Probabilistic Risk Assessment: The Shift to More Realistic Risk Decision-Making

Risk Assessment in Spectrum Policy
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What is Risk Assessment?

Risk assessment is a process where information is analyzed to determine if a potential hazard might cause harm in specific real-world scenarios

Paraphrased from **"Risk Assessment in the Federal Government"** (National Research Council, 1983)


Risk Assessment
• Analytically based
Risk Management
• Policy and preference based
Risk Communication
•Interactive exchange of information, opinions, and preferences concerning risks

Why We Need Risk Assessment

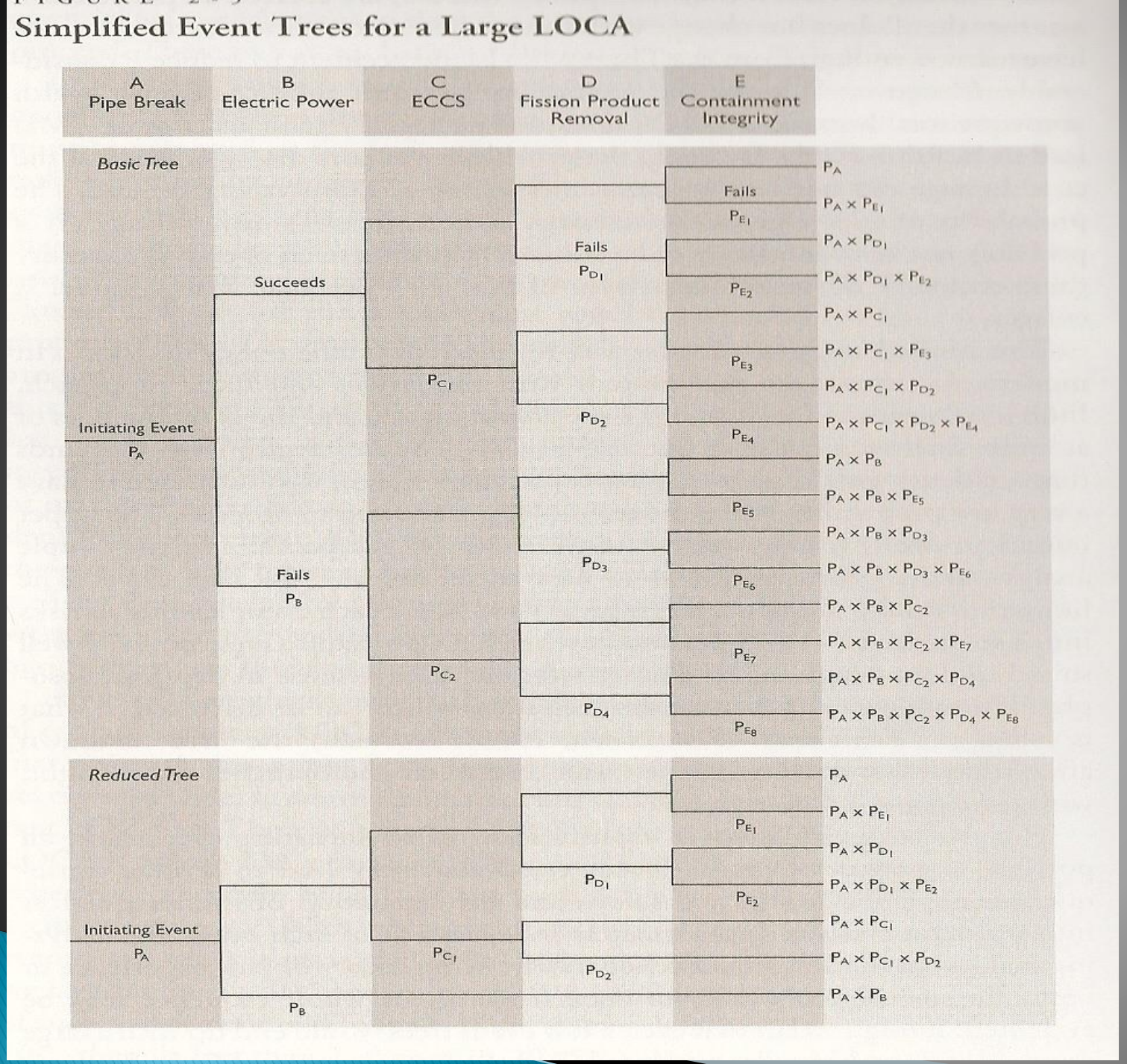
THE ROANOKE TIMES
Monday, September 20, 2004

STEPHANIE KLEIN-DAVIS | The Roanoke Times

Mellisa Williamson, 35, a Bullitt Avenue resident, worries about the effect on her unborn child from the sound of jackhammers.

