# Ethical Issues in Emerging Technologies to Extend the Viability of Biological Materials Across Time and Space

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**Abstract:** This article presents a framework of ethical analysis for anticipatory evaluation of advanced biopreservation technologies and employs the framework illustratively in three domains. The framework features four clusters of general ethical considerations: (1) Producing Benefits, Minimizing Harms, Balancing Benefits, Risk, and Costs; (2) Justice, Fairness, Equity; (3) Respect for Autonomy; and (4) Transparency, Trustworthiness, and Public Trust.

### Introduction

This article examines several major ethical and societal issues in emerging, advanced technologies for biopreservation that can extend the viability of biological materials across time and space — for example, indefinitely preserving organs for transplantation. The terminology for these technologies is still unsettled, but we will usually refer to them as advanced technologies for biopreservation.<sup>1</sup> They are best viewed as *platform* technologies that enable prolonged biopreservation across several domains.<sup>2</sup> The website of the National Science Foundation (NSF) Engineering Research Center for Advanced Technologies for the Preservation of Biological Systems (ATP-Bio) highlights three large areas of anticipated societal benefits of these technologies: healthcare, the food supply and sustainability, and environmental conservation and biodiversity.<sup>3</sup> In exploring the ethical and societal implications of developing and deploying these platform technologies, we will focus for illustrative purposes on three specific domains within these areas: organ and tissue transplantation; food production, storage, and transportation; and biobanking and restoration in environmental conservation. Other papers in this symposium examine the ethical issues in these three domains in greater depth.4

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We begin by delineating a framework of ethical analysis that features four clusters of general ethical considerations: (1) Producing Benefits, Minimizing Harms, Balancing Benefits, Risks, and Costs; (2) Justice, Fairness, and Equity; (3) Respect for Autonomy/ Autonomous Choices and Actions; and (4) Transparency, Trustworthiness, and Public Trust. These broad, abstract, general ethical considerations, in various formulations, are embedded in many U.S. institutions, laws, regulations, policies, and practices; are evident in different areas of practical or applied ethics (including bioethics or biomedical ethics, food ethics, conservation ethics, and engineering ethics); and represent a rough convergence of several ethical theories on what is often called mid-level ethical principles.<sup>5</sup>

### I. General Ethical Considerations

#### A. Producing Benefits, Minimizing Harms, Balancing Benefits, Risks, and Costs

A key set of ethical considerations for evaluating and guiding new technologies, including advanced biopreservation, focuses on responsibilities for the short-term and long-term consequences of those technologies and of policies and practices to develop and implement them. It is ethically important to produce benefits, to minimize harms — here primarily but not exclusively understood as setbacks to individual and group interests — and to balance probable benefits against probable harms (risks), burdens, and costs. Consequence-based ethical deliberations are marked by varying degrees of uncertainty. This stems from

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We further note widespread appeals to similar ethical considerations in evaluating emerging technologies in different domains. For instance, the National Academy of Medicine's Committee on Emerging Science, Technology, and Innovation (CESTI) has employed similar ethical considerations, in somewhat different language and conceptual clusters, in constructing a framework specifically designed for the ethical evaluation of emerging technologies.<sup>6</sup> CESTI's ethical principles, which it views as shared values, are justice, autonomy, fairness, collective good, and individual good.<sup>7</sup> CESTI further specifies these principles in policy goals such as transparency and reasonable risk–benefit balance. epistemological difficulties of accurately predicting future consequences and difficulties assessing those consequences as good or bad or mixed because of disagreements about the relevant values or the indeterminateness of accepted values.

Attention to consequences is ethically indispensable, but this does not entail a form of consequentialism that views as ethically significant only the good or bad outcomes of actions and polices. Other ethical considerations such as justice and respect for autonomy are also indispensable and may constrain or override consequence-based considerations under certain circumstances.

Utilitarian ethical approaches (employing the principle of utility, i.e., maximization of good outcomes) are perhaps the best-known consequentialist theories.

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But other consequentialist and non-consequentialist approaches worry about utilitarians' tendency to evaluate consequences by summing up the positive and negative effects of actions and policies on individuals and their interests without adequate regard for more substantive common goods, including the value of nature. Whatever values are used, consequentialist principles require moral agents to seek to produce the best consequences overall, through balancing probable positive outcomes against probable negative outcomes of different actions and policies. This balancing may occur through informal or formal calculations of probable benefit-risk-cost ratios.

#### B. Justice, Fairness, Equity

It is important ethically not only to seek a net balance of positive over negative effects but also to seek a *just* distribution of benefits, risks, burdens, and costs. Justice, which may be defined as rendering to each person their "due" (often expressed as their "right"), includes both formal and material criteria.8 The formal criterion of justice requires similar treatment of similar cases and equal treatment of equals. Various material criteria of justice identify relevant similarities and dissimilarities among affected parties or stakeholders, and thus structure how particular benefits and burdens should be distributed. Debate often centers on the moral relevance and weights of different material criteria, such as need, merit, societal contribution, status, ownership, and ability to pay. While different theories of justice tend to stress different material criteria, some material criteria may be acceptable in some areas of life, such as employment, but not in others, such as the allocation of scarce life-saving organ transplants.9

The terms "fairness" and "equity" are sometimes used interchangeably with "justice," but they often highlight particular aspects of just actions and policies. "Fairness" often has a distinctive focus on procedures and processes, while "equity" frequently directs attention to background conditions, such as racist structures, that significantly determine outcomes, such as poor health, for individuals and groups. A recent National Academies report rightly calls for building equity considerations into the entire process of technological innovation rather than introducing them simply at the point of distribution of a new technology.<sup>10</sup>

# C. Respect for Autonomy/Autonomous Choices and Actions

The abstract formulation "respect for autonomy" can be restated as "respect for persons' autonomous choices and actions." "Respect" includes actions as well as attitudes. Some respectful actions are *nega*tive, such as refraining from interfering with others' autonomous choices and actions through controlling influences such as coercion and manipulation of information. This negative formulation of respect for autonomy can be specified in various concrete rights (and correlative duties) — for example, the right to liberty of action and the right to consent to or refuse medical treatments. The scope of liberty of action includes the practice of science as well as personal choices of lifestyles and behavioral patterns.

