



Benefit Sharing

Looking for Global Justice

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Abstract

Research cannot be done by researchers alone. In most cases, additional resources are required, including human research participants, access to biodiversity for biological and genetic resources, or traditional knowledge. Benefit sharing has been part of global conventions and international ethics guidelines for over 25 years, predicated on the understanding that those who contribute to the research process and its outcomes should share in the benefits as a matter of fairness. This chapter explores the different understandings of benefit sharing in a historical context, from the “Grand Bargain” of the Convention on Biological Diversity in 1992 to the Global Code of Conduct for Research in Resource-Poor Settings in 2018, and examines the contemporary potential for the UN Sustainable Development Goals (Agenda 2030) to facilitate benefit sharing. The discussion provides guidance to researchers, through examples and short case studies, on how to discharge the obligations of benefit sharing effectively and fairly, in pursuit of research integrity.

Keywords

Benefit sharing Global justice Genetic resources Research ethics Research integrity Convention on Biological Diversity Vulnerable populations Fairness Global Code of Conduct for Research in Resource-Poor Settings PIP Framework [Download reference work entry PDF](#)

Introduction and Background

Benefit sharing can be understood in two ways. First, it can be related to *fairness-in-exchange*, when several parties are involved in an interaction and benefits derived from the interaction are distributed fairly. Second, it can be related to *distributive fairness* where, for instance, the benefits from scientific progress are shared fairly among potential recipients, whether or not they were involved in the research process.

Aristotle gives examples for fairness-in-exchange, which are as valid today as they were almost 2,500 years ago, namely, acquisition and sale of goods, loans, bonds, and rents (Aristotle 2004: 1130b–1131a). The development and acquisition of goods and services is the main field where benefit sharing is relevant to research. Instances of fairness-in-exchange usually involve individual agents, such as researchers (from universities or private companies) or entrepreneurs, and those who contribute to their activities. States are only involved indirectly, through their legislative powers to influence theoretical understandings of and practical realizations of fairness.

By contrast, distributive fairness is usually understood as a question of relationships between the state and its citizens. A typical distributive fairness question would be: “How should benefits derived from taxation be distributed between the privileged and the underprivileged?” John Rawls (1999: 65) gave one of the most famous answers of the twentieth century to this question:

The higher expectations of those better situated are just if and only if they work as part of a scheme which improves the expectations of the least advantaged members of society.

Benefit sharing to achieve fairness-in-exchange will be explained with reference to the Convention on Biological Diversity (1992), the Nagoya Protocol on Access and Benefit Sharing (2010), the World Health Organization’s PIP Framework (2011a), and the Declaration of Helsinki (2013). Benefit sharing to achieve distributive fairness will be explained with reference to the Human Genome Project’s Ethics Committee Statement on Benefit Sharing (2000) and the UNESCO Universal Declaration on Bioethics and Human Rights (2005). Where the two converge will be illustrated with the Global Code of Conduct for Research in Resource-Poor Setting (2018).

The following table gives an overview of relevant legal and ethical instruments grouped according to the type of benefit sharing covered (Table 1).

Table 1

Overview of main legal and ethical instruments for benefit sharing

Benefit sharing as fairness-in-exchange

Benefit sharing as distributive fairness

Convention on Biological Diversity 1992	Council of Europe's Convention on Human Rights and Biomedicine, 1997
CBD-linked legislation	
Nagoya Protocol 2010	
National laws	"Affirming that progress in biology and medicine should be used for the benefit of present and future generations"
Biological Diversity Act India 2002	
Biodiversity Act South Africa 2004	
WHO Pandemic Influenza Preparedness (PIP) WHO 2011a	Human Genome Project's Ethics Committee Statement on Benefit Sharing, 2000
Declaration of Helsinki, 2013	UNESCO Universal Declaration on Bioethics and Human Rights, 2005
CIOMS International Ethical Guidelines for Health-Related Research Involving Humans, 2016	
Global Code of Conduct for Research in Resource-Poor Settings, 2018	

Benefit Sharing as Fairness-in-Exchange

To explain the main features of benefit sharing as fairness-in-exchange, three binding international legal instruments (the CBD, its Nagoya Protocol, and the PIP Framework) and one non-binding international ethics guideline (Declaration of Helsinki) will be introduced.

The Convention on Biological Diversity

Human destruction of nature is rapidly eroding the world's capacity to provide food, water and security to billions of people... Such is the rate of decline that the risks posed by biodiversity loss should be considered on the same scale as those of climate change. (Watts [2018](#))

Twenty-six years before this assessment, a United Nations conference of unparalleled size and scope was held in Rio de Janeiro in 1992. What became known as the "Earth Summit" provided a platform for launching the Convention on Biological Diversity. The CBD recognized that the conservation of biodiversity is a common concern of humankind.

