Uncertainty, Expert Judgment, and the Regulatory Process: Challenges and Issues

Robert Hetes

USEPA, National Health and Environmental Effects Research Laboratory

DIMACS Workshop on the Science of Expert Opinion
October 25, 2011

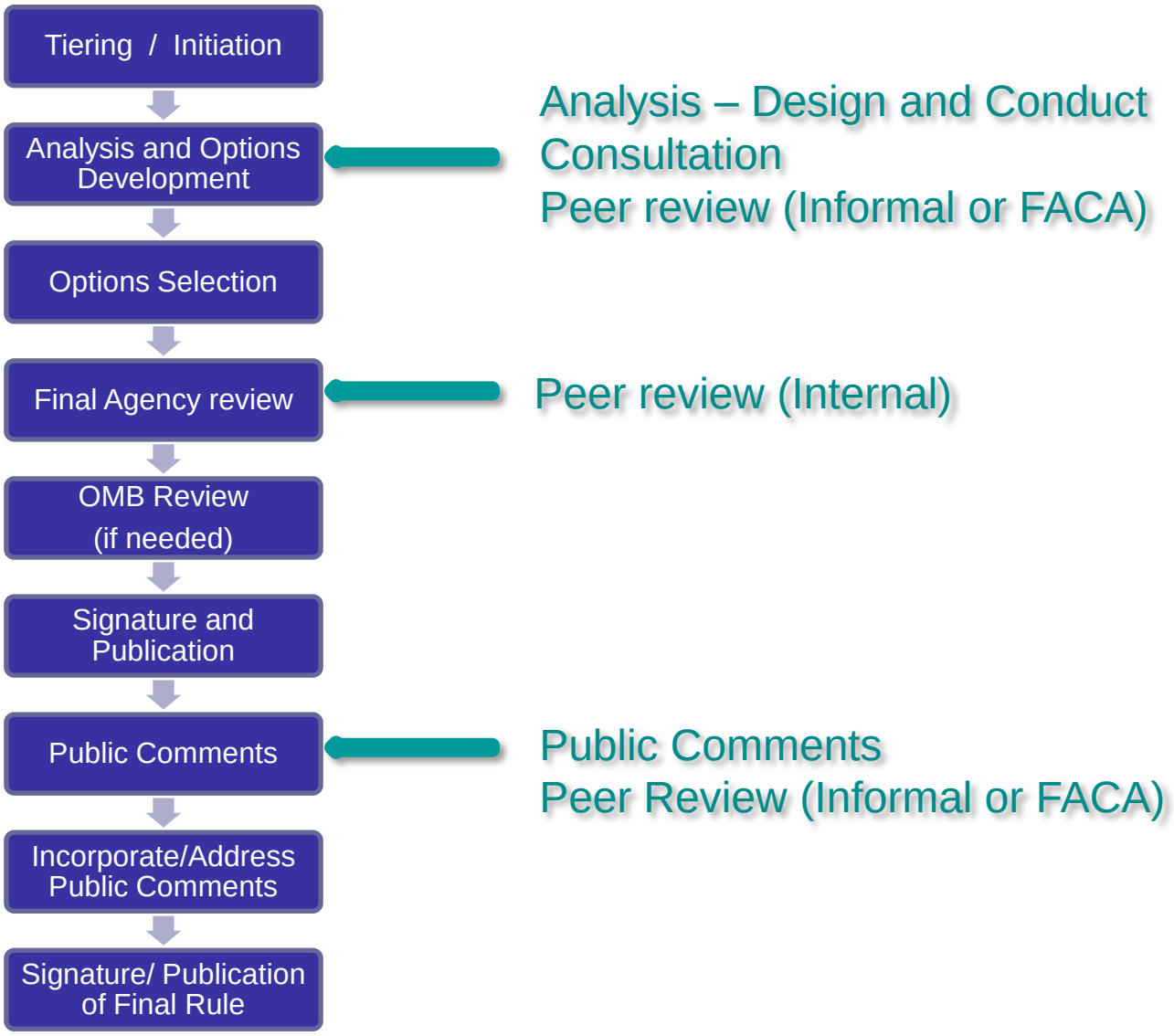
Caveat

- This presentation reflects personal views based on experience and discussions with the EPA's EE Task Force. It is not intended to reflect Agency policy.

