BMJ Public Health

Global patterns in access and benefit-sharing: a comprehensive review of national policies

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To cite: Ljungqvist GV, Weets CM, Stevens T, *et al*. Global patterns in access and benefit-sharing: a comprehensive review of national policies. *BMJ Public Health* 2025;**3**:e001800. doi:10.1136/bmjph-2024-001800

► Additional supplemental material is published online only. To view, please visit the journal online (https://doi.org/10.1136/bmjph-2024-001800).

Received 24 July 2024
Accepted 6 February 2025

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ABSTRACT

Introduction The goal of access and benefit-sharing (ABS) in global health governance is to ensure that countries that provide access to genetic resources, including pathogens, receive equitable access to the benefits derived from their use. The increasing digitalisation of health data has brought this issue to the forefront of discussions on global health security and health equity. While originally conceptualised in supranational agreements, implementation of these treaties requires national-level legislation in each country. This descriptive analysis represents to our knowledge the first open-access comprehensive effort to map ABS policies in all 193 United Nations member states.

Methods We conducted a standardised review of the legislation for 193 United Nations Member States across three global legal databases (ABS Clearing House, WIPOLEX and FAOLEX), national legal databases and a systematic Google search. Legally enforceable policies were identified, and data were extracted across the following eight aspects of ABS legislation: Scope of Legislation, Digital Sequence Information (DSI), Access to Resources, Prior Informed Consent, Contractual Terms, Benefit-Sharing, Compliance and Legal Sanctions.

Results We found that 104 countries have legally enforceable policies on ABS, with 92 countries having ABS policies relevant to microorganisms. Of these, 74 countries have chosen to restrict access to their domestic pathogens, and 53 have chosen to link access to pathogenic resources with an obligation to share benefits. Altogether 22 countries have a codified position on DSI with regard to ABS in legally enforceable policy: 16 have explicitly included it, 2 have explicitly excluded it and 4 have ambiguous wording. WHO regional coverage of ABS policy on genetic resources ranged from 28% (3/11) of countries in the Eastern Mediterranean Region to 57% (21/35) in the Region of the Americas. Likewise, regional coverage of legally enforceable ABS policy related to DSI ranged from 0% in the Eastern Mediterranean and European Regions to 36% (4/11) of countries in the Southeast Asian Region.

Conclusion These findings highlight the heterogeneity found in the global policy landscape as it pertains to ABS, and provide data to inform future agreements and research efforts related to ABS.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Recent pandemics and technological advances have put access and benefit-sharing (ABS) in the centre stage of global health and environmental diplomacy. Yet, efforts to harmonise these policies have stagnated in multilateral negotiations. There is a distinct scarcity of evidence on the differing interpretations of ABS around the world, and further research is urgently needed to inform ongoing negotiations.

WHAT THIS STUDY ADDS

⇒ To the best of our knowledge, this study provides the first detailed publicly available global mapping exercise of the ABS policy landscape. We found that over half of the world's countries have legally enforceable policies relevant to ABS with significant geographic variation in policy coverage within WHO regions, and distinct global heterogeneity on the role of Digital Sequence Information within the ABS framework.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This study provides data to inform future research endeavours, highlighting global trends in national policy and identifying governance gaps. This open-source policy repository could inform future evidence-based policy-making on ABS at the national level and enhance understanding of the current legal environment for ongoing negotiations related to ABS mechanisms.

INTRODUCTION

Access and benefit-sharing (ABS) in global health security is the concept of regulating access to genetic resources (GR) to ensure some level of distribution of benefits derived from their uses. ABS has become one of the most important, and at times divisive,[1] issues in global health governance and has emerged as a key factor in discussions around equity, information sharing and outbreak response. The Convention on Biological Diversity (CBD), which entered into force in 1993, established ABS as a critical component of both the sustainable use of natural resources

and conservation of biodiversity. Article 3 established the states' sovereign right to control the use of GR physically located within their borders.[2] CBD also affirmed that access to GR was subject to national legislation, required prior informed consent (PIC), could be denied and had to be granted on mutually agreed terms (MATs).[3] In particular, it established that the benefits arising from the utilisation of accessed resources should be given, in priority and on a fair and equitable basis, to low-income and middle-income countries (LMICs). In generating a new revenue stream for biodiversity-rich countries, the Convention endeavoured to promote economic growth in LMICs, while simultaneously creating financial incentives for governments to combat biodiversity losses due to deforestation, pollution and biopiracy.[4–6] ABS mechanisms thus sit at the nexus of ecological legislation, economic policy and global equity.

- Genetic resources: usually taken to mean the physical samples derived from biological sources. In the context of pathogen research, this may refer to a pathogen sample, and by extension any medium they may be suspended in or grown on.
- Biological resources: a broader term than 'genetic resources', often encompassing plants, animals and microorganisms, including their genetic components as well as non-genetic derivatives. Sometimes used interchangeably with 'flora & fauna' or 'natural resources'. These terms are usually defined explicitly in individual policies, and the exact extent of their scope can vary.
- Digital sequence information (DSI): this refers to genetic resource data in terms of its constitutive genetic nucleotide base pair sequences, rather than physical material. While the use of the term DSI over the term 'Genetic Sequence Data' (GSD) is a matter of some debate, in this paper, these terms are used synonymously for the sake of clarity.

