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# Ethical, Legal, and Social Implications of Metabolomics in Low and Middle-Income Countries: Consent, Governance, and Trust

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## ABSTRACT

Metabolomics, the comprehensive analysis of small-molecule metabolites in biological samples, offers significant potential to improve health outcomes and support sustainable development in low- and middle-income countries (LMICs). However, its implementation raises complex ethical, legal, and social implications, particularly regarding informed consent, governance, data sharing, and community trust. LMICs face unique challenges, including variable regulatory frameworks, limited institutional capacity, and socio-cultural factors that influence participation and understanding of research. Broad and specific consent models, data stewardship practices, equitable benefit-sharing, and participatory community engagement emerge as critical mechanisms for ethical metabolomics research. Case studies from Ghana and Zimbabwe highlight the importance of context-specific governance and culturally appropriate engagement strategies. Addressing these challenges requires strengthening governance frameworks, enhancing interoperability of metabolomics data, and fostering durable trust through transparency, stakeholder engagement, and fair access to benefits. This paper emphasises the need for evidence-informed policy development and localised ethical standards to ensure that metabolomics research contributes meaningfully to health equity, scientific advancement, and sustainable development in LMICs.

**Keywords:** Metabolomics, Low- and middle-income countries (LMICs), Informed consent, Governance and data stewardship and Community trust.

## INTRODUCTION

The term "metabolomics" encompasses a range of technologies that quantitatively analyse significant fractions of all small-molecule metabolites in biological fluids and tissues [1]. Metabolomics is regarded as the third major omics discipline, complementing genomics and proteomics. Metabolomics characterises small-molecule metabolite profiles as indicators of biological status and as sources for disease and health-condition biomarkers. Metabolomic analyses can be conducted on body fluids such as blood and urine, as well as on tissues such as skin and plasma, using targeted or untargeted approaches [2]. These technologies produce mass-spectral data or nuclear-magnetic-resonance signals. Health systems in lower- and middle-income countries (LMICs) comprise a broad swath of socioeconomic and institutional diversity, influencing metabolomics technologies' capacity to contribute. Nevertheless, the potential benefits from the significance of biochemical targets in holistic systems approaches are similar [3]. Health and development policymakers can therefore benefit from understanding these concepts. An overview of the socio-economic and technological implementing environment is also pertinent, given the rapid pace of health technology shifts [4]. Low and middle-income countries (LMICs) face a dual burden of communicable and non-communicable diseases, and an epidemiological transition has begun. Nutrition-related non-communicable diseases have different underlying causes than in high-income countries [4]. Synchronised global and national frameworks are needed to operationalise the shared goals of the UN Sustainable Development Goals to build healthy and productive systems and support inclusive sustainable growth [2]. Investments in omics are mandated, underpinning international collaborations on integrated systems protection for health, nutrition, and systems security. Since metabolomics is among the earliest-articulated systems disciplines, consideration of its incorporation is timely [5].

## Conceptual foundations: metabolomics in health and development

Metabolomics, the study of small-molecule metabolites, plays an important role in understanding health and disease in low- and middle-income countries (LMICs) [6]. Metabolomics is relevant to research and development because it supports the global commitment to achieve the Sustainable Development Goals (SDGs), particularly Goal 3 on health and well-being, and is included in the integrated science and technology framework for the UN's 2030 agenda for sustainable development [2]. Orthogonal to the health and development discourse is the policy analysis of ethical, legal, and social implications of metabolomics in LMICs [5]. The ethical, legal, and social analysis focuses on those aspects that have fundamentally ethical, legal, or social dimensions, framing the analysis within three analytical frameworks: the governance capacity framework, the social–civic framework, and the acceptable–trust framework [7]. The analytic frameworks are adapted from existing literature and organised into informal matrices that facilitate showing connections between analytical concepts and research questions in a structured manner [1, 2].

## Ethical Considerations

Involving the collection of biological samples and related data to derive metabolic fingerprints, metabolomics can generate detailed insights into the health status of exposed individuals [8]. Candidate biomarkers promise to assist in the early diagnosis of illnesses, provide individual-level prognostic information, and identify targets for interventions and exposure assessments [6]. Beyond health, global agencies frame a range of development challenges, including ensuring food security, improving nutrition services, creating affordable and scientific knowledge-based products and technologies, ensuring competitive benefits, and sustaining a healthy environment [9]. Stakeholder participation hinges on a good understanding of the context and commitments of data use. Analytical frameworks can support metabolomics activities across four macro domains: development priorities, health system strengthening, social inclusion, and international cooperation, linked to explicit contributions for the health and development agendas [1]. The requirements for obtaining informed consent from individuals who participate in metabolomics research in LMICs differ from those in local contexts or upper-income economies [7]. Several factors need to be fully understood to guarantee that participants are well informed and can freely accept or refuse without risks. These factors revolve around the interaction between biobanks and the nature of the metabolomics study [10]. Broad consent enables the use of samples, data, or information for unspecified future studies that may be unrelated to the original research purpose, while specific consent restricts their use or integration with other resources [12]. Although broad consent apparently seems better suited to accelerate metabolomics research, these two very different forms have critical operational and regulatory implications. Biobanks and sampling, and the consequences of collecting additional metabolomics data among different institutions, countries, and legal traditions [12].