The legally binding convention has 196 parties (all countries in the world are signatories except for the USA and the Vatican) and 3 major objectives:

- The conservation of biological diversity
- The sustainable use of its components
- The fair and equitable sharing of benefits from the use of genetic resources

The first objective relates to the common interest of humankind, namely, to deal with the serious loss of biodiversity and its potential implications for global ecological functions as well as future uses. According to scientists, the extinction of biodiversity currently proceeds at a rate not experienced since the loss of the dinosaurs over 65 million years ago. It is estimated that 1,000–10,000 times more species are lost today through human action than would be lost naturally (Chivian and Bernstein [2008](#)).

Such biodiversity loss risks "burning the library of life," as biodiversity can be seen as the knowledge acquired by species over many million years to survive in vastly different terrains (Carrington [2018](#)). Hence, the main aim of the CBD is also its most pressing.

The sustainable use of biodiversity components (the second objective of the CBD) becomes increasingly restricted as a result of biodiversity loss, including restrictions for scientific or commercial endeavors or to support human livelihoods. Hence, if the first objective were achieved, the second objective only adds the request to use biodiversity *sustainably* from now on.

The third objective explains why the CBD has also been called the "Grand Bargain" (ten Kate and Laird [2000](#)), between low- and middle-income countries (LMICs) on the one hand and high-income countries (HICs) on the other. Until the CBD was adopted, access to resources had mostly been on a first-come-first-served basis. Another formulation for this was the concept of the common heritage of humankind. Vandana Shiva described this approach critically as follows:

The North has always used Third World germplasm as a freely available resource and treated it as valueless. The advanced capitalist nations wish to retain free access to the developing world's storehouse of genetic diversity, while the South would like to have the proprietary varieties of the North's industry declared a similarly 'public' good. (Shiva 1991)

If LMICs were meant to protect their biodiversity (objective 1) to enable scientific and commercial use (objective 2), the first-come-first-served approach for access to resources had to stop. The CBD therefore required that plants, animals, microorganisms, and related traditional knowledge fall under the sovereignty of nation states and that access to and use of them be governed by specific rules, in particular prior informed consent for access and "fair and equitable sharing of benefits" related to their use (objective 3). How fair and equitable sharing of benefits for nonhuman genetic resources could be realized was such a challenging question that an associated protocol was painstakingly negotiated: the Nagoya Protocol.

The Nagoya Protocol

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, also known as the Nagoya Protocol on Access and Benefit Sharing, is a supplementary agreement to the CBD adopted in 2010.

One of the main achievements of the Nagoya Protocol is the detailed list of possible benefit sharing measures. The list includes monetary and nonmonetary benefits, and the following table summarizes the main ones (Table 2).

Table 2

Overview of benefit sharing examples from the Nagoya Protocol*

Monetary benefits	Nonmonetary benefits
Access fees per sample collected	Collaboration in scientific research
Payment of royalties or license fees	Technology transfer under fair and most favorable terms
Research funding	Institutional capacity building
Joint ventures	Research directed toward priority needs
Joint ownership of intellectual property rights	Food and livelihood security benefit

*For the full list, see the Nagoya Protocol (2010) pp. 24–25

One hundred and ninety-three countries agreed the Protocol after 6 years of challenging negotiations. These "years of intense, complex and fractious talks ... frequently pitted developed countries against developing countries, and providers of genetic resources against users of those resources" (Andanda et al. 2013).

One disagreement between LMICs and HICs was the original exclusion of human genetic resources from the CBD (Chaturvedi et al. 2013) (early on in CBD negotiations, it was decided that human biological resources were to be excluded from its scope). While the Nagoya Protocol was negotiated, a major crisis about access to human materials emerged between Indonesia and the World Health Organization (WHO). In the end, the disagreement led to the PIP Framework (2011) (see below). But prior to the PIP Framework's adoption, some senior LMIC policymakers and advisors argued instead for an expansion of the CBD to include human genetic resources (Chaturvedi et al. 2013).

When one looks at the arguments brought forward by the Indonesian government in the dispute with the WHO about human genetic samples, one can see why Indonesia was concerned about justice issues:

Disease affected countries, which are usually developing countries, provide information and share biological specimens/virus with the WHO system; then pharmaceutical industries of developed countries obtain free access to this information and specimens, produce and patent the products (diagnostics, vaccines, therapeutics or other technologies), and sell them back to the developing countries at unaffordable prices. Although it is general knowledge that this practice has been going on for a long time for other major communicable diseases – not just for avian influenza – the fear of potential pandemic influenza has magnified this gap. (Sedyaningsih et al. 2008)

The exploitative spirit of the first-come-first-served approach to accessing genetic resources makes no distinctions between type of resources and their origins. The drafters of the Nagoya Protocol therefore decided to add a nod toward human resources in the introduction, to precede the main text:

Mindful of the International Health Regulations (2005) of the World Health Organization (WHO) and the importance of ensuring access to human pathogens for public health preparedness and response purposes.

As a result, the Nagoya Protocol includes a reference to regulations which govern human genetic resources, something the CBD does not.

