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Researcher and Institutional Review Board Perspectives on the Benefits and Challenges of Reporting Back Biomonitoring and Environmental Exposure Results

Jennifer Liss Ohayon[1], **Elicia Cousins**[2], **Phil Brown**[2], **Rachel Morello-Frosch**[3], and **Julia Green Brody**[1]

[1]Silent Spring Institute, 320 Nevada Street, Suite 302, Newton, MA, US, 02460

[2]Department of Sociology and Anthropology and Social Science Environmental Health Research Institute, Northeastern University, 360 Huntington Avenue, 310INV, Boston, MA, US, 02115

[3]School of Public Health and Department of Environmental Science, Policy and Management, University of California, Berkeley, 130 Mulford Hall, Berkeley, CA, US, 94720

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

*Corresponding author. ohayon@silentspring.org.

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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.

Keywords

Bioethics; results communication; biomonitoring; exposure assessment; exposure reduction; risk communication; community-based participatory research

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. 2009; Saxton et al. 2015). 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. 2009).

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-Frosh et al. 2009, 2015; Nelson et al. 2009; Wu et al. 2009; Adams et al. 2011; Judge et al. 2016), and report-back can motivate participants to consider both personal and collective strategies to reduce toxics in their environment (Altman et al. 2011). In addition, the benefits for environmental literacy and positive health outcomes (Adams et al. 2011; Ramirez-Andreotta 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 training encompassed the fields of epidemiology, toxicology, public health, cancer biology, engineering, and clinical practice (physicians and nurses).

These interviews are not meant to be broadly representative of the perspectives of environmental health researchers or IRB members, many of whom do not have experience with results communication, but rather provide insight into the ethical, scientific, and logistical issues that emerge in studies pioneering report-back. Each interview lasted approximately one hour and questions were primarily semi-structured, followed by probes designed to seek responses on specific issues not mentioned in open-ended responses. Interview questions (available in supplemental material) focused on whether and how to report individual results to study participants and the broader study community; experiences reporting back results or overseeing report-back protocols; researcher-IRB interactions; the main ethical issues raised by report-back; and recommendations for other studies interested in reporting back results. We also analyzed report-back materials provided to study participants. Our study protocols were approved by the institutional review boards of the University of California, Berkeley (#2010-07-1959) and Northeastern University (#12-08-03) and informed consent was obtained prior to interviews.

Interviews were transcribed and analyzed using Dedoose, a qualitative data management and analysis tool. Our coding approach had two phases: we first generated *a priori* codes based on the specific questions in our interview protocol, as well as on the broader categories and conceptual themes reflected in the interview questions. In the second phase we examined the interview transcripts, creating new codes that emerged from the interview material. Five members of the research team coded sample transcripts in multiple meetings, comparing coding schema to ensure inter-coder reliability and to make any necessary alterations to initial codes. The rest of the transcripts were coded and analyzed by two members of the research team who met frequently to compare and ensure consistency with code applications for the remaining interviews.

3. RESULTS

Researchers who have experience reporting personal exposure results and IRB members most involved in report-back viewed this practice as ethical and beneficial, especially noting knowledge gains for the participants, opportunities for exposure reduction actions, and improved participant retention and trust in research. Researchers unanimously supported the notion of participant right-to-know, even in the face of uncertainty about health effects, and reported that participants do not seem excessively worried by results. In contrast, IRB members with less experience in report-back were uncertain and conflicted about the balance between the right-to-know personal results and potential harm. Ethical tensions for both researchers and IRB members focused on how to advise study participants on the action implications of their results. While we found little reluctance among researchers to suggest individual behavior changes to reduce exposures, the appropriate role and capacity of

researchers to advance and support collective action and policy advocacy was controversial. Some researchers assisted study participants and communities in responding to exposure results, while others expressed concern that this would compromise the integrity of the research or cited a lack of ability or legal authority. IRB members were particularly worried about promoting collective action to support chemical reform when existing research only partially elucidated links between environmental chemicals and health outcomes. Other challenges of report-back include maintaining connections with participants over time as new health information emerges, adopting protocols for the notification of high results for chemicals without health guidelines, developing appropriate report-back content, and obtaining adequate funding for report-back.

3.1 Reasons for and Benefits of Report-Back

Researchers noted that both ethical and instrumental factors influenced their decisions to adopt individualized report-back (Table 2), and they reported both expected and unexpected benefits of doing so. Ethical reasons focused on participants' right-to-know and to act on their results. Instrumental reasons included the benefits of increased recruitment and retention of study participants.

Requests from participants were an important factor in the decision to report results for 7 interviewees representing three of the studies; a survey from one study that included a racially and ethnically diverse sample population indicated that upwards of 90% of participants wanted individual study results returned. These three studies involved biomonitoring children and two of the studies involved an industrial source of contamination.

