

When Should Genome Researchers Disclose MISATTRIBUTED PARENTAGE?

BY AMULYA MANDAVA, JOSEPH MILLUM, AND BENJAMIN E. BERKMAN

Researchers need a decision-making framework about disclosing a finding of misattributed parentage that accounts for nonclinical factors like the effects on personal identity and familial relationships.

The ability to efficiently generate massive amounts of genomic sequence data is emerging as a powerful tool in biomedical research,¹ but it has also prompted a vigorous debate about the ethics of managing the breadth of clinical information produced.² There is already a substantial literature on how to handle incidental findings with potential clinical significance, and consensus remains elusive.³ In this paper, we return to one of the earliest documented examples of an incidental finding: misattributed parentage.⁴

As costs decrease and analytic tools improve, a growing proportion of research studies will use genomic sequencing to draw inferences based on comparisons between the genetic data of a set of individuals thought to be related to each other. Among

the cases in which genomic sequencing will be very useful are those in which a child has a rare or undiagnosed disease that might have an underlying genetic etiology. Researchers will be able to sequence the pediatric proband and both parents to compare their genomes in hopes of finding novel variants that point toward a diagnosis and perhaps to treatment.⁵ As the use of this analytic method progresses, however, researchers are sure to discover that, in a growing number of cases, the assumed biological relationships between the individuals do not actually exist. Consequently, they will have to grapple with decisions about whether to return incidental findings of misattributed parentage on a much larger scale than ever before. The significance of this issue was acknowledged by the Presidential Commission for the Study of Bioethical Issues in a 2013 report on incidental findings, in which they used misattributed paternity as a paradigmatic example of a “relatively common” anticipatable incidental finding.⁶ For example, even among men who are highly confident

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about their paternity, there is a 1.7 percent rate of misattribution.⁷

Misattributed parentage is defined here as the misattribution of *genetic* parentage: that is, that the putative parent of an individual is not that individual's genetic parent. Although the literature tends to focus on misattributed paternity, with the presumption that it results from infidelity, there are a variety of cases in which researchers may discover that an individual's paternity or maternity is misattributed. An individual may not know that she is adopted, for example, or the wrong egg and sperm may have been used during in vitro fertilization (IVF), or a child may have been switched at birth.

While we make no normative claims about whether or not individuals *ought* to value genetic relationships, the correct attribution of genetic parentage may be important to parents and children for a variety of reasons. For some, the genetic parent-child relationship may carry emotional weight. Some individuals may want accurate information about their biological parentage in order to gain an accurate familial medical history for their personal medical treatment or for reproductive decision-making. In many countries, genetic parentage grounds certain legal obligations of parents toward their children. Whether it ought to or not, the disclosure of information about misattributed genetic parentage has the potential to affect familial relationships on many levels.

We argue that nondisclosure should be the default position for researchers. We begin by assessing the limited guidance that can be found in the literature on incidental research findings and on disclosure of misattributed parentage in the clinical setting. We then sketch the normative argument that underlies our view that the default should be nondisclosure. In order to assess whether to disclose in a particular case, it is necessary to weigh the expected harms and benefits of disclosure, and we provide a taxonomy of the possible harms and

benefits and show how our normative argument applies to them. We close by considering three objections: that nondisclosure may cause false beliefs in participants, that researchers may have relationships of trust with their participants that entail a duty to disclose, and that participant preferences should be solicited and followed. We close by suggesting ways in which the consent process could minimize possible harms related to nondisclosure.

Existing Guidance

There has been considerable discussion in the research ethics literature about incidental findings flowing from genomic research. This literature has tended to focus on de-

disclosing findings of misattributed paternity discovered during research. Some researchers qualify this by stating that exceptions will be made in cases where the information has clinical utility. In the research ethics literature, there is occasional discussion of the inadvisability of returning findings of misattributed paternity, but the reasoning behind these conclusions is not well developed.⁹ Researchers need a decision-making framework that accounts for nonclinical factors alongside factors that the incidental findings literature already emphasizes as relevant.

Unlike the research ethics literature, the medical ethics literature on genetic testing and counseling does identify and analyze morally relevant

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fining the scope of the clinical significance of an incidental finding—that is, the implications of the finding for a participant's medical care—with the assumption that it is primarily the clinical significance of a finding that will morally justify its disclosure.⁸

In focusing on defining clinical significance, the existing research ethics literature on incidental findings largely overlooks the extent to which other factors may also be relevant to a researcher's decision about whether or not to disclose a finding. Learning of misattributed parentage may implicate familial relationships, notions of personal identity, and the like even when it does not affect medical decision-making.

