Ethics considerations for precision medicine research and genetic testing in low- and middle-income countries

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Abstract

Background: Genetic data transfer within multicentre clinical trials conducted in low- and middle-income countries is common and must be communicated to study participants as part of ethical requirements.

Aims: To analyse ethics practices in precision medicine research in low- and middle-income countries and make useful recommendations.

Methods: We conducted a narrative review of published literature and existing ethics frameworks regarding under-representation of low- and middle-income countries in genomic databases, informed consent and data security discussions, as well as the potential for exploitation and limited access to benefits.

Results: The findings highlight the need for increased diversity in research participation, robust ethical frameworks, and knowledge sharing between developed and developing countries. The findings show that strengthening national research ethics committees and fostering collaboration can help low- and middle-income countries in addressing unique challenges and harnessing the potential of precision medicine while ensuring ethical conduct and equitable access for all. Our review emphasizes the importance of ethical considerations in precision medicine research to ensure that its benefits reach all affected populations, promoting a more just and more equitable healthcare future.

Conclusion: There is a need to ensure that research participants are accorded the rights, whether in the ownership of their samples or the right to know what type of genetic studies have been conducted on their samples. It is important to have binding agreements that will allow clinical trial participants to access drugs that proof effective based on the trials they participated in.

Keywords: precision medicine research, research equity, low- and middle-income countries, ethics principles, ethics committees, ethical considerations, clinical trials

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Introduction

Do we need innovative concepts in biomedical ethics to maintain pace with genomics innovations, or are we compelled to tailor genomics and its applications, such as pharmacogenomics and precision medicine research, to fit into existing ethical frameworks? Should additional protections be established for so-called vulnerable populations residing in low- and middle-income countries (LMICs)? What are the ethical implications governing research in an international context and recruiting populations from developing countries and LMICs, as defined by the World Bank (*1*)?

Ethical considerations for the inclusion of different populations in genetic research include assessing all ethical implications regarding privacy, beneficence, confidentiality, non-maleficence and autonomy (*2*). Genetic data transfer during multicentre clinical trials conducted in LMICs is common practice and must be communicated as a part of the informed consent process.

The concept of personalised medicine is controversial, and is defined as "the use of drugs and procedures to provide the optimal treatment for every individual patient" (*1*). Pharmacogenetics is an advanced area of personalized medicine, which aims to reduce adverse drug reactions and achieve a better response by tailoring the pharmaceutical regimen to the individual genome of the patient. Many such approaches have been used to treat cancer patients. Pharmacogenomics has been used to treat infectious diseases such as hepatitis to avoid severe adverse drug events in patients who are genetically more sensitive to standard treatments (*3*). The discovery of the Goldilocks gene, which plays a role in the inflammatory response to tuberculosis, could have a major impact on medical practice in developing countries for predicting the risk of contracting tuberculosis and identifying who will benefit from steroids (*3*). Given the pace of development of precision medicine, it is only a matter of time before other benefits for socioeconomically underserved populations can be identified (*4*). In this article, we address the lack of diversity in genomics databases, which is a barrier to translating precision medicine research into practice. We also explore the concept of privacy and its associated ethical standards. Precision medicine research in LMICs

necessitates a nuanced approach that balances the potential benefits with ethical considerations, including informed consent, data security and ensuring equitable access to the advancements for all populations.

Addressing evidence limitation related to precision medicine

Patients should be well educated about all the options of precision medicine and the potential results so that they can make informed decisions. Educational materials should be tailored to the awareness of different populations. It is important to support communication with families when there is an identifiable family risk because, for example, first-degree relatives have a 50% chance of inheriting conditions such as Lynch syndrome. Clinicians have an ethical duty to inform patients about this kind of risk and to encourage family members to undergo testing. However, it is arguable how far this duty of clinicians extends and whether it ends with telling the patient, who then has to inform their family (5).

The other aspect under consideration pertains to the implementation of clinical innovation in small or rural clinics and hospitals. It is imperative to ensure equitable access to the advantages of precision medicine for all individuals. Notably, while conducting research and implementing innovations in academic medical centres and larger healthcare facilities, these endeavours can function as instructive templates for the broader integration of genomic medicine *(6)*.

