

NTP Evaluation Concept: Adverse Health Effects Associated With Occupational Exposure To Cancer Chemotherapy Agents

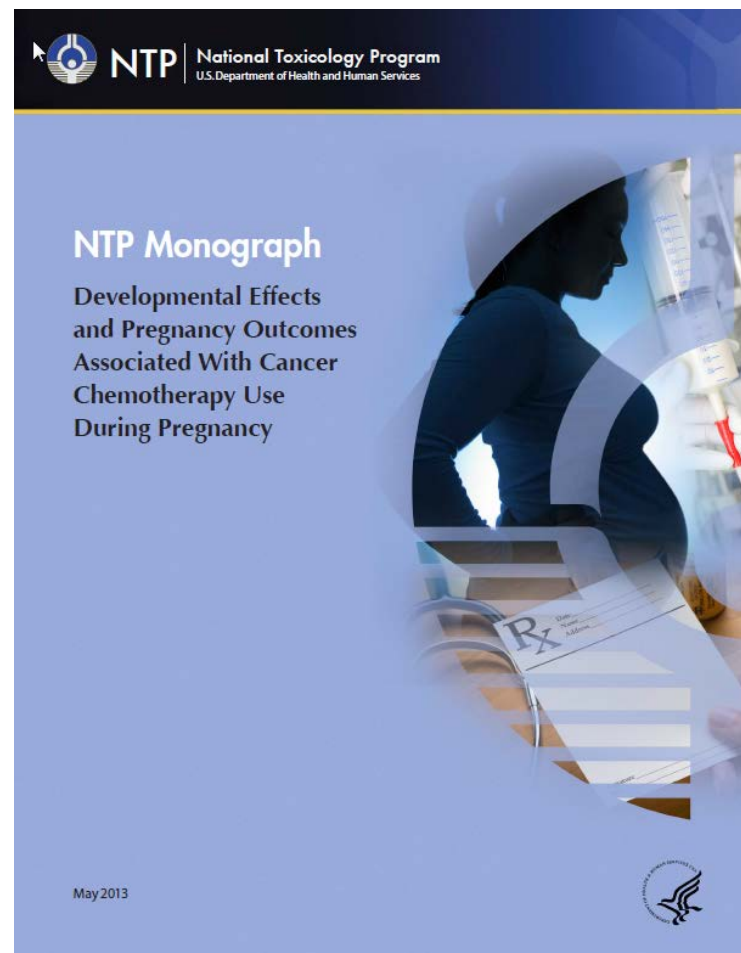
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NTP Board of Scientific Counselors
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Background and Rationale

- Identified as a data need during 2012 peer review meeting of draft NTP Monograph on Cancer Chemotherapy Use During Pregnancy
 - Monograph published 2013
- Occupational exposure to cancer chemotherapeutic agents occurs in many professions
- Exposure may occur over a long period of time and involve many chemotherapeutic agents



Background and Rationale (cont'd)

- Biomarkers of exposure in oncology nurses and pharmacists began appearing in the 1970s
- OSHA published guidelines for safe handling in the 1980s and 1990s
 - However, occupational exposure to cancer chemotherapeutic drugs continues to occur

