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governance, ethics, evidence, policy, practice

Center for Genomic Medicine Ethics & Policy

Genomic Medicine Governance, Ethics, Policy, Practice – A Monthly Digest

June 2023 Number 05

Genomic medicine – spanning pre-clinical basic science through clinical development and translation to daily patient interventions – continues to evolve at an extraordinary pace. Advances in the scientific and technical dimensions of genomic medicine are extensively communicated through the peer-reviewed journal ecology and supporting grey literature.

Complementing this technical literature is a growing body of commentary, analysis and research around the governance, ethics, regulation, and policy dimensions of genomic medicine. Much of this content is communicated through academic journals and grey literature but is also appearing in the general media. This digest intends to capture and curate the most substantive examples of this non-technical content.

In aggregating and editing this digest, we directly review a broad spectrum of peer-reviewed journals and grey literature, as well as announcements and strategic actions from various practice domains and organization types including international agencies, INGOs, governments/regulatory bodies, academic and research institutions, consortiums and collaborations, foundations, and commercial organizations. More broadly, we utilize *Google Scholar's* alert capability to scan current literature. We acknowledge that this approach and scope yields an indicative and not an exhaustive digest product.

This digest is a service of the GE2P2 Global Foundation and its newly-formed Center for Genomic Medicine Governance, Ethics & Policy. The Foundation is solely responsible for its content. Comments and suggestions should be directed to the Editor or Associate Editor as below:

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We organize content using subject categories to help readers navigate to areas of interest as detailed below. We expect that these categories will evolve over time. We lead each edition with a "short list" section which highlights articles we assess to be strategically important and well aligned to our thematic focus areas of governance, ethics, policy and practice. Active categories in this edition include:

EDITOR'S SHORT LIST

:: We lead this edition's short list with **A draft human pangenome reference** – an article discussing an important "technical milestone" by Liao et al. published in *Nature* on 10 May 2023. The authors note that "…The openly accessible, diverse assemblies and pangenome graphs we present here form a draft of a pangenome reference…Our near-term goal is to expand the pangenome to a diverse cohort of 350 individuals (which should capture most common variants), to push towards T2T genomes for this cohort (to properly represent the entire genome in almost all individuals) and to refine the pangenome alignment methods (so that telomere-to-telomere alignment is possible, capturing more complex regions of the genome). This will give us a more comprehensive representation of all types of human variation…"

A paper published in *Nature Medicine* on 09 May 2023 by Christoffels, et al. – **A pan-African pathogen genomics data sharing platform to support disease outbreaks** – discusses challenges and opportunities associated with data management infrastructure within individual countries or across the continent in the context of genomics data sharing for assessment of and response to disease outbreaks. The authors note the important work undertaken by the African Pathogen Genomics Initiative, a project by the Africa CDC.

An important analysis of comparative HTA [health technology assessment] strategies for cell and gene therapies across eight jurisdictions is presented in **How are health technology assessment bodies responding to the assessment challenges posed by cell and gene therapy?** by Drummond, et al. in *BMC Health Services Research* on 13 May 2023.

We also highlight here four papers focusing on public engagement approaches involving gene editing:
:: In **Promoting equality in the governance of heritable human genome editing through Ubuntu: Reflecting on a South African public engagement study**, the authors argue that the Ubuntu philosophy can be applied in discussions around heritable genome editing, particularly regarding considerations of potential benefits for future generations on the context of HHGE [heritable human genome editing].

:: In **Towards an appropriate African framework for public engagement with human genome editing: a call to synergistic action**, the author strives to "…lay the groundwork for the possible development of an appropriate African framework for public engagement with human genome editing and calls upon all stakeholders to urgent synergistic action…"

:: In **The promise and reality of public engagement in the governance of human genome editing research,** the author analyses the approaches of five organizations/initiatives regarding public engagement [PE] noting wide variance and limited effectiveness in their practices.

:: In **Co-Creation and Engagement in a DNA Integrity Cohort Study,** the authors present a case study around "…engaging with a minoritized community [which] focused on respect, accessibility, and expanded engagement" forging a partnership which "resulted in the co-creation of recruitment and consent materials that facilitated the enrollment of 191 individuals into the study."

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SHORT LIST ABSTRACTS

A draft human pangenome reference

Article
Wen-Wei Liao, Benedict Paten, et al.
Nature, **volume 617, pages 312–324 (2023)** Open Access Published: 10 May 2023
Abstract

Here the Human Pangenome Reference Consortium presents a first draft of the human pangenome reference. The pangenome contains 47 phased, diploid assemblies from a cohort of genetically diverse individuals. These assemblies cover more than 99% of the expected sequence in each genome and are more than 99% accurate at the structural and base pair levels. Based on alignments of the assemblies, we generate a draft pangenome that captures known variants and haplotypes and reveals new alleles at structurally complex loci. We also add 119 million base pairs of euchromatic polymorphic sequences and 1,115 gene duplications relative to the existing reference GRCh38. Roughly 90 million of the additional base pairs are derived from structural variation. Using our draft pangenome to analyse short-read data reduced small variant discovery errors by 34% and increased the number of structural variants detected per haplotype by 104% compared with GRCh38-based workflows, which enabled the typing of the vast majority of structural variant alleles per sample.

A pan-African pathogen genomics data sharing platform to support disease outbreaks

Commentary

Christoffels, A., Mboowa, G., van Heusden, P. et al.

Nature Medicine volume 29, pages 1052–1055 (2023). 09 May 2023

Infectious diseases pose a considerable threat to health in Africa — a threat that is compounded by an unpredictable rise in emerging and re-emerging infections, with more than 100 disease outbreaks reported annually within the continent. In addition to the COVID-19 pandemic, Africa has grappled with three Ebola virus epidemics, a re-emergence of Marburg virus, continued antimicrobial resistance, and increased burden to health-care systems. Effective control and monitoring of these disease threats have been successfully demonstrated in high-income countries, mainly in Europe and North America, in which next-generation sequencing (NGS) analysis of pathogens has been incorporated into disease surveillance systems, allowing for timely and in-depth pathogen characterization.

In high-income countries, prompt response to disease threats is facilitated by access to a critical mass of genomics and bioinformatics expertise, amassed over time and embedded in strong collaborative networks. By contrast, fragmented surveillance systems in Africa required a multifaceted strategy to respond to COVID-19; notably, the mobilization of resources for 55 countries; the coordination of logistics to ensure timely deployment of equipment, supplies, and reagents; and the provision of training in SARS-CoV-2 analytics to detect genetic variants and understand disease transmission.

The sustained use of genomics in Africa throughout the period 2020–2022 has been widely acknowledged. Its success can be ascribed to heightened coordination among regional bodies such as the Africa Centers for Disease Control and Prevention (Africa CDC), the World Health Organization Regional Office for Africa (WHO-AFRO), the West African Health Organization (WAHO) and others.

