

## EDITORIAL

Precision oncology:  
ethical challenges and justificationOksana SULAIEVA<sup>1</sup>, Tetyana FALALYEYEVA<sup>1,2\*</sup>,  
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The revolutionary concept of precision oncology has numerous advantages compared to conventional cancer care. It is anticipated that a personalized approach will improve early diagnostics, targeted and more effective treatment and finally prevention of cancer enhancing the quality of life. However, there are some drawbacks of this approach related to a wide range of economic, social, and ethical challenges.<sup>1</sup>

Ironically, implementing new advanced technologies can provoke inequity and deepen the existing disparities in health care services. The current health care systems around the World demonstrate the profound injustice in access to essential cancer health care services contradicting the basic human rights for health.<sup>2</sup> Assessing the incidence and prevalence of cancers, mortality rate and survival of cancer patients it has been shown that particular population groups are disproportionately higher affected by this disease due to structural injustice. In addition to poverty, culture (low educational level, myths, stigmatization), and lifestyle (heavy smoking, alcohol consumption, heavy smoking, and a high animal fat diet), forms of social injustice such as racism are critical factors in creating and maintaining disparities.<sup>3</sup> Many people from low-income countries receive no effective biomedical care at all or are deprived of essential cancer-preventing measures including vaccines. For instance, the lack of cer-

vical cancer screening and anti-human papillomavirus (HPV) vaccination defines the high rate of cervical cancer morbidity and mortality in low-income countries, including Ukraine though this cancer is preventable. The gap between various social groups has appeared even wider under the ongoing coronavirus disease (COVID)-19 pandemic illuminating the disproportion in access to health care including various cancer care services and facilities distribution accelerating inequities in health care provision.<sup>4</sup> This touched first of all those who faced current health inequities and underlined the existing barriers to health equity.<sup>5</sup> Even in high-income countries, there are remarkable differences in cancer patients' access to specialized medical care, molecular testing, and genetic counseling in oncology across various geographical areas, social and economic groups.<sup>1</sup>

So that despite the progress in cancer biology understanding treatment,<sup>6</sup> some racial and ethnic groups, sexual and gender minorities, patients living in rural areas, as well as populations with a poor financial background and low educational level have a higher rate and worse survival for many malignancies due to lack of insurance, limited access to cancer care and suboptimal treatment.<sup>6-8</sup> From this perspective, it is crucial to realize to what extent the society and health care system are ready for implementing precision oncology.

This paper is addressing the following questions:

1. is developing precision oncology ethically justifiable?;
2. what factors contribute to cancer health care disparity, and how does this affect further precision oncology evolution?

Is it ethical to invest in precision oncology? Although the precision oncology approach is focused on improving health care practice, it also possesses ethical contradictions rooted in structural injustice.<sup>2</sup> Inequity in cancer care relies on numerous determinants including social, cultural, economic, environmental factors, and genetic diversity impacting the predisposition to various cancers, prognosis and outcomes. In addition, there are some infrastructural features impacting the opportunities for timely screening, early diagnostics and appropriate treatment. A low level of awareness about cancer prevention and screening as well as long distances to health sites may affect the inability for preventing and early diagnostics of cancer.<sup>9</sup> Furthermore, it should be considered the lack of health insurance and obstacles to access to medical facilities due to distributional inequity that reduces the probability of the appropriate treatment.<sup>10</sup>

Lacking equal access to basic cancer care, should we invest in the development of costly precision oncology? Let us look at this issue from the theoretical concepts of justice focusing on ends and outcomes. From the utilitarian point of view, employing a single standard in determining policy and selecting the option which results in maximal utility for the highest amount of people, it seems that precision oncology would be never chosen.<sup>11</sup> As far as “a utilitarian conception of justice is committed to treating people as equals and to deliberately ignoring relational and relative differences between individuals”, they would neglect investments in new personalized therapies. It seems that the utilitarian perspective — *prima facie* — might support the use of existing limited resources for improving “one-size-fits-all therapies” and getting the maximum benefits for more people, even if some minorities or individuals with rare genotypes could not receive optimal treatment. It is irrelevant for utilitarianism who exactly will get benefits and how. In contrast, precision oncology is committed to individualizing the treatment for every patient. Although the

utilitarian concept of justice is quite popular and widely used it does not pursue the interests of every individual and is not patient-centric.

An alternative to utilitarianism is Rawls’ libertarian concept of justice proclaiming the commitment to the equality of political liberties and opportunities. Rawls’ principles are focused on “a liberal democratic political regime to ensure that its citizens’ basic needs for primary good are met and there are “adequate all-purpose means” for citizens to use their liberties and opportunities effectively. At the same time, the second Rawls’ principle is important for reducing unequal distributions.<sup>12</sup> Later these ideas were expanded by Daniels for the health care system.<sup>11</sup> From Daniels’ perspective, allocation of health care resources should be aimed at equalizing social opportunity that together with maximizing the minimum level of primary goods could be essential for solving the problem of cancer disparities.