Two Types of Probabilistic Risk Assessment

1. Event Tree/Fault Tree Analysis
   - Multiply probabilities along fault tree to give specific probabilities for specific accident events
   - Mostly uses deterministic inputs
2. Provide probability distribution for each input and output



Event Tree Probabilistic Risk Assessment
From Rasmussen (1975) Nuclear Reactor Safety Study

Risk Assessments Always Involve Variability and Uncertainty

- **Variability**: refers to the certainty that
  - different members of a population will have different values (inter-individual variability)
  - values will vary over time for a given member of the population (intra-individual variability)
- **Uncertainty**: refers to lack of knowledge regarding
  - True value of a fixed but unknown quantity
  - True population distribution for variability

National Academy of Sciences: The "Red Book" (1983)

- Regulatory agencies must address uncertainty and variability inherent in risk assessment
- When science cannot provide answers, agencies should adopt "inference options" to fill gaps
- These inference options can serve as defaults in risk assessment in absence of actual data

EPA Response to Red Book

- EPA responded to Red Book by adopting a series of risk assessment guidelines in the 1980s (e.g., Carcinogenicity Risk Assessment Guidelines, Exposure Assessment Guidelines)
- Guidelines defined series of default assumptions that would be used in absence of real data
- Default assumptions tended to be “conservative” – plausible upper bound – consistent with Agency’s public health/protective mission

EPA's "Deterministic" Risk Assessments

- "The Agency has developed simplified approaches to characterize risks associated with such complex assessments through the use of point estimates for model variables or parameters. Such an approach typically produces point estimates of risks (e.g., 10-5 or a lifetime probability of cancer risk of one individual in 100,000). These often are called "deterministic" assessments. As a result of the use of point estimates for variables in model algorithms, deterministic risk results usually are reported as what are assumed to be either average or worst-case estimates. They do not contain any quantitative estimate of the uncertainty in that estimate, nor report what percentile of the exposed population the estimate applies." (EPA, 2014)

EPA – Use of Defaults

- “Deterministic risk assessment (DRA) often is considered a traditional approach to risk analysis because of the existence of established guidance and procedures regarding its use, the ease with which it can be performed, and its limited data and resource needs. The use of defaults supporting DRA provides a procedural consistency that allows for risk assessments to be feasible and tractable. Decision makers and members of the public tend to be relatively familiar with DRA, and the use of such an approach addresses assessment-related uncertainties primarily through the incorporation of predetermined default values and conservative assumptions. It addresses variability by combining input parameters intended to be representative of typical or higher end exposure (i.e., considered to be conservative assumptions).” (EPA, 2014)

Use of "Conservative" Risk Assessment Defaults

- Government generally errs on the side of safety by adopting "conservative" assumptions – intended to be plausible worst-case estimates
  - e.g., exposure at fence line of a facility – used to assume 24 hours per day for 70 years
- Erring on side of safety not per se unreasonable – we do generally favor lives over dollars
- "The greater the uncertainty about a given effect, the more likely it is to be overestimated." Nichols & Zeckhauser
- But problem – when add together so many safety factors – get compounding effect that may grossly exaggerate risk
  - 95% %ile x 95%ile ≠ 95%ile
  - e.g., formaldehyde – endogenous FH production (58 g/day) should produce over 37 fatal cancers in each of us
    - Waddell, Drug Metabolism Reviews 28:181, 191 (1996)