The WHO Pandemic Influenza Preparedness (PIP) Framework

In the mid- to late 2000s, the dispute between the WHO and Indonesia was reminiscent of the “Grand Bargain” debates of the CBD, focusing on the exploitation of LMICs (Box 1), first-come-first-served-style. Indonesia argued that it provided avian flu samples to the WHO for vaccine development, but the benefits and resulting vaccines stayed in high-income countries.

Box 1 Exploitation

Robert Mayer (2007) developed a formulation of exploitation that is highly appropriate for discussions of benefit sharing:

Exploitation is the failure to benefit another as fairness requires thereby obtaining wrongful gain.

In this dispute, the WHO stressed countries’ responsibilities to share their specimens or viruses without imposing “agreements or administrative procedures that may inhibit the proper functioning of the ... [system], including in particular the timely sharing of material and information” (Sedyaningsih et al. 2008: 486; WHO 2007). By contrast, Caplan and Curry (2007) were sympathetic to Indonesian efforts to prevent exploitation and noted:

Indonesia is basically correct: pandemic vaccines that are in development and early testing are largely already obligated by contract to a limited group of national governments. That list does not include Indonesia or developing nations in general.

Indonesia’s refusal to cooperate with a system it deemed unfair catalyzed an effort to develop a new framework for global virus sharing.

In 2011, after 4 years of negotiations, the WHO’s Open-Ended Working Group of Member States on Pandemic Influenza Preparedness reached agreement on the new framework for influenza virus sharing. The PIP Framework was ratified by the World Health Assembly in May 2011, and it recognizes the “sovereign right of States over their biological resources” (WHO 2011b). The formulation was chosen in line with the CBD, even though human resources are excluded from the latter.

The PIP Framework has two aims (WHO 2017):

- Sharing of influenza viruses that could cause a pandemic
- Access to capacity development and products such as vaccines

One can see here how the “Grand Bargain” of PIP operates. Aim 1 promotes access to resources, in line with objective 2 of the CBD (the sustainable use of its [biodiversity’s] components). Aim 2 is the result of bargaining between HICs and LMICs, prompted by legitimate concerns over exploitation. This mirrors objective 3 of the CBD (the fair and equitable sharing of benefits from the use of genetic resources). Interestingly, the PIP Framework does not promote its overall aim (securing global public health through an effective fight against viruses) as the CBD does as part of wider objectives or aims. But if it did, the structure of the fairness-in-exchange efforts would be identical (see Fig. 1).

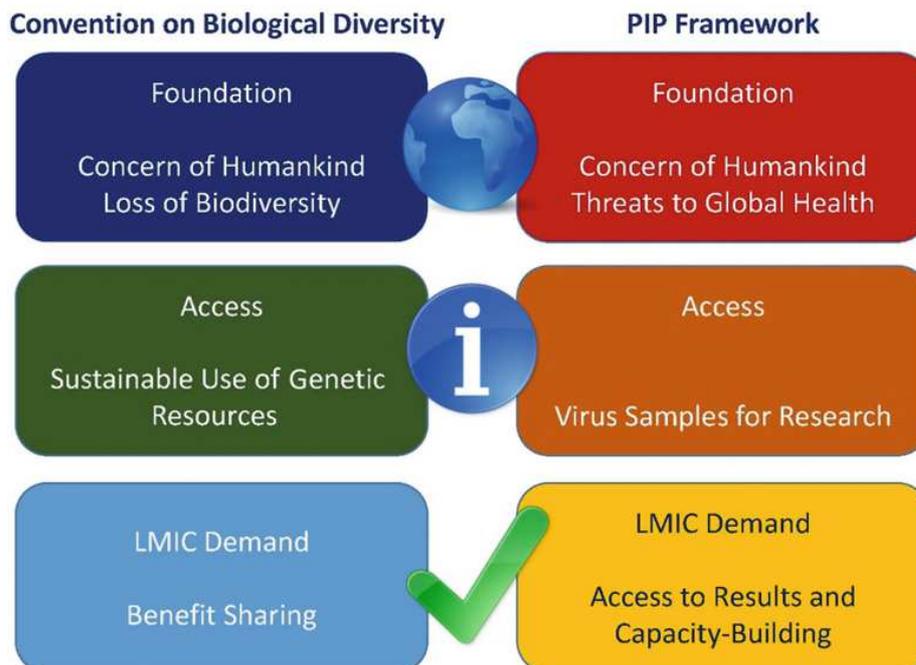


Fig. 1

Structure of fairness-in-exchange models of benefit sharing

How does the PIP Framework ensure its aims are achieved? In line with the CBD approach to accessing biological resources, the PIP Framework requires binding standard material transfer agreements (SMTAs). The main difference from the CBD approach is that the institutions accessing the samples sign the SMTA with the WHO, rather than with the countries of origins of the samples. In turn, it is the WHO's responsibility to ensure that the second aim of the PIP Framework, access to capacity development and products such as vaccines, is achieved.

