




Biobanking as a contentious issue in global health governance diversification and contestation of policy frames in international biobanking debates

Maria Weickardt Soares^{a,b}, Anna Holzscheiter^{a,c,*} , Tim Henrichsen^d

^a Institute of Political Science, Faculty of Philosophy, TUD Dresden University of Technology, Germany

^b School of Law, University of Warwick, UK

^c Department of International Relations, London School of Economics, UK

^d College of Social Sciences, School of Government, University of Birmingham, UK

ABSTRACT

Biobanks are an integral part of contemporary biomedical and biotechnological research, nationally and internationally. Over time, biobanking has also become invariably more transnationalised, following broader developments of biomedical research across borders and the increasing transnational circulation of human specimen and related data. The manifold technical, legal, ethical and governance challenges resulting from such transboundary, potentially global, circulation of human specimens and related data, however, have to date not resulted in any binding truly international agreement regulating transnational issues with biobanking. In this paper, we analyse when and in what way biobanking has been subject to policy debates in international organisations, with a particular interest in the most prominent policy frames that have informed these debates. We identify biobanking as an underexplored area of research on international policy-making, notwithstanding its prominence in global health cooperation and the many contentious issues that surround it. Our empirical analysis traces the diversification of policy frames over time (1995 to 2019) and, zooming in on those policy frames that emerge as salient yet contested in our analysis, exposes the trajectories of debates on the rules and norms that should govern the transnational circulation and commodification of the human body. We find that biobanking has evolved from a technical, apolitical matter into a multi-faceted issue, which is reflected in the diversification of frames circulating in international organisations. On the basis of our study, we identify a number of policy frames that have emerged as particularly contested over time, with human rights frames standing out as having the most divisive potential.

1. Introduction

Biobanking as the retrieval, collection, storage, and preservation of human biological samples is an integral part of contemporary biomedical and biotechnological research, nationally and internationally. With biobanking having become widely recognised as indispensable for medical progress and huge advances in technology allowing to build massive research infrastructures, the number of biobanks has been growing fast since the early 2000s. A 2010 survey counted 145 active research biobanks across Europe (Zika et al., 2010); in 2021, the European biobanking infrastructure BBMRI-ERIC listed 618 biobanks, storing millions of samples derived from humans such as blood, cell lines, umbilical cord blood, tissue (BBMRI-ERIC, 2021). Most of these biobanks store DNA combined with serum, whole blood, and tissue i.e. samples surrounded by contentious ethical debates (Zika et al., 2010). Over time, biobanking has also become invariably more transnationalised, following broader developments of biomedical research

across borders and the increasing transnational circulation of human biological samples and related data. In this paper, we target international organisations as arenas for debates on norms – as formalised and informal standards of appropriate behaviour (Katzenstein, 1996) – that should incentivize and regulate transnational cooperation on biobanking, the benefits and risks of biobanking, and the many technical, legal and ethical challenges associated with it. The starting-point for our analysis is the observation that, in contrast to varied and controversial debates on the consequences of storing, classifying, and circulating information on the human body and human material in domestic parliamentary and public debates as well as medical ethics research (e.g. concerning genetic information and racial bias), international institutions have rather sporadically and hesitantly engaged with this policy issue.

Contemporary biobanking is marked by three significant parameters: first, unprecedented technical and infrastructure capacities to make use of human biological materials and the data derived from them; secondly,

* Corresponding author. TUD Dresden University of Technology, Institute of Political Science, Faculty of Philosophy, Bergstraße 53, 01069, Dresden, Germany.
E-mail address: anna.holzscheiter@tu-dresden.de (A. Holzscheiter).

the transnationalisation of biobanking, reflected in a steady increase in cross-border circulation of samples and related data resulting in unprecedented accessibility and (ab)use of samples and data as well as growth in international biobank networks (Mayrhofer and Prainsack, 2009); and thirdly, the embeddedness of biobanking in a complex landscape of actors and institutions. Recent noteworthy examples such as GISAID – the central data repository for all data related to COVID-19 – expose the dangers of weak international legislation as much as they show the extent to which biobanking is surrounded by a vast assembly of transnationally operating public and private, not-for-profit and for-profit actors, with ample potential for conflicts of interest.

Acknowledging the transnational nature of biobanking as well as the heterogeneity of actors involved in its practice, we conceptualise biobanking as the process of creating physical and virtual repositories for biological material of human origin, including the distribution of human samples and related data as well as networking between various actors within national jurisdictions and beyond. Biobanks and the practice of biobanking have been subject to debates in international organisations at different points in time, with the aim to further enable transnational cooperation while, at the same time, setting rules for appropriate and safe handling and use of both samples and related data within jurisdictions and across borders. Typically, the establishment of national biobanks has been accompanied by domestic law regulating storage and use of as well as access to human biological material and related data collected in biobanks. The more countries have established national biobanking infrastructures, the more incompatibilities between national jurisdictions have been identified as a policy issue, obstructing the transnational use and circulation of human samples and data (Hewitt and Hainaut, 2011). To date, however, the 1997 Council of Europe Oviedo Convention on Human Rights and Biomedicine, a regional treaty, remains the only comprehensive treaty with binding international rules on biobanking. Other codified norms relevant to biobanking are, before all, those pertaining to privacy and data protection, such as Art. 12 of the Universal Declaration on Human Rights (i.e. general privacy considerations); Art. 17 of the International Covenant on Civil and Political Rights (ICCPS); Art. 8 of the European Convention on Human Rights (Bernier et al., 2022); the 1980 OECD Privacy Guidelines (renewed in 2013); the Council of Europe Convention 108+; and lately the EU General Data Protection Regulation (GDPR).

In the light of these observations, our paper asks: when and in what way has biobanking become subject to policy debates within international organisations? Which policy frames have shaped these debates and how can an understanding of the salience and contestedness of specific frames explain the status of contemporary international debates on biobanking? By means of a mixed-methods analysis of the policy frames surrounding the global circulation of human biological material and related data, and using the programme Discourse Network Analyzer, our paper seeks to expose the diversification and contentious dynamics of policy frames on biobanking over time. Our focus lies on exposing biobanking as a contentious policy issue, tracing those policy frames that, over time, have been particularly contested in international discourse. Based on our data, we are able to provide systematic evidence for frame diversification (Ayoub and Chetaille, 2020) – understood as a growing frame universe in which new causal and normative statements on biobanking emerge over time and compete with each other in policy debates. More importantly still, we aim to expose contestation of policy frames on biobanking – which allows us to draw conclusions on the politicisation of biobanking in international discourse over time, defined as raising awareness, mobilisation, and contestation of an issue (Abbott, 1992). Our study of the different phases of international debates on biobanking shows that it is particularly the porous boundary between human biological material (and samples as the traditional resource of biobanks) and the data associated and circulated together with that material that has transformed biobanking into a political issue rather than merely a matter of technical standardisation across borders. We also infer from our data analysis that human rights frames that became a

salient aspect of biobanking from the early 2000s onwards have had the biggest effect on the politicisation of biobanking in international discourse.

We will start the paper by defining the boundaries of the policy field we study and reviewing the extent to which Political Science, including International Relations, scholarship has engaged in international debates on biobanking. Section 3 introduces the theoretical perspective we adopt to study diversification and contestation of policy frames in international organisations' policy debates and, to a lesser extent, in broader international media debate on biobanking and the methodology we used to capture these frame dynamics that render biobanking a contentious and increasingly politicised area of international cooperation.

2. Biobanking as a transnational policy issue

With the advent of transplant surgery in the second half of the 20th century, the use of living tissues gained increasing relevance in medicine, changing the practice of biobanking as well (Eiseman and Haga, 1999). The specific term "biobanking", however, only dates back to the 1990s (Cambon-Thomsen et al., 2007). In a period of approximately 35 years, biobanking has grown into a large sector of biomedical practice with sometimes enormous infrastructures for research and development enabling the "flow of body parts in international circuits" (Beltrame, 2014) and the collection, mapping, classifying and sharing of sheer limitless amount of human material and data. To date, the international dimensions of biobanks and biobanking and the activities of international organisations in this field have received rather limited attention. Research on international policy-making and debate on biobanking has largely focused on the European region, with very limited Political Science research as regards the transnational regulation of biobanks and the ways in which international organisations have responded to this ever-expanding activity. This appears even more surprising in light of extensive Social Science research on national debates and policies surrounding biobanking (Bledsoe, 2017; Dive et al., 2020; Nansumba et al., 2019; Samuel and Lucassen, 2023). It is also surprising considering the fact that some international institutions such as the European Union or the WHO are not only central to international regulation of the global circulation of human material but themselves engaging in practices of biobanking or funding networks of biobanking. Noteworthy biobanks are the International Agency for Research on Cancer Biobank IBB hosted by the WHO or the European Biobanking Research Infrastructure.

