

Health Effects Institute's Energy Research Program

Scoping Meeting for Human Health Study Critique

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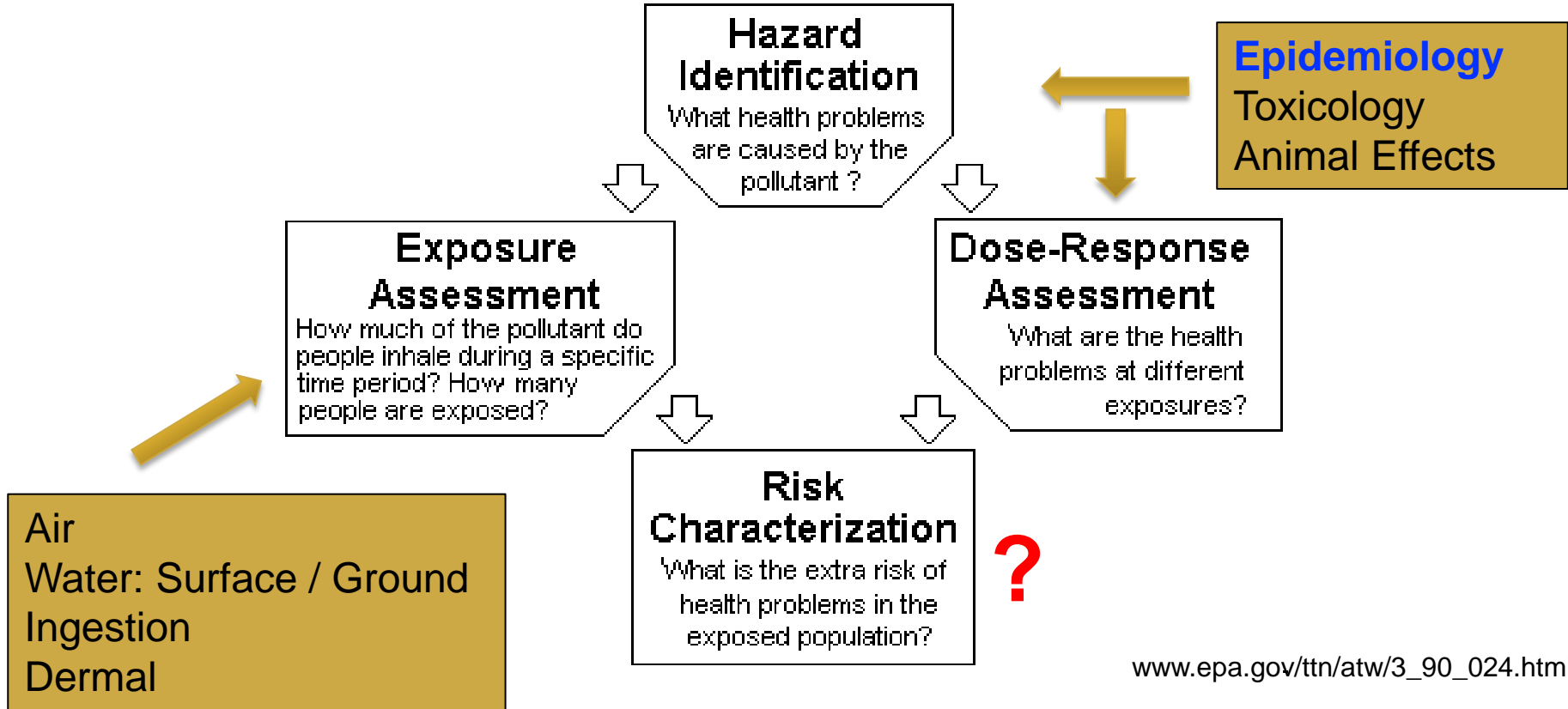


Determining the Health Risks?