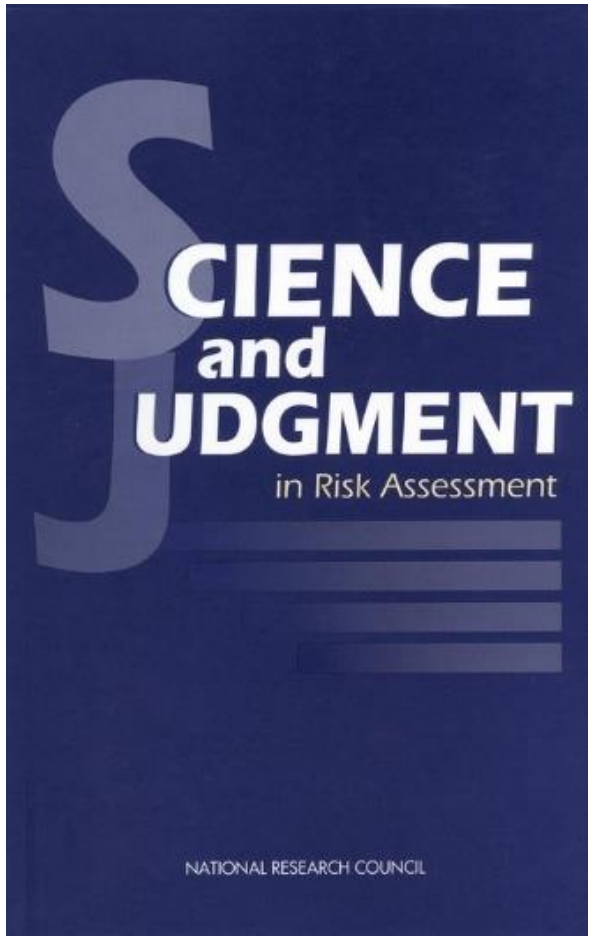
The Perils of Prudence

- "At the EPA, … the agency's administrator and political deputies… are rarely told the range of plausible estimates, or the most likely estimate, of the risk they are asked to regulate. Instead they are usually only told the up "plausible upper bound" estimate, a term of art indicating that the actual risk is almost certain to be no higher."
  - Nichols & Zeckhauser, *The Perils of Prudence* (1986)

Criticisms of EPA Risk Assessments

- OMB, NRC, and EPA SAB all criticized EPA risk assessments in the late 1990s and 2000's:
  - EPA intermingles policy judgments within the scientific assessment of risk
  - Risk assessments rely on conservative ("worst case") assumptions that distort outcomes and yield estimates that grossly overstate risk
  - Risk assessments fail to acknowledge the presence of considerable uncertainty

National Academies of Science: "Blue Book" (1994)



"Uncertainty analysis is the only way to combat the 'false security of certainty,' which is *caused* by a refusal to acknowledge and [attempt to]quantify the uncertainty in risk predictions."

William Ruckelshaus (1984)

- “[W]e must insist on risk calculations being expressed as distribution of estimates and not as magic numbers that can be manipulated without regard to what they really mean. We must try to display more realistic estimates of risk to show a range of probabilities. To help us to this we need new tools for quantifying and ordering sources of uncertainty and for putting them in perspective.”

Alternatives

- Late 1990's – EPA concedes upper worst bound approach is flawed, starts considering changes:
  - More reasonable worst case assumptions – instead of assuming 24/day chemical exposure for 70 years, assume 2- 6 hr/day exposure for 10-35 years
  - Provide range of outcomes
  - Mean, "best estimate," or expected value approach
  - Probabilistic risk assessment

What is Probabilistic Risk Assessment?

- “PRA is a group of techniques that incorporate variability and uncertainty into the risk assessment process. It provides estimates of the range and likelihood of a hazard, exposure or risk, rather than a single point estimate. It can provide a more complete characterization of risks, including uncertainties and variability, to protect more sensitive or vulnerable populations and lifestages. The information obtained from a PRA can be used by decision makers to weigh the risks of decision alternatives, or to invest in research with the greatest impact on risk estimate uncertainty.” (EPA, 2014)

PRA Methods (EPA)?

- Monte Carlo analysis
- Other statistical models (unspecified)
- Sensitivity analysis
- Expert elicitation

What is Monte Carlo Analysis?

- It is a tool for combining distributions, and thereby propagating more than just summary statistics
- Numerous inputs determine output
  - eg: Risk = probability × consequence
- For each input, use either a probability distribution, multi-choice variable, or binary choice
- Computer draws randomly from each input, calculates output
- Repeats this sampling thousands of times
- This set of results is displayed as a new, combined distribution

Adapted from David M. Hassenzahl

Equation 1. Deterministic Risk Assessment

$$\left[\begin{array}{c}\text{Concentration}\\ \text{in environment}\end{array}\right] \times \left[\begin{array}{c}\text{Exposure}\\ \text{Duration}\end{array}\right] \times \left[\begin{array}{c}\text{Ingestion or}\\ \text{Inhalation Rate}\end{array}\right] \times \left[\begin{array}{c}\text{Toxicity}\\ \text{Factor}\end{array}\right] = \textbf{RISK}$$

