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Medical Ethics

"My Research Is Their Business, but I'm Not Their Business": Patient and Clinician Perspectives on Commercialization of Precision Oncology Data

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Key Words. Commercialization • Ethics • Industry • Data use • Research

Abstract

Background. Genetic sequencing and precision oncology have supported clinical breakthroughs but depend upon access to vast arrays of research specimens and data. One way for academic medical centers to fund such infrastructure and research is "commercialization" of access to specimens and data to industry. Here we explore patient and clinician perspectives regarding cancer specimen and data commercialization with the goal of improving such processes in the future.

Materials and Methods. This qualitative analysis was embedded within a prospective precision oncology sequencing study of adults with head and neck cancer. Via semistructured dyadic interviews with patients with cancer and their doctors, we assessed understanding and concerns regarding potential commercialization, opinions regarding investment of profits, and perspectives regarding the return of information directly to participants from industry.

Results. Several patient- and clinician-participants did not understand that the consent form already permitted commercialization of patient genetic data and expressed concerns regarding who would profit from the data, how profits would be used, and privacy and access. Patients were generally more comfortable with commercialization than clinicians. Many patients and clinicians were comfortable with investing profits back into research, but clinicians were more interested in investment in head and neck cancer research specifically. Patients generally supported potential return-of-results from a private entity, but their clinicians were more skeptical.

Conclusion. Our results illustrate the limitations of mandatory disclosures in the informed consent process. The voices of both patients and their doctors are critical to mitigate violations of privacy and a degradation of trust as stakeholders negotiate the terms of academic and commercial engagement. ***The Oncologist*** 2020;25:620–626

Implications for Practice: Further education is needed regarding how and why specimens and data in precision oncology research may be commercialized for both patients and providers alike. This process will require increased transparency, comprehension, and engagement of involved stakeholders.

Introduction

Ongoing advances in next-generation genetic sequencing and precision oncology have yielded encouraging breakthroughs in our understanding and treatment of cancer [1]. But such advances in "precision medicine" depend upon researchers having access to vast arrays of genetic and corresponding clinical and phenotypic data to enable scientific discovery [2]. The breadth of such data sets permits an otherwise inaccessible depth of analysis that can ultimately translate into substantive improvements in cancer discovery, patient survival, and quality of life [1, 3]. Accordingly, with the increasing utility of emerging technologies and methodological approaches, the cost of translational cancer research programs continues to escalate.

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Researchers, and the databanks and biobanks upon which they rely, require steady streams of funding, the sources of which are often unreliable and inconsistent [4]. One possible solution to these dual needs is to "commercialize" patient or research participant ("contributor") specimens or data, a process in which an academic medical center (AMC) sells access to specimens or data to a company for profit [5]. But such commercialization raises a number of both practical and ethical challenges relating to contributor consent and the appropriate uses of such profits.

Biospecimens and health data are generally regulated by how they are originally collected, differentiating between those from patients, research participants, and customers. However, the combination of inexpensive and accessible direct-to-consumer personal genetic testing; growing public interest in ancestry, wellness, and genetic health information; and an increased focus on precision medicine and big data analytics has incentivized increased sharing of genetic data between AMCs and commercial entities [6, 7]. This sharing, in turn, blurs the original distinctions between data collectors.

Such data sharing might be necessary for achieving promising (and profitable) medical and technological advances. Yet some contributors are uncomfortable with the sale of their specimens or data from an AMC to a private company. Failure to be sufficiently transparent could therefore lead to a degradation of trust and decrease in willingness to donate specimens and data to research in the future [8].

Recent changes to the Federal Policy for the Protection of Human Subjects (the "Common Rule") now require that regulated researchers notify potential participants if their biospecimens may be shared for commercial profit. However, these regulations only apply to biospecimens that are "identifiable" (the definition of which is still in debate) and do not apply to the data derived from such specimens [9]. Although this revision provides additional disclosure obligations for regulated researchers, disclosure only achieves an additional layer of *protection* if participants actually read and comprehend such information [10]. Yet we know that participants already have substantial difficulty comprehending complex informed consent forms because of poor readability, therapeutic misconception, and other factors [11–14]. To simply add a statement regarding data commercialization to a consent form, as required by the regulations, may be insufficient to ensure that consent is truly informed.