Respect for autonomy also has *positive* implications in certain contexts, such as research involving human participants and healthcare, where there are significant differences in power and knowledge. Often there are affirmative obligations to disclose information and to create the conditions for autonomous choices and actions, for instance, by seeking to ensure comprehension and understanding. Hence, respect for autonomy undergirds rules of informed consent and refusal in research, clinical care, and the like. Despite some misinterpretations, respect for autonomy properly recognizes the importance of relationships in autonomous choices and actions. What feminist thinkers and others have called "relational autonomy" captures the positive and negative impacts on personal autonomy of relationships of all kinds.11

Finally, not only does respect for autonomy apply to individual persons, but it also extends to communities — indeed, historically, "autonomy" was initially applied to political communities. Recognizing the rights and values of community participation at various levels is crucial in developing and deploying advanced biopreservation technologies, both for participatory justice and for public trust. The language of "autonomy of nature" also captures some environmentalists' and conservationists' suspicion of various interventions into nature.<sup>12</sup>

### D. Transparency, Trustworthiness, and Public Trust

Public trust is vital in developing and implementing new technologies such as advanced biopreservation. But trust is sometimes blind, malleable, and susceptible to manipulation. What is ethically important is not public trust itself but, rather, *warranted* public trust. Such trust rests on accurately perceived trustworthiness, which, in the case of advanced biopreservation, includes both scientific and engineering expertise as well as adherence to relevant ethical standards. Transparency is "a crucial precondition for engendering and sustaining public trust."<sup>13</sup> It incorporates ethical requirements of honesty and truthfulness and includes both general and specific disclosures of infor-

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The Journal of Law, Medicine & Ethics, 52 (2024): 570-584. © The Author(s), 2024. Published by Cambridge University Press on behalf of American Society of Law, Medicine & Ethics. mation about the novel technology and its probable benefits, risks, etc. Transparency by itself can rarely generate the understanding necessary for warranted public trust. Public education and engagement along with strong oversight are also indispensable in creating and sustaining warranted public trust.<sup>14</sup>

### E. Interpreting, Specifying, and Balancing Ethical Considerations

Throughout our analyses, we seek to interpret, specify, and, where necessary, balance the several general ethical considerations previously noted. It is not possible simply to apply these ethical considerations to different uses of advanced biopreservation technologies in different domains. Instead, an interactive, reflective process is required, involving movement back and forth between the general ethical considerations and the specifics of the concrete domains of biopreservation. This process includes specifying these broad ethical considerations for the concrete domains being explored. It also entails balancing these ethical considerations when conflicts among them cannot be resolved by more specific interpretations of these considerations.<sup>15</sup> Our discussion is designed to display the rich and complex ethical analyses required in the interactive, reflective process of bringing ethical considerations to bear on domains of advanced biopreservation. We intend our analyses to be exploratory, illuminative, and illustrative, rather than exhaustive.

#### **II. Organs and Tissues for Transplantation** *A. Introduction: Time as Enemy*

"Time is our enemy. The faster we can get [a heart] from the donor to the recipient, the better the heart is going to work." So spoke Dr. Joseph Rubelowsky, a surgeon for Transplant Advocates, who in May 2023 transported a human heart donated in Alaska to transplant surgeons at Massachusetts General Hospital in Boston, Massachusetts - a distance of 2,506 miles by air.<sup>16</sup> Currently organ transplantation is shaped throughout by the need to hold the "enemy" of time at bay. For example, organ allocation criteria stress geographical limits and boundaries because of time constraints - retrieved hearts and lungs must be transplanted within 4 to 6 hours, livers 12 to 15 hours, kidneys 36 to 48 hours.<sup>17</sup> Various strategies attempt to address these time constraints, not only by expediting the transportation and transplantation of organs, as in this case, but also by keeping organs as viable as possible for transplantation by using normothermic regional or machine perfusion, or by pausing biological time, as in new technologies

of advanced biopreservation. Here we examine only the ethical issues and challenges posed by innovative biopreservation technologies to maintain organ viability across time and space. We do not engage in a comparative analysis and assessment of the different strategies and tactics in organ transplantation's battle against time.<sup>18</sup>

If successful in pausing biological time, advanced biopreservation will benefit recipients of organ transplants in several ways: improving assessment of the quality and safety of organs for transplantation; better matching of donated organs with potential recipients; conditioning organs for transplantation; preparing and pre-conditioning transplant recipients; scheduling transplantation at the best time for recipients, rather than as an emergency procedure; and improving transplantation outcomes.<sup>19</sup> Advanced biopreservation should also increase the number of organ transplants by reducing non-use of donated organs; for instance, a donated organ could be saved for later use if no matched patient is immediately available to receive the transplant.