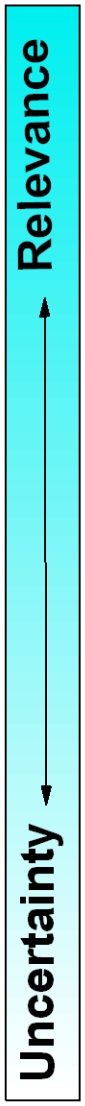
Outline

- Expert Opinion and the Regulatory Process
- Uncertainty and the Regulatory Process
  - Issues of uncertainty
  - Issues specific to EE
- EE versus Expert Judgment
- EPA experience with EE
  - Lessons learned
- General issues / conclusions on use of EE

Regulatory Process and Expert Opinion



Types of Evidence – Basis for Expert Opinion



Direct empirical evidence – direct measurement of the phenomenon of interest under the conditions of interest

Semi-empirical evidence – measurement of the phenomenom of interest under conditions that differ in some systematic way from that of interest, requiring extrapolation

Empirical correlations – measurement of other effects correlated with the one of interest

Theory-based inference – model-based estimates, where measured phenomenon is part of the causal chain leading to the effect, and mechanisms linking the elements of this chain are understood well enough to allow modeling of the final effect

Existential insight – opinions that are the result of experience and training

Nature of the Regulatory Process

- Complex multi-factor problems
  - Risk, legal, science, economic, social, political
- Multiple stakeholders – each with their own positions, frames, and agendas
- Adversarial -- challenging

Necessitates a high degree of scrutiny

Uncertainty and the Regulatory Process

- Uncertainty analysis in general
  - Essential to understand implications of findings
  - Concern that reflects criticism of assessment -- inadequate
  - Opens decisions to legal challenge
  - Can be misused to delay appropriate actions
- Decision Analytic approaches
  - Formalized framework reduces flexibility in decisions

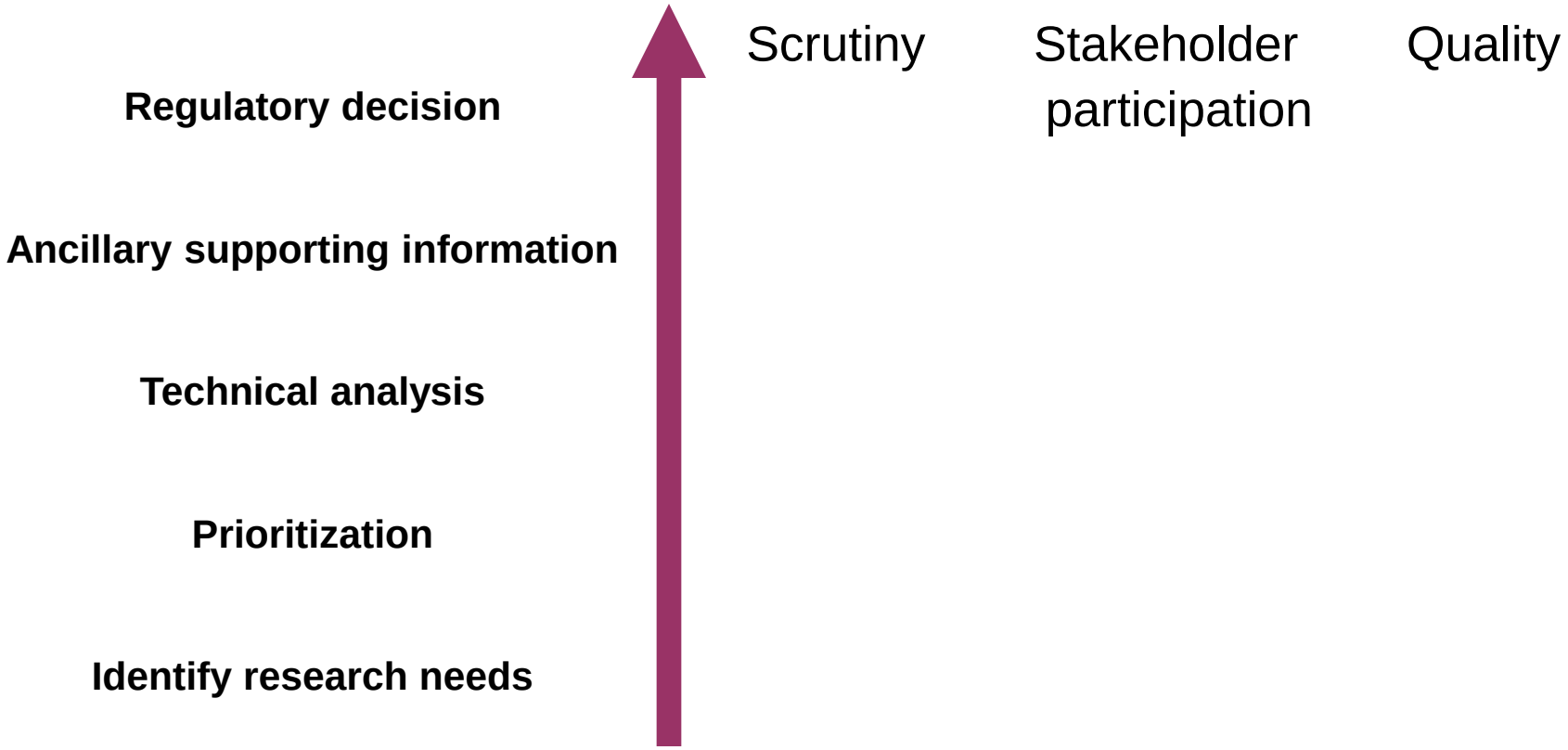
Factors which influence the defensibility and acceptability (of an EE)

