* cards instructing players to "take 5 drinks" but warning them that it is "not intended for use with alcoholic beverages."

Even noticing a risk message is no guarantee of responding appropriately. To do so, one also needs to understand what it is asking,⁵ agree with that recommended course of action,⁶ and have the ability to do it.⁷ Promoting these steps toward improving a communication's effectiveness and determining whether it has worked requires evaluation.

Why formal evaluation is important

Communicators sometimes forego evaluation as an unnecessary and costly step that merely demonstrates what they think they know already.⁸ After devoting time, energy, and passion to creating and disseminating a communication, people deeply desire to believe that it works. But faith is no substitute for scientific evidence of effectiveness. Reliance on intuition and anecdotal observation can result in devoting scarce resources to well-intentioned but ineffective communications.⁹

A formal evaluation will dispassionately reveal whether a communication is effective. If it's not, the communication should be revised or discontinued, freeing up resources so that more promising communications get wider audiences. Future work can then build on the evidence of successes and failures.

Evaluation informs three areas of communication development. *Formative evaluation* guides development by identifying the optimal content, format, delivery channels, and other critical aspects of the message. *Process evaluation* assesses communication delivery, measuring outreach, consistency, and implementation. *Outcome evaluation* determines whether a communication meets its goals.

Formative evaluation. Creating a risk communication requires choices about the best approach. Formative evaluation is used to *form* the communication, helping designers choose content, format, and delivery strategies through participatory (user-centered) design.¹⁰ Sound research focuses members of the target audience on their understanding of the target risk, rather than hypothetical situations, as people have little insight into their reasons for action.¹¹

The *focus group* is a popular method.¹² Unfortunately, the rich data from interactions among group members are difficult to analyze and, indeed, often largely ignored.¹³ Statistical analyses of focus groups require large samples because the interdependency of what members say requires using groups (rather than individuals) as the unit of analysis.¹⁴ *Usability testing*, popular in engineering, asks prospective users of a new tool or communication to “think aloud” as they review it.^{15,16} *Key informant interviews*, popular in ethnography, ask select individuals to share their experience and expertise.¹⁷ The *mental models* approach uses semi-structured interviews and quantitative surveys to map understanding into a scientifically derived expert model.^{5,18}

All these approaches requiring listening to members of the target audience to inform communication development, a labor-intensive step that can be tempting to skip, relying instead on intuition. It's exciting to have a flash of insight into how to get across a message. Indeed, the best communications typically do start out as an idea in the communicator's head. Unfortunately,

that's how the worst ones start out, too. Such intuitions can miss the mark, in part, because the communicator is often not part of the target audience. For example, scientists studying a specific risk may feel that nobody would chance exposure, if they just knew about the risk. According to this intuition, mere awareness of the problem and knowledge of personal susceptibility should be sufficient to motivate action. However, professionals who have dedicated their lives to reducing a particular risk may not appreciate the perspective of people for whom that problem is just one of many. Such misunderstandings increase when the communicator is not a member of the target audience at all. For example, public health officials, parents, and teachers hoping to educate adolescents about drug abuse may have little insight into how teenagers think about drugs and, hence, how they will perceive well-intentioned, but tone-deaf, messages.

A research-based approach takes the guesswork out of communication development. Formative research needs to incorporate creative input when creating a risk communication. However, testing is needed to guide improvements of draft communications so as to promote audience members' comprehension, trust, and empowerment.

Process evaluation. The path from the developer's desk to the target audience presents many obstacles. Process evaluation assesses how well this path is followed, documenting each step to ensure that a communication has maximal impact.¹⁹ Evaluators describe the program and document the procedures needed to implement it, identifying who will deliver the communication and who will receive it. Such evaluators develop a data collection plan with steps, such as identifying stakeholders for consultation or observation and developing instruments to measure their variables of interest.²⁰ A process evaluation can help to explain why a communication had the effects that it did and let others know what to expect if they follow a similar strategy.

Process evaluation is particularly valuable for assessing how well procedures follow the communication plan conceived during development. Assessing *fidelity* to the plan is especially important when there is variability across settings, differences in the communication media, or other opportunities for variability. Deviating from well-conceived procedures can undermine the value of careful formative research.

One common trap is changing a communication's content or delivery to meet *perceived* needs of a specific audience segment. For example, educators may change a communication hoping to make it even better for their own students. Because teachers know their students better than far-off researchers and take pride in their sometimes-difficult job, it is only natural for them to want to try to improve an intervention in ways that suit their classroom and students. Unfortunately, without a research base for guidance, such idiosyncratic

tailoring is more likely to weaken the communication than improve it. If audiences differ sufficiently in their needs to justify such changes, tailoring mechanisms should be devised as part of formative evaluation.

Communication procedures should plan for foreseeable contingencies affecting the planned distribution. People who deliver information or facilitate discussions should be well trained. Unless they are very highly skilled and knowledgeable, their authority to change the content should be minimized. Delivery systems that rely on the Socratic method (asking questions so that audience members infer the message by themselves) or other audience-generated content require special care to ensure that the critical information will be reliably conveyed. Process evaluation can identify and alleviate such problems with dissemination and implementation, and provide documentation to guide future communications.

Outcome evaluation. A high-quality development process should create communications with the best chances of working. The best-laid plans, however, often go awry. To find out if a communication actually has had its intended effect, outcome evaluation is needed.²¹

Outcomes can take many forms, including behaviors (quitting smoking), attitudes (decreased prejudice), knowledge (emergency evacuation plans), skills (using a condom correctly), or intentions (exercising daily). Some outcomes may serve as proxies for larger goals that are difficult to measure. The more distant the outcome is from the goal, the less confidence can be drawn from positive results.²²

Although any outcome evaluation is better than none, high-quality evaluations are costly, making it tempting to cut corners. One common shortcut is to rely on immediate post-test surveys, rather than waiting for changes in behavior. However, self-reports on surveys are often problematic, especially for attitudes, knowledge, and intentions. The attitudes that participants report may be biased by their desire to help the researcher or to look good, leading them to answer how they think they should, rather than give their real opinions. Such *demand effects* are particularly prevalent following transparent communications: Presenting risks of smoking and then asking how the audience feels about smoking is likely to generate biased answers. Self-reported knowledge levels can be unreliable, too, insofar as people tend to be poor judges of how much they know, failing to appreciate what they do not know; a validated test assessing actual knowledge of relevant facts is preferred. Self-reported intentions to engage in behavior can suffer from both demand effects and lack of self-insight (seen in forecasting errors). The more abstract the stated intention, the less well it predicts behavior. For example, the intention “to give blood today at 3:15 at the blood drive in my building” will be a better predictor of actually giving blood than a general intention to help others. Even specific intentions may not predict behavior very well, as people

are often unaware of what causes their behavior.¹¹ When imagining future behaviors, people tend to neglect the situational details that might interfere with even the best of intentions.

Another common, but problematic, approach is to compare those who happened to see or use a communication — possibly due to their own choice — to others who didn't see it. Such self-selection can reflect group differences that are confounded with evaluation outcomes, making comparisons tricky. For example, diners ordering from children's menus probably order fewer martinis than diners with regular menus, but nobody would argue that children's menus constitute an effective anti-drinking campaign. Similarly, the finding that diners who read calorie information on menus eat lower-calorie meals (compared to those who say they didn't look at that information)²³ says little about the causal effects of calorie labeling. Correlation need not imply causation. In this case, concern about nutrition may have motivated both the reading and the eating.

Rigorous outcome evaluations (Table) compare the outcomes for a group that is given a communication to a group that doesn't get it, but is otherwise equivalent.²⁴ The strongest design is a randomized controlled trial, with participants randomly assigned to receive the communication or to a control group, making it possible to attribute differences in outcomes to the communication.

Outcome evaluation research designs

Design type	Factors to consider
Randomized controlled trials	Highest quality design for outcome evaluation
	Can definitively establish causality
	Can assess mediators to demonstrate process
Observation of environmental changes	Useful when external validity is especially important
	Gradual, long-term changes
	Inclusion of yoked control population raises confidence in results
Limited comparisons (pre- versus post-communication)	Can be done with very small budget
	Partial support of causality, if other factors are well controlled
	Better than nothing, if measures are well designed

In addition to determining the effect of a communication, randomized controlled trials can measure intervening variables that may explain the mechanisms underlying any observed effects. For example, a communication promoting mammography screening was found to increase the perceived benefits of screening. A mediation analysis found that it worked by increasing readers' perceived susceptibility to breast cancer, not by increasing the perceived severity of the cancer.²⁵

Randomized controlled trials are not always feasible, such as when behaviors are subject to multiple situational forces or the intervention occurs naturally (e.g., exposure to a widely publicized celebrity's illness). In such cases, a quasi-experimental design can still be useful, such as systematically exploring differences between people who were and were not exposed to the communication. Crisis communications (e.g., regarding the anthrax attacks or the SARS outbreak) typically have such confounds and are evaluated poorly, if at all.²⁶ However, whatever the limits to a systematic retrospective evaluation, it is still better than relying on intuition, which can be misleading or even self-serving. Often, reasonable inferences can be made, given precautions such as selecting comparison groups to ensure maximum similarity to those receiving the communication (e.g., drawing people from nearby, similar regions). A *mixed-methods design* might, for example, combine quantitative reports of knowledge or behavior with qualitative descriptions of reactions to the risk communication, to triangulate measures.²⁷ Evaluating crisis communications before they are deployed can both improve their effectiveness (e.g., by reducing terms that mislead or offend recipients) and clarify their impacts (e.g., by knowing how well they are understood in different groups).

When a high-quality comparison is needed, but the resources are lacking, any evaluation is better than none, as long as its limits are understood. One might just measure outcomes of interest in a single group before and after exposure to a communication, taking as much care as possible to craft measures that avoid demand effects (e.g., by using disinterested intermediaries to elicit candid and critical responses) and forecasting errors (e.g., by eliciting knowledge of preferred behaviors, rather than predictions of intended ones). Thoughtful measures that find substantial improvement in pre/post comparisons might even provide the impetus to secure additional funding for a rigorous evaluation. In this spirit, each chapter in the next section of this guide considers how to evaluate one's success in applying its lessons with no budget, a small budget, or an appropriate budget.

Conclusions

Formative evaluation can help create a promising risk communication, process evaluation can improve and document its delivery, and outcome evaluation can quantify its effects. Using strong research methods at each stage will improve both the chances for immediate success and for learning from experience. Understanding those methods can not only make the best of a limited budget, but can also help avoid using misleading methods, such as asking people whether they believe a communication would affect their behavior. The key principle underlying sound evaluation is to measure the desired outcomes as directly as possible (e.g., actual behavior or knowledge), rather than trusting distant proxies (e.g., general intentions or attitudes) or, worse, relying on intuition.

Organizations that view communication as a strategic function²⁸ will find ways to evaluate critical communications, including those that will be used only in rare circumstances. They will realize, for example, that even though telling people to evacuate a burning building may seem to require no testing, a proper process evaluation will ensure that exits are clearly marked—with familiar words and symbols—near doors that allow effective evacuation.¹⁵ They will realize that even messages that seem very simple (e.g., roping off a slippery surface to prevent falls) require evaluation (e.g., whether people choose alternate routes that are actually safer.)²⁹ In these cases, a little forethought and casual input from others can help avoid problems stemming from assumptions that other people will act as we anticipate. Becoming more aware of the assumptions that we make about communication may be the first step in making them better.

Additional resources

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3. Renn O and Levine D. (1991). Credibility and trust in risk communication. In: Kasperson R, Stallen P, Eds. *Communicating Risks to the Public*. Boston, MA: Kluwer Academic Publishers; 175–218. This chapter discusses the need for openness and public involvement in communicating about risk.
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Chapter 4: Duty to Inform

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Summary

After using the best available science and their limited resources to design and evaluate communications, agencies must decide whether the result is adequate to demonstrate fulfilling their duty to inform and use their resources efficiently. To be considered adequate, communications must pass three tests: Contain the information that users need, connect users with that information, and be understood by users.

Introduction

A Definition of Adequacy. The ultimate test of any communication is enabling effective action. To that end, users must receive the communication and extract the information they need.

A communication is adequate if

- it contains the information needed for effective decision making,
- users can access that information, and
- users can comprehend what they access.

This chapter elaborates on these three tests and the choices they pose for policy makers in deciding whether inevitably imperfect communications are, nonetheless, good enough.

Evaluating whether a communication contains the information needed for effective decision making. One way to capture this aspect of adequacy is found in the legal doctrine of informed consent. About half of U.S states require physicians to provide the information that is material to their patients' decisions — the other states have a *professional* standard and require physicians to provide the information that is the customary practice in their specialty.¹ Applied to communications, this test leads to a materiality standard for communication content.

A materiality standard for communication content: A communication is adequate if it contains any information that might affect a significant fraction of users' choices.

This standard could apply to both persuasive communications, designed to encourage desired behaviors (e.g., not smoking, evacuating dangerous places), and to *non-persuasive* communications, designed to facilitate independent choices, when those could legitimately vary across individuals (e.g., whether to undergo a medical procedure with both risks and benefits). In either case, the test takes users' perspective, asking what they need to know to make decisions that provide giving them the best chance of realizing their goals.

One way to formalize this test is with *value-of-information analysis*, a standard decision theory method.²⁻⁴ It asks how much knowing each possible item of information would affect users' ability to choose the best option. In a communication context, value-of-information analysis sets priorities, showing which facts are most worth knowing and which would affect few, if any, decisions. The analysis might find that one item (e.g., a dreaded side effect, a highly valued benefit) is so decisive that a communication is adequate if it includes just that fact. Or, it might identify several potentially relevant facts, which the analysis ranks by decreasing marginal utility. Without setting such priorities, meeting this test could mean failing the other two tests — there is too much information to access and comprehend the facts that really matter.

When users' information priorities vary, applying this test also requires setting priorities among those users. One possible policy is to treat all users equally, so that communications focus on the facts most needed by the most users. Table 1 shows such an application, analyzing the information most material to patients deciding about carotid endarterectomy. This common surgery reduces stroke risk for qualified patients. However, it also poses its own risks, some unique to the procedure, others associated with major surgery per se. The table shows some of these risks, along with the estimated percentage of patients who should decline the surgery, if told about each risk. For example, learning about the risk of death should dissuade 15%, whereas learning about the risk of broken teeth should dissuade only a very few patients (for whom the surgery has only marginal benefit). Based on this analysis, including the top three risks (death, stroke, facial paralysis) would satisfy the materiality standard for most users. Not hiding the other, less material, risks is important for other reasons (e.g., transparency).

Table 1. Value of information for carotid endarterectomy decisions
(percent of patients who would decline surgery, if they knew of each risk)

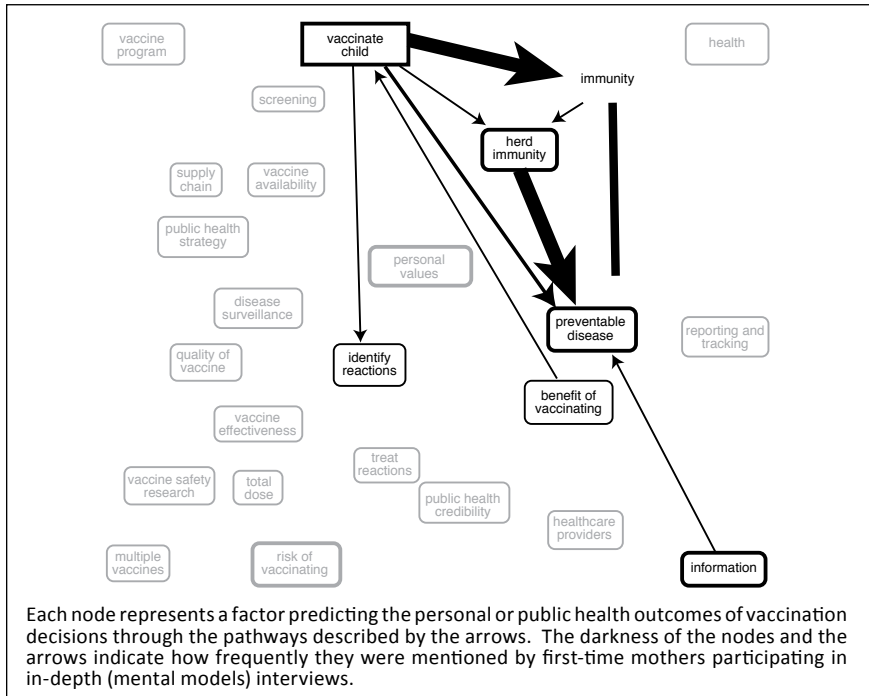
death	15.0%
stroke	5.0
facial pparalysis	3.0
myocardial infarction	1.1
lung damage	0.9
headache	0.8
resurgery	0.4
tracheostomy	0.2
gastrointestinal upset	0.09
broken teeth	0.01

Source: Merz et al. (1993)²⁷

These information priorities might be different, however, if some users were particularly important to policy makers. For example, a communication with just the top three risks in Table 1 would be less adequate if myocardial infarction (#4) were material to the decisions of some especially important users (e.g., those with special needs or without other access to information). When needs vary, any definition of adequacy makes a policy statement about how important users are, if only to say that that they are all treated equally. Feldman-Stewart and her colleagues analyze the adequacy of communications for men with different information needs regarding early stage prostate cancer.^{5,6}

Figure 1 shows a less formal materiality analysis, looking at the facts that might be conveyed to parents deciding about immunizing their children against measles-mumps-rubella (MMR). The full analysis (partially grayed in the figure) is an *expert model* of the factors affecting the risks and benefits of vaccination, patterned after the *influence diagrams* used in risk and decision analysis.^{2,7} The nodes represent variables; the arrows indicate dependencies (such that knowing the value of a tail variable should influence predictions of the head variable).

Figure 1. Expert model of factors relevant to vaccination decisions



Source: Downs et al. (2008)⁸

The dark nodes and links are the ones mentioned most frequently by a sample of first-time mothers as being material to their decisions. Thus, for example, all mentioned the connection between vaccination and disease prevention for their child. None, however, spontaneously mentioned the role of herd immunity, a concern that would be material to decisions that considered public health benefits, such as reducing disease prevalence so as to protect people whose health precludes being vaccinated. Some were concerned about adverse reactions; none, however, mentioned research designed to improve vaccine safety (e.g., post-licensing surveillance). A *communication audit* was used to map publicly available messages into the expert model, as indicators of the topics that their authors considered material. It found that, compared to public health officials, vaccine skeptics did a better job of addressing the issues that the interviewees considered material.⁸ For example, the officials' messages did not to present their view of vaccine safety.

Applying a materiality standard requires knowing what people know already, so as to focus on the facts that they still need to be told. Repeating known facts not only wastes a limited communication opportunity, but can shrink it, by showing insensitivity to users' information needs. As stressed throughout this volume, even modest studies of users' current beliefs can reduce this risk.

Evaluating whether users can access that information. People face two potential barriers to accessing the information that they need (assuming that it has been included in a communication). One barrier is not connecting with the communication. The second is not finding the information in it. In that light, adequate communications must meet a proximity standard for Information accessibility.

A proximity standard for information accessibility: A communication is adequate if it puts most users within X degrees of separation from the needed information, given their normal search patterns.

Access to Information Sources. Adequate communications require distribution systems that reach their audiences. Those systems could include direct links, such as informed consent briefings (e.g., with surgery or human subjects research), standard warnings (e.g., vaccine information sheets, consumer medication pages, home delivered *boil-water* notices), and computer alerts (e.g., product recalls, airline fare changes). These systems could also include indirect links, such as physicians who relay information that they receive directly (e.g., from the pitches of pharmaceutical detailers, Dear Doctor letters, or continuing medical information), friends who follow an issue, or media reports.

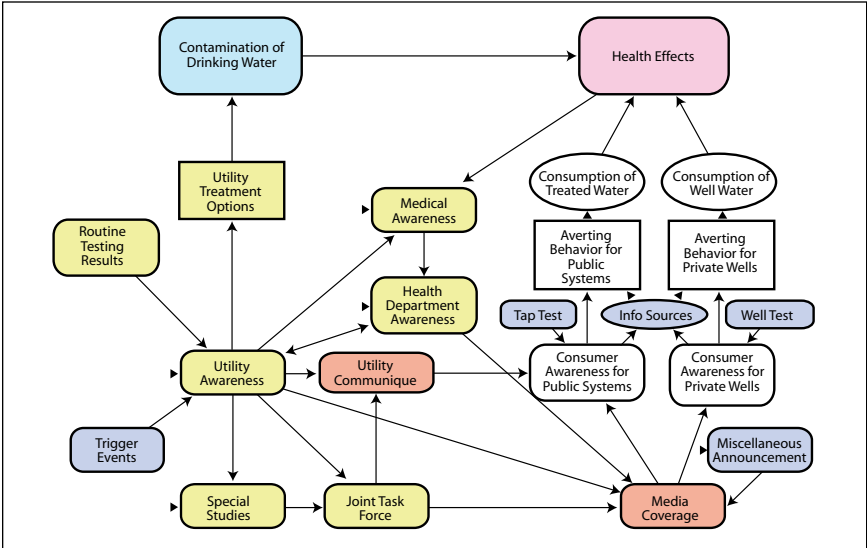
If natural distribution channels are inadequate, then communicators must create additional ones. For example, pharmaceutical communications rely on the natural, indirect channel of having health care professionals convey information that they receive directly, but then supplement it by delivering information directly at the point of purchase. The success of the former channel is partially revealed by studies of how often various kinds of information are conveyed in physician–patient interactions.^{9,10} The success of the latter channel is partially seen in the finding that most U.S. consumers receive mandated consumer medication information along with their prescriptions.¹¹ In the United States, federally mandated vaccine information sheets may have even higher coverage rates. On the other hand, Downs et al. found that the search terms used by the first-time mothers were more likely to take them to web sites of vaccine skeptics, compared to those of vaccine proponents (meaning that the latter are less accessible).⁸

Heterogeneous target populations may require heterogeneous channels. For example, some people are reached most easily by mail, product labels, radio, television, landline, mobile phone, or various social networks. Some people rely on channels within their ethnic, language, faith, or ideological communities. Some need help with seeing, hearing, reading, or concentrating. Some need handholding with technical or threatening information.

Social network analysis provides methods for assessing the flow of information through various channels and to various people, depending on how they are connected.^{12,13} One general lesson from the research is that these flows can be unintuitive, in terms of how quickly word gets around and who gets left out. Christakis and Fowler summarize many network effects, such as the seeming “contagion” of obesity and divorce.¹⁴ Flawed intuitions about networks can lead communicators to overestimate the accessibility of their messages, as when organizations rely too heavily on their partners to contact constituents, or to underestimate it, as when people expect their email communications to remain private forever.¹⁵

The science of networks and the practice of partnering^{16,17} offer guidance on how to design effective channels. Their success is always an empirical question. It can be answered either by assessing which users receive messages or by modeling distribution channels. In an example of the latter approach, Casman et al., created the model in Figure 2 to predict the efficacy of different ways to reduce the health effects of contaminants in domestic water supplies.¹⁸ In an application to cryptosporidium intrusions, for which detection is slow, they found that boil water notices would reach vulnerable (immuno-compromised) individuals too late to be of any value. Thus, for those users, access to the communication would be wholly inadequate. For water contaminants that can be detected more rapidly, the same distribution system might allow timely access.

Figure 2. Model predicting the effects of measures to reduce health effects of contaminants in domestic water supplies



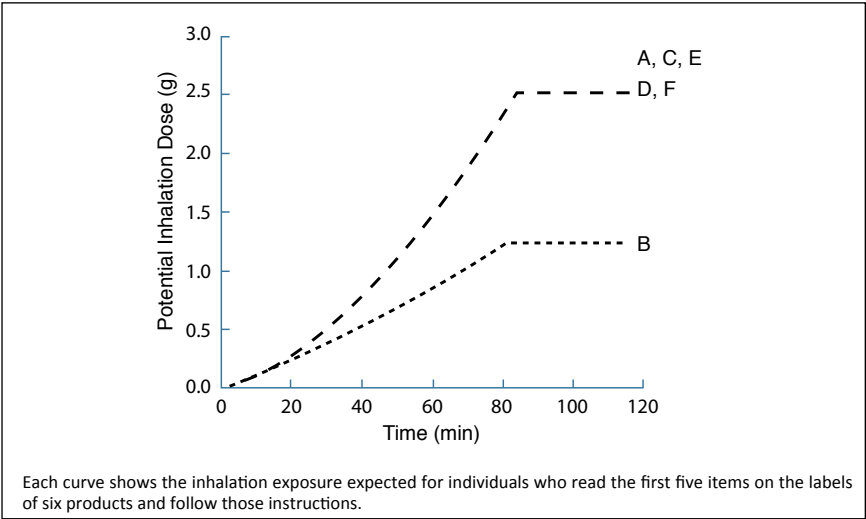
Source: Casman et al. (2000)¹⁸

Access to Message Content. Once users have connected with a communication, they must find the information that they need in it. That process requires effective document design. The principles of such design are well understood.¹⁹⁻²³ They involve addressing both technical issues, such as legibility and clutter, and cognitive ones, such as how attention is directed, how urgency is evoked, and how authority is established. Design guidelines typically provide best guesses for how to meet the needs of modal users, meaning that they cannot guarantee success with any individual, much less a diverse audience.²⁴

As a result, users' access to information within messages is also an empirical question, which also can be answered by direct observation or with models using empirically based assumptions. As an example of the former kind of evidence, Winterstein and Kimberlin found that, although most users receive consumer medication information sheets, few can access needed information within them — or even try.¹¹ Online information about protecting personal privacy or computer security is similarly inaccessible to many users, even when system operators are eager to enlist their support.²⁵ Electric utility bills often have information about rates, taxes, conservation, ancillary services, and other things. However, most of that information just gets in the way of users looking for the box that says, "Pay this amount."

Figure 3 shows results from an assessment of information accessibility, focused on the risks of methylene chloride-based paint stripper, a probable carcinogen. A quantitative risk analysis determined the materiality of information about possible protective measures (e.g., move across the room while the solvent is curing, open windows with a fan blowing inward — or outward), by estimating inhalation doses for users who follow them. The analysis then assumes that users adopt each measure that they access on the product label. It determines access based on how they search the label and whether that natural search pattern takes them to where the information is located on it. The figure shows doses for users who naturally read the first five items that they encounter. With Product B, such users would access much more useful information than with the other labels. Users with other search patterns (e.g., read everything on the front, read only warnings, read only use instructions) would access different information and experience different exposures. Information has little value, if users cannot find it with a reasonable effort.

Figure 3. Predicted effects of using methylene chloride-based paint stripper



Source: Riley et al. (2000)²⁸

Evaluating whether users can understand that information. Accessing material content is necessary but not sufficient for users to learn what they need. They must also comprehend the content well enough to incorporate it in their decision making. How well communicators succeed is expressed in a comprehensibility standard for user understanding.

A comprehensibility standard for user understanding: A communication is adequate if most users can extract enough information to make sound choices.

Applying this standard means comparing the decisions made by users with access to the communication to the decisions that fully informed decision makers would make. A poor communication can pass this test if users happen to know enough without it. For example, Eggers and Fischhoff examined how a court-mandated disclaimer for dietary supplements affected user decisions.²⁶ They found that the disclaimer, which said that FDA had not approved the product, confused many users. Some mistakenly thought that the disclaimer reflected antipathy to alternative medicine (meaning that FDA would never approve any dietary supplement); some mistakenly thought that it meant that the product was so effective that FDA allowed its side effects. However, in a case study of effects on men’s decisions regarding saw palmetto (an herb that may provide symptomatic relief for benign prostatic hyperplasia), the poor disclaimer appeared to do no harm. The only way that this specific decision can go badly wrong is if users self-medicate with the supplement, while leaving

serious problems untreated. However, none of the men in this study had enough faith in saw palmetto to self-medicate for long. In decisions involving other products and other users, the disclaimer might fail the comprehensibility standard. That is an empirical and analytical question.

Thus, each decision requires its own evaluation. For example, based on the analysis in Table 1, a communication about carotid endarterectomy would pass the comprehensibility test if its users understood the three top risks well enough to apply that knowledge to their surgery decisions. Based on the study in Figure 1, a vaccine communication would pass if it left most users sufficiently informed about the safety assurances to incorporate that information in their decisions. Based on the study in Figure 3, a paint stripper label should lead users to have fans blow outward from their workspaces (the most effective safety measure) or to knowingly accept the risks of other work practices. (There is no comprehensibility test for communications about cryptosporidium intrusions (Figure 2), as they can say nothing that will enable users to protect themselves.)

Thus, the materiality standard asks whether communications have the information that users must master, the accessibility standard assesses whether that information has reached users, and the comprehensibility standard considers whether users have integrated it well enough with their existing knowledge to apply it when making decisions (Table 2). Other chapters in this volume summarize the science relevant to meeting these tests, when conveying information that is quantitative (Chapters 7, 15), qualitative (Chapter 8), emotion laden (Chapters 5, 10), unfamiliar (Chapters 8, 12, 14), technical (Chapters 7, 9, 12, 16), or persuasive (Chapter 11).

Table 2. Adequacy tests in communication design

A communication is adequate if • It contains the information needed for effective decision making, • users can access that information, and • users can comprehend what they access.
A Materiality Standard for Communication Content A communication is adequate if it contains any information that might affect a significant fraction of users’ choices.
A Proximity Standard for Information Accessibility A communication is adequate if it puts most users within X degrees of separation of the needed information, given their normal search patterns.
A Comprehensibility Standard User Understanding A communication is adequate if most users can extract enough information to make sound choices.

Policy judgments in adequacy decisions. Each of these standards includes verbal quantifiers that must be resolved for it to be applied. For example, the materiality standard recognizes that users' information needs might be so varied that no single communication could serve more than a significant fraction of users, without becoming hopelessly cluttered (and then fail the accessibility standard). Scientists can try to create designs reducing that fraction, then run studies estimating its size. However, policy makers must decide whether the remaining fraction achieved is acceptable (and the communication adequate).

Similarly, the accessibility standard recognizes that reaching all users directly may be infeasible. Hence, it allows putting most users *within X degrees of separation* from the communication. Here, too, scientists can create better designs and evaluate their success (e.g., how well partner organizations relay communications to their constituents). However, policy makers must decide whether too many users are still too far away from the information, however material and comprehensible it might be. Their deliberations might consider such issues as when people are best served by relying on trusted intermediaries, rather than receiving messages directly, so that more separation is better.

Similar questions arise with the other standards. In resolving each, policy makers must decide whether to treat all users equally — and when, for example, communicating well with a few very vulnerable users justifies serving less vulnerable users less well. For example, if forced to choose, policy makers with limited resources might favor hand-delivering boil water notices to immune-compromised individuals over mailing the notices to everyone else. They might also decide that any communication is inadequate and invest those resources in providing vulnerable users with bottled water.

Conclusions

Communications are adequate if they reach people with the information that they need in a form they can use. The adequacy tests presented here specify those requirements in terms that allow assessing compliance, using methods drawn from social and decision science. The results of these assessments characterize the decisions facing policy makers in determining whether a communication is adequate. If it passes the tests, then policy makers may be able to reduce the resources invested in communication. If it fails, then the tests show where the problems lie and how resources might be redeployed (e.g., "People read our messages and understand what we're saying. However, we aren't telling them what they need to know. We should invest more in figuring out what the content of our messages should be."). Having these test results might even help to secure the resources needed for better communications, by demonstrating unacceptable risks created by inadequate ones.

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Chapter 5: Language

Musa Mayer - Patient Advocate

It has been well over two decades since I learned I had breast cancer, but every moment of the day of my diagnosis is still etched permanently in my brain: the look on my husband's face when we were told, the steadying hand of the surgeon and his reassurance that released a flood of tears — and then, later, a sharp stab of anger: how did *he* know I'd be okay? The throb of the biopsy incision as the local anesthetic wore off. The intolerable brightness and noise of the traffic on First Avenue on the ride home. I also felt betrayal, and a sense of shame. My diagnosis had been delayed for well over a year as this tumor grew. How could I have been so gullible, to have blindly accepted my gynecologist's false reassurance that because the palpable lump in my breast wasn't visible on the mammogram, it was nothing to be concerned about? How could he have failed to send me to a surgeon sooner?

Although that afternoon was clouded with emotion, the strongest imperative I felt was to understand, to learn. What, exactly, was I dealing with? I had to know. The biopsy had taken place that same morning, followed within hours by the diagnosis, so my husband and I had been too stunned to think straight when we'd spoken to the surgeon that afternoon. We didn't know what questions to ask. That day, all I knew was that I had choices to make and that they were choices that would change my life.

Within the next few days I would somehow need to absorb a flood of terrifying information about surgery, radiation, and chemotherapy; about whether or not my large tumor had already spread to the lymph nodes under my arm. I was only 46 and had yet to directly confront my mortality. Suddenly, here we were talking about Stage II and optimizing my chances for survival. There was so much to learn, and so little time to learn it. I was clearly in strange territory, with no medical or scientific background and only a slim patient brochure that spoke in useless generalities. This was 1989, before the Internet, before the many patient guides that have since been published. Before we left, we made an appointment to talk with the surgeon again, after the weekend. But how would I manage until then? Where to turn? Who to talk to?

That evening after work, my brother-in-law, a surgeon, dropped off the medical text I'd asked him to buy for me, entitled *Cancer of the Breast*. Unable

to sleep, I sat up all that night and the next day and night, devouring its 800 pages, a medical dictionary at my side, trying to avoid the disturbing pictures of tumors that had broken through the skin and escaped the breast.

Over the next week my crash course expanded as I consulted not only radiation and medical oncologists and a plastic surgeon, but friends of friends, and some of my doctors' other patients who were willing to share their own experiences. These generous women helped most of all—offering warmth, perspective, and the simple but profound observation that I could get through this, as they had, and that life would go on, as it had for them. Quite literally, they bared their breasts to me.

It's worth noting that when weighing the risks and benefits of my treatment decisions, I was as much guided by these women's experiences as I was by my research, or the advice of my doctors. Had I met a woman whose immediate breast reconstruction had failed or been complicated by infection, I might have made a different choice. Later, much later, I met a few women with side effects so severe that they were unable to complete their chemotherapy, but at the time, my point of reference became the cheerful woman my oncologist introduced me to, who appeared to be sailing easily through her treatments. In the mind of a woman in crisis, a fellow patient you can actually talk to may influence you more than any data. A vivid anecdote can easily trump evidence.

By the night before my mastectomy, I felt I understood, at least on a basic level, what I was confronting. I'd cobbled together a small shelter of facts, studies, and first-hand experiences, and that would have to be enough, whatever unknowns inhabited the shadows. As I lay in my hospital bed that night, looking out at the lights of the city, that first desperate turbulence of feelings and dilemmas subsided into a kind of resignation as the scenario I'd chosen began to play itself out. Intense as it was, my crash course had worked, for me. I felt at peace with the choices I'd made. I feel that way now, although in retrospect there was plenty I didn't understand that might have factored into those choices. However limited in its scope, my decision was informed.

Over the years, in my role as patient advocate, I've accompanied many women along the precarious path of treatment decision-making. Some are newly diagnosed; others, having far outlived expectations, bargain for more time. Some have rosy prognoses; others linger at the threshold of hospice care. All struggle with the choices before them.

There is the evidence to draw on, clinical trials of greater or lesser size, merit, and relevance. When talking with these women, I always stress the evidence — when there is evidence. Once you move past initial diagnosis and treatment, however, good evidence from randomized trials is often slim or absent. The term “evidence-based medicine” may be viewed with suspicion. Quoting David Sackett's corrective definition doesn't help much: “The integration of best research evidence with clinical expertise and patient values.”¹ The

term has become politicized, tainted by labels like “rationing,” or “socialized medicine.” Besides, can numbers based on groups of patients be relied on to describe an individual? “I am not a statistic!” women protest, claiming that their circumstances do not fit the cookie cutter formulas they associate with treatment guidelines based on the results of clinical trials.

Personalized medicine is the new buzzword. The emerging genomic reality that breast cancer is not a single disease, but at least five distinct entities, each having its own prognosis and requiring its own set of treatments, only adds further confusion. As molecular markers join staging as a determinant of treatment recommendations, the firm foundation of the large adjuvant trials in early breast cancer begins to erode. Yet, the tools to individualize care are still buried somewhere in a mountain of data and unvalidated biomarkers. Straightforward answers remain few. Discoveries exciting to clinicians and researchers prove unnerving for patients. No one can reliably predict which treatment will work. Complexity reigns. No wonder women feel confused.

Because breast cancer is so common, most people know someone with the disease. We are strongly influenced by the personal experiences of people we know — or even learn about indirectly. Stories of outrage and inspiration, stories of real people trying to cope, are everywhere online, in blogs and on bulletin boards. Understandably anxious about what is to come, the newly diagnosed are often hungry, as I was, for stories that offer a glimpse of what to expect. And as every journalist knows, personal stories can be far more compelling than scientific studies.

One sobering example of this has stayed with me over the years. During the 1990s, repeated media accounts told of young mothers with advanced breast cancer fighting for insurance coverage of an unproven treatment known as bone-marrow or stem-cell transplant. Women were given doses of chemotherapy high enough to kill them (and hopefully eradicate the cancer), then rescued by their own previously donated bone marrow or stem cells. These dramatic stories of a drastic treatment for dire circumstances cast the patient warriors and their heroes, the savior transplanters, against the evil insurers.

In one such case, an HMO called HealthNet refused to pay for a transplant for Nelene Fox, a 40-year-old California woman with advanced breast cancer, on the grounds that the treatment was unproven, and therefore experimental — which was true. But emotion trumped data. She received her transplant anyway, having raised \$212,000 privately, but died eight months later in 1993. The family sued HealthNet, and the jury awarded them \$89 million in punitive damages and for reckless infliction of emotional distress. Though later reduced, this huge award set a precedent for across-the-board insurance coverage for bone marrow transplants and further legitimized and enabled the widespread delivery of what was an unproven and highly toxic treatment, undergone by an estimated 40,000 American women by the end of the decade.²

Oncologists had been persuaded by early-phase studies that showed a greater tumor response, confirming the prevailing dose-response theory that more chemotherapy must be better and by the technology that permitted the stem-cell harvesting and reinfusion that could pull the patient back from the brink of death. Never mind the lack of randomized trials — these doctors were certain it would work, citing patients they knew who had benefitted and recovered fully.

When the randomized trials were finally completed at the end of the decade — the definitive studies that had languished for years, accruing at a snail's pace because of the prevailing belief that the transplants worked — no benefit over standard chemotherapy could be found. By then, the treatment itself had killed thousands of women, many more than it helped.

Although many breast cancer advocates were still helping women with locally advanced and metastatic breast cancer gain access to this treatment, cruel circumstance had mobilized me in the opposite direction. I'd already had two close friends die horrible deaths from this treatment, a loss made doubly horrible when I learned — too late! — how scanty the evidence was. What happened to Pat and Mary, the way that they died, will probably always haunt me.

This was a treatment that made people desperately ill, that required hospitalization and isolation, that was hugely expensive. What made it so compelling? Certainly the heart wrenching stories in the media played a role. Another part of the answer may lie in language, in the warlike metaphors so common to the public discourse on cancer that we barely notice them anymore: Clearly, this treatment was “the big guns,” engaging patients in a heroic, last-ditch fight that brought them to the brink, then pulled them back. Cancer, the devious invader, is fought with the strongest weapon. Often described as “brave warriors,” those with the disease either “emerge victorious,” or they die, having “lost their battles,” to quote the typical obituary. Those who survive being “slashed, burned, and poisoned,” as surgery, radiation, and chemo have been characterized, are celebrated as courageous survivors.

Cancer patients certainly deserve our respect for enduring the rigors of treatment, but my point is that when it comes to treatment choices, warlike habits of language and thought may have unwelcome consequences. They encourage overly aggressive treatment and burden end-of-life decisions with the shame-inducing freight of “surrender” and “giving up the fight.”

Entwined with the military metaphors is the entrenched belief that stronger, more arduous treatment must be better. Women newly diagnosed with metastatic breast cancer have just received the devastating news that their disease is no longer curable and will ultimately cost them their lives. Emerging from the shock and grief of that prognosis, they prepare to do battle. Yet more likely than not, their oncologists prescribe a once-a-day anti-estrogenic pill

that for most has few side effects. This worries them. “Shouldn’t I be getting something stronger?” they want to know. Actually, no, I explain: this little pill is the most effective targeted treatment for your particular kind of breast cancer, more effective than strong chemo would be, more long-lasting and less toxic — and you won’t lose your hair! I show them the data, and I can see them struggling to reconcile this with their previous beliefs about what constitutes effective treatment, that being sick and bald is proof of potency.

But paradigms are changing in cancer treatment. For some patients different metaphors work better. “I really find myself drawn to living with, and finding accommodations,” wrote Jenilu Schoolman. At Stage IV, her cancer could not be cured, so she chose to see herself cohabiting in relative peace with her cancer, in what she called a “multi-cultural housing unit.”³ Many imagine a journey to an unfamiliar land, including writer Susan Sontag, who argued for a language of illness purged of metaphor. “Illness is the night-side of life, a more onerous citizenship,” Sontag wrote. “Everyone who is born holds dual citizenship, in the kingdom of the well and in the kingdom of the sick. Although we all prefer to use only the good passport, sooner or later each of us is obliged, at least for a spell, to identify ourselves as citizens of that other place.”⁴

We definitely require new metaphors, or perhaps no metaphors beyond the science itself. Where military metaphors persist, it’s clearly becoming a different kind of war. These days, we’re talking about the new “smart bombs” that avoid “collateral damage.” Other misunderstandings can color treatment decisions. Hope conspires with lack of evidence to make treatments that are new look far more appealing than older, approved approaches whose efficacy and safety are well-characterized. But newer may not be better. Because they’ve undergone only limited testing in select patient groups, a minimal amount is known about cancer drugs when they are first approved by FDA. Describing an arc familiar to those who follow cancer drug development, hope and excitement flourish for each new agent in its early days. Inevitably this honeymoon is followed by disappointment, as evidence for resistance, lessened efficacy and side-effects begins to emerge.

In making treatment decisions, we’re also encumbered by our own history and memories. A woman I knew who had witnessed her father suffering terribly from chemotherapy when she was a child, was so traumatized by that memory that she refused treatment altogether for her Stage II breast cancer. Yet, after meeting several women who were tolerating their chemotherapy well, she felt able to begin treatment.

Complicating treatment choices further is the yearning we all feel for some kind of certainty. When your life is threatened, you want these choices to be simple and obvious. You want the treatment whose benefit is *proven*. You want the *answer*. But what if the truth is far more complicated? Some

questions — including those most important to us — have no ready answers: “Will my cancer come back? Am I cured?” Sometimes, even the most avid information-seekers feel very small, overtaken by a childlike longing for reassurance and certainty.

Even when the facts are presented clearly to us, we may not be able to take them in. Selective listening and avoidance may be in some ways protective, serving to keep hope alive. Yet, informed consent for treatment and clinical trials participation depends upon a realistic understanding of the benefits and risks of treatment. When they are scared, people will often underestimate risk, and overestimate benefits. They may be willing to take very significant risks of being harmed by treatment for a very small likelihood of benefit. Where clinical trials are concerned, this has been called the “therapeutic misconception.” Bioethics expert Paul Applebaum estimates that as many as 70% of patients enrolling in research studies believe that the research will offer them a direct benefit, despite an informed consent process that clearly states otherwise.⁵

One ethical requirement for controlled, randomized trials — the studies that offer the highest level of evidence — is “clinical equipoise,” which holds that the researchers must not know which of the treatments being compared is superior.⁶ Yet both patients and investigators may share a strong belief in the superiority of the experimental treatment long before the outcome of the trial is known, sometimes even before the trial begins. This may lead them to see such a trial as unethical.

