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Individual Breast Cancer risk assessment in Underserved Populations: Integrating empirical Bioethics and Health Disparities Research

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Abstract

Research suggests that individual breast cancer risk assessment may improve adherence to recommended screening and prevention guidelines, thereby decreasing morbidity and mortality. Further research on the use of risk assessment models in underserved minority populations is critical to informing national public health efforts to eliminate breast cancer disparities. However, implementing individual breast cancer risk assessment in underserved patient populations raises particular ethical issues that require further examination. After reviewing these issues, we will discuss how empirical bioethics research can be integrated with health disparities research to inform the translation of research findings. Our in-progress National Cancer Institute (NCI) funded study, How Do Underserved Minority Women Think About Breast Cancer?, conducted in the context of a larger study on individual breast cancer risk assessment, is presented as a model.

Keywords

Health disparities; risk assessment; risk communication; ethics; bioethics

Despite declines in the annual death rate from breast cancer since 1991, significant racial and ethnic disparities in breast cancer morbidity and mortality persist.[1,2] Research employing a range of disciplinary theories and methods explores the complex relationships among the numerous individual, social, environmental, and systemic factors that contribute to these disparities. Interventionists test methods of mediating and modifying these factors. Although there is still more to learn, there is a prevailing, evidence-based explanation for breast cancer disparities. Simplified, it goes something like this: Socioeconomic disadvantages—including income, education, and insurance status—limit mammography utilization.[3,4] (It should be noted that while income, education, and insurance are all to some extent race-dependent, women who are uninsured or who receive Medicaid are more likely to present with advanced stages of breast cancer and have lower survival compared to women with private insurance regardless of race.[5,6]) This results in delayed time to breast cancer diagnosis and treatment[7] as well as higher likelihood of advanced stage at diagnosis.[8] Uninsured women and women of color have limited access to optimal therapies,[8] resulting in increased mortality. This picture is further complicated by the facts that many underserved women have limited knowledge (or have misconceptions) about breast cancer

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signs, symptoms, screening guidelines, and prevention and treatment options[9-11] and that facility characteristics influence mammography quality and accuracy.[12]

The unfortunate reality is that even when financial barriers are removed, low-income women do not always get mammograms as recommended.[13] One study that controlled for known prognostic factors found that even when they received optimal therapy, African American women with early breast cancer participating in adjuvant chemotherapy trials had worse survival outcomes than White women.[14] In African American women, breast tumors are more likely to exhibit high risk features such as high tumor grade, absence of hormone receptors, and the "triple negative" or basal-like phenotype.[8,15] It is therefore hypothesized that there is a key biological component contributing to disparities in breast cancer outcomes.

Given this picture, both increasing breast cancer screening (early detection) and improving adherence to recommended risk-reduction strategies (prevention) are critical to the elimination of racial and ethnic disparities in breast cancer morbidity and mortality. However, breast cancer is not a uniform disease. Individual and population risk vary tremendously, as do disease progression and the efficacy of various treatments. Therefore, simply promoting screening and general prevention measures will not suffice for eliminating disparities between groups.

In the last 20 years, cancer risk assessment models have been developed that incorporate easily acquired familial and non-familial risk-factor data to characterize a woman's chance of developing breast cancer in a defined period of time (e.g., within five years, lifetime).[17–20] These empirically-derived models are used in clinical settings in order to guide dcision-making about future screening behavior or adoption of risk-reduction strategies.[21–23] Given the variance in breast cancer risk, surveillance and primary prevention *adapted to each patient's individual risk level* may be the most effective use of resources for preventing, detecting, and improving breast cancer survival;[24] indeed, guidelines from the U.S. Preventive Services Task Force (USPSTF),[25,26] American Cancer Society,[27,28] and National Comprehensive Cancer Network (NCCN) (www.nccn.org) signal a new, risk level-specific standard of care for risk prediction and prevention. Evidence is continually being gathered on the effectiveness of the recommended interventions; additionally, in order to produce a population-level reduction in breast cancer mortality there must be widespread application of the guidelines by clinicians and a high level of patient adherence to physician recommendations. Further research on the potential impact of individual breast cancer risk assessment on adherence to recommended screening and prevention guidelines, morbidity, and mortality is essential to inform national public health efforts to eliminate health disparities.[29]