To support the implementation of the principles outlined in the CBD, the Nagoya Protocol on Access to Genetic Resources was adopted in 2010.[7] This protocol, open to Member States of CBD, further developed the language to safeguard traditionally exploited entities, including indigenous groups, to ensure equitable negotiations between providers and users of genetic materials.[8] Taken together, these agreements, rooted in biodiversity conservation efforts, provided a foundational legal framework for the transfer of biological materials.

While originally conceptualised in biodiversity agreements, ABS was recognised to have implications for pandemic preparedness and response, particularly with respect to pathogen sharing. In 2007, during an outbreak of H5N1 influenza in Indonesia, the Minister of Health announced a decision to cease pathogen sample sharing with the WHO and other global partners after a company in a high-income country (HIC) expressed interest in creating a vaccine from Indonesian samples. Indonesia cited CBD, claiming that a country's right to control its GR explicitly included those pathogens isolated within its borders and used the principle of 'viral sovereignty' to force discussion of more equitable access to benefits (eg, vaccines) derived from free sharing of such samples.[9–12] However, the exertion of such sovereignty was controversial, as timely sharing of pathogens with pandemic potential within the international community facilitates surveillance activities and the development of medical countermeasures.[13] Thus, there were concerns that sovereignty claims would delay timely sharing of pathogens.[14 15] The debates around 'viral sovereignty' influenced the Nagoya Protocol negotiations and also led to the development of a new agreement under the auspices of the WHO. Adopted in 2011, the Pandemic Influenza Preparedness (PIP) framework was the first international agreement to acknowledge viral sovereignty and address the need for a mechanism that could rapidly share pathogen materials while simultaneously upholding the principles of ABS.[16] Within PIP, this mechanism took the form of legally binding terms using Standard Material Transfer Agreements (SMTAs) that would be applied to all entities internationally transferring influenza GR. The intent was that the SMTAs would ensure an equitable process for sharing and deriving benefits from influenza genetic material, including access to vaccines in the case of an outbreak.

A robust ABS system has become increasingly critical to many LMICs. Due to the growing use of genomic sequencing and DNA resynthesis technologies, information regarding GR has become an important commodity.[17] As these technologies usher in a new era of pathogen data sharing, in addition to concerns over sharing physical GR samples, there is a need to consider Genomic Sequence Data (GSD), or Digital Sequence Information (DSI), as it is referred to within the CBD community. During the 2015 outbreak of Ebola in West Africa, DSI was used by entities from HICs to develop a novel medical countermeasure from GSD isolated in Guinea and publicly shared.[18] As this product was developed based on freely available DSI, there was no explicit obligation for the developer to share benefits, monetary or non-monetary, with the country of origin. But the question of whether DSI is already captured by ABS policies under the definition of 'GR' is a controversial one.[19] This issue was further underscored during the COVID-19 pandemic, where millions of genetic sequences were shared, highlighting the differences in the platforms used to share this information, and the disconnect between sharing DSI and eventual access to medical countermeasures.[20–22]

The CBD States Parties decided at the 2022 Conference of Parties to implement a multilateral ABS mechanism to equitably share the benefits of DSI to donor countries with legal clarity and efficient access, with instructions to refrain from introducing new legislation pertaining to DSI until such a mechanism could be introduced.[23 24] In another forum, negotiations for a new international agreement on pandemics include a proposal for a new pathogen ABS (PABS) system.[25]

At the 77th World Health Assembly in 2024, member states were unable to agree on this new international agreement and were granted a 1 year extension for negotiations.[26] On 24 October 2024, the CBD 16th Conference Of Parties (COP16) operationalised this multilateral mechanism, which aimed to facilitate the equitable sharing of benefits arising from DSI.[27 28] This agreement reaffirms that country-level policies to govern the transfer of GR and DSI are foundational to their effective implementation. Expanding on previous case-study research on specific aspects of ABS policy,[29 30] our research systematically describes the national-level policies at a defined point in time from the 193 UN Member States on ABS as they relate to microorganisms. To the best of our knowledge, this is the most comprehensive open-access mapping of national-level policies governing all aspects of ABS for both pathogens (GR) and DSI, and will provide a useful reference for scientists seeking to share pathogens and DSI around the world. We believe this mapping to be a critical foundation for understanding the state of ABS in the world, and to inform future bilateral, regional and global negotiations.

METHODS

Project scoping and country inclusion

We identified and analysed national ABS policies relevant to GR and DSI for all 193 UN Member States, regardless of their membership in international agreements, including the Nagoya Protocol, in order to provide an accurate and up-to-date reporting of the global policy environment (figure 1).