Situation analysis

As previously described by Landry et al. in 2018, "Precision medicine is predicted to revolutionize the clinical practice of medicine by using molecular biomarkers to assess a patient's prognosis, risk, and therapeutic modalities more precisely" (2). However, dependence on biomarkers may create challenges for countries that are not equitably represented in precision medicine research. The representation of different populations in genomic studies listed in the following 2 public databases has been investigated: the genome-wide association study catalog and the database of genotypes and phenotypes (2). The findings showed fewer studies among African, Latin American and Asian than European populations. These patterns were consistent across various information types. Although the number of genomic research studies that include non-European populations is increasing, the overall number is still low, "and action is needed to implement the changes necessary for realising the promise of precision medicine for all" (2).

There is a lack of genetic counselling for prenatal genetic testing in LMICs, and clinicians use negative language to influence the decisions significantly more than in higher-income countries. Genetic counselling should involve reducing the fear and anxiety related to genetic testing and the need for support to achieve the maximum benefit of counselling (7).

There are many organizations that control biobanks, such as the International Society for Biological and Environmental Repositories, which produces guidelines to guarantee high-quality specimens, and the European, Middle Eastern and African Society for Biopreservation and Biobanking, which aims to improve sharing of biological specimens (7). The use of human blood and tissue is critical to biomedical research; however, there are no clearly defined regulations regarding the ownership of human tissue specimens and who controls their fate. Hence, there is a need to address this issue at the national level to ensure that policies are compliant with local cultural customs and beliefs, rather than relying on external agencies to address underlying issues related to national security and privacy of data.

Africa

As Ramsay mentioned in 2012, the genomic composition of African populations is poorly understood and there is considerable variation between ethnolinguistic groups (*8*). The unique genomic dynamics among African populations have an important role to play in understanding human health and susceptibility to disease (*9*). Extensive genomic analyses have been conducted among Europeans to examine associations with complex traits but few such studies have been conducted among Africans (*8*). This is mainly because of lack of funding, poor healthcare infrastructure and public health facilities, and a small pool of trained scientists (*10*). Africa is currently host to several international genomics research and biobanking consortia; each with a mandate to advance genomics research and biobanking in the continent. However, many of these consortia have yet to specify exactly how they plan to revolutionise international health research in Africa, despite their ambitious claims (*10*). When African researchers were interviewed, 2 major concerns about being part of these collaborative initiatives were voiced: (1) that there is a possibility of exploitation of African researchers and their countries; and (2) a lack of sustainable measures for research capacity building to allow researchers to begin conducting the research themselves (*10*).

The 4 principles of Beauchamp and Childress: principles of biomedical ethics

The principles of biomedical ethics were first published in 1979. They have become one of the best-known theories of bioethics and are practiced worldwide in medical research. Here, we use them to analyse questions related to the use of emergent techniques and areas of research related to the human genome, the investigation of precision medicine, and incorporating developing nations into these research frameworks (*11*).

Examination of the principles of biomedical ethics in the context of genetic research and marginalised populations

Respect for autonomy

Vulnerable populations in LMICs do not practice autonomous decision-making in the same way

that western populations do (12); therefore, further consideration of what autonomy means in such vulnerable communities is needed. One should consider how they perceive the offer to participate in a clinical trial or any kind of data collection. For them, it may be considered a way to improve health care provision, which may not necessarily be the case. One could argue that health literacy issues hinder the practice of such concepts as autonomy and informed decision-making among these populations. As defined by WHO, during the 7th Global Conference on Health Promotion, "Health literacy is the cognitive and social skills which determine the motivation and ability of individuals to get access to, perceive and use information in ways which promote and maintain good health" (13). Health literacy means more than being able to read and browse pamphlets successfully and make doctors' appointments, and goes beyond the concepts of health education and individual behaviour-oriented communication. Health education properly applied through the effective participation of healthcare teams and patients could slowly close the communication gap between them and reduce the level of paternalism practiced by healthcare providers. This could lead to further health literacy, resulting in effective community action and development of social capital (13).