Critical questions therefore persist: what do participants actually understand from disclosures regarding commercialization of their specimens and data? What specific concerns do participants and their referring clinicians have regarding such commercialization? And, although the public is generally assuaged by knowing funds earned from the commercialization of their specimens will be used for further research [5], what kinds of research are contributors most interested in supporting? Last, would it be appropriate for the private entity to return additional results (such as ancestry information) directly to participants?

To better understand both patient and clinician perspectives on cancer specimen and data commercialization, we conducted dydactic interviews of patients participating in a prospective precision medicine cancer sequencing study along with their referring cancer doctors. Our goal was to inform how researchers at AMCs can better design and implement a transparent consent process for biospecimen and health data sharing and commercialization.

Materials and Methods

This qualitative ethical inquiry was embedded within a prospective precision oncology sequencing study of adult patients with biopsy-proven cancer of the head and neck at an National Cancer Institute–designated academic comprehensive cancer center. Dyadic interviews were conducted throughout 2018. This research was approved by the University of Michigan Medical School IRB.

Overarching Study Design

The overarching study, "Developing Precision Medicine Protocols for Head and Neck Cancer Michigan Otolaryngology Sequencing Center (MiOtoSeq)," is an institutional review board–approved precision medicine study in the Michigan Medicine Department of Otolaryngology–Head and Neck Surgery [15]. Patients diagnosed with head and neck cancer were offered enrollment via a counseling and form-based informed consent process, followed by targeted genomic sequencing. We then nested a multimethod empirical ethics protocol (conducting surveys and semistructured interviews with both patients and their clinicians) within the MiOtoSeq study to explore why patients chose to participate in the precision oncology sequencing, the role that their clinicians played in enrollment, and a variety of other topics of ethical and legal interest. Here, we present results regarding participant and clinician perspectives on the potential commercialization of patient genetic data.

Interviews

A purposive subset of MiOtoSeq participants were sampled, based on diversity in demographic, clinical, and oncological factors. Interviews were conducted by trained researchers using a semistructured interview guide to ensure consistency while still permitting flexibility to thoroughly explore each patient's responses [16]. Interviews lasted approximately 1 hour and were audio recorded, professionally transcribed, and de-identified. All data were maintained in a secure, cross-platform data management system.

Participants were asked about their feelings regarding their genetic data being "commercialized" or sold to a private company, such as a pharmaceutical company, for their own use without any identifying information. We then queried patient- and clinician-participant feelings regarding investing profits back into cancer research or University of Michigan research more broadly. Last we asked about patient- and clinician-participant feelings regarding return of information from a private company directly (see Table 1).

Responses from 14 interviews are included: 8 patients and 6 clinicians (1 clinician provided care to 2 patients and another clinician's responses were excluded from quotation as he is an author on this analysis [A.G.S.]). Recruitment was complete once thematic saturation was reached [16]. Two members of the study team (C.D.K., K.S.-B.) independently read the interview transcripts to inductively develop an iterative coding schema [16, 17]. Transcripts were then

