Population Biobanks and the Principle of Reciprocity

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Abstract Samples and data from population studies are stored for long periods of time, and can be accessed by national and international researchers to further their own studies and contribute to their understanding of the impact of a number of factors (e.g., environment, lifestyle) on common diseases and their progression. Part 2 of this Chapter discusses the nature of the researcher's duty to inform, which is the result of an individualistic conception of autonomy. Parts 3 and 4 review this restrictive conception of autonomy, and concludes that it is rooted in a unilateral approach that is incongruous with the nature of biobank genomic research. Finally, Part 5 proposes that autonomy be complemented by the principle of reciprocity, which would not only create a fair and balanced relationship between researchers and participants, but would also recognize the public as a key contributor to genomic research.

Keywords Autonomy • Consent • Duty to inform • Incidental findings • Individual research results • International collaboration • Liberal individualism • Population biobanks • Reciprocity • Trust

1 Introduction

The last two decades have witnessed a key development within the field of biomedicine, namely the transition from genetic to genomic research [1]. Having moved from DNA sequence mapping to the use of haplotypes [2], future advances in our understanding of disease risk and health may well be achieved through the study of

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P. Hainaut et al. (eds.), *Biobanking of Human Biospecimens*,
DOI 10.1007/978-3-319-55120-3_6

normal genomic variation across whole populations [3]. Such studies require not only samples and data from multiple sources (e.g., socio-demographic, biological, etc.), but also highly sophisticated infrastructures. Enter population biobanks: longitudinal and largely epidemiological studies designed for a multiplicity of research projects at both national and international levels. In population biobanks, asymptomatic individuals are randomly recruited via health insurance systems or public notice to participate in a "mapping" of heterogeneous populations [3]. After consenting to participate in such a longitudinal study, individuals are asked to provide biological samples and data (derived from self-administered and interviewer-assisted questionnaires, for example). These samples and data are then stored for long periods of time, and can be accessed by national and international researchers to further their own studies and contribute to their understanding of the impact of a number of factors (e.g., environment, lifestyle) on common diseases and their progression [4].

Unlike clinical trials for drugs or devices, future research using population biobanks cannot be specifically identified at the time of consent. This issue has been extensively debated in the literature over the past few years. Authors have debated whether broad consent—a model increasingly used in population studies—satisfies the legal requirements of informed consent [5, 6]. Uneasiness stems from the fact that, in some jurisdictions, a researcher's legal duty to inform is extensive [7]. *Prima facie*, it could be argued that this legal obligation is met by population biobanks. In fact, the epidemiological objectives and longitudinal nature of biobanks can be well described in consent-related documents; this consent can also stipulate the manner in which samples will be conserved, the mechanisms for data security, and, most importantly, the ongoing governance structures for access and ethics monitoring. If a competent adult decides that these conditions and protections are sufficient, why would such consent—broad as to future studies yet also specific as to the governance and oversight of biobanks themselves—be invalid [8]? The answer to this question, it seems, continues to rest on a certain concept of autonomy still applied in both contemporary bioethics [9, 10] and medical law [11, 12]. This concept maintains that the less an individual is expected to benefit therapeutically from a procedure, the higher the duty to inform becomes—hence requiring full and frank disclosure of all facts and probabilities for each research endeavor.

While much ink has been spilled in the last decade on the type of consent required for population biobanks, the following Chapter will not delve too deeply into this debate. Rather, this Chapter focuses on the roots of the predicament created by the researcher's onerous duty to inform. More specifically, this Chapter asserts that such an increase in obligations is the result of an individualistic conception of autonomy (Part 2), which is both restrictive and rooted in a unilateral approach incongruous with the nature of genomic research (Parts 3 and 4). Using population biobanks as a case study, this Chapter will then present a different conception of autonomy, this time founded on the principle of reciprocity (Part 5).

2 Origins of the Conception of Individual Autonomy

Respect for autonomy runs deep in common morality [13]. The word "autonomous" derives from the Greek words "auto" (self) and "nomos" (law), meaning "having one's own laws" [14]. Early use of the word autonomy did not refer to individuals, but to cities that made their own laws [15]. When applied to an individual, the word autonomy can refer to a variety of concepts, including: "the capacity of reason for moral self-determination" [14] and the "liberty to follow one's will; control over one's own affairs; freedom from external influence, personal independence" [14]. Strictly speaking then, autonomy requires two conditions: liberty and agency [13]. Accordingly, someone in a comatose state or in a state of mental incapacity is not considered autonomous.