Local expertise was harnessed through a coordinated NGS pathogen surveillance network across Africa, supported by industry partners and funding agencies. Unfortunately, the anticipated increase in NGS data has not been accompanied by adequate data management infrastructure within individual countries or across the continent. Nevertheless, the continental response to COVID-19 showed marked improvements in throughput, leading to reduced times to generate viral genome data, which was facilitated by sustained regional-led capacity building, training, and quality-assurance efforts. Evidence obtained from the African Pathogen Genomics Initiative, a project by the Africa CDC, identified data governance, including data sharing mechanisms, as a key element of a functional and real-time disease surveillance system in the continent.

How are health technology assessment bodies responding to the assessment challenges posed by cell and gene therapy?

Research

Michael Drummond, Oriana Ciani, Giulia Fornaro, Claudio Jommi, Eva Susanne Dietrich, Jaime Espin, Jean Mossman & Gerard de Pouvourville

BMC Health Services Research volume 23, Article number: 484 (2023). 13 May 2023

Open access

Abstract

Background

The aims of this research were to provide a better understanding of the specific evidence needs for assessment of clinical and cost-effectiveness of cell and gene therapies, and to explore the extent that the relevant categories of evidence are considered in health technology assessment (HTA) processes.

Methods

A targeted literature review was conducted to identify the specific categories of evidence relevant to the assessment of these therapies. Forty-six HTA reports for 9 products in 10 cell and gene therapy indications across 8 jurisdictions were analysed to determine the extent to which various items of evidence were considered.

Results

The items to which the HTA bodies reacted positively were: treatment was for a rare disease or serious condition, lack of alternative therapies, evidence indicating substantial health gains, and when alternative payment models could be agreed. The items to which they reacted negatively were: use of unvalidated surrogate endpoints, single arm trials without an adequately matched alternative therapy, inadequate reporting of adverse consequences and risks, short length of follow-up in clinical trials, extrapolating to long-term outcomes, and uncertainty around the economic estimates.

Conclusions

The consideration by HTA bodies of evidence relating to the particular features of cell and gene therapies is variable. Several suggestions are made for addressing the assessment challenges posed by these therapies. Jurisdictions conducting HTAs of these therapies can consider whether these suggestions could be incorporated within their existing approach through strengthening deliberative decision-making or performing additional analyses.

Table 1 HTA reports analyzed

	NICE (GB)	ICER (US)	CADTH (CA)	SMC (GB)	AIFA (IT)	HAS (FR)	G-BA (DE)	AEMPS (ES)
Kymriah DLBCL	X			X	X	X	X	X
Kymriah ALL	X	X			X	X	X	X
Yescarta	X	X		X	X	X	X	X
Luxturna	X	X	X	X		X	X	X
Strimvelis	X							
Imlygic	X						X	X
Alofisel	X					X	X	X
Provenge	X						X	
Glybera						X	X	
Zolgensma	X	X	X	X	X	X	X	

Key: *AEMPS* Agencia Española de Medicamentos y Productos Sanitarios, *AIFA* Agenzia Italiana del Farmaco, *ALL* acute lymphoblastic leukemia, *CADTH* Canadian Agency for Drugs and Technologies in Health, *DLBCL* diffuse large B-cell lymphoma, *G-BA* Gemeinsamer Bundesausschuss, *HAS* Haute Autorité de Santé, *ICER* Institute for Clinical and Economic Review, *NICE* National Institute for Health and Clinical Excellence, *SMC* Scottish Medicines Consortium

> ***Editor's Note:*** The 8 jurisdictions were based in the 5 largest European countries, plus the US and Canada: Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) in Spain, Agenzia Italiana del Farmaco (AIFA) in Italy, Canadian Agency for Drugs and Technologies in Health (CADTH) in Canada, Gemeinsamer Bundesausschuss (G-BA) in Germany, Haute Autorité de Santé (HAS) in France, Institute for Clinical and Economic Review (ICER) in USA, National Institute for Health and Care Excellence (NICE) in England, and Scottish Medicines Consortium (SMC) in Scotland.

Promoting equality in the governance of heritable human genome editing through Ubuntu: Reflecting on a South African public engagement study

Target Article

Bonginkosi Shozi & Donrich Thaldar
The American Journal of Bioethics, 19 May 2023
Open access
Abstract
In a recent public engagement study on heritable human genome editing (HHGE) conducted among South Africans, participants approved of using HHGE for serious health conditions—viewing it as a means of bringing about valuable social goods—and proposed that the government should actively invest resources to ensure everyone has equal access to the technology for these purposes. This position was animated by the view that future generations have a claim to these social goods, and this entitlement justified making HHGE available in the present. This claim can be ethically justified in the Ubuntu ethic (deriving from South Africa) as it (a) emphasizes the interests of the community, and (b) espouses a metaphysical conception of the community that transcends the present generation and includes past and future generations. On this basis, a compelling claim can be made on behalf of prospective persons in favor of equal access to HHGE.

Towards an appropriate African framework for public engagement with human genome editing: a call to synergistic action [version 2; peer review: 1 approved, 1 approved with reservations, 1 not approved]

Open Letter
Gerald Michael Ssebunnya
Wellcome Open Research (pre-print), 2023, 7:302. 12 May 2023
Open access
Abstract
The CRISPR-Cas9 system has revolutionised the biotechnology of human genome editing. Human germline gene editing promises exponential benefits to many in Africa and elsewhere, especially those affected by the highly prevalent monogenic disorders - for which, thanks to CRISPR, a relatively safe heritable radical therapy is a real possibility. Africa evidently presents a unique opportunity for empirical research in human germline gene editing because of its high prevalence of monogenic disorders. Critically, however, germline gene editing has raised serious ethical concerns especially because of the significant risks of inadvertent and intentional misuse of its transgenerational heritability. Calls for due prudence have become even more pronounced in the wake of the 2018 case of He Jiankui's 'CRISPR'd babies'. Meanwhile, Africa is seriously lagging in articulating its position on human genome editing. Conspicuously, there has been little to no attempt at comprehensively engaging the African public in discussions on the promises and concerns about human genome editing. Thus, the echoing key question remains as to how Africa should prudently embrace and govern this revolutionary biotechnology. In this article, therefore, I lay the groundwork for the possible development of an appropriate African framework for public engagement with human genome editing and call upon all stakeholders to urgent synergistic action. I particularly highlight the World Health Organisation's possible leadership role in promptly establishing the requisite expert working group for this urgent need.

> ***Editor's note:*** Amendments from Version 1, which was published in our March 2023 edition. With regard to the revision above the author notes:
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> "…In the revised version of my open letter, I have made some significant clarifications. I have specified the serious ethical concerns about heritable human genome editing and highlighted the current global consensus on its prohibition at its current level of advancement. I have noted, however, CRISPR's rapidly evolving safety profile and its potential benefits, particularly in the therapeutic management of sickle cell disease. I have clarified the urgent need for authentic African public engagement with human genome editing - Africa's resource-limited setting and competing priorities notwithstanding - highlighting the invaluable potential contribution of Africa's unique genomic diversity to global human genomics. I have also specified the nature and composition of the desirable African Framework for Public Engagement with the Human Genome Editing Working

Group. Effectively, I have given a more realistic and balanced view of the urgent need for African public engagement with human genome editing and, hence, the call to synergistic action…"

The promise and reality of public engagement in the governance of human genome editing research

Target Article
John M. Conley, et al.
Published online: 19 May 2023
The American Journal of Bioethics, 19 May 2023
Abstract
This paper analyses the activities of five organizations shaping the debate over the global governance of genome editing in order to assess current approaches to public engagement (PE). We compare the recommendations of each group with its own practices. All recommend broad engagement with the general public, but their practices vary from expert-driven models dominated by scientists, experts, and civil society groups to citizen deliberation-driven models that feature bidirectional consultation with local citizens, as well as hybrid models that combine elements of both approaches. Only one group practices PE that seeks community perspectives to advance equity. In most cases, PE does little more than record already well-known views held by the most vocal groups, and thus is unlikely to produce more just or equitable processes or policy outcomes. Our exploration of the strengths, weaknesses, and possibilities of current forms of PE suggests a need to rethink both "public" and "engagement."