Although experienced genetic researchers will probably have developed views about what to do in these cases, there is no clear guidance or data on how genetic researchers have typically handled findings of misattributed parentage. Anecdotally, there seems to be a trend away from

factors that bear on decisions about disclosure and that extend beyond the “clinical,” narrowly conceived.¹⁰ However, many of the arguments in the medical ethics literature are based on aspects of the clinical context that cannot be neatly transposed to the research context. First, many scholars ground obligations to disclose or not disclose in the role-based duties of physicians and genetic counselors.¹¹ These duties are usually not shared by researchers: given the diversity of research studies and participant-researcher relationships, there is currently no convincing positive account of researchers having an obligation to disclose that derives from a role-based duty.¹² Second, while the information-seeking context of medical genetics is relatively homogenous and may ground a general default of disclosure, the context of genetic research is not homogenous. Patients who undergo whole genome sequencing in a clinical context seek it out themselves in the hopes of finding

out information that may have decision-making utility, or simply out of curiosity, and physicians and genetic counselors are tasked with returning useful information to them. This cannot be said of the research context—research participants enrolled in a study with a genetic sequencing component do not generally enroll in order to collect information that will answer their questions or help them make decisions, nor do researchers usually promise that they will fulfill such expectations.

The debate over disclosure of misattributed parentage has recently received some renewed attention. A recent paper by Marissa Palmor and Autumn Fiester takes up the issue, arguing that clinical institutions should adopt a universal stance of nondisclosure as a policy decision, which is largely consistent with our ultimate conclusions.¹³ However, Palmor and Fiester decline to draw ethical conclusions, on the ground that “there are compelling arguments on both sides of the disclosure debate.”¹⁴ We contend that it is both necessary and possible to think through the ethical implications of the disclosure of misattributed parentage. Thus, although it makes a useful contribution to the debate, Palmor and Fiester’s paper does not go far enough. First, given the emotional weight of cases of misattributed parentage, researchers often experience real moral distress when faced with such findings. A blanket policy of nondisclosure does not do away with that distress, nor does it allow for researcher flexibility and discretion. Having a framework for ethical decision-making allows researchers to come to terms with nondisclosure as ethical agents. Second, the authors do not distinguish between the clinical and research contexts—even though, as we argue, the research context poses unique problems for decisions about disclosure. While it might be possible to institute a nondisclosure policy across clinical contexts, research contexts vary widely and are thus less clearly amenable to broad policy solutions.

Overall, the incidental findings literature is attuned to the unique features of the research context but does not provide a robust framework for the inclusion of factors other than clinical significance. The medical ethics literature provides some resources for addressing factors that are not explicitly “clinical,” and even addresses misattributed parentage explicitly, but it does not account for features that are unique to the research context. Researchers need a framework that bridges the gap.

A Framework for Decisions about Disclosure

Our argument that there is normally a duty not to disclose misattributed genetic parentage identified during research is premised on an asymmetry between harms and benefits.¹⁵ It is generally agreed that moral agents have a stringent duty of nonmaleficence to avoid harming innocent others without their consent. Even minor harms require substantial justification. However, moral agents have much more limited duties to provide benefits. Taking twenty dollars from a stranger’s wallet without permission would be wrong unless one had a very good reason for doing so, but there is no correspondingly strong duty to give twenty-dollar bills to strangers. Likewise, if one is responsible for causing a harm to someone who has not consented to being put at risk, then one ought at least to repair or compensate the harm. However, if the other person has incurred that harm through natural causes, then one normally does not have a duty to repair it or make amends for it. The driver who negligently wrecks another person’s car is liable for the damages; a passerby merits praise if he offers his phone to the driver of the wreck to call for roadside assistance.

This is not to deny that there are some duties to provide benefits to others, but such duties of beneficence arise in a far narrower range of cases than the duties to avoid causing

harm. First, there may be collective duties to benefit others, such as requirements of justice that involve the state’s providing social assistance. These will not apply to the cases with which we are concerned, however. Second, Kant argued for an “imperfect” duty of beneficence, which is widely interpreted as requiring that agents act beneficently toward others, with latitude as to exactly whom to help and when.¹⁶ Given this latitude, the imperfect duty will not entail a specific obligation to return incidental findings either. Third, there may be special duties to provide benefits. These can be incurred by making promises or through specific role responsibilities, such as the duties of care that parents have to their children and physicians have to their patients. Fourth, all moral agents have a duty to rescue—that is, a duty to avert imminent, very serious harms to others when they can do so at a sufficiently low cost to themselves.

