

Ethical considerations in genetic research: Contributions towards a strategy for personalized medicine

Ljupcho Chakar*, Aleksandar Stankov, Goran Pavlovski, Natasha Bitoljanu,
Viktorija Belakaposka Srpanova, Ana Ivcheva, Rosica Chakar, Zlatko Jakovski

*Institute of Forensic Medicine, Criminalistics and Medical Deontology,
Medical Faculty, Ss. Cyril and Methodius University in Skopje, Majka Tereza 19,
1000 Skopje, Republic of North Macedonia*

Received: January 2025; Accepted: February 2025

Abstract

Genetic/genomic testing and research serve as vital tools for health improvement and disease prevention. Nevertheless, given that genetic/genomic testing and research involve handling sensitive personal information with significant potential impacts on patients' lives or their families, it is imperative to consider the ethical, legal, and social implications (ELSI). This study aims to evaluate the ethical attitudes and practices among staff in genetic laboratories in the Republic of North Macedonia and to offer guidance on ethical conduct in accordance with ethical norms outlined in international laws, codes, and recommendations.

The findings primarily highlight two considerations. First, there is an essential need to establish genetic counseling centers to elucidate genetics, genetic research, and treatment modalities based on ELSI principles to a broader segment of the population. Secondly, given the critical nature of these issues and their impact on public health, we propose that genetic counseling centers be legally mandated to ensure the provision of medical care conducive to the development of our country. Finally, with the advancement of genetics in medicine, we can cautiously introduce personalized medicine as an ultimate goal in treatment to maximize individualized health care, thereby strengthening the healthcare landscape in the Republic of North Macedonia.

Key words: ethics, genetic research, strategy, personalized medicine

Introduction

Genetic medicine is a multidisciplinary field encompassing a wide range of contexts. Its extreme complexity, along with the potential repercussions on an individual's life, raises significant issues within ethical, deontological, and legal medical domains.

The facets related to performing genetic testing need to be addressed at various levels, starting from providing accurate information about its "cognitive" intentions

(distinctly separating from the peculiar "preventative aspect") to addressing the exciting legal medical questions in areas like forensic pathology, medical liability, and insurance. Undoubtedly, in recent years, following the decoding of the human genome, genetic research has expanded with a simultaneous exponential increase in its application in clinical practice and its ethical and social evolution.

In simple terms, the concept of "What is good, and what is bad?" simplifies the definition of ethics, which, when applied in medicine, is termed medical ethics.

*email: ljchakar@yahoo.com

Without its application, the aforementioned loses its significance. Fundamentally, it is expected that a physician must act in a certain manner and adhere to specified rules. It is imperative that physicians follow professional standards. Later, bioethics emerged and evolved as a branch of medical ethics, dealing with complex issues such as euthanasia, transplantation, genetic medicine, assisted reproduction therapy, human cloning, and medical genomics. The father of medicine, as well as of medical ethics, created an oath known by his name, Hippocrates, in which doctors swear and thus commit to uphold it. In China, the concepts of ethics were established by Confucius (Guo, 1995). In 1947, following the Second World War, the historic Nuremberg Tribunal investigated the crimes of Hitler and the Nazis, leading to the establishment of the Nuremberg Code, which now serves as a foundation for modern ethics (Dorner and Weindling, 2001). In 1949, the Geneva Declaration was announced, followed by the Helsinki Declaration in 1964, which revised the ethical code. In 1996, the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) included 13 basic principles that continue to guide researchers today (Vijayananthan and Nawawi, 2008).

Genetic testing raises serious questions about medicine, public health, and social policy regarding the circumstances under which tests should be used, particularly regarding the use of the results. Key questions include: 1) Should individuals have the right to choose or refuse the test? 2) Should the test be mandatory, such as newborn screening? 3) Should patients be able to control access to their test results? (Dwyer et al., 2021) and 4) If test results are disclosed to third parties such as employers or insurance companies, what protections should be in place to ensure that individuals are not unfairly treated based on their genotype? The answers to these questions partially depend on the interpretation of four fundamental ethical and legal priorities: autonomy (dignity), confidentiality, privacy, and fairness.

