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Seminar article

Integrating genomics into clinical oncology: Ethical and social challenges from proponents of personalized medicine

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Abstract

Introduction: 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" (PM). Enthusiasm for PM 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 PM, little is known about the ethical and social implications of personalized approaches in clinical oncology.

Objective: The objective of this study is to assess how a range of stakeholders engaged in promoting, monitoring, and providing PM understand the challenges of integrating genomic testing and targeted therapies into clinical oncology.

Methods and materials: The study involved the analysis of in-depth interviews with 117 stakeholders whose experiences and perspectives on PM span a wide variety of institutional and professional settings.

Results: Despite their considerable enthusiasm for this shift, promoters, monitors, and providers of PM identified 4 domains that 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.

Conclusions: These specific concerns are not unique to oncology, or even genomics. However, those most invested in the success of PM 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 PM approaches in clinical oncology provides a crucial lens for identifying 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

Introduction

"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.

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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 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 4 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. The Case Western Reserve University's institutional review board approved this study. It involved interviews with individuals whose experiences with, and perspectives of, 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. M.L.M., J.R.F., and 4 research assistants conducted semistructured in-depth interviews by phone (or 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 nonprofit 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. Interviewee case numbers are provided after each quote.

Table 1
Distribution of study participants across key constituent groups in the development and practice of translational genomic research and personalized medicine

Stakeholder arenas[a]	Constituency	No. of interviewees
Promoters		
Architects and builders, particularly in setting agendas and positing vision for the TGR and PM movements	Basic scientists and translational researchers	12
	Commercial and nonprofit developers	14
	TGR and PM research and development funders	11
Monitors		
Gatekeepers as a professional movement, especially in setting standards, policing boundaries, and defining the canons of TGR and PM	Medical journal editors	9
	Health professional educators and advocates	7
	Payers	4
Providers		
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	Academic PM program directors	18
	Clinical researchers and health care providers in academic medical centers	26
	Clinicians in private practice	16
	Total	117

[a]Stakeholder typology originally presented by Juengst et al. [1].