Misperceptions of benefits and risks are not only the result of human foibles. They are purposefully cultivated by forces in society. Media alarmism, exaggeration, and oversimplification of health care issues is pervasive. Although often justified as educational, marketing and advertizing of drugs and other products to physicians and patients is carefully crafted to enhance perception of benefits and minimize perception of risk. Marketing works, as our massive consumption of these products clearly demonstrates. The lack of comparative, quantifiable data in direct-to-consumer drug marketing makes any kind of deliberative process almost impossible. All of this is compounded by an almost total lack of education in how to be an informed consumer of health care. How do we know what we know in medicine? Where does the evidence come from, and how believable is it? Most people have no idea.

Faced with diagnosis, each woman with breast cancer discovers her own path. I’ve learned that some do not thirst for all the medical details, nor do they want to learn anything specific about the research that supports one choice over another. Many just want the bottom line. Their quest is for a trusted doctor to tell them what’s best for them. Some find their equilibrium much more easily; others are simply overwhelmed. Some make their choices quickly, while others agonize for weeks. Some find relief in focusing on the cancer, diving as deep as they can into a sea of information, as I did; others

seek distraction and screen out most medical details. Some need to know the worst that can happen, but many more do not and turn away from any discussion of prognosis. Some only want to be alone, while others find great relief in sharing. As I reached out to help others, I learned not to impose my way on them and to take their lead.

Filled with conflicting emotions, desperate to know, yet struggling to absorb and understand, and with so much to learn in the way of context — this is what it is like to be a patient diagnosed with a life-threatening disease, especially at first. We can be rational, brave, even a bit cavalier, at one moment, but give us a bit of bad news, or another bitter dose of uncertainty, and we abruptly find ourselves weeping and feeling betrayed by our bodies, once again. In the beginning, it doesn't take much. In time, we adapt and stabilize, as the strange and once-frightening landscape of cancer becomes familiar ground.

I've tried here to suggest some of the ways in which circumstance, personality, expectations, hopes, and fears can complicate a rational weighing of risks and benefits for patients. Clearly, we need an anchor in turbulent waters, so as not to be swept away. I believe that truth must be that anchor — even if we find it upsetting, even if we can't look at it for long, or absorb it easily, even if we need to revisit it repeatedly to grasp what is actually being said. We may not seek out the truth ourselves, or be able to pay much attention to it in moments of crisis, but we need to know it is there when we and our family members are ready to face it. Answers may be what we long for, but it is truth, however incomplete, that sustains us in the end.

We deserve accurate, quantified information about the known benefits of treatments we are considering. We need answers to questions like how good the treatments are that we're being asked to consider, and what level of evidence we have for their use. How long have they been studied, and in how many patients? Are those patients like us, or do they differ in meaningful ways? If high-quality research has not yet produced the answers we seek, we need to know that too. Although we would love to banish uncertainty, we would far rather face the unknown mindfully than blindly.

We deserve to learn about both short- and long-term risks of treatments, in so far as they are known. Many of the drugs cancer patients take are highly toxic. Not only do they make us sick and tired and bald while we are taking them, but they can damage our hearts and other organs, and cause secondary cancers in the years that follow. Although we appreciate the protective instincts that lead our health care professionals to simplify and soft-pedal toxicities, sparing us these scary possibilities is fundamentally untruthful and leads to decisions in which we do not fully participate and may later regret. What we really need are the tools that can help us make sense of potential benefits and potential harms.

We deserve accurate, readily available, culturally sensitive, evidence-based patient informational materials on diseases and conditions, drugs and other forms of treatment, prepared by independent arbiters of information skilled in risk communication. Although good examples do exist online, we lack a way to reliably guide people to the best sources. Much of what I do as a patient advocate is to tailor such information for patient needs, not only to help people find the information and research relevant to their particular situation, but also to aid them in developing the ability to search on their own.

We deserve to be taught the fundamentals of how evidence is gathered in medicine as a matter of public education and public health and how to evaluate its quality. Since we are all lifelong health care consumers, understanding research ought to be as fundamental to our education as reading and math. Personal health crises are arguably the worst time to try to make sense of these complex issues. Yet without some sort of basic understanding, we are easily misled and confused. We need to learn, as part of the curriculum, about observational studies, clinical trials, levels of evidence, and the basics of assessing risk. If we can learn to balance our checkbooks and prepare our taxes, surely a simple grounding in statistics is not completely out of reach.

We deserve to know when we are being marketed and who stands to profit from the treatments we take. The usual defense of direct-to-consumer marketing is that it educates patients about diseases and conditions, who may then be helped by the product in question. Although some patient educational materials produced by industry are clearly well-intentioned and well-designed, how are patients to know where the unbiased information leaves off and the flat-out promotion begins? Advertising works for the companies and their shareholders, but how much does it really benefit the patient? As a citizen of one of the only two countries in the world that permits public advertising of prescription drugs, I have a hard time believing that the disproportionately larger quantities of drugs and medical procedures we consume in the United States have made us healthier—not when World Health Organization statistics tell us we lag far behind most other developed countries in measures of public health.⁷

We deserve research that asks and answers questions that matter, especially comparative effectiveness research to resolve important clinical uncertainties. In my view, too much current research asks questions that really don't matter to patients. Every year at the San Antonio Breast Cancer Symposium I find myself wondering: how many more single-arm, phase II trials of chemo combinations do we need? Is anyone helped by these studies? Where are the large comparative trials to help us find the best treatment among similar drugs? Where are the studies that incorporate non-drug strategies, like lifestyle changes? We need large, simple studies and expanded access programs of promising agents in late-phase development. The lack of such

studies is surely a contributory factor to low enrollment in cancer clinical trials and to the dearth of safety data in real-world populations prior to drug approval.

We deserve time with our health care professionals to help us make informed decisions. Most patients count on their doctors as learned intermediaries, to help them navigate difficult treatment decisions. Yet too often, appointments are brief and rushed. Our doctors and nurses are not reimbursed for the time it takes to sit down and talk through a complex issue. But there is no substitute for the time a doctor spends with a prepared patient and family. By prepared, I mean that patients will have already learned and absorbed the bad news, perhaps at an earlier visit, had time to process their feelings and be comforted by those who love them, and that they will have had access to some basic information about the condition and their treatment options.

I see patient education as the most important part of my work as an advocate, helping women with metastatic breast cancer and their families learn about the specific form of the disease they have and available treatments. How far they take this learning process varies according to their abilities and motivation, but all can grasp the fundamentals—or a trusted family member can learn and act on their behalf. My goal is to empower women and their families with the information they need, to help them enter into a collaborative process of informed decision-making with their doctors.

I will end where I began, with that vulnerable patient having to make tough and irrevocable choices based on imperfect knowledge. This is the human condition; nothing is more basic or more necessary for us to understand. We should never lose sight of how lost that woman is feeling and how much she depends on all of us, working together, to offer her the very best we can provide.

Endnotes

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Chapter 6: Definitions

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Summary

Useful communications must address the outcomes that interest users. Meeting that challenge means appropriately defining the risks, other costs, and benefits of the choices facing users. Social and decision science research offers ways to avoid missing the target, when choosing the topics of communications.

Introduction

Successful communications tell people what they need to know about the risks, other costs, and benefits of the decisions they face. *Non-persuasive* communications, which make no recommendations, succeed if recipients know enough to choose the option most likely to achieve their goals. Persuasive communications succeed if recipients feel that they are being told to do the things that they would choose, were they fully informed.

Both kinds of communication require knowing which outcomes matter to people. Those may include uncertain negative outcomes, or *risks* (e.g., possible drug side effects); certain negative outcomes, or *costs* (e.g., the price of a drug); certain positive outcomes, or *benefits* (e.g., social approval), and uncertain *positive outcomes* (e.g., better health). For example, open-heart surgery has a risk of dying, certain costs of pain and expense, and uncertain benefits of better health and longer life.

Without knowing which outcomes their audience values, communicators cannot know which facts to gather and convey. Research has identified several barriers to getting the outcomes right. Some reflect communicators not understanding their audiences' circumstances (e.g., talking about the importance of regular medical checkups to people who lack the health insurance needed to pay for it; talking about safety to teens who also want to have fun). Some reflect their audiences not understanding their own circumstances (e.g., what does palliative care entail? What else do I need to know about it? How can I compare it to intensive care?).

Theoretical background: what does the science say?

The design of any communication should begin by asking which options its recipients might choose and how that choice might affect outcomes that

matter to them. Technical specialists are an obvious source of knowledge about what those outcomes might be (e.g., the scientists who manage a medical clinical trial, the engineers who analyze system failures, or the designers who create new products). However, the research finds that people cannot reliably predict which outcomes matter to other people; indeed, they sometimes cannot even predict what they themselves value. As a result, determining the content of communications requires consulting with both experts and decision makers, along with research that reveals perspectives that they miss.

People exaggerate how well they understand others' perspectives.

This general tendency, perhaps familiar to most people in their everyday communication¹ has many expressions. One is the *common knowledge effect*² : People exaggerate how much of their knowledge is shared by others. As a result, they fail to say important things, expecting others to know them already. Thus, a physician might assume that patients know that they will be tired long after a surgery; salespeople might assume that customers know that they will be hot (or itchy) wearing a new fabric; grocers may assume that people know that bar codes do not guarantee that a food is traceable to its source, in case of an outbreak. Without knowing what people know already, communicators cannot know which outcomes to include in their messages.

Researcher sometimes fall prey to this bias when they charge people with *attitude-behavior inconsistency*,³ when attitudes (e.g., healthy living is important to me) do not predict behavior (e.g., diet, exercise). However, those charges are misplaced if researchers have overlooked other outcomes that influence those choices (e.g., Healthy living is important, however, I also need to spend time with my family and have a long commute. I know that I should eat better, but it's hard to get fresh vegetables in my neighborhood). Some miscommunication arises when people do not realize that they are using the same term to refer to different outcomes. For example, *healthy living* might imply eating right, exercising often, or being spiritually balanced — to different people. *Eating right* might refer to fat, calories, animal content, or processed food content. *Animal content* might or might not include fish, cheese, or honey.

Even elaborate communications can miss the mark if they neglect important outcomes. For example, women entering college often receive instruction in how to reduce their risk of sexual assault. However, that instruction often addresses one outcome, physical wellbeing, when young women also consider others, such as developing sustained (and safe) relationships.⁴ Instruction is also limited if it defines key terms (e.g., sex, coerced, safe sex) differently than do members of its audience.⁵ Vaccine communications can miss the mark if they fail to mention relevant benefits, such as the protection that herd immunity provides to people who cannot get vaccinated because of other health problems — or if they fail to address costs relevant to some

recipients, such as the effects of compulsory vaccination on civil liberties.⁶ The communicators may reject those costs or see straightforward ways to opt out of *compulsory* vaccination. However, unless they address these outcomes, their communications are incomplete.⁷

When faced with novel choices or difficult tradeoffs, people may not know what matters most to them, making them vulnerable to how options are presented (or framed). Psychologists have demonstrated many *context effects*, whereby seemingly irrelevant changes in wording affect choices. For example, people are typically more willing to refuse to allow an action (e.g., smoking near a building) than they are willing to forbid it, even though the outcome is the same.³ People are more likely to be organ donors if that option is the *default* on their driver's license than if they must choose that status, even when opting in or out is easy.⁸ People will often pay more for a good, if the bidding starts at a higher price.⁹ People make promises when feeling energetic (or calm) that they find hard to keep when feeling tired (or angry).¹⁰

In such situations, when people do not know what they want, they must construct their preferences from whichever concerns come to mind.¹¹ Under favorable conditions, the construction process produces stable preferences, immune to context effects. For example, some people figure out what kind of end-of-life care they want, then stay the course come what may (in their health status, family pressure, etc.). One condition favorable to achieving stable preferences is being shown alternative perspectives. That way, for example, patients won't find themselves suffering from regret (e.g., I didn't think about palliative care as a form of treatment and not just giving up. I wish I had). A second favorable condition is getting an appreciation of the range of possible outcomes. That way, for example, patients don't find themselves suffering from needless surprises (e.g., I never realized that the treatment could be so painful (satisfying, expensive, etc.)). Except for sacred values that cannot be compromised (e.g., taboos, deeply shared cultural norms), the importance of any outcome depends on that range.¹² Thus, even people obsessed with money worry about other outcomes, when all options have roughly similar prices.¹³

Personal advisors (e.g., client-centered counselors; decision consultants) try to create these conditions, so that people understand all the outcomes that their choices might affect and why they might care about them. Communicators addressing broader audiences, however, cannot engage in the extended interactions needed to explore alternative definitions of the costs, risks, and benefits of a decision. Unless they have studied the audience, their communications may not raise perspectives that people want to consider. Not showing the full context of a decision can lead to biased choices — even when no bias is intended. For example, drivers renewing their licenses might think, “If I have to make an effort to become an organ donor, I guess that's not what most people do (or what my society values).”

Values are sometimes embedded in how choices are defined. Some context effects reflect deliberate attempts to manipulate choices by highlighting particular perspectives. Others are unwitting results of communicators' natural ways of thinking, such that they do not even realize which values they are conveying. Uncovering hidden values has long been a focus of risk research. For example, if a decision entails a chance of dying, that outcome will be part of the definition of *risk*. One common way to define *dying* is in terms of annual fatalities. Although seemingly uncontroversial, that definition makes a strong value statement, namely that all deaths are equal.¹⁴ An alternative definition of the *risk of dying* is in terms of *life-years lost* when a person dies prematurely. It places greater weight on deaths of young people, as more years are lost when they die — and hence on accidents, which affect young people disproportionately. *Quality-adjusted life years* (QALYs; pronounced “kwallies”), a definition favored by some health policy analysts, considers the health of the deceased, placing greater value on losing a healthy year than an unhealthy one.

However *risk* (or *cost* or *benefit*) is defined, its expected size must be expressed in some statistical term. That choice, too, can favor some perspectives over others. For example, McNeil et al.,¹⁵ observed that lung cancer patients who had surgery (rather than radiation) were more likely to be alive five years later, but not two years later — because surgery extended the life of those who survived it. As a result, reporting survival statistics for just one period (two or five years) presents an incomplete picture. Similarly, reporting just the lifetime probability of a disease obscures how those risks are distributed over time, such as how breast and prostate cancers occur primarily late in life. Another statistical choice is between reporting relative or absolute risks. Because there is no way to infer the latter from the former, absolute risks are always more informative. Doubling a risk means very different things if that entails going from 10% to 20% or from 0.001% to 0.002%.¹⁶ Even when they contain the same information, different summaries can highlight different perspectives, hence bias choices.¹⁷

Although quantitative summaries can be problematic, they are essential for communicating how big risks (and benefits) are. Verbal expressions (e.g., rare, possible, large) are known to mean different things to different people and to the same people in different contexts.¹⁸ Among themselves, say, physicians may know what one another means by a “rare side effect”; however, patients can only guess, hence might misunderstand the risk they are facing. However, an undue focus on readily quantifiable outcomes can obscure other features that matter when evaluating risks. In a seminal analysis, Starr¹⁹ proposed that people treat voluntary and involuntary risks differently, demanding greater benefits from involuntary ones, before finding them acceptable. Subsequent research identified many other features that people sometimes consider when evaluating risks. These features include how uncertain, uncontrollable, inequitable, and dreaded risks are.²⁰ Unless these qualitative features of risk

are mentioned explicitly, people may overlook them or think that they are less legitimate than the quantitative measures of risk that are presented. Analogous issues arise with measures of benefits and costs. Fortunately, the science that has identified these potential problems also offers ways to address them.

What general practical advice can the science support?

The first step in any communication is to define risks, costs, and benefits in ways that allow people to construct stable, informed preferences. Doing so requires knowing what is at stake, crafting suitable measures, and testing the result to see how well it serves users' needs.

Life would be simpler, if there were a universal set of basic human values that all communications could address. Indeed, there have been some notable attempts to identify such values.²¹ Unfortunately, the lists are typically both too long and too general to guide any specific communication. Thus, knowing, say, that people have a need for achievement or for self-realization is not that much help to deciding what to say about the costs, risks, or benefits of a medical procedure or financial product. A more feasible strategy might be to create standard general definitions for particular kinds of decisions. Three examples follow, each combining substantive knowledge (of what the outcomes might be), analytical expertise (in defining those outcomes), and empirical research (into how the communications actually work).

Use standard definitions for risks with multiple outcomes. At times, people know so little that they must rely on experts to identify the outcomes that might matter to them. For example, nutrition facts boxes present some food constituents related to some health outcomes. The boxes require users to make the connections, such as the complex one between sodium and hypertension. Lists of ingredient report everything that is in a product, enabling knowledgeable users to make connections to any outcome that matters to them (although they won't know how much there is of each). As a result, these lists are necessary, but not sufficient, for users to create their own outcome measures. The Drug Fact box in Figure 1 has experts choose outcomes for specific products (rather than have the same items for every product). The box also structures the choice for users, by comparing two options (taking the drug or sugar pill) on seven outcomes (for this product), without saying how they should be weighed. Most people can extract the information needed for decision-making purposes from such displays.²² The same strategy could be tried wherever experts can identify and quantify the risks and benefits that matter to users.

Use standard definitions for risks with multiple features. Figure 2 shows an approach to capturing the many features that a single outcome (such as the risk of dying) may have.^{19,20} On the left, it includes readily quantified outcomes

(deaths, other forms of physical harm). On the right, it has six features chosen to represent qualitative features of risk, recognizing that people may judge risks differently if they are uncertain, uncontrollable, inequitable, or dreaded than if they have the complementary properties. For example, people often are more accepting of familiar risks, perhaps because they have a better feeling for what they entail. They are often less accepting of inequitably distributed risks, perhaps because of moral objections or fear of the insult added to injury, if they are treated badly. The British government, which advanced this proposal,²³ found it straightforward to complete the left-hand side with

Figure 1. A sample Drug Fact box

Prescription Drug Facts: Lunesta (Eszopiclone)		
What is this drug for?	To make it easier to fall or to stay asleep	
Who might consider taking it?	Adults age 18 and older with insomnia for at least 1 month	
Who should NOT take it?	People under 18	
Recommended testing	No blood tests, watch out for abnormal behavior	
Other things to consider doing	Reducing caffeine (especially at night), exercise, regular bedtime, avoid daytime naps	

LUNESTA Study Findings		
788 healthy adults with insomnia for at least 1 month – sleeping less than 6.5 hours per night and/or taking more than 30 minutes to fall asleep – were given LUNESTA or a sugar pill nightly for 6 months. Here's what happened:		
What difference did LUNESTA make?	People given a sugar pill	People given LUNESTA (3 mg each night)
Did LUNESTA help?		
LUNESTA users fell asleep faster (15 minutes faster)	45 minutes to fall asleep	30 minutes to fall asleep
LUNESTA users slept longer (37 minutes longer)	5 hours 45 minutes	6 hours 22 minutes
Did LUNESTA have side effects?	None observed	
Life threatening side effects		
No difference between LUNESTA and sugar pill		
Symptom side effects		
More had unpleasant taste in their mouth (additional 20% due to drug)	6% 6 in 100	26% 26 in 100
More had dizziness (additional 7% due to drug)	3% 3 in 100	10% 10 in 100
More had drowsiness (additional 6% due to drug)	3% 3 in 100	9% 9 in 100
More had dry mouth (additional 5% due to drug)	2% 2 in 100	7% 7 in 100
More had nausea (additional 5% due to drug)	6% 6 in 100	11% 11 in 100

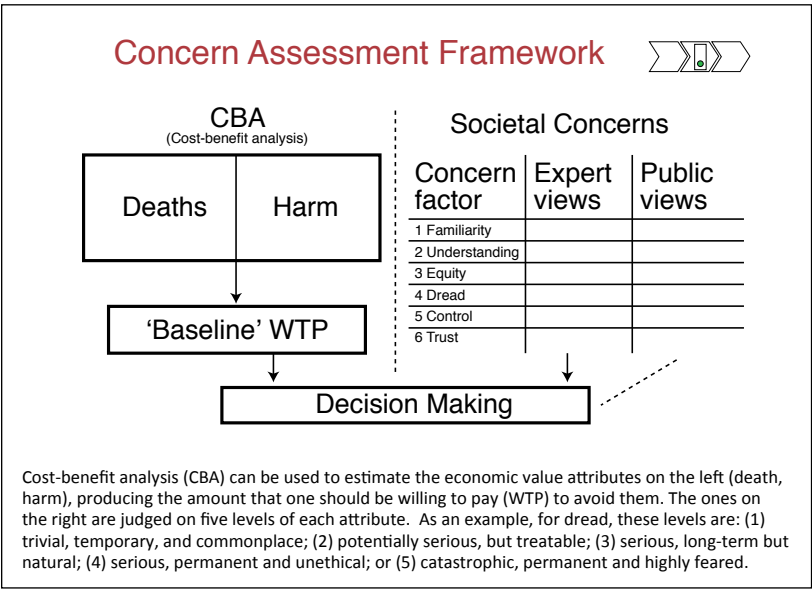
How long has the drug been in use?

Lunesta was approved by FDA in 2005. As with all new drugs we simply don't know how its safety record will hold up over time. In general, if there are unforeseen, serious drug side effects, they emerge after the drug is on the market (when a large enough number of people have used the drug).

This display offers precise definitions of outcomes identified in clinical trials, presented in a format based on behavioral science and evaluated empirically. It includes quantitative estimates of risks, costs, and benefits, as well as indicating the quality of the evidence.

Source: Schwartz, L.M., Woloshin, S. and Welch, G.. Self-published, The Center for Medicine and the Media at The Dartmouth Institute, http://tdi.dartmouth.edu/documents/cmm/LUNESTA_box.pdf.

Figure 2. A standard method for defining risks.



Source: HM Treasury (2005). *Managing risks to the public*. London: Author.

routinely produced estimates, and the right-hand side with simple surveys of members of staff and of the public. Studies find that people can use such displays to construct stable preferences.²⁴

Use standard definitions for outcomes that occur over time. Some decisions involve *streams* of outcomes, such as regular payments or the varying chance of something going wrong at different times. According to economic theory, future monetary outcomes should be *discounted* because the money could be invested at interest (the discount rate) in the interim. (If invested money earns 5% annually, then \$100 today is worth \$105 in a year.) That logic does not extend to non-monetary outcomes. There is no principled reason, though, why, say, pain tomorrow should be less aversive than pain today — although people are free to have that personal preference. Table 1 summarizes behavioral research into reason why people may treat an outcome differently depending on when it is received.²⁵ The first is simply caring less (or more) about one’s present self than one’s future self. Other reasons include caring less about future outcomes because one might not live to receive them or have less ability to enjoy them (e.g., having lost one’s sweet tooth or sense of novelty). Based on this research, communications about outcomes experienced over time must convey when those outcomes may occur. They should also help recipients to think through which of these reasons matter to them (e.g., Will you enjoy (or hate) thinking about this possibility in your future

(or past)? Offering such prompts could help people avoid the regret of having missed something seemingly obvious (e.g., I should have known that I would not be able to get it out of my mind).

Table 1. Reasons for valuing outcomes differently at different times

Differences in	Explanation
Pure time preference	We care less (or more) about our future selves.
Probability	We are less certain about receiving the promised outcome at different times.
Objective consequence	The outcome will have different properties at different times.
Utility	The pleasure (or pain) from the outcome will be different at different times.
Anticipation	The pleasure (or pain) from anticipating the outcome depends on when it is experienced.
Memory	The pleasure (or pain) from remembering an outcome depends on when it is experienced.
Opportunity cost	The value of the outcome depends on how related resources are invested and consumed.

Source: Adapted from Frederick, S., Loewenstein, G. & O'Donoghue, T. (2002). Time discounting and time preference: A critical review. *Journal of Economic Literature*, 40, 351-401

Evaluation

No expense. The minimal test of how well a communication includes the outcomes that matter to people is its *face validity*: Does it include the outcomes relevant to recipients’ choices? Making that determination requires analyzing what is known about the recipients (i.e., which outcomes generally matter to them) and the choices (i.e., which of those valued outcomes are at stake). Problems are to be expected if the communication team (1) lacks some of the requisite expertise (subject matter knowledge, analytical ability, behavioral science), (2) is socially distant from the audience (and its perspectives), or (3) has different goals than that audience (e.g., focuses on health effects to the exclusion of all other outcomes).

Low expense. With a small budget, one can conduct *think-aloud interviews* with people like the eventual recipients, asking them to read through successive drafts, interpreting as they go, encouraged to report problems. Their observations (recorded and perhaps transcribed) can be evaluated for:

- (1) **Comprehensibility:** Do they interpret the content as it was intended? Do they feel like they understand it?
- (2) **Bias:** Do they find the wording biased or offensive? Do they feel inappropriate pressure to make particular choices?

(3) Completeness: Do they perceive omissions? What inferences do they make about the quality of the science?

In a pinch, interviews with staff members not on the communication team, or even friends and family, can provide valuable input if it is clear that the drafts are being tested (and not the interviewees). Community samples can often be recruited inexpensively (e.g., in return for contributions to favorite organizations).

Modest expense. A larger budget allows assessing *construct validity*, asking how sensitive users are to relevant variations in the communications and insensitive to irrelevant ones? For example, the top and bottom sections of Table 2 represent the same outcomes in two different *frames*, cast in positive or negative terms (e.g., survival or mortality). If presenting just the top or the bottom section leads to different choices, each would be inadequate alone. Conversely, one can examine users' sensitivity to the different statistics in the two columns or in the cells, if the five risk factors at the top are varied. Like all tests of construct validity, these require an independent assessment of which differences should matter to which people.²⁶

**Table 2. NICHD Neonatal Research Network (NRN):
Extremely preterm birth outcome data**

Based on the following characteristics:

Gestational Age (Best obstetric Estimate in Completed Weeks: 24 weeks
Birth Weight: 700 grams
Sex: Male
Singleton Birth: Yes
Antenatal Corticosteroids: Yes

Estimated outcomes for infants in the NRN sample are as follows:		
Outcomes	Outcomes for All Infants	Outcomes for Mechanically Ventilated Infants
Survival	62%	64%
Survival without Profound Neurodevelopmental Impairment	44%	46%
Survival without Moderate to Severe Neurodevelopmental Impairment	27%	29%
Death	38%	36%
Death or Profound Neurodevelopmental Impairment	56%	54%
Death or Moderate to Severe Neurodevelopmental Impairment	73%	71%

A standard representation for the predicted outcomes of intensive care (resuscitation) for extremely premature infants, with the alternative choice being palliative (comfort) care. It considers just physical outcomes, saying nothing about social and psychological consequences that cannot be predicted from the physical ones. It presents all outcomes in both a positive frame (chances of survival and escaping disability) and a negative one (chances of death and disability), hoping to avoid the context effect that might arise with just one frame.

Source: NICHD Neonatal Health Network
http://www.nichd.nih.gov/about/org/cdbpm/pp/prog_epbo/epbo_case.cfm (accessed June 11, 2011).

Conclusions

Relevant communications describe the outcomes that matter in the decisions that users face. Unless they define those outcomes appropriately, communications cannot serve users' needs. One threat to such definitions is exaggerating how well one understands the audience. A second is not realizing the values embedded in alternative definitions. A third is presenting incomplete perspectives, thereby biasing the choices. As a result, getting the definitions right requires systematically analyzing the decision and studying the users. Its execution can draw on all the knowledge represented in this volume.

Additional resources

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Chapter 7: Quantitative Information

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Summary

For patients to make informed decisions about their health care, they must understand the risks and benefits of their treatment options, including the numeric likelihoods. Unfortunately, many patients have difficulty understanding numerical information. Evidence-based recommendations are made for improving the communication of numerical information.

Introduction

Approximately 50% of Americans cannot accurately calculate a tip.¹ Almost a quarter of college educated adults do not know what is a higher risk: 1%, 5%, or 10%.² The innumeracy that plagues Americans has a profound impact on patients' ability to understand statistical rates of the risks and benefits of treatment options. Thus, it is not sufficient to simply tell patients that 10% of people experience a side effect...because in many cases, the patients will not be able to understand that information or incorporate it into their decision making.

In the present chapter, we review the concept and measurement of numeracy and summarize the evidence for communicating quantitative health information. We close the chapter by offering practical evidence-based advice on how best to communicate quantitative health information.

What does the science say about this aspect of communication?

Numeracy: its concept, measurement, and influence on information processing. Numeracy has been defined in a number of ways,³ with the broadest definition being the ability to comprehend, use, and attach meaning to numbers. Numeracy is assessed using both objective and subjective measures. Objective measures are basically math tests. Among the first objective measures of numeracy was a three-item test created by Schwartz et al.⁴ The questions revolved around probability, the ability to convert percentages to proportions and vice versa. This scale was incorporated into larger measures by Lipkus et al.,² and Peters et al.,⁵ that used health-related questions. Other objective numeracy measures include the Test of Functional

Health Literacy (TOFHLA)⁶ the Medical Data Interpretation Test,⁷ which measures ability to interpret medical statistics and understand information related to disease, and the New Vital Sign, which uses nutrition panels as the context.⁸ Objective measures of numeracy provide the best estimate of people's ability to understand and use numbers. A weakness of such measures is the significant time required to complete them, which may reduce their usefulness in research or clinical practice, and the frustration people report when completing them.⁹

Subjective numeracy scales assess numerical ability without asking participants to perform mathematical computations. Rather, people assess their own ability to handle numeric information. Several measures currently use this approach. The Subjective Numeracy Scale (SNS) asks four questions that measure perceived ability (e.g., How good are you at calculating a 15% tip?) and four that measure preference for receiving information.^{9,10} The SNS measure takes less time to complete than Lipkus et al.'s objective numeracy measure and is less frustrating and stressful to complete.⁹ Furthermore, it has been found to correlate moderately with Lipkus's objective numeracy measure and to predict some of the behaviors and abilities that Lipkus's measure predicts (e.g., comprehension of survival curves).¹⁰ Additionally, the STAT-Confidence scale assesses people's confidence in their understanding of medical statistics.¹¹

Individuals with higher numeracy skills comprehend more health information¹² and attend to, remember, weigh, and, ultimately, use quantitative information more in their judgments and decisions.¹³⁻¹⁶ Less numerate individuals, on the other hand, appear more likely to weigh and use non-quantitative information, such as narratives and their own mood states, to inform their decision making.

In sum, researchers interested in numeracy have two types of measures from which to choose: objective and subjective. The best measure for any study will depend on the time constraints of participants, the importance of retaining participants in follow-up studies, and the value of obtaining actual numeric ability.

Communicating risk and benefit in qualitative vs. quantitative terms.

Risks and benefits of patient treatments can be described qualitatively and/or quantitatively. With a qualitative description, a patient might be told there is a "low chance" of a side effect from a surgical procedure. In contrast, a quantitative description would describe the same risk numerically — the patient has a 1 out of 100 (1%) chance of developing the side effect. The two approaches, however, are not equally effective.¹⁷ One significant concern is the lack of agreement about what terms, such as *low risk*, mean. To one person a low risk is equated with a risk of 1%, whereas to a second person a low risk might be 10%.¹⁸ Furthermore, research has shown that, in the absence

of numeric benefits and risks (with only verbal descriptors of likelihood), consumers exhibit heightened (and perhaps exaggerated) perceptions of risks and benefits and are less able to identify which are the superior drugs.¹⁹⁻²¹ To make quantitative information easier to understand, it is critical that the information be presented in an understandable way.

Making numerical information comprehensible and useable

Less Is more. In three studies, Peters and colleagues tested whether providing lay decision makers with less information, rather than more, could result in the best outcomes.⁵ These studies showed that requiring less cognitive effort (e.g., by providing less information) in hospital quality reports resulted in better decision making through improved comprehension and higher quality choices, particularly among participants with lower numeracy skills.

This effect was also demonstrated with the breast cancer communication tool called “Adjuvant Online!” (<http://www.adjuvantonline.com>). This on-line tool is designed to help oncologists communicate patient benefits from receiving hormonal therapy and chemotherapy.²² Typically, patients are presented with the risks of no additional treatment, each treatment alone, or both hormonal therapy and chemotherapy. However, for most women, only two choices are appropriate. Zikmund-Fisher and colleagues tested the impact of providing only those two choices and found that, when fewer options were presented, knowledge and speed of processing increased significantly.²³ These studies point towards the importance of having medical experts identify more and less critical elements of a decision so that risk communicators can choose strategically how to present them.

Gain and loss framing. Gain and loss framing refers to how one describes risks and benefits (e.g., the number of people who survive or die, respectively). Research has shown that decisions are sensitive to this information framing.²⁴⁻²⁹ For example, McNeil and colleagues asked patients, graduate students, and physicians to imagine they had lung cancer and make a treatment decision (surgery vs. radiation) based on cumulative probabilities and life-expectancy data.³⁰ The authors manipulated the description of surgery, presenting it in terms of survival or mortality chances. In all three populations, more individuals chose surgery when they were told that it had a 90% survival rate than when they were told that the surgery had a 10% mortality rate.

Edwards and colleagues’ review of the literature found that loss frames messages were generally more effective than gain frames.³¹ When the target behavior is prevention (e.g., infant car restraints, regular physical exercise), however, gain-framed messages are more effective^{25,27} as gain frames work better in situations where the outcomes are certain (e.g., using car seats decreases injuries and deaths of children). On the other hand, with uncertainty and risk (e.g., whether a mammogram will result in a cancer diagnosis), loss frames are more effective in promoting the desired behavior.²⁵

Absolute risk, relative risk, and number needed to treat (NNT). When explaining risks associated with treatment, three approaches exist to describe how the treatment changes risk. For example, when explaining the benefits of taking chemoprevention to prevent breast cancer, risk reduction could be described as (1) a 50% risk reduction (relative risk reduction), (2) a reduction from a 6% risk of breast cancer to 3% (absolute risk reduction) or (3) the number of women needed to take chemoprevention to prevent cancer in one of them (NNT).

Comprehension of information and risk perceptions differ across these three formats. Sheridan and colleagues found that NNT was the most difficult format for patients to understand and recommended that it never be the sole way that information is presented.³² Additionally, when information is presented in a relative risk format, the risk reduction seems larger and treatments are viewed more favorably than when the same information is presented using an absolute risk format.³³⁻³⁵ This is as true for the lay public as it is for medical students.³⁶

Natural frequency versus percentages. When providing data to patients about the risks and benefits of treatment, clinicians can present the data using either percentages (10% of patients) or natural frequencies (10 out of every 100 patients). A number of studies have examined people's understanding of risk and benefit information based on whether the data were presented in terms of frequencies or percentages. Results (and their underlying explanation) have been equivocal.³⁷⁻⁴⁰

The choice between frequencies and percentages also can affect people's perceptions of the riskiness of the treatment.⁴¹ For instance, Peters and colleagues asked participants to imagine they had severe headaches and that a medicine existed that could decrease headache frequency.⁴² Participants read about a possible side effect of the drug in a percentage format (10% of patients get a blistering rash) or frequency format (10 patients out of 100 get a blistering rash). Less numerate participants perceived the medicine as less risky when side-effect information was presented using percentages rather than frequencies. Peters et al., interpreted their results as being due to the frequency formats eliciting greater emotional imagery compared to percentage formats, which were relatively abstract and meaningless.

Time frames. When considering the time frame to use when presenting risk or benefit information, it is critical to consider the following: (1) the time frame for which the best statistics are currently available, (2) the time frame over which events occur, and (3) the time frame that is most understood by patients.⁴³

The time span chosen can influence both knowledge and risk perceptions. People often fail to adjust their risk perceptions to account for longer time spans. For example, people are more likely to increase their use of seatbelts if told they have a 33% lifetime risk of serious injury without seat belts compared

with being told the much smaller risk of injury in a single trip.⁴⁴ Even when people receive risk information in survival graph format (which explicitly shows how risk changes with time), they often fail to adjust their risk perceptions to account for the time span displayed.^{45,46}

Graphical presentation of risk. It is often recommended that graphs be used in addition to presenting numerical information.⁴⁶ Graph types each have their advantages and drawbacks.^{47,48} Identifying the goal of the communication can help to identify the best graph type. If the goal is to help people comprehend comparisons, bar graphs are an excellent choice. If understanding trends over time is the goal, a line graph would be most beneficial. Similarly, pie graphs are superior for accurate judgments about proportions, whereas pictographs are most successful at highlighting the number of people affected, and not affected, by a medical treatment.

Graphs can influence more than one kind of comprehension. Some graphs influence verbatim understanding of precise information, whereas others facilitate understanding the gist of information.⁴⁹ A recent study compared the ability of five graph types (bar graph, pie graph, clock graph, pictograph, and sparkplug) to communicate gist and verbatim information (See Figure 1).¹² Pie and pictographs were superior for communicating gist information (e.g., Which drug resulted in the fewest number of patients needing a bypass surgery?), whereas bar graphs and pictographs were best at communicating verbatim knowledge (accurate reporting of precise numerical information). Systematic studies of the effects of graphs, however, have not been conducted with increasing numbers of attributes (e.g., a medication with ten side effects that each required its own graph). Graphs can influence behavior too. For example, graphs that emphasize the numerator of a risk produce more risk-avoidant behaviors. Conversely, pictographs, which display numerator and denominator information, decrease risk-avoidant behaviors.³⁹

Incremental risk format. As most treatments have side effects, it is important for patients to understand the likelihood they will experience one. Thus, it is important to make clear the differences between the baseline risk of a side effect (i.e., risk that is present without treatment) and the additional/incremental risk experienced due to the treatment.

One method to facilitate comprehension is to visually separate baseline risk from treatment risk. To do this, an initial pictograph presents the patient's baseline risk. A second pictograph adds a new color to represent the additional people who would experience the side effect due to treatment (See Figure 2). In a study of over 600 women considering taking tamoxifen as chemoprevention, we found that this method reduced worry about medication side effects and reduced perceived likelihoods of experiencing a side effect.⁵⁰ Debate exists in the literature whether this approach can be used successfully with tables.^{50,51}

Figure 1. Five types of graphical formats

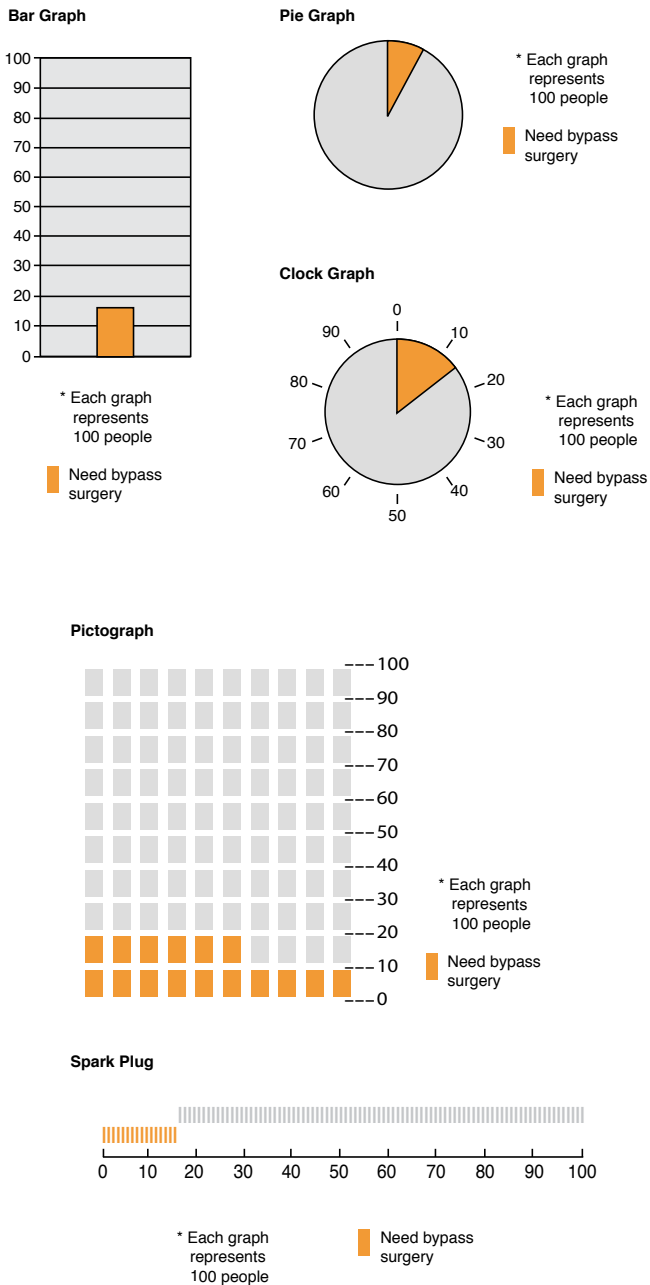
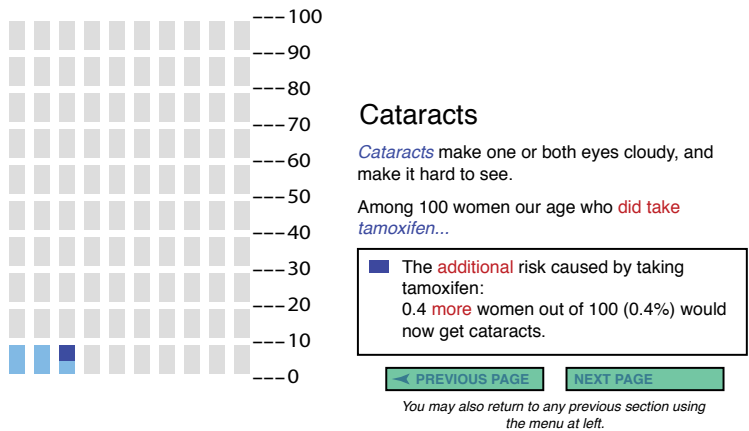


Figure 2. Pictograph showing added risk



The use of interpretive labels. People making decisions can be quite poor at using numeric information in making decisions. Interpreting the meaning of numeric information (e.g., tell patients how good or bad a 9% risk is) can have a robust influence in health judgments and choices across diverse adult populations.¹⁴ In one series of studies, providing interpretive labels resulted in greater use of numeric quality-of-care information in judgments and less reliance on an irrelevant affective state among the less numerate. Decision makers given interpretive labels nonetheless appeared to process the numeric information (and not ignore it due to the presence of labels). In another study, interpretive labels for test results (that a test came back “positive” or “abnormal”) induced larger changes to risk perceptions and behavioral intentions than did numeric results alone.⁵² The normative appropriateness of these changes is often unclear, however, so that interpretive labels should be applied with great care.

What general practical advice can the science support?

In this final section, we recommend ways to *nudge* individuals towards better comprehension and greater welfare. How to present information is an important choice for information providers that should be made with care using an evidence-based approach.

- 1. **Provide numeric likelihoods of risks and benefits.** Describing risks solely with words, such as *You have a low chance of experiencing a side effect* is ineffective. It does not provide patients with the details needed to make an informed decision; it increases risk perceptions, and patients vary in their interpretations of what low and high risks are. Thus, it is imperative to provide patients with numerical estimates of the risks and benefits associated with treatment options. The existence of individuals with lower numeracy skills does not mean that we should avoid presenting numerical

information. Instead, we should work to make numbers more accessible for all individuals. Furthermore, making numbers more accessible is unlikely to have a negative impact on those with higher numeracy skills as they can more flexibly understand information presented in different formats. In addition, information-processing skills decrease under stress. Thus, even highly numerate people can benefit from simple educational materials.