Table 1. Interview questions on the commercialization of genetic data

Topic	Questions to clinicians	Questions to patients
Selling de-identified genetic data to private companies	In the informed consent form we told your patient that their genetic data might be used by the [university] for future research. Tell me about how you would feel about **referring your patients to this research study if we were planning on selling their genetic data** to private companies, such as pharmaceutical companies, for their own use without any **patient** identifying information?	In the informed consent form we told you that your genetic data might be used by the [university] for future research. How would you feel **if we also asked your permission to sell your data** to private companies, such as pharmaceutical companies, for their own use without any **of your** identifying information?
Investing profits in cancer research	How would you feel if we invested any profits that we made from selling **your patients'** genetic data back into advancing our own research into treating and curing cancer?	How would you feel if we invested any profits that we made from selling **your** genetic data back into advancing our own research into treating and curing cancer?
Investing profits in University of Michigan research generally	What about using any profits to support [university] research generally?	What about using any profits to support [university] research generally?
Receiving personal info (e.g., ancestry data) from private companies	How would you feel if **your patients** got some information in return from the private company directly—such as ancestry information or other genetic information we would not otherwise give **them**?	How would you feel if **you** got some information in return from the private company directly—such as ancestry information or other genetic information we would not otherwise give **you**?

Differences between the patient and clinician questions are bolded.

double coded (K.S.-B., C.D.K.) and discrepancies were reconciled (A.G.S.). Additional details regarding the methodology of this qualitative inquiry are available elsewhere [18].

Results

We had five male and three female patient-participants, seven of whom were white, with an average age of 54, and a variety of prognoses (with 10-year estimated mortality ranging from 10% to 95%) [19, 20]. We had four male and two female clinician-participants, all doctors of medicine, with a median of 9 years (range 2–11) in faculty practice. We will use she/her for presentation of all results to enhance privacy for participants.

Overall, we found that several patient- and clinician-participants did not understand that the consent form already permitted commercialization of patient genetic data. Both groups also expressed concerns regarding who would profit from the data, how profits would be used, and privacy and access issues. Patients were generally more comfortable with commercialization than clinicians. Most patients and clinicians were comfortable with investing profits back into research, but clinicians were more interested in the investment in head and neck cancer research specifically. Many patients supported potential return-of-results from a private entity, but their clinicians were more skeptical.

Confusion Regarding the Scope of Informed Consent

Our first thematic finding was that several patient- and clinician-participants in our interviews did not realize that the MiOtoSeq informed consent disclosed potential future commercialization of genetic data. Of note, this was not one of our initial hypotheses but was rather an emergent finding that we further explored through the interviews. The MiOtoSeq informed consent process included clinicians presenting their patients with the opportunity to participate in the research, including a general overview of what participation would entail, and providing them with a 15-page consent form with further details. If the patient was interested in participation, they reviewed relevant details in person with a study coordinator. The overarching MiOtoSeq consent form met current regulatory standards for the disclosure of commercialization and contained (see Table 2).

Despite the above disclosure, when asked about her feelings regarding data commercialization, one patient-participant stated: "…I hope you don't, because I don't think you said you would, or did you? I don't remember the consent form" (P04). This participant not only did not recall such a disclosure, but in fact recalled the opposite to be true—she followed up that if she found out her data had been commercialized "I'd get my lawyer because you promised that none of my personal information would be given to anyone outside the university!" (P04). Another patient-participant agreed that "all of a sudden, my information is going for things…that I wasn't originally told about" (P06), but also admitted that she did not actually recall what the informed consent form said.

In agreement, the clinician of the patient who threatened to get her lawyer wondered why researchers had not already sent "something out and find out if people would opt out…"(C04/06)? Another clinician stated that she "wouldn't be excited about" the possibility of commercialization if she were a patient and understood "that there would have to be some language in the consent form that this could potentially occur…" (C08). A third admitted she was "less comfortable" about the possibility of commercialization and wanted to "verify with the patients prospectively" that they understood that that was a possibility (C11).

Concerns with the Commercialization of Patient Data

Participants also expressed several concerns regarding the commercialization of genetic data, most notably regarding

Table 2. Informed consent form language

Topic	Excerpt from consent form
Data sharing	"Researchers can ask to study the materials stored in the Biobank. This includes researchers from the [university], as well as from other universities, the government, and drug- or health-related companies. Some researchers will be from the U.S.; some may be from other countries around the world. All of the information collected about you will be preserved and made available to others for research. The researchers and officials of the National Institutes of Health will be responsible for deciding how the data will be shared."
Commercialization	"This information may ultimately have significant therapeutic or commercial value. By agreeing to participate in this study, you consent to such uses."

