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Biobanking and public health: is a human rights approach the tie that binds?

Eric M. Meslin · Ibrahim Garba

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Abstract Ethical principles guiding public health and genomic medicine are often at odds: whereas public health practice adopts collectivist principles that emphasize population-based benefits, recent advances in genomic and personalized medicine are grounded in an individualist ethic that privileges informed consent, and the balancing of individual risk and benefit. Indeed, the attraction of personalized medicine is the promise it holds out to help individuals get the "right medicine for the right problem at the right time." Research biobanks are an effective tool in the genomic medicine toolbox. Biobanking in public health presents a unique case study to unpack some of these issues in more detail. For example, there is a long history of using banked tissue obtained under clinical diagnostic conditions for later public health uses. But despite the collectivist approach of public health, the principles applied to the ethical challenges of biobanking (e.g. informed consent, autonomy, privacy) remain individualist. We demonstrate the value of using human rights as a public health ethics framework to address this tension in biobanking by applying it to two illustrative cases.

Introduction

At first blush, the ethical foundations guiding public health and genomic medicine are at odds: whereas public health practice adopts collectivist principles that emphasize utilitarian and population-based benefits, genomic (and especially personalized) medicine is squarely grounded in an individualist ethic that emphasizes autonomous decision-making for personal benefits. One definition of public health illustrates its breadth and focus:

> the promotion of health and the prevention of disease and disability; the collection and use of epidemiological data, population surveillance, and other forms of empirical quantitative assessment; a recognition of the multidimensional nature of the determinants of health; and a focus on the complex interactions of many factors – biological, behavioral, social, and environmental – in developing effective interventions (Childress et al. 2002).

Lawrence O. Gostin (2001) further highlights the critical role of collective entities like communities and governments in ensuring the public's health because although individuals, given the means, can do many things to protect their own health, there are health benefits such as a healthy environment, safe roads, potable water and clean air that require "organized and sustained community activities". In short, public health programs deliver to populations health benefits that cannot be effectively secured on an individual or small group basis (Childress et al. 2002).

In contrast, genomic medicine—sometimes conflated with personalized medicine—has been described as an endeavor that "will provide a link between an individual's molecular and clinical profiles, allowing physicians to make the right patient-care decisions and allowing patients the opportunity to make informed and directed lifestyle decisions for their future well-being" (Ginsburg and McCarthy 2001). It envisions medical care in which "drugs and drug doses are made safer and more effective because they are chosen according to an individual's genetic makeup" (Lesko 2007). Others, such as the Ickworth Group (Burke et al. 2010), characterize personalized

E. M. Meslin (✉) · I. Garba
Indiana University Center for Bioethics, 410 W 10th Street, Suite 3100, Indianapolis, IN 46202, USA
e-mail: emeslin@iupui.edu

medicine as any medical "care that is tailored to the individual or stratified by the population subgroup". Common to all of these definitions is the emphasis on customizing therapy to the individual patient. Indeed, for as long as clinicians have been caring for patients, medicine has been personalized (Ramsey 1961), but it is the accelerant of genetic technology that has led some to think that today's medicine has the potential to be even more "personalized" than its historical predecessors.

Of course, with the benefit of further reflection, the contrast between personalized medicine and public health is not so stark. For instance, the collectivist approach of public health does not preclude a role for clinical interventions and choices at the individual level. Moreover, the claim that the treatment of a sick individual improves the health of the population of which she is a member is all but tautologous. Vaccination is an example that fits both conditions. Seen this way, personalized medicine and public health are not mutually exclusive, but rather incompletely overlapping. The goals of public health practice certainly include the impact on the health of individuals, and included in the potential value of a genomic approach to medical care is its generalizability to the public's health, for example through better screening and prevention programs (Burke et al. 2010). Recognition of this potential for demonstrating the relationship between public health and genomics is evident in a new area of study complete with its own journal, *Public Health Genomics* that hopes to address some of these very issues. It has been noted, for instance, that

> a better understanding of what lies between the genes that make up the genome, the role of the environment on gene expression and the role of the interaction between genes will help us to know why some individuals remain healthy while others are more susceptible to genetic diseases. This understanding will also benefit the public health sector where the prevention and expression of communicable and infectious diseases, for example, is related in part to understanding genetic susceptibility… (Knoppers et al. 2010).

The Ickworth Group recently examined the potential for genomics and personalized medicine to inform public health practice and concluded that much still needs to be done before the promise can be realized (Burke et al. 2010). In particular, they made six recommendations:

1. Efforts to integrate genomics into public health and practice should continue.
2. An appropriate research infrastructure for generating an evidence base for genomic medicine needs to be established and maintained.
3. Model public health genomics programs and clinical services need to be developed, implemented and evaluated.
4. International collaborations should be promoted.
5. Appropriate genetic services and genome-based research should be fostered within low and middle income countries.
6. Programs, research and strategies in public health genomics should be informed by accepted ethical principles and practices.

