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Quantitative Summary of the Benefits and Risks of Prescription Drugs:

A Literature Review

Draft Report

Prepared for

Food and Drug Administration

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EXECUTIVE SUMMARY

Introduction

Under the Food, Drug, and Cosmetic Act (FDCA), all promotional materials for prescription drugs must strike a fair balance in the presentation of risks and benefits. Further, section 502(n) of the FDCA specifies that prescription drug advertisements must contain a true statement of the side effects, contraindications, and effectiveness of the advertised product. How to best present that information, however, continues to be an open question that warrants further inquiry. Meeting or exceeding the minimum requirements for fair balance currently set by the U.S. Food and Drug Administration (FDA), for example, does not completely ensure that an advertisement will contain information presented in a format that is easily understandable for a reasonable consumer.

In light of this background, Congress is currently interested in whether adding quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as a table or drug facts box) to the promotional labeling or print advertising of such drugs would improve health care decision making by clinicians and patients and consumers. In response to this request for information, the following key questions (KQs) have been developed.

KQ1. What is the value of quantitative information or summaries about the risks and benefits of medical interventions for consumers, patients, and clinicians?

KQ2. How does presentation of the quantitative information influence consumers', patients', and clinicians' processing and understanding of the risks and benefits of medical interventions?

Both of these research questions involve the provision of *quantitative* information in direct-to-consumer (DTC) advertisements. That focus reflects the notion that any information that addresses the likelihood of different risks or benefits (e.g., 1 in 500 people have a given infection, or the condition improvement rate is 95%) is essentially quantitative in nature. In the context of DTC ads, we can broadly define quantitative information as empirically quantifiable evidence about the advertised product. Importantly, the specificity of the quantitative information can vary; risks can either be described using numbers (e.g., "30% of patients," "1 in 4 patients") or through descriptive labels (e.g., increased, many, frequently). We can refer to the former as *numeric* formats and the latter as *non-numeric.* At the heart of this literature review is a distinction between numeric and non-numeric risk information formats and our assessment of what impact each type of format might have on important outcomes related to informed decision making about prescription drugs.

Methods

We used the PubMed database for the literature search, limiting the studies to human populations, the English language, specific publication types (randomized controlled studies, observational studies, focus group research, and others), the core clinical journals (a group of

119 journals, as of August 2010), and the journals most frequently publishing risk communication research (14 journals). A Technical Expert Panel (TEP) also provided guidance on the search strategy by providing keywords and medical search headings (MeSH) they found valuable in their research. Because we were concerned that the PubMed search might miss critical literature needed to address the key questions, we identified publications from other sources. We included citations suggested by the TEP (*n* = 105), and an additional 104 citations from hand searches stemming from a previous literature scan conducted by RTI to investigate effective ways to deliver risk and benefit information in DTC prescription drug advertisements, additional literature searches to refine the KQs, a Cochrane database search on decision aids, and citations from published literature reviews relevant to this work. The systematic literature search identified 550 relevant citations. Combining these with citations suggested by the TEP (*n* = 105) and additional citations from hand searches (*n* = 104), led to a total of 759 articles (674 unduplicated) to be examined for possible inclusion.

Two reviewers independently reviewed the titles and abstracts for inclusion or exclusion in the body of evidence, initially for KQ1, KQ2, or both KQ1 and KQ2. When the two reviewers disagreed on whether an article should be included, the reviewers discussed their disagreement with the project director and a final inclusion status was reached. The reviewers then reviewed the full text of all citations that were categorized as potentials to determine whether they should be abstracted for inclusion in the body of evidence for KQ1, KQ2, or both KQs. Using this process, we included 52 articles for review.

We trained two team members to extract the relevant data from each article into preformatted evidence table templates to ensure consistency in reporting. As staff reviewed information from their set of articles in preparation for abstraction, they made sure that all the inclusion/exclusion criteria were met; those articles that met the criteria were abstracted into the evidence tables.

We then created an organizing structure for the studies based on elements of leading theoretical models of consumer behavior. Using this approach, we categorized studies into the following outcome categories: (1) information format and style preferences, (2) knowledge and comprehension, (3) perceived risks and benefits, and (4) behavioral intentions and behaviors. Evidence tables described results in terms of data relevant to those central outcome categories.

Results and discussion

Of the 52 studies we reviewed, 37 focused on prescription drugs or hypothetical drugs. Other topics ranged from decisions about immunizations and other screenings, risk of disease, treatment decisions (e.g., surgery options), and environmental health issues, including advisories related to fish consumption. The populations studied were quite diverse as well but focused primarily on adults. The studies encompassed student populations, patients with selected illnesses, jurors, parents or other surrogate decision makers, people who use the Internet, and the general population of adults. Most of the studies focused on patient or consumer behavior, as opposed to health care providers.

More studies in our review examined risk information alone as opposed to both risk and benefit information**.** Some studies presented both risk and benefit information; few studies focused only on benefits. Even this descriptive result is noteworthy, as presenting only risk or benefit information is arguably unbalanced and potentially unethical. Often there is a presumption of benefit for all medical care, without a consideration of the potential harm. Consequently, one of the key issues in communicating risk information is communicating potential harms and uncertain benefits.

Some of the limitations of the current literature are apparent even at the level of general description of study design and focus. In terms of central outcomes related to informed decision making, for example, a disproportionate share of the studies addressed outcomes at the "early end" of the consumer behavior continuum—that is, information preferences, knowledge, understanding, or risk perceptions. Fewer studies focused on distal outcomes, including behavioral intentions and actual behaviors. In fact, researchers in some studies manipulated multiple information features simultaneously in creating comparison groups, sometimes making it difficult to tease apart the specific reason for why significant effects may have occurred. Moreover, of the studies that examined behavioral outcomes (e.g., taking medications) in our review, many often focused on hypothetical situations (i.e., if you had *x* disease and needed to choose a drug). It is unknown whether these findings can be generalized to real patients in actual, real-world situations outside of the experimental laboratory.

Despite limitations of the literature, our review did yield several important themes. First, **numeric presentation of risk/benefit information appears to have had a positive impact on several outcomes relative to non-numeric presentation of risk/benefit information.** This pattern existed for a variety of outcomes including information preferences, knowledge/understanding, and perceived risk. The pattern was clearest for studies that examined the impact of risk/benefit information on knowledge gained, with the presence of numeric information associated with more accurate knowledge gain. Whether this pattern continues to hold for behavioral outcomes is less clear presently. A few studies that focused on actual behaviors provide some evidence supporting the utility of providing numeric information to patients, but most studies did not investigate such outcomes.

Presenting *both* numeric and non-numeric information may offer a useful approach in some circumstances because of the combination of the precision of numeric data and the qualitative or directive context provided by non-numeric information. Some studies in our review support this notion, particularly with regard to helping the reader understand relative or comparative risk. Discussion of contextual risk provides a reference point for interpreting risk so individuals do not resort to their own internal reference point or anchor to understand it. Visual information also may provide support with interpretation. Of course, presenting more than one type of information risks information overload; when using multiple formats, one should be careful not to provide too much information, especially too much narrative, or people likely will not absorb all the information presented.

Second, **no single specific format, structure, or graphical approach emerged as consistently superior.** Part of the reason for this conclusion is that the studies included in our review assessed a wide range of different format possibilities rather than providing a crucial test of multiple format types at once. Based on both consumer preference and knowledge gain data reported in the review (and mentioned previously), it seems prudent to keep presented material relatively simple. Exactly which specific method of presentation one should use remains an empirical question. Some researchers contributing studies to the review have specifically advocated for certain approaches, such as using pictographs (versus tables and text) but a necessary next step is to conduct a more comprehensive comparison of a large set of format options.

Third, **numeracy and health literacy are variables that deserve more empirical attention, because results may vary for different people depending on their numeracy or literacy levels**. Numeracy refers to how facile people are with mathematical concepts and their applications; we can think of health literacy as the degree to which people can obtain, process, understand, and communicate about information needed to make informed health decisions. Our review revealed a number of studies in which either numeracy or health literacy appeared to play a moderating role, such that results were different for those who had high numeracy or literacy versus those who had low numeracy or literacy. Although such data suggest that future recommendations should acknowledge the variation among the general population in terms of their numeracy and literacy skills, we need more evidence to confirm the potential role of those variables because many studies have not included indicators of numeracy or literacy.

In sum, there are important gaps in the current literature. For example, many of the studies in our review insufficiently investigated actual behaviors and many studies in our review focused only on risk information rather than on both risk and benefit information. Beyond such limitations, however, evidence suggests that people typically claim to prefer numeric presentation of risk information and such numeric presentation has been linked to greater knowledge gain, more accurate risk perceptions, and certain behavioral outcomes. At the same time, evidence also suggests that a person’s numeracy or literacy level can affect the extent to which they prefer numeric formats and the extent to which they glean information from such formats. No single recipe for presentation of risk and benefit information currently enjoys overwhelming support in available literature, in part because many studies each assess somewhat different formats instead of comparing formats to one another. Nonetheless, evidence also suggests that using relatively simple presentations of numeric and non-numeric information appears to be important to prevent overwhelming viewers, regardless of the specific approach employed.

I. BACKGROUND

With the passage of the Federal Food, Drug and Cosmetic Act (FDCA) in 1938, the Federal government required that all medications be proven safe before they could be marketed. This act was amended in 1962 to require that, in addition to being safe, medications had to be proven efficacious prior to being advertised to the public, opening an era of oversight for the presentation of drugs to audiences in the United States (Gellad & Lyles, 2007). Under the current version of the FDCA, all promotional materials for prescription drugs must strike a fair balance in presenting risks and benefits and contain a brief summary of the product label, including all risk-related, contraindication, and side-effect information that is detailed there. Further, section 502(n) of the FDCA specifies that prescription drug advertisements (ads) must contain a true statement of the side effects, contraindications, and effectiveness of the advertised product (Food and Drug Administration, 2001). How to best present that information, however, continues to be an open question that warrants further inquiry.

A brief history of direct-to-consumer advertising and issues in risk and benefit presentation

Regulation and oversight of prescription drug advertising has been the domain of the U.S. Food and Drug Administration (FDA) for roughly 50 years, since the passage of the Kefauver-Harris Drug Amendment in 1962 (Chandra & Miller, 2005; Lyles, 2002). FDA specifically regulates what are called product claim (or full product) ads and reminder ads that focus on brand awareness (as opposed to help-seeking ads that focus on general disease awareness). The goal of product claim ads is to promote a *specific* drug directly by providing the details of the drug's name and the condition it is designed to treat (Hoek, 2008). FDA is primarily concerned with ensuring that such product claim ads provide an accurate, balanced, nonmisleading picture of the product's characteristics that permits and allows consumers and health care professionals to make informed decisions about drug choice and use.

The primary audiences of concern for FDA have shifted over time. Over the past few decades, a number of changes to the U.S. health care system and the regulatory environment surrounding prescription drug marketing have made direct-to-consumer (DTC) advertising a viable marketing strategy that has grown rapidly (Government Accountability Office, 2006, November 16). For much of the 20th century, prescription drug promotion in the United States was directed toward health care providers. The rise of patient autonomy in popular discourse and in the examination room in the second half of the 20th century, however, helped to change the course of drug promotion. In addition to advertising to health care professionals, pharmaceutical companies began sponsoring ads in popular newspapers and magazines in the early 1980s (Auton, 2004; Gellad & Lyles, 2007). Uncertainty about the potential ill effects of this new marketing strategy prompted FDA to ask the pharmaceutical industry to impose a voluntary moratorium on the promotion of prescription medications directly to consumers in order to evaluate whether existing regulations provided adequate protection for consumer-directed promotion (Chandra & Miller, 2005). After an initial review, in 1985, FDA determined that the brief summary and fair balance requirements that must be met by all promotional materials directed at physicians also would apply to ads directed toward consumers. From the industry's perspective, this decision substantially limited the appeal of directing print ads to consumers because it was believed that presenting detailed risk information to a lay audience would counteract any promotional effect the message might otherwise have (Gellad & Lyles, 2007). Also, the brevity of standard television or radio spots and the technological difficulties associated with meeting the brief summary requirement through these media made broadcast DTC ads virtually impossible (Lyles, 2002).

The past 15 years have been a particularly active period in the evolution of oversight of prescription drug advertising. A dramatic change occurred in 1997 when FDA issued guidance that clarified the agency's interpretation of existing regulations as they applied to broadcast and electronic media (Calfee, 2002; Chandra & Miller, 2005). For print advertising, the regulations require a brief summary; broadcast ads are required to have either a brief summary or a combination of a major statement of the product's risks (typically the most serious risks and most common side effects) along with adequate provision for consumers to access the information contained in the package labeling. The guidance suggested ways in which the adequate provision requirement could be met by referring consumers to more complete sources of information—including a toll-free number, a Web site address, a concurrently running print ad, or specific publicly accessible locations where the information is available—and by recommending that they talk to a physician or pharmacist (Calfee, 2002). In 2004, FDA issued another voluntary guidance that sought to improve the readability of the brief summary that is required of all DTC print ads ("Draft guidance for industry. Consumer-directed broadcast advertisements: availability," 1997).

Despite guidance and legislation, however, the system continues to leave room for debate. Meeting or exceeding the minimum requirements for fair balance set by FDA does not completely ensure that an ad will contain information presented in a format that is easily digestible for a reasonable consumer. Currently, there are no uniform standards for the exact presentation of risk information in print ads. Schwartz, Woloshin, and Welch (2009) note that DTC ads often fail to provide data on how well the drug works, for example, which they claim is the "most fundamental information consumers need to make informed decisions" (p. 516). Moreover, Hoek (2008) notes that DTC marketing activities sometimes provide inadequate risk information, inaccurate efficacy information, and unbalanced risk and benefit information. Some DTC print ads display the relative risk reduction from the medication in large, prominent letters, whereas the risk information is presented in long lists of fine print. A study conducted in 2005 found that, at the time, more time was devoted to presenting benefit information than side-effect information in TV ads, resulting in better recall of purported benefits (Kaphingst, Rudd, Dejong, & Daltroy, 2005). Further, whether such presentation always provides necessary information in an appropriate balance is an unanswered question. In a content analysis of print ads promoting prescription medications for bleeding disorders in a magazine targeted toward hematology patients, Abel, Neufeld, Sorel, and Weeks (2008) observed that the amount of copy devoted to describing the benefits of the promoted drugs was twice as great as that dedicated to communicating the adverse effects. Based on scores derived from a standardized readability scale, they also found that the risk/side-effect information tended to be more difficult to read than the benefit information.

Potential outcomes of DTC ads

What are the consequences of information presented in DTC print ads in general? There are numerous conceivable outcomes of consumer engagement with such ads. Relatively obvious, perhaps, is the primary ostensible goal of DTC ad sponsors: to prompt consumers for whom a drug is relevant to discuss the drug with their health care provider. Proponents suggest that DTC ads can help combat underdiagnosis of disease by making the public aware of health conditions and treatment options that might otherwise be widely ignored or not considered serious enough to seek medical intervention, citing studies that have found an increase in patients seeking and receiving medical treatment after being exposed to DTC ads (Aikin, Swasy, & Braman, 2004; Donohue, Berndt, Rosenthal, Epstein, & Frank, 2004; Toshiaki & Ginger, 2005; Weissman et al., 2003). Less obvious but nonetheless plausible outcomes are negative and perhaps unintended consequences (Fenter, 2006; Friedman & Gould, 2007; Lansing & Fricke, 2005; Paul, Handlin, & Stanton, 2002). Rather than serve as a corrective to underdiagnosis of certain conditions, DTC ads also may lead patients to request prescriptions for medications that are not right for them (Lansing & Fricke, 2005). A recent national survey of physicians, for example, suggested that the majority of respondents believe DTC ads lead patients to request unnecessary prescriptions and drive consumer preference for brand-name drugs (Friedman & Gould, 2007).

Of the array of potential outcomes, variables of particular importance for our discussion will be those specifically linked to *informed decision making*. Understanding the extent to which decision making is affected by the format and presentation of DTC advertising elements requires that we first step back to consider how we might describe informed decision making, admittedly an ideal behavior but a reasonable goal for public reaction in the face of DTC ads. According to Mullen and colleagues (2006), informed decision making occurs when an individual understands that there is a decision to be made and understands their personal risk, is able to consider their preferences for various outcomes, participates in the decision at a personally desirable level, and makes a decision consistent with their own values. To make an informed decision about an advertised prescription drug, then, a person would need to be provided with “adequate, high-quality, relevant, unbiased information of all the consequences of making her/his choice” (Jepson, Hewison, Thompson, & Weller, 2005, p. 193). Under these circumstances, in other words, a person’s decision-making behavior both is a function of his or her comprehension of facts and the weighing of those facts against personal values and is a multistep process that occurs as a function of volitional intention. (Of course, in the case of prescription drugs, the decision in question may be a decision to talk to one's doctor about the drug, given that consumers must get a prescription in order to obtain the drug.)

