Sharing Research Findings with Research Participants and Communities

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Abstract

In occupational and environmental health research, individual, group and community research participants have a unique and vested interest in the research findings. The ethical principles of autonomy, non-maleficence and beneficence are helpful in considering the ethical issues in the disclosure of research findings in occupational and environmental health research. Researchers need to include stakeholders, such as groups and communities, in these discussions and in planning for the dissemination of research findings. These discussions need to occur early in the research process.

Keywords: Ethics, research; Communication; Environmental exposures; Occupational exposures; Biological markers; Informed consent

Introduction

With its focus on studying health concerns related to exposures in the workplace and in the environment and their health effects, it is clear that the results of research in Occupational and Environmental (O&E) medicine have the capacity to profoundly affect the lives of both research participants and those of the wider communities of interest. Given the influence of this research, appropriate attention has been paid to the importance of maintaining scientific integrity in the design, conduct, analysis, and reporting of the results.¹⁻⁵

Independent of the design of O&E health studies, individual, group and community research participants, while not the only study stakeholders, have a unique and vested interest in the findings. This may be especially true of prospective studies.

We shall focus on key ethical issues that pertain to disclosing and sharing research findings with research participants and communities in O&E health research.

There are four generally accepted core ethical principles⁶ that are widely used to guide ethical reasoning: 1) respect for autonomy (“respect for the decision-making capacities of autonomous persons”); 2) non-maleficence (“not causing harm to others”); 3) beneficence (“prevent harm, provide benefits and balance benefits against risks and costs”); and 4) justice (“appropriate distribution of benefits, risks and costs fairly”). In practice, ethical reasoning involves balancing these principles or determining that one principle must have priority over others when considering a specific ethical issue.⁸ For this paper, we focus on three of these principles—respect for autonomy, non-maleficence and beneficence—as these especially relate to the purpose of this paper which is to discuss the ethical issues in sharing research findings with research participants and communities.

The appeal of these ethical principles is that they offer an important analytical framework that helps us to think about ethical issues and provides us with some common language.⁹ Readers should be
guided by other instruments, as appropriate including the Nuremberg Code and others developed since then (e.g., World Health Association's Declaration of Helsinki, EU Directives, International Ethical Guidelines for Biomedical Research Involving Human Subjects; Belmont Report, The Council for International Organizations of Medical Sciences). Readers may be interested in reading a very useful inventory of various countries' laws, regulations, and guidelines governing research with people.10

Sharing Research Findings and the Ethical Principles

General biomedical/clinical literature

There is no consensus in the general biomedical/clinical literature about disclosing research results to study participants. Fernandez and colleagues have advocated for offering a summary of research results to individual participants and including information in the consent form on the harms and benefits of receiving the results with options to decline all or any of the results (which they advocate for all human subjects research).11,12 This position puts a priority on the principle of autonomy by respecting the decision-making capacities of the research participant. It also provides individuals with the information they need to make informed decisions in light of knowledge of potential risks, benefits and harms. Others put a priority on the principle of autonomy by arguing that researchers are accountable to research participants and therefore owe research participants research results.13 This may be difficult to accomplish in practice—for example, one study sampled researchers presenting at an American Society of Hematology annual meeting and showed that 69% supported or strongly supported offering research results to participants, but only 30% of these had a formal plan to do so.14 We concur with Rigby and Fernandez14 that there needs to be more research on needs and concerns of researchers and research participants with respect to how best to offer results to research participants. In contrast, there is a body of opinion that cautions against disclosures as a routine practice, even aggregated results, because of postulated potential harm to research participants.15,16 Those with this view believe the decision as to whether to provide research results should be based on various considerations, such as balancing harms and risks to the individual16,17 and the clinical significance of the findings. Additional considerations to be weighted include whether there is scientific or clinical uncertainty about the meaning of the results or the ability to act to address or to use the findings.18 Proponents of disclosure approaches that attempt to balance considerations of harms and risks to determine if research participants will be offered or provided with research results are putting a priority on the principles of non-maleficence and beneficence rather than on the principle of autonomy.