The asymmetry between duties of nonmaleficence and those of beneficence has direct implications for the disclosure of incidental findings. If disclosure is likely to harm a participant or family member, then it is normally impermissible. Disclosure will also normally be impermissible in a situation in which there is no clear evidence of either harm or benefit—since the researcher has a more stringent duty of nonmaleficence, she ought to err on the side of caution and avoid the possibility of disclosure-related harms. If disclosure is very unlikely to harm a participant but may confer substantial benefit, then it may be morally praiseworthy, but it will not be obligatory. Only if the researcher had taken on some special duty toward a participant or were faced with an opportunity to rescue him through disclosure would she have a duty to disclose. We argue later that these conditions rarely, if ever, apply.

The Harms and Benefits of Disclosing Misattributed Parentage

We understand a harm as a setback to someone's interests,¹⁷ and we do not elevate medical harms and benefits above others: harms and benefits may fall into any category of impact that sets back or aids participant interests, whether medical, emotional, or financial. In the following sections, we outline the types of harm and benefit to which a researcher ought to be attuned in cases in which she identifies misattributed parentage, and we discuss the type of evidence she would have to collect in order to assess the likelihood and severity of the harm or benefit in a particular case.

Our taxonomy of harms and benefits is limited to those that are reasonably identifiable prior to disclosure. Reasonably identifiable harms and benefits are those that should become apparent through the researcher's normal interaction with a participant within the researcher's specific protocol or institutional context, or those that could otherwise be anticipated through further inquiries with minimal effort. There are hundreds of possible harms and benefits that *might* result from a decision about disclosure, but researchers can make decisions only about the harms and benefits they can realistically identify. Just possibly, for example, disclosure of misattributed parentage could have the effect that the proband's father mistreats future grandchildren because they are not biologically related to him, but that harm is too difficult either to predict or to link causally to disclosure to be weighed in a decision about whether to disclose.

Harms

The following harms are setbacks to proband or family interests that might result when the proband or his family comes to know about misattributed parentage.

Direct harms. Disclosing misattributed parentage is likely to cause

considerable distress, although the frequency, magnitude, and duration of the distress is uncertain. Worse, disclosure might provoke or worsen a mental illness or cause someone to physically harm himself. Researchers ought to evaluate the probability of these two harms by considering the participant's psychiatric history and present condition. If a participant has a history of mental illness, the researcher might consider the possibility that the condition will worsen if misattributed parentage is disclosed. Similarly, if a participant has a history of hospitalization for self-harm, the researcher might consider the possibility that he may self-harm again. As far as we have been able to ascertain, no data is available on the probability that finding out about misattributed

be assumed that the mother is aware of the misattribution of her child's paternity in all cases, researchers ought to be attuned to the threat of family conflict over presumed infidelity in such cases. If disclosure were necessary, researchers might need support from outside institutions in order to mitigate this harm. Researchers working in a hospital inpatient setting might request a social work or psychiatric consultation. Researchers in a clinic outpatient setting might refer the case to the participant's primary care provider, to a genetic counselor in the participant's community, or to a support group. The involvement of law enforcement might also be appropriate.

Second, researchers should consider the age of the proband. If the pro-

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parentage will lead to these harms.

Harm from others. The disclosure of misattributed parentage might also result in the participant or a family member suffering verbal, physical, or financial harm from another person (either in or associated with the family). Harm from others is uniquely associated with disclosure of misattributed parentage because this finding involves several family members and has the potential to incite psychological distress around issues like personal identity, infidelity, and truthfulness.

There are two aspects of the threat of harm to others that researchers ought to take into account in their evaluations. The first is the threat of gendered violence in cases of misattributed paternity. Potential violence initiated by the putative father toward the mother after he discovers her infidelity is a topic widely touched on in the clinical ethics literature on misattributed paternity.¹⁸ While it cannot

band is a legal minor, the researcher would have to disclose the finding to the proband's legal guardians, who are most likely the proband's putative genetic parents. If so, the researcher would need to take into account potential harms to the child resulting from disclosure to the parents—for example, violence between the parents or abandonment of the child by one parent. If the proband is an adult whose parentage is misattributed, then the researcher would be able to disclose only to the proband, who could then make a decision about whether or how to communicate the result to his putative parents and the rest of his family. In this latter case, the probability of some relational harms, like domestic violence, might be reduced.