Egalitarian conceptualizations of the data as belonging to the participants and participants' right to make their own decisions also contributed to decisions to return results. As one researcher stated, "We are really stewards of their information not owners of their information. We felt that this is important enough that it is worth making some sort of commitment of time and resources." Researchers frequently said it was "unethical" to hold back information, indicating that they wanted their teams to partner with individuals and communities rather than be "gatekeepers" or "caretakers" of which information people receive and do not receive. One study reported back in part to reduce information disparities between scientists and disenfranchised populations, and thereby address justice concerns, as many communities have a history of taking part in studies that do not translate results.

In addition, studies reported back personal data to increase knowledge and facilitate or motivate health-protective action at the individual, community, and policy levels. A researcher underscored report-back as an "obligation," stating that "it should be a central component of doing ethical research because it involves not only the right-to-know but the right that people have to make informed decisions that can help change their lives and reduce exposures." Similarly, some researchers mentioned that report-back was spurred by wanting to respond to potentially urgent exposure risks, such as discovering participants with relatively high chemical levels. Several researchers noted that participants were motivated to make individual behavior changes to reduce their exposures and also observed the benefits of report-back for helping policy shifts in government and corporate practices.

For example, one study prompted the industry responsible for groundwater contamination to provide an alternative drinking water source. In the wake of this drinking water intervention, researchers found significant reductions in the blood levels of perfluorinated chemicals within months of individual and community-wide results dissemination.

In addition to ethical factors influencing report-back decisions, researchers also reported back for instrumental reasons, mainly to encourage the recruitment and retention of participants by offering the incentive of learning individual results. While none of the studies directly measured the effects of report-back on these metrics, several researcher and IRB interviewees observed that participants were particularly engaged in studies that reported back.

Researchers also discovered some unanticipated benefits. For example, report-back processes helped researchers identify novel and potentially significant sources of exposure by consulting with study participants about their product use and employment history. In one study, researchers initially assumed that a participant's high levels of mercury originated from fish consumption, but through engaging the participant they identified mercury in a skin cream product as the exposure source.

3.2 Key Ethical Tensions

Researchers and IRBs revealed tensions about presenting results in cases of scientific uncertainty, causing undue worry, and finding appropriate ways to address vulnerable populations and sensitive report-back situations. They also grappled with the responsibility of researchers to assist in exposure reduction actions.

3.2.1 Scientific Uncertainty—Respondent's views on whether to report-back and how to do so were influenced by concerns over scientific uncertainty about the relevance of exposure results for health outcomes and their ability to accurately characterize typical exposures. Both researchers and IRBs raised concerns about the absence of clinical health guidelines, temporal variability in exposure levels, and the analytic validity of laboratory testing.

Researchers and IRBs referenced several factors that make it difficult to clearly link exposure results to health outcomes and develop clinical health guidelines. Chemicals are often chosen for human exposure studies based on animal evidence or cell bioassays, but knowledge of the effects on humans at various exposure levels and via various pathways lags behind. As a result, exposure results precede certainty about the health endpoints of concern (for example, should the focus be on cancer, fertility, birth defects, immunological, or neurocognitive effects?). Further complexities arise in accounting for synergistic or additive effects of chemical mixtures, as well as differences in susceptibility associated with age, sex, genetics, ethnicity, or health status.

About half of the IRB interviewees indicated that the uncertainty about links to health outcomes may make the data inappropriate for individual-level report-back. They believed that the harms of report-back, such as participant anxiety over their results, would outweigh the benefits when personal results lack regulatory or clinical significance. As one IRB

interviewee stated, “If it’s truly uncertain…I would question that the kind and the safest thing to do for people would be to not tell them the results and to explain to them why we’re not telling them.” Another said, “If there’s really no good science that really correlates relative differences in levels of these exposure chemicals to actual health outcomes, I would question why are they even telling people the answers. I think you could make a case that it shouldn’t even be done because there’s an anxiety-provoking risk to that.” These IRB members expressed a preference for only reporting aggregate study results.

Other IRB members, however, strongly supported participant rights to access personal data, as long as scientific uncertainties were explained during the consent and report-back stages. One IRB interviewee linked report-back to reciprocity, which dovetails with a main motivation for researchers to report-back. They stated, “If it has a known ramification or not, I think that one of the gifts you give back to somebody who has been kind enough to participate in the study is knowledge about what you found.” Another IRB interviewee distinguished personal exposure studies as different from clinical studies in that an individual’s chemical body burden is not diagnostic for developing a particular disease, but rather the information has preventative utility: “You’re not going to a doctor’s office to get a diagnosis. It’s a different kind of test… Do you want to help them re-imagine a life where they don’t have as much chemical exposure?” IRB members more acquainted with report-back studies were typically more supportive of reporting individualized results. Those whose experience was largely restricted to reviewing modifications to approved protocols or had limited interactions with researchers tended to be more wary about reporting-back results with uncertain health implications.