Frameworks and sharing results in O&E health research

In the area of O&E, there are various perspectives about the sharing of research results to research participants and to communities. In their article, Morello-Frosch and colleagues identify three frameworks for communicating human biomonitoring (HBM) results—clinical ethics; community-based participatory research; and “citizen-science data judo.”19 We believe this categorization of frameworks offers a helpful way to discuss the various approaches to sharing research results more generally for O&E health research. The clinical ethics approach is rooted in the biomedical model. The discussion above about the biomedical/clinical literature
describes some approaches to address ethical issues considered in that approach. There is an approach stemming from community-based participatory research which is more rooted in community and population health and which has an emphasis on the principle of autonomy. Here the community is more involved in the research process (including in protocol development) and there is a strong focus on sharing aggregate research results with communities. There also is a strong focus on sharing aggregate (or individual) research results with research participants. Typically communities and research participants make decisions about whether to receive the research results. The third approach is rooted in an advocacy model which “encourages report-back of aggregate and individual-level results to study participants to support precautionary individual action, communications, and policy change.”

Core ethical principles and sharing results in O&E health research

Discussions about human biomonitoring (HBM) research have highlighted various ethical issues in the O&E health field. Sometimes HBM can produce clear evidence that an exposure occurred, how much, and what health impact it may have. However, in other situations the HBM results might reveal uncertainty as to the source of the exposure, whether there is a health risk, or if prevention or treatment is warranted. Thus, if there is an identifiable participant (that is, if the data are not anonymized) providing individual results could offer research participants with an opportunity to obtain treatment or avoid the exposure or, it could lead to unclear conclusions and no specific action recommended. This latter possibility (unclear conclusions and no specific action recommended) provides us with a scenario as to how the ethical principles of autonomy, non-maleficence and beneficence might be balanced, particularly in the clinical ethics approach. If a researcher, for example, believes harm will be done, and/or that there are more risks and costs than there are benefits, then they would probably decide not to share the research results. For those researchers, they would be considering, for example, if uncertainty or lack of ability to rectify exposure consequences confers a measurable harm to participants. Exposure information may still lead to life-altering plans despite the lack of certainty or clinical recourse and they would likely want to consider this as well. Conversely, if a researcher believes it is best that the research participant is given (or is offered) the research results rather than to shield them from knowing, then they would probably decide to share the research results. For community-based participatory research or “citizen-science data judo” there is a strong emphasis on the principle of autonomy and for the former, to also have strategies to protect research participants and communities right to determine what research results are shared with them.

There has been an examination of what research participants want with respect to being provided or offered their research results. Fifteen US lay public citizens participated in “A Boston Consensus Conference on Human Biomonitoring” and reported, among other things, that biomonitoring finding reports need to accurately state what is, and is not known about the cause-effect relationship; and, that participants should be able to decide for themselves if they want individual results (and that participants should be notified how to reduce exposure to the monitored chemicals if this is known). What emerges here is that for this lay public, autonomy is the primary principle and they transferred the “disclosure/nondisclosure” into a requirement to inform with research partici-
pants autonomously deciding about levels of information provided (opt in or opt out). Morello-Frosch and colleagues who offered the frameworks for communicating biomonitoring results discussed above, reported results of their study designed to determine stakeholder (researchers and participants) views on the reporting of individual exposure data. They suggest that there is a trend in favour of disclosing chemical exposure information to participants, even if the clinical significance is not known (perhaps even in the clinical ethics framework with respect to biomonitoring).

Fernandez, Kodish and Weijer offer a parallel to the ethical principle of respect for persons they used to support their view that researchers have an obligation to offer participant results, by proposing an ethical principle of respect for communities. In the context of O&E health studies, the relevant stakeholders and communities include, for example, individual participants (workers or individual community members), employers, unions (those that represent a group of workers), advocacy groups, or/and a community surrounding an environmental risk. There could be multiple levels of data being collected and which could potentially be shared. For example, the research results could be available at an aggregate level of risk (e.g., the workforce or community has been exposed to high levels of the toxic entity); a group level (e.g., some members of the workforce have high blood levels of the toxin); or an individual level (specific individuals have high blood levels of the toxin). Various ethical scenarios might emerge as a result of the different levels of data collected and reported. For example, there may be group exposure data shared and additionally, some research participants in that group may also decide they wish to receive their individual research results which, if released, could result in them being able to identify other participants with similar results. Another scenario might be if the individual results have been anonymized at source such that the researchers cannot identify those with abnormal findings; there could be a situation where individual disclosure takes the form of “one individual of 10 has a high risk exposure” (but we do not know which one). The balancing of the ethical principles needs to consider these multiple levels of data when determining if, and if what, research results will be provided or offered. Complicated scenarios, such as those above, are best identified and discussed early in the planning process among those involved in the research process.