Such qualified support for the potential for genomic impact on public health is not surprising, as others have commented on the status of promises made and kept (Evans et al. 2011; Hall et al. 2010).

Biobanking in public health

Biobanking is a useful case study to unpack issues at the intersection of genomics and public health. The storied history of the many uses of biological materials that help to improve the understanding, clinical diagnosis and treatment of human disease is long and impressive with detailed reports of the clinical value of banked specimens dating to the early eighteenth century (Ackerknecht 1967; Korn 2000). Without access to stored specimens of blood, urine, tumors, body tissues, DNA and other human biological materials, important advances in cancer, infectious disease, cardiovascular care and mental disorders would not have been possible (Nat'l Bioethics Adv. Comm. 2000). For example, the Pap smear would not have been developed (Younge et al. 1949) and the nonsteroidal estrogen hormone, diethylstilbestrol (DES), would not have been found to be carcinogenic (Herbst 1981). Without the knowledge gained from autopsies of Korean War veterans, science would have known less about the age of onset for atherosclerosis (Enos et al. 1955). Moreover, the CDC would not have been able to isolate and understand the Hantavirus (Wrobel 1995) and researchers would not have been able to make progress on certain brain tumors (Will et al. 1996). No doubt researchers hoping to understand the impact of radiation leaks on residents near the Fukushima nuclear plant in Japan will make use of the Chernobyl Tissue Bank established in 1998 to study the effects from (until this point) the world's foremost nuclear plant disaster (http://www.chernobyltissuebank.com).

The completion of the human genome sequence (and other genomes) greatly expanded the capacity of science to use and obtain greater value from both previously collected biological specimens and those still to be collected (Meslin and Quaid 2004). For example, the international community, led by Canadian researchers, was able to rapidly

sequence the SARS virus from obtained specimens (Marra et al. 2003). Others used similar technology for the H1N1 virus (Graham et al. 2011; Zhang and Chen 2009), dramatically shortening the time it took to understand the nature of the threat and prepare a public health response. Moreover, the prospect of using genome technology on already stored specimens for enhanced genetic diagnostics, drug development, and even domestic and international security threat analysis (Meslin 2003; Bugl et al. 2007; Atlas 2002) offers a glimpse into the future of a genetically-informed public health capacity for nation-states. Indeed, it is the fortuitous combination of genomics and pharmacology that gives rise to the most promising example of personalized medicine—the field of pharmacogenomics (Evans 2006; Evans et al. 2004; Desta and Flockhart 2007).

Just as the past benefits to human health from using banked human biological materials stand on their own merit, any future benefits will need to be assessed over time. For us, the important challenge is whether the ethical and legal basis for using banked materials is sufficient to support its expanded use in more areas of public health practice and research. In other words, while we acknowledge that the boundary between the two domains is by no means a stark one; the failure to appreciate what makes them different may prevent productive engagement between these two domains of health care to serve the health interests of society.

Challenges for public health and genomics

Several explanations have been offered for why public health approaches to health and disease differ from clinical medical approaches, each of which have ethical valence. One theory credits medicine's increasing focus early in the twentieth century on treating the biological causes of disease, and public health's contrasting occupation with the social and environmental causes of illness, resulting in efforts geared toward health promotion and prevention (Khoury et al. 2007). The vectors of medicine and public health diverged further when schools of medicine and public health in the United States were officially separated in 1916 (Khoury et al. 2007), in part due to the conflicting goals of professionals in the fields (Porter 2006). Additional ideas include "the rise of medical authority with the expansion of hospital-based specialist practices" (Porter 2006) as well as a corresponding split between individualist and collectivist modes of analysis in the social sciences (Arah 2009). This disciplinary, professional and institutional dissociation between the two fields has been blamed for the current gap between personal medical care and public health (Arah 2009).

The public health approach presupposes that an exclusive focus on the treatment of individuals is not sufficient to protect, promote and sustain effectively the health of a population. This is evident in the work and writings of public health practitioners such as the Sanitarians (Susser and Susser 1996a), Thomas McKeown (Szreter 2002), Geoffrey Rose (Marmot 2001), Dan E. Beauchamp (Kass 2004), Marc Lappe (Kass 2004), Marvin Susser (Susser and Susser 1996b), Ezra Susser (March and Susser 2006), Norman Daniels (Kass 2004), Paula Braveman (Braveman et al. 2004) and the World Health Organization (WHO) Commission on the Social Determinants of Health among numerous others (Marmot 2005).

Whatever the historical source of the "schism" between clinical medicine and public health (Khoury et al. 2007), the gap between them translates directly into the ethical plane. The individuating drive of personalized medicine could make the breach felt all the more keenly, especially when values of individual and population health conflict. For instance, genomics research has focused on "individually rare single gene disorders," prompting warnings that such investments redirect limited resources from "efforts to address the social and environmental causes of ill health" (Khoury et al. 2007).