(EE) is perceived by some as easily an manipulated “black box” and arbitrary and non-scientific

Defensibility is improved by the degree to which the (EE) addresses the following dimensions

- Transparency
- Credibility – use of reasonable evidence
- Objectivity -- unbiased and balanced
- Rigor - control of heuristics and biases
- Relevance

Intended Use / Activity



Note: impact of any decision or activity provides another dimension in determining necessary quality

Factors influencing quality, defensibility, and acceptability

Informal	Formal
Unstructured	Structured
Heuristic/biases unaddressed	Control of heuristic and biases
Opaque	Transparent
Sponsor Control (Perceived bias manipulation)	Independent of Sponsor (Objective / unbiased)

Questionable Quality
Potentially Suspect

High Quality
Broadly Accepted

Sponsor Control (Perceived bias manipulation)

Independent of Sponsor (Objective / unbiased)

Questionable Quality
Potentially Suspect

High Quality
Broadly Accepted

Sponsor includes stakeholders, control includes influence

Control over any particular element

- problem definition
- selection of experts
- characterization and use of results

Especially important in a political setting that one must protect against even the appearance of undue influence and control

Also applies to considering use of 3rd party assessments

EE-Specific Issues or Concerns

- Trust and credibility are critical
  - Transparency
  - Rigor
- Resource intensive and time consuming
- Rigor of the effort depends on intended purpose /use
  - QA requirements differ by category
    - Category 1 – directly or immediately supports specific Agency rule-making or action
    - Category 4 – gain more comprehensive knowledge or understanding of theory or process without concern for specific applications
- Methodological

What is EPA's Experience with EE?

- Office of Air and Radiation
  - 1977-78 Ozone NAAQS Review
    - SAB Subcommittee on Health Risk Assessment established in 1979
  - Lead health risk assessment for 2 endpoints (1986)
  - Chronic ozone lung injury assessment
  - Fine particulate matter ($PM_{2.5}$) mortality for health benefits
    - pilot project (2004) – used in non-road RIA benefits analysis
    - full elicitation– 2006
  - Radioactive Waste Disposal – 40 CFR 194.26 (July 2003)

Lessons Learned

- EE is an accepted methodology
- Early efforts (late 1970s) criticized due to lack of experience and formal methods
  - Highlights the importance of the collaborative efforts to move the method along
  - Similar activities will likely be needed to promote the use in other program offices
    - Quality
    - Relevance

Why the need for an Intra-Agency Task Force?

- Greater interest in Expert Elicitation
  - NAS (2002) *Estimating the Public Health Benefits of Proposed Air Pollution Regulations*
  - OMB Circular A-4
  - EPA Cancer Risk Assessment Guidelines (March 2005)
- While EPA acknowledges the potential value of this method:
  - Most EPA analysts/decision makers unfamiliar with method
  - No clear guidelines on how to conduct within EPA (or elsewhere)
  - Desire to promote consistency
  - Consider the potential impacts of precedents from near-term projects utilizing EE
  - Need to promote technically defensible assessments

What is Expert Elicitation?