Non-maleficence

Non-maleficence is the principle of not doing harm. Beneficence is an action that is taken, whereas non-maleficence is avoidance of an action. For research that is externally sponsored (conducted in a country and funded by sponsors from another), international guidelines advise that independent ethics committees in both countries should approve the research to ensure that the ethical standards of both countries are met, and avoid exploitation arising from potential imbalances of power and resources. The non-maleficence principle, which emphasizes avoiding harm, may be challenged when selecting certain populations for research. This could be the case if these populations lack the same level of health care as developed nations, making them unfamiliar with the specific experimental drugs being tested.

Beneficence

The bodies that regulate clinical trials (such as the United States Food and Drug Administration, European Medicines Agency, and Medicines and Healthcare Products Regulatory Agency in the United Kingdom of Great Britain and Norther Ireland) should ensure that pharmaceutical companies register their drugs after trial completion and that the drugs have been proven safe. The drugs should be registered in countries where the trials were conducted. This would form a post-clinical trial agreement that would benefit the populations that participated in the trial. If genetic tests for future exploratory studies are requested during clinical trials, participants must be informed of the purpose of the study, what type of tests will be conducted, how long any data or biological specimens will be kept, and whether they will be informed of any new findings related to their data or specimens.

Professional–patient relationship

Examining privacy parameters

The concept of privacy has long played a central role in human rights law. Worldwide, various bodies have enacted several binding and nonbinding regulations for physicians and researchers to protect the autonomy, dignity and privacy of patients and research subjects (14). With the development of new technology, the right to privacy has gained a new perspective: the right to protection of personal data.

According to Carrieri et al., "Genomic research has the potential to generate incidental findings, that is, findings that were not an intended objective of the study but were discovered as a consequence of the current technologies employed in this field" (15). Although institutional review boards expect doctors and researchers to discuss the return of research findings to participants in their research, this is something that does not usually happen in developing countries.

The importance of data protection has increased in the European Union (EU). Data protection laws are considered crucial to regulate the use of health data in medical research and research related to biobanks (16). In May 2018, the EU released the EU General Data Protection Regulation, which is considered the most important change in data privacy regulations over the past 20 years. The EU Charter includes explicit rules for handling human biological samples and personal data, requiring informed consent from the sample donors and research participants, or with regard to data, some other legal basis has been laid down. Similar provisions should be made for research in developing countries, especially for cross-border transfer of health data or biological samples, to protect the privacy of citizens (14).

Data sharing in the era of precision medicine research

Data sharing is an important component in scientific research. However, it is a challenge in genetic research because of the nature of the research itself and the genome is an identifiable feature of the participants (17). In studies involving humans, consent from donors must be obtained to use their data for research.

There have been claims about differences in human research practice in relation to standards in western countries and other parts of the world. There is an argument that what are called western standards are actually international standards and should be respected everywhere. In contrast, opponents of this view state that there is a need to tailor standards to the context and cultural perspectives in particular countries (18). Protection of communities is an important element of research; however, the potential harm to communities of individuals' participation in research has not been fully considered.

One study that actually addressed this issue was a genetic study of Askhenazi Jews, whose findings illustrated how it is possible for a research study to put the whole community at risk (*18*). There have been frequent reports of a particular mutation (185delAG) in the *BRCA1* gene among Ashkenazi Jews, which results in a high risk of ovarian and breast cancer. The study samples were collected from the data banks established in association with Tay–Sachs disease and cystic fibrosis screening. The National Institutes of Health Review Committee required no individual informed consent because all the identifiers were erased from the samples. The results showed that 0.9% of Ashkenazi Jews carried the mutation, at a higher rate than among the general population. Another study found that 6.1% of Jews had the I1307K mutation of the APC gene, which is related to susceptibility to colon cancer, but it was not found in the non-Jewish population (*17*). This study also used anonymous samples from a Tay–Sachs database. In both the above studies, any identifying information was removed from the DNA samples, thus there was no risk to individuals' participation in the studies. However, the results of these studies could have a substantial impact on the wider Ashkenazi Jewish community. The results give credibility to the suggestion that Jews are more susceptible to malignant diseases, such as breast cancer, and this in turn could lead to discrimination (*18*).