Moreover, the challenge of ethical analysis is exacerbated by a disparity in the maturity of ethical frameworks governing medicine and public health. Whereas early bioethics scholarship often focused on the individual patient receiving care and to ethical principles supporting this relationship, a similar comprehensive and widely-accepted ethical framework for public health is yet to be established (Nixon and Forman 2008; Mann 1998; Callahan and Jennings 2002). Tellingly, Nancy E. Kass (2004) observes that the language of public health was conspicuously absent among the early bioethicists, despite some achievements with implications for public health ethics. Daniel Callahan and Bruce Jennings (2002) likewise point out the focus in bioethics on novel medical technologies in clinical settings at the expense of social and economic inequities.

Another reason an individualist outlook has prevailed in bioethics is that some public health interventions are conducted on the individual rather than the population level. For instance, postwar antismoking campaigns in Great Britain set a trend that involved educating and influencing individual behavior and lifestyles (Porter 2006). The approach, later adopted to combat heart disease, obesity and cancer, helped solidify the individualist and behavioral model already prevalent in clinical medicine (Beauchamp 1985; Porter 2006). Hence, the population perspective implicit in public health ethics was at times at odds with the individualist methods employed to serve the public's health. A further rationale for the individualist bias of

bioethics is the backlash against the misuse of population-based policies in the field of eugenics, resulting in an understandable suspicion of collectivist bioethical analysis (Pernick 1997; Kirkman 2005; Lombardo 2011).

These factors have combined to generate a rich framework for ethical analysis, but one that has remained individualist in orientation. The inadequacy of the framework was noted by bioethicists such as Dan E. Beauchamp who argued, against the prevailing political valorization of individual autonomy, that a framework that privileged "individual interests" and "market justice" was detrimental to public health (Kass 2004). Beauchamp suggested that public health might require its own "ethic," a proposal taken up by Marc Lappé (1986) who differentiated medical ethics from public health ethics.

As the new millennium unfolded, several efforts were undertaken to establish frameworks for public health ethics. Among these was the American Public Health Association's (APHA) adoption of the Public Health Code of Ethics in early 2002. The APHA was the first national organization to adopt the Code (Thomas et al. 2002), which is based on the Public Health Leadership Society's Principles of the Ethical Practice of Public Health. The Code is relatively narrow in scope, catering primarily to an audience in traditional public health institutions such as public health departments and schools of public health (Thomas et al. 2002). Moreover, it focuses on public health practice rather than research, and has in view the United States' public health system. Meanwhile, efforts were underway to mainstream another and more comprehensive ethical framework for public health ethics in the form of human rights.

Ethics, law and human rights

The appeal and promise of human rights as an ethics framework for public health was articulated by the late Jonathan Mann:

> Given that the major determinants of health status are societal in nature, it seems evident that only a framework that expresses fundamental values in societal terms, and a vocabulary of values that links directly with societal structure and function, can be useful to the work of public health. For this reason, modern human rights, arising entirely outside the health domain, and seeking to articulate the societal level preconditions for human well-being, seems a more useful framework, vocabulary, and template for public health efforts to analyze and respond directly to the societal determinants of health than any framework inherited from the past biomedical or public health tradition. (Mann 1998)

Apart from the capacity of human rights to speak in "societal terms," a crucial part of Mann's argument was his identification of the goals of human rights as virtually inseparable from those of health, i.e., human well-being (Mann 1997).

Although a human rights perspective has the practical advantage over other frameworks of being realized in (mostly international) law, it also benefits from being rooted in an established and fertile ethical vision. Human rights can be traced back to the ancient world, but we describe here the prevailing view, which has origins in the writings of such philosophers as Hugo Grotius, Thomas Hobbes, Jean Jacques-Rousseau and John Locke. Modern human rights assume that all persons possess inherent dignity and certain inalienable rights by the simple fact of their being human. The words "inherent" and "inalienable" mean these things belong to them naturally and are not granted to them by any political authority. To advance their individual and common well-being, however, people give up certain rights to set up a government that serves their needs.

A functioning human rights framework is based on the proposition that a government should not take more rights from people than people give to the government in the first place. On this view, the government exists to ensure the well-being of the individuals who give up certain rights in exchange for certain protections and benefits from the government. The same applies to the community they jointly establish. From this analysis, the traditional roles of government include such things as collective security, the administration of justice, the protection of property and, relevant for our purposes, the promotion of the public's health. Seen in this way, a human rights perspective provides an ethical framework for describing the conditions under which the government can protect and promote both individual and community well-being.