Investigators at the National Cancer Institute (NCI)-funded Center for Population Health and Health Disparities at the University of Illinois at Chicago (UIC) are partnering with a federally qualified health center (FQHC) to implement breast cancer risk assessment in primary care. One of the authors (KH) has developed a computerized tool that includes the Contraceptive and Reproductive Experiences (CARE) model (which provides more accurate risk estimates for African Americans),[30] the Gail model (more accurate for Latinas),[18] a Claus model estimate (which incorporates more extensive family history information than the Gail model),[19] and a pedigree assessment tool (PAT) for women with a family history of breast cancer.[23] The tool stratifies women into one of three risk categories: high risk if their lifetime risk is between 30–80%; moderate risk if their lifetime risk is between 15–20%; or general population risk if their lifetime risk is below 15%.[31] In addition to risk category, the tool also generates tailored recommendations for breast cancer screening, risk reduction practices, and/or referral to a specialist. Clinic providers will be trained to use the tool and to

discuss personalized risk information with patients. A randomized trial, A Breast Cancer Screening Intervention to Improve Adherence to Cancer Control Guidelines in Underserved Minority Women, will evaluate the impact of implementing individual breast cancer risk assessment in primary care on provider recommendation of and patient adherence to recommended risk-appropriate screening and risk reduction measures (e.g., lifestyle changes, frequency and type of mammography, referral to high-risk clinic). Using the Health Belief Model,[32] the study also aims to assess the impact of patient navigation and tailored messaging in mediating structural and behavioral barriers to screening and preventive services.

Such an approach to cancer surveillance and prevention is consistent with current trends towards patient-centered care[33] and personalized medicine.[34] Within these paradigms, individual risk assessment can be characterized as a tool (or "product") that is marketed to individuals who are then encouraged to take responsibility for their own health. This is not problematic *per se*; research suggests that many people want to discuss cancer risk and prevention options with their PCP.[35] However, risk assessment introduces unique kinds of prevention and risk reduction options including chemoprevention, prophylactic surgery, and genetic counseling; such options require otherwise healthy patients to interact with health care providers and the health care system as if they were sick. Furthermore, we have yet to fully consider the implications of risk assessment when implemented in low-resourced health care settings in communities with background conditions of inequity. Thus far, research on the use of risk assessment models in underserved minority communities has been limited,[36] although there is evidence that access to and use of genetic testing services is comparatively low.[37]

Implementing individual breast cancer risk assessment in underserved patient populations—in both research and clinical settings—raises unique ethical issues that deserve exploration. Here, we will first briefly review these ethical issues. Then we will discuss how empirical research on ethical implications can be integrated with health disparities research in order to not only ensure the protection of research participants but also to strengthen the translation of research findings and prevent further harm and injustice to underserved communities. We will describe our in-progress NCI-funded supplemental study, How Do Underserved Minority Women Think About Breast Cancer? and discuss how we plan to address some of the ethical concerns raised by the use of individual breast cancer risk assessment in a primary care setting at a FQHC through interdisciplinary empirical research. We conclude with a recommendation for broadly integrating interdisciplinary research on ethical issues into the national health disparities research agenda.