This ABS data set is just one aspect of the multifaceted analysis and mapping of policies for emerging infectious diseases research effort, which seeks to create an unparalleled repository of global outbreak preparedness and response policies across various topics. We employ a standardised operating procedure (SOP) across all policies for data collection. The SOP includes a literature review for each topic to identify relevant search terms for the topic's policy collection protocol. After the completion of the ABS literature review, we conducted a proof-of-concept study of 10 geopolitically and economically diverse countries to test the methodology and determine a final series of query terms to be employed. After proof-of-concept, we reviewed and resolved gaps in the policy collection protocol and coding methodology. The research team then created the customised data taxonomy (online supplemental figure 1).

Identification of relevant policies

To collate a comprehensive data set of relevant policies, we developed a standardised, sequential policy identification protocol for each country. Three online policy databases were systematically investigated. The ABS Clearing House was first consulted.[31] This online platform, administered by the CBD Secretariat, requires countries to upload their relevant ABS legislations. We reviewed each country's profile and downloaded all available active legislation for review. Interim National Reports on the Clearing House were reviewed to help the interpretation and identification of relevant documents, but were not uploaded onto our repository. We then utilised the World Intellectual Property Organization legal database (WIPOLEX).[32] This filterable database contains intellectual property legislation and is centrally administered by the WIPO. We filtered for the subject matter of 'Genetic Resources', and downloaded relevant policies for each country. Finally, we examined the Food and Agriculture Organization's legal database (FAOLEX).[33] We reviewed the Environment and Wild Species and Ecosystems categories for each country. Laws mentioning 'Access and Benefit-Sharing' and 'Genetic Resources' were included. Relevant overarching acts, containing the terms 'Biological Diversity/Biodiversity', 'Nature', 'Natural Resources', 'Environmental' and 'Conservation', were also included, unless explicitly unrelated (for instance, the Japanese 'Act preventing the Environmental Pollution of Mercury'). We screened the full text of these overarching acts for relevant sections to ABS, and those lacking any mention of 'access and benefit-sharing' or 'genetic/biological resources' were excluded. All remaining legislation was included for further analysis.

After completion of the database consultation, we conducted a manual search of the national government's legal database, where possible. If a legal database maintained on a country domain was available and

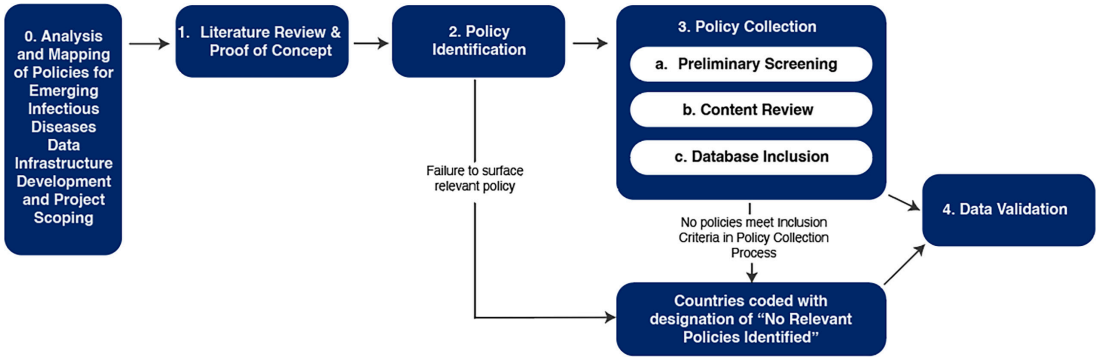

Figure 1 Methodology protocol utilised in the analysis and mapping of policies for emerging infectious diseases topic on access and benefit-sharing. Numbering illustrates the sequential approach to project completion.

open-access, all potentially relevant policies, utilising the collection criteria described above, were captured.

Finally, we completed a manual search in the Google search engine using a standardised series of search terms developed through the literature and landscape review (online supplemental table 1), using a machine translator to translate the search terms into the language used by the government in each target country.

Once all potentially relevant policies from a country were surfaced, we used Google Translate to complete the translation of policies in languages not spoken by the research team. Where possible, fluent speakers of non-English languages were contacted to verify machine translations.

In the case that this standardised collection protocol failed to surface any potentially relevant policies, we coded the country as 'No ABS legislation identified'. Importantly, we identified all relevant, legally enforceable policies in a country, though research on the extent to which any of these policies are implemented and enforced in the country was beyond the scope of this project. Thus, it is possible that the execution of policies may be inconsistent with the policy mandate. Furthermore, we concentrated our efforts on national-level policies, assessing that state-level, subregional or otherwise geographically defined legislation was beyond the scope of this project.

All policy identification and collection for the repository took place between October 2023 and May 2024.

Repository creation

Primary and secondary policy review by inclusion criteria

Potentially relevant policies identified through the standardised collection process were subject to a preliminary screening to eliminate documents that were not legally binding or were no longer enforceable, including strategies, reports, draft laws and repealed laws. As an exception, supporting documents designed to clarify the interpretation of associated active laws or policies were included to provide critical contextual information. This is the case, for instance, with the EU Regulations 511/2014 which regulate how member states check compliance, but which still requires implementation into member states' domestic law to be active.[34] These entries have been clearly identified as supporting documents in the data set. We did not consider such position statements to be synonymous with legally enforceable policy. Thus, while we have noted the existence of such positions in our results, they were not considered in our reporting of the proportion of countries with codified policies.