With the onset of the Cold War, however, rights that were part of a single ethical vision in the Universal Declaration of Human Rights (1948) were gradually split into two categories. The two classes of rights reflected the ideological priorities of the contending sides and were enshrined in two separate treaties in the 1960s. The International Covenant on Civil and Political Rights (1966) (ICCPR) reflected the capitalist and liberal emphasis on such rights as free speech, freedom of movement, freedom of religion, the right to vote and the right to privacy. These civil and political rights required governments to refrain from interfering with the liberties of their individual citizens.

On the other hand, the International Covenant on Economic, Social and Cultural Rights (1966) (ICESCR), spearheaded by the communist Eastern bloc, focused on such priorities as the right to work, the right to housing, the

right to education and the right to health—rights that require governments to take some kind of action for the benefit of the whole society. In part due to their being costlier than civil and political rights and also because of their questionable justiciability (i.e., their enforcement in courts of law) (Tarantola 2008), social and economic rights were not given the same priority as civil and political rights by governments. The main result of this focus on individualist civil and political rights is that many governments have not invested as heavily in addressing issues at societal or population level—issues such as housing, education and health. Hence, human rights norms in the twentieth century have developed along broadly individualist rather than collectivist lines.

Roberto Adorno (2009) describes the potential for human rights as a framework for biomedicine and public health in the global context. He notes that "[a]s our world becomes increasingly interconnected and threats to the global public health continue to proliferate, it is hard to see how the global governance of health could be managed without assigning an integral role to human rights". The reasons he provides in support of a human rights framework include the fact that much biomedical activity has clear human rights implications (e.g., the rights to life and physical integrity); human rights have developed into a transcultural ethical discourse with the potential for setting common standards; and there are few if any other viable mechanisms that can serve as a "global normative foundation". Considering the then incipient UNESCO Universal Declaration on Bioethics and Human Rights, T. A. Faunce (2005) noted the increasing application of human rights to address challenges traditionally considered within the sole purview of bioethics and medical ethics. In the narrower context of genomics, Knoppers (2000) has argued that benefit-sharing in the context of genetic research "is an aspect of fundamental human rights and serves to counterbalance the effects of commercialization and patenting". She has also proposed human rights as a compelling model for policy governing new genetic technologies (Knoppers 2004).

These developments notwithstanding, commentators have been quick to point out the limitations of adopting human rights approach for public health and genome-based medicine. Meier and Mori (2005) criticize the "limited, atomized right to health" contained in the ICESCR, a provision that establishes neither a robust individual right to health nor an effective means of ensuring public health. Similarly, Adorno (2009) acknowledges the criticism "that human rights are conceived as excessively individualist for non-Western mentalities and lack a significant concern for personal duties and for the common interest of society".

With particular reference to the field of genomics, Iles (1996) points to two specific shortcomings of human rights as an ethical framework, both of which are traceable to the individualist orientation of the current system. His first criticism is that such a framework pays inadequate attention to the structural and social effects of genetic information. He argues that because economic, racial, ethnic and power disparities already exist between groups in societies, genetic information used without ethical oversight can exacerbate these differences and result in discrimination and exclusion. Iles infers that human rights may adequately protect individuals facing genetic profiling in employment or insurance contexts, but it is questionable whether the framework's individualist lens can monitor the effects of genetic information on relations between and among groups. Iles' second criticism of the applicability of human rights as a foundation for ethical uses of genomics is that individual freedom of choice regarding the use of genetic information can have an aggregate population-wide effect. For example, the choice parents make to have a "normal" child rather than one with a "comparatively inert and tolerable" disorder is not only heavily influenced by society's values but also determines eventually the society's constitution (Iles 1996). A narrow focus on individual choice, therefore, may obscure the effects of the uses of genetic information on a society.

The preceding discussion demonstrates that even human rights as a framework for public health ethics are not immune from the individualist approach that characterized early bioethics. Toward the end of the Cold War, however, there were renewed efforts to reintegrate the individualist civil and political rights with the community-oriented economic and social rights (Meier and Fox 2010). We outline three of these developments below.

The first development is the increasing recognition of a category of rights known as "solidarity" or third-generation rights (Wellman 2000). The phrase "third-generation" distinguishes solidarity rights from the more individualist civil and political rights ("first-generation" rights) and the more collectivist social, economic and cultural rights ("second-generation" rights). Like the other two generations of rights, solidarity rights were a response to a particular set of problems facing the international community. These included "securing peace after the First and Second World Wars, achieving freedom for colonial peoples, reducing the gross economic inequalities between developed and underdeveloped countries, and preserving a healthy environment when the technologies in one nation seriously damage an environment shared by all nations" (Wellman 2000). Solidarity rights, in other words, are aimed at conditions that can be addressed only by global efforts rather than the laws of any single country.