#### B. Research and Implementation Phases and Activities

It is useful to distinguish research and implementation phases in developing and deploying advanced technologies for biopreservation, though research can also occur in the context of implementation. The ethical issues in the activities in these phases substantially overlap, but each has distinctive features and emphases. Following laboratory and animal research on advanced biopreservation of organs, with the latter governed by the ethics and rules for animal research, clinical research will be necessary to determine the safety and efficacy of transplanted biopreserved organs compared with non-biopreserved organs. These clinical trials will be governed by the ethical requirements of research involving human participants with attention to transplant recipients' fair selection for, and voluntary, informed consent to participate in, studies that have a probable balance of benefit over risk and meet specific regulatory requirements.<sup>20</sup>

It will be necessary to determine which donated organs should be biopreserved in the research process rather than immediately transplanted. One possibility is to use in biopreservation research only organs that are otherwise unusable for transplantation at the time of retrieval because of problems with the organs themselves or because of the lack of a contemporaneous well-matched recipient. However, what is possible, as we will see in the next section, also depends on organ donors' (or their surrogates') authorization as well as

The Journal of Law, Medicine & Ethics, 52 (2024): 570-584. (© The Author(s), 2024. Published by Cambridge University Press on behalf of American Society of Law, Medicine & Ethics. on the prioritization structure established by the Uniform Anatomical Gift Act (UAGA).

#### C. Organ Donation/Authorization Process

According to the UAGA, versions of which have been adopted in 48 states and the District of Columbia, an individual while alive or the next-of-kin (hereafter referred to as "surrogate") after an individual's death (if the decedent did not indicate a decision) can decide whether to donate some or all organs for transplantation or therapy, for research, or for education.<sup>21</sup> They may also choose to prioritize these different purposes. If the donor or surrogate does not specify priorities, or indicates multiple unranked purposes, such as research and transplantation/therapy, the UAGA requires that the organs be used for transplantation/ therapy.<sup>22</sup>

Deceased organ donors are not research subjects/ participants under federal regulations, but their prior or their surrogate's current authorization for various uses of organs, including research, is crucial. Early on, organs will be needed for biopreservation studies; in later phases, they will be needed for biopreservation research followed by transplantation; and, after convincing evidence is produced on the safety and efficacy of biopreserved organs for transplantation, biopreserved organs will be needed for transplantation itself.

The language of the UAGA and state laws based on it is ambiguous about what is often called "organ donor intervention research," that is, experimental research interventions on donated organs, either in vivo or ex vivo, prior to their use in transplantation.23 This is research followed by transplantation, not merely research or transplantation. While important for developing advanced biopreservation in organ transplantation, research followed by transplantation does not clearly fit within the UAGA's categories. Revising the UAGA and securing states' adoption is a process that takes many years. Nor is information about the option of research followed by transplantation widely available in organ donor registries or in public education about organ donation. This lack of transparency and of adequate information may be particularly problematic for marginalized communities which are sometimes suspicious of research because of prior research abuses in those communities.24

If advanced biopreservation technologies succeed, it will become possible to store donated organs indefinitely for future transplantation. Prospective organ donors (or their surrogate decision-makers) will need to be informed about this possibility. It is not difficult to imagine some reluctance to authorize extended preservation and storage of certain organs, such as hearts, for future transplantation. Some organs tend to evoke strong emotional and symbolic responses, as is evident in Richard Selzer's short story about a woman who wants to visit the recipient of her late husband's transplanted heart so she can hear it beat again.<sup>25</sup> It will also be unsurprising if some decision-makers choose to designate their or their relatives' organs for immediate transplantation rather than for extended preservation followed by future transplantation. For example, in some interpretations of Jewish law and ethics, the immediate and direct benefit of saving a life through organ donation and transplantation is important in justifiably overriding the tradition's rules regarding rapid interment of the dead body.<sup>26</sup>

#### D. Equitable Access and Equitable Organ Allocation

What impact is advanced biopreservation likely to have on *equitable access* to transplantation services? According to current evidence, several social determinants of health, by themselves and in interaction with each other, contribute to major disparities in access to transplantation services. These include race, gender, insurance status, education, and geographic distance from a transplant center.<sup>27</sup> These and other factors contribute to disparities in timely diagnosis of chronic organ failure, referral for transplantation, and admission to transplant waiting lists.28 Advanced biopreservation will do little to remove these disparities and their underlying causes. However, by reducing constraints of time and geography, it could make more organs available to transplant centers that serve rural areas with widely dispersed populations. Even so, individuals' distances from transplant centers may still be a significant factor. If advanced biopreservation significantly increases the number of transplantable organs, this will expand transplantation opportunities and could further improve equitable access. However, if advanced biopreservation adds substantial costs to transplantation because of the necessity of new and expensive facilities and equipment, it could increase inequities in access.

Beyond access, how can justice, fairness, and equity be achieved in organ *allocation* in the implementation of advanced biopreservation? One critical question is whether and which organs should be allocated for preservation for later transplantation rather than used for immediate transplantation. As we have seen, donors' preferences and the prioritization schema established by the UAGA will be determinative in some situations. More generally, given the chronic shortage of organs for transplantation — a shortage that results in many patient deaths each year — it is difficult to justify removing organs from the immediate transplant pool for biopreservation and later use.<sup>29</sup>

Still, as we previously indicated, selecting donated organs for biopreservation that cannot be immediately transplanted because of their quality or the absence of a match is ethically justifiable. This would reduce non-use of donated organs, often referred to as organ wastage, without compromising equity.

Because the removal of time constraints reduces geographical constraints, the transplant community, broadly construed, will need to reconsider current geographical boundaries of allocation, including national boundaries. At the same time, it must consider any new geographical constraints created by advanced biopreservation requirements for a reliable cold chain, distributed cryostorage infrastructure, and the like.