Policies that passed the preliminary screening stage were then reviewed by the standardised inclusion criteria for eight distinct subtopics: Access, Compliance, Scope of Legislation, Benefit-Sharing, DSI, PIC, Contractual Terms and Legal Sanctions (online supplemental table 2). Policies that met the inclusion criteria were interrogated for each subtopic sequentially, and an applicable status was assigned when relevant language was identified (online supplemental figure 1). Each policy document was assigned to their respective country to populate the data set. Policies were then downloaded as PDFs and collated in Airtable, a cloud-based platform for relational repositories. All documents included in this data set are publicly available for download in a comma-separated values (.csv) file.

Data validation

Literature review, collection protocol and inclusion criteria were reviewed by the entire research team and approved by the Principal Investigator. Policy collection and primary review by inclusion criteria were completed by a lead researcher. Once included in the repository, a second member of the research team completed a secondary review of policies, assessing the primary researcher's coding. Any coding discrepancies that arose between researchers were deconflicted and reviewed by the Principal Investigator. Finally, the data went through a quality control review by the research team before being uploaded to a publicly available website.

Data availability

All data sets, reproducible code and figures are available in a public, open-access repository at https://github.com/cghss/ABS.[35]

Patient and public involvement

Given the nature of this work, no patients were involved in the research process, nor was any public involvement solicited.

RESULTS

We found ABS policies were applied, either explicitly or implicitly, to a broad range of sectors from fisheries to agriculture. Of the UN member states reviewed, 54% (104/193) had broad legislation pertaining to ABS in any context, although 12 countries, such as Mongolia or Niger, had legislation not applicable to microorganisms, referring instead to 'plants and animals'.[36 37] Some countries employed multiple policies to regulate various aspects of ABS, while others used a single policy to do so. In comparing our results with the existing database of ABS-Clearing House overseen by the CBD, we found that, of the 181 documents our methodology identified, 61% were also found in the ABS-Clearing House (111/181). Just under half of countries, 46% (89/193), have not codified legally enforceable policy on any aspect of ABS.

Relatively few countries (11%; 22/193) had included language referring to DSI in legally enforceable policy. Nations that have codified a position on ABS of DSI tended to address both DSI and GR in the same legally enforceable ABS policy. However, this was not universally true, meaning that some countries had GR legislation that did not include provisions on DSI. This lack of uniformity accounts for discrepancies between the total number of states within a WHO region with GR or DSI-related policies and the number of states within the