The classic examples of solidarity rights are the rights to peace, development, a healthy environment, self-determination, humanitarian intervention, communication and

ownership of the common heritage of humankind (Wellman 2000; Monshipouri et al. 2003). Apart from requiring the concerted efforts of all countries, solidarity rights have two other criteria: first, that the rights belong to peoples (i.e., groups), not just individuals; second, that obligations apply to all actors on the international scene, not just governments. More recently, solidarity has been described as a key ethical foundation for biobanks (Chadwick and Berg 2001).

From an ethical perspective, solidarity rights complement first- and second-generation rights. Whereas first-generation rights protect individuals from the abuses of their governments (e.g., no torture or arbitrary arrests), and second-generation rights enable individuals to claim benefits from their governments (e.g., education, housing), solidarity rights recognize that individuals cannot reach their full potential without "cooperative participation in the social life of the various communities to which they belong" (Wellman 2000). Hence, solidarity rights further establish in human rights the ethical principle that human well-being has a communal dimension that goes beyond an individual citizen's relationship with her government.

The second development emphasizing a collectivist approach in human rights is growth in the area of indigenous peoples' rights. The United Nations General Assembly adopted the Declaration on the Rights of Indigenous Peoples in 2007. What makes this Declaration unique is that it explicitly recognizes a category of "collective" rights. Until the Declaration's adoption, human rights were concerned primarily with "the rights of the individual against the state, without much attention to the collective and associational dimensions of human existence beyond the state" (Anaya 2006). In an historic shift, the Declaration recognizes rights to indigenous peoples as groups rather than merely as individual members of their communities. It is a particular instance of the ethical principle underlying solidarity rights, which proposes that community is not an elective component of human well-being. This development, moreover, has significant ethical implications for the involvement of indigenous peoples in research and in access to health benefits, and exemplifies the relevance of indigenous perspectives on genomics research generally (Dodson and Williamson 1999).

The third and final development pertains to regional human rights instruments. The major global regions are encouraged to adopt their own treaties, thereby customizing global human rights norms to their particular situations for more effective implementation. Of particular relevance is the African Charter on Human and Peoples' Rights (also known as the Banjul Charter), which was adopted by the Organization of African Unity (now the African Union) in 1981, and which includes "a mixture of all three generations of rights" (Shepherd 1985). As its official title suggests, the Banjul Charter includes the concept of peoples' rights, which, like the collective rights of indigenous peoples, is a version of group rights. The Banjul Charter deliberately omits a definition of the term "people," thereby leaving the term open to several interpretations, e.g., persons struggling to gain political independence, persons living in a territory and sharing certain characteristics, or simply all people living in a country (Kiwanuka 1988). Whatever their precise legal definition, peoples' rights in the Banjul Charter are based on the African philosophical belief that a human being is not "an isolated and abstract individual, but an integral member of a group animated by a spirit of solidarity" (Kiwanuka 1988). The kinship between this African principle and the ethical norms undergirding solidarity rights and the rights of indigenous peoples discussed above is evident. They all recognize the importance of community to human well-being and reject an approach to human rights that focuses exclusively on the individual.

These three developments demonstrate how human rights have been finding ways to complement the protection of individual rights with approaches that recognize the ethical importance of community. These attempts to expand the vision of human rights beyond the individual are analogous to the efforts of public health ethicists to develop a population perspective that transcends the clinical encounter between a single patient and her caregiver. This similarity makes the human rights framework a compelling candidate for analyzing the ethics of biobanking and public health.

Human rights, public health and biobanking

As with early debates in medical ethics and bioethics generally, much of the ethical and legal attention in biobanking has been individualistic, focusing on informed consent (Beskow and Dean 2008; Brekke and Sirnes 2006), privacy protections (Chen et al. 2011; Evans 2009), and risks of exploitation, especially in vulnerable populations (Lo 2004; Bernhardt et al. 2003; Dodson and Williamson 1999). Important as these topics are, some now believe the time has come to update the ethical/legal dialog about biobanks to accommodate broader social and political perspectives (Meslin and Cho 2010; Kaye 2004; Caulfield et al. 2007). It is against this backdrop that our analysis is set.

A human rights approach may offer two advantages over other potential public health ethics frameworks. First, it may avoid having to resolve the seemingly interminable debate about the proper approach to obtaining individual informed consent for research using human biological materials. In situations in which groups may be consulted, approached and from which permission to participate in

biobanks may be sought, informed consent may be necessary but not a sufficient mechanism for engaging a community. Second, it recognizes the institutionalization and application of human rights discourse at international forums by providing tools for discussing the values of public health across national borders. This is important in light of observations by recent commentators of a linguistic shift with both practical and ethical implications: the gradual transition of the term "international health" to "global health." "International health" was used to describe a technical endeavor conducted jointly by developing countries and their partners in the industrialized world through such large institutions as the World Health Organization (WHO) and CARE International (Elmendorf 2010). It was useful in this context to distinguish between "international" and "domestic" health.