Capacity development and affordable access to vaccines is costly. The standard SMTA drawn up for the PIP Framework therefore includes benefit sharing options, one of which is for users of resources to pay an annual Partnership Contribution (WHO [2017](#)). Funds from the Partnership Contribution can then be used to help countries respond to pandemics, both in terms of prevention and in actual cases.

The PIP Framework has been praised as “an innovative way to make global solidarity a reality and to protect the world against devastating pandemics” (Briand [2016:180](#)). No withholding of virus samples involving protests over benefit sharing – as in the Indonesian case – has been revealed in the literature since it came into effect.

Declaration of Helsinki: Posttrial Obligations

“I have been used like a guinea pig, so how does he just leave me without compensation?” (Shaffer et al. [2006](#)). The sentiment expressed by this clinical trial participant in Kenya is what a particular form of benefit sharing tries to avoid: post-study obligations.

In 2000, at a meeting in Edinburgh, the World Medical Association (WMA) General Assembly added posttrial obligations to the Declaration of Helsinki, the main source of ethical guidance for medical researchers since 1964. The new article reads as follows (Carlson et al. [2004](#)):

At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.

Who was going to monitor whether posttrial obligations had been discharged was not clear. As a result, in 2004, at the next General Assembly in Tokyo, the WMA added a note requesting that post-study access to drugs, medical procedures, or care be discussed during the planning of trials and documented in the study protocol (Schroeder [2008](#)). Very few, if any, success stories were openly reported. Yet, in 2008, expectations for benefit sharing with clinical trial participants became more ambitious. Article 33 of the 2008 Declaration of Helsinki (adopted in Seoul) noted (Schroeder and Gefenas [2012](#)):

At the conclusion of the study, patients ... are entitled ... to share any benefits that result from it, for example, access to interventions identified as beneficial in the study or to other appropriate care or benefits.

This was the strongest benefit sharing article of the Declaration of Helsinki to date. Still, very few if any success stories were reported, and significant challenges were summarized in the literature (Schroeder and Gefenas [2012](#)). By 2013, the term benefit sharing (“share any benefits”) had been removed from the Declaration of Helsinki, as well as the reference to “other appropriate care or benefits.” The current version of the benefit sharing article, Art 34, reads as follows (Declaration of Helsinki [2013](#)):

In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.

Box 2 describes the efforts of one pharmaceutical company to discharge posttrial obligations.

Box 2 Roche's Approach to Posttrial Access (Kelman et al. [2018](#))

In 2013, Roche – a Swiss multinational healthcare company – publicly posted its *Global Policy on Continued Access to Investigational Medicinal Products*. The policy had been co-developed by Roche clinical trial professionals with experts from the fields of genetics, bioethics, law, science policy, and patient advocacy. In the policy's Executive Summary section, it reads:

Roche offers patients who participate in Roche-sponsored clinical trials continued access to the investigational medicinal product that they received after trial completion, when appropriate.

Four exemptions are made. The medicinal product will not be provided:

1. 1.

When it is reasonably available to the clinical trial participant (e.g., covered by his or her health insurance)

2. 2.

When Roche has discontinued its development

3. 3.

When safety concerns exist about the product

4. 4.

When provision of the product would violate local laws

An example of provision of posttrial access is Roche's etrolizumab clinical trial program, which studies a potential treatment for ulcerative colitis. For up to 7 years after the conclusion of the initial trial program, patients can receive the intervention as part of an open-label. (In an open-label clinical trial, both the researcher and the research participant know which medicine is being administered. This is in contrast to a traditional double-blind clinical trial where neither researcher nor participant knows if they are receiving the intervention or a placebo extension program.) After the conclusion of the open-label extension, research participants who continue to require etrolizumab can receive it on an individual basis.

The above three legal instruments and the Declaration of Helsinki rely on the concept of fairness-in-exchange. Those who do not contribute to the scientific process, for instance, by sharing samples or acting as participants, have no right to benefit sharing claims on the outcomes, according to the instruments just introduced. However, the UNESCO Universal Declaration on Bioethics and Human Rights and the Human Genome Project's Ethics Committee Statement on Benefit Sharing see this differently.

Benefit Sharing as Distributive Fairness

To explain the main features of benefit sharing as distributive fairness, two ethical instruments will be introduced: the Human Genome Project's Ethics Committee Statement on Benefit Sharing (HUGO [2000](#)) and the UNESCO Universal Declaration on Bioethics and Human Rights ([2005](#)).

The Human Genome Project's Ethics Committee Statement on Benefit Sharing

The Human Genome Project's Ethics Committee was the first major ethics group to produce a specific statement on benefit sharing. The committee was prompted by the fact that by 2000 commercial expenditure on genetic research exceeded the contributions from governments (HUGO [2000](#)). And as noted earlier, the CBD had excluded human genetic resources, leaving a legal and ethical vacuum regarding access to human genetic resources.