There is an inevitable need for the creation of exceptionally meticulous and expert legislation, the work of top experts in the field rather than politically appointed drafters. Only then will a legal act be produced that competently addresses the specifics of the country and the psychology of its population and includes practical ethical, legal, and social implications (ELSI).

Therefore, the objectives of this study were to evaluate the ethical attitudes and behaviors of employees in genetic laboratories in the Republic of North Macedonia and to provide guidelines for ethical conduct according to the ethical rules outlined in international laws, codes, and recommendations.

To successfully achieve the stated goals, the following activities were undertaken: 1) Designing an anonymous pilot questionnaire to assess the posed questions from the perspective of readability and comprehensibility within the target groups, coverage of the research problem, an excess or deficiency of offered responses, and the suitability of the

responses, as well as to gather additional suggestions from the participants; 2) Designing and distributing a final anonymous questionnaire; and 3) Analyzing the collected responses and comparing them with the literature.

Material and methods

To design an appropriate anonymous questionnaire, preliminary research involved the creation of a closed, descriptive pilot questionnaire using targeted focus group methodology. This questionnaire was uploaded to the Google Forms platform (as a data collection tool) and sent via email to a pre-defined target group of employees working in genetic laboratories across the Republic of North Macedonia ($n=5$). The pilot questionnaire included five questions on socio-demographic data of the respondents and twelve questions on ethical behavior in patient interactions within genetic laboratories.

The survey was conducted from December 1st to December 10th, 2023. This pilot questionnaire helped evaluate the posed questions in terms of readability, understandability within the target group, coverage of the research problem, the appropriateness of the offered answers, and the required time to complete the questionnaire, as well as collecting additional suggestions from respondents about the research problem.

The final questionnaire comprised five socio-demographic questions and twelve closed questions concerning the ethical aspects of working in genetic laboratories in the Republic of North Macedonia. It was distributed electronically via personal email addresses or social networks to the genetic laboratories. The survey was conducted from February 10th to March 10th, 2024, and a total of 34 questionnaires were completed.

Data were sorted and processed using Microsoft Excel® (Microsoft Corp., Redmond, WA, USA) and STATGRAPHICS Centurion XVI evaluation software for multivariate data analysis (Stat Point Technologies Inc., USA).

Results and discussion

Pilot survey is a strategy that helps to evaluate or test a questionnaire using a smaller sample size than the planned project sample. After obtaining and analyzing results from the pilot survey, logistical, technical and any other issues can be addressed. Based on the feedback from the pilot questionnaire (5 selected respondents), the questions were clear and unambiguous and only 20% of the respondents reported that two questions were not clear enough and should be modified. Therefore, these questions were further refined and adjusted.

The final project questionnaire was completed by 34 respondents from genetic laboratories across the Republic of North Macedonia. The demographic data of the respondents are presented in Table 1.

Table 1. Demographic profile of respondents (n=34)

Characteristics of the responders	n	%
Gender		
Male	7	20.6
Female	27	79.4
Age (years)		
20-30	8	23.5
31-40	6	17.6
41-50	11	32.4
51-60	6	17.6
>60	3	8.8
Level of education		
Secondary education	1	2.9
Higher education	23	67.6
Doctorate	10	29.4
Work position		
Laboratory technician	6	17.6
Researcher	21	61.8
Manager	7	20.6
Work experience in molecular genetics (years)		
0-5	9	26.5
6-10	8	23.5
11-20	7	20.6
21-30	8	23.5
>31	2	5.9

Respondents' Opinions on Specific Questions

For the first question, "Do you think that molecular-genetic research poses a unique ethical challenge compared to other kinds of research?", 91.2% of respondents indicated that genetic testing differs from other research, while only 8.8% believed that molecular-genetic research does not pose a unique ethical challenge. Our findings align with the prevailing global views that genetic research, due to its particularities, represents a distinct type of research. This conclusion is supported by numerical data found in the consulted global literature, which highlights its familial, social, educational nature, and its unique identification characteristics (Annas, 1993; Andrews et al., 1994; Jonsen et al., 1996; ASHG statement, 1998). Genetic

research is distinct from other types of research because it delves deeply into the fundamental structure of an individual. It often provides crucial information for identifying specific genetic disorders, predispositions to health conditions not yet manifested, and other exceptionally sensitive data (Andrews et al., 1994; NBCA, 1999). This capability enables medical interventions before the onset of disease symptoms, facilitating timely prevention and treatment, risk assessment for family members, and reducing the risk of passing conditions to descendants (Bruke, 2002; Khoury, 2009).