## Informed Consent in Metabolomics Research

In metabolomics research, consent models based on both predetermined data use and consent upon each specific data use require transparency about intended uses and obligations [2]. Potential for long-term health impacts and linkage to sensitive backgrounds often necessitates re-consent when, for example, ongoing biomarker- or genotype–phenotype-based studies are planned after samples or data have been shared [2]. Culturally appropriate communication about future-use permissions and consent principles might improve understanding and acceptance among participants [3]. About 60% of participants in a Sri Lankan genomics study relied more on trust than comprehension when consenting; trust in researchers and research emphasises the need to build relationships to support ethical practices [5]. In repeated cancer studies, mechanisms for continuous ongoing consent and further participant engagement were incorporated [3]. Participants also benefited from a better understanding of research than at baselines. Ongoing consent checks and opportunities for re-consent regarding future data uses without major structural changes still remain relevant [4]. Obtaining valid informed consent in low-resource settings remains ethically complex, particularly concerning biobanking and genomic research. Multidisease community-based health screening and biobanking platforms in rural South Africa encountered challenges in communicating complex topics in a manner understandable to local populations [7]. Numerous pragmatic societal and socio-economic influences, alongside logistical obstacles and potential coercion driven by economic needs, favour consent processes based on authority rather than full understanding [2]. Principles of transparency and reciprocity with local communities alongside appropriate context-driven terminology are crucial for compliance with ethical guidelines [3].

## Beneficence, Non-maleficence, and Justice

Research involving biological materials, genetic information, and other human-subject data has potential benefits for health systems and broader development goals (Simmonds, 2022). The epistemic, economic, and scientific significance of biorepositories and country-specific health-related datasets has grown globally and underpins global development efforts [4]. Such initiatives carry ethical, legal, and social implications. Guidance on consent procedures, intellectual property strategies, regulations, and data-sharing modalities aligns with several United Nations Sustainable Development Goals (SDGs) and the corresponding operational private-sector components of

the Global Strategy for Women's, Children's and Adolescents' Health 2016–2030 [7]. Health–economy policymakers at the national and international levels prioritise trustworthy metabolomic research to support health systems, improve education, and boost economic productivity in low- and middle-income countries [6]. Generating relevant biobanks and supplementary data-lifecycle information for metabolomics and linking health data on specific conditions continues to present challenges [7]. Harm-based ethical assessment weighs potential benefits against likely adverse consequences; accordingly, the appropriateness of health-related trend analyses remains an open question [11].

**Privacy and Data Sovereignty**

The principles of data minimisation, de-identification, and participant control over data, community rights to governance of data localisation, and participant rights to governance of community data are critical to effective metabolomics research that preserves data sovereignty and trust [6]. Data minimisation is generally understood as the principle of collecting no more information than is necessary, but it has multiple configurations in metabolomics [2]. For instance, individual metabolomics sampling data can be combined across patients to yield population averages; this is posited to reduce the risk of re-identification. However, population-level models of human metabolism derived from analysis of pooled metabolomic samples are also capable of drawing inferences that apply to individuals [5]. Population averages might reduce anonymity at a national level, but they could increase the risk of re-identification at an ethno-linguistic or geographical level. Data requesting blood, urine, or environmental samples typically constitutes a first request, as many further analyses may be carried out on those samples. Representatives of minority groups, including underrepresented populations in genomics, may therefore require level-2 access to two types of further requests [7]. First, they may wish to ensure that samples are not transferred to other countries or jurisdictions where regulations governing analysis, storage, or security are weaker or less clear than in their own countries. The second type of further request concerns what the communities themselves might permit, particularly in respect of more sensitive or hazardous analyses reflecting ethical interests at higher levels of analysis than those of datasets limited to chemicals per se[4]. Community groups might wish to govern access to specific items, such as metadata recording birth weight or particular environmental exposures, or to specific classes of analysis, such as extensive natural language processing of medical records or collection of text data from social-media platforms [12]. They may also require broad access to freedom of configuration settings related to detailed types of chemicals or analyses permitted [1].