As in the case of harm to self, we are not aware of any systematic data on the incidence or severity of harm from others as a result of the disclosure of misattributed parentage.

Researchers may base their evaluations of the probability and severity of such harms on a history of violence in the family, the past or present psychiatric condition of a particular family member, or fears articulated by the participant or a family member.

It might be objected that researchers should not be held responsible for what others do with information researchers disclose about misattributed parentage. This objection stems from the notion that if someone tells the truth in good faith, then she is not responsible for the effects of her truth-telling on others. Even if people are generally at liberty to tell the truth, however, we think this liberty can be limited by other duties, including the duty to avoid harming others. As the likelihood and magnitude of harm resulting from truth-telling increases, so does one's duty to avoid truth-telling. To take an extreme example, it would be wrong to knowingly tell an assassin that his intended victim was hiding in a closet. The truth teller would not herself be a murderer, but would certainly be complicit in the murder. Researchers may not be directly responsible for the harms that others perpetrate based on the information they disclose, but they must account for the risk in their decision-making about disclosure and must provide a countervailing reason to justify putting others at this risk.

Benefits

The possible benefits of disclosing a misattributed-parentage finding can be divided into three types.

Clinical benefits. At least in theory, the disclosure of misattributed parentage could provide some clinical benefits—that is, improvements in the symptoms or course of a patient's disease (inclusive of preventative action). First, genetics can predict one's susceptibility to certain diseases, which can have a real impact on the preventative actions one opts to employ. For most people, even without knowledge of specific clinically significant genetic variants, there is a

tendency to focus most on preventing conditions that have been known to affect immediate family members, particularly parents. Reliance on such information about one's parents' health would be misplaced in a situation of misattributed parentage. Second, knowledge of misattributed parentage could have implications for organ donation. Close relatives (and biologically related parents, in particular) have a much higher chance of being an appropriate organ donor. If a family relied on incorrect assumptions about biological relationships, it could lead to dangerous delays and unnecessary invasive testing for the potential donors. Knowledge of misattributed parentage could aid an individual in either of these situations.

However, other diagnostic tests (including genetic tests) can provide the necessary information instead. These tests are regularly performed when a patient experiences otherwise unexplained symptoms or when he needs an organ donation. The cases in which acting on a clinically significant incidental finding requires disclosing misattributed parentage are very few.

Aiding diagnosis. The disclosure of misattributed parentage might be a necessary step in alerting a participant that genetic testing will not lead to a diagnosis of his disease. For example, someone searching for a diagnosis might enroll in a research study with the hope that sequencing his and his parents' genomes could help identify a genetic mutation underlying his disease. In such a case, if the researcher told him only that the team was unable to discover a genetic basis for his condition, he might assume that this particular protocol or set of techniques was not useful, and that other genetic testing might yield results. He might take off on a diagnostic odyssey, wasting time, money, and effort attempting to participate in more gene-based research. However, if the investigator informed him that testing failed because his parents are not biologically related to him, he would

be able to make progress toward a diagnosis in one of two ways. He might shut the door on genetic inquiry and move onto another diagnostic approach. Alternatively, he might be able to take steps to locate his biological parents and continue testing with their genetic material. Narrowing his search in this way could bring him closer to discovery of the etiology of his illness and, perhaps, to treatment.

This benefit is likely to be uncommon, however, and most patients with undiagnosed conditions on whom genetic tests will be conducted are likely to know that they have those conditions, even if they are unaware that the condition has a genetic component. Researchers should ask participants whether they are seeking genetic testing because they think it will get them closer to a diagnosis for their rare diseases.

Providing information that will be useful in reproductive decision-making. Disclosure of misattributed parentage might provide health-related information that would help a research participant (or that person's parents) make reproductive decisions. For example, suppose a couple gives birth to a child with cystic fibrosis, a recessive disorder. They could reasonably assume that each of them had passed on a recessive mutation to their affected child. They could also reasonably infer that there is a 25 percent chance that future children will be affected. As a result, they might make important reproductive choices: to adopt, to pursue IVF and preimplantation genetic testing, to stop trying to conceive, or to terminate an existing pregnancy. But if they learned that the child with CF is not actually biologically related to the father, then they would realize that the chances of having a second child with cystic fibrosis are much lower than they thought, perhaps causing them to make a different reproductive choice. If a research team discovered misattributed parentage in such a case, there would be no way to impart this information about lower

risk to the couple without disclosing this particular incidental finding.