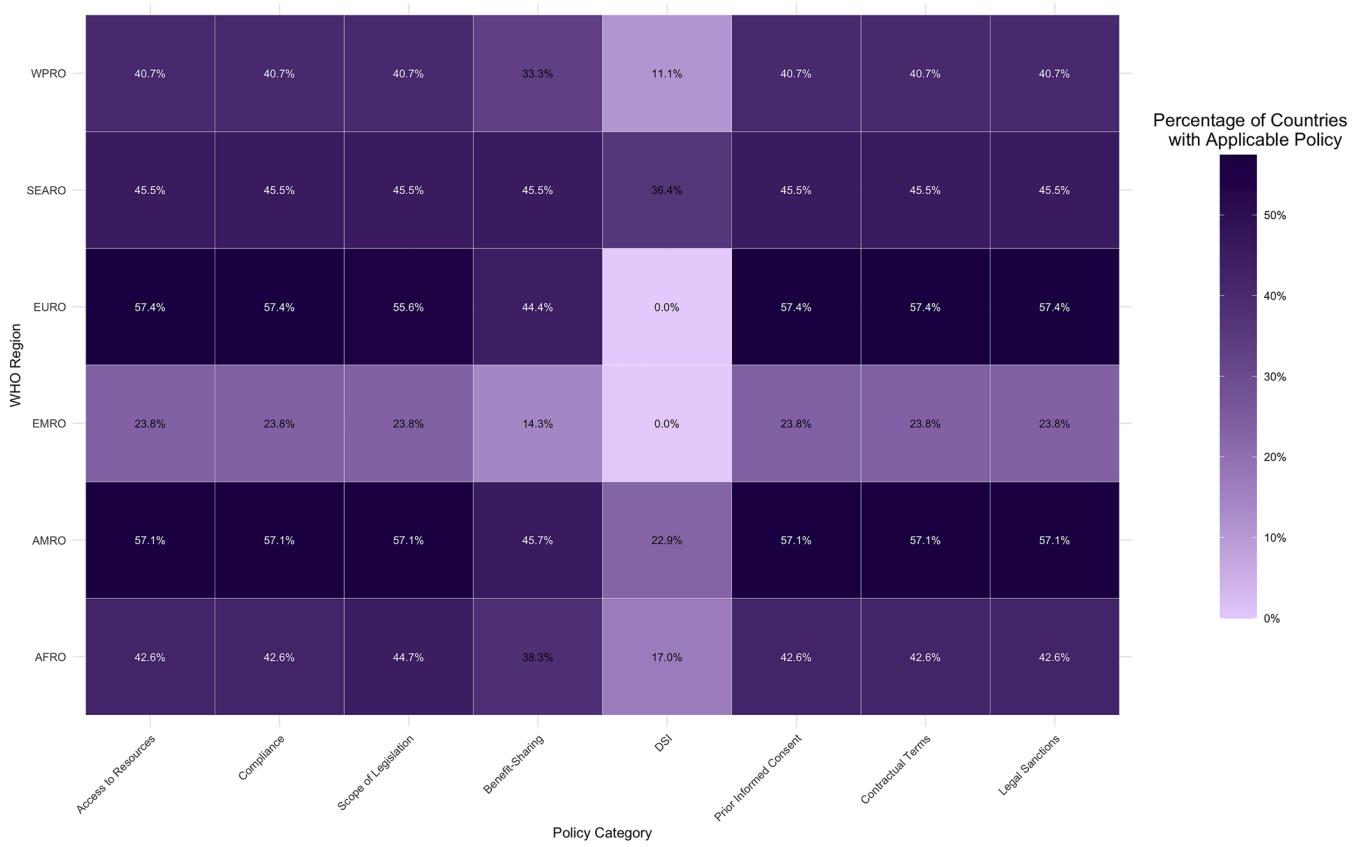

Figure 2 Heat map of percentage of countries within World Health Organization regions with legally-enforceable policy applicable to each subtopic. Shading represents the percentage of countries with applicable legislation, with darker shading indicating a higher percentage of countries with identifiable legislation pertaining to that subtopic category. Black numbering represents percentages less than 40.0%, while white numbering demonstrates percentages over 40.0%. Percentages were calculated as the number of countries within a WHO region with applicable policies for a subtopic divided by the total number of countries in the WHO region and rounded to the nearest tenth.

region with policies that pertained to individual policy categorisations (figure 2).

Regional variations in genetic resource and DSI ABS policies

There is substantial inter-regional variation in the presence of legally enforceable ABS policy. No WHO region had greater than 57% of countries with applicable policies. However, some regions had a significantly higher proportion of countries with applicable legislation than others (figure 2).

Although we observed substantial variation between regions in the number of countries with legally enforceable policies governing GR, this type of ABS policy was the most comprehensive across the world. The European Region and Region of the Americas had the greatest coverage of policies pertinent to GR ABS with applicable legislation identified in 57% of countries in each region (31/54 and 20/35, respectively). Likewise, nearly half of countries in the Southeast Asian (46%; 5/11) and African regions (45%; 21/47) were found to have applicable policies. Countries in the Western Pacific (41%; 11/27) and Eastern Mediterranean Regions (24%; 5/21) were found to have the lowest proportion of states with ABS policies related to ABS.

Legally enforceable policy related to ABS of DSI was found much less frequently across all regions when compared with ABS policy on GR. The Southeast Asian Region and Region of the Americas were found to have the highest percentage of countries with applicable policies with 36% (4/11) and 20% (7/35), respectively. Similarly, the African (17%; 8/47) and Western Pacific (11%; 3/27) regions each had a small number of countries where an explicit stance on ABS for DSI had been codified in policy. However, in the European and Eastern Mediterranean regions, no countries had codified ABS policy for DSI in legislation at the time of this research.[38]

Diversity in policy content

Access restrictions and scope of application

Policies governing the access to microorganisms were identified in 48% of countries (92/193). A further 46% (89/193) of countries were found not to have any national-level ABS policies relevant to GR, while the remaining 6% (12/193) were found to have legislation that could broadly be interpreted to encompass ABS but did not include provisions on microorganisms. Therefore, 52% (101/193) of studied countries were found not

to have any national-level policies relevant to ABS of GR applicable to pathogens.

Of those countries with relevant policies, 89% (82/92) encompass access to GR, including microorganisms, as well as traditional knowledge, while the other 11% (10/92) only include GR, including microorganisms. Of the 92 countries with policies regulating access to GR, 80% (74/92) chose to restrict access. These restrictions may be stated explicitly, as in Algeria, which comprehensively outlines the assessments and declarations needed to garner access to resources,[39] or implicitly, as in Tanzania, where resource sovereignty is codified, but regulatory mechanisms have not been established.[40] Access restrictions included in relevant policies may also differ based on the intended use of the extracted resource. For instance, as a precondition to access, Filipino law requires a Commercial Research Agreement if GR are intended for commercialisation, whereas an Academic Research Agreement suffices otherwise.[41] The remaining 20% (18/92) of countries with policy on resource access opted for unrestricted access. This may be done through explicit provisions in legislation, as is the case in Japan,[42] or through implicit authorisation. For example, some EU countries such as Sweden and Luxembourg do not outline any access restrictions in their relevant ABS policy, thereby effectively authorising extraction and usage of their GR.[43 44]

Preconditions for resource access

A subset of countries' national-level policies require benefit-sharing, consisting of either monetary benefit-sharing such as royalties or milestone payments or non-monetary benefits such as technology transfer and academic credentials, as a precondition for access. We found that 53 countries have legislation linking benefit-sharing with access. For instance, in Brazil, the documentation of benefits required for commercial entities to gain access to GR is outlined in relevant law.[45] The remaining 28% (21/74) do not explicitly establish an obligation to share benefits related to accessed GR, despite having restricted access. This is the case for the Central African Republic, where the law states that the sharing of benefits should be 'taken into account', but is not explicitly mandated[46] (figure 3).

