No person left behind: Mapping the health policy landscape for genomics research in the Caribbean

*Jyothsna Bolleddula,[a] Donald Simeon,[b] Simon G. Anderson,[c] Lester Shields,[d] Jasneth Mullings,[d] Pilar Ossorio,[e] Averell Bethelmey,[b] and Anna Kasafi Perkins [f]**

[a]Cornell University, Ithaca, NY, USA
[b]The University of the West Indies, St Augustine, Trinidad and Tobago
[c]Glasgow Caribbean Centre for Development Research, The University of the West Indies, Cave Hill, Barbados
[d]The University of the West Indies, Mona, Jamaica
[e]University of Wisconsin, Madison, WI, USA
[f]The University of the West Indies, Regional Headquarters, Jamaica

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Summary

The Caribbean has long been an under-represented geographical region in the field of genomics research. Such under-representation may result in Caribbean people being underserved by precision medicine and other public health benefits of genomics. A collaboration among regional and international researchers aims to address this issue through the H3ECaribbean project (Human Heredity, Environment, and Health in the Caribbean), which builds on the lessons and success of H3Africa. The Caribbean project aims to target issues of social justice by encouraging the inclusion of diverse Caribbean communities in genomics research. This paper explores a framework for the ethical and socially acceptable conduct of genomics research in the Caribbean, taking account of the cultural peculiarities of the region. This is done in part by exploring research ethics issues identified in indigenous communities in North America, Small Island Developing States, and similar endeavours from the African continent. The framework provides guidance for interacting with local community leaders, as well as detailing steps for obtaining informed consent of all participants. Specifically, the authors outline the methods to ensure effective interaction and enforce full transparency with study participants to combat historical neglect when working with under-represented communities in the Caribbean.

Keywords: Caribbean; Genomics; Social; Legal; Ethical; ELSI; Health policy; H3ECaribbean

Introduction

In recent years, medical and public health professionals have become increasingly interested in developing more individualised approaches to disease prevention and treatment.[1] Sometimes referred to as precision medicine, these individualised treatment methods account for differences in an individual's phenotypic and molecular environment, and lifestyle. This includes specific molecular information from multiple platforms, including genomics, proteomic and metabolomic technologies. Recent advances in genomics data collection and analysis across multiple population groups are enabling precision medicine to develop in the field of individualised treatments.[1] In addition, certain populations are susceptible to medical conditions at higher rates than others, for example, persons with African ancestry face higher rates of stroke compared to their White counterparts due to genetic factors and some social determinants of health.[2,3] Genome-wide association studies (GWAS) in the past have aided in the identification of genes that can be targeted to innovate cures for a host of diseases.[3]

Existent genomics data have been generated primarily from North American and European Caucasian populations.[4] There is minimal data on people from most parts of the world, including people of African ancestry or many indigenous populations. Persons of European ancestry account for at least 78% of genomics association studies, while those of African ancestry account for less than 3%.[5] A lack of data, in certain ethno-geographic populations, means that the influence of context on disease risk, adverse drug reactions, and other clinical information necessary to make clinical decisions are reduced or not meaningfully transferable. Indeed, there are examples of misdiagnoses in patients of African descent because a variant is rare among Europeans but of higher frequency among those of African descent. Even so, the representation of traditionally

*Corresponding author.
E-mail addresses: anna.perkins@uwimona.edu.jm, jb2366@cornell.edu (A.K. Perkins).

underserved groups in genomics research continues to be low, in spite of the recognition of the social justice and equity issues as well as scientific and clinical need.[6]

Disparities also exist in the levels and the development of infrastructure to support genomics research including gene x environment considerations that can translate into precision medicine.[7] Currently, many large centres that conduct genome research are housed in developed countries. Low- and middle-income countries (LMICs), where most of the world's population resides, have a paucity of resources as a result of insignificant governmental financing or the high costs for infrastructure that supports genome research. Where LMICs implement large-scale genomics projects, local physicians and researchers tend to lack the expertise and conceptual framework to conduct such research in an ethical manner.[8] At the same time, where such research had increased in the developing world, it is often being carried out by specialists and trainees from developed nations, with little or no benefit to local institutions, researchers, participants and health priorities.[6] In addition, local ethics oversight may be ignored, compounding sensitive ethical concerns.[9,10] These issues are relevant to the development of health policy research on genomics, especially in regions such as the Caribbean, which are made up primarily of LMICs.

