



Towards policies that capture the expected value of biomolecular diversity for drug discovery, human health, and well-being

Milica Pesic^{1,2} · Dilfuza Egamberdieva^{1,3} · Bart Kolodziejczyk^{1,4} · Simon J. Elsässer^{1,5}  · Vidushi S. Neergheen^{1,6} · Alexander Kagansky^{1,7}

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Abstract

This paper aims to help policy makers with a characterization of the intrinsic value of biodiversity and its role as a critical foundation for sustainable development, human health, and well-being. Our objective is to highlight the urgent need to overcome economic, disciplinary, national, cultural, and regional barriers, in order to work out innovative measures to create a sustainable future and prevent the mutual extinction of humans and other species. We emphasize the pervasive neglect paid to the cross-dependency of planetary health, the health of individual human beings and other species. It is critical that social and natural sciences are taken into account as key contributors to forming policies related to biodiversity, conservation, and health management. We are reaching the target date of Nagoya treaty signatories to have accomplished measures to prevent biodiversity loss, providing a unique opportunity for policy makers to make necessary adjustments and refocus targets for the next decade. We propose recommendations for policy makers to explore novel avenues to halt the accelerated global loss of biodiversity. Beyond the critical ecological functions biodiversity performs, its enormous untapped repertoire of natural molecular diversity is needed for solving accelerating global healthcare challenges.

Keywords Biodiversity · Biomedicine · Biosecurity · Bioeconomy · Science-policy development

<https://globalyoungacademy.net>

✉ Simon J. Elsässer
simon.elsasser@scilifelab.se

✉ Alexander Kagansky
kagasha@yahoo.com

Milica Pesic
camala@ibiss.bg.ac.rs

Dilfuza Egamberdieva
egamberdieva@yahoo.com

Bart Kolodziejczyk
kolodziejczykbartlomiej@gmail.com

Vidushi S. Neergheen
v.neergheen@uom.ac.mu

³ Faculty of Biology, National University of Uzbekistan, Tashkent, Uzbekistan

⁴ Department of Pedagogical, Curricular and Professional Studies, University of Gothenburg, Gothenburg, Sweden

⁵ Science for Life Laboratory, Division of Genome Biology, Department of Medical Biochemistry and Biophysics, Karolinska Institutet, Stockholm, Sweden

⁶ Department of Health Sciences, Faculty of Science and Centre for Biomedical and Biomaterials Research, University of Mauritius, Réduit, Republic of Mauritius

⁷ Centre for Genomic and Regenerative Medicine, School of Biomedicine, Far Eastern Federal University, Vladivostok, Russian Federation

¹ 'Biodiversity for Survival via Biomedicine' Working Group, Global Young Academy, Halle (Saale), Germany

² Institute for Biological Research "Siniša Stanković"-National Institute of Republic of Serbia, University of Belgrade, Belgrade, Serbia

Introduction

It is estimated that only 1% of the 2–50 million species are being studied or utilized by humans (Scheffers et al. 2012) yet rapidly accelerating rates of species extinction, and the lack of knowledge of most species on Earth poses a direct threat for identifying molecules with biomedical properties and potential use for human health. Seventy percent of drugs used for treating human health are directly or indirectly derived from nature. Eleven percent of the 252 drugs considered as basic and essential by the World Health Organization are derived from flowering plants. More than 85% of people around the world use natural products as their primary source for health care (Fabricant et al. 2001).

The effectiveness of natural products comes from symbiotic and competitive evolution in our complex biosphere. Billions of years of co-evolutionary interactions among millions of species have produced a huge repertoire of defence molecules effective in restricting bacteria, viral, and fungal pathogens. Because each species contains millions of different, useful molecules, one can imagine the economic and health prosperity that could be achieved by discovering more of our planet's biodiversity. While new research technologies have emerged to streamline screening of molecules and complex mixtures from diverse biological sources, the loss of biodiversity is accelerating, reducing the potential for discovery of new natural compounds with therapeutic properties. It is hard to estimate the price humanity will pay in lives and care for patients suffering from diseases due to the lost drug lead opportunities as a result of biodiversity extinction. The continued loss of biodiversity threatens compound discovery and benefits that could be used to protect communities and the biodiversity they depend on. The preservation of biodiversity is perhaps the single most important building block for achieving the 17 Sustainable Development Goals set by the United Nations, for example, Zero Hunger (SDG-2), Climate Action (SDG-13), Life below Water (SDG-14), and Life on Land (SDG-15). Large-scale environmental genomics and proteomics provide an unprecedented opportunity for renewed efforts in protecting biodiversity, indigenous knowledge, and personalized medicine. This raises an urgent need for facilitating legal and practical frameworks that promote and regulate cataloguing, characterizing, and at the same time, protecting biodiversity. For example, new models are needed for harnessing biodiversity for biomedical applications including policy development for sustainable harvesting.

