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REVIEW

Risk Communication and Decision Tools for Children's Health Protection

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Scientific discovery linking the environment to beneficial and adverse health children's health outcomes is rapidly expanding, leading scientists and health professionals to call for timely action to prevent harm and secure benefits. A robust method to synthesize what is known about the environmental drivers of health is a foundational step to making the science actionable by individuals and decision-makers. To meet this need, a methodology called the Navigation Guide was crafted by a collaboration of 22 clinical and environmental health scientists. The Navigation Guide proceeds from methods of research synthesis used in clinical settings but accounts for differences between environmental and clinical health sciences related to the evidence-base and decision-context. The methodology can be used to develop evidence profiles that provide simple, transparent summaries, such as practice guidelines or other evidence-based recommendations for prevention. Establishing proof-of-concept of the method is underway. Development of the Navigation Guide is extremely timely as it coincides with growing recognition of the need for updated methods in risk assessment. The costs in 2008 to the US healthcare system for treatment of childhood illnesses linked to toxic environmental exposures is conservatively estimated to be over $76 billion, and it is anticipated that US healthcare policy decisions will increasingly rely on systematic reviews of the evidence. The Navigation Guide is poised to provide a methodological bridge to link healthcare decision-making to efforts to reduce toxic environmental exposures. The institutionalization of the Navigation Guide would provide a concrete mechanism for linking science to action to protect children's health. **Birth Defects Research (Part C) 99:45–49, 2013.** © **2013 Wiley Periodicals, Inc.**

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INTRODUCTION

Scientific discovery linking the environment to beneficial and adverse health children's health outcomes is rapidly expanding. Studies find that individually and together, the social, built and nutritional environment, and physical and chemical agents are key drivers of child health (Schneider et al., 2001; Morello-Frosch and Shenassa, 2006; Weiss and Bellinger, 2006; Wright, 2008, 2010; Guilloteau et al., 2009; Marmot and Bell, 2009; Cheadle et al., 2010; Kordas, 2010; Ren et al., 2010; Williams and Sternthal, 2010; Wright et al., 2010; Burke and Miller, 2011; Morello-Frosch et al., 2011). Science over the last decade spotlights the importance of environmental exposures that occur during periods of development, that is, in utero, and during infancy, childhood and adolescence. This is because these periods are windows of increased vulnerability to environmental contributors to health (Crain et al., 2008; Grandjean et al., 2008; Newbold and Heindel, 2010; Woodruff et al., 2010). Moreover, the consequences of developmental exposures can extend across the lifetime of individuals and potentially across generations (Olden et al., 2011). In recognition of the science linking environmental exposures during periods of development to a myriad of health outcomes that can manifest from infancy to old age, leading scientists and health professionals have called for timely action to prevent harm and secure benefits (Grandjean et al., 2008; Woodruff et al., 2008; Diamanti-Kandarakis et al., 2009; Reuben and President's Cancer Panel, 2010; UCSF Program on Reproductive Health and the Environment, 2012).

Communication and decision tools for preventing exposure to environmental chemicals need to encompass not only individual action but also action at policy levels (Lubick, 2011). While action at the individual level can potentially reduce exposure to some toxic chemicals (Lu et al., 2006; Ji et al., 2010; Rudel et al., 2011), and informed consumer-purchasing patterns can send a signal to the marketplace to help drive societal change (Bailin et al., 2008; Layton, 2011), individuals alone can do little to impact many exposures, such as air and water pollution. Further, decisions on the individual level about avoiding toxic exposures are also often affected by external factors that limit making healthier choices (Adler and Stewart, 2009).

Moreover, a formidable barrier to prevention is that in their efforts to take action on the science, clinicians, parents, and policy makers

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are confronted with a plethora of information, some contradictory, about environmental and chemical risks to children's health. They want and need evidence-based information to inform what they do to prevent exposures and promote health. Better decision tools are needed to evaluate the soundness of available information, synthesize it and translate it into public-friendly prevention strategies for health professionals, parents and decision-makers.