Scholarship has, to date, limited itself to strong methodological nationalism and problem-focused research aiming to offer concrete solutions for regulatory or ethical problems associated with the issue. It has studied biobanking in terms of public awareness, deliberation, and societal legitimacy with the aim to increase public trust in the digital technologies and medical infrastructures that collect and store human tissue and potentially circulate and share them across borders (Grežo and Sedlár, 2023; Samuel and Lucassen, 2023; Zhang et al., 2023). Where policy-making (nationally and, to a lesser extent, internationally) is concerned, research has been focusing on questions of standardisation and coordination of practices and harmonisation of rules mainly with the aim to ensure the provision of (global) public goods for health (Hewitt and Hainaut, 2011; Mayrhofer and Prainsack, 2009).

Biobanking has also attracted considerable scholarly interest with regard to its legal and ethical implications, including studies on the difficulty of cooperation across different jurisdictions, and the various norm collisions (Hoeyer, 2008; Knoppers et al., 2014; Solbakk et al., 2009). A particularly lively debate surrounds the global circulation of umbilical cord blood (Beltrame, 2014) or the storage and use of embryonic stem cells. Bioethical scholarship confirms that the public perception of human tissue and related health data has "dynamically changed with context and over time" (Hoeyer, 2008, 430). This change in ethical status has made these resources and the practices surrounding them an issue in public debates on their ethical, regulatory,

technological, and legal challenges, nationally and internationally. As a result, biobanking is found to be characterised by “ethical ambiguities and regulatory uncertainty” (O’Doherty and Hawkins, 2010, 197). From a decidedly more critical perspective, scholars of Science and Technology Studies (STS) and Political Science have highlighted how strongly governance frameworks in this field are shaped by biobanking as an issue of science and technology, with little room to address questions of the “social and political legitimacy” of these institutions (Tutton, 2009, 2). Biobanking, thus, is conceived of as a terrain of biopolitics through body surveillance or “bio-objectification” (Tamminen, 2015, 67) that has, in the form of biocolonialism, also geopolitical dimensions where tissue samples are unrightfully extracted, stored, and explored from, for example, the African continent (Elbe, 2021; Parry and Greenhough, 2017).

The main conclusion that we take from existing scholarship is that biobanking has evolved into an area full of contentious policy issues, regarding the nature of its commodity and how this commodity changed from being waste to a potentially profit-yielding resource. We note a significant research gap in Political Science/International Relations surrounding international policy- and rule-making – most fundamentally the question why there has been little international debate on this issue despite the lively national public debates and the enormous increase in the global circulation of human tissue, especially in the past 15 years. While, in recent years and especially in the wake of the COVID-19 pandemic, there has been a growing corpus of literature on the transnational dimensions of biobanking and resulting policy implications, there is still very little exploration of the role of international organisations in policy debates on biobanking. Existing scholarship discusses technical, political, ethical and legal challenges particularly for (bio) medical practice and R&D. It does, however, not explore how these challenges are debated in international organisations. Tamminen’s work on European integration and international cooperation and rule-making on biobanking (Tamminen, 2015) or Elbe’s discussion of health security and data sharing are exceptions in this regard (Elbe, 2021).

Looking to global health institutions as salient sites of international debates on biobanking, our paper aims to make a valuable contribution to Political Science scholarship on pertinent global health issues. The study presented in this paper exposes the universe of policy frames circulating in IOs’ debates on biobanking and the dynamics of diversification and contestation of policy frames in this field. The trajectory and dynamics of the international debate, we conclude on the basis of our findings, helps to understand why, so far, international organisations have only to a limited extent targeted biobanking as a matter of global standard-setting, despite being repeatedly called upon to resolve ethical, legal, and technical issues associated with transnational biobanking (Çami et al., 2023).

3. Biobanking as an issue of international debate

By identifying policy frames circulating in the international debate on biobanking and by exposing and measuring their contestedness, also across different actor types, our paper aims to make a valuable contribution to an underexplored yet highly relevant field in the study of global health governance. We build our theoretical framework on the notion of policy frames as a suitable concept for capturing the politicised nature of global health (Hanrieder, 2016). Following other global health scholars, we argue that the history of the politics of global health can be told as a history of changing and shifting frames, and the actors and coalitions that support and contest them. Rather than inquiring into the effectiveness of translating frames in the process of health policy-making, thus, we address contestation, ambiguity, and potential incompatibility of policy frames, paying particular attention to their normative component, i.e. the ‘oughtness’ dimension of frames, as reflected in Entman’s frame definition (Entman, 1993).

As studies on frame dynamics in global health have shown, the history of global health politics is not a matter of one frame replacing

another, but a history of diversifying frames that co-exist and compete with each other, with alternating centrality in the frame universe (McInnes et al., 2014; McInnes and Lee, 2016). This diversification of frames that co-exist and compete is taken to be an effect of an ever-increasing density of international norms and rules (Burci and Toebe, 2018), an overlap between different international institutions governing global health matters and a proliferation and diversification of actors (Orsini, 2013) and their networks in global health (Holzscheiter et al., 2022; McDougall, 2016). A heightened potential for politicisation and contestation is taken to be both cause and effect of these processes (Ayoub and Chetaille, 2020). Following these theoretical propositions, we expect to find both a diversification of frames, a shifting salience/dominance/marginalisation of certain frames over time and a growing dynamic of contestation and polarisation, i.e. a growing rift between support and contestation for salient statements circulating in international policy debates on biobanking.

Frames are, most broadly, understood as schemes with which individuals perceive reality – they are schemes of interpretation (Goffman, 1974), used to organise experiences and the social world. As Goffman’s framing theory proposes, there may be multiple schemes at play in interpreting one and the same social situation/event. Extending Goffman’s frame theory and translating it into a conceptual framework suitable to capture the emergence and potential contestedness of frames, we use Entman’s definition of frames as being composed of at least one of the following four components: problem definition; treatment recommendation (solution); causal interpretation; and moral evaluation (Entman, 1993). On all of these levels, frames can be contested, i.e. actors may disagree on the nature of the policy issue, the origins and solution to that issue, and the normatively desirable responses to the policy issue. It is a central claim of our paper that frame analysis following Entman’s differentiation allows identifying the normative environment, i.e. the ways in which specific norms and rules surrounding biobanking are presented as right, good, appropriate and the ways in which actors may agree more or less on moral evaluations of the policy issue.

The study we present in this paper is the first study that systematically explores frame emergence and dynamics in international debates on biobanking. Rather than looking at framing as an actor-centred strategy, we study the historical trajectories of policy frames as they have diversified and circulated in international debates on biobanking inside intergovernmental organisations (IOs). The paper’s ambition lies not with exploring the causal pathways of frame emergence and diffusion, but rather to expand the understanding of the “complexity of norm dynamics by also exploring the process of contestation” (Coppéolle et al., 2023, 3) that is reflected in the frame dynamics we expose. Following established theories on contestation (Wiener, 2014), we understand contestation as the social practice of disapproving with descriptive, causal, and normative statements about a policy issue or problem. Contestation is, first and foremost, a discursive practice, which implies that disapproval or rejection of statements is primarily observable via speech and language. The key purpose of our study of frame dynamics presented below, therefore, lies in highlighting the major fault lines in international debates on biobanking, and to identify both stability and shifts as regards the least and most contentious issues that mark these debates. We do so by means of a mixed methods analysis that focuses on the aspect of contestedness of policy frames, i.e. the way in which they emerge as particularly undisputed or, in fact, very contentious, across time and across different types of actors.

