

The Annapolis Center For Science-Based Public Policy



"Our greatest responsibility is to be good ancestors."

...Jonas Salk

How Can I Judge Good Science?

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We are pleased to attribute the cover photograph of the earth to Harrison H. Schmitt, Ph.D. This photograph was taken during the 1972 Apollo 17 flight on which Dr. Schmitt served as Lunar Module Pilot. Dr. Schmitt, the last person to step onto the moon, is Chairman Emeritus of The Annapolis Center.

Rational Thinking vs. Emotional Responses

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As that great American Philosopher and former New York Yankee baseball great, Yogi Berra, said, “When you come to a fork in the road, take it!”

Yogi was right, of course. We all come to those forks along whatever roads we travel...and in order to keep moving, we do “take it”. But the question will always remain, which one? How do we know which of two (or more) choices is the right one, the correct one, or the one which produces the maximum result for the least expenditure of resources, the most efficient expenditure of limited resources, and the biggest payoff for our efforts?

It seems that weekly, if not daily, Americans are faced with new alleged hazards to their health and environment. Well-meaning scientists, with impressive credentials, provide “scientific conclusions” that prove, beyond the shadow of a doubt, ostensibly valid, but polar opposite conclusions on the risks of these threats. How can scientists, doctors, and a plethora of “experts” come up with contradictory results with what appears to be the same facts? How is this even possible in an enlightened society and how, pray tell, does a policy-maker sort through this conflicting evidence to bring forth proper judgements?

Policy-makers make decisions that can have immense impact on millions of people. These decisions and the resultant actions they will effect BETTER be right because there are not many “do-overs” if they are wrong. The cost of bad decisions is not always readily apparent, either. What may seem like the “right thing to do” can, over time, prove to be exactly the wrong thing to do.

To benefit society as a whole, leaders in many fields MUST make the most responsible environmental, health, and safety decisions possible by applying a sound “science foundation” to the public policy process. The United States Environmental Protection Agency (EPA) Science Advisory Board (SAB), Relative Risk Reduction Strategies Committee issued a report ***“Reducing Risk: Setting Priorities and Strategies for Environmental Protection”***. It states, “good public policy is founded upon sound science”. However, all too often decisions appear to be based on the latest “spin” on the nightly news, or as former EPA Administrator William Reilly described, “episodic panic”.

After September 11th, we have learned that the world as we knew it has changed. No longer do we have the luxury, or the resources, of making wrong decisions based on emotion. We need “rational” thinking as described by the “Reducing Risk” report.

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There are several steps suggested in the Reducing Risk Report. These steps include:

- **Risk Assessment**, which is the analysis of the risk posed by a potential hazard. An example may be that you are walking on a busy metropolitan sidewalk and come to a ladder. Forgetting about your superstitions, you look above the ladder to see if anything is falling from above you and if your journey under the ladder will be safe.
- **Risk Comparison**, which is when after you have analyzed this risk, you compare the potential risk from this hazard to other risks. In this case, you look at the street to see how much risk seems to be posed if you step off of the sidewalk and on to the street so you don't have to walk under the ladder.
- **Risk Prioritization**, which is a process where you decide how hazardous a risk is compared to others. In the example, you notice that the street is very busy with drivers changing lanes as if they are driving in the Indy 500. You realize that you are in much greater danger if you attempt to walk on the street, so you walk under the ladder.

It goes without saying that there are potential heavy costs if policy makers fails to set priorities based on risks identified by a thorough risk assessment. If finite resources are expended on lower-priority problems at the expense of greater hazards, then society will needlessly face high risks. If priorities are established based on the greatest opportunities to **reduce risk**, total risk will be reduced in a more efficient and effective way, lessening threats to both public health and to local and global ecosystems.

What is risk assessment? Basically, it's a scientific process of evaluating the potential adverse effects caused by a substance, activity, lifestyle, or natural phenomenon. It comes with fair warning, however. Risk assessment is always characterized by uncertainty. (In science, there are few "certainties".) As science progresses, we continually learn more and increase our knowledge base. Although many scientists have learned about potential hazards, limited data and the lack of finite knowledge still requires researchers to make assumptions throughout the assessment process. But assumptions can affect the quality of scientific research. For example, assumptions can be skewed so as to show that almost any substance poses a terrible risk or no risk at all. Thus, results of a risk assessment should report ***what assumptions were made in the first place!*** The type of possible or potential harm and the magnitude thereof should be a critical element of any valid risk assessment.

Usually there is uncertainty in risk assessment because assessors cannot precisely define many risks. This may be stating the obvious, but it is easily glossed over in the desire to be compelling in one's conclusions. Accordingly, assessors would be well advised to state the range of possibilities for the possible harm the risk they have identified may cause.

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An example of such a statement might be: *“Our best estimate of the risk of cancer from exposure to chemical X is one additional case in 1,000,000 people, but the risk could be as high as one additional case in 10,000 or as low as no additional cases whatsoever.”*

Assessments of environmental human health risks must combine information on the amount of a substance to which human are exposed already and the toxicity of that substance in order to estimate possible outcomes.