To create new paradigms for conservation based on the ecosystem service of drug discovery, partnerships are needed among scientists to identify species and isolate compounds, social scientists to assess community needs and ensure community empowerment, and policy makers to

produce legislation to guide protection and to develop models for sustainable agriculture and research involving modern biotechnology and chemistry. Given the potential for overexploitation and the unknown amount of compounds lost, this scenario of biodiversity—a focus on drugs lost from species extinction—is largely unexplored.

Tackling the aforementioned challenges will require continuous integration and cooperative engagement of policy-makers, researchers, social scientists, and members of indigenous communities world-wide. Several action teams have been recently established, including the Commission on Planetary Health by the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES) Rockefeller Foundation (Planetary Health commission), Digital Forest (started in Brazil to evaluate genomic and metabolomic diversity in the Amazon), and the Biodiversity for Survival via Biomedicine (Bio2Bio) consortium put forward by the Global Young Academy (Neerghen-Bhujun et al. 2017). Engagement with these initiatives can serve as a platform to highlight the urgency of biodiversity protection for biomedical applications and to lay out a strategic plan forward.

Problem

Governments need to put urgent consolidated efforts into proposing innovative schemes for making renewed research on natural products feasible under international legislation and attractive for investment, even despite high risks and the long time needed for commercialization of resulting drugs. On the other hand governments need assure the protection vulnerable local communities associated with, and depending on, natural resources, to reassure continuous benefit to these communities.

Existing policies

The dominant existing policy is the Nagoya protocol, which has been signed by around hundred nations and includes twenty 'Aichi' targets to be met by 2020 (Gómez-Castro and Kipper 2019). The rationale is that biological diversity underpins ecosystem functioning and the provision of ecosystem services is essential for human well-being. It entered into force on 12 October 2014. There is a controversy with regards of the effectiveness of the strict access and benefit sharing regulations. While the situation has not changed for countries that didn't ratify the aforementioned agreement, it is nearly prohibitive for research and development of novel natural products in the countries that follow the agreement.

At its meeting in June 2011, the Environment Council, in its Conclusions (Council of the European Union 2011) endorsed the new EU Biodiversity Strategy fully in line with the Nagoya treaty. The new strategy has been adopted in recognition of the EU's failure to meet the 2010 biodiversity target, set by the European Council in Gothenburg in 2001 where Member States committed "to halt the decline of biodiversity in the EU by 2010".

Implementing optimal policy requires actions based on existing international laws and national legal and policy frameworks, economic incentives, and public and stakeholder engagement. Importantly knowledge by the indigenous populations should have more share in the future, as these populations themselves, their languages, culture, and their knowledge itself are endangered.

A growing number of countries have specific regulations in place for the development of projects, but the regulations surrounding the outcomes differ between countries.

It is high time to develop the innovative international policy options in the aftermath of the failure to meet the 2020 targets, as it was with the 2010 biodiversity targets.

Challenge

Escalating challenges in context of medical issues amidst international disparity