4. An analysis of frame dynamics and contestation in international biobanking debates (1995 to 2019)

For the purpose of studying the dynamics and diversification of policy frames on the transnational circulation of human material and derived data, we conducted a frame analysis using the programme DNA 2.0 developed by Leifeld (2020). This programme allows us to identify

the totality of policy frames marking this issue area and to trace actors and actor types that endorse specific positions surrounding a policy frame.

The objective of our analysis is to highlight the contestedness surrounding actors' positions and inherent polarisations in biobanking. According to [Bhattacharya \(2020\)](#), contestation (S_c) can be measured through three main factors: (1) the balance between agreement (a_c) and disagreement (d_c) with a particular concept; (2) the relative salience of a concept; and (3) the salience ratio, a comparison between the minimum and maximum frequency for agreement and disagreement. D_{max} denotes the maximum frequency of agreement (a_i) and disagreement (d_i) of all coded concepts. The aggregated scores of these three factors then constitutes the overall contestedness of a concept ([Bhattacharya, 2020](#), [Bhattacharya, 2023](#)):

$$S_c = \sqrt[3]{\left(1 - \frac{|a_c - d_c|}{a_c + d_c}\right) x \frac{a_c + d_c}{D_{max}(a_i + d_i)} x \frac{\min(a_c, d_c)}{\min(D_{max}(a_i), D_{max}(d_i))}}$$

Contestation is a novel approach and measures the extent to which individual concepts polarise or unite actors within a political debate. Following the equation, a contested concept is thus considered to be more polarising (1) and salient (2) in relation to other concepts within a debate. The third factor is introduced in order to add more weight to frequently mentioned concepts. The score ranges between zero and one, whereby the more contested a concept is, the closer the value is to one.

4.1. Data corpus and coding process

Our empirical analysis on biobanking focuses on the years from 1995 to 2019. We realised that with the emergence of the COVID-19 pandemic, global health issues have become invariably more prominent within political discourses, leading to an exponential increase in the number of frames per year. We thus consider the years since 2020 as a separate level of discourse that may be covered in a future paper.

We analysed reports, speeches, and verbatim records from the EU, OECD, UN, UNESCO, and WHO, as these organisations have been key institutions for policy debates and (dis)agreement on international norms on human biobanking and bioethics since the 1990s. There were a number of rationales motivating our selection of specific IOs: firstly, our focus on IO documents resulted from the scarcity of research that examines discourses on biobanking from within the largest IOs. Secondly, as concerns our choice of IOs, we explicitly included international organisations that were identified as particularly relevant to transnational biobanking regulation in the secondary literature, not least because these organisations themselves have been maintaining biobanking infrastructures ([Gottweis and Lauss, 2012](#)) or because they represent wealthy countries maintaining resource-intensive biobanking structures such as the EU and the OECD. Finally, the ambition of our study was to focus on international rather than regional debates on biobanking, thus selecting five big international organisations whose mandates are relevant to transnational biobanking policies and practices.

The search string included the main keyword “biobanking”, synonyms like “biorepository” as well as variations like “bio bank” or “biological bank”. We reached 272 research results (excluding false positives¹) and coded roughly 1,200 statements for the whole research period for four variables: person, organisational affiliation, concept, and agreement/disagreement to the concept. Only documents available in English were considered in the analysis.

We contrasted the findings from the IO debate with policy frames informing the international public debate. To this end, we analysed news releases on biobanking from press agencies (*Agence France Press*,

The Associated Press, *Reuters*) and a broad range of worldwide newspapers and newswires – obtained through a systematic search in the *Factiva* newspaper database and using the same search string. The most common ones were: *All Africa*, *GlobeNewswire* and *The Straits Times*. We contextualised the findings from our analysis of primary sources with selected secondary literature on biobanking. We maintained intercoder reliability, by conducting several intercoder reliability tests using Krippendorff's alpha coefficient (a statistical value that measures agreement between coders) over time (four coders in total; for further details on the coding procedure see Appendix). These tests served to highlight weaknesses in the coding framework (the concepts used) and to adjust the coding scheme accordingly.

69 concepts were identified, which were derived inductively from the dataset and deductively from secondary literature on the topic. Subsequently, we categorised the concepts into ten frames that are composed of a varying number of concepts. [Fig. 1](#) provides examples of the coding process for each of the ten larger frames identified.

4.2. Analysis and definition of time slices

As we will show in the frame analysis, there has been a steady diversification of policy frames over our 25-years research period. Yet we find that European governmental and private actors, rather than international organisations, have been the driving forces behind what various authors call the “modern era of biobanking” ([Gao et al., 2022](#)), starting in the 1990s. Modern biobanking, according to [Gao et al. \(2022\)](#), is defined by technological advancements like the systematic storage of samples and the usage of deep freezers. “Through these advances, the concept of biobank was formed.” (p. 285) As [Fig. 2](#) illustrates, the first *modern* biobanks emerged as population projects supported by national legislation (for instance, in Iceland).

In recent years, biobanks have evolved from national population-based research projects into large-scale projects of international scale. WHO acted as a precursor in this policy field, addressing the international collection of human pathological tissue as a tool for disease surveillance from the mid-1950s onwards. Since then, discussions on the storage and distribution of human materials have not resulted in any specific international agreement on technical, legal and ethical standards for biobanking. International norms in this policy issue rather focus on the broader field of bioethics as an umbrella term for all research activities on the human body ([Cambon-Thomsen et al., 2007](#)) or they are only partially legally binding, as in the case of the *WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks (adopted 2002, revised 2016)*. A similar trend is apparent at the European level. Although European countries have made the strongest efforts to promote the internationalisation of biobanking, legislation continues to lag behind innovation. Contemporary biobanking governance rests on a “mosaic of formal legal instruments and regulatory bodies (...) as well as more informal types of governance tools and instruments” ([European Commission, 2012](#), 34).

Exposing the trajectory of the international biobanking debate and the frame dynamics that characterise it, we define four time slices reflecting the aforementioned international evolution. The first time slice covers the years 1995 to 2000, a period in which the first European national population biobanks were developed. We call this phase the *emergence of modern biobanking*. The second period (2001 to 2007) – which we term *internationalisation of biobanking* – has been marked by an intensification of transnational biobanking collaboration and the emergence of international, mostly non-binding regulations of biobanking. The years 2008 to 2013, referred to as the *consolidation and commercialisation of biobanking*, are marked by a shift towards a growing commercialisation of biobanking and a multiplication of biobanks worldwide. The fourth time slice of our research study (2014 to –2019) covers the period following the adoption of the General Data Protection Regulation (GDPR) and the emergence of actors from outside Europe/North America in the debate (including biobanks themselves). The

¹ False positives are research results that were incorrectly identified as relevant for the data analysis, but did not contain any codes that could be applied to the analysis.

Statement	Concept	Frame
“In such cases, the informed consent may be waived by an authorised entity such as a research ethics committee in accordance with the applicable law and regulations.”	Consent regulations should be waivable under specific circumstances. (agreement)	Consent Frame
“Though Korea’s basic life sciences research is highly developed, it is not being translated into commercial opportunities. The biobank must work more closely with local biotech businesses to encourage their growth.”	Cooperation between private and public biobanks should be intensified. (agreement)	Cooperation & Multilateralism Frame
„So the cost cannot be justified as there's little chance of a child ever being able to use his/her cord blood.“	Biobanking saves costs for medicine and health care. (disagreement)	Commodification & Economisation Frame
“CSIR Director Shekhar Mande said that the outcomes of the IndiGen will be utilised towards understanding the genetic diversity of a population scale [...]”	Biobanking reinforces genetic discrimination. (disagreement)	Human Rights Frame
“For example, the issues concerning the repository of this data, the authority holding the coding system of its anonymity and the authority responsible for its possible uses, will have to be addressed in each country with its legal framework.”	Biobanking should be based on an international (overarching) regulatory framework. (disagreement)	Law & Administration Frame
“Our vision [of biobanking] is to improve the quality of future health for the local society [...]”	Biobanking reduces shortages in health care and thus saves lives. (agreement)	Medical Innovation & Health Care Frame
“WPB recommended that the Committee for Scientific and Technological Policy declassify the draft Guidelines for Human Biobanks and Genetic Research Databases for the purposes of public consultation.”	Debates on biobanking should be open beyond expert groups to the wider public. (agreement)	Politicisation & Public Policy Frame
“Dr BRADY said [...] that knowledge of world pathology was limited since most pathological studies covered only Europe and North America.”	Global South must be stronger partnered in biobanking cooperation/networks (agreement).	Research & Benefit Sharing Frame
“The eye and tissue bank, now known as Dakota Lions Sight & Health, said in its response to the federal lawsuit that problems with the transplants were beyond its control [...]”	Biobanking practices that violate applicable law should be subject to criminal liability. (disagreement)	Securitisation & Criminalisation Frame
“Another difficulty could be the sheer volume of tissues submitted to voluntary laboratories, much of which would be routine material not yielding any worthwhile information.”	Human specimens are saved in biobanking that would be otherwise biological waste. (disagreement)	Sustainability Frame

Fig. 1. The aggregation of statements into broader policy frames. For a detailed overview of the data collection and coding process, see <https://datashare.tu-dresden.de/s/N37kGYMgP6b7zrM>.