In this light, numerous aspects of DTC ad presentation might have an effect. Any element of an ad that limits or inappropriately skews consumers' perception of a drug's effectiveness and its potential risks could affect consumers' ability to make informed decisions (Frosch, Krueger, Hornik, Cronholm, & Barg, 2007). At least some preliminary evidence suggests that such miscomprehension and inadequate understanding is common among consumers. Extant research to date suggests that consumers do not always adequately understand risk and benefit information presented in DTC ads and sometimes focus on presented benefits more than on presented risks even when risks warrant consideration (Bowman, 2002; Cohen, Ferrell, & Johnson, 2002; Hoek, 2008; Morris, Brinberg, Klimberg, Rivera, & Millstein, 1986). Some DTC ads implicitly overstate drug benefits by presenting benefit information using relative risks (which tend to be large numbers) and side-effect information using absolute risk (which tends to be small). Consequently, consumers tend to magnify benefits and minimize harms, resulting in undue enthusiasm for the treatment (Gigerenzer, Gaissmaier, Kurz-Milcke, Schwartz, & Woloshin, 2007).

The contraceptive pill scare in the 1990s helps to illustrate how framing of risk information can have serious consequences for health. In 1995, the U.K. Committee on Safety of Medicines issued a warning to all doctors and pharmacists stating that third generation oral contraceptives were associated with about twice the risk of venous thromboembolism as compared with levonorgestrel, a second-generation oral contraceptive. Based on this information, media outlets released an emergency announcement that third-generation oral contraceptive pills increased the risk of blood clots by 100%. Understandably, the news caused great anxiety and is purported to have led to unwanted pregnancies and an estimated 13,000 abortions as women stopped taking the pill (Furedi, 1999). One can speculate that, had the absolute risk—which was only 1 in 7,000—been reported, fewer women would have panicked and stopped taking the pill. What we know about human behavior suggests that such risk perceptions likely matter for actual decision-making behavior.

Such a perspective on consumer behavior is consistent with efforts among cognitive behavioral theorists to reach at least some basic consensus, across the myriad models of behavior that exist, as to what determines health behavior. In the early 1990s, the U.S. National Institute of Mental Health organized a workshop that included many major behavioral theorists, including Albert Bandura (of Social Cognitive Theory fame), Marshall Becker (who helped refine the Health Belief Model), Martin Fishbein (of the Theory of Reasoned Action), Frederick Kanfer (who has worked on self-regulation), and Harry Triandis (of the Theory of Interpersonal Behavior). As Fishbein and colleagues (Fishbein et al., 2001) have summarized, the group achieved consensus, recognizing three necessary and sufficient determinants of behavior as well as a series of other variables that can predict intention to behave. In the necessary and sufficient category were intention to behave, the necessary skills to act, and the absence of environmental barriers. In turn, predictors of intention include perception of advantages and disadvantages of the behavior, social pressure, consistency of the behavior with self-image, anticipation of positive emotional outcomes, and self-efficacy (or confidence in performing).

In sum, then, we can expect decision making in response to the type of DTC advertising elements considered here to be a function of intention that in turn is influenced by attitudinal beliefs (as well as social norm and self-efficacy perceptions). Among those beliefs will be knowledge regarding DTC drug outcomes and perceived risk in the face of that knowledge. People also likely will have various preferences for how information about outcomes and risk is presented, though exactly how people's information preferences ultimately shape their decisions is unclear. These considerations suggest an array of possible categories of outcome variables described in Table 1. We will use these categories as an organizing framework for discussing the results reported in the articles considered for this review. Researchers have focused on some types of outcomes more than others to date, with important implications for our discussion.

Table 1. Key Variables Linked to Potential Direct-to-Consumer Ad Format Effects

Independent variables	Potential outcomes	Potential moderators
Exposure to numeric vs. non-numeric presentation	Information format and style preferences Knowledge Attitude toward prescription drug choice and use Perceived risks and benefits Behavioral intention Behavior	Health literacy Numeracy Socioeconomic status

Potential moderators of DTC ad effects

Although our review of results describes what we actually found in terms of variables that appear to mitigate or enhance the effects of numeric and non-numeric risk and benefit information exposure, we first can briefly consider some factors that theoretically could have an impact, including health literacy, numeracy, and socioeconomic status.

Health Literacy and Numeracy. Health literacy can be defined as "the degree to which individuals can obtain, process, understand, and communicate about health-related information needed to make informed health decisions" (Berkman, Davis, & McCormack, 2010, p. 16). Those with poor health literacy engage in less preventive care (Scott, Gazmararian, Williams, & Baker, 2002), have poorer health knowledge and comprehension of disease and treatment implications (Gazmararian, Williams, Peel, & Baker, 2003), and have higher rates of emergency department and hospital utilization (Baker, Parker, Williams, Clark, & Nurss, 1997). Given the prevalence of low health literacy and its considerable social costs, understanding health literacy deficits among consumers and designing better information products and decision-support tools to overcome those deficits has been at the forefront of the nation’s health agenda (U.S. Department of Health and Human Services, 2000).

Health literacy, as an umbrella concept, comprises several different specific skills, one of which is numeracy. Numeracy, defined as the ability to understand, use, and attach meaning to numbers, is a component of health literacy that appears to make an independent contribution to comprehension and choices (Hibbard, Peters, Dixon, & Tusler, 2007). Rothman and colleagues (Rothman, Montori, Cherrington, & Pignone, 2008) describe numeracy as a multidimensional skill that encompasses assessing when to use numerical skills, using those skills effectively, and then interpreting the results appropriately. Numeracy has received somewhat less research attention than health literacy. However, not only is low numeracy pervasive, but it constrains informed patient choice, reduces medication adherence, impairs risk communication, and affects medical outcomes (Nelson, Reyna, Fagerlin, Lipkus, & Peters, 2008).

Numeracy is especially relevant to a discussion of DTC ads, in that numerical competence seems requisite to understanding the likelihood information inherent in the discussion of risks and benefits. Several researchers have argued that many consumers do not have the requisite medical knowledge or ability to critically interpret the information provided in DTC ads (Hoek, 2008; Lyles, 2002). According to the most recent National Assessment of Adult Literacy (Kutner, Greenberg, Lin, Paulsen, & White, 2006), 22% of U.S. adults performed below a basic quantitative skill level, 66% performed at a basic or intermediate quantitative skill level, and only 13% performed at a proficient quantitative skill level (Kutner, et al., 2006). At the proficient level, numeracy encompasses the ability to perform complex and challenging literacy activities and an understanding of fractions, proportions, percentages, and probabilities (Reyna & Brainerd, 2007). Notably, this proficient level is precisely the level of numeracy required to fully understand health-related risks and make informed medical decisions with numerical information (Galesic & Garcia-Retamero, 2010; Kutner, et al., 2006).

In a recent review of research from the cognitive and developmental literatures, Reyna and colleagues (2009) examined the effect of numeracy on cognition, health behavior, and medical outcomes across several studies and found that participants lower in numeracy tend to overestimate risks, are less able to use risk reduction information to adjust risk estimates, and may overestimate benefits of uncertain treatments. Additionally, participants low in numeracy tend to be more susceptible to framing effects (a cognitive bias that leads people to make different choices depending on whether a decision is described as a gain or loss, such as the chance of survival versus the chance of death), more sensitive to the formatting of probability and risk information, and more trusting of descriptive than numerical information. Finally, research has demonstrated that even highly educated people, such as physicians, are often unable to understand the meaning of numbers (Gigerenzer et al., 2007).

Other potential moderators. Socioeconomic status appears to differentiate audiences in terms of their ability to engage DTC ads. If we consider socioeconomic status (SES) to involve one's possession of both material resources and education (Ensminger & Fothergill, 2003), then it is not surprising that those at lower SES levels perform worse on key information engagement tasks. Larrick, Nisbett, and Morgan (1993), for example, found that people with lower income are more likely to make errors in economic reasoning. Johnson (2001), in another example, found that certain SES groups tend to misunderstand their own risk or that of a family member, which resonates with Parker and Fischoff's (2005) finding that lower SES teenagers fared worse than their peers in the consistency of their risk perceptions and ability to apply decision rules, among other tasks. These discrepancies may very well be explained, at least in part, by differences in literacy and numeracy, but nonetheless are noteworthy as we approach the present review.

Overview of key research questions

Our brief consideration of FDA regulation of DTC product claim ads and the potential consequences of consumer engagement with certain ad elements points to several research questions. Moreover, Congress is specifically interested in whether adding quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as a table or drug facts box) to the promotional labeling or print advertising of such drugs would improve health care decision making by clinicians and patients and consumers. This suggests the following key questions (KQs).

KQ1. What is the value of quantitative information or summaries about the risks and benefits of medical interventions for consumers, patients, and clinicians?

KQ2. How does presentation of the quantitative information influence consumers', patients', and clinicians' processing and understanding of the risks and benefits of medical interventions?

Both of these research questions involve quantitative information in DTC ads. That focus reflects the notion that any information that addresses the likelihood of different risks or benefits (e.g., 1 in 500 people have a given infection, or the condition improvement rate is 95%) is essentially quantitative in nature. In the context of DTC ads, we can broadly define quantitative information as empirically quantifiable evidence about the advertised product. Importantly, the specificity of the quantitative information can vary; evidence can either be described using numbers (e.g., "30% of patients," "1 in 4 patients") or descriptive labels (e.g., "increased," "many," "frequently"). In this report, the former will be referred to as *numeric* formats and the latter *non-numeric* formats.

Numeric Information. Quantitative information is most often conveyed using statistics or numbers. This numerical information, such as the probability of a risk or benefit, can be presented in several ways. Despite being mathematically equivalent, each format has different strengths and weaknesses and, subsequently, has different effects on cognitive processing.

The most commonly used formats are probabilities, frequencies, and percentages (Gigerenzer et al., 2007; Lyles, 2002). Probability values, for example, can range from 0 (e.g., a drug side effect will definitely not happen) to 1 (e.g., a drug side effect will definitely happen). In a DTC ad, probability information might state that “there is a 0.33 probability of experiencing symptom X.” Frequencies, in turn, reflect counting of the specific number of cases in a given population. Among frequencies, there are natural frequencies and simple frequencies. A *natural* frequency—sometimes called absolute frequency—is the total number of times an event occurs within a sample (e.g., 7,500 women reported experiencing nausea). These numbers result from counting specific cases (e.g., occurrence of side effects) within a specific reference group (e.g., people taking drug X). A *simple* frequency—which is more likely to be presented in a DTC ad—is a natural frequency that has been scaled down to smaller numerical values (e.g., one out of every three women reported experiencing nausea). Similar to probability information, percentages are bound at both ends of the scale and range from 0 to 100. Using a percentage, the previous example would be stated as “33% of women reported experiencing nausea.”

There are at least three other prominent numeric figures often reported. *Absolute risk reduction* (ARR) describes the absolute difference between the percentage of people affected if the preventive measure succeeds and percentage of people affected in the current situation. Consider the risk for having a stroke for patients with diabetes. If the risk for having a stroke is 2 in 100 (2%) in a group of patients treated conventionally and 1 in 100 (1%) in patients treated with the new drug, the ARR would be 1% (2% - 1%). This information can also be presented as a *relative risk reduction* (RRR), which describes the ARR divided by the percentage of people affected in the current situation (Visschers, Meertens, Passchier, & de Vries, 2009). Using the previous example, expressed as a relative difference (1% ÷ 2% = 50%), the new drug reduces the risk for having a stroke by half. The *number needed to treat* (NNT) is the number of patients who need to be treated to prevent one additional bad outcome, calculated as the inverse of ARR or 1 / ARR. Using the previous example, the NNT would be 100 (1 ÷ 1%); therefore, 100 people with diabetes would need to be treated in order to prevent one case of stroke.

Non-numeric Information. Likelihood information also can be presented using a wide variety of descriptive terms that communicate the chance that an outcome will occur. This approach to non-numerical information presentation expresses probabilities by using words like *often* or *rare* (Vahabi, 2010). Descriptive labels are generally viewed as easier to understand than numerical representation; however, presentation of risks and benefits using non-numerical information also has some drawbacks. For example, descriptive probability expressions can have multiple interpretations, can lead to skewed perceptions of risk severity, and can inadvertently signal a vague or uncertain probability (Burkell, 2004).

Quantitative information also can be conveyed graphically using visual displays such as bar graphs, pie charts, line graphs, icon arrays, and the use of face icons (i.e., happy/sad). Icon arrays are graphical representations consisting of circles or other icons (e.g., stick figures or faces) symbolizing individuals who are affected by some risk (Galesic, Garcia-Retamero, & Gigerenzer, 2009). Graphical displays have the advantage of being able to summarize a great deal of data and display quantitative information in concrete, visual terms (Lipkus, 2007). Because of the added transparency afforded by the use of graphical displays, research on numeracy suggests that non-numerical formats, such as graphical displays, should be used for people with low numeracy (Galesic & Garcia-Retamero, 2010). Despite advances, research on the general efficacy of visual formats for presenting risk information is still somewhat limited and largely atheoretical.

Summary

Numerous potential outcomes exist from consumer engagement with risk information presented in DTC ads. Our review considers preferences for information formats and effects on risk and benefit perceptions as well as consumer intentions and actual behaviors. There is reason to believe that such impacts might vary as a function of consumer characteristics such as numeracy. Moreover, the likely effect of various information formats is still unclear. Although previous studies have compared one or more formats to identify differences in outcomes, the results of these comparisons are largely inconclusive owing to a lack of consistency in testing formats using the same outcomes, a lack of critical tests using controlled studies that compare one format to another, and finally, a lack of theory to identify and test mechanisms regarding why formats lead to particular outcomes (Lipkus, 2007). With this background in mind, we can proceed to describe the present review of studies specifically focused on risk information presentation related to prescription drugs.

II. METHODS

This section of the report describes our approach to the literature review. The most critical step is the development and refinement of the key questions. From this follows specification of the inclusion and exclusion criteria using a PICOTS (population, intervention, comparator, outcome, timing, and setting) framework (Counsell, 1997). We used the key questions and the inclusion/exclusion criteria to create a framework for our literature search using medical search headings (MeSH) and specific words for which we would search in the title and abstract portions of the citation (text words). After we determined the MeSH terms and identified text words, we had an experienced librarian conduct the search. The literature search was an iterative process—beginning with a search that identified thousands of publications, only a few of which were relevant to the key questions. We refined and focused the search so that only the most useful publications remained. Staff conducted a dual review of the titles and abstracts from the citations that were identified to assess their relevance for the project based on the key questions and inclusion/exclusion criteria. We subsequently describe the process in more detail.

Development and refinement of KQs

To refine our initial key questions and approach to the literature review, we convened a technical expert panel (TEP) consisting of five academics well known for their expertise in risk communication to participate in a 2-hour conference call (***Appendix A***). The TEP was given a draft work plan describing the purpose of the review, the steps in carrying out the review, initial key questions to structure the search strategy, and citations to several articles that appeared relevant to the objectives of the review. Besides commenting on the work plan and providing guidance on the search strategy, the TEP was asked to discuss the challenges of communicating risk and benefit in general. They also provided guidance on how to frame the issues and formulate the key questions for the review. The TEP was not an oversight body; it assisted in framing the issues and identifying relevant literature only.

After several iterations, the final KQs were as follows.

KQ1: What is the value of quantitative information or summaries about the risks and benefits of medical interventions for consumers, patients, and clinicians?

KQ2: How does presentation of the quantitative information influence consumers', patients', and clinicians' processing and understanding of the risks and benefits of medical interventions?

Inclusion and exclusion criteria

Based on the key questions, we developed a list of inclusion and exclusion criteria for the literature search (Table 2). We limited studies to those with outcomes relevant to risk communication such as the following:

Table 2. Inclusion and Exclusion Criteria

Study population	
	Adults
Study settings and geography	
	KQ1: Studies conducted, not limited by geography
	KQ2: Studies conducted in the United States or New Zealand (i.e., where DTC advertising is allowed)
Time period	
	Published from 1990 until February 23, 2011
Publication criteria	
	Full-text article in English
Comparisons	
	KQ1: Risk and/or benefit information provided in numeric vs. non-numeric (text or narrative) format
	KQ2: Graphics such as pictographs and survival curves; numeric formats such as frequencies, probabilities, NNT, and others.
Admissible evidence	
	KQ1: Original research that focused on communicating information on risk and/or benefits comparing numeric vs. non-numeric presentations of this information.
	KQ2: Original research conducted in the United States or New Zealand, used an experimental design, and focused on comparing numeric formats for conveying risk and/or benefit information of medication use.

- Knowledge and comprehension
- Perceived risk and/or benefit
- Attitudes and perceptions
- Behaviors and behavioral intention
- Decision and decision making
- Emotional response
- Information seeking

Literature search and retrieval process

We used the PubMed database for the literature search, limiting the studies to human populations, the English language, specific publication types (randomized controlled studies, observational studies, focus group research, and others), the core clinical journals (a group of 119 journals, as of August 2010), and the journals most frequently publishing risk communication research (14 journals). The TEP also provided guidance on the search strategy by providing keywords and MeSH they found valuable in their research. ***Appendix B*** provides the search strategy that used major and minor MeSH, text words, and truncation to identify 550 citations.