**Legal and Governance Frameworks**

Metabolomics, the systematic analysis of small-molecule metabolites, stands at the forefront of multiomics technologies [2]. It provides key biochemically relevant and clinically useful information regarding cellular function and homeostatic balance. "For clinical disease monitoring, metabolomics has potential in the development of early, non-invasive and low-cost diagnostics, prognosis, disease pathway determination, and rapid assessment of drug efficacy [7]. From the public health perspective, the advent of metabolomics technology promises a deeper understanding of disease development, population health risk assessment, and drug development tracking" [2]. Data are thus produced about the metabolic phenotype of samples (such as biofluids), the influence of external factors on metabolism, and the identification of biomarkers related to disease state or even to the administration of drugs or vaccines[2]. The use of omic technologies in biomedical research in low- and middle-income countries (LMICs) makes health and development issues urgent at local, national, and global levels. Synergies emerge between the Sustainable Development Goals associated with health and the Global Health Strategy and the research agenda of the World Health Organisation [2]. One specific challenge is to attain metabolic profiles and metabolites associated with the disease spectrum pertinent to LMICs (e.g., tuberculosis, human immunodeficiency virus/acquired immune deficiency syndrome, schistosomiasis) rather than those typical of high-income contexts [1].

**Intellectual Property and Data Sharing**

Access to data derived from metabolomics holds significant promise. However, LMIC researchers express concern about the equitable sharing of benefits, as data-producing countries often hold power over commercial and non-commercial utilisation [5]. Unrestricted data access may undermine local involvement. Studies have identified a preference for open-access data, yet concerns about recognition, wrongful claims of ownership of local knowledge, and restriction to local populations persist [6]. Two- to three-tiered data-sharing models that govern accessibility based on the generation of metadata, partial datasets, and fully anonymised data merit exploration. Licensing options aligning with the principles of the research community, industry, and governing bodies would facilitate broader data access while addressing these issues. The Creative Commons model offers opportunities for the innovative licensing of publicly available data [7]. The ownership of intellectual property related to generated metabolomic data remains ambiguous. This uncertainty affects the decision to share data and extract subsequent benefits [7]. The early-stage LMIC metabolomics landscape necessitates the emergence of data-sharing practices from within the academic community, enabling publication opportunities and interaction with institutional repositories. Such practices would complement ongoing consultations with policy makers and industry

representatives [2]. Existing practices of open access to raw data do not, however, adequately encompass the multi-dimensional nature of particular data [1].

**Regulation of Omics Research in Low- and Middle-income Countries**

Regulatory frameworks governing human subject research, omics research, and biotechnology are still under development in low- and middle-income countries (LMICs); the existence of laws or mechanisms, as well as awareness and institutional capacity to comply with them, varies widely across these countries [7]. Although many LMICs have adopted legislation and ethical guidelines concerning human subject research, some regulations refer generically to "biotechnology" without specific mention of genomics or omit biotechnology altogether [1]. Even when relevant biotechnology legislation and related technical documentation exist, compliance remains challenging because of a limited understanding of laws and insufficient institutional capacity to implement them. Biotech laws also continue to develop in some countries, leading to uncertainty about ongoing compliance requirements such as monitoring and reporting [5]. Laws governing human subject research are generally broad and enshrine underlying principles such as beneficence and respect for persons rather than spelling out requirements that are specific to genetics, genomics, or omics research. To guide assessment of potential compliance gaps, authorities in Africa recently recommended that relevant documents be evaluated for coverage of twenty-eight aspects of genomics research, including ethical review procedures and intellectual property provisions [8].

**Governance Models for International Collaborations**

Governance frameworks for metabolomics in low and middle-income countries (LMICs) must balance donor priorities with local needs and capacities [7]. Each framework dictates the extent of local autonomy in governance, data handling, and benefit distribution, as well as the nature, timing, and formality of consent processes. Existing models for international partnerships incorporate a spectrum of approaches: some depend heavily on external governance, while others foster a high degree of local ownership [8]. In LMICs engaged in metabolomics research through international partnerships, expectations and established norms regarding consent practices may vary considerably. Consent processes thus risk non-alignment with either overseas expectations or local customs [6]. Frameworks to support equitable international collaborations and foster reciprocal benefit sharing have adopted a spectrum of formality. At one extreme, broad verbal or written agreements indicate a commitment to reciprocity without specifying modalities or explicitly delineating expected benefits. Collaborative expectations remain informal and discretionary, empowering governance bodies in both donor and recipient jurisdictions to establish specific protocols [4]. Most pre-existing LMIC collaborations fall abroad; therefore, anticipated reciprocal benefits and avenues for verification remain ambiguous [3].