> ***Editor's Note:*** The five "organizations" referenced in the abstract are: ARRIGE (Association for Responsible Research and Innovation in Genome Editing; National Academies of Science, Engineering and Medicine (US)-Royal Society (UK), International Commission on the Clinical Use of Human Germline Genome Editing (International Commission); The World Health Organization (WHO) Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing; European Group on Ethics in Science and New Technologies (EGE); Global Citizens' Assembly on Genome Editing (GCA).

Co-Creation and Engagement in a DNA integrity Cohort Study

Research Article
L. Lynette Parker, Chantel M. Bonner, Robert W. Sobol and Martha I. Arrieta
Journal of Clinical and Translational Science 7: e122, 1–8. 22 May 2023
Abstract
Introduction
The partnership between a research community engagement team (CE Team) and a community advisory board (CAB) formed the basis for bidirectional communication in developing resources for participant recruitment in a DNA integrity study. Engaging with a minoritized community, this partnership focused on respect, accessibility, and expanded engagement.
Methods
A ten-member CAB, working in two groups defined by meeting time convenience, provided insight and feedback to the CE Team in the creation of recruitment and consent materials, via an iterative design process in which one CAB group reviewed and enhanced materials, and the second group tested and refined them further. The continuous analysis of CE Team notes from CAB meetings captured information needed both for materials refinement and implementation of CAB-suggested activities.
Results
The partnership resulted in the co-creation of recruitment and consent materials that facilitated the enrollment of 191 individuals into the study. The CAB encouraged and assisted in expanded engagement inclusive of community leaders. This broader engagement provided information about the DNA integrity

study to community decision-makers as well as responded to questions and concerns about the research. The bidirectional communication between the CAB and the CE Team encouraged the researchers to consider topics and research interests related to the current study but also responsive to community concerns.
Conclusions
The CAB helped the CE Team develop a better understanding of the language of partnership and respect. In this way, the partnership opened doors for expanded community engagement and effective communication with potential study participants.

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SPECIAL ISSUE: *SOUTH AFRICAN JOURNAL OF SCIENCE* – BIG DATA AND AI IN HEALTH SCIENCES RESEARCH IN SUB-SAHARAN AFRICA

Exploring perspectives of research ethics committee members on the governance of big data in sub-Saharan Africa

Research Article
Nezerith Cengiz, Siti M. Kabanda, Tonya M. Esterhuizen, Keymanthri Moodley
South African Journal of Science, 119(5/6). 30 May 2023
Abstract
Interest in the governance of big data is growing exponentially. However, finding the right balance between making large volumes of data accessible, safeguarding privacy, preventing data misuse, determining authorship and protecting intellectual property remain challenging. In sub-Saharan Africa (SSA), research ethics committees (RECs) play an important role in reviewing data-intense research protocols. However, this regulatory role must be embedded in a context of robust governance. There is currently a paucity of published literature on how big data are regulated in SSA and if the capacity to review protocols is sufficient. The aim of this study was to provide a broad overview of REC members' awareness and perceptions of big data governance in SSA. A descriptive cross-sectional survey was conducted from April to July 2022. We invited 300 REC members to participate in our online survey via Research Electronic Data Capture (REDCap). A total of 140 REC members, representing 34 SSA countries, completed the online survey. Awareness of data governance laws, policies and guidelines was variable across the subcontinent. A quarter of respondents (25%) indicated that national regulations on the transborder flow of research data are inadequate. Institutional policies on research data protection were also regarded as being inadequate. Most respondents (64%) believed that they lacked experience in reviewing data-intense protocols. Data governance and regulation in SSA need to be strengthened at both national and institutional levels. There is a strong need for capacity development in the review of data-intense research protocols on the subcontinent.
Significance
This is the first empirical survey in SSA in which awareness and perspectives of REC members have been explored specifically relating to the review of data-intense research protocols. Big data have raised new ethics and legal challenges, and this survey provides a broad overview of these challenges in SSA. Our study confirms that knowledge and awareness of legislative frameworks and ethics guidance in SSA vary considerably where big data are concerned. The research results could be useful for a range of stakeholders, including RECs, data scientists, researchers, research and academic institutions, government decision makers and artificial intelligence (AI) coders.

Data sharing and data governance in sub-Saharan Africa: Perspectives from researchers and scientists engaged in data-intensive research

Research Article
Siti M. Kabanda, Nezerith Cengiz, Kanshukan Rajaratnam, Bruce W. Watson, Qunita Brown, Tonya M. Esterhuizen, Keymanthri Moodley

South African Journal of Science, 119(5/6). 30 May 2023
Abstract

The data ecosystem is complex and involves multiple stakeholders. Researchers and scientists engaging in data-intensive research collect, analyse, store, manage and share large volumes of data. Consequently, capturing researchers' and scientists' views from multidisciplinary fields on data use, sharing and governance adds an important African perspective to emerging debates.

We conducted a descriptive cross-sectional survey and received 160 responses from researchers and scientists representing 43 sub-Saharan African countries. Whilst most respondents were satisfied with institutional data storage processes, 40% indicated that their organisations or institutions did not have a formally established process for storing data beyond the life cycle of the project. Willingness to share data was generally high, but increased when data privacy was ensured.

Robust governance frameworks increased the willingness to share, as did the regulation of access to data on shared platforms. Incentivising data sharing remains controversial. Respondents were satisfied with exchanging their data for co-authorship on publications (89.4%) and collaboration on projects (77.6%). However, respondents were split almost equally in terms of sharing their data for commercial gain. Regarding the process of managing data, 40.6% indicated that their organisations do not provide training on best practices for data management. This could be related to a lack of resources, chronic institutional under-investment, and suboptimal research training and mentorship in sub-Saharan Africa. The sustainability of data sharing may require ethical incentive structures to further encourage researchers and scientists. Tangible infrastructure to facilitate such sharing is a prerequisite. Capacity development in data governance for researchers and scientists is sorely needed.

Significance

Data sharing is necessary to advance science, yet there are many constraints. In this study, we explored factors that promote a willingness to share, as well as constraining factors. Seeking potential solutions to improve data sharing is a scientific and ethical imperative. The standardisation of basic data sharing and data transfer agreements, and the development of a Data Access Committee will strengthen data governance and facilitate responsible data sharing in sub-Saharan Africa. Funders, institutions, researchers and scientists ought to jointly contribute to fair and equitable data use and sharing during and beyond the life cycle of research projects.

