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Biobanking, digital health and privacy: the choices of 1410 volunteers and neurological patients regarding limitations on use of data and biological samples, return of results and sharing

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Abstract

Background The growing diffusion of artificial intelligence, data science and digital health has highlighted the role of collection of data and biological samples, thus raising legal and ethical concerns regarding its use and dissemination. Further, the expansion of biobanking, from the basic collection of frozen specimens to the virtual biobanks of specimens and associated data that exist today, has given a revolutionary potential on healthcare systems, particularly in the field of neurological diseases, due to the inaccessibility of central nervous system and the need of non-invasive investigation approaches. Informed Consent (IC) is considered mandatory in all research studies and specimen collections, and must specifically take into account the ethical respect to the individuals to whom the used biological material and data belong.

Methods We evaluated the attitudes of patients with neurological diseases (NP) and healthy volunteers (HV) towards the donation of biological samples to a biobank for future research studies on neurological diseases, and limitations on the use of data, related to the requirements set by the General Data Protection Regulation (GDPR). The study involved a total of 1454 subjects, including 502 HVs and 952 NPs, recruited at Santa Lucia Foundation IRCCS, Rome, from 2020 to 2024.

Results We found that (i) almost all subjects agreed with the participation in biobanking (ii) and authorization to genetic studies (HV = 99.1%; NP = 98.3%); Regarding the return of results, (iii) we found a statistically significant difference between NP and HV, the latter preferring not to be informed of potential results (HV = 43%; NP = 11.3%; $p < 0.0001$); (iv) a small number limited the sharing inside European Union (EU) (HV = 4.6%; NP = 6.6%), whereas

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patients were more likely to refuse transfer outside EU (HV = 7.4%; NP = 10.7% $p = 0.05$); (v) nearly all patients agreed with the use of additional health data from EMR for research purposes (98.9%).

Conclusions Consent for the donation of material for research purposes is crucial for biobanking and biomedical research studies that use biological material of human origin. Here, we have shown that choices regarding participation in a neurological biobank can be different between HVs and NPs, even if the benefit for research and scientific progress is recognized. NP have a strong interest in being informed of possible results but limit sharing of samples, highlighting a perception of greater individual or relative benefit, while HV prefer a wide dissemination and sharing of data but not to have the return of the results, favoring a possible benefit for society and knowledge. The results underline the need to carefully manage biological material and data collected in biobanks, in compliance with the GDPR and the specific requests of donors.

Keywords Biobanking, Neurological diseases, Bioethics, Privacy, Data Treatment, Biomarkers, Donors, Digital Health, GDPR, Data Science

Introduction

Currently, millions of people worldwide are affected by serious neurological diseases or injuries, for which there are few, and often no treatments capable of curing, delaying or reversing symptoms, or preventing major disabilities. With the growing diffusion of artificial intelligence (AI), data science, big data and digital health, the collection of data and biological samples is receiving increasing attention. This raises legal and ethical concerns regarding its use, storage and dissemination. In parallel, the expansion of biobanking, from the basic collection of frozen specimens to the virtual biobanks of specimens and associated data that exist today, has given a revolutionary potential on healthcare systems [1], particularly in the field of neurological diseases, due to the inaccessibility of central nervous system and the need of non-invasive investigation approaches. The availability of huge amounts of data related to lifestyle, environmental, genetic, biological and medical factors from populations and individuals with different illnesses, across the stages of life, which can be collected with the help of smart technologies, raises serious considerations concerning the transparency and authorized use. Scientific research involving human individuals depends on a collaborative and productive relationship between participants, who offer their time and samples, and the teams who conduct the research. This complex relationship is based on the principles of transparency and ethics, enshrined in several national and international documents, e.g. the Declaration of Helsinki [2], which unanimously recognize the importance of research on human samples for the promotion of health, but most of all privilege individual values over possible benefits for public health or relevance to science.

In the last years, several health databases, named databanks, biobanks and imaging banks have been established with the aim of promoting biomedical progress and offer to a larger number of researchers access to data and samples, for transnational, multipurpose, and multidisciplinary research studies [3, 4]. While databases and biobanks have a barrier-free horizon, potential harm due to unauthorized use or dissemination of sensitive data, as well as cyber attacks, must be taken into account. Collections in biobanks are obtained from both patients and healthy populations, giving rise to similar concerns regarding dignity, autonomy, privacy, confidentiality and discrimination. Ethical guidance has been provided by the Taipei Declaration, which sets out guidelines on the collection, storage and use of identifiable data and biological material beyond the individual care of patients [5].

