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Integrating Genomics into Clinical Oncology: Ethical and Social Challenges from Proponents of Personalized Medicine

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Summary

The use of molecular tools to individualize health care, predict appropriate therapies and prevent adverse health outcomes has gained significant traction in the field of oncology, under the banner of “personalized medicine.” Enthusiasm for personalized medicine in oncology has been fueled by success stories of targeted treatments for a variety of cancers based on their molecular profiles. Though these are clear indications of optimism for personalized medicine, little is known about the ethical and social implications of personalized approaches in clinical oncology. The objective of this study is to assess how a range of stakeholders engaged in promoting, monitoring, and providing personalized medicine understand the challenges of integrating genomic testing and targeted therapies into clinical oncology. The study involved the analysis of in-depth interviews with 117 basic scientists, clinician-researchers, clinicians in private practice, health professional educators, representatives of funding agencies, medical journal editors, entrepreneurs, and insurers whose experiences and perspectives on personalized medicine span a wide variety of institutional and professional settings. Despite considerable enthusiasm for this shift, promoters, monitors and providers of personalized medicine identified four domains which will still provoke heightened ethical and social concerns: (1) informed consent for cancer genomic testing, (2) privacy, confidentiality, and disclosure of genomic test results, (3) access to genomic testing and targeted therapies in oncology, and (4) the costs of scaling up pharmacogenomic testing and targeted cancer therapies. These specific concerns are not unique to oncology, or even genomics. However, those most invested in the success of personalized medicine view oncologists’ responses to these challenges as precedent-setting because oncology is farther along the path of clinical integration of genomic technologies than other fields of medicine. This study illustrates that the rapid emergence of personalized medicine approaches in clinical oncology provides a crucial lens for identifying

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and managing potential frictions and pitfalls that emerge as health care paradigms shift in these directions.

Keywords

personalized medicine; cancer genomics; targeted therapies; genomic testing; ethics; social implications

Objectives

“Personalized medicine” (PM) is a banner that has united proponents of the use of molecular tools to individualize health care, predict appropriate therapies and prevent adverse health outcomes[1]. Enthusiasm for PM runs high for the field of oncology [2], illustrated by the increasing availability of molecular tests to inform cancer treatment [3] and fed by the dramatically successful applications of targeted treatments for various molecular profiles in chronic myelogenous leukemia and other cancers [4]. Although there is good reason for optimism, little is known about the ethical and social challenges that will accompany PM approaches as they are more widely disseminated in oncology. To date, research has only addressed general barriers to health care delivery as PM is integrated into cancer care, such as the logistics of coordinating genomic testing and the uneven insurance coverage of testing and targeted therapeutics [5, 6].

Research has not yet anticipated the specific problems that clinical oncologists may face in using genomic tools. There have been numerous attempts to extrapolate potential ethical and social issues of incorporating genomics into other clinical settings, such as predictive testing for late onset hereditary disease [7–9]. But these extrapolations may not be transferable to oncology, nor do they draw on the expertise of professionals who are promoting, monitoring and providing genomic tools and services in oncology. To bridge this gap, we turn to those who are directly involved in oncology’s “paradigm shift” to PM to assess the challenges they perceive in integrating genomics into clinical oncology. We discuss four key ethical and social issues that most concern these stakeholders, despite their considerable enthusiasm for PM: (1) informed consent, (2) privacy, confidentiality, and disclosure of test results, (3) access to clinical genomic testing and therapies, and (4) the costs of scaling up targeted cancer therapies.

Methods and Materials

The study investigated how the goals, benefits, challenges, and consequences of translational genomic research (TGR) and PM are interpreted and anticipated by its proponents.¹ It involved interviews with individuals whose experiences with, and perspectives on, PM span a wide range of institutional and professional settings. The research team used a purposive sampling strategy to identify leaders within key stakeholder groups shaping the development and practice of TGR and PM [1], such as research funders, scientists, journal editors, clinicians, educators, and entrepreneurs. These groups were classified into larger categories of “promoters,” “monitors,” or “providers” of TGR or PM, as depicted in Table 1. Given our focus on professional perspectives on TGR and PM, patients fell outside the scope of the study.