2. **Provide absolute risks, not just relative risks.** Patients are unduly influenced when risk information is presented using a relative risk approach; this can result in suboptimal decisions. Thus, an absolute risk format should be used.
3. **Keep denominators constant for comparisons.** It is difficult for patients to compare across treatments when different denominators are used. A single denominator should be chosen for comparisons (e.g., 1 in 10,000, 337 in 10,000). It is easier for patients to understand whole numbers (e.g., 1 in 10,000) rather than fractions or decimals (.01 in 100); thus, if risks are very small, larger denominators will be necessary.
4. **Keep time frames constant.** To facilitate comparisons, use the same time frame when presenting risks and benefits.
5. **Use pictographs and other visual aids when possible.** Graphs make numeric information easier to understand and pictographs are the best graph for communicating both gist and verbatim knowledge.
6. **Make the differences between baseline and treatment risks and benefits clear.** Use pictographs to show baseline risks in one color and the risks due to treatment in a different color.
7. **Reduce the amount of information shown as much as possible.** Health educators and clinicians are often motivated to provide patients with as much information as possible. However, with more information, patients may not know where to focus their attention and what information should be most important in their decisions. Thus, it is critical that providers of medical information think carefully about which information is key and exclude non-critical information.
8. **Provide both positive and negative frames.** People, particularly those who are less numerate, are unduly influenced by whether a treatment is described in positive or negative terms (e.g., survival rates versus mortality rates). Whenever possible, describe the risks and benefits using both frames. For instance “60% of men who have surgery to treat their prostate cancer will be impotent. This means that 40% of men will not experience impotence.”
9. **Take care using interpretive labels or symbols to convey the meaning of important information.** Interpreting the meaning of numeric information

(in terms of its goodness or badness) can affect people's risk perceptions and change their decision making. It can also improve integration of multiple pieces of numeric information. This technique should, however, be used only when it appears that decision makers are using numeric information inappropriately (e.g., ignoring objective quality-of-care indicators in hospital judgments).

- 10. Test communications prior to use.** It is critical to test educational materials prior to use to determine understandability and to make sure patients do not perceive bias in the materials and like them well enough to use. An iterative testing process is critical (see below for suggestions).

How does one evaluate communications implementing this advice?

No budget. Even when developing communications with no budget, opportunities exist to evaluate them. First, ask experts to review the materials for accuracy and balance. Second, ask coworkers (e.g., housecleaning and cafeteria staff), colleagues, friends, or family (particularly those with less education and experience in risk communication) to evaluate and comment on materials. Ask (1) how understandable the material seemed, (2) whether the amount of information was right, (3) how balanced the material was (in terms of presenting the treatment options), (4) how much they would recommend this material, and (5) how it could be improved.

Modest budget. Additional strategies include one-on-one cognitive interviews. During the cognitive interviews, you can (1) test for comprehension of the materials (e.g., with quizzes after each section) and (2) ask participants to describe their emotional reactions to different sections. It is especially important to include people with less education and lower numeracy and literacy levels and those of different races and genders.

Serious budget. Additional strategies include (1) employ a literacy expert to test the reading and numeracy levels of materials to ensure they are around 6th to 8th grade level (and to provide recommendations for improving the materials if necessary) and (2) test your materials (and alternatives) with a representative sample.

Conclusions

Just as it is no longer appropriate for physicians to dictate treatments to patients, it is also no longer appropriate to write educational materials without thought for how people will understand or use it. Although it is a significant challenge to create materials understandable to populations with low literacy and numeracy skills, the reality is that many individuals have difficulty reading simple text and working with numbers.^{1,2} Therefore, care must be taken to ensure that patients can use educational materials and understand the risks and benefits of their options to make an informed decision.

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Chapter 8: Qualitative Information

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Summary

People often need to understand not only how large risks and benefits are, but also why they are that large. Such qualitative knowledge can make quantitative estimates more intuitive and credible. It enables people to understand their circumstances and adapt their actions when conditions change. Qualitative knowledge affords people active mastery and a warranted feeling of self-efficacy. As a result, it should help people to make better, more confident decisions. Communications designed to improve qualitative knowledge begin by describing the intuitive theories (or mental models) that people currently hold and then proceed to addressing critical gaps in their knowledge. As with all communications, empirical evaluation is needed to determine their adequacy.

Introduction

A simple model of persuasive communication envisions people receiving expert advice and then following it as instructed. A simple model of non-persuasive communication envisions people receiving authoritative risk and benefit estimates and then using them to make independent decisions. For either simple model of communication to work, people must accept the content of the communications without further explanation.

At times, though, people want to know why communications make their claims. That is, they need qualitative information about the processes that create the risks and benefits that their actions might bring — whether they follow a recommendation or make the choice on their own. One reason why qualitative information is needed is to evaluate claims by seeing the evidence supporting them. A second reason is to master a topic to be able to act more effectively, adapt to changing circumstances, and make sense of competing claims. A third reason is to have a warranted feeling of self-efficacy, which comes with understanding one's environment. A fourth reason is to receive the respect that comes with being offered an explanation, rather than being expected to accept claims on faith.

Creating communications for qualitative information follows the same basic steps as creating communications for quantitative information¹: Identify the most relevant information, determine audience members' current beliefs, draft messages focused on critical gaps, evaluate those drafts, revise them as needed,² and assess the resulting communication's adequacy, relative to the demands placed on it.³ An added burden on qualitative communications is that recipients must be able to integrate the new information with their existing beliefs. Unless they can create a coherent mental model from all they have learned, the new information will confuse, rather than inform them.⁴

Theoretical background: what does the science say?

Qualitative information can vary widely in its importance. There are many factors that affect the risks and benefits of foods, pharmaceuticals, motor vehicles, life styles, and most other things. However, typically, only a few of those factors really matter.⁵ Focusing on those few factors makes best use of individuals' inevitably limited attention. For dieters, a critical piece of information might be how the body metabolizes whole versus refined grains. For homeowners with radon concerns, it might be how the gas concentrates and dissipates. For patients managing chronic health issues, it might be how drugs interact with one another and with foods (e.g., statins and grapefruit).

People interpret specific situations by assembling mental models from general beliefs that they have acquired over their lives. These mental models enable them to make inferences in diverse, even novel situations. However, those inferences will be flawed if the mental models are incomplete or include erroneous beliefs. For example, fears of electromagnetic fields are exacerbated by not realizing how quickly they fall off, as one moves away from them.⁶ Fears of hypertension are attenuated by not realizing the threat lurking in an asymptomatic condition.⁷ People believe that their homes will heat (or cool) faster if they turn their thermostat past the target value, increasing the chance that it will get too hot (or cold).⁸ Often, such misconceptions are easy enough to correct, if one knows that they are there.

Some physical and biological processes are unintuitive. When that happens, people may not appreciate the efficacy of protective behaviors. For example, people who cannot imagine how tenaciously some pathogens adhere to porous surfaces are less likely to wash their hands (or their cantaloupe) adequately. People who expect underinflated tires to be visibly flat are less likely to check their air pressure. People who think that having a fan circulate the air protects them from dangerous fumes are less likely to have one blowing outward through an open window. People who think that expansive lawns represent healthy environments are less likely to plant pollinators. Correcting these mental models may require offering new ways of thinking about the unintuitive processes (e.g., how pathogens hang on, how air circulates in rooms, how tires hold their shape, how complex healthy ecosystems are).

Some behavioral processes are unintuitive. The social and behavioral sciences exist because people have incomplete insight into how they, and others, respond to many situations.⁹ For example, people are often surprised to learn that one is more likely to get help in an emergency if there is just one person nearby than if there are dozens, or that panic is rare in disasters, or that most people adjust even to great adversity.¹⁰ Here, too, creating stable changes in individuals' mental models requires offering them new ways to think about these processes, in effect, teaching them the relevant social and behavioral theory. For example, communications might explain how diffusion of responsibility makes helping less likely; how panic seems common because we see it in movies, but not reality; how status quo bias leads to exaggerating the value of our current state and underestimating our ability to find meaning in a new one.

Some dynamic processes are unintuitive. Even when individual processes are understood, their interactions may not be. For example, patients may unwittingly take risks not realizing that taking two over-the-counter drugs for a problem exceeds the safety limit of a shared ingredient (e.g., acetaminophen). Dieters may be unpleasantly surprised when improving one eating habit triggers negative changes in another. Proponents of abstinence-only education may experience unexpected disappointment when formerly abstinent teens fail to use protection because they have not learned to manage sexual encounters. Climate and the economy are other familiar domains in which individually comprehensible components interact in unintuitive ways. Sometimes, learning the integrating principle will be enough to correct these problems (e.g., acetaminophen adds up); sometimes, the implications must be spelled out (e.g., how foods interact to affect craving).

Some terms trigger inappropriate mental models. Because individuals must assemble a mental model for each risk decision, they are vulnerable to descriptions that prompt inappropriate inferences. For example, mentioning that radon intrusions involve radioactivity evokes beliefs about long-term contamination from nuclear waste that are accurate, but irrelevant, given the rapid decay of radon byproducts (meaning that the problem vanishes once the intrusions stop). Palliative care can be seen as *giving up*, rather than as an alternative form of treatment.¹¹ Potential systemic effects of silicon breast implants, though questionable, are so widely known that the undisputed risks of local complications may not come to mind.¹²

Qualitative understanding may not translate into quantitative understanding. Processes that are easily understood in the short run often have unintuitive properties as they develop over time — if people consider the long term at all.¹³ For example, when thinking about the benefits of savings, people are familiar with annual interest rates; however, they underestimate how interest compounds over time and, therefore, the value of saving at all

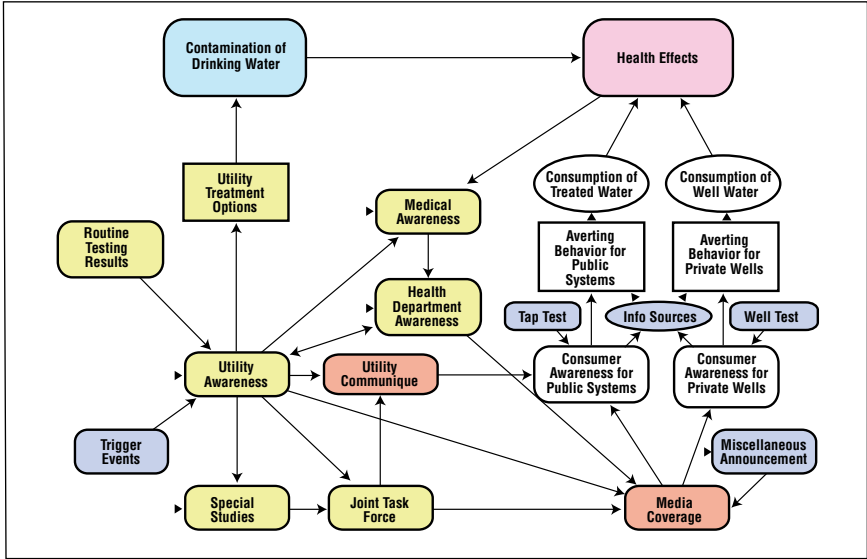
and the impact of seemingly small differences in interest rates.¹⁴ Similarly, people underestimate how quickly risks increase through repeated exposure, whether of driving, unprotected sex, contraceptive failure, or small doses of radiation. And they may not appreciate the importance of early responses to exponentially growing problems, whether cancers or invasive species.¹⁵ For those processes, intuitive estimation is so difficult that it may be necessary to run the numbers for people.¹⁶

What general practical advice can the science support?

Any communication must consider how its new information can be integrated with existing beliefs to create a more accurate mental model. The research process for achieving this goal has three steps:

Step 1. Identify the main factors determining the risks and benefits of a choice, along with the relationships among them. Figures 1 and 2 show two examples of a standard representation of such factors and relationships, patterned after the influence diagrams of decision theory.¹⁷ The nodes represent factors predicting the risks and benefits; the arrows represent predictive relationships. In Figure 1, the critical outcome is the health effects from a cryptosporidium intrusion in water supplies; it appears in the upper right corner.¹⁸ In Figure 2, the critical outcome (again in the upper right) is the health effects associated with uptake of measles-mumps-rubella (MMR) vaccine.¹⁹

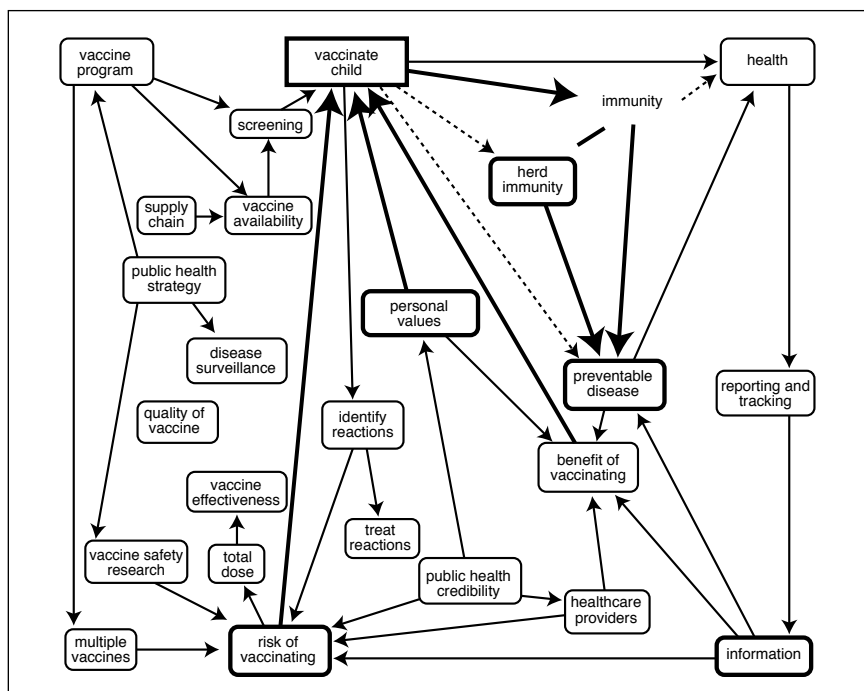
Figure 1. Model predicting the effects of measures to reduce health effects of contaminants in domestic water supplies



Source: Casman et al. (2000)¹⁸

Although there are many things that might be learned about these complex domains, the only facts that decision makers need to know are those that predict the outcomes that matter. Sketching diagrams like Figures 1 and 2 provides a structured way to identify those facts. Creating them requires no expertise in formal modeling, just clear thinking, informed by substantive knowledge of the domains.

Figure 2. Model predicting health effects associated with uptake of measles-mumps-rubella (MMR) vaccine



Source: Downs et al. (2008)¹⁹

Models are created by working backward from the outcomes, adding the factors that affect them, then the factors that affect those proximal factors, and so on, going as far upstream as desired. That analysis entails hard, clear thinking by people who know about the issues, reviewing one another's work until the logic of the model seems right. Table 1 offers rules to use to check the work. Although models can be made precise enough to produce quantitative predictions, analyses done to structure communications often have the more modest goal of *potential computability*: The model's variables and relationships should be defined clearly enough to allow quantitative predictions were all the needed data available. However, getting the structure right, without the numbers, can identify the qualitative *story* explaining quantitative estimates.

Table 1. Methodology for assessing the clarity of an expert model

Review the Nodes 1. Check that the name of the variable at each node is appropriate. 2. Consider possible values for each variable. 3. Consider ways to measure each variable.
Review Individual Links 1. Write a statement explaining the causal or predictive relationship for each link. 2. Summarize the evidence for each link and its quality (use dashed lines for speculative or disputed links). 3. Identify ways to study each link. 4. Identify strategies for interventions affecting each link.
Review Relationships Between Links 1. Consider eliminating nodes with one input and one output. 2. Consider combining nodes with identical inputs and outputs. 3. Avoid circular chains of links.
Review Overall Model 1. Ensure that critical endpoints are easily identifiable. 2. See if connecting unconnected nodes will improve predictive value. 3. Allow for feedback from endpoint to earlier nodes if there are time dependencies. 4. Identify “index variables” (e.g., demographics) that affect many values.

Source: Adapted from Fischhoff et al. (2006)²⁰

Step 2: Characterize existing beliefs in terms comparable to the formal model. Many risks are so complex, novel, and unintuitive that one cannot presume to guess how people will conceptualize them. As a result, one needs an open-ended approach to determine which factors come to people’s minds and how they think about them. A standard approach uses semi-structured interviews that begin by asking people to offer any thoughts that they have on the topic (e.g., “what have you heard about the MMR vaccine?”). Follow-up questions ask them to elaborate on each issue that they raise, using their own terms, so as not to prejudge what they say. Once those thoughts have been exhausted, interviewees can be asked increasingly specific questions about topics in the formal models (e.g., “Have you heard anything about vaccine risks?” “Do you have any thoughts about how vaccines are tested?”). Table 2 presents text for introducing such an interview and encouraging the conversation it is meant to have.

Once transcribed, the interviews can be separated into discrete thoughts and then coded into the formal model. With a well-defined model, such coding can typically be done quite reliably. If resources permit, two (or more) coders can jointly define the coding scheme, apply it independently, compare their work, and then refine the scheme as needed. After the coding has been completed,

comments falling into each topic can be examined to identify common beliefs and ways of thinking and expression. If people raise topics outside the formal model, those must be analyzed as well, either as misconceptions that should be corrected or as issues that the formal model has missed.

Table 2. Representative introduction and cues for semi-structured interviews.

Excerpt from introduction: “Our discussion should take about 30 minutes. I have some questions to guide us, but please feel free to raise whatever thoughts come to mind as we go along. There are no right or wrong answers, and all the comments that we get will add value to our research.... We will start very generally, just talking about the purpose of vaccines.”	
1. Can you tell me, to the best of your knowledge, how vaccines are supposed to work in the body to prevent a disease?	Follow-up: Can you tell me anything about what happens once many people get vaccinated for a disease? Prompt if necessary: Do you think that would make any difference in preventing the disease?
16. How do you feel about letting parents choose whether to get the MMR vaccination for their children, as opposed to being required by the state?	Follow-up: Are your feelings about this any different for your own children versus other children?
22. Have you read or heard that some parents are choosing not to give their children the MMR vaccine?	Follow-up if yes: Can you tell me what you’ve heard? Where did you hear about that?
23. What do you think about these parents’ decision not to vaccinate their children?	Follow-up: Do you think their decision helps or hurts their children in any way? Do you think their decision helps or hurts other children in any way?

Source: Adapted from the research protocol for Downs et al. (2008)¹⁹

Such in-depth interviews are an irreplaceable source of insight into audience members’ intuitive ways of thinking about a topic. Without them, one can miss critical information needs and opportunities to connect new information with existing beliefs. If members of the target population have relatively homogeneous beliefs, a modest sample (20 or 30) should reveal each belief held by any significant fraction. However, even the most representative sample of that size can provide only a rough estimate of the prevalence of those beliefs, especially given respondents’ role in defining the direction of the interviews and which topics are raised. If more precise estimates are needed, a structured survey can be constructed, asking standard questions of a suitably sized sample. Creating questions that represent the factors in a formal model affords such a survey a kind of ecological validity — in the sense that it touches the issues that affect the outcomes that matter.²¹

Step 3: Draft, test, and redraft communications, addressing the critical differences between what people know and what they need to know.

Identifying those differences requires expertise in risk analysis and human behavior. For example, interviews structured about the risk analysis in Figure 1 revealed misconceptions about several critical facts. One is the erroneous belief that consumers can tell when their water is bad, either by inspection or by in-home tests. A second is that vulnerable individuals will receive warnings in time to take protective actions, which is not the case for hard-to-detect pathogens (e.g., cryptosporidium). A third is how to boil water effectively. Communications addressing these beliefs would have to convey: “You can’t tell if your water is bad”; “The water authorities may not be able to tell either”; “Here’s what ‘boil water’ means.”¹⁸

In the interviews based on Figure 2, one critical gap was ignorance about vaccine safety research, including the post-licensing surveillance programs designed to catch negative reactions. A second was not realizing the protection that herd immunity provides to those who cannot be vaccinated due to allergies or health conditions. Communications addressing these beliefs would have to describe safety programs and herd immunity authoritatively, in ways that addressed the accounts offered by vaccine skeptics.^{19,22}

These suggested messages, like all other ones, are speculative until they have been subjected to empirical testing. They might make immediate sense, for example, if consumers are generally skeptical about the efficacy of home tests, about the water authorities doing their job, or about their ability to boil water. Or, they might require explanations that complete parts of their mental models (e.g., “Cryptosporidium is hard to culture and detect. If we have trouble testing, then do-it-yourself kits will only leave you overestimating how much you know.”). Similarly, a mere reminder of herd immunity may allow people to complete the picture of vaccination effects. Or, they may need help working through the risks to vulnerable individuals moving about a population X% of which has not been vaccinated. The interviews (Step 2) and the basic research literature (described briefly above) will suggest problems and solutions; evaluations will show how adequate the resulting communications are.

Evaluation

The goal of qualitative communication is not to achieve general mastery of the domain, as measured by tests of financial, health, or climate *literacy*. Rather, it is to ensure that people know the facts germane to specific decisions, building on their existing mental models. Depending on the decision and their prior knowledge, people may need to learn a little or a lot.

No expense. A simple, straightforward evaluation method asks a few people from the target audience to review the draft communication, thinking aloud as they go, raising any issues that come to mind, but without receiving any

feedback. Once finished, they are asked to summarize its content to someone else, being explicit enough for a subject-matter expert to evaluate the accuracy of their accounts. Finally, an expert presents a fuller account than that in the draft communication, then sees which facts surprise or confuse the test readers. The communication is then revised to address the residual problems and tested again until it is adequate — or can no longer be improved.

Low expense. With a small budget, one can conduct more formal versions of the no-expense tests. Rather than impressionistic evaluation of test readers' responses, one can create transcripts of their comments for review by the communication team, being sure that the test readers' concerns, confusions, and suggestions are heard. Particular attention should be paid to perceptions of comprehensibility and fairness (especially with controversial topics) and readers' ability to draw inferences from its content, indicating that they have active mastery. In all cases, it should be made clear that it is the draft communications that are being evaluated, not the test readers, whose help has been enlisted.

Modest expense. A more systematic evaluation would create questions testing for knowledge of the key factors affecting the critical risks and benefits. The communication's success would be evaluated in terms of test users' ability to answer these questions — which could be used in both pre-tests and field tests. The evaluation should be able to detect negative as well as positive effects on understanding, by including questions that people typically get right without the communication, as well as ones that they typically get wrong. Results should be published in the peer-review literature, both to improve their quality and to create an accessible archive of solutions (and failures) in conveying the qualitative information needed to explain risks and benefits.

Conclusions

Communication of qualitative information involves the same steps as communication of quantitative information. First, determine what information people need to know if they are to understand the processes creating the risks and benefits that could follow from their decisions. Second, characterize their current beliefs in terms that enable comparing them with the analysis of what they need to know. Third, design, evaluate, refine, and re-evaluate communications that seek to bridge the critical knowledge gaps. If successful, qualitative communications leave recipients with a warranted sense of having mastered the relevant aspects of a topic, enabling them to make effective decisions on their own and evaluate recommendations made by others.

Additional resources

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3. Gentner, D. and Stevens, A.L. (Eds.) (1983). *Mental Models*. Hillsdale, NJ: Erlbaum. A collection showing some of the diverse approaches to capturing mental models.
4. Morgan, M.G., Fischhoff, B, Bostrom, A, and Atman, C. (2001). *Risk communication: The Mental Models Approach*. New York: Cambridge University Press. This book illustrates the steps described in the current chapter, with examples of interviews and communications.
5. Slovic, P. (Ed.) (2000). *The Perception of Risk*. London: Earthscan. An important collection showing diverse approaches to describing and informing risk perceptions.

Endnotes

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Chapter 9: Health Literacy

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Summary

Health literacy reflects both individual capabilities and the complexity of demands placed on the individual by the health care system. Over the past two decades, an extensive body of research has linked various functional literacy and numeracy skills to a range of health outcomes. The literature is summarized in this chapter, as are some practical steps for addressing known health literacy barriers in the larger context of health communication.

Introduction

In 2004, the Institute of Medicine (IOM) convened an expert panel to review the evidence, generating a seminal report entitled *Health Literacy: A Prescription to End Confusion*.¹ The agreed on definition of *health literacy* put forth by the IOM was that it is “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.” In a similar yet slightly different perspective of the topic, the World Health Organization (WHO) recognized a definition presented earlier by Don Nutbeam, referring to *health literacy* as “the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health.”² Both the IOM and WHO therefore recognize health literacy as comprising cognitive and psychosocial abilities that serve as antecedents to health behavior.

Both Nutbeam and Wolf and colleagues acknowledge that despite these accepted definitions, there is often disagreement among health professionals and researchers in this field as what *health literacy* truly means.²⁻⁴ For some, it is a broad public health agenda to promote clear health communication and individual engagement in health care. And to others, *health literacy* is an underlying clinical risk factor for misunderstanding medical instructions, worse self-care, and poorer health — the latter view being derived from the body of evidence that has served as the foundation for the field of health literacy. Early studies linking health literacy to health knowledge and outcomes have assessed and continue to assess the construct using crude measures of vocabulary, reading fluency, or numeracy.⁵ More recent, but less-used, tools have relied on

subjective assessment or even the use of population data to derive individual skills.^{6,7} Clearly, there is a disconnect between the findings manifested in the literature and the broad interpretations and implications set forth by some. However, all can agree that health literacy is a multifaceted concept; reading ability and numeracy as measured by the most commonly used tests in the field are just a few of the fundamental components.

What does the science say about health literacy?

According to the National Assessment of Adult Literacy (NAAL) of 2003, approximately 14% of U.S. adults possess skills in the lowest level of prose and document literacy (below basic), and 22% are at the lowest level for quantitative literacy.⁸ These individuals can perform only the most simple and concrete tasks associated with each of these domains. However, those with only basic literacy proficiency have limited abilities and are likely to be hindered in routine daily activities. When considering individuals with basic and below basic skills combined, as many as 34% to 55% of U.S. adults have limited literacy skills. Those who are older, less educated, belonging to racial or ethnic minority groups, socioeconomically disadvantaged, and from rural areas of the country have higher rates of limited health literacy. Similar population estimates and associations have been found in the United Kingdom, throughout Europe, Australia, and Canada.⁹

As health information and tasks may be more difficult and unfamiliar to many, estimates of health literacy using general literacy assessments in these national surveys may under-estimate the problem. Therefore, the NAAL included a health literacy component.¹⁰ The report showed the average health literacy scores of Americans to be lower than average general literacy scores of adults, although general literacy proficiency is strongly correlated with health literacy.

The methods for assessing adult literacy and health literacy skills follow traditional approaches used in education for evaluating basic reading and numeracy skills. All of the current tools used in the health literacy literature rely on individuals pronouncing words, retrieving information, and/or making inferences from print materials, including prose text and tables. By far the most common measures of literacy in health care include the Rapid Estimate of Adult Literacy in Medicine (REALM) and the Short Test of Functional Health Literacy in Adults (S-TOFHLA).^{11,12} Other measures have emerged to improve the timeliness of assessment or to provide opportunities for measuring literacy across languages.^{5,13} All of these new tools, whether they leverage technologies or expand assessment tasks, fall back on the same premise: that mainly reading fluency and/or numeracy skills are to be evaluated to determine health literacy.

Extent and associations. Although the relationship between literacy and health outcomes is not entirely clear, there are plausible mechanisms by which literacy could directly affect health behaviors, compliance with medications, and other pathways to health.^{1,14,15} Empirical data collected over the past two decades support these links.⁵ It is this body of literature demonstrating associations between measures of reading skills and numeracy with outcomes (>1,000 related studies to date) that has driven the formation of the health literacy field. Specifically, lower literacy has repeatedly been associated with less health knowledge, worse self-management skills, higher hospitalization rates, poorer health, and greater mortality.^{5,16,17} In prospective analyses, literacy is more strongly associated with these outcomes than years of education.^{5,17}

Health knowledge. The large number of relevant empirical studies have most often linked limited literacy with less health knowledge.^{18,19} Early work by Williams and colleagues found patients presenting to an emergency room with low health literacy had poorer asthma knowledge.²⁰ In a similar study, lower literate patients with hypertension and diabetes were also reported to have poorer understanding of disease.²¹ Other research studies have since confirmed this relationship in a multitude of contexts. Among individuals living with HIV/AIDS, those with limited literacy were less able to define CD4 lymphocyte count and viral load and to identify antiviral medications in their regimen even with the aid of pictures.^{22,23}

A great deal of attention has also highlighted the association between low health literacy and treatment misunderstanding, including medication names, indications, and instructions. Davis, et al., conducted two multi-site studies among adults and found those with limited literacy had higher rates of misunderstanding their directions for medications provided by either the physician or pharmacist.^{24,25} The problem extended to text and icons used for medication warnings and precautions. Wolf and colleagues most recently reported that lower literate patients would over-complicate multi-prescription drug regimens, taking medicine at more times a day than necessary.²⁶ Finally, in perhaps one of the most indicting studies linking literacy skills to medical understanding, Gazmararian, Williams, Peel, and Baker interviewed patients with asthma, hypertension, diabetes, or congestive heart failure and found that low health literacy was an independent predictor of poor functional understanding across each of these chronic conditions.¹⁸

Self-efficacy and health behaviors. Fewer studies have directly examined the relationship between literacy skills and individual health-related self-efficacy and behaviors, and some of the evidence on these outcomes is conflicting. For self-efficacy, Wolf and colleagues examined self-efficacy, knowledge, and medication adherence among a sample of patients living with HIV/AIDS in Chicago and Shreveport, LA.²⁷ Those with limited literacy had lower self-efficacy to engage in treatment. Self-efficacy was found to mediate the literacy-medication adherence association. Yet DeWalt and colleagues did not find an

association between literacy skills and self-efficacy among a sample of diabetic patients.²⁸

Research on health literacy and health behaviors offers some insights and, similarly, a lack of concordant findings. In a single sample, Arnold, Davis, Berkel, and colleagues reported on an association between smoking and health literacy.²⁹ However, Wolf, Gazmararian, and Baker found no significant associations between literacy skills and health risk behaviors (smoking, alcohol use, physical activity, body mass index) in a large multi-site sample of Medicare managed care enrollees.³⁰ Findings are more conclusive with regard to the significance of the association between literacy and health promoting behaviors, including cancer screening and vaccinations. Schillinger and colleagues presented seminal evidence of the relationship between limited literacy and inadequate self-care for diabetes, although recent studies have not been able to replicate these findings.³¹ In addition, there are an equivalent number of studies that document associations between literacy and medication adherence as those that report this relationship to not be significant.^{23,27,32}

Clinical outcomes and mortality risk. Individuals with limited health literacy experience poorer health. Baker, Parker, Williams, and Clark examined the relationship between literacy and self-reported health among patients at two urban public hospitals.³³ Patients with low literacy were more than twice as likely to self-report poor health, even after adjusting for demographic and socioeconomic factors. Wolf, Gazmararian, Baker investigated the relationship between low literacy and self-reported functional health status among older adults.¹⁶ Those with low literacy had a higher prevalence of diabetes and congestive heart failure, reported worse physical and mental health, greater difficulties with activities of daily living, and limitations due to physical health. Likewise, Mancuso and Rincon reported that among adult asthma patients, limited health literacy was associated with poorer physical health, worse quality of life, and a greater number of emergency department visits.³⁴ Two studies by Baker and colleagues had previously reported that patients with inadequate health literacy had a greater risk of hospital admission- compared to those with adequate literacy.^{33,35}

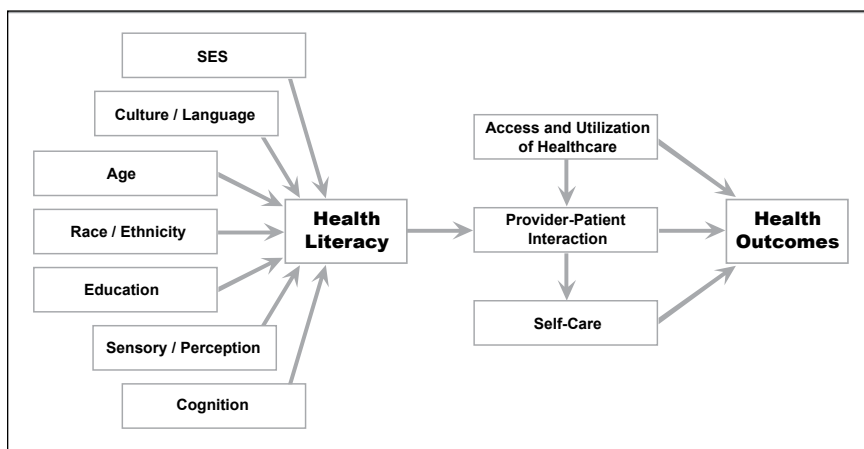
Most recently, research has identified low health literacy as a significant risk factor to greater mortality. Sudore and colleagues reported that low health literacy was associated with a 75% increased risk for all-cause mortality, compared to those with adequate health literacy.³⁶ Similarly, Baker, Wolf and colleagues found low health literacy to be significantly and independently associated with a 51% greater mortality risk; the association was found to be significant for cardiovascular causes but not for cancer.¹⁷

Limitations of available evidence. Among the hundreds of studies that have evaluated the literacy–health relationship, only a limited number to date have gone beyond cross-sectional investigations to report on prospectively

collected outcomes, thereby truly being able to comment on causality. Also, as the far majority of the research examines individual comprehension of health information and instructions, without the extended connection to actual clinical outcomes, many have criticized the legitimacy of health literacy as a true risk factor to poorer health.

Paasche-Orlow and Wolf previously proposed certain causal pathways in which it would be plausible to assume how limited literacy and health literacy skills affect health outcomes, (see Figure 1), although further research is needed to elucidate these connections.¹⁴ For instance, it has been proposed that individuals with limited literacy may face greater difficulty in accessing health information in a timely manner, engaging with health care practitioners during spoken encounters, and following through on medical instructions and the everyday problem-solving required to promote, protect, and maintain optimal health. In addition, those with low literacy may feel shame and consequently lack the self-efficacy to seek out clarification or acquire information elsewhere.³⁷⁻³⁹ Over time, these factors contribute to poorer health as a result of inadequate use of health services, negative health behaviors, and poorer self-care. While this conceptual framework is logical, the evidence reviewed above has shown that there is evidence supporting and also refuting a few of these pathways, making the big picture not entirely clear as of yet. On a final related note, unlike longstanding public health research into health behavior and health education, the field of health literacy continues to lack a unifying theory. Regardless of these limitations, the evidence that continues to be gathered on the topic demands considerable attention.

Figure 1. Proposed causal pathways linking health literacy to health outcomes



Adapted from Paasche-Orlow and Wolf (2007)¹⁴

What general practice advice can the science support?

Although there are a multitude of research studies that have examined the problem of limited health literacy, only a fraction currently report on viable solutions to address known mitigating effects in various health contexts.^{40,41} Most of the early interventions that have been published began by solely rewriting health materials at a simpler reading level or following other design techniques to improve comprehension.^{42,43} Further research is necessary to fully understand how to reduce known health literacy disparities, however, a few studies have highlighted some approaches that could be very promising. Specifically, identified targets for health literacy interventions include (1) the content and design of health materials, including print and multimedia communications; (2) counseling skills of health care practitioners and allied health professionals; and (3) the delivery of health care services.

Numerous longstanding resources and related references already exist that can inform *best practices* for designing health care materials, whether it be a print brochure, web site, or educational video. The Table describes some key techniques identified by prominent practitioners in the field. Studies have shown that the majority of audiences, regardless of literacy level, prefer health materials that are clear and concise. What may vary is the depth of information desired, therefore limiting and layering content is essential. This means that materials should both provide individuals with triage, *need-to-know* information on a topic, but also opportunities to seek out more detailed background content.

‘Best Practices’ for Rx labeling

Organize label components	The label should be organized to reflect how patients process instructions. The most important information should be prominently featured.
Emphasize patient content	Critical information should be easy to locate. Patient name, drug name, strength, and instructions should be located at the top of the label. Less critical information should be located in a separate area.
Simplify language	Jargon / medical terminology should be removed; short sentences should be used.
Give explicit time periods	Use standard time periods (morning, noon, evening, bedtime), instead of vague instructions based on times per day (twice daily) or hourly intervals (every 12 hours).
Include purpose for use	Use simple terms to describe indication (high blood pressure instead of hypertension).
Limit auxiliary information	Provide only the most salient information to not overload the patient.
Address English proficiency	Provide instructions in multiple languages. Ensure that translations are accurate and of high quality.
Select appropriate font	Optimize typography by using high-contrast print, simple, uncondensed fonts (Times Roman or Arial), in a large font size (11-12 point). Refrain from using ALL CAPITALIZED letters.
Improve readability	Use numeric rather than alphabetic characters when possible (Take 2 tablets instead of Take two tablets). Maximize white space (25-30% of point size) and utilize highlighting, bolding or typographical cues to enhance readability. Text should be oriented horizontally, not vertically.

Some evidence is available that suggests the use of visual aids may help lower literate patients attend to, process, and remember health information. One study demonstrated that subjects who listened to medical instructions accompanied by a pictograph remembered 85% of what they heard in contrast to 14% for patients who did not receive a visual aid.⁴⁴ Wolf and colleagues also found the inclusion of patient-centered icons on auxiliary drug warning labels significantly improved comprehension, compared to concordant text messages without the icons. Those with lower literacy benefited the most.⁴⁵ As described by Webb and colleagues, visual aids can be optimized for individuals across all literacy levels so long as the picture or symbol matches mental representations held by the intended viewer.⁴⁶ Therefore, the target audience should be included in the development and evaluation of visual aids.

Beyond health materials, limited research is available describing efforts to improve how health care providers verbally communicate to effectively engage with patients. There are some initial evaluations of interactive communication strategies, such as confirming understanding using the *teach back* technique, or through *guided imagery* approaches during clinical encounters with patients that support the efficacy of these methods.

The *teach back* technique is a particularly useful and simple way to confirm patient understanding during the encounter.⁴⁷ After describing a diagnosis and or recommending a course of treatment, the health care practitioner asks the patient to reiterate what has been discussed by reviewing the core elements of the encounter. If a patient provides incorrect information, the practitioner can review the information again and give the patient another opportunity to demonstrate understanding. In this manner, the practitioner gains assurance that the patient has adequately understood instructions and information. In contrast, *guided imagery* requires the patient to not only reiterate content of a spoken encounter, but to describe how a recommended behavior should be performed in the specific context of the individual's personal situation. This might include explicitly asking a patient when they will take a prescribed medicine, where they will store the medicine, and how they will remind themselves of the activity. In essence, the practitioner is requiring the patient to perform a *dress rehearsal* of the behavior. Park and colleagues found the use of guided imagery to significantly improve adherence.⁴⁸

A final health literacy strategy, and perhaps the most daunting, is that of practice redesign. The interventions that have demonstrated the greatest effectiveness in closing the health literacy gap have been *intensive care management* strategies among patients with certain chronic conditions, such as heart failure and diabetes.^{40,41,49} These include minimizing, whenever possible, the patient's role and responsibilities in managing health. For instance, health care practices can streamline tasks, more closely track and follow-up chronically ill patients, use *navigators* or other forms of care coordination to

deliver preventive services or set action plans for disease management. These broad strategies have incorporated several of these approaches to address system complexity, unfortunately, making it difficult to elucidate the true cause for any reduction in the effect of health literacy on outcomes. It is also unclear whether these comprehensive interventions involving system change can be sustained and/or translated to other settings.

Perhaps the biggest challenge the health literacy field has brought to light is finding a way to incorporate a long-term objective in health care pertaining to orienting people to the health care system and their role and responsibility within it.³ This will likely require standard training and education early in life (i.e., through schools) that deconstructs everyday tasks across the life course, how to more effectively communicate with health care practitioners, or giving explicit guidance on typical questions one should always ask. This equates to providing anticipatory guidance to individuals and families to convey typical expectations and experiences when interacting with health care practitioners and systems. The intention would likely be to increase self-efficacy to seek and obtain health information in a more productive manner and to develop effective health and health care problem solving skills.

How does one evaluate communications implementing this advice?

Addressing health literacy in practice can refer to a range of activities, many of which can be performed easily with minimal orientation and at little or no cost. For instance, health systems and practitioners should review the manner in which they communicate with patients and families and take steps to ensure that distributed materials can be understood by patients with more limited literacy. For print tools, the readability of materials can be analyzed using several different formulas and internet tools. One recommended assessment includes Lexile analysis, which can be accessed with a free subscription on the internet.⁵⁰ Davis and colleagues previously found that readability as determined by Lexile scores was a significant independent predictor of patient comprehension of drug warning information.²⁴ Doak, Doak, and Root's Suitability Assessment of Materials (SAM) is another more comprehensive procedure for systematically critiquing materials for low literate audiences.⁵¹ In general, there are a multitude of available options that can offer an initial, although crude, assessment of the quality and comprehensibility of print content, whether conveyed via print tools or the web.

Another inexpensive approach to evaluating the extent of health literacy concerns within a health system or community is to use demographic data to gain estimates of limited health literacy. Algorithms that include age, race or ethnicity, and educational attainment have considerable predictive power in determining the likelihood of low literacy and could be used to promote the need for health literacy interventions in more resistant corporate cultures and systems.⁶ Some currently recommend performing basic surveys that include a

literacy assessment among a representative sample within a practice setting, albeit this would be at a nominal cost.

With modest funds, patient and practitioner surveys could be performed to determine and identify with more precision any health literacy concerns and needs. Surveys of patients might go beyond a literacy assessment; the use of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey developed by the Agency for Healthcare Research and Quality (AHRQ) includes health literacy-related questions pertaining to patient satisfaction with practitioner professionalism and spoken communication. This could be performed periodically after a baseline has been established to evaluate any ongoing efforts to improve communications, particularly among patients with limited literacy. Other tools similar to the CAHPS are available. More costly, but informative for continuing education opportunities, would be to video-record clinical encounters before and after any training activities and engage in fidelity assessments of any new strategies to improve patient access to health information. For instance, a practice may seek to confirm that patients are receiving mailings, phone calls, emails, and requests from patient portals embedded in electronic health records.

In all, a standard uniform approach to delivering health information is necessary and practitioners and health systems should coordinate their efforts to ensure patients and families have multiple access points to receive the same content. A recent example in the health literacy literature has been with medication education and labeling. The use of a universal medication schedule (UMS) has been proposed to standardize the way physicians prescribe medicines in the most patient-centered manner and to equally request pharmacies to use the same instructions and information when labeling and dispensing medicines (see Figure 2).⁵²

Figure 2. Universal medication schedule

Take	1 pill in the morning (bedtime)
Take	1 pill in the morning 1 pill in the evening
Take	1 pill in the morning 1 pill at noon 1 pill in the evening
Take	1 pill in the morning 1 pill at noon 1 pill in the evening 1 pill at bedtime

 Morning: 6-8 am
 Noon: 11-1 pm
 Evening: 4-6 pm
 Bedtime: 9-11 pm

Source: IOM Workshop summary ⁵²

Conclusion

In its seminal 2004 health literacy report, *A Prescription to End Confusion*, the IOM recognized that patients' health-related knowledge, skills, and behaviors are primarily shaped by: (1) cultural background, (2) health system demands, and (3) prior learning opportunities.¹ This report aptly frames limited health literacy not as an individual problem, but as a challenge to health care practitioners and health systems to reach out and more effectively communicate with those they serve. Long-term health literacy interventions must engage communities to develop sustainable health promotion strategies. The educational system must support public health efforts by imparting relevant skills and familiarizing learners to the U.S. health care system and their role within it. Most important, steps can be taken **now** to increase the quality of and access to meaningful health information and simplify the health care experiences of those in greatest need.