Sounds logical, but it is difficult!

To help non-scientist policy-makers decide if the scientific information they have been given, The Annapolis Center established the following accords. Any risk assessment has three steps:

- **Problem Identification.** *What substance or activity should be studied?*
- **Exposure Assessment.** *How much of a substance or activity are people actually exposed to?*
- **Toxicity Assessment.** *How much of the substance causes what kind of harm?*

Risk analysis includes risk assessment and risk management, which are distinct from each other. **Risk assessment** is a scientific process of investigating phenomena to estimate the level of safety or risk. Once risk assessment is completed, **risk management** is what is done with the information – the policies that are made based upon the scientific information.

Safety managers use the results of risk assessments, plus economic, social, and legal considerations to make regulatory and policy decisions. While economic, social, and legal considerations have a legitimate place in risk management, they have no place in the scientific process of risk assessment.

In order to better understand how one can become more confident in the ability to separate ‘agenda-driven’ or ‘inadequate’ science, The Annapolis Center for Science-Based Public Policy created ***“The Annapolis Accords for Risk Analysis: A Citizen’s Guide for Risk-Assessment and Risk-Management”*** which sets out generally accepted principles that can be employed by those who make policy decisions. These accords allow policy-makers to make informed decisions when they reach . . . “the fork in the road.”

A risk assessment should be complete. Hardly a profound statement, but often overlooked. A complete assessment of a hazard, using peer-reviewed, state-of-the-art information, includes consideration of potential consequences for human health, quality of life, health of ecosystems and economic well-being.

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All relevant information should be used in risk assessments. This is necessary to characterize a potential health or environmental hazard. If an assessment does not include all relevant information, there should be a clear explanation of the reasons for omissions and explicit judgments about the quality and weight of the evidence presented.

Estimating risk should be based on clear definitions. Both quantitative and qualitative estimates of risk should be based on clear definitions of hazards, types and amount of exposures, the variability of response among affected populations, and effects over time.

Claims about scientific certainty should be spelled out and sources given. Risk assessment is an ongoing process that needs to carefully reflect the latest information. Claims about scientific truths and consensus should, therefore, be made with caution. Assessments should clearly communicate sources, assumptions, limitations and uncertainties in the available scientific data.

Risk considerations should be clearly communicated. Judgments of the seriousness of hazards should include quantitative estimates of risk and consideration of qualitative factors to enhance their understanding and use not only by scientists and policy-makers but also by the public at large.

Risk-Management Accords

Opportunities should exist for informed public contribution in risk-management decisions. Risk-management plans and policies should include early opportunities for participation by a variety of interests. Such participation should involve evaluating risk estimates and risk-reduction alternatives that are compatible with other significant societal goals. Risk-assessment information should be available and understood by all participants in the risk-management process.

Decision-makers should use risk assessments to prioritize public health and environmental-risk management. Risk-based priorities should be identified, using the best possible assessment to help assure that significant resources are allocated to addressing the largest and most important health and environmental threats. Risk-ranking techniques should be developed to compare the quality of assessments of natural and manmade risks.

Risk-management decisions should consider the benefits and costs of alternative policies. When risk-management policies are developed, policy-makers should insist on having information about what the expected benefits will be, who will incur gains or losses, and how much each alternative will cost and who will pay. When combined with the insight provided by risk assessments, such benefit and cost information can yield the fairest level of public health, environmental and economic protection.

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Risk-management decisions should encourage the development and use of new knowledge and insight. Policies should be designed so that they provide incentives for new scientific knowledge and social, ethical and legal insight. Such incentives will continuously improve the quality of risk-based decisions.

Implementation strategies are a key element of risk management. Risk-management actions should consider a range of innovative and adaptive policies and administrative steps to achieve public health and environmental goals more rapidly and cost-effectively. These strategies should include non-regulatory approaches.

Likewise, after September 11th, we understand that we do not have unlimited funds to address various threats. As such, we need to get “the most bang for our buck”. To assist in this effort, we look to cost-benefit analysis. This analysis asks what benefits will one get for the money expended.

The Annapolis Center has also developed accords for cost-benefit analysis to help a non-economist determine if a study meets minimal requirements. These accords are as follows:

Cost-benefit analysis should be an integral part of the decision-making process. Cost-benefit analysis should be used to provide information to decision-makers and the public on the benefits and costs of policies to protect public environmental, health and safety quality. Decision-makers should not be bound by a strict cost-benefit test, but they should be able to justify decisions where expected costs exceed expected benefits, or where costs are uncertain or in dispute.

Cost-benefit analysis should be used to identify the distributional consequences of a policy. As a decision-making tool, cost-benefit analysis allows decision-makers to consider the positive and negative impacts of a policy before it is implemented. The analysis should be used to compare the negative impacts of policy decisions, such as job losses or increased costs to an industry in a local economy, with the positive impacts, such as improved health.