The Caribbean

The Caribbean is the geographical region in the Americas, comprising the island nations in the Caribbean Sea and some countries in the South and Central American mainland. Jamaica, Haiti, Trinidad and Tobago, Belize, Cuba, and Suriname are all part of the Caribbean. (See Figure 1). All the nations of the Caribbean are classified as small island developing states (SIDS), which acknowledges their particular socio-economic and environmental vulnerabilities. These vulnerabilities place them among the least developed, in spite of some being designated as high or middle-income countries.[11] This means that there exists a diversity within the region regarding the human experience. The wide discrepancies between social classes in terms of education, access to technology, and living infrastructure make the region difficult to classify under one umbrella.[12]

At the same time, the Caribbean, like many areas in the global South, can be described as research-naïve in some areas but under-resourced and underrepresented across the board, and, therefore, underserved in the area of genomics research.[13] Indeed, among the most notable features of the region are marginality, inequity and poverty in certain countries, with varying degrees of research ethics infrastructure across the board.[14,15] Furthermore, the Caribbean is a context with a deep colonial legacy spanning centuries.[9] Unsurprisingly, therefore, minimal efforts to develop genomics infrastructure in the region have been reported to date.[13]

Despite the general lack of infrastructure and expertise, large-scale genome research projects have been undertaken in less-developed areas around the world. The Human Heredity and Health in Africa (H3Africa) initiative, funded by the National Institutes of Health in the United States of America (NIH), is a premier example.[16] H3Africa is the largest initiative in Africa working on deep whole-genome sequencing, developing and harmonising ethics standards, and data-sharing across Africa.[6] No similar large-scale genomics project has yet been undertaken in the Caribbean, although several

Figure 1. Map of the Caribbean.

research entities engage on a small, often-targeted scale. These include research initiatives conducted by The Caribbean Public Health Agency (CARPHA), the Caribbean Institute for Health Research (CAIHR) (https://www.uwi.edu/caihr/), and the George Alleyne Chronic Disease Research Centre (https://www.uwi.edu/cdrc/), a unit of CAIHR. Many of these centres conduct research in collaboration with overseas partners, including the NIH. Nonetheless, the Caribbean faces genomics research infrastructure challenges similar to those in Africa and other parts of the global South.

This article arises from the initial explorations into the feasibility of a Caribbean Initiative similar to H3Africa entitled, Human Heredity, Environment, and Health in the Caribbean (H3ECaribbean), beginning with the Anglophone Caribbean.[17] In conceptualising H3ECaribbean, the question of the ethical, legal, and social implications (ELSI) emerged as particularly significant. The discussion countenances the context within which health policy on genomics research is undertaken in the region and, as such, issues of social justice (inclusion and access, protection from exploitation), privacy, valid consent, and ethical legislative frameworks come to the forefront, time and time again. Expanded genomics research in the Caribbean will require consideration of policy guidelines and activities leading to ethically increased representation of this population in global genome datasets as well as increased participation in the benefits of research. The ELSI framework outlined draws upon methodology used for genomics studies conducted among indigenous communities in North America, SIDS, as well as Africa, to provide a frame of reference for arriving at coherent and well-reasoned solutions to specific problems, which may arise in the Caribbean context.

Genomics and public health

Genomic research contributes to the understanding of disease mechanisms; it is therefore expected to lead to the development of public health interventions such as vaccines. In addition, knowledge of the genomics risk profile of populations could result in the implementation of strategies for disease prevention and clinical care, targeting those at greatest risk.[18] The concept of precision public health has been proposed but while it would improve efficiency, policymakers must also consider ethical issues.[19] Such interventions must be properly planned, and the population sensitised and exposed to appropriate health education.[20] Importantly, the public health programmes emanating from genomic research, such as for the early detection of certain inherited disorders, should complement, and not replace, the existing ones that address the social determinants of health. If well planned and managed, a programme of genomics research addressing priority issues can guide the development of public health interventions and policy and therefore contribute to the improved health of the multi-ethnic peoples of the Caribbean.[21] A report of the WHO Science Council highlights the promotion of affordable access to genomic technology, especially in LMICs, to enhance the adoption and expansion of the use of genomics research for better health and other benefits.[22]

Search strategy and selection criteria

Given the focus of this review, the major search terms employed using PubMed and Elsevier databases were Caribbean, ELSI, H3Africa, genetics, genomics, ethics review board, informed consent, genomics health policy, genomics research in developing countries (LMIC), among indigenous groups, SIDS, and in Africa. PubMed searches often elicited suggested articles to pursue expanding the pool of relevant articles. The reference lists from relevant articles were also perused for useful material. Material which did not relate to ethical, legal, and social implications were generally excluded. Articles pertaining to genomics research in the Caribbean were specifically targeted, though few were identified.