**Social Implications and Community Trust**

As co-creation of knowledge between research institutions and communities occurs, restoring and enhancing trust is vital for successful and sustainable metabolomics research in low and middle-income countries (LMICs) [3]. The historical context influencing local perceptions of credibility and reliability shapes community expectations. Although communities appreciate the promise of local research, they often approach new projects with significant mistrust [6]. Issues of active participation, co-ownership of results, and the capacity to generate downstream benefits remain crucial for securing local support. Stakeholders engaging with community representatives must recognise and account for these complexities to foster robust, effective collaboration and enhance the prospects of successful metabolomics research [1].

**Trust in Research Institutions and Governance Bodies**

Research institutions and governance bodies must earn and maintain the trust of communities to establish biobanks and share genomic data [1]. Governance structures should provide regular audits, oversight mechanisms, and public access to audit reports. Repositories must develop targeted approaches for transparent and ethical collection when science advances faster than regulation. Broad consent is the preferred model, complemented by re-consenting whenever feasible or relying on research-ethics-committee (REC) approval when re-consenting is impractical [3]. Participants expect their samples to be used only for research purposes that do not compromise community trust and ethical practice [2]. Governance models drawn from African collaborative experiences can mitigate negative perceptions associated with international research. Transparency and clear agreements are essential, particularly when national- and donor-level power dynamics complicate collaborative frameworks [5]. Privacy is paramount in research involving biomaterials and genomic or health data, particularly when these involve sensitive information about ethnic groups, diseases, and social factors. Adherence to state regulations, national laws, and codes of practice is vital [2]. Researchers must ensure confidentiality, undertake risk assessments to identify and mitigate unforeseen dangers, and develop communication strategies for clearly conveying risks to participants and the wider community [3]. When broad-based or broad-spectrum consent permits sample or data sharing, guidelines that inform participants of anticipated uses, rights, and precautions remain critical. International collaboration necessitates collaborative guidelines covering ownership, sharing, liability, and compliance with statutes in various jurisdictions, particularly when samples or information are

transferred abroad, raising serious trust concerns [5]. At the community level, the emergence of biobanks and genomic data repositories indicates a move to a tiered consent system: general consent to collect samples and data from the target group and subsequent, specific consent for the first study proposal[7]. At the institutional level, challenges may arise if the overarching target group provides general consent, but the institution where the proposal is made has no access to samples or data. Considerations about under-researched phenomena affecting "ethnic" or religious groups have shifted into the broader discourse surrounding biobanks and an equitably distributed genomic literature [9].

**Stakeholder Engagement and Community Benefits**

The need for stakeholder engagement arises because the potential benefits of metabolomics research need to be communicated to stakeholders [3]. Building trust among stakeholders is essential for successful engagement 10. Specific technical and operational issues can undermine stakeholder trust [1]. Addressing capacity deficits in public health, data governance, or oversight structures can enhance research credibility and community awareness enables stakeholders to make informed decisions about study participation and appropriate safety measures. Diplomacy, at both individual and institutional levels, can be beneficial [7].

**Equity in Access to Benefits from Metabolomics Research**

Beneficiaries of biobanks and metabolomics research in low- and middle-income countries (LMICs) must be determined [1]. Finding precise mechanisms for the distribution of diagnostics, treatments, and technologies derived from research initiatives is crucial to honour the societal contract regulating access to LMIC specimens, biological materials, and data; it is also vital for promoting community-level engagement[5]. Accordingly, it is important to clarify which materials, including the original specimen, genomic archives, secondary biospecimens, and data, are generated through metabolomics initiatives, to what extent international metabolomics activities genuinely deliver benefits, and to what degree access to technologies for biobanks coordinated through institutions within LMICs arises from disclosure of the metabolomic analyses carried out on biospecimens assigned to these institutions [9].

**Current Evidence: Landscape and Gaps**

Despite the emergence of LMIC-centric guidelines and discussions about local ownership, material benefit-sharing, academic freedom, and decolonising epigenetics, current evidence of metabolomics-related ethical, legal, and social opportunities and challenges in low and middle-income countries remains thin [1]. Reviews, guidelines, and case studies from other regions have addressed consent practices, governance arrangements among stakeholders, community engagement, trust-building, and the provision of benefits [5]. A few empirical studies report participants' engagement with and expectations of genomic and biobanking research. Nevertheless, limitations in data quality, institutional affiliations, cross-country comparability, and research design hamper the generalizability and representativeness of insights [9]. Gaps persist in governance frameworks and practices, compliance with international standards, and the capacity to assess and convey the likely uses of existing samples. Further empirical research within LMICs should elucidate the factors that contribute to a trustworthy metabolomics ecosystem geared toward equitable health and development [7].