GDPR has significantly altered the processing of data of all kinds in Europe and beyond (Slokenberga et al., 2021), including data associated with human biological material. As both genetic and health data are defined as being particularly sensitive in the GDPR, its adoption led to more stringent regulations for the import and export of data obtained

from human material stored in EU-based biobanks. As such, we assume that the *GDPR* marks another turning point in the international biobanking debate (Ho, 2017; Shabani et al., 2021). At the same time, scholarship on contemporary issues in international biobanking suggests that our most recent period of investigation coincides with accelerated



Fig. 2. National biobanking projects (blue) and international norms (green) since 1995 (selection). (For interpretation of the references to colour in this figure legend, the reader is referred to the Web version of this article.)

globalisation of biobanking, i.e. the emergence of biobanks beyond Europe/North America, and a stronger North-South dimension of biobanking debates. We have thus called this phase the *globalisation of biobanking*.

Our data analysis followed a longitudinal approach, which was aimed at highlighting the salience, contestation, and polarisation of policy frames in biobanking over the entire research period of 25 years. We identified time slices based on pertinent secondary literature in order to allow a more in-depth study of these developments. Since the overall objective is to highlight contention in international political debates in biobanking, we firstly present findings on the salience of policy frames in biobanking for the entire study period before then providing a more in-depth analysis of contestation in international biobanking politics for the four time slices, using the contestedness score. To this end, we combined quantitative frame analysis with qualitative manual coding and contextualisation of research findings.

5. The contentious politics of biobanking

Our data analysis highlights that biobanking has evolved from a matter of technical standardisation into a contested subject of global health governance. Controversial issues include the commodification of human biological material, the question of informed consent, the infringement of privacy rights, and the compliance with existing norms and regulations. It is human rights considerations in particular that have made this policy field a terrain for norm collisions (Bernier et al., 2022).

In our data, we expected a successive intensification of the debate on biobanking from the emergence of the first *modern* biobanks to the GDPR era. However, rather than a gradual intensification, we observed a significant inter-year variation in the number of coded statements. Peaks are especially noticeable in the year of or the year following the adoption of an international legal instrument or policy measure. As a result, the second time slice (2001 to 2007) accounts for the majority of coded statements (61%), due to numerous initiatives to establish stricter international regulations for biobanking, i. a. leading to the adoption of the International Declaration on Human Genetic Data (UNESCO, 2003). A similar concentration of statements is apparent in the years prior to the GDPR (European Union, 2016).

Another general finding is that there has been an increasingly diverse range of policy frames informing the IO and public debates on biobanking over time (Fig. 3). While some frames are less prominent in the debate over time, for instance the cooperation and the economisation frame, biobanking has been relevant to and discussed in various other (related) policy fields, such as public health, economy, and foreign policy since the development of the first *modern* biobanks. The increase in the number of frames informing biobanking debates does not necessarily entail diversification in terms of distribution across the frames – with a predominance of the human rights frame in IOs in all periods and a predominance of the medical innovation frame in the media debate since 2008. Still, there is a rather limited – and specialised – debate on biobanking, as this policy issue is predominantly treated as an epiphenomenal, largely technical and logistical aspect of international

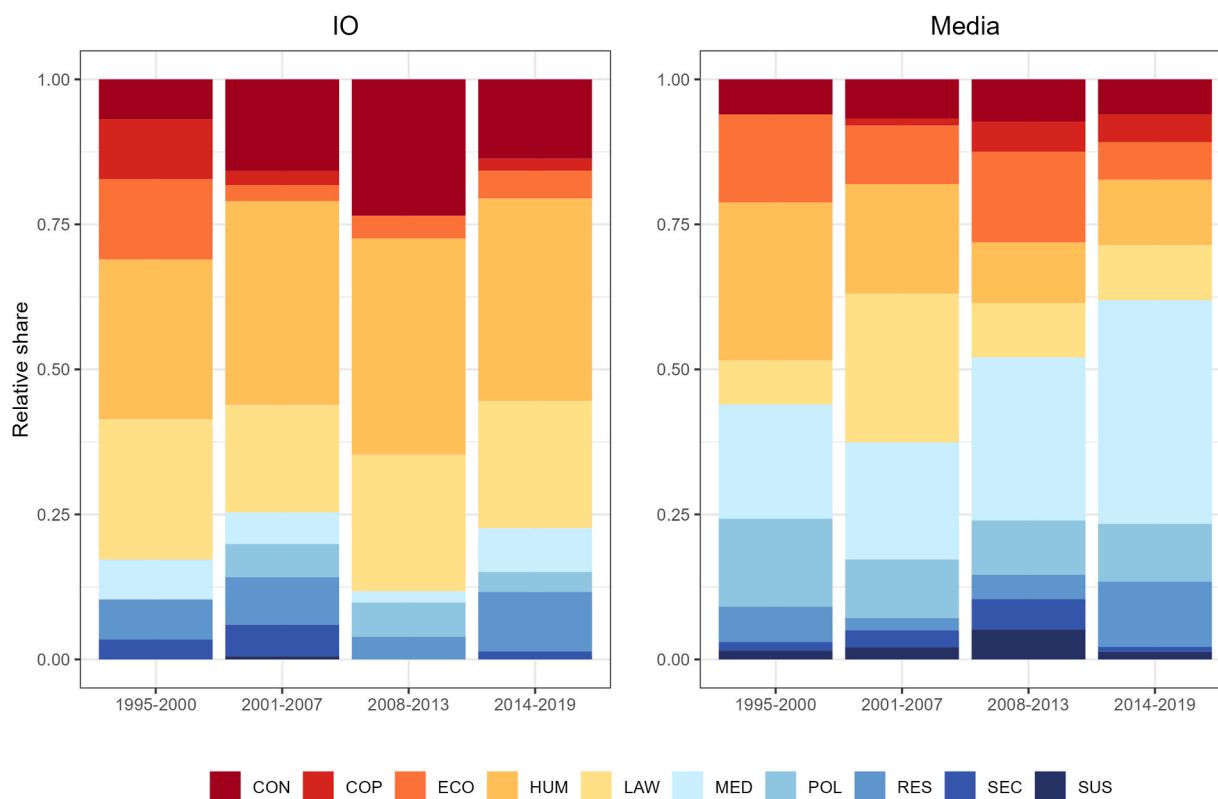


Fig. 3. Salience of frames in the IO (left) and the public (media) debate (right) throughout the four time slices.

cooperation in the field of global health – and beyond. As a result, biobanking so far, has not evolved into a stand-alone agenda item in global (health) governance discussions.

Around 250 actors have voiced their positions throughout the 25-years research period; yet just a few of them have been able to dominate the overall discourse regarding the number of statements and the contribution of new frames. About three quarter of all statements are made by persons affiliated with organisations and institutions located in Europe and North America, with for instance the UNESCO being one of the most dominant IOs in the dataset.