Regarding the second question, "Does your laboratory have protocols in place to ensure patient dignity?", nearly all respondents, 97.1%, answered affirmatively, with only

2.9% indicating the absence of such protocols. According to our survey, our laboratories implement mechanisms to protect dignity, including non-maleficence, beneficence, autonomy, and justice. These principles were established by Beauchamp and Childress (1979) and have provided a common framework for medical practice (Erdmann et al., 2021). The World Health Organization also issues guidelines on genetic/genomic testing services that adhere to these principles (Wertz et al., 2003). In 1997, UNESCO's Universal Declaration on the Human Genome and Human Rights was recognized as a foundational document in the international legal framework for the ethical principles of genomic medicine, serving as a basis for subsequent documents in this field. This declaration underscores that the paramount interest of human rights—dignity and freedom—takes precedence over any other interest (Mayor, 2003).

Regarding the third question, "How is informed consent obtained in your laboratory for genetic testing or participation in research?", 85.3% of respondents indicated that informed consent is acquired personally through written consent, while only 8.8% reported obtaining it through verbal consent. The results confirm that our laboratories obtain informed consent appropriately, in accordance with international standards (Nuremberg, Belmont, and Helsinki, etc.) (Nijhawan et al., 2013). The informed consent process is the principal mechanism through which we protect patients and it provides the capacity for decision-making, voluntariness, understanding, and appropriate information. The question of how 'appropriate' the information is remains highly subjective and poorly defined, presenting a significant challenge for geneticists and physicians regarding the amount of information necessary for the patient (Rego et al., 2020).

In the fourth question, one of the most critical elements of medical ethics was addressed: "Has your laboratory ever faced challenges in maintaining the confidentiality of genetic information?". A majority of the respondents, 73.5%, indicated that they had not faced these challenges, while 26.5% reported challenges in maintaining the confidentiality of genetic information. The continual drive to protect privacy, the motivation for non-identification of biospecimens and associated research data, can excessively restrict the return of relevant results that could benefit patients and their families. Thus, a level of information must be found that satisfies the needs of the research while not compromising the dignity and autonomy of the patient. As such, it presents a challenge for national laws to improve over time. These mismatches and complications often compel professional geneticists to focus on making the right decisions for their patients and their families based on their best judgment - yet they remain uncertain about where this practice positions them in relation to existing state laws (Spector et al., 2018).

In response to the question, "How are the results of genetic testing delivered to patients from your laboratory?",

85.3% of respondents stated that they deliver results directly/in person, 8.8% via email, 2.9% by telephone, and 2.9% reported that results are delivered in other ways. The results of genetic tests can be conveyed through various means, but in our laboratories, the predominant, logical, and safest method is direct and personal delivery. This mode of delivery is both practical and ethically preferable for both physicians and patients. Put another way, it minimizes the potential for misinterpretations or manipulation of the results.

Regarding the question, "Does your laboratory have a designated contact person for the patient?", 70.6% of respondents answered affirmatively, while 29.4% said no. It is important to emphasize that appointing a designated contact person carries significant responsibility as they must maintain data confidentiality and ensure proper delivery to the patient or subject. Hence, in the event of a data breach, it becomes easier to trace the source of the leakage. This data, by its nature, should not be accessible to everyone, emphasizing the need for stringent confidentiality measures. Thus, from both a principled and legal standpoint, the data are intended solely for the use of the subject or their family, or both.

In response to the question, "What system does your laboratory use for storing genetic data and records?", the majority of respondents (73.5%) reported that genetic data and records are stored in a digital database within the institution, while 26.5% indicated that the records are kept in paper form. The International Declaration on Human Genetic Data (HGD), published by UNESCO in 2003, establishes principles for the collection, processing, use, and storage of human genetic data and the biological samples from which these data are derived. Furthermore, it reaffirms the need for the creation of regulations and calls upon countries to work on them to regulate the cross-border transfer of human genetic data and biological samples to ensure equitable access to such data (Ascencio-Carbajal et al., 2021; UNESCO, 2003). From this, we believe that the storage of genetic data is a serious task for genetic institutions, which should be guided not only by international regulations but also consider local specificities.

