

Strategic Risk Communication

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People face many decisions where they need trusted, comprehensible information about risks and benefits.

People face many decisions where they need trusted, comprehensible information about risks and benefits.

What they get is often disappointing.

Use of therapy to inhibit hyperandrogenic reactions to steroid hormones may occur after the chronic administration of budesonide. Side reactions of wheezing, nasal stuffiness, and increased mucous production have been reported following the long-term use of inhaled glucocorticosteroids. Like other glucocorticosteroids, budesonide is absorbed into the circulation. Use of oral and nasal glucocorticosteroids may lead to signs or symptoms of hyperandrogenism. Suppression of hair growth and/or suppression of growth in children or teenagers is not known to be a clinical effect of budesonide. The degree of hair loss may be greater than expected if the other adrenal and/or pituitary hormones which have been shown to suppress hair growth are also inhibited. The clinical significance of the finding is not known. In long-term studies of 32 chronic steroid-requiring patients of 16-year-old black female height and weight, there were associations with osteoporosis. Physicians should closely follow the growth of chronically treated, by age 16, girls, and weigh the benefits of chronic therapy against the possibility of growth suppression if a child's growth appears slowed.

Although systemic effects have been minimal with recommended doses of Budesonide Nasal Inhaler, the potential risk increases with long-term therapy. Therefore, longer than recommended doses of Budesonide Nasal Inhaler are to be avoided.

What side effects may occur? Systemic glucocorticosteroid effects such as hyperandrogenism and adrenal suppression may occur. If such changes occur, the degree of Budesonide Nasal Inhaler should be reduced until symptoms with proper procedures for decreasing the glucocorticosteroid therapy.

In clinical studies with budesonide administered intranasally, the development of localized infections of the nose and pharynx with *Candida albicans* was reported only rarely. When such an infection develops, treatment with appropriate oral therapy and discontinuation of treatment with Budesonide Nasal Inhaler. Patients using Budesonide Nasal Inhaler over several months or longer should be examined periodically for evidence of *Candida albicans* or other signs of infection, either in the nasal mucosa.

Patients using Budesonide Nasal Inhaler should be aware that, if in use, in patients with signs or symptoms of tuberculosis, untreated, untreated, latent, or untreated and untreated, or acute tuberculous infection.

Because of the inhibitory effect of glucocorticosteroids on several bodily systems, side effects have been reported which may include osteoporosis, nasal bleeding, or nasal burning should not use a nasal glucocorticosteroid nasal inhaler for longer than 3 months unless you have been instructed by your physician. Patients using Budesonide Nasal Inhaler should be instructed in the following administration and maintenance.

Patients should use Budesonide Nasal Inhaler as prescribed. A decrease in symptoms may occur as soon as 24 hours after correct glucocorticosteroid therapy has been initiated and assessed in prior weeks. A few days of continuing therapy in alternate nostrils. The patient should consult the physician if symptoms do not improve by three weeks, or if the condition worsens. Never inhale directly during after use of the spray since spray directly into the product. The patient should contact the physician if they notice any side effects which are not characteristic of the product. If any side effects are observed, the patient should consult the physician. Patients should also be advised that if they are exposed they should consult the physician without delay.

For the proper use of this and all other inhalers on improvement, the patient should read and follow the accompanying patient instructions carefully.

Contraindications, Warnings, Impairment of fertility, Long-term studies were conducted in mice and rats using oral administration to evaluate the carcinogenic potential of budesonide.

There was no evidence of a carcinogenic or mutagenic budesonide was administered orally for 27 weeks at two or three times the ED₀₁ (approximately 100 µg/day).

In a 104-week carcinogenicity study in Sprague-Dawley rats, it is a statistically significant increase in the incidence of adenomas was observed in male rats receiving 30 µg/kg/day (300 µg/m²/day), but not observed in male rats receiving 10 µg/kg/day (100 µg/m²/day) or 30 µg/kg/day (300 µg/m²/day) or in female rats at any dose. Two additional 104-week carcinogenicity studies have been performed with the budesonide doses of 30 µg/kg/day (300 µg/m²/day) in male Sprague-Dawley and F344 rats. These studies did not demonstrate an increase in adenomas or adenocarcinomas in either sex compared with untreated controls. In reference glucocorticosteroid treated groups (prednisone and hydrocortisone acetate).

