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By Tracey J. Woodruff, Patrice Sutton, and The Navigation Guide Work Group

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# An Evidence-Based Medicine Methodology To Bridge The Gap Between Clinical And Environmental Health Sciences

**ABSTRACT Physicians and other clinicians could help educate patients about hazardous environmental exposures, especially to substances that could affect their reproductive health. But the relevant scientific evidence is voluminous, of variable quality, and largely unfamiliar to health professionals caring for people of childbearing age. To bridge this gap between clinical and environmental health, we created a methodology to help evaluate the quality of evidence and to support evidence-based decision making by clinicians and patients. The methodology can also support professional societies, health care organizations, government agencies, and others in developing prevention-oriented guidelines for use in clinical and policy settings.**

**Tracey J. Woodruff** (woodruff@obgyn.ucsf.edu) is an associate professor and director of the Program on Reproductive Health and the Environment, University of California, San Francisco.

**Patrice Sutton** is a research scientist at the Program on Reproductive Health and the Environment.

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Widespread exposure to environmental chemicals at levels encountered in daily life can affect reproductive and developmental health adversely.[1,2] Studies have demonstrated that the levels of chemicals to which an average person is exposed can prevent genes from functioning normally and interfere with the hormonal regulation critical to healthy reproduction.[3,4]

For example, environmental chemicals such as polybrominated diphenyl ethers (PBDEs) from flame retardants in furniture and computers,[5] phthalates in commonly used plastics,[2] and persistent organochlorine pesticides such as DDT[6,7] share the ability to alter the endocrine, neurological, and other biological systems. Virtually everyone in the United States is constantly exposed to these and many other toxic chemicals found in homes, communities, and workplaces.[8,9]

Exposures to ambient levels of environmental chemicals during critical periods of growth and development—in utero and during infancy, childhood, and adolescence—are of particular concern because they can have a profound and lasting effect on health.[10–12] Virtually all pregnant women in the United States have detectable levels of all of the following environmental chemicals in their bodies: lead, mercury, toluene, perchlorate, bisphenol A (BPA), and some phthalates, pesticides, perfluorochemicals (PFCs), polychlorinated biphenyls (PCBs), and PBDEs.

Studies have documented that each of these chemicals can be harmful to human reproduction or development, or both. Many of these chemicals in pregnant women are at levels associated with adverse health outcomes in human studies.[13] The reproductive and other potential health impacts of daily and simultaneous exposure to environmental chemicals has not been studied. This shortcoming is recognized by the National Academies to be a gap in current scientific methodologies that inform public policy.[1]

Based on their expert assessment of the strength of the existing science, leading scientists and reproductive and other health care professionals recommend timely action to prevent harm.[11,14–16] The evidence of harm for some chemicals is also strong enough to warrant regulatory action to reduce or prevent exposure, albeit after the chemicals have been allowed to enter the market, the environment, and people.[17] The

inadequacy of this postmarket regulatory framework is receiving increased scrutiny by the federal government,[18] nongovernmental organizations,[19] industry,[20] and professional medical organizations.[21]

## Intervening In Clinical Settings To Prevent Harm

Although efforts to improve the regulatory framework for chemicals in commerce are fundamental to preventing harm, the clinical practice of physicians and others offers a complementary point of intervention. Clinical practice presents an opportunity to identify and evaluate factors that influence patients' health and to counsel them about those factors, thus preventing harm from hazardous environmental exposures.

Pediatricians have long been attuned to this opportunity. The American Academy of Pediatrics has had an environmental health committee for more than half a century and publishes a clinician handbook for the prevention of childhood diseases linked to environmental exposures.[22] The Centers for Disease Control and Prevention and the Environmental Protection Agency (EPA) support a network of pediatric environmental health specialty units across the country.[23] These specialty units respond to requests for information throughout North America on prevention, diagnosis, management, and treatment of environmentally related health effects in children.