Central tendency (average) values for all parameters: [c] x [e] x [i] x [t] =

High-end values for some or all parameters: [C] x [E] x [I] x [T] =

Yields a reasonable estimate for average or typical individual

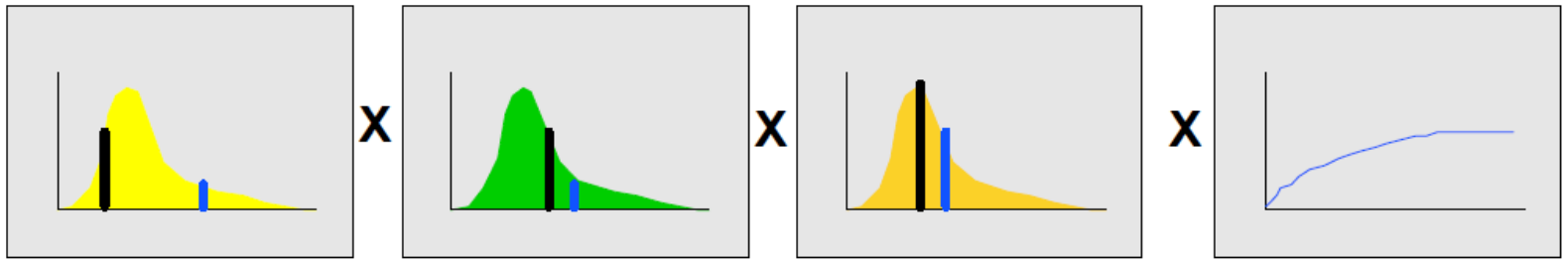
Risk

Yields estimate that is likely biased high (conservative)

Source: EPA 2014

Equation 2. Probabilistic Risk Assessment

[Concentration in environment] X [Exposure Duration] X [Ingestion or Inhalation Rate] X [Toxicity Factor] = **RISK**



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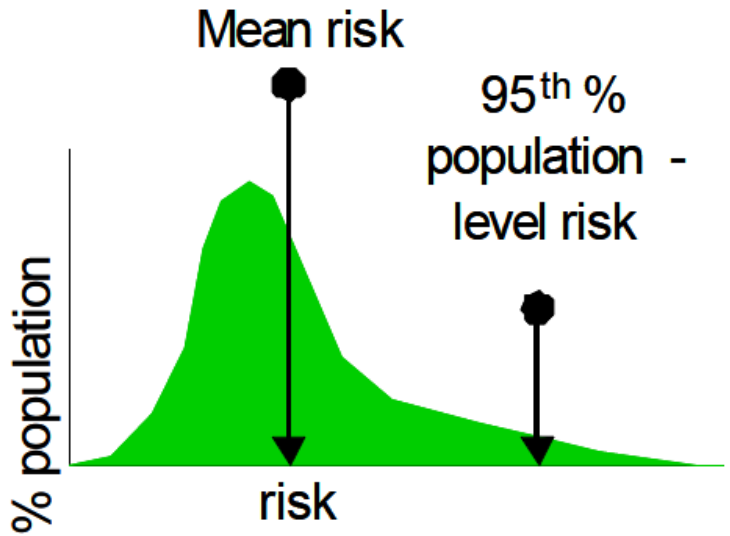


Source: EPA 2014

POLICY FOR USE OF PROBABILISTIC ANALYSIS IN RISK ASSESSMENT

at the U.S. Environmental Protection Agency

May 15, 1997

EPA/630/R-97/001
March 1997

Guiding Principles for Monte Carlo Analysis

Technical Panel

Office of Prevention, Pesticides, and Toxic Substances

Michael Firestone (Chair) Penelope Fenner-Crisp

Office of Policy, Planning, and Evaluation

Timothy Barry

Office of Solid Waste and Emergency Response

David Bennett Steven Chang

Risk Assessment Guidance for Superfund:

Volume III - Part A, Process for Conducting Probabilistic Risk Assessment

2001

EPA/100/R-14/004 July 2014
www.epa.gov/raf

Risk Assessment Forum White Paper: Probabilistic Risk Assessment Methods and Case Studies

EPA/100/R-14/003 July 2014
www.epa.gov/raf

Probabilistic Risk Assessment to Inform Decision Making: Frequently Asked Questions

EPA Endorsement of PRA (2014)

- “Probabilistic risk assessment (PRA) is one way to characterize the uncertainty associated with any risk assessment. As part of a decision analysis, the enhanced use of PRA and characterization of uncertainty would allow EPA decision-makers opportunities to assess uncertainty pertaining to its effect on decisions and explore the defensibility of the available risk management options through a more robust and transparent process. Most often, risk managers want to know if better understanding of uncertainties might support a different decision alternative or provide further support for the selected decision.”