Despite positive tendencies to globalize the policy in Europe, via EU policy, and to some extent in other parts of the world (e.g. Asia Pacific region, etc.), national policies significantly differ across the world. Moreover, policies developed separately across different sectors, i.e. biodiversity and health policies are largely uncoordinated, since the importance of their convergence was not appreciated in the past. To better integrate biodiversity and health in research and policy within the future policy space, international cooperation has to be exercised to systematically assess the problem, as well as the adoption of multidisciplinary approaches with contributions from both the social and natural sciences. For example, EcoHealth, One Health and "one medicine" are approaches that aim to bridge human health and the health of other species. While being compatible with Convention on Biological Diversity (CBD), these initiatives were designed to incorporate a unified inter-disciplinary approach, taking lessons from ecosystem management, conservation, traditional medicine, animal health, and sustainability (Zinsstag et al. 2011). Since most medical and conservation science has a foundation in the scientific literature, predominantly coming from technologically developed countries, it is plausible to expect it has significant bias to the problems relevant to these countries. Meanwhile it is important that UN policy incorporates traditional knowledge, and agendas of the

biodiversity hotspots. Therefore, new, inclusive approaches have to be adopted to be inclusive of the majority of the planets' population and species within economically disadvantaged developing states. So there are challenges to create sustainable common language, compatible with the needs of those who for thousands of years have lived in 'molecular exchange' with the forest for medical and nutritional needs (with both being largely indistinguishable). In summary, it is crucial to put forward the integral links between biodiversity and human health thus promoting a more complete understanding of mutual dependencies, risks and solutions. These perspectives allow us to move beyond disciplinary argument to a broader and more upstream consideration of the key principles, mechanisms of the mutual molecular exchange in the prevention and treatment of human and animal diseases. Moreover, it is high time to break the vicious circle, where when given species are known to be the solution, their commercial exploitations would in many cases lead to their extinction. The former has led to the access and benefit sharing complications that differ across the globe and are nearly prohibitive for medical research on natural products. New hope may only be possible if competitive commercial opportunities, urgently offered by the renewed UN policy, incorporate traditional knowledge, best conservation practices, up-to-date medical research, and state-of-the-art digital and molecular technologies (e.g. next-generation sequencing, mass spectrometry).

The pressing need of the biomedical research and drug development agendas linked to the necessity to provide care for ever-increasing number of sufferers from deadly diseases like cancers, viral diseases and multi-drug resistant infections warrants the urgent global policy changes. Therefore, we have recently released (Neergheen-Bhujun et al. 2017) a call for action to:

- Create open interdisciplinary international dialogue among conservation and molecular scientists, physicians, patients, policy-makers, and commercial bodies in the areas of medicine, health, and well-being.
- Establish best practices, including ethical and legal considerations, for sustainable natural product exploration, collection, production, storage, preparation, and purification of compounds.
- Standardize high capacity bio-molecular and cell-based assays to test natural products against cell-based disease models.
- Implement best practices in sustainable commercialization of natural products, considering the balance of ecosystem, community, and commercial interests.
- Promote equitable sharing of benefits obtained from drug discoveries among stakeholders and the sustainability of natural products and the systems to which they are integral.

To progress in these directions, coordination of local and international policies is required. The increasingly strict permit standards to conduct biodiversity work around the world, while necessary to protect and manage resources, are creating barriers that decrease collaboration at a time when biodiversity is being lost at unprecedented rates. New interdisciplinary efforts are needed to create partnerships that help overcome barriers to protecting biodiversity, increase research for biomedical discovery, and bring forth equitable distribution of research outcomes. The 2010 Nagoya Protocol on Access and Benefit Sharing, a supplement to the 1992 Convention on Biological Diversity, provides a framework for sharing the benefits that arise from research on natural resources, especially molecules that improve human health. It is also essential to acknowledge the unique relationships of indigenous peoples with nature and their ancient knowledge on the medical properties of plants, animals, and fungi. This knowledge can help guide research and every effort is needed safeguard this knowledge and to conduct responsible research that will protect these communities and benefit human health.

Delegates from 179 countries meeting at the Convention on Biological Diversity (CBD) in Nagoya, Japan, agreed to “take effective and urgent action to halt the loss of biodiversity” to try to ensure the resilience of ecosystems by 2020. They also adopted agreements to generate financing to support these efforts and to share the proceeds of the commercialization of genetic materials with the countries of origin. Four years later, the CBD report stated “There has been significant progress towards meeting some components of the majority of the Aichi Biodiversity Targets”. Some target components, such as conserving at least 17 per cent of terrestrial and inland water areas, are on track to be met. However, in most cases this progress will not be sufficient to achieve the targets set for 2020, and additional action is required to keep the Strategic Plan for Biodiversity 2011–2020 on course Schöbel and Pollmann (1980). In the very end of 2016 CBD reported “Progress Report Toward the Aichi Biodiversity Targets,” found that while 75% of reporting countries have made some progress toward meeting the Targets, their pace is largely insufficient to meet the agreed upon deadline. Twenty percent of reporting countries have made no progress at all. Eight years since Nagoya, 2 years from the deadline, we do not have enough evidence that nature conservation is on the path of recovery even across the nations which are part of the protocol. Nations in the developing world are losing their species heritage partially due to the inability to prove the value for the developed world, while research and innovation in the developed countries are halted since novel natural compounds are not deemed commercially competitive. Without equitable sharing of biomedical discoveries, we will continue to lose