Knowing about misattributed parentage is helpful in reproductive decision-making, however, only if it reveals an inheritable condition that is likely to be relevant to a decision about having children. By and large, the conditions important in that context are those that may cause the child to suffer. The possibility that one's child may inherit cystic fibrosis is clearly relevant to future reproductive decisions. By contrast, suppose a sports medicine study recruited families to study the genetic basis for acquisition of muscle mass and discovered that the parents in one family are not genetically related to their son, the proband. In this case, disclosure of misattributed parentage would not help in the family's future reproductive decision-making because acquisition of muscle mass is highly unlikely to be relevant to a decision about whether or not to have a child.

There is no evidence about how often disclosing misattributed parentage would confer benefits for reproductive decision-making, but such cases are likely to be very rare. In order to determine whether disclosure is likely to confer this benefit, a researcher would have to preemptively ask participants whether they are seeking information that would be helpful in reproductive decision-making, which could be very burdensome for researchers.

Application of the Taxonomy

Before the researcher can decide whether she should disclose a finding of misattributed parentage, she must weigh the possible harms and benefits against each other. How does this work in practice? Two questions are especially important: How should the researcher compare harms and benefits when evidence for harms and benefits varies? Second, given the numerous individuals implicated in a misattributed-parentage finding, does it matter whether the harms and

benefits of disclosure or nondisclosure apply to the proband or to other family members?

The problem of evidence. Harms are harder to assess than benefits. While it is possible to collect evidence of the benefits of disclosure simply by asking the participant whether he is seeking a diagnosis or contemplating having children, collecting evidence about whether disclosure will harm a participant is much more difficult. Straightforward questions about family dynamics or domestic violence are unlikely to yield straightforward and accurate answers, and they may be seen as intrusive. In cases where evidence is lacking and the researcher is therefore unable to judge the relative

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likelihood of harms and benefits, she should opt for nondisclosure. Since the researcher has a duty to avoid doing harm, but typically not a duty to confer a benefit, hypothetical or weakly indicated harms outweigh hypothetical or weakly indicated benefits.

Comparing harms. In some cases, the probability and magnitude of the harms and benefits of disclosure may be clearer. Researchers should approach these cases by evaluating the probability and severity of each harm. The probability assigned to a harm will be based on what the researcher knows about the participant and the family—for example, it is more probable that disclosure will provoke domestic violence if there is already a history of violence in the family, and it is less probable that it will provoke self-harm if the proband has no history of psychiatric instability.

Cases in which the possible harms and benefits will accrue to the same individual are different from cases in which they will accrue to multiple

people. In the former, we can usually add up the expected harms and benefits of an action and proceed according to whether the sum is a net benefit or a net harm.¹⁹ This is how we proceed in clinical practice when we cannot obtain a patient's consent to an intervention and his preferences are unknown. By contrast, in cases involving benefits and harms to more than one person, simply adding up the expected harms and benefits is impermissible because it would allow us to harm one person in exchange for providing a countervailing benefit to someone else. In these cases, we place much greater weight on preventing harms than conveying benefits, such that the latter outweighs

the former only when the benefits are much higher.

Harms and benefits to the proband versus those to family members. By definition, cases of misattributed parentage involve more than one individual—the proband and the family members from whom samples have been collected. Family members can be enrolled in the protocol as probands in their own right, enrolled only in order to facilitate sample collection, or not enrolled in the research at all. When the researcher considers the possible harms and benefits of disclosure, how should she include these individuals in her deliberations?

There may be good reasons to pay greater attention to the possible harms and benefits to the proband. For example, the proband and researcher may have an ongoing research relationship with a strong therapeutic component, wherein continuity of care is important. If the proband expects the researcher to disclose a misattributed-parentage finding but the researcher keeps that finding

hidden, then the relationship might be damaged by a perceived betrayal of trust, possibly jeopardizing the proband's care. In such cases, harm to the proband may take precedence above harm to other participants because the harm to the proband may be more severe than the potential harms to those other participants.

However, the proband's interests should not always be privileged above the interests of other family members.²⁰ Recall that the researcher has a duty of nonmaleficence and a comparatively minimal duty of beneficence. If benefits to family members would result in possible harm to the proband, then the proband's interests will take precedence because the researcher's primary duty is to avoid causing harm. If benefit to the proband would result in harm to other family members, then the researcher's duty of nonmaleficence would dictate that she avoid this harm (even if that means withholding benefit from the proband). In sum, a researcher should not give special weight to the harms and benefits that affect the proband merely because of his proband status.