These issues raise another important question of justice and fairness -who should be involved in setting organ allocation criteria? The 1986 report of the U.S. Task Force on Transplantation marked an important shift in perspective on the process of allocating transplantable organs.<sup>30</sup> It held that, apart from cases of directed donation to specific recipients, donated organs are scarce public resources that belong to the community and are to be used for the welfare of the community. Organ procurement and transplant teams receive these donated organs as trustees and stewards on behalf of the whole community, and policies of organ allocation should be designed accordingly. This view of community ownership of donated organs supports wide and diverse public participation in transparent processes for setting allocation criteria. Public input — which occurs, and should be further increased, in developing policies of allocation in the Organ Procurement and Transplantation Network (OPTN) – is important and even indispensable to ensure perceived and actual fairness.<sup>31</sup> Transparent, fair allocation criteria are crucial for the public's trust and its willingness to donate organs.32

Criteria of organ allocation usually include, among other factors, urgency of patient need, probability of a successful outcome, and time waiting for a transplant.<sup>33</sup> These can be expected to remain relevant and important and to require further specification and balancing with the advent of advanced biopreservation.

#### E. Commodification and Commercialization in Organ Transplantation

The possibility of extended preservation, long-term storage, and long-range transportation of organs raises concerns about advanced biopreservation's implications for organ trafficking. One fear is that it will stimulate, encourage, and facilitate illegal global markets for organs from both living and deceased individuals.34 The dangers of exploitation and coercion of potential "sources" of organs, who are often not "donors" strictly speaking, are likely to be exacerbated when advanced biopreservation removes constraints of time and geography from the transplantation process. Prolonging the time from organ donation to transplantation increases the likelihood of organ commodification and diminishes the sense that another human being donated the organ. As a result, the current safeguards that ensure donor recognition will likely be compromised with organ biobanking.35 However, rather than supposing that the risks of increased organ trafficking will inevitably outweigh the probable benefits of advanced biopreservation in organ transplantation, we need to develop better and stronger ways to combat global organ trafficking.

The long-simmering debate about whether to financially compensate providers of transplantable organs will likely heat up if advanced biopreservation is successful in organ transplantation. The National Organ Transplant Act (NOTA) prohibits knowingly acquiring, receiving, or transferring "any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce."36 This ban reflects several ethical and social concerns including possible damage to the powerful culture of organ donation — providing the "gift of life" — by crowding out important altruistic motivations.37 As advanced biopreservation makes transplantable organs seem more like commodities and commercial objects, we can expect greater pressures, including moral pressures, to compensate organ donors.

Two major ethical arguments for compensating providers of organs for transplantation are utilitarian and libertarian; the former appeals to utility (making more organs available for transplantation), while the latter appeals to liberty (respecting individuals' autonomous decisions whether to provide organs for compensation or other reasons). A third ethical argument contends that it is unjust and unfair to prohibit compensation to providers of organs, who, after all, are the only parties in the process of transplantation ineligible to receive financial benefits.<sup>38</sup> So far, all three arguments have been effectively countered for purposes of public policy, but all three - perhaps especially the justice/fairness argument — are likely to become more powerful rhetorically if advanced biopreservation of transplantable organs becomes prevalent.

#### F. Human Tissue in Transplantation

In some ways, tissue transplantation is a harbinger of what may happen in organ transplantation if advanced biopreservation technologies can successfully prolong

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organ viability for extended periods. Currently many tissues used in transplantation are already successfully preserved for prolonged periods. The following comparison is perceptive:

Unlike organs, which are transported quickly and changed little from donor to recipient, human tissues are often highly processed, radically transformed in appearance, and packed and stored in tissue banks, often for years. Thus, the commodification of tissues is more palpable — and the role of commerce more difficult to deny. On its way from donor to recipient, tissue often passes through several organizations, what law professor Julia Mahoney has termed a "chain of distribution" in which "money changes hands at numerous points" and value is added along the way.<sup>39</sup>

In 2022 in the USA, there were almost 43,000 organ transplants, but each year there are about 2.5 million tissue grafts, mainly of skin, bones, tendons, ligaments, heart valves, blood vessels, and corneas.<sup>40</sup> In considering tissue transplantation, it may be useful to focus on skin allografts, which provide temporary coverage for severe burns, thereby saving lives, in contrast to many tissue transplants that mainly improve bodily function and quality of life. Skin, the human body's "largest organ,"<sup>41</sup> can be cryopreserved with current methods for up to several years and successfully used for allografts.<sup>42</sup>

On the one hand, the use of advanced biopreservation technologies may not be so crucial for skin because it can already be biobanked for years. Emerging advanced biopreservation might enable a larger and longerlasting stockpile of preserved skin in preparation for possible mass casualties following, for example, an accidental or intentional nuclear event.<sup>43</sup> However, an adequate assessment of this possible use would require careful comparative benefit-risk-cost analyses of current and emerging technologies for preserving skin.

On the other hand, if emerging advanced biopreservation technologies are applied to tissue, including skin, their impact is likely to be incremental rather than transformative. Much human tissue, in contrast to solid organs, can already be preserved and stored for years before use. Hence, new advanced biopreservation technologies would probably not seriously disrupt policies and practices in tissue transplantation as much as in organ transplantation.