Breast cancer screening versus individual risk assessment

Potential benefits and harms. Before discussing ethical issues that arise in breast cancer risk assessment, it is important to distinguish risk assessment from screening. The goal of screening is to detect pre-symptomatic cancer early enough to treat it effectively. Theoretically, screening is beneficial because early detection and treatment will improve survival beyond what it would have been had disease not been identified and treated sooner. However, screening does not necessarily improve survival from the time when the patient would have presented clinically. Screening may also introduce difficult choices about interventions of unknown efficacy that may significantly affect quality of life.[38] Therefore, from an ethical perspective, while there are clear population-level benefits of mass cancer screening programs, the individual-level benefits of screening are less certain.[39] The USPSTF outlines several potential individual-level harms of breast cancer screening (specifically film mammography), including psychological harms, unnecessary imaging tests and biopsies in women without cancer, and inconvenience due to false-positive

screening results. Not surprisingly, a major conclusion of the USPSTF is that shared decision-making about mammography screening should take context and patients' values regarding potential benefits and harms into account.[25]

Unlike screening, which aims to detect malignancies, cancer risk assessment aims to characterize an individual's chance of developing cancer in a defined period of time (e.g., within one year, two years, five years, lifetime) in order guide decision-making about future screening behavior and adoption of risk-reduction (preventive) strategies. Existing data suggest that potential responses to risk information (e.g., emotional distress, planned behavior change) will vary considerably based on overall understanding of risk, perceived risk of breast cancer, past screening behaviors, and cultural beliefs.[40] A patient's decision to increase surveillance or initiate other preventive measures (e.g., chemoprevention, prophylactic surgery, lifestyle modifications) on the basis of individual risk assessment results is influenced by many factors, including health care provider recommendations, the patient's values as they pertain to specific benefits and harms of potential actions, access to health care resources, social support, and psychological state. Therefore, while assessing individual cancer risk presents many similar concerns as screening, it engenders additional psychosocial and physical risks and potential benefits and presents patients with an even more complex set of choices. However, unlike screening, individual breast cancer risk assessment also offers an additional potential benefit of breast cancer prevention or delay.

Ethical Issues in Individual Breast Cancer risk assessment

A review of the research literature addressing psychological, social, and cultural issues related to breast cancer highlights ethical issues related to the use of risk assessment in primary care settings in low-income communities. This is not meant to be an exhaustive review. Rather, our aim was to identify gaps in knowledge regarding potential benefits and harms of risk assessment that could be approached through empirical research.

What, if any, psychological harm is associated with breast cancer risk assessment?

Breast cancer is a significant source of anxiety for many women, independent of actual risk.[41] A woman who learns that she is at increased risk for breast cancer may be concerned about discrimination or worry about what her risk means for her children or other family members.[42] Coping with uncertainty can be a significant source of stress, and stress has tangible effects on behavior.[43]

Are there specific psychological harms that can result from being labeled "at-risk" or "high risk"?

Previous research has identified potential harms of labeling patients "at-risk" for cardiovascular disease, including depression and problems at home and at work.[44–46] Additional diagnostic procedures can artificially increase sense of risk.[47] Patients may also inappropriately blame themselves for their risk status.[48] Given our current health care climate, the "at-risk" label also has significant implications for future health care costs. Anxiety and worry are associated with longer delay in seeking medical attention for possible breast cancer symptoms.[49] Theoretically, increased psychological distress from risk labeling may contribute to future non-adherence to screening and risk reduction recommendations.[41] Emotional (as well as behavioral) responses may not be consistent with actual risk level and are therefore difficult to predict and mediate. Strategies for health care providers to identify and mediate potential psychological harms are needed.

How does uncertainty about the various risks and benefits of various surveillance and prevention options affect decision-making?

Depending upon their risk category, patients may face difficult decisions about managing or reducing risk. In some cases, the results of an individual breast cancer risk assessment may present women with information that contrasts with previously held beliefs, requiring a period of acceptance and adjustment prior to any consideration of preventive options. Further, information received may not be something women will immediately act upon—either because risk is average or no immediate changes are warranted, or because more informationgathering, screening, or assessment is needed in order to support an informed decision (e.g., genetic counseling and possibly testing for women at high risk). The fast pace of genetic and genomic science also means that clinical utility of individual risk information is constantly shifting.