Conducted with Sprague-Dawley rats. Male Sprague-Dawley rats were a statistically significant increase in the incidence of hepatocellular adenomas, adenocarcinomas, and/or adenomas in the female rats in the Sprague-Dawley rats.

The mutagenic potential of budesonide was evaluated in an altered test system: Ames Salmonella mutagenicity assay. Budesonide was tested in the Ames Salmonella mutagenicity assay with *S. typhimurium* and *S. typhimurium* histidine revertant. No mutagenic or cytogenic properties of budesonide were found in any of the tests.

The effect of budesonide on general reproductive performance was studied in rats given budesonide subcutaneous. At 25 µg/kg/day (250 µg/m²/day) and higher doses there is a decrease in maternal body weight gain who observed along with a decrease in prenatally and viability of the young at birth and during lactation. No such effects were noted at the dose level 10 µg/kg/day (100 µg/m²/day).

Reproductive Effects. Pregnancy. Category C. Do not use oral glucocorticosteroids budesonide (budesonide) if you are pregnant and especially in early and late when given subcutaneously at doses exceeding 5 and 10 µg/kg/day (50 and 100 µg/m²/day), respectively. In these studies budesonide at 25 µg/kg/day (250 µg/m²/day) given to rats from 14 days prior to pregnancy until day 21 of pregnancy, the incidence of stillbirths and abortions were decreased but weight and survival decreased. No teratogenic or embryotoxic effects have been seen in rats when budesonide was administered by inhalation at doses of 100-250 µg/kg/day (1000-2500 µg/m²/day), approximately 21-42 days before the human recommended starting dose based on body weight of 4-16 times the human dose based on µg/m²/day.

There are no adequate and well-controlled studies in pregnant women. Budesonide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Experience with oral glucocorticosteroids shows their administration in pregnancy is associated with an increased risk of congenital anomalies. In addition, consider there is a slight increase in glucocorticosteroid production during pregnancy, most women will require a lower degree of glucocorticosteroid therapy and long-term oral glucocorticosteroid treatment during pregnancy.

When pregnancy occurs, budesonide may cause an embryo-fetal risk. Maternal glucocorticosteroids during pregnancy, such as budesonide, should be carefully monitored. During lactation, it is not known whether budesonide is excreted in human milk. Because oral glucocorticosteroids are excreted in human milk, caution should be exercised when Budesonide Nasal Inhaler is administered to nursing women. Budesonide Nasal Inhaler, and other corticosteroids in children under 2 years of age, have not been evaluated. Oral glucocorticosteroids have been shown to cause growth suppression in children and teenagers with untreated airway disease or teenagers on any glucocorticosteroid therapy. It is not known whether the position that they are particularly sensitive to the effect of glucocorticosteroids should be evaluated (see PRECAUTIONS).

ADVERSE REACTIONS: Information is derived from controlled clinical trials and Group 1 trials, even when studies and marketing experience. In the description below, side effects are derived principally from marketing experience and publications, and accurate estimates of incidence are not possible.

The incidence of common adverse reactions is based upon controlled clinical trials in 806 patients (101 girls and 146 boys 1-16 years of age and 200 women age 17-65 years) treated with Budesonide Nasal Inhaler. 120 µg/day (120 µg/day) only once 2-4 weeks. The most common adverse reactions were symptoms of infection of the nasal mucosa/membrane. All common adverse reactions were treated with appropriate, the same frequency to placebo patients suggesting the possibility that the vehicle or the nasal itself was responsible for the symptoms. Bleeding after use of the Budesonide Nasal Inhaler in 2% of Budesonide treated patients and in 11% of placebo using the placebo. Systemic glucocorticosteroid side effects were not reported during controlled clinical studies with Budesonide Nasal Inhaler. If hyperandrogenism or an excessive increase, or if individuals are particularly sensitive, symptoms of hyperandrogenism, i.e., Cushing's syndrome, may occur.

