ELSI challenges and strategies of national biobank infrastructures

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ABSTRACT

National biobank infrastructures are now being implemented in several European countries. Individually, biobanks are invaluable as national research resources; collectively, they are the critical elements needed for the actualization of the pan-European biobank infrastructure. The national biobank infrastructures are confronted with a number of challenges of legal, ethical, political, societal, financial and educational nature which must be articulated and addressed in order to optimize the use of the biobanks in national and international research. The community of researchers involved with these biobanks has charted the most pressing issues experienced by the national biobanks in their nascent stages of development. Our findings reveal great commonalities in the nature of the challenges that the national hubs are facing. These challenges and the strategies developed to address them are described in this paper.

Considerable efforts and resources are currently being allocated to facilitate the construction of research infrastructures across Europe. The preparatory phase of the "Biobanking and Biomolecular Resources Research Infrastructure" (BBMRI, FP7, GA Nr. 212111) project has laid the ground work for a pan-European biobank research infrastructure to facilitate the use and exchange of high quality biological samples and health data for European research (1). Over the past few years BBMRI has grown into a 53-member consortium with over 280 associated organisations (largely biobanks) from over 30 countries, making it the largest research infrastructure project in Europe. While waiting for the implementation of the "European Research Infrastructure Consortium" (BBMRI-ERIC, ERIC is a legal entity registered at the EU level) expected for 2012, many European countries are already launching national biobank infrastructures – BBMRI national hubs – to function as national operational units for the larger, envisioned pan-European biobank infrastructure. Sweden was the first country to establish a national hub in June 2010 (2) followed by Italy (3), The Netherlands (4), Norway (5), Finland (6), France (7) and Denmark (8), and more are being planned.

Biobank infrastructures of national and international scale need to be ethically robust, legally compliant with national legal frameworks, and supported by the general public in order to maximize their benefit for medical research and public health (9). It is crucial that: 1) the major ethical, legal and societal (ELSI) challenges that may be encountered when implementing and utilising such infrastructures are identified at an early stage, 2) strategies to address these challenges are developed, and 3) dynamic ELSI frameworks are developed to be responsive to unforeseen challenges that arise in tandem with rapid advancements in technology and knowledge. Potential ELSI challenges and strategies of the BBMRI national hubs have recently been discussed by representatives from the newly funded and anticipated BBMRI national hubs and representatives from the ELSI stream of the collaborative project "Biobank Standardisation and Harmonisation for Research Excellence in the European Union" – BioSHaRE-EU[1] (10), at a meeting[2] held in Spain in June 2011. The meeting was jointly organised by the Norwegian initia-

[1] BioSHaRE-EU (Biobank Standardisation and Harmonisation for Research Excellence in the European Union project) is an EU-funded collaborative research consortium whose aim is to develop methods and tools to facilitate the use of pooled data from different cohort and biobank studies to investigate current questions in multifactorial diseases, notably on gene-environment interactions.

[2] Joint BioSHaRE/BBMRI ELSI meeting, June 28 2011, Hotell Ciudad de Castelldefels, Barcelona, Spain.

tive Biobank Norway and the Strategic Integration and Co-ordination work package[3] of BioSHaRE-EU. The goal of this paper is to provide an overview of the main challenges discussed at the meeting and the strategies under development to address these challenges. It should be noted that this paper does not provide an exhaustive coverage of all the ELSI-related issues that could be encountered in building a national biobank infrastructure but rather describes and illustrates the challenges currently encountered in one or more of the BBMRI national hubs. These challenges are summarized in Table 1.

CHALLENGES OF NATIONAL BIOBANK INFRASTRUCTURES

Generally, we found a large overlap in the nature of the challenges confronting the BBMRI national hubs. This suggests that there may be opportunities for these challenges to be addressed in an internationally co-ordinated manner. However, it is important to recognize that there is also variation in the nature of some of the challenges encountered by national hubs. The major types of challenges could be broadly classified as legal, ethical, political, societal, financial and educational.