PIC is a mechanism that requires users to inform relevant authorities of the materials sought, their intended use and the project timeframe as a precondition to resource access. The 20% (18/92) of countries that have codified open access to domestic GR in policy, by definition do not require PIC agreements. However, of

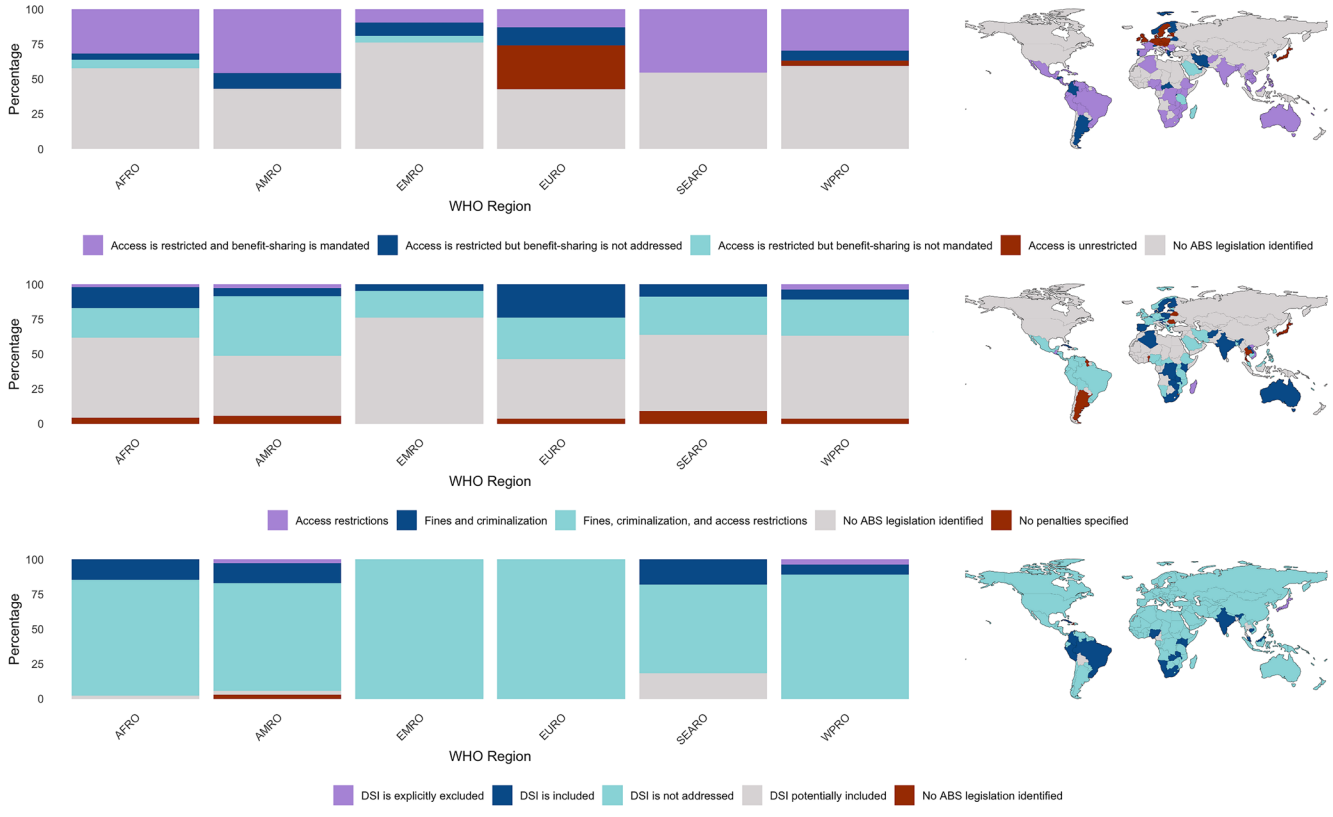

Figure 3 Graphical and mapped representation of countries with (A) legally-enforceable policy pertaining to genetic resource access, (B) sanctions included in legally-enforceable ABS policy, and (C) legally-enforceable policy that covers Digital Sequence Information (DSI). Bar graphs are arranged by WHO regions, with bars illustrating the percentage of countries within the region with identifiable policy for each of the subtopics. The corresponding maps, located to the right of each bar graph, demonstrate country-level status.

the 74 countries that do restrict access to resources, PIC mandates are codified by 82% (61/74) of the countries that restrict access to GR. Often, these provisions have been included in legislation to protect indigenous populations, as is the case in Zimbabwe. Zimbabwean law outlines requirements for consent-seeking and encodes the rights of indigenous communities to be consulted in granting access to indigenous GR for non-indigenous entities.[47] The remaining 18% (13/74) have not included PIC provisions in their legally binding ABS policies.