Endnotes

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Chapter 10: Affect and Emotion

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Summary

Affect and emotion influence perceptions of likelihood, value, and the risk–benefit balance. These feelings and thoughts interact but also separately predict risk perceptions and decisions. Feelings can limit effective risk communication sometimes, but are often critical to good decision-making; their power can be harnessed in persuasive and non-persuasive communication.

Introduction

Early psychological research on risk perception and communication focused on cognitive forces that shape risk attitudes and behaviors.^{1,2} More recent research has developed and tested theories of risk perception that incorporate affect and emotion as key components. Within these theories, integral feelings (good and bad feelings experienced about a stimulus, e.g., prescription drugs) and incidental feelings (positive and negative feelings, such as mood states that are stimulus-independent but may be misattributed to it) are used to predict and explain how people react to risks in our complex world. The experience of mild affect and emotion is ubiquitous in everyday life. It influences the decisions of consumers, including patients, as well as the decisions of physicians, health care providers, and risk communicators.³ Although these feelings can have a negative impact on decision making (he was overcome with fear; she was filled with grief; both persons are incapable as decision makers). Damasio⁴ and others argue (and provide evidence) that feelings generally increase the accuracy and efficiency of the decision process, and their absence degrades decision performance. Communication efforts can be improved by understanding this descriptive research and its implications for risk communication.

What does the science say about this aspect of communication?

Two main and interrelated theoretical frameworks exist. The first concerns affect — simple, valenced, good/bad feelings — and is represented by research on the Affect Heuristic^{5,6} and the Risk-As-Feelings hypothesis.⁷ The second framework is the Appraisal–Tendency framework, which elaborates on cognitive–appraisal theories and examines the influence on risk perceptions of

the appraisals and behavioral motivations underlying specific emotions, such as anger and fear.^{8,9} The two frameworks are related in that both focus primarily on feelings experienced at the moment of judgment or choice, and valenced affect is similar to pleasantness — a primary appraisal underlying specific emotions.

Valence and the affect heuristic. Support for the first framework and the relationship between affective valence and risk perceptions comes from a variety of experimental, survey, and field studies. Whereas risks and benefits tend to be positively correlated in the world (e.g., risky stocks tend to offer higher return; if they don't, they don't last long in the market). However, risk and benefit perceptions tend to be negatively correlated (e.g., prescription drugs tend to be perceived as high benefit and low risk¹). This inverse relation between perceived risks and perceived benefits has been linked to the strength of positive or negative affect associated with the product or activity.¹⁰ People seem to use an affect heuristic and base their judgments of an activity or product not only on what they think about it but also on how they feel about it. If they feel good about an activity, they tend to judge risks as low and benefits as high; if they feel bad about it, they may judge the opposite — high risk and low benefit. Under this model, affect comes prior to and acts as information in judgments of risk and benefit (e.g., in the domain of prescription drugs¹¹). Peters^{12,13} extended the Affect-Heuristic model to examine multiple ways that affect influences judgment and decision processes. For example, apart from information, affect also can act as a spotlight, causing some decision-related information to be used while other information is ignored.

Although much Affect-Heuristic evidence is correlational, experimental manipulations also exist. Research demonstrates that reliance on affect (and the negative correlation between risk and benefit perceptions) increases under time pressure.⁵ Additionally, providing one type of information (e.g., about increased risk in the absence of any benefit information) influences perceptions of the other (i.e., perceptions of benefit are reduced⁵). Affect can also be manipulated incidentally to examine its causal impact on risk perceptions. In one paper and consistent with the Affect-Heuristic model, increasing negative affect through a mood manipulation (reading an unpleasant news story) increased risk perceptions of a variety of hazards and diseases whereas increasing positive affect in a similar manner decreased risk perceptions.¹⁴ Finally, effects of individual differences such as affective reactivity can also be seen on risk perceptions, with individuals higher in neuroticism and other measures of negative reactivity perceiving greater risk.^{15,16} Some evidence also exists that older adults and less numerate adults may perceive greater risk than those who are younger and those who are more numerate¹⁷⁻²¹; the results presumably are due to older and less numerate populations relying more on affect (and less on deliberation) to derive their risk perceptions.

Incidental and integral sources of affect appear to influence risk reactions (and, based on Affect-Heuristic findings, likely influence benefit perceptions although this has not been studied systematically). Decision makers also appear to be insensitive to probabilities of risky events that are strongly affective.^{7,22,23} Moreover, greater risk is communicated through the use of frequency data (the number of people at risk) than through a percentage format (the percent of people at risk). The greater impact of frequencies compared to percentages appears due to focusing on and imagining the numerator (the number of people at risk) and neglecting the denominator, resulting in more affective risk-relevant images.^{6,24-26} Finally, existing data do not support the idea of a curvilinear relationship with extreme negative affect and worry inhibiting action; instead, they suggest that the more worry one has (if nonpathological), the more one is motivated to take on self-protective health behaviors.²⁷⁻²⁹

Affect also appears to play an important role when numeric risks are compared.⁶ For example, Fagerlin, Zikmund-Fisher and Ubel²¹ found that women asked to estimate their personal risk of breast cancer over-estimated their risk (with more negative affect about cancer associated with higher risk estimates, consistent with the Affect Heuristic). In addition, after being told their actual risk (and presumably comparing it to the higher risk estimate they just produced), they reported feelings of greater relief and lesser anxiety compared to women who did not estimate their personal risk first. The authors suggest that risk perceptions “are not merely cognitive appraisals of numeric risk ... They include intuitive and emotional reactions, which translate being “high” or “low” into “something to worry about” or “something to be relieved about” (p.143).

Of course, because much Affect-Heuristic research has been conducted using self-reported affect and emotion, it is not always clear whether results are due entirely to experienced feelings or to thoughts about the product (“I feel it’s good” and “I think it’s good” can be quite similar). Effects of experimental manipulations of experienced feelings on risk perceptions, however, support the causal role of affect in risk perceptions.¹⁴ Research on specific emotions poses a different challenge to the Affect-Heuristic approach. As reviewed in the next section, some research suggests that emotions of the same valence (anger and fear) can have opposing effects on risk perceptions.

Discrete-emotion research and implications for risk communication. Public reaction to risks also can include more complex feelings such as fear and anger that go beyond valenced affect. These emotions are generally thought to be derived, in part, from feelings of goodness or badness, but they also appear to result from additional cognitive appraisals of the environment, such as predictability and coping potential.^{30,31} These specific emotions are generally studied as incidental emotion states (e.g., angry mood³²), but they can be studied as integral to (part of the representation of) an object, such as a prescription drug or FDA itself.¹⁵

Some elegant work by Lerner and Keltner^{8,9} highlights the benefits of examining risk perceptions in an emotion-specific manner. For example, they predicted and found that fear and anger had opposite effects on risk perception. Whereas fearful people expressed pessimistic risk estimates and risk-averse choices, angry people expressed optimistic risk estimates and risk-seeking choices. Lerner, Gonzalez, Small, and Fischhoff³³ found that an experimental manipulation of fear (writing about what makes you most fearful about terrorist attacks and then listening to a fear-inducing audio clip about bioterrorism) increased risk estimates of a future terrorist attack and plans for precautionary measures after the September 11 attack; a similar anger manipulation did the opposite.

Little evidence exists, however, for naturally occurring emotion states, whether incidental or integral, existing in such pure states for time periods long enough to exert significant emotion-specific effects; mixed emotions and mixed appraisal patterns appear to dominate.¹⁵ However, individuals who tend to be more angry than fearful may generally perceive less risk.^{9,33} In addition, emotion-specific effects may have important effects in risk communications that can convey more pure emotions. Nabi,³⁴ for example, experimentally manipulated anger versus fear about drunk driving and demonstrated an impact in subsequent policy preferences for retribution versus protection, respectively. Research is needed to understand the effects of more complex mixtures of incidental and integral sources of affect and emotion on risk perceptions.

Predictive power of feelings versus thoughts. Research suggests that our feelings about risks are important. They can diverge from and be more predictive of behaviors and behavioral intentions than thoughts about those risks.⁷ For example, Diefenbach, Miller, and Daly²⁷ found that affect (cancer-specific worry) predicted mammography adherence whereas a cognitive variable (perceived likelihood of cancer) did not. Similarly, Peters, Burraston, and Mertz¹⁵ demonstrated that radiation-related stigma responses (e.g., to nuclear power) emerged more from negative emotion (mixed fear and anger responses) and less from an activation of risk perceptions (of potential hazards or threats).

The power of feelings versus thoughts to influence behaviors and intentions can be altered. Experimental evidence suggests that increasing deliberation, for example, by having participants provide reasons for a choice or even doing math problems prior to a choice reduces the influence of affect in decisions.³⁵⁻³⁷ Conversely, methods exist to increase affective input into decisions by decreasing the capacity to think (e.g., time pressure and cognitive load^{15,38}) and by increasing affective meaning (e.g., through the use of ordering, symbols, evaluative categories and other methods to make the “gist” of information more easily accessible³⁹⁻⁴¹).

What general practical advice can the science support?

Understand what is important to know about the regulated product and know the audience for the risk/benefit communication. A descriptive understanding of the various effects that emotions and affect can have on consumer behavior related to FDA-regulated products — combined with a normative analysis of whether those effects are harmful or helpful to individual or public health concerns — can lead to development of prescriptive advice about how to harness or rein in the power of affect and emotions. For example, a case can be made for the targeted use of affect and emotion to decrease smoking through graphic warning labels on cigarette packages.⁴² In situations (e.g., statins) where long-term benefits of a medication are difficult for a patient to evaluate, but short-term costs are clear and obvious, promoting adherence might require highlighting the affective meaning of long-term benefits. Affect and emotion can be used to promote public health; they can also undermine it.

Often, however, the normative appropriateness of altering affect towards a product or towards information is unclear. Should benefit information about a medication be made easier to evaluate so that consumers use it more? Should extreme negative affect associated with the side effect of a particular medication be reduced in patient communications? The use of affect and emotion to alter behaviors and the comprehension and use of information poses serious ethical concerns. On the other hand, neglecting to consider their effects also poses ethical concerns. Understanding their effects allows policy makers to make thoughtful choices about how and what information to present rather than making such choices in random fashion, naïve to their effects.

Provide risk and benefit information about taking an action. If the Affect Heuristic is correct and providing information about increased risk (e.g., about a medication) reduces benefit perceptions (in the absence of benefit information), then FDA and others should provide information about both risks and benefits in communications.

Consider presenting risks and benefits of not taking an action. Because comparisons influence affective evaluations and thereby subsequent behaviors, a fully informed consumer should have information about what happens if she takes an action (e.g., a recommended medication) and if she does not.

Make the affective meaning of important information easy to access. Simply providing information is not enough. Research suggests that, when provided information that does not convey affective meaning, consumers are unable to use that information. The use of evaluative labels (excellent, fair), symbols (e.g., similar to *Consumer Reports*), or ordering can help consumers to access the meaning of important information and thereby use it in place of less relevant sources of information. Use of these techniques can also facilitate the integration of important information.⁴⁰

When emotions are expected to be high (and potentially harm decisions), provide methods to “stop and think” to reduce affective input. Consumers and patients sometimes react with fear, alarm, anger, or dread in ways that can overwhelm their ability to understand and use risk communications and make effective decisions. In cases where FDA or others can predict this may happen, encouraging the patient or consumer to stop and think (including to think and try to better understand their own emotional reactions) may help to reduce strong reactions so that, for example, a patient can weigh pros and cons of treatment options.

Fight fire with fire. In cases where FDA believes that persuasive communication is the best approach, emotional communications, especially those that are fear-based, can be used to increase risk perceptions and change behaviors.⁴³ An example of this might be requiring the use of particularly graphic warning labels on cigarette packages.

Consider the effects of advertising, brand names, and other promotional efforts on perceptions of the risks and benefits of products that FDA regulates. Work on the affect-heuristic and risk-as-feelings hypotheses have demonstrated that incidental sources of positive and negative affect, respectively, can reduce and increase risk perceptions. Promotional efforts intended to increase sales often do so by conveying positive affect; they show happy, successful patients, not those who are suffering. As a result, these promotional efforts (even in the absence of any information about benefits) likely increase perceptions of those benefits and decrease perceptions of risks. Their effects, however, are less clear and predictable given the preponderance of side-effect information generally required in FDA-regulated advertisements; this topic deserves further study.

How does one evaluate communications implementing this advice?

Evidence collected across a wide variety of domains, using diverse experimental and survey methods, highlight the potential importance of affective processes in how consumers and patients process and use information related to FDA-regulated products. The scientific study of affect and emotion in risk perception and decision making is relatively new, however, and differences exist across situations with respect to the nature of emotional sources of information (e.g., whether integral or incidental, specific to fear and worry or involving depression) and of the normative appropriateness of emotional experience (and the many situations where the normative appropriateness is unclear). This combination suggests that communications should be tested for their impact on affect and emotions, thoughts, risk and benefit perceptions, and, ultimately, health behaviors prior to their use. Such research should be conducted in appropriate populations and particularly in vulnerable populations who are likely to or should be affected by the communication.

Affect and emotions can be measured in a variety of ways, including simple self-report measures³⁶ (“How do you feel about it?” on scales that range from good to bad or not at all angry to very angry). Pictorial scales⁴⁴ may provide a particularly accessible method to measure affect in less literate populations. Less reportable affect can be measured using reaction times and physiological measures (e.g., heart rate or skin conductance responses). Individual differences in affective reactivity and experimental manipulations of affect or particular emotions can also be employed (See Peters¹² for a brief review).

Without any budget for testing communications, FDA can nonetheless ask its internal experts to prioritize information from most to least important and highlight the affective meaning of the most important information. The agency can develop communications that present both risk and benefit information, including comparative risks and benefits of not taking an action. FDA can conduct semi-structured cognitive interviews with employees (particularly those with less education and experience in risk communication) who evaluate and comment on the message. Is the message clear? Is there anything that is not understood? If FDA knows from internal conversations that previous messages have “missed the mark” in some way (e.g., comprehension of a particular aspect of an important message), targeted questions can be asked. Risk communication experts, with knowledge about the role of affect and emotion, should be included early on in discussions about possible regulatory approval of products to maximize the potential for strategic risk communication.

With a modest budget, the methods above can be used to refine a specific communication before conducting one-on-one cognitive interviews with individuals who read and evaluate FDA’s message. Testing of message comprehension is critical, and it is particularly important to include people with less education and lower levels of numeracy and literacy. This testing should include comparative testing with previous messages (or alternative message forms that emerged in earlier testing) in order to examine how the communication alters feelings and perceptions of risks and benefits of the disease and possible treatments. If FDA has a particular message that decision analysis has revealed as important, does the communication successfully convey the message?

A serious budget for the testing of risk communications would allow FDA to take a more refined approach to testing specific messages, and also to fund and/or conduct research to uncover the general mechanisms underlying how consumers and patients process and use information that FDA provides or regulates. For specific messages, semi-structured interviews can be used to refine different versions of the message and then a nationally representative test of the messages can be conducted to maximize comprehension and use of information highlighted by the normative analysis of the particular situation. It

could allow for a randomized controlled trial of that specific communication in the specific segment of the population that will most likely use the product and to test the messages in relevant vulnerable patient populations.

Testing could also be more systematic and uncover general underlying mechanisms to guide FDA in future risk communications across a range of products and situations. Systematic research across different FDA-regulated products could reveal, for example, how and when direct-to-consumer advertising influences benefit and risk perceptions. Systematically varying the information-presentation format (e.g., percentages vs. frequencies) with which benefits and/or risks of prescription drugs are presented across different types of drugs and devices could assist FDA in predicting what formats will work best to facilitate comprehension and use of information and in what kinds of situations. Such systematic studies could have impact within and beyond FDA. It is through such systematic studies that a general theoretical framework of effective risk communication will ultimately emerge.

Additional resources

1. Slovic, P., Peters, E., Finucane, M.L., and MacGregor, D.G. (2005). Affect, risk, and decision making. *Health Psychology*, 24, S35-S40. The authors examine evidence supporting the affect heuristic and discuss its implications for risk communication and health decision making.
2. Loewenstein, G. F., Weber, E. U., Hsee, C. K., and Welch, E. S. (2001). Risk as feelings. *Psychological Bulletin*, 127(2), 267-286. The authors present their risk-as-feelings hypothesis and show that emotional reactions to risky situations often diverge from cognitive assessments of those risks.
3. Lerner, J. S., and Keltner, D. (2001). Fear, anger, and risk. *Journal of Personality and Social Psychology*, 81(1), 146-59. Drawing on an appraisal-tendency framework, the authors found that fear and anger have opposite effects on risk perception with fearful people being risk averse and angry people being risk seeking.
4. McComas, K.A. (2006). Defining moments in risk communication research: 1996-2005. *Journal of Health Communication*, 11(1), 75-91. This article reviews risk communication research appearing in the published literature from 1996-2005.
5. Wardman, J.K. (2006). Toward a critical discourse on affect and risk perception. *Journal of Risk Research*, 9(2), 109-124. The author examines critiques of the affect-heuristic and appraisal-tendency frameworks in risk perception research.
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Chapter 11: Information and Persuasion

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Summary

Research on informative and persuasive communication shows that many well-known health behavior change theories and other research can help practitioners create, disseminate, and evaluate effective health messages. Characteristics of the message, the sender, recipients, channel, and situation can affect how audiences respond. Evaluation is essential to measure success and should be based on the message purpose and the resources available.

Introduction

People make many decisions daily that affect their health, usually with a degree of uncertainty about what is the best course of action. The *public health information* role of government agencies like FDA is to provide the public with the factual information they need, in a timely, appropriate way, to understand issues of concern and to make informed decisions about their health. The primary goal of public health communication is to engage, inform, and educate the audience, thereby equipping them to take actions that promote their health. The intended outcomes often involve changes in health behavior that well-informed persons would make. In this way public health communication can be both informative and persuasive. With this dual role of informing and influencing behavior in mind, in this chapter we present an overview of research and recommendations about effective public communication that aims to protect or promote public health.

What does the science say about this aspect of communication?

Communication researchers agree that the message a communicator intends to convey is never exactly the same message that the recipient receives. Research has shown that multiple factors, both internal and external, can affect whether communication succeeds in achieving its purpose, including, for example, the skill and credibility of the communicator, the suitability of the message, the way in which the message is delivered, the receptivity of the audience, and distractions in the environment. Because of the influence of such factors the intended outcome of a public health message often varies from

the actual outcome. Given the many potential obstacles, how can we achieve outcomes that are closer to our intentions as public health communicators?

Many theories that concern the effects of informative and persuasive messages on target audiences are considered touchstones in the field of health communication. These theories originate from many fields, such as social psychology, communication, and advertising. They concern how aspects of the sender, the message, the channel, the receiver, and the environment affect knowledge, attitudes, and behavior of the intended audience. Descriptions of major theories, their strengths and weaknesses, and related research can be found in recent texts.^{1,2} These theories have been tested individually and supported by correlational, experimental, quasi-experimental and survey research, but randomized controlled studies are rare. And since there are few studies that directly compare these theories against each other, we don't yet have strong empirical data on which ones are better in different situations.

Aside from theory-based research, many factors have been shown to contribute to changes in audience knowledge, attitudes, and behavior. Much of this research has been in the area of persuasion. Following are noteworthy findings for public health professionals.

Communicator factors. Whether the message sender is a person or an organization, the source can affect how audiences interpret and respond to messages. Evidence suggests that an audience is most likely to believe sources that they perceive to be credible (expert, trustworthy, and concerned about the audience's interests), likeable, appealing, and similar to them. Credibility and likeability appear to have the strongest impact on an audience. Credibility is influential when it is established before the message is given. Generally, the credibility and attractiveness of the communicator have more influence on receivers who are not highly involved with the issue.³ Culturally appropriate messages tend to be more accepted by their intended audience.

Message factors. Many aspects of the message have been shown to affect audience outcomes. Written messages are helpful when the information is difficult to understand. In contrast, live, interactive, or video messages are often more effective when content is simple.⁴ In written materials, illustrations such as cartoons, charts and pictographs labeled with numbers aid understanding.⁵⁻⁷ Reductions in risk tend to be more persuasive when they are presented in relative terms rather than in absolute terms.⁸

Words affect audience perceptions and responses. Labels, euphemisms, and language familiarity, vividness, and intensity can influence how receivers react to messages.³ Information describing what can be gained by changing health behavior is more persuasive than describing what can be lost.¹⁰ Written information can improve knowledge, but the evidence is generally not strong enough to say whether written information is effective in changing attitudes and behaviors related to taking medicines.⁹ Messages that present two sides

of an argument and refute the opposing side are more effective than one-sided messages.⁴ Finally, repetition with variation and consistent reinforcement increase the effectiveness of messages.^{10,11}

Receiver factors. To be affected by a message, a person must not only pay attention to it, but understand it. Receivers' responses to messages may occur through arousal of emotion and/or through careful consideration. Evidence suggests that when the audience is distracted or not highly interested in the topic, they are likely to process the information superficially. If a message is not relevant or appealing, they may ignore it altogether.¹² In contrast, people who are highly involved with the topic are more likely to pay attention to detail, remember the message longer, evaluate the message more completely, and act upon the message.¹³

People who are confident in their ability to perform a recommended action (high in self-efficacy) and believe that a recommendation will be effective are more likely to respond to messages about health threats.¹⁴ Recall of medical information is often inaccurate, especially when the patient is old or anxious. Messages that use warnings or other fear appeals can be more effective with older adults or with youth and young adults, depending on the subject and situation. In addition to age, several other demographic variables may affect how public health messages affect receivers. Common variables include gender, cultural background, ethnicity, literacy, primary language, and education level.

Channel factors. Properties of the channel or medium (e.g., Internet, TV, radio, social media, written materials) can influence the effects of messages. Different communication channels serve as primary health information sources for different population segments. People who are health conscious and health-oriented use communication channels that involve active seeking and processing of information, such as print media (e.g., newspapers, magazines), Internet and interpersonal networks, as primary sources for health information. In contrast, people who are not health oriented tend to use passive consumption channels such as TV and radio as primary sources of health information.¹⁵ The Internet is a particularly effective channel for tailoring messages to the needs of individual consumers. A majority of Americans go to the Internet first for health information, rather than to a practitioner,¹⁶ and new web-based applications are making the Internet and social networks increasingly more accessible, user-friendly, and personalized channels for health messages. Television is still the primary source of information on food safety and many other health topics, and television and radio have wider reach, serving larger, more diverse audiences than other media. However use of the Internet for health messages, such as the CDC's use of social media in the H1N1 campaign, is rapidly increasing. The Internet is considered a more credible source than television. Family and friends are also frequently used and credible information sources.¹⁷

Health information in mass media may result in changes in the use of health services and health care interventions, both through planned campaigns and unplanned coverage. However, how long these effects last is uncertain due to a lack of studies with adequate follow-up.¹⁸

Environmental factors. Both physical and social environments play an important role in personal health decisions and can influence how audiences respond to health messages. Social norms and pressure to conform, as well as external stressors, competing messages and physical barriers, can diminish message impact. For example, moderate to strong environmental distractions reduce the comprehension and effectiveness of educational or persuasive messages.⁴

Translating research findings into real-life practices can be problematic because studies have been conducted in a variety of settings using different designs and outcome measures. Furthermore, real-world circumstances, audiences, and conditions occur in unique combinations that can result in outcomes that differ from research findings. Although the research does not translate cleanly into practice, the consistency of evidence across settings enables us to offer several general recommendations.

What general practical advice can the science support?

Understand the problem, the audience, and the situation to determine how best to design and deliver the message. First, thoroughly research the problem of concern and clearly define it. Understanding the nature of the problem is vital to the success of the message.¹⁹ Assess audience understanding of an issue, the information they want to receive, and the way they want to receive it. Include members of the target audience when developing the message. Adapt the message to their needs, preferences, values, and circumstances. For example, information needs of people with very serious chronic conditions, such as life-threatening allergies and blood clots, were assessed through personal interviews and or focus groups. The resulting educational materials were evaluated by the target audience and made available as pdf files for patients and/or physicians through free internet access or continuing medical education.^{20,21}

Behavior is more likely to change if people understand the reason for the change and it fits within their existing practices. For example, to improve safe handling of fresh produce to reduce the likelihood of food-borne illness, a nationwide survey identified current practices, and consumer research determined what people were currently doing, what they were willing to do, and how they wanted to receive information. Based on this information, a flyer was developed and refined with the target audience.²² See Hoffman et al., for the application of a food safety message model to special audiences.²³

Design the message that is most likely to succeed in the given situation with the intended audience. Based on the identified problem, set a goal for the message with a clear endpoint. Establishing the intended outcome guides planning and measures of success. Evaluation of the message should be included in the planning process.¹⁹ Examples of outcome measures include reductions in adverse drug events or rates of food-borne illness.

We encourage practitioners to review the literature and use appropriate health behavior change theories in designing and evaluating public health messages. Select theories based on evidence supporting their suitability for the purpose, the situation and the intended audience.²⁴

Health messages should be tailored to their audience to enhance their self-efficacy and overcome barriers to self-efficacy.¹⁴ Therefore, include specific recommendations for avoiding potential risks and provide reassurances that following these recommendations will control or reduce potential harm.

Communicators should consider using pictographs labeled with numbers to communicate risk and benefit information to patients of different numeracy levels.²⁵ Even people with a high level of literacy prefer material that is easy to read. People ask that text be kept to a minimum, important points be bolded, and pictures used to illustrate recommended practices.^{20,22} *Clear communication* techniques are especially recommended for people with low health literacy. These techniques include only giving advice that is immediately essential, dividing information into easy-to-understand parts, using bullets and summaries of important information, using active voice and conversational style, using culturally appropriate content, using ample margins and white space, and using a minimum 12-point font size.²⁶

Pretest the message before sending it. Research shows that outcomes are more likely to succeed when targeted recipients are involved in the design and dissemination of health communication.¹⁶ Involving the community can be especially effective when cultural values are recognized. A good example is the *grandmother project*. Hispanic families were experiencing a high rate of miscarriages due to listeriosis which was traced to illegal cheese manufacturer. Rather than advising Hispanic families not to buy traditional cheese from out of market vendors, the Cooperative Extension educators worked with the Hispanic community to develop safe ways to make traditional cheese. Rather than external groups prohibiting traditional cheese use, Hispanic grandmothers encouraged eating safe cheese to protect family health.²⁷

Decide on the best channel to deliver the message. Base the choice of communication channels on a thorough audience analysis, matching channels to media preferences of the audience. However, be careful not to exclude important audience segments. As Neuhauser and Kreps state, "If we overlook barriers of literacy, language, culture, and disability, we are likely to miss our goal of improving health for all."²⁸ Often the best approach is to repeat health

messages using several different channels because different people use and prefer different channels.²⁹ Multiple channels also increase the possibility that opinion leaders, friends and family members will relay media messages to others.³⁰

Monitor to determine the success of the message and use knowledge gained to improve subsequent messages. Determining if a message is heard, believed, and acted on is a critical part of all communication systems. Monitoring is important not only for assessing message effectiveness, but for modifying subsequent communications to better achieve their goal with the intended audience. Individual interviews or focus groups can provide insight as to the relevance of a message and why or why not a message has been acted on. This information can be used to revise or adjust the content and delivery medium. Several good resources for using these recommendations and for evaluating messages are available in the *Additional Resources* list.

How does one evaluate communications implementing this advice?

Health messages in the mass media should be evaluated in the context of an overall planning and evaluation model that specifies goals, objectives, and indicators of success prior to sending the message. When possible, evaluation should include measures of process (was the message delivered as intended?), reach (what proportion of the targeted recipients did the message theoretically reach?), exposure (how many of the targeted recipients actually received and remembered the message?), and impact or outcome (what effects — intended and unintended — did the message have?).^{19,31} A variety of methods can be used, depending on the message purpose and the resources available.^{32,33}

Minimum budget. Assess whatever is feasible and affordable. Ask qualified in-house and external colleagues to evaluate messages or materials prior to widespread distribution. Assess impact by using surveys or focus groups of accessible volunteers who are similar to the target audience in regard to resources, interest, and literacy. Partner with interested academics who can help with program evaluation and service, professional or school groups who can help defray evaluation costs. Track easy-to-obtain indicators of reach and exposure, such as web hits, Internet-based media coverage, and local man-on-the-street interviews. Collect audience responses via short online interviews using free survey programs such as *SurveyMonkey*.

Modest budget. The above measures can be expanded or enhanced, including providing compensation for volunteers' time and collecting data from more sources such as Internet news; TV and radio coverage; and relevant social media activity. In some cases, public uptake of messages can be tracked through their use in entertainment programming. In addition, use a simple and inexpensive evaluation design such as a pretest-posttest design or a post-test only design including a retrospective pretest. These survey-based approaches

can assess changes in self-reported knowledge, attitudes and behavior in the intended recipients.

Unlimited budget. A comprehensive evaluation approach can be used that incorporates strong evaluation designs to provide sound evidence of effectiveness, such as a randomized controlled trial or a time series (longitudinal) design with a control or comparison group. Multiple measures can be used, such as observation, validated self-report measures, and appropriate biomedical data to assess outcomes.³⁴ Although personal reports and observation can indicate if people are applying the communication, changes in medical indicators are the most definitive gauge of success. In the Hispanic cheese scenario, for example, rates of listeriosis and incidence of miscarriage decreased while the project was on-going.

Conclusions

There has been a great deal of research on the effects of informative and persuasive communication about health. However, the available evidence is not sufficient to recommend clear best practices. The literature generally lacks direct comparisons of different approaches using randomized controlled studies, and the use of different outcome measures in different domains makes conclusions difficult. However, as the editors of this book have stated, we have accumulated enough evidence and experience to make good guesses at best general practices for communicating useful informative messages to help the public make informed decisions about their health. This chapter provides a brief overview of these good guesses. We encourage readers to consult the resources and references in this chapter for more detailed information.

Additional resources

1. U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute: *Making Health Communication Programs Work*. Available online at <http://www.cancer.gov/cancertopics/cancerlibrary/pinkbook/page1>. A free, practical step-by-step guide for planning, implementing and evaluating health communication programs.
2. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. Office of the Director, Office of Strategy and Innovation. (2005). *Introduction to program evaluation for public health programs: A self-study guide*. Atlanta, GA: Centers for Disease Control and Prevention. A free "how to" manual for planning and implementing evaluation activities that includes helpful worksheets from the CDC. Available online at <http://www.cdc.gov/eval/evalguide.pdf>.
3. K. Witte, G. Meyer, and D. P. Martell. (2001). *Effective Health Risk Messages: A Step-By-Step Guide*. Thousand Oaks, CA: Sage Publications. A practical guide with step-by-step instructions and worksheets for developing theoretically-based campaigns.
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Chapter 12: Across the Life Span

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Summary

Risk communication messages bombard people, from cartoon characters promoting cigarettes to direct-to-consumer drug advertisements. Messages that have an impact are processed and remembered — cognitive abilities that change dramatically from childhood to old age. Overall, these abilities improve early in life, but then gradually decline. However, the ability to remember the *gist* (meaning) of information grows in childhood and remains strong in the healthy brain. Remembering the gist of information is important because it lasts longer and is relied on to make most decisions. Instilling the gist of a message should be the goal of risk communication, which can be assessed using tests of recall, recognition, and comprehension.

Introduction

The audience for risk communications ranges from children to older adults. One might assume that, at the younger end of the age spectrum, children do not make risk–benefit decisions; adults make decisions for them. However, this assumption would be false. Minors make risky decisions with enormous consequences for public health, including decisions to consume products regulated by the FDA.

For example, the FDA recently issued warnings to 25 Mississippi convenience stores to stop selling cigarettes to minors. Children influence family food purchases and make food choices at school (and those who buy, rather than bring, lunch are more likely to be obese).¹ Adolescents buy food for themselves and shop for their families, too. Children and adolescents also make decisions about drugs and about adherence to medical regimens. They may have to self-administer drugs (e.g., inject insulin) or adhere to dietary restrictions (e.g., refuse foods with peanuts or other allergens).

Moreover, many adult attitudes about risks and benefits take root in childhood or adolescence (e.g., eating disorders, alcohol and drug use, and other risky behaviors).^{2,3} Risk communication begins early in life: 91% of six-year-olds recognized Old Joe, a cartoon character promoting cigarettes.⁴ In another study, four-year-olds preferred foods if they thought they were from a highly advertised fast-food chain.⁵ Children and youth are among the most

vulnerable recipients of persuasive messages, despite efforts to limit their access to risky substances.⁶

At the opposite end of the lifespan, older adults face a bewildering array of risky decisions. Older adults make risk–benefit decisions about diagnostic tests, medications, and surgical procedures, as well as retirement-related and other important financial decisions. National surveys suggest that older adults are less likely than other age groups to understand risk.⁷ Older adults are also more likely to be cognitively impaired, further compromising their comprehension of complex risks.^{8–10} To have an impact, risk communication must change what is being processed and remembered.

Here, I briefly review age changes in memory and information processing relevant to risk communication. Those changes include variation in the speed of information processing; the capacity to bring information into temporary memory and maintain it (to encode it into working memory so that it can be thought about and acted on); and the ability to store and retain information in long-term memory for later use.¹¹ I also discuss recent work distinguishing verbatim (exact memory for details) from gist (essential meaning) memories.¹² Remembering gist is important for risk communication because it lasts longer and forms the basis for decision making.

What does the science say about these aspects of communication?

People process information faster as they age from childhood through young adulthood, but then more slowly from young adulthood to old age.^{13,14} Children are less able to keep up with the pace of rapidly presented information than young adults are, and they take away less. Initial increases in speed of processing during childhood are ascribed to the development of myelination in the brain. Myelin is a fatty sheath that surrounds and insulates nerves, improving the conduction of nerve signals. In old age, conversely, demyelination occurs, along with other abnormalities in white matter resulting from trauma and disease, which contributes to general slowing of processing.

Sensory changes beginning in middle age, such as loss of hearing or visual acuity, can also contribute to slow motor response. Thus, the *hardware* of the brain changes across the lifespan in ways that affect information-processing speed, but not always the quality of responses (i.e., some responses can be slow but accurate). Speed affects accuracy when it limits the capacity of the temporary memory store or working memory.

Like processing speed, analogous increases in childhood and decreases in adulthood are posited for working memory capacity. *Working memory* refers to the ability to maintain and manipulate information, as well as to selectively inhibit irrelevant information (also referred to as *executive processes*). Capacity per se is relatively constant during childhood, but speed of processing, resistance to interference, and chunking information into meaningful units

increases, augmenting functional capacity — the ability to hold and operate on information.

Thus, children have difficulty maintaining information long enough to act on it by extracting meaning, solving problems, or drawing inferences. Younger children require more repetition of information (more opportunities to study) to achieve the same level of learning compared to older children or adults. Their rate of learning is slower: They learn less than older children do from the same presentations of information.

Working memory is used immediately, but long-term memory stores information over days, weeks, or even years. Long-term recall (what were the side effects the doctor told me about?; which foods have calcium in them?) improves from childhood to adulthood and declines in adulthood. Recognition (was fever a side effect?; does spinach have calcium?) shows a similar trajectory, but is a less sensitive measure because questions provide items, resulting in better performance. The rate of change in long-term memory slows as children get older, so that differences between adolescents and young adults are subtle.¹⁵ Again, the upside-down U-shaped developmental curve is observed, with improvement in childhood followed by noticeable decline in old age. There are also individual differences in the decline of long-term memory: Education is a major protective factor for cognitive impairment. However, people with genetic markers, such as the $\epsilon 4$ allele of the APOE gene that predisposes some to Alzheimer's disease, show declines in memory prior to disease onset, often in late middle age.

The information-processing model of *computer as mind* stresses rote memory, including capacity of short-term buffers and accuracy of long-term stores. Although the computer metaphor of mind has been very useful, newer approaches, such as fuzzy-trace theory, emphasize the meaning of information, not just memorization of rote facts.¹⁶ Understanding information, as opposed to merely memorizing it, helps people retain and apply learning to new problems or situations.

For example, Bransford and Franks found that new sentences that combined information — sentences that “connected the dots” — were “recognized” more often than presented sentences that did not integrate information.¹⁷ Presented with sentences such as “The bird is in the cage” and “The cage is under the table,” people falsely recognize having heard the sentence “The bird is under the table.” Despite crucial constraints on this effect (instructions must specify that true but unrepresented sentences should be rejected), the finding that memory emphasizes meaning has been upheld.¹⁸ That is, children and adults misremember the gist of presented information as having been presented (although they also retain verbatim memories to a surprising degree, contrary to Bransford & Franks,¹⁷ and other older studies). Told that the risk of dying during surgery is 2%, for instance, patients misremember the risk as zero if the meaning they infer is “no risk.”¹⁹

Older adults rely on gist (meaning-based memories) more than young adults do.²⁰ Similarly, semantic knowledge, such as vocabulary, characterized as crystallized rather than fluid intelligence, remains stable during old age. As the labels “crystallized” and “fluid” imply, world knowledge may remain stable and even improve after about age 30.¹⁴

It is important to separate effects of verbatim memory (which can be used to reject meaning-based lures* on a recognition test) from effects of gist memory (which can be used to wrongly accept meaning-based lures on a recognition test). Thus, increases in gist-based responding can be due to either decreases in verbatim memory or increased reliance on gist memory. The net effect of these two, independent parts of memory determine memory performance in the laboratory and in real life.

Both verbatim and gist memories improve in childhood, with gist often improving more rapidly than verbatim memory.¹⁵ This pattern leads to greater meaning-based recognition and recall as children get older and, paradoxically, greater meaning-based memory errors (net lower accuracy, once guessing and other response biases are eliminated). Figure 1 illustrates this paradoxical pattern for recall of semantically related lists of words: Recall of presented words and intrusions of semantically related (but non-presented) words both increase in childhood and adolescence, but the latter gist-based intrusions *increase more*. (During adolescence, the ability to use gist effectively — to judge reconstructed gist to be familiar — goes up; Figure 2.) Hence, net accuracy actually goes down from childhood to adulthood, as shown by the convergence of the true and *false* recall lines in Figure 1. Discovered in 2002, this effect has been replicated in more than 50 studies.^{21,22}

Verbatim and gist memory decline reliably in old age, but verbatim memory declines more than gist. Memory for gist carries most of the load of remembering during old age, sustaining performance. Therefore, understand meaning is crucial for older adults. Transitions from healthy aging to memory impairment are marked by a decline in this *backup* system of gist-based memory.¹⁰

Recall of word lists is the most often used neuropsychological assessment of memory impairment, and the most predictive single test of conversion from impairment to Alzheimer’s disease. Memory for word lists predicts memory for more complex and ecologically valid stimuli, too, such as narratives. Models that fit data for word lists also fit data for narratives, using the same concepts of verbatim and gist memory. Gist applies to the level of individual words or sentences as well as to semantic integrations across words or sentences, such as the theme of related words or inferences that integrate related sentences,

*Tempting, but wrong, answers.

as well as to numbers and other kinds of meaningful information. Small numbers are understood early in life, but it is difficult to get the gist of ratio concepts such as probability or risk (e.g., 1 out of 8 women will develop breast cancer) even for many adults.²³

Many of the group differences that have been discussed in this chapter are summarized in Figure 2: Verbatim memory and both types of gist memory increase from childhood to young adulthood, and then they decline. Gist-based familiarity judgment increases sharply from adolescence to adulthood. When gist memory estimates are combined, the paradoxical pattern from childhood to adulthood of greater growth in gist (compared to verbatim memory) is evident, as is the greater decline in verbatim memory (compared to gist) for Alzheimer's patients.

The last pair of groups on the right, of older adults and Alzheimer's patients, was presented with materials that provided greater verbatim support (materials for all other pairs were similar to one another). As can be seen from the figure, older adults' verbatim memory in that task can be as strong as younger adults' verbatim memory in a harder task, illustrating that memory performance is not a fixed quantity. Instead, performance is a function of both task and ability. I now turn to the implications of these differences in information processing for risk communication.

Figure 1. Age-Related Increases in the Proportion of True and Gist-Based "False" Recall for Semantically Related Word Lists

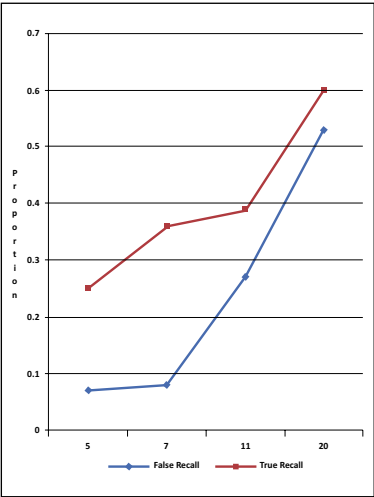


Figure 2. Estimates of Verbatim Readout, Gist Reconstruction, and Gist Familiarity in Recall of word Lists across Groups

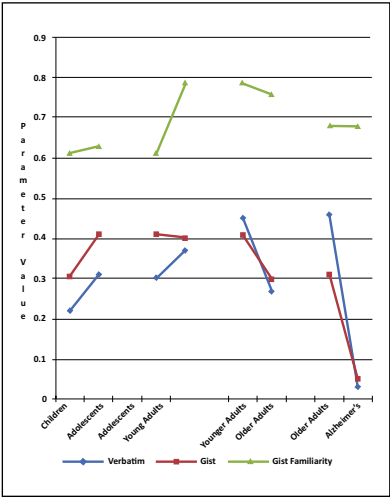


Figure 2 shows results from recall tests for a list of unrelated words across the life span, including Alzheimer's patients. Two groups are compared at a time (e.g., children to adolescents) regarding their memories for the same materials, averaging across studies (see Brainerd et al., 2009 for details).¹⁵ Verbatim memory (exact recall of presented words) and two kinds of gist memory are depicted: The ability to reconstruct the gist meaning of presented words and the ability to judge reconstructed gist as sufficiently familiar to report it as a recalled item. Parameter values are empirical estimates of these abilities, using mathematical models tested for fit with recall data.

What general practical advice can the science support?

Messages about risks and benefits are received from family, schooling, the media (e.g., from advertising), and other cultural influences and may be explicit or implicit (e.g., role modeling). In the laboratory, boundaries are drawn between cognitive, social, and emotional factors, but, in practice, these factors are intertwined.²⁴ Social values and emotional reactions are often learned by processing cultural messages, and, conversely, information must be processed to elicit emotional reactions.²⁵ In the preceding section, evidence was presented that how information is processed differs developmentally and across individuals.

Consider the dictum to eat five or more vegetables per day, which is taught in schools and reported in the media. Elementary school-aged children can certainly count up to five and know the word vegetable. This message is more likely to be remembered by children if it is presented repeatedly, in small chunks of fewer than about five words (not long sentences) and at a slower pace: “Eat vegetables. Five *vegetables* every day. Eat five vegetables a day.” Pictures accompanying words are a form of repetition and can support memory.