LEGAL CHALLENGES

Lack of appropriate regulation for research biobanks is a common problem reported by the national hubs. Currently, several countries, including Finland and Sweden, are either in the process of developing new laws or revising their existing biobank laws. In some countries the regulations governing biobanks are specifically crafted for biobanks while in other countries they are subsumed under other regulatory domains. Often the regulations in place may be so restrictive or burdensome that biobank-based research is hindered (11). This is illustrated, for example, by the case of Italy where the Italian Personal Data Protection Code for General Authorization for the Processing of Genetic Data [June 24, 2011, doc. web n. 1389918] states that samples can be stored for research purposes but simultaneously requires that specific written consent be systematically signed and renewed for each new research study (12). Another example comes from France where the regulation of biobanks does not fall under the purview of a specific law but rather is scattered in several pieces of legislation. Consequently, a number of specific authorisations are required from the Ministry of Research for various biobank activities, including exporting and importing samples. Obtaining these separate authorisations is often time consuming and burdensome for researchers. In contrast, biobank regulation in other countries can have the effect of promoting, rather than hindering biobank-based research. For example, no specific biobank regulation exists in Denmark, but the national regulations that pertain to biobanked samples and data do not pose major obstacles to biobank-based research (13).

Another challenge encountered by the BBMRI national hubs is that national regulations are often interpreted differently by national agencies within the same country. For example, in Norway there is a debate ongoing as to whether the Biotechnology Law of 2004 for research applies to genome sequencing (14), a method that was not available at the time the law was crafted. This has critical ramifications for biobank-based research projects because of the requirements surrounding informed consent and genetic counselling mandated under this law. The Norwegian Biotechnology Law is currently being re-evaluated in order to address recent technological developments but it will take time before a revised law is instituted. In the meantime, several Norwegian projects are grappling with understanding which regulations will govern their specific research projects and how to proceed to ensure that the research they plan to conduct complies with legal requirements. Several countries also report disparities at the national level regarding the requirements from oversight bodies such as data protection authorities or ethics committees in relation to issues such as informed consent, intellectual property and data sharing. These requirements can unexpectedly change over time. This is illustrated by a recent case in Italy where the data protection authority organised an open consultation on the secondary use of biochemical and medical data related to the health status of patients and donors. This consultation, in which the Italian national hub participated, paved the way for the implementation of a new rule allowing secondary use in the specific case of new retrospective observational studies without any requirement to re-contact the individuals from whom the data originate (15).

Within-country legal disparities also arise when the legal authority is decentralised and resides at the regional level. This is the case in Italy where legislation applying to biobank research can vary from one region to another. Although an inter-Regional Commission (Tavolo interegionale) on "biobanks" has recently been established to set up a common set of requisites for the certification of "regional biobanks", consistent national regulation is still missing. This has the unfortunate consequence that variation exists regarding the requirements that are applied to biobanks depending on their geographical location.

Finally, changes in the European legal framework may have significant implications for biobank research. For example, the General Data Protection Regulation, newly proposed by the European Commission, categorizes genetic data as personal data and thereby procedures to ensure special protections must be applied (16).

[3] The Strategic Integration and Co-ordination work package of BioSHaRE-EU aims at interfacing regularly with relevant initiatives to 1) develop complementarities across projects and ensure that there is no unnecessary duplication of effort, and to 2) ensure that new developments occurring in the field in terms of harmonization, ELSI, and informatics are taken into consideration.

A general observation is that the legal landscape is aimed at structuring biobank research activities within each country and there is relatively little focus on paving the way for international collaboration even though this is part of the vision behind the national hub structure of BBMRI.

ETHICAL CHALLENGES

The design, scope and interpretation of informed consent are the primary ethical challenges reported by the BBMRI national hubs. Most countries do not have a generic model of informed consent for research biobanks and the terms of consent may vary between research studies. When biobanks contain collections derived from a variety of studies that have banked samples, it can be difficult to determine from the original consents which sets of human biological samples and associated data may come under the auspices of the national biobank infrastructure and the specific research purposes for which they can be used and shared. This issue also applies to the use of samples from deceased individuals and children when these samples become part of a biobank and regulation may not provide sufficient guidance (17,18).

Issues surrounding consent are particularly salient in countries where the national infrastructure is envisioned to integrate clinical and population-based biobanks as it is for instance the case in Norway. Population-based biobanks often contain data and biospecimens for which use has been broadly consented to enable a large range of research studies. However, consent is not always required for data and biospecimens that may be in the clinic, or consent may be quite narrow and pertain only to clinical research, or to research on a specific disease. In principle, consent restrictions should not be an issue since the Norwegian Health Research Law allows for biological material collected in the context of health care services to be used in research without requiring specific consent as long as the patients are properly informed about their right to opt-out (19). However, in practice, this requires that patients have sufficient information about their right to opt out of the Norwegian BBMRI. An opt-out registry was established in 2009 and contains a few names (20). A similar registry was established in Denmark in 2004; six years later, the Danish registry contains less than 200 names. No mechanisms are in place to determine whether the low frequency of opt-out reflects whether the patients are insufficiently informed about the registries or if it means that the Norwegian and Danish patients support that their biological material is used for research.