In contrast to IRB members, no researcher interviewees indicated that uncertainty regarding health outcomes could justify withholding individual results or reporting back only in aggregate form. However, they did state that communicating scientific uncertainties requires careful consideration and effort. Report-back materials from the studies cautioned that the presence of chemicals in biological samples is not predictive of future health status or the risk of developing an illness. Researchers from several studies said that study participants generally understood the concept of uncertainty, especially if they were informed from the outset (i.e., before data collection) of the limits of what the study could and could not tell people. As one researcher emphasized,

> “We invested a lot of energy in having meetings and being very realistic with the community about what the study would do, what the data would look like, what the data was not going to look like. You know, it’s not going to look at your risk of cancer…we were very clear that the study could not move into the arena of personal health risk. And I think that investment up front in expectation-setting helped.”

One researcher said their study adopted the messaging that the research was being done to advance health knowledge and help establish future clinical levels of concern.

A second significant source of data uncertainty is that for some chemicals the levels in the body can vary widely over time; some chemicals are more persistent, whereas others are rapidly metabolized, making interpreting a one-time measurement difficult. Approximately

half of the researcher interviewees said it was challenging to explain how biological levels of chemicals can vary across time, and that results do not necessarily represent average exposures. IRB members mentioned similar concerns, with one stating “[a result] could be drawn from the extreme high end of a distribution and create a lot of anxiety when the actual day-to-day value is much lower.” Conversely, another IRB official alluded to how a low measurement one day does not indicate an absence of significant exposures over longer time periods and could create a false sense of reassurance.

Almost all IRB interviewees also referred to concerns about the analytic validity of measurements. They wanted to make sure that quality assurance and quality control protocols were in place to avoid, for example, laboratory contamination of samples. Two IRB members expressed the expectation that data shared with individuals should be produced in a Clinical Laboratory Improvement Amendments (CLIA)-certified setting so results were robust to procedural errors. Such an expectation may not be feasible, however, because CLIA certification does not cover lab work for the majority of chemicals measured in biological or environmental media samples, but rather is primarily relevant for diagnostic and treatment-related tests such as genetic screening and cholesterol measurements (NRC 2006). One researcher stated that while their lab likely has the same quality controls and quality assurance as a CLIA-certified laboratory, for example with regards to ensuring that samples are stored and tracked appropriately, the lack of well-validated methods for measuring some cutting-edge biomonitoring analytes precludes their ability to be accredited.

3.2.2 Undue Worry—IRB respondents frequently emphasized the potential harms of report-back, particularly provoking undue worry among study participants. Researchers, in contrast, reported that participants do not appear to react with panic or anxiety, and some researchers conceptualized concern over results as a potentially motivating force for health protective actions.

Several IRB members believed that the chance of inducing anxiety could be greater than the chance of yielding benefits, and that this could justify withholding individual results. They used descriptors such as “mental anguish”, “panic”, and “psychological unrest” to describe participants’ potential reactions to receiving results, although none reported receiving any reports about increased anxiety from learning individual results. In contrast, researcher interviewees drew from direct interactions with study participants and described participant reactions to report-back with more moderate language. Researchers stated that study participants could display concern, worry, or dismay, but didn’t seem “panicked” or “alarmed.” One researcher stated that participants “tend to have reasonable concern…There may be some dismay, especially if you’re a breastfeeding woman, but there is also an awareness that it’s better to know this than not.” One researcher said that “People, in general, if they’re treated respectfully, and if you’re willing to be available to talk with them, can handle more information about themselves than we usually give them credit for.” Researchers from a youth study anticipated that parents would be anxious about their children’s results, but found that this was not the case. As one stated, “I’m glad that the fear that we initially had, you know, it proved us wrong. You know, there was no reaction or backlash for putting that information out there, so that I was happy to see."

Several researchers further referenced how worry could be a motivating factor for bringing about positive public health outcomes at an individual, familial, or broader policy level. As one researcher explained,

> "I think that one of the things that disturbed people was the fact that levels in children were so high…That's not good from a public health point of view, because they are considered the more vulnerable populations and especially with the potential effect on development. That wasn't what people wanted to see, but on the other hand it's the reality and [could help people take] measures to reduce the exposure."

Multiple researcher respondents said some study participants even seemed indifferent about relatively high exposure results and expressed disappointment that these participants showed little motivation to change exposure levels.