Because we were concerned that the PubMed search might miss critical literature needed to address the key questions, we identified publications from other sources. We included citations suggested by the TEP (n = 105), and an additional 104 citations from hand searches, identified as follows:

- A previous literature scan conducted by RTI to investigate the most effective ways to deliver quantitative risk and benefit information in direct-to-consumer (DTC) prescription drug ads.
- Literature searches conducted to:
  - refine the KQs,
  - identify relevant research conducted by the TEP, and
  - assess the adequacy of our final PubMed search.
- A Cochrane database search on decision aids.
- Citations from literature reviews (Berkman et al. 2011; Trevena, Davey, Barratt, Butow, & Caldwell, 2006; Visschers et al.; Woloshin & Schwartz, 1999) and provided as references to other publications.

The systematic literature search identified 550 relevant citations. Combining these with citations suggested by the TEP (*n* = 105) and additional citations from hand searches (*n* = 104) led to a total of 759 articles to be examined. However, as there were many duplicate citations, 674 unduplicated citations were reviewed.

Article selection and review

Two reviewers independently reviewed the titles and abstracts for inclusion or exclusion in the body of evidence, initially for KQ1, KQ2, or both KQ1 and KQ2. When the two reviewers disagreed on whether an article should be included, the reviewers discussed their disagreement with the project director and a final inclusion status was reached. The reviewers then reviewed the full text of all citations that were categorized as potentials to determine whether they should be abstracted for inclusion in the body of evidence for KQ1, KQ2, or both KQs.

For inclusion in the evidence base for KQ1, the publication had to focus on risk and/or benefit and compare numeric with non-numeric information. Information such as “10% of individuals who take drug A have side effect B” is an example of numeric quantitative risk information whereas a statement such as “those taking drug A have an *increased* risk of side effect B” was considered non-numeric quantitative information.

Because KQ1 was the main focus of the literature search, we included all articles that addressed KQ1, regardless of their focus, study design, or the country in which the study was conducted (Table 2). We found many articles that addressed KQ2, and we therefore narrowed the list to focus on studies that most directly addressed the question. To do so, we limited the search to articles that dealt with risk communication related to medication use and focused on the US or New Zealand populations (i.e., the two countries where DTC advertising is allowed). To ensure high-quality studies, we also limited this list to studies that used a randomized design. We made this determination by reviewing the full text of the articles.

Two team members were trained to extract the relevant data from each article into the preformatted evidence table templates to ensure that a consistent approach was maintained. As staff reviewed information from their set of articles in preparation for abstraction, they made sure that all the inclusion/exclusion criteria were met; those that met the criteria were abstracted into the evidence tables. The evidence tables captured data on the study objective, study design, factors being compared, and results (Table 3). The results were described in terms of (1) information format and style preferences, (2) knowledge and comprehension, (3) perceived risk, and (4) behavioral intentions and behaviors as discussed in the background section of this report.

Table 3. Elements in the Evidence Table

Study characteristics
Objective
Country in which study population recruited
Study design
Start date (for enrollment)
Duration
Communication format and brief description of content
Inclusion and exclusion criteria
Eligibility criteria
Sampling frame, if applicable
Inclusion/exclusion criteria
Intervention description
Number of individuals in each intervention group
Participant characteristics
Demographic information (e.g., age, gender, race/ethnicity)
Outcomes evaluated
Primary outcomes
Secondary outcomes
Results
Qualitative and quantitative outcome and intervention group with summary statistics
Bottom line
Brief summary of study design, methods, and findings

Each evidence table was reviewed twice using a stepped approach, first for accuracy and completeness and a second time to provide an overview of the study and its findings (bottom line). The evidence tables are in alphabetical order by first author in ***Appendix C***. All of the evidence tables are in one appendix because many studies addressed both KQ1 and KQ2, and we believed it would be easier for the reader to search through only one appendix for the relevant evidence table.

We considered some type of numeric summary using meta-analysis or meta-regression, but the studies were too varied for this to be appropriate.

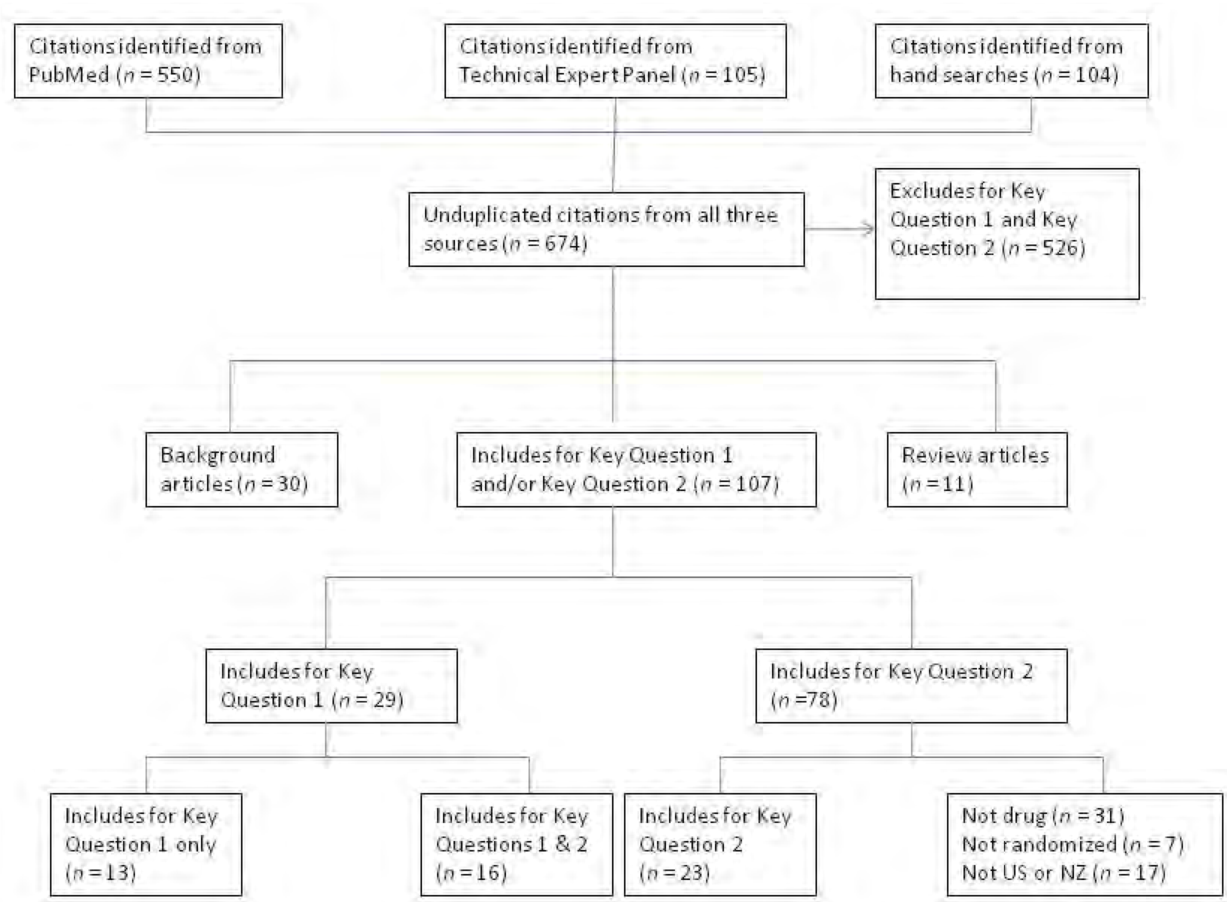
III. RESULTS

This section of the report describes our findings with regard to the literature search and summarizes what we learned for the four outcomes we evaluated: (1) information format and style preferences, (2) knowledge and comprehension, (3) perceived risk, and (4) behavioral intentions and behaviors.

Summary of the literature search

The completeness and integrity of this review are documented in the PRISMA diagram (Preferred Reporting Items for Systematic Reviews and Meta-Analyses; Moher, Liberati, Tetzlaff, & Altman, 2009). Figure 1 provides the PRISMA diagram showing how the citations included in the literature review were identified as well as the citation exclusions and why they were excluded. As noted in the Methods section, the focus was on identifying articles that addressed KQ1 because that was the main focus of the review. As can be seen in Figure 1, 16 articles addressed both KQ1 and KQ2, so we have included subsequent discussion of these articles for both key questions.

Figure 1. PRISMA diagram



Characterizing the studies

Of the 52 studies we reviewed, 37 focused on prescription drugs or hypothetical drugs. Other topics ranged from decisions about immunizations and other screenings, risk of disease, treatment decisions (e.g., surgery options), and environmental health issues, including advisories related to fish consumption. The populations studied were quite diverse but focused primarily on adults. The studies encompassed student populations, patients with selected illnesses, jurors, parents or other surrogate decision makers, people who use the Internet, and the general population of adults. Most of the studies focused on patient or consumer behavior, as opposed to health care providers.

Several of the studies include both *numeric* and *non-numeric* presentation of quantitative information. This made it challenging at times to determine whether the study should be categorized as addressing KQ1 (which focused on the value of quantitative information or summaries) or KQ2 (which focused on which method of presenting quantitative information was most effective). Studies that examined the presentation of risk information in a strictly non-numeric format were less common than studies that compared different numeric formats. In practice, a combination of a numeric and non-numeric presentation of risk information together is likely to be more commonly used and may prove to be most effective. Few studies were designed to investigate the effectiveness of a combined approach.

More studies in our review examined risk information alone as opposed to both risk and benefit information**.** Some studies presented both risk and benefit information; the least number of studies focused only on benefits. Presenting only risk or benefit information is arguably unbalanced and potentially unethical (Raffle, 1997). Often there is a presumption of benefit for all medical care, without a consideration of the potential harm (Dartmouth Atlas Project, 2006; Merenstein, Daumit, & Powe, 2006). Consequently, one of the key issues in communicating risk information is communicating potential harms and uncertain benefits (Driscoll et al., 2008; Kilo & Larson, 2009; McCormack et al., 2009; McCormack, Williams-Piehota, & Bann, 2009; Soloe, McCormack, Treiman, Driscoll, & Harris, 2009; Welch & Black, 2010; Williams-Piehota, McCormack, Treiman, & Bann, 2008).

In the following sections, we synthesize our findings by outcome. Included with each section is a summary table listing the information being communicated, the type of intervention, and a brief summary of findings.

Information format and style preferences

A minority but nonetheless sizable proportion of studies in our review focused directly on respondents' expressed preferences for information format and style with regard to risk and benefit presentation. These papers reveal a general pattern of preference in favor of numerical presentation of risk and benefit information, especially among patients and members of the lay public and among those with relatively more education (see Table 4).

Table 4. Studies Focused on Information Format and Style Preferences

Reference	Information being communicated	Communication format	Findings
Berry, Raynor, Knapp, & Bersellini, 2004	Adverse events from ibuprofen	**Non-numeric**: Description of adverse events using the European Commission recommended "action" labels **Numeric**: As percents	• Difference in subjective feelings by patients about risk presented in numerical and descriptive formats • Patients more satisfied, more likely to take, and perceived a smaller percentage of side effects with numerical presentation of risk
Brun & Teigen, 1988	Chances that the new vaccine will have its intended effect	**Non-numeric**: Qualitative probabilistic expressions such as probably, likely, perhaps, and 11 others **Numeric**: Numeric assignment, from 0 to 6, for each of the probabilistic expressions	• Physicians preferred to use words and thought patients understood words better than numbers • Parents of small children preferred information presented in numbers because they were easier to understand • When asked to interpret a concrete numerical example, physicians and parents rated the 14 descriptive risks formats differently, but the physicians' ratings had less variability than parents' ratings
Brundage et al., 2005	Health-related quality of life	**Non-numeric**: Text summary **Numeric**: Line and bar graphs	• Line graphs preferred format • Text summaries least preferred format • Participants preferred RRR
Carling et al., 2008	Six different summary statistics expressing the reduced risk of coronary heart disease with statin therapy	**Numeric**: RRR, ARR, NNT, Event Rates, Tablets Needed to Take, and Whole Numbers	• Participants preferred RRR
Cheung et al., 2010	Information on side effects of a new medication for pain relief prior to seeking participation in a clinical trial	**Non-numeric**: Description of adverse events according to those derived by the European Union **Numeric**: Percents and frequencies	• When presented risks in a percentage, frequency, or a descriptive format, participants preferred risks presented as a frequency • Level of education related to a preference for risks presented as a frequency • Overall, participants tended to prefer a risk presentation format they did not initially receive
Connelly & Knuth, 1998	Health advisories related to eating fish contaminated with polychlorinated biphenyls	**Non-numeric**: Risk presented as lower, moderate, and higher in a risk ladder comparing varying exposures **Numeric:** • Diagram with descriptive text vs. text only • Risks out of 1,000 on a risk	• Anglers felt they had a better understanding of health risks when information provided using quantitative risk ladder and a diagram accompanying text (comprehension was not tested)

		ladder for varying exposures	

Table 4. Studies Focused on Information Format and Style Preferences (continued)

Reference	Information being communicated	Communication format	Findings
De Abreu, Gafni, & Ferraz, 2009	Benefits and risks of medications to treat systemic lupus erythematosus (SLE)	Was not a comparative study (i.e., did not have patients who used the DB tool vs. others who did not). Participants saw a DB tool that had clinical information, two different treatment options, a description of the potential to control SLE within 5 years, and a list of potential side effects.	• DB tool understandable to patients and could potentially improve the quality of time spent in medical consultations • Describing side effects as life threatening tended to influence decisions
Edwards & Elwyn, 1999	Benefits and risks of hormone replacement therapy	**Non-numeric**: Explanations using terms such as frequently and rarely **Numeric**: Numerical risk presented as absolute and relative risk and graphical presentation of risk using histograms and percentages	• In focus groups, practitioners reported numerical data helpful for presenting risk, however, graphical presentation is a simple format that is not too statistical, but very efficient for conveying risk information • The graphical presentation also fostered shared decision-making between the practitioner and patient • Some practitioners prefer to present risk information numerically
Edwards et al., 2006	Risk presentation formats addressing the pros and cons of tight control vs. usual treatment for diabetes	**Control**: Control, unclear about the content for the control group **Numeric:** • Numerical **Mixed:** • Numerical + Anchoring • Numerical + Graphs • Numerical + Anchoring + Graphs	• Graphical presentations are most helpful, specifically bar chart formats • Using multiple, numerical formats for presenting risk is not helpful and can be too much information for people to process
Gurmankin, Baron, & Armstrong, 2004a	Risk of four different types of cancer	**Non-numeric**: Risk portrayed using descriptive expressions **Numeric**: • Fraction • Percentage	• Participants were more trusting and comfortable with risk information provided by clinicians when it included numeric information than when it did not include numeric information • Magnitude of effect diminished in those who were innumerate
Knapp, Raynor, & Berry, 2004	Risk of medication side effects	**Non-numeric**: Received information about constipation and pancreatitis in descriptive format **Numeric**: Received information about constipation and pancreatitis in numerical format	• Participants who received risk information numerically more satisfied with information received than participants who received descriptors of risk

Table 4. Studies Focused on Information Format and Style Preferences (continued)

Reference	Information being communicated	Communication format	Findings
Knapp et al., 2009	Risk of side effects to tamoxifen	**Non-numeric**: descriptive format **Numeric**: Frequency of side effects **Mixed:** Both verbal and frequency of side effects	• Those given frequency information more satisfied with information received than those given descriptors
Knapp, Gardner, Raynor, Woolf, & McMillan, 2010	Perceived risk of tamoxifen side effects	**Non-numeric**: Descriptive format **Numeric:** • Absolute frequency of side effects (e.g., occurs in about 48 in 1,000 people) • Frequency band (e.g., occurs in more than 1 of 10 people) **Mixed:** • Descriptor plus absolute frequency • Descriptor plus frequency band	• Most preferred method for presenting risk was descriptors plus absolute frequencies, followed by absolute frequencies • Risks presented via a frequency band least preferred method
Mazur, Hickam, & Mazur, 1999	Treatment for asymptomatic gland-confined prostate cancer	**Non-numeric:** Non-numeric for the outcomes of the “surgery-now” and “watchful waiting” options **Numeric:** • Numeric description of the probabilities of occurrence of adverse outcomes associated with the “surgery-now” option	• More patients preferred numeric rather than non-numeric presentation of risk • Patients who preferred words only more likely to choose surgery for treatment
Shaw & Dear, 1990	Common newborn problems	**Non-numeric**: Non-numeric text using words such "probably, likely, occasionally, etc." **Numeric**: Numeric information such as 3 in 10	• Mothers preferred receiving information using numeric format rather than qualitative, text-based expressions
Studts et al., 2005	Medications used for breast cancer	**Numeric:** • RRR • ARR • ASB • NNT	• Differences in an individual’s preference for different risk presentation formats found when making health care decisions • ASB risk presentation format most helpful and most influential format when used to describe benefits and risks of adjuvant chemotherapy for breast cancer when compared to RRR, NNT, and ARR formats

Table 4. Studies Focused on Information Format and Style Preferences (continued)

Reference	Information being communicated	Communication format	Findings
Tait, Voepel-Lewis, Zikmund-Fisher, & Fagerlin, 2010a	Risks and benefits of a hypothetical research study comparing two drugs for postoperative pain in children	**Non-numeric:** • Tabular format • Pictograph **Numeric:** • Percentages	• Pictographs significantly more ''effective,'' ''helpful,'' ''trustworthy,'' and ''scientific'' than text or tables in describing risks and benefits of the two drugs

Note. ARR = absolute risk reduction; ASB = absolute survival benefit; DB = decision board; NNT = number needed to treat; RRR = relative risk reduction

Studies of patient preferences have consistently generated data in favor of using numeric information to describe risk. Berry and colleagues (2004) studied the impact of presenting information about adverse events from use of ibuprofen. Among other results, they found that participants expressed more satisfaction with numerical presentation of risks in terms of percentages as opposed to a description of adverse events. Brundage and colleagues (2005) assessed the impact of various methods of presenting health-related quality of life information, including a text summary and line and bar graphs. Participants preferred line graphs. Work by Mazur, Hickam, and Mazur (1999) on decision making among patients with asymptomatic, localized prostate cancer found that more patients preferred numeric information about treatment options than preferred only descriptive, non-numeric information. In a study of reactions to risk information regarding consumption of potentially contaminated fish, Connelly and Knuth (1998) found that participants felt more informed when shown numeric information rather than descriptive, non-numeric information. A study by Cheung and colleagues (2010) directly assessed a recent recommendation by the Royal Statistical Society (in the United Kingdom) that "[g]reater use should be made of numerical, as opposed to descriptive, descriptions of risk" by asking patients about their reactions to risk information about a hypothetical pain relief medication. Patients generally preferred risk information that included a frequency as opposed to a description, though that preference appears to have been pronounced only among those with relatively more formal education. Importantly, Edwards and colleagues (2006) offer an additional caveat, in that they found that including multiple numeric formats led to information overload and people expressed less preference for a combination of multiple numeric formats.