Potential threats and benefits to the populations of LMICs

Precision medicine faces several challenges that need to be addressed. There are foreseeable benefits and threats to the populations of LMICs. We are examining the challenges and opportunities facing developing countries as they begin to harness genomics for the benefit of their populations, in genetic research and development of treatment options.

The main role of institutional review boards is to help researchers protect the rights and welfare of study participants through periodic independent review of different ethical proposals for human research. The diverse membership of the boards includes scientists, nonscientists and institutional members, which allows the boards to systematically evaluate each study to ensure that the rights and welfare of participants are adequately protected by the study objectives. Each member of the board has the opportunity to contribute their concerns and life experiences to the discussion.

There are gaps between developed and developing countries in terms of adequate research infrastructure and equipment, and in applying the results of research and any lessons to be learned. Insufficient technology can make it difficult for researchers in developing countries to communicate their findings with researchers in similar fields in other countries (*19*).

Who will have ownership of research data is an important question; whether it should be governments or the institutions and companies responsible for conducting the research. In the United States of America, it is noteworthy that the Food and Drug Administration has stopped companies from allowing individuals to access their own genetic information *(19)*.

Gene sequencing and precision medicine generate huge amounts of personal data that require massive infrastructure for storage and further analysis, and create concerns for data security and privacy. It is possible that organizations involved in research and sponsors of trials could support the establishment of such infrastructure as part of a moral duty towards the host country. Such support could be compensated through tax exemptions for any agencies working in a particular country, such as multinational pharmaceutical companies *(19)*.

Precision medicine could improve the cost-effectiveness of health care, as developing countries have scarce resources to meet the need for provision of health care to all. Pharmacogenomics research could result in substantial cost savings by enabling the introduction of drugs that are effective for particular targeted populations in developing countries.

Countries should consider how their citizens' personal information can be shared or disclosed among different parties, such as police officers and national security services. There is a need to prevent abuse of information for unintended purposes, such as screening potential partners, or racial discrimination based on genetics (*19*).

We do not know all the implications of precision medicine and the discussion is ongoing, although there are many benefits and threats to populations in LMICs.

One issue that arises when considering whether it is appropriate to conduct a specific study in a developing country is whether the intervention is likely to be affordable in that country if it is shown to be effective (*19*). This will often not be a straightforward issue. For example, there is a need for technology-driven tools that help integrate different healthcare facilities and communities in Africa, as well as investigate knowledge, attitudes and barriers surrounding precision medicine (*20*). The role, scope and perception of genetic testing have changed because of technological advances. Genomic testing has yielded advances in diagnosis and prediction of diseases; however, it has also brought an increased chance of uncertain or unexpected findings that may have an impact on several members of a person's family. Previously, genetic testing was unable to provide results rapidly but its progressive development has resulted in the ability to achieve rapid accurate results that can aid appropriate decision-making (*21*).

This review highlights several issues to address when considering the way forward in trying to resolve the ethical dilemmas surrounding precision medicine research in humans. Some countries consider that such research is an infringement of national security and makes their populations vulnerable to harm. One possibility is to establish national research ethics committees to conduct proper reviews of research, provide clear regulations and determine the post-trial benefits. Effective ethical review of medical research

is essential in developed and developing countries to ensure that unethical practice is not allowed, and to protect the population from exploitation. There is a need to ensure that research participants are accorded their rights, whether in the ownership of their samples or the right to know what type of genetic studies will be conducted using their samples. There must be binding agreements for clinical trial participants to have access to any drugs that prove effective during trials in which they participated.

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Considérations éthiques relatives à la recherche en médecine de précision et aux tests génétiques dans les pays à revenu faible et intermédiaire

Résumé

Contexte : Le transfert de données génétiques dans le cadre d'essais cliniques multicentriques menés dans des pays à revenu faible et intermédiaire est courant et les participants à l'étude doivent en être informés conformément aux exigences éthiques.

Objectifs : Analyser les pratiques éthiques relatives à la recherche en médecine de précision dans les pays à revenu faible et intermédiaire, et formuler des recommandations utiles.