Note that verbatim repetition *stamps in* memories, but is unlikely to produce transfer or long-term retention of information. Cuing meaning (e.g., saying, “Vegetables make us strong. These are all vegetables” and then listing vegetables) can boost memory for gist or meaning in younger children and helps children connect the dots to new situations (raw carrots at home, cooked green beans in school lunches, etc.). Although these connections seem obvious to adults, young children can be quite literal. Also, children may be unable to carry out a series of instructions not because they are dumb, but simply because they cannot remember multiple steps. Breaking the steps down so that they can be executed one at a time, especially with repetition and reminders along the way, should improve adherence.

As children get older, after about 11 years of age on average, verbatim repetition can give way to emphasizing the meaning of information. Environmental support for remembering verbatim information (e.g., oral or written reminders) remains useful at all ages as verbatim memory is evanescent and vulnerable to interference. However, older children and adolescents are more likely than younger children to integrate information, noticing semantic themes and drawing inferences that go beyond literal facts. (Even adolescents are not as readily able to spontaneously connect the dots as adults, for example, between actions and probable consequences despite *knowing* the consequences.) For example, older children will get the gist of a list such as “fries, taco, Coke, burger” (fast food or junk food) versus “apple, spinach, carrots, fish” (healthy food). Recognition of healthy foods is not sufficient for behavior change, but it can facilitate such change when accompanied by retrieval of relevant values in the context of behavior.^{12,26}

Communications should be presented more slowly to older than younger adults, and their responses are likely to be slowed. However, slower does not mean dumber; information should not be dumbed down for older adults. Despite general slowing and an inability to retain details, vocabulary and reading ability of older adults can remain high. Unlike children, despite lower levels of verbatim memory, older adults can rely on fairly high levels of gist familiarity. Therefore, for older adults, we can expect impairments in verbatim memory for detailed dietary instructions or in prospective memory for exact dosages or exact times of day to take medications. Written instructions, as well as alerts and reminders delivered electronically (e.g., to take medication or to signal that medication has already been taken) are likely to be helpful cognitive prosthetics because they support verbatim memory.

Because of older adults' conserved gist memory, it is also essential to explain the reasons for dietary recommendations or medications to them. Comprehension, or extraction of gist, is the main mechanism through which older adults remember information. Therefore, if they do not understand the meaning of information, they cannot fall back on rote recall as easily as younger adults can. Even patients with mild to moderate Alzheimer's disease retain some ability to remember the gist of information.

How does one evaluate communications implementing this advice?

Information must first be taken into memory to influence attitudes, values, or preferences, which, in turn, influence behavior. Therefore, memory tests can assess whether messages have been received, and if so, how they have been interpreted (or mentally represented). Use recall or recognition tests, not only to measure *true* or accurate memories, but to measure distortions in recall (intrusions) or *false* recognitions that reveal how the *meaning* of messages has been understood. Immediate memory tests are not sufficient, as transfer and long-term retention are more likely to shape behavior. Immediate memory performance cannot be assumed to reflect the same factors as long-term retention because verbatim memory is tapped more often on immediate tests but gist memory is tapped more often on delayed tests.

Successful information processing should also lead to changes in attitudes, values clarification, and modification of preferences. Attitudes, values, and preferences are often assessed through verbal self-reports (or reports by others, such as family members). However, self-reports are subject to a variety of biases. In childhood, the ability to explain reasons for behaviors (i.e., to articulate attitudes or preferences) lags years behind the ability to demonstrate those attitudes or preferences. In adulthood, biases are more likely due to such factors as social desirability (e.g., underreporting weight). Thus, communications can be assessed behaviorally (e.g., by offering food choices and determining which options are chosen or weighing the amounts of particular types of food that are eaten in a controlled setting). Although

behavioral measures are ideal, they are not direct windows on the mind; self-reports do correlate with behavior, just not perfectly. Both self-reports and behaviors must be interpreted via theories of underlying mechanisms. Assessments should be designed based on theories grounded in experiments in which hypotheses have been tested.

Although memory tests and attitude surveys can be administered relatively cheaply in the short term, long-term follow-up requires monetary incentives to combat attrition. Access to community samples of older adults is also expensive, and such subjects must be assessed for medical conditions (to obtain a “healthy” aged sample, isolating the effect of aging). Randomized assignment of people receiving different risk communications with pre-tests and post-tests, efforts to avoid cross-contamination, and proper statistical analysis remain the best methods for assessing effectiveness. Recall tests are more discriminating than recognition tests, but require scoring by hand (which is labor intensive, and therefore costly). Finally, assessing multiple levels of information processing, not simply acquisition of knowledge, but also extraction and transfer of meaning to situations that were not directly taught, requires extensive batteries of tests (i.e., costly multiple sessions).

Additional resources

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Chapter 13: Health Care Professionals

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Summary

This chapter reviews the existing literature on health care professional risk–benefit communication and offers advice to practitioners on how to better communicate the risks and benefits of medications, medical devices, and foods to patients. First, we present what the science says about health care professional risk–benefit communication. Next, we discuss what general practical advice the science can support. Finally, we give suggestions on how one might evaluate strategies used to improve risk–benefit communication by health care professionals.

Introduction

In 2000, the Institute of Medicine published an influential report, *Crossing the Quality Chasm*, which specifies six characteristics that are essential for high-quality health care: patient-centered, safe, effective, timely, efficient, and equitable.¹ Each of these characteristics interacts with the others to influence quality. Thus, patient safety is linked to timely access to effective interventions. Patient safety is also related to effective patient-centered communications that help patients understand and respond to health care information, including information about the risks and benefits of medications, medical devices, and foods.¹

A substantial body of research links effective, patient-centered communication principles and a wide range of health outcomes, including symptom control, patient satisfaction and patient follow-through with treatment recommendations and health behavior change.^{2–7} However, we know relatively little about the impact of health professional–patient communication about risks and benefits on either patients' understanding or their subsequent behavior. In this chapter, we will share what we do know about this aspect of risk communication and its implications for practitioners.

What does the science say about this aspect of communication?

Physician–patient communication. According to Frosch and Kaplan, shared medical decision making (SDM) is a process by which patients and practitioners consider outcome probabilities and patient preferences, in the course of reaching health care decisions based on mutual agreement.⁸ Makoul and Clayman identify several essential elements of SDM: define and explain the problem, present options, discuss pros and cons (benefits/risks/costs), elicit patients' values and preferences, discuss patient ability and self-efficacy, offer knowledge and recommendations, check and clarify patient understanding, make or explicitly defer a decision, and arrange follow-up.⁹ However, in studies that have examined actual professional–patient interactions, researchers find that health care professionals almost always fail to adequately educate patients and enlist them in a process that meets the criteria for fully informed decision making.^{10,11} For example, Braddock and colleagues' study of 1057 physician–patient encounters and 3552 decisions, including 893 that concerned medication use, found that that only 9% met their criteria for completeness of informed decision making. Moreover, only 8% of encounters included a discussion of risks and benefits, and only 1.5% included an assessment of the patient's understanding of the information provided.¹⁰

A few studies have specifically examined how physicians communicate the risks and benefits of medications during medical visits.^{12–14} Sleath and colleagues investigated physician and patient question-asking about medications in a sample of 467 audio-taped primary care visits.¹² All patients were on at least one prescribed medication and were on an average of four. The researchers found that physicians asked patients about how the medication was working for them during 56% of visits and about side effects during only 27% of visits. Patients asked about side effects during 5% of visits. This study did not examine physician information-giving about risks and benefits of medications.

Two other studies focused on physician–patient communication about antidepressants during medical visits.^{13,14} In a sample of 40 audio-taped encounters with veterans who had previously been prescribed antidepressants, Sleath and colleagues found that practitioners asked only 6% of veterans about adverse events and only 15% of patients about how well the antidepressants were working.¹³ Practitioners gave 10% of patients information about adverse events and 5% information on how well it works. Young and colleagues used standardized patients (patients who presented to the doctor with standardized symptoms) to assess doctor behavior during 131 visits during which antidepressants were prescribed.¹⁴ In this study, physicians provided information about side effects to 85% of patients, but provided information about the benefits of the medication to only 38% of patients. A recent study found that older persons' willingness to take medication for primary prevention of cardiovascular disease was relatively insensitive to benefit communication, but highly sensitive to adverse effect communication.¹⁵

Future research should examine how risks and benefits are communicated to patients when medications are first prescribed, as well as the extent to which physicians monitor patients' experience of medication risks and benefits so that potential problems can be detected and therapy can be optimized. Intervention research is also needed to develop and test strategies to promote physician and patient participation in discussions about the risks and benefits of treatments and to improve the quality of shared decision making.

Pharmacist–patient communication. Very little work has specifically examined how pharmacists verbally communicate medication risks and benefits to patients.^{16–18} Schommer and Wiederholt examined the number of pieces of information that pharmacists provided to patients about their medications, but did not specify the types of information provided.¹⁷ Sleath examined pharmacists' question-asking and found that pharmacists asked 16% of patients questions related to medication use (e.g., asking about benefits, side effects).¹²

Svarstad and colleagues evaluated pharmacists' communication in 306 community pharmacies in 8 states using individuals who were trained to act as patients with new prescriptions.¹⁸ The researchers defined *adequate risk communication* as providing information about one or more side effects or precautions. Adverse events were discussed for 17% of amoxicillin prescriptions, 31% of ibuprofen prescriptions, and 37% of paroxetine prescriptions. The researchers found that younger pharmacists were more likely to provide risk information than older ones. They also found that patients who received prescriptions in states with more regulatory intensity surrounding pharmacist counseling (e.g., states that require that patients be given face-to-face counseling by pharmacists) were more likely to receive risk information than patients in states with weaker regulations (e.g., states that only mandate an offer for pharmacist counseling be given).

Studies have also found that the written consumer medication information provided to patients in pharmacies is not adequate.^{18–20} Raynor and colleagues found that the side-effects section was the most commonly read section of written medication information.¹⁹ Most recently, Winterstein and colleagues trained individuals to fill prescriptions for lisinopril and metformin in 365 pharmacies.²⁰ The shoppers gathered the written information sheets they received, which were subsequently evaluated by an expert panel. The researchers found that, although the distribution of written information through pharmacies was effective, the content, format, reading level, and excessive length of the consumer medication information needed improvement.

Patients do want to receive written medication information. However, they do not want written information to substitute for verbal communication from health care professionals.^{21,22} Grime and colleagues found that patients prefer

written information tailored to their conditions.²¹ Sleath and colleagues found that the majority of Latino patients in their sample wanted verbal and written medication information and almost one quarter wanted it in both Spanish and English.²² A recent Cochrane systematic review of the literature by Nicholson and colleagues concluded that there was not enough evidence to say whether written medication information positively influences patient knowledge, attitudes, and behaviors regarding medication taking.²³ Thus, additional research is needed to examine whether patients read, comprehend, and use the written medication information that they receive in pharmacies.¹⁹

What general practical advice can the science support?

Health care professionals need to receive specific training on how to communicate with patients about the risks and benefits of treatments.

Although relatively few studies have examined the risk and benefit communication practices of health care professionals, the evidence shows substantial room for improvement in health professionals' use of communication strategies. Two controlled trials successfully demonstrated that health care professionals' risk communication skills could be improved.^{16,24} In Wales, Elwyn and colleagues conducted a controlled trial with 20 physicians that tested several intervention efforts, including workshops that trained the physicians in risk communication and shared decision making.^{24,25} Physicians attended four 3-hour workshops, two devoted to risk communication and two focused on shared decision making. Delivery of risk information to patients improved dramatically after the workshops, which included the use of visual formats to illustrate treatment risks to patients. Rickles and colleagues conducted a randomized, controlled trial with patients who had received an initial prescription of an antidepressant.¹⁶ Patients were randomized to receive usual care from pharmacists or an intervention that included pharmacist training in guided education and monitoring. Patients were significantly more likely to report changes in depressive symptoms and side effects if they saw a pharmacist who was trained. These two trials suggest that physicians and pharmacists can be trained to communicate more effectively about medication risks and benefits, although additional trials are needed to identify the most efficient and effective strategies for improving professionals' skills and promoting their use in actual encounters with patients. Also, existing models of patient-centered communication²⁶⁻²⁸ and shared decision making^{8,9} can be incorporated into this training.

State pharmacy boards should consider requiring patient counseling on all prescriptions. Svarstad and colleagues found that patients who received prescriptions in states with more stringent regulation of pharmacist counseling (e.g., states that require face-to-face counseling by a pharmacist) were more likely to receive medication risk information than patients in states with less regulatory intensity.¹⁸ State pharmacy boards need to consider requiring that

patients receive face-to-face counseling by pharmacists, so that risk–benefit communication can be improved.

Health care professionals need to provide useful written information about the risks and benefits of treatment to complement their verbal communication. Both written and verbal information regarding medication treatment is important to patients.^{21,22,24} Elwyn and colleagues found that practitioners used written information more often to explain treatment risks to patients after they received training in shared decision making.²⁴ Given the low frequency of health professional–patient discussions about medication risks and benefits documented in the current literature, future research should also test: (1) the impact of communication strategies delivered by other members of the health care team (e.g., nurses, care managers); (2) the impact of decision aids that prompt professionals to communicate and facilitate information sharing;²⁹ and (3) interventions delivered via alternative technologies, such as web-based decision aids that the patient can access between medical visits.³⁰

As noted above, the written information provided to patients in pharmacies is often not adequate to enable them to understand the risks and benefits of medications.¹⁸⁻²⁰ Personalizing the written information (e.g. using the word “you”), providing risk–benefit information in different formats, and giving patients a reflective task to work on when reading the information may improve patient perceptions of risk.³¹⁻³³ However, additional research is needed to develop better ways to promote patients’ exposure to, comprehension of, and actual use of the written medication information about risks and benefits of medication received in pharmacy settings.³⁴

Health care professionals should employ strategies that activate patients, encourage their participation in care, and increase their capacity to self-manage their conditions. Patients who are more knowledgeable about their conditions, participate more actively in medical visits, and feel more confident about managing their conditions are more likely to follow through with treatment and achieve better outcomes.³⁵⁻³⁸ Thus, strategies that focus on increasing patient participation in care may increase the likelihood that patients will ask for and receive needed information about the risks and benefits of medical treatments. Controlled trials of self-management support interventions that focus on increasing patients’ confidence to self-manage have produced improvements in clinical outcomes across a number of other chronic conditions.³⁹⁻⁴¹ Recent efforts to integrate self-management support into general health care settings suggest that the following elements are critical to individual patient and program success: (1) assessment of patient beliefs, behavior, and knowledge; (2) collaborative goal setting; (3) identification of personal barriers and supports; (4) skills in teaching, including problem-solving, to address barriers; (5) increasing access to resources and supports; and (6) developing a personal action plan that is based on the previous steps.^{42,43}

How does one evaluate communications implementing this advice?

The ultimate test of the effectiveness of health professionals' communication is direct assessment of the patients' understanding of the risks and benefits and their satisfaction with the communication process. To assess the impact of health professional training in risk-benefit communication skills, one can assess the impact of the training on several levels at no cost or a low cost by examining: (1) were the training objectives achieved?; and (2) did health professionals who attended the training report an increase their knowledge, skills, and attitudes (e.g., importance, confidence)? . If one wants to assess the impact of health professional training in risk-benefit communication skills at a more moderate cost, one can investigate: (1) do trained professionals apply new knowledge and skills in actual interactions with patients; (2) do patients of trained professionals report increased understanding of risks and benefits of treatments, greater involvement in decision making, and the capacity to make high-quality decisions? ; and (3) are training participants in training able to demonstrate the use of the targeted skills in simulated interactions?

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Chapter 14: Readability, Comprehension, and Usability

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Summary

More than 1,000 studies have documented the problem that most health information, including risk communication, greatly exceeds the comprehension of the average US adult. We describe specific ways to assess text readability and usability and practical steps to make risk communication more understandable, especially by engaging users in its design and testing.

Introduction

Playwright George Bernard Shaw famously commented: “The single biggest problem in communication is the illusion that it has occurred.”¹ Two decades of research now support his witticism with evidence. Much of our well-intentioned health communication is not comprehensible, especially by people with barriers related to literacy, language, culture, or disability. For example, it is estimated that more than 90 million Americans have trouble understanding printed information about how to take medication correctly.² Communication problems are thought to be an important reason why our nation is slow to achieve its health goals.³ Fortunately, communication research and practice are illuminating a better path forward. US policies, like the National Action Plan to Improve Health Literacy and the Plain Writing Act, reflect the growing national movement to align health communication with people’s needs.^{4,5} In this chapter, we describe issues, evidence, and guidance to improve health risk communication.

What does the science say about this aspect of communication?

The scientific study of risk communication, “communication intended to supply lay people with the information they need to make informed, independent judgments about risks to health, safety and the environment,”⁶ began in the 1970s. Risk communication about health often includes high concern or controversial topics or situations and is particularly relevant to the U.S. Food and Drug Administration’s (FDA) important safety communication to the public about drugs, biologics, medical devices, and food safety (see Chapter 21).

How theory has shaped health and risk communication. Many conceptual models have contributed to our understanding of how people interact with health and risk communication. For example, social-ecological and social-cognitive models suggest that people are more likely to learn and take action when information is tailored to their needs and preferences and is relevant to their social situations.^{7,8} According to adult learning theory, communication is more effective when it builds on people's prior experiences.⁹ Mental models concepts emphasize the importance of bridging the gaps between people's initial risk perceptions and the more objectively known risks.^{6,10} Social semiotic theory helps explain how people interpret the meaning of the communication they receive and why health messages will only have an impact if they are understandable, engaging, and motivating.¹¹ Models of participatory design used in communication development draw on knowledge from multiple disciplines, including human factors, engineering, sociology, and marketing and focus on the power of involving the target audiences as co-developers in those processes.¹²⁻¹⁴

Comprehension issues in health and risk communication. Traditional health and risk communications have emphasized developing and delivering generic (one-size-fits-all) information that is not usually well aligned with people's specific communication needs.¹⁵ Not surprisingly, substantial research indicates that this expert approach is often ineffective in improving people's health knowledge and actions.^{15,16} A critical problem documented in the past two decades is that most health and risk communication is written and presented in ways that far exceed most people's comprehension.¹⁷⁻²¹

Literacy studies. The 2003 National Assessment of Adult Literacy (NAAL) defines literacy as "using printed and written information to function in society, to achieve one's goals, and to develop one's knowledge and potential."² The NAAL is a national, population-based survey conducted every decade and is the best data source about Americans' literacy levels. In 2003, an estimated 43% of adults in the United States (approximately 93 million) had *basic* or *below basic* prose literacy skills — the 2 lowest of 4 levels. Most adults with a high school education or less and 13% of those with a college degree tested at these lower literacy levels.² Although there are no national data on the average grade reading level of US adults, estimates have ranged between 7th and 9th grade levels.²²⁻²⁴ One study found that adults read about 4 grade levels below their highest grade completed.²⁵ Furthermore, 20% of adults are estimated to read at the 5th grade level or below.²⁴

Health literacy studies. Because of its scientific content, health information is thought to pose literacy requirements beyond general reading comprehension, such as knowledge about health and medical concepts and terminology.²⁶ Beginning in the 1990s, the field of health literacy has emerged to focus on the effectiveness of health communication relative to people's needs and

skills. In 2000, the US Department of Health and Human Services defined *health literacy* as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.”²⁷ The concept of health literacy includes components of reading, comprehension, speaking and numeracy “the ability to use and understand numbers in daily life,” such as reading a food nutrition or medication label (also see Chapters 7 and 9).^{26, 28}

The 2003 NAAL survey is also the best source of population-based data about Americans' health literacy. It found that most people scoring at the lowest two health literacy levels (*below basic* and *basic*) were unable to answer questions correctly asking about hypothetical scenarios of taking medications at certain times of the day, filling out patient information forms, and other important health tasks. Those in the below basic level also had trouble correctly reading a health appointment slip. Even people scoring at the *intermediate* literacy level had numeracy issues, such as difficulties understanding health information graphs and calculating health insurance costs. Only the 12% of respondents who scored as *proficient* in health literacy were able to answer questions correctly on the set of health literacy tasks routinely required of Americans. Health literacy skills are generally lower among people with lower education, lower income, who are members of a minority group, or are 65 years of age or older.²⁹

Readability of health information. Because so many Americans have difficulties understanding health information, literacy experts recommend increasing text readability so that it matches audiences' reading levels — especially for people with limited literacy.^{17,25,30,31} Readability testing is a standardized method to estimate the US grade reading level of text content. It is performed either manually or with computer software. Readability tests typically measure the difficulty (length) of individual words and sentences in a text document.

Disturbingly, more than 1,000 studies of health print materials (including medication labels and packaging) and web sites have found that text readability significantly exceeded the estimated reading skills of the audiences for whom they were developed.^{17,32-34} Most studies have reported health text readability at or above the 10th grade reading level. College and graduate school levels are not unusual for patient health communications that describe risk and that are written or reviewed by lawyers and/or scientists. For example, patient consent documents are notoriously hard to read. In a study of more than 600 consent forms, average readability was at the college level; only an estimated 5% of the forms would be understandable to patients who read at the 8th grade (US average) level.³⁵

Readability scores provide a rough indicator of word and sentence difficulty at grade levels, but are not adequate proxy measures of overall

text *comprehensibility*.³⁶ Also, readability scores are imprecise, especially at high and low levels, and may not accurately reflect actual reading difficulty. Although readability testing is an important tool, grade level scores should be interpreted with caution.

Other factors that affect comprehension. Research is defining other factors that affect the reading ease and usability of health information for various audiences. Such characteristics are often grouped into *clear communication* or *plain language* design criteria. Although there is no agreed upon single set of such criteria, the recommendations provided in the Additional Resources section at the end of this chapter are among the most-commonly used.

US Government reports, such as the Department of Health and Human Services' *Quick Guide to Health Literacy*, *Simply Put*, *Toolkit for Making Written Material Clear and Effective*, and others describe these principles and how to apply them to health communication materials.³⁶⁻³⁸ The key criteria are also embodied in tools, such as Suitability Assessment of Materials (SAM), used to assess health communication materials. The SAM is the most validated and most commonly used tool and includes readability and 21 other evidence-based design principles as shown in Table 1 at the end of this chapter.^{30,39,40}

Web navigation and usability. In addition to basic literacy skills, web-based sources of health information pose additional computer literacy requirements, such as the ability to locate and search sites, spell search terms, and follow threads to related sources.³¹ Similar to findings for print materials, decades of research about online content have identified problems of low readability and usability.^{34, 41-43}

Participatory design. The design principles described above have contributed greatly to improved health communication. However, no set of design criteria can adequately encompass the multiplicity of factors that affect people's comprehension of health risk communication. Furthermore, *comprehensibility* alone does not ensure that communication will be effective. It must also be engaging, personally relevant, and actionable for users.^{44,45} Participatory, or user-centered design leverages important design principles, but goes beyond them to engage users in more complex, realistic, and nuanced scenarios as co-creators of communication.^{12,14,46,47,50} Research over the past 30 years increasingly indicates that participatory design processes —structured formative inquiry with intended users — are critical to create successful health communication.^{13,14,16,48-50}

Strength of the scientific evidence. The past 30 years of research on health and risk communication provide a rich foundation on which to assess and improve the readability and comprehension of our communications. Strengths of the research include evidence about literacy and health literacy skills in the United States and how those relate to people's abilities to comprehend and perform common health tasks and, ultimately, affect their health status.

Likewise, substantial evidence now documents the serious gap between people's literacy and health literacy skills and the readability of the health information they receive. Research has increasingly identified many other design factors that affect people's comprehension and use of health risk communication. Numeracy studies have provided important evidence about how people understand and misunderstand the quantitative presentation of health risks and offer practical guidance about ways to present such information to make it more comprehensible, such as easier-to-understand graphics and medication measuring devices.^{28,51} Finally, research about user-centered design has documented the central value of these processes to develop and distribute effective health risk communication. Studies are beginning to show that adhering more closely to readability and other design principles can improve user's comprehension of health and risk communication.^{16,25,28,44,46,49,50,52}

Although evidence is increasing about the value of the many non-readability design principles embodied in the SAM test, finer empirical testing is needed for each of these criteria. Further research is needed to demonstrate the pre-post improvement in comprehension when health risk communication is developed according to *plain language* guidelines and user-centered design processes. Perhaps the area in which research is most needed is in establishing stronger links between improved comprehension of health risk communication and behavioral outcomes. For example, does better understanding of medication instructions improve how well patients take their medications?

What general practical advice can the science support?

Given the current state of research evidence and the national recommendations related to health literacy and plain language communication, we suggest six key approaches to improve the readability and understandability of health communication. We provide only a very brief overview of these strategies, and refer readers to references for more detailed guidance.

1. Learn more about health literacy and plain language communication.

An important first step for practitioners and decision-makers interested in improving health risk communication is to undergo training and to study important background documents. Training is available from public and private organizations. For example, the Centers for Disease Control and Prevention (CDC) offers a free online overview course Health Literacy Training for Public Health Professionals at <http://www.cdc.gov/healthmarketing/healthliteracy/training>. We also recommend the ten selected Additional Resources as well as the references at the end of this chapter.

2. Define the intended audiences and purpose of the communication.

Because generic health communication is often ineffective, it's important to identify the specific audiences and learn as much as possible about them,

including their age ranges, health conditions, cultures, languages, educational and income levels, literacy skills, and media preferences. Research studies, government reports, health care organization information and other documents can provide useful profiles. It is also helpful to survey or interview members of the intended user groups. Another key step is to define what the communication resource is expected to accomplish. Is the information intended to help patients understand how to take medication correctly? Is it intended to persuade them to detect and report certain side effects? Defining communication objectives is important to prioritize information and identify outcomes to evaluate.

3. Involve the intended audiences through the design process. As discussed earlier, there are many known as well as poorly understood factors that affect the readability and understandability of health risk communication. The only way to ensure that the communication will meet the needs of the intended audiences is to involve users as co-creators from the beginning. At an early stage, intended user input is needed about the topic and purpose of the communication, including problems people have experienced related to the topic, such as taking diabetes medications, and ways they recommend to overcome those barriers. Do older adults report they have difficulty reading the font size of medication labels? Do Hispanic groups prefer information that engages multiple family members? Do people want to hear about the most serious risks first?

There are many participatory, or user-centered design techniques, including focus groups, individual interviews, and usability testing. *Usability testing* refers to a broad range of structured methods to engage users in designing communication materials.^{12,50} Usability tests are often one-on-one situations that involve a tester asking a user to read and navigate a draft document or web site (see www.usability.gov), accomplish specific tasks related to it, and to recommend changes to the text, format, and graphics. The draft is then revised with participant input. User-centered design begins with recruiting members of the intended audiences. It is important to include people with limited literacy skills in this process — they often get left out because they have trouble reading the recruitment flyer or are uncomfortable about their reading skills. One effective and respectful approach is to recruit (and pay) people from adult literacy programs. Another approach is to recruit people with less than a 10th grade education as they are likely to have limited literacy skills. Participants' health literacy skills can be assessed using tests such as the short form of the Test of Functional Health Literacy in Adults (TOFHLA), but such tests should be used sparingly, because they can embarrass participants.⁵³

4. Set and test for readability and other communication design criteria. After the intended audiences are identified and researched and members of those groups are engaged in the communication design, design standards should be specified. Because it is difficult to know which patients or consumers

will be among the half of Americans with limited health literacy skills, federal agencies and other organizations recommend a *universal precautions* approach — it both minimizes risk to the most vulnerable groups and also promotes better understanding for all.⁵⁴ Fortunately, communication studies show that people at all health literacy levels prefer easier-to-read information.³⁹

Readability levels. As discussed earlier, readability is an important measurement tool, but it is only a rough indicator of some aspects of comprehension. Therefore, it should not be mistakenly considered the prime indicator of easy-to-use information — as is too often done. There is no single best readability level, given the diversity of American's health literacy skills. However, there is general agreement that readability should not exceed 7th to 8th grade (*average*), the lower end of the estimated average reading level of the US population. In addition, because many people read below that level, a 4th to 6th grade level (*easy*) is a better goal for information that is critical for people to understand (such as medication instructions) or that is delivered to groups with lower health literacy (such as older adults).³⁶ In our experience, most health risk information can be written well at about a 6th grade level without sacrificing content or style. Most current health communications are written above the 9th grade (*difficult*) level. See the helpful readability discussion in the Centers for Medicaid and Medicare Toolkit.³⁶

Readability testing. There are more than 40 readability tests, and their reliability at various grade-reading levels differs, as do their underlying readability *formulas*. We recommend becoming familiar with the following widely used, validated tools, and their limitations.

- SMOG (the Simplified Measure of Gobbledygook test)^{30,55}
- The Fry Readability Test³⁹
- The Flesch Reading Ease Test⁵⁶
- The Lexile® Framework for Reading⁵⁷

The Flesch-Kincaid Readability Test is incorporated into Microsoft Word's (Microsoft, Redmond, WA) readability software and is easily accessible. However, the formula is truncated at a 12th-grade level in Microsoft Word and frequently presents falsely low evaluations.⁵⁸

Because the readability tests vary in their reliability at various grade levels (especially below 6th grade and above 12th grade) and because draft health communication materials often contain text at many readability levels, we recommend assessing materials using multiple tests (excluding the Flesch-Kinkaid test). Content should be sampled, prepared, and tested according to the test instructions. Table 2 shows an original sample of health risk communication text and scores from four readability tests computed with two readability software programs. Table 3 shows a revision to improve readability from the original college level (15+) to a 5th-to- 6th grade level. (See Tables 2 and 3.)

Table 2. Readability assessment: first paragraph of FDA patient safety alert: glucose test strips*

Advice for patients: serious errors with certain blood glucose monitoring test strips			
Patient Concerns If you are taking drug products or therapies that contain certain non-glucose sugars, such as maltose, galactose and xylose, these sugars will produce a falsely elevated glucose result if you are measuring your blood glucose using a GDH-PQQ test strip. If you then use this falsely elevated result to determine your dose of insulin, you could give yourself too much insulin, which could result in dangerously low blood glucose. In addition, if your blood glucose is actually low, it could go unrecognized and untreated because the test result could read higher than it actually is and appear to be within the normal range. In this case, you may not know your blood glucose is low unless you have certain symptoms, including confusion, hunger, nervousness, dizziness, irritability, sweating, heart pounding (palpitations), shaking, unusual fatigue or weakness, or tunnel or darkened vision. Low blood glucose must be recognized and treated promptly to avoid serious complications, such as coma and death.			
Readability Assessment			
Test	Grade level	Reading ease	% Passive Sentences
SMOG	15.0		
Flesch-Kincaid	16.2	35% (very easy to read)	0
Fry	college	very long sentences	
Lexile**	Graduate school		

*Advice for Patients: Serious Errors with Certain Blood Glucose Monitoring Test Strips
<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PatientAlerts/ucm177189.htm>

** A Lexile measure is a computer-driven algorithm that provides a numeric assessment (Lexile score) of the difficulty of a text. www.lexile.com

Table 3. Readability assessment: revised version of FDA patient safety alert: glucose test strips*

Patient Concerns Do you test your blood sugar with GDH-PQQ test strips? Do you take drugs or treatments that have maltose, galactose, or xylose? These are sugars, but are not the same as the blood sugar you test (glucose). If you answer “Yes” to both questions, you could have a problem with your blood sugar test results. Maltose, galactose, or xylose can react with the GDH-PQQ test strips. They can make the test strips give false results. • Your test results may be falsely high when your blood glucose is really normal. If this happens, you might give yourself too much insulin. • Your test results may be falsely normal when your blood glucose is really low. You would not know your blood sugar is low until you start to feel confused, hungry, or sweaty. In both cases, your blood sugar can get too low. This can be dangerous. If you do not treat low blood sugar right away, you can have serious problems, even death.			
Readability assessment			
Test	Grade level	Reading ease	% Passive Sentences
SMOG	6.3		
Flesch-Kincaid	4.5	84.6 (very easy to read)	0
Fry	6th (5th)		
Lexile	5-6th Grade		

*Advice for Patients: Serious Errors with Certain Blood Glucose Monitoring Test Strips
<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PatientAlerts/ucm177189.htm>

The elements of the SAM tool were shown in Table 1. They include readability and 21 design factors thought to be important for *plain language* health information. We recommend that at least two experienced writers independently score draft materials using the SAM tool. One caveat about the SAM tool is that readability is included as just one of 22 assessments, and materials could score superior even with a high reading level. We suggest an adequate score on readability be required for an adequate SAM score. Table 4 shows a sample original FDA document, and Table 5 shows a SAM test of it. (See Tables 4 and 5 at the end of the chapter.)

5. Use plain language writing and design strategies. There are many excellent sources of advice about creating easier-to-understand information. In addition to formal training, we recommend that readers use the tips, toolkits, and other resources cited in this chapter. Although comprehensive strategies are too detailed to present here, key advice includes:

Writing style tips:

- Focus on what the reader needs to know, especially for actions to take
- Limit content to 1 to 3 main messages
- Avoid medical jargon and use easier to understand terms
- Use short sentences and short words
- Use active voice and address the reader personally
- Use positive rather than negative messages

Visual presentation tips:

- Use a font size of 12 (or 14 or 16 for groups with vision limitations)
- Put text in chunks and use lots of white (clear) space around text
- Avoid italics and words in all capital letters
- Use colors that appeal to the intended audiences
- Use graphics to show fractions
- Avoid graphs and charts, when possible

6. Test and revise communications with the intended users. In steps 1 to 5 above, users provide input to help create the initial draft health information according to plain language principles. The draft is then tested and revised, if necessary, to meet the readability and suitability criteria. Then, further usability testing is needed with members of the intended audiences to ensure that the communication resource is readable, understandable, engaging, culturally respectful, and actionable (users believe they can carry out the recommended behaviors). These factors go beyond what is codified in readability and SAM testing, and beyond the basic requirements for *readable* and *understandable* information, but are essential if users are to actually use and benefit from the information. Usability testing should be done on successive drafts until diverse users, including those with limited health literacy skills, are satisfied with the communication.⁵⁰

How can we evaluate communications implementing this advice?

Evaluation is critical to assess the effectiveness of health risk communication. In this respect, user-centered design is especially powerful. It incorporates formative evaluation methods (e.g., usability testing, focus groups, etc.) throughout the entire development process. It is also important to conduct outcome evaluations to test whether the intended audiences were able to use and ultimately benefit from the information in real-world settings.^{50,59} For example, could patients understand how to take their medication correctly and did they adhere to the regimen over time? If not, what were the barriers? We recommend several evaluation approaches at various budget levels:

- No budget: Readability and SAM testing should be done. True user-centered design cannot be conducted without at least some testing with users.
- Modest budget: Besides readability and SAM testing, conduct usability tests with the intended audiences. Conduct qualitative outcome evaluations with focus groups and/or individual interviews, as funding allows.
- Substantial budget: In addition to the above evaluation activities, conduct pre-post surveys with statistical samples the intended user groups.

Conclusions

Thirty years of scientific evidence has helped us understand the health literacy skills of Americans and many factors that affect the readability and understandability of health risk communication. Research also shows that most health information is too difficult for users and is often disappointing in its ability to improve people's health risk awareness and behaviors. Fortunately, national health literacy and plain language guidelines offer practical and evidence-based recommendations about improving health risk communication. The core lesson learned is that the intended users must be co-creators and testers of the communications.

Table 1. Suitability assessment of materials (SAM)*

Factor to be Rated	Score	Comments
	0 = Not Suitable 1 = Adequate 2 = Superior	
1. Content		
a. Purpose is evident		
b. Content about behaviors		
c. Scope is limited		
d. Summary or review included		
2. Literacy Demand		
a. Reading grade level		
b. Writing style, active voice		
c. Vocabulary with common words		
d. Context given first		
e. Learning aids via "road signs"		
3. Graphics		
a. Cover graphic showing purpose		
b. Type of graphics		
c. Relevance of illustrations		
d. List, tables, etc. explained		
e. Captions used for graphics		
4. Layout and Typography		
a. Layout easy to follow		
b. Typography appropriate		
c. Subheads ("chunking") used		
5. Learning Stimulation and Motivation		
a. Interaction used		
b. Behaviors modeled and specific		
c. Motivation / self-efficacy		
6. Cultural Appropriateness		
a. Match in logic, language, experience		
b. Cultural image and examples		
Total SAM Score: Total Possible Score: Percent Score: % Not Suitable Material		

Interpretation of SAM percentage ratings:

70 – 100% = superior material 40 – 69% = adequate material 0 – 39% = not suitable material

* The SAM tool was validated with 172 health care providers from several cultures, including Southwest Asians, Native Americans, and African Americans, as well as students and faculty from the University of North Carolina School of public Health and Johns Hopkins School of Medicine. The SAM was developed under the Johns Hopkins School of Medicine project, "Nutrition Education in Urban African Americans," funded by the National Institutes of Health, National Heart, Lung and Blood Institute, Bethesda, MD, 1993.

Table 4. FDA safety alert: advice for patients: serious errors with certain blood glucose monitoring test strips*



U.S. Department of Health & Human Services

Issued: August 13, 2009

For

Diabetic patients and/or their caregivers

Advice

***NEVER** use GDH-PQQ* glucose meters or test strips if you are using drug products or therapies that contain certain sugars other than glucose.*

- GDH-PQQ stands for glucose dehydrogenase pyrroloquinoline quinone

Issue

Diabetic patients who receive drug products or therapies containing certain sugars other than glucose could experience serious, although rare, injuries if they use blood glucose meters with a particular type of test-strip technology. Strips that use this technology, known as GDH-PQQ, will react with certain non-glucose sugars, including maltose, galactose and xylose, and produce a falsely high (elevated) result. If a diabetic patient then takes too much insulin because of this falsely high result, it could lead to abnormally low blood sugar (hypoglycemia), coma, or even death.

Certain patients may be more likely to be using drug products or therapies that contain other sugars, including those who:

- are on peritoneal dialysis
- have recently had surgery

Glucose test strips other than the GDH-PQQ type are not affected by this problem, and can be used by patients taking drug products or therapies that contain non-glucose sugars.

List of GDH-PQQ test strips and their associated meters

List of GDH-PQQ Glucose Test Strips

Drug products or therapies with non-glucose sugars

- Extraneal (icodextrin) peritoneal dialysis solution
 - Some immunoglobulins: Octagam 5%, Gamimune N 5% **, WinRho SDF Liquid, Vaccinia Immune Globulin Intravenous (Human) and HepaGamB
- Orencia (abatacept)
- Adept adhesion reduction solution (4% icodextrin)
- BEXXAR radioimmunotherapy agent
- Any product that contains, or the body breaks down into, the sugars maltose, galactose or xylose

*** Within the U.S., Gamimune N 5% has not been manufactured since December 2005, and no lots are in distribution in the U.S.*

Patient concerns

If you are taking drug products or therapies that contain certain non-glucose sugars, such as maltose, galactose and xylose, these sugars will produce a falsely elevated glucose result if you are measuring your blood glucose using a GDH-PQQ test strip. If you then use this falsely

Table 4. Continued.

elevated result to determine your dose of insulin, you could give yourself too much insulin, which could result in dangerously low blood glucose. In addition, if your blood glucose is actually low, it could go unrecognized and untreated because the test result could read higher than it actually is and appear to be within the normal range. In this case, you may not know your blood glucose is low unless you have certain symptoms, including confusion, hunger, nervousness, dizziness, irritability, sweating, heart pounding (palpitations), shaking, unusual fatigue or weakness, or tunnel or darkened vision. Low blood glucose must be recognized and treated promptly to avoid serious complications, such as coma and death.

Recommendations for diabetic patients using interfering drug products or therapies

If you are a diabetic patient who uses any of the drug products or therapies that contain certain non-glucose sugars (or care for someone who does), you should:

- **NEVER** use GDH-PQQ glucose meters or test strips.
- Instead, use another type of glucose monitoring technology and continue to monitor your blood glucose as instructed by your healthcare provider.
- Contact your healthcare provider if your results do not reflect the way you feel.

You may be able to determine the type of glucose monitoring technology you are using by looking at the instructions that accompanied your meter or test strips, or at your meter's box. If you can't tell what kind of technology your meter and test strips use, ask your healthcare provider or pharmacist to help you find out, and/or contact the manufacturer of your meter and test strips.

General recommendations for all diabetic patients

- Continue testing your blood glucose as directed by your healthcare provider.
- Use only test strips specified for your glucose meter.
- Know the type of glucose monitoring technology you are using.
- Know that GDH-PQQ meters and strips should NOT be used if you are using an interfering drug product or therapy.
- Know that GDH-PQQ meters and strips are okay to use if you are not using an interfering drug product or therapy.
- Know the medications you are taking and keep a current list of your medications. If you do not have a current list of medications, ask your healthcare provider to provide you with a list.

Reports received by FDA

From 1997 - 2009, FDA received 13 reports of death associated with GDH-PQQ glucose test strips in which there was interference from maltose or other non-glucose sugars. The deaths occurred in healthcare facilities. Some reports indicated that serious patient injury, such as low blood glucose (hypoglycemia), confusion, neurologic deterioration, too little oxygen in the tissues (severe hypoxia), brain damage and coma, occurred prior to death.

FDA is working with manufacturers to resolve the problems with GDH-PQQ glucose test strips, and is continuing to monitor adverse events associated with these products.

Questions to ask your healthcare provider

- How do I determine which glucose meter and strips I have?
- Which drugs am I currently taking? Am I taking or receiving an interfering drug product or therapy?
- Should I continue testing my blood glucose with my current meter and strips or should I get a new meter and strips? If so, how do I do this?

For more information see [FDA Public Health Notification: Potentially Fatal Errors with GDH-PQQ Glucose Monitoring Technology](http://www.fda.gov/medicaldevices/safety/alertsandnotices/patientalerts/ucm177189.htm)¹

¹**Advice for Patients: Serious Errors with Certain Blood Glucose Monitoring Test Strips**
(<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PatientAlerts/ucm177189.htm>)

Table 5. Suitability assessment of materials for FDA safety alert: advice for patients: serious errors with certain blood glucose monitoring test strips*

Factor to be Rated	Score	Comments
0= Not suitable 1 = Adequate 2 = Superior		
1. Content		
a. Purpose is evident	1	While the title explicitly states that the document is about “serious errors,” the document is difficult to read and may not alert patients to the seriousness of the issue.
b. Content about behaviors	2	The document explains what to do, what not do, and who is most likely be impacted.
c. Scope is limited	2	The scope of the document is limited to essential patient information and is directly related to the stated purpose.
d. Summary or review included	NA	No summary is provided, but a summary is not needed because the document is short.
2. Literacy Demand		
a. Reading grade level	0	The reading level is between the 14th – 16th grade (post-graduate) levels, based on the SMOG, Flesch Reading Ease, and FRY validated reading tests. The average American adult reads between the 7th – 9th grade reading levels.
b. Writing style, active voice	0	Sentences are frequently in the active voice, but most are complex and/or long. Most sentences contain embedded information.
c. Vocabulary with common words	0	Many technical words are used and the vocabulary is quite high. There are jargon, acronyms, and numerical information, little of which is explained or defined.
d. Context given first	0	Minimal context is provided.
e. Learning aids via “road signs”	1	Headers precede text, but the headers are frequently unclear, misleading, or contain jargon. Sections could be presented in a more logical manner.
3. Graphics		
a. Cover graphic showing purpose	0	There are no graphics other than the FDA/ HHS logos; these graphics do not attract attention or portray the purpose of the document to the intended audience.
b. Type of graphics	NA	There are no graphics.
c. Relevance of illustrations	0	The FDA and HHS graphics are not relevant to the key message.
d. List, tables, etc. explained	NA	There are no lists or tables.
e. Captions used for graphics	NA	There are no graphics to have captions.