Researchers spoke about difficult decisions in the design of report-back content, knowing that their words would influence participants' level of concern about their results. Some wanted to invoke enough concern to encourage participants to take precautionary measures, but they also wanted to reassure participants by noting that results have uncertain predictive value for disease risk. As a researcher explained, "One of the difficulties we have in communicating the nature of science and the uncertain nature of it [is] how to balance off how we tell people about what we know and what we don't know. We want them to take precautions and be informed and protect themselves, but we also don't want to alarm them."

3.2.3 Sensitive and Vulnerable Report-Back Situations—While researchers with experience in results communications have become increasingly supportive of report-back, there are still sensitive or vulnerable report-back situations for which respondents displayed heightened uncertainty. Both researchers and IRBs were concerned about repercussions against workers from employers when investigating industrial exposures. To attempt to remedy this, the study investigating worker exposure to perfluorinated compounds had a certificate of confidentiality to protect employees recruited into the study from having their information disclosed by impending lawsuits. For the study adjacent to a Superfund site, researchers stated that participants were concerned about risks of liability and declining property values if they received reports that their land was contaminated with heavy metals. IRBs also were concerned about counterproductive behavior change, such as women ceasing breastfeeding after learning about the presence of chemicals in breastmilk. Both researchers and IRBs raised concerns about report-back practices for populations with social and economic disadvantages that pose barriers to reducing exposures, as they feared these groups would be left feeling particularly powerless or frustrated upon learning their results. One IRB member wondered about the types of special considerations that need to be made for reporting back to "a group of really poor people who cannot make changes as readily as a white, well-educated, middle-class [individual]."

3.2.4 Responsibility of Researchers to Assist in Exposure Reduction Actions —While some report-back issues, particularly concerns around harm from worry, are resolved as researchers and IRBs gain experience, other ethical tensions remain. In particular, report-back studies continue to debate whether and how researchers can assist

study participants and communities in responding to their exposure results. Researchers and IRB members frequently expressed feeling limited in logistical and legal capacity on this front, as well as a reluctance to take on advocacy roles.

In all of the studies for which we conducted interviews, report-back materials included information about individual actions that participants could take to reduce exposure, usually by avoiding particular types of personal care, food, and home products. However, researchers pointed to limitations in the effectiveness of recommendations based on individual behavior changes or altered consumer habits. Researchers and IRBs referenced how individuals cannot always afford to make changes or otherwise access environmentally preferable products, they may be exposed in situations of limited autonomy (e.g., workers), and it is difficult to know the main exposure sources in order to pursue appropriate mitigation (e.g., chemical additives or residues in consumer products are often unlabeled). One researcher quoted a participant who highlighted the problem with managing environmental risks through lifestyle modifications: “[they] said ‘I’m not going stop washing or buying towels or eating canned food. So really shouldn’t you guys be focusing on getting the chemicals out of the products in the first place so I don’t have to worry about it myself?’” Several respondents expressed concern that exposure reduction advice, rather than empowering people to make a choice, would make them feel “stuck” in their situation.

Researchers from all seven studies discussed the importance of broader policy changes or government-level interventions to reduce chemical exposures, but many felt reluctant to facilitate community activism to achieve policy gains. Researchers studying the industrial contamination of water supplies by perfluorinated chemicals took some targeted actions, including giving presentations to state and federal legislators about reducing community-wide exposures. Those involved in advocacy biomonitoring aided participants in speaking publically about their results to the media and policymakers to stimulate changes in environmental health policy and regulation. Most researchers, however, expressed concern that advocacy activities would compromise the integrity of the research itself, seeing these types of actions as belonging to the activist realm. For their part, government scientists referenced legal limits to their ability to rally support for regulatory reform. For example, one government scientist stated that while they hope their research identifies likely exposure sources and informs chemical policies, their mandate does not allow them to engage in advocacy. Many scientists expressed that they did not see their role as engaging in advocacy, but rather indicated that study results could be used by activists or community groups in their organizing. As one researcher said, “We provide the data, and people can do what they want with the data… we do try not to get involved so much politically in these things.”

IRB interviewees likewise expressed concern that researchers engaging in advocacy would undermine what is meant to be “neutral research,” and suggested that a better strategy would be to translate results to the advocacy community. As one stated, “My personal bias is to say if you’re in a research mode, stay in a research mode. The call to action is because you’ve put your good data in the hands of people whose job it is to advocate.” Moreover, for some IRB interviewees, uncertainty about how exposures translated into health outcomes discouraged them from promoting community advocacy. As one cautioned, “Are they going to be activists around something that’s not proven yet?”

