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Researcher and institutional review board perspectives on the benefits and challenges of reporting back biomonitoring and environmental exposure results

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ABSTRACT

As the number of personal exposure studies expands and trends favor greater openness and transparency in the health sciences, ethical issues arise around reporting back individual results for contaminants without clear health guidelines. Past research demonstrates that research participants want their results even when the health implications are not known. The experiences of researchers and institutional review boards (IRBs) in studies that have reported personal chemical exposures can provide insights about ethical and practical approaches while also revealing areas of continued uncertainty. We conducted semi-structured interviews with 17 researchers and nine IRB members from seven personal exposure studies across the United States to investigate their experiences and attitudes about the report-back process. Researchers reported multiple benefits of report-back, including increasing retention and recruitment, advancing environmental health literacy, empowering study participants to take actions to reduce exposures, encouraging shifts in government and industry practices, and helping researchers discover sources of exposure through participant consultation. Researchers also reported challenges, including maintaining ongoing contact with participants, adopting protocols for notification of high exposures to chemicals without health guidelines, developing meaningful report-back materials, and resource limitations. IRB members reported concern for potential harm to participants, such as anxiety about personal results and counterproductive behavior changes. In contrast, researchers who have conducted personal report-back in their studies said that participants did not appear overly alarmed and noted that worry can be a positive outcome to motivate action to reduce harmful exposures. While key concerns raised during the early days of report-back have been substantially resolved for scientists with report-back experience, areas of uncertainty remain. These include ethical tensions surrounding the responsibility of researchers to leverage study results and resources to assist participants in policy or community-level actions to reduce chemical exposures, and how to navigate report-back to vulnerable populations.

1. Introduction

Biomonitoring studies, which measure chemicals in bodily fluids like blood, urine, and breast milk, and environmental exposure assessments of indoor air, drinking water, food, and house dust, have become increasingly common in environmental health studies and public health surveillance. Reporting back individual data from these studies was previously controversial, with research scientists apprehensive about allocating the required resources and unsure what to communicate to study participants about chemicals without clear health guidelines or exposure-reduction strategies. Researchers attempting to communicate individual-level results sometimes faced resistance from IRBs that were reluctant to approve report-back protocols given these scientific uncertainties and the concern that study participants may be harmed by undue worry or change their behavior in detrimental ways (Brown et al., 2010; Saxton et al., 2015).

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Table 1
Characteristics of the 7 environmental report-back studies that were selected for interviews.

Study	Study aims and exposure assessments	Population and location	Study type
1	A study of exposures to metals, perfluorinated compounds, and phenols.	Mothers and children; Urban, racially and ethnically diverse, and low-income participants.	Government- academic collaboration
2	A cohort study of health outcomes from exposure to flame retardants, PCBs, perfluorinated compounds, phenols, parabens, and phthalates.	Children (female only); Urban, racially and ethnically diverse participants.	Medical institution, government, and community collaboration.
3	A study of the health outcomes and exposure remediation for industrial contamination of water supplies by perfluorinated chemicals.	Children and adults; Rural residents and workers.	Academic
4	A study analyzing heavy metal exposure, particularly lead and arsenic, based on proximity of residents to a Superfund site.	Rural children.	Academic
5	An advocacy biomonitoring project aimed at highlighting the shortcomings of U.S. chemical policies by measuring flame retardants, bisphenol A, and phthalates.	Rural and urban residents across the U.S. Racially and ethnically diverse participants, including participants from tribal populations.	Nongovernmental Agency
6	A cohort study of health outcomes and environmental chemicals including flame retardants, PCBs, pesticides, and perfluorinated compounds.	Women, with a high percentage of urban residents and of African-Americans.	Nongovernmental agency
7	A cohort study of health outcomes from exposure to pesticides, flame retardants, bisphenol A, and phthalates.	Mothers and children; Rural, low-income and primarily Hispanic.	Academic-community collaboration.

In some instances, the ethical guidelines of human subjects research as outlined by the Belmont Report (U.S. Department of Health and Human Services, 1979) were interpreted by IRBs to oppose reporting individual results on emerging contaminants (Brown et al., 2010).