4. Layout and Typography		
a. Layout easy to follow	1	The layout/sequence of information is consistent. There is a wide left margin [white space], which reduces the appearance of clutter. However, the amount of text per line is excessive and overwhelming, many paragraphs are too long, and there are no illustrations or graphics to guide the reader. The subheads help with visual cuing.
b. Typography appropriate	2	Text is written in sentence case in at least a 12-point font with a sans serif font for the main text.
c. Subheads ("chunking") used	1	Lists are grouped under descriptive subheadings, or "chunks." Most lists are less than 5 items, but some of the lists are too long to be easily read and understood.
5. Learning Stimulation and Motivation		
a. Interaction used	1	Questions are provided for the patient to ask their health care provider, and links are provided for additional information. However, a question and answer format would be helpful and more engaging.
b. Behaviors modeled and specific	1	Information is mainly abstract, and behaviors are not modeled.
c. Motivation / self-efficacy	1	Topics on the website are sub-divided or "chunked" to facilitate reading and the "questions" section supports self-efficacy.
6. Cultural Appropriateness		
a. Match in logic, language, experience	0	This page appears to be available in English only. Font size can be increased, which is especially important for users with diabetes, but the size does not increase dramatically. This web page is quite advanced and assumes the language, literacy level, and medical understanding of the target audience is quite high.
b. Cultural image and examples	NA	The site is not adapted to the needs (cultures) of all end users (seniors, people with disabilities, people with low incomes, etc). The site looks formal and professional, which is appropriate to a certain degree because it is from the FDA, but the formality may make some end users uncomfortable.
Total SAM Score: 13		
Total Possible Score: 34		
Percent Score: 38% = "Not Suitable Material"		

*Advice for Patients: Serious Errors with Certain Blood Glucose Monitoring Test Strips
<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PatientAlerts/ucm177189.htm>

Additional resources

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10. The Harvard School of Public Health: Health Literacy Studies Web Site. Available at <http://www.hsph.harvard.edu/healthliteracy>. A useful site for professionals in health and education who are interested in health literacy and health outcomes related to communication and literacy skills.

Endnotes

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Chapter 15: Warnings and Disclosures

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Summary

This chapter reviews nearly six decades of research on warnings and disclosures, including common misperceptions and their importance to public health policy, and offers an answer to the key question, “Do warnings and disclosures really work?” Supporting theory and research applications are discussed.

Introduction

Warnings and disclosures are ubiquitous and a part of everyday life. Nutrition disclosures greet us at breakfast; low tire pressure warnings sound off driving to work; signs saying “danger – do not enter” block construction sites; and skull and crossbones, alcohol warning labels, Drug Facts boxes, and written and graphic visual tobacco warnings appear on packages around the world. Common misperceptions about warnings are that they often are ignored, or they backfire (*boomerang*), with the audience doing exactly the opposite of the proposed behavior change.¹ Statements in disclosures are often derided as containing *legalese*, or *mouse print*, in which vague qualifications, such as “Void where prohibited” and “Use only as directed,” are used with mind-numbing repetitiveness.^{2,3}

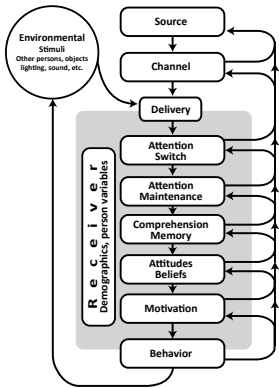
Yet, when taking into account audience characteristics, prior beliefs, message content, and proper delivery modes, warnings and disclosures can be effective communication tools and remedies for consumer and public health policy. For example, the Federal Trade Commission (FTC) has long encouraged the use of clear and conspicuous disclosures to prevent possible deception and unfairness from ad claims.⁴⁻⁶ Specifically, the qualification and disclosure of ambiguous and misleading environmental benefit claims (“Environmentally Safe,” “Clean Energy,” “Carbon Neutral”) have been a priority in cases and guides over the years.⁷ Other examples include encouraging clear and conspicuous disclosures for misleading online ad claims,⁸ and qualifying material connections not expected by consumers between endorsers (including bloggers) and promoted companies.⁹ Likewise, the FDA has advocated warnings and disclosures to benefit consumers and public health. This includes the use of black box warnings for prescription drugs with potentially serious risks and side effects,¹⁰ the future inclusion of graphic visual warnings on tobacco packages with text warnings,¹¹ and Nutrition Facts and Drug Facts information.

Information disclosures represent potentially helpful statements that can clarify, deflate, or reduce misleading impressions from ad, package, or other claims in the marketplace.^{2, 12, 13} Such statements can include (1) an *affirmative disclosure*, in which a marketer is *required* to disclose certain information¹⁴ or (2) a disclosure that is more voluntary in nature. The affirmative (required) disclosure can be negative, triggered, or mandated. Examples of negative disclosures include corrective advertising, in which the advertiser is required to correct misleading impressions likely to linger in the minds of consumers (e.g., the FTC Listerine case).^{15, 16} Other negative disclosures include warnings, defined as “a special class of disclosures for the purpose of alerting consumers to certain risks or harms from a product or service.”¹² Affirmative disclosures are sometimes triggered (e.g., if one mentions “cholesterol,” they must disclose saturated fat levels)⁶ or mandated for an entire industry (e.g., tobacco package warnings). In other instances, disclosures are more voluntary in nature, such as current front-of-package nutrition symbols (e.g., traffic lights) sponsored by U.K. grocery store chains.¹⁷

What does the research evidence say about warnings and disclosures?

Warning research. Research has shown that warnings can communicate benefits and risks to consumers successfully, but only if they are appropriately designed for the target audience, accounting for initial beliefs, message content, message modality, and source and receiver effects. McGuire’s steps in information processing (exposure, perception (attention), comprehension, agreement (credibility, attitude change), retention, retrieval, decision making (intentions), and action (behavior)) provide a key organizing framework for research evidence about warning effects.¹⁸ These output steps have been expanded by McGuire in his Communication-Persuasion Matrix also include input variables (source, message, channel, receiver, destination).¹⁹ These are further refined by Wogalter in his Communication – Human Information Processing (C-HIP) Model presented in the following Figure.²⁰

Communication-human information processing (C-HIP) model



Source: Wogalter, M. 2006. Communication-Human Information Processing (C-HIP) Model. In Wogalter, M., ed., Handbook of Warnings. Lawrence Erlbaum Associates, 51-61.

For example, several reviews of alcohol warning label effects are organized around these input and output variables.²¹⁻²³ Regarding source effects, the words *Government Warning* are found to improve alcohol warning detection times.²⁴ For channel and delivery, audio-only and audio-visual formats significantly increased alcohol warning recall compared to video-only formats.²⁵ National and state field surveys have shown positive effects of the alcohol warning labels on attention.^{26,27} Experimentation has found that visual aids (icons, color, pictorial elements)²⁸ and enhanced conspicuity (size and contrast)²⁹ both improve noticeability and recall of the warnings. Alcohol warnings are noticed more when they contain fewer characters per inch, occupy a larger area, and are more isolated.³⁰ Although frequent drinkers are likely to be aware of the text-based alcohol warnings, they perceive these warnings as significantly less believable and less favorable than occasional or nonusers.³¹

Six months following the appearance of the warning label, alcohol consumption for pregnant, lighter (non-risk) drinkers declined by a small, yet significant, amount.³² In the case of tobacco warnings, the more graphic the pictorial warning depiction on tobacco packages, the greater are smoker intentions to quit.³³

Although alcohol warning labels and graphic visual tobacco warnings have received substantial attention,³³⁻³⁶ many warning areas have not, and behavior compliance often is not measured. Such behavioral measures are encouraged (e.g., using accident data³⁷), yet there is a need to have adequate controls, proper warning design, and exposure evidence to help gauge the impact of warnings on behavior. Perhaps the best method to evaluate the effectiveness of warnings research is with meta analyses integrating findings across empirical studies. In a meta analysis of 15 warning studies for 79 experimental conditions with controls, warnings increased safe behavior for both non-student and student subjects.³⁸ This conclusion held despite considerable variance in the absolute level of compliance and a few studies displaying boomerang effects. Others have explored moderator effects in meta analyses of warning effectiveness, across a broader array of communication variables. A meta analysis of moderator effects for more than 44 empirical studies found that (1) enhanced vividness, having on-product warnings, and less product familiarity increased warning attention; (2) no moderators influenced warning comprehension; (3) evaluating shopping (vs. convenience) goods increased risk perceptions; and (4) *greater* product familiarity and higher compliance costs increased warning compliance.³⁹ Recently, a meta analysis of 60 health communication studies (with 584 experimental conditions) revealed that *message tactics* (e.g., using specific cases, social consequences, other referencing, prevention focus) and *audience characteristics* (e.g., being female, high involvement) significantly influenced health intentions.⁴⁰ Additional reviews offer valuable summaries of warnings and risk communication research.^{41, 42}

Disclosure research. Disclosure effects research is not as prolific and, arguably, in desperate need for a meta-analysis. However, *dual modality* disclosures, in which video disclosures are accompanied by an audio voice-over, achieve higher levels of message recall than print-only disclosures⁴³⁻⁴⁶ or audio-only disclosures.⁴⁷ Improving disclosure *conspicuity* (size – 11 pt. vs. 8pt.font; contrast – white vs. dark background) enhances recall of disclosure messages.^{2,45} Shorter disclosures (10 words or less) are comprehended better than longer disclosures.⁴⁶ *Distractors*, such as background noise and ad clutter, tend to reduce disclosure awareness. Distinctive *peripheral cues* (e.g., color, celebrities, music) can interfere with viewers' processing of message disclosures — especially if the cue is *unrelated* to the message.^{45,49} Yet, when related to the message, distinctive cues actually can draw attention into the message arguments.^{49,50} For disclosure *content*, general advisories and claims (e.g., “read the label,” “consult your doctor,” “healthy,” “environmentally friendly”) tend not to be comprehended as well as more specific information.^{36,43,47,48,51-54} However, lengthy disclosures should not be used to increase specificity. Finally, ability levels (age, education, literacy, knowledge) should be considered in the design and content of disclosures, especially for senior citizens and children (“Some assembly required” vs. “You have to put this together”).

Experimental research has found that evaluative disclosures (e.g., characterizing the per-serving level of the nutrient to be “high” as determined by the FDA) can be effective in reducing misperceptions and inaccurate generalizations from nutrition claims (e.g., “No Cholesterol” and “1/3 Less Salt”) when related nutrients are at high levels.^{51,52} Yet, when the product is perceived to be “good for you” (e.g., soup), the effect of disclosing high sodium content depends on nutrition knowledge levels.⁵² When products are viewed as less nutritious (e.g., margarine), the disclosures work regardless of knowledge levels.⁵¹ Based on processing research, the FTC developed its “Clear and Conspicuous Standard” (CCS) in 1970 for effectively presenting disclosures in TV ads and for strengthening disclosure remedies in deception and unfairness cases. These elements include (1) dual modality, (2) sufficient size, (3) background contrast, (4) single color background, (5) sufficient duration, (6) no distracting sounds, (7) immediately following claims and (8) consider the audience (e.g., children). Content analysis of the adherence of televised ad disclosures to the FTC’s CCS found that 25% of prime time TV ads in 1990 contained disclosures, yet none had all of the CCS elements.⁵⁵ In 2002, 67% of TV ads contained disclosures, yet adherence had either declined or remained unchanged since 1990 for most of the CCS elements.¹³

Theoretical support. Almost 60 years of research and theory development has been conducted on the primary mechanism and context for warnings: fear appeals. This research has had three primary independent variables: fear, perceived threat, and perceived efficacy.⁵⁶⁻⁵⁸ Typically, researchers manipulate

fear appeal (or warning) strength and assess its immediate impact on evoked fear.^{33, 35} Perceived threat has two components: perceived threat severity and perceived threat susceptibility. Perceived efficacy consists of perceived response efficacy (i.e., the belief that the recommended response works in reducing the perceived threat) and perceived self-efficacy (i.e., the belief about one's ability to perform the recommended response).⁵⁸ Unfortunately, the efficacy elements are often neglected, yet can serve as key drivers of preventive effectiveness for consumers.

Early theoretical work proposed an inverted-U relationship between fear intensity and persuasiveness.^{59, 60} However, this has not received consistent support.⁵⁸ Indeed, considerable evidence suggests a positive linear relationship, with stronger fear-arousing conditions producing greater message acceptance.⁶¹⁻⁶⁵ In a meta-analysis of more than 100 fear appeal articles, Witte and Allen⁵⁸ conclude that "the stronger the fear aroused by a fear appeal, the more persuasive it is" (p. 601). Other strategies, such as offering a solution to the warning to help objective processing (e.g., 1-800-QUIT-NOW), are at the heart of the Parallel Response Model⁶³ and the Health Belief Model.⁶⁶ An evaluation of the warning's impact on *all* Protection Motivation Theory (PMT) elements (i.e., evoked fear, perceived threat (severity, susceptibility), and perceived efficacy (response efficacy, self-efficacy))^{56-58, 67} is preferable in gauging effectiveness of warning outcomes.

Accounting for initial opinions and prior involvement of the target audience is essential in evaluating effects of warnings and fear appeals. For example, the use of strong graphic visual warnings may be needed to counteract some smokers' biased and entrenched initial opinions about smoking and quitting.^{33, 35, 49, 68} As supporting theory, the Elaboration Likelihood Model (ELM) accounts for elements that affect the persuasiveness of warnings, including the target audience's initial opinion, motivation, ability, and opportunity to process warning information, message cogency, and other peripheral processing cues.^{49, 69}

Most disclosure research has focused on regulatory, public health, or media-related questions, without supporting theory. However, in Andrews et al.,⁵¹ Spreading Activation Theory⁷⁰ is used to demonstrate how concepts that are primed (e.g., a "No Cholesterol" claim) might spread to an expanding set of nodes in a memory network (e.g., "Low Fat" inferences) or to fewer nodes due to disclosure information (e.g., "Contains 14 grams of fat per serving – an amount determined to be high by the FDA"). Clearly, however, there is room for greater theoretical development in disclosure research.

What general practical advice about warnings and disclosures can the evidence support?

What belongs in a warning or disclosure? This important question can be answered by following a series of steps in developing warning/disclosure content proposed by Fischhoff et al.⁷¹ First, determine from experts what information is most critical to understanding how a risk is created and communicated (i.e., “What Matters?”). Second, assess consumers’ current beliefs regarding those facts (i.e., their “mental models”). Third, design messages focused on the critical gaps between what consumers know and what they need to know. Fourth, consumer testing should be used to evaluate the effectiveness of those messages in closing the gaps. Fifth, develop and evaluate a delivery mechanism capable (e.g., message channels and media) of drawing actual consumers’ interest.

Matching warnings and disclosures with audience processing objectives. Once content is set, the warning or disclosure should be matched with the target audience’s appropriate stage(s) in information processing (e.g., exposure? awareness? comprehension? behavior? all of these?). Wilkie¹⁴ illustrates these options in his landslide warning example in “Welcome to Mount Hazard in FTC National Park.” Options might range from the more cognitive (e.g., a “Danger – Landslides” sign; print literature with statistics; trail hazard signs; PSAs on safety measures) to the more behavioral (e.g., signing a release paper with a “cooling off” period; blocking trails).

Factors influencing availability and processing of warnings and disclosures. Even if content and communication objectives are correctly matched, certain audience characteristics, organization, and format issues can affect the availability and processing of warnings and disclosures.⁷² Effectiveness is enhanced when warning or disclosure frequency is increased, is dramatic or sensational, is immediate to the risk, is personally relevant, and when risk immunity is reduced. It also helps to reduce the number of alternatives to process, have sufficient processing time, provide proper framing (e.g., per trip vs. lifetime), format (e.g., symbols, color, type size), organization, and offer an expected hierarchy of warning information. The following hierarchy is suggested based on the natural order for which consumers are likely to use warning information: (1) What is the product? (2) What are its benefits and risks, (3) How should it be used? (4) What risks are there in use? (5) How can these risks be avoided? (6) What should be done if the product is not properly used? ⁷³

Unintended consequences: why do consumers fail to attend to warnings? Several errors by designers can lead to an inability of consumers to attend to warnings. As noted by Stewart and Martin,⁷⁴ these include (1) inadequate measures of attention or recall (e.g., warning recall is not the same as message recall), (2) warning information that is not personally relevant, (3) consumers

may be already familiar with information, (4) consumers may be distracted from the information, and (5) consumers may be desensitized after repeated exposures (especially with false alarms, incorrect warnings, being more extreme than necessary, no immediate harm). Also, trust of the warning source is important in ensuring attention (e.g., countering teen reactance).

Cautions and vulnerable populations. Finally, in addition to making sure that the warnings and disclosures are clear and conspicuous, and in the right media channels, caution is advised when focusing on vulnerable populations. When appealing to seniors, children, and non-native speakers, literacy and learning deficits are likely to reduce exposure, recall, comprehension, and coping strategies when presented with warning and disclosure information.⁷⁵ Yet, warnings and disclosures often are not delivered in a vacuum. Entire integrated communication efforts help,²⁰ as found in the delivery of prescription drug warning information (e.g., black box information, patient inserts, labeling, medication guides, pharmacy leaflets, and direct-to-consumer ads).

The evaluation of warning and disclosure communication

Evaluating marketing communications, such as warnings and disclosures, usually involves (1) focus groups (copy and rough stage development), (2) copy testing (pretests), and (3) tracking (post-tests).⁷⁶ Four major study designs are possible: (1) quasi-experiments in the field (full-scale evaluation), (2) experiments in the field (field tests), (3) quasi-experiments in the lab (audience subgroup tests without random assignment), and (4) experiments in the lab (random assignment in controlled copy tests).⁷⁷

No budget. In this challenging scenario, tests of warnings and disclosures may be limited to the use of student subjects in academic environments or clinical patients affected by the communication. Although students may respond to protection motivation or elaboration likelihood measures that assess warnings or disclosures, such samples may lack external validity and generalizability.⁷⁸ For example, a lack of direct experience with the product and its warnings may lead to highly inconsistent correlations of product warning attitudes with actual behavior.⁷⁹ Usually, focus groups in quasi-experiment studies in the lab can offer insights into the warning and disclosure stimuli, but cannot be used for definitive cause and effect conclusions.^{78,80} Other creative possibilities include the tracking of reactions to specific company warnings and disclosures on search engines that compile thousands of blog sites (e.g., www.blogpulse.com). Yet, this also can be problematic due to the convenience nature of the sample and viewpoints.

Modest budget. Here, both focus groups (or cognitive interviews in pretesting), as well as controlled experiments are possible that randomly assign respondents to test (warning) and control (no warning) groups using covariates of major demographic variables.^{33,35-36} With adequate confound checks (i.e.,

measuring what the warnings should not influence),⁸¹ use of attention filters,⁸² and target audience screening, online experiments can be run to help not only with internal validity, but generalizability issues as well.

Serious budget. One *gold standard* for evaluating public health initiatives is that of the National Youth Anti-Drug Media Campaign, which spent upwards of \$100 to \$200 million yearly since 1998 and used focus groups,⁸³ copy tests with controls,^{76,84} and longitudinal tracking of attitudes, intentions and behaviors.⁸⁵ Although the impact of the campaign has been debated over the years,^{77,86} including the need for an initial baseline tracking measure, it nonetheless provides an example of the full range of evaluation tools from focus groups to copy tests to tracking. A serious budget would allow such a comprehensive effort in the evaluation of warnings and disclosures used as part of major public health programs.

Conclusions

Warnings and disclosures are ubiquitous and a part of everyday life. Common misperceptions about warnings and disclosures are that they often are ignored due to their design (e.g., *mouse print*, *legalese*) or can backfire. Moreover, warnings and disclosures cannot compensate for product design flaws, and the effects of warnings and disclosures may be temporary when not reinforced. However, this review of nearly six decades of research evidence shows that when accounting for audience characteristics, prior beliefs, message content, and proper delivery modes, warnings and disclosures can indeed be effective communication tools and remedies for consumer and public health policy.

Additional resources

1. Andrews, J.C. and Netemeyer, R.G. (1996). Alcohol warning label effects: Socialization, addiction, and public policy issues. In R. P. Hill (Ed.), *Marketing and Consumer Research in the Public Interest*, Thousand Oaks, CA: Sage, 153-175. This chapter reviews alcohol warning label research, then offers theoretical explanations for resistance to alcohol warning labels by at-risk groups and concludes by examining the alcohol socialization process, models of addiction, and public policy alternatives.
2. Argo, J.J. and Main, K. J. (2004). Meta-analyses of the effectiveness of warning labels. *Journal of Public Policy & Marketing*, 23 (2), 193-208. A meta-analysis of over 44 empirical warning studies examines their impact across five dimensions of effectiveness: attention, reading and comprehension, recall, judgments, and behavioral compliance.
3. Bettman, J. R., Payne, J. W., and Staelin, R. (1986). Cognitive considerations in designing effective labels for presenting risk information. *Journal of Public Policy & Marketing*, 5, 1-28. This thorough review presents how people process risk information, offers general guidelines for designing warning labels, and gives specific examples of these guidelines for cleaning agent and drain opener products.
4. Cox, E.P., Wogalter, M.S., Stokes, S.L., and Murff, E.J.T. (1997). Do product warnings increase safe behavior? A meta-analysis. *Journal of Public Policy & Marketing*, 16 (2), 195-204. A meta analysis of 15 studies for 79 experimental conditions shows that (1) warnings increase safe behavior and (2) this increase occurs for both student and non-student subjects.

5. Fischhoff, B., Riley, D., Kovacs, D. C., and Small, M. (1998). What information belongs in a warning? A mental models approach. *Psychology & Marketing*, 15, 663-686. A step-by-step approach is described for determining the information content of warnings, including understanding risk estimates, risk processes, and methods to reduce risk.
6. Hoy, M. G., and Andrews, J.C. (2004). Adherence of prime-time televised advertising disclosures to the "clear and conspicuous" standard: 1990 versus 2002. *Journal of Public Policy & Marketing*, 23 (2), 170-182. In a content analysis of over 1600 prime-time TV commercials in 2002, over 2/3 contained disclosures, yet adherence to most of the FTC's clear and conspicuous elements for the disclosures had either declined or remained unchanged compared to 1990.
7. Keller, P. A., and Lehmann, D. R. (2008). Designing effective health communications: A meta-analysis. *Journal of Public Policy & Marketing*, 27(2), 117-130. A meta-analysis of 60 health communication studies indicates that message tactics and individual characteristics interact to determine health intentions.
8. Kees, J., Burton, S., Andrews, J.C., and Kozup, J. (2010). Understanding how graphic pictorial warnings work on cigarette packaging. *Journal of Public Policy & Marketing*, 29 (2), 265-276. A between-subjects, controlled experiment with over 500 smokers indicates that stronger (versus moderate or less) graphic visual warnings strengthen smokers' intentions to quit and that evoked fear fully mediates the effect of the graphic visual warning on intentions to quit.
9. Morris, L.A., Mazis, M.B. and Barofsky, I. (Eds.) (1980). *Banbury Report 6: Product Labeling and Health Risks*. Cold Spring Harbor, NY: Cold Spring Harbor Laboratory. This edited volume provides one of the first compilations of readings on product warning labels and health risks based on a conference held at the Banbury Center at Cold Spring Harbor, NY in 1980.
10. Stewart, D. W. and Martin, I. M. (1994). Intended and unintended consequences of warning messages: A review and synthesis of empirical research. *Journal of Public Policy & Marketing*, 13, 1-19. The authors first review the diverse literature on warnings, and then discuss their potential ineffectiveness due to frequent use, reactive behavior, and poor message design, primarily due to a lack of reliance on empirical research.
11. Witte, K. and Allen, M. (2000). A meta-analysis of fear appeals: Implications for effective public health campaigns. *Health Education & Behavior*, 27 (5), 591-615. Fear appeal theory is first reviewed and a meta-analysis of more than 100 fear appeal studies is conducted showing that strong fear appeals and high efficacy messages produce the greatest behavior changes.
12. Wogalter, M.S., DeJoy, D.M. and Laughery, K.R. (Eds.) (1999). *Warnings and Risk Communication*. London: Taylor & Francis. This edited volume offers an earlier review of the warnings and risk communication literature, organized by stages of information processing and concludes with a discussion of practical and legal aspects of warnings.

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Chapter 16: Human Factors

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Summary

Human factors is a multi-disciplinary behavioral science concerned with human perceptual, cognitive, and behavioral capabilities and limitations in real-world settings. One goal of this applied field is to understand the psychological factors underlying effective hazard communications.

What does the science say about this aspect of communication?

Historically, human factors engineering emerged to study and prevent pilot errors in WWII military aircraft and operator errors in manufacturing. Today, the field is highly interdisciplinary and applied well beyond military and manufacturing contexts. Contributing disciplines include natural sciences, such as biology and physics; social sciences, such as psychology and sociology; and applied fields, such as industrial engineering and ergonomics. Human factors researchers and practitioners include cognitive psychologists, ergonomists, and industrial engineers. A hallmark of the human factors mindset is that product (or system) designers should seek to build products (design systems) that function safely and effectively in a broad range of real-world conditions, taking into account foreseeable human shortcomings.

Human factors science developed in recognition that human error is a significant contributor to accidents and injuries. Researchers who study patterns of injury data, such as motor vehicle accident reports, partition causes into *product design* factors (e.g., brake failure, airbag malfunction), *environmental* factors (e.g., lighting, weather), and *human* factors (e.g., distraction, fatigue).¹ Human factors have been estimated to cause, or contribute to, 60% to 90% of motor vehicle accidents^{2,3} and more than 80% of medical errors.⁴ Detailed forensic analyses of specific events often find breakdowns in visual or auditory processing, attention, comprehension, reasoning, and task execution.

Human factors researchers address human error, in part, by studying the impacts of visual and auditory communications, such as on-product warnings, workplace signs, and alarms, on perceived risk and safety-related behavior. In this research, communication is often conceptualized in terms of a *source* or originator, a *channel* or mode of communication, and a *receiver* or

target.⁵ Each element can affect risk-related beliefs and behavior. For example, presenting information consistently through mutually reinforcing visual and auditory channels can facilitate comprehension. Because each target person has limited information processing capacity, important safety messages can become lost among less critical information, making it essential to set priorities.

The volume of published research concerning the impact of communications on perceived risk has grown sharply in the past 40 years.⁶ Much current research concerns the effects of warning format and content. Studies mostly occur in laboratory settings and simulated real world environments.⁷ Researchers use human subject experiments, surveys, and focus groups to examine the impact of formatting, such as color, font size/shape, symbols and positioning (e.g., placing safety information on the product versus embedding it into instructions). Researchers measure changes in safety-related attitudes and beliefs, behavioral intentions, and, in some cases, actual safety-related behavior.

A general observation in the literature is that signal words (e.g., DANGER, WARNING, CAUTION), safety alert symbols (e.g., flames for fire hazards), and even colors (e.g., red for DANGER) can affect noticing of warnings, understanding of information, and even behavioral intentions. Additionally, environmental conditions (e.g., daylight, ambient sound levels) and target demographic factors, such as age, are important considerations when determining the potential visibility of signs, audibility of alarms, or legibility of written information. Nevertheless, laboratory studies find that the impact of such characteristics on actual safety-related behavior declines as a function of increasing product familiarity and difficulty of complying with instructions (even if the *difficulty* is having to walk a short distance to procure safety goggles).⁸ Moreover, compliance is higher in laboratory situations than in the real world.⁹ Many research findings have been incorporated into practice via standards and guidelines for industry (e.g., ANSI Z535 “Safety Alerting Standards” and ANSI AAMI HE75-2009 “Human factors engineering - Design of medical devices”). However, the relatively few studies of real world outcomes show mixed results. On one hand, some studies have found desired changes in attitudes and behavior, for example, smokers exposed to graphic warnings on cigarette packages appear to be more motivated to quit smoking¹⁰; on the other hand, there is no evidence of declining injury rates relative to enhanced formatting of warnings.¹¹ In sum, interventions can predictably affect behavior in the laboratory and potentially change attitudes. However, real world behavioral change in response to hazard communications remains limited.

An important limiting factor is the individual perception of risk, one of the best-studied areas in cognitive psychology. Many classic findings are reviewed in Kahneman et al. (1982).¹² These perceptions are subject to systematic biases; for example, being swayed by whether facts are presented in ways that emphasize risks or benefits. Because many adverse events are quite rare,

people must rely on such imperfect inferences when estimating their risks.¹³ Finally, emotions affect the perception of risk¹⁴; therefore, information that stimulates worry, fear, or anxiety can color our assessment of risk–benefit related facts¹⁵ (see also Chapter 10).

Cognitive and social psychologists have also examined the effects of stable individual differences, including age, gender, culture, and other demographic factors, on how risk communications are perceived.¹⁶ Some of the most important of these factors are literacy and language barriers (see also Chapters 9, 11, and 14). The research here contains some surprising findings: although symbols are intuitively a way to communicate across language barriers, comprehension of common symbols used in hazard communications varies significantly across cultures.¹⁷ For example, in 1971 thousands of Iraqi farmers were poisoned when they ate imported seed wheat instead of planting it.¹⁸ The seed, which was not intended for ingestion, had been treated with a fungicide, dyed red, and placed into bags marked with the skull and crossbones symbol¹⁹ — the *universal* symbol of hazard. It is not necessary to cross international borders to find cultural disparities in risk perception. In the United States, African Americans are more likely to distrust the medical establishment, which contributes to marked racial disparities in health.²⁰ The credibility of the source of hazard communications can vary tremendously even within sub-populations; for example, medical professionals view government health authorities as a credible source of health risk information,²¹ whereas many anti-vaccine activists do not.

A general challenge for all hazard communications is that the modern world is full of risk information, especially in the form of warnings. Legally mandated on-product warnings have a long history. An 1829 New York State law requiring labeling for caustic substances and poisons was likely the first legal mandate for on-product warnings in the United States.²² By the 1850s, use of the skull and crossbones to warn of possible death was common. Design specifications for workplace safety signs began to emerge in the early 20th century.²³ Yet until the mid-to-late 1960s, with the advent of on-package warnings for cigarettes, on-product warnings were confined to a narrow range of products such as medicines and industrial products.²⁴ Today, we live in what some have described as a “culture of warnings.”²⁵ In the United States, consumer products, medications and medical devices usually have associated hazard communications. Warnings and other health risk information appear in menus and even on buildings. Some of this change reflects the sharp rise in federally mandated on-product labeling since the mid- to late-1960s.²⁶ Litigation has prompted additional warnings.⁵ As a consequence of the mass exposure to hazard communications, the American public is sometimes indifferent to news about risk.²⁷ Despite this state of affairs, there are some recommendations to be made that the science can support.

What general practical advice can the science support?

1. Use a risk-based communications design to streamline messages and create structured communication across multiple platforms/channels.

Audiences are more likely to pay attention to messages that are succinct, relevant, and timely. The prominence of hazard information should be defined by the degree of risks that people face and the usefulness of the information in reducing them — where risk is defined in terms of the severity and probability of negative outcomes (see also Chapters 6 and 7). For structure hazard communications that are embedded in long-form documents, such as instructions or manuals: repeat only information about higher risks and use repetition across channels strategically to enhance retention and comprehension (e.g., drawings can reinforce key information in text-based messages).

2. Use research to guide choices and avoid the failures and unintended consequences that can arise when risk messages are counterintuitive to recipients. The field of human factors contains a number of surprising or counterintuitive findings (some of which were discussed here; see also Chapters 3, 7, and 8). For example, emphasizing the expertise of authorities with the intention of reassuring an audience can sometimes have unintended consequences. Confidence declines and fear increases when experts appear out-of-touch or are perceived as belonging to a mistrusted government office. Message designers should beware of the possibility that a planned message could be misinterpreted due to messenger, content, or audience characteristics and test messages, rather than rely on their own intuitions.

Each risk poses its own communication challenges. There is, fortunately, a large body of science to guide selection of message elements. See the Resources section for further information. In addition, organizations such as the Human Factors and Ergonomics Society (www.hfes.org) have publicly searchable, peer reviewed research pertaining to various audiences, messages and hazards.

3. Target your audiences when they are most likely to be receptive to the content of your messages. As mentioned, modern environments are awash in risk (and benefit) information that is routinely overlooked. Audiences have limited attention capacity. Studies find that warnings are more effective when the recipient of the information is *safety-minded*: alert and intentionally seeking such information.²⁸ Thus, communicators should try to engage the target audience when they are likely to be receptive. For example, persons searching a website for medical information may be more attentive to messages regarding the specific health risks associated with treatment during the search.

4. To boost message credibility, be sure that both the messages and the messengers create trust. The credibility of messages is context dependent and can be influenced by the source as well as the message content.²⁹ It should not be assumed that a source that is credible for a message on vaccine safety would be similarly credible for a message on the risk of food borne illness. When uncertain about which sources an audience trusts, consider multiple sources, such as “the Surgeon General says...,” and “Pharmacists recommend...” One way to identify credible sources and content is to involve members of the targeted group in program planning and message pre-testing.

How does one evaluate communications based on this advice?

A number of best-practice based evaluation frameworks are available in the literature. For example in the 1990s, the National Cancer Institute promulgated evaluation guidelines in a framework document that organized evaluations into phases: “formative,” “process,” “outcome,” and “impact.”³⁰ Formative evaluations assess “the strengths and weaknesses of materials or campaign strategies before implementation.” Outcome evaluations “obtain descriptive data on a project and document the immediate effects of the project on the target audience” At these stages, which require collection of user data, human factors research provides ways to develop appropriate measures, testing protocols, and data analyses about changes in attitudes, beliefs, and behaviors.

Caveats about common approaches to formative and outcome assessments may be helpful. One approach to formative evaluation involves software-based *readability analysis* to determine message comprehensibility. However, most readability analyses focus on vocabulary rather than message content or grammar. Therefore, computed reading level scores should be interpreted with great caution. It is far preferable to evaluate reading comprehension using specific content-based questions (see also Chapters 11 and 14). The human factors research literature also contains many examples of outcome assessments (see Resources and the discussion above). Most involve small groups of test subjects in controlled laboratory conditions. A common measure of the effectiveness of hazard communications is to ask study participants for their behavioral intention (e.g., Would you comply with a warning about hazard x?). Note that behavioral intentions are not always reliable indicators of real world choices, as persons often overestimate the likelihood of their compliance with warnings.³¹

The primary costs of evaluation arise from recruiting human subjects, testing, and data evaluation. Such studies can also be time consuming. When communicators have not been left the time for extensive evaluations, quick email or Internet-based surveys can be very valuable. Note, Internet-based approaches should be used with care as their validity can be limited. However,

peer-reviewed research involving commonly used online survey software is cited in PubMed.gov. The Table that follows illustrates the tasks involved and the investments for the various evaluation types.

Evaluation tasks and Investments

Type of Evaluation	Budget Level		
	Low	Modest (includes “low”)	Serious (includes “moderate”)
Formative (pre implementation assessment of strengths and weaknesses)	• Review message content internally taking care to ensure that the communication is compliant with any applicable standards or regulations • Review existing and related hazard communications for consistency, problems to avoid, and best practices • Gather and analyze any internal data that may inform messaging: consumer complaints, letters, questions to call centers, etc.	• Develop and assess multiple messages based on internal brainstorming; review messages with internal panels/focus groups • Draw on current research literature regarding message content, presentation of quantitative information, source credibility, etc. • Deploy email or Internet-based surveys iteratively, incorporating feedback in successive drafts	• Quantitatively assess current knowledge of hazard and safety-related behavioral patterns in target audience • Assess understanding of risk for each target group • Use target audience-based focus group to develop multiple test messages • Refine final message based on group feedback, baseline knowledge, etc. • Test messengers/sources/channels; refine as needed
Outcome (descriptive data regarding effects on target audiences)	• Track reach in terms of media source mentions, spikes in Internet searches, etc.	• Monitor published reports relating to risk-related phenomena of interest • Surveillance of publically available hazard/injury data such as ER visits	• Assess behavioral change following risk communication (see Resources) • Follow up with in-depth interviews of targeted populations to assess reach and comprehension of messages

Conclusion

The field of human factors can help guide effective risk communication. The role of human factors research in risk communication is to focus attention on the limitations and capabilities of human information processing and decision-making. Identifying those limitations and capabilities can help enhance our ability to conceive and implement a risk communication plan of action that will or, at least, mitigate the risk of injury to us or others.

Additional resources

1. Human Factors and Ergonomics Society contains links to the society's publications including: *Human Factors*, *Ergonomics in Design*, *Journal of Cognitive Engineering and Decision Making*, and HFES Proceedings. <http://www.hfes.org/Publications/>.
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Chapter 17: Shared Decision Making

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Summary

Shared decision making (SDM) interventions attempt to change doctor-patient communication by involving patients in clinical decision making to the extent that they desire. Decision aids, a common SDM intervention, decrease patient passivity and help patients make choices that are consistent with their circumstances, preferences, and values, but their impact on resources and clinical outcomes is uncertain. SDM should be encouraged to improve the processes and outcomes of health care, and new SDM approaches are needed.

Introduction

Medical decisions are especially difficult when there are two or more reasonable options, and each option has good and bad features that people value differently. What is important for one person may be different for another, and no clear answer applies to everyone. Shared decision making (SDM) interventions help people make more informed choices in partnership with their clinicians. Many medical organizations¹ recommend SDM, and the Patient Protection and Affordable Care Act of 2010 supports a national SDM program.²

SDM refers to the process by which a decision is made: Patients and clinicians share information and come to agreement on preferred treatments.³ The terms *SDM* and *informed decision making* are often used interchangeably, though they differ in important ways. Both promote informed decisions, and neither presumes that the right course of action is known. However, informed decision making interventions need not involve clinicians nor occur in a clinical setting. A patient decision aid (DA), a common SDM approach, is an intervention designed to help a person decide among treatment options by providing objective information about the options and the likely consequences (harms and benefits) of each option. Common DAs include videos, interactive web programs, or printed material.

Most are designed to be used by patients, but some target patients and practitioners.^{4,5} The level and type of tailoring varies. Some DAs provide quantitative risk information to practitioners to guide individualized care for common diseases or genetic mutations. For example, BRCAPro,⁶ an interactive

website, assesses the probability of carrying a germline mutation, based on family history of cancer. Adjuvant!, another interactive website, estimates the 10-year risks of breast cancer recurrence or death, informing decisions about adjuvant therapy.^{7,8}

What does the science say about shared decision making?

Most of what we know about SDM is based on clinical trials of DAs that compared outcomes among patients exposed to DAs versus standard care in a range of health contexts.^{9,10} These trials typically addressed one-off screening or treatment decisions with short-term measures of effectiveness. Measures include: perceptions of being informed, decision satisfaction, decision regret, knowledge, perception of risks and benefits, values and expectations about treatment and side-effects, treatment preference, perceived usefulness, and acceptability. Some measured effect on treatment choice, adherence, quality of life, and resource use, typically as secondary or tertiary outcomes.

Our understanding of **how** DAs affect decisions draws on cross-sectional surveys that describe how people make decisions in different contexts (e.g., business, health, law) and test how people's judgments, reasoning, and thinking are affected by aspects of the decision context (e.g., time-pressure, emotion, framing). Qualitative methods assess recordings or observations of practice, transcripts of people thinking aloud about their reasoning while making decisions, and electronic monitoring of people using web sites. Quantitative methods assess decision preference, knowledge, affect, cognitions (e.g., risk perceptions, judgments, attitudes, and values), and mediating/moderating traits (e.g., cognition, affect, numeracy). These studies often use simplified hypothetical choices in non-patient samples. Although people's knowledge, values, and judgments may change with experience, inputs are assumed to be integrated using the same decision processes.

Interest in SDM and decision aids. SDM occurs infrequently, either as a process¹¹ or an outcome.¹² Participation in SDM can require substantial time and attention to process complex risk information and to make difficult — often stressful — trade-offs. Patient interest in SDM is understandably variable (19–68%), with higher interest among the young and educated.¹³ *Patient barriers* to SDM include being unaware that there is a decision to make, believing that clinicians prescribe the only treatment available, discomfort or inexperience with SDM, or preconceptions about care.

It has been difficult to embed DAs into health care settings.^{14,15} *Physician barriers* include concerns about time, lack of training, pessimism about patients' ability to assume a more active role, believing it is not applicable to their patients, the clinical situation, or clinical care patterns, difficulty reconciling patient preferences,^{16,17} and concerns that DA could bias patients to choose less expensive options.²

Impact of decision aids. Findings from the Cochrane Collaboration review of 85 randomized trials of DAs^{10,18} are described here.

1. **Knowledge.** DAs improved knowledge of options and outcomes and led to more realistic expectations.
2. **Decision processes.** DAs helped patients match their values to their choices. DAs reduced decisional conflict and passivity in decision making and helped the undecided to decide. DAs did not improve satisfaction with the decision, the process of decision making, or preparation for decision making.
3. **Adherence to treatment.** DAs do not improve adherence to medication (including warfarin vs aspirin, bisphosphonate, blood pressure medication, anti-depressants, and statins).
4. **Treatment decisions.** The impact of DAs on treatment choice is modest and variable. DAs decreased screening rates for prostate cancer (15%), non-significantly increased screening rates for colorectal cancer (20%), and had no impact on genetic testing. Because DAs target tests perceived to be either overused (e.g., PSA) or underused (e.g., colorectal cancer screening), variable impact is expected.

The impact of DAs on elective surgery varies by procedure and setting.^{9,10} DAs had no effect on minor surgeries (circumcision, surgical abortion, or dental surgery). DA targeting procedures perceived to be overused led to decreased use. The few trials that examined DAs in the setting of underuse found a trend towards increased use (prostatectomy in the UK¹⁹ and surgery for spinal stenosis in the U.S.).²⁰

5. **Potential harms.** DAs have no known negative effect on anxiety, depression, or emotional distress. Some DA trials reported a higher net cost per patient^{19,21} and longer physician consultation time,²² but findings were variable.^{23,24}
6. **How DAs work:** Potential active ingredients in DAs include an accurate description of the decision with all options and consequences made explicit, facilitation with constructing a fair mental representation of the decision, and exercises that help people reason about their values and preferences and make tradeoffs.

Controversies. Many DA's were developed without a clear conceptual framework for how they might influence decisions. There is debate about how to measure a good decision when there is no clear *right* choice. Is a good decision one that is made using a good decision process (regardless of the outcome), one that is correct for that individual (choice is consistent with patient values), or one that is correct for society (most cost-effective)? The relevance and significance of many commonly used short-term process measures (knowledge, decisional conflict) have been questioned.^{25,26}

Limitations of the evidence. Studies have focused on video DAs, with scant attention to other types of DAs or other approaches to SDM, such as training practitioners in SDM, incentivizing practitioners to engage in SDM, or restructuring care (e.g., using a coach). In addition, many DA trials were too short or too narrowly defined to examine their effect on long-term health outcomes. The impact of DAs in the real world is often incorrectly assumed to equal the impact observed in clinical trials. For example, in a frequently cited study, only 344 of 3,212 referred subjects (11%) participated.²⁰ Most were excluded for clinical reasons; many refused. The 22% reduction in surgery in the DA group corresponds to a 2.4% reduction (22% x 11%) among the referred population. Accounting for eligibility and interest in SDM dilutes impact by an order of magnitude.