Workers

Community

The 4-Step Risk Assessment Process



NIEHS National Toxicology Program (NTP)

u PAC Research Project

- Evaluation of toxicity of a wide range of PACs & defined PAH mixtures
- Short-term in-vitro panels and in-vivo models for diverse health endpoints
- Increase availability of compounds for analytical chemistry and toxicity testing
- Develop better exposure and effect biomarkers
- Evaluate genetic and epigenetic effects of various PACs
- Develop and evaluate relevant pharmacokinetic models
- Develop experimental models to evaluate effects of low level exposures

u Hydrogen Sulfide (H₂S) Research

- Individual and species toxicity research
- Better understanding of long-term effects associated with short-term high level exposures and chronic low-level exposures

Available Literature re: Health Effects & Concerns

Individual Health Impacts (both workers & residents)

- **Acute:** *asthma/respiratory function, eye/nose/ throat/skin irritation, constitutional symptoms (headaches, fatigue, etc.); deaths from VOC exposures*
- **Longer-term:** *pregnancy, fetal development, cardiovascular, lung disease (silicosis?), cancers (leukemia)?, neurobehavioral, hearing loss, stress reactions....*

Community Health Stressors

- *Concerns: resource availability, traffic, noise, light, crime, social disruption, seismicity, waste & water disposal*

Key Exposures to Consider: **Air:** VOC's; ozone, PM2.5, silica, diesel exhaust, road dust/particulate, gas release outdoor/indoor
Water: contaminated ground & surface waters (exposure food, drinking, bathing); **Soils/Dust:** spills, surface contamination



What information should the committee review to assess the epidemiological literature related to the onshore development of oil and natural gas from unconventional resources?

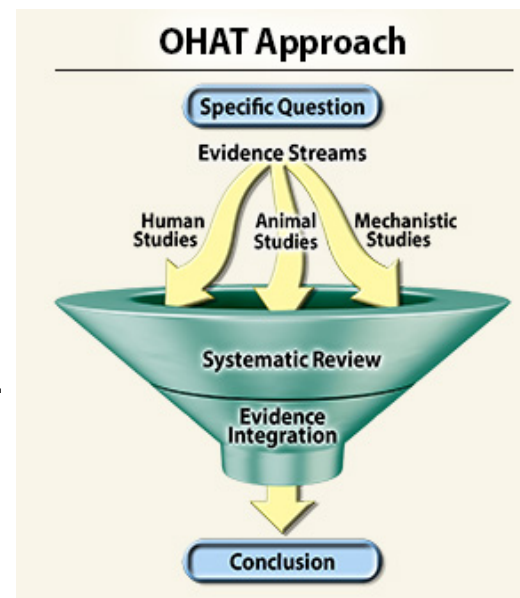
Systematic review of community health impacts of mountaintop removal mining.
[Environ Int.](#) 2017 Oct;107:163-172. [Boyles et. al.](#)

Handbook for Conducting a Literature-Based Health Assessment Using OHAT Approach for Systematic Review and Evidence Integration

What are the 7 steps in the NTP systematic review process?

1. Formulate problem and develop protocol.
2. Search for and select studies for inclusion.
3. Extract data from studies.
4. Assess internal validity of individual studies.
5. Synthesize evidence and rate confidence in the body of evidence.
6. Translate confidence ratings into level of evidence for health effect.
7. Integrate evidence to develop hazard identification conclusions.

<https://ntp.niehs.nih.gov/pubhealth/hat/review/index-2.html>



What criteria should the committee use to evaluate study quality?

Metrics of Study Design & Exposure Characterization

- **Study representativeness and generalizability** (locations, exposures, populations)
- **Population:** who, workers/community, demographics
- **Size /robustness:** needed to identify health endpoints of concern
- **Assessment of health effect:** self-reported, objective measures, medical records
- **Baselines or Comparison Groups:** how are changes identified, strength of effect
- **Clarity of relationship:** bias, confounders accounted for, pre-existing conditions

Exposure

- **Characterization / What's being measured:** baselines, pathways, surrogates (distance) vs measured exposures, sensitivity/limits of detection, etc.
- **Concentration & duration:** when, where, how long, change in background
- **Intensity and Frequency:** peaks & averages
- **Confounders:** other sources, changes in production, environmental factors



Looking beyond the initial Human Health Study Critique task, what do you see as key contributions from the Committee's review of literature and research planning in Year 1 and beyond?

Limited epidemiologic studies (ecological, X-sectional, case-control) often using surrogates of exposure (distance) or estimates based on area air sampling of only a few target analytes. "Hypothesis Generation"

What Critical Data is Missing and Why?