Benefits of PRA

- Provides decision-maker with a more realistic and robust representation of variability and uncertainty
- Provides greater transparency to risk managers and stakeholders
- Eliminates distorting effect of compounding conservative default values
- Shifts judgment about how to handle uncertainty to risk manager from risk assessor
- “By understanding and explicitly accounting for uncertainties underlying a decision, EPA can estimate formally the value of gathering more information” (EPA, 2014)

EPA: Challenges of PRA

- “A clear institutional understanding of how to incorporate the results of probabilistic analyses into decision making is lacking;
- PRA typically requires a different skill set than used in current evaluations, and limited resources (staff, time, training or methods) to conduct PRA are available;
- Communicating probabilistic analysis results and the impact of those results on the decision/policy options can be complex;
- Communication with stakeholders is often difficult and results in the appearance of regulatory delays due the necessity of analyzing numerous scenarios using various models;
- PRA complicates decision making and risk communication in instances where a more comprehensive characterization of the uncertainties leads to a decrease in clarity regarding how to estimate risk for the scenario under consideration.”
  - EPA (2014)

Communicating Results of PRA

- "Communicating the results of probabilistic risk assessment requires particular attention.... Risk assessors are responsible for sharing information on probabilistic results so that risk managers have a clear understanding of quantitative assessments of uncertainty and variability and how this information will affect the risk management decision. Clear communication between the risk assessment team and the decision maker is essential in aiding the decision maker's understanding and use of the results from the probabilistic risk assessment.
  - EPA, Framework for Human Health Risk Assessment to Inform Decision-Making 45 (2014)

More on Communicating PRA

- “The lack of familiarity with PRA presents a challenge in effectively presenting results to decision makers, stakeholders and the public. Many view PRA as a highly technical discipline that uses sophisticated mathematics and requires extensive training to apply and understand. Single point estimates are easier to grasp for most people, based in part on familiarity with this approach over the history of EPA. Although some people initially have difficulty interpreting probability distributions of values, everyone has a common baseline experience with probability, uncertainty and variability from everyday life (e.g., weather forecasting, odds of winning a lottery), and this experience could be used to frame the discussion of results. It is not necessary to understand the underlying mathematics or even to include results as full distributions. Results can be distilled down to the critical essence or decision-meaningful input of interest.” (EPA 2014)

Life is Messy: Deal with It!

- “It is the mark of an instructed mind to rest satisfied with the degree of precision which the nature of the subject permits and not to seek an exactness where only an approximation of the truth is possible.”

  –Aristotle

Risk is Messy…

A4 ||| NEWS

Sister hits moose on way to visit sister who hit moose

One woman in 100 Mile House hospital, the other recovering in Vancouver

BY LAURA KOOVI

A pair of Kelowna sisters have had their fill of close encounters with moose on the loose.

Recently ago, Yvonne Hadley, 49, finally injured when she hit a moose with her vehicle, so last Friday her sister decided to visit her in Vancouver General Hospital.

But sister Connie Harris, 51, fared little better — she also hit a moose and ended up in hospital.

In the first accident a month ago, Hadley was on her way home from a business trip when a moose ran in front of her car.

The animal went through the windshield and landed on her, inflicting a broken wrist, arm and hand, five fractured ribs and bleeding in her brain.

The pregnant moose died near the collision.

The calf did not survive.

When Hadley came out of her coma her sister Connie Harris and her husband Steve decided to visit her.

She and her husband were in two cars last Friday afternoon. Harris, in the first car, was going around a corner near 70 Mile House when she saw "a brown blur."

"I know right away it was a moose," she said. "I slammed on the brakes with both my feet.

"It was like two explosions. The moose came through the windshield on the passenger side, and then the body flipped around and the shoulder came into the side window."

She was taken to the hospital in 100 Mile House with mostly soft-tissue injuries.

The coincidence of hitting a moose just like her sister "really threw me for a loop."

"My first thought was, 'Are the moose going out [on a] hunting season for my family?' Because so far, we've been lucky because we got three of them dead."