**Empirical Studies from LMICs**

Governance arrangements, community engagement, and benefit-sharing in genomic research have been examined in LMICs [7]. A study of twenty-two research projects across ten LMICs found broad consensus on the need for a locally relevant governance framework, equitable benefit-sharing arrangements, and community engagement based on respect and accountability [4]. Three of these projects concentrated on ethnically diverse populations; local and international researchers relied on diverse policy instruments, documentation, and practices to define the target community, while partners engaged local, national, and international stakeholders [1].

**Methodological Challenges and Biases**

Widespread concerns regarding the ethics of consent and governance in international biomedical research have led to intense scrutiny and debate concerning these areas within LMICs [1]. Such debates remain ongoing because of the plethora of challenges facing LMICs when analysing research materials obtained from international studies. In the case of metabolomics research, conceptual uncertainties exist as to which institutional settings and governance infrastructures represent appropriate environments for metabolomics research [3]. There is also an unresolved debate regarding whether institutions in the Global South should engage in metabolomics research involving the collection of human samples derived from countries within the Global North [5]. Although considerable evidence exists concerning consent and ethics challenges across various research domains, practical accounts concerning metabolomics research implementation in LMICs remain limited, as do studies investigating the ethical and social dynamics of various country contexts. A comparative synthesis of the scope of the evidence is needed to highlight key methodological issues and the types of governance or data-sharing arrangements that research actors have sought to implement already [2]. Several studies have engaged with consent and governance themes within health research in LMIC contexts. Existing research thus already covers a number of documented positions and issues concerning the governance and consent framework [7]. Nevertheless, evidence remains scarce on a

selection of much larger related concerns, as have been repeatedly noted in the literature. Specific LMIC-country empirical accounts of metabolomics projects, alongside more extensive research reviews compiled at the General Level and studies addressing significant secondary or broader themes directly influencing metabolomics variations across regions, remain absent to date [8]. Important analytical gaps also exist with respect to comparable groupings of project cases across geographical classifiers, consent and governance dynamics spanning time-series datasets, and internationally applicable project-classification schemas linking key attributes through generic definitions [8]. Methodological foundations, therefore, emerge as key preliminary practical and analytical themes concerning metabolomics practices in LMIC settings.

**Gaps in Governance and Consent Practices**

Several papers outline issues regarding the governance of research on human biospecimens, concepts that can be transferred directly to the study of omics and metabolomics in LMICs [1]. However, in 2010, a strategic initiative by the UK government reviewed evidence to assess whether the existing legislative framework was "fit for purpose" in relation to omitted research and concluded that it was not [3]. The question must be asked, since metabolomics research commonly utilises people as a source of data, whether the current policy and legal environment in many, if not all, LMICs is also "fit for purpose"[7]. Such initiatives can either lead to an improvement in policies that underpin consent and data governance or to chaos where misleading information by other authors lists the LMICs comply and fails to identify the significant limitations that apply [9].

**Policy and practice implications**

Worldwide attention has shifted to the health needs of low and middle-income countries (LMICs). As investments in biomedical research in LMICs grow, the ethical, legal, and social implications of such research require scrutiny [9]. The goal is to ensure that research meets the norms of ethical conduct while also enabling capacity building and the development of equitable partnerships [1]. Individual LMICs have different situations, challenges, development needs, and capacities to carry out ethical national and international research; however, specific ethical issues consistently emerge, particularly regarding consent and governance arrangements. Metabolomics holds promise for addressing health problems, but no empirical analysis explores the consent, governance, and trust issues raised by metabolomics research in LMICs [4]. Investigating these issues constitutes a first step toward identifying the implications of metabolomics and informing policy and practice in LMICs [7].

Research in LMICs raises different ethical, legal, and social challenges than research in high-income countries, including regulatory compliance, benefit sharing, and governance models [8]. The urgency for formal approval from ethics review boards contrasts with the need for practice-oriented approaches and the institutionalisation of participatory codes of ethics such as community-engaged research [11]. There is a need to balance protection and empowerment, with community-led frameworks and codes of conduct serving as potential solutions. Communities report low awareness of community-engaged research, creating a gap between large-scale international commitments to such research and actual benefits for communities. Evidence-based alternatives to community engagement exist, but the increased scrutiny and need for justification for health research in large-scale longitudinal studies pose a challenge for LMICs [12].