At least two studies have gone further than the numeric versus non-numeric comparison to assess participant preference for the manner in which quantitative risk and benefit information is framed. In reacting to various presentations regarding adjuvant chemotherapy for breast cancer, participants in the Studts and colleagues (2005) study preferred information framed in terms of absolute survival benefit (ASB) information over negatively framed information, such as RRR or ARR. Carling and colleagues (2008) found that participants shown various statistics linked to statin drugs expressed greater preference for RRR statistics than for other statistical presentations such as natural frequencies or the number of tablets necessary to take. These various results suggest an interest among many patients for numeric information about survival opportunity and benefit.

At least two other studies have looked at preferences among physicians and health care professionals, who often appear to prefer numerical presentations of risk. Edwards, Elwyn, and Gwyn (1999), for example, studied health professionals and their assessment of how best to present risk information related to hormone replacement therapy. They found that participants preferred numerical presentation over non-numerical description, and consequently recommend the use of simple graphics to depict numerical risk information. At the same time, at least two studies have found a disjuncture between what some health care professionals think patients want and what patients actually say they want. Brun and Teigen (1988) investigated reactions among physicians and parents of young children regarding various presentations of risk information about a vaccine, including the use of non-numeric phrases such as *probably* or *likely* and a numeric assignment (from 0 to 6) of a probability. They found that whereas physicians reported a preference for using non-numeric phrases and thought patients better understood such phrases, parents tended to prefer numeric expression. Shaw and Dear (1990) both further confirmed this discrepancy—their study of mothers and doctors suggested a similar contrast in views between the groups—and confirmed that mothers preferred numeric presentations when asked. (Importantly, both of these studies are more than 20 years old; the shift toward greater patient autonomy and perhaps greater sophistication among some patients may have eliminated some of this discrepancy between health care professionals and patients.)

Summary. These studies suggest that investment in numeric presentation of risk and benefit information is likely to satisfy consumers—at least in general—more than simple descriptions. At least some evidence suggests that preferences might be at least partially a function of numeracy; for example, Gurmankin, Baron, and Armstrong (2004a) found that those lower in numeracy were less likely to find numeric presentations more trustworthy, but participants in the selected studies nonetheless often reported preference for numeric information. What these data cannot tell us, however, is whether those preferences for numeric risk information translate into better comprehension or behavioral intention. For assessment of those outcomes, we must turn to additional studies in our review.

Knowledge and comprehension

Although one might assume that people who are exposed to risk information learn and retain the information to which they are exposed, a long tradition of communication research suggests that exposure does not always directly equate to knowledge. For that reason, in part, researchers have investigated the extent to which various presentations of risk information are more or less likely to result in people gaining accurate knowledge. Much of our discussion will later focus on perceptions about one's personal risk that result from risk information exposure, but first we will focus on studies that have assessed knowledge gain more generally. In our review, almost half of the studies examined how the numeric presentation of quantitative information affected study participants' knowledge in some way in comparison with non-numeric presentation. Other studies compared a wide variety of different numeric and graphical formats.

Many of the studies in our review that included knowledge as an outcome focused on accuracy of knowledge retained: at least nine studies (Brundage et al., 2005; Char, Evans, Malvar, & White, 2010; Gattellari & Ward, 2003; Knapp et al., 2010; Man-Son-Hing et al., 2002; Marteau et al., 2000; Shaw & Dear, 1990; Weymiller et al., 2007; Woloshin, Schwartz, & Welch, 2004) examined whether a numeric presentation of information compared with a non-numeric presentation specifically resulted in more accurate or correct knowledge. Another group of studies in our review went further than the numeric versus non-numeric distinction to assess which type of numeric presentation had the most desirable influence on subsequent knowledge. Specifically, a somewhat larger group of studies (Armstrong, Schwartz, Fitzgerald, Putt, & Ubel, 2002; Chao et al., 2003; Cuite, Weinstein, Emmons, & Colditz, 2008; Garcia-Retamero & Galesic, 2009, 2010b; Hawley et al., 2008; Schwartz et al., 2009; Sheridan & Pignone, 2002; Sheridan, Pignone, & Lewis, 2003; Steiner, Dalebout, Condon, Dominik, & Trussell, 2003; Tait, Voepel-Lewis, et al., 2010a; Tait, Voepel-Lewis, Zikmund-Fisher, & Fagerlin, 2010b; Tait, Zikmund-Fisher, Fagerlin, & Voepel-Lewis, 2010; Ubel et al., 2010; Waters, Weinstein, Colditz, & Emmons, 2006; Waters, Weinstein, Colditz, & Emmons, 2007; Zikmund-Fisher, Fagerlin, & Ubel, 2008a; Zikmund-Fisher et al., 2008b) investigated which type of numeric format had the most positive effects on knowledge (see Table 5).

Table 5. Studies Focusing on Knowledge and Comprehension

Reference	Information being communicated	Communication format	Findings
Armstrong et al., 2002	Probabilities of survival or mortality	**Non-numeric**: Survival and mortality graphs	• People understand information more accurately when information presented using a survival curve or both survival and mortality curves, rather than seeing mortality curves only • Effects of survival compared to mortality curves are greater for those with less education and with ethnicities other than Caucasian • Presenting information in terms of survival curves (compared to mortality only and both mortality and survival curves) also made participants more likely to choose to undergo preventive surgery to reduce their increased risk of colon cancer in a hypothetical scenario • Way in which quantitative information is framed (in terms of survival versus mortality curves) can affect understanding and treatment choice

Table 5. Studies Focusing on Knowledge and Comprehension (continued)

Reference	Information being communicated	Communication format	Findings
Brundage et al., 2005	Health-related quality of life	**Non-numeric**: Text summary Line and bar graphs	• Line graphs interpreted correctly most often; however, text summaries better understood than bar graphs
Chao et al., 2003	Breast cancer prognosis	**Numeric**: RRR, ARR, ASB, and NNT	• RRR format leads to greater endorsement of chemotherapy • Prognosis best understood when data presented in ASB format • Presenting individuals with all four formats increased confusion
Char et al., 2010	Prognostic information for patients in intensive care	**Non-numeric**: Very unlikely to live or said another way, likely to die **Numeric**: Chance, in percent, of surviving or said another way, chance, in percent, of dying	• No difference in understanding of prognosis physician intended to convey between surrogates receiving numeric versus those receiving qualitative prognostic statements
Cuite et al., 2008	Risk of disease and treatment success along with operations performed with the risks	**Numeric**: 3 formats (1-in-*n*, frequency, and percentages)	• Accuracy rates by format of risk information varied by the mathematical operation performed • However, overall, accuracy higher for percentage and frequency formats than the 1-in-*n* format; education had a strong moderating effect on accuracy
Garcia-Retamero & Galesic, 2009	Reduced risk of a heart attack if using a hypothetical statin	**Non-numeric:** Icon displays **Numeric**: • Use of different numerators and denominators to achieve a RRR of 50%	• Participants with lower numeracy less likely to use denominators in the assessment of risk • Participants provided icon arrays in addition to the numerical information more likely to accurately interpret risk information, in both high and low-numeracy groups
Garcia-Retamero & Galesic, 2010b	Reduced risk of a heart attack or stroke if using a hypothetical drug	**Non-numeric**: • Use of different visual displays to achieve a RRR of 25% and 75% • The study tested five different visual aids: 1. icons-sick 2. icons-overall 3. bars-sick 4. bars-overall **Numeric:** Numerical information without visual aids	• Participants more likely to understand information presented when numerical information presented in conjunction with graphical representation • Higher proportion of participants with high numeracy were able to provide correct estimates of treatment risk reduction • Understanding medical information more difficult (and therefore less accurate) for United States participants compared with German participants, particularly when information was presented in terms of RRR

Table 5. Studies Focusing on Knowledge and Comprehension (continued)

Reference	Information being communicated	Communication format	Findings
Gattellari & Ward, 2003	Prostate cancer screening information	**Non-numeric**: Pamphlet (conventional information that is non-numeric) **Numeric**: Evidence-based booklet with numeric risk information	• Participants randomized to evidence-based booklet were statistically significantly more likely to correctly estimate their lifetime incidence and mortality from cancer and had an overall greater understanding of PSA screening • Those randomized to the evidence-based pamphlet were also more likely to feel like they could make an informed decision about PSA screening
Hawley et al., 2008	Risk and benefit information of hypothetical bypass surgery	**Non-numeric**: Use of different risk presentations • Table • Pictograph • Pie Chart • Bar graph • Modified pictograph "sparkplug") • Modified pie graph ("clock")	• Presentation format of risk and benefit information influences an individual's ability to understand the information that is conveyed; should be tailored to the type of informed decision that needs to be made • Pictograph is recommended format when medical decision making is required because it effectively conveys both verbatim knowledge and gist across numeracy levels and was well received by my different types of respondents
Knapp et al., 2010	Perceived risk of tamoxifen side effects	**Non-numeric**: Descriptive format **Numeric:** • Absolute frequency of side effects (e.g., occurs in about 48 in 1,000 people) • Frequency band (e.g., occurs in more than 1 of 10 people) **Mixed:** • Descriptor plus absolute frequency • Descriptor plus frequency band	• Regardless of the format, participants overestimated the risk of side effects, especially when side effects occurred less frequently • Participants in frequency format significantly more accurate at estimating risk of side effects than participants receiving frequency band information • Combination of non-numeric and numeric descriptors do not increase the accuracy of risk estimation
Man-Son-Hing et al., 2002	Risk of stroke	**Non-numeric**: Risk information presented using terms such as low, moderate, and others) **Mixed:** Decision aid providing risk information frequency information (e.g., 8 out of 10) and a pictograph	• No significant differences in knowledge of options or accuracy of risk perceptions between the quantitative group and the qualitative group • Participants who received the quantitative information better able to quantitatively estimate their chance of stroke and bleeding for each treatment option compared to participants who received qualitative risk information • Overall, decisional conflict approximately equal for both groups, except quantitative group felt slightly more informed than qualitative group

Table 5. Studies Focusing on Knowledge and Comprehension (continued)

Reference	Information being communicated	Communication format	Findings
Marteau et al., 2000	Screening test results for Down syndrome to pregnant women	**Non-numeric**: Letter providing screening test result in descriptive format, "The result of your test is screen negative and your chance of having a baby with Down syndrome is low" with descriptive anchor "it is unlikely that your baby has Down syndrome" **Numeric:** Letter using a numeric probability, "The result of your test is screen negative and your chance of having a baby with Down syndrome is 1 in 650" and descriptive anchor, "it is unlikely that your baby has Down syndrome"	• Numeric format slightly more effective in helping women understanding the test result, especially for women with lower education
Schwartz et al., 2009	Risks and benefits of prescription medications	**Numeric Control**: Information typically found in drug advertisements and summaries **Numeric:** Drug fact box quantifying outcomes with and without the drug	• Participants exposed to drug facts box had more accurate understanding of the effectiveness and risks of two medications: one to treat symptoms and the other for disease prevention
Sheridan & Pignone, 2002	Benefits of medications to treat a hypothetical disease	**Numeric**: • RRR • ARR • NNT • Combination	• No statistically significant difference in ability to interpret comparative information by risk reduction presentation format; however, respondents had more difficulty interpreting quantitative data when presented in the NNT format
Sheridan et al., 2003	Benefits of medications to treat a hypothetical disease	**Numeric:** Use of different risk presentations • RRR • ARR • NNT • Combination	• Benefits of treatment are best understood by patients when presented in RRR formats (as well as ARR formats) with a given baseline risk of disease, and are least understood when presented in an NNT format • Therefore, RRR formats (as well as ARR formats) are preferred whereas NNT formats should be avoided for risk communication purposes

Table 5. Studies Focusing on Knowledge and Comprehension (continued)

Reference	Information being communicated	Communication format	Findings
Steiner et al., 2003	Effectiveness of contraceptives	**Non-numeric**: Text descriptor **Numeric:** • Percentages **Mixed**: • Both text and numeric format	• Table using text-based descriptors communicated relative contraceptive effectiveness better than the two tables with numbers, which were equivalent in their effectiveness • Those who received information as text-based descriptors only were more likely to overestimate the risk of getting pregnant when using a particular contraceptive • The authors suggest that presenting both text-based descriptors along with a numeric range of pregnancy risk may provide the most accurate understanding of both relative and absolute pregnancy risk
Tait, Voepel-Lewis et al., 2010a	Risks and benefits of a hypothetical research study comparing two drugs for postoperative pain in children	**Non-numeric**: • Tabular format • Pictograph **Numeric:** • Percentages	• Pictographs significantly better than tables and text in providing both adequate gist and verbatim understanding
Tait, Voepel-Lewis et al., 2010b	Risks and benefits of two drugs	**Non-numeric**: • Text • Tabular format • Pictograph	• Parents who received the medication information in the form of a table or pictograph as opposed to text were more likely to demonstrate greater gist and verbatim knowledge of the medication risks and benefits
Tait, Zikmund-Fisher et al., 2010	Risks and benefits related to postoperative pain in children	**Numeric**: Complex risk/benefit trade-offs between two drugs presented as four different scenarios. One scenario showed one drug to be superior to another in both risks and benefits. The other three scenarios showed varying trade-offs in risk and benefit.	• Parents presented only with quantitative information about improved outcomes had better understanding of information than parents presented with only quantitative information about reductions in risk • Better understanding associated with being white, having a college education, and having higher numeracy
Ubel et al., 2010	Risks and benefits of tamoxifen	**Numeric:** Decision aid that varied the order of risk and benefit information, and the presence or absence of contextual information about risk. All women learned their 5-year risk of breast cancer (e.g., 2.5%). Half of the women were given information on competing risks they faced over the next 5 years—risks of experiencing colon cancer, a heart attack, or all-cause mortality. The remaining half did not receive any contextual information.	• Women who did not receive contextual information demonstrated order effects (women who were presented risks of medication first answered fewer questions about the risks/benefits of the medications correctly); when contextual information presented with the decision aid, women did not display this order effect

Table 5. Studies Focusing on Knowledge and Comprehension (continued)

Reference	Information being communicated	Communication format	Findings
Waters et al., 2006	Risk trade-offs for hypothetical illness	**Non-numeric:** • Graph **Numeric:** • Three levels of cognitive effort (using frequency and frequency plus percentages) • Two levels of magnitude of change (using probabilities) **Mixed:** • Text + graph Each participant was assigned to a single level of cognitive effort, graphical display, numerical format, and direction of change and responded to two different problems: one large magnitude of change and one small magnitude of change	• Results suggest that requiring less cognitive effort, using a graphical display, expressing numbers in percentages rather than frequencies, using large net changes in risk, and increases (rather than decreases) in total risk improved accuracy and helped laypeople evaluate medical trade-offs
Waters et al., 2007	Risk trade-offs for hypothetical illness	**Non-numeric:** • Bar graph • Array of stick figures **Numeric:** • Numbers only	• Perception of medication side effects negatively influences the use of therapies • Using arrays of stick figures for graphic representation of probabilities reduces side effect aversion and slightly increases accuracy in evaluating changes in risk
Weymiller et al., 2007	Risks and benefits of using statin medications	**Non-numeric**: Pamphlet described cholesterol management **Numeric:** Decision aid presented tailored cardiovascular risks; benefits and risks of taking statins	• Participants who received information on ARR (decision aid) had more accurate estimates of their cardiovascular risk without statin therapy, more accurate estimates of absolute cardiovascular risk reduction, and higher levels of knowledge about statins when compared to participants who did not receive information about ARR (pamphlet)
Woloshin et al., 2004	Benefits of prescription medications	**Control**: Standard version of a drug ad that did not contain quantitative information on drug benefits **Mixed:** Drug benefit box with efficacy data presented numerically (using percentages) and non-numerically (using descriptive labels)	• Including quantitative risk and benefit information decreases adults' perceived effectiveness of drug and increases adults' ability to correctly estimation the drug's effectiveness

Table 5. Studies Focusing on Knowledge and Comprehension (continued)

Reference	Information being communicated	Communication format	Findings
Zikmund-Fisher et al., 2008a	Risk statistics for tailored estimates of mortality and recurrence risks for breast cancer patients	Four risk graphics: • Base version that mirrored the Adjuvant! Format • Also varied side-effect order (increasing vs. decreasing likelihood) **Numeric:** • Frequency (e.g., 2.1 out of 100) **Mixed:** • Frequency + pictograph	• Findings showed that both simplified presentations, which included only two options • The simplified pictograph had greatest effect on improving comprehension; therefore, comprehension may be improved by using pictographs rather than bar graphs
Zikmund-Fisher et al., 2008b	Side effect risks concerning prophylactic use of tamoxifen to prevent primary breast cancers	**Non-numeric:** • Pictograph **Numeric:** • Frequency and percentage • Incremental risk (vs. total) • 1,000 risk denominator (vs. 100) **Mixed:** • Pictograph x incremental risk • Pictograph x denominator • Incremental risk x denominator	• Whether risk information is presented as incremental risk or total risk, pictograph formats are a better for increasing knowledge than numeric text • Higher numeracy scores associated with lower perceived risk and higher knowledge of risks

Note. ARR = absolute risk reduction; ASB = absolute survival benefit; NNT = number needed to treat; RRR = relative risk reduction

Across these studies, some patterns emerged. Of the group of studies comparing numeric and non-numeric presentations, for example, the vast majority found that, when compared with non-numeric presentation of information, numeric presentation resulted in more accurate knowledge or understanding. Evidence regarding the most appropriate way to present numeric information, however, was varied in focus and comparability, an issue to which we will return. Moreover, many of the results reported appear to be conditional on numeracy level.