In light of the importance of preconception and prenatal environmental exposures to the health of the pregnancy, and thus to tomorrow's children and adults, these pediatric approaches to incorporating environmental health into clinical care are equally relevant to reproductive health. Many people hoping to have children are intensely and justifiably interested in the impact of environmental exposures on their pregnancies and the health of their future children. Health care professionals serving people of childbearing age can serve as a science-based source of guidance on how to avoid potentially adverse exposures.[24]

More important, many people who may eventually have or want to have children are unaware that their home, workplace, and community environments may influence their fertility and their future children's health, and they do not know about steps they can take to reduce exposure and potential harm. Environmental health science provides much evidence about the contribution of the environment to reproductive health, but this information is not available to clinicians in a readily usable form.

One factor that makes it difficult for clinicians, patients, and policy makers to make use of the science is that it is not systematically and transparently evaluated and synthesized in a timely manner. The scientific evidence is voluminous, of variable quality, and largely unfamiliar to health professionals caring for people of childbearing age. And there is no trusted ready reference or compendium that provides health professionals and patients with timely, evidence-based advice about exposure to environmental contaminants.

There are many steps and complexities involved in the use of current best evidence in health care settings.[25] However, the process can be accelerated when knowledge-based information is readily available.[26] Therefore, we undertook an interdisciplinary collaborative process to develop a transparent and systematic methodology to sort out the scientific evidence linking environmental exposures to reproductive health outcomes. Although its purpose is to support the development of prevention-oriented guidelines for use in clinical settings, the methodology can also be used to review the evidence in broader policy arenas.

## Bridging The Gap Between Environmental Health And Clinical Sciences

Timely incorporation of scientific evidence into clinical care to improve health outcomes has long been a goal in the clinical arena, exemplified by the establishment of the Agency for Healthcare Research and Quality.[27] The experience gained in advancing this goal is directly relevant to incorporating environmental health science into clinical practice.

Currently, environmental health scientists use many different methodologies based on expert opinions to sort out the science. Historically, the clinical field generally relied on a system of expert reviews on which to base treatment decisions.[28] However, starting in the 1970s, the role of expert reviews began to be questioned, and systematic approaches that harness expertise to a rigorous, transparent, and explicit methodology to evaluate a clearly formulated question were advanced.

Landmark papers published in the clinical literature, such as the work of Elliott Antman and colleagues,[27] demonstrated the superiority of systematic reviews for patient outcomes.[28] Antman and colleagues compared recommendations based on expert opinions for treatment of myocardial infarction that had been published in scientific reviews and clinical textbooks to statistical analyses of the combined results of

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randomized controlled trials. This research documented the lack of timely incorporation of experimental evidence into expert-based recommendations: Some reviewers did not mention effective therapies, and others recommended therapies already proven to be ineffective.

In response to these and other similar research findings, by 2002 at least 121 methodologies of varying usefulness had been developed to evaluate health care research to guide clinical decision making.[29] Subsequently, attempts were made to address the limitations of many of these methods and the related concern that the abundance of methodologies could lead to confusion rather than clarity.[30,31]

An approach emerged—the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system—that was based on contemporary principles of evidence-based medicine and that built on the strengths of existing systems and addressed their shortcomings.[32,33] GRADE systematically rates the quality of evidence and grades the strength of the recommendations to administer—or not administer—an intervention based on the trade-offs between benefits, on the one hand, and risks, burden, and potential costs, on the other hand. Grading recommendations provides health care decision makers with a qualitative estimate of how good the recommendations are—strong or weak, with "weak" sometimes called "discretionary."

Thus, GRADE provided our effort to bridge the gap between clinical and environmental health sciences with a well-developed and transparent organizing framework to use in evaluating the strength of evidence, integrating expertise and patients' values and preferences, and effectively communicating the results. GRADE is also in wide use, having been adopted by more than fifty organizations such as the World Health Organization, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, and Kaiser Permanente.

However, along with these strengths, GRADE and other evidence-based medicine methodologies have limitations in terms of their direct applicability to environmental health science. These limitations exist because clinical evidence differs in character from evidence streams in environmental science, and because clinical decision making differs in context from decision making in environmental health science. Each of these two essential differences is described below.