Regulating scientific and technological uncertainty: The precautionary principle in the context of human genomics and AI

Research Article

Marietjie Botes

South African Journal of Science, 119(5/6). 30 May 2023

Abstract

Considered in isolation, the ethical and societal challenges posed by genomics and artificial intelligence (AI) are profound and include issues relating to autonomy, privacy, equality, bias, discrimination, and the abuse of power, amongst others. When these two technologies are combined, the ethical, legal and societal issues increase substantially, become much more complex, and can be scaled enormously, which increases the impact. Adding to these complexities, both genomics and AI-enabled technologies are rife with scientific and technological uncertainties, which makes the regulation of these technologies not only challenging in itself, but also creates legal uncertainties. In science, the precautionary principle has been used globally to govern uncertainty, with the specific aim to prevent irreversible harm to human beings. The regulation of uncertainties in AI-enabled technologies is based on risk as set out in the AI Regulation that was recently proposed by the European Commission. However, when genomics and artificial intelligence are combined, not only do uncertainties double, but the current regulation of such uncertainties towards the safe use thereof for humans seems contradictory, considering the different approaches followed by science and technology in this regard. In this article, I explore the regulation of both scientific and technological uncertainties and argue that the application of the precautionary principle in the context of human genomics

and AI seems to be the most effective way to regulate the uncertainties brought about by the combination of these two technologies.

Significance

The significance of this article rests in the criteria framework proposed for the determination of the applicability of the precautionary principle and lessons learnt from the European Union's attempt to regulate artificial intelligence.

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GENOMIC DATA, BIOBANKING, GENOMIC RESEARCH

Genetic and Genomic Researchers' Perspectives on Biological Sample Sharing in Collaborative Research in Uganda: A Qualitative Study

Research Article

David Kaawa-Mafigiri, Deborah Ekusai Sebatta, Ian Munabi, and Erisa Sabakaki Mwaka

Journal of Empirical Research on Human Research Ethics, 07 May 2023

Abstract

Numerous ethical, legal, and social issues arise with biological sample sharing. The study explored the perspectives of genetic and genomic researchers on the sharing of biological samples in international collaborative research. Qualitative in-depth interviews were conducted with 15 researchers. Participants expressed positive attitudes towards biobanking and appreciated the benefits of cross-border sharing of biological samples but noted that this practice had adversely affected local capacity building efforts. There was limited understanding of the ethical and regulatory frameworks governing sample sharing. Researchers emphasized the importance of respecting cultural values in biobanking research. Issues concerning poor governance and inequitable benefit sharing were also raised. There is a need for fair and equitable international collaborations where all researchers are treated with respect and as equal partners.

Mothers' views on the storage and usage of their children's biological material under the Danish biobanking model. A narrative approach using epistemic injustice

Themed Section

Anne Wettergren Karlsson, Helle Holm Lundsgaard, Astrid Janssens

Value in Health, 13 May 2023

Open access

Abstract

Objectives

To investigate the knowledge and attitudes of mothers living in Denmark on the storage and usage of their children's biological material. The Danish Neonatal Screening Biobank contains blood from the Phenylketonuria-screening test. Legal, ethical, and moral concerns have been raised in several countries of how consent is obtained best in pediatric biobank governance. Research on knowledge and attitudes of Danish parents on the usage of their children's biological material is scarce.

Methods

A coproduced study between a mother and 2 researchers. We analyzed 5 online focus group interviews using Ricoeur's hermeneutical narrative analysis.

Results

Mothers have very little knowledge on the storage and usage of their children's biological material. They consider the Phenylketonuria-screening test to be part of a birth package, which leaves very little option of choice. They accept donating the material as a token of appreciation in an act of altruism toward the wider society but are only comfortable supporting Danish research.

Conclusions

An exploration of the communal narrative build in the interviews reveal an overall feeling of duty to help benefit society, an overwhelming trust toward the health system, and epistemic unjust storage information practices.

Returning Individual Research Results from Digital Phenotyping in Psychiatry

Target Article

Francis X. Shen, Matthew L. Baum, Nicole Martinez-Martin, …., Jason L. Vassy, Justin T. Baker, Barbara E. Bierer & Benjamin C. Silverman

The American Journal of Bioethics, 08 May 2023

Open access

Abstract

Psychiatry is rapidly adopting digital phenotyping and artificial intelligence/machine learning tools to study mental illness based on tracking participants' locations, online activity, phone and text message usage, heart rate, sleep, physical activity, and more. Existing ethical frameworks for return of individual research results (IRRs) are inadequate to guide researchers for when, if, and how to return this unprecedented number of potentially sensitive results about each participant's real-world behavior. To address this gap, we convened an interdisciplinary expert working group, supported by a National Institute of Mental Health grant. Building on established guidelines and the emerging norm of returning results in participant-centered research, we present a novel framework specific to the ethical, legal, and social implications of returning IRRs in digital phenotyping research. Our framework offers researchers, clinicians, and Institutional Review Boards (IRBs) urgently needed guidance, and the principles developed here in the context of psychiatry will be readily adaptable to other therapeutic areas.

Ethical and governance considerations for genomic data sharing in the development of medical technologies for melanoma-The iToBoS Project.

Article

Robin Renwick & Niamh Aspell

International Conference on Computer Ethics Vol 1 (1): Philosophical Enquiry (CEPE) 2023, Chicago, IL, 10 May 2023

Abstract

Balancing the risks and benefits of using genomics data in health service provision is a complex task. Social, ethical, and legal considerations are nuanced, often complicated by the fact that regulations lag behind rapid pace of technological development. Ethical considerations such as autonomy, beneficence, and non-maleficence are weighed against (and within) complex concepts such as privacy, security, safety, and proportionality. This paper will discuss European H2020 funded project IToBoS, in which an AI diagnostic platform for the 1 early detection of melanoma is being developed. Assuring the project's solutions are produced in an ethically and socially responsible manner, with regulatory compliance at their core, is one of the project's primary goals. This paper will communicate the existing tensions within the health sector, including between the European Commission's desire for open-data – governed through its proposed Digital Strategy and practically achieved through the creation of a European Health Data Space – and the risks inherent with the generalised sharing of 2 genomics (and other health related) data.

Australian public perspectives on genomic data governance: responsibility, regulation, and logistical considerations

Article

Fiona Lynch, Yan Meng, Stephanie Best, Ilias Goranitis, Julian Savulescu, Christopher Gyngell & Danya F. Vears

European Journal of Human Genetics (2023), 10 May 2023

Abstract

Genomic sequencing generates huge volumes of data, which may be collected or donated to form large genomic databases. Such information can be stored for future use, either for the data donor themselves or by researchers to help improve our understanding of the genetic basis of disease. Creating datasets of this magnitude and diversity is only possible if patients, their families, and members of the public worldwide share their data. However, there is no consensus on the best technical approach to data sharing that also minimizes risks to individuals and exploration of stakeholders' views on aspects of genomic data governance models—the ways genomic data is stored, managed, shared and used—has been minimal.