Beyond the legal or perceived institutional pressure to keep science and policy spheres separate, researchers expressed a feeling of helplessness concerning their capacity to help participants act on their results. A researcher mentioned that during public meetings and phone calls with participants, their team would be repeatedly asked who was going to provide the public with an alternative to the contaminated water supplies. The interviewee stated, “Do you tell people you should be doing this or that? But if there isn't money to do it, then what are you doing for them?” Some IRB members likewise grappled with the extent of researcher responsibility, particularly when socioeconomic barriers prevent participants from responding to their results. One IRB interviewee asked,

> “How far do you have to go out from the point of the stone dropping in that you’re able and willing to say, ‘This is no longer my responsibility’?… I think with something like, ‘We have done monitoring in your home. We know that you are being exposed to lead... We need to tell you right now get away from this environment.’ The person says, ‘I can’t afford to get away from the environment.’ What does the researcher do then?”

Another IRB interviewee similarly queried, “At what point is the researcher the guarantor of that person’s behavior?... Where does the researcher’s responsibility end?”

3.3 Practical Challenges for Researchers—Researchers and IRBs were aligned in their views on the practical challenges of report-back, although these topics were more salient for researchers. Challenges (summarized in Table 3) include establishing and maintaining communications with participants, designing meaningful and understandable reports, deciding how to share data while protecting autonomy and privacy, and working within resource constraints.

While report-back helped engage participants in exposure studies, several researchers still discussed difficulties with maintaining these connections over time. Extensive time gaps, sometimes several years, between collecting samples, receiving laboratory results, and analyzing data are common. Studies sometimes recruit from transient populations, such as low-income communities without stable housing, which can cause research teams to lose contact with participants. Studies adopted various strategies to partially ameliorate these challenges, including obtaining alternative contact information, indicating during the consent stage when research results might be disclosed, and disseminating partial results as they became available to ensure more frequent communication with participants.

Interviewees also discussed how reports can serve as a reference document in the future as more information develops about possible health risks and health-related findings that are remediable, but referenced the difficulty of ensuring post hoc contact with participants after the study terminates. As one IRB member stated, “To me the idea of knowing that somewhere in a drawer, there’s a bunch of blood levels for somebody or groups of somebodies that we now know there’s a way we can fix this and we’re not addressing it with those people is just not right.” That same IRB member said that while they would like studies to develop mechanisms to effectively track and contact participants as clinical insights emerge, it was unclear how to implement that if responsible investigators have moved on or the funding period has expired.

Studies also struggled with developing early notification protocols for reporting back “high” results. For chemicals without clinical guidelines, what constitutes a level of concern for which researchers should quickly inform study participants? For example, should participants be notified if they are above the 90 or 95th percentile or a more extreme outlier? The studies that included a chemical with clinical action levels (e.g., mercury and lead) promptly informed people who were above these levels through personal phone calls, but research teams had extended discussions about what to do for contaminants without guidelines. One researcher recommended that studies adopt internal guidelines before samples are collected.

Researchers also spoke about the difficulty of explaining results and uncertainties in a meaningful way, for example in providing enough detail so that study participants could understand their results without “overloading” them, and representing the intra-individual variability in measurements for some chemicals. However, both researchers and IRB members listed solutions to such challenges: the inclusion of explicit content about what is known and unknown regarding potential health outcomes, including comparisons to a representative sample of the U.S. population reported by the National Health and Nutrition Examination Study (NHANES) or to regulatory benchmarks; communicating for different literacy levels; and having one-on-one support available to answer questions. While the studies we analyzed had different levels of community involvement, most conducted focus groups or had community advisory groups that researchers repeatedly cited as helpful for designing understandable and relevant report-back materials, and evaluating the efficacy and outcomes of results communication.

Sharing data with relevant parties other than the study participants constituted another challenge cited by interviewees. Researchers and IRB members from several studies wanted mechanisms to share data with health consequences with a participant’s doctor or include it in their medical record. One study recommended in their report-back materials that participants speak with their primary care physicians about their results for heavy metals. Researchers, however, recurrently acknowledged that clinicians often do not have environmental health training and might be unable to advise their patients. Both researcher and IRB interviewees also referenced the unsettled question of when data should be reported back to older children participating in the study as well as their parents. Researchers in one study were surprised when a survey of youth participants revealed that none of their parents had shared their personal reports with them. Another study grappled with how to represent the spatial distribution of pollutants in a way that was helpful for community knowledge, but sufficiently de-identified to protect individuals’ privacy and property value.

Researchers also described logistical constraints, particularly the funding and staff-time requirements for disclosing results. An interviewee suggested report-back be budgeted for in proposals.