biomedical benefits from nature and mechanisms to support local communities that depend on biodiversity.

Proposals

Proposal 1: Flexible, dynamic, and evidence-based policy aimed at evaluation, protection, and sustainable use of known and putative medicinal species and compounds

Our first goal is to identify remaining species with natural, therapeutic compounds. Recent high-throughput screening methods in conjunction with omics technologies at world’s leading research institutions and pharmaceutical companies enable efficient and economical identification of antimicrobial, anti-oxidant, anti-tumorigenic, immuno-modulatory, and other medicinal properties of existing species and isolated natural compounds. A large body of published data suggest that despite the drastic loss of biodiversity and hence chemical diversity on the planet, the remaining heritage would afford solutions to most if not all known and emerging conditions. To date, over a half of all existing drugs guarding the health and wellbeing of humans and other mammals worldwide are derived from natural species and molecules. Due to current national and international policies, many medicinal species are now extinct or endangered, making their research, development, and use prohibitive for curing patients and increasing financial pressure, deaths, and suffering worldwide. Therefore, there is unprecedented opportunity for creating a new generation of UN policies aimed at the sustainable protection of bio- and molecular diversity on the basis of our own survival.

Researchers across UN should create a universal library of species and their constituent compounds. The databases available at GBIF and IUCN should provide solid foundation for such cross-disciplinary information hub. This library should be combined with a multi-lingual database portal, which would allow patients, researchers, and medical professionals, to find up-to-date scientific information on relevant compounds and would detail the medical value of compounds that occur within common and endangered species, local or endemic foods, traditional medicine, and a phylogeny to predict new species for potential research and use. Species extracts repositories, herbariums, and seed banks should be linked to these data either in dedicated international institution, or as a distributed repository, i.e. species are stored at the countries of origins or regional hubs. Protected areas such as UNESCO wildlife reserves are well suited for the comprehensive assessment, including digital sequence, metabolomic, and other information. Importantly, the intellectual property linked to materials and information should not be prohibitive for the commercial development,

provided that such developments should protect the natural reservoir of the affected species. Synthetic biology and chemistry should allow development of the molecule of interest without further exploiting the species of origin.

Proposal 2: Disseminate policies in community-centric approaches and protect local biodiversity to UN governments

When properly managed, biodiversity is sustainable and natural products are renewable. However, too often humanity's pursuit of a valuable commodity has driven valuable species to extinction and destroyed habitats that support diverse species. Only talking of 'large' animals—mammals, birds, and reptiles—human development accounts for 322 species lost in last 500 years. It is much harder to establish the rate of extinction for the species that did not attract any interest due to little or no associated research. Humans are a part of the same ecosystems and often depend on the same biodiversity as does the species of interest. There are numerous drivers associated with species exploitation that may impact local communities, from loss of cultural identity, livelihoods, historical lands, historical knowledge, and more. Additionally, there is the potential for the interests of local people to be disregarded in the pursuit of a drug discovery, including economic interests both related and unrelated to medicinal value of species in question. Economic potential related to drug development is well established. Local and national governments have a stake in making sure that the drug potential of local species is not "stolen" by investors with little interest in sustainability of local communities and local ecosystems. Of comparable importance, drug development should not rob local communities of their identities, traditions, and futures.