Philosophers such as Immanuel Kant and John Stuart Mill have strongly influenced current interpretations of respect for autonomy [16]. In his *Foundations of the Metaphysics of Morals* [17], Kant contends that individuals have the capacity to determine their own moral destiny [17, 18]. Based on his view that all persons have unconditional worth, Kant argues that a violation of a person's autonomy is equivalent to treating that person as a means; "that is, in accordance with others' goals without regard to that person's own goals" [13]. Similarly, in his essay "On Liberty" [19], John Stuart Mill focuses on the "individuality" of the autonomous individual. He asserts that nothing should warrant the limitation of an individual's liberty of action, except self-protection [19, 20]. In other words, individuals should be allowed to develop according to their own beliefs.

In brief, autonomy is used broadly and could also be associated with "dignity, integrity, individuality […], responsibility, and self-knowledge" [21]. These diverse conceptions have, unfortunately, resulted in an inability to formulate a unique definition of autonomy. Gerald Dworkin thus notes: "[w]hat is more likely is that there is no single conception of autonomy but that we have one concept and many conceptions of autonomy" [21]. One of these various conceptions is "individual autonomy" [15, 22], which continues to be applied in contemporary bioethics and medical law.

According to Onora O'Neill, individual autonomy "[…] is generally seen as a matter of independence or at least as a capacity for independent decisions and action" [15]. This conception has its roots in Mill's utilitarian principle of liberty. According to Mill:

> That principle is, that the sole end for which mankind are warranted, individually or collectively, in interfering with the liberty of action of any of their number, is self-protection. That the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. He cannot rightfully be compelled to do or forbear because it will be better for him to do so, because it will make him happier, because, in the opinion of others, to do so would be wise, or even right. [19]

Mill's focus on individuality stems from his belief that it comprises one of the elements of well-being [19, 23]. Thus, not only should autonomous expression remain unimpeded, but it should also be actively strengthened. Some authors have

labeled this notion as one of liberal individualism [11]. According to Dworkin, it refers more concretely to the:

> […] right of a patient to make his own decisions about important personal matters and to effectuate those decisions (or have them effectuated). Properly understood this would mean that the *patient is entitled to all the information relevant to the decision*, including information the patient does not know he wants or needs. To exercise autonomy the patient would have to be *fully informed* and counseled about what decision to make. [11] (our emphasis)

There are many similarities between the above definition of liberal individualism and the stringent requirements laid out in a number of jurisdictions on the provision of information by researchers to participants. In the United Kingdom for example, disclosure requirements in the context of research are considered greater than those during treatment 'by virtue of the additional contribution to the public interest in particular' [24]—and thus create an even higher duty of 'subjective' disclosure. This is the case for both therapeutic and non-therapeutic research [24]. Similarly, Canadian courts have maintained that participants are entitled to "full and frank disclosure" [25] and that researchers' duties in this regard are as great, if not greater, than the duties owed by physicians in the clinical setting [25]. These legal tenets—often used to create stringent requirements for the provision of information—appear to have liberal individualism at their core. While an emphasis on individual autonomy (with its roots in liberal individualism) may help reduce paternalistic practices [26], it also poses a significant hurdle to genomic research by encouraging a unilateral approach to the researcher-participant relationship. To help us understand this notion of unilateralism, we will briefly review some of the main criticisms of individual autonomy. While most of these were formulated in the clinical setting, reviewing them we will clarify how such criticism could transcend the clinical setting and become significant for researchers that using population biobanks.

One of the main criticisms of individual autonomy is its "highly individualistic" [9] nature. According to some authors, this means that "rights" tend to be claimed "without any sense of reciprocal obligations" [22]. As some authors note, "a competent patient's decision is good simply by virtue of having been made by the patient" [22]. Under individual autonomy, "the patient-doctor relationship is reduced to that of client and technician" [22]. An example of this type of situation is where genetic counsellors are asked to provide non-directive information to patients following a diagnosis [11, 27, 28]. In this context, "non-directive" refers to professionals withholding their opinion so as not to influence their patients [29]. Dworkin finds the roots of this approach in individual autonomy [11]. Other authors have gone so far as to qualify the resulting patient-physician relationship as one of bioethical paternalism, which leads "some doctors to consider mistakenly that unthinking acquiescence to a requested intervention against their clinical judgment is honouring 'patient autonomy' when it is, in fact, [an] abrogation of their duty as doctors" [22].

