Health Assessment Plan: Scope and Methods for Risk Assessment

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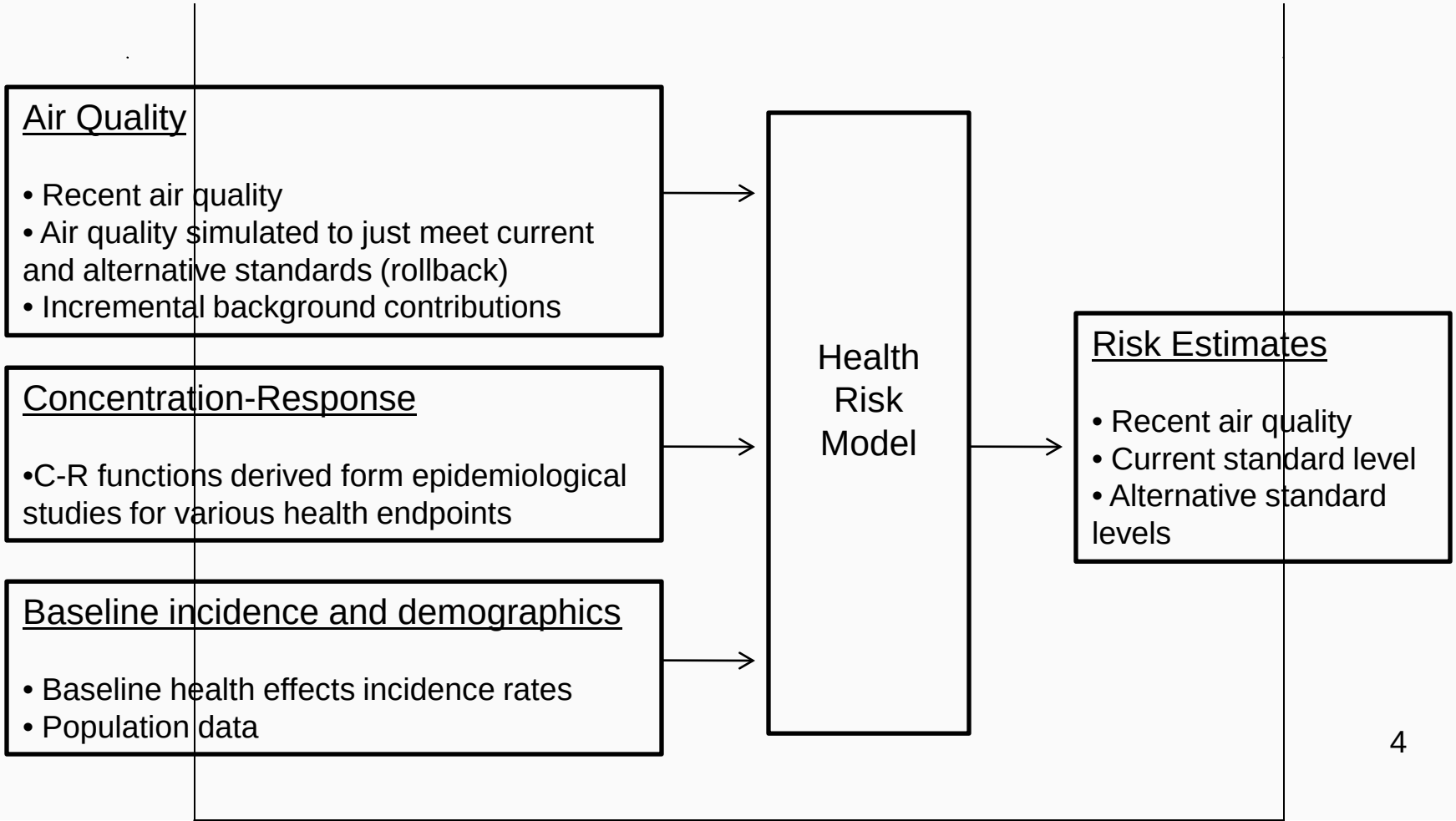
Highlights of the risk assessment from the 2008 review

- Risks were estimated for 12 urban study areas using effect estimates based on epidemiological studies
- Risk estimates included risk associated with “as-is” ozone concentrations and estimated risk reductions reflecting simulated attainment of the current and alternative 8-hr standard levels
- Following short-term exposure-related endpoints were modeled: (a) hospital admissions for respiratory illness (four study areas), (b) asthmatic symptoms in asthmatic children (one study area) and (c) premature total, respiratory and cardio-respiratory mortality (all12 study areas).
- Estimates provided by the risk assessment played an important role in rationale for decision on establishing new 8-hr standard

Policy-related questions for the current risk assessment

- Nature and magnitude of public health impacts:
  - Risk remaining after attainment of the current standard
  - Incremental risk reductions for alternative standard levels
- How varied are risk estimates across the urban study areas?
- How representative are the urban study areas of the urban U.S.
  - Have we captured areas of elevated risk?
- What are the important sources of uncertainty and variability?
- What degree of overall confidence do we have in these risk estimates?