Normative Implications

There is no conclusive data on the frequency or probability of the harms and benefits we have described above. Despite the lack of available evidence, though, the asymmetry between the duties of beneficence and nonmaleficence allows us to draw some general normative conclusions.

We noted above two types of cases in which conferring a benefit might be obligatory—those in which the special circumstances of the relationship generate a role-based duty of beneficence and those in which there is a duty to rescue—but we pointed out that neither of these special obligations will normally apply to a researcher who discovers misattributed parentage. Researchers will therefore normally have no obligation to disclose misattributed parentage.

Even if disclosure of misattributed parentage is not morally required, it

would still be morally praiseworthy if the net benefit to the participant seemed great (for example, helping him bring a diagnostic odyssey to an end) and if disclosure were unlikely to cause harm to anyone else (since a benefit to one person does not justify harm to another). Under these conditions, disclosure would be unlikely to violate the researcher's duty of nonmaleficence, and she could choose to disclose the finding at her discretion.

Disclosure of misattributed parentage would be impermissible either if it were likely to cause harm to a participant (or family member) or if the researcher had no clear evidence of harms or benefits, given the duty to avoid harming others and lack of a duty to benefit. Since in most cases the disclosure of misattributed parentage carries the risk of serious harms, disclosure will usually be impermissible.

Objections

It might be objected that our analysis fails to recognize ways in which nondisclosure might breach a duty to a participant independent of the level of benefit that the information would provide. Nondisclosure might wrong someone by creating a false belief about biological parentage or by betraying trust. Alternatively, it might be argued that participants' autonomy is not being respected if their preferences about disclosure are not solicited.

Creation of a false belief. The first objection is that if a researcher does not disclose misattributed parentage, then she might cause the participant to mistakenly believe that his social parents are in fact his genetic parents. This outcome is likeliest if the consent process has caused the participant to believe that if any findings point to misattributed parentage, they will be disclosed. In addition, the participant may be likelier to expect disclosure if his relationship with the research team is deep and longstanding, insofar as people are likelier to think that people to whom they are close are

likelier to share important information with them.

The harm of creating a false belief is relatively minor, however, and can be minimized with a transparent consent process. In this process the researcher should make clear that there is no guarantee that misattributed-parentage findings will be disclosed and that nondisclosure is not equivalent to a confirmation of one's putative parentage. Thus, rather than avoiding causing people to have false beliefs by informing them of incidental findings, researchers should preemptively disabuse people of the misconception that such findings will be returned to them. An informational letter or a discussion with a participant should suffice.

Betrayal of trust. If a researcher withholds information about parentage, it might be thought that she is betraying the trust that has been built by their relationship. There is probably little danger of betrayal in contexts in which the researcher-participant relationship is minimal—such as a study in which an investigator receives de-identified blood samples from another lab and has no knowledge of or interaction with the participants who provided those samples. A betrayal of trust is most likely if the researcher-participant relationship is deep and longstanding and the researcher has played a significant role in the participant's medical care. In such cases, the length and depth of engagement makes the researcher-participant relationship look similar to a clinician-patient relationship in which trust is highly valued.²¹

If researchers do not disclose misattributed-parentage findings in these cases, they risk betraying a participant's trust on two different levels. First, if a participant has good reason to believe that he has the kind of relationship with the researcher that would result in disclosure, then a betrayal of his trust wrongs him, even if he never finds out that the researcher has kept the information from him. Secondary harms may occur if the participant discovers the withholding

of information. The discovery might be emotionally painful for the participant, and the researcher-participant relationship might be damaged so badly that the participant's care or the research project is compromised. Again, there is no data to indicate the actual frequency or magnitude of this harm.

A thorough consent process can decrease the likelihood of a breach of trust. If the researcher is able to clearly communicate that information about misattributed parentage will not be disclosed except in the very unlikely event that it confers substantial benefits, then the participant is less likely to expect that the researcher owes him the information simply as a function of their close relationship. If the researcher-participant relationship is indeed quite close, then the expectation of disclosure that emerges from the relationship may be so strong that even clear articulation of a non-disclosure policy might not mitigate the perceived betrayal of trust, but if the consent process is thorough, these cases will be relatively rare.

Participants' preferences. A third objection to our analysis is that it does not take into account whether participants would like to receive information about misattributed parentage. Underlying this objection is the notion that soliciting participants' preferences about disclosure would respect their autonomy. There are several reasons that we think it advisable to focus on harms and benefits rather than soliciting and making decisions on the basis of participant preferences.