When biological samples and identifiable data obtained at the time of consent or subsequently [6] are taken for research purposes, or leftover samples are stored together with data for purposes beyond the initial ones, e.g. diagnostics or screening, all the authorizations for their use must be defined within the informed consent (IC). The General Data Protection Regulation (GDPR) [7] and the Council of Europe Recommendation on the Protection of Data relating to Health establish rules on the processing of personal data and data related to the health of individuals within the European Union (EU) [8] and also provide important guidelines regarding the IC content and format. Consent is defined as a voluntary, informed and specific agreement given by the potential donor to the donation process, including the use of biological samples for additional tests, beyond the care of the individual patient, and is provided in written form after the donor has been adequately informed about the purpose, potential risks, financing and all possible information associated with the donation [7, 8]. The request for IC may, in some cases, be considered implicit, implied or not harmful to the person if the research is conducted on residual material from routine diagnostic investigations. However, IC is considered mandatory in all research studies, which must specifically take into account the ethical respect of the individuals to whom the used biological material and data belong. This can generate multiple obstacles, which, despite the dedication of researchers and determination

of patients, can further hinder scientific progress, clinical and translational research.

Recently, some studies have evaluated the perspective of research participants in a context of potential donation of samples for research purposes, e.g. stroke genomics neurobiobanking and brain organoids, an extremely ethically-sensitive topic, since brain organoids may continue to be generated from a single biological sample for many years. Interviews have been conducted on participants and parents of pediatric patients who had previously donated biospecimens for biomedical research (related to autism spectrum disorder or adult-onset neurogenetic disease).The interviews showed that adult participants are comfortable with organoids from their cells being used after their death, while the majority of parent participants (60%) felt that their child should assume decision-making authority and be consented for continued use of their samples when they reach age 18 [9]. Focus Group Discussions (FGDs) conducted on 213 subjects, including stroke survivors, caregivers, stroke - free controls and Community Advisory Board members explored ethical issues in stroke genomics and neurobiobanking research, enlightening the need for adequate information through the consent process and receiving detailed explanation of the purpose of the research, as well as the risk and benefits associated with the use of samples obtained through the research [10]. Notwithstanding, most of these studies are surveys and interviews, which may reflect preferences and opinions, but do not evaluate the actual choice expressed and signed in the consent document. To date, there is a paucity of information on donors' specific choices, which may be expressed during consent.

In this work, our intention is to present the first data collected on attitudes of biospecimen donors of a neurological biobank toward use and sharing of samples and data, as defined by GDPR.

The purpose of this study was to evaluate the attitudes of neurological patients and healthy volunteers towards the donation of biological samples to a biobank for future research studies. Further, we analyzed preferences regarding the limitation of the use of samples as well as data, and potential implications, including employment for genetic studies, return of results and use of data from the Electronic medical record. Finally, we assessed the attitude towards sharing with institutions other than the one primarily authorized, inside or outside the European Union, supporting future collaborative research.

Methods

Subjects

The study involved a total of 1454 subjects, including 502 healthy volunteers (HV) and 952 patients with neurological disorders (NP) recruited at Santa Lucia Foundation IRCCS, Rome, Italy, during May 2020 - April 2024. Participation to biobank was proposed to every adult patient over the age of 18 who was able to give consent; moreover, informative flyers and brochures on the biobank's activity were always available for every patient and user of the hospital. Patients temporarily or permanently not able to consent, and below 18 years of age were excluded from the study. Given the nature of the subjects' population, ensuring proper communication and patient comprehension was deemed ethically crucial. The ability of subjects to give consent was determined by the individual rehabilitation plan (IRP) of the patient, which is a document that describes the care plan of the patient and includes cognitive status and the capacity to autonomously consent. The IRP is determined by expert physicians and medical equipe, including psychologists and other specialists. Data collection included medical history and demographics. Neurological diseases included stroke, multiple sclerosis, Alzheimer's disease, mild cognitive impairment, frontotemporal dementia, Parkinson's disease, traumatic brain injury, cerebrovascular diseases, brain tumors, neuropathies, amyotrophic lateral sclerosis, and others.

Pre-donation counseling

Informed consent (IC) was collected by physicians or Biobank personnel during pre-donation counseling to prevent selection bias. In this occasion the donor had the opportunity to raise questions and receive information about: structure organization, funding and mission of the biobank, storage time, researchers involved in the project, policy for data protection, procedures for pseudonymisation, processing and dissemination of personal data, possibility of communication about unusual or abnormal test results, transfer of samples or data to other institutes, in accordance with the national policies and GDPR. Both pre-counselling and donation were executed following standardized procedures. Moreover, when filling out the survey, every question was followed by an explanation in simpler terms of the procedures and tests to be carried out. For example, the question ''Do you authorize the use of samples for genetic studies?" was followed by a brief explanation regarding the type of studies, for example screening for potential risk factors, excluding any biotechnological applications.

As for the production of the IC, the questions were developed in collaboration with the Data Protection Office (DPO), in accordance to European guidelines [8] and GDPR [7], as already published (4). Also, the paper option was preferred instead of a digital IC as patients with physical limitations such as upper paralysis could better make use of it. Further, all individuals were informed about the blood collection process and potential adverse reactions, as well as tests and procedures to be performed on the donated samples.