In response to the eighth question, "Is the practice of your laboratory influenced by international ethical guidelines?", the responses varied: 76.5% of the participants stated that their laboratory's practices are influenced by international ethical guidelines, 17.6% reported that the laboratory's practices are influenced by international ethical guidelines only in certain operational aspects, and 5.9% indicated that their laboratory's practices are not influenced by international ethical guidelines at all. These responses demonstrate that a high percentage (over 76%) of our laboratories operate in accordance with international ethical guidelines. However, it is recommended that the remaining laboratories also adhere to international behavioral norms (laws, codes, regulations, conventions).

Regarding the question, "Should there be public education about molecular genetic testing?", a significant majority of respondents, 91.2%, answered affirmatively, while only 8.8% believed that no education is necessary. This outcome indicates a strong need for establishing a genetic counseling service at the national level, which would facilitate the public's understanding of the significance and benefits of genetic testing and reinforce the principles of informed consent, autonomy, non-maleficence, confidentiality, privacy, and fairness. According to Cappelli et al. (1999), adequate knowledge concerning the genetic components of diseases and personal attitudes towards DNA testing are crucial determinants for optimizing the use of genetic testing. Population studies, including those conducted in Finnish and Dutch populations, generally demonstrated insufficient knowledge, thereby affecting understanding of genes and heredity (Henneman et al., 2004; Jallinoja and Aro, 1999). The results from the study by Morren et al. (2007) also indicated low levels of knowledge, particularly among older and less educated patients which aligns with our observations on the need for establishing a genetic counseling service.

The tenth question focused on, "Should there be better resolution of ethical issues in molecular genetics?", According to the responses, 82.4% of participants agreed that there should be a better resolution concerning ethical issues, while 17.6% felt there was no need for improved resolution in molecular genetics. A majority of respondents indicated that additional insights are needed in the application of ethical norms, especially those utilized in developed countries. In the European Union (EU), the General Data Protection Regulation 2016/679 (GDPR) took effect in 2018. At the time of writing, GDPR is still being implemented in the UK despite its departure from the EU. As the Republic of North Macedonia progresses towards EU accession, GDPR will become part of Macedonian legislation. GDPR promotes the responsible processing of data for the common good while respecting the fundamental rights of individuals. Although it is a binding legislative act, it also provides considerable leeway for EU member states, including for the processing of 'sensitive data' such as genetic data (Mitchell et al., 2020).

Regarding the question, "Does your laboratory offer support or counseling to patients who receive distressing genetic information?", 61.8% of respondents indicated that they provide counseling to patients, while 38.2% reported that they do not have mechanisms in place for patient support.

As with any medical test, the expectations regarding the performance of a genetic test should be discussed with the patient prior to its execution. Pre-test counseling includes information about the levels of potential results, as well as the risks, limitations, and benefits of testing. Counseling before and after the test should be conducted in a clear, objective, and non-directive manner, enabling

patients to make informed decisions regarding the testing and any subsequent evaluation or treatment (Committee Opinion No. 693 Summary, 2017).

In recent decades, genomic sequencing has enabled the rapid and cost-effective acquisition of a vast array of genetic information. However, this advancement can pose challenges for researchers and clinicians in determining how deeply to delve into this complexity when discussing consent with participants (Lejeune and Amado, 2022). This is another reason why genetic counselors are needed as specialists to tailor discussions about consent. Tailoring may involve determining the appropriate amount of information to facilitate patient decision-making based on informed values, without compromising understanding, and also adjusting the complexity of the information based on the patient's level of comprehension. The capacity for decision-making, another crucial condition for valid consent, is subjective and can be difficult to define; thus, its definition may need to be flexible depending on the level of risk and potential benefit involved in the context of genomic sequencing. For some families, the level of risk involved in genetic sequencing may be higher than for others. A higher threshold for decision-making capacity might make sense in situations with more significant risks and/or lesser potential for direct benefits (Rego et al., 2020).