Another major set of ethical issues is related to the information generated from the use of advanced sequencing technologies for research. Intense discussions are currently taking place as to whether individual research results from whole-genome sequencing should be communicated to research participants as this information may have consequences for health decision-making or be of general interest to individuals (21). These discussions are taking place in all European countries and also more widely, internationally. While some research projects in Europe have been proactive and developed policies to address this issue (22,23), most biobanks have neither a clear strategy in place nor do they have the possibility to develop one due to the lack of clear legal guidance in their country.

Finally, issues related to privacy and data protection exist and are expected to become more critical as technology develops and the information produced through research becomes more personalized. Such issues can be encountered in the different phases of research planning and design, e.g. when linking data stored in biobanks to health registries or when sharing data with other research groups nationally and internationally.

SOCIETAL AND POLITICAL CHALLENGES

Most European citizens are not familiar with biobanks, although the general public in European northern countries seems to be more familiar with biobanks than in European southern countries (24). Current knowledge is scant concerning the perspectives of the general public and their support for biobank research and the establishment of national biobank infrastructures (25). Even in countries where biobank research is relatively known to the general public, little public debate has taken place surrounding biobank research, which makes it difficult for researchers to determine the wishes and attitudes of the various populations regarding the use of biological samples and data. In some countries, mechanisms have been implemented to inform donors and allow them to make individual choices regarding the use of their samples and data. This is illustrated by the case of France where an opt-out system for secondary uses of samples that requires researchers to inform donors about future uses was introduced in the law in 2004. However, this opt-out system does not apply when genetic analyses are to be undertaken and thereby limits biobank research and renders complex the information to the public (26). Public debate is also needed to discuss other facets of biobanking. For instance, the use of biobank resources for commercial purposes, as recently proposed in the mandate of the Norwegian BBMRI infrastructure (27-28), has not been fully discussed among Norwegian milieus and was not anticipated in the original consents. Although a recent Norwegian study shows that donors may have a positive attitude towards commercialisation, more research is needed to gain insights into the general perceptions and concerns of the general public surrounding potential commercialisation of biobank resources (29).

The existence of competing interests in society makes it difficult for biobank researchers to set their priorities. While legislators and ethicists aim at regulating and sometimes restricting the use of stored human biological samples and associated health data for research, patient groups and interest organisations lobby

Table 1. Examples of challenges and strategies of national biobank infrastructures (all examples may not be encountered in all BBMRI national hubs).

Challenges	Strategies
Legal challenges	
• Lack of appropriate biobank regulation • Varying interpretation of national regulations by national institutions • Varying requirements from oversight bodies • Within-country legal disparities	• Co-operation with national authorities for the development of appropriate biobank regulation • Development of biobank networks • Development of self-regulatory codes and legal platforms
Ethical challenges	
• Varying design, scope and interpretation of consent • Return of individual research results to research participants • Privacy and data protection	• Consultation of expert and stakeholders groups • Development of ELSI guidelines • Development of IT-based solutions for privacy and data protection and for secured data sharing
Social/political challenges	
• Lack of knowledge surrounding biobank research among the general public • Lack of public debate surrounding biobank research • Different views on how biobank resources should be used	• Organisation of public forums and meetings • Development of information channels such as web sites, newsletters and participant interfaces
Financial and educational challenges	
• Insufficient funding of national infrastructure • Lack of expertise among researchers and members of ethics committees regarding biobank research • Lack of tradition and incentive to encourage sharing of stored biobank resources	• Development of cost-recovery systems • Development of training courses • Development of incentive tools

to encourage such research. Some of the arguments forwarded are that it is unethical to bother patients or research participants with new collections of blood samples or biopsies when samples are already available in the health care system, or in research biobanks, or that research persons and families should not be excluded from potentially beneficial research (30). Conducting broad and systematic consultation of the various publics concerned would help inform this issue and provide valuable insights to guide this work forward. Such consultation should be planned and budgeted early in the implementation of the national hubs.

An additional challenge is the lack of tradition or incentives to encourage researchers to make the research data and samples stored in their biobanks available to others in a national biobank infrastructure. Paradoxically, funders increasingly promote (31), and often require the sharing of data to optimize the scientific yield and to achieve the highest cost-benefit return on data collections that are financed through public funds. Thus, in the absence of a robust framework to help align and address the perspectives from various stakeholders, biobanks must negotiate a terrain of competing demands in order to establish their policies and procedures.

