Social Behavioral and Decision Science in Risk Management

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Governance of Dual Use Research in the Life Sciences:
Advancing Global Consensus on Research Oversight

Zagreb, Croatia
May 1, 2018
Human Behavior in Risk Management

Biosafety: How materials are handled
Biosecurity: How other parties use research
Risk analysis: Predicting risks (and benefits)
Risk management: Addressing risks (and missed benefits)
Risk communication: Addressing others’ concerns
Behavior Follows Simple Principles
Some Simple Principles of Judgment

People are good at tracking what they see, but not at detecting sample bias.
People have limited ability to evaluate the extent of their own knowledge.
People have difficulty imagining themselves in other visceral states.
People have difficulty projecting non-linear trends.
People confuse ignorance and stupidity.
Some Simple Principles of Choice

People consider the return on their investment in making decisions.
People dislike uncertainty, but can live with it.
People are insensitive to opportunity costs.
People are prisoners to sunk costs, hating to recognize losses.
People may not know what they want, especially with novel questions.
Behavior Follows Simple Principles

However, the set of principles is large, the contextual triggers are subtle, and the interactions are complex. As a result, broad knowledge and detailed analysis are needed.
Application Design Process

Analysis: What decisions do people face?
Description: How do they make them?
Intervention: How can they make them better?
Some Applications

radon  sexual assault
pre-term birth  methylene chloride
LNG  EMF
climate change  avian flu
phishing  palliative care
breast cancer  breast implants
nuclear explosions  nuclear energy in space
tornadoes  Plan B (morning after pill)
xenotransplantation  HIV/AIDS
smart meters  vaccines (anthrax, MMR)
...
...
Gain-of-Function Research for Pathogens with Pandemic Potential
Infectious Disease Threats

Environmental Justice

BOX 1-1 THREE PRINCIPLES FOR PUBLIC HEALTH RESEARCH TO ADDRESS ENVIRONMENTAL JUSTICE ISSUES

1. Improve the science base. More research is needed to identify and verify environmental etiologies of disease and to develop and validate improved research methods.

2. Involve the affected populations. Citizens from the affected population in communities of concern should be actively recruited to participate in the design and execution of research.

3. Communicate the findings to all stakeholders. Researchers should have open, two-way communication with communities of concern regarding the conduct and results of their research activities.

http://www.nap.edu/catalog/6034/toward-environmental-justice-research-education-and-health-policy-needs
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Human Behavior in Risk Management: Good News

A century-plus of basic science
Applications to many risks
Benefits to basic science from applications
  applied basic science
  basic applied science
Human Behavior in Risk Management: Bad News

Everyone is an intuitive behavioral scientist (so actual science seems unneeded). Institutions lack expertise or absorptive capacity. Scientists may have perverse incentives.
Possible Solutions

Make research accessible
Create adaptable templates
Establish working relations
Possible Solutions

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Possible Solutions

Make research accessible
**Create adaptable templates**
Establish working relations
Communication Process

H5N1: Pharmacological Interventions

COMMUNICATING RISKS AND BENEFITS:
An Evidence-Based User’s Guide

Baruch Fischhoff PhD,
Noel T. Brewer PhD, & Julie S. Downs PhD, editors

http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm268078.htm
Each Chapter

Summarizes the science
Offers best guesses at practical implications
Shows how to evaluate communications
  for no money at all
  for a little money
  for money commensurate with the personal, organizational, and political stakes riding on effective communication
Possible Solutions

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Establish working relations
NRC Committee on Behavioral Science for Intelligence Analysis

Consensus Report

http://www.nap.edu/catalog.php?record_id=13040

Edited Readings

http://www.nap.edu/catalog.php?record_id=13062
FOUNDATIONAL CYBERSECURITY RESEARCH
IMPROVING SCIENCE, ENGINEERING, AND INSTITUTIONS
An Organizational Model for Behavioral Science

Basic familiarity with behavioral science
Ongoing contact with behavioral scientists
In-house absorptive capacity
FDA'S
STRATEGIC PLAN
FOR
RISK COMMUNICATION