Social justice in genomics research in the Caribbean

Equity in inclusion in genomics research

While the African experience cannot simply be mapped unto the Caribbean context, the considerations of ELSI in H3ECaribbean build on relevant experiences of the H3Africa project, to centre on issues of social justice: non-harmful inclusion in genomics research, access to benefits of genomics research, and availability of findings to various communities while protecting the disadvantaged. Typically, genomics studies have relied on increasing overall participant numbers, with less of an emphasis on recruitment of participants from underrepresented minority groups, which this framework attempts to address.[1]

Currently, research on the attitude of various publics towards genetics research is concentrated mostly in the global North. Indigenous ELSI scholars in the USA have developed a framework for ethical inclusion of native communities in genome research. Elements of this framework's ELSI may be salient for the Caribbean context as well.[23]

- Engaging with the local community by forging community partnerships.
- Building cultural competency among the researchers.
- Improving transparency of research practices to community members.
- Building research capacity in local community.

- Distributing research findings in a way that is available and accessible to the community (availability is defined as high quality, culturally sensitive, non-discriminatory conclusions from research data).

Ensuring that the issues above are addressed is expected to aid genomics researchers in building trust in local Caribbean communities, and, subsequently, recruiting a diverse cohort of participants for the collection of genomic data.

Minority groups and research distrust

The development of more diverse and inclusive genomics research depends on the willingness of diverse groups to donate data, bio-samples, and participate in clinical trials. This willingness is shaped by multiple factors, including familiarity with genetics and their cultural perceptions of the power and value of genetic material.[6] In particular, experiences of exploitation have been a mark of the Caribbean from the time of European conquest and colonisation. Exploitation in scientific research has been no exception with British smallpox experiments on enslaved men in rural Jamaica in the 18th Century, US experiments with venereal diseases on Guatemalans in the 1940s, and the use of placebos in clinical trials to determine efficacy of interventions in maternal-foetal transmission of HIV in the Dominican Republic in the 1990s.[24–26] Unsurprisingly, therefore, Caribbean populations are sceptical about research efforts, especially from players outside the region. Importantly, communities within the Caribbean are more likely to express distrust or fear regarding genomics research when compared with their Caucasian counterparts.[27] This mistrust would perhaps be elevated in cases where samples from genetic research might have to be sent abroad for analysis given the lack of resources locally. This is an issue that the H3ECaribbean project would have to address since the engagement would include vulnerable populations characterised by lower than average income and literacy levels.[28]

Minority groups in the Caribbean are diverse, such as ethnic (Maroons in Jamaica and Suriname), cultural (Garifuna in Belize, Kalinago in Dominica, and Javanese in Suriname), indigenous (Maya and other groups in Belize, Guyana, Suriname) and religious (Rastafari, Spiritual Baptist, Hindus, Muslims, Jehovah's Witnesses) communities. Some groups may belong to more than one category, having multiple identities; some may exist as a minority in one territory but not in another, for example, Muslims in Jamaica vs Muslims in Guyana. Rastafarians in Jamaica are examples of how such minority communities are often distrustful of conventional medical treatment and research, particularly in light of experiences of oppression and discrimination from within the colonial space.[29,30] Jehovah's Witnesses are known to refuse certain medical treatments such as blood transfusions and tissue transplants.[31]

Building trust among minority populations in the Caribbean

The onus is on the genomics researchers to demonstrate to potential participants that trust in them is well-placed and not likely to be betrayed. Building trust and demonstrating trustworthiness require transparency about the value of the research to society and who will be accessing the data along with highlighting the protections in place and the personal control of data.[6] In addition, cross-cultural sensitization, interaction with local community leaders as well as careful attention to diversity and representation (ethnic, gender, religious, etc.) among research staff is strongly encouraged, as it has been successfully implemented in the Alaska-Native Indigenous context in the USA.[32] Ensuring diverse research teams is necessary as they perform better than homogenous ones.[6] In addition, their framework encourages researchers to provide updates to community leaders regarding the status of research and the destination of specimens and data during and after the study has been conducted.[32]