To address this need, we conducted focus groups with 39 members of the Australian public exploring their views and preferences for different aspects of genomic data governance models. We found that consent and control were essential to participants, as they wanted the option to choose who had access to their data and for what purposes. Critically, participants wanted a trustworthy body to enforce regulation of data storage, sharing and usage. While participants recognized the importance of data accessibility, they also expressed a strong desire for data security.

Finally, financial responsibility for data storage raised concerns for inequity as well as organizations and individuals using data in ethically contentious ways to generate profit. Our findings highlight some of the trade-offs that need to be considered in the development of genomic data governance systems.

Who Will Own Our Global Digital Twin: The Power of Genetic and Biographic Information to Shape Our Lives

Chapter

Sarah Pilz, Talea Hellweg, Christian Harteis, Ulrich Rückert & Martin Schneider

The Digital Twin of Humans, pp 11–35, Springer, 17 May 2023

Abstract

Today, it is possible to collect and connect large amounts of digital data from various sources and life domains. This chapter examines the potential and the risks of this development from an interdisciplinary perspective. It defines the 'global digital twin' of a human being as the sum of all digitally stored information and predictive knowledge about a person. It points out that, compared to the digital twin of a machine, the human global digital twin is far more complex because it comprises the genetic code and the biographic code of a person.

The genetic code contains not only a simple 'construction plan' but also hereditary information, in a form that is difficult to read. The biographic code contains all other information that can be assembled about a person, which is obtained via data from cameras, microphones, or other sensors, as well as general personal information. When the growing wealth of information concerning the genetic code and the biographical code is properly utilised, insights from biology and the behavioural sciences may be used to predict personal events such as health problems, job resignations, or even crimes. Because our own interests and those of private firms are partly in conflict over the use of this powerful knowledge, it is still unclear whether the global digital twins of humans will become a liberating or disciplining force for citizens.

On the one hand, human beings are not machines: They are aware of their digital twin and therefore are able to influence it throughout their lives. Because of their free will, human beings are in general difficult to predict. Dystopias of full control over individual behaviour are therefore unlikely to materialise. On the other hand, private firms are beginning to take advantage of the available digital twins of humans by monopolising data access and by commercialising predictive knowledge.

This is problematic because, unlike machines, human beings cannot only benefit from but also suffer due to their digital twins as they attempt to shape their own lives. We illustrate these issues with some examples and arrive at two conclusions: It is in the public interest for people to be granted more property rights over their personal global digital twins, and publicly funded research needs to become more interdisciplinary, much like private firms that have already begun to perform interdisciplinary research.

Addressing the ethical and societal challenges posed by genome-wide association studies of behavioral and brain-related traits

Perspective

Matthieu C. de Hemptinne & Danielle Posthuma

Nature Neuroscience (2023), 22 May 2023

Abstract

Genome-wide association studies have led to the identification of robust statistical associations of genetic variants with numerous brain-related traits, including neurological and psychiatric conditions, and psychological and behavioral measures. These results may provide insight into the biology underlying these traits and may facilitate clinically useful predictions. However, these results also carry the risk of harm, including possible negative effects of inaccurate predictions, violations of privacy, stigma and genomic discrimination, raising serious ethical and legal implications. Here, we discuss ethical concerns surrounding the results of genome-wide association studies for individuals, society and researchers. Given the success of genome-wide association studies and the increasing availability of nonclinical genomic prediction technologies, better laws and guidelines are urgently needed to regulate the storage, processing and responsible use of genetic data. Also, researchers should be aware of possible misuse of their results, and we provide guidance to help avoid such negative impacts on individuals and society.

Get this thing out of my body! Factors determining consent for translational oncology research: qualitative research

Research

Després Caroline & Mamzer Marie-France

Journal of Translational Medicine volume 21, Article number: 336 (2023), 21 May 2023

Open access

Abstract

Background

Depending on the needs of scientific research at a given time, biobanks make biological samples and data available to researchers. In this article, we aim to describe the reasons and underlying logic that determine the decision to grant or deny consent to the conservation of tumour samples in a biological resource platform for research purposes. We make use of the CARPEM biological resource platform model, where broad consent is required.

Methods

The results are based on semi-structured interviews, conducted between 2019 and 2021, with 25 individuals having various profiles.

Results

All the people interviewed readily accepted the principle of conserving a tumour sample for research purposes. They explained their decision by citing the desire to participate in research dedicated to improving therapeutic medicine. Their trust in research institutions or in doctors was an important factor in their consent. The tumorous nature of the samples also played an important role, as did the absence of constraints. Finally, the high level of consent was also based on the difficulty they had in conceiving what the future risks might be once the sample had been taken, whereas the fact that they did not know the nature or purpose of the research to be carried out when they signed the consent form posed some problems. These results stem from a lack of a culture of ethics among the people interviewed.

Conclusion

The information provided in the context of consent at the CARPEM tumor bank seems inadequate for consent to be considered 'informed', given the low level of knowledge that people have of the risks and issues. Information is missing even though we feel it would not change consent or only marginally. This raises questions, since part of the act of granting consent is based on the implicit trust French people have in the hospital that collects the data and in research practices in general. In the minds of those who participate, transparency is the ground on which trust rests. Lack of transparency could be deleterious for future research

practices. However, it is not by striving to improve information leaflets that the consent-related information will improve but, rather, by more effectively helping future patients to assimilate that information.

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GOVERNANCE AND REGULATION: HUMAN CLONING AND GENE-EDITING TECHNOLOGIES

Regulating Human Germline Editing

Opinion
Veronica Orbecchi
King's Think Tank, 4 April 2023
Current policy landscape for germline editing
Despite the numerous potential healthcare benefits of gene editing, it is important that public policy takes into account the practical and moral drawbacks of these tools in order to appropriately regulate the use of CRISPR-Cas9. Compared to policies for somatic gene editing, regulations on germline editing are far more restrictive. A comprehensive survey of 96 countries found that none explicitly permitted germline editing on embryos meant for reproduction, and that 70 out of 75 countries with relevant policy documents explicitly prohibited germline editing, with 5 countries allowing minor exceptions. However, several countries permit gene editing on embryos purely for research purposes, where embryos will not be successively used for pregnancy. Beyond outright prohibition, other regulatory approaches that significantly affect the development and use of gene editing technologies include the extent to which research on these practices is funded.
Considerations relevant to human germline editing policy
The tendency for restrictive policies towards germline editing reflect a cautious approach that is being taken because of a variety of ethical and practical concerns related to gene editing. In this regard, in a 2018 report, the Nuffield Council on Bioethics highlights the value of procreative freedom, emphasizing the value of germline gene editing to allow healthy procreation from carriers of genetic diseases. Still, two ethical principles are highlighted: safety and social justice (Nuffield Council on Bioethics, 2018).
Safety: One important question for public policy is how to deal with uncertainty and risk. While CRISPR-Cas9 is undeniably more precise and safer compared to previous gene editing technologies, many still do not deem it sufficiently precise to be used on human embryos for reproduction. For instance, off-target effects are possible. These are unintended alterations in locations of the genome other than the targeted mutation. Since these off-target alterations may lead to unknown irreversible effects on the edited embryos, it is argued that germline gene editing would create unacceptable risks for the unborn individual. For example, in the USA, the National Institutes of Health (NIH) made the decision to not provide funding for human gene editing technologies on the basis that the concept of human germline editing raises "serious and unquantifiable safety issues" (NIH, 2015). Still, although the potential risks of CRISPR may warrant a restrictive regulatory approach with regards to the actual utilization of this tool for germline editing, the issue of safety also speaks in favor for the encouragement of research on embryos that will not be used for reproduction. Current bans of germline editing for reproduction would thereby be seen as temporary prohibitions until the practice is deemed sufficiently safe. Moreover, in order for safety to be a viable argument in favor of prohibition, it must also be the case that the risks involved in making genetic alterations to embryos to prevent genetic diseases are greater than the risks of the genetic diseases themselves.
Social inequality: Even if germline gene therapy were considered fully safe to use, proper regulation would have to ensure that there is equitable access to it, in order to avoid exacerbating social inequality. Indeed, inequitable access to gene editing might lead to a situation where only the wealthy are able to prevent certain genetic disorders. This Again, rather than justifying permanent prohibition, this concern elicits the need for policies which attempt to circumvent issues of social inequality.
Other considerations: Other common considerations include worries about germline editing on healthy embryos for non-therapeutic purposes— purely to select particular features. While some believe that