In response to the final question, "In the case of a global health threat, should public health concerns override standard ethical practices?" the largest group of respondents indicated 'sometimes' at 41.2%, 23.5% answered 'never', 14.7% said 'always', and 20.6% responded with "I don't know". The most common response reflects the reality of handling such situations. Why? During epidemics, the causative agent of the disease presents different clinical manifestations, risks, and outcomes. Accordingly, the approaches or measures taken will depend on various factors such as the age, general health condition of patients, individual reactivity, and many other factors influencing the course of the disease. Ethical behavior is implied and closely linked with individual medical knowledge, as well as the conditions within the health system. We often witness shortages of medications or lack of personnel for various reasons. In such situations, mechanisms of beneficence are invoked, which often means that a portion of the population with high ethical standards allocates resources for treating individuals, regardless of the system's policies. In cases of epidemics caused by various agents, the mechanism of utilitarianism is employed, meaning the health system focuses on maximizing benefits for the largest number of sick individuals, while the principle of egalitarianism, or providing help to only some of the sick or 'the chosen ones' based on any criterion, is excluded. The dominant response, or the stance of the respondents, aligns with the views presented in the studies by Perin and De Panfilis (2021) and Gaille et al. (2021).

Conclusion

From the study conducted, two main reflections emerge, which, in our humble opinion, could lead to the modernization and improvement of medical theory and practice in our country.

Firstly, considering the development strategies in various countries, particularly in developed nations, there emerges a vital need to establish genetic counseling centers. These centers aim to elucidate genetic concepts, genetic research, and treatment modalities to a broader population segment (potential patients). It is imperative that these genetic counseling centers are formed by leading authorities in genetic research and treatment, adhering to the principles of ethical, legal, and social implications (ELSI), without the interference of quasi-experts, politics, or businessmen who seek not the health benefits but solely personal financial gain from such genetic research.

Secondly, due to the seriousness of the issues involved and given that they concern the health of the entire population, we propose that these genetic counseling centers should be legally mandated to ensure the implementation of medical care for the development of our country.

Lastly, as a third conclusion, it can be stated that with the development of genetics in medicine and with all due caution, we can gradually introduce personalized medicine as the ultimate ideal in treatment to maximize personalized health care. This approach will strengthen the healthcare in the Republic of North Macedonia.

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Резиме

Етички проценувања во генетското истражување: Придонес кон стратегијата за персонализирана медицина

Љупчо Чакар*, Александар Станков, Горан Павловски, Наташа Битољану,
Викторија Белакапоска Српанова, Ана Ивчева, Росица Чакар, Златко Јаковски

*Институт за судска медицина, криминалистика и медицинска деонтологија,
Медицински факултет, Универзитет „Св. Кирил и Методиј“, Мајка Тереза 19,
1000 Скопје, Република Северна Македонија*

Клучни зборови: етика, генетски истражувања, стратегија, персонализирана медицина

Генетските/геномските тестирања и истражувања се корисни алатки за подобрување на здравјето и спречување на болести. Сепак, бидејќи генетските/геномските тестирања и истражувања се занимаваат со чувствителни лични информации што би можеле значително да влијаат на животот на пациентот или на неговото семејство, станува императив да се земат предвид етичките, правните и социјалните импликации (ethical, legal, and social implications – ELSI). Од тука, произлегоа целите на оваа студија да се евалуираат етичките ставови и постапувања на вработените во генетските лаборатории во Р.С. Македонија и да се дадат насоки за етичкото однесување согласно етичките правила содржани во меѓународните закони, кодекси и препораки.

Од спроведеното испитување доминантно се јавуваат две заклучни размислувања. Прво, се јавува суштинска потреба од формирање на генетско/и советувањата со цел на појаснувањата за што поголем број на население за генетиката, генетските истражувања и начините на лекување по принципите на ELSI и второ, заради сериозноста на проблематиката, а бидејќи се работи за здравјето на населението, предлагаме генетските советувањата да бидат законски детерминирани заради задолжителното спроведување на медицинската заштита во полза на развитокот на нашата држава. На крај, како трет заклучок, може да се каже дека со развитокот на генетиката во медицината со сите каути можаме постепено да ја внесуваме персонализираната медицина како врвен идеал во лекувањето со цел на максимизирање на персоналната здравствена грижа преку лекување, а со тоа да се зајакне здравствената заштита во Северна Македонија.