In contrast, the term "global health" reflects an acknowledgment that intensifying interaction between countries through trade and travel renders national borders increasingly immaterial for health challenges (Elmendorf 2010). The shift in terms represents the change from health conceived as an issue for diplomacy and knowledge transfer between countries to health conceived as a common asset and concern of the international community. Importantly, the terminological shift from "international" to "global health" is also reflected in the bioethics literature (Chadwick et al. 2011). A specific example of the application of "global" rather than "international" health is the "One World, One Health" initiative, a framework that builds on efforts to contain the avian influenza outbreak (FAO et al. 2008). The initiative is built on the premise that infectious diseases have potentially national, regional and international effects, thus requiring approaches that are not only "interdisciplinary" and "cross-sectoral" but indeed global.

The changes signified by the term "global health" have implications for biobanking in many ways (Burke et al. 2010). Public health genomics research is becoming "increasingly international and collaborative" resulting from the need for larger and more diverse datasets to evaluate genetic differences within groups (Ickworth 2010). Aided by more robust bioinformatics, genotypic and phenotypic data will be employed with greater frequency to study the significance of genetic variation (Mendoza 2010). This will involve the use of larger databases and the consolidation of samples from sites around the globe (Meslin and Goodman 2010; Ickworth 2010). This raises the obvious challenge of harmonizing norms concerning privacy and confidentiality across jurisdictions and, beyond that, consideration of the varied cultural norms guiding data sharing particularly when information moves between developed and lower and middle income countries (LMIC) (Chalmers 2007; Holman et al. 1999; Asslaber and Zatloukal 2007).

Biobanking in the global public health arena is also faced with the challenge of determining research priorities given the different health problems facing populations in developed and LMIC. Although both regions face the complex diseases of urbanization (e.g., cancer, heart disease, diabetes), environmental factors like climate change and resource scarcity are likely to affect LMIC more profoundly than their developed country counterparts. This is especially troubling given that a research imbalance exists between the regions: although African populations are "the 'root and branch of genetic variability'" the bulk of genomic research is conducted by developed countries and among European populations (Ickworth 2010). Fortunately, new initiatives such as H3Africa may begin to redress this historic injustice (Nordling 2011).

These challenges confirm the need for an ethical framework that can be understood and implemented at global forums. S. H. E. Harmon (2006) echoes the need for global frameworks "given the rise of predictive medicine (involving genetic research and clinical genetics), which is driven by private *global* operators, thereby suggesting a need for regulatory responses which are similarly global".

Although a 2003 WHO report on genetic databases concludes that biobanks are based more on "communal value" than on "individual gain," the reality is that the ethics of biobanking has been analyzed predominantly in the traditional individualist bioethical categories of confidentiality, autonomy and informed consent (Knoppers and Chadwick 2005).

The fact has not been lost on some commentators. Garrath Williams, for instance, discusses the daunting task of developing ethical principles for large-scale biobanks. He attributes the difficulty in part to an excessive focus on the individual research subject's right to informed consent, an emphasis he finds inconsistent with the inevitably collective nature of large-scale biobanking (Williams 2005). Williams maintains that this conceptual incongruity obscures important ethical questions about how research priorities are set and how to accommodate the diverse motives of actors in health care systems. He warns that ignoring analyses that transcend individualist frameworks may, paradoxically, end up harming the interests of individuals (Williams 2005). Human rights can make no original contributions to the ethics of biobanking if they are incapable of transcending their individualist biases.

The second challenge of a human rights framework for biobanking involves developments in global politics. The observation by Knoppers and Chadwick (2005) that genetic research has compelled "a public and therefore a political examination of personal and social values" illustrates the close connection between politics and ethics in biobanking. Therefore, ethical analyses of international biobanking and public health that omit the global political context will likely remain deficient.

The developments in global politics that pose the greatest challenge to human rights as an ethical framework for biobanking are efforts, in the context of globalization, to entrench policies that entail an increasing delegation of governmental responsibilities to private actors. In a publication on health and human rights, WHO (2002) notes that

> [w]ithin the human rights community, certain trends associated with globalization have raised concern with respect to their effect on states' capacity to ensure the protection of human rights, especially for the most vulnerable members of society. Located primarily in the economic-political realm of globalization, these trends include: an increasing reliance upon the free market; a significant growth in the influence of international financial markets and institutions in determining national policies; cutbacks in public sector spending; the privatization of functions previously considered to be the exclusive domain of the state; and the deregulation of a range of activities with a view to facilitating investment and rewarding entrepreneurial initiative. These trends serve to reduce the role of the state in economic affairs, and at the same time increase the role and responsibilities of private (non-state) actors, especially those in corporate business, but also those in civil society.