FINANCIAL AND EDUCATIONAL CHALLENGES

While several countries, including Norway, Sweden and the Netherlands have financial resources at their disposal for the establishment of national biobank infrastructures, other countries report insufficient funding to support their activities. Within the last decade biobanking has emerged as a field in its own right requiring specific technological and scientific expertise (32). Support is needed to finance the biobank infrastructure as well as the human resources necessary for it to function successfully. Researchers often lack the necessary skills, knowledge and expertise to fulfil these requirements. In addition, the level of knowledge about biobanks and the research they support can be low amongst local and national ethics committees. This lack of knowledge and expertise may make communication between biobankers and ethics committees challenging and time consuming.

PLANS AND STRATEGIES OF NATIONAL HUBS

The BBMRI national hubs report that they are developing action plans and strategies to face the challenges described herein. Representatives of national BBMRI hubs are working in co-operation with national authorities to develop appropriate regulations for biobank research in e.g. Finland, Sweden and Italy. The Nordic countries have implemented a Nordic network called BBMRI Nordic (33), which was recently joined by Estonia, to develop common strategies in Northern Europe. Self regulatory codes and legal platforms are being proposed and implemented by several BBMRI national hubs (34-37). In France, a harmonisation platform of ELSI services is being developed by "Biobanques" (http://www.crbfrance.fr/, the French national hub for BBMRI), in close contact with the regulatory part of the national infrastructure for clinical trials (F-CRIN) that represents the national branch of the ECRIN European infrastructure (http://

www.ecrin.org/). National and international advisory and stakeholders groups are being established to discuss the main issues and develop technical documents (e.g. ELSI guidelines or standard operating procedures – SOP's) and practical solutions. For instance, Sweden has adopted a national standard for collection of informed consent from patients in public health care (38). The ethical advisory group of the UK10K project has developed an ethical governance framework to deal with issues related to next generation sequencing such as e.g. the design of informed consent forms, the protection of confidentiality and management procedures to feedback results to research participants (22). Italy is developing a common model for consent and material transfer agreement (3), and the same activity has also been started in France. Tools to facilitate the simultaneous secondary use of samples and data from clinical and population research environments have recently been proposed (39). In Norway, a national council for biobanks and registries is envisioned to better coordinate biobank activities (40). IT-tools are being developed as the result of cross-country collaborations to safeguard privacy protection and facilitate a secured use of biobank resources by diverse research groups (41) and to encourage researchers to participate in research collaboration projects (42,43). Strategies for public engagement, through the organisation of public forums and open meetings or the publication of newsletters are also being developed alongside participant interfaces (44). Simultaneously, the national hubs work at developing financial solutions for sustainability as it is the case in Italy where a system of cost-recovery for biobank services that would be recognised by the national public health system is being planned. Finally, the national hubs develop and organise training courses to increase the skills and knowledge base of biobank staff.

CONCLUSION

The BBMRI national hubs are facing a number of significant ethical, legal and societal challenges. While some of these challenges are country specific, the majority are encountered in all BBMRI national hubs. It is therefore essential that these challenges be discussed across national hubs in order to develop good solutions, avoid duplication of effort, and facilitate international collaborations. Biobank harmonization has been ongoing through initiatives such as the GenomEUtwin project (45), the PHOEBE project (Promoting Harmonisation of Epidemiological Biobanks in Europe) (46), the Public Population Project in Genomics P^3G (47), and more recently BBMRI and the BioSHaRE-EU project. Building interoperability of the ELSI platforms has been central to these projects and will be further facilitated through the implementation of an ELSI forum involving the ELSI teams at the BBMRI national hubs working in conjunction with BioSHaRE-EU. Appropriate regulatory mechanisms, ethical frameworks, tools for public engagement and capacity building are under development. It is foreseen that their implementation will influence the shape and design of the forthcoming pan-European research infrastructure.

ACKNOWLEDGMENTS

The authors would like to thank Jasper Bovenberg, Legal Pathways, and Institute for Health and Bio-Law, The Netherlands, for providing useful comments. This work was supported through funds from the European Union's Seventh Framework Programme (FP7/2007-2013), ENGAGE Consortium, grant agreement HEALTH-F4-2007-201413; BioSHaRE-EU, grant agreement HEALTH-F4-2010-261433; and through funds from Biobank Norway – a national infrastructure for biobanks and biobank related activity in Norway – funded by the Norwegian Research Council (NFR 197443/F50). MP is partly financially supported for this work by the Finnish Academy SALVE program ''Pubgensense'' 129322.

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