germline gene therapy may only be morally acceptable for therapeutic purposes, the distinction between therapy and enhancement is arbitrary and difficult to discern. Moreover, certain religious groups seek to protect the moral status of an embryo, leading to restrictive approaches to research on germline editing (NIH, 2017). Due to the controversial nature of the issue of human germline editing, it is important that public policy simultaneously appreciate the potential social benefits of these techniques while remaining mindful of their risks and ethical permissibility.

> ***Editor's Note:*** King's Think Tank is the largest student-led policy institute in Europe which aims to provide a platform for students to engage with the world of policy. Website: https://kings-think-tank.com

Health Ethics & Governance at WHO: The importance of the Global Summit of National Ethics Committees

Chapter

Patrik Hummel, Katherine Littler, Andreas Reis

The Kaleidoscope of Global Bioethics, pp 211-220, May 2023, Conselho Nacional de Ética para as Ciências da Vida (CNECV) {Editors: Maria do Céu Patrão Neves}

…WHO's 13th Program of Work (2019-2023) is an ambitious program (World Health Organization, 2019). It defines a set of interconnected strategic priorities, ensuring healthy lives and promote well-being for all. In particular, it formulates the triple goals of the "three billions": One billion more people better protected from health emergencies, one billion more people enjoying better health, and one billion more people benefitting from universal health coverage. One of WHO's six core functions is to "articulate ethical and evidence-based policy options" and it declares that "WHO will work to ensure that all policies, public health interventions and research are grounded in ethics" (World Health Organization, 2019).

Particular importance is given to ethical issues in new and emerging scientific disciplines and Universal Health Coverage, where both the opportunities and risks to global health are noted. WHO's Member States recognize that it is crucial to proactively address ethical issues to ensure that Universal Health Coverage is enhanced and not undermined by novel technologies: "WHO's normative guidance will be informed by developments at the frontier of new scientific disciplines such as genomics, epigenetics, gene editing, artificial intelligence, and big data, all of which pose transformational opportunities but also risks to global health" (World Health Organization, 2019).

Thus, WHO's Member States recognize the Organization's key function to ensure that new technologies will benefit everyone, and not further exacerbate existing inequities. "WHO is uniquely positioned to understand and tackle proactively the ethical, regulatory, professional and economic implications and to provide independent guidance with universal legitimacy to ensure that UHC is enhanced and not undermined by new scientific frontiers." This has been a strong mandate for WHO's Health Ethics and Governance Unit to undertake work on the ethical aspects of new technologies, for example in the areas of human genome editing and artificial intelligence for health.

> ***Editor's Note:*** This chapter is part of the publication that was developed following the 13th Global Summit of National Ethics Committees which took place in Lisbon in September 2022, jointly organised by the Portuguese National Council of Ethics for the Life Sciences and the World Health Organisation, in close collaboration with UNESCO, under the theme "Health Justice: Health Care 4 All".

Ethical choreography in China's Human Gene Editing controversy

Research Article

Larry AU

Science as Culture, 31 May 2023

Abstract
He Jiankui announced to the world in November 2018 that his team had genetically edited twin human embryos that were then brought to term. Recruiting participants through an HIV outreach group and using CRISPR/Cas9 technology, He targeted the CCR5 genes claiming this would make the children immune to HIV. One way to understand He's case is through Charis Thompson's concept of *ethical choreography*, which shows how scientists 'invent around' potential ethical objections to their work. In particular, such a focus on ethical choreography traces how individual scientists can exploit ambiguity in institutional boundaries to recombine different logics to advance their vision of good, innovative, and ethical science. He's actions can be seen to be the result of his traversal of blurred boundaries that demarcate science/market and science/medicine in order to recombine academic, market, medical, and cultural logics. This combination of logics is seen in ethical justifications that He put forth for his experiment, which provoked much criticism and controversy, but should nonetheless be taken seriously and placed in context. While He's vision of good science was rejected, examples of ethical choreography can be found in other instances of biomedical innovation and there remains the potential for other scientists to pick up where He left off. Following the ethical choreography of scientists also allows for more specificity in discussions about what and when boundaries should be strengthened or relaxed in order to advance a more equitable vision of science and technology.

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GENE-EDITING TECHNOLOGIES: EQUITY AND COMMUNITY ENGAGEMENT

Translating Precision Health for Pediatrics: A Scoping Review

Review
Mathushan Subasri, Celine Cressman, Danielle Arje, Leighton Schreyer, Erin Cooper, Komal Patel, Wendy J. Ungar, Melanie Barwick, Avram Denburg and Robin Z. Hayeems
Children 2023, 10(5), 897, 17 May 2023
Abstract
Precision health aims to personalize treatment and prevention strategies based on individual genetic differences. While it has significantly improved healthcare for specific patient groups, broader translation faces challenges with evidence development, evidence appraisal, and implementation. These challenges are compounded in child health as existing methods fail to incorporate the physiology and socio-biology unique to childhood. This scoping review synthesizes the existing literature on evidence development, appraisal, prioritization, and implementation of precision child health. PubMed, Scopus, Web of Science, and Embase were searched. The included articles were related to pediatrics, precision health, and the translational pathway. Articles were excluded if they were too narrow in scope. In total, 74 articles identified challenges and solutions for putting pediatric precision health interventions into practice. The literature reinforced the unique attributes of children and their implications for study design and identified major themes for the value assessment of precision health interventions for children, including clinical benefit, cost-effectiveness, stakeholder values and preferences, and ethics and equity. Tackling these identified challenges will require developing international data networks and guidelines, re-thinking methods for value assessment, and broadening stakeholder support for the effective implementation of precision health within healthcare organizations. This research was funded by the SickKids Precision Child Health Catalyst Grant.