This transfer of responsibilities from governments to private actors is critical because the operation of international law depends both on governments assuming legal obligations by signing agreements and on these governments being held accountable for fulfilling the responsibilities they undertake. Generally speaking and despite recent changes in international criminal law, private actors are not accountable under public international law, the branch of international law to which human rights belong (Jessberger 2010). Hence, the transfer of governmental responsibilities such as health provision to private actors removes a growing number of issues from the direct supervision of human rights. Governments retain the duty to ensure that private actors such as transnational corporations do not violate human rights, but monitoring and enforcing the norms remains a major challenge (Gruskin et al. 2007; Tarantola 2008).

Two illustrative cases for adopting a human rights approach for public health biobanking

We conclude this discussion with two examples of key ethical issues raised by the prospect of expanding international biobanking: the first addressing differences in national laws governing biobanks, and the second addressing ethical obligations of transnational corporations operating in LMIC.

Differences in national laws

Various commentators have discussed the problem for international biobanking arising from the absence of common regulations applying across country borders. The regulatory terrain has been depicted as "a patchwork of national laws, regulations and ethics advisory body guidelines" (Maschke 2005), and comparisons have proven "laborious and defy generalizations" (Helgesson et al. 2007). The discrepancies in ethical rules governing such issues as consent and secondary uses raise obvious barriers to the principled collection of tissue samples and the development of personalized medicine.

Adopting human rights as a public health ethic is not an ideal guide for drafting specific rules governing individual focused biobanking issues such as consent, privacy and secondary uses. However, such an ethic can inform efforts to determine the general principles that should govern the activity of biobanking as a broader societal undertaking. Human rights can do this by integrating three concepts: (1) collective rights (from international human rights); (2) global public goods (from economics); and (3) the common heritage of humanity (from international environmental law).

We have discussed above the welcome and increasing recognition of community-oriented socio-economic rights as well as solidarity rights in international human rights toward the end of the Cold War. We noted also how the change was reflected in the explicit recognition of "collective" rights in the 2007 United Nations Declaration on the Rights of Indigenous Peoples. These rights "operate at an international level to assure public goods that can only be enjoyed in common with similarly-situated individuals and thus cannot be realized through individual rights claims against the state" (Meier and Fox 2010). The premise grounding the recognition of collective rights is that the realization of some human rights is simply not reducible to their exercise by an aggregate of individuals. Harmon (2008) writes that social solidarity has been incorporated, even if implicitly, into UNESCO's major instruments on genomic research, namely the Universal Declaration on the Human Genome and Human Rights (1997) and the Universal Declaration on Bioethics and Human Rights (2005). He maintains that the emergent notion of social solidarity mitigates the excesses of modern individualism and is "grounded in the recognition that individuals are socially embedded". His analysis of the UNESCO documents describes a solidarity based on the fundamental unity of all humans, a focus on "the collective, the observance of duties and the creation and

preservation, through personal and collective action, of a just and decent society".

The notion that the human genome is the "common heritage of humanity" has been eloquently defended (Knoppers 2005a), but has not avoided the disquiet among some commentators, some of whom suggest that the human genome be classified as a common resource rather than the common heritage of humanity (Spectar 2001; Resnik 2005). Developed in the context of international law governing the management of resources in outer space and the high seas, this concept is founded on three basic principles: "(1) absence of private property rights i.e. the right [usually of governments] to use resources but not to own them; (2) international management of all uses of the common heritage; and (3) sharing of benefits derived from such use" (White 1982). Also included in the concept is an obligation to use the resource in a peaceful and responsible way, keeping the resource accessible to all and considering the interests of future generations (Knoppers 2005a).

In economic terms, a global public good is a good "for which the cost of extending the service to an additional person is zero and for which it is impossible or expensive to exclude individuals from enjoying" (Nordhaus 2005). A global public good is marked by two criteria: that the good be non-excludable and non-rivalrous. Stated differently, "[a] good is non-excludable if persons cannot be excluded from accessing it, and non-rivalrous if one person's use of the good does not diminish the supply of that good" (Chadwick and Wilson 2004). A classic example is a lighthouse that lights the sea and which is not diminished in its use by multiple sailors (Chadwick and Wilson 2004). Other examples include a global positioning system (GPS) whose value is not compromised by multiple users, or the eradication of an infectious disease, the benefits of which cannot be diverted from any susceptible persons (Nordhaus 2005). It has been argued that both genetic information (Knoppers and Fecteau 2003; Chadwick and Wilson 2004) and public health (Meier and Fox 2010) should be classified as global public goods in this same way.

These three concepts have been integrated by several commentators in efforts to develop ethics frameworks for public health and biobanking. Meier and Fox (2010) consider public health a public good and make a case for its recognition in international law as a collective right. Knoppers (2005a) notes growing support in international normative documents for the human genome to be classified as the common heritage of humanity, and argues, as do Chadwick and Wilson (2004), that genetic databases should be considered a global public good (Knoppers and Fecteau 2003; Knoppers 2005b; Chadwick and Wilson 2004).