A final important issue is biovigilance. In tissue transplantation, the extended time between tissue acquisition (donation) and usage (transplantation) has already generated complexities in system biovigilance. Recent efforts to trace the tissue products from a donor bone matrix that transmitted tuberculosis to a plethora of recipients highlight the need for more vigorous and extensive biovigilance with products derived from people now as well as in the future with advanced biopreservation.<sup>44</sup>

#### **III. Food Production, Storage, Transportation** *A. Introduction*

Another important domain of application of advanced biopreservation is the production, storage, and transportation of food. The agricultural (and aquacultural) ethics of any innovative technology - advanced biopreservation included - range from obvious, but possibly defeasible, ethical judgments to claims whose ethical validity will itself be challenged. At the obvious end of this spectrum, there is no debate over the ethical importance of having enough to eat. It is not surprising, then, that human rights documents often recognize a universal right to food, as in the United Nations Universal Declaration of Human Rights and Sustainable Development Goals (SDG).<sup>45</sup> Recognition of a positive human right to food, as part of an adequate standard of living, establishes what is due to individuals and groups as a matter of justice, not mere societal benevolence or generosity. Nevertheless, there are vigorous scientific and ethical disputes about the means to implement this human right and to increase the global food supply. Evaluating these various means will require a comparison of probable benefits, risks, and costs. In addition, there are competing needs, for example, for shelter and health care, among the goods crucial for human welfare. Further questions of distributive justice also arise, for instance, in the distribution of the costs and burdens of implementing any technology to increase the food supply.

However implemented, food security for consumers presupposes farm-level production; thus commitment to future generations' ability to meet food needs is the ethical rationale behind modernization of agricultural methods. Equally obvious, it is ethically problematic indeed, prima facie unfair and unjust — to disproportionately place the burden of implementing technological innovations on the backs of smallholders who are already among the least advantaged. Even for issues where the ethical implications are uncontested, the empirical connection between any technology and its good or bad consequences becomes fraught. As one moves to ethical claims about environmental or socioeconomic impact, both the causality and the ethical significance will begin to seem obscure to those who pay little attention to farming - and that is most of us.

## B. Uses and Probable Benefits of Advanced Biopreservation in Food Production

Emerging advanced biopreservation technologies will be applied to cellular tissues of importance for agriculture. These include gametes and zygotes of food animals, as well as seeds and clonally propagated plants. On the one hand, these applications are expected to improve the efficiency of cold storage methods that have been in use since the 1960s in the case of animals, and for well over a century in the case of plants. Repositories for these tissues preserve the genetic diversity existing within crop varieties, landraces, and wild relatives, primarily for breeding and research. When compared to in situ preservation of whole organisms, biopreservation of genetic resources has the potential to reduce energy cost. When compared to current methods of cold preservation, advanced biopreservation tools could maintain viability for longer periods of time.46

More significantly from an ethics perspective, existing cold storage of gametes or embryos is relatively ineffective for some types of food animals. Important fish species are a case in point. While in many agricultural domains, the effects of advances in biopreservation are best described as incremental improvements in well-established applications, the impact in aquaculture could transform the industry. Enabling the use of artificial insemination and embryo transfer would streamline the process of genetic improvement. Similar effects could occur when isochoric cooling reduces energy costs for post-harvest transport and storage of perishable food items.<sup>47</sup> Again, the most dramatic effects may occur for fruits and vegetables that deteriorate when frozen by existing methods.

These impacts are ethically significant in virtue of food's importance for the health and survival of human beings. The Food and Agriculture Organization (FAO) and the Intergovernmental Panel on Climate Change (IPCC) are both predicting global shortages of food by 2050.48 Causes include continued human population growth, loss of arable lands due to flooding, and crop failures from storms, droughts, and other climaterelated events. In addition, increased consumption of animal products correlates strongly with increasing wealth, especially among the poorest group.<sup>49</sup> This creates a multiplier effect in food demand, as animals consume between two and six units of edible plant protein for every unit of meat, milk or eggs consumed by the human population.<sup>50</sup> Thus, if the commitment to a universal right to food is taken seriously, there is a compelling moral rationale for supporting technological innovations that will maintain and even increase global food production.<sup>51</sup>

# C. Potential Ethical Pitfalls

However, a number of countervailing points must also be taken into consideration. Although the benefits of innovations in food storage are significant, the case for the urgency of their implementation is weaker than that for organ storage for three reasons. First, advanced biopreservation will be one of many food storage technologies, each with advantages in cost, convenience, and safety. In some instances, drying, canning, and pickling will continue to be attractive alternatives. Second, the costs and energy requirements of any cold chain limit its relevance to the ethical challenges of food security in the least industrialized regions. Finally, whereas in the case of organs there is no substitute possible for the organ needed for transplantation (ongoing work on xenotransplantation aside), in the advanced economies where advanced biopreservation is most feasible there are alternatives to foods that respond poorly to existing flash freezing and other forms of cold storage. One can simply eat something else. While the ethical benefits of advanced biopreservation in food and agriculture should not be ignored, these factors militate in favor of tempering the expectation of revolutionary impact comparable to the hopes for medical applications.