**EVIDENCE-STREAM DIFFERENCES** Differences exist between clinical and environmental health sciences in the types of evidence generally available to decision makers. The GRADE method considers only human experimental and observational evidence. This is because in vitro and in vivo data have been accounted for by regulatory processes prior to the entry of pharmaceuticals—a primary application of GRADE—into the marketplace (Exhibit 1).

In contrast, clinicians cannot assume, as they do with pharmaceuticals, that adequate in vitro and in vivo testing of environmental contaminants has been undertaken and considered by regulatory agencies before widespread human exposure occurs. The vast majority of chemicals in commerce have entered the marketplace without comprehensive and standardized information on their reproductive or other chronic toxicities (Exhibit 1).

**DECISION-CONTEXT DIFFERENCES** Environmental and clinical sciences also differ in how decisions to expose populations and patients are made. GRADE rates the quality of evidence about exposure to exogenous substances based on how reliably the evidence informs a clinical risk-benefit decision.[34] This is consistent with regulatory and medical ethical requirements that human exposure to pharmaceuticals not occur in the absence of some potential benefit greater than the known risks.

The "gold standard" for informing clinical risk-benefit decisions about medical interventions is a well-conducted randomized controlled trial. There is no comparable comprehensive weighing of health benefits and risks in the environmental arena.[35] The benefits of environmental chemicals are mostly not directed toward improving health, and exposures vary and may or may not be significant depending on the toxicity of the agent. Randomized controlled trials on environmental contaminants are virtually precluded from the evidence stream because of ethical considerations.

## The Navigation Guide

To bridge this gap between the evidence streams and decision contexts in clinical and environmental health sciences, we undertook an interdisciplinary collaboration to craft an evidence-based medicine methodology for evaluating environmental contaminants and their potential effects on reproductive and developmental health. The result is the Navigation Guide, the product of a year-long collaboration of twenty-two clinical practitioners and environmental health scientists from governmental and nongovernmental organizations in the United States and Europe.

The Navigation Guide proceeds from GRADE but accounts for the differences in evidence and decision context described above. The method is

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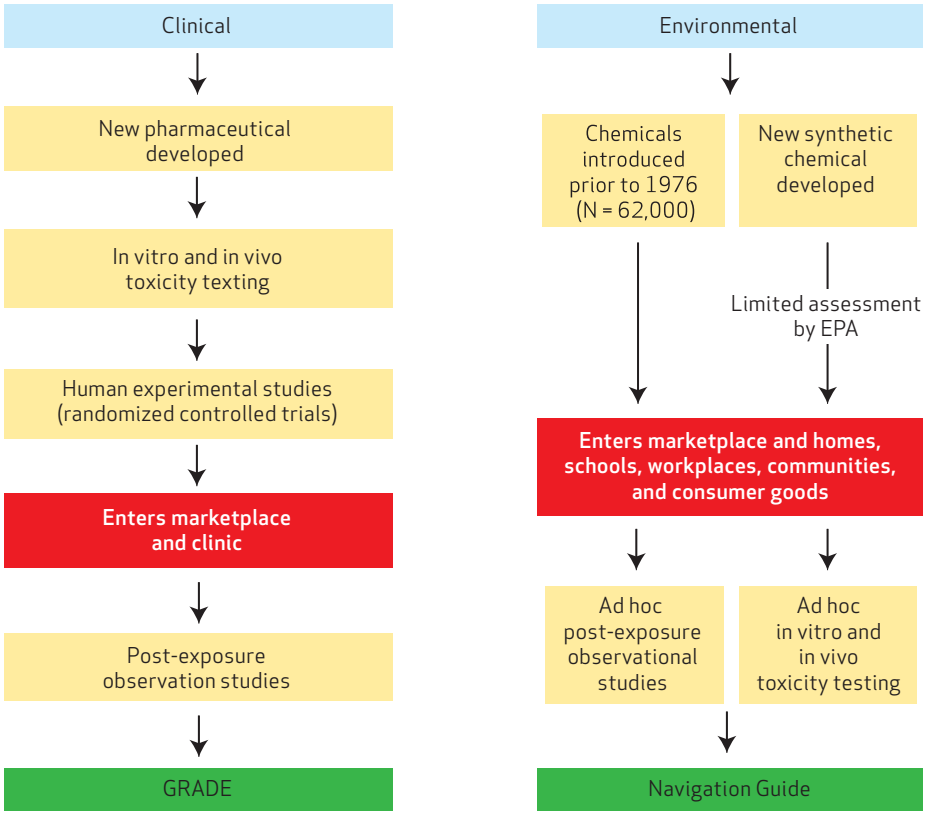
**EXHIBIT 1**