The above-mentioned examples reflect a sense of unease towards the relationship created by this individualistic conception of autonomy. Indeed, through the resulting unidirectional relationship, the role of the physician is limited to that of a "passive information provider" [30]. Such an approach puts physicians in an awkward position, in which they can no longer easily make their cases by relying

on logical or rational persuasion characterized by the professional use of facts and rationality [31, 32]. Instead, clinical focus is being increasingly placed on perfunctorily providing the patient with the information.

More troublingly, individual autonomy can transcend the clinical setting and have significant implications for what is largely epidemiological, longitudinal research, such as that involving population biobanks. Indeed, population biobanks, like many other genomic research projects, rely on altruistic public participation, as there are no direct, individual benefits. In this case, the application of a unilateral, unidirectional approach is detrimental in that it fails to recognize the public and its involvement (Part 3), or the inherent limitations of this form of research that confront the researcher (Part 4).

3 Individual Autonomy and the Public

Research—especially in population genomics—not only involves contributions from researchers and participants, but also implicates the general public [33]. In fact, while the clinical setting strives to provide direct benefit to the patient, human genetic research in population biobanks aims at benefiting the general public as well as future generations. A sole focus on the autonomy of every individual participant destabilizes the balance created by various stakeholders involved in population studies. Indeed, it would neglect both the contributions made by the public and the fact that future generations remain the ultimate benefactors.

By taking part in a population biobank study, the research participant is largely contributing data and samples for altruistic reasons. Once these data and samples are stored, there is a scientific and ethical imperative for the biobank to make them available to the research community. This increases the statistical power needed to generate useful results, which are then ultimately translated into the clinical environment. The goal is to ensure better health for the population overall, which in turn, increases public trust in these research endeavors. This characteristic of human genomic research has stimulated the emergence of new trends in the field of ethics, among them solidarity and universality [34, 35]. Solidarity refers to a common willingness to share information for the benefit of others, for the common good [8, 34]. Universality, in turn, emphasizes that genetic knowledge is beneficial beyond borders and so for other "publics" [34]. Both trends highlight the importance of public engagement. Indeed, given that genomic research can cover isolated populations or whole countries, it is essential that researchers communicate and consult with policymakers and the public. This engagement could affect decisions relating to the type of consent and access modalities [36]. Indeed, a narrow view of autonomy through liberal individualism devalues public influence over, and underestimates public interest in, population studies and the sustainability thereof. How would a strict access system, which requires that participants explicitly re-consent to every access request to a biobank, efficiently contribute to the orderly translation of knowledge to the clinic? How would such a narrow approach increase public trust in these research endeavors?

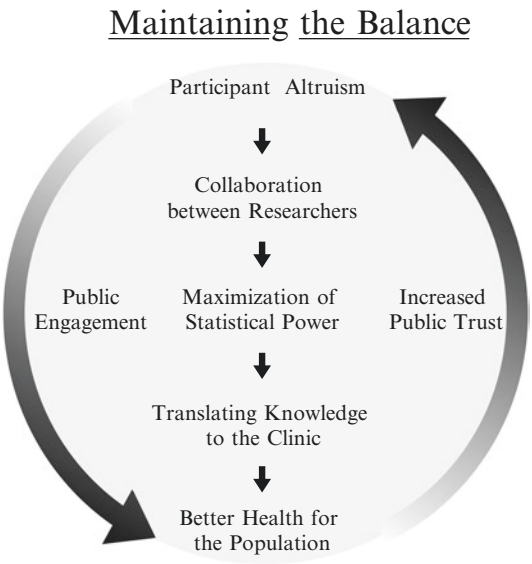

Fig. 1 Maintaining the balance. This figure portrays the delicate balance population biobanks have to maintain in order to sustain the public's trust in their endeavors

The reality is that the public plays a central role in population research, and that this role is fuelled by trust, a shared belief in the common good, and thoughtful engagement. These necessities are not captured by individual autonomy because the latter has become shorthand for independence [37] (in this case, participant independence). This creates a negative imbalance that will ultimately affect all the different stakeholders involved (Fig. 1).