How do underserved minority women understand the relationship between breast cancer and genetics, and how does this understanding influence decision making about prevention and screening?

As discussed in the introduction, breast cancer is a common yet complex disease. Genetic as well as social, environmental, and behavioral factors contribute to disparities. Individual risk assessment, while not entirely based on genetics, focuses heavily on familial risk factors. Teasing apart the various contributions of all factors—as well as understanding the complicated interaction between genes and environments—will take time and effort. Our "expectation(s) for genetics research to explain health disparities must be calibrated appropriately."[50[p.2988]] Research on how to improve public and provider communication about genetics and genomics is a priority.[51]

How can health care providers best frame risk information to enhance understanding?

Overwhelmingly, data suggest that, regardless of age, race/ethnicity, educational background, and other demographic factors, most people have a very poor understanding of risk, both in terms of personal risk for disease and the risk/benefit profiles of potential preventive or therapeutic options.[52–56] Research on risk communication specifically with underserved minority populations is sparse, but it is clear that risk perception is affected by a variety of factors including knowledge of one's own family history, health literacy and numeracy (but not necessarily educational level), and religious and cultural beliefs. Studies show that subtle differences in how risk information is framed can significantly affect risk perception and health behavior[57] and that the conceptual frameworks applied by patients to understand risk information are very different from those of clinicians.[48] Studies have shown that women of color tend to underestimate their risk of cancer.[58] Conversely, women with an exaggerated estimate of their breast cancer risk may erringly focus on breast cancer when they are actually at greater risk for other chronic diseases. It is also possible for women at high risk to hold inaccurate views of potential side effects of preventive strategies and base decisions on these mistaken beliefs.[40]

Unfortunately, evidence suggests that primary care providers may not be sufficiently prepared to address the concerns of women who are identified as being at increased risk for breast cancer.[59] Individual risk information should be communicated using an approach that addresses patients' understanding of and beliefs about risk; promotes respect for individual patient autonomy and cultural beliefs; and minimizes potential psychosocial harms. The potential benefits and burdens of screening and risk reduction decisions should be thoroughly explained, and patients' individual preferences and values must be considered.[40] In order to minimize harm and promote autonomous decision making, health care providers must be aware of the potential for negative psychosocial sequelae, but even more importantly, they should be able to assess individual patients to identify psychosocial harms

and develop appropriate action plans based on values and preferences—even if these values and preferences are inconsistent with professional recommendations). Without attention to these critical ethical factors, individual risk assessment could do more harm than good. However, more research is needed in order to identify optimal ways to present risk information to various kinds of patients.

How can health care providers elicit patients' values and preferences—particularly as they relate to medical options for prevention—and integrate these with evidencebased recommendations in order to support informed decision-making?

Women evaluate the risks and benefits of various preventive measures differently; this evaluation depends on cognitive understanding of recommendations, trust in one's health care provider, cultural beliefs, access to resources, and life circumstances, but is also in large part a matter of preference, personality, and habit. Current clinical guidelines contain minimal guidance regarding how to elicit patient preferences or balance preferences and values against recommendations and their potential risks and benefits.

What additional ethical issues may arise with respect to individual risk assessment in limited resource settings?

At many community clinics that serve low-income minority women, demand far exceeds capacity. Physicians may have little time to spend with patients, forcing them to focus on immediate problems rather than preventive care. Patients do not always have a regular primary care provider. If research indicates that individualized risk assessment is effective in delaying and preventing breast cancer, financial and logistical barriers may prevent widespread implementation precisely where it may be most needed.