5.1. The emergence of modern biobanking

During the emergence of *modern* biobanking, two dominant yet competing frames are ostensibly present in the data set: the medical innovation and the human rights frame. On the one hand, the medical innovation frame defines the practice of biobanking as a means for efficient and sustainable innovation in medicine, thereby challenging existing patent rights on the use and trade of samples – beyond the monopolisation of knowledge and the *overprotection* of samples. On the other hand, the human rights frame advocates for fundamental human rights principles as the right to life, data protection, anonymisation, and privacy, with the aim to establish ethical boundaries of medical innovation or even to prevent cases of “*mad science*” (Walmsley, 2009). Since the end of the 1990s, particularly intergovernmental actors like the International Bioethics Committee (IBC) have demanded stricter safety measures for the transnational circulation of human biological material. In doing so, they advocated for the restriction of the legal capacity of certain actors like pharmaceutical companies, which *discovered* biobanks as an economic resource in the early 2000s.

During such a period with minimal national regulation on human biological collections of any form, global health discussions on human rights standards appear to be strongly entangled with normative framing processes, particularly concerning the topicality and sufficiency of

existing legislation. For instance in 1998, the Ethics Group of the European Union urged that the “[l]ack of regulation makes it difficult to control the tissues’ origin, namely the identity and the medical history of the donor” (EGE, 1998). The IBC equally advocated in favour of a stricter pro-regulatory approach at that time, yet they emphasised the potential dangers of the retrieval of human (body) data: “Will insurers have access to this genetic information? Will employers be able to ask for the information?” (International Bioethics Committee, 1999) In line with these developments, the contestedness scores are the highest for human rights (orange in Fig. 4)² and legalisation concepts (yellow in Fig. 4) throughout the first time slice. In particular the concept ‘Specimens and collected data must be anonymised throughout the whole biobanking process.’ and thus human rights standards are highly contested. We further observe an increasing number of references to human rights – however, the human rights frame in itself accommodates a multiplicity of concepts that are difficult to reconcile, most prominently the individual rights to self-determination and privacy on the one hand and the right to health on the other, which might include public health measures impinging on these individual rights.

To qualify the aforementioned remarks, we have to stress that the number of statements coded for the emergence of modern biobanking is low ($n = 71$); thus, the validity of our findings for this time slice is limited. Nevertheless, we observe two trends that continue to shape the discussions on biobanking throughout the entire research period: firstly, from the onset of *modern* biobanking, private sector actors and research

² In Figs. 4, 6–8 we arranged the concepts based on contestedness (high-low score) rather than salience, with the aim to highlight how contestedness within the frame spectrum varies over time. We did not group them alongside the larger frames they belong to.

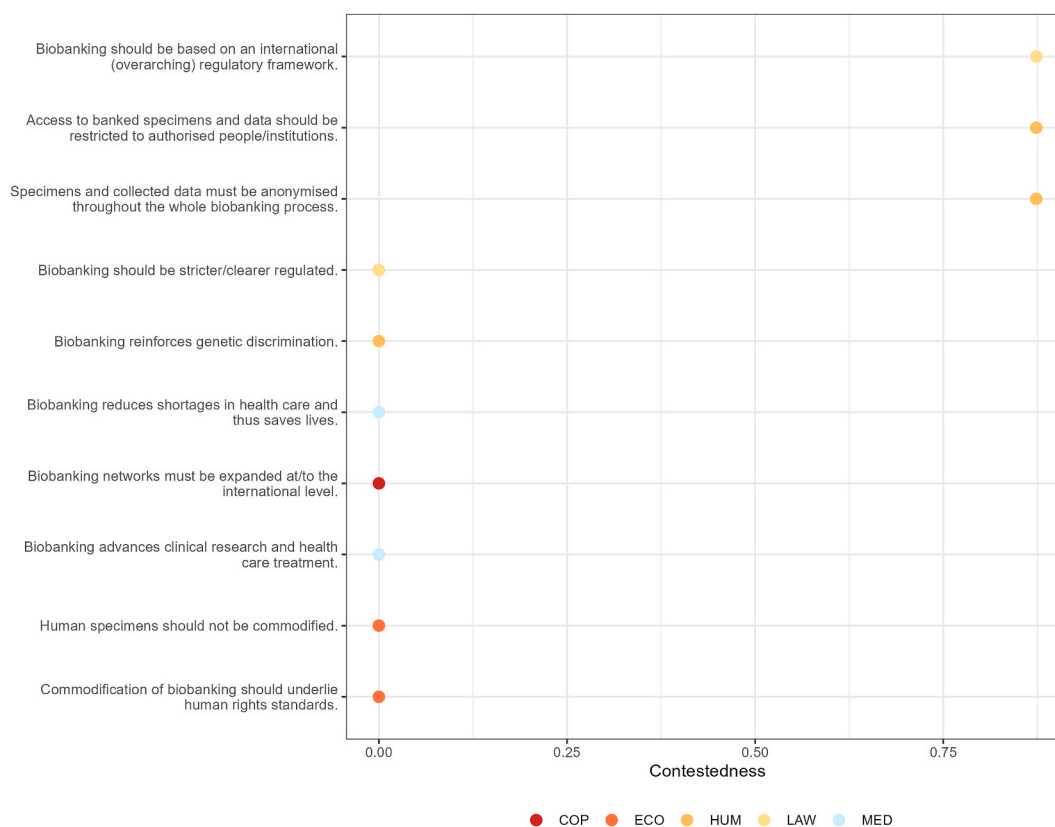


Fig. 4. Contestedness score between 1995 and 2000 for the top 10 concepts.

institutions have established themselves as prominent contributors to the biobanking debate alongside intergovernmental organisations. Secondly, as visible in Fig. 5,³ the human rights frame is the most salient frame for intergovernmental organisations. Business actors and research institutions, on the other hand, are more prone to discuss biobanking from a (positive) medical innovation perspective. For instance, a representative of the Estonian Human Genome Heredity Project argued, “Privacy is in our heads, not in our genes” (Nullis, 2000).

5.2. The internationalisation of biobanking

In the era of internationalisation – from 2001 to 2007, we observe a sudden intensification of the debate on biobanking in global health governance. As Fig. 5 above shows IGOs are most active in the debate in this period. The increasing institutionalisation of biobanking as an issue of international debate also caused a substantive change in the framing of the discourses surrounding the circulation and storage of samples and related data. For instance, as a result of the International Declaration on Human Genetic Data (IDHGD) and especially the preliminary public hearings, issues such as discrimination based on age, gender/sex, ethnicity, heritage, pre-existing medical conditions, disabilities and religion became the subject of international debate and norm-setting. New critical and controversial topics emerged as a result of past experience involving the discrimination of vulnerable groups on the basis of biological samples, i. a. in the NS time and colonialism, but also in more recent incidents such as the Alder Hey scandal (McKie, 2003). Discrimination as a sub-debate of the human rights frame is based on

three concepts that represent three forms of discrimination: intersectionality and social discrimination; genetic discrimination; and medical discrimination.

While the potential perils of gender-, ethnicity-, genetic-, or disability-centric biobanking have been criticised since the institutionalisation of biobanking, with IOs taking a lead in these discussions, the benefits and merits of a *target population* for biobanking have only been widely recognised from 2014 onwards (Lieb, 2024). For instance, researchers at Qatar Biobank argued that including samples from the Arabian Peninsula contributes “to promoting the understanding of local and regional health and diseases” (Qatar University, 2016). This shift toward a more positive perspective on discrimination also caused a decline in the contestedness score for the discrimination concepts from 0.3 (for social and genetic discrimination in the IO debate, Fig. 6) to no contestedness (value of zero) in recent years. Our data hence exposes the divisive nature of policy-debates on biobanking, i. e. where they involve questions of racial and social discrimination and vulnerabilities. On the other hand, the analysis highlights what Soares, (2023) describe as emancipation from biocolonialism, a re-framing in the understanding and handling of human samples and related data.

Contentious dynamics are also visible at the actor level throughout the years 2001 and 2007, reflecting norm conflicts that extend beyond human rights discussions and led to the emergence of new enduring frames, such as the politicisation and the research frame. Our analysis also reveals significant variations between and within IOs in their positioning on the storage and circulation of human samples during this *internationalisation* phase.