**Recommendations for Consent Processes**

The heterogeneity of metabolomics in health and development chronotopes leads to practising multi- temporality (including but not limited to anticipation, convergence, acceleration, divergence, and recollection) across corresponding scenarios and foci [9]. These chronotopes structure the identification and mitigation of potential negative externalities that may accompany metabolomics interventions in low- and middle-income countries (LMICs), supporting the broad adoption of related technologies pertaining to the Sustainable Development Goals enshrined in the 2030 Agenda[10]. Chronotopic engagement with metabolomics initiatives should begin at the pre-initiation stage, during which considerations of governance, trust, legitimacy, standardisation, interoperability, conceptualisation, epistemology, and spatiality remain as crucial determinants [11].

**Strengthening Governance and Data Stewardship**

As a condition for instilling trust and promoting data-sharing and collaboration, clear data stewardship plans are essential at the outset of metabolomics research [8]. Data stewardship encompasses both consideration of who can access and derive benefits from data and standards for the handling of shared data. Governance boards, independent of research teams and at a national or regional level, can provide data access guidelines [5]. Interoperability standards that facilitate comparability and analysis of data across multiple complementary datasets, together with consistent use of terminology, population descriptors, methods, units, and other metadata, improve prospects for maximal data utility while also protecting data [4]. Such plans also clarify the positive impact of planned research on the local community, thereby enhancing trust and ease of data mobilisation [6].

**Building Durable Trust and Benefit-sharing Mechanisms**

Efforts to build durable trust and implement equitable benefit-sharing mechanisms must be integral to metabolomic research initiatives grounded in health services in low and middle-income countries (LMICs) [4]. When the motivation for metabolomics research is individual health benefits, open connections between

participants and researchers may help establish trust and reduce anxieties regarding data use [12]. Regardless of the level of public trust, a history of unethical practices in certain areas of biomedical research in LMICs highlights the need for appropriate measures and safeguards to ensure that community trust is established and maintained [7]. Detailed planning, including the development of structures and agreements governing stakeholder engagement and the systematic articulation of expected benefits at the outset of the project, may foster durable community confidence [9]. Community-engagement strategies must identify potential health benefits and seek to establish commitments to deliver these benefits alongside the scientific and technical activities of a metabolomics project [6]. Agreements specifying benefit-sharing terms and establishing scientific governance arrangements prior to initiating metabolomics research may encourage trust and underscore the potential for national and local benefits. Transparency about who determines the appropriate conditions for governance can enhance participants' confidence in the influence of LMIC scientists and institutions [11].

## Case Studies

Recent research conducted in South Africa demonstrates a conscious effort to address ethics-related shortcomings in High Throughput Sequencing (HTS) studies and the necessity for enhanced governance models to assure further development of these projects within Africa and the Global South [1]. A review of HTS biosample studies published between 2005 and 2020 exposed several ethics-related issues: insufficient consent models (e.g., temperature-sensitive, temporal, non-commercial, secondary use), insufficient biosafety measures, and gaps in benefit-sharing provisions (acceptance of any benefits in exchange for biosamples; assurance or benefit-sharing requirements even if the study ends before the samples) were noted[2]. Following that review, more appropriate governance models based on Global South sensitivities and cultural aspirations were elaborated in papers and envisioned for use in forthcoming studies involving long-term biosamples such as HTS [3].

### Case study from a middle-income country

Epidemiological studies focusing on non-communicable diseases currently receive significant attention in the middle-income country of Ghana [1]. The detection of metabolic biomarkers indicative of these diseases could enhance research efforts. Research in Ghana on informed consent has revealed challenges when applying ethical guidelines developed in high-income settings [3]. The consent process is seldom transparent with respect to future uses of data. Many institutions lack the requisite capacity for ethical review of scientific proposals, even though ethics review has become mandatory in Ghana [5]. Research governance reflects the country's long-standing tradition of hierarchy, which can cause significant obstacles to the desired engagement of multiple stakeholders [7]. These issues have broad implications for the consideration of ethical, legal, and social implications of metabolomics and genomics research in many low- and middle-income countries [2]. The findings from Ghana illustrate how factors specific to the country influence both consent and ethics more generally. Even more remarkably, they demonstrate that a middle-income country can have an ethical, legal, and social research landscape markedly different from that of a low-income country. Research of this kind highlights the need to gather local evidence before formulating conclusions about ethical, legal, and social implications within a particular context [5]. From Ghana, it would therefore seem prudent to develop new approaches to consent, governance, and stakeholder engagement for metabolomics and genomics research in low- and middle-income countries [6].