(a) who will profit and how such profits will be used and (b) privacy and access to data.

When discussing concerns regarding who will profit and how such profits will be used, one patient-participant said she would object to profits being used to "line some doctors' [or] administrators' pockets…" (P04). Another patient said that if the funds were used to make a profit "that doesn't sit well…I'd rather you guys not make a profit off of research on me" (P06). Several of our clinician-participants were also skeptical, with one observing that "…the waters probably get very muddy…with regard to who ends up profiting from those types of studies" (C11) and another stating that "…if the money is going to profit any one person…then it becomes ethically problematic" (C07).

A second area of concern for participants was ensuring data privacy and control over access. Some patient-participants seemed well-versed in recent advances in big-data usage and sharing practices. As one put it, "You know all the world has become a data collection model, and sometimes not all that data is used for the right purposes…sometimes that could be a little scary, I guess, to think that if somebody with ill intentions could get their hands on data" (P09). Another alluded to the practice of 'mosaicking', where individual data sets are combined to analyze broader swaths of data like "government combined with big industry and medical pharma…" (P02). However, in contrast, a clinician admitted that she did not have a concern with "de-identified genetic data…and pooled resources" as long as it was for the purposes of "understanding disease processes…" (C10).

Patient-participants were concerned that data might be bought and used by government, industry, and advertisers specifically. For example, one patient worried that "Even though it's supposed to be confidential…it doesn't take much for the head of Health and Human Services to say, 'Yeah, we're gonna look at all [the genetic data]. We're going to put them on a database and we're gonna see what we got here'" (P02). Concerns with private industry use included that "depending on the company, they may get greedy and…continue passing this information on…and then…the whole confidentiality thing is down the toilet" (P08); or "I feel like here at [the AMC], I get…what [the genetic data is] being used for. At Merck or a huge pharmaceutical company…quite often their eyes are much more focused on the profits of the company. So…that would be where I would worry about the usage…" (P09).

Regarding concerns with advertising, one patient worried that "when I'm online and I'm looking up bathing suits on Macy's and I click on the top and the bottoms, and then 5 minutes later an ad pops up for bathing suits at somewhere else, I'm really not happy…And I don't want [a pharmaceutical] company to do that to me because I'm none of their business. My research is their business, but I'm not their business" (P04). One clinician also confirmed this concern, observing that the data should not be sold to see "who buys what or Googles what" (C10).

All of that said, we found that our patient-participants were actually generally more comfortable with the idea of commercialization of their own data than their clinicians. For example, whereas one patient stated "I would be completely okay with that" (P05), her clinician worried that her patient would have a negative response. Another patient stated that "I wouldn't have a problem with [commercialization] if [industry is] doing research, too–or maybe they're coming up with a pill or vaccine or something that might help. Maybe my genetic material might help with that? I'm completely fine with that" (P07). And a third patient clearly stated "that would be fine" (P08), whereas her clinician threated to take herself off the study if she found out her patients' data were being commercialized. As this clinician reasoned,

> …if you look at just the stuff in the media…the Immortal Life of Henrietta [Lacks]… I would just say that a good rule of thumb for me is that…if I read in the newspaper one day that this happened at x, y, or z University, and I'm sitting here at our university thinking, well… they shouldn't have done that, and what were they thinking? And we would never do that… And then we do something like that? I mean, I would not want that [we sold patient materials to a pharmaceutical company] on the front page of the *New York Times*. If it's going to look bad, and you're going to be embarrassed, then you just know it's not the right thing to do (C08).

Other patients and clinicians agreed on the potential benefits of commercialization; as one patient put it, "I would have no problem with that, and I would be very glad to help" (P10), and her clinician concurred: "I think this data should free flow much more than it already does…" (P10).