A number of areas need further investigation:

1. What constitutes good decision making and how do we measure this?
2. How do SDM interventions affect health care delivery, resource use, unwarranted variation, and clinical outcomes? What is the cost-effectiveness of different approaches to SDM?
3. How do we integrate SDM into routine clinical care?
4. Are we giving patients the right information to help them with decisions? DAs present treatment-associated risks derived from national samples. Although risks vary according to where one lives, where one seeks care, and, for invasive procedures, who performs the procedure, such tailoring of risks variables is not presented.
5. How do we ensure quality control of DAs, which could be created as marketing tools to encourage patients to choose more (or less) expensive options? Measures of bias and disclosure of conflicts of interests of groups creating SDM tools are needed.
6. How do different approaches to promoting SDM compare? There are no head-to-head comparisons of different approaches to SDM, including the impact of different types of DAs, different methods of deploying DAs (before, during, or after the clinical encounter), training providers in SDM, and restructuring care (using navigators, incentives).
7. How do different approaches to SDM influence the process of SDM and outcomes?

What general practical advice can the science support?

Facilitate active participation and SDM. Patients should have a right to be involved in decisions about their health and should be encouraged to do so to the level that they desire. Some practical approaches for facilitating SDM are described here and in the Table that follows.

- 1. Identify and prioritize decisions appropriate for SDM.** SDM is not appropriate for all clinical decisions. It may not always be feasible in the office setting, especially for screening and chemoprevention. And clinicians have no obligation to initiate discussion about services that either have no benefit or have a net harm. However, practitioners should work with their patients to identify and prioritize decisions requiring SDM. Discussions can be staggered across several office visits. Clinicians should be prepared to explain why certain services are discouraged and should consider a proactive discussion for such services with high-visibility, special individual importance, or a change in evidence.¹
- 2. Inform patients when they need to make a decision.** Patients are often unaware that there is a decision to be made. Clinicians should draw attention to problems that require a shared decision making process (those for which the patient's preferences are critical in selecting treatment).
- 3. Explain why patient input matters.** Patients do not always understand why or how their preferences and values factor into a decision and may assume that their clinician knows best. Clinicians should explain that there is more than one way to deal with the problem, that options have pros and cons that need to be considered, and that there is genuine professional uncertainty as to the best way of managing a problem.
- 4. Screen patients for their desired level of involvement in decision making and preferred approach to receiving information.** Not all patients want to be involved in all decisions at all times, and patients have differing needs for information. Discordance between desired and actual involvement in decision making leads to decision regret and low satisfaction.²⁷ It is possible to screen for involvement in decision making. For example, the clinician can ask: "Realizing that there may be risks as well as benefits for any treatment, who do you think should decide which treatment options are best for you?"²⁸
- 5. Help interested patients be more involved in SDM.** Many patients want to participate in decision making, but lack the requisite skills, confidence, knowledge, or tools. Inquire about the patient's interest in information: printed material, graphical data, videotapes, websites or other media. Clinicians can offer patients a variety of educational tools to help them with their decision, trying not to rely on a single developer to minimize bias.

Practical ways clinicians can promote SDM with their patients

Explain why patient preferences and value matter in this decision.

Explain that you will support their decision.

Help frame the decision for the patient.

Focus on treatments that are effective for that patient, focus on most important dimensions and compare options using the same outcomes.

Let patients know how their preferences affect the decision.

Inform patients of the option of doing nothing and its consequences.

Ask the patient to explain to you how they frame the decision, correct any misconceptions or misunderstandings, provide any needed information.

Offer patients a variety of support and/or educational tools to help them with their decision, trying not to rely on a single developer to minimize bias.

Select decision aids, based on evaluations like those in the *Ottawa A to Z Inventory of Decision Aids*.

Cautions. Informing patients of *all* options and *all* consequent risks and benefits is often unfeasible and undesirable. Too much information can confuse patients.²⁹ It is best to focus on options for which the evidence is strongest that the benefits outweigh the risks for that patient. If the patient is not satisfied with the *first tier* treatment options, other options should be presented. Clinicians should always include the consequences of no treatment.

It is important to help patients tolerate and cope with uncertainty, rather than simply understand it. Most patients prefer to avoid ambiguity, which can lead to higher risk perceptions, distrust, pessimism, and decision avoidance.³⁰ When physicians are comfortable with uncertainty, patient trust and satisfaction are high.³¹

The specific content, framing, and emphasis of DAs addressing the same decision can vary substantially.²⁴ No guidelines govern the selection of evidence to include in a DA; how information is framed, ordered, and presented (e.g., testimonials³²) can influence values and how information is used.²⁹ Biases can be intentional or not.³³ Practitioners should be comfortable with the content of DAs they recommend to patients.

How does one evaluate communications implementing this advice?

Drawing on chapter 1, the ultimate test of SDM communications is whether:

1. the communication contains the information needed to support informed decision making,
2. users can access that information, and
3. users can comprehend what they access.

Because SDM requires the active involvement of both patients and clinicians, both perspectives are important. This section focuses on evaluating DAs, but also whether it supports the process of SDM between users and their clinician.

No Budget. Rely on existing evaluations of DA, obtained through the A-Z inventory (<http://decisionaid.ohri.ca/AZlist.html>). This database can be searched for specific decisions, generating a list of DAs with information on their content, how to access them, and includes ratings from IPDASi. This web site includes many, but not all DAs. Many are available free of charge.

Modest budget. There are several validated questionnaires that can be incorporated into routine clinical practice or quality improvement evaluations.

1. Whether the DA contains the information needed to support informed decision making can be evaluated using the validated 11-item Preparation for Decision Making scale. It assesses perceptions of how well a DA prepares the respondent to communicate with their provider and make a decision.³⁴
2. Whether users can access the information can be evaluated by asking patients whether they read or viewed the DA (and if not, why not).
3. Evaluating the extent to which users understood the material is problematic because each DA is content-specific, and self-report may be inaccurate. However, one could evaluate whether the patient feels informed after viewing the DA by using the 'feeling informed' subscale from the validated "Decision Conflict" scale,³⁵ or the question: "I feel I have made an informed choice."
4. Evaluating whether SDM occurred during the clinical encounter can be accomplished using the 12-item OPTIONS scale (<http://www.optioninstrument.com/>), completed by observing patient encounters. This scale would be particularly useful for determining the effect of training programs in which students' skills in SDM are evaluated before and after training.

Alternatively, patients could be asked about their provider's performance using the SDM quality of care measures: "In the last 12 months, (1) did a health practitioner talk with you about the pros and cons of each choice for your treatment or health care?", and (2) when there was more than one choice for your treatment or health care, did a health practitioner ask which choice was best for you?"³⁶

High cost approaches. Convening an NIH 'State of the Science on SDM' would help to obtain clarity on SDM, to guide future research in this area, and to inform the proposed national SDM program. Because of the limited number of SDM interventions that have been tested, and the limited number of outcomes that have been tracked in these trials, rigorous randomized controlled trials are needed that compare alternative approaches to facilitating

and integrating SDM into clinical practice. Trials should measure the process of decision making (including decision quality and extent of SDM) and long- and short-term consequences of the decision: patient behavior, health outcomes, quality of life, and decisional regret. Trials should capture mechanisms of action, moderating effects, confounders, costs, and resource use, including potential substitution effects (the substitution of one treatment with other treatments or tests). The duration of the trial should be sufficiently long to measure persistence of choice and/or adherence to selected treatment.

Conclusion

SDM can improve risk communication between patients and practitioners and can influence treatment choice, but the field is nascent. More clarity is needed on what constitutes SDM, what SDM interventions should accomplish, as well as what are realistic expectations for their impact in different settings. New approaches to SDM are needed that can be implemented in a range of clinical settings.

Additional resources

1. Edwards, A., and Elwyn, G. *Shared Decision-Making in Health Care: Achieving Evidence-Based Patient Choice*. Second Edition. Oxford University Press, 2009. This comprehensive book represents the state-of-the-art overview of the field. It addresses the evidence, theoretical perspectives, and practical case studies from actual health care practice, covering both general and specific conditions, including offering tangible examples for both patients and doctors.
2. Bekker, H.L. (2010). The loss of reason in patient decision aid research: Do checklists damage the quality of informed choice interventions? *Patient Education and Counseling*. 78, 357-364. A conceptual review of the field that integrates the science behind individuals' decision making with the demands of designing complex, health care interventions. It discusses whether using the International Patient Decision Aids Standards (IPDAS) Collaboration checklist as a gold standard to judge interventions' quality is premature and potentially detrimental to the validity of resources designed to help patients make treatment choices.
3. Elwyn, G., O'Connor, A., Bennett, C., et al. (2009). Assessing the quality of decision support technologies using the international patient decision aid standards instrument (IPDASI). *PLoS ONE* 4, e4705. <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0004705>. Describes the process and criteria for evaluating patient decision aids. Evaluation criteria include: content, development process, and effectiveness. The International Patient Decision Aids Standards (IPDAS) Collaboration is a multi-disciplinary effort to establish criteria for evaluating the quality of patient decision aids.
4. Sheridan, S.L., Harris, R.P., and Woolf, S.H., The Shared Decision-Making Workgroup of the U.S. Preventive Services Task Force. (2004). Shared decision making about screening and chemoprevention: a suggested approach from the U.S. Preventive Services Task Force. *American Journal of Preventive Medicine*, 26, 55-56. <http://www.ahrq.gov/clinic/3rduspstf/shared/sharedba.htm>. This paper clarifies the U.S. Preventive Services Task Force (USPSTF) vision for applying shared decision making in the execution of screening and chemoprevention. It is neither a systematic review nor a formal recommendation. Instead, it is a concept paper that includes a commentary on the current thinking and evidence regarding SDM.

5. Braddock, C.H., Edwards, K.A., Hasenberg, N.M., et al. (1999). Informed decision making in outpatient practice: Time to Get Back to Basics. *JAMA*. 282, 2313-2320. <http://jama.ama-assn.org/cgi/content/full/282/24/2313>. This landmark study characterizes the nature and completeness of informed decision making in routine office visits of both primary care physicians and surgeons. It uses a cross-sectional descriptive evaluation of audiotaped office visits during 1993.
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The CAHPS Improvement Guide Practical Strategies for Improving the Patient Care Experience.

Chapter 18: News Coverage

Gary Schwitzer - HealthNewsReview.org

Summary

Health care news coverage can educate and inform the public and help people make smarter health care decisions. But it can also confuse public discussion on public health, health care and health policy concerns. Studies have shown that health care news stories often exaggerate benefits and minimize harms or risks.

Introduction

Having worked in health care journalism for 37 years, I care deeply about helping my colleagues achieve accuracy, balance, and completeness in their stories. Health care news coverage can educate and inform the public and help people make smarter health care decisions. But it can also confuse public discussion on public health, health care, and health policy concerns. It is painful to see news coverage that promotes anecdote and emotion over data and evidence.

That is what happened in much of the news coverage of the recommendations on mammography, released by the U.S. Preventive Services Task Force in 2009. This was one of the worst such episodes I have witnessed to date.¹ Evidence was often ignored. Personal, emotional anecdotes dominated many stories. Benefits of mammography were exaggerated while potential harms were downplayed or totally ignored. A public opinion poll 17 months later showed that women were still confused and misinformed about what the Task Force had recommended.²

In another case, the DECISIONS study found evidence of poor quality in many physician-patient discussions on the tradeoffs involved in prostate cancer screening.³

Clinicians often report that patients come to their office visits asking questions about news stories they've seen — news stories that may be imbalanced on benefits and harms. If the office visit then amplifies the emphasis on what one stands to gain while minimizing what one stands to lose, the opportunity for a fully informed, shared decision-making experience is lost.

This chapter is intended to help people think about the imbalance that exists in so many health care messages — and what can be done about it.

What does the science say about this aspect of communication?

Over the past 20 years, many researchers have written about how the news media affects consumers on behavior change issues such as smoking, diet, and cancer screening. But it remains unclear how consumers receive, comprehend, or act on news stories about the benefits and harms of health care interventions when uncertainty prevails.

In 2000, Moynihan et al., published a groundbreaking analysis in the *New England Journal of Medicine*, “Coverage by the News Media of the Benefits and Risks of Medications.”⁴ Their analysis of 207 stories on three widely prescribed drugs showed that 40% did not quantify benefits. Of those stories that did, most reported only in relative, not absolute, terms. Fewer than half the stories mentioned potential harms. The authors concluded:

When reporting on new forms of technology or new treatments, journalists and editors might consider the evidence available in relation to the following questions: What is the magnitude of the benefit (e.g., both absolute and relative), and what groups of patients can be helped? What are the associated risks and costs? What are the possible links between the sources of information (studies or experts) and those (such as the manufacturers) who promote the therapy? Although not exhaustive, these questions could inform attempts to improve the quality of medical reporting.

Focusing on news coverage of just one issue, Woloshin and Schwartz published *Giving Legs to Restless Legs: A Case Study of How the Media Helps Make People Sick*, which analyzed 33 stories about restless leg syndrome over a two-year period.⁵ Only one story quantified a benefit for the first FDA-approved drug for the condition. But about half the stories used anecdotes about people taking the drug (most noting substantial improvement). Of stories mentioning the drug, only 5 of 15 reported anything about side effects, and only 1 quantified that risk of harm. The authors wrote:

Journalists should question the assumption that treatment always makes sense. Medical treatments always involve trade-offs; people with mild symptoms have little to gain, and treatment may end up causing more harm than good...Instead of extreme, unrepresentative anecdotes about miracle cures, journalists should help readers understand how well the treatment works (e.g., what is the chance that I will feel better if I take the medicine versus if I do not?) and what problems it might cause (e.g., whether I might be trading less restless legs for daytime nausea, dizziness, and somnolence).

(Earlier, this same team studied medical journal news releases, finding that “Data are often presented using formats that may exaggerate the perceived importance of findings.”⁶)

One cancer news analysis concluded that news stories about cancer “rarely discuss treatment failure or adverse events...(and) may give patients an inappropriately optimistic view of cancer treatment, outcomes, and prognosis.”⁷

Gigerenzer et al., “provide evidence that statistical illiteracy (a) is common to patients, journalists, and physicians; (b) is created by nontransparent framing of information that is sometimes an unintentional result of lack of understanding, but can also be a result of intentional efforts to manipulate or persuade people; and (c) can have serious consequences for health.”⁸ The authors place much of the blame on medical journals, “surprisingly, nontransparent health statistics such as relative risks without the base rate often appear in leading medical journals, and it is often from these sources that the numbers spread to physicians, the media, and the public.” (p.25)

Journalism watchdog/improvement projects. Within the last 10 years, eight international health care journalism “watchdog” website projects have begun analyzing how journalists evaluate the evidence behind claims made about health care interventions, often with a special emphasis on how benefits and risks are presented. Australian, Canadian, and U.S. teams have published their findings, which, although coming from independent teams from three countries, are very similar.⁹⁻¹²

Each of these projects assigns multiple reviewers to evaluate stories, each using the same basic set of systematic criteria. Data from thousands of stories in these three countries demonstrate that journalists don’t do a good job in quantifying benefits and harms.

For example, our five-year, 1,400-story database on the HealthNewsReview.org project shows that nearly 70% of stories fail to adequately quantify the harms and benefits of the interventions they report on.¹³

Our judges grade a story as unsatisfactory if it doesn’t quantify results or if it does so using only relative, not absolute, risk–benefit data. The net effect of so many of these stories is that they fail to explain how small the potential benefit is and how large the potential harm. In the course of our daily journalism reviews, we also see troublesome journal practices in the studies on which the stories are based. We have seen journal articles that use relative numbers to describe benefits and absolute numbers to describe harms — within the same article — when it seems to suit the conclusion of the study.

The following statistics may help explain some of these criticisms. Surveys have shown that many daily newspaper reporters have not been trained in how to cover health care news or interpret statistics, and most find this a major challenge in their jobs.¹⁴ Additionally, 43 percent of respondents to a nationwide survey of health care journalists in 2008 said training opportunities at their news organization had decreased over the past few years; although

20 percent had seen an increase.¹⁵ But, for many reasons, the time may have arrived to effect change: the large number of people now devoted to health care journalism improvement, the training opportunities that have arisen, and a growing recognition on the part of many health journalists that they need help.

What general practical advice can the science support?

Health care journalism training programs. Within the past decade, many high-quality health care journalism training opportunities have become available, some of them focusing on helping journalists scrutinize evidence.

- The National Institutes of Health hosts an annual Medicine in the Media workshop (<http://medmediacourse.nih.gov/>).
- The Association of Health Care Journalists (AHCJ) has more than 1,000 members and holds national and regional meetings (<http://www.healthjournalism.org>). In 2010, AHCJ published, “Covering Medical Research: A Guide for Reporting on Studies” and distributed to all members online.¹⁶
- The Knight Foundation funds a medical evidence boot camp for journalists at MIT (<http://web.mit.edu/knight-science/bootcamps/fall2010.html>). The Knight Foundation also funds public health journalism fellowships and a boot camp at the Centers for Disease Control and Prevention (http://www.journalismtraining.org/action/provider_detail?id=869).
- The University of Southern California Annenberg School for Communication offers The California Endowment Health Journalism Fellowships (<http://www.reportingonhealth.org/fellowships>).
- There are at least 10 graduate programs in some form of health, medical, and science journalism at various universities across the United States.

Researchers offer practical advice for health care journalism improvement.

Woloshin, Schwartz, and Kramer published an editorial, “Promoting Healthy Skepticism in the News: Helping Journalists Get It Right,”¹⁷ in which they announced that the *Journal of the National Cancer Institute*, which published the editorial, was “launching a web site for science and health journalists to help them ‘get it right’ (we also think medical students, residents, practicing physicians, and of course the public will find these materials helpful).” The site includes tip sheets on absolute versus relative risks, the number needed to treat, p values, confidence intervals, statistics especially relevant to screening (survival and mortality), limitations inherent in various research designs, and suggested language for journalists to use or adapt when they write about these recurring issues. They urged medical journals to “work harder to promote the accurate translation of research into news” by “ensuring that both the journal and the corresponding press releases routinely present absolute risks found in the study (or estimated, when possible, in case-control studies) to describe the effects of interventions and to highlight study limitations.”

Gigerenzer recommends that all health communicators — journalists included — use “frequency statements instead of single-event probabilities, absolute risks instead of relative risks, mortality rates instead of survival rates, and natural frequencies instead of conditional probabilities.”⁸

The HealthNewsReview.org web site offers free tips for understanding studies, <http://www.healthnewsreview.org/tips-for-understanding-studies.php>. Brief primers are available on appropriate language to describe observational study findings, absolute versus relative risk, the number needed to treat, the limitations of drawing conclusions from presentations at scientific meetings, the phases of drug trials, and more.

Evidence that some news organizations are acting on the advice. The most recent positive trend in journalism is the publication by several major news organizations of regular columns devoted to evaluating the evidence in new studies or analyzing claims made about benefits of health care interventions. Examples:

- Los Angeles Times “Healthy Skeptic” monthly column (http://www.latimes.com/features/health/la-he-skeptic-sg_0,5361483.storygallery);
- New York Times “Really?” weekly column (<http://topics.nytimes.com/topics/news/health/columns/really/index.html>);
- Wall Street Journal “Research Report” biweekly column (http://online.wsj.com/public/search?article-doc-type={Research+Report}&HEADER_TEXT=research+report);
- Washington Post “Quick Study” column (<http://www.washingtonpost.com/wp-dyn/content/article/2011/02/21/AR2011022102524.html>).

These are small but encouraging signs of progress. By publishing regular columns, these news organizations are delivering a powerful message to their readers that evidence must be scrutinized and that claims of efficacy and safety in health care interventions must be evaluated carefully.

How does one evaluate communications implementing this advice?

Journalists have a bigger megaphone with a voice that reaches more people, more broadly, more often. Their work can influence both individual health care decision-making and public policy making. Helping journalists improve has the potential to affect the quality and flow of information to a broad population of health care consumers.

No cost evaluation methods. It costs nothing to use the checklists that six international projects use to evaluate health care journalism. They are all free to all users on the Web.

- HealthNewsReview.org (U.S.) – <http://www.healthnewsreview.org>
- Media Doctor Australia - <http://www.mediadoctor.org.au/>
- Media Doctor Canada - <http://www.mediadoctor.ca/>

- Medien Doktor: The German HealthNewsReview – <http://www.medien-doktor.de/>
- Media Doctor Hong Kong - <http://www.mediadoctor.hk/>
- Media Doctor Japan - <http://mediadoctor.jp/>

Two other free resources that publish daily commentary on the quality of health care news, although they don't employ the systematic criteria used by the projects above, are:

- NHS Choices "Behind the Headlines" (UK) <http://www.nhs.uk/news/Pages/NewsIndex.aspx>
- Knight Science Journalism Tracker (US) - <http://ksjtracker.mit.edu/category/health-medicine-stories/>

Low-cost evaluation methods. Others could join the movement to evaluate the quality of health care journalism at low cost by adopting the methods and criteria employed by the six international projects listed above. The HealthNewsReview.org project in the United States evaluates only a small percentage of the stories published by only a few dozen news organizations. There are many other stories in many other formats and in many other media that are not being reviewed. With the growth in alternative media, web sites and blogs, new issues in the delivery of health care news and information arise every day that are worthy of evaluation.

With a little investment of time and effort, professionals who are trained in the evaluation of evidence could help journals and their own medical centers to improve their news releases. Woloshin and Schwartz have written about problems with news releases from both sources.^{6,18}

High-cost evaluation methods. Because one of the gaps in the literature is an evaluation of how Americans receive, perceive, comprehend, and act on stories that include information about benefits and harms of health care interventions, a higher cost evaluation project would be to present such stories to a random sample of Americans and follow them over time to see if they affect their behavior or well-being and how. However, if we move from evaluation to intervention, a number of opportunities can be identified that can expand training for journalists, but at a greater investment. The wise old advice is expensive: "Tell me and I forget. Teach me and I remember. Involve me and I learn." Interactive workshops or, better, individual assistance to help journalists evaluate their own work, can be costly. Any health care professional, biostatistician, epidemiologist, or anyone trained in how to evaluate evidence who devotes time to help journalists do a better job will presumably not be compensated for that effort. But this type of dedication of time and effort can achieve real public good. Behind most important, effective health care news stories, someone outside of journalism worked with someone in journalism to get the story right.

Conclusion

Anyone who communicates to the public about health care has a stake in improving health care journalism. In an analysis of cancer news coverage and information seeking, Niederdeppe, Frosch, and Hornik suggest that physicians are left with an “essential role” of bridging the gap that limited news stories create in peoples’ minds. “Our findings indicate that many people do not seek additional information after hearing news reports about new studies. If news reports are inevitably limited in scope and do not drive much of the population to further information seeking, these results reinforce the view that health care providers play an essential role in making up for this gap. Innovative interventions to help a greater part of the population become more informed consumers of health care are warranted.”¹⁹

Mathematics professor Rebecca Goldin thinks statisticians can help: “In an era in which Wikipedia and WebMD are considered by experts more reliable than journalism for certain kinds of information, journalists and media sources need to evolve to maintain their relevance. At the same time, journalists are under newer and greater pressures than previously due to budget cuts and shrinking of the news industry. Statisticians can play an important role in this: work with journalists to represent scientific findings accurately and wholly, and encourage them to promote scientific thinking in the mainstream. Statistical literacy is an essential part of life, not just for our students, but also for our media-consuming public.”²⁰ We hope that journalists, journal editors, and health care and other professionals are inspired by some of these ideas.

Additional resources

1. Eight websites around the world now evaluate health care journalism:

- HealthNewsReview.org (U.S.) – <http://www.healthnewsreview.org>
- Media Doctor Australia - <http://www.mediadoctor.org.au/>
- Media Doctor Canada - <http://www.mediadoctor.ca/>
- Medien Doktor: The German HealthNewsReview – <http://www.medien-doktor.de/>
- Media Doctor Hong Kong - <http://www.mediadoctor.hk/>
- Media Doctor Japan - <http://mediadoctor.jp/>
- NHS Choices “Behind the Headlines” (UK) - <http://www.nhs.uk/news/Pages/NewsIndex.aspx>
- Knight Science Journalism Tracker (US) - <http://ksjtracker.mit.edu/category/health-medicine-stories/>

2. Journalism training opportunities:

- The Association of Health Care Journalists is the leading professional organization in this field. <http://www.healthjournalism.org>
- The National Institutes of Health hosts an annual Medicine in the Media workshop (<http://medmediacourse.nih.gov/>).
- The Knight Foundation funds a medical evidence boot camp for journalists at MIT (<http://web.mit.edu/knight-science/bootcamps/fall2010.html>).

- The Knight Foundation also funds public health journalism fellowships and a boot camp at the Centers for Disease Control (http://www.journalismtraining.org/action/provider_detail?id=869).
- The University of Southern California Annenberg School for Communication offers The California Endowment Health Journalism Fellowships (<http://www.reportingonhealth.org/fellowships>).

3. Books:

Cohn, V., and Cope, L. (2001). *News & numbers: A Guide to Reporting Statistical Claims and Controversies in Health and Other Fields*. Iowa State Press.

Gigerenzer, G. (2002). *Calculated Risks: How To Know When Numbers Deceive You*. New York: Simon & Schuster.

Schwitzer, G. (2010). *Covering Medical Research: A Guide to Reporting on Studies*. Association of Health Care Journalists. (E-mail: info@healthjournalism.org)

Woloshin, S., Schwartz, L.M., and Welch, H.G. (2008). *Know Your Chances: Understanding Health Statistics*. Berkeley: University of California Press.

Endnotes

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Chapter 19: Inside the Organization

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Summary

If risk communication is defined as, at minimum, a two-way process, studying the source is almost as important as studying the audience. The source organizations, at minimum, shape the message, and they may also be responsible for risk decisions that set the context for the message. In short, although risk communication research focuses on the perceptions of laypeople, relatively few studies explore the powerful organizations that serve as sources of the messages that dominate the dialogue. Given the importance of these issues, our understanding of risk communication is not as rich as it might be.

Introduction

Studies of risk communication about anthrax* from government agencies in 2001 provide insight into some of the organizational factors that facilitate or hinder implementation of effective risk communication practices. Although insufficient research to generalize, there are a number of studies of organizational issues related to anthrax communication that can provide a basis for discussion. The enormity and importance of the risk communication effort piqued sufficient interest for multiple studies, and the crisis highlighted organizational issues that might otherwise go unnoticed. Anthrax communication took place during crisis conditions, but many of the identified issues have relevance to more routine communication.

Examined as a whole, we can begin to understand how managers and staff, including those with expertise and commitment, may confront barriers that make it difficult for them to implement best practices from *Risk Communication 101*. In addition, training, which could provide agency personnel with the risk communication fundamentals, may have limited impact because of these organizational barriers. This chapter argues that an understanding of organizational limitations and strengths is needed to develop an effective risk communication effort. It argues further that, if risk communication training does not address organizational issues, the advice in *Risk Communication 101* will remain unheeded.

*Technically, *B. anthracis* is the bacterium that creates the disease called anthrax. For simplicity, the term *anthrax* is used when referring to either.

This chapter does not attribute blame to the government agencies that communicated about anthrax. Much media coverage has discussed failures, which is not surprising in a political climate that tends to label government personnel as heroes or villains, according to research exploring communication about anthrax and West Nile virus.¹

What the science says

Not surprisingly, given the dearth of research, the science is hardly robust. Many studies are qualitative, which increases depth, but limits generalization.

Consider a risk communication truism: if relevant information does not reach those making agency decisions about releasing risk information, the agency cannot effectively release the information. For example, after trace amounts of anthrax were found in the U.S. Postal Service Stamp Fulfillment Service Center in Kansas City, Missouri, public health officials in that state were swamped with calls. However, inconsistent sharing of information between the Kansas City Public Health department (KCPH) and other public health officials meant that these agencies had to refer calls they received back to the overburdened KCPH. Communication problems at KCPH were compounded by severe deficiencies in communications technology;—the agency had to resort to using runners to carry messages between floors.²

Local and state health departments across the country, even those far from contaminated sites, received calls from anxious residents about white powder. Idaho's centralized emergency medical center, established to serve this rural state, facilitated interagency communication among public health, law enforcement, and hazmat officials. However, coordinating agencies' roles, decisions, and communication with the public was more problematic because some agencies did not have strong relationships. In addition, local health departments were not in the loop, in part, because they did not have pagers.³

CDC — responding to inquiries. Not surprisingly, CDC, the hub of the public health and communication efforts, was challenged by the unprecedented volume of calls. The agency adapted by combining its emergency operations centers into an agency-wide Emergency Operations Center with a Clinical Communication Team that developed communication products, an Office of Communication Media Team, and a Public Inquiries Team.⁴

CDC developed a triage system that ultimately handled more than 11,000 calls.⁴ Managers quickly understood that calls would need varying levels of expertise, and they developed units capable of responding differently. However, during the crisis when the triage system developed problems, CDC had difficulty adapting further because the agency was unable to learn and adjust in real time to the strengths and limitations of the system. For example, because the system to document the topics and calls was not computerized,

CDC used paper forms.⁵ But the volume of calls often prevented the staff who were answering the phones from efficiently updating the paper records. As a result, staff and managers rarely had up-to-date or complete information — less than 40% of records contained even basic information such as the topic under discussion.⁴

Retrospective analysis indicated that CDC squandered the expertise of the epidemiologists, physicians, and veterinarians who composed the State Liaison Team (SLT) that was meant to field *high-risk* calls. Almost 75% of calls forwarded to the SLT did not meet the definition of high risk (p.1091).⁴

CDC: learning under pressure. Another problem that limited learning at CDC was physical location — personnel wasted time walking the halls because the hub of operations was in one building; the communication staff developing materials for release was in a second building; and the CDC media staff were housed in a third building.⁵ In this situation when email boxes were jammed and all staff were immersed in solving immediate problems, in your face discussion was arguably critical to command scientists' attention to communication issues.

Some of the teams in the field had even greater constraints. The addition of CDC personnel overloaded already stressed systems, with everyone short of land lines, cell phones, and faxes.⁵ As with CDC headquarters, lack of physical proximity was also problematic.

Despite these difficulties, CDC adapted well to other problems. When calls from reporters were overwhelming, CDC decided to start holding frequent *tele-briefings* (telephone-based news conferences with reporters).⁵ This process was largely effective. Nonetheless, CDC personnel were sometimes dismayed that reporters failed to stress what CDC saw as key information. Analysis has shown that the agency failed to appreciate the extent to which it needed to emphasize and repeat specific information that was apt to be confusing, such as the usefulness of swabbing or changes in recommendations about antibiotics.⁶ During the crisis, CDC defined the problem as "poor reporting," which was seen as largely outside the agency's control. Instead, the problem was its own communication, which should have focused to a greater extent on misunderstandings.

Particularly problematic was CDC's routine process for reviewing materials prior to release: (1) Scientists collected and interpreted information; (2) communication staff and scientists discussed written material; (3) communication staff drafted material; (4) varied levels of personnel conducted internal peer review; (5) communication staff redrafted; and (6) varied levels of personnel further reworked material. This process, cumbersome under the best of circumstances, was unworkable in a crisis, let alone one of this magnitude. The communication staff adapted by working from transcripts of the tele-briefings, using these as the basis of questions and answers for the web and elsewhere.⁶

Organizational theory. Unfortunately this area of limited empirical research does not have a strong theoretical base. As a recent review noted there is not a “robust theory that takes into account the complex nature of public services organizations’ institutional, governance, and structural process.”⁷

According to Finger and Brand, organizational learning is a dynamic process facilitating adaptation and change essential for agency survival.⁸ Processes of collaboration and formation of communities of practice seem of particular relevance to public organizations. A “dynamic model” of organizational learning depends on factors related to the source organization (or unit within the organization), the relationships among organizations, and the external environment.⁷

Thus, organizational learning is seen as a social process in which new employees learn informally from more experienced employees. According to this socially constructed perspective, employees must interpret information in ways that are meaningful to them. Learning exists within a community of practice, where employees use what they learn and learn from each other. Learning does not reside in the heads of isolated individuals.⁹

Agyris and Schon have popularized the application of systems theory and speak of single-loop and double-loop learning.¹⁰ When considering the application systems theory to organizational learning, CDC communication staff showed single-loop learning when they developed *work-arounds* for getting information cleared.¹⁰ Double-loop learning would have required questioning the underlying assumptions or norms to reveal the difficulty of trying to provide the public quickly with practical information that also needs to be extensively peer-reviewed and drafted internally before it can be released. Norms, by definition are unexamined and value laden, hence difficult and risky to question.

Based on this limited case study, CDC’s norms might be that (1) extensive peer review results in greater scientific accuracy and (2) science is more important than responsive communication. Another norm might be that evaluation of the science is more important than evaluation of the communication. Unless CDC probed the problem by questioning its underlying assumptions, the agency would not identify its norms and would have difficulty addressing this systemic problem.

Training and organizational learning. The case of CDC’s communication about anthrax points to the limitations of risk communication training that focuses largely on building employees’ understandings of public perception or skills in message design. These topics dominate many basic risk communication trainings, and they might improve staff and managers’ ability to communicate. However, it is difficult to see how personnel could actually use these new skills. Communication trainings cannot effectively reduce agency constraints, such as CDC’s problems with informational systems, physical layout, transfer

of information, etc. If personnel do not function in a context that promotes (or, at minimum, does not constrain) effective communication, improving their skills is unlikely to improve agency communication.

Although many federal and state agencies have conducted risk communication training, there are no peer-reviewed assessments. Anecdotal reports focus on participant satisfaction, rather than changes in knowledge, let alone changes in agency practice. Thus, despite consultants' promotion of the importance of training, there is no evidence about its value. However, training development is more appealing because it is far easier than evaluating agency systems and norms.

Literature reviews of training on a variety of topics in the private sector have found that success depends on the training's congruence with organizational "constraints and conflict, that surface during a meaningful needs assessment."¹¹ Effectiveness relies not only on the training method used, but also on how training (and learning) is positioned, supported, and reinforced by the organization.¹¹ Therefore, training requires sufficient needs assessment to uncover organizational problems. Positioning training in context and then implementing follow up activities may facilitate organizational learning.

Suggestions for practice

Personnel. Without the input of communication experts into major agency decisions, communication issues are unlikely to be identified, let alone addressed. Therefore, an agency needs at least one senior communications manager in the inner-circle of the agency, the so-called dominant coalition.¹² This manager should have extensive experience integrating communications goals and strategies with program planning. In addition, evaluation and needs assessment skills are imperative. Working with other members of the dominant coalition, this manager may identify organizational barriers and facilitators of effective risk communication.

If communication personnel are part of agency decision making, the communication gaps between scientists and communicators may be reduced. Organizational priorities, standard operating procedures, and funding decisions are more likely to reflect a communications perspective.

Unfortunately, personnel whose experience is primarily limited to mass media may not have the necessary background in risk communication, communication strategy, evaluation, and stakeholder involvement. Therefore, media relations managers are less able to play a significant role in a dominant coalition, which grapples with a range of complex problems.

Similarly, communications technicians (e.g., those who develop communication products, such as brochures and press releases) are necessary to implement communication strategies, but they are not sufficient for an effective communications unit.¹² Technicians lack the experience or skills for

designing complex programs or integrating communications and program development. Instead, technicians develop materials (such as press releases and brochures), draft presentations, and conduct routine outreach. Often, they are public information or media relations personnel with limited experience.

Organizational learning. Agencies need to explore the relationship between internal organizational factors and external communication. The CDC case points out some of the problems that hindered that agency. Other agencies need to examine their own practices. Agencies should look at the factors that thwarted CDC, such as limitations in technology, interaction among different units, and clearance practices. However, other organizational issues also warrant exploration. A National Academy report on public participation raised issues of relevance to agency risk communication, such as strength of agency commitment, agency capacity and resources, and organization of implementation.¹³

Training. Agencies need to consider how training might facilitate organizational goals and fit within the organizational system. A review of organizational constraints and conflicts is critical to determine if training personnel will solve the organizational problems that have been identified. Although skills training may be useful in some situations, agencies need to consider whether personnel can implement the guidance. Effectiveness depends in part on manager support for others practicing their skills. Review procedures must be workable, and agency systems must facilitate communication. Moreover, the training itself should reflect the research on design and implementation of training, including consideration of organizational goals and meaningful follow-up.¹¹

Among practitioners and scholars, there has been much discussion of creating learning organizations, that is, organizations with the capacity to learn. On-the-spot learning and activities on the job may be more instrumental than training programs. In addition to or instead of training, Finger and Brand suggest agencies might build the capacity to learn by using (1) internal learning sources, such as performance standards, job rotation, and mentoring; (2) external learning sources such as analysis of complaints, convening of stakeholder panels, and benchmarking of communication efforts.⁸

Evaluation

As the other chapters in this volume attest, agencies too often fail to evaluate risk communication products or processes. Not surprisingly, evaluation of organizational issues lags even further behind. Evaluation goals and processes have yet to be formally developed for organizational aspects of risk communication. There is a literature dealing with organizational aspects of symmetric public relations, which promotes a dialogue with organizations and stakeholders on equal footing. However, for the most part, studies focus primarily on the business sector and with issues other than risk communication.

No Budget. Developing a training program without, at minimum, an informal needs assessment, is likely to waste resources, according to the research on training. Similarly, development of a training program without evaluation and follow up is unlikely to succeed and likely to squander resources. If training exists, the agency should, at minimum, ask participants several months after the training to discuss their current communication practices and identify any changes resulting from the training. This informal feedback has significant limitations, but may identify the strengths and limitations of the training and the potential organizational barriers to communication change.

Agencies may also routinely debrief communication efforts and consider the extent to which organizational factors may have facilitated or hindered the process. A rigorous evaluation is far preferable because developing an institutional memory is unlikely with such informal, undocumented processes. But debriefing may facilitate on the spot learning and identify potential improvements. Agencies might benefit from organizational units sharing their experiences and thus potentially learning from each other and building agency capacity. However, if the agency does not attend to the larger organizational issues, meaningful change is unlikely.

Modest budget. Agencies might develop written protocols for debriefing and keep records of key learnings. These records might inform a process of organizational change. Using internal resources, agencies may conduct studies that develop some understanding of perceptions of the organizational barriers and facilitators of effective risk communication. Such studies may build on other efforts, such as the survey of employees' risk communication practices conducted by the staff of the New Jersey Department of Environmental Protection.¹⁴ Recently, the agency developed a more in-depth understanding of organizational barriers.¹⁵

Serious budget. Ideally an agency would conduct a "360 degree" study that explores through surveys and qualitative research the perceptions of internal and external stakeholders about risk communication cases. In addition to exploring the responses of external audiences to agency risk communication, the agency might simultaneously explore the internal organizational processes. Such a study should give an agency a far richer sense of how internal organizational issues affect specific risk communication actions.

Additional resources

1. Chess, C. and Clark, L. (2007). Facilitation of risk communication during the anthrax attacks of 2001: The organizational backstory. *American Journal of Public Health* 97, 1578-1583. Explores how organizational issues, particularly those related to networks, affected communication about anthrax.
2. Grunig J.E. (1992). *Excellence in Public Relations and Communication Management*. Hillsdale, NJ: Lawrence Erlbaum. A classic that summarizes key research on "symmetric, two-way communication."

3. *Journal of Health Communication*, Volume 8, 2003. Devoted to risk communication about anthrax and contains several articles with organizational themes.
4. Natural Hazards Center University of Colorado. <http://www.colorado.edu/hazards>. The disaster field has long linked organizational and communication issues. The searchable database provides citations to relevant articles and access to many reports.
5. Rashman, L., Withers, E., Hartley, J. (2009). Organizational learning and knowledge in public service organizations: A systematic review of the literature. *International Journal of Management Reviews*, 11(4), 463-494. An excellent overview, which discusses current theories.
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7. Salas, E., and Cannon-Bowers, J.A. (2001). The science of trading: A decade of progress. *Annual Reviews, Psychology*, 2001(52), 471-499. Does not deal specifically with risk communication training, but it provides insight into key issues that apply to such trainings.
8. Scott and Davis. 2007. *Organizations and Organizing: Rational, Natural, and Open Systems Perspectives*. Prentice Hall, A classic summary of organizational theories.
9. United States Environmental Protection Agency. *Evaluation Toolbox*. <http://www.epa.gov/evaluate/toolbox/summary4.htm#adr>. Links to many agency reports about stakeholder involvement. Some of the reports, which are written for practitioners, contain frank assessments of organizational problems.

Endnotes

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- ⁵ Robinson S.J. and Newstetter, W.C. (2003). Uncertain science and certain deadlines: CDC responses to the media during the anthrax attacks of 2001. *Journal of Health Communication*, 2003(8), 17-34.
- ⁶ Mbane, F., Temin, S. and Parvanta, C.F. (2003). Communicating anthrax in 2001: A comparison of CDC information and print media accounts. *Journal of Health Communication*, 8, 50-82.
- ⁷ Rashman, L., Withers, E. and Hartley, J. (2009). Organizational learning and knowledge in public service organizations: A systematic review of the literature. *International Journal of Management Reviews*, 11(4), 463-494.
- ⁸ Finger, M. and Brand, S.B. (1999). The concept of the learning organization applied to the public sector: Conceptual contributions to theory development. In M. Easterby-Smith, L. Araujo, and J. Burgoyne (Eds.). *Organizational Learning and the Learning Organization: Developments in Theory and Practice*. Thousand Oaks, California: Sage.
- ⁹ Easterby-Smith, L. A. and J. Burgoyne (Eds.). *Organizational Learning and the Learning Organization: Developments in Theory and Practice*. Thousand Oaks, CA: Sage.
- ¹⁰ Agyris, C. and Schon, D. (1978). *Organizational Learning: A Theory of Action Approach*. Reading, MA: Addison Wesley.

- ¹¹ Salas, E. and Cannon-Bowers, J.A. (2001). The Science of Trading: A Decade of Progress. *Annual Reviews, Psychology*, (52), 471-499, see p. 475.
- ¹² Grunig, L. A. (1992). How public relations/communications departments should adapt to the structure and environment of an organization...and what they actually do. In J.E.Grunig (Ed.), *Excellence in Public Relations and Communication Management* (pp. 467-482). Hillsdale, NJ: Lawrence Erlbaum.
- ¹³ Dietz, T. and Stern, P. (2008) *Public Participation in Environmental Assessment and Decision Making*. Washington DC: National Academies Press.
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Chapter 20: Practitioner Perspectives

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Summary

Communicators find most success when they shape messages to begin with key information that is relevant for the target audiences. Communicators should use plain language and formats and use pictures and stories to help clarify and reinforce the message for the audience. Communicators should check audience understanding and plan ahead for communicating in times of crisis.

Introduction

Risk communication is a practice as well as a science. As practitioners of risk communication, we want to apply the results of scientific research on effective communication as discussed in previous chapters. We also see successful and unsuccessful communication in daily practice. We hope the following observations will be useful to communicators and researchers in general, but especially to FDA.