This project proposes development of a decision support tool. This will be accomplished through an iterative relationship of UN policymakers with national governments and local communities across the world, where local stakeholders can both express their concerns (to be incorporated into the model) and use the model to weigh the projected potential ramifications of their actions on the sustainability of the systems on which they rely alongside economic potential for this and future generations. While this project may include an ethnobotanical survey, as a sample activity, this survey is only the first step in the iterative relationship. The survey will identify key species for testing, but will also identify other ecosystem services these species provide. During the interviews and during species collection, habitats and co-occurring species will be identified. These co-occurring species may have no medical significance, but may be essential to the sustainability of the ecosystem (e.g. pollinators) and may provide important ecosystem services to the local community, the interplay and value of which we aim to quantify in our model. Thus, through a series of surveys and field

collections, we will develop a better understanding of the current socio-economic values of these systems independent of the biomedical potential in question. Our model will include these values alongside projections of economic impacts of biomedical development for the UN.

The project will work with local stakeholders to develop outreach materials in the languages of the regions studied to communicate the benefits of biodiversity to local communities and governments, reaching a broader audience than the scientific community. The outreach will explain how species and biodiversity preservation is linked to a variety of ecosystem services, including human health and wellbeing. Thus, in addition to improved scientific understanding of medical potential of biota, the project will demonstrate the intrinsic values of diverse species for human health to local communities, raising awareness of the importance of preserving biodiversity. It is important that the biomedical benefits of species be contextualized within the current values of these communities towards these systems, as the biodiverse systems have current economic and social values through the ecosystem services they provide independent of drug development, including but not limited to food, water, shelter, flood mitigation, etc.

In the long term, the project aims to address biodiversity loss and to preserve species by showing their potential value and ecosystem services to a broader audience. The project aims to educate and communicate the responsible use of biodiversity for medicinal purposes. Preferably, we will provide outreach to additional communities living in biodiverse regions around the world to demonstrate that biodiversity and ecosystem services are directly linked to their health and well-being. Additionally, we propose to promote responsible development of natural resources so that local communities share in the health and economic benefits associated with sustainable utilization of local biota. This should be done by creating incentives for creating eco-friendly startups around sustainable development of natural resources. While these policies will differ depending on national laws, every effort should be made to make national policies in synergistic cohesive ways. Thus this project will provide the basis to promote the conservation of biodiversity and indigenous knowledge as means to enable continued discovery of natural compounds with medicinal properties.

Proposal 3: Support local and regional policy solutions that protect biodiversity for biomedical applications

The loss of biodiversity minimizes the potential for harvesting new medicines and for future medical discoveries. This is due to the interdependence of sustainability of the environment, human wellbeing, and the development of new public health practices. We aim to create practical

recommendations for the sustainable use of Earth's finite natural resources for healing purposes and request the support from policy makers. With the expanding loss of biodiversity, we must act now to avoid losing new solutions for human-focused problems. Connections of the biomedical researchers with organizations like IUCN, Convention on Biological Diversity (CBD), as well as local governments, should be fostered.

The primary impact or main change this project is expected to deliver is to develop a novel lens by which to promote the preservation of biodiversity. This project will develop a body of knowledge (biota-medicinal library) and use this knowledge to both benefit human health and raise awareness around a human-centric value of biodiversity. Thus, in the short and long term, this change will lead to preservation of biodiversity and improve health, wellbeing, and life expectancy for current and future generations. Education about the vital role of biodiversity protection for the survival of global population should be ubiquitously available starting from the primary school level. Preservation of the diverse systems in which medicinally important species live will also continue to provide diverse ecosystem services to the local communities.

A major challenge for creating mutual benefits from the ecosystem service of drug discovery is the equitable sharing of resources. To create equitable sharing of resources, data from this project will be used to develop policies that ensure equitable sharing with local communities. Brazil has created a legislative framework for biomedical discoveries that builds on the foundation of the Nagoya Protocol for the Preservation of Genetic Resources. The law, titled, Biodiversity Act, creates benefit sharing programs between communities that provide traditional knowledge and industries that bring compounds to market, and a sharing fund to manage any compensation that is received from market profits to be used to promote the sustainable use of biodiversity for biomedical applications.

In this aim, we propose to model the impact of these policies on local communities and work with policy makers in the global policy space, and to further reach out to the world at large, with a promise to create new policies that partner researchers and the local communities in a just way. This implies policy makers to cooperate with researchers, health professionals and elders of the traditional communities into legislature action, learning from successful policies to create more global policies for protecting biodiversity for biomedical discoveries that are socially just and create equitable sharing models with local communities.