**Streams Of Evidence For Chemical Toxicity Assessment In Clinical And Environmental Health Sciences**




**SOURCE** University of California, San Francisco, Program on Reproductive Health and the Environment, Navigation Guide Work Group.

briefly summarized here and presented in detail in the Appendix.[36] The methodology involves four steps.

**SPECIFY THE STUDY QUESTION** The first step is to frame a specific question relevant to health care decision makers about whether human exposure to a chemical or class of chemicals is a reproductive health risk. An example would be, "Does maternal exposure to perfluorooctane sulfonate affect fetal growth?"

**SELECT THE EVIDENCE** The next step involves conducting and documenting a systematic search for published and unpublished evidence. The Navigation Guide does not incorporate most existing lists of reproductive or developmental toxicants because the methods used to compile these lists are many and varied, and typically not systematic or transparent.

**RATE THE EVIDENCE** Consistent with GRADE, the Navigation Guide systematically rates the quality of individual studies and the quality of the overall body of evidence based on a priori and clearly stated criteria. However, because of the nature of the evidence stream in environmental health, the Navigation Guide conducts this process for studies of humans as well as for studies of laboratory animals and other nonhuman streams of evidence.

As a consequence, the methodology involves an additional step to integrate the quality ratings of each of these two streams of evidence. The result is one of five possible statements about the overall strength of the evidence pertaining to a particular environmental exposure: "known to be toxic," "probably toxic," "possibly toxic," "not classifiable," or "probably not toxic" to reproductive or developmental health.

**GRADE THE STRENGTH OF THE RECOMMENDATIONS** In the final step, the Navigation Guide integrates the strength of the evidence on toxicity with information about exposure, the availability of a less toxic alternative, and patients' values and preferences.

The result of applying the Navigation Guide is a concise, evidence-based recommendation for prevention, based on all of these considerations, such as, "Chemical *X* is known to be toxic to reproductive health. Doing *x*, *y*, or *z* to prevent exposure is strongly recommended. Doing *a*, *b*, or *c* is discretionary."

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## Future Directions

A large body of science links exposure to environmental chemicals to adverse reproductive health outcomes across the lifespan of individuals and generations. Thus, there is enormous potential to reduce harm and associated health costs by bridging the divide that too often separates clinical and environmental health sciences.

To this end, the Navigation Guide offers a methodology to vet the science linking environmental exposure to chemicals to reproductive and developmental health in a systematic and transparent way. Professional societies, health care organizations, government agencies, and other potential guideline developers, working with toxicologists, can use the Navigation Guide to craft consistent and timely recommendations to improve health outcomes for patients, and ultimately populations.

The evidence stream is rapidly changing in both clinical and environmental health sciences. The Navigation Guide and other evidence-based systems will need constant review to ensure that the most current approaches to identifying the evidence are rapidly incorporated and evaluated.

It is also expected that electronic health records will revolutionize medical research by facilitating the compilation of both instant data and longitudinal data.[37] Having such information could greatly accelerate the creation of knowledge about the impact of the environment on human health.

