

Informed Consent: The Case of “-Omics” Literacy

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The world of “-omics” is vastly changing the landscape of accelerated research and its translation to patient care. Understanding this complex science, particularly in the world of oncogenomics, can be daunting. Questions arise pertaining to how nurses can best educate patients who are forced to make difficult decisions without fully understanding to what they are consenting. This article follows a patient story that drives home the need to improve -omics literacy.

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The accelerated rate of knowledge gained from genomics and other “-omics” scientific investigations is anticipated to vastly enhance patient care. The translation from research to patient care is termed *implementation science* (Williams, Feero, Leonard, & Coleman, 2016). Implementing the science requires alterations of current practice and adaptation of the new treatments, procedures, and protocols. To successfully make this transition, knowledge and belief are essential for patients and providers. In addition, education and training of all healthcare team members must be instituted to put protocols into action.

However, understanding the -omics language and implications for health care can be challenging. In recognition of the need to enhance -omics, particularly in genomics, the National Institutes of Health and National Human Genome Research Institute held a workshop in 2011 to discuss genomic health literacy and genomic science literacy (Hurle et al., 2013). Clearly articulated was the challenge of a public not well versed in the basic biology and math necessary to understand the implications of genomic and epigenomic science to better address their healthcare needs (Hurle et al., 2013). Six years later, and with the National Cancer Moonshot Initiative and Precision Medicine Initiative accelerating -omics research and practice, the public is still not omically literate.

Using a case study example, the following will explore this challenge from a patient perspective.

Case Study

Mr. X is a 48-year-old male high school math teacher who was diagnosed with acute myeloid leukemia (AML) three years ago. Standard therapies of cytarabine (Depocyt®) and idarubicin (Idamycin®) initially led to remission. He also had an allogeneic hematopoietic cell transplantation and was doing well until he relapsed six months ago. Consultations with two different oncologists have left him with two options. One, based on a review of pharmacogenomics in patients with AML that discussed the multiple DNA polymorphisms associated with anthracycline and cytarabine pathways (Megias-Vericat et al., 2016), was to sequence his genome to assess for any of these polymorphisms. If detected, he would be offered a trial of a new regimen for patients with such polymorphisms. The second oncologist suggested that he enter a small radioimmunotherapy trial that had been yielding some promising results (Bodet-Milin et al., 2016). In both cases, the explanations were unclear, and neither approach seemed to offer more hope than the other. As a well-educated, middle-aged adult, Mr. X felt out of sorts and unsure of what decision to make. He sought the opinion of a third oncologist at one of the top research-intensive

cancer centers in the nation. Based on some successes in patients with relapsed acute lymphoblastic leukemia who had received treatment using a chimeric antigen receptor lentiviral vector transduced into autologous T cells (Maude et al., 2014) (meaning using a viral vector containing targeted healthy DNA and incorporating that into a patient's own T cells), this oncologist suggested a similar experimental treatment for Mr. X's AML.

Discussion

One of the great challenges is that cancer is estimated by some to be more than 200 diseases (Kaiser & Couzin-Frankel, 2016). The heterogeneity of AML alone speaks volumes about the complexity and treatment challenges of this disease (Megías-Vericat et al., 2016), as Mr. X was starting to realize with the diverse and varied treatments being offered. Translating these complexities, microlevel treatment options, and advanced statistical modeling methods to best estimate prognosis to even highly educated individuals is daunting. Explaining this to less educated patients and family members may seem unachievable. Even with the numerous resources, including videos, to relay basic genetic information, more than one-third of the population may struggle to understand these concepts (Kusnoor et al., 2016).

With a strong background in math, Mr. X is above the norm but is still overwhelmed with his treatment choices, none of which are strong guarantees for long-term survival. To help with his decision, as a mathematician, he will take a logical approach and calculate his best options by carefully reading through each of the consent forms for each of the treatment options.

Most patients are not as educated and methodical as Mr. X. Health disparities are pronounced in such situations in which individuals in

some racial and ethnic minority populations may not even be within a healthcare system that offers such options, much less understand the implications for these options. In addition, many of these populations continue to be tremendously underrepresented in large genomic databases (Smith et al., 2016). In a more inclusive direction, the Precision Medicine Initiative recognizes this disparity and has a concerted effort to target such populations in advanced research studies (Budinjøsne & Harris, 2015). In addition, strong efforts to increase -omics literacy are underway. Kusnoor et al. (2016) developed an educational model to increase precision medicine knowledge based on health literacy, taking into account learning styles. The combination of such educational models with great efforts to enroll more diverse populations into -omics studies will lead to the contribution of diverse variables into large datasets that will be representative of the world's population.

Diversity is not only representative of the planet's population, but is also a necessity of the population's genome over generations. An irony is that diversity is needed for optimizing survival, but the diversity of cancer creates these complex challenges that make eradicating it from this species so difficult. Cancer is multifactorial, not just genetic. In fact, about one-third of cancer-associated deaths are related to behaviors (World Health Organization, 2015). Understanding this is another challenge in healthcare literacy (Waters, Wheeler, & Hamilton, 2016). Educating patients for better understanding of research studies in which they are being sought to enroll is important, but researchers must also understand how individuals are obtaining, processing, and using health information (Waters et al., 2016). Another aspect of the Precision Medicine Initiative is

stronger partnerships with patients (Collins & Varmus, 2015). To do this successfully, health literacy must be improved, particularly in the complex -omics area.

Conclusion

Ultimately, Mr. X selects the third option of using a viral vector containing healthy DNA, which is the greatest risk but has the best potential for survival. The physician is excited to have Mr. X as a case study for using this treatment approach for AML, an area of science being implemented into practice that is still nascent. Mr. X signs the consent and is treated. He experiences severe side effects of high fevers, extreme pain, and multiorgan dysfunction. Although these side effects were detailed in the consent form, Mr. X admits he did not understand how severe these symptoms would feel. He felt that, as a strong individual, he would have avoided them altogether. His regret is not having had a discussion with any of his providers about a fourth option—hospice care to optimize quality of life with whatever life he had left if untreated.

How much does -omics literacy matter in this case? Even for such an educated patient, having a better understanding of the systemic consequences of this therapy may have led him to a different decision. Mr. X ultimately did gain some benefit. His life was extended six months past his prognosis, but he was not living in the capacity he had anticipated. In the world of oncogenomics, how do nurses help patients reach a level of health and -omics literacy that will allow them to make healthcare decisions they can live with and, for some, ultimately die with?

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