The HUGO ([2000](#)) Ethics Committee recommends:

1. 1.
that all humanity share in, and have access to, the benefits of genetic research.
2. 2.
that benefits not be limited to those individuals who participated in such research.
3. 3.
that there be prior discussion with groups or communities on the issue of benefit-sharing.
4. 4.
that even in the absence of profits, immediate health benefits as determined by community needs could be provided.
5. 5.
that at a minimum, all research participants should receive information about general research outcomes and an indication of appreciation.
6. 6.
that profit-making entities dedicate a percentage (e.g., 1–3%) of their annual net profit to healthcare infrastructure and/or to humanitarian efforts.

The above recommendations of the HUGO Ethics Committee make strong and clear claims on distributive fairness. Benefits are *not* to be limited only to those who contributed to the research. The genetic heritage of humankind warrants the demand that all humans should benefit.

While these recommendations focus specifically on the Human Genome Project ("the Human Genome Project should benefit all humanity," HUGO [2000](#)), the Committee's decision to take an alternative approach to the CBD was later followed by UNESCO.

The UNESCO Universal Declaration on Bioethics and Human Rights

In 2005, UNESCO published its Universal Declaration on Bioethics and Human Rights. The idea for the Declaration was launched by French President Jacques Chirac in 2001, upon which the International Bioethics Committee (IBC) of UNESCO started a three-level consultation (Bergel 2015) (Fig. 2).



Fig. 2

Stages in the development of the UNESCO declaration

Of the 28 articles of the Declaration, one of the longest is dedicated to benefit sharing (see Box 3).

Box 3 UNESCO Universal Declaration on Bioethics and Human Rights, Article 15: Sharing of Benefit

1. 1.

Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:

1. (a)

Special and sustainable assistance to, and acknowledgment of, the persons and groups that have taken part in the research

2. (b)

Access to quality healthcare

3. (c)

Provision of new diagnostic and therapeutic modalities or products stemming from research

4. (d)

Support for health services

5. (e)

Access to scientific and technological knowledge

6. (f)

Capacity building facilities for research purposes

7. (g)

Other forms of benefit consistent with the principles set out in this Declaration

2. 2.

Benefits should not constitute improper inducements to participate in research.

As in the HUGO Statement on Benefit Sharing, UNESCO subscribes to a distributive fairness interpretation of benefit sharing. While the Declaration does not explicitly state that benefits should also go to those who do *not* take part in scientific research, this is clear from the initial statement of the article.

Benefits resulting from any scientific research and its applications should be shared with *society as a whole* and within the international community, *in particular with developing countries*. [emphasis added]

The three instruments introduced earlier regarding fairness-in-exchange are legally binding. This gives them considerable legal power. It is difficult to say how effective a non-binding Declaration such as UNESCO's can be in practice. But it is important to note that the Declaration has the support of states rather than "only" professional organizations, such as the Declaration of Helsinki's link to the World Health Assembly. This has been emphasized as a considerable advantage (Langlois [2008](#)).

Aristotle famously promoted the golden mean, that is, the space between two polar opposites (Aristotle [2004](#): 1104a25). Is there a middle way between the fairness-in-exchange and distributive fairness models of benefit sharing?

Combining Fairness-in-Exchange and Distributive Fairness?

In 2018, the European Commission added a mandatory reference document to its Horizon 2020 research framework, the Global Code of Conduct for Research in Resource-Poor Settings (GCC) (Nordling [2018](#)). The GCC was developed by a European Commission funded project, TRUST (TRUST is a pluralistic project, which aims to foster adherence to high ethical standards in research globally and to counteract the practice of "Ethics dumping" or the application of double standards in research, by co-developing with vulnerable populations tools and mechanisms for the improvement of research governance structures <http://trust-project.eu> (<http://trust-project.eu/>)). The project involved global stakeholders as partners, including universities, multilevel ethics bodies, policy advisors, civil society organizations, funding organizations, industry, and representatives from vulnerable research populations in LMICs. It combined elements of distributive fairness with elements of fairness-in-exchange. Does this attempt to combine the best of both worlds reach a golden mean?

The Global Code of Conduct for Research in Resource-Poor Settings

The GCC ([2018](#)) provides guidance to researchers of *all* disciplines and focuses especially on research in resource-poor settings. It was developed to address ethics dumping (Schroeder et al. [2018](#)), the practice of exporting unethical research from HICs to regions with more malleable regulatory frameworks.

While not legally binding, the GCC has bite through its adoption by both the European Commission and the European and Developing Countries Clinical Trials Partnership (EDCTP). Those in receipt of research funds have to demonstrate that they abide by the GCC and ethics reviewers working on behalf of the two funders assess ethics protocols against the GCC's articles. As Ron Iphofen noted (Nordling [2018](#)):

I could envisage reviewers now looking suspiciously at any application for funds that entailed research by wealthy nations on the less wealthy that did not mention the code.