CRISPR in Public Health: The Health Equity Implications and Role of Community in Gene-Editing Research and Applications

Analytic essay
Andrew M. Subica,
American Journal of Public Health, 18 May 2023

Abstract
CRISPR (clustered regularly interspaced short palindromic repeats) is a Nobel Prize–winning technology that holds significant promise for revolutionizing the prevention and treatment of human disease through gene editing. However, CRISPR's public health implications remain relatively uncertain and underdiscussed because (1) targeting genetic factors alone will have limited influence on population health, and (2) minority populations (racial/ethnic, sexual and gender)—who bear the nation's greatest health burdens—historically suffer unequal benefits from emerging health care innovations and tools. This article introduces CRISPR and its potential public health benefits (e.g., improving virus surveillance, curing genetic diseases that pose public health problems such as sickle cell anemia) while outlining several major ethical and practical threats to health equity. This includes minorities' grave underrepresentation in genomics research, which may lead to less effective and accepted CRISPR tools and therapies for these groups, and their anticipated unequal access to these tools and therapies in health care. Informed by the principles of fairness, justice, and equitable access, ensuring gene editing promotes rather than diminishes health equity will require the meaningful centering and engagement of minority patients and populations in gene-editing research using community-based participatory research approaches.

A survey of experts on personalized medicine landscape in European Union and China

Research Article
Ilda Hoxhaj, Flavia Beccia, Alisha Morsella, Chiara Cadeddu, Walter Ricciardi & Stefania Boccia
BMC Health Services Research volume 23, Article number: 517 (2023), 23 May 2023
Abstract
Introduction
Personalized Medicine (PM) is one of the main priorities of the research agenda of the European Commission and the focus of the European Coordination and Support Action titled "Integrating China into the International Consortium for Personalized Medicine" (IC2PerMed). Similar to the European focus, PM is a current priority of the Chinese Government, through dedicated policies and its five-year investment plans. In the context of IC2PerMed, we implemented a survey to understand the state of the art of the implementation of PM related policies in EU and China, and to identify opportunities for future Sino-European collaborations.
Methods
The survey was elaborated by the IC2PerMed consortium and validated by a focus group of experts. The final version, in English and Chinese, was administered online to a pool of accurately selected experts. Participation was anonymous and voluntary. The survey consists of 19 questions in 3 sections: (1) personal information; (2) policy in PM; (3) facilitating and hindering factors for Sino-European collaboration in PM.
Results
Forty-seven experts completed the survey, 27 from Europe and 20 from China. Only four participants were aware of the implementation of PM-related policies in their working country. Expert reported that PM areas with greatest policy impact so far were: Big Data and digital solutions; citizen and patient literacy; and translational research. The main obstacles found were the lack of shared investment strategies and the limited application of scientific developments in clinical practice. Aligning European and Chinese efforts, finding common ground across cultural, social, and language barriers, were considered as actions needed to enhance efforts in applying PM strategies internationally.
Conclusion
To achieve efficiency and sustainability of health systems, it remains crucial to transform PM into an opportunity for all citizens and patients with the commitment of all the stakeholders involved. The results obtained aim to help define common research and development approaches, standards and priorities and increase collaboration at international level, as well as provide key solutions to enable convergence towards a common PM research, innovation, development and implementation approach between Europe and China.

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GENETIC TESTING/ GENETIC SCREENING

In this section we have included three (3) articles from Australia (2) and New Zealand (1) , focusing on genetic discrimination and insurance policies;

Community concerns about genetic discrimination in life insurance persist in Australia: A survey of consumers offered genetic testing

Article

Jane Tiller, Andrew Bakshi, Grace Dowling, Louise Keogh, Aideen McInerney-Leo, Kristine Barlow-Stewart, Tiffany Boughtwood, Penny Gleeson, Martin B. Delatycki, Ingrid Winship, Margaret Otlowski & Paul Lacaze

European Journal of Human Genetics (2023), 11 May 2023

Open access

Abstract

Fears of genetic discrimination in life insurance continue to deter some Australians from genetic testing. In July 2019, the life insurance industry introduced a partial, self-regulated moratorium restricting the use of genetic results in underwriting, applicable to policies up to certain limits (e.g. AUD$500,000 for death cover). We administered an online survey to consumers who had taken, or been offered, clinical genetic testing for adult-onset conditions, to gather views and experiences about the moratorium and the use of genetic results in life insurance, including its regulation.

Most respondents (*n* = 367) had undertaken a genetic test (89%) and had a positive test result (76%; *n* = 243/321). Almost 30% (*n* = 94/326) reported testing after 1 July 2019. Relatively few respondents reported knowing about the moratorium (16%; *n* = 54/340) or that use of genetic results in life insurance underwriting is legal (17%; *n* = 60/348). Only 4% (*n* = 14/350) consider this practice should be allowed. Some respondents reported ongoing difficulties accessing life insurance products, even after the moratorium. Further, discrimination concerns continue to affect some consumers' decision-making about having clinical testing and applying for life insurance products, despite the Moratorium being in place. Most respondents (88%; *n* = 298/340) support the introduction of legislation by the Australian government to regulate this issue.

Despite the introduction of a partial moratorium in Australia, fears of genetic discrimination persist, and continue to deter people from genetic testing. Consumers overwhelmingly consider life insurers should not be allowed to use genetic results in underwriting, and that federal legislation is required to regulate this area.

Human Genetics Society of Australasia Position Statement: Genetic Testing and Personal Insurance Products in Australia

Article

Aideen M. McInerney-Leo, Samantha Ayres, Jackie Boyle, Chris Jacobs, Ainsley J. Newson and on behalf of the Education, Ethics and Social Issues Committee of the Human Genetics Society of Australasia

Twin Research and Human Genetics (2023), 1–4. 25 May 2023

Open access

Abstract

The expansion of genetic and genomic testing in clinical practice and research, and the growing market for direct-to-consumer genomic testing has led to increased awareness about the impact of this form of testing on insurance. Genetic or genomic information can be requested by providers of mutually rated insurance products, who may then use it when setting premiums or determining eligibility for cover under a particular product. Australian insurers are subject to relevant legislation and an industry led standard that was updated in 2019 to introduce a moratorium on the use of genetic test results in life insurance underwriting for policies.

Genetic discrimination by insurance companies in Aotearoa New Zealand: experiences and views of health professionals

Article

Harry Fraser, Kimberley Gamet, Sally Jackson, Andrew Neil Shelling, Paul Lacaze, Jane Tiller

The New Zealand Medical Journal (Online); Christchurch Vol. 136, Issue. 1574, (Apr 28, 2023): 32-52.

Abstract

Aims

Genetic discrimination in insurance is a significant clinical, research and consumer issue. Recently, the Australian life insurance industry introduced a partial moratorium on the use of genetic test results. However, in Aotearoa New Zealand, both life and health insurers can still use genetic results legally to discriminate against applicants. We aimed to document experiences and concerns of New Zealand-based health professionals (HPs) around the potential misuse of genetic test results for insurance purposes.

Methods

We administered an online survey to New Zealand HPs who discuss genetic testing with patients, their experiences regarding the use of genetic test results in insurance and views on regulation.

Results

Twenty-three New Zealand HPs responded, 15 of whom worked in genetics clinics, representing >60% of the total New Zealand clinical genetics workforce. Eleven respondents reported having patients who experienced adverse outcomes related to insurance based on genetic results. Respondents reported patients sometimes/often delayed (n=11) or refused (n=4) genetic testing due to insurance concerns. Over 80% of those who answered (n=17/21) believe insurers' use of genetic results should be legally regulated.