The balance of this section provides a brief inventory of potential ethical pitfalls. Whether any given application of advanced biopreservation falls into them is a question for further research, analysis, and assessment. Most significantly, global agriculture has long delivered a supply of food capable of feeding the entire human population, yet hunger persists and, relative to 2015 when the Sustainable Development Goals were introduced, has risen sharply in part because of the COVID-19 pandemic.52 It is unclear whether increasing farm-level output is an effective strategy for securing the basic right to food. In fact, technologically based increases in the productivity of crop and animal production often displace small farmers, especially in less industrialized regions. Complex interactions of market forces, policy, and the biophysical impact of tools and techniques are generally at fault. Most basically, the greatest benefits of improved productivity go to early adopters of the technology. These are generally comparatively better-off farmers. As prices adjust to reflect a cost structure in which the new tools are widely used, late adopters may experience costs that exceed the benefits of improved technology.53 Farm economist Willard Cochrane called this "the technology treadmill," arguing that it fuels an inexorable trend toward fewer and larger farms, as early adopters use windfall profits to buy lands vacated by failing late adopters.54

The economics of the technology treadmill can be exacerbated when technological innovations have a scale bias (for example, when they cannot be operated efficiently on smaller acreage) or require an infrastructure such as paved roads, an energy grid, or a farm-supply sector that may not be available to all producers. Those forced to exit food production may lack non-farm skills, becoming unemployable in other sectors of a developing economy. In this way, innovations can shunt people into extreme poverty, even as they reduce food prices and benefit those who are only marginally better off.55 Further impact occurs when productivity gains are bid into land values, in some cases stimulating "land grabs" that exploit farming households with legally or politically weak forms of title or land tenure.56 Each of these events is ethically significant both in terms of a direct impact on the welfare of affected parties, as well as because these impacts are disproportionately felt among people who are already among the poorest segment of the global population. Economic impact on smallholders may be greater or less depending on the policy environment (including finance and property law) and politics, as well as whether innovations have scaling costs that make them proportionally less expensive for the larger operators to utilize. Such contingencies create an opening for case-by-case debates over the socioeconomic impact of any particular innovation. Finally, seed repositories and collections of genetic resources stimulate ethical debates over ownership, control, and access to these potentially valuable agricultural resources.57

Beyond these impacts on human welfare and justice, ethical arguments also emerge in connection with the environmental impact of advanced technology and structural significance of the "fewer and larger" influence of the treadmill. Again, environmental consequences result from a nexus of causes. Although advanced biopreservation may not seem likely to have the toxicity of pesticides, synthetic fertilizers, and other agricultural chemicals, it is still necessary to consider its potential for soil or water degradation and impact on biodiversity. As noted above, foodrelated applications of biopreservation are part of the larger project to increase productivity. Increasing productivity is, in turn, intended to increase the intensity of land use.58 But sustainable intensification presupposes careful monitoring of impact on renewable resources.<sup>59</sup> Improper use of any farm or food system technology may be accidental or intentional, but can affect the use of more dangerous techniques, including pesticides and adulterants.<sup>60</sup> Agriculture itself is environmentally controversial in areas where there is

a strong constituency for preservation of unmanaged ecosystems. Even more generally, environmental ethicists have largely neglected discussions of agricultural ethics, treating agriculture on a par with industrial manufacturing and other polluting activities. As such, the philosophical discourse on sustainable agriculture is comparatively undeveloped.<sup>61</sup>

The ethics of farm structure may be even more underappreciated among most contemporary observers, despite having a much longer philosophical history than that of environmental ethics. Hesiod, Aristotle, Virgil, and many Stoics argued that the cultural tenor and character of a society depends upon its farming people. Hegel's philosophy of history associates the rise of civil society with unique features of the topography and farming methods of the Peloponnesian peninsula.<sup>62</sup> While such claims generate little sympathy among many leading contemporary ethicists, they arguably provide a promising entrée to environmental stewardship for many non-Western cultures.63 The rise of "food sovereignty" ties solidarity with a local farming population to the political claim that simply having enough to eat is not enough: ethics requires community control over its own food system.<sup>64</sup> Many ordinary Americans appear to cheer for (and patronize) small farmers with an enthusiasm that is seldom lavished on small business entrepreneurs in other sectors of the economy.65 As such, ethical claims about the farm structure's relevance to moral character and national identity should remain on the table for deliberations about the impact of advanced biopreservation, even if their significance is difficult to cash out in the terms favored by 21st century bioethics.66

# IV. Conservation: Restoration and Biobanking

#### A. Introduction

We now turn to the implications of advanced biopreservation for conservation, with particular attention to restoration and biodiversity banking, in light of the general ethical considerations identified earlier. The loss of biodiversity constitutes a moral harm not only because human well-being depends on a stable and productive natural world and because of the value of humans' relationships to nature, but also because nonhuman life is considered valuable in itself.67 Conservationists view biodiversity loss as an emergent crisis that may require new technological solutions. Advanced biopreservation technologies can support conservation through storing and transporting biological materials for research, population management programs, ecosystem restoration, and the reintroduction or translocation of populations and

species. Ethical questions about balancing benefits and costs and managing risks arise in both direct and indirect forms. Questions about how to measure and evaluate direct costs arise because of the investment required to build and maintain infrastructure, given limited financial support for conservation initiatives. The consideration of indirect benefits, costs, and risks arises because biopreservation supports conservation interventions that are themselves novel and, in many cases, controversial.

As in organ transplantation and food production, ethical attention in conservation centers on producing benefits and minimizing harms, but here the focus is primarily on natural entities and processes. While some conservation projects seek to maintain ecosystem services to meet human needs (such as flood control, erosion protection, or sources of wild-caught food), a greater ethical emphasis is placed on the intrinsic value of natural species and ecosystems. In the policy context, priority is often given to conservation objectives for which the preservation of natural value for its own sake coincides with anthropocentric goals, such as ecotourism. Issues of justice emerge throughout decision-making around collecting and preserving specimens and the siting of conservation projects. As we will see, advanced biopreservation technologies extend and intensify these issues.