Overview of ozone-related risk assessment approach (epidemiological study-based)



Air Quality Characterization

- *Background ozone:*
  - Previous RA: used single estimate, called Policy Relevant Background (PRB)
  - For this analysis, considering a more refined look at <u>attributable background contributions</u>
    - Natural background (no anthropogenic emissions)
    - Only anthropogenic emissions outside of N. America
    - Only anthropogenic emissions outside of U.S.
    - Current conditions
- Monitor-based exposure surrogate
  - Previous RA: used composite monitors matched to design of underlying epi studies
  - For this analysis, considering use of Vroni Neighbor Averaging within BenMAP (see below) depending on results of an evaluation
- Simulated attainment of current and alternative standards (quadratic rollback)

Risk Characterization – *selection of health effects endpoint categories*

- For this analysis, planning to focus on categories classified in ISA as having a *causal* or *likely-causal* relationship with ambient ozone exposures
  - Short-term exposure:
    - Respiratory morbidity (causal association)
    - Mortality (likely casual association)
  - *Long-term exposure* - respiratory morbidity and mortality.
    - Evidence for long-term respiratory effects is likely-causal – therefore,
    - Long-term respiratory-related mortality may be included in primary estimate
- Consider generating multi-city (national) estimate of short-term mortality and long-term mortality
  - Supports representativeness analysis (see below)
  - Also provides broader-scale estimate of ozone mortality across urban areas

Risk Characterization – *selection of urban study areas*

- Previous RA – considered following factors in study area selection:
  - Sufficient air quality data
  - Included in the epi study providing the basis for at least one of CR functions used in the RA
  - Sufficient baseline incidence data (for hospital admissions primarily)
  - Provide coverage for range of geographic areas and population demographics
- For this analysis:
  - Likely begin with 12 urban study areas modeled in previous RA
  - Consider air quality distributions (to cover areas with different exposure profiles for long-term exposure-related risk)
    - Air quality statistics for long-term respiratory effects studies are more complex (e.g., often season average of daily peaks)
    - Therefore, interpretation of implications of different distributions (in context of study areas selection) can be challenging

Risk Characterization – *methods for addressing uncertainty and variability*

- Previous RA:
  - Included qualitative discussion of key sources of uncertainty (e.g., extrapolation beyond observed air quality data, simulation of standard levels, estimation of PRB)
- For this analysis, planning to use 4-tiered WHO approach to address uncertainty.
  - Include detailed discussion of uncertainty and variability
    - qualitative assessment of potential impact of sources of uncertainty on risk estimates
    - Discussion of degree to which design of risk assessment provides coverage for key sources of variability associated with ozone risk
  - Sensitivity analysis exploring alternative model and input choices
    - Rollback methods
    - Specification of monitor-based exposure surrogate
  - Include confidence intervals based on statistical power associated with effect estimates
  - In-line with what was done for last PM NAAQS review.

Risk Characterization – *representativeness analysis*

- For current analysis, planning to compare urban study areas with national distributions of:
  - Ozone risk-related parameters (e.g., baseline incidence, ozone peak/mean ratios, demographic breakdown)
  - National-scale mortality (short-term and long-term)

  - Allows us to assess degree to which urban study areas provide coverage for broader set of urban areas in the U.S.
    - Assess degree of coverage for high-ozone risk urban areas

BenMAP as the risk modeling platform

- For this analysis, consider using BenMAP as the risk modeling platform
  - BenMAP – US EPA's Environmental Benefits Mapping and Analysis Program
    - Flexible health impact (incidence) modeling capability for ambient air pollutants
    - Publically available at: http://epa.gov/air/benmap/
  - Risk modeled using BenMAP has a number of advantages:
    - potential to reduce QA/QC issues through automation and scripting,
    - reduced computation time,
    - greater flexibility to consider sensitivity analyses.