Side Effect Group 1: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 2: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 3: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 4: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 5: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 6: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 7: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 8: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 9: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 10: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 11: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 12: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 13: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 14: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 15: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 16: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 17: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 18: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 19: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 20: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 21: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 22: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 23: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 24: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 25: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 26: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 27: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 28: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

Side Effect Group 29: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

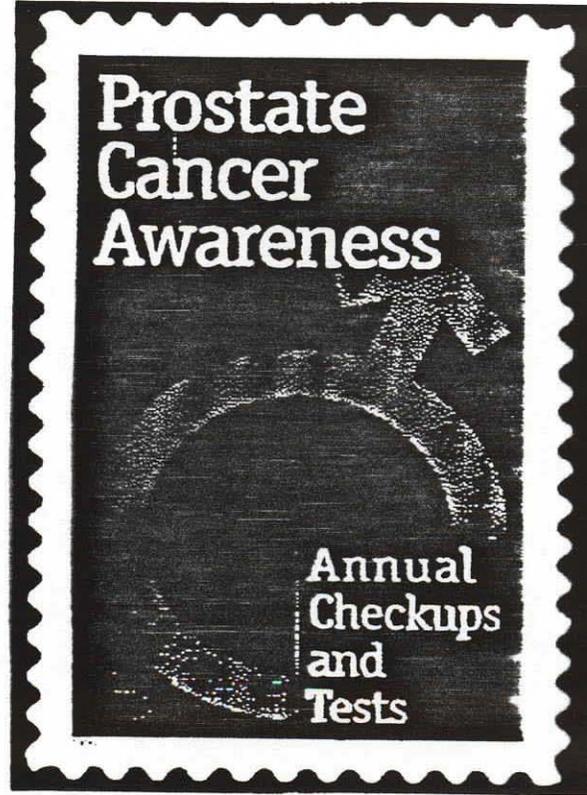
Side Effect Group 30: 15. (Based on controlled clinical trials):
Respiratory tract infection, pharyngitis, cough increased, asthma, Epistaxis, dry mouth, dysphagia.

IN-TACH-FLU-DA FOR PATIENT'S INSTRUCTIONS FOR USE

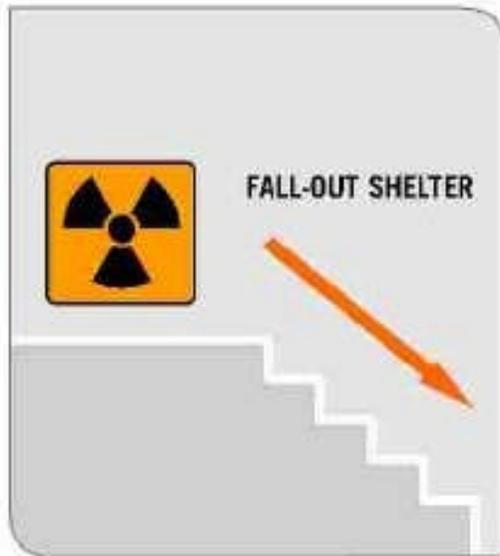
WARNING: Contains xylometazoline/hydrocortisone, decongestant/steroid, and dexamethasone, substances which harm the environment by destroying ozone in the upper atmosphere. Your physician has determined that this product is likely to help your general health. USE THIS PRODUCT AS DIRECTED, UNLESS INSTRUCTED TO DO OTHERWISE BY YOUR PHYSICIAN. If you have any questions about alternatives, consult with your physician.

N.B.
Follow your doctor's directions and do not use Budesonide Nasal Inhaler more often than prescribed. Contact your doctor if you find the effect strongly reduced.