The combination of features from all three concepts can provide the basic constituents of a human rights public health ethic for international biobanking. First, collective rights, premised conceptually on the fact that certain rights can be protected only in groups, is virtually analogous to the population perspective of public health, which presumes that certain health challenges require society-wide, rather than individual, interventions. The kinship of the two perspectives is highlighted in the argument made by Meier and Fox (2010) that public health be recognized as a collective right. Second, the classification of genetic databases as the common heritage of humanity, which precludes private ownership while requiring shared uses and benefits, buttresses the view that biobanks should be managed under principles that consider the whole of humanity rather than narrower interests, no matter how seemingly benign. Again, these principles would share an affinity with the principles of public health that target the health of the *whole* population. Third, the arguments for the status of genetic information as a non-rivalrous and non-excludable global public good also support an approach to managing biobanks that recognizes the public character of the resource. Together, these features ground the management of international biobanking in a framework that keeps foremost the population perspective of public health.

The ethical obligations of transnational corporations (TNCs)/private businesses to LMIC populations

Biobanking and developments in personalized medicine entail the involvement of private investors. Commentators have pointed out the costs associated with this infusion of private funding. They raise concerns that such involvement

> may influence the type of research, distort the process by restricting the direction of research, prevent collaboration, and restrict the sharing of the raw data generated by the research. It also might prevent the results of the research being disseminated effectively or cause publication bias. Most importantly, it may serve to reduce public trust in the research process. Some evidence suggests that potential participants may be less willing to engage in research if this is privately funded (as they perceive themselves to be more exposed to potential exploitation) (Ickworth 2010).

The risks expand significantly when, as projected, biobanking expands globally. Most LMICs have vulnerable populations and lax to minimal research regulation. But even where LMIC governments have the ability to regulate research activity, we have noted above the growing trend under globalization for governments to delegate traditional responsibilities to private actors. This constitutes a major administrative and ethical challenge in the regulation of biobanks because, as a rule, governments rather than

private actors assume international obligations (Ratner 2001). The situation requires an ethical framework for protecting vulnerable populations living under governments either unwilling or incapable of protecting their interests.

In 2005, John Ruggie was appointed the United Nations Special Representative of the Secretary General (SRSG) on business and human rights for an initial term of 2 years. Ruggie's primary charge was to clarify the human rights obligations of companies operating internationally and the responsibilities of host governments to regulate such businesses (U.N. Comm. on Human Rights 2005). In extending the SRSG's mandate another 3 years in 2008, the Human Rights Council[1] observed

> that weak national legislation and implementation cannot effectively mitigate the negative impact of globalization on vulnerable economies, fully realize the benefits of globalization or derive maximally the benefits of activities of transnational corporations and other business enterprises and that therefore efforts to bridge governance gaps at the national, regional and international levels are necessary… (U.N. Human Rights Council 2008)

The appointment of the SRSG underscores the ethical implications of international trade and politics. It also testifies to the potential of human rights as a framework for addressing global governance challenges.

The SRSG fulfills his mandate through research, consultations and workshops that lead to recommendations, standards and tools for the use of businesses and other stakeholders. In the course of his mandate, the SRSG has developed a human rights framework for business in the global economy. The framework (known as the "UN Framework") has three pillars: the duty of governments to protect their citizens from human rights violations by third parties (particularly international businesses); the responsibility of businesses to respect human rights (typically contained in corporate codes of conduct); and the establishment of remedies for people whose human rights have been violated (U.N. Spec. Rep. of the Sec. Gen. 2008).

The UN Framework provides a useful tool for helping mitigate the regulatory hazards associated with privately-funded biobanking enterprises in LMICs. By further clarifying the responsibilities of both host governments and foreign investors, the UN Framework increases the chances that clear laws regulating biobanking will be passed by LMIC governments. Effective biobanking governance models (Kaye and Stranger 2009) are necessary if biobanking is to benefit public health as governments remain the primary actors in public heath practice. Moreover, by ensuring the availability of remedies for violations, the UN Framework reduces the incentive of foreign investors to take advantage of weak and/or corrupt governments unwilling to implement existing biobanking regulations.

The UN Framework was endorsed by the Human Rights Council in June 2011, thereby enhancing its credibility as a global ethical standard for regulating international business activity. This endorsement ensures that the UN Framework will help guarantee that the projected extension of especially privately financed biobanking to LMICs will take into account the public health interests of LMIC populations.

[1] Until 2006, the United Nations Commission on Human Rights.

Conclusion

We have taken the view that one of the ethical challenges raised by genomic medicine reflects an enduring problem in public health: the appropriate balancing of individual and collective values, rights and interests. Biobanking in the context of public health genomics reflects a unique case study in this classical problem because it must accommodate both individual and community interests (including multiple types of affected communities). While no single ethical–legal framework has been accepted to bridge this gap, we believe that a renewed attention to a human rights perspective in the context of global health may offer a way forward.

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