While the GCC was published by a group funded through the European Commission (see <http://www.globalcodeofconduct.org/> (<http://www.globalcodeofconduct.org/>)), its authors include high-profile individuals who are part of other major global efforts, in particular:

- The Chief of Bioethics of UNESCO, who had a major role in drafting the UNESCO Universal Declaration on Bioethics and Human Rights
- The Director of the EDCTP
- The Director of the Council on Health Research for Development (COHRED) who advised the Council for International Organizations of Medical Sciences (CIOMS) on their 2017 International Ethical Guidelines for Health-Related Research Involving Humans
- The lead UN advisor on the UN Global Compact, a major UN initiative on corporate responsibility
- Two previous Heads of the Ethics Unit of the European Commission
- The main drafter of all Indian ethics guidelines on involving human participants in research

What is widely regarded as a major achievement of the GCC is that vulnerable research populations in LMICs, in particular indigenous peoples from the Kalahari and sex workers from Nairobi, were represented throughout the process of drafting; this represents the GCC's co-design process or bottom-up approach (Burtscher [2018](#)).

The spirit of benefit sharing is included in many of the GCC's 23 articles, rather than added as a specific article. Using a four-value framework (fairness, respect, care, and honesty), the GCC takes the following stance on benefit sharing (all articles are summarized rather than written out in full; see the full code to understand subtleties):

1. I.

The seven articles under the value of *fairness* all address benefit sharing.

Art 1 – Locally relevant research

Art 2 and Art 4 – Research co-created with LMIC stakeholders

Art 3 – Feedback provided

Art 5 and Art 6 – Access and benefit sharing as per CBD or PIP

Art 7 – Fair remuneration of local research support systems

2. II.

The four articles under the value of *respect* promote good communication across nations and cultures, as a basis for avoiding subsequent exploitation claims.

Art 8 – Due diligence regarding cultural sensitivities

Art 9 – Community assent

Art 10 – Local ethics review

Art 11 – Respectful collaboration with local ethics committees

3. III.

The eight articles under the value of *care* aim to mitigate the effects of substantial power differentials, one of the legitimate bases for benefit sharing demands.

Art 12 – Adapted informed consent

Art 13 – Locally suitable complaints mechanism

Art 14 – No double standards

Art 15 – Measures against specific risks for research participants

Art 16 – Due diligence on depletion of local resources

Art 17 – High animal welfare standards, if necessary matched to HIC standards

Art 18 – High environmental standards, if necessary matched to HIC standards

Art 19 – Managing health and safety risks for researchers

4. IV.

The four articles under the value of *honesty* promote equitable partnerships in practical ways.

Art 20 – Honesty in distribution of research labor

Art 21 – Plain language and non-patronizing communication

Art 22 – No corruption, nor bribery

Art 23 – Special efforts on privacy preservation

As can be seen from the above summary, the GCC does not present a golden mean between the two benefit sharing types but weighs toward fairness-in-exchange (Fig. 3). Distributive fairness requires that all of humanity benefit from science and innovation. Fairness-in-exchange is restricted to those who contribute directly to research. The GCC deals mostly with research participants and other direct stakeholders (e.g., researchers in LMICs), but it does make reference to community needs, for instance, in the context of necessary community assent to studies. Hence, it is a step to the right (in terms of the figure below), toward distributive fairness.

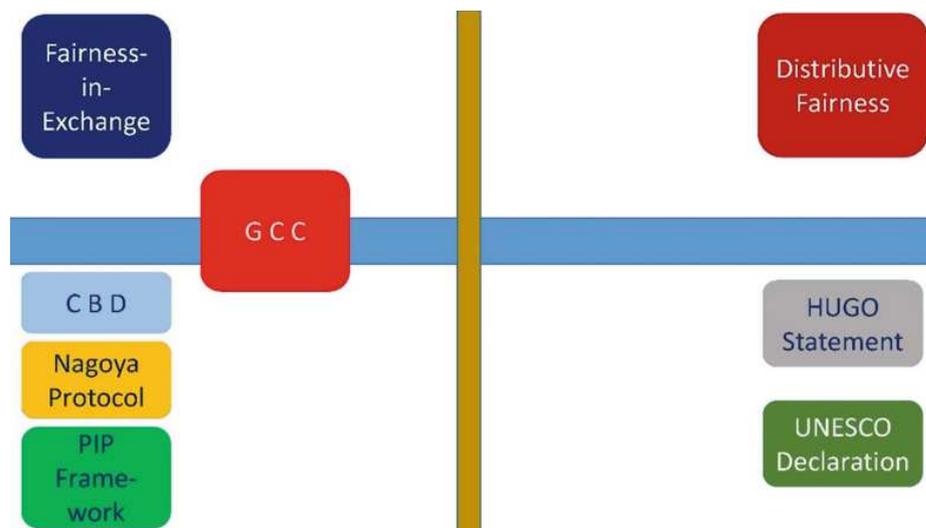


Fig. 3

Position of instruments on Aristotle's golden mean

The reason for this is that the GCC governs *research*. It is beyond the power of researchers and their funders to ensure that “society as a whole” and “in particular ... developing countries” benefit “from *any* scientific research and its applications” (UNESCO 2005, emphasis added). However, through the building of equitable research partnerships, the previously unbalanced power distributions in global research and innovation can begin to be addressed. For instance, if “Local researchers ... [from resource-poor settings are] included, wherever possible, throughout the research process, including in study design, study implementation, data ownership, intellectual property and authorship of publications” (Art 4, GCC), it is more likely that research would be tailored toward the needs of LMICs and not be exploitative.