First, we agree that if researchers offer participants a choice as to whether or not to receive information about misattributed parentage, then they have an obligation to act accordingly. However, we are skeptical that there is an obligation to offer the choice to participants in the first place. Researchers do not have the obligation to ask participants ahead of time about every type of finding they might be interested in receiving. Only, it seems to us, in those

scenarios in which a researcher would independently have some obligation to disclose information could she have a prior duty to offer the participants the option of whether to receive it.

Based on the harms and benefits we have outlined, we know that the benefits of information about misattributed parentage are unlikely to be great enough to generate an obligation of beneficence. We have also already established that the researcher-participant relationship does not generate a special duty to offer any and all relevant information to the participant (in the way a genetic counselor-client relationship might). Moreover, research does not provide unique access to information about

not align with those of others in their family, raising questions about whose preferences should settle the matter.

Lastly, disclosure can be resource intensive: investigators would have to provide rigorous counseling to ensure that the information is delivered with sensitivity and care. Some researchers—for example, those who use samples from a blood bank and lack both any preexisting relationship with participants and the support of genetic counselors—do not have the resources to provide that counseling. The burden of mitigating harms caused by disclosure—for example, retaining a genetic counselor—and the time and expense of contacting participants is great. It seems only reasonable to ask researchers to divert

A thorough consent process can decrease the likelihood that the participant will experience a breach of trust by the researcher.

nonparentage; paternity or maternity testing is widely available and can easily be obtained commercially. Since there are other avenues for obtaining this information, the fact that a given individual has a strong preference for knowing information about genetic parentage seems less relevant to the question of whether a finding generated in the research context should be disclosed. Therefore, we do not recognize any obligation on the researcher's part to offer participants the option to choose whether or not misattributed-parentage findings are returned to them.

Second, the reliability of any information that could be collected about an individual's preferences to receive misattributed-parentage findings is questionable. If an individual believes that he is biologically related to his parents, then it may be difficult for him to imagine otherwise and therefore difficult for him to accurately weigh the harms and benefits that might accrue upon disclosure of misattributed parentage. Additionally, there are concerns about family members' holding different views. The preferences of one person might

resources from the goal of producing generalizable knowledge when there is a prospect of substantial net benefits, which preference alone cannot guarantee.

Setting Expectations

We have identified various harms and benefits that may be caused by disclosure or nondisclosure of misattributed parentage. Overall, given the asymmetry between duties to benefit and duties not to harm, our analysis supports a default of nondisclosure. Medically significant misattributed-parentage findings are extremely uncommon, so the duty to rescue will rarely be triggered. Similarly, other harms of nondisclosure (including creation of a false belief or betrayal of trust) are usually harms that can be mitigated by a thorough consent process and effective communication with participants. In the absence of systematic data on researchers' misattributed-parentage disclosure policies, we suggest that researchers highlight misattributed-parentage findings in the consent document and process. The disclo-

sure policy described in the consent document and discussions will set participants' expectations about which incidental findings will be disclosed.

In these communications, researchers should explicitly state that since it is extremely difficult for the research team to anticipate how the revelation of information about parentage will affect the participant and his family, these findings will not be disclosed unless there is very clear evidence that it will be helpful and not harmful—and that this standard is so hard to meet that the findings will in fact almost never be disclosed. The research team may also wish to add that they understand that some participants and families may want to know about genetic relationships for personal reasons and that those participants are encouraged to discuss the topic with the research team further.

Decisions about disclosure will require discretion and careful judgment on the part of the researcher, and evidence of harms and benefits may be difficult to acquire. However, we hope that with an improved consent process that educates participants about disclosure policies and with improved communication between participants and researchers to determine the likelihood of different harms and benefits, researchers will be able to make informed and ethically sensitive decisions about whether or not to disclose incidental findings of misattributed parentage.

Disclaimer

The opinions expressed here are our own and do not reflect the policies or positions of the National Institutes of Health, the U.S. Public Health Service, or the U.S. Department of Health and Human Services.

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Notes

1. E. D. Green and M. S. Guyer, "Charting a Course for Genomic Medicine from Base Pairs to Bedside," *Nature* 470 (2011): 24.

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3. L. Eckstein et al., "A Framework for Analyzing the Ethics of Disclosing Genetic Research Findings," *Journal of Law, Medicine and Ethics*, forthcoming.