Numeric versus non-numeric presentation. A closer look at these various individual studies suggests the general supremacy of numeric presentations. It also suggests an initial indication that some of the studies that did not find such an advantage may have failed to do so because of study weaknesses. Some of the challenges in interpretation result from nonexperimental designs or designs that confound numerous content characteristics rather than carefully comparing various formats.

Brundage and colleagues (2005) offer a useful place to start our discussion. Using a within-subjects design, they presented a group of randomly selected patients with a hypothetical scenario in which they were asked to imagine they had just been diagnosed with a new lung cancer and had the option of one of two treatments. Patients were presented with data representing quality of life while on each of the two treatments using six different formats, five of which were numeric (a line graph, a line graph with ranges, side-by-side change response bars, stacked change response bars, or stacked raw data) and one that was a text description of health-related quality of life. Line graphs (both with and without ranges) were slightly more likely to produce accurate knowledge of quality of life data among patients than the text description. Although numeric presentation via the line graphs produced the highest levels of accurate knowledge, text descriptors were more effective than three other numeric formats (side-by-side change response bars, stacked response bars, stacked raw data). Participants in this study were not randomly assigned to see a particular presentation, so it is difficult to disentangle order effects and the impact of seeing multiple presentations from specific format effects.

A study by Weymiller and colleagues (2007) illustrates another issue affecting some of the studies in our review: the extent to which the comparisons made in studies in our review do not always speak directly to the numeric versus non-numeric distinction. Weymiller found that participants who reviewed a decision aid that presented numeric information on the risk and benefits of taking statins for cardiovascular disease risk reduction had higher subsequent levels of knowledge about statins than those who reviewed a descriptive pamphlet describing how to manage high cholesterol. Unfortunately, the study design did not allow researchers to determine whether the differences in content or the presentation format (numeric versus non-numeric) determined knowledge differences. In another study, Woloshin and colleagues (2004) used two designs (before and after and random assignment to condition) to examine the value of including information about the benefits and risks of a prescription drug and whether the addition of benefit information affects how accurately adults can estimate the drug's effectiveness. Findings show that including benefit information (presented with both numeric and non-numeric information) along with risk information increases adults' ability to correctly estimate the drugs' effectiveness overall relative to a control condition for which the information is not included. Again, however, the combination of numeric and non-numeric information in the treatment condition means that we cannot empirically disentangle the effect in this instance.

Several papers in our review do not report full details of the various content compared. Gattellari and Ward (2003) found that an evidence-based presentation of numeric risk information about prostate cancer improved knowledge relative to a control pamphlet developed by the Australian government. Other than reporting that one version contained numeric information and the other contained non-numeric information and was shorter, however, the paper does not provide much information about what exactly differed between the experimental conditions.

At least one paper in our review suggests no significant difference between numeric and non-numeric presentations in knowledge about side-effect frequency, although it carries important caveats. Knapp and colleagues (2010) tested whether the addition of descriptors to the numeric presentation of risk via frequency bands and to absolute frequencies resulted in more accurate estimates of risk of side effects. They found that the addition of descriptors did not significantly improve the accuracy of their estimates of how frequently side effects would occur for three of the four side effects assessed, whereas the combination of numeric and non-numeric presentations solicited more accurate estimates for one of the side effects. Their study, however, does not permit comparison of numeric and non-numeric presentation, given that they compared numeric presentation only with a *combination* of numeric and non-numeric.

At least one paper highlights a key advantage for non-numeric descriptors in presenting risk information. A 2003 study by Steiner assessed differences in the effectiveness of using various tables with numbers compared with a table with non-numeric categories to communicate risk. The table using text-based descriptors to communicate relative contraceptive effectiveness resulted in greater improvements in knowledge about *relative* effectiveness of methods (i.e., correct responses to questions about the effectiveness of different contraceptive methods) than the two tables with numbers, which were equivalent in their effectiveness. It might be the case that non-numeric categories are more useful than numeric descriptors alone in depicting the relative or comparative risk of different medical options.

Other studies in our review employ an experimental design and suggest at least some advantages for numeric presentations. Studies that directly compare numeric and non-numeric formats in carefully controlled experimental designs free of some of the aforementioned confounds paint a clearer picture of advantage for numeric formats. Marteau and colleagues (2000), for example, investigated whether presenting the results of a screening test indicating the risk of a baby having Down syndrome to patients numerically (e.g., your chance of having a baby with Down syndrome is 1 in 650) resulted in better understanding of the risk information than presenting the results non-numerically (e.g., your chance of having a baby with Down syndrome is low). Results suggest that the numeric format was slightly more effective in helping women understand the test results, especially for women with lower education. In another study, Man-Son-Hing and colleagues (2002) compared two decisions aids for a hypothetical scenario. The first decision aid presented the risk of stroke and side effects from three different treatment options with numbers (e.g., 8 out of 100) plus a pictograph. A pictograph is a graphic that employs symbols to depict quantitative information, such as a number of variously colored human figures to display a total population with blue figures illustrating those developing a side effect and gray figures illustrating those who do not. The second decision aid presented risk information through descriptive phrases (e.g., moderate risk). Knowledge about stroke, atrial fibrillation, and advantages and disadvantages of taking the different medications did not differ among those who received the numeric and non-numeric decision aids. Participants who reviewed the numeric decision aid were better able to estimate their chance of stroke while taking warfarin (with 76% answering correctly), however, than those who reviewed the non-numeric decision aid (with 32% answering correctly). In addition, a significantly higher percentage of those who used the numeric decision aid had realistic estimates of the numeric probabilities for all outcomes compared with those who used the non-numeric decision aid.

In a different study, Char and colleagues (2010) studied whether statements made about a hypothetical patient at the end-of-life by a physician in a video more reliably conveyed prognostic estimates (of survival) if the prognosis was conveyed in a numeric (e.g., he has a 10% chance of surviving and there is a 90% chance that he's going to die) or in non-numeric format (e.g., "it's very unlikely he will survive" and "it's very likely he's going to die"). Findings indicate that numeric statements were no better than non-numeric statements for ensuring participants' understanding of the prognostic estimate conveyed by the physician. However, those to whom the prognosis was conveyed numerically demonstrated greater agreement between their understanding of the physician's prognostic estimate and their personal estimate of the patient's prognosis.

Collectively, these studies suggest that the use of numeric information results in more accurate knowledge than non-numeric information, though the nature of the information in question probably matters as some data suggested non-numeric categories result in more accurate knowledge about *comparative or relative* risks. We turn next to the question of what is known about the relative utility of various numeric formats.

Comparison of various numeric formats. In our review, researchers compared a wide variety of different numeric formats including statements of relative risk, absolute risk, NNT, ASB, percentages, frequencies, ratio, 1-in-*n* statements, pictographs, pie charts, bar charts, tables, and drug facts boxes. Beyond that, several studies explored how different ways of framing information (e.g., survival versus mortality or risk and benefit trade-offs or the order in which risk and benefit information is presented), affected subsequent knowledge.

A number of studies have compared various numeric formats and found no substantive differences. In addition to the aforementioned study (Steiner et al., 2003), Steiner and colleagues also conducted another study on the use of different formats to communicate contraception risks that appeared in our review. In a randomized controlled trial of women 18 to 44 years of age in India and Jamaica, Steiner and colleagues (2006) assessed which of three different combination formats (stratified comparison of various contraception methods according to usefulness for average users versus usefulness for correct and consistent users, categorical comparison of various methods ranging from most to least effective, or a continuum of different methods ranging from most to least effective) was most effective in helping women understand the relative effectiveness of different methods of contraception. There were no differences in subsequent knowledge following exposure across the three formats, though in that study all of the formats included combinations of numeric and non-numeric descriptors. In another example, Sheridan and Pignone (2002) randomized medical students into one of four different presentation formats: RRR, ARR, NNT, or a combination of these formats. Students viewed data about the risk for developing a hypothetical disease and were randomly assigned to receive information about two treatments that would reduce this risk. They were asked to interpret the data presented in the format to which they were assigned and then answer a question that assessed the accuracy of their knowledge or interpretation of the data. There were no significant differences among the different risk reduction formats in this relatively well-educated group.

Some studies have attempted to compare various types of numeric statements of risk; results have varied tremendously in part because the nature of what has been compared has varied tremendously. Chao and colleagues (2003) compared the effects of four numerical risk and benefit presentation formats (RRR, ARR, ASB, and NNT) used to convey prognosis on treatment decisions and understanding of prognosis. Findings suggest that participants best understood prognosis when data were presented in the ASB format. In addition, presenting individuals with all four formats included actually increased confusion. Cuite and colleagues (2008) compared the effects of risk estimates presented using three different numerical formats (as a percentage, frequency, or 1-in-*n* statement) on understanding among laypeople, measured by the accuracy with which they were able to perform various mathematical operations on risk information. In general, participants were most accurate when presented either the percentage or the frequency format rather than the 1-in-*n* format, although education had a strong moderating effect on accuracy. Sheridan, Pignone, and Lewis (2003) tested whether the NNT format helps patients interpret treatment benefits better than ARR, RRR, or a combination. Results suggest that patients best understood the benefits of treatment when presented information in RRR formats or ARR formats against a given baseline risk of disease, and that patients least understood risk when presented in an NNT format.

The utility of graphics. A series of studies by Zikmund-Fisher and colleagues (2008a; 2010; 2008b) in our review demonstrate the utility of pictographs compared with plain numeric text. In one example, Zikmund-Fisher and colleagues (2008b) found that using a pictograph to depict risk improved knowledge about prophylactic use of tamoxifen to prevent primary breast cancers relative to providing only numeric statements about risk. Studies by Zikmund-Fisher and his team also have underscored the importance of simplicity in graphic presentation. For example, in one paper, Zikmund-Fisher and colleagues (2008a) found that a simplified presentation (i.e., one that illustrated only two breast cancer treatment options compared with four options) improved comprehension of the options in question.

Tait and colleagues also have specifically focused on the potential utility of pictographs. Tait and colleagues (2010b) randomized parents of children undergoing elective surgery to receive information pertaining to the risks and benefits of two different hypothetical medications in one of three different formats (numeric text, tables, or pictographs). The Tait and colleagues (2010b) study demonstrated that parents who received the medication information in the form of a table or pictograph (as opposed to text) were more likely to demonstrate greater gist (i.e., overall or general notion) and verbatim (i.e., specific detail) knowledge of the medication risks and benefits. Another study by Tait and colleagues (2010a) used an Internet survey with a fully randomized between-subjects factorial design to test the effects of three different quantiative message formats (non-numeric, text vs. numeric, table vs. numeric, pictograph) on parents' understanding of risks and benefits of clinical research with pediatric patients. Results again show that pictographs were significantly better than tables or text in providing both adequate gist and verbatim understanding.

At least two studies by Garcia-Retamero and colleagues have investigated whether adding graphical icons to numeric information aids comprehension, and both suggest that graphical aids offer some potential for improvement in knowledge gain. Using a cross-sectional telephone survey, for example, Garcia-Retamero and Galesic (2009) first investigated how well participants were able to compare information about the risk of dying from a heart attack when taking a statin drug (5/100) and when not taking a drug (80/800) when each condition used a different denominator. They hypothesized that individuals pay more attention to the number in the numerator rather than the number in the denominator (or, more precisely, the percentage that the ratio represents). The authors refer to this phenomenon as *denominator neglect*. They also investigated whether icon arrays (graphical representations that consist of circles or other icons symbolizing individuals who are affected by some risk) aid comprehension. All icon arrays contained either 800 or 100 circles depending on the overall number of patients who did and did not take the drug. Results indicated that when information about the drug was provided numerically only and the size of the denominators was different, many participants provided inaccurate estimates about how well the drug reduced the risk of heart attack. This was especially true for participants with low numeracy. Participants who were provided icon arrays in addition to the numerical information were more likely to accurately interpret risk information, in both high- and low-numeracy groups.

In a second study, Garcia-Retamero and colleagues (2010b) presented information to participants about the usefulness of a hypothetical antihypertensive medication to reduce the risk of heart attack or stroke to determine which of the following formats was most effective: numeric information in a relative risk format, numeric information in an absolute risk format, and four graphs with icons or bars. Results suggest that estimation accuracy improved both when icon arrays and when bar graphs were added to numerical information, especially when the visual aids depicted the entire population at risk. Visual aids were most useful for the participants who had low numeracy but relatively high graphical literacy skills.

Waters and colleagues (2006) attempted to determine how best to present probability information in a situation in which there are trade-offs; that is, when a treatment decreases one risk but increases another. Their results suggest that participants' accuracy was greater when the probability information was represented as a graphic display rather than as text only, and also when participants needed less cognitive effort to evaluate the trade-off and when information was presented as percentages rather than as frequencies (i.e., *n* in 100). Later work by Waters and colleagues (2006) again suggests the utility of simple graphics over and above only including numbers.

On a somewhat similar plane, Schwartz and colleagues (2009) conducted two trials that examined knowledge. The first study sought to determine whether using a special graphic element—a drug facts box—to present numeric information about the outcomes from using and not using a medication resulted in more accurate knowledge about understanding of side effects and benefits than did the standard information patients typically receive in current drug advertising and drug summaries. Overall, participants who were exposed to the drug facts box had more accurate understanding of the side effects and benefits of the different medications. The second study focused on which format resulted in more accurate knowledge of the drug's treatment benefits. The drug advertising and summary in the control condition did not contain information about the benefits, but the drug fact box did. Results indicate that participants who received the quantitative information (via the drug facts box) about the drug's effectivness in treating symptoms had more accurate knowledge of the drug's benefits than did participants who received no information. As a demonstration of knowledge, participants who reviewed the drug facts box were better able to select the superior drug compared with participants who reviewed the standard information provided in drug advertising. Unfortunately, this second study only compared numeric information against a no-information control, so it is unclear whether improved understanding was due to the simple presentation of a drug fact box, the specific addition of numeric information, or the combination of the two.

Framing and order effects. Several studies examined how the framing or ordering of information affected knowledge. Armstrong and colleagues (2002) conducted a study to determine whether framing information in terms of survival curves, mortality curves, or both affected understanding and treatment preference. Results suggest that participants better understand information about the chances of survival after a medical procedure or treatment when the information is presented using a survival curve or both survival and mortality curves, rather than mortality curves alone. Results also show that the effects of survival compared with mortality curves were greater for those with less education and with ethnicities other than Caucasian. In a different example, Tait and colleagues (2010) examined the effect of manipulating risk/benefit trade-offs on parents' understanding of risks and benefits related to postoperative pain in children. Parents who were presented only with numerical quantitative information about improved outcomes had a better understanding of the information than parents who were presented with only numerical quantitative information about reductions in risk. One study examined how the order in which risks and benefits are presented can affect knowledge. Ubel (2010) investigated whether the order in which risks and benefits of taking tamoxifen were presented affected knowledge and whether presenting contextual information on competing risks that they faced over the next 5 years (colon cancer, heart attack, or all-cause mortality) affected knowledge about the risks and benefits of taking tamoxifen. Women who did not receive contextual information demonstrated order effects: women who were presented risks of medication first answered fewer questions about the risks and benefits of the medications correctly. When contextual information appeared with the decision aid, women did not demonstrate this order effect.