Is this stepped approach to benefit sharing satisfactory, or could benefit sharing become more ambitious, moving more toward distributive fairness and into the golden mean?

Benefit Sharing: Open Questions and Solutions?

While benefit sharing is a relatively new concept, which only came to the fore internationally with the CBD in 1992, its spirit is both ancient and global due to its direct link to justice demands. To examine whether there are open questions in benefit sharing is therefore like asking: “Is the world just yet?” The answer has to be “no,” and the news is not that good on the benefit sharing front.

The two types of benefit sharing face highly different problems or open questions. The fairness-in-exchange approach links efforts for benefit sharing with specific actions in the real world, e.g., accessing microorganisms with prior informed consent and the signing of SMTAs. The distributive fairness approach, on the other hand, is inspirational and idealistic. It is, in fact, unclear how it would practically invite action or operationalization. The following sections outline which problems and open questions each approach faces.

Three Elephants in the Fairness-in-Exchange Room

Trying to achieve fairness-in-exchange on a global scale through legal instruments has led to highly technical requirements, which have delivered few success stories and a lot of criticism (an elephant in the room is an English metaphor for a very large problem that nobody discusses openly or at all). Box 4 describes one success story of the application of the South African Biodiversity Act. But it is one of few.

Box 4 Successful Benefit Sharing Under the South African Biodiversity Act

Zembrin® is a standardized, patent-protected botanical extract developed by HG&H Pharmaceuticals Pty Ltd. of South Africa. The extract is used primarily for anxiety, stress, and depression and is made from a cultivated selection of *Sceletium tortuosum* which was brought to market under the leadership of South African doctor and ethnobotanist Nigel Gericke after research in the Kamiesberg Mountains of South Africa.

Gericke had first read about indigenous uses of the *Sceletium* plant in a library in Sydney, Australia. In 1995 Gericke engaged the services of a leading addictionologist, Dr. Greg McCarthy, to accompany him on a field visit to two communities in Namaqualand where the plant was still in common use. Based on structured interviews with rural people, it was provisionally concluded that the plant was likely to be safe and nonaddictive and may have potential mental health benefits.

A year later, in 1996, active components were isolated from the plant, leading to a patent filed shortly afterward. It took almost a decade before a specific selection of the plant could be cultivated on a commercial scale and a plant extract be produced that was standardized in terms of both the content and relative composition of the key active compounds. At this point, a venture capital company, Halls Investments, invested in further research, development, and commercialization.

In recognition of the ethnobotanical basis for the project, Gericke initiated benefit sharing negotiations with the South African San Council. Parties to the benefit sharing agreement, which was concluded in 2008, were the San peoples of South Africa, through the South African San Council, and HG&H Pharmaceuticals, the newly founded company intending to market Zembrin®.

The agreement contained three central points:

1. 1.

Should commercialization be successful, 5% of all sales of the extract would be paid into a trust fund for the San peoples.

2. 2.

An additional 1% of all sales would be paid into the trust fund as a license for the use of a San logo by HG&H Pharmaceuticals.

3. 3.

In recognition of the foundational ethnobotanical research conducted in Namaqualand, the San Council agreed to pay 50% of the income received from HG&H to two committees representing the communities in Namaqualand.

Zembrin® was first launched in South Africa in 2012 and has since been launched in the USA, Canada, Brazil, Malaysia, and Japan. The terms of the benefit sharing agreement have been respected through yearly payments to the trust fund and a mutually supportive relationship between HG&H Pharmaceuticals and the San Council.

Criticism of the fairness-in-exchange approach to benefit sharing ranges from a serious rejection of the effort itself through to highly specific objections, which are in principle resolvable. For instance, objections which are in principle resolvable (drawn from Wynberg et al. 2009) are:

- The CBD commodifies knowledge by requiring benefit sharing for traditional knowledge holders who agree to share their knowledge. When knowledge holders live in remote, rural areas, adequate community consent is a major challenge.
- Benefit sharing with traditional communities requires stable, robust, and representative institutions. Sufficient time, financial support, and advice, for instance legal advice, are essential elements in the process. However, these might not be available to the people who need them.
- Bioprospecting activities, which lead to benefit sharing, often raise unreasonable expectations in communities.
- When indigenous traditional knowledge holders reside in several countries and biological resources are shared across national borders, they are unlikely to have the government support they would need to obtain justice.