Investment of Profits

We also asked whether investment in cancer research, versus research more generally, would have an effect on willingness to participate. A plurality of patients were supportive of reinvesting profits back into cancer research specifically: "I would be delighted…if they would do precisely that!" (P05); "that's what I would hope you do with the money…" (P07); "I think that's wonderful…" (P11); and "Absolutely, I won't be doing anything with this data; you're

welcome to have it all!" (P10). However, two of our patient-participants remained skeptical: "As good and as nice and forthright as you guys are, I'd rather you guys not make a profit off of research on me" (P06); and "I understand that's what you would want to do with any money you made off us…[but] I wouldn't want to be part of it…" (P09).

Several clinician-participants also felt positive about reinvesting commercialization profits back in cancer research: "I think that's appropriate…as long as…the monies obtained stay within the sequencing program to move the field forward" (C07). Another pointed out that this is typically how other types of research, such as cell line research, already work. One clinician, however, remained staid in her objection to commercialization across the board: "No, I would not [be comfortable with reinvesting profits in cancer research]. I think, again, it's a means and an ends question… [just because] the end product is lofty and good, does not mean that it's okay…to take any pathway there that you want" (C08).

Patient-participants were likewise overall supportive of the prospect of investing commercialization profits back into research generally (rather than just into oncology). One patient agreed to investing in "any sort of expanding of knowledge" (P05). Another said that as long as the research was toward "helping humanity" and the researchers used the money "to get smarter on this stuff" (P06), she would consent. As another put it, "You guys make some amazing…diagnoses… and they don't necessarily have to do with cancer. I think that your research is amazing, and the only way it could get even more amazing is if you do it—and you have to do it! And you can't do it unless you have the tools you need" (P07).

Most of the cancer doctors, however, were skeptical about investing profits derived from commercialization of their patients' data outside their own research area. One argued that the reason she felt that way is because she believed that was what her patients would assume: "[Investing profits elsewhere is] problematic because these patients have committed to that department or that program. That's what they consented to, and that's what they believe their biology would go to" (C07). Another clinician argued that any profits should be routed back to the original department because they "put in the initial investment…" (C09). And, as a last clinician joked, "we gotta pay my salary!" (C10).

Return of Information

A last area of analysis was how patient- and clinician-participants would feel about return of some information, such as ancestry information, from the private entity directly. Six patients reported they would be comfortable with that, and two reported discomfort. One patient enthusiastically endorsed the idea: "That would be awesome and fun and exciting. Yeah!" (P07). Another admitted "that'd be cool," but only if the information was relayed through the AMC as an "honest broker" such that the outside entity never had patient-identifying information (P04).

In contrast, clinicians were—again—more concerned about this prospect than their patients. One clinician was specifically worried about the return of ancestry information being "just kind of thrown on afterwards, and not really for helping these patients." She argued that "This superfluous information I would tend to avoid" (P07). Another pointed out "that would be very alarming to me as a patient…" because the informed consent form had already promised that any data being commercialized would be de-identified (which would obviate the ability of an outside organization contacting the patient directly) (P11). And, as a last clinician worried, "I hope we aren't selling it to 23andMe!" (P04).

Possible Solutions

Although we did not prospectively ask our patient- and clinician-participants about possible solutions to the concerns elucidated above, several volunteered their thoughts on the topic. Two patients and one clinician suggested that the AMC put in place an oversight board to ensure transparency and to contract for acceptable future uses of data before agreeing to commercialized. Two clinicians also suggested modification of the informed consent form: either that a separate informed consent form for commercialization should be provided or that there should be an affirmative opt-in check box for patients to indicate their wishes.

Discussion

Our work demonstrates that at least some participants, including both patients and clinicians, did not understand that the consent process permitted the commercialization of patient specimens or data, because they did not hear, read, process, or retain such information. If institutions value ensuring that participants in genetic research are adequately informed, they will need to simplify or otherwise clearly explain this conceptually to participants, particularly when it comes to the complex and confusing nature of genetic data commercialization.