5.3. The consolidation and commercialisation of biobanking

During the consolidation and commercialisation of biobanking between the years 2008–2013, the number of frames and concepts in our data reached the highest diversification. We observed in our analysis

³ Fig. 5 is based on data obtained from both our databases – biobanking debates in international organisations and in the wider public (media) discourse. Due to the scarcity of data (even for an extended period of investigation), we decided to combine the data for the sake of identifying the most popular frames endorsed by specific actor types.

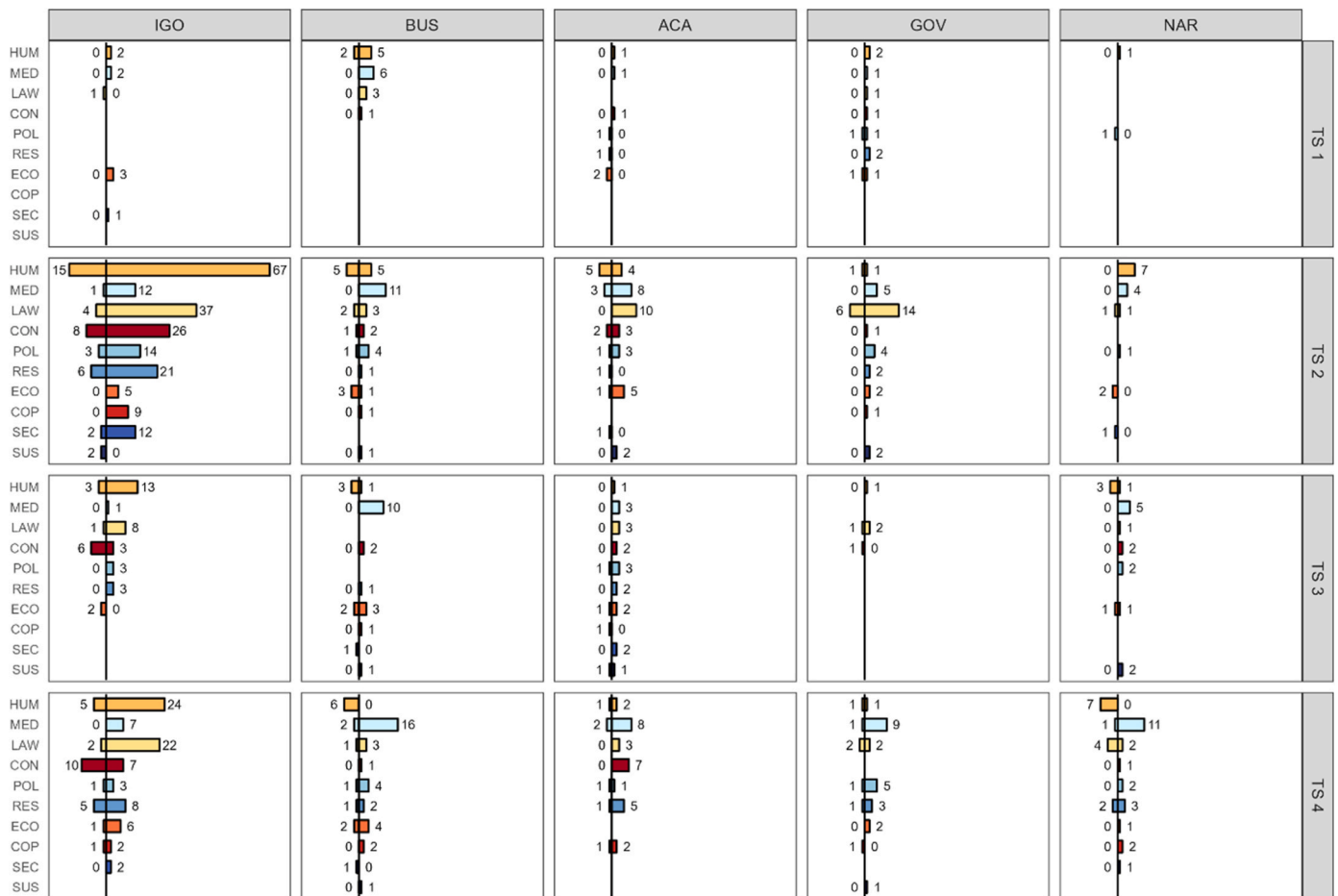


Fig. 5. Number of agreements (right of the line) and disagreements (left of the line) with the frames for the five most common actor types (columns) for all four time slices (rows).

that actors with commercial interests are much more prevalent in the debate in this period – with the economisation frame being more prominent in the public debate than in the other three phases. During that phase, several bankruptcy cases of biobanking businesses (such as DeCode Genetics in Iceland) were attracting attention to biobanking as a commercial enterprise. Terms such as ‘biobankonomics’ emerged in the scholarly debate on biobanks and the critical discussion surrounding them led to more scrutiny of the biobanking sector and to an awareness of risks and challenges of biobanking (Vaught et al., 2011) and the potential “sell-out” of the human body. We find that this development towards a more critical engagement with the commercial aspects of biobanking is to a certain extent reflected in our data. In the IO discourse, the phase is characterised by increasing discussions on the appropriateness of commodifying biobanking, coupled with a growing awareness of the risks and dangers associated with commercialisation and transnationalisation in the IO debate. While some previously dominant concepts continued to shape the debate on biobanking, i. a. the concept of data anonymity, demands for more concrete regulations on consent for the transnational circulation of samples and data grew, pushed by various actor types, including IOs and academia.

Informed consent in particular became an issue of increased contestation, leading to a shift in the discourse on medical innovation. The medical innovation frame established itself as a juxtaposition to the legalisation and human rights frames (with the consent sub-frame), challenging the boundaries of good (research) ethics and determining whether restrictive measures and safeguards are compatible with medical progress. As Hoeyer shows, “for more than 80 years tissue has been derived from human bodies, stored, distributed and used for

therapeutic, educational, forensic and research purposes as part of healthcare routine in most western countries” (Hoeyer, 2008, 429). However, there had been growing concern around the medical value of stored human material, resulting in controversies surrounding the need to protect biobank participants and hence increased actor polarisation, notably in the phase of the consolidation of biobanks. This is also apparent in the contestedness score. Our analysis highlights that three consent concepts – those discussing the relevance of re-consent and informed consent as a medical prerequisite, as well as altruism as a motive for consent – are among the most contested in the IO discussions with a score of 0.65 (Fig. 7) during this phase. Even though the consent frame had been continually present in the biobanking debate since the emergence of *modern* biobanks, it only became subject to increasingly controversial discussions in the late 2000s.

5.4. The globalisation of biobanking

The analysis of the final years of the study period, covering the years from 2014 to 2019, brings to light a less critical framing of biobanking in contrast to previous years. The focus of the discourse has successively shifted to the importance of collecting human biological samples for safeguarding global (public) health, enabling medical innovation, and improving personalised health care. Since scholarly research on the GDPR has uncovered vigorous debate on the implications of this new legal instrument particularly for international biomedical cooperation (Gefenas et al., 2022; Slokenberga, 2018), we assumed that it would be relevant to the biobanking discourse. However, the GDPR itself has only marginally featured in more specific debates on biobanking. Instead, our