Education and numeracy. It is clear from our review that education and numeracy are key moderators in the translation of risk information exposure into knowledge. A number of studies in our review found education or numeracy to matter (Cuite et al., 2008; Garcia-Retamero & Galesic, 2009, 2010a; Hawley et al., 2008; Tait, Zikmund-Fisher et al., 2010; Zikmund-Fisher et al., 2010; Zikmund-Fisher et al., 2008b). For example, the results of at least one study appear to be heavily dependent on the numeracy level of participants. Hawley (2008) evaluated six numeric communication (5 graphs, 1 table) formats embedded in a hypothetical medical scenario whereby respondents of high and low numeracy considered the benefits of using a medication to prevent bypass surgery that poses risks of adverse events. They measured verbatim knowledge (i.e., the ability to correctly read numbers from graphs) and gist knowledge (i.e., the ability to identify the essential point of the information presented). Results indicated that pictographs, bar charts, and tables were equally effective in conveying verbatim knowledge among low-numeracy respondents, whereas the other formats (modified pictograph, pie chart, and modified pie chart) were less effective. For higher numeracy respondents, the table and bar charts were equally effective in conveying verbatim knowledge, and all other formats were less effective. Results for gist knowledge were somewhat different. Many of the graph formats were more likely than the table to be associated with adequate gist knowledge. Among lower numeracy respondents, those who viewed the pie graph and those who viewed a pictograph were significantly more likely than those who viewed the table to report adequate gist knowledge. For higher numeracy respondents, none of the graph formats were significantly better than the table in conveying gist knowledge (although the pictograph and the pie chart were borderline significant). In other words, those with lower numeracy appear to have benefited from the inclusion of a graphical element, especially with regard to gist understanding.

Summary. Several patterns emerge from our review of studies that assessed the impact of various formats on risk-related knowledge and understanding. First, numeric formats appear to hold some advantage relative to non-numeric formats in general accuracy and knowledge gain, though non-numeric categories apparently can assist people in discerning relative or comparative risk among various options. Second, it appears that elements that reduce cognitive load can be important in facilitating processing and knowledge gain. Various types of evidence support this conclusion. For example, results of numerous studies suggested that simple graphics aid comprehension. Also, including non-numeric as well as numeric information helps guide the reader; however, the inclusion of numerous formats can sometimes lead to confusion. Nonetheless, several studies in our review actually found a combination of numeric and non-numeric information to be useful, although some of these studies included only a combination of information relative to a control condition with no information. It also appears that education or numeracy plays an important role, with simple graphics such as pictographs offering assistance to low-numeracy people, especially with regard to gist understanding.

What is currently unclear is exactly whether there is a particular numeric statement of risk or a graphical approach that is ideal across numerous topics. Studies to date have compared a wide variety of different types of formats; until we have more systematic comparison of various elements across various different types of risk scenarios, we likely will continue to have a somewhat muddled picture as to exactly which numeric and graphic formats work best.

Perceived risks and benefits

Researchers have addressed the question of whether risk and benefit information format affects personal risk and benefit perception in a variety of ways (Berry et al., 2004; Dieckmann, Slovic, & Peters, 2009; Gurmankin, Baron, & Armstrong, 2004b; Halpern, Blackman, & Salzman, 1989; Knapp et al., 2010; Knapp et al., 2004; Knapp et al., 2009; Peters, Sol Hart, & Fraenkel, 2010; Shaw & Dear, 1990; Tait, Zikmund-Fisher et al., 2010; Tan et al., 2005; Teigen & Brun, 1999; Zikmund-Fisher et al., 2008b). Some of the studies (see Table 6) focused on exploring main effects of presentation format on perceived risk. Others shed light on how people engage numeric risk presentations and why descriptive, non-numeric presentations might differ from numeric risk presentations in their effects on risk perceptions.

Table 6. Studies Focused on Perceived Risks and Benefits

Reference	Information being communicated	Communication format	Perceived Risk Findings
Berry et al., 2004	Adverse events from ibuprofen	**Non-numeric**: Description of adverse events using the European Commission recommended "action" labels **Numeric:** Percentages	• Patients more likely to perceive greater likelihood of side effects, more risk to health and greater side effect severity when risk presented in a non-numeric format
Gurmankin et al., 2004b	Risk of four different types of cancer	**Non-numeric**: Risk portrayed descriptively **Mixed:** Descriptive plus numeric probability as a percent, and descriptive plus numeric probability as a fraction	• In the descriptive versions, participants' risk perceptions were strongly in the direction of overestimating their risk relative to stated risk in the numeric versions but participants' risk perceptions are highly variable across three risk presentation formats • Participants overestimated risks when provided with scenarios with numeric information, however, this format only slightly decreased the variability of risk perceptions

Table 6. Studies Focused on Perceived Risks and Benefits (continued)

Reference	Information being communicated	Communication format	Perceived Risk Findings
Halpern et al., 1989	Oral contraceptive safety	**Numeric**: Use of different risk presentations • 99991.7 out of 100,000 • 0.0083% probability of dying • 1 in 12,000 die • 8.3 in 100,000 die • 4.15 times greater risk of death • 415% greater risk of death	• Results suggest respondents make a judgment about whether numbers are “big” or “small” when assessing probabilities and then use rest of information provided to determine if number refers to a benefit (will not die) or a risk (will die or is at greater risk)
Knapp et al., 2004	Risk of medication side effects	**Non-numeric**: Received information about constipation and pancreatitis in descriptive format **Numeric:** Received information about constipation and pancreatitis in numerical format	• Patients who were provided descriptors overestimated the probability of side effects, regardless of the frequency in which the side effects occurred • Participants' perceptions about likelihood of side effects affect their own perceived risk of having side effects and potentially their decisions about whether to take the medication
Knapp et al., 2009	Risk of side effects to tamoxifen	**Non-numeric**: Descriptive format **Numeric:** Frequency of side effects **Mixed:** Both descriptive format and frequency of side effects	• Descriptors resulted in higher perceived likelihood of a side effect and higher perceived risk to health than frequencies or the combined format • Compared to descriptive and combined formats, frequency format produced most accurate estimates of risk of side effects
Knapp et al., 2010	Perceived risk of tamoxifen side effects	**Non-numeric**: Descriptive format **Numeric:** • Absolute frequency of side effects (e.g., occurs in about 48 in 1,000 people) • Frequency band (e.g., occurs in more than 1 of 10 people) **Mixed:** • Descriptive format plus absolute frequency • Descriptive format plus frequency band	• No significant differences in personal estimates of patient’s prognosis between participants who received numeric statements and participants who received descriptive statements
Peters et al., 2010	Benefits and risks of headache medication	**Numeric:** Risks and benefits were described using number and framing formats: <u>Number</u> <u>Frame</u> Percent Negative Percent Positive Percent Combined Frequency Negative Frequency Positive Frequency Combined	• Number formats affect risk perceptions in individuals based on level of numeracy, with less numerate individuals perceiving higher risk when numbers are presented in frequency formats (vs. percentage formats) • Framing affects risk perception, with individuals receiving information in positive frame perceiving lower risk than those receiving the same information in a negative frame

Table 6. Studies Focused on Perceived Risks and Benefits (continued)

Reference	Information being communicated	Communication format	Perceived Risk Findings
Shaw & Dear, 1990	Common newborn problems	**Non-numeric**: Non-numeric text using words such as "probably," "likely," "occasionally," etc." **Numeric:** Frequency (e.g., 3 in 10)	• Large variations in interpreting common expressions of probability by mothers and health care providers; when provided with numeric expressions, mothers and health care providers differed significantly in assigning text-based expressions to the numeric probabilities
Tait, Zikmund-Fisher et al., 2010	Risks and benefits related to postoperative pain in children	Complex risk/benefit trade-offs between two drugs presented as four different scenarios: one scenario showed one drug to be superior to another in both risks and benefits; the other three scenarios showed varying trade-offs in risk and benefit **Numeric:** Percentages	• When provided with only improved benefits, parents perceived the risks to be lower than the scenarios that offered the same risks but less benefit
Tan et al., 2005	Vaccine risk	**Numeric**: • Frequency (e.g., 1 out of 20) • Percentages	• Presenting risk in a probability format lowers perceived risk as compared to a frequency format
Teigen & Brun, 1999	Physicians' certainty in the efficacy of acupuncture as a treatment for migraine headaches	**Non-numeric**: Terms such as uncertain, a chance, some possibility, others **Numeric:** Percentages	• Positive expressions (e.g., a possibility, a chance, or a hope) lead to predictions in a positive direction; negative phrases lead to fewer positive predictions • Descriptive expressions have consistent meaning from which individuals can infer content • Descriptive expressions may provide more information from a linguistic perspective than numerical expressions
Zikmund-Fisher et al., 2010	Side effect risks concerning prophylactic use of tamoxifen to prevent primary breast cancers	**Non-numeric:** • Pictograph **Numeric:** • Frequency and percentage • Incremental risk (vs. total) • 1,000 risk denominator (vs. 100) **Mixed:** • Pictograph x incremental risk • Pictograph x denominator • Incremental risk x denominator	• Risk perceptions lower when incremental risk (as opposed to total risk of experiencing the complication) presented

General effects on risk perceptions. Across the studies we reviewed, we can see some impact of numeric presentation of risk information compared with presentations that use non-numeric descriptors (such as "common"). Berry and colleagues (2004), for example, reported an experimental study focused on risk perceptions associated with side effects of an over-the-counter medication that one might take in the event of a hypothetical stiff neck. Patients in the Berry and colleagues study were more likely to perceive a greater likelihood of side effects, more risk to health, and a greater side effect severity when risk was presented in a descriptive, non-numeric format (compared with a numeric format). Similarly, Knapp, Raynor, and Berry (2004) manipulated risk information format in statements about statin drug effects and found that patients who were provided descriptors overestimated the probability of side effects, regardless of the frequency with which the side effects actually occurred. A later paper by Knapp and colleagues (2009) also provides some relevant evidence. Knapp and colleagues assigned users of the Cancer Research UK patient information Web site to one of three formats of risk information about cancer treatment side effects: descriptors of side effects commonality, absolute frequencies to describe side effect frequency, or a combination of non-numeric and numeric descriptors. Those assigned the absolute frequency format tended to be more accurate in their assessment of personal risk for side effects and tended to rate the risk to health of the described drug as lower than those in the other two formats.

Explanations for numeric vs. non-numeric differences. Why exactly do non-numeric risk descriptors and numeric risk descriptors vary? There are at least two major reasons this might be the case. Numbers might simply offer more precision to people as they develop risk perceptions. In a 2004 risk analysis paper, Gurmankin, Baron, and Armstrong (2004b) found some support for this idea, at least in the aggregate. They found that inclusion of a numeric statement of risk in a statement about cancer risk reduced the degree of variation in risk perception compared with a non-numeric statement (although they do note that the effect was relatively small). In other words, people who saw numeric presentations tended to answer similarly to one another whereas presentation of non-numeric expressions of probability led to more variation in participants' probability judgments. Shaw and Dear (1990) provide some additional evidence that is relevant to this apparent phenomenon; they compared what happens when patients attempted to translate non-numeric probabilities into numeric probabilities with what happens when physicians did so and found that the range of responses offered by patients tended to be much greater than the range of physician responses. It appears that non-numeric descriptions invite more variation in patient response than health care professionals might anticipate. A focus on the precision of non-numeric and numeric presentations, however, does not necessarily tell us about biased tendencies in the response to particular formats. For that, we need to turn to explanations that focus on differences in the perceived nature of the different formats.

Teigen and Brun (1999) take a different approach in considering the differences between non-numeric and numeric formats for risk information. They suggest that descriptive non-numeric probabilistic phrases are different from numeric probabilities not primarily because they are somehow more vague and imprecise but actually because they have more power to be directive in suggesting the types of inferences to be drawn. Results from a series of experiments with Norwegian students appear to support their conclusion. In one of the experiments, for example, Teigen and Brun report that students were more likely to recommend a hypothetical acupuncture treatment for a migraine sufferer described in a vignette when the treatment was described as having some possibility of success compared with a description with a numeric probability of a 30% to 35% success probability. Moreover, students in a descriptive non-numeric probability condition in which the treatment was described as quite uncertain in its success forecast were less likely than either the numeric condition or the positively framed condition to recommend the treatment. In presenting these and other results, Teigen and Brun thus draw a distinction not only between numeric and non-numeric framing but also between positively and negatively phrased probabilities.

Framing effects on risk perceptions. Whether a probability is described in terms of a gain realized, loss occurring, or outcome (such as a side effect not occurring) appears to affect how risk information affects perceptions. For Teigen and Brun, a so-called positive probability suggests the occurrence of a target outcome whereas a negative probability draws attention to the nonoccurrence of a target outcome. In the Teigen and Brun paper, the impact of descriptive, non-numeric framing, in turn, appears to be most evident with regard to negative probabilities, an effect that might occur because of the nature of such uncertainties. In the face of uncertainty, a person may want more than a neutral numeric estimate; linguistic phrases indicate not only a level of probability but also a point of view from which this probability should be regarded. Peters, Hart, and Fraenkel (2010) offer another example of the effect of positive and negative framing, as they recently compared participants offered either a positive or a negative frame regarding risks associated with a medication. Participants given the positive frame perceived the medication as less risky than those given the negative frame, meaning that the negative frame may have invited a more biased reaction (at least relative to what the authors assumed to be an accurate understanding).

Exactly how positive and negative framing is operationalized and what the desired response is, however, also appear to affect results. On first glance, Halpern, Blackman, and Salzman (1989) present somewhat of a counterexample to the general idea that negative framing about the risk of something not happening is more likely to invite extreme risk perceptions. Halpern and colleagues found that people tend to estimate smaller risks when presented with information about the likelihood of people not dying in comparison with peers who were offered information about the risk of death happening as a side effect. It is conceivable, however, that the nature of the event in question might affect risk perception tendency and explain these results. Note that Halpern and colleagues study risk presentations regarding death, which for most people would count as a loss. At least one other paper reviewed suggests a tendency among people to generally overestimate risk when faced with information about possible loss. Gurmankin, Baron, and Armstrong (2004a) found that people generally overestimated their own risk in response to a variety of numeric presentations, a pattern they speculate might have occurred because people saw the disease in question—cancer—as relatively uncontrollable.

In light of these findings, it is worthwhile to return to the recent Peters and colleagues (2010) study, in which the researchers actually operationalized “negatively” framed messages as presentations of the probability of getting a “bad blistering rash” whereas the positive messages in their study presented the probability of not getting a bad blistering rash. In their study, then, the condition that invited lower risk perceptions actually was the one involving a frame focused on the probability of escaping loss as opposed to the chance of loss occurring (in the form of a bad rash). Similarly, the Teigen and Brun paper, especially the study described above, focuses on the potential gain that one might get from using a treatment to combat migraines. Perhaps what we see here is a general possibility that the prospect of loss, either in the form of an unrealized gain or in the form of material loss occurring, might invite greater tendency for risk information to spur biased risk perceptions.

The importance of absolute numbers. Another idea evident in some of the papers reviewed for this study is that people tend to focus on the absolute number actually listed in a numeric presentation rather than accurately processing additional information provided to contextualize the number. For example, Halpern, Blackman, and Salzman (1989) found that people tended to assess the absolute size of the number presented and use it, in part, to guide them, such that a 415% greater likelihood apparently seemed bigger to people, on average, than did a 4.15 times greater likelihood. Similarly, a 2010 paper by Knapp and colleagues offers some assessment of the relative contribution of different types of numeric descriptors. In short, they found that those in an absolute frequencies condition (e.g., “in about 48 people in 100”) estimated the risk of experiencing hot flashes, cataracts, or any side effects as significantly more likely than those in the frequency bands condition (e.g., “affects more than 1 in 10 people”). Given the examples provided by Knapp and collaborators, one does not need to necessarily assume the greater influence of an absolute frequency over a frequency band (e.g., “more than 1 in 10”), per se. We can read the difference between the two conditions in the Knapp and colleagues paper as not particularly surprising if we simply assume that people likely focus on the actual number listed, such as 48 out of 100 or 1 in 10 rather than grasping the notion of a confidence interval with lower and upper bounds implied by saying that a side effect occurs in “more than 1 in 10.”

The importance of numeracy and education. Numeracy and education appear to affect the impacts of information format. In Gurmankin, Baron, and Armstrong (2004a), for example, those at higher levels of numeracy and education were less likely to overestimate risks. Dieckmann, Slovic, and Peters (2009) found that those higher in numeracy tended to rely on stated numeric likelihood whereas those lower in numeracy tended to rely on non-numeric narrative statements in estimating risk. In Shaw and Dear’s (1990) study, they found that differences between mothers and physicians in the translation of non-numeric risk information into numeric risk information were greatest among relatively less educated mothers. Peters, Hart, and Fraenkel (2010) recently found a similar influence of numeracy. In their study, they found that less-numerate participants who were offered risk information in a percentage format perceived a medication as less risky than when they were offered risk information in a frequency format. Highly numerate participants, however, perceived similar risks regardless of risk information format. In other words, numeracy moderated the effect of risk information format on perceived risk.