Rather than applying existing protections to all under-represented communities, policymakers should develop ethical frameworks that take a step-by-step approach tailored to each community. Researchers need to demonstrate and work along with communities to ensure that their values and concerns are understood and respected in the research design and methodology.[6] It is essential that the participants be shown that their contribution will lead to their benefit and that of others. If a community has a recognised set of leaders, researchers should engage in "community consent," while communities that lack a centralised governing body can engage in "community consultation." The Maroons in Jamaica and Suriname, and the Garifuna in Belize, who have local forms of leadership, are examples that may require community consent. Ultimately, it is vital that these protections be applied in addition to existing individual consent to protect autonomy.[33] Importantly, such specific engagements with minority groups should be supported by the wider population to establish the relationship between the research agenda and their values and priorities.[6]

Research ethics oversight in the Caribbean

Like other LMICs, research oversight capacity is a particular challenge in the Caribbean. Local capacity for undertaking research must also include the capacity to undertake ethics review of the planned research and monitor its conduct.[34] Indeed, ethics governance

through the expansion of the scope to include all research with human subjects, the establishment of entities to undertake research oversight as well as formalising existing practices are critical to advancing research ethics systems in the Caribbean.[35] A 2016 population-based genetics study in Trinidad and Tobago identified inadequately trained research ethics committees (REC) as one of the deficiencies in the region's research infrastructure; other deficiencies were lack of cultural inclusion and community education.[13] Arguably, Caribbean countries have generally been slow in establishing ethics committees to monitor human subjects and health-related research. In addition, oversight processes may be poorly resourced, bureaucratic and slow, often resulting in loss of time, since proposed research is usually time-sensitive.[14]

Nonetheless, research ethics oversight in the region exists in varying spaces such as ministries of health, CARPHA, and universities. For example, the regional University of the West Indies (UWI), which serves mainly the Anglophone Caribbean, has a research ethics policy, campus-based ethics review committees and a University Ethics Review Committee to provide the requisite oversight of research. The UWI's Research Ethics Committee Handbook (2020) provides useful information concerning the ethics review process, including the identification and treatment of vulnerable populations as well as the different kinds of reviews. CARPHA, which has its own ethics review committee, had been involved in training research ethics committee members from across the region, since 2014, and, in 2016, launched the Caribbean Network of Research Ethics (CANREC) to increase networking among them.[36] In addition, the NIH-Fogarty-funded Caribbean Research Ethics Education Initiative (CREii) offered scholarships for a one-year graduate-level certificate programme and a two-year Master's in research ethics. Graduates were able to, among other things, serve and lead RECs, educate stakeholders, and contribute to policy development.

In engaging with ethics oversight in the region, H3ECaribbean would build on the already existing ethics oversight mechanisms while working to strengthen them. These can be strengthened by partnerships, without substituting external oversight for local action.[34]

Valid informed consent

Informed consent is the foundation for conducting and regulating research in an ethical fashion. Yet little research has been undertaken in the developing world with its particular circumstances. As noted previously, consent is central, therefore, to guidelines for conducting research and ethics oversight of research. Matters of informed consent are of utmost importance when dealing with vulnerable, research-illiterate and illiterate populations.[37] Bhutta raises the issue of informed consent vs "understood consent", which is particularly important among illiterate and variously disenfranchised populations such as those in the Caribbean.[37] Arguably, consent should be an ongoing process throughout the research.[9] As shown in Roach et al., involving local leaders to increase cultural sensitivity is important.[13] In addition, an audit of the informed consent process to ensure its validity is vital. Even the language of consent is important, as the case of Jamaica, where "Standard English [can be] a language that represents division and oppression," demonstrates.[38]

Researchers in many under-represented countries have also adopted a framework for tiered consent which mandates the inclusion of the following criteria in informed consent documents:[39]

1. Information about genetics.
2. Focus of the study.
3. What participants will be asked to provide (blood, saliva, health history, etc.), when and how much.
4. Potential benefits and risks to the study for the participants. If there are no direct benefits (which is often the case in genomics research) that should be stated.
5. Protocols for ensuring privacy and protecting samples.
6. Locations where samples will be stored, and specific protocols should be outlined.
7. Return of results. If there are plans for the results to be returned, these plans should be reviewed by research ethics committees. If there is no plan to return results to the participants, that should also be stated.
8. A brief outline of where their data could go during the initial consent process, should researchers decide to make data available for other research studies in the future.[40]
9. Process for withdrawal of consent and point of contact for questions.[39]

