NTP
National Toxicology Program

Draft OHAT Approach for Systematic Review and Evidence Integration for Literature-Based Health Assessments – February 2013

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Web-Based Informational Meeting
April 23, 2013 12:00 - 4:00PM EDT

Webinar Logistics

- **Format:**
  - Overview of the OHAT Approach in 2 presentations by OHAT staff
  - Focus on this framework (protocols illustrate detailed application)
  - Slides will be posted at a later date http://ntp.niehs.nih.gov/go/38751
- **Clarifying Questions:**
  - Clarifying questions after each speaker
  - Please **type in** your questions via the web "chat" feature
    - Use "chat" window to type questions during the presentations
    - Please keep your line on mute during the presentations
- **Mediated Question and Answer Session:**
  - NTP hosts will manage questions via "chat" window
  - We will open phone lines to allow audience to ask direct questions after both speakers

Presentation Outline

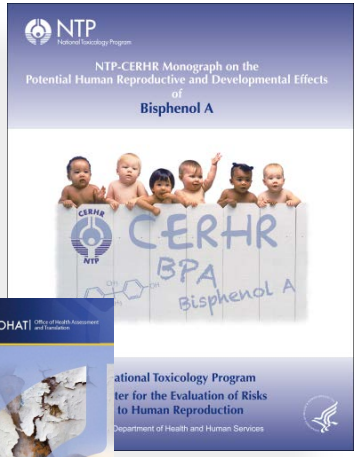
- The NTP Office of Health Assessment and Translation
- Background on Systematic Review
- Steps in the Draft OHAT Approach
  1. Prepare topic
  2. Search for and select studies for review
  3. Extract data from studies
  4. Assess quality or risk of bias of individual studies
     - Questions

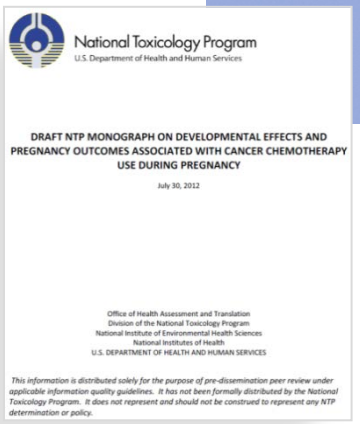
  5. Rate the confidence in the body of evidence
  6. Translate confidence ratings into evidence for health effects
  7. Integrate evidence to develop hazard identification conclusions
     - Questions
- Question and Answer Session

Office of Health Assessment and Translation

- Conduct literature-based evaluations to assess the evidence that environmental chemicals, physical substances, or mixtures cause adverse health effects
- Provide opinions on whether these substances may be of concern given what is known about current human exposure levels
- Serve as an environmental health resource to the public and to regulatory and health agencies

Monographs





Workshops

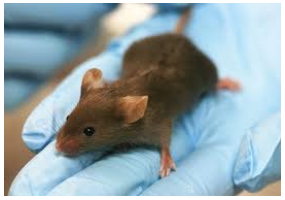
Systematic Review

- A scientific investigation that focuses on a specific question, and uses explicit, pre-specified methods to identify, select, summarize, and assess the findings of similar studies
- Provides greater transparency
- Used to:
  - reach evidence-based conclusions
  - clarify need for additional research
  - may or may not result in quantitative meta-analysis
- Existing methodologies are primarily used for assessment of healthcare interventions

What Does A Systematic Review Not Do?

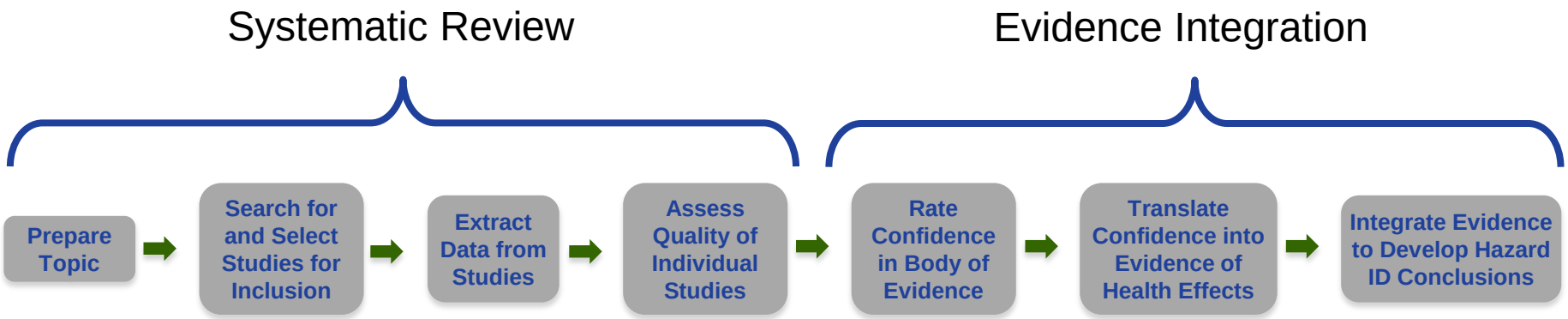
- Does not eliminate the need for expert judgment
- Does not guarantee reproducibility of conclusions
  - Increased transparency does not necessarily eliminate differences in scientific judgment
- Existing methods do not provide guidance on how to
  - Reach hazard identification conclusions
  - Integrate evidence across human, animal, and mechanistic studies





Draft OHAT Approach

- Builds on and extends existing systematic review methods
  - **Evidence integration** is the process for reaching conclusions on the NTP's confidence across a body of studies within an evidence stream (i.e., human and animal data separately) and then integrating those conclusions across the evidence streams with consideration of other relevant data such as supporting evidence from mechanistic studies
  - Lack of consensus on term "Weight of Evidence"? (Weed et al., 2005)



Developing the Draft OHAT Approach

- 18 months of consultation, communication, input, and review
  - **Engaged technical experts in systematic review** (webinars Jan-May 2012)
  - **Review of draft OHAT Approach**
    - August 2012 - NTP Board of Scientific Counselors Working Group
    - December 2012 - NTP Board of Scientific Counselors Meeting (public meeting)
  - **Development of protocols to illustrate draft OHAT Approach**
  - **Public release and discussion**
    - Release of “Draft OHAT Approach – February 2013”
    - March 2013 – Session at SOT “Implementing Systematic Review at NTP”
    - April 9 2013 – Release of Draft Protocols
    - April 23 2013 – Today’s Web-Based Informational Meeting

Sources Considered

- Published systematic review methods and resources
  - **AHRQ** - Agency for Healthcare Research and Quality
  - **CAMARADES** - Collaborative Approach to Meta Analysis and Review of Animal Data from Experimental Studies
  - **Cochrane Collaboration**
  - **GRADE Working Group** - Grading of Recommendations, Assessment, Development, and Evaluation
  - **Navigation Guide Work Group**

- Technical expert consultation on concepts and existing methods
  - **Lisa Bero** - Director, Cochrane Center at UCSF
  - **Gordon Guyatt** - Co-chair, GRADE Working Group, McMaster University
  - **Malcolm Macleod** - CAMARADES Centre, University of Edinburgh
  - **Karen Robinson** - Co-Director, AHRQ Evidence-Based Practice Center, Johns Hopkins
  - **Holger Schünenmann** - Co-chair, GRADE Working Group, McMaster University
  - **Tracey Woodruff** - Director, Program on Reproductive Health and the Environment, UCSF

- NTP BSC Working Group

- Technical expert consultation on draft protocols (listed in documents)