Méthodes : Nous avons mené une revue narrative de la littérature publiée et des cadres éthiques existants concernant la sous-représentation des pays à revenu faible et intermédiaire dans les bases de données génomiques, les discussions sur le consentement éclairé et la sécurité des données, ainsi que le potentiel d'exploitation et l'accès limité aux avantages de cette discipline.

Résultats : Les résultats mettent en évidence la nécessité d'accroître la diversité des participants à la recherche, de définir des cadres éthiques solides et de promouvoir le partage des connaissances entre les pays développés et les pays en développement. Ils montrent que le renforcement des comités nationaux d'éthique de la recherche ainsi qu'une meilleure collaboration peuvent aider les pays à revenu faible et intermédiaire à relever des défis spécifiques et à exploiter le potentiel de la médecine de précision, tout en garantissant une conduite éthique et un accès équitable pour tous. Notre examen souligne l'importance de prendre en compte les considérations éthiques dans la recherche en médecine de précision afin de permettre à toutes les populations concernées de bénéficier de ses avantages et de promouvoir un avenir plus juste et plus équitable en matière de soins de santé.

Conclusion : Il est nécessaire de veiller à ce que les participants à la recherche puissent jouir de leurs droits, qu'il s'agisse de la propriété de leurs échantillons ou du droit de savoir quels types d'études génétiques ont été menés sur ces derniers. La mise en place d'accords contraignants, autorisant les participants à des essais cliniques à avoir accès aux médicaments dont l'efficacité sera prouvée par lesdits essais auxquels ils ont pris part, est essentielle.

الاعتبارات الأخلاقية المتعلقة ببحوث طب الدقة والاختبارات الجينية في البلدان ذات الدخل المنخفض والمتوسط

محمد أشرف، سندس مبارك

الخلاصة

الخلفية: يُعد نقل البيانات الجينية في إطار التجارب السريرية المتعددة المراكز التي تُجرى في البلدان ذات الدخل المنخفض والمتوسط أمرًا شائعًا، ويجب إبلاغ المشاركين في الدراسة به بوصفه جزءًا من المتطلبات الأخلاقية.

الأهداف: هدفت هذه الدراسة إلى تحليل الممارسات الأخلاقية في بحوث طب الدقة في البلدان ذات الدخل المنخفض والمتوسط وتقديم توصيات مفيدة.

طرق البحث: أجرينا استعراضًا سرديًّا للمؤلفات المنشورة والأطر الأخلاقية القائمة فيما يتعلق بنقص تمثيل البلدان ذات الدخل المنخفض والمتوسط في قواعد البيانات الجينومية، والمناقشات بشأن الموافقات المستنيرة وأمن البيانات، وكذلك إمكانية الاستغلال ومحدودية الحصول على الفوائد.

النتائج: تُبرز نتائجُ الدراسة الحاجةَ إلى زيادة التنوع في المشاركة في البحوث، ووجود أُطر أخلاقية قوية، وتبادل المعلومات بين البلدان المتقدِّمة والنامية. وتُظهر النتائجُ أن تقوية اللجان الوطنية لأخلاقيات البحوث وتشجيع التعاون من شأنها أن يساعدا البلدان ذات الدخل المنخفض والمتوسط على التصدّي للتحديات الفريدة، وتسخير إمكانات طب الدقة مع ضمان السلوك الأخلاقي والإتاحة المنصفة للجميع. ويؤكد الاستعراض الذي أجريناه أهمية الاعتبارات الأخلاقية في بحوث طب الدقة، لضمان وصول فوائدها إلى جميع الفئات السكانية المتضررة، وهو ما يعزز تحقيق مستقبل أكثر عدلًا وإنصافًا للرعاية الصحية.

الاستنتاجات: ثمة حاجة إلى ضمان منح المشاركين في البحوث حقوقهم، سواء في ملكية عيناتهم أو في معرفة نوع الدراسات الجينية التي أُجريت على عيناتهم. ومن المهم كذلك إبرام اتفاقات مُلزِمة تتيح للمشاركين في التجارب السريرية الحصول على الأدوية التي تثبت فعاليتها استنادًا إلى التجارب التي شاركوا فيها.

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