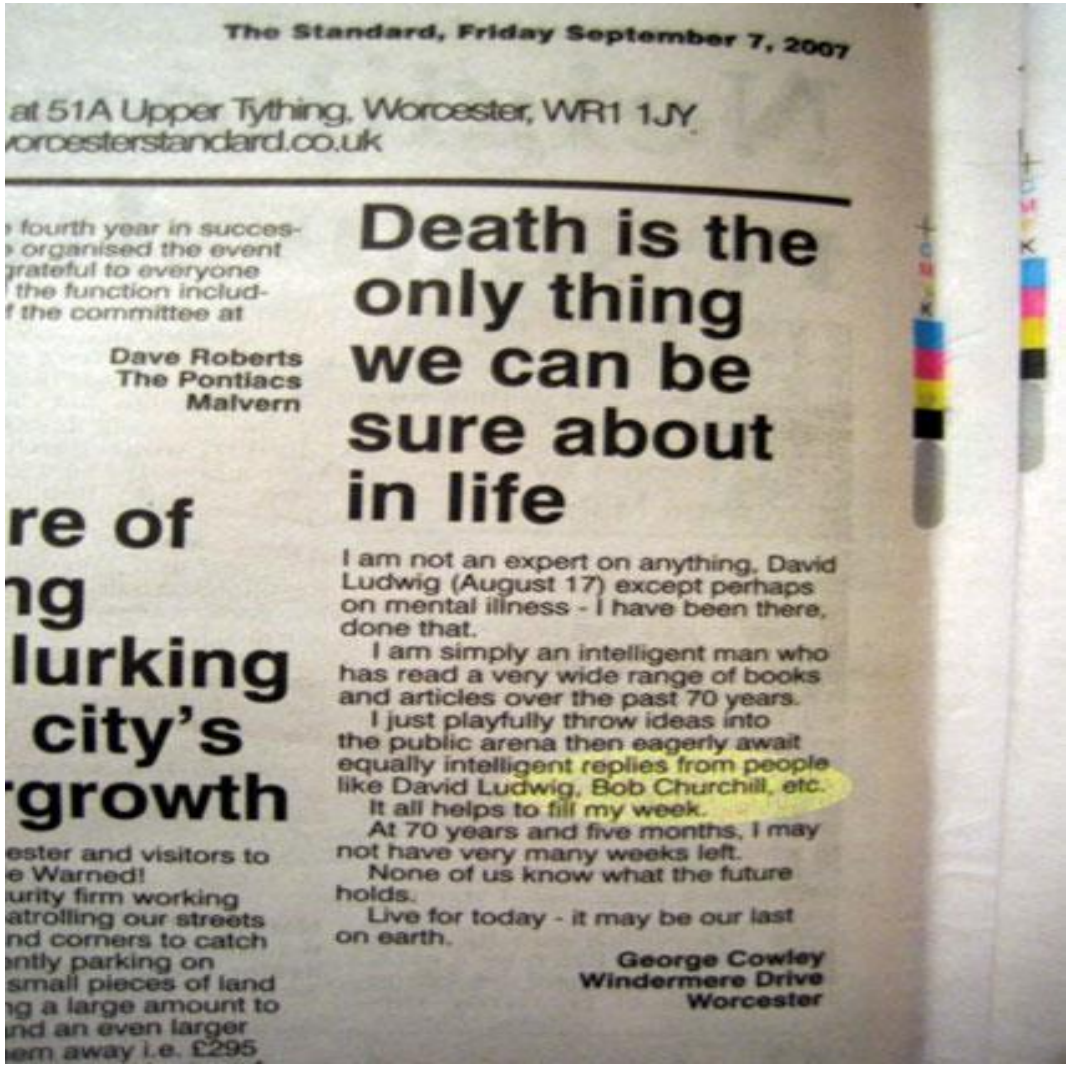
Moose are involved in about eight per cent of all wildlife vehicle collisions, according to the Wildlife Collision Prevention Program's website.

"Moose will always be a wildlife

Conclusion

"Life really is about risk and it ends badly."

- Senator Patrick Moynihan



The Standard, Friday September 7, 2007

at 51A Upper Tything, Worcester, WR1 1JY
worcesterstandard.co.uk

fourth year in succes-
organised the event
grateful to everyone
the function includ-
the committee at

Dave Roberts
The Pontiacs
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Death is the only thing we can be sure about in life

I am not an expert on anything, David Ludwig (August 17) except perhaps on mental illness - I have been there, done that.

I am simply an intelligent man who has read a very wide range of books and articles over the past 70 years.

I just playfully throw ideas into the public arena then eagerly await equally intelligent replies from people like David Ludwig, Bob Churchill, etc.

It all helps to fill my week.

At 70 years and five months, I may not have very many weeks left.

None of us know what the future holds.

Live for today - it may be our last on earth.

George Cowley
Windermere Drive
Worcester