#### B. Functions of Advanced Biopreservation for Conservation

Advanced biopreservation technologies serve two primary functions for conservation: facilitating ecological restoration or management, and long-term biobanking. They facilitate restoration in that they allow biological materials from animals and plants to be collected, transported at extremely low temperatures, and returned to normal biological function for use in research and captive breeding programs or for release into the wild.<sup>68</sup> While preservation is already possible with some gametes and embryos, advancements in biopreservation technologies will expand the types of biological materials that can be stored and moved for the sake of research, broodstock management, reintroduction, and translocation. These capabilities could transform coral reef management, for example, by addressing a restoration problem particular to corals: they would allow reproductive propagation of coral in facilities that operate year-round rather than being closely tied to the brief annual natural window of coral reproduction.<sup>69</sup> These technologies will simplify the storage and transport of genetic resources for aquatic species,<sup>70</sup> and they could support a variety of novel conservation efforts, including assisted migration (or assisted gene flow as has been demonstrated in  $coral^{71}$ ) and de-extinction.<sup>72</sup>

The second use of advanced biopreservation technologies is for long-term storage of biomaterials in biobanks. Advances in biopreservation could allow storage of biological materials that cannot currently be cooled and rewarmed without damage and could extend the cold storage period indefinitely. Biodiversity banks serve a variety of purposes; these include facilitating research on model organisms, storing gametes and embryos for use in breeding programs, and serving as long-term repositories of biodiversity for future uses that are as yet unforeseen.73 For example, in 2023 the US Fish and Wildlife Service initiated a biobanking program that collects skin cell samples from endangered species for long-term storage.74 For mammal species, this is less difficult and invasive than collecting gametes. These samples can be turned into living cell lines, which makes it possible to conduct genomic studies without sacrificing individuals from small populations and, through cloning, these cells are potential sources of genetic diversity in future breeding programs.

#### C. Assessment of Possible Consequences

The potential direct harms and costs of advanced biopreservation include environmental pollution from nanoparticles used in certain rapid rewarming processes and the energy costs of indefinite longterm storage. There are also failure risks to consider: in the case of a disruption to the energy and liquid nitrogen supplies needed to maintain extremely low temperatures, valuable conservation investments could be lost. Although there is uncertainty in predicting the likelihood of these possible harms, practical steps can be taken to minimize risks in the design of biopreservation systems — for example, by planning for redundant power supplies, substantial on-site liquid nitrogen reserves, and duplicate, geographically dispersed storage facilities.

Positively, advanced biopreservation technologies will play an essential role in technologically mediated restoration activities that involve assisted reproductive technologies, such as in vitro fertilization and cloning, and in certain programs for translocation, assisted migration, or assisted gene flow. Such technologies expand the kinds of biological materials that can be stored and extend the duration of storage time. They also simplify the logistics of transport. They are therefore critical tools for scaling up novel conservation activities such as translocation, assisted gene flow, assisted reproduction, hybridization, and de-extinction. These techniques, while promising to address

The Journal of Law, Medicine & Ethics, 52 (2024): 570-584. © The Author(s), 2024. Published by Cambridge University Press on behalf of American Society of Law, Medicine & Ethics. biodiversity decline, intervene in nature in ways that are the subject of ethical debate among environmental philosophers, conservation scientists, and practitioners because they risk unintended consequences that could further disturb ecosystem stability and may be interpreted as undermining the autonomy of nature.<sup>75</sup>

While it is clear that biodiversity loss is accelerating, and that conservation actions are effective overall, there are considerable unknowns about how to restore declining populations, species, and ecosystems most effectively. Because biopreservation is key to assisted reproduction and captive breeding programs, it provides support to restoration strategies that target the most threatened organisms, and it is essential to genetic rescues — initiatives that manage gene flow to overcome genetic bottlenecks in small populations mediate step to repopulation, transport genetic material and enable sexual reproduction across great distances, and settle preserved larvae and deploy juvenile corals to the reef out of the cycle of the usual breeding season.<sup>78</sup> The menu of management options provided by advanced biopreservation technologies thus has the potential to create more resilient reefs.

Expanding the scale of marine and terrestrial restoration projects may increase risks that accompany ecological restoration, such as the unintentional introduction of organisms to areas where they could outcompete other desired species and populations. So far, these risks have rarely materialized,<sup>79</sup> but the urgency felt by the conservation community could create pressure to override cautious study and testing. A final concern about scaling up restoration is that it could

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and, in the extreme case, overcome extinction.<sup>76</sup> Such high-tech programs are sometimes criticized as inefficient or boutique: they require large amounts of resources in order to take a gamble on saving struggling populations. Given the limited funding for conservation, some conservationists see genetic rescues as diverting resources from traditional strategies that aim to protect ecosystems from human development and disturbance, a significant cause of biodiversity loss. However, advancements in biopreservation could facilitate standardizing and scaling up genetic rescue techniques so that they become less resource intensive, and their development so far has drawn from funding streams different from those directed to land purchases.

Advanced biopreservation could transform coral reef restoration, in particular. Currently, coral restoration projects are small and inefficient — typically under an acre in size — and limited in scalability. A much larger acreage is needed to make a dent in restoring lost reef function,<sup>77</sup> but carefully managed and enhanced genetic diversity in a diminished population can help. Advanced biopreservation could facilitate and complement large-scale coral restoration by making it simpler to transport viable adult coral polyps, manage and enhance captive broodstock as an inter-

camouflage the need to address the underlying causes of biodiversity loss. This would be self-defeating because no amount of restoration activity will succeed without slowing the pace of climate change and environmental degradation.