Information derived from individual risk assessment may translate into a need for additional health care resources and social support. However, underserved minority women who are at high risk for breast cancer also face significant barriers to accessing health care and preventive services. While the Centers for Disease Control and Prevention (CDC) National Breast and Cervical Cancer Early Detection Program (NBCCEDP) (http://www.cdc.gov/cancer/nbccedp/about.htm) and other related federal and state government-sponsored programs can provide low-income, uninsured, and underserved women access to breast cancer screening and diagnostic services (and in some cases, treatment), the extent to which these programs have funds for medical (chemoprevention) or surgical (prophylactic mastectomy) prevention, genetic counseling and testing, smoking cessation, or nutritional counseling is not uniform. Furthermore, sustained funding for public programs is uncertain, and for many women negotiating the requirements of such programs and identifying participating service providers is not easy. Policy changes related to payment of preventive services for breast cancer may be necessary in order to support the implementation of individual risk assessment.

The Value of empirical Bioethics research

Although we have delineated numerous ethical concerns that arise when considering widespread implementation of breast cancer risk assessment, there is evidence that this is a particularly promising strategy for decreasing breast cancer disparities. Therefore, additional research on the potential impact of risk assessment on morbidity and mortality is critical—but research must also address the potential ethical implications of risk assessment, particularly in underserved populations. Given limited existing data, the potential harm of risk assessment is largely theoretical. Additionally, given the potential benefits, it could equally be considered paternalistic or even harmful to fail to offer risk assessment to underserved women. Research on stakeholder perspectives (or "patient-centered

research"[60]) that incorporates attention to ethical details has the potential to fill in some of these key knowledge gaps. Resolving these ethical dilemmas cannot be left to individual health care providers or systems who aim to adopt evidence-based recommendations as standard practice.

Empirical bioethics research can be defined broadly as research that produces data, that when analyzed through the lens of various ethical principles such as respect for autonomy, beneficence, non-maleficence, and justice, is relevant to determining what constitutes respectful treatment of humans. Put simply, empirical bioethics research is that which is relevant to determining what is right or wrong, good or bad, respectful or disrespectful, caring or not caring.[61] While the goal of research on the ethical implications of scientific research unfortunately can be narrowly framed as aiming to prevent adverse effects and minimize social disruption, empirical bioethics research should also focus on ensuring that positive findings are translated to the communities of patients that need them, especially underserved communities. Empirical bioethics research should be concurrent with and proximal to the "actual science," contextualized and inclusive of voices of a variety of key stakeholders, and focused on translating research to patient and population-level benefits.[62] Importantly, bioethics research has to be both "user friendly" for health disparities researchers and "policy relevant" for decision-makers.[63] Reliably gathering, analyzing, and applying ethically relevant data requires interdisciplinary collaboration that combines the empirical methods and tools of the behavioral and social sciences with ethical analysis.[64]

How Do Underserved minority Women Think about Breast Cancer risk?

In order to address some of the ethical concerns that were identified in relation to breast cancer risk assessment, the authors proposed and received funding to conduct supplemental research on bioethics (the supplemental research being entitled, How Do Underserved Minority Women Think About Breast Cancer Risk?) to the planned project described in the introduction, A Breast Cancer Screening Intervention to Improve Adherence to Cancer Control Guidelines in Underserved Minority Women. The primary goal of the bioethics supplement, which is an exploratory, mixed methods pilot project that will be conducted prior to full implementation of the parent study, is to explore how women understand and process risk information and make decisions regarding how to act on that information. The specific aims focus both on enhancing informed decision-making of research participants in the parent project and identifying factors that can mediate risks and potential benefits of individual breast cancer risk assessment in underserved minority populations more broadly. Study findings will be integrated into the parent study to refine primary care provider education and delivery of breast cancer risk information to support informed decision-making, enhance benefits, and reduce risks to patients.