- Task Force defines EE as “formal systematic process of obtaining and quantifying expert judgment” – probability as degree of belief and is a subset of the broader category of approaches involving expert judgment
  - **Focuses on science <u>not</u> societal values and preferences** (other tools address values and preferences)
  - **Characterizes state of knowledge <u>not</u> creation of new empirical data**
- Task Force recognizes that EE represents one type of tool and that whether to use it and the degree of resources and time needed to conduct an EE depend on:
  - Nature of the question
  - Context
  - Intended use of the results
- Well suited for critical uncertainties and data gaps

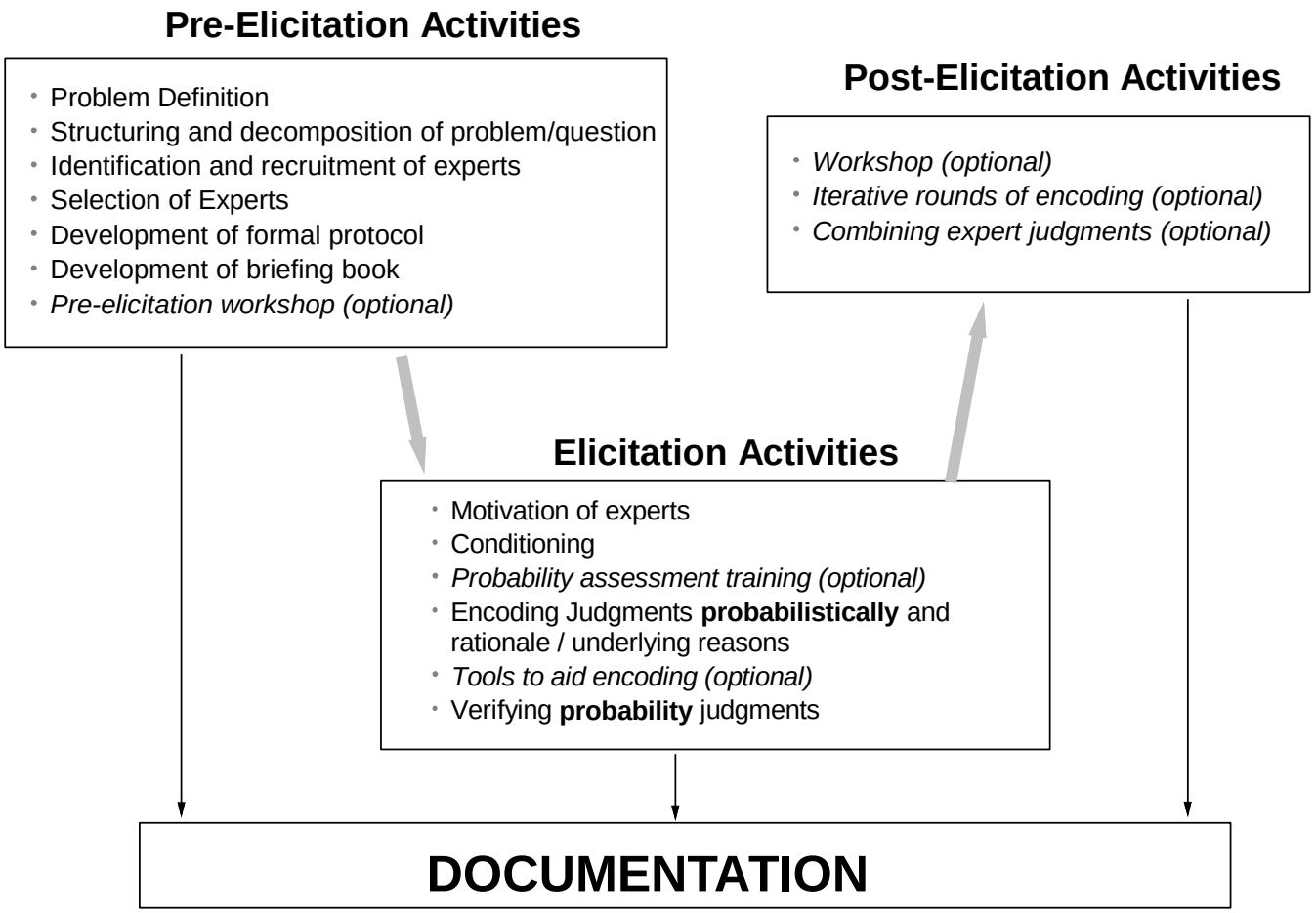
Distinguishing EE within the Context of Expert Judgment

- **Expert judgment** is inherent in the scientific process and covers a range of activities
  - Analysis – problem formulation/scoping, model choices
  - Evaluation and interpretation of results
- **Expert peer review** commonly provides expert judgment and feedback on planned or completed products and projects
- **Expert Elicitation** (EE) is a formal systematic process of obtaining and quantifying expert judgment, expressed as probabilities
  - Ensures quality output consistent with OMB guidelines etc

When is something an Expert Elicitation versus Expert Judgment?