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5. For example, the National Institutes of Health Undiagnosed Diseases Program enrolls subjects who have serious conditions that have proven impossible to diagnose using traditional methods. It has been able to provide diagnoses for 20 to 25 percent of their subjects; approximately 15 percent of these successes were due in large part to the use of genomic sequencing. See W. A. Gahl et al., "The National Institutes of Health Undiagnosed Diseases Program: Insights into Rare Diseases," *Genetics in Medicine* 14, no. 1 (2012): 51-59; W. A. Gahl and C. J. Tift, "The NIH Undiagnosed Diseases Program: Lessons Learned," *Journal of the American Medical Association* 305 (2011): 1904-05.

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8. J. S. Berg et al., "Deploying Whole Genome Sequencing in Clinical Practice and Public Health: Meeting the Challenge One Bin at a Time," *Genetics in Medicine* 13, no. 6 (2011): 499-504.

9. See Wolf, "Managing Incidental Findings," 239.

10. See N. M. Schroder, "The Dilemma of Unintentional Discovery of Misattributed Paternity in Living Kidney Donors and Recipients," *Current Opinions in Organ Transplantation* 14, no. 2 (2009): 196-200; L. Wright et al., "Disclosure of Misattributed Paternity: Issues Involved in the Discovery of Unsought Information," *Seminars in Dialysis* 15, no. 3 (2002): 202-06; A. Lucassen and M. Parker, "Revealing False Paternity: Some Ethical Considerations," *Lancet* 357 (2001): 1033-35.; E. K. Lucast, "Informed Consent and the Misattributed Paternity Problem in Genetic Counseling," *Bioethics* 21, no. 1 (2007): 41-50; D. C. Wertz and J. C. Fletcher, "Privacy and Disclosure in Medical Genetics Examined in an Ethics of Care," *Bioethics* 5, no. 3 (1991): 212-32; L. F. Ross, "Disclosing Misattributed Paternity," *Bioethics* 10, no. 2 (1996): 114-30.

11. Among these duties are the genetic counselor's duty to nondirectively help clients make autonomous decisions by providing them with all relevant information, which may include information that the client does not initially

ask for (Lucast, "Informed Consent and the Misattributed Paternity Problem in Genetic Counseling") and a clinician's or counselor's responsibility to work within the framework of an ethics of care (Wertz and Fletcher, "Privacy and Disclosure in Medical Genetics Examined in an Ethics of Care").

12. A. L. Bredenoord et al., "Disclosure of Individual Genetic Data to Research Participants: The Debate Reconsidered," *Trends in Genetics* 27, no. 2 (2010): 41-47.

13. M. Palmor and A. Fiester, "Incidental Findings of Nonparentage: A Case for Universal Nondisclosure," *Pediatrics* 134 (2014): 163-68.

14. Palmor and Fiester, "Incidental Findings of Nonparentage," 167.

15. See S. V. Shiffrin, "Harm and Its Moral Significance," *Legal Theory* 18 (1996): 357-98.

16. K. Stohr, "Kantian Beneficence and the Problem of Obligatory Aid," *Journal of Moral Philosophy* 8, no.1 (2011): 45-67.

17. J. Feinberg, *Harm to Others: The Moral Limits of the Criminal Law*, vol. 1 (New York: Oxford University Press, 1987).

18. Lucassen, "Revealing False Paternity"; Ross, "Disclosing Misattributed Paternity"; Wright, "Disclosure of Misattributed Paternity."

19. There might be difficult cases where simply summing expected harms and benefits does not seem like the right thing to do. For example, we might judge that a very small risk of death is not worth taking for a certain but relatively small benefit. These complications, while important whenever we make decisions on someone else's behalf, are not relevant to the distinction we are drawing here.

20. For an example of competing harms to a proband and his relative, consider a case involving fragile X syndrome, a condition that can cause intellectual disability and abnormal physical characteristics. Earlier generations can carry a premutated allele, which when passed on to subsequent generations can expand to a full mutation. Suppose a research team has identified the premutated allele in a man and also discovered that he is not the biological father of his daughter. Failure to reveal the father's premutated allele could increase the time spent diagnosing his disease and might adversely impact the medical management of his eventual symptoms—he might not pursue testing until he has experienced symptoms for some time, causing him unnecessary pain and suffering. But revealing his premutated allele without also revealing the misattributed paternity might unnecessarily cause his daughter to preserve eggs (an invasive procedure) or select eggs without the premutation.

21. Compare H. S. Richardson and L. Belsky, "The Ancillary-Care Responsibilities of Medical Researchers," *Hastings Center Report* 34, no.1 (2004): 25-33.