Taking Action to Prevent Harm and Secure Benefits: The Role of Research Synthesis

Clinicians, health impacted populations, advocates and policy makers generally lack the capacity to efficiently, systematically and transparently incorporate the meaning of the science into their decision-making. The science linking the environment to health is voluminous, of variable quality, complex, and largely unfamiliar to decision-makers in clinical and policy arenas. Keeping abreast of its meaning can be overwhelming. An unrelenting deluge of bits and pieces of information can serve to mask rather than amplify early warning signals and undermine our capacity to act wisely. A robust method to synthesize what is known about the environmental drivers of health is a necessary foundational step to making the science actionable by individuals and decision-makers.

Methods in Research Synthesis

Common features of the many and varied methods currently used by environmental health scientists are that they are expert opinion-based narratives and do not provide weight of evidence summaries for noncancer effects. Historically, similar methods prevailed in the clinical field which largely relied on a system of expert reviews on which to base treatment decisions (Rennie and Chalmers, 2009). 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. Empirical evidence in clinical health sciences demonstrates the superiority of systematic reviews for patient outcomes (Rennie and Chalmers, 2009). A landmark paper by Antman et al. compared expert opinion-based recommendations for treatment of myocardial infarction published in scientific reviews and clinical textbooks to statistical analyses of the combined results of randomized controlled trials (Antman et al., 1992). This research documented the lack of timely incorporation of experimental evidence into expert-based recommendations with some reviewers not even mentioning effective therapies, and others recommending therapies proven to be ineffective or even dangerous.

Methods to synthesize the science into evidence-based decisions have been developed and validated in clinical arenas (Montori and Guyatt, 2008; GRADE Working Group, 2011). But due to differences between environmental and clinical health sciences related to the evidence-base and decision-context these methods are not seamlessly applicable to environmental exposures.

In the clinical setting, *in vivo*, *in vitro*, and human experimental evidence combined with an analysis of risks and benefits inform human exposure decisions prior to the entry of substances into the marketplace (Fig. 1). The "gold standard" of evidence for clinical risk benefit decisions is a well-conducted randomized control trial. Systematic reviews in the clinical sciences proceed from this evidence and context.

In stark contrast, population exposure to exogenous substances in the environment typically occurs before regulatory scrutiny of a compound and in the absence of risk-benefit analysis, because of the current regulatory structure for governing manufactured chemicals. Ethical considerations virtually preclude experimental human data from the environmental health evidence stream, so we must rely on in vitro and in vivo studies for early warnings of adverse effects and on human observational studies to assess the nature and extent of the damage (Zapponi et al., 2008).

To bridge this gap between the evidence streams and decision contexts in clinical and environmental health sciences, the University of California, San Francisco Program on Reproductive Health and the Environment undertook an interdisciplinary collaboration to craft an evidence-based medicine methodology to evaluate environmental contaminants and their potential effects on reproductive and developmental health. The result is the Navigation Guide, the product of a yearlong collaboration of 22 clinical and environmental health scientists and/or practitioners, from governmental and nongovernmental organizations in the US and Europe (Woodruff et al., 2011). The Navigation Guide proceeds from methods in the clinical sciences but accounts for the differences in evidence and decision context described above.

Overview of the Navigation Guide

The Navigation Guide methodology involves four steps (Fig. 2). Applying the methodology requires the expertise of toxicologists, epidemiologists, statisticians, industrial hygienists, clinicians, and other potential scientific expertise. The method also provides for the incorporation of the expertise of nonscientists, including health-impacted populations and their advocates, for example, in framing a meaningful study question and incorporating local knowledge, values and preferences into recommendations for prevention.

While such expertise is incorporated into every step, it is not an "expert-opinion" methodology. What is a fundamental shift from existing methods of expert review in environmental health science is that each of the four steps is conducted in a thorough, consistent and transparent manner, every "judgment" is