### Case Study from a Low-Income Country

In metabolomics studies conducted within low-income settings, researchers encounter hurdles related to governance, consent, and community trust that directly influence scientific conduct [7]. These issues arise against the backdrop of high exposure to environmental hazards in such contexts. Even where national research frameworks exist, compliance is considerably hindered owing to limited regulatory oversight, deficient community engagement strategies, and a widespread absence of ethics committees and review bodies [8]. Research activities conducted in Zimbabwe, a country characterised by persistent socio-economic instability and weak regulatory frameworks, exemplify these challenges. Even though the country has ratified the Convention on Biological Diversity and the Nagoya Protocol, numerous researchers remain unsure of the operational principles of their national frameworks and of how to establish the appropriate institutional structures for compliance. In parallel, international funding agencies have begun to emphasise equitable sharing of benefits obtained through bioprospecting, and the establishment of such arrangements has emerged as a focus area [7]. However, a sizeable proportion of the research community maintains the perspective that the knowledge generated through metabolomics work is too abstract to yield tangible national benefits [3]. Consequently, community members continue to voice concerns that the knowledge gained is preserved and custodianship is assured rather than distributed as direct benefits [2]. In Zimbabwe, the current climate of uncertainty regarding compliance mechanisms and benefit-sharing arrangements has resulted in the development of plans to address these needs through capacity-building workshops involving researchers from both the funding and host countries. Scholarship on metabolomics is mounting, yet the literature addressing the ethical, legal, and social implications of this

Millennium Development Goal and Sustainable Development Goal–driven science in low-income countries remains scarce and rarely focuses on a specific country [7]. In general, ethical guidelines for research involving human participants in such settings have been proposed at the global level, but agrarian researchers advocating biobanking and additional environmental studies closely related to metabolomics have noted the absence of comprehensive country-based national guidelines that engage an international audience [1].

**Methodological Considerations for Future Research**

International dialogues proposed by global health organisations seldom endorse sweeping, prescriptive governance models that might be ill-suited to diverse low- and middle-income countries (LMICs) [3]. Systemic challenges persist: odious legacies and pre-existing governance failures undercut public trust in scientific institutions, and poorly constructed policies frame data as state property rather than a community resource [1]. Consequently, much existing governance is neither adequate nor contextually relevant [1]. Policy thought-leadership is essential for revitalising metabolomics governance in LMICs and stimulating regional discussions on better, more trusted governance models [2]. Professor Rukangira's intervention on toxic masculinity was necessarily cross-disciplinary. Securing an understanding of ethical, legal, and social implications requires not only technical data but also perspectives from the humanities and social sciences [3]. Other contributing challenges are pressing: the scholarship lacks the analytical depth or conceptual rigour methylomics warrants, and the social-science literature on LMICs is geographically and thematically distinct from methylomic scholarship [1]. Finally, official policies governing only psychopathological annotations should not define the spectrum of need. Initially coveted footage of a high-ranking African Union official was necessarily excluded from outreach activities for data security and integrity reasons. Data-collection protocols should underpin analysis designs and consent processes; an operational hampered by an accumulated backlog of filmic data further limits community-responsive decisions on public dissemination [2]. Methodological drawing on consent and governance literature in LMICs should address the proffered questions ecologically by first gathering evidence from alongside metabolomic, methylomic, and mobilomic researchers, before apportioning time for cross-disciplinary engagement with metabolomics specifically [2]. Contemporaneous theory building in any of these fields would assume substantial shape from emerging learnings. Grounding analysis within a broader, international framework remains desirable, yet seek cut transversal consideration of multiple subfields renders additional methodological steps of garnering ethnographic evidence less germane than ensuring structured engagement with the aims of specific data-collection bodies has received expedition shape[3].

**Ethical Review and Oversight**

An important aspect of health and development in lower and middle-income countries (LMICs) involves the implementation of health systems and public health initiatives that target the prevention, management, or treatment of health conditions that result in premature disability or death [3]. Such conditions often lead to the greatest number of years of life lost and associated economic impact for LMICs. Given the lack of health data for a number of health conditions across LMICs and the rapid urbanisation that is occurring, new methods of gathering health information are required [3]. Metabolomics is an emerging technology that has the potential to enable the intensive observation of environmental factors that influence the onset and progression of health conditions. Questions that have been considered in relation to metabolomics include the methods that are used to implement metabolomics, the type of data that is generated by its use, the potential benefits of metabolomics for LMICs, and equity considerations that arise from its implementation [2]. Metabolomics is defined as the comprehensive analysis of specific chemical substances in a biological sample, and the associated interpretation of these measurements. The time dimensions of a metabolomics study could include cross-sectional, longitudinal, or time series observations. The biological sample may include urine, plasma, serum, saliva, breath, and extracts from tissues or food materials [6]. Metabolomics does not only focus on endogenous metabolites or the biological consequences of human cell metabolism. Exogenous metabolites of environmental pollutants and non-desired amounts of nutrients consumed are also investigated as part of exometabolomics. Furthermore, xenobiotics in food and drugs that can cause long-term toxic effects to human metabolism are characterized under the field of alimentomics [9]. Metabolomics generates observational data concerning particular conditions or individual exposures in the context of larger time-points that do not specifically identify a time-sequence. Such observational data of relevant exposures cannot yet be fully obtained from non-omics datasets [10]. An initial exploit of the potential of metabolomics at the national scale began in 2014 across Singapore and Indonesia. A national-scale metabolomics study targeting diabetes and tobacco was undertaken as part of the Singapore/Indonesia Joint Funding Program by the Singapore Economic Development Board and the National Research Foundation. Economic and environmental analytic approach frames country-specific funding priorities, consistency of citizen well-being is enhanced, while recognition of needs and priorities by citizens has been rising [7]. Health equity researchers have raised concerns regarding the dual-edge of OMICS when used in low-income or low-middle-income contexts. The centre of OMICS readings might shift towards recognised high-income, high-middle-income contexts and health inequity becomes worsened [4]. Health equity must appear at the centre to respect national