With regards to withdrawal and return of results, the participants should be able to withdraw their samples at any time during the research timeline and should be assured that these would be destroyed if they choose to have that done. Additionally, participants should be informed of findings if they suggest something of significance to their livelihood and wellbeing.[41]

Research done on consent forms in H3Africa can provide insight into which practices may be relevant for the H3ECaribbean. Munung et al. found that only one consent document mentioned individual feedback on data from the study.[16] Six out of thirteen did not mention the H3Africa Project in the consent forms, while the rest made a brief mention of the Project or where the samples would be stored. The study mainly focused

on documents in English and French, and did not examine those translated into native African languages. For the future, the authors urged consent documents in the H3Africa Project (and in other projects) to address discrepancies between the policy framework and collaboration with local ethics leaders to forge more transparent consent documents.[16]

Importantly, the process of documenting consent should not disenfranchise persons whose voices need to be heard. Alternative means of acquiring and recording consent should also be utilised, including community engagement, verbal consent, and art-based methods, which ensure the process is culturally sensitive.[9] Furthermore, ethical tensions involved in consent in vulnerable populations, as unearthed in the context of the Dream-A-World (DAW) programme in impoverished inner-city communities in Kingston, Jamaica, should be addressed. D'Souza and colleagues questioned whether people's willingness to participate in the programme was influenced by explicit or tacit expectations of assistance such as school-related expenses or allowances.[9] Many parents made assumptions about care in spite of explanations of the focus of the research, and that no direct material support would be provided. Poverty, it is well-documented, can be a driving force in research participation. This is complicated by contexts like the Caribbean where often anything "foreign" is considered "better/best" or "the solution".[14] A reflexive approach to consent needs to be undertaken to unpack the ethical unknowns in the process of the research, particularly the tensions surrounding consent.[9] Importantly, the researchers need to pay attention to the nature of the relationship between themselves and participants, including power differentials and privilege.[6]

Ensuring community engagement in decision-making

The general public are more likely than researchers to express concerns regarding privacy, data feedback, and trust in informed consent processes.[42] Following an analysis of community consultation strategies in Iceland, Estonia, United Kingdom, and Quebec in Canada, it was shown that all groups expressed the same concern regarding a lack of transparency and the desire to access their own results. Though forging community partnerships is costly and might take a longer time, it is still important to balance individual and community interests to increase participation in studies.[43] The following strategies should be implemented to ensure ethical and safe relationships between study participants and researchers:

- Not engage persons who are clearly in a position of power over the subject in the recruitment and consent process.[44]
- Visibly and clearly define the meaning of citizen science and the expectations of the participants before being recruited into the study in order to retain individual autonomy for the subjects of the study.[45]
- Address historical mistreatment of the population and outline steps taken in the study to curb and prevent these.
- Outline database safeguards.
- Address community concerns in relation to equitable distribution of research benefits and alter for each community if necessary.[43]

Communities and/or groups who choose not to participate in the study, despite attempts to forge community partnerships, should be respected and disengaged in a courteous manner.

Potential legal issues and legislative framework

Legal provisions for the conduct and surveillance of genomics research often do not exist in the global South or where they do, relevant expertise does not exist or is inadequate.[14] Proper regulation of the research projects involving genetics will help to minimise such occurrences. In the case of H3ECaribbean, there are little to no regulatory frameworks in place to help guide and protect both researchers and participants. Guyana is the only Anglophone Caribbean country that has laws on research.[46] Legal frameworks for research ethics exist in about 25 Latin American and Caribbean countries.[36] All other countries have research guidelines. Whenever such regulations are being discussed, conflict resolution, liability, consent, quality, and privacy should be paramount.[47] Regulation on the return of results is also important to consider. The importance of respecting individual choices to know or not know is widely recognised. International instruments exist that H3ECaribbean could adopt which provide rules for when results must be returned, should be returned, may be returned or should not be returned at all. The common goal here is to illustrate the "right of everyone to share in scientific advancement and its benefits".[48]