- There is no bright line between EE and Expert Judgment
  - Depends on rigor and the needs of the assessment
- Minimum elements
  - Problem definition -- meets Clairvoyance Test,
  - Formal protocol -- required to ensure consistency in elicitation and control for heuristics and biases,
  - Identification, summary, and sharing of the relevant body of evidence with experts,
  - Formal elicitation -- encoding of probabilistic values or distributions of expert (interactively involving EE practitioner and subject matter expert), and
  - Output: judgment (degree of belief) is expressed quantitatively (in terms of probabilities)

Overview of Expert Elicitation Process



When is EE appropriate?

- Acceptable quantitative estimates of uncertainty cannot be made with additional data collection, cannot be observed *directly*, or the events are so rare that data are limited.
- Uncertainty estimates using other techniques will not be quantified adequately because of the timeframe for a decision or limited available resources
  - data collection needs more time than analysis based on expert judgment,
  - data collection not technically feasible.
  - Benefits of additional data collection may not justify the costs/time

Other factors to consider in deciding when and how to conduct EE

- Importance of characterizing critical uncertainties
- Nature of the debate – analytical v. deliberative
- Perceived major bias among stakeholders
- Nature of available data – sufficient data to carry out EE or use empirical-based methods
- Relative value of EE v other uncertainty methods
- Role of peer review -- same pool of experts, experts excluded from peer review

	Public Comments	Limited (Letter) Peer Review	Formal FACA (or Panel) Peer Review	Expert Elicitation
Problem addressed	Broad, no limit, defined by commenter	Broad, but defined by charge	Broad, but defined by the charge	Narrow, specific, and well-defined
Timeframe	Typically 30–90 days	1–4 months	4–12 months	8 months–2 years
Resource needs	Limited	~$25K	~$250K	~$250K–$2M
Role of public/ stakeholders	Open to all to provide comments	Formal selection process	Public nomination, selection process, open public process	Nominations by peers and limited involvement of public/stakeholders
Evidence considered	No limit	No limit	No limit	No limit but must be formally shared with all experts to evaluate
Acceptance	Publicly acceptable	Familiar though not transparent to public	Generally accepted, recognized	Some wary of method (i.e., concerns about perceived bias)
Selection of experts	None	Formal selection process	Formal and public nomination process	Systematic process usually involving nomination by technical experts

Well-conducted EE is time and resource intensive

- Resources
  - technical skills – availability and LOE internal/external
  - Cost – most > $100K
  - Time – ≥ 1 yr to design/implement
- Pressure to reduce these demands
  - Numerous methodological adjustments can be implemented to lower level of effort and resource needs
  - Can affect the overall quality and therefore acceptability of the result

Guidance and/or Minimum Standards Needed

- To insure the acceptability of EE
  - Minimum quality standards dependent on intended use of the results
  - Guidance on applicability of results beyond intended use (secondary use)
  - Describe pedigree of findings

What to Consider in Deciding Whether to Use EE

- How Important is it to Consider Uncertainty?
- What is the Nature of the Uncertainties to be Addressed?
- What are Other Methods to Characterize Uncertainty?
- What Role may Context play for an EE?
- What Resources are Required for an EE?

Methodological Considerations

- Who selects experts
- Anonymity of experts
- Combining expert judgments
- Number of experts – ICR limits