Summary. In summary, numeric and non-numeric risk information appear to differ in the risk perceptions each invites. Non-numeric risk information often seems to invite more extreme risk perceptions than does numeric risk information. This pattern might be due to the precision offered by numeric information, as some evidence about the extent to which numeric presentations limit perception variability between respondents suggests. The pattern might also reflect the idea that descriptive, non-numeric risk information is more likely to be perceived as editorial and directive in nature compared with numeric risk information, as Teigen and Brun suggest. In addition, these effects appear to be tempered by numeracy and education, such that those with greater levels of numeracy and education are less likely to be affected by the type of risk information presented.

Behavioral intentions and behaviors

Our review included several studies that assessed participants' behavioral intention, behavior, or decision making with regard to presented risks (Berry et al., 2004; Carling et al., 2009; Carling et al., 2008; Carling et al., 2010; Cheung et al., 2010; De Abreu et al., 2009; Fagerlin, Wang, & Ubel, 2005; Hembroff, Holmes-Rovner, & Wills, 2004; Man-Son-Hing et al., 2002; Mazur et al., 1999; Peele, Siminoff, Xu, & Ravdin, 2005; Tan et al., 2005; Weymiller et al., 2007; Zikmund-Fisher et al., 2010). All of these studies (Table 7) assess expressed intention or actual behavior in some way, and yet the nature of the outcomes studied varies considerably. In some cases, the authors assess simple willingness to engage in a certain medical act, such as taking a medication. In other cases, the authors actually incorporate and adjust for one's expressed values, meaning that they attempt to assess informed decision making in some way as a function of various presentations.

Table 7. Studies Focused on Behavioral Intentions and Behaviors

Reference	Information being communicated	Communication format	Findings
Berry et al., 2004	Adverse events from ibuprofen	**Non-numeric:** Description of adverse events using the European Commission recommended "action" labels **Numeric:** Percentages	• There were stronger intentions to take ibuprofen when the information was presented numerically as opposed to non-numerically; no statistically significant difference in type of European Commission's recommended action with regards to numerical or non-numerical formats

Table 7. Studies Focused on Behavioral Intentions and Behaviors (continued)

Reference	Information being communicated	Communication format	Findings
Carling et al., 2008	Reduced risk of CHD with statin therapy	**Numeric**: RRR, ARR, NNT, Event Rates, Tablets Needed to Take, and Whole Numbers	• Participants who received RRR presentation were most likely to say they would start taking statins and most likely to take them independent of their values with regard to the possibility of having heart disease, taking statin drugs daily, and the cost of the medication • Across presentation formats, participants who were scientists and engineers, had higher numeracy scores, and those with 17 or more years of education were less likely to say they would take statins
Carling et al., 2009	Advantages and disadvantages associated with getting and taking antibiotics for sore throat	**Non-numeric:** • Pictograph comparing sore throat occurrence with and without antibiotics • Bar graph comparing sore throat occurrence with and without antibiotics • Bar graphs comparing duration of sore throat symptoms with and without use of antibiotics • Bar graphs showing sore throat occurrence with and without antibiotics at two time points	• For people considering whether to go to the doctor for a sore throat, information is more likely to help people make well informed decisions if bar graphs of the duration of symptoms are used; participants shown the other three presentations were less likely to make decisions that were consistent with their values associated with health care intervention
Carling et al., 2010	Decision to take antihypertensive medication	**Control:** No information **Numeric:** Frequencies: • Individuals free of cardiovascular disease for 10 years with medication use (positive framing) • Individuals experiencing cardiovascular disease over the next 10 years without medication use (negative framing) • Individuals experiencing cardiovascular disease each year over the next 10 years without medication use (negative framing per year)	• Participants who were more concerned about cardiovascular disease occurrence than the side effects of the medication had a higher likelihood of choosing to take medications regardless of how the information was presented to them • Most participants chose to take antihypertensive medication when initially given the choice to do so, but after being given additional information, were less likely to take the medication • When information was framed positively, participants were least likely to choose the medication
Cheung et al., 2010	Information on side effects of a new medication for pain relief prior to seeking participation in a clinical trial	**Non-numeric:** Description of adverse events according to those derived by the European Union **Numeric:** Percents and frequencies	• Type of risk format (non-numeric, percents, or frequencies) did not influence a participants' willingness to participate in a clinical trial

Table 7. Studies Focused on Behavioral Intentions and Behaviors (continued)

Reference	Information being communicated	Communication format	Findings
De Abreu et al., 2009	Benefits and risks of medications to treat systemic lupus erythematosus	Was not a comparative study (i.e., did not have patients who used the DB tool vs. others who did not)	• DB tool is understandable to patients and could potentially improve the quality of time spent in medical consultations • Describing side effects as life threatening tended to influence decisions
Fagerlin et al., 2005	Length of hospitalization and cure rates	**Non-numeric:** Risk portrayed as text with no accompanying pictograph **Mixed:** Use of a pictograph, a trade-off quiz, or a pictograph and quiz combination	• Statistical information presented graphically using a pictograph promotes use of numeric information in making treatment choices
Hembroff et al., 2004	Additional information provided on the risks (increasing risk for breast cancer) and benefits (reducing risk of heart disease) if one used a medication for preventing bone disease	**Numeric:** • Use of different risk presentations • Breast cancer risk doubles • Breast cancer risk increases risk from 1/10,000-2/10,0000 • Heart disease risk reduced by more than half • Heart disease risk decreases from 1/200 to 1/500 • Competing risks (breast cancer) coincident with benefits (reduced risk of heart disease)	• Individuals make different health decisions based on presentation of risk information (absolute vs. relative) and these decisions are further influenced by disease risk type • Participants in this study were more likely to change initial medication recommendation decisions when provided risk information in absolute terms
Man-Son-Hing et al., 2002	Risk of stroke	**Non-numeric:** Risk information presented using terms such as low, moderate, and others **Mixed:** Decision aid providing risk information frequency information (e.g., 8 out of 10) and a pictograph	• Treatment choices slightly different between two groups in moderate risk arm, with patients in quantitative group more likely to choose therapy at extremes of effectiveness (warfarin or no therapy) than patients in qualitative group • Difference not found in low-risk arm
Mazur et al., 1999	Early surgical treatment for asymptomatic gland-confined prostate cancer	**Non-numeric:** Non-numeric for the outcomes of the “surgery-now” and “watchful waiting” options **Numeric:** Numeric description of the probabilities of occurrence of adverse outcomes associated with the “surgery-now” option	• Patients who preferred words only more likely to choose surgery for treatment

Table 7. Studies Focused on Behavioral Intentions and Behaviors (continued)

Reference	Information being communicated	Communication format	Findings
Peele et al., 2005	Survival with and without adjuvant chemotherapy	**Non-numeric:** Information pamphlet providing general information on use of adjuvant therapies **Numeric:** Individualized decision aid providing survival estimates with and without adjuvant therapies	• Low risk patients, i.e., those women with little to gain from adjuvant therapy, were more likely to forego therapy when provided with detailed, evidence-based, individualized risk information
Tan et al., 2005	Presentation of vaccine risk	**Numeric:** • Percentages • Frequency	• No significant differences in willingness to accept vaccination between two groups • Respondents in frequency group were significantly more likely to say vaccine risk was "common" compared to respondents in the probability group
Weymiller et al., 2007	Risks and benefits of using statin medications	**Control (presumed to be non-numeric):** Pamphlet described cholesterol management **Mixed:** Decision aid presented tailored cardiovascular risks; benefits and risks of taking statins	• Participants who received risk information via decision aid reduced decisional conflict and improved scores on effective decision making subscale compared to participants who did not receive risk information (pamphlet)
Zikmund-Fisher et al., 2010	Risk statistics for breast cancer treatment choices	**Mixed:** • Multi-outcome graph including survival, mortality, and deaths from other causes for hormonal therapy AND the incremental survival benefit by adding chemotherapy using pictographs • Survival only pictograph comparing hormonal therapy alone to that when chemotherapy is added	• Women who reviewed survival-only graphic were less likely to prefer adding chemotherapy to hormonal therapy, but numeracy moderated this effect in that more numerate women were less likely to choose addition of chemotherapy to the regimen

Note. ARR = absolute risk reduction; DB = decision board; NNT = number needed to treat; RRR = relative risk reduction

The impact of various formats and types of information is not completely consistent across studies in this review. Among studies that assess simple willingness or intention to take a particular medication, for example, we see variation in the impact of numeric and non-numeric information. Berry and colleagues (2004) compared non-numeric descriptions of adverse events with numeric presentation of risk information about an over-the-counter medication for a hypothetical stiff neck. Those who received numeric risk information were not only more satisfied with the presentation, as noted earlier, but also were more likely to intend to take the medicine. Cheung and colleagues (2010), however, assessed willingness to participate in a hypothetical clinical trial for a pain relief medication in Singapore. Although the researchers found information format preference differences, they did not find a significant difference between non-numeric and numeric formats in terms of willingness to participate in the trial. Tan and colleagues also present data that undermine the case for a simple effect of numeric risk information on behavioral intention to take a medication. Although Tan and colleagues suggest that participants who were shown a probability format for risks associated with an influenza vaccine were more likely to accept the vaccine than were those shown associated risks in a frequency format; the difference between groups was not actually statistically significant, $p > .10$.

Fourteen articles in our study assessed behavioral intentions as a function of different types of numeric risk information exposure. In particular, a paper from Carling and colleagues provides some evidence for the type of numeric information that appears to be most likely to lead to statin uptake. Carling and colleagues assessed patients' reaction to one of six statistics describing risks related to statins, including RRR and five absolute measures of effect: ARR, NNT, event rates, tablets needed to take, and natural frequencies (whole numbers). Not only did patients generally prefer the RRR presentation, but they also were more likely to decide to take the statin when shown the RRR compared with other statistics. We should also note that educational background and numeracy affected participant willingness to take the described statins. Participants with a scientific background, who were more numerate, or who had more years of education were more likely to decide not to take statins.

We face limitations in drawing conclusions from this first array of studies, however, because they focus on hypothetical engagement with a medication without necessarily accounting for patient circumstance or what an appropriate decision might be and do not directly track actual real-world behavior that occurs in the context of one's own specific circumstances. Hembroff and colleagues (2004), for example, assessed reaction to hypothetical information regarding risks of breast cancer stemming from a bone disease treatment and investigated whether women would recommend treatment to a friend on the basis of various types of numeric risk information. When we look at a second set of studies that largely involve what we might view as appropriate decision making, either with regard to concordance with patient preferences and informed decision making or with regard to decision making that conforms to what the researchers deem appropriate given clinical recommendations, evidence suggests some utility for numeric information presentation, at least for some types of patients.

Carling and various colleagues contributed two additional studies to our review that are relevant to informed decision making. The studies vary somewhat in their focus, but both relate to the notion of informed decision making. In a 2009 paper, for example, Carling and colleagues (2009) compared the effect on people's decision to see a physician of various types of graphics and bar charts depicting the average duration of sore throat symptoms or proportion of people with symptoms at various stages. Importantly, Carling and colleagues assess the correspondence of one's decision with his or her expressed values and preferences in terms of undesirable consequences and symptom relief. In other words, they assessed the extent to which a person made a decision consistent with his or her values as a function of exposure to the various graphics. They found that a bar graph depicting the average duration of symptoms was most predictive of such an outcome and that approach performed better than simple happy or sad face graphics and more complex graphics depicting the proportion of people experiencing symptoms at various stages.

Carling and colleagues (2010) published another study that investigated patient reaction to variously framed information. They compared those receiving no information about cardiovascular disease drugs with those receiving information that was either framed negatively (in terms of risk of developing cardiovascular disease) or positively (in terms of possibility of avoiding cardiovascular disease). Carling and colleagues found that exposure to negatively framed information seemed to have been most likely to result in decisions inconsistent with the average decision made by relatively informed patients (who had seen all of the variously framed information). As a result, they recommend that those developing decision aid materials (for people at relatively low risk) be cautious when considering including only negatively framed information.

Other studies included in our review highlight the notion of decisional conflict. We can define decisional conflict as an umbrella notion that includes uncertainty about a treatment decision and perceptions of support and efficacy in decision making. Man-Son-Hing and colleagues (2002) compared people who were relatively low risk for stroke with people at moderate risk to determine whether numeric or non-numeric risk information about negative outcomes would affect decisional conflict. Participants were either presented information quantitatively (in which the 2-year probabilities of stroke and major hemorrhage were presented both numerically and graphically) or what they call qualitatively (or in non-numeric fashion in which these probabilities were presented with the use of descriptive phrases, e.g., very low, moderate). Those presented with numeric information were less likely to demonstrate decision conflict. Actual treatment choices, though, differed only among those at moderate risk, with those viewing the numeric information more likely to make a choice at the extremes of available options. Weymiller and colleagues (2007) conducted a randomized trial among diabetes patients who were offered statin drugs that also suggests that numeric information reduces decisional conflict (and, by implication, improves the likelihood of informed decision making). They compared a tailored decision aid that included numeric and non-numeric information with standard practice (which was a descriptive pamphlet that defined lipid disorders and provided dietary information) and found that those who received the decision aid not only were less likely to report decisional conflict but also more likely to adhere to recommended dosage during the 3 months afterward.

Some studies included in our review did not focus on informed decision making explicitly, but nonetheless assessed the degree to which exposure to various formats of risk information encourages behavioral intention or behavior that was consistent with a recommendation. In all of these examples, the authors suggest that a particular behavior is preferable and then look at the impact of various formats on tendency of patients to select that option compared to other alternatives. Fagerlin, Wang, and Ubel (2005), for example, offer an example of a study that assesses not just intended behavior but intended behavior that conforms to a certain ideal. Fagerlin and colleagues specifically investigated the impact of graphic numerical information versus anecdotal descriptions of patient experiences assessed on patient's choice of treatment for hypothetical angina. Importantly, they assessed whether the inclusion of a graphical pictograph influenced the extent to which people relied on text anecdotes in selecting the intended behavior consistent with known cure rates for the treatment in question. In short, they found that inclusion of a pictograph seems to help; people were less likely to respond to unrepresentative anecdotal information when also shown a pictograph than when such a graphic was not included. They also assessed whether inclusion of a quiz to illustrate risk and benefit trade-offs would have a significant impact; it did not. Similarly, Peele and colleagues (2005) studied women with breast cancer and found that those who were presented with numeric information were more likely to make a decision consistent with general clinical recommendations. They presented patients with a pamphlet about adjuvant therapy that did not include numeric information or a patient-specific decision aid that included graphical numeric survival information on risk associated with the treatment. Fewer women with low-grade tumors chose adjuvant therapy when presented the individualized decision aid than did women presented only the pamphlet. In a third example, Mazur, Hickam, and Mazur (1999), as noted earlier, conducted a cross-sectional study of decision making among patients with asymptomatic, localized prostate cancer and the relationship of that decision making to information preferences. Although they found that more patients in their study preferred numeric information about treatment options over descriptive, non-numeric information, the information preferences of those who selected surgery over a watchful waiting approach are noteworthy, as those who preferred descriptive, non-numeric information tended to choose surgery.

Summary. Currently, there are fewer studies of actual behavior in response to various formats of risk and benefit information presentation than there are studies of more proximal outcomes such as perceived risk and information format preferences. Some evidence nonetheless suggests that numeric presentations of risk information sometimes are more likely to prompt decisions, such as the decision to take a particular drug, relative to non-numeric presentations. Such results might be a function of reduced perceptions of uncertainty provided with numeric formats. Our review nonetheless also highlights a key distinction that is relevant to thinking about behavior as an outcome—namely, that there is a difference between studying decision behavior generally and studying outcomes specifically associated with informed decision making. Although our review suggests that exposure to numeric presentations might be associated with some variables important to informed decision making (e.g., by reducing decisional conflict), the paucity of behavioral outcomes in many studies leaves us unable to offer a definitive conclusion.

IV. DISCUSSION

The purpose of this review was to examine the scientific evidence available to date to help assess the advantages and disadvantages of including quantitative summaries of the benefits and risks of drugs in a standardized format in promotional labeling and print advertising for prescription drugs. Our two key questions were

> **KQ1. What is the value of quantitative information or summaries about the risks and benefits of medical interventions for consumers, patients, and clinicians?**
>
> **KQ2. How does presentation of the quantitative information influence consumers', patients', and clinicians' processing and understanding of the risks and benefits of medical interventions?**

We created an organizing structure for the studies based on elements of leading models of consumer behavior. Using this approach, we categorized studies into the following outcome categories: (1) information format and style preferences, (2) knowledge and comprehension, (3) perceived risks and benefits, and (4) behavioral intentions and behaviors.

A disproportionate share of the studies addressed outcomes at the "early end" of the consumer behavior continuum—that is, information preferences, knowledge/understanding, and risk perceptions, which are considered more proximal outcomes. Fewer studies focused on distal outcomes, including behavioral intentions and actual behaviors. Almost all of the studies involved an intervention, which was often manipulated for research purposes. In some studies, multiple features of the intervention were manipulated, making it difficult to tease apart the specific reason for a significant effect if it occurred.

Finally, the quality of the studies varied in several ways. Some had important design limitations, including lack of randomization, nonexperimental designs, small sample sizes, comparison group constraints, problematic order effects, and simultaneously manipulating too many variables. Some studies used control groups that received a variation of the primary intervention; other control groups received a completely different intervention; and some studies had control groups that received no intervention at all. Given these limitations, it was not always possible to isolate the effects of certain conditions or features or draw firm conclusions. However, our synthesis of the literature allows us to draw some conclusions about the addition of quantitative information and summaries of benefits and risks to promotional labeling of prescription drugs, as well as limitations and suggestions for future research.