There must also be clear rules governing genetic research in children. Genetic studies in children can be very beneficial when investigating developmental and physical congenital disorders. Parents or guardians should be informed about the potential benefits and potential harms of testing, and their permission should be obtained. Medical benefits include the possibility of preventive or therapeutic interventions, the clarification of diagnosis and prognosis, and recurrence risks. Medical harms occur if parents or guardians respond to the results by pursuing unproven treatments or preventive measures, particularly if they are ineffective or have significant adverse effects.[49]

Specimen and data repositories

As biobanks become more common in low and middle income countries, protecting research subject data and

keeping patients informed becomes a priority for communities where genomics research is taking place. Concerns with biobanks are tied with issues of informed consent and the storage of patient data. Biobanking in LMICs faces a host of challenges, including procuring informed consent for multiple investigations, and future research, particularly since consent is often project-specific. More importantly, retaining public trust in biobanking research has also faced challenges, as participants worry that their data may be mismanaged or lost during the transfer process.[50] This is in contrast to the patterns observed in developed countries, where most participants express confidence in biobanking and only ~15% express significant concern regarding privacy.[51] To curb this in LMICs, it is encouraged that partnerships with community leaders as well as local government outreach programmes are implemented to build trust in data repository mechanisms. In addition, explanations regarding biobanking infrastructure in the region would also be vital information to place in informed consent documents. It is also important to note that, internationally, countries have varying biobank legislation in place, ranging from mere "guidance," to strict laws (in the case of Taiwan and Spain) to no legislation at all.[52] Navigating government policies within the region will be of utmost importance.

Creation of committee to oversee ELSI issues

As with research generally, ethics governance is central in the H3ECaribbean initiative. In addition to contributing to building capacity in the existing review structures, increasing stakeholder education, and deepening networks as the various initiatives highlighted above indicate, a larger oversight committee will be established for H3ECaribbean. Within the limits of the H3Africa initiative, their model of the Data and Biospecimen Access Committee (DBAC) may be a useful one to consider for H3ECaribbean.[17] Of course, adaptations will be necessary for the Committee to more properly fit the needs of SIDs, such as those found in the Caribbean. The development of such a Committee should emphasise sustainable intersectoral collaboration, strengthened regional institutions, and bolster transnational integration efforts.[11] The Committee would consist of professionals from multiple ELSI disciplines, and support the implementation of the ELSI working group's recommendations. Functions of this Committee would include:

- Ensuring broad based stakeholder engagement.
- Monitoring informed consent implementation in keeping with local and international norms.[53]
- Reviewing informed consent documentation prior to distribution.
- Building capacity in ELSI matters among stakeholders.[54]
- Monitoring the ongoing development of regulatory framework and policies among nations in the region.[55]

Such a Committee would ensure that opportunistic and unscrupulous research, which exploits the vulnerability and needs of the populations of the Caribbean or neglects the existing research oversight processes in the region do not take root.[10]

Implementation strategies

Although there may be challenges in implementation of the proposed strategies, the precedent of the H3Africa initiative can serve as a guide to overcoming such barriers. The H3Africa project, when initiated in 2010, was fraught with challenges that affected participation and outcomes, primarily during the planning and implementations stages.[56] Many of the challenges and lessons learned can be applied to the Caribbean context. Some prominent threats included a general lack of resources, delayed funding, poor training and recruitment, and data sharing challenges.[56] It can be assumed that the Caribbean region would face similar threats due to the similarities of the demographics/government systems, as well as their status as LMICs.

The key to successful implementation is well-trained scientists and research staff. Efforts should focus on the integration of training programmes for non-genetics-trained healthcare providers, particularly those who work in primary care.[57] An example of how this might be accomplished and utilised in the Caribbean setting is the African Genomic Medicine Training (AGMT) Initiative which was established to implement a sustainable genomic medicine training protocol, primarily for healthcare professionals who are not geneticists, that is nurses, doctors, and pharmacists.[58] In addition, periodic trainings that include pre- and post-training comprehension are recommended. Lastly, mentorship between local scientists and counterparts in high income countries is encouraged to build sustainable research capacity.[56]

Recruitment of diverse peoples is key to achieving the goals of the H3E Caribbean project. Utilisation of social media (Facebook, Instagram, etc.) as well as radio and television advertisements to recruit participants would expand outreach of the project, and have been proved effective in the H3Africa context. Compensation for travel to the testing site, and providing a meal on the day of testing, and other non-coercive forms of remuneration are also encouraged.[56]