Conclusion

New Zealand HPs have concerns about insurance companies using genetic test results in underwriting, including the effect on patients, and strongly believe government legislation is required.

Preimplantation genetic testing for embryos predisposed to hereditary cancer: Possibilities and challenges

Review Article

Mohammed H. Albujja, Maher Al-Ghedan, Lakshmidevi Dakshnamoorthy, Josep Pla Victori

Cancer Pathogenesis and Therapy, 16 May 2023

Abstract

Preimplantation genetic testing (PGT), which was developed as an alternative to prenatal genetic testing, allows couples to avoid pregnancies with abnormal chromosomes and the subsequent termination of the affected fetus. Originally used for early onset monogenic conditions, PGT is now used to prevent various types of inherited cancer conditions based on the development of PGT technology, assisted reproductive techniques (ARTs), and *in vitro* fertilization (IVF).

This review provides insights into the potential benefits and challenges associated with the application of PGT for hereditary cancer and provides an overview of the existing literature on this test, with a particular focus on the current challenges related to laws, ethics, counseling, and technology. Additionally, this review predicts the future potential applications of this method. Although PGT may be utilized to predict and prevent hereditary cancer, each case should be comprehensively evaluated.

The motives of couples must be assessed to prevent the misuse of this technique for eugenic purposes, and non-pathogenic phenotypes must be carefully evaluated. Pathological cases that require this technology should also be carefully considered based on legal and ethical reasoning. PGT may be the preferred treatment for hereditary cancer cases; however, such cases require careful case-by-case evaluations. Therefore, this study concludes that multidisciplinary counseling and support for patients and their families are essential to ensure that PGT is a viable option that meets all legal and ethical concerns.

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PLANTS, CROPS, AGRICULTURE, ANIMALS

Identifying public trust building priorities of gene editing in agriculture and food

Article

Christopher Cummings, Theresa Selfa, Sonja Lindberg & Carmen Bain

Agriculture and Human Values (2023), 17 May 2023

Abstract

Gene editing in agriculture and food (GEAF) is a nascent development with few products and is unfamiliar among the wider US public. GEAF has garnered significant praise for its potential to solve for a variety of agronomic problems but has also evoked controversy regarding safety and ethical standards of development and application. Given the wake of other agribiotechnology debates including GMOs (genetically modified organisms), this study made use of 36 in-depth key interviews to build the first U.S. based typology of proponent and critic priorities for shaping public trust in GEAF actors and objects. Key organizational actors provide early and foundational messaging, which is likely to contribute heavily to public salience, comprehension, and decision-making as potential consumers reflect upon their experiences, envision future outcomes, and consider the reputation of those trying to influence them. As is documented in our results, the trust-building priorities of these groups often stand in opposition to one another and are influenced by distinct motivations for how the public will come to trust or distrust GEAF actors and objects as more products are developed and enter the market.

CRISPR-Cas Genome Editing for Insect Pest Stress

Article

Tasfia Tasnim Moon, Ishrat Jahan Maliha, Abdullah Al Moin Khan, Moutoshi Chakraborty, Md Sharaf Uddin, Md Ruhul Amin, Tofazzal Islam

Stresses, 2022, *2*(4), 493-514, 07 December 2022

Abstract

Global crop yield and food security are being threatened by phytophagous insects. Innovative methods are required to increase agricultural output while reducing reliance on hazardous synthetic insecticides. Using the revolutionary CRISPR-Cas technology to develop insect-resistant plants appears to be highly efficient at lowering production costs and increasing farm profitability. The genomes of a model insect, Drosophila melanogaster, and major phytophagous insect genera, viz. Spodoptera, Helicoverpa, Nilaparvata, Locusta, Tribolium, Agrotis, etc., were successfully edited by the CRISPR-Cas toolkits.

However, this new method can alter an insect's DNA to either induce a gene drive or overcome an insect's tolerance to certain insecticides. The rapid progress in the methodologies of CRISPR technology and their diverse applications show a high promise in the development of insect-resistant plant varieties or other strategies for the sustainable management of insect pests to ensure food security. This paper reviewed and critically discussed the use of CRISPR-Cas genome-editing technology in long-term insect pest management. The emphasis of this review was on the prospective uses of the CRISPR-Cas system for insect stress management in crop production through the creation of genome-edited crop plants or insects. The potential and the difficulties of using CRISPR-Cas technology to reduce pest stress in crop plants were critically examined and discussed.

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FDA :: Approved Cellular and Gene Therapy Products [Accessed 13 June 2023]

Below is a list of licensed products from the Office of Tissues and Advanced Therapies (OTAT).

ABECMA (idecabtagene vicleucel)
Celgene Corporation, a Bristol-Myers Squibb Company
ADSTILADRIN
Ferring Pharmaceuticals A/S
ALLOCORD (HPC, Cord Blood)
SSM Cardinal Glennon Children's Medical Center
BREYANZI
Juno Therapeutics, Inc., a Bristol-Myers Squibb Company
CARVYKTI (ciltacabtagene autoleucel)
Janssen Biotech, Inc.
CLEVECORD (HPC Cord Blood)
Cleveland Cord Blood Center
Ducord, HPC Cord Blood
Duke University School of Medicine
GINTUIT (Allogeneic Cultured Keratinocytes and Fibroblasts in Bovine Collagen)
Organogenesis Incorporated
HEMACORD (HPC, cord blood)
New York Blood Center
HEMGENIX
CSL Behring LLC
HPC, Cord Blood
Clinimmune Labs, University of Colorado Cord Blood Bank
HPC, Cord Blood - MD Anderson Cord Blood Bank
MD Anderson Cord Blood Bank
HPC, Cord Blood - LifeSouth
LifeSouth Community Blood Centers, Inc.
HPC, Cord Blood - Bloodworks
Bloodworks
IMLYGIC (talimogene laherparepvec)
BioVex, Inc., a subsidiary of Amgen Inc.
KYMRIAH (tisagenlecleucel)
Novartis Pharmaceuticals Corporation
LAVIV (Azficel-T)
Fibrocell Technologies
LUXTURNA
Spark Therapeutics, Inc.
MACI (Autologous Cultured Chondrocytes on a Porcine Collagen Membrane)
Vericel Corp.
OMISIRGE (omidubicel-onlv)
Gamida Cell Ltd.
PROVENGE (sipuleucel-T)
Dendreon Corp.
RETHYMIC
Enzyvant Therapeutics GmbH
SKYSONA (elivaldogene autotemcel)
bluebird bio, Inc.
STRATAGRAFT
Stratatech Corporation
TECARTUS (brexucabtagene autoleucel)
Kite Pharma, Inc.

VYJUVEK
Krystal Biotech, Inc.
YESCARTA (axicabtagene ciloleucel)
Kite Pharma, Incorporated
ZYNTEGLO (betibeglogene autotemcel)
bluebird bio, Inc.
ZOLGENSMA (onasemnogene abeparvovec-xioi)
Novartis Gene Therapies, Inc.

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