There are some very informative studies on how research results have been shared with individuals and with communities. Hernick and colleagues discuss the balancing of ethical principles (e.g., autonomy, non-maleficence, and beneficence) in their paper describing how they decided to report individual results about unexpected biomarker results to study participants and to the community. Their deliberations reflected the complexity of the issue and their solution illustrated the importance of a clear and well-thought out communication plan with stakeholder involvement. Another example is the discussion by Brody and colleagues on whether and what to report in exposure studies, which reviews the (“expert-researcher”) model where the research participant’s physician receives the test results if these are clinically significant to newer models (a community based-participatory model) that provide results directly to research participants (and to communities) to respect their autonomy. These newer models often involve more collaboration and partnering with communities and we discussed them earlier with respect to the frameworks offered by Morello-Frosch and colleagues.
TAKE-HOME MESSAGE

- Individual, group and community research participants have a unique and vested interest in the research findings and it is important there are discussions and decisions made about sharing research results with these stakeholders early in the research process.

- Applying ethical principles can offer an important analytical framework for considering the issue of sharing research results.

- Researchers and others involved in the research process (e.g., groups or communities) need to consider at the time the research is planned what results will be shared, to whom and how.

- Care needs to be taken so that the research protocol includes relevant information about the sharing of research finding, including a clear communication strategy. A data acquisition table included in the protocol and consent form may be helpful as it could include information such as the data elements, identifiers, relevance, how (and when) it will be measured, possible reporting ranges, the level at which the data will be collected and analyzed, and explicit disclosure points (what and when, to whom).

offer four ethical goals associated with incorporating community input in research: enhanced research participant and community protection, enhanced benefits, increased legitimacy, and shared responsibility. These ethical goals mesh well with the principles of non-maleficence, beneficence and autonomy. Protecting research participants and enhancing benefits are consistent with the principles of non-maleficence and beneficence. Increasing legitimacy and shared responsibility is arguably consistent with a principle of autonomy (as long as the individuals' and communities' input is treated as coming from independent agents). The Dickert and Sugerman framework is relevant for O&E health research as it highlights the importance of having buy-in and input from stakeholders and relevant communities. While incorporating community input into O&E health studies is important, it must be emphasized that communities should be provided with aggregate and not individual research results and they must not have an opportunity to change or veto the subsequent reports or publications with respect to matters related to scientific integrity.

Comments on some unique O&E settings

There are a number of unique settings for O&E health research. For example, Resnik and Zeldin use an ethics framework to discuss the “duty to warn” of household hazards when conducting environmental health research in people’s homes. This is an especially important topic as occupants may not be research participants leading to questions about what the ethical response ought to be to non-research participants. They conclude there is an ethical (and US legal duty) to warn research participants and occupants. They end saying that tests conducted as a part of the research protocol should be provided to research subjects and occupants only if the results are “accurate, reliable and medically useful.” Interestingly, they advise that researchers should help those receiving the results make effective use of the information (e.g., referrals for remediation). The topic of environmental health research and household hazards has become an important ethics topic after Grimes v. Kennedy Krieger Institute, Inc where the US Court of Appeals found that the corporation did have a duty to warn “minor volunteer participants and/or their...
legal guardians regarding dangers present when the research had knowledge of the potential for harm and the subjects were unaware of the danger.”

A subsequent report from the US Institute of Medicine provides guidance for researchers conducting environmental research in private homes.