Navigating the sharing of genomics data poses a unique set of challenges for project implementation. The H3Africa Biorepository Programme can serve as a

model for the storage of patient specimens in the Caribbean. That programme established three regional biorepositories throughout the continent (in West, East, and South Africa), while following internationally accepted guidelines set forth by the International Society for Biological and Environmental Repositories (ISBER). While there have been attempts to standardise Material Transfer Agreements for genomics specimens, there remain much variability in the time it takes to process these agreements.[59] In order to remove this nation-to-nation variability when implemented in the Caribbean, it is suggested that the aforementioned ELSI Committee review all Material Transfer Agreements, instead of individual governments. Similar to the H3Africa, it is recommended that multiple biorepository centres be constructed throughout the region (2–3 to start), using the ISBER guidelines as a framework. Partnership with private stakeholders, as well as communication with professionals in the H3Africa Biorepository Program will be vital to ensuring the success of the similar program in the Caribbean.

One further aspect to consider for implementation is funding for the project. As noted previously, the H3Africa project was heavily funded by the NIH.[17] In addition to external funding to initiate the H3ECaribbean project, the authors encourage the formation of cross-nation collaboration in the region to facilitate sustainability well into the future.

Conclusion

Significant advances have taken place in disease diagnosis, treatment and personalised care driven by advances in genomics research. However, there is a lack of ethnogeographic diversity in the research that informs genomics medicine.[6] There are important ethical justifications for increasing diversity and representation of underserved groups to ensure just distribution of the health benefits. At the same time, pragmatically, greater scientific success in genomics medicine depends on the availability of large amounts of data, which can be readily shared across scientific and geographic boundaries. Caribbean populations are among the groups that are underrepresented in this area of genomics research.

The H3ECaribbean initiative can serve to build an infrastructure for genomics research in the Caribbean.

Potential Issue	Framework Proposal
Individual & Community mistrust of researchers/Lack of inclusion	i. Engage with the local community by forging community partnerships. ii. Build cultural competency among the researchers. iii. Improve transparency of research practices to community members. iv. Build local community research capacity.
Non-equitable distribution of benefits of research	i. Recruit diverse cohorts of researchers. ii. Distribute research findings in a way that is available and accessible to the community (availability is defined as high quality, culturally sensitive, non-discriminatory conclusions from research data).
Invalid informed consent	i. Adopt a framework for tiered consent which mandates the inclusion of various detailed criteria in informed consent documents. ii. Allow participants to withdraw their sample at any time during the course of the research and be assured that their samples will be destroyed if they choose to do so.
Lack of accountability by/to national review committees	i. Create a committee to oversee ELSI issues which would build capacity in ELSI matters among stakeholders. ii. Monitor the ongoing development of regulatory framework and policies among nations in the region.
Specimen and Data repository challenges	i. Partner with community leaders as well as implement local government outreach programmes to build trust in data repository mechanisms. ii. Navigate pre-existing government policies.

***Table 1*: Genomics research practices in the Caribbean: potential issues and responses.**

However, the current level of investment in the political, administrative, legal, and social framework is relatively low in comparison to other jurisdictions. It promises immense benefit to the region and external collaborators, including transfer of appropriate technology, advances in medical treatment, and potential discovery of cures or treatments for diseases endemic to the region, while contributing to the public health needs of the region and the global human family. The project incorporates an ethical, legal and social framework to strengthen the capacity-building and outcomes in genomics research while ensuring research subjects and other stakeholders are protected. A few important parameters that define the successful execution of this project include engaging with local community leaders, building cultural competency among researchers, obtaining informed consent in a transparent manner, and ensuring community engagement in decision-making. Perhaps most important, is a robust ethics governance system to catalyse ethical research in a structured health policy, leading to the improvement of the health and wellbeing of Caribbean people.[35]

Table 1 captures the various issues and proposes solutions for research practices in light of the discussions. The suggestions take account of the critical role of the Caribbean's cultural, historical and socio-economic context in shaping responses to genomics research, while learning from experiences of conducting research among similarly positioned groups such as indigenous communities in North America, Africa, and other LMICs.

Contributors

JB is an undergraduate student at Cornell University and the concept for the manuscript was developed as a part of JB's internship work with the H3ECaribbean project. JB and AP were involved in literature review, writing of the manuscript, and construction of the figures. DS, SA, JM, PO, LS, and AB assisted in literature review and in providing feedback throughout the revision process. All authors reviewed and edited the manuscript.

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