Observations and conclusions

Whereas none of the 52 studies were designed to specifically address our project's research questions, they provide some support for including numeric information in prescription drug ads. However, no one numeric format appeared to be superior to any other. This may be due to study design (i.e., not controlling for numeracy or level of education). Taken together, we made the following observations and drew the following conclusions from the body of literature we reviewed.

Numeric presentation of risk/benefit information was associated with a positive impact on several outcomes relative to non-numeric presentation of risk/benefit information. This pattern existed for a variety of outcomes, including information preferences, knowledge/understanding, and perceived risk. The pattern was clearest for studies that examined the impact of risk/benefit information on knowledge gained, with the presence of numeric information associated with more accurate knowledge gain.

Although study participants frequently *preferred* numeric information relative to non-numeric information in the studies we examined, consumer preferences can change over time (Slovic, 1987). The studies that examined behavioral outcomes (e.g., taking medications) often focused on hypothetical situations (i.e., if you had *x* disease and needed to choose a drug). It is unknown whether these findings can be generalized to real patients. A few studies that focused on actual behaviors provide some evidence supporting the utility of providing numeric information to patients. Most studies that looked at patient preferences did not examine how health literacy or numeracy skills related to preferences. Thus, it is difficult to know how preferences vary on these factors and whether these skills affect preferences.

Numeric information offers more precision that non-numeric data, which may be one reason for these findings. Presenting information non-numerically has some disadvantages—namely that descriptive terms (e.g., risk, increased, slight chance, very likely, and severe) are subject to individual interpretation. However, non-numeric information is descriptive and could be helpful for interpretation. We believe lack of common understanding of non-numeric terms used in interventions resulted in confounding in some of the studies, possibly even when researchers devised definitions for “standard” labels.

Psychological research has demonstrated that medical decisions are influenced by the way information is presented (Man-Son-Hing et al., 2002). Presenting *both* numeric and non-numeric information may be a middle ground because if offers the precision of numeric data with the qualitative context provided by non-numeric information. Some studies in our review support this notion, particularly helping the reader to understand relative or comparative risk. Discussion of contextual risk provides a reference point for interpreting risk so individuals do not resort to their own internal reference point or anchor for understanding it. Visual information may also provide support with interpretation. Of course, presenting more than one type of information risks information overload, but some (Lipkus, 2007) promote this approach. When using multiple formats, one should be careful not to provide too much information—especially too much narrative—or people will not absorb it.

The International Patient Decision Aids Standards Collaboration (IPDAS; http://www.decisionlaboratory.com/resources/background.pdf) makes several recommendations about how to clearly present medical information to promote informed decision making. IPDAS is a collaborative work group of experts from a variety of disciplines. IPDAS recommendations are based largely on theoretical grounds, borrowing heavily from work in clinical epidemiology and evidence-based health care, psychology, risk communication and risk perception research, and decision theory. Although the IPDAS recommendations provide guidance for developing decision aids, many of the principles and much of the guidance is likely to be relevant to prescription drug promotion. When presenting numbers, IPDAS indicates that numerical probabilities improve the accuracy of understanding. They recommend using event rates (natural frequencies) for presenting these probabilities. Event rates for all relevant options and all relevant outcomes should be made available according to IPDAS. One study (Garcia-Retamero & Galesic, 2009) in our review contradicts this recommendation, however. It discusses a phenomenon called *denominator neglect*, in which people focus on the numerator when numeric information is presented. Nonetheless, there is general agreement in the field that absolute risk should be used instead of relative risk (Edwards, Elwyn, & Mulley, 2002).

No format, structure, or graphical approach emerged as superior. Based on the studies we examined for this literature review, no single format, structure, or graphical approach rose above the others. Some studies advocated for certain approaches, such as Tait and colleagues (2010a), who favor and provide some support for the use of pictographs (versus tables and text). This falls in line with cognitive science research that offers insight into the design of information for consumers (Vaiana & McGlynn, 2002). According to Schank and Abelson (1977), a document's structure affects how well it is understood and remembered. Humans rely on hierarchal structure for comprehension and memory tasks. A hierarchical structure organizes more general information at the top with more specific information to follow, and schemata aid comprehension. Shah, Mayer, and Hegarty (1999) found that the perceptual organization of data significantly affects viewers' interpretation and understanding. They recommend visually "chunking" information in many data formats. It seems prudent that whatever is presented be kept simple.

Issues of scientific and statistical literacy, health literacy, and numeracy need to be considered when evaluating the literature. A few studies controlled for participants' health literacy or numeracy when examining their reactions to and the impact of numeric and non-numeric information. Numeracy is frequently considered to be a subset of health literacy. Lipkus and Peters (2009) define numeracy as how facile people are with mathematical concepts and their applications. Numeracy was an important moderating variable in some of the studies we examined, but it was not consistency evaluated across the pool of studies. Fagerlin and colleagues (2007) have previously noted that different risk communication methods may be needed for individuals with high versus low levels of numeracy.

Gigerenzer and colleagues (2008) purport that statistical illiteracy is common among patients and clinicians, and its causes should not be attributed to cognitive biases alone. Statistical and scientific literacy issues are pertinent when conveying issues of medical uncertainty, which is typical with risk communication. The risk communication literature offers some insight about effective ways to communicate complicated information and related uncertainty (Fischhoff, 1995; Slovic, 1987). Additionally, early randomized controlled trials have begun to examine the effects of alternate presentations of imprecision and uncertainty (Han, Klein, Killam, et al., 2011; Han, Klein, Lehman, et al., 2011).

When considering uncertainty, it is important to keep in mind that there are different sources of uncertainty that may need to be conveyed. Politi and colleagues (2007) summarize the five major categories as follows: (1) risk, or uncertainty about future outcomes; (2) ambiguity, or uncertainty about the strength or validity of evidence about risks; (3) uncertainty about the personal significance of particular risks (e.g., their severity, timing); (4) uncertainty arising from the complexity of risk information (e.g., the multiplicity of risks and benefits or the instability of risks and benefits over time); and (5) uncertainty resulting from ignorance. When communicating messages about medical uncertainty, those developing interventions must first educate audiences that there are limits to medical science, which some lay people find surprising (Evans & McCormack, 2008). Tailoring health information to individuals' needs, interests, and/or preferences can help mitigate the complexity of complex health information (Lewis & McCormack, 2008; Politi et al., 2007).

The way that information (numeric and non-numeric) about risk and benefits was presented makes interpretation of study results complicated. As noted previously, most of the studies we reviewed contained some type of intervention that was often manipulated for research purposes. Examples of interventions include randomized trials using Internet-based information, pamphlets, and decision aids. Often, risk and benefit information was presented simply as information on a piece of paper or computer screen to respondents who had no stake in the decision. For example, when the intervention involved medication, many of the studies included respondents who did not have the condition for which the drug would be used. Further, the amount of information about the drug or drug choices varied widely, and it did not appear that this factor was always considered when interpreting some study results.

Intervention framing is a major source of potential bias that can also affect interpretation of health-related information. Traditional framing research has focused on whether the information is presented with a negative or positive frame (Edwards, Elwyn, Covey, Matthews, & Pill, 2001). In general, negative framing has been shown to negatively influence perceptions and other outcomes (O'Connor, Llewellyn-Thomas, & Stacey, 2005). But several other kinds of frames exist, including subtle differences such as *the number of people who are likely to benefit from a treatment* versus *the number of people who are not likely to benefit*. Sometimes benefits are presented as relative risks (larger numbers), whereas risks are presented as absolute risk (smaller numbers). Gigerenzer and colleagues (2008) refer to this as "mismatched framing," which is one of several types of "non-transparent framing." It may be unintentional but is nonetheless potentially misleading.

We saw a variety of different ways to frame information in the studies we reviewed. Sustein and Thaler (2009) believe that neutral framing of information does not exist. They suggest that communications should employ formats that are likely to promote patients' welfare. Peters and colleagues (2007) encourage striving to present important health information to patients and their families so as to encourage the best decisions for all, without hurting those who might already be disadvantaged. IPDAS indicates that formats such as relative risk reduction (RRR), absolute risk reduction (ARR), and number need to treat (NNT) can be misleading because they do not make explicit the baseline risk of the target condition. Gigerenzer and colleagues (2008) also note the potential danger when presenting relative risk information without clearly specifying the base rate.

Limitations and future research

Overall, when reviewing the literature, we found similar limitations as previously reported by Lipkus (2007). These include the following: "1) lack of consistency in testing formats using the same outcome measures in the domain of interest, 2) lack of critical tests using randomized controlled studies pitting formats against one another, and 3) lack of theoretical progress detailing and testing mechanisms why one format should be more efficacious in a specific context to affect risk magnitudes than others" (p. 710). In addition, we could not determine whether the authors cognitively pretested their interventions, which is advisable (Forsyth & Lessler, 1991). Some studies did not consider health literacy best practices when developing their interventions, and, in the case of computer-based interventions, human factors engineering issues. As noted previously, several studies did not consider important moderators such as health literacy and numeracy.

Among the studies we reviewed, too few addressed the end point of the health communication spectrum (i.e., actual behaviors), which is needed for a more complete picture. Our search did not address the impact of providing information on patient-provider communication (McCormack, Williams-Piethota, & Bann, 2009), which is an underlying element of informed decision making. Clinicians need to take careful account of what their patients understand and correct misinterpretations to promote informed decision making (McCormack, Bann, et al., 2009). Given the limited consensus over any single modality of translating medical evidence, it is essential that physicians be patient centered, generate trust, and build a partnership with their patients (Epstein, Alper, & Quill, 2004; Ghosh & Ghosh, 2005). Finally, longitudinal studies with real patients would provide the opportunity to draw more firm conclusions.

Overall, few guidelines exist on evaluating the efficacy of risk communication (Edwards & Elwyn, 1999; Fischhoff, 1995; Rohrmann, 1992; Weinstein & Sandman, 1993), but some recommendations have begun to emerge (Lipkus, 2007). Future studies should consult these guidelines and use well-designed studies that specifically pit numeric and non-numeric data and different formats against one another. When these limitations are addressed, the following question can be more directly answered: *What is the impact of adding quantitative data or summaries to drug ads on informed decision making?*

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Appendix B: Literature Search Strategy

February 23, 2011. PubMed update: expanded search terms and journals, and limiting to 1990-present.

Search	Queries	Result
#1	Search Risk Assessment [MeSH] OR "risk communication"[TW] OR "communicating risk"[TW] OR "communic* risk"[TW]	127008
#2	Search “drug risks” OR (benefit[tiab] AND risk[tiab])	39950
#3	Search #1 or #2	162839
	Line #3 collects the risk terms.	
#4	Search Communication[Majr]	156411
#5	Search #3 and #4	2069
	Here and below, combining individual communication/comprehension terms with the pool of articles about risk	
#6	Search Comprehension[Majr]	2189
#7	Search #3 and #6	134
#8	Search Decision Making[Majr]	39634
#9	Search #3 and #8	1518
#10	Search Patient Participation[Majr]	7298
#11	Search #3 and #10	352
#12	Search "Knowledge of Results (Psychology)"[Mesh]	745
#13	Search #3 and #12	7
#14	Search "Patient Education as Topic"[Mesh]	60227
#15	Search #3 and #14	1839
#16	Search Physician-Patient Relations[Mesh]	52138
#17	Search #3 and #16	1300
#18	Search Numeracy[TW]	310

#19	Search #3 and #18	43
#20	Search "decision aids"[TW] OR "decision aid"[TW]	905
#21	Search #3 and #20	103
#22	Search "Attitude to Health"[Majr]	112089
#23	Search #3 and #22	3402
#24	Search "Decision Support Techniques"[Majr]	12871
#25	Search #3 and #24	761
#26	Search Uncertainty[Mesh]	3694
#27	Search #3 and #26	706
#28	Search "Drug Labeling"[Mesh]	4837
#29	Search #3 and #28	167

I included Drug Labeling here, with the rest of the communications terms. The other extra terms I "fit into the search" were searched on their own below, without combining them first with the pool of risk literature.

#30	Search #5 or #7 or #9 or #11 or #13 or #15 or #17 or #19 or #21 or #23 or #25 or #27 or #29	9690

Collecting all communication and risk literature, before limits

#31	Search #30 Limits: Humans, English	8806
#32	Search #31 Limits: Editorial, Letter, Meta-Analysis, Practice Guideline	667
#33	Search #31 NOT #32	8139
#34	Search #33 Limits: Publication Date from 1990/01/01 to 2011/02/23	7337
#35	Search "Program Development"[MeSH] OR "Program Evaluation"[MeSH] OR "Disease Management"[MeSH] OR "Risk Factors"[Mesh] OR "Logistic Models"[Mesh]	531307
#36	Search #34 NOT #35	**5413**

Line #36 is the "base literature," with limits. We limited to Human populations, English language articles published between January 1, 1990 - February 23, 2011, and removed various unwanted study and publication types.

#37	Search "Randomized Controlled Trial"[Publication Type] OR "Single-Blind Method"[MeSH] OR "Double-Blind Method"[MeSH] OR "Random Allocation"[MeSH]	377848
#38	Search #36 and #37	**277**
	277 citations are RCTs.	
#39	Search "Comparative Study"[Publication Type] OR "Cohort Studies"[Mesh] OR "Cross-Sectional Studies"[Mesh] OR "Evaluation Studies as Topic"[Mesh] OR "Prospective Studies"[Mesh]	3053481
#40	Search #36 and #39	**1684**
	1684 citations are prospective studies.	
#41	Search Interview[Publication Type] OR "Interviews as Topic"[Mesh] OR Questionnaires[Mesh] OR "Health Care Surveys"[Mesh]	292872
#42	Search #36 and #41	**1001**
	1001 citations are qualitative studies.	
#43	Search #38 or #40 or #42	**2384**
	Line #43 collects the RCTs, prospective and qualitative studies and removes duplicates.	
#44	Search "Am J Health Behav"[Journal]	691
#45	Search "Risk Anal"[Journal]	2106
#46	Search "Patient Educ Couns"[Journal]	3140
#47	Search "Med Decis Making"[Journal]	1675
#48	Search "Health Commun"[Journal]	581
#49	Search "J Health Commun"[Journal]	755
#50	Search "J Exp Psychol Appl"[Journal]	267
#51	Search "Med Care Res Rev"[Journal]	555
#52	Search "Health Educ Behav"[Journal]	744
#53	Search "Health Expect"[Journal]	509
#54	Search "BMC Public Health"[Journal]	2848

#55 Search "BMC Med Inform Decis Mak"[Journal] 391

#56 Search "PLoS Med"[Journal] 1728

#57 Search "PLoS One"[Journal] 16289

#58 Search #44 or #45 or #46 or #47 or #48 or #49 or #50 or #51 or #52 or #53 or #54 or #55 or #56 or #57 32279

We are limiting the search further to specific journals of interest. Line 58 collects these.

#59 Search #43 and #58 **162**

162 of the 2384 RCTs, prospective and qualitative studies are in these selected journals.

#60 Search #43 Limits: Core clinical journals **333**

We are also including the RCTs, prospective and qualitative studies we found that are in the Core clinical journals subset in Medline, the most prestigious peer-reviewed clinical literature indexed in Medline.

#61 Search #59 or #60 **495**

Combining the 162 hand-selected journal results with the Core clinical journal subset and removing duplicates, there are 495 results.

#62 Search “drug benefit”[tw] OR “drug facts box”[tw] OR “benefit data”[tw] OR "Advertising as Topic/methods"[Majr] OR "Consumer Health Information/methods"[Majr] 1471

These are terms that did not fit neatly into the main search, and which I searched on their own, without combining them with the risk pool of literature. They are, however, subject to all the same limits as the main risk/communication search above.

#63 Search #62 Limits: Humans, English, Publication Date from 1990/01/01 to 2011/02/23 1110

#64 Search #63 Limits: Editorial, Letter, Meta-Analysis, Practice Guideline 67

#65 Search #63 NOT #64 1043

#66 Search #65 NOT #35 952

Above, removing unwanted study types and publication types from the “extra” search terms’ results.

#67 Search #66 and #37 **32**

Combining extra search terms with the RCT search string – 32 are RCTs

#68 Search #66 and #39 **198**

Combining extra search terms with the prospective studies search string - 198

#69 Search #66 and #41 **94**

Combining extra search terms with the qualitative studies search string - 94

#70 Search #67 or #68 or #69 268

Combining all study types for the extra search terms and removing duplicates

#71 Search #70 and #58 **19**

Limiting the various study types for the extra terms to the journals selected - 19

#72 Search #70 Limits: Core clinical journals **40**

Also limiting the various study types for the extra terms to the Core clinical journals subset - 40

#73 Search #71 or #72 **59**

Combining selected journals with Core clinical journal results and removing duplicates.

#74 Search #61 or #73 **550**

Combining the main search results with the extra search term results and removing duplicates. This is the final total.

Appendix C: Evidence Tables in Alphabetical Order by First Author

Evidence Tables