What do studies of disease / adverse health impacts in populations tell us?

Who has been studied specifically, where, demographics, population sizes, etc.?

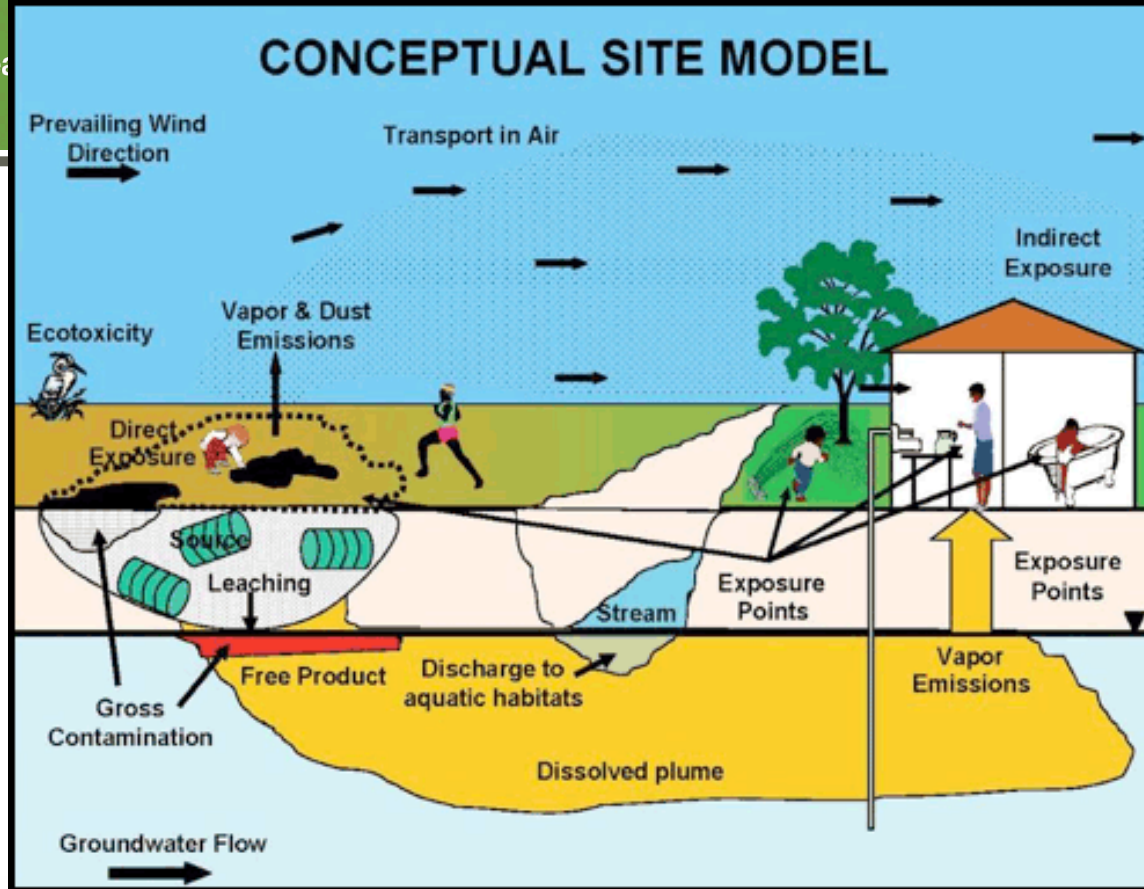
What kinds of health effects have been found (acute, chronic, cancer/non-cancer, heritable, etc.) and what do the findings indicate?

What do we understand about the pathways of exposure, the specific exposures themselves, the magnitude, duration, etc.?