Women in the study (eligibility criteria will be the same as for the parent study) will be between the ages of 25–69 and presenting for a well-visit appointment with her PCP at our partner FQHC. Women are not eligible if they have a personal history of breast cancer (either invasive or ductal carcinoma in situ) or bilateral mastectomies. Participants will first complete the computerized breast cancer risk assessment, then they will be asked if they would like to receive their results. Four primary types of data will be obtained.* Pre- and (two-week) post-risk assessment survey questionnaires will assess breast cancer knowledge, perceived susceptibility to breast cancer, perceived benefits of screening, breast cancer worry, and distress as well as demographic information; data collected from the baseline survey will be analyzed: 1) to determine the relationship between demographic and

*For data sources 2 and 3, a smaller subset of participants will be selected to participate based on race/ethnicity, risk category (average, moderate, or high), and desire to know results or not.

psychosocial variables and interest in knowing results of the individual risk assessment (primary outcome variable); 2) to characterize the clinic population in terms of risk status; and 3) to assess representativeness with regard to certain criteria (race, risk status, and interest in knowing personal risk status) of the sample that participates in in-depth interviews. Data collected from the followup survey will be analyzed: 1) to assess changes in psychological distress before and after breast cancer risk assessment and provider education and determine factors (prepsychological distress, demographic and psychosocial) that are significantly associated with follow-up distress; 2) to assess changes in knowledge of modifiable risk factors (e.g., lifestyle changes, medication) to breast cancer before and after breast cancer risk assessment and provider education; and 3) to assess changes in willingness to take part in breast cancer risk reduction methods (e.g., lifestyle changes, medication) before and after breast cancer risk assessment and provider education.

Second, patient-physician conversations about risk assessment results will be audiorecorded, transcribed and analyzed inductively as well as according to pre-determined categories such as directness of communication of risk strata information (i.e., did the physician say “high risk”?); completeness of information; language/vocabulary used; two-way dialogue (e.g., was the patient invited to ask questions?); and missed opportunities for the physician to demonstrate empathy, provide clarification, or offer other support/information about resources.

Third, in-depth, semi-structured interviews with patient-participants will explore participants’ interpretation of the personalized risk information provided by the PCP; initial reactions to learning about their individual breast cancer risk; what it means to them to be “at (low, moderate, high) risk”; views of the value of/potential benefits of personalized risk as well as potential harm; level of trust in the information; and views and preferences regarding recommended surveillance and risk reduction strategies.

Finally, in-depth interviews with PCPs will assess overall level of comfort with the breast cancer risk stratification program as standard practice. They will also be asked about their confidence in their ability to communicate risk information to patients. They will be asked to discuss their perceptions of potential harm and benefits to patients that may result from personalized risk assessment. They may also identify potential risks to physicians (e.g., feeling unprepared, powerless, burdened). They will discuss their views and understanding of the risk-category specific recommendations for surveillance and prevention. They will be invited to provide suggestions for improvement and additional training for physicians based on their experiences.

Conclusion

Although still in the early stages of implementation, our interdisciplinary work demonstrates a model for how exploration of ethical issues can be integrated into health disparities research. Recognition of the potential social implications of research on cutting-edge technological innovations such as genomics and nanotechnology has resulted in ethics-specific funding streams (for example, http://www.genome.gov/10001618; http://www.nano.gov/you/ethical-legal-issues; and http://www.genomecanada.ca/en/ge3ls/). However, as has been demonstrated with the example of cancer risk assessment, even comparatively “low-tech” research can raise critical ethical issues, particularly given the current (albeit changing) health care environment. The National Institutes of Health is making a significant investment in health disparities research; indeed, addressing health disparities has been called a *moral imperative*.[29] To echo those involved in the Grand Challenges in Global Health initiative of the Bill and Melinda Gates Foundation, “Such a significant investment in scientific research must be accompanied by a program addressing

the ethical, social, and cultural issues that may arise—either in the development and implementation of the research projects themselves, or in the subsequent appropriate use of resultant knowledge and technologies by communities in need."[62[p.1440]] We must consider the policy and practice implications of health disparities research sooner rather than later; interdisciplinary, empirical bioethics research is one arrow in our quiver to help hit this target.

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