Preservation of healthy ecosystems and restoration of degraded ecosystems are the ultimate goals of all conservation activities.<sup>80</sup> Biobanks play a role in this endeavor. Repositories of diverse non-human biological materials are growing rapidly in number, size, and importance, and advanced biopreservation technologies expand options as to which materials are banked, how much, where, and for how long. Biobanked materials can be used in the near term as a source from which to derive cell lines that can be used in research, as well as a source for breeding programs leading to restoration. In the longer term, many conservationists are concerned that we will see a severe bottleneck for biodiversity in the next century due to climate change, and biobanking is seen as a source of genetic diversity from which withdrawals can be made once the planet's climate and ocean systems stabilize.<sup>81</sup> Complicated questions that require weighing economic, ecological, ethical, and cultural values come into decisions about the scale, scope, organization, and prioritization of biobank resources, including which species to sample.82

#### D. Incorporating Justice, Fairness, and Equity into Biobanking and Restoration

Both biobanking and restoration activities have the potential either to exacerbate or to remedy injustice because decisions about how to manage land, plants, and animals inevitably intersect with territorial claims and land and property rights. Conservation has a complicated history that is intertwined with colonialism and the dispossession of Indigenous peoples.<sup>83</sup> Some noteworthy species extinctions and introductions of invasive species resulted from colonialism, and some collections of biomaterials in zoos, botanical gardens, and museums were obtained without permission. Conservationists should make every effort to include local and Indigenous populations in decision-making about which specimens to collect and in defining appropriate and respectful procedures for storing biomaterials.

Even more can and should be done to build future conservation activities on a democratic and just foundation. Justice requires anticipating and seeking to share benefits, risks, burdens, and costs in a fair manner. Ideally, the benefits of conservation will include healthier local ecosystems and the preservation of cultural goods grounded in nature, but since some conservation activities can threaten communities' access to resources with economic value, inclusive and accessible decision-making should be prioritized. Conservation activities should be planned to support local communities through educational and employment opportunities. Since the goal of biobanking is to store materials for both short-term and longterm use, environmental justice demands transparent, fair, and inclusive procedures for setting rules to govern future decisions about who can make withdrawals from repositories and within what limits, as well as how long materials will be stored. Advanced biopreservation technologies have the potential to change how research and conservation are accomplished; we are currently in an important period of norm-setting for conservation practice.

#### V. Conclusion

The platform technology of advanced biopreservation can extend the viability of human and non-human biological materials across time and space in ways that can help achieve valuable goals related to health and healthcare, food, and the environment. Ethical deliberations about various uses of this technology — whether undertaken by scientists, engineers, public advisory bodies, policy makers, companies, or others — can best proceed by attending to the specifics of different practical domains in light of general, widely accepted ethical considerations. At the outset, this article delineated a framework for ethical analysis that featured several ethical considerations for anticipatory assessments of emerging technologies, and then for illustrative purposes brought these to bear on potential applications of advanced biopreservation in three domains. Although the aim is to employ these broad ethical considerations holistically, they inevitably require interpretation, specification, and balancing to adequately address concrete issues, especially when their directives appear to conflict.

It is unreasonable to expect to develop a single, sufficient set of concrete ethical judgments about the acceptability or priority of advanced biopreservation. Instead, deliberative processes and judgments must be context-dependent and responsive to how possible uses of these technologies raise distinctive as well as cross-cutting ethical issues.

Many of the ethical issues raised by advanced biopreservation are neither novel nor unique. Instead, they intensify the ethical issues already posed by other approaches (both technological and non-technological) that such biopreservation may supplement or even supplant. These preexisting issues include, for example, the "technology treadmill" that threatens small farms; economic and cultural risks of conservation projects to certain communities; and organ commodification and organ trafficking.

An adequate anticipatory evaluation of possible uses of advanced biopreservation will depend on careful analyses of their probable benefits, risks, and costs. However, the ethical benefit-risk-cost analysis of advanced biopreservation in each domain must be compared to the benefit-risk-cost analyses of other current and emergent approaches that attempt to address the same problems. Hence, we need *comparative* evaluations of the range of different methods for storing and transporting organs and tissues; for producing, storing, and transporting food; or for conservation biobanking and restoration.

A more favorable benefit-risk-cost calculus may emerge if there are reasonable and effective ways to mitigate the risks of harms from advanced biopreservation — for instance, mitigating the increased risk of organ trafficking resulting from increased organ commodification under advanced biopreservation. Similarly, reductions in the costs of the infrastructure for advanced biopreservation, including essential equipment and facilities, could make the benefit-risk-cost ratio more favorable for this new technology.

Questions of just, fair, and equitable distribution of the benefits, risks, and costs of advanced biopreservation require close attention. Who will gain the benefits and who will bear the risks and costs of

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different applications? What do justice, fairness, and equity require, for instance, in allocating organs for immediate transplantation versus biopreservation for later transplantation? And what do those principles require in mitigating, as noted above, the disproportionate burdens technological innovations place "on the backs of smallholders who are already among the least advantaged"? Issues of justice and fairness also permeate decisions about withdrawals from biobanks — that is, what can be withdrawn, by whom, and for what purposes?

Likewise, issues of respect for personal autonomous choices loom large in some situations, such as donating organs and tissues to be biopreserved for research and transplantation. In other areas, respect for the self-determination of particular communities may be important, as in collecting and handling specimens for biobanking from Indigenous communities. Throughout, transparency and full disclosure of information about advanced biopreservation and its benefits, risks, and costs are essential. Broad democratic participation in assessments of emerging technologies depends on transparent and truthful disclosures from scientific experts, accompanied by respectful engagement with affected communities. Finally, warranted public trust, so crucial for the successful deployment of advanced biopreservation, depends on transparent policies and on robust public engagement.

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#### EMERGING TECHNOLOGIES TO STOP BIOLOGICAL TIME • FALL 2024

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