Participants were recruited for interviews between January 2011 and December 2012. MLM, JRF and four research assistants conducted semi-structured in-depth interviews by phone (or

¹The Case Western Reserve University Institutional Review Board approved this study.

in person, when feasible). The interview guide contained a standard set of questions that could be asked in a flexible order to allow interviewers to respond appropriately to and probe participants' remarks and collect consistent information across participants [10]. Interviewers asked questions about participants' work as it relates to TGR or PM, and about their perspectives on developments in and the future of the field.

Interviews were audio-recorded and transcribed. Using standard social scientific strategies for qualitative analysis, transcripts were coded using a codebook with precise definitions of each code [11]. To promote reliability in coding, the research team first coded a batch of initial interviews together to establish guidelines for applying codes [10]. Two research assistants then coded and analyzed each interview using Atlas.ti 6 software. The research team drafted summaries of coded data, working across summaries to identify major themes [10, 12].

Results

Participant Characteristics

The project involved 143 interviews with scientists, translational researchers, commercial and non-profit developers, research funding agencies, clinician-researchers, clinicians in private practice, health professional educators, medical journal editors, and payers. The themes reported here are based on a subset of 117 interviews with participants who explicitly discussed cancer genomics in relation to PM and the ethical and social challenges of PM for clinical oncology (whether because oncology is their specialty or because they chose to discuss it). The distribution of participants across stakeholder groups appears in Table 1.

Promises of Personalized Genomics in Oncology

As promoters of a personalized medicine paradigm, interviewees naturally expressed enthusiasm for oncology as a site for realizing the promises of PM. As described by a federal research institute division chief, "the one area in medicine that personalized medicine has a great standing: it is cancer" (I197). The director of a genetic research laboratory explained why:

There's an acceptance among oncologists that you need personalized medicine, whereas in some other fields I think it's going to be slower to be adapted for that, and it's clear that for the most of the drugs where there is a companion diagnostic in the [Food and Drug Administration] label are for cancer drug appropriateness for a given tumor type, so ... I think that will also be a relatively early big impact ... which is good news as cancer is a major killer in the US and especially kills a lot of young people, and so I think that's where you'll see the earliest first impact. (I51)

Some proponents even argued that PM has already "arrived" in oncology, with tumor sequencing and pharmacogenomics becoming standard of care. Other participants emphasized the transformative potential of PM for clinical oncology. As the director of a clinical genetics institute argued:

Our whole approach to treating cancer is going to be turned on its head in the next five to ten years, as we will be defining cancer by its molecular signatures as opposed to its histology, and that we're going to be targeting the tumors based on their molecular signatures. (I218)

Despite their considerable enthusiasm for integrating PM into cancer care, interviewees identified numerous ethical and social challenges that may impede its incorporation. Themes clustered around four potential challenges, which are described in Table 2.

Informed Consent in Clinical Oncology

Interviewees identified informed consent as a significant challenge to integrating PM into cancer care. They expressed concern about the inability of many cancer patients to adequately comprehend the purpose and complexities of pharmacogenomic testing, especially the potential psychosocial implications of germline and somatic genetic testing (which may be differentially indicated depending on the patient's family history or diagnosis).

For example, in discussing the use of BRCA1 genotyping to predict a breast cancer patient's pharmacologic response to chemotherapeutics, the research director of a nonprofit genomics laboratory (I47), argued that germline testing is not likely to bring psychological harm to that patient. But, he said, these test results might negatively impact the patient's family members, who share the risks of inherited mutations associated with increased lifetime cancer risk. Other interviewees gave the example of tumor sequencing to assess which drug compounds target the genetic mutations in the tumor (e.g., vemurafenib and dabrafenib treatment for melanoma patients with oncogenic BRAF mutations). Most patients, they said, would not have the genetic literacy to understanding the differences between somatic and germline testing, let alone be in a position to judge their differential personal and familial disease-predictive and psychosocial risks.