Budesonide Nasal Inhaler does not give immediate relief. Generally it will take a few days to achieve full effect. It is therefore very important that Budesonide Nasal Inhaler be used regularly.
To be used within 8 months after the aluminum pouch has been opened.
After opening the pouch, avoid storage in areas of high humidity.
Cleaning: Remove the aerosol container and wash the plastic parts regularly in warm-hot water with addition of mild detergent if necessary. Allow the plastic parts to dry completely and then replace the container.
Contents under pressure. Do not puncture or throw container into fire, water, using or placing near open flame or heating above 120°F (50°C). May cause container to burst.
Manufactured by Astra-USA, Inc., Middleburg, NJ 07941
100713707 (1-86)



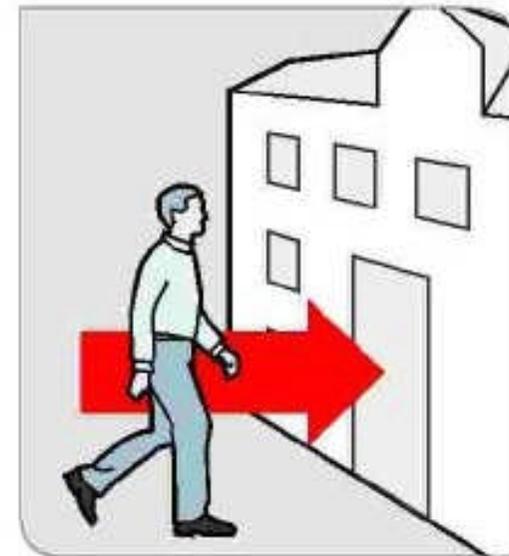
BE INFORMED NUCLEAR BLAST



1. Take cover immediately, below ground if possible, though any shield or shelter will help protect you from the immediate effects of the blast and the pressure wave.



2. Consider if you can get out of the area;



3. Or if it would be better to go inside a building and follow your plan to "shelter-in-place".

(http://www.ready.gov/america/_downloads/nuclear.pdf
)

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**Failure, despite good intentions,
suggests flawed management.**

Strategic Management Requires

Philosophy

Leadership

Staffing

Methodology

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Staffing

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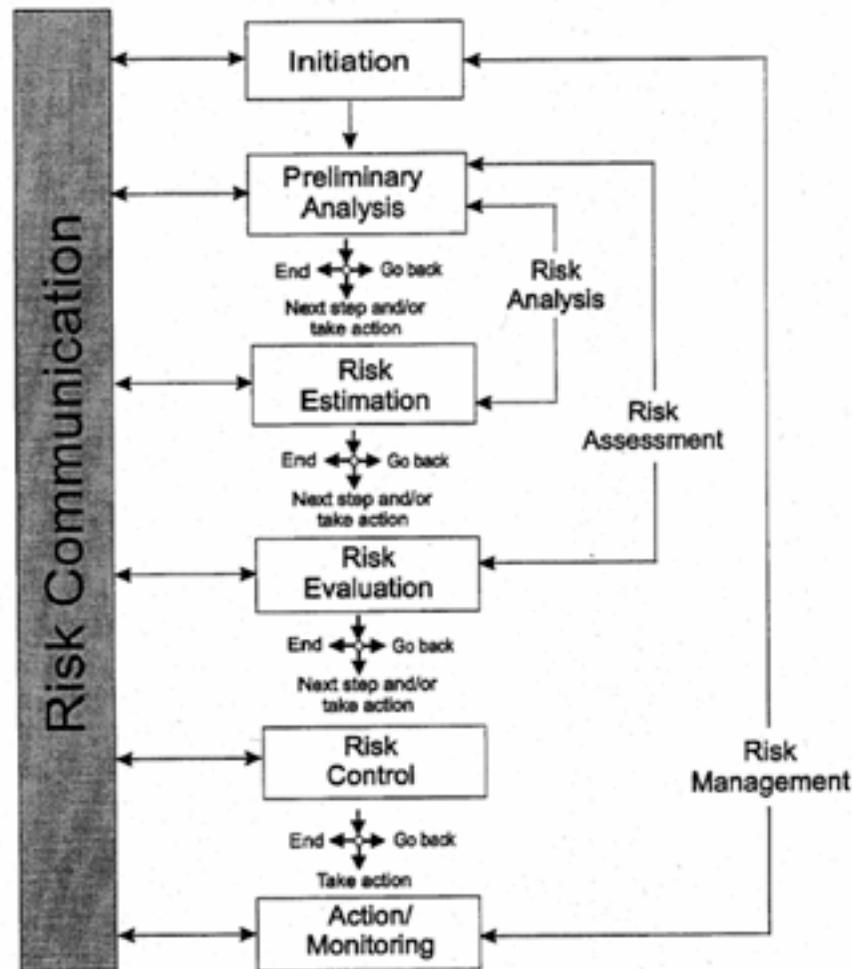
Methodology