Risk communication practices have changed over the years, as patients and consumers are taking more active roles in their health. Effective communication is two-way communication, and more open communications with health care professionals can lead to better health in the end (see Chapters 13 and 17). For example, one of us had an experience with a patient we'll call Mrs. Smith, a 60-something-year-old grandmother anxious to shed a few pounds. She selected a popular weight loss program and enlisted her doctor's support. Several weeks later, however, she had actually *gained* weight. Flabbergasted, her doctor asked what happened. Near tears, she replied "Doctor, I just don't know. I followed the directions: I had a healthy breakfast and then I had a shake. I ate a hearty lunch, and then I had another

* Thanks go also to 2010 FDA summer intern Karen Bassett and to all open public hearing speakers at the 2008 – 2010 meetings of the Risk Communication Advisory Committee.

shake. And every night I had a healthy and hearty dinner.” The doctor gently told Mrs. Smith that she should substitute the shake for the breakfast and lunch meals!

Although little of FDA’s communication is directly person-to-person, as in this doctor-patient interaction, some of the common communication pointers still apply, like checking understanding and letting communication flow in both directions. Our goal here is to help practitioners, and FDA, communicate better and more easily, as summarized in the Table, both to provide information and to make recommendations (Chapter 2).

Practitioners’ perspectives: Lessons at a glance

- Communicators should:

 - Give the key messages at the start of the communication
 - Speak to the target audience and let them know who they are
 - Shape the message to the needs of the target audience:
 - o Relevant to audience needs
 - o Sensitive to audience situation
 - o Accessible in format and language
 - Use pictures and stories for illustration and break up text in written communication
 - Check audience understanding
 - Plan ahead to be ready for urgent communications

What does our practical experience suggest for communicators?

The first point is, in brief, be brief! To be effective while brief, communicators should know their audience and tailor the message appropriately (see Chapters 7,14,16).

As a communicator, you need to define the target audience and what that audience needs to know. Communicators should start by answering these key questions:

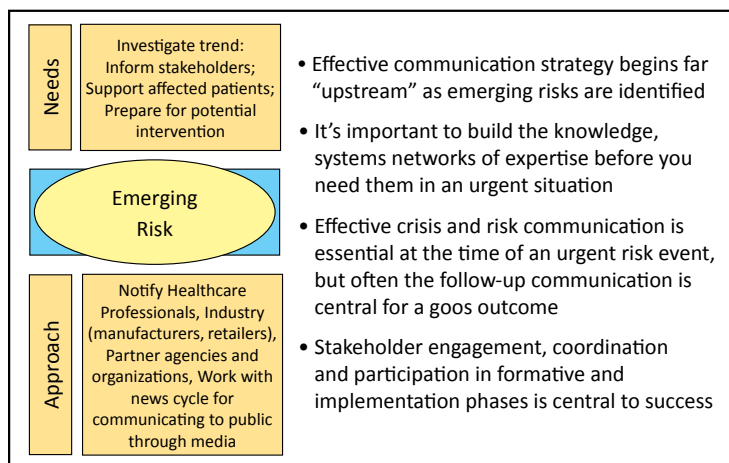
- Who should pay attention to the information?
- What should those people know about it?
- What should those people do about it?

Then the communication should provide a pathway for more information, for people who have more questions (see Chapter 4 for more on factors needed in adequate communication).

Plan ahead. Our key theme: Prepare for crisis communication so the process itself is not a crisis. FDA must be ready to manage bad or risky situations like newly discovered product defects, tainted food shipments, or unexpected side effects (see Figure 1). Prior planning is key: The communication system cannot

work to get urgent information to the public efficiently, unless the system itself is already set up before the crisis occurs (see Chapter 19 and Figure 1). When a crisis does occur, communicators should focus on delivering clear messages, not on inventing the process for developing and clearing communications.

Figure 1. Planning for urgent communication of new or emerging risks¹



Source: AnnaMaria DeSalva (2008)¹

Knowing your audience is key. Different audiences have different information needs, but they may also have points in common. For example, health care professionals want more detailed scientific information and technical directions than many patients would (see Chapter 6). Everyone benefits from clear, direct, and timely information. Using illustrative examples — pictures and stories — clarifies your message. As a communicator, you should be on the look out for barriers that could keep some members of the audience from either getting or acting on your message.

Barriers to getting the message. First, no one should assume that everyone can read (see Chapter 9). More than 10 % of Americans read at only a below basic level, and that jumps to more than 20 % who struggle below basic if the information is quantitative.² Even people who can read general material may struggle with health information and find the presentations too technical. “Health literacy” means being able to take in and use information to make informed health decisions. More than 30 % of Americans struggle with health literacy at a level of basic or below, and a good deal of important health information is more complex than basic.³ People with lower health literacy may have difficulty making informed health decisions for themselves or their families and may be unable to follow health advice even though they try.⁴

Reading is important but not the only factor; stage of life also makes a difference (see Chapter 12). Children may be strongly affected by persuasion, for example, in choosing foods.

And despite the benefit of life experience, some older people face vision, hearing, or cognitive challenges. Communicators should take care to explain risks and benefits and check listeners' understanding.

- When possible, ask the audience or patients to teach the information back, as a check on their understanding.
- Be prepared to slow down and repeat information and demonstrations for better audience understanding.

Communicators can have a big impact on informed health decision making, especially when people have difficulty getting information from other places because of their literacy level, vision, or other barriers.

Language barriers. According to the 2000 Census (latest data available), about 18 % of Americans live in households speaking a language other than English.⁵ Many health care documents are available in languages other than English, either online or from advocacy organizations.⁶ We applaud, but also stress that the intended meaning of a message can be garbled in translation, so take care to test the translation with the intended users.

What the message means to the audience. As communicators, we start with an idea of what information is important. Audience members also bring experience and expectations, which affects how they hear the message. This experience may give our messages unintended meanings with unintended effects. We may try to give a limited warning, but some audience members may hear something severe. For example, a warning to eat only moderate amounts of certain types of fish while pregnant could lead some concerned mothers to avoid fish altogether and so miss out on the benefits of fish for their developing babies.⁷

Audience emotional and social context can also influence whether they can or will take actions that the message recommends (see Chapter 10). For example, if the message warns of a new risk and directs patients to see their doctors, those without easy transportation may not be able to act quickly. And when we counsel patients to lose weight by balancing healthy carbohydrate, protein, and fat intake, we imply that everyone has access to a range of healthy foods. In reality, they may not have access, or more subtly, may need help on thinking through how to work the advice into their usual menus. Similarly, when we counsel patients to take their medicines as prescribed, we are assuming they have access to the medicine. But the copayment may be unaffordable, the dosing schedule may seem complicated, or the medicine may call for refrigeration the patient does not have. Ignoring audience context could cause people in the target audience to disregard the whole message as

unusable or irrelevant. As a communicator, you may not be able to address all those difficulties, but at least you should consider contextual barriers when designing and evaluating messages.

Audience needs and preferences. Targeting health messages to the right population is important (see Chapter 11). When addressing a group of older men on symptom awareness of cancer, we would pick the topic of prostate cancer over testicular cancer. When addressing patients with Type 2 Diabetes about a healthy lifestyle, however, we would cover awareness of end-organ damage and heart disease, rather than of range of motion exercises. Our work with varied audiences reminds us that we are in the end communicating with individuals. Diversity exists within any group, and so information needs and background beliefs may also vary widely.

When the communicator speaks on a national level like FDA does, addressing each individual is impossible. But remembering that individual differences and needs exist may help avoid some communication mistakes. Some strategies for connecting with individuals in large and diverse audiences follow.

Connecting with your audience. Communication is a two-way interaction and is most effective when communicators and audiences achieve a connection. In written communications, keeping the individual reader in mind helps create more of a connection; for example, write recommendations to “you” not “the patient.”

Person-to-person. Person-to-person communication is powerful. FDA is a large organization that can create personal connections by developing one, or a few, high-profile and easily recognizable spokespersons to be the face and voice communicating for FDA. Another way to tap into person-to-person power would be for FDA to develop partnerships with organizations that can reach subsets of the population, extending FDA's. People might be even more likely to get the message if it comes from a familiar organization.

When FDA has to address an urgent situation, such as a possible outbreak of food-borne illness, oftentimes, information continues to emerge. It is important for communicators to be forthright about what is known and what is unknown. Although people may want to know more than you can tell them at that time, they will probably respect your honesty about the genuine uncertainty of the situation.

Share stories. Sharing stories can be a powerful part of communication because it both offers an example and makes an interpersonal connection. Stories should be used to help communicate FDA's message, not to substitute for or hide evidence (see Chapters 5 and 18). One way FDA has used stories in the past in communications is to describe cases about outbreaks, or more generally, to illustrate why a safety problem exists. Another way stories can

be important is that when individuals present their stories in public meetings, listeners remember not only the data, but the emotions and personal impact, of safety problems.

Use different media channels. Fewer and fewer individuals rely only on traditional media or direct conversation for their health information. Many people are now regular users of websites and email. Still others now see email as totally outmoded by fast-paced social media. Partly because of the prevalence of public use of the Internet for health information, as well as the low cost to FDA and the ability to display large amounts of information, posting information on FDA's website is the agency's first choice channel of communication. For faster communications, FDA is also using Twitter and Facebook. However, the popularity of the Internet for both FDA and its audiences means that the FDA website must be understandable and easy to navigate. Yet outside users tell us they often have trouble finding what they need on FDA's website. This works against the interests of millions of consumers who visit the site for advice and information and who might give up the search if they don't find what they need. FDA continues to work on improving its website, with the help of regular and contract experts.⁸ In the meantime, it is important to remember that many people do not have regular Internet access. This is why it remains vital for FDA to partner with state agencies and associations that have direct connections with the public. Even if FDA cannot itself effectively reach the entire population, it can provide information in a form that other organizations can use to disseminate important health messages.

Shaping your message. When you give your audience the information they need, in a form they can use, without unnecessary barriers, you show respect for them as individuals and make the information more likely to reach them (see Chapters 7 and 8).

Lead with key messages. Individuals of all levels of education are not likely to sort through long complicated documents to find the key health messages — often they just don't have the time. Health care professionals aren't the only ones who are very busy; we're all busy. The first few sentences or moments of communication might be your only chance to share key messages. Follow up with more details and contact information because some of your audience will want to go further and get more information.

Use plain language. Audiences of all educational levels more readily grasp clear, concise messages that are written in a straightforward manner. That doesn't mean dumbing down the message or avoiding quantitative data. It does mean avoiding unnecessary specialized vocabulary or technical terms. If the communication involves probabilities and uncertainty, or if information is still emerging, you should be frank about what you know and what you don't

know. When quantitative information is available, it should be presented clearly, with numbers. Using only words like “low,” “medium,” and “high” can mean different things to different people and be confusing.

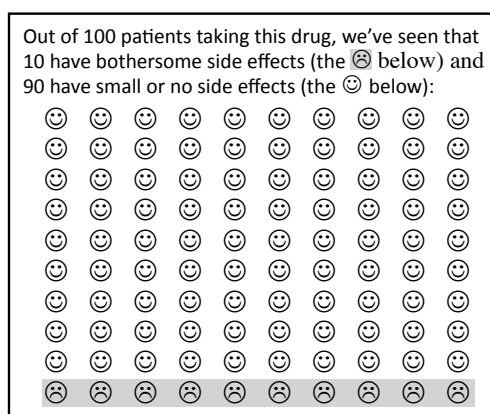
Show AND tell. Showing your audience what to do or what you mean can help in three ways. It can help the audience:

- master actions
- feel vividness, and
- understand quantitative information.

Demonstrations and pictures can help make directions simpler to understand and follow for any literacy level. For example, the directions for using a medical device like an Epi-Pen must be written, but a video showing what to do could be worth more than a thousand words. FDA discussed this in the program Patient Safety News and included a link to the manufacturer's video instructions.⁹ Photos or diagrams of action steps can also be helpful and would probably be even more helpful as reminders, if the patient had previously seen them as real actions.

Pictures can make a warning more vivid (see Chapter 15). A photo of oral cancer from heavy tobacco use can be so convincing that individuals are more likely to act on it, even if they forget the details of the message.¹⁰ At the same time, as with any message, you should test a picture with actual users to make sure that it communicates the message you intend.¹¹

Figure 2. Pictures that communicate a message



Source: Lee Zwanziger, based on suggestions and slides from FDA Risk Communication Advisory Committee meetings.¹²

Diagrams can help make quantitative information easier to see. For example, suppose we have to communicate that test results indicate that 10%

of patients taking a medicine had side effects (Figure 2). Data and practical experience show that this type of pictogram is a powerful aid to understanding quantitative risk (see Chapter 7).¹²

What does our practical experience suggest about evaluating communications?

Audiences may receive a very different message than the one we tried to communicate. They may not understand our message. Or, we may not understand what our patients or members of the public are trying to tell us. The possibility of misunderstanding does not go away even with experienced communicators. This is why, as discussed in Chapter 3, we must keep checking with the audience to learn whether they heard what we meant.

- In one-on-one situations, the fastest and easiest test is to ask the other person to “teach back” what they just heard.
- In written communications, we’ve all had the experience of showing a draft to someone else and had the fresh-eyed reader find mistakes or garbled sentences.

These informal reviews become even more important in health communications, where unclear messages might lead to poor, or poorly informed, health decisions. So even without formal testing, it is important to find a few new readers or listeners for a draft communication. The broader the audience and the further removed from person-to-person contact, the more important understandability checking will be for effective communication.

Conclusions

As a communicator, you will be more effective if you respect your audience. Give them the information they need, in a form they can use, and without unnecessary communication barriers. Lead with the key information. Know who the message is for, what these people should know, and what they should do about it. Make the message clear with plain language, pictures, and demonstrations. Finally, check audience understanding.

Additional resources

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3. *Communicating Health: Priorities and Strategies for Progress*. This publication provides in-depth action plans for each of the six Healthy People 2010 Health Communication Objectives, including Objectives 11-2 and 11-6 on health literacy. Available at: <http://odphp.osophhs.dhhs.gov/projects/HealthComm/>.

4. *Bibliography Understanding Health Literacy and Its Barriers*. The National Library of Medicine's (NLM) bibliography provides a comprehensive list of health literacy citations from varying disciplines and publications. The bibliography is divided into specific topic areas. Available at: www.nlm.nih.gov/pubs/cbm/healthliteracybarriers.html.
5. *Scientific and Technical Information: Simply Put*. This guide from the Centers for Disease Control and Prevention (CDC) will help you translate complicated scientific and technical information into material that captures and keeps the interest of your intended audience. Available at: <http://www.cdc.gov/od/oc/simpput.pdf>

Endnotes

- ¹ This graphic is based on several slides presented at the August 2008 meeting of the Risk Communication Advisory Committee by charter member AnnaMaria DeSalva. For full presentation see slides (accessed 1/13/2011) <http://www.fda.gov/ohrms/dockets/ac/08/slides/2008-4377s2-01.pdf>
- ² http://nces.ed.gov/naal/kf_demographics.asp, accessed 1/13/2011.
- ³ http://nces.ed.gov/naal/health_results.asp, accessed 1/13/2011.
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- ⁵ <http://www.census.gov/prod/2003pubs/c2kbr-29.pdf>, accessed 1/13/2011.
- ⁶ For example, The National Diabetes Education Program provides educational materials and tools on diabetes awareness and maintenance tailored for Hispanic populations, see <http://www.ndep.nih.gov> (accessed 1/13/2011).
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- ⁸ For status, see <http://www.fda.gov/AboutFDA/AboutThisWebsite/default.htm>, accessed 1/13/2011.
- ⁹ For *FDA Patient Safety News*, see <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/printer.cfm?id=225>, and for manufacturers video, see <http://www.epipen.com/how-to-use-epipen> (both accessed 1/13/2011).
- ¹⁰ Research on graphics in warning on cigarette packages, presented at May 2010 meeting of the Risk Communication Advisory Committee by member C. Andrews, see slides (accessed 1/13/2011). <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/UCM211341.pdf>.
- ¹¹ One memorable communication featured a fried egg and the caption “this is your brain on drugs,” but testing later showed the campaign it was part of had little effect on reducing drug use. Discussed at May 2010 meeting of Risk Communication Advisory Committee by guest speaker Julie Downs, see slides <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/UCM211334.pdf> (accessed 1/13/2011).
- ¹² This diagram is smaller and simpler but similar in style to those suggested in meetings of the Risk Communication Advisory Committee by member J. Paling, see http://www.riskcomm.com/paling_palettes.htm (accessed 1/13/2011). Also note that the usefulness of this type of diagram is supported by data presented at the May 2010 meeting of the Risk Communication Advisory Committee by member A. Fagerlin, see slides (accessed 1/13/2011). <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/RiskCommunicationAdvisoryCommittee/UCM211338.pdf>.

Chapter 21: An Agency Perspective

Nancy M. Ostrove, PhD - Food and Drug Administration

Summary

FDA is committed to effectively communicating about regulated products that affect the public on a daily basis. But challenges abound for federal agencies wanting to take an evidence-based approach to creating and regulating communications. Nonetheless, as demonstrated by its *Strategic Plan for Risk Communication* and the increasing use of external risk communication experts, FDA is rising to this challenge to ensure that the public has and understands the needed information to appropriately use products that can ensure a healthier and safer America.

Introduction

Like many other federal, state, and local agencies, the Food and Drug Administration (FDA) communicates daily with stakeholders. Much of its communication focuses on the benefits and risks of regulated products. In recent decades, many have questioned whether federal agencies, including FDA, communicate as effectively as possible. As Hamburg and Sharfstein recently asserted, “one of the greatest challenges facing any public health agency is that of risk communication.”¹ The National Research Council defined *risk communication* as encompassing the process of information and opinion exchange among individuals, groups, and institutions. It involves multiple messages — not strictly about risk — and is successful when it raises understanding of relevant issues and actions and satisfies people that they are reasonably informed within the limits of available knowledge.²

FDA's *Strategic Plan for Risk Communication* (SPRC) laid out three interlocking FDA goals as the foundation for an evidence-based approach to risk communication: Strengthening science, expanding capacity, and optimizing policy.³ The SPRC recognizes that there is a science behind communications and that understanding and applying this science is critical to effective communication about regulated products. FDA faces a number of challenges in implementing the science-focused goal toward improving its risk communications. Some of these are common to many government agencies, and even to private-sector organizations, whereas some are specific to FDA. This chapter discusses the most significant of these challenges.

The context behind FDA communications

FDA is committed to ensuring that the regulatory and policy decisions underlying its communications are evidence-based. However, consistent with the nature of scientific knowledge, that evidence inevitably evolves and is often uncertain. In fact, even the methodologies used to gather the data that guide these decisions are not perfect.

For example, the decision to approve a sponsor's request to market a new prescription drug, biologic, or novel medical device relies on data from randomized controlled clinical trials. These data enable clear inferences about causality, but only for the populations, circumstances, and specific questions studied. Uncertainties remain about how well the data predict a product's effectiveness and safety when prescribed and used under *real world* conditions — in untested populations and circumstances. It is challenging enough to communicate the concept of relative safety and efficacy. Given that the legal descriptor for approved products — “safe and effective” — implies *absolute* safety and effectiveness, the general public may see approvals as clear yes-no decisions. Unfortunately, this creates ripe ground for confusion when new data appear on a product's safety or effectiveness, making the communication of data uncertainty especially relevant to creating a fully informed understanding of product risks and benefits.

Uncertainties also arise when FDA must decide whether to temporarily recall or completely withdraw a product already on the market. Sometimes products get contaminated, either deliberately or inadvertently. Sometimes, experience with a product in the uncontrolled (real world) market raises safety concerns — suggesting new problems or confirming previously suspected ones. For example, voluntary reports from health care professionals and consumers of patients' or consumers' adverse experiences, as well as data from epidemiologic studies of large databases, can signal possible product problems. Unfortunately, these methodologies typically cannot confidently establish causation, ruling out potential confounding factors. Sometimes, data obtained by following up on safety signals cannot be easily interpreted. For example, extensive detective work may still produce a weak signal regarding the cause of a food-borne illness outbreak — was it the tomatoes or the peppers in the salad? The substance initially identified ultimately may turn out to have been misidentified. Sometimes, the cause is never known for sure.

This discussion of the context of FDA communications demonstrates the challenge of communicating effectively about evolving product problems and related uncertainties. Although some general research suggests how to accomplish this, it has not addressed FDA's specific needs.

Challenges to implementing evidence-based communication

All federal agencies experience challenges in implementing an evidence-based approach to communicating with the public. This section first addresses challenges that are common to FDA and other agencies and then addresses challenges unique to FDA.

Informed communications development and evaluation. Effective communication requires understanding and addressing audience needs that can only be identified by talking with the targeted audiences. Recognizing this, FDA is striving toward instituting the standard practice of testing communications prior to use to increase effectiveness, reduce the likelihood of negative responses, and guide future efforts.

To do such testing, however, all government agencies share the challenge of addressing the clearance process required by the Paperwork Reduction Act (PRA) to obtain similar information from 10 or more individuals. The PRA is designed to protect the public from excessive government information requests, but it greatly slows the conduct of needed research. Without that clearance, research is limited to collecting similar information from 9 or fewer individuals, obviously limiting the generalizability of results. Larger samples require specified time periods to allow public comment on the proposed information collections, a detailed justification for the information collection, and review by the Office of Management and Budget (OMB). For FDA requests, the process for a new information collection typically takes at least 5 to 8 months. This creates a challenge to conduct research to inform needed communications on a fast turnaround basis. *Generic clearances* can significantly shorten the approval process for communications-related pre-testing and formative research.⁴ As part of the SPRC, FDA has begun to establish additional generic clearances to facilitate expeditious approval of needed communications pre-testing and formative research and for survey questions to evaluate communication effectiveness.

Applying past experience to planning for the future. Another challenge shared by other agencies is how to learn from experience (and plan for the future) by assessing the effectiveness of ongoing standard and emergency communication experiences. A challenge unique to FDA is communicating, and evaluating communications, while still conducting product reviews, product and facility inspections, and other significant work. The subject matter experts who carry out this ongoing work are more often than not the same experts who are needed to collaborate with communications staff in planning both ongoing and emergency communications. Once a communications event is past, the subject matter experts return to their daily work and communications professionals turn to the next topic on their list. It then becomes challenging to focus on evaluating the effectiveness of the now-past event. To address this challenge, FDA has begun instituting mechanisms to gather both process and impact measures of communications development and effectiveness.

Trust and competition from other information sources. As with many government agencies, FDA is not the only source of information about the products it regulates. Information about foods and medical products comes in the form of promotional and educational materials from product sponsors (producers and distributors of regulated products), from people acting on sponsors' behalf, and from completely independent sources. FDA is not even the only regulatory entity that oversees information from producers and distributors of many FDA-regulated products.⁵ The explosion of information available through the Internet provides ever more competition to FDA-developed or -regulated communications. Although some of these communications are congruent with FDA's messages, some are conflicting.

For FDA, the challenge is to ensure that the public perceives the agency as reasonably trusted and credible. If the public does not see FDA as trusted and credible, its communications will be less effective — even if all its practices and procedures are solidly evidence-based. Lack of self-interest should make FDA a highly credible source of information — especially compared with product sponsors. However, since the passage of the first Prescription Drug User Fee Act of 1992, requiring sponsors to pay user fees for FDA to review prescription drug market approval submissions within set time frames, some members of the public have claimed that FDA is now too dependent on industry and cannot be trusted to give independent reviews.

Public poll results show varying pictures of the degree of trust in FDA as a communication source. Answers to questions that ask about trust in FDA in general do not address trust in FDA as a source of information about the wide variety of regulated products (accounting for about 20 cents of every consumer dollar). The bottom line is that FDA needs to understand its perceived credibility and trustworthiness with the public for practical planning for effective communications.

Precision versus understandability. FDA's regulatory authority is not absolute; it is subject to nuanced constraints often clear only to those with scientific or legal training. The precision sought by scientists and attorneys who are the backbone of FDA as a science-driven regulatory agency can result in highly caveated statements. Unfortunately, providing a large quantity of information does not lend itself to effective communication. In fact, communicating multiple caveats and uncertainties can dilute a message to the point of cognitive inaccessibility (see also the discussion about audiences in the next section). From a perceptual perspective, the proliferation of caveats about uncertainties can result in discrediting the decisions to which they are so carefully applied.

Range of audiences and audience needs. Like many other organizations, FDA has stakeholders in audiences with widely varying information needs and cognitive capabilities. Those audiences include the general public (patients,

consumers, and lay care givers), medical professionals (individuals, institutions, and associations), manufacturers, producers, distributors, retailers, advocacy groups, government (state, local, national and international), and other non-government organizations. Audience knowledge about products, health, medicine and pharmacy practice, regulations, and public policy ranges from very little to a lot. Audience capabilities also can vary with respect to general literacy, health literacy, and cognitive abilities. One challenge, discussed below, is how to target communications, especially in addressing the needs of members of the general public with lower literacy skills and cognitive capabilities.

Deciding when and with whom to communicate. A communication challenge shared with many organizations is deciding when to communicate about an issue. This is especially relevant to FDA when a signal arises of a possible product problem. FDA receives such signals daily, but in determining whether to communicate about them, the agency must balance the public's need to know with the risks of overburdening the public with an unwieldy barrage of information. Should FDA use a low threshold for public notification, thereby possibly *crying wolf* too often and perhaps lowering signal value? Or should FDA use a high threshold for public notification, thereby risking the perception that it lacks transparency and hides information critical to an informed public?

Common sense might suggest a solution of communicating signals early on only to experts who can understand more fully the inherent uncertainties while delaying communication with the general public until there is greater certainty. However, the responsibility to be fair requires that all members of the public get information at the same time. Thus, for example, FDA policy is that it does not provide early warnings to medical providers before providing information to the general public about a new, increased, or decreased drug or medical device problem. Yet many health care practitioners have told us that they would like to be better prepared for the deluge of questions they can get once patients hear about a possible problem.

Indirect communications. A challenge FDA shares with other regulatory agencies is when to communicate directly with the public rather than relying on regulatory influence over product sponsor communications. Historically, much of FDA's communications role was indirect, ensuring that product labeling is accurate and comprehensive. FDA could do this because of its premarket approval authority over certain products. Product labeling is drafted by product sponsors and then reviewed and ultimately approved by FDA staff. However, FDA's ability to compel sponsors to accept the agency's interpretation of issues is constrained by both scientific and regulatory-legal considerations. FDA and sponsors often negotiate disagreements, with each side arguing for its interpretation of often ambiguous data. Furthermore, it is typically hard to

compel changes based purely on communications concerns. For example, it might be difficult to justify denying approval to market a product because its labeling explained a potential warning in language FDA believes is not optimally effective for communicating that danger.

Historically, for medical products, FDA often communicated directly to the public when it believed a product should be recalled because of an imminent danger to public health. But new and uncertain signals typically would not generate sufficient certainty to justify the extreme action of a recall or market withdrawal. Instead, the focus was on ensuring revisions to the product's labeling that would accurately communicate the current state of knowledge. Ultimately, belief about the lack of immediate danger coupled with the legal mandate to protect confidential information has often led to delaying public disclosure about a possible problem until revisions to product labeling were finalized. Because contentious and lengthy negotiations on proposed revisions often resulted from disagreements about how to interpret the data, public disclosure could be further delayed.

In recent years, FDA has become increasingly likely to communicate directly with its public stakeholders as problems arise and rely less on communicating through product labeling. FDA alerts both health professionals and the general public to potential product problems, often despite uncertainties about what the data mean and what recommendations would best help stakeholders address the problem's implications for them.

Internal communications expertise. FDA has long had extensive internal expertise in the sciences needed to review and approve regulated products and to ensure their identity, strength, quality, and purity (e.g., chemistry, toxicology, pharmacology, physiology, engineering, statistics, nutrition, medicine, pharmacy). FDA has less of the internal expertise needed to communicate with the public about the results of its review and enforcement activities (e.g., social, decision, behavioral, and communication sciences). However, FDA has been increasing its internal capacity and using the additional capacity offered by external experts on the Risk Communication Advisory Committee FDA established in 2007.

Range of covered products and regulatory authorities. As mentioned previously, FDA enforces laws covering multiple product types under different legal authorities and scopes. Even within the drug-focused program areas, new staffers learn that actions possible for one regulated drug or class are not possible for another. More significant differences exist across product-focused organizations — especially between those with and without premarketing approval authority. For example, although prescription drugs require prior approval to be marketed, foods (except for food additives) do not need prior approval; instead, FDA must first prove they are dangerous to be able to demand they be removed from marketing. Unfortunately, it is likely that

FDA's public audience sees "FDA" as the source of messages, rather than the source being an FDA Center with authority for a particular regulated product. Thus, although these legal distinctions are important to FDA and its regulated industries, they may not be meaningful and may, in fact, be confusing to the public.

Other regulatory constraints also significantly affect FDA's ability to communicate. For example, laws protecting sponsor's intellectual property rights constrain FDA's disclosure of trade secret and confidential information. As a result, FDA often cannot communicate about a certain product without the sponsor's prior approval. As mentioned before, in the face of uncertain data about the existence of a product safety issue, FDA and product sponsors may legitimately disagree about the public health risk involved. That risk judgment often needs to be resolved before FDA can secure a sponsor's agreement to discuss the data in a public forum.

Conclusion

Many factors, including some common to federal agencies in general, affect FDA's ability to develop, disseminate, and oversee effective product communications in an evidence-based manner. The nature of the evidence that FDA uses for its decision making creates significant uncertainties about conclusions and consequent challenges to effective communication. Nonetheless, FDA's commitment to greater transparency, its championing of an Advisory Committee of external risk communication experts, and its issuance and implementation of a *Strategic Plan for Risk Communication* clearly continue to support an evidence-based approach to communications.

Additional resources

1. *FDA Basics* on the Food and Drug Administration's Internet site provides useful information about FDA's organization, staff, and transparency efforts and gives answers to commonly asked questions about what FDA does. (<http://www.fda.gov/AboutFDA/Transparency/Basics/default.htm>).
2. *FDA's Strategic Plan for Risk Communication*. (2009). outlines its plan for improving FDA risk communication through strengthening science, expanding capacity, and optimizing policies, with the underlying principles that risk communication is science-based, provides sufficient context, is adapted to audience needs, and is results-oriented. Retrieved from <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM183683.pdf>.
3. Internet site members of the public can search (under Department of Health and Human Services) for the information collection requests submitted under requirements of the Paperwork Reduction Act that are currently under review at the Office of Management and Budget (<http://www.reginfo.gov/public/do/PRAMain>).

Endnotes

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³ Food and Drug Administration. (2009). *FDA's Strategic Plan for Risk Communication*. Retrieved from <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM183683.pdf>.

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⁵ For example, the Federal Trade Commission oversees the advertising of foods and all medical products, except human and prescription drugs and biologics and a limited category of medical devices.

Chapter 22: Strategic Planning

Baruch Fischhoff, Noel Brewer, and Julie Downs (Editors)

With this guide, we have sought to strengthen the scientific foundations of risk (and benefit) communications. The guide offers lots of specific advice. However, not all of it has to be mastered for it to help an organization improve its communications. Just sampling here and there will show incremental, affordable steps, putting better risk (and benefit) communication within everyone's reach.

The guide offers authoritative summaries of essential research, written as accessibly as possible, while preserving the detail needed to represent the science faithfully and avoid oversimplification. That research is then translated into concrete recommendations for designing communications and coupled with the testing procedures needed to make communications as good as possible. The guide emphasizes practicality, hoping to improve communications, even when time and resources are limited. The guide intends to make the science of communication as sound as the science that is being communicated.

Each chapter offers a concise introduction to its domain. For example, Chapter 16 shows how a product's design can suggest its risks and benefits, then suggests ways to create designs that create more realistic expectations. Chapter 10 summarizes what is known about how emotions affect risk judgments, how to anticipate those emotions, and how to evaluate attempts to address them. Chapter 14 identifies the barriers to reaching low-literacy audiences, strategies for overcoming them, and ways to evaluate their success.

Each chapter should help practitioners not only perform that aspect of their own work, but also work more effectively with the relevant experts. For example, knowing something about the science of product design can show when help is needed, how to find it, and how to speak the language of design. Knowing something about emotion research can sensitize communicators to those concerns and encourage them to work with specialists in addressing them. Knowing something about health literacy research can highlight the risks of needlessly confusing one's audience and create an appreciation of the professionals who are trained to simplify a message's language while preserving its content. In each case, knowing some of the science can protect practitioners from placing undue faith in simplistic solutions.

Communication as a strategic responsibility

Knowing the science should help practitioners work better with whatever resources they have. It might also help them gain more resources, by showing the stakes riding on effective communication and the challenges to delivering it. Table 1 shows the strategic vision of the U.S. Food and Drug Administration (FDA)^{1,2} for creating the communications needed to serve its many audiences. Although the details reflect FDA’s particular circumstances, all organizations face the same basic tasks: Strengthen the science needed to support effective communication, expand the capacity to deliver those communications, and create policies compatible with them.

Table 1. US FDA communication principles and strategies

Strengthen the science that supports effective risk communication
Science Strategy 1: Identify gaps in key areas of risk communication knowledge and implementation and work toward filling those gaps
Science Strategy 2: Evaluate the effectiveness of FDA’s risk communication and related activities and monitor those of other stakeholders
Science Strategy 3: Translate and integrate knowledge gained through - research/evaluation into practice -
Expand FDA capacity to generate, disseminate, and oversee effective risk communication
Capacity Strategy 1: Streamline and more effectively coordinate the development of communication messages and activities
Capacity Strategy 2: Plan for crisis communications
Capacity Strategy 3: Streamline processes for conducting communication research and testing, including evaluation
Capacity Strategy 4: Clarify roles and responsibilities of staff involved in drafting, reviewing, testing, and clearing messages
Capacity Strategy 5: Increase staff with decision and behavioral science expertise and involve them in communication design and message development
Capacity Strategy 6: Improve the effectiveness of FDA’s Web site and Web tools as primary mechanisms for communicating with different stakeholders
Capacity Strategy 7: Improve two-way communication and dissemination through enhanced partnering with government and nongovernment organizations
Optimize FDA policies on communicating risks and benefits
Policy Strategy 1: Develop principles to guide consistent and easily understood FDA communications
Policy Strategy 2: Identify consistent criteria for when and how to communicate emerging risk information
Policy Strategy 3: Re-evaluate and optimize policies for engaging with partners to facilitate effective communication about regulated products
Policy Strategy 4: Assess and improve FDA communication policies in areas of high public health impact

Elsewhere in its *Strategic Plan for Risk Communication*, FDA identifies three underlying principles that could apply to any organization. Expressed in general terms, they are:

- 1. Communication should be based on science.** Without supporting evidence, even widely accepted best practices can be terrible. As a result, organizations need an evidence-based strategy if they are to survive and advance. That means reviewing their current practices in terms of their consistency with the science (i.e., Is the organization doing things known not to work? Is it ignoring known problems?). It also means evaluating the effectiveness of all communications, recognizing that even the best science cannot guarantee results — only provide better best guesses at how to communicate about specific issues with specific audiences.
- 2. Communication should inform choices.** Unless people know the risks and benefits of possible actions, they cannot evaluate the choices facing them. As a result, communications must focus on conveying the risks and benefits of those choices. That is true whether the organization hopes people will make a particular choice (e.g., get vaccinated) or is indifferent (e.g., use a drug that has been approved for sale). Informed choices often require knowing something about the organization behind the communication. For example, people may want to know why FDA has recommended a vaccine; why FDA has approved, but not recommended, a drug; why FDA has added a warning, rather than pulling a product from the market.
- 3. Communication should be results oriented.** Effective communications enable people to live better lives thus, placing a deservedly higher value on organizations that provide such help. As a result, communication must involve more than just pro forma fulfillment of an obligation to consult or inform. To have something meaningful to say, organizations must produce information that matters, rather than force communicators to take whatever they can get.

Implementing these principles can be disruptive at first for organizations that have not treated communication as a strategic function. However, it need not be costly. Knowing the research enables organizations to use resources more efficiently. For example, following good communication principles might focus communications on the benefits of choices when the risks are already understood; or direct research to resolving critical uncertainties (e.g., evaluating the quality of postmarket monitoring). Shifting resources within an organization requires leadership. Clearly defining communication priorities can show where that leadership is needed.

Implementing these principles can help organizations in other ways as well. It can reduce internal friction by providing a disciplined way to decide what to say and how to say it (rather than letting staff argue among themselves). It can make better use of external vendors of communication services by avoiding those who cannot demonstrate mastery of the science and a commitment to evaluation. It can ensure that communications get needed resources by demonstrating their scientific foundations.

Organizing for evidence-based communication

The top half of Table 2 summarizes the steps in evidence-based communication. Accomplishing them requires the skills in the bottom half of the table. Although each skill is particularly important at one step, each also is needed throughout the process. For example, although risk and decision analysis are central to identifying the information most relevant to audience needs, identifying those needs requires behavioral science research (to know what matters to the audience), subject matter expertise (to know what is at stake), and communication work (to create trusted channels for hearing and addressing that audience). Leadership is needed to recruit the right people and then coordinate their work. Without that coordination, communicators may distort facts as they try to simplify them, and subject matter experts may provide long lectures to audiences that want just a few critical details. In healthy group processes, all opinions are welcome and heard, but experts should have the final say in their domains.

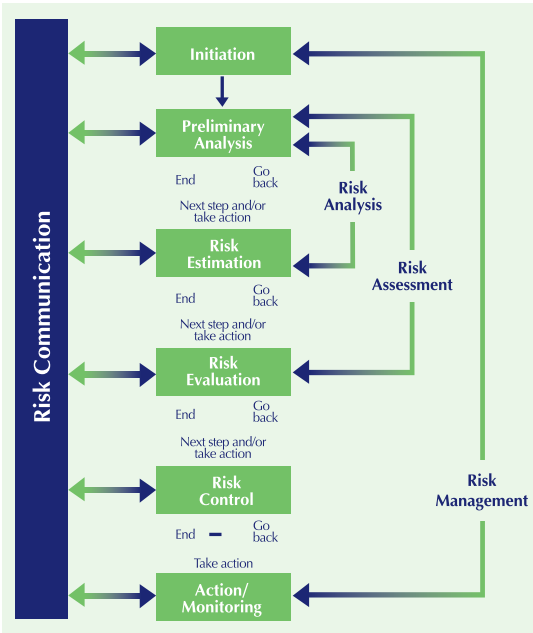
Table 2. Organizing for evidence-based risk and benefit communications

Steps
<i>Analysis.</i> Identify the information most relevant to helping audience members make decisions that achieve their goals.
<i>Design.</i> Draft communications that provide needed information in concise, comprehensible, usable form.
<i>Evaluation.</i> Subject drafts to empirical evaluation, assessing whether people can extract enough information to make sound choices, then follow them through.
<i>Iteration.</i> Repeat as needed, looking for weakness in the analysis, design, or evaluation.
Skills
<i>Subject matter expertise,</i> to ensure fidelity to the best available technical knowledge.
<i>Risk and decision analysis,</i> to identify facts most relevant decisions that audience members face.
<i>Behavioral science,</i> to design outstanding communications and evaluate them.
<i>Communication,</i> to create and sustain respectful two-way communication channels.
<i>Leadership,</i> to recruit the needed staff and coordinate their activities, consistent with the overall communication strategy.

Figure 1 shows a process for managing risks that enables such coordination. Issued by the quasi-governmental Canadian Standards Association³, the figure echoes proposals from many similar bodies. In the middle are the normal steps in managing any risk.⁴ The process begins with defining the decision problem, then proceeds to estimating the size of the risks, evaluating their relative importance, devising ways to control them, taking action, and monitoring progress. Between each two steps is a reality check, asking whether the work has been done well enough to proceed (next step), whether it needs to be improved (go back), or whether it should be abandoned as irredeemably inadequate (end).

Notably, each stage requires two-way communication between those responsible for managing the risk and those affected by it. Thus, members of the relevant audiences must be consulted when the process begins, so that risk management focuses on their concerns and they are not blindsided by its conclusions. Even after a decision has been made (at the bottom), those audiences must continue to be part of the process, helping to monitor what has been learned and reporting their own experiences. Skipping the reality check at any step risks leaving the audience or the organization in the dark, unless they know what is happening without being told. As the chapters in this volume show, it is unrealistic to expect people to read each others' minds.

Figure 1. A process for integrating communication and analysis



In executing a communication program, any scientific knowledge is better than relying on pure intuition. Any evaluation is better than assuming that a communication that looks okay is okay. However, strategic communication requires deeper organizational commitment, ensuring that communication issues become integrated with the entire risk management process (Figure 1). Lest this seem too daunting, most organizations of any size already have many of the needed skills (Table 2). They could not function, if they did not have people who know about the risks they manage, people who handle press releases, people who do test marketing, and so on. The challenge is to complete the roster of skilled experts and get them working together. An organization could do that alone or pool its resources with related ones (e.g., industry associations, interagency research groups).⁵ A structure that can balance the routine and fluctuating needs of risk communication has:

- An intramural core with decision analysts, behavioral scientists, and communication specialists dedicated to designing, evaluating, and disseminating communications
- An extramural program with opportunities for collaboration with scientists elsewhere, drawing them into studying communications and keeping core staff connected with the research world
- Contracted services that respond to the demand for delivering specific communications, under the core staff's guidance

Assembling a strategic communication program may require additional resources. However, it may also mean just using current resources more effectively. It might even save resources by reducing activities that were never effective. However, even if greater resources are needed, given the stakes riding on sound communication, it would be a false economy not to invest them. Given the science available to guide that communication, it would be a shame to use anything less. This guide provides access to that science as well as instructions on how to use it.

Endnotes

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⁵ Pidgeon, N., and Fischhoff, B. (2011). The role of social and decision sciences in communicating uncertain climate risks. *Nature Climate Change*, 1(1), 35-41.

Biographical Sketches

J. Craig Andrews, PhD is Professor and Charles H. Kellstadt Chair in Marketing, Marquette University. His research focuses on advertising and public health issues. Andrews currently serves on FDA's Risk Communication Advisory Committee, has served on the Behavior Change Expert Panel for the National Youth Anti-Drug Media Campaign, was Editor of the *Journal of Public Policy & Marketing*, and Consumer Research Specialist in the FTC's Division of Advertising Practices in Washington, DC. Andrews' work has appeared in the *Journal of Marketing*, *Journal of Public Policy & Marketing*, *Journal of Consumer Research*, *Journal of Advertising*, *Journal of International Business Studies*, *Journal of Retailing*, and the *American Journal of Public Health*, among others.

Noel T. Brewer, PhD is an expert in medical decision making with an emphasis on risk communication about vaccination as well as the psychological impact of medical tests. He is Associate Professor of Health Behavior and Health Education in the Department of Health Behavior and Health Education at the University of North Carolina Gillings School of Global Public Health. His research projects are described at <http://www.unc.edu/~ntbrewer>. Dr. Brewer is associate editor of *Health Psychology Review* and on the editorial boards of *Journal of Behavioral Medicine* and *Medical Decision Making*.

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Effective risk communication is essential to the well-being of any organization and those people who depend on it. Ineffective communication can cost lives, money, and reputations.

Communicating Risks and Benefits: An Evidence-Based User's Guide provides the scientific foundations for effective communication. The book authoritatively summarizes the relevant research, draws out its implications for communication design, and provides practical ways to evaluate and improve communications for any decision involving risks and benefits. Topics include the communication of quantitative information and warnings, the roles of emotion and the news media, the effects of age and literacy, and tests of how well communications meet the organization's goals. The guide will help users in any organization, with any budget, to make the science of their communications as sound as the science that they are communicating.