Privacy, Confidentiality and Disclosure of Cancer Genomic Test Results

Interviewees contemplated concerns about the privacy and confidentiality of genetic information that have garnered attention in the ethics literature [13, 14], but they also raised concerns that seem unique to genomic testing in oncology. One of the primary problems identified was not about protecting patient privacy per se, but patients' concerns about their genetic privacy. For example, when considering putting cancer genomic test results into electronic medical records (EMRs), the director of an academic medical center's PM program cautioned that most patients are "still paranoid about sharing that information with their employers and insurance companies, even though we have the [Genetic Information Non-discrimination Act] laws" (I7).

Oncology patients' genetic privacy and discrimination concerns have been documented in case studies, yet ambiguity remains in the law and in professional guidelines regarding how to manage patient concerns [15]. These issues are likely to become increasingly challenging for clinicians as genomic testing is further integrated into cancer care. Distinctions between germline and somatic testing, as noted above, need to be carefully explained to patients in order to address their concerns about privacy, disclosure, and risk of discrimination based on cancer genetic test results. Simultaneously, one could argue, as one clinician-researcher did, that the efficiency and utility of securing accurate personal genomic information through genomic testing and EMRs may outweigh patient privacy concerns if cancer treatment outcomes can be improved (I68). This stance may signal a shift toward paternalism in an era of cancer genomics, where the logistic challenges of collecting family histories and decision support are heavy and where genetic counseling time and personnel—and even the genomic expertise of physicians—are in short supply [5, 16, 17].

Access to Cancer Genomic Testing and Therapies

Many participants shared a vision of the future similar to that provided by a co-founder of a company that produces genome-sequencing machines:

Every cancer patient is going to have their sequence done, as well as the sequence of the tumor done, and therapies and drugs will be implemented based on the

genetic makeup of that tumor and directed in a much more impactful fashion than it is today. (I57)

Yet, interviewees generally recognized that population-wide access to genomic testing and therapeutics is not presently attainable. In reality, access to genomic testing and therapeutics is highly differentiated by patient socioeconomic status, insurance providers, and site of cancer care—all of which raised ethical and social concerns about fair and just distribution of health care resources in society.

Participants described distribution challenges both in terms of patients' access to genomic tests and targeted therapeutics and clinicians' access to genomic resources. An editor of a genetics journal explained that although some cancer hospitals offer continuing medical education on cancer genetics and genetic cancer risk susceptibilities, these courses tend to be geared towards physicians who already specialize in genetic testing. This practice leaves out “the majority of physicians do not have ready access to training about interpretation of genetic test results” (I91) —the very physicians who need the most help navigating the shifting terrain of cancer genomic testing. The director of a community hospital's cancer center further explained this predicament:

A lot of [patients] are taken care of by very good people and very good places who don't have this technology, and they're really scrambling right now because every journal article they pick up, 85% of the articles relate to some genomic correlations, 'cause virtually every clinical research trial now has a molecular correlation. It's a beautiful thing, but it's a scary thing too because you know many places can't do it. (I306)

Even when clinicians and patients have access to genomic resources, interviewees noted that access to PM may be cost-prohibitive if patients' genotypes indicate expensive targeted therapeutics that fall outside the standard of care for their type of cancer and/or are not covered by insurance. For example, genome sequencing and tumor typing are particularly appealing to cancer patients who have exhausted standard therapies, but these approaches are rarely covered by insurance plans. Interviewees often said that these situations further exacerbate inequalities in patient access to targeted therapeutics based on ability to pay. This creates an inherent ethical problem, as explained by the director of a federal research institute:

We sit in a situation right now... where there's [sic] certain kinds of cancer where it's very clear that standard care is very close to being now getting genomes analyzed usually by sequencing, you know situations where rich people are just paying out of pocket to get that analysis done, and poor people can't afford it. So the rich people get probably better care, and if we don't fix this soon I think the discoveries are going to come fast and furious, which means the discrepancies will get wider if we're not careful. (I168)

Another clinician-researcher even projected the emergence of new health disparities, whereby some cancers eventually become orphan diseases that affect an underserved patient population. Specific genomic signatures may also have adverse consequences at the population level because “there are a lot of rare tumors and rare subsets of tumors which may have unique biological properties that might be potentially treated with a biologically honed, individualized (if you will) approach, but which no drug company will ever [target], because there just aren't enough patients who fit that description” (I78). Participants expressed concern that differential access will cast a dark shadow over PM in oncology by stratifying the care that groups of cancer patients receive—not only on the basis on their molecular profiles [1], but also on the basis of their socioeconomic status, insurance coverage, and pervasiveness of tumor types.

Costs of Scaling Up Targeted Cancer Therapies

Interviewees also considered the implications of personalized cancer therapies for resource allocation at a higher level: the affordability of cancer genomics for the health care system and society. On this matter, degrees of trepidation ranged considerably among interviewees. The president of a cancer diagnostics company exemplified the optimistic end of the spectrum:

The greater challenge in the future will be health care costs and how these products will be afforded in the healthcare system, but again ultimately, if the drugs are shown to work more effectively for a smaller patient population and you've identified that smaller patient population based on a diagnostic test, at the end of the day I believe that that will be a more efficient utilization of limited healthcare dollars and then should be encouraged. (I229)

Many interviewees voiced the sentiment that a "one-size-fits-all" approach to prescribing drugs creates inefficiencies in the health care system by pouring scarce resources into non-responders. They felt strongly that pharmacogenomics holds the promise of better allocating resources by pre-emptively assigning patients to the appropriate drug regimen based on their genomic profiles.

At the skeptical end of the spectrum is the perspective that it is neither practical nor appropriate to implement cancer genomic testing (and subsequent targeted treatment) on a system-wide basis. A clinical oncologist explained this challenge using the example of EGFR analysis of brain tumors:

We still pretty much leave that up to the clinician to ask for that if it's appropriate, because ... these tests are expensive. Whether the patient's insurance covers or not is less material than the just general cost to society, and you just don't want to have the knee-jerk reaction of doing everything for everybody if it's not going to make a difference. (I306)

Stakeholders in PM from outside of oncology took a broader and more critical view of the distribution of scarce resources in biomedicine, suggesting that the predominance of attention to cancer in TGR and PM demands pause. As the editor of a genetics journal explained:

A lot of money is often targeted towards cancer for obvious reasons, but you know there are other areas of personalized medicine, other fields which do need some funding: cardiovascular, psychiatry, [central nervous system] diseases, [gastrointestinal] diseases, for example. So ... I don't think it should be particularly targeted towards one particular area, for example cancer. I think it needs to be much broader. (I83)

Despite such critiques, resource investment has been fruitful in cancer genomics, with accelerated incorporation of genomic tools into risk surveillance, classification, and treatment of germline and somatic contributions. It is unknown, however, whether this focus on oncology has resulted from initial investment in and enthusiasm for cancer genomics, or whether early successes have garnered substantial pooling of investments.

Conclusions

Proponents of PM see some ethical and social challenges within cancer genomics as broader challenges of PM: meaningful and adequate informed consent for genetic testing, privacy and confidentiality of personal genomic information, differential access to health care resources for patients and clinicians, and the costs of integrating new technologies into the health care system. These are not unique to oncology, or even genomics.