4 Individual Autonomy Does not Consider the Limitations of all the Parties Involved

Autonomy and its unidirectional focus on research participants solely as individuals also creates a general inability to consider the limitations of both parties in the researcher-participant relationship. A good example of this inability is the disclosure of information surrounding future access to data and samples. Here, the unilateral approach focuses only on what needs to be provided to the participant—in this case, everything—without fair consideration of the possible confines in which researchers might find themselves. Population biobanks are clearly limited in what information they are able to divulge. Moreover, as mentioned above, it would be too cumbersome for these projects—which usually involve more than 10,000 participants—to obtain individual re-consent every time a request for access is received [38].

Mill's liberal individualism calls for society to allow individuals to progress according to their own views, as long as they do not interfere with the autonomous expression of others or "unjustifiably harm them" [13]. That said, Mill made no

mention of the possible limitations that could arise from the strengthening of autonomous expression. The nature of consent and the specificity of its content are just two examples of such limitations in a field where increasingly cutting-edge technologies are being used to generate vast amount of non-interpretable data.

The return of individual research results (IRRs) and incidental findings (IFs) is another case in point. It is also one that illustrates the limitations faced by both researchers and participants in genomics and population biobanks. While IRRs pertain to the objectives of a research project, IFs fall outside the scope of the project [39]. By definition—and if we follow the principle of liberal individualism—both types of findings could fall under a broad duty of disclosure, which is limited in the context of genomics. Indeed, the nature of the information discovered (whether IRRs or IFs) will not necessarily provide the participant with an actionable result. It may even lack analytical validity or any form of clinical significance [7]. The imposition of a stringent duty to return such findings not only creates more harm than benefit, but could also put the researcher in a difficult and unduly onerous position. Indeed, researchers might not always have the required in-house expertise to feed this information back to the participant. Even if they have the requisite expertise, researchers should nevertheless take into consideration the participants' situations and constraints (e.g. social, familial, etc.). Disclosure of information and of results in research should be personalized, and should not follow a "one-size-fits-all" approach. Moreover, "return" in population biobanks could be considered to create a therapeutic misconception between research and the clinic, or be considered an inducement [40]. Population biobanks could be overwhelmed with obligations that are essentially inimical to genomic research (in general) and population biobanks (in particular). This has the damaging effect of breaking the fabric of trust between all parties involved in population studies (Fig. 2).

Participants trust biobank researchers with their data and samples and expect that any benefits accrued will be achieved through collaborative, high-quality research. The public trusts that any funding of these endeavors will generate benefits for future generations [41]. In turn, the biobank researcher trusts that the research community will use these data and samples according to the agreed-upon terms and

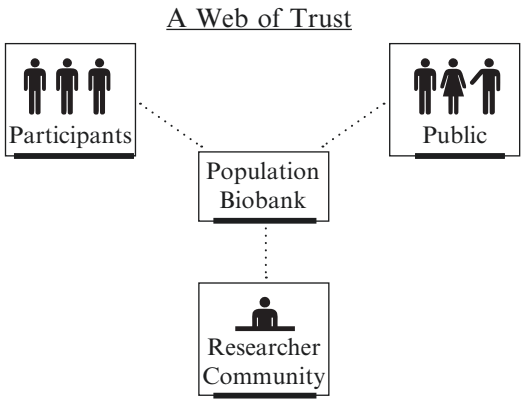

Fig. 2 A Web of Trust. This figure identifies the main stakeholders in the population biobanking sphere. It aims to exemplify the importance of moving away from a bilateral participant-researcher relationship to a multilateral one that also includes the public as well

conditions, and will strive to return derived data back to the biobank to enrich its resources [42]. Through an individualistic conception of autonomy, researchers do not enter into relationships of trust with participants, but rather are forced into unremitting professional accountability [15]. This unidirectional relationship weakens the remaining threads in the joint web of trust.