legitimate health priorities. Omics may become a dominating consideration due to the strict combination of experimental OMICS, voltage OMICS, and Belgian OMICS processed by the accumulated available data at the national scale [4]. Metabolomics is one important key item among a few health systems priorities in many developing economies, but not the only one [3]. There is too much financial support required compared to other key health systems priorities, such as health information systems, health financing, Human Resources for Health, Health Governance, and Leadership in many developing economies[3]. International health collaboration, whether under the banner of "South-South" or "triangular" collaborations, remains essential for LMIC, strengthening the collective engagement with global health challenges [8]. The continuities in international health collaboration mainly focus on the biomedical area. Health systems in national priority setting and health equity in all collaborative contexts are also internationally important. International health collaboration itself may face new obstacles and should encourage multi-participation beyond traditional public institutions [9]. The urban population has now exceeded covering 50% of the Asian population. Urbanisation brings both health opportunities and health challenges. Metabolomics approaches are studied in economically developed Asia, such as Japan and the Republic of Korea [10]. It remains a soft matter science study in low-income Asian countries. For many eastern LMICS, urbanism is still underway. Caution is needed on whether LMICS can tackle urban-nutrition or urban-Gorham well by receiving urbanism-related metabolomics observations from developed Asia, or preventive and curative actions covering urban-urbanism can be incorporated into national level prioritization framework [11].

## Community-Engaged Research Methods

Community-based participatory research (CBPR), community-engaged research (CEnR), and participatory action research (PAR) contribute to trust-building between communities and researchers by involving community members in defining the research question, project design, implementation, data interpretation, and dissemination [12]. Integrating these participatory approaches and involving trusted local institutions in metabolomics research in low- and middle-income countries can ease consent and governance challenges [11]. Meaningful community engagement promotes researchers' accountability to the community and ensures that research acknowledges local knowledge and priorities [10].

## Data Governance and Interoperability

Research outputs in metabolomics and other omics fields involve the creation and retention of large databases containing complex and sensitive information about individuals, which requires careful management of the governance and stewardship of the data [5]. Comparable issues arise at different points in the research process: in the collection of data, in its storage and processing, in the distribution of its results, and in any subsequent secondary use of the data or its results [6]. Systems for managing the governance and stewardship of metabolic and other omics data in an international context must address many of the same factors, such as tiers of access rights, responsibilities, and rights of implementation, and links to material-transfer agreements, as those designed for foundational genomic research in low, middle, and high-income countries [10]. Crucial preliminary issues requiring formal stakeholder analysis, policy study, and data management-handling systems must also be resolved prior to the undertaking of such planning [11]. Standardization of relevant metadata; development of tiered governance and consent frameworks; establishment of harmonized data-sharing and assessment protocols; and identification of data-sharing objectives and appropriate complementary access systems are all key objectives that need to be pursued through ongoing community engagement involving a diverse range of sponsors, stakeholders and potential beneficiaries, and sufficient time and visibility granted for public-consultation feedback to be processed[12].

## CONCLUSION

Metabolomics holds transformative potential for addressing health and development challenges in low- and middle-income countries. Nevertheless, ethical, legal, and social considerations, especially consent, governance, and trust, must be central to research design and implementation. Effective engagement with communities, transparent governance models, equitable benefit-sharing, and robust data stewardship are critical to building sustainable research ecosystems. Empirical evidence from LMICs underscores that context-specific strategies are essential for addressing local needs and priorities, while international collaborations should prioritise reciprocity and ethical alignment. By integrating participatory approaches and strengthening regulatory and institutional frameworks, LMICs can leverage metabolomics to advance health equity, enhance scientific capacity, and contribute to sustainable development goals in a responsible and socially accountable manner.

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