The recent revisions to the Common Rule require that regulated researchers disclose whether biospecimens might be used in the future for "commercial profit" [9]. MiOtoSeq investigators in this study voluntarily extended this obligation to genetic data. However, these disclosures may be of limited value if relegated to a lengthy informed consent form, the signing of which may imply little regarding the degree to which the consenting individual was actually informed.

In addition, and despite the specification that their data would be de-identified, most of our patient-participants either expressed reservations with some aspect of commercialization (e.g., discomfort with the very idea of anyone "profiting" from their data) or stipulated conditions for the use of their data or the profits derived thereof (e.g., that profits should be reinvested back into research). Despite these concerns, many patients indicated they would still be comfortable with their data being sold to a private company. In fact, some patients were enthusiastic about such an opportunity, perhaps in part motivated by altruism rather than a desire for personal gain, as in prior work exploring motivations for donating tissue to a biobank [21]. These responses indicate that patients have a strong interest in whether their data are sold for profit, even when those data are de-identified. This suggests that the disclosure mandated by the Common Rule—which only applies to identified biospecimens and neither de-identified biospecimens nor data—might be too narrow in scope to fully assuage the concerns of participants. Somewhat

predictably, our head and neck cancer clinician-participants felt more strongly than our patient ones that profits derived from data commercialization be invested back into head and neck cancer research specifically; they were also protective of their patients receiving additional results (such as ancestry) from a private company directly.

This study has limitations. First, as appropriate for an exploratory qualitative design, the sample was small and drawn from a single precision oncology sequencing study of one disease site and might not be representative of patients with cancer generally. In addition, patients with cancer comprise a special population and might be more willing to contribute sensitive genetic data to research, given the serious nature of their disease, than other patients [22, 23]. Also, we originally designed our interview instrument to assess participant feelings regarding profit investment rather than informed consent form comprehension; an explicit question or knowledge test about the consent form may have revealed such misunderstandings to be more widespread. Given that responses fell across a spectrum suggestive of heterogeneity, a larger, multisite evaluation of patients' preferences for, and comprehension of, genetic data commercialization is still warranted to further explore these hypotheses.

Precision oncology researchers might hesitate to be thoroughly transparent regarding potential commercialization of participants' specimens and genetic data, particularly if they are not legally required to do so, because of the concern that enrollment rates may suffer. Indeed, past quantitative research has indicated that the majority of participants are not comfortable with such use [5]. However this qualitative exploration has demonstrated that patients with cancer (such as in precision medicine trials) might in fact be more comfortable with commercialization than their practitioners assume. Additional protections at the institutional level that exceed legal requirements, such as a data and specimen commercialization oversight committee [24, 25], might generate additional assurance both to patients and cautious providers.

Conclusion

As various stakeholders continue to negotiate the terms of academic and commercial engagement, the voices of participants are critical to mitigate both dignitary harms such as violations of privacy as well as a degradation of trust in the research enterprise. Precision oncology participants did not always understand that they had already "consented" to commercialization of their specimens and data, and had additional concerns about privacy and resultant profits. Moreover, patients were generally more comfortable with commercialization than their clinicians were. These findings can be integrated into a consent process designed to increase both transparency and comprehension, as well as ensure that the profits from patient data commercialization are reinvested in a manner that both advances oncology research and encourages engagement of patients.

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Disclosures

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For Further Reading:
Jeffrey Peppercorn, Eric Campbell, Steve Isakoff et al. Patient Preferences for Use of Archived Biospecimens from Oncology Trials When Adequacy of Informed Consent Is Unclear. ***The Oncologist*** 2020;25:78–86.

Implications for Practice:
This survey evaluated views of patients with cancer regarding the permissible use of stored biospecimens from cancer trials when modern scientific methods are not well described in the original informed consent document. The vast majority of patients support translational research and expect that any biospecimens they donate will be used to advance knowledge. When researchers, policy makers, and those charged with research oversight debate use of stored biospecimens, it is important to recognize that research participants have an interest in productive use of their blood, tissue, or data, in addition to considerations of risks and the adequacy of documented consent.