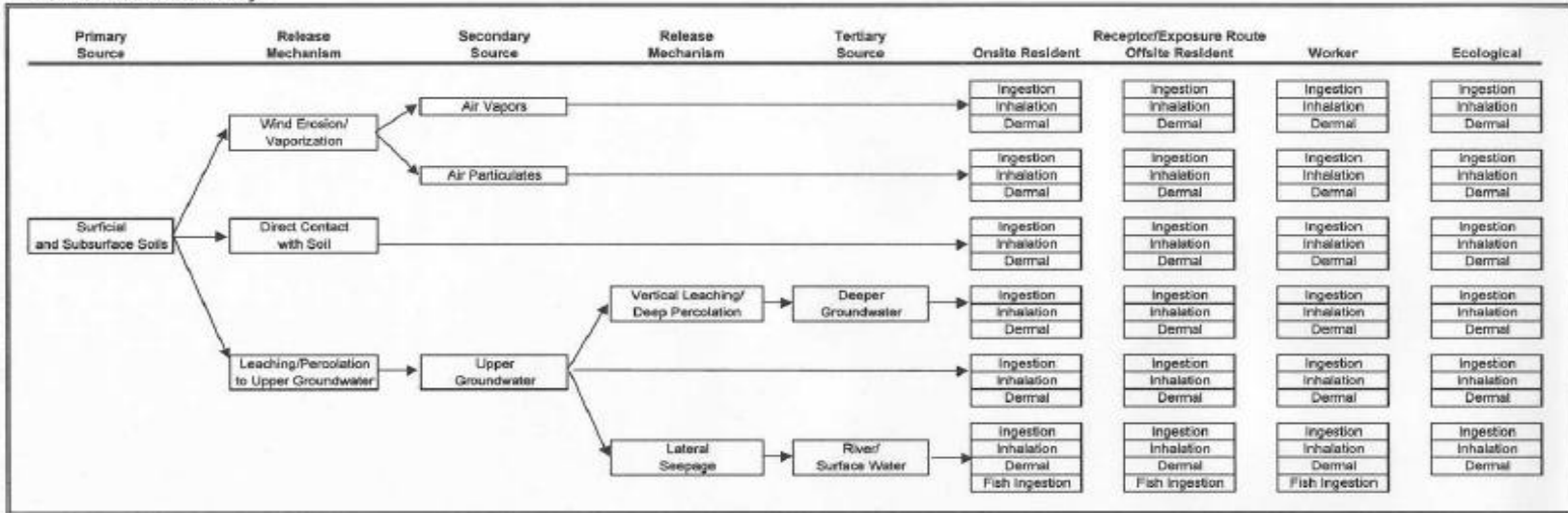
What do we understand about the health hazard / toxicity of each exposure individually, at what levels, and cumulatively? Mixed exposures?

SYSTEMATIC DATA COLLECTION by Design

- Routes of Exposure
- Measured Exposures
- Fate & Transport Considerations
- Receptor Populations
- Health Endpoints of Concern



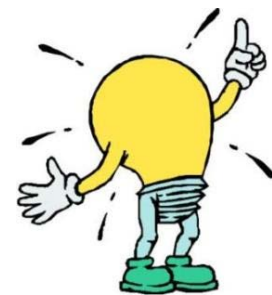
Human Health Risk Pathways



What do you see as key contributions that the Committee can make to the science and the public dialogue around the development of oil and natural gas from shale and other unconventional resources?

Roadmap for the science needed to inform understanding of health risks & exposures including types of data to be collected, metadata, quality assurance, data management, risk communications, community engagement, etc.

- Human health prioritized research plan
- Identification of risk factors of injury & illness
- Identification of "best practices" to reduce health risks
- Identification of priority toxicology and risk assessments
- Open Platform: access to protocols, data, findings, lessons-learned, other issues to help facilitate future research



Suggested Approach Priorities for Future Research

- Initially focus on worst case: workers & close proximity residences to pilot best methods for capturing exposures and health effects!!
- Prospective systematic design across multiple sites and populations
- Build off of well characterized areas with available data where possible
- Combined health data: medical records, surveys, medical testing, biomarkers of exposure and effect.
- Combined exposure assessments: extant data EPA, USGS, area monitors, personal sampling (e.g. wrist bands), home dust, water, air
 - **GIS coding & continuous samples for peak & average exposures**
 - **Archiving samples** (air, water, soil, ozone, dust PM 2.5)
 - **Sensitivity/ limit of detection** set for health effect research, not regulations
 - **Baseline testing** vital as well as comparison areas & groups



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Thank you!



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