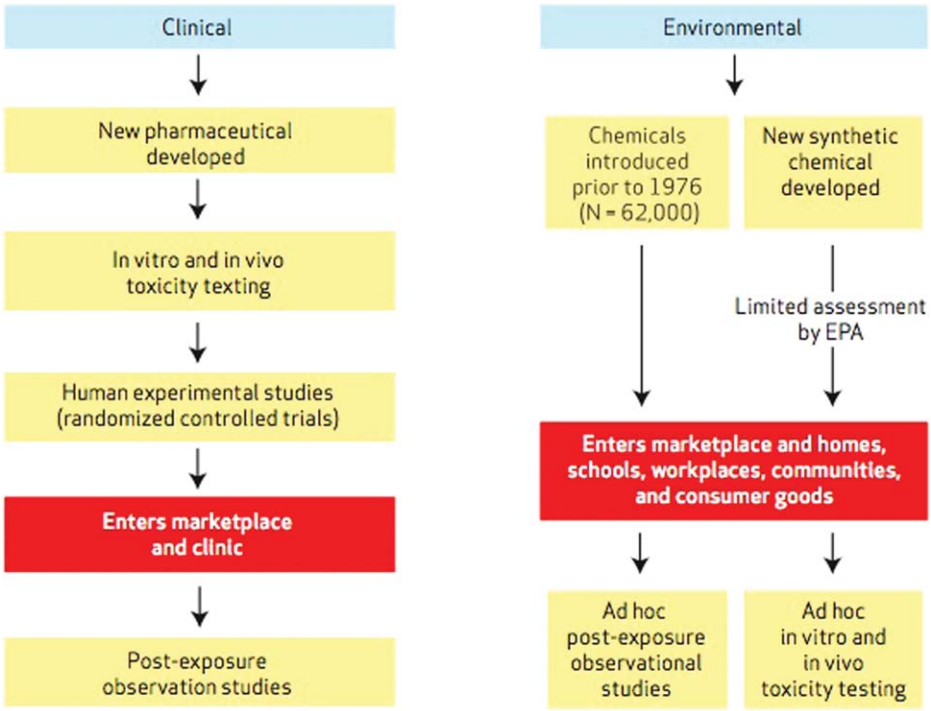

Figure 1. Comparison of streams of evidence in clinical and environmental health sciences.

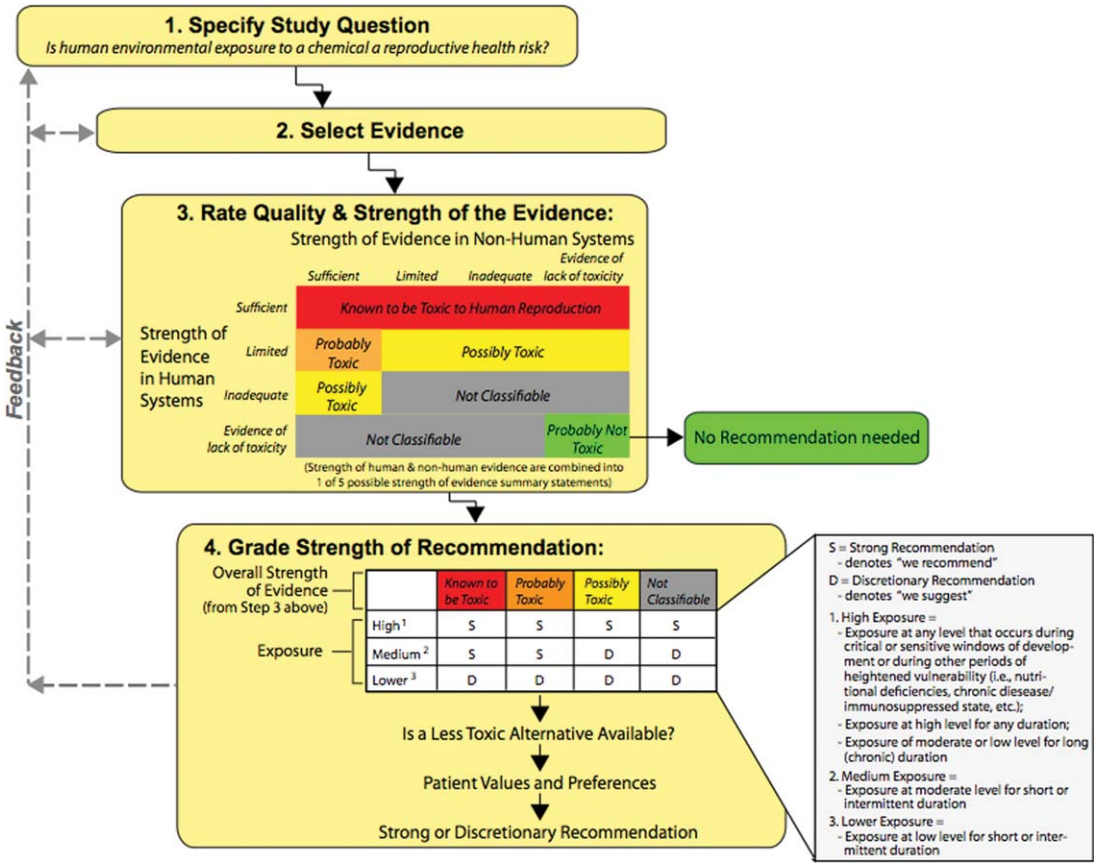

Figure 2. Overview of the navigation guide methodology. Source: Woodruff TJ, Sutton P. The navigation guide work group. 2011.

documented, and that the science is clearly delineated from values, preferences, costs and/or other considerations. In short, the rationale for a decision is traceable, reproducible, comprehensible, and, therefore, testable over time.