Another “vulnerable population” are workers in workplace health studies. The workplace setting requires a different approach than those used in the “academic and pharmaceutical biomedical model” of research. Typically O&E health research is non-therapeutic and as such there is generally no direct clinical or health benefit to the participant; instead, there is a potential future clinical or health benefit to others in a similar occupation or environment. In the workplace setting, it will be important to consider the issue of sharing research results with research participants and other stakeholders. Rose and Pietri have elaborated in a letter to the editor that in the US, “worker and/or community feedback of results is a condition of the funding mechanism, as it should be.”

It is not clear from the literature if there is general agreement about sharing research results with participants in workplace studies however, Rothstein has offered guidelines for medical research on workers that address the issue. Guideline 8 says that research participants should be provided with the opportunity to receive general research findings and to decide after all the potential risks of disclosure have been disclosed, if they want to receive individual research results if researchers believe they are of “sufficient scientific validity and clinical utility to warrant offering participants the opportunity to obtain their individual results.”

Guidelines 2 says various stakeholders (employers, employees and union representatives) should be involved in developing all aspects of the study including the dissemination of findings. In these guidelines there seems to be a priority on the autonomy of people, although there is an incongruity as it is the researchers who decide if they are of the opinion that the study warrants sharing the individual research results.

Research Planning

It is important for those involved in the research process to consider the issue as to whether research results will be shared (and if so, how) at the time the research is being planned. The decision should be clearly articulated in the protocol along with other relevant details such as how the decision was made and who participated in the decision-making.

Researchers will need to be compliant with legal instruments and also consider codes, treaties, directives and policy or guidance documents in considering the issue of sharing research results. Miller, Christensen, Giacomini and Robert reviewed policies and legal instruments as well as scholarly opinions and found differing positions about disclosing research results to study participants. For example, these authors note that some policy guidance articulate a duty to disclose (others articulate a duty to clearly inform research participants what will be disclosed to them); some point to a duty to offer the results (others express a duty to provide results when asked); some policy guidance make the decision to disclose based on various factors such as clinical usefulness and relevancy of the results to an individual (others do not refer to decision making factors); and, some require disclosure of aggregate results (or duty to provide aggregate results when asked) while others seem to create an obligation to disclose individual results. This highlights the importance of considering these instruments and documents at the time of planning the research so that researchers can seek clari-
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Ethics Corner

Clarification early on about applicable laws and the relevance of the other documents. For international studies, it will be particularly important to determine which laws have relevance in various relevant jurisdictions (and how to handle any conflicts of laws) as well as which documents may be most significant.

Research ethics committees mandated to review human research will have their own views on sharing of research results. Brown and his colleagues describe obstacles they had to overcome in obtaining ethical approval for their community-based participatory research on exposure to environmental toxins.32 They suggest that their HBM community-based partnership seemed to weigh ethical principles differently than did the research ethics committees that reviewed their study and biomedical research. Research ethics committees may be reluctant to approve the sharing of research findings with participants when there is scientific uncertainty about the health risks and effects.33,34 In their comparison of two Canadian studies on HBM, Haines and colleagues draw attention to how the different research ethics committees weighed the ethical principles and how this influenced the community strategy.33 Roger Rawbone offered observations as a past chair of a Health and Safety Research Ethics Committee where they had a large concentration (“mostly or nearly mostly”) of workforce studies or healthy volunteers as compared to studies in clinical settings.27 Interestingly, he says that “the fact that an individual’s results may not be interpretable is not considered a reason for not offering them to the volunteer.”27 He noted that his committee expected a full explanation of the study outcome presented to volunteers in the consent process. Given that there may be a diversity of opinion, researchers will want to initiate discussions at the time they are planning the research with the relevant research ethics committees so that there may be resolution of these issues prior to the protocol being submitted for review. This early consultation is particularly important given that communities and other stakeholders involved at the planning stage may have certain expectations about the sharing of the research results. Perhaps this fact alone can be documented as institutional ethics committees could be helped in their deliberations if they know what the community wants with respect to the sharing of research results. Brown and colleagues offer helpful strategies for researchers/community partners and institutional research ethics boards with respect to community based participatory research.32

Key Protocol Elements when the Decision is to Offer or Provide Research Results

If the decision is to offer or to provide results then it is important that the protocol include specific information so that it can be adequately reviewed and considered by those who have a reason to do so, such as institutional ethics boards or community partners. Below are some recommendations:

1. Clear statements about what data is being collected and what data will be shared.

The protocol must clearly specify what data are being collected, including for example what biomarkers will be analyzed, and what we know, and do not know, about the health effects of exposure and what data will be shared. The protocol must include the information being providing to potential communities and research participants about the study as well as a copy of the consent form.

