Research Ethics Considerations Regarding the Cancer Moonshot Initiative

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Key words: ethics; genetics; biology of cancer; comorbidities

ONF, 43(4), 428–431.

doi: 10.1188/16.ONF.428-431

If the Precision Medicine Initiative was the launching pad, the Cancer Moonshot Initiative is the liftoff. A billion-dollar mission to "eliminate cancer as we know it" (Whitehouse.gov, 2016, para. 1), the Cancer Moonshot Initiative underscores the Precision Medicine Initiative's near-term focus in oncology research and translation, described in the March 2016 Research Ethics column (Hammer, 2016). Spearheaded by Vice President Biden, the goal is to condense a decade of research into actionable results within five years (Kaiser & Couzin-Frankel, 2016). Such an effort has not been put forth since the War on Cancer was announced in the early 1970s (Kaiser & Couzin-Frankel, 2016). Priority areas have been outlined to reach this goal, and those areas are creating new challenges in the ethical conduct of research. The following is a summary of these priorities and ethical considerations for each.

Prevention and Cancer Vaccine Development

The focus of this priority is to target microbial-associated cancers and alter genotypes of various malignancies. The vaccine to prevent infection from the human papillomavirus (HPV) is an exemplar for the prevention of 93%–98% of cervical cancer cases (Malmqvist, Helgesson, Lehtinen, Natunen, & Lehtinen, 2011). Creating other vaccines for microbial-associated cancers can potentially have similar positive effects.

About 80% of the population is HPV positive, and about 12,990 cases of cervical cancer are expected to be diagnosed in 2016 (American Cancer Society, 2016), which would affect 0.007% of the female population in the United States. With regular Papanicolaou screening, this number could be even lower. Although it may seem overzealous to vaccinate to prevent cancer in less than 0.001% of this population, the link with HPV and the ability to prevent cervical cancer and other HPV-associated cancers in both sexes is compelling. Using this model for the prevention of other microbial-associated cancers is intriguing; however, other infective agents are not as prevalent. Creating these vaccines, identifying the populations who would benefit most, and conducting clinical trials can take time. Weighing the risks and benefits of entering these trials will take careful consideration.

Aside from microorganisms, targeted cancer vaccines are a large part of this priority area (Whitehouse.gov, 2016). Using retroviral and lentiviral vectors to introduce healthy DNA into individuals with leukemia is showing great promise (Berkhout, 2013). Also called oncolytic viruses, these viral vectors are programmed to solely target malignant tissue and trigger an immune response against cancerous

cells (Yuan, Webb, Lemoine, & Wang, 2016).

Testing these therapies, however, is not without risks. The first patient to be treated with a lentivirus for chronic lymphocytic leukemia developed tumor lysis syndrome, but the patient recovered and went into remission (Porter, Levine, Kalos, Bagg, & June, 2011). As advances are made and trials are conducted, numerous challenges will arise. The issues in conducting these studies in human participants at an accelerated rate may be concerning. However, the potential for survival in a patient who would not otherwise survive is often worth the risk. Considerations for entering these types of trials should include quality of life. For some, living a shorter duration with a better quality of life is preferable to taking a risk for longer-term survival with the possibility of compromising side effects. Educating patients and their family members about the risks and benefits of entering such a trial would be a priority.

Early Cancer Detection

Efforts to increase screening for cancers through the use of genomic and proteomic approaches are expected to uncover cancer formation early in its course (Whitehouse.gov, 2016). However, the focus on screening and early detection with new novel technologies may be far reaching for individuals in underserved communities who are already underscreened with current protocols.

The importance of targeting underrepresented populations is outlined in the initiative. The efforts to enroll individuals from these socioeconomically disadvantaged or underserved populations are not yet known but will be essential for comprehensive genetic assessments and, most importantly, to reach the population. The National Institute on Minority Health and Health Disparities Centers of Excellence are anticipated to be at the forefront of ensuring inclusion (Kashyap et al., 2015).

Enhanced Data Sharing and Oncology Center of Excellence

Highly encouraged collaboration through data sharing and the assembly of experts across disciplines is expected to accelerate advances in screening, detection, and treatment of cancers. Pooling of genetic data has been underway. The American Association for Cancer Research and the National Cancer Institute have been creating enormous databases to expedite clinical and genetic investigations (Kaiser & Couzin-Frankel, 2016). To facilitate collaboration between experts, a virtual oncology center of excellence will be created and coordinated by the U.S. Food and Drug Administration (Whitehouse.gov, 2016). This center is expected to expedite the development of new therapies. Using this type of collective effort approach has already been proven to be extremely successful. The exemplar is the Human Genome Project, which unveiled the genetic code; researchers completed the task several years ahead of schedule by including scientists from around the world (Lander et al., 2001).

Collecting data is one challenge, and pooling it is another. Data sharing is not a new concept and has yielded far-reaching insightful results. Genotypic and phenotypic data are shared through collective databases, such as the National Center for Biotechnology Information (2016) dbGaP Database. However, some databases necessitate applications, permissions, and costs to gain access. To accelerate use of datasets, access needs to be more readily available and also maintain protection of participant information. In addition, some of these datasets require advanced biostatistical support for complex analyses. Concerted efforts to train statisticians in these roles will be needed to meet demands.