One more substantial aspect of libertarianism is a priority of individual liberty and demands. When applying this concept to the industry, libertarianism supports and facilitates a free market.<sup>11</sup> This, on the one side, increases the investments in promising innovative technologies development for further commercialization and profit. On the other side, the market regulates the price including prices for targeted treatments, so that access to goods (tailored treatment) is an individual issue, rather than a social responsibility. In this context, let us answer the question: Can unemployed people, minorities or individuals lacking medical insurance get access to precision oncology? The discrepancy between market and social needs might provoke additional financial toxicity of the innovative technologies making them unaffordable for most people and deepening cancer care disparities. So that it seems challenging to implement precision oncology under the existing economic and social inequalities. On the flip side, cancer disparities might diminish the effectiveness of precision medicine globally.

Also, cancer disparities can delay the development of precision oncology. Existing cancer disparities provoke imprecision of precision oncology. As far as precision medicine is based on “big data” analysis comprising clinical and genetic testing, the representative sample is essential for

understanding tumor biology, its interplay with environmental factors, and finding the best targets for future therapies.<sup>9, 13, 14</sup> There are at least three specific aspects that impact the outcomes and opportunities for spreading precision oncology: the quality of health data collected; the integration of these data into precision medicine initiatives and the development of new medications.<sup>9</sup>

The personalized approach could be compromised due to the disproportional representation of different social, racial and ethnic groups in the primary set of data. Implementing precision oncology is based on expensive genomic testing and includes “big data” analysis that inherently relies on the integration of clinical and research data.<sup>13, 14</sup> Unequal access to health care services and clinical trials defined the disproportion of certain groups of population and underrepresentation of minorities in research datasets.<sup>5</sup> Similarly, most biobanks collecting tissues samples and associated data are present in developed countries whose genotypes are well collected and investigated.<sup>9</sup> However, the genetic peculiarities of the population in developing countries are still uncovered.

Shifted access of various populations and groups to precision oncology initiatives provides biased data for further analysis that can delay the development of effective solutions in personalized cancer treatment and negatively affect the quality of health care in general. For overcoming this trend, some genetic initiatives have been taken to extend the representation of populations that historically were neglected in genetic studies.<sup>15</sup>

Despite the innovative approach and high efficacy, by now precision oncology can improve health for some, but not all individuals due to existing cancer disparities. To provide the platform for precision oncology development there is a need to reach cancer health equity in general. For this aim, reconsidering the current health care system approach and building the ethical

environment for the further restructuring of cancer care services are required.

## References

1. Wagner JK. Ethical and Legal Considerations for the Inclusion of Underserved and Underrepresented Immigrant Populations in Precision Health and Genomic Research in the United States. *Ethn Dis* 2019;29(Suppl 3):641–50.
2. Essex R, Markowski M, Miller D. Structural injustice and dismantling racism in health and healthcare. *Nurs Inq* 2022;29:e12441.
3. Geneviève LD, Martani A, Shaw D, Elger BS, Wangmo T. Structural racism in precision medicine: leaving no one behind. *BMC Med Ethics* 2020;21:17.
4. Fagoonee I, Pellicano R. COVID-19 brings the world economy to its knees. *Minerva Med* 2020;111:297–9.
5. Patel MI, Lopez AM, Blackstock W, Reeder-Hayes K, Moushey EA, Phillips J, *et al.* Cancer Disparities and Health Equity: A Policy Statement From the American Society of Clinical Oncology. *J Clin Oncol* 2020;38:3439–48.
6. Dhasmana A, Dhasmana S, Kotnala S, Anukriti A, Kashyap VK, Shaji PD, *et al.* A topography of immunotherapies against gastrointestinal malignancies. *Panminerva Med* 2022;64:56–71.
7. Zavala VA, Bracci PM, Carethers JM, Carvajal-Carmona L, Coggins NB, Cruz-Correa MR, *et al.* Cancer health disparities in racial/ethnic minorities in the United States. *Br J Cancer* 2021;124:315–32.
8. Schwartz-Marin E. Genomic Justice and Imagined Communities. *Hastings Cent Rep* 2017;47:30–1.
9. Wesson P, Hswen Y, Valdez G, Stojanovski K, Handley MA. Risks and Opportunities to Ensure Equity in the Application of Big Data Research in Public Health. *Annu Rev Public Health* 2021;43.
10. Cohn EG, Henderson GE, Appelbaum PS. Distributive justice, diversity, and inclusion in precision medicine: what will success look like? *Genet Med* 2017;19:157–9.
11. Brall C, Schröder-Bäck P. Personalised Medicine and Scarce Resources: A Discussion of Ethical Chances and Challenges from the Perspective of the Capability Approach. *Public Health Genomics* 2016;19:178–86.
12. Fritz Z, Cox C. Conflicting demands on a modern healthcare service: can Rawlsian justice provide a guiding philosophy for the NHS and other socialized health services? *Bioethics* 2019;33:609–16.
13. Davis MB. Genomics and Cancer Disparities: The Justice and Power of Inclusion. *Cancer Discov* 2021;11:805–9.
14. Nedungadi P, Iyer A, Gutjahr G, Bhaskar J, Pillai AB. Data-Driven Methods for Advancing Precision Oncology. *Curr Pharmacol Rep* 2018;4:145–56.
15. Precision medicine needs an equity agenda. *Nat Med* 2021;27:737.

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