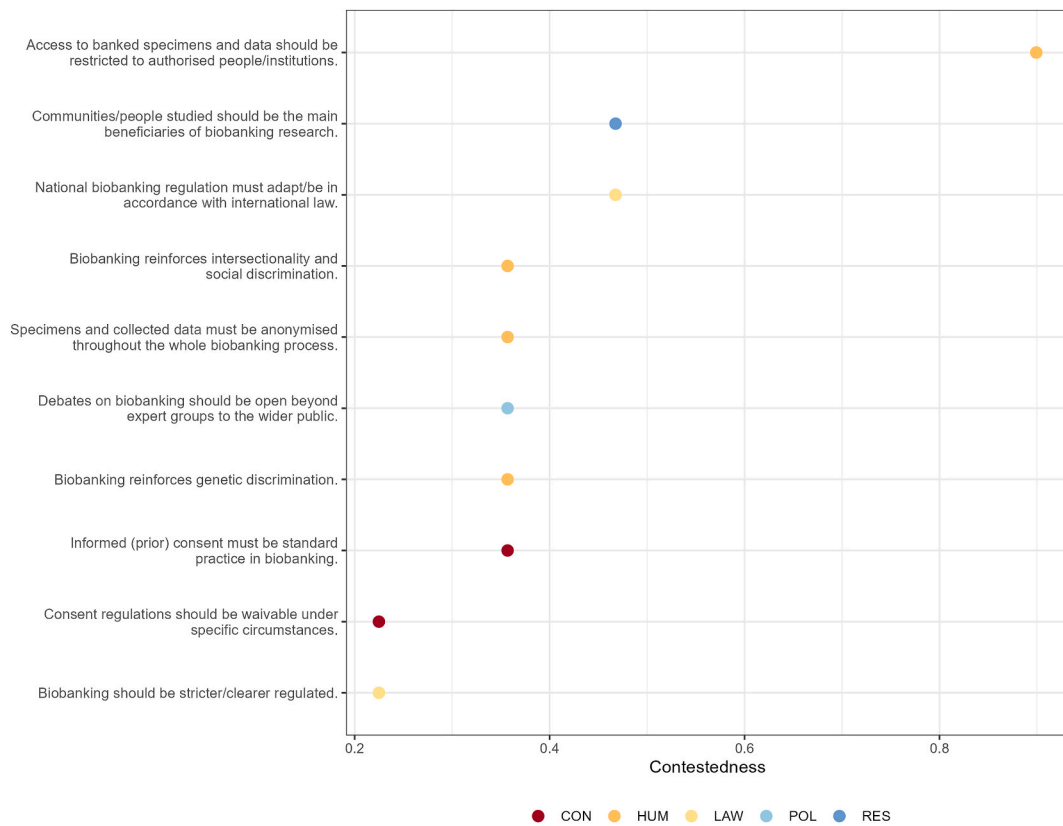


Fig. 6. Contestedness score between 2001 and 2007 for the top 10 concepts.

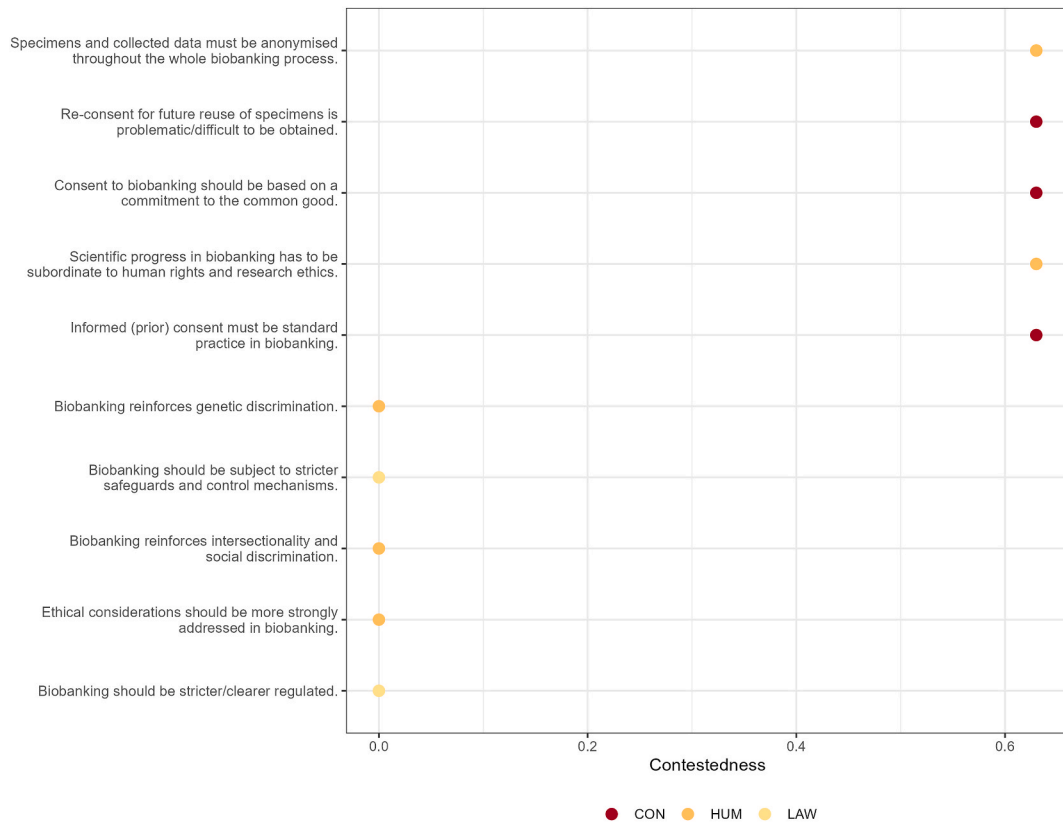


Fig. 7. Contestedness score between 2008 and 2013 for the top 10 concepts.

in-depth qualitative analysis of the coded statements led us to conclude that two aspects are prevalent in this study period: first, the increasing relevance of biobanks from outside the European and North American context in the debate; and second, the stronger legislation of privacy, data protection and informed consent norms in the European Union that are immediately relevant to biobanking.

As regards the first aspect, biobanks from outside Europe and North America emerge and successively establish themselves as relevant actors since the mid-2000s in our data corpus. Prominent examples here are the Qatar Biobank and Stellenbosch University which, in the context of the Human Genome Project, has addressed the relevance of biobanking for the systematic collection of African genetic material. Following this trend, we observe, on the one hand, that the debate is shaped by concepts through which populations in countries of the Global South are framed as *victims* of the transnational circulation of human materials, thus deserving increased protection. On the other hand, our analysis reveals that it is precisely biobanks and private biobanking actors from outside Europe and North America that are perceived to disregard ethical and legal principles for biobanking. Overall, we observe a heightened visibility of perspectives and positions from the Global South, coupled with demands for benefit sharing and capacity building and a rejection of the Global South as merely a provider of samples and data. For instance, a representative of the Liberian Institute for Biomedical Research stated in 2019: “After the samples were collected, we were left out of the picture. [...] The research that you’re going to do with these samples [abroad], should be done here [...]” (Freudenthal, 2019).

The debate on appropriate norms and rules pertaining to biobanking has hence been considerably broadened by perspectives and positions from the Global South, with human rights frames extending towards the recognition of “knowledges from the Global South” (Pratt and Vries, 2023).⁴ The ways in which national jurisdictions handle these conflicts of interests vary greatly – a finding which renders international cooperation and transnational policy-making at once essential and complicated (European Commission, 2012: 47). Yet, the transnationalisation of biobanking networks undermines trust of citizens who donate tissue or other human biological material to biobanks or willingly share health data. While they trust national biobanks and national health systems, they are suspicious of international networks with a supposedly low level of oversight and control (Dive et al., 2020). We find evidence for this in the contestedness score. The benefit-sharing frame causes significant polarisation between actors. In particular, the concept on biobanking participants as main beneficiaries is highly contested with a score of above 0.9 (Fig. 8).

In contrast to those actors who consider the storage and circulation of human samples and data beyond nation-state borders as an opportunity for improving medicine and health, actors from the Global South are more critical towards this research practice, advocating for stronger rights for biobanking participants. We therefore conclude that while European and North American actors had already been focusing on the regulation of human rights matters since 1995, this development had been lagging behind in other regions, leading to an increased advocacy for human rights protection and benefit-sharing in the Global South in the last period under investigation. This, in our view, explains why the human rights frame remained consistently highly salient and consistently contested throughout the entire research period, despite a shift towards different human rights concepts in the last period under investigation.

⁴ We acknowledge that the term “Global South” is an artifact that does not pay heed to the diversity of countries and societies subsumed under the term. For the purpose of our study, though, we defined the Global South as all regions and all actors that are non-European and non-North American (excluding Mexico) and located in a low- or middle-income country (LMICs).

6. Discussion

The results of our study of the diversification and contestation of policy frames in international biobanking debates lead us to draw the following conclusions. First, our study exposes that, over time, biobanking has become a multi-faceted issue in global health governance, which is reflected in the diversification of frames circulating in international organisations. Policy frames circulating in global health organisations have not simply been replaced by other frames. Rather, we find a growing frame universe characterising the debate. Secondly, our study brings to light the heterogeneous constellations of interests and related audiences that characterise the international debate on biobanking – reflected in the finding that different types of actors endorse specific frames to varying degrees. Our study evidences that heterogeneous policy interests and perspectives identified in national biobanking debates also characterise international discourses, most prominently those between public research institutions on the one hand and (semi-)commercial actors on the other. Based on our findings, we predict that such a heterogeneous field of stakeholders with multiple conflicts of interests is unfavourable towards a strengthening of international rules and legislation.