Government agencies can use the Navigation Guide methodology to craft evidence-based statements regarding the relationship between an environmental exposure and health (steps 1–3). The first case study of steps 1 to 3 of the Navigation Guide methodology was completed in 2013 by a collaboration of scientists at USEPA, UCSF, and Johns Hopkins. The results established proof-of-concept for applying a systematic and transparent method of review in environmental health to link the science to timely, prevention-oriented action. The case study addressed the question, "What is the impact of developmental exposure to perfluorooctanoic acid (PFOA) on fetal growth?"

Government agencies called on to make risk management decisions can also apply Step 4 of the Navigation Guide to grade the strength of recommendations for prevention. Decision-tools need to distinguish the "strength of the evidence" from the "strength of the recommendation" to make transparent the values and preferences that underlie risk management decisions. This distinction also allows for incorporating the recommendations made by the National Academy of Sciences (NAS) in Science and Decisions to identify and protect against chemicals that can harm human health before entering into a long process to establish numerical levels of risk and to cull those decisions that are not sensitive to the resolution of uncertainty from the risk assessment process, that is, decisions for which additional information would have little or no value added to support the decision. (National Research Council, 2008) Professional societies, healthcare organizations, and other potential guideline developers working with toxicologists can use the Navigation Guide to craft consistent and timely recommendations to improve patient, and ultimately population, health outcomes.

CONCLUSION

Providing clinicians, parents and policy-makers with evidence-based information about the environmental drivers of children's health is key to prevention. The Navigation Guide is a method to develop evidence profiles that provide simple, transparent summaries, such as practice guidelines or other evidence-based recommendations for prevention. Development of the Navigation Guide methodology is extremely timely as it coincides with growing recognition of the need for updated methods in risk assessment (National Research Council, 2008; National Research Council (U.S.) Committee on Improving Risk Analysis Approaches Used by the U.S. EPA et al., 2009) and related calls for government agencies such as the USEPA to incorporate systematic approaches into decision-making (Charnley, 2011; Hopkinson, 2011; Lovell, 2011; Vitter and Inhofe, 2011) Beginning in 2012, systematic methods of research synthesis in environmental health science have been advanced by the National Toxicology Program Office of Health Assessment and Translation (OHAT) in its development of literature-based evaluations to reach conclusions about potential human health hazards and to examine the state of the science. Their aim is to use these new methods to increase efficiency and provide greater transparency to the rigor and objectivity of their approach peer-reviewed journal publication (Birnbaum et al., 2013).

Having a method that understands the opportunities and challenges of applying current clinical approaches to environmental health is also critical. While not yet on the radar of healthcare decision-makers, the costs in 2008 to the US healthcare system for treatment of childhood illnesses linked to toxic environmental exposures is conservatively estimated to be over $76 billion (Trasande and Liu, 2011). At the same time, it is anticipated that US healthcare policy decisions will increasingly rely on systematic reviews of the evidence; the recent healthcare reform legislation allocated $1.1 billion dollars for comparative effectiveness research (Department of Health and Human Services, 2009). The Navigation Guide is poised to provide a methodological bridge to link healthcare decision-making to efforts to reduce toxic environmental exposures.

Realization of this goal could transform the science by making it actionable in a timely manner. Conversely, it would also shed light on the consequences of our inaction that now finds refuge under a mounting pile of scientific publications. In 1961, Sir Bradford Hill emphasized that "strong evidence" does not imply "crossing every 't', and swords with every critic, before we act" (Hill, 1965). He proposed differential standards of evidence for different actions, a recommendation echoed by the NAS a half-century later in Science and Decisions. The institutionalization of the Navigation Guide would provide a concrete mechanism for linking science to action to protect children's health.

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