The context, however, has shifted. As evolving research ethics support a community-engaged approach to environmental health research (Brody et al., 2009; Morello-Frosch et al., 2015), reporting back individual results is becoming a more common and less contentious practice. Past research on report-back in environmental exposure assessment and biomonitoring research has indicated that participants who receive understandable and meaningful reports of individual level data are often surprised, but not overly psychologically stressed, to learn that their bodies contain possibly harmful chemicals (Brody et al., 2014). Moreover, participants, including those from different socioeconomic backgrounds, overwhelmingly want to know their personal exposure results if given the choice (Brody et al., 2007; Altman et al., 2008; Morello-Frosch et al., 2009, 2015; Nelson et al., 2009; Wu et al., 2009; Judge et al., 2016), and report-back can motivate participants to consider both personal and collective strategies to reduce toxics in their environment (Adams et al., 2011). In addition, the benefits for environmental literacy and positive health outcomes (Adams et al., 2011; Ramirez-Andreotta et al., 2016) have provided a rationale for reporting back personal results and contributed to guidelines for designing report-back content and evaluating outcomes (Dunagan et al., 2013). Major guidance documents now call for report-back, including those published by the National Academy of Sciences, the National Conversation on Public Health and Chemical Exposures, and European and Canadian biomonitoring programs, and California state biomonitoring law requires it (Brody et al., 2014).

Despite the trend in favor of report-back, however, many studies have not adopted these practices. In order to learn what motivates researchers and IRBs to share personal results, and how they navigate the ethical, scientific, and communication challenges of reporting back personal exposure results, we interviewed environmental health researchers and IRB members from seven key U.S. studies that included report-back. While previous studies have focused primarily on the views of participants, we provide the first analysis of report-back from the perspective of researchers and IRBs involved in multiple exposure assessment studies. In doing so, we highlight areas of convergence over previously controversial aspects of report-back, while showing where underlying points of uncertainty or contention remain.

2. Methods

We investigated the experiences and perspectives of researchers and IRB members involved in seven studies that included individual-level exposure assessment for environmental chemicals. We selected these case studies to represent academic, regulatory, and advocacy research contexts. We sought out studies that measured endocrine disrupting compounds (EDCs), because these are chemicals of emerging concern for which health guidelines are not yet established. Studies were selected from our knowledge of federal and state biomonitoring programs, environmental health advocacy, and NIEHS-funded research, including the Breast Cancer and the Environment Research Program, Superfund Research Program, and Children's Environmental Health Centers. We did not randomly select studies from a list, because we wanted to establish strong collaborative relationships with our case studies in order to interview their participants as well as researchers and IRB members. Also, the universe of studies reporting personal results for EDCs at the time, in 2009, was small, and we wanted to include a variety of settings. The selected studies represented a significant proportion of those reporting back individual results for chemicals without health guidelines. The studies include a large variety of chemical analytes, some that are regulated and have been extensively studied (e.g., lead), and many that are newly emerging concerns based on recent toxicological and epidemiological evidence (e.g., phthalates, bisphenol A, perfluorinated chemicals, and brominated flame retardants). The case studies also encompass regional and demographic diversity across the U.S. and varying levels of public involvement in study development, implementation, and results dissemination. Several of the studies incorporated report-back protocols while designing the study, while others decided to report back personal results after the initiation of research. The selected studies thus represent a spectrum of research contexts in which ethical questions about report-back may arise. We anonymized results to protect interviewee confidentiality, but descriptions of the study aims, exposure measurements, and population characteristics are included in Table 1.

We conducted semi-structured interviews with 17 researchers and nine IRB members to assess their experiences, values, and attitudes related to reporting individual exposure results. Several of the researchers and IRBs were involved in additional report-back studies beyond the seven we selected, and interviewees also drew from these experiences. IRB members had training in the biosciences, law, public health, and medicine. Of the 17 researchers interviewed, four were primarily affiliated with advocacy nonprofits, three with government research branches, seven with academic institutions, and three with a medical center. Boundaries among these various sectors were not strict (e.g., researchers primarily working in academic settings could have close connections to advocacy organizations). Researchers' disciplinary