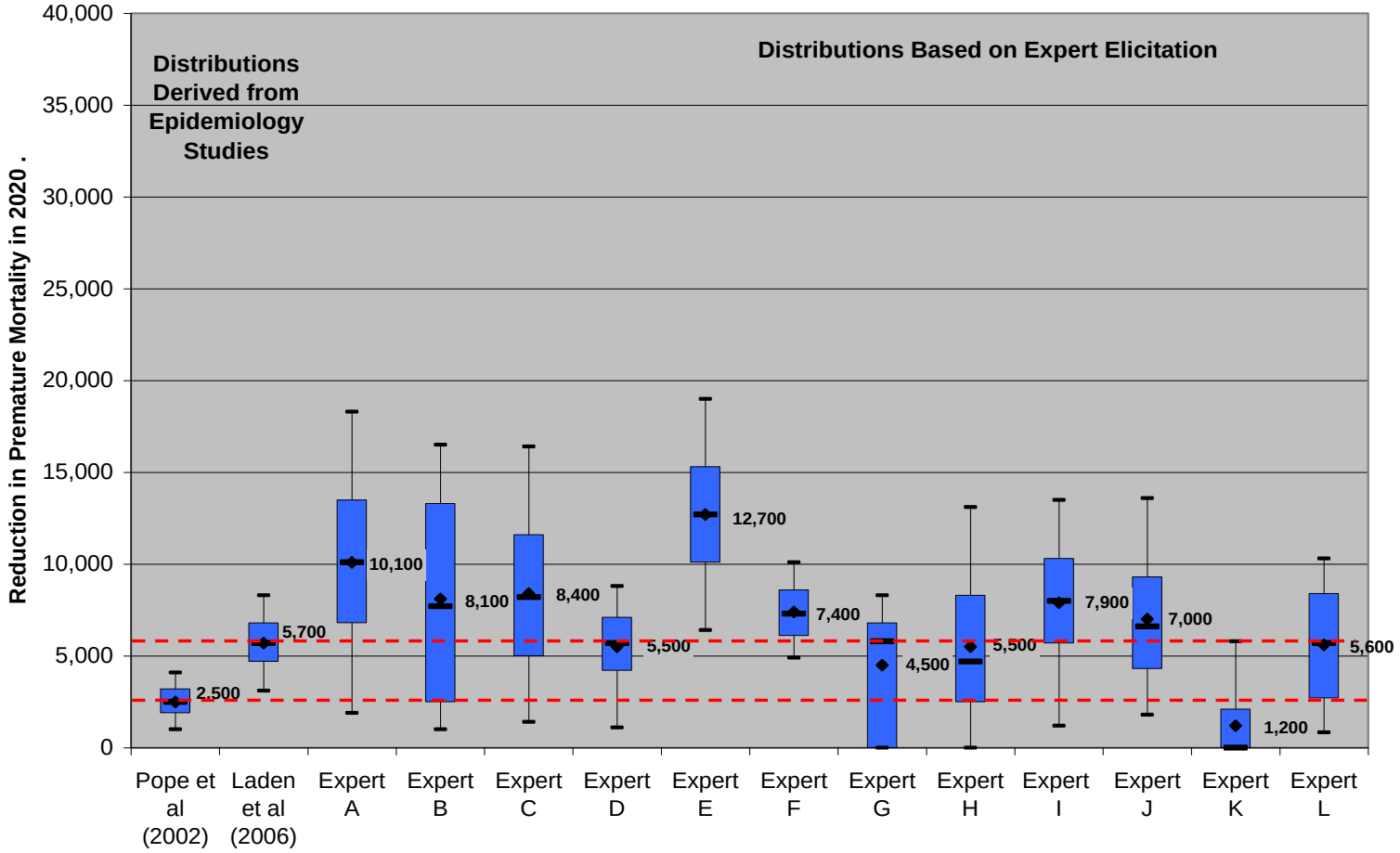
(Selected) Findings of the EE Task Force

- EE is powerful and accepted tool to **characterize uncertainty/provide estimates for specific data gaps**
  - EE is not always appropriate or best in all cases and is not a panacea in addressing emerging uncertainty requirements
  - EE is not equivalent to valid empirical data, nor should it be used as a substitute for collecting additional data, where such studies are feasible within timeframe and resources available
- Generally, EE requires significant investment of resources and time to provide sound results
  - Use of EE is appropriate for some situations and not for others
  - Users must be aware of both strengths and limitations of this approach
  - Analysts should keep in mind that there are other approaches
- Nature of the regulatory process introduces complexities and variety of considerations that will influence decisions on:
  - Whether to conduct an EE
  - How to conduct the EE
  - How to communicate and use the results.

(Selected) Recommendations of the Task Force

- Decision to conduct an EE should involve discussions between staff organizing the EE and managers.
- EPA should develop guidance and/or policy, training and tools supporting the conduct and use of EE
  - Consult White Paper until they are ready
- Credibility, acceptability, and utility of using EE within EPA will depend on early efforts
  - Collaboration with knowledgeable staff within EPA and/or external EE practitioners
  - Provide training and tools (e.g., develop a clearinghouse on EE to facilitate sharing of methods, lessons learned, etc.
- Peer review of EE draft reports should focus on the process of elicitation and scientific evidence used

http://www.epa.gov/stpc/pdfs/ee-white-paper-final.pdf



Note: Distributions labeled Expert A - Expert L are based on individual expert responses. The distributions labeled Pope et al. (2002) and Laden et al (2006) are based on the means and standard errors of the C-R functions from the studies. The red dotted lines enclose a range bounded by the means of the two data-derived distributions.