At the same time, the rapid clinical integration of genomics in oncology makes these challenges more urgent to resolve, and gives their resolution by oncologists a precedent-setting role with respect to the larger field. Hence, it becomes imperative to monitor the field of oncology in an effort to anticipate and track the larger promises and problems of PM and work toward solutions. While these are recognized ethical challenges, they point to systemic issues that are often ignored or lost in the face of technocratic and technological challenges that garner more attention.

In responding to these ethical and social challenges, cancer genomics providers can draw some lessons from clinical genetics and genetic counseling, fields which have actively mitigated the challenges of informed consent for increasing complex genomic tests while establishing parameters of privacy, confidentiality and disclosure of results. Previous research on scaling up genomic applications in clinical genetics settings may be particularly instructive for recommending informed consent guidelines, duties regarding patient privacy, reimbursement strategies for genomic interventions, and for assessing patient perspectives on PM [18–22].

Some ethical and social challenges raised by proponents of PM may require insights from the field of clinical oncology. The burden of managing costs of genomic technologies within the health care system loom large, and there is little consensus across consistencies about how to effectively and efficiently incorporate genomics into health care [23]. However, leaders in clinical oncology are taking active measures to identify and address reimbursement challenges that may result in disparate access to cancer genomics through appealing to insurers and policymakers [5, 24]. Weighing the social costs of expensive technologies and treatments is also a longstanding health care rationing problem in oncology and elsewhere. Some guidance can therefore be found in deliberative democratic approaches to assessing the fair distribution of scarce health care resources [25] and in national health services' conditions for public health funding for targeted therapies on the basis of medical necessity [26], though proposed solutions are nonetheless fraught with practical and moral complexity [25].

The rapid emergence of PM approaches in cancer care provides a crucial “early warning system” for identifying and managing potential frictions and pitfalls that emerge as health care paradigms shift. The increasing integration of genomics into clinical oncology demands further empirical assessment of cancer patients' attitudes and values regarding genomics, and clinical oncologists' perspectives on responsible management of ethical and social challenges unique to cancer genomics.

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Table 1

Distribution of Study Participants across Key Constituent Groups in the Development and Practice of Translational Genomic Research (TGR) and Personalized Medicine (PM)

Stakeholder Arenas*	Constituency	Number of Interviewees
“Promoters” <i>Architects and builders, particularly in setting agendas and positing vision for the TGR and PM movements</i>	Basic Scientists and Translational Researchers	12
	Commercial and Non-Profit Developers	14
	TGR and PM Research and Development Funders	11
“Monitors” <i>Gatekeepers as a professional movement, especially in setting standards, policing boundaries and defining the canons of TGR and PM</i>	Medical Journal Editors	9
	Health Professional Educators and Advocates	7
	Payers	4
“Providers” <i>Constituencies’ operationalizing TGR and PM, particularly in delimiting its scope and content for health care institutions and professionals and in providing personalized genomic medical services in practice</i>	Academic PM Program Directors	18
	Clinical Researchers and Health Care Providers in Academic Medical Centers	26
	Clinicians in Private Practice	16
	Total	117

* Stakeholder typology originally presented in Juengst et al. 2012

Table 2

Constituents' Views on General and Specific Ethical and Social Challenges to the Realization of Personalized Medicine in Clinical Oncology

Informed consent for clinical cancer genomic testing	Inadequate genetic literacy among patients; limited understanding of personal and familial implications of germline and somatic genomic testing
Privacy, confidentiality and disclosure of genomic test results	Balancing patient concerns about genetic privacy and discrimination in regard to germline and somatic genomic testing against efficiency and utility of patients' genomic information for improving cancer treatment outcomes
Access to clinical genomic testing and therapies	Disparities in in genomics training among health care providers and genomic health resource allocation among patients; uneven insurance coverage of cancer genomic testing and therapies; potential for cancers with rare genomic signatures to become orphan diseases
Costs of scaling up targeted cancer therapies	Current and future affordability of cancer genomic testing and targeted treatment for the health care system and society