## Conclusion

Just as the thalidomide tragedy of the 1950s and 1960s led to strengthened regulatory oversight of the safety and efficacy of all prescription drugs,[38] recent advances in testing for toxicity,[39–44] in understanding the health risks of exposure to environmental contaminants,[1,2,45,46] and in the regulation of chemicals in commerce[18–21,47] are likely to result in important changes in the amount, type, and availability of data on chemical toxicity and related health impacts. We need to be able to translate these data in a timely way into prevention-oriented guidelines for use by clinicians and patients. The Navigation Guide provides a framework for doing so, with the ultimate goal of improving patient and population health. ■

The authors acknowledge the other members of the Navigation Guide Work Group: Vincent James Cogliano (International Agency for Research on Cancer), Kate Guyton (Environmental Protection Agency [EPA]), Julia Quint (Retired, California Department of Public Health), Lauren Zeise (CA-EPA), Judith Balk (University of Pittsburgh [UP]), Lisa Bero (UCSF), Jeanne Conry (Kaiser Permanente, American College of Obstetricians and Gynecologists District IX), Daniel M. Fox (Emeritus, Milbank Memorial Fund), David Gee (European Environmental Agency), Rivka Gordon (Association of Reproductive Health Professionals [ARHP]), Sarah Janssen (Natural Resources Defense Council), Beth Jordan (ARHP), Victoria Maizes (University of Arizona), Mark Miller (UCSF), Michele Ondeck (UP), Karen Pierce (San Francisco Department of Public Health), Pablo Rodriguez (Brown Medical School and Women & Infants Hospital of Rhode Island), Heather Sarantis (Collaborative on Health and the Environment), Ted Schettler (Science and Environmental Health Network), and Sandy Worthington (Planned Parenthood Federation of America). Jason Harless provided essential administrative support to this project. The views expressed in this article are those of the authors and do not necessarily reflect the views or policies of the US Environmental Protection Agency or any other government agency. Financial support for development of the Navigation Guide was provided to UCSF Program on Reproductive Health and the Environment by: Clarence Heller Foundation, Passport Foundation, the Heinz Endowments, the Fred Gellert Foundation, Rose Foundation, Kaiser Permanente, New York Community Trust, University of California, San Francisco Institute for Health Policy Studies, Planned Parenthood Federation of America, National Institute for Environmental Health Sciences (ES018135) and US Environmental Protection Agency STAR (RD83467801.

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## ABOUT THE AUTHOR: TRACEY J. WOODRUFF

**Tracey J. Woodruff** is director of the Program on Reproductive Health and the Environment, University of California, San Francisco.

In this month's *Health Affairs*, Tracey Woodruff, Patrice Sutton, and twenty other scientists and clinicians from the Navigation Guide Work Group note that although widespread exposure to environmental hazards can adversely affect reproductive and developmental health, much of that evidence is either not available to clinicians or does not use a methodology familiar to them.

The authors, researchers, and scientists from the United States and Europe working on the interplay between the environment and health, and practicing clinicians and experts in systematic reviews have therefore created a Navigation Guide, an evidence-based methodology to review and evaluate the quality of evidence and strength of recommendations pertaining to environmental risks and reproductive health. The guide is intended to help clinicians and health policy makers make evidence-based decisions to ensure healthy pregnancies and children.

Woodruff is director of the Program on Reproductive Health and the Environment at the University of California, San Francisco, and an associate professor in the Department of Obstetrics, Gynecology, and Reproductive Sciences and Philip R. Lee Institute for Health Policy Studies. She has done extensive research and policy development on environmental health issues, with a particular emphasis on early-life development. Her research areas include evaluating prenatal exposures to environmental chemicals and related adverse pregnancy outcomes, and characterizing developmental risks.

Woodruff was previously at the Environmental Protection Agency, where she was a senior scientist and policy adviser in the Office of Policy, Economics, and Innovation. She received a master of public health degree and a doctorate in bioengineering from the University of California, Berkeley and San Francisco, and completed a Pew Postdoctoral Fellowship at the Institute for Health Policy Studies, University of California, San Francisco.

Woodruff is also the lead author of another paper in this issue that details the weaknesses in current approaches to prevent environmental contamination of foods and recommends incorporating environmental science into risk-management decisions. She is a coauthor on another paper for which Sutton is the lead author: a call to arms—aimed in part at the health care community—to advance production of healthy foods to prevent adverse reproductive health effects.

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