Most researchers, however, did not emphasize difficulties with report-back. Moreover, they mentioned that they did not feel resistance from IRBs, colleagues, or funding agencies. One researcher described funders as even more committed to the “translation” of research results than most researchers. Others said that their colleagues did not always see the value of

reporting back, but that this was not a deterrent. Several speculated that other researchers may choose not to report-back because that is the "path of least resistance", or because they overestimate the challenges. As one researcher stated, "I think researchers have a perception that they're going to generate massive hysteria with their report back, and that they're going to have a thousand phone calls. People are going be up in arms, it's going get out of control." Researchers, however, indicated that participants generally appreciated seeing their results and study teams received few unsolicited phone calls.

3.4 Conflicting Values and Evolving Perspectives

Several IRB members grappled with conflicting values that made them ambivalent or inconsistent about report-back during interviews. These IRB members discussed the positive features of report-back for encouraging precautionary actions to reduce chemical exposures or acknowledged that participants wanted this information but were hesitant about the desirability of results communications given their concerns about participant anxiety. One IRB member who was unsure about report-back policies for research could clearly see the benefits when the process was personalized and said she would be "thrilled" if her teenage daughter received information about her exposures to emerging contaminants.

Although apprehensive about some of the ethical issues, IRBs were generally supportive of researchers and saw them as a source of guidance on report-back. As one stated, "When you are in uncharted territory and you're trying to devise a protocol or a consent form, the expertise of the researchers in their fields becomes invaluable… Each time a new type of research is born the people on the front lines have to figure it out." Multiple researchers mentioned that it was productive to have contact with IRB members before the committee engaged in formal deliberations, as this helped IRBs see the "rationale" for report-back.

In spite of initial hesitations, as researchers and IRB members became more familiar with report-back's utility for engaging and educating participants, their perspectives evolved. Researchers continued report-back in later studies because of their past success with it.

4. DISCUSSION AND CONCLUSIONS

In a climate of greater openness and transparency about health issues, including major advances by patients' movements in gaining access to personal data, the landscape of professional medical disclosure has changed enormously (Fernandez et al. 2003; Knoppers et al. 2006; Wolf et al. 2009; Wolf et al. 2015). But such openness is only in the early stages for environmental health research when it comes to sharing individual-level data with uncertain implications for health status. Our analysis highlights points of convergence, uncertainty, and contestation over the ethics, benefits, and challenges of reporting back personal results in environmental health studies. In studying how researchers and IRB members approach this question, we found that major issues included how to deal with scientific uncertainty, concerns about causing undue worry, finding appropriate ways to address sensitive report-back situations, and thinking about researchers' responsibility to assist in exposure reduction actions.

Notwithstanding greater openness in medicine, resistance to report-back in environmental health studies curiously draws on a medical model that considers it inappropriate to share data unless there is clinical relevance to adverse health outcomes (Deck and Kosatsky 1999; Brody et al. 2007; Morello-Frosch et al. 2009). Such expectations about evidence of human health outcomes and dose-response relationships do not match the nature of scientific research on emerging contaminants (NRC 2006), nor do they fit with what we term “post-Belmont ethics” that are influenced by community-engaged research methodologies (Davis and Webster 2002; Morello-Frosch et al. 2015). To support the right-to-know as the science unfolds, environmental researchers advocate for report-back within a precautionary framework. Report-back aligns with the Precautionary Principle (Raffensperger and Tickner 1999; Kriebel et al. 2001) by informing participants of results so they can act on suggestive evidence of harm to human health by reducing preventable exposures.

Our interviews show a substantial shift in ethical considerations of autonomy and non-malfeasance as studies demonstrate that report-back can be done without creating harmful anxiety. Researchers drew from direct interactions with study participants and discovered participants were not overly alarmed by results, and such findings are consistent with previous research on the experiences of participants in report-back studies (Altman et al. 2008; Hernick et al. 2011; Brody et al. 2014; Haynes et al. 2016; Judge et al. 2016). Moreover, multiple researchers expressed that worry can be a productive force if it influences people to take precautionary action. Several frameworks within health communication literature posit that uncertainty generates worry, which in turn stimulates health-related information seeking (Tallis et al. 1994; Kahlor 2010; Lee and Hawkins 2016).

Researchers identified multiple additional benefits, including increasing study participant engagement, advancing environmental literacy, encouraging shifts in government and industry practices, and helping researchers discover new sources of exposure. IRB members with limited experience in individual results communication are often unaware that participants generally do not react with undue anxiety and tension remains about whether the benefits are sufficient to justify report-back given their concerns about participant worry. Researchers and IRB members became stronger proponents of report-back as they gained experience, and greater interaction with researchers practicing results communication may help IRB members develop experience-based perspectives.