5 The Case for Reciprocity

Presented by some authors as an emerging trend in bioethics [34, 43], and widely used in public health ethics [44], reciprocity is based on the premise that individuals "incur obligations to help or benefit others at least in part because [they] have received, will receive, or stand to receive beneficial assistance from them" [13]. More concretely, reciprocity is associated with mutuality, which requires that "parties [be] jointly bound as regards the benefits and risks from their interaction and that one's obligation of return is conditional to the value of the benefit received" [45]. This, in turn, requires both trust and empowerment [45]. Trust is strengthened by "positive collaboration and experience between […] parties" [45]. Empowerment refers to the idea that "participants are protected in mobilizing themselves efficiently and that their contribution to the research enterprise is acknowledged and respected" [45]. In other words, reciprocity is based on a participatory approach that: "[…] demands proportionate balancing of the benefits and burdens of social cooperation […] so that any resulting inequalities in benefits and burdens resulting from some relevant social practice are not unfair or intolerable" [44].

Though disclosure is an important component of reciprocity, clarity and transparency as to proper governance in return for trust are its driving force [46]. That said, is the principle of reciprocity better-suited to large-scale population studies? More importantly, does it represent a multilateral approach that could complement the principle of autonomy in researchers' duty to inform? The answer to both questions is yes. Autonomy supplemented by reciprocity would be grounded in fairly balanced, communal obligations. This would help to alleviate the deficiencies of an individualistic conception of autonomy as presented in previous sections (Parts 3 and 4).

First, reciprocity would be grounded in fair and balanced obligations because it follows the general principle that individuals who "make a social contribution through accepting burdens of research risk should receive benefits in return, but not by disproportionately increasing burdens on others" [47]. For example, the consent process would consider that researchers are necessarily and honestly limited in the amount of information that they can provide to participants on future use of samples and data. The same applies for the return of IRRs and IFs: researchers should not be under ambiguous, onerous or speculative obligations to return findings in the context of biobanks. As some authors have noted, reciprocity is "fundamental to the very concept of justice" [48]. In other words, "*when you can*, return good in proportion to the good you receive" [48] (emphasis added). Reciprocity increases the level of trust between participants and researchers by eliminating inefficient and onerous obligations for researchers (whether for consent or for individual research results).

Second, reciprocity is communal because it establishes an "ongoing and long-term relationship between participants, researchers and society" [49], and values prior consultation and communication with the general public [34]. In other words, reciprocity recognizes the public as a distinct party whose opinions and thoughts could shape policies and the overall direction of a research project. As seen in Fig. 1, such engagement increases public trust, which, in turn, sustains the continued altruistic participation of individuals who are generally asymptomatic. Reciprocity also facilitates the overarching goal of population biobanks by creating generalizable knowledge for the benefit of future generations and by regularly communicating to the population the results of research gleaned by accessing the biobank. But, by excluding onerous obligations that unduly limit access to data and samples through delays and constant re-consent, reciprocity facilitates collaboration between researchers and so maximizes statistical power, which translates into better science for population health. Successfully achieving this not only impacts the population, but also recognizes participant contributions, which lie at the core of the notion of empowerment. What better way to nurture and sustain the tri-partite, trust-based relationship between the researcher, the public and the participant than to apply reciprocity to the researcher's duty to inform?

6 Conclusion

The move towards personalized medicine will require the creation of reference maps of whole populations. These maps will serve "as controls for replication, comparison, and validation of personalized genomic discoveries and profiles" [3]. Population biobanks are at the center of important undertakings such as public health planning; the only way to achieve these goals is to collect, store and share data and samples for future unspecified research. Today, at the international level, the focus is on facilitating such collaborative efforts. In that respect, the Public Population Project in Genomics and Society (P^3G)—an international consortium whose members are leading public organizations involved in large-scale genetic epidemiological studies—is developing research tools for effective collaboration between researchers, whether in ethics, information technology or data harmonization [50]. In the same vein, the Global Alliance for Genomics and Health (GA4GH) is building an endeavor that fosters "frameworks and tools for genomic and clinical data sharing […] [as well as] the translation of the benefits of research for health" [51] while recognizing the contribution of the scientists that make this possible.

While this text is in no way a repudiation of the concept of autonomy, it represents a call for a complementary principle that could offer a more proportionate approach to the researcher's duty to inform.[1] Proportionality here refers to the imposition of a fair and balanced intensity of professional responsibilities by taking into

[1] "Critiques of autonomy should not be taken as suggestions to do away with it. Instead, we should seek principles to complement it, especially when autonomy falters or is inapplicable" [52].

account the types of services they are providing, the multilateral characteristics of their duties, and the nature of the research. Additionally, it is also a call for a principle that acknowledges the important role played by the public, premised on multilateral trust and transparency. Researchers need it and participants deserve it.

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