Overall, conducting robust analyses from these large datasets can yield faster information than prospectively collecting the data. This area of research, referred to as "big data" or "data science," is one that can yield highly informative five-year answers. Nurse scientists are already immersed in such studies, which should continue to be encouraged for enhanced knowledge before proposing more invasive prospective studies.

Cancer Immunotherapy, Combination Therapy, and Genomic Analysis

Cancer immunotherapy, combination therapy, and genomic analysis will focus on the immune system to help in the detection, elimination, and prevention of cancer cell formation. Targeting the immune system to combat cancer is not a new concept. The theory of cancer immune surveillance was first described by Paul Ehrlich in 1909, with additional development in the 1950s (Baron & Storb, 2006). However, the technology to use this information to combat cancer is new. Along with targeted immunotherapies, these areas will seemingly be complementary to the work in cancer vaccine development.

The goal of the oncology center of excellence described in the Cancer Moonshot Initiative is to expedite the development of these therapies. However, the challenge is testing their long-term effects (favorable or adverse), which sometimes need more than half a decade to be identified. On average, it takes 12 years (and about $350 million) for a pharmaceutical to be approved by the U.S. Food and Drug Administration (Drugs.com, 2016). Questions then arise pertaining to the established

protocols for safety and efficacy. Another thing to consider is whether, in this fast-moving environment, patients will become overwhelmed with being targeted to enter multiple research studies. The emphasis on informed decision making by patients should be a priority. With the excitement about fast advances, potential exists for patients to be encouraged by providers and researchers to participate in these studies. However, ensuring patient autonomy is paramount.

Pediatric Cancer

In the first half of the 20th century, childhood leukemia was incurable. Through the gallant efforts of Sidney Farber and others, advances in pediatric oncology have been enormous (Mukherjee, 2010); however, many pediatric cancers are still difficult to treat. The Cancer Moonshot Initiative will focus on improved methods for early detection and novel approaches for the treatment of rare and difficult-to-treat cancers in the pediatric population (Whitehouse.gov, 2016).

The same ethical concerns for enrolling pediatric patients into research studies will be necessary for studies born out of the Cancer Moonshot Initiative priority. With an emphasis on the development of drug libraries and a focus on cellular targets, more pediatric trials are likely to occur. Working closely with these pediatric patients and their parents to ensure full disclosure about study involvement and potential risks and benefits of participating in these trials will be essential.

Exceptional Opportunities in Cancer Research Fund

Underscoring collaboration and data sharing, a cancer research fund will focus on targeting research that will yield large and fast results. A main focus will be combining pharmaceutical and biotechnology experts (Whitehouse.gov, 2016).

With this expedited approach to research, questions arise in how established layers of security and confidentiality will be maintained. The collective goal is to significantly reduce the incidence and prevalence of cancer and increase survival among those who are diagnosed, so patients may be encouraged to be more open about sharing information about themselves. In this vast world of social media, where sharing one's information is already so forthcoming, this may be highly acceptable to patients.

Being open is also becoming mainstream under the current buzzword of transparency. Being transparent, however, can create risks for individuals with cancer or for those with increased cancer risk based on genetic predisposition. The potential for repercussions from employers or health and life insurance providers is still real. If the judicial system could truly enforce health-related antidiscrimination practices, this would not be an issue. Better yet, if employers and insurers would elect to encourage and support individuals to participate in these studies, healthcare privacy issues could certainly be less of an issue.

Personal family dynamics with open knowledge may even be a bigger challenge. Genetic ethicists are continually faced with determining how, when, and with whom in a family to discuss genetic findings that could alter the health future of family members. Nurse scientists excel in ensuring that patients are well informed in their decision making in all of these areas. Decisions about enrolling in these studies should include full information. Although the science is being proposed to move at a faster pace, allowing patients the time they need to consider being part of these studies without undue pressure is important.

Conclusion

The Cancer Moonshot Initiative is an exciting prospect. Tremendous advancements have been made in the past several decades. However, the realization that cancer has been invading the species for at least two million years (Mukherjee, 2010) and that it may be 200 different diseases rather than a single disease (Kaiser & Couzin-Frankel, 2016) is overwhelming no matter what amount of money, scientific collaboration, and technological advances exist. In addition, environmental and food system factors, as well as biobehavioral activities, that contribute to cancer risk are not included in the Cancer Moonshot Initiative. This component is another area where nursing excels, particularly in biobehavioral research. A number of Oncology Nursing Society research scientists are already immersed in bringing nursing science to the Cancer Moonshot Initiative table. If some of the major contributors to cancer formation are not addressed, the Cancer Moonshot Initiative will risk being out of orbit.

Coinciding with the fast-paced goals, greater patient involvement, and continuous challenges with individual privacy, healthcare providers may need a major paradigm shift for how the ethical conduct of research is viewed. Patient safety and the ethical principles of autonomy, beneficence, non-maleficence, and justice should never be compromised. However, the right to privacy is potentially at stake. Do we want to forfeit privacy to decrease the incidence and lethality of cancer? Most patients with cancer would likely contribute if the payoff would be improved survival and quality of life.

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Authorship Opportunity

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