Some situations are still considered sensitive, and researchers and IRBs seek additional guidance on how best to report back in contexts that include pregnant or breastfeeding women, socioeconomically disadvantaged populations, or individuals with unusually high exposures. During interviews, respondents expressed concerns that report-back may encourage unnecessary or counterproductive behaviors or disempower participants who face socioeconomic barriers to reducing exposures, and this concern has prevented IRBs from approving report-back in the past. For example, a research team was not allowed to conduct a study and report back results, despite a request from tribal leaders and community members for this information, as their IRB feared it would dissuade indigenous women from breastfeeding or relying on traditional foods (Saxton et al. 2015).

Yet encouraging report-back for vulnerable populations or sensitive situations can serve to operationalize and advance the Belmont principles of *autonomy*, *justice*, and *beneficence* throughout the course of research (Morello-Frosch et al. 2009; Ferris and Sass-Kortsak 2011; Morello-Frosch et al. 2015). In addition to supporting autonomy by giving participants access to information that comes from their own bodies or homes, report-back can expand justice by helping address the disparities in access to knowledge that traditionally characterize lay-professional relationships, particularly in communities of color or low-income communities (Sullivan et al. 2001; Morello-Frosch et al. 2009; Brown et al. 2012). Indeed, most tribal research ethics codes, rules of conducts, and reviews, promote communicating personal and/or community-level results (American Indian Law Center 1999; Freeman 2004). Even in particularly sensitive report-back situations, the beneficence principle, which compels researchers to maximize benefits for participants as well as minimize harm, encourages IRBs and researchers to consider the potential for individuals and communities to use research findings to support local cleanup efforts and toxics regulation and, where possible, individual-level interventions that reduce the risk of harm.

Developing and testing model protocols for sensitive situations will help researchers and IRBs carry out report-back with confidence in these contexts. For example, model informed consent protocols have been proposed that encourage participants to breastfeed, and future studies could focus on mothers' responses to such protocols (Bates et al. 2002; Morello-Frosch et al. 2009). Future work can also create protocols that systemize guidance about when and how to follow up on unexpected high exposures for unregulated chemicals. Engaging community members in the process of creating such protocols may also be valuable. For example, most researchers stressed that focus groups or community advisory boards were helpful in advising them on the content and format of report-back materials to make them culturally relevant. Moreover, engaging community partners in developing report-back protocols has been demonstrated to enhance the translation of research findings (Haynes et al. 2016).

A key ethical tension remains, however, as to what research teams and individual scientists can and should do to assist participants in responding to their personal results, particularly when community action is needed. While researchers gave participants recommendations for individual actions to reduce chemical exposures, they recognized that some participants, particularly low-income people and workers, may not be able to make changes. In medical studies, participants can be referred to healthcare agencies for follow-up, but environmental researchers have trouble referring participants to public health agencies or physicians due to an absence of environmental health training among most health professionals (Gehle et al. 2011; Stotland et al. 2014). While one study we followed had an established relationship with a county health department, and a protocol in place to follow up with participants with unusually high lead exposures, such relationships are rare. More work needs to be done to not only ensure that clinicians have adequate environmental health training, but to also earmark funds to establish public health centers that can proactively respond to problematic results uncovered during biomonitoring research.

In addition, researchers recognized a need for systematic changes in regulatory and corporate practices, but they were hesitant to promote community or policy-level actions for

reasons including pressure to keep science and politics separate, exposure-reduction strategies being beyond the scope of their capabilities or resources (e.g., remediating lead paint in homes or helping study participants relocate), or legal barriers to advocacy, particularly for government scientists. Community action, however, is not considered a violation of the research process within community-based participatory research (CBPR), a methodology that promotes community engagement in all research stages (Israel et al. 2001; Minkler and Wallerstein 2008). The last two decades have seen a rapid proliferation of examples of affected communities collaborating with innovative scientists to leverage exposure data to protect public health (Frickel 2004; Minkler et al. 2006; Brody et al. 2009; Brown et al. 2012; Balazs and Morello-Frosch 2013) and federal agencies increasingly support community-engaged environmental health research (O'Fallon and Dearry 2002; NRC 2012; Finn and O'Fallon 2015). For example, some federal funding mechanisms, such as the National Institute of Environmental Health Sciences' (NIEHS) Research to Action program, partner community members and researchers in investigating environmental health risks of community concern and translating research directly into public health impacts (Cook 2008). While NIEHS promotes CBPR research, it does not offer guidance to IRBs for reviewing academic-community partnerships. Our research team has found that IRBs are often unfamiliar with CBPR and are reluctant to adopt activities that challenge traditional academic norms by participating in community-engaged research (Brown 2010). Thus to complement federal funding support, agencies like NIEHS can offer clearer guidelines and training on CBPR's principles, scientific and community benefits, and the ethical considerations of academic-community collaborations.