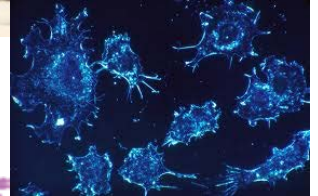


Recent systematic reviews

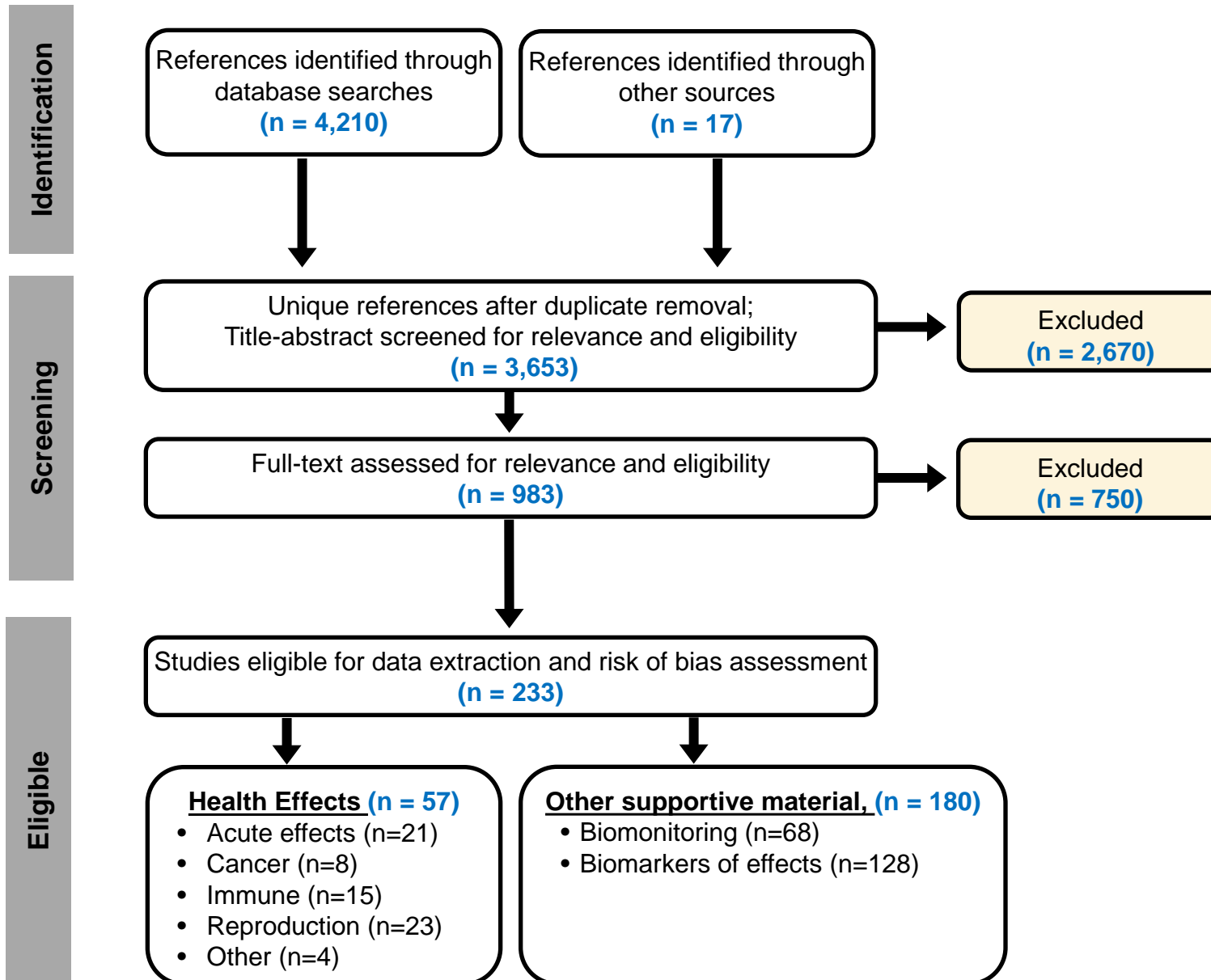
- Dranitsaris et al. (2005) focused on occupational exposure to cancer drugs in nurses, pharmacists, or pharmacy technicians/assistants
 - Reviewed literature on cancer, pregnancy outcomes, and acute toxic effects
 - Reported a “small incremental risk for spontaneous abortion”
- Quansah and Jaakola (2010) evaluated occupational exposure of nurses to anesthetic gases, chemotherapy drugs or shift work
 - Only congenital malformations and spontaneous abortion included
 - Reported that “nurses had an increased risk of adverse pregnancy outcomes, but the strength of association was weaker in the well-designed studies”
- NIOSH recently completed a review of hazardous drugs and reproductive health outcomes (under editorial review)

Preliminary literature search

- Search strategy combined 4 concepts:
 - Chemotherapy
 - Health staff
 - Occupational exposure
 - Health outcomes/genotoxicity



Preliminary Literature Screening



Concept Objective

- Conduct a systematic review of the evidence for adverse health effects associated with occupational exposure to cancer chemotherapy
 - Including all health effects:
 - Acute effects
 - Cancer
 - Immune system effects
 - Reproduction (e.g., spontaneous abortion, congenital malformations)
 - Other
 - Including all occupations exposed

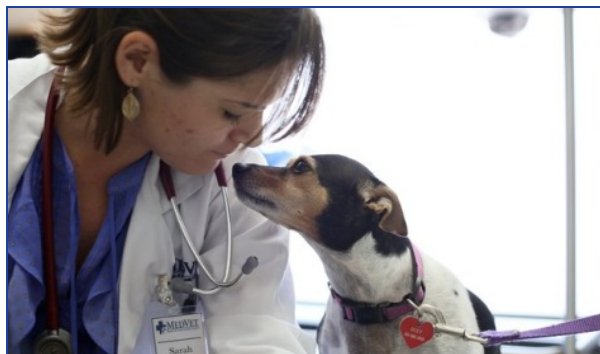


Key Issues

- Temporal nature of occupational exposure to cancer chemotherapeutic agents
- Differences in exposure (i.e., single agent versus combination therapy)
- Difficulty in estimating the internal exposure based on surface contamination
 - Biomonitoring studies may provide data on internal dose levels of select cytotoxic chemicals

Key Question

- What is our confidence in the body of evidence for an association between occupational exposure to cancer chemotherapy agents and adverse health effects based on the results of observational studies in humans?
- Specific Aims
 - To develop hazard identification conclusions
 - If insufficient data exist, write a state-of-the-science paper



Proposed Approach

- Work with technical advisors and evaluation design team to further refine the scope of the evaluation following initial characterization of studies
- Conduct evaluation using the OHAT Approach to Systematic Review and Evidence Integration



Significance

- Proposed evaluation will build upon and extend the NIOSH efforts to understand the health effects associated with occupational exposure to cancer chemotherapy
 - If sufficient data exist, will reach hazard identification conclusions
- Data management will be conducted in a manner that permits public sharing of:
 - Exploratory literature search strategy results
 - Data extracted from relevant studies



Acknowledgments

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Charge Questions

1. Please comment on the clarity and validity of the rationale for the proposed evaluation as articulated in the draft concept.
2. Please comment on the merit of the proposed evaluation relative to the goals of the NTP.

The NTP's objectives are to: provide information on potentially hazardous substances; develop and validate improved test methods; strengthen the science base in toxicology; coordinate toxicology testing programs across DHHS.

3. Please comment on the proposed approach for the evaluation.
4. Please comment on the scope of the proposed evaluation and its appropriateness, relative to the public health importance of the issue.
5. What priority (low, moderate, or high) should NTP give the proposed evaluation given the rationale, merit, and scope?
6. Provide any other comments you feel staff should consider in developing this evaluation