CAN/CSA-Q850-97
***Risk Management:
Guideline for
Decision-Makers***

*A National Standard of
Canada*





Note: Risk communication with stakeholders is an important part of each step in the decision process.

Figure 2
Steps in the Q850 Risk Management Decision-Making
Process — Simple Model

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**Strategic Plan for
Risk Communication at the
Food and Drug
Administration**

Draft: April 15, 2009

Principles: Risk Communication

is multi-faceted

conveys potential for good and bad
outcomes

is a two-way street

is science based

provides context

is tailored to audience needs

Strategic Goals

Strengthen the *science* that supports effective risk communication

Expand FDA's *capacity* to generate, disseminate, and oversee effective risk communication

Optimize FDA's *policies* on communicating product risks and benefits

The FDA as a Public Health Agency

Margaret A. Hamburg, M.D., and Joshua M. Sharfstein, M.D.

A little more than a century ago, concerned about the potential dangers of food preservatives such as formaldehyde, Congress passed, and President Theodore Roosevelt signed, the Pure Food and Drug

Act. The act sought to prevent the “manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors.” The office initially charged with this responsibility was the Bureau of Chemistry of the Department of Agriculture.

Since that time, the bureau has grown into the Food and Drug Administration (FDA), an agency in the Department of Health and Human Services (DHHS) responsible for oversight of more than \$2 trillion in medical products, food, and other consumer goods. What has remained constant is the agency’s “overriding purpose,” in the words of the Supreme Court

of protecting the public health.¹ As the new commissioner and principal deputy commissioner of the FDA chosen by President Barack Obama, we would like to provide a broad overview of how we intend to embrace this role.

The Institute of Medicine has defined the mission of public health as “fulfilling society’s interest in assuring the conditions in which people can be healthy.” To be healthy, people need access to a safe and nutritious food supply and to innovative, safe, and effective medical products. The FDA’s job is to support this access and, in doing so, to promote health, prevent illness, and prolong life. The ultimate mea-

asures of the FDA’s success should reflect its fundamental goals and go beyond such intermediate measures as the number of facilities inspected or drugs approved.

The urgent need to develop and produce a vaccine against H1N1 influenza virus provides an illustration of the agency’s public health role. Laboratory scientists at the FDA are growing the virus and will make reagents for vaccine-potency testing, reviewers will help to design and oversee the clinical trials, and inspectors will oversee the quality of the production process. The agency’s success will be determined by the nation’s access to a safe and effective vaccine.

The traditional tools of a regulatory agency are regulation, approval or disapproval of applications, and enforcement. As a public health agency, the FDA should always ask whether delays

The FDA's job is to minimize risks through education, regulation, and enforcement. To be credible ..., the agency must communicate frequently and clearly about risks and benefits...

For these communications to have credibility, the public must trust the agency to base its decisions on science. [That] requires a culture that encourages scientific exchange and respects alternative viewpoints.

Transparency is a potent element ... to enhance the work of the FDA and its credibility ... Whenever possible, the FDA should provide the data on which it bases its regulatory decisions ... and explain its decision-making process to the public.