As an example of a serious rejection of the fairness-in-exchange effort, 172 scientists from 35 countries published “When the cure kills – CBD limits biodiversity research” in *Science* (Prathapan et al. 2018). They argued that the CBD is producing overly high hurdles for biodiversity research and thereby prevents international collaborations which aim to preserve biodiversity. Paradoxically, the tool developed to secure the preservation of biodiversity is seen in practice to undermine the preservation of biodiversity.

The vast administrative and legal burden on countries to operationalize CBD benefit sharing arrangements and the burden on innovators to comply is not often mentioned. It is the first big elephant in the fairness-in-exchange room. The second elephant in the room is the fact that the USA, the country with the highest absolute research and innovation budget (OECD 2018), is not a signatory to the CBD nor to its Nagoya Protocol. Hence, the largest research and innovation funder in the world sidesteps all benefit sharing requirements.

At the same time, supporters of the fairness-in-exchange approach to benefit sharing are also not satisfied. (Due to space constraints and as the criticisms are many in number, only the three “elephants” are described. However, for the interested reader, it is worth seeing the reply to the criticism that benefit sharing creates undue inducements, written by R. Chennells (2016).) For instance, even the PIP Framework, which relates only to very specific specimens in a well-established global network, faces criticism. Gostin et al. (2014) question whether the PIP Framework can handle the “growing likelihood that genetic sequence data might be shared instead of physical virus samples.” This problem has now also been examined by a CBD (2018) fact-finding mission: *Fact-Finding and Scoping Study on Digital Sequence Information on Genetic Resources in the Context of the CBD and the Nagoya Protocol*. The Executive Summary of the mission report is ten pages long, an indicator of the level of technicality and challenge, and ends with the following statement:

This study has revealed a number of important areas which we have only touched upon, and which warrant further and deeper investigation. These include: determining/estimating the value of digital sequence information; exploring the approaches of public and private databases; investigating new and traditional forms of benefit sharing in the context of digital sequence information; reviewing user notices, MTAs, agreements and other benefit-sharing tools; reviewing national ABS measures and how they regulate sequence information; exploring the interface between scientific and technological developments and ABS; reviewing the relationship between sequence information, biodiversity conservation, and sustainable use; and investigating ways in which intellectual property rights are asserted for sequence information, and ABS implications.

The third elephant in the fairness-in-exchange room is related to and also hinted at by the CBD fact-finding report (2018). “Paralleling dramatic changes in science and technology are developments in the institutional, legal and social context of research.” Can a global legal framework, such as the CBD, stay ahead of changes in science, technology, and society to ensure fairness-in-exchange? The answer to this question is unclear.

A Partner for the Distributive Fairness Approach

If the more concrete fairness-in-exchange approach to benefit sharing faces such severe challenges, how about the distributive fairness approach, which makes even higher demands: Sharing the benefits of research and innovation with *all* of humanity? Are there perhaps partners for the UNESCO Declaration, and if so, what would a successful partnership look like? The partner would certainly have to be pro-research and innovation and simultaneously pro-uplifting of LMICs to achieve global justice.

Luckily for the distributive fairness approach, there is such a partner. The biggest justice effort of our generation, the UN Sustainable Development Goals, also called Agenda 2030, was released by the UN General Assembly in 2015. Goal 9 of Agenda 2030 makes it clear that the goals are pro-research and innovation (UN [2015](#)).

Without technology and innovation, industrialization will not happen, and without industrialization, development will not happen. There needs to be more investments in high-tech products that dominate the manufacturing productions to increase efficiency and a focus on mobile cellular services that increase connections between people.

At the same time, Agenda 2030 pursues the underlying spirit of distributive fairness efforts, namely, to leave no one behind. The key to leaving no one behind “is the prioritisation and fast-tracking of actions for the poorest and most marginalised people” (Stuart and Samman [2017](#)). This interpretation of the UN Sustainable Development Goals and their focus is reminiscent of John Rawls’ ([1999](#): 65) approach to justice, quoted earlier:

The higher expectations of those better situated are just if and only if they work as part of a scheme which improves the expectations of the least advantaged members of society.

What does this all mean for the prospect of benefit sharing?

Wouldn’t one have to be very optimistic to assume that we could persuade the three elephants in the fairness-in-exchange room to leave? Or that Agenda 2030 can erase the need for a distributive justice platform for benefit sharing? Yes, one would have to be *very* optimistic. But there is also a much simpler solution. The need for benefit sharing has only arisen because LMICs have been and continue to be exploited (Rabitz [2015](#)). This is what is meant by ethics dumping. Yet, *not* to exploit LMICs is within the power of *every* single researcher and innovator. Individuals can take the initiative on the benefit sharing agenda and achieve compliance with the spirit of all of the above instruments through sheer decency.

Highly complex legal instruments are only necessary where researchers do not have the willingness or compassion *not* to exploit the vulnerable, i.e., where researchers do not show research integrity. When they do, highly technical benefit sharing discussions could become obsolete.

Notes

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