Separately, states may also require a written contract for ABS, which often takes the form of material transfer agreements or MATs. Of the 74 countries that restrict access to resources, 74% (55/74) require the establishment of a contractual agreement between the resource provider and the user, while the remaining 26% (19/74) of countries have not established a requirement for contractual terms despite having legislation restricting access to resources.

Compliance mechanisms

The vast majority of countries (95%; 87/92) that restrict access to GR include provisions for compliance mechanisms in legally binding policy. However, countries use diverse approaches to enforcing their ABS laws. Many countries, such as Brazil, require registration of users and declaration of outcomes at various points of the ABS process.[45] Malaysia, for instance, requires those international entities exporting GR to pass through checkpoints,[48] while France empowers specific enforcement officers responsible for ensuring compliance with ABS policies.[49]

Legal sanctions, or punishments for international entities found to have violated ABS legislation, are less commonly included in policy than mechanisms to proactively ensure compliance. Of the countries that restrict access to GR, 91% (84/92) include legal sanctions in their legally enforceable policies (figure 3). Such sanctions may include fines, criminalisation and further restrictions on access. Of these, some states (4%; 3/84) solely employ restrictions on access as sanctions, such as in legislation from Madagascar, which established the revocation of access permits and bans on future access.[50] Others (31%; 26/84) chose to use fines and criminal processes. More commonly, these sanctions are used in concert, as is the case in Cambodia where delinquent entities are both charged a monetary fine and access permits are revoked.[51] The combination of fines and criminal prosecution with access restrictions was the most commonly identified legal sanction (65%; 55/84).

Digital sequence information

As of May 2024, 11% of countries (22/193) made mentions of DSI in their legislation, whereas the remaining 89% of countries (171/193) had not codified a position on DSI (figure 3). Of those with mentions of DSI, 73% (16/22) of countries explicitly stated that DSI was included in their ABS legislation, while a further 9% (2/22) explicitly excluded DSI from ABS policies. A 2009 Nigerian policy, for instance, includes DSI by stating that access to GR pertains to all 'intangible components', as defined by 'information associated with or regarding genetic resources'.[52] In contrast, Japanese policy explicitly excluded DSI from guidelines about ABS of GR.[42] Some countries (18%; 4/22) included ambiguous language which may be interpreted to cover DSI, without explicitly doing so. For example, ABS legislation from Bangladesh includes 'biological material including (…) its various expressions and embodiments in knowledge', which might effectively cover DSI.[53]

DISCUSSION

ABS policy is a critical part of the current governance between nations engaging in the international transfer of GR and information. Mapping these policies creates transparency around processes in place to govern equitable relationships between entities in compliance with national-level policy and facilitates access to information by providing all parties with clarity on the policy landscape in partner nations. We found that 54% of UN Member States have publicly available, legally enforceable ABS policy on GR at the national level, while just 11% of UN Member States have included explicit language on DSI in enforceable policies. Moreover, there is significant variability within most WHO regions in the presence of legally enforceable GR and DSI ABS policies, with no region found to have greater than 57% of countries with applicable legislation. Despite this interregional heterogeneity, we did find notable thematic trends. Policy categories that were broader, such as those affirming sovereignty and regulating access to GR, as well as those that outlined legal sanctions and mechanisms to ensure compliance, were identified in a greater proportion of countries. By contrast, we found that subtopics representing niche areas applicable only to ABS-specific policy, such as benefit-sharing requirements and regulation of DSI, were less likely to exist in the current national policy landscape.

Regional variation in policy coverage may be largely explained by geopolitical relationships and economic factors. Regions with relatively strong cultural, political and historical ties, including Western Europe, Andean South America and sub-Saharan Africa, tend to carry similarities in their ABS legislation. We found that ABS policy was coordinated to the greatest extent between countries within formal supranational organisations, such as the EU[34 54] or Andean Community.[55] The majority of the countries within these custom unions had reached broad consensus over their views on ABS, which were reflected in national-level policy. While not always geographically clustered, we also found that countries in similar economic strata tended to adopt substantively similar stances on ABS. For example, wealthier nations tended to either leave access to resources unregulated at the national level, as was the case in the USA and

Canada, or explicitly allow for free access to domestic GR, as is permissible in many Western European nations and Japan. Conversely, many LMICs, particularly in areas known to be highly biodiverse,[56] were more likely to have adopted national legislation restricting access to GR, requiring benefit-sharing and creating compliance mechanisms relative to their wealthier counterparts.

Variation in policy coverage by category was observed across regions, suggesting similar factors affected the inclusion of certain aspects of policy across geographic and economic groups. Legislation that broadly affirms state sovereignty over GR and defines which resources fall under legal protection are the most commonly identified, but also the most diverse and unclear. Often these laws predate discourse on bioprospecting, yet the laws establishing resource sovereignty have been retrofitted to cover GR or traditional knowledge, contributing to the observed heterogeneity and ambiguity of their contents.[57] For example, some policies restricting access to resources fail to explicitly define the scope of the protections, create unclear compliance processes or simply fail to outline any pathway to resource access. Nevertheless, most countries that restrict access to GR include both preconditions to resource access, in the form of PIC and benefit-sharing, as well as compliance mechanisms and legal sanctions in legally enforceable policy. However, there were notable qualitative differences between countries in these categories that may have implications for equitable sharing of benefits derived from resources and compliance with these policies.