The main actors involved in debates on biobanking are public organisations such as universities, research ethics councils or committees, professional associations, governments, and intergovernmental organisations, most of them located in the Global North. To a lesser extent, we identified for-profit or semi-commercial organisations (i.e. biorepositories focusing on research but also charging researchers for samples/data) in the debates. As regards civil society organisations active in this field, we found only disease advocacy organisations as strong supporters of biobanks, whereas other civil society organisations such as, for example, consumer protection or overall human rights organisations were absent. In fact, the homogeneous positions of different not-for-profit, public interest organisations in international policy debates offer a powerful explanation for why biobanking can be characterised as low-salience issue overall (Carpenter, 2007). Both at the domestic and the international level, we observe a steady but low-key attention to biobanking and little public awareness, which may indicate that there is too little pressure on governments and/or private actors to address the legal, political, and ethical issues associated with biobanking.

By means of the study presented in this paper, we were able to observe that cooperation and coordination issues in biobanking have recurrently been debated in various international institutions – both public (WHO, ICB, OECD) and private (WMA) – but that none of these debates have led to the strengthening of international law (rather than European law) in this field. Among the most salient concepts we identified as informing debates during the four time periods studied, the need for stricter regulation of biobanking, domestically and internationally, was present at all times. With the GDPR as the most relevant legal framework for biobanking being adopted, the need for stricter regulation, however, scores higher in terms of contestedness. This appears plausible considering the origins of transnational biobanking infrastructures and related regional policies in the European region. With the GDPR, it appears, the issue of harmonising legislation on informed consent and privacy rights seemed to have been resolved at least in the European context and one major obstacle towards further transnationalisation of biobanking removed.

More generally, biobanking as a relatively new issue in global health represents a suitable case to illustrate the effects of the weak legalisation of global health and the rather limited authority of the WHO – as the focal institution in global health governance – to set binding international standards. Our study on biobanking confirms the complexity of actor landscapes and institutional architectures addressing global health issues, which explains conflicts of interests and norm contestation, particularly with regard to human rights and commercialisation of biobanks (Yu, 2019). Our study speaks to theories on power in global

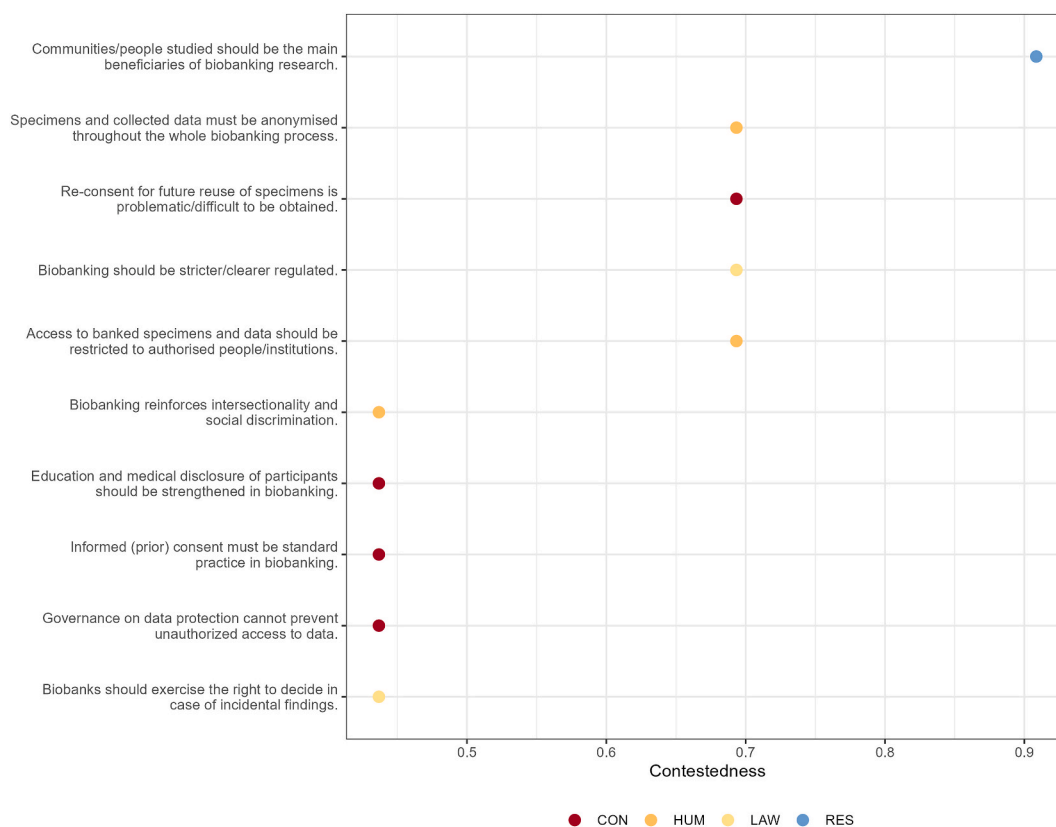


Fig. 8. Contestedness score between 2014 and 2019 for the top 10 concepts.

governance and (global) public policy making (Barnett and Duvall, 2005). However, our ambition to trace biobanking as a policy issue over an extensive period of time, to capture the diversity of policy frames in biobanking debates (and their weight in the debate), and to expose to what extent biobanking has been treated as a truly global issue has imposed limitations on our ability to highlight the power of individual actors/agencies/sectors and the mechanisms through which the frames they endorse become powerful in the debates we studied. Methodologically, we were constrained by the necessity to ensure compatibility of primary sources for our quantitative analysis via DNA on the one hand and the public accessibility of data on the other. These limitations imply that our study does not capture every actor relevant to international debates on biobanking but only those that left traces in IO and media discourse during our study period.

As regards our finding that human rights have the most disruptive potential when it comes to broad international agreement on biobanking regulations, our study revealed that policy frames involved a variety of human rights concerns, ranging from the human right to health and well-being, to the right to own one's body, the right to informed consent, or to the right to be forgotten. Even though all of these concepts may be classified as being about human rights, our empirical analysis brings to light that even within the human rights frame there are considerable norm collisions that mark the debate. On the one hand, the right to life and the right to health are mobilised for endorsing liberal approaches to biobanking with less strict consent and privacy regulations, often by disease/patient advocacy organisations, while actors concerned about the potential abuse of biobanks and lack of oversight of their transnational dimensions (in particular governmental actors and legal experts) embrace human rights policy frames on consent and privacy. In future research, we will seek to explore these norm collisions further by comparing biobanking to similar issues (health data sharing), and by looking more closely at the specific structure of policy and advocacy networks surrounding these issues. Building on previous work on advocacy coalition constellations (Holzscheiter et al., 2022), we aim to

study the nature of discourse networks not only in terms of conflict and cooperation between different advocacy coalitions but also extend our analysis to the power/marginalisation of specific expert groups and networks.

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CRediT authorship contribution statement

Maria Weickardt Soares: Writing – review & editing, Writing – original draft, Visualization, Validation, Software, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Anna Holzscheiter:** Writing – review & editing, Writing – original draft, Supervision, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization. **Tim Henrichsen:** Visualization, Software, Resources, Methodology, Data curation.

Statement ethical approval not required

Our research complied with the ethical standards outlined in the General Data Protection Regulation (GDPR), which is the guiding normative framework for research in German universities. Ethical approval by TUD Dresden University of Technology's ethical board would only have to be obtained in case our paper was drawing on medical research/experiments with human beings or animals. The research presented here did not require and ethical approval as the data used for the analysis was publicly available through repositories of international organisations and media databases. As our research did not include sensitive information on specific persons, it did not require any informed consent procedures.

Declaration of competing interest

None of the authors of this manuscript has to disclose interests that may affect their ability to present data objectively.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.socscimed.2025.117773>.

Data availability

Data will be made available on request.

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