Strategic Management Requires

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Staffing Needs

Domain specialists, for representing the science relevant to the decisions

Decision analysts, for identifying the information critical to choices

Social scientists, for designing and evaluating human engagement

System specialists, for creating and maintaining engagement channels

Staffing Needs

Domain specialists, for representing the science relevant to the decisions

Decision analysts, for identifying the information critical to choices

Social scientists, for designing and evaluating human engagement

System specialists, for creating and maintaining engagement channels

All working on their own tasks

Supply-Side Barriers

separation of analytical, descriptive,
intervention researchers

isolation of researchers from
practitioners

sweeping claims about competence

predisposition toward manipulation

...

Demand-Side Barriers

institutional inertia

inappropriate staffing

isolation from lay concerns

indifference to lay concerns

incentive for lay confusion

...

Political Aversion to Evidence: Claims of Public Competence

Political predisposition:	“liberal”	“conservative”
Behavioral assumption:		
hyper-rational public	popular democracy	free markets
irrational public	paternalistic regulation	technocratic control

Strategic Management Requires

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A Complex Working Hypothesis

People usually do sensible things if they

- get relevant information in a concise, credible, comprehensible form
- are judged by their own goals.
- have control over their environment
- have basic decision-making competence

- Downs, J. S., Bruine de Bruin, W., & Fischhoff, B. (2008). Patients' vaccination comprehension and decisions, *Vaccine*, 26, 1595-1607.
- Eggers, S.L., & Fischhoff, B. (2004). A defensible claim? Behaviorally realistic evaluation standards. *Journal of Public Policy and Marketing*, 23, 14-27.
- Fischhoff, B. (1992). Giving advice: Decision theory perspectives on sexual assault. *American Psychologist*, 47, 577-588.
- Fischhoff, B. (1994). What forecasts (seem to) mean. *International Journal of Forecasting*, 10, 387-403.
- Fischhoff, B. (1995). Risk perception and communication unplugged. *Risk Analysis*, 15, 137-145.
- Fischhoff, B. (2005). Cognitive processes in stated preference methods. In K-G. Mäler & J. Vincent (Eds.), *Handbook of Environmental Economics* (pp. 937-968). Amsterdam: Elsevier
- Fischhoff, B. (2005). Decision research strategies. *Health Psychology*, 24(4), 1-8.
- Fischhoff, B. (2006, May). Communication: Getting straight talk right. *Harvard Business Review*, 8.
- Fischhoff, B. (2007). Non-persuasive communication about matters of greatest urgency: Climate change. *Environmental Science & Technology*, 41, 7204-7208.
- Fischhoff, B. (2009). The nuclear energy industry's communication problem. *Bulletin of the Atomic Scientists*. <http://www.thebulletin.org/web-edition/features/the-nuclear-energy-industrys-communication-problem>
- Fischhoff, B. (2009). Risk perception and communication. In R. Detels, R. Beaglehole, M.A. Lansang, and M. Gulliford (eds), *Oxford Textbook of Public Health, Fifth Edition*. Oxford: OUP.
- Fischhoff, B., Atran, S., & Fischhoff, N. (2007). Counting casualties: A framework for respectful, useful records. *Journal of Risk and Uncertainty*, 34, 1-19
- Fischhoff, B., Bruine de Bruin, W., Guvenc, U., Caruso, D., & Brilliant, L. (2006). Analyzing disaster risks and plans: An avian flu example. *Journal of Risk and Uncertainty*, 33, 133-151,
- Krishnamurti, T.P., Eggers, S.L., & Fischhoff, B. (2008). The effects of OTC availability of Plan B on teens' contraceptive decision-making. *Social Science and Medicine*, 67, 618-627.
- Morgan, M.G., Fischhoff, B., Bostrom, A., & Atman, C. (2001). *Risk communication: The mental models approach*. New York: Cambridge University Press.

Center for Risk Perception and Communication: <http://sds.hss.cmu.edu/risk/>
Center for Behavioral Decision Research <http://cbdr.cmu.edu/>