Fall, 2009
Charter of the Risk Communication Advisory Committee to the Food and Drug Administration

Authority:
The Advisory Committee on Risk Communication, referred to herein as the Risk Communication Advisory Committee, was established by 21 U.S.C. 360bbb-6, as added by section 917 of the Food and Drug Administration Amendments Act of 2007. The Committee is also governed by 21 CFR Part 14 and Pub. L. 92-463 (5 U.S.C. App.), the Federal Advisory Committee Act, which sets forth standards for the formation and use of advisory committees.

http://www.fda.gov/oc/advisory/OCRCACACpg.html
Recommendations for Managing Emerging Events

Have a consistent policy in all domains
Provide useful, timely information
Address: risks and benefits, uncertainty, personal actions, FDA actions
Audience needs should drive agency analyses
Use standard formats; evaluate routinely
Consider needs of diverse populations

http://www.fda.gov/oc/advisory/OCRCACACpg.html
Structured Approach to Benefit-Risk Assessment in Drug Regulatory Decision-Making
Draft PDUFA V Implementation Plan - February 2013
Fiscal Years 2013-2017
Benefit-Risk Framework Development Process

Three years of consultation with review staff.
Testing with twelve reviews.
Oversight by senior FDA staff.
Topic in PDUFA V (and VI) negotiations.
Five years of staff implementation.
Informed by FDA Risk Communication Advisory Committee work.
Figure 1: FDA Benefit-Risk Framework

<table>
<thead>
<tr>
<th>Decision Factor</th>
<th>Evidence and Uncertainties</th>
<th>Conclusions and Reasons</th>
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</thead>
<tbody>
<tr>
<td>Analysis of Condition</td>
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<td>Current Treatment Options</td>
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<td>Benefit</td>
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<td>Risk</td>
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<tr>
<td>Risk Management</td>
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Benefit-Risk Summary Assessment

Benefit-Risk Framework
Design Principles - Internal

Inform, not replace judgment.
Facilitate review staff work.
Quantify what is possible, analyze the rest.
Accommodate heterogeneous patient preferences.
Accommodate heterogeneous regulatory objectives.
Benefit-Risk Framework
Design Principles - External

Immediately communicate key FDA concerns.
Gradually communicate FDA’s regulatory tradeoffs.
Facilitate hearing stakeholder voices.
Encourage appropriate product development and usage.
Improve transparency of regulatory process.
The Voice of the Patient

A series of reports from the U.S. Food and Drug Administration’s (FDA’s) Patient-Focused Drug Development Initiative

Chronic Fatigue Syndrome and Myalgic Encephalomyelitis

Public Meeting: April 25, 2013
Report Date: September 2013
Design Principles in Voice of the Patient Initiative

Enlist stakeholders in informing agency. Allow stakeholders to express themselves in their own terms. Preface interactions with regulatory view. Leave relevance assessment to regulators. Developed iteratively with diverse stakeholders.

Opioids

<table>
<thead>
<tr>
<th>Decision Factor</th>
<th>Evidence and Uncertainties</th>
<th>Conclusions and Reasons</th>
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<tbody>
<tr>
<td>Characteristics of Opioid</td>
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<td>How Opioid Fits among Currently Available Pain Treatment Options</td>
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<td>Benefits Observed in Clinical Trials, Overall</td>
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<tr>
<td>• Benefits to patients</td>
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<td>• Public health benefits</td>
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<tr>
<td>Predicted Benefits/Risks to Families of Patients</td>
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<td>Predicted Benefits/Risks to Society, Overall</td>
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<td>• Special communities</td>
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<td>• Subpopulations</td>
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<td>Diversion Potential</td>
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<tr>
<td>Predicted Effects on Use of Other Opioids or Illicit Drugs</td>
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<td>Risk Management, Overall</td>
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<tr>
<td>• Potential for off-label use</td>
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<tr>
<td>• Advertising/promotion</td>
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Possible Solutions

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Establish working relations