Proposal 4: Examination of breakthrough technologies for their implementation within 2020–2030 UN policy: at the nexus of bioeconomy, biodiversity, biomedicine, biosecurity, and open data

OECD, in its Bioeconomy 2030 report (OECD, 2009), estimates that 35% of all chemicals, 80% of all pharmaceuticals and 50% of all agricultural output will come from biotech, contributing with almost 3% of OECD GDP. Synthetic biology is rapidly marching into our lives, with new organisms and new molecules becoming part of our ecosystems. While we don't see the consequences of the recent genome editing revolution in genetic engineering yet, the consequences for human population are hard to overestimate. Starting from ~2011 to 2016, there was a 1453% increase in the number of publication for only CRISPR-Cas subcategory within genome editing technologies. (Despite ever-tightening regulations on genetically modified materials, invasive species, biological security, and more recently emerged synthetic biology with its front-end, namely genome editing (including gene drives) is coming into practice with the immediate effects for Bioeconomy.) In brief and broadly speaking, gene-drive technology assumes production of the genetically modified species, engineered to change distribution and/or properties of the biological species to achieve some effects by human design. Therefore biotechnological innovations and their commercial implications won't wait long to change our world. Scientists of all times were warning against 'wishful thinking' applications of the latest scientific findings, including their dual use, and certainly, in biomedicine. However we may envision dramatic interventions in order to terminate the 'bad' species, and proliferate the 'good' ones, with unknown consequences for the larger ecosystems. Therefore apart from the direct implications for the biomedicine (for example making new vaccines for cancer, or gene-drive mosquitoes to fight diseases like malaria and dengue fever), synthetic biology is also likely to change the distribution of the species on a certain level, and these effects for the biodiversity are yet hard to measure.

Times are coming to also research the potential benefits of the predominantly negative side effects of humankind activity, including various types of biological waste production, synthetic chemicals, by-products of human developments, as well as species previously not considered significant for human health, which could be on the rise as a result of technological development. National and international policies should make haste not to lose the 'genie-off-the-bottle' momentum, at the same time, research of the technologies using waste, by-products, and leakages of the breakthrough new developments, such as nanoparticles, integrating into species of all kingdoms and variously modifying their biology. Here biosecurity becomes even more complicated for

both biodiversity and biomedicine, so urgent interdisciplinary academic advice including the voice of the genetic designers and futurologists here is unavoidable.

Due to the rapidly escalating nature of the aforementioned issues within national/cultural/lingual and disciplinary silos, society witnesses distrust within communities, law abuse, and technological insufficiency. Since information technologies allow widest range of public to participate in debating over these pressing issues, all of these stakeholders are striving for generating of a unified information hub containing live information about the biodiversity, chemical compounds, and the open research database with up-to-date scientific information. Although wide range of databases are now present to cover all sorts of subjects and purposes, a modern commonplace for data on living organisms and their chemical constituents is necessary, that would have robustness, transparency, and a high level of security to comply the rigorous conditions of the international law, and would progressively empower the common survival. We suggest that a transdisciplinary data portal should be assumed by the UN policy, where conservation, ecology, molecular biology, climate, geoscience, medical, and other data will be made available publicly through a database of species, compounds, extracts and other user defined effects entered across the wide range of users world-wide, including machine generated data from automated sensors and algorithm outputs. This database will act as an information hub to be used during ecological modelling analysis and for information that can be used for policy makers and integrated with local communities for input. The data generated from this project will be made publicly available complying with the according standards for the long-term storage and curation of the datasets.

We suggest that novel artificial intelligence powered by distributed computing is used for integrating big data from different disciplines, aiming to optimize conservation of planetary health spanning human health and the sustainable propagation of the wildlife species. We foresee that naturally occurring chemical or genomic ‘fingerprints’ omnipresent in biological material will help to bring justice to the bioeconomy profit distribution, as these would be invariably traceable to the geographic origin.

In conclusion we want to note that it is a vital challenge for the academics across borders and disciplines, ethicists, moral philosophers, etc., to collaborate with activists and artists, in order to create a broad and solid evidence-based imperative for putting every effort into urgent research and protection of the remaining neglected species, as it is absolutely vital for further survival of humankind.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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