Cost-benefit analysis should be used to design policy strategies that achieve a desired goal at the lowest possible cost. In the past, environmental, health and safety policies have relied on a “one-size-fits-all” or “command-and-control” approach. Cost-benefit analysis can highlight the extent to which cost savings can be achieved using alternative, more flexible approaches, such as performance standards and market-based approaches, that reward compliance at a lower overall cost to society.

Policymakers should attempt to incorporate cost-benefit analysis in the decision-making process at all levels of government. Decision-makers at all levels of government should be encouraged to consider the benefits and cost of proposed policies. The scale of the cost-benefit analysis should depend on the risks involved, the timeframe of the decision-making process, and the available scientific and economic information.

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Although a comprehensive cost-benefit analysis may not be warranted in all cases, a rough cost-benefit analysis can be useful in providing decision-makers with an estimate of the benefits and costs of a proposed policy.

Whenever possible, decision-makers should rely on more than one cost-benefit analysis to consider, and weigh, a variety of regulatory options. To increase the amount of information available to decision-makers, a variety of policy alternatives for achieving a desired goal should be considered. To accomplish this, more than one cost-benefit analysis should be performed so that the benefits and costs associated with various alternatives can be estimated and compared.

A quality cost-benefit analysis depends on the availability of a scientifically sound risk assessment. A scientifically sound risk assessment of a hazard should include all relevant peer-reviewed, up-to-date information, which takes into consideration all potential consequences for human health, quality of life, and health of ecosystems. A risk assessment should clearly communicate sources, assumptions, limitations and uncertainties in the available scientific data.

Risks need to be estimated qualitatively and quantitatively before benefits and costs can be measured. Assessments of risk should use all relevant information necessary to characterize a potential health or environmental hazard. Both quantitative and qualitative estimates of risk should be based on clear definitions of hazards, types and amounts of exposures, the variability of response among affected populations, and effects over time. The benefits and costs of protecting the public from a hazard cannot be estimated until the risks of that hazard and the uncertainties are qualitatively and quantitatively identified.

All key assumptions should be spelled out clearly and, whenever possible; uncertainties should be identified and discussed. A core set of economic assumptions should be used in calculating the benefits and costs associated with environmental, health and safety regulations. Key assumptions include the social discount rate, the value of reducing risks and accidents and premature death, and the value associated with other improvements in health. If uncertainties exist in the available scientific and economic information, estimates based on this information should be clearly identified and discussed.

Benefits and costs should be quantified whenever possible. Not all impacts of a regulatory policy can be quantified, or expressed in monetary terms. The available information may imply ranges of possible values for estimating benefits and costs, and not single numbers, which makes quantification difficult. When this occurs, best estimates of the costs and benefits should be included along with a description of the uncertainties. This will prevent qualitative factors that are not easily quantified from being ignored in a cost-benefit analysis.

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Peer review is a necessary part of a complete cost-benefit analysis. Given the uncertainties inherent in cost-benefit analysis, the results should be peer-reviewed by an outside panel of economic and scientific experts. Before a cost-benefit analysis is performed, guidelines should be established by an outside review body for agencies to follow in conducting cost-benefit analysis, and revised periodically on the basis of new scientific and economic information.

So the next time Yogi Berra or YOU come to that fork in the road...take it! But do so with information, knowledge, expertise, and confidence engendered through the application of appropriate risk assessment and management techniques. There is plenty of inadequate or science based on differing political agendas out there, but it can be avoided so your decision-making process is properly based on “good” science and economics. Think rationally!



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Vice Admiral Harold M. Koenig, Medical Corps, US Navy (Retired), became the thirty-second Surgeon General of the Navy and Chief, Bureau of Medicine and Surgery, on June 29, 1995. He retired from that position on June 30, 1998 after completing 32 years of active duty service. He currently serves as Chair and President of The Annapolis Center.

A native of Salinas, California, he attended the U.S. Naval Academy and received his Bachelor of Science Degree from Brigham Young University. He received his Medical Degree from Baylor University College of Medicine. He is certified by the American Board of Pediatrics in general pediatrics and pediatric hematology-oncology.

VADM Koenig is a Diplomate of the American College of Healthcare Executives. In 1994 the American Hospital Association named him "The Federal Health Care Executive of the Year".

VADM Koenig served in a variety of clinical roles in the Navy, including general medical officer, residency training program director, department chairman, hospital executive officer and commanding officer. His staff assignments before becoming the Navy Surgeon General included: command of the Naval Health Sciences Education and Training Command, Director of Health Care Operations in the Office of the Chief of Naval Operations, Deputy Assistant Secretary of Defense (Health Affairs) for Health Services Operations and Deputy Surgeon General and Chief of the Medical Corps.

VADM Koenig's personal awards include the Navy Distinguished Service Medal, Defense Superior Service Medal, Legion of Merit with Gold Star, Meritorious Service Medal with Gold Star, Navy Commendation Medal, and the Navy Achievement Medal.

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The Annapolis Center for Science-Based Public Policy supports and promotes responsible environmental, health, and safety decision-making. The Annapolis Center is a nonprofit 501(c)3 educational organization.

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