In contrast to GR ABS policies, states' stances on DSI were not typically included in legally enforceable policy. Instead, many nations, including the USA, the Republic of Korea and members of the European Union have published position statements declaring views on how their current ABS policies should be interpreted with regard to DSI.[38] Given the dynamic nature of this area, such statements may offer states greater flexibility to evolve their positions and interpretations as the utilisation of DSI becomes more commonplace. DSI sharing, when addressed in legally enforceable policy, used inconsistent terminology, including 'sequential information',[58 59] 'genetic heritage',[38 45] 'intangible components',[52 60–62] 'information related to genetic resources'[48 63 64] and 'utilisation of resource'.[38 65] These inconsistencies in the policy environment suggest a lag time between advances in data-sharing techniques and policy development. Indeed, the multilateral community has yet to agree on a concrete definition of DSI, let alone tackle logistical issues such as storing, tracking and intellectual property.[66–68]

There are efforts within the international community to try to address both heterogeneities in GR ABS policies and variation in how DSI is addressed. A PABS system has been proposed as part of negotiations on a new Pandemic Agreement.[25] The World Intellectual Property Organization (WIPO) has debated compliance mechanisms in international patenting laws of biotechnology, starting with the Colombian proposal of 1999[69] and settling in 2024 on a treaty establishing a disclosure requirement when applying for a patent based on a GR.[70] Most recently, the COP16 agreed on a new multilateral mechanism for the sharing of DSI and associated benefits, with the newly established Cali Fund dedicated to its financing.[28] As negotiations resume ahead of the 78th World Health Assembly, these issues will continue to be at the centre of discussions moving forward.

Limitations

This research has important limitations and creates opportunities for further study. The policy identification protocol relies on the digitisation of policy in publicly available repositories. Thus, nations without freely accessible online policy databases may not have been accurately captured in this work. Additionally, this study was constrained to national-level policy, though some countries regulate ABS or DSI at the subnational level. For example, Australia utilises a combination of subnational and national level policy to regulate ABS for both GR and DSI;[29] however, in accordance with the project methodology, we captured only the policy enforceable at a national level. Given the complexity of this issue, for countries that utilise subnational policy to govern ABS, a case-study approach may be more appropriate to accurately capture the policy environment. Furthermore, we were only able to analyse what was explicit in the policy, though implementation and enforcement of these policies may be inconsistent with the policy mandate. Without data on the implementation and enforcement of these policies, including local cultural contexts, our results should only be considered informative of the current policy landscape. Finally, the data are intended as a snapshot report and therefore do not capture legislative changes that may have occurred since data collection in this rapidly evolving arena.

CONCLUSION

ABS is a critical part of global health governance, and, from past events, one of the most controversial. With the ongoing evolution of multilateral mechanisms to ensure the fair and equitable sharing of benefits derived from DSI, domestic legislation remains crucial to its successful implementation. It remains, therefore, critical to understand what policy already exists and where differences emerge. This research supports engagement by both researchers and other governments in approaching their own ABS legislation. It also provides an opportunity for empirical research and examination of national-level ABS legislation for specific outcomes and enables future comparative analyses to monitor the progress of implementation of national-level legislation. Such efforts will be crucial to help support an evidence-based approach to global governance of disease moving forward.

Contributors The study was conceptualised by GVL and RK. Data collection was conducted by GVL, and supervised by CMW, TS and RK. Data structure was

validated by TS, CMW and HR. Data repository was created by RZ and EG. CMW performed the data analysis and created the figures for the manuscript. The first draft was written by GVL and CMW, with further input from RK. All authors provided substantial critical feedback to improve the manuscript and all authors approved the final draft. RK and GVL are the guarantors of this study. GVL and RK accept full responsibility for the finished work and the conduct of the study, had access to the data and controlled the decision to publish.

Funding This work was funded by the Rockefeller Foundation under grant AWD-7775263 GR425219.

Map disclaimer The inclusion of any map (including the depiction of any boundaries therein), or of any geographic or locational reference, does not imply the expression of any opinion whatsoever on the part of BMJ concerning the legal status of any country, territory, jurisdiction or area or of its authorities. Any such expression remains solely that of the relevant source and is not endorsed by BMJ. Maps are provided without any warranty of any kind, either express or implied.

Competing interests RK is a member of the Technical Advisory Panel for the Pandemic Fund. No other authors have competing interests to report.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available in a public, open access repository. (datset). Ljungqvist G, Weets CM, Stevens T, Robertson H, Zimmerman R, Graeden E, *et al*. Data from: Global patterns in access and benefit-sharing: a comprehensive review of national policies [Internet]. GitHub; 2024. Available from: https://github.com/cghss/ABS.

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