It is important the consent form clearly
and in appropriate language for the target audience state, “what, when, and how aggregated and individual data will be communicated to whom” and options for a participant to determine for themselves what information they wish to receive (e.g., individual and/or aggregate results) if this is being offered to them or a statement about what research results will be shared with them. The information and consent form needs to provide sufficient information so that participants (and communities, if relevant) can make an informed decision about participating in the study and about receiving the results. We favor having a clear data acquisition table included in the consent form (and in the protocol) so that participants can know exactly what data are collected, when and how. For example, the data acquisition table could include information such as the data elements, identifiers, relevance, how (and when) it will be measured, possible reporting ranges, the level at which the data will be collected and analyzed, and explicit disclosure points (what and when, to whom). It may be best if researchers ask participants to go through the consent process again once the results have been analyzed to ensure the participant has not changed his or her mind and to be able to inform participants of unexpected or new results that were found after consent was obtained. The issue of future uses of biomaterials is an important ethical issue which has been addressed by others, such as Merlo and colleagues.1

2. A clear communication strategy

A communication strategy should be included as part of the protocol. The strategy should include how results will be disseminated to those who are to receive them. It is important the communication strategy includes information about what support will be provided to those receiving research results. Fernandez, Kodish and Weijer emphasize the importance of offering immediate support to those receiving research results and not sharing in a “psychological or medical vacuum.” Several authors have provided valuable insight into communicating results to participants and to communities. Kalman reminds us of the importance of ensuring that the protocol details how the results will be handled when he recounts the 1990 case where UK nuclear workers who were research participants did not know until the publication in the British Medical Journal that the study found an association between radiation dose to fathers at work and the incidence of leukemia in their children. An interesting paper by Kalman discussed the role that case had in a subsequent policy in Britain’s nuclear industry about providing pre-publication information to research participants (and the agreement at that time by the editors of The Lancet and the British Medical Journal for such pre-publication disclosure).

Developing a communication strategy cannot be done by researchers in isolation. The US National Research Council’s Committee on Human Biomonitoring for Environmental Chemicals emphasizes the importance of identifying the informational needs of the audiences while planning the (HBM) study so that, when feasible, the study is designed to provide this information. It will be important, says that Committee, to form partnerships with “one or more audiences on project design, implementation, or interpretation, and communication.” The importance of identifying stakeholders early in the planning process and considering ways to engage them, such as advisory boards have been recommended. For example, the International Society for Environmental Epidemiology’s Ethics Guidelines include seeking consultation with “members of affected group or their representatives” whenever appropri-
ate so that their potential concerns can be addressed in the study protocol and so that community research includes input from that community throughout the entire research process.40

The protocol needs to include information about how researchers will ensure that their commitment to scientific integrity is not compromised. For example, while consulting with employers or unions, it is important that researchers ensure the scientific merits and contribution of the study are not compromised by negotiations about the design, conduct or reportage of study findings.

**Conclusion**

Research participants and communities are major stakeholders in occupational and environmental health studies. Because they have a vested interest in the research, it is important to carefully consider whether research findings will be shared with them. Researchers need to apply ethical reasoning to think carefully about this issue, along with being mindful of applicable laws, and considering, as appropriate, various codes, directives, guidance as well as following the instructions from institutional research ethics boards. Various forms of community-research partnerships offer important advances in decision-making about sharing research results and highlight the need to consider the various ethical issues together so that informed decisions can be made. It would be fascinating if researchers publishing O&E health studies generally included information on their sharing of research results with research participants, groups and communities so that we could develop a better understanding, and over time, of the practices in the field.

**Conflicts of Interest:** None declared.

**References**


25. Grimes v. Kennedy Krieger Institute, Inc. 2001 Md LEXIS 496