As a result of evolving research ethics and increased civic participation in science, reporting back individual results is becoming an increasingly accepted practice. For example, due to public advocacy, California legislation that requires report-back in the state's biomonitoring program represents the first U.S. mandate for reporting back individual chemical exposure results.

One limitation of our study is that we had a non-randomized approach to study selection, and we approached investigators we knew through our research connections. The universe of studies reporting back results was small at the time, and we selected studies to be diverse in terms of regions, demographics, chemical analytes, and research context (i.e., academic, advocacy, and regulatory). Another limitation is that we only interviewed those with report-back experience, and thus we do not provide insights into why other researchers do not integrate this practice into their studies. Despite changing norms in favor of reporting-back study results, the percentage of studies across disciplines that return results is unknown (Rigby and Fernandez 2005) and the prevalence still appears to be low in environmental health studies. Research within the medical field found that investigators and clinicians often support the practice, yet face financial and expertise barriers to its adoption (Rigby and Fernandez 2005).

To extend this practice widely in environmental health research, federal funding programs could identify report-back as desirable in proposal solicitations. In addition to directed funding, we recommend conferences and other forums to share experiences from the field on ethical, effective, and feasible approaches to reporting back results. NIEHS, together with

the Department of Health and Human Services' Office of Human Research Protections, can take the lead in informing researchers and IRBs about report-back through guidance documents, professional meetings, and training programs. These meetings can strategize practical solutions for challenges such as keeping participants engaged during the lag between biospecimen collection and reporting back results, and informing participants post hoc of the significance of their results if future scientific advancements establish links between exposure and health outcomes. Representatives from the public could co-author guidance documents and present at conferences and training programs alongside researchers, to give the participant perspective of report-back. Consensus conferences (Wortman et al. 1988; Joss and Durant. 1995; Nelson et al. 2009) that include a "lay panel" that is demographically diverse and encompasses affected populations can address areas where ethics remain less resolved. The practical benefits of report-back for both participants and the studies themselves, alongside the underlying ethical reasons to share personal results, support routinely integrating individual report-back into environmental health research.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Highlights

- Researchers report ethical and practical benefits of personal report-back
- Researchers demonstrate report-back can be done without causing undue anxiety
- Ethical tensions remain about how best to report-back to vulnerable populations
- Researchers are conflicted about assisting participants in responding to results

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.

Table 2

Reasons for reporting back personal exposure results as stated by 17 researchers with experience in reporting back across the U.S. Interviewees have multiple reasons for reporting back results.

Reason for Reporting-Back	Example quotations	Frequency of reason across N interviewees
Right-to-know	"In a sense we're not owners of these data, we're more custodians on their behalf so it just made sense… it seemed like information that they really did have more ownership of than we did even, almost."	15
To provide participants with information that helps them reduce their personal or family's chemical exposures.	"It prompted curiosity, concern, and action on the part of most of the participants. A keener interest in examining their own lives for ways that they could reduce their exposure"	9
Participant or community request	"…they communicated a great interest in having some indication of whether they were being exposed, and if so, at what level."	7
Desire to return something to participants	"They have given their time and have reasons for being in the study. And I assume that one of the reasons would be because they are concerned about their exposures."	7
To support activism around chemical policy	… no matter who you are, we're all contaminated without our consent, and there is something fundamentally wrong with that... And the idea is to really inform people so they can take that information to the next level to change the policies that allow that exposure.	5
Influence from colleagues	"…seeing what … others have been thinking about, that we should be moving in that direction as well."	4
Retention and recruitment	"I believe [report-back is] one of the things that has helped with retention… that was always the message, 'you are part of this and we want to hear from you.'"	4
To increase general environmental literacy	"Maybe people will become more informed, not just about that site in particular, but about environmental health and environmental science in general."	1

Table 3

Challenges in reporting back personal exposure results.

Ongoing contact with study participants
• Maintaining connections with participants given long gaps between collecting samples and reporting results
• Post hoc contact with study participants if new health guidelines emerge
• Protocols for the timing of reporting back high results for chemicals without health guidelines
Developing meaningful reports
• Deciding on clear takeaway messages and summaries, including conveying scientific uncertainty about health outcomes
• Avoiding information overload
• Representing intra-individual temporal variability for rapidly metabolized chemicals
Sharing data beyond the study participant
• Deciding who to share research results with (e.g., physicians, family members, and wider communities) and how to protect privacy
Logistical and financial constraints
• Limitations in staff time, funding, and other resources