Informed consent

The IC consists of two parts, for a total of seven questions, and allows for dichotomic answers (yes/no) to be provided for each one. The first part, called "Informed Consent" itself, includes the authorization to participate in the Biobank by donating biological samples for future research purposes. In particular, the participation in the biobank consists of blood collection and separation of its derivatives: serum, plasma and peripheral blood mononuclear cells (PBMC). In some cases, other non-blood body fluids (urine and feces) may also be collected. The second part, called "Consent to data treatment and use of the biological sample" regards the authorization to (i) data treatment; (ii) use of samples for genetic studies; (iii) return of potential research results and mode of communication; (iv) transfer of samples/data to third parties in European Union (EU) and (v) outside EU; (vi) use of additional health data from the electronic medical records (EMRs). As of 2024 EMR development in Italy is ongoing and presents a heterogeneous distribution across the country depending on the regional health-care system [11].

Statistical analysis

The authors evaluated the answers registered in the "Informed Consent" and in the "Consent to data treatment and use of biological sample" of all HV and NP enrolled. The descriptive statistics, presented as counts and percentages, were employed to characterize the attitudes of both groups towards the specific authorizations. The chi-square test was used to assess for any significant associations or differences among the variables under investigation.

Ethics approval

The study was performed in agreement with ethical principles of the Declaration of Helsinki. The Santa Lucia Foundation Biobank project has been approved by the Santa Lucia Foundation Ethic Committee (CE/PROG.796 04-12-19).

Results

During the assessed period, a total of 1454 individuals were included in the study: 502 healthy volunteers (HV, 62.4% female) and 952 patients with neurological disabilities (NP, 47.6% female). Excluding those who denied the consent to biobanking, the choices of a total of 1,410 donors have been evaluated.

Attitudes towards biobanking

During the pre-donation counseling, we evaluated the awareness and attitudes of participants regarding the donation of biological samples for biobanking and future research purposes.

First, we involved a population of 502 consecutive HV, who had blood collected for diagnostic or screening purposes, and we asked them whether they would like to participate in biobanking. Participation included the collection of additional blood samples and authorization to data treatment, explaining that any refusal would have no consequence on any treatment and clinical assistance. Most of them (n=458/502, 91.2%, 62.7% female) gave free consent, only a small number denied (59.1% female), mainly due to fear of phlebotomy or a concern about privacy. Since consent was optional and freely given, the authors decided to suspend the signature for those subjects who denied consent, to minimize the amount of data collected, according to the principle of data minimization[7] and to avoid individuals having to sign a refusal document. Accordingly, in the patient group, consent was not collected from those who denied participation in the biobank. Excluding those who denied the consent, 1410 participants were enrolled and underwent blood sampling on the same day or within a week from consent. No patients had adverse events from the blood draw. Additional urine and feces samples were collected from a subgroup of patients (n=63), who were specifically enrolled for ongoing research studies.

Attitudes towards using of sample for genetic research

All participants were asked for permission to use a part of their samples for research by using cytogenetic and molecular genetic techniques, including the investigation of new potential risk factors. The response was free and optional, not linked to the other authorizations reported in the IC, and did not preclude participation in the biobank for the other terms defined therein.

When we asked if a part of the donated biological sample might be used for genetic research, only a minority of HV (4/458, 0.9%) and NP (16/952, 1.7) did not agree (Table 1).

Among respondents refusing permission, no gender-related differences were found between HV (p=0.599) and patients (p=0.228), nor in the overall sample (p=0.498).

Attitudes towards returning of clinically relevant research results

Next, we asked all participants if they wanted to be informed about possible research results. Communication of results to donors generally includes genetic predisposition to disease, or the discovery of some kind of novel treatment or preventive intervention, which could be of potential interest to the donor/patient or their families.

We found a highly significant difference between the group of HV and patients regarding the wish of return of results. In particular, HV highly preferred not being

Table 1 Choices of volunteers and patients regarding limitations on use, transfer of data and biological samples and return of results

	Healthy Volunteers (HV)			Neurological Patients (NP)			Total		
	Males	**Females**	**Total HV**	**Males**	**Females**	**Total NP**	**Males**	**Females**	**Total**
Total population	171 (37.3)	287 (62.7)	458 (32.5)	499 (52.4)	453 (47.6)	952 (67.5)	670 (47.5)	740 (52.5)	1410 (100)
Among subjects who denied consent	n (% HV refusing)	n (% HV refusing)	n (% total HV)	n (% NP refusing)	n (% NP refusing)	n (% total NP)	n (% refusing)	n (% refusing)	n (% total)
Refused use of samples for genetic studies	2 (50)	2 (50)	4 (0.9)	6 (37.5)	10 (62.5)	16 (1.7)	8 (40)	12 (60)	20 (1.4)
Refused being informed about potential research results	78 (39.6)	119 (60.4)	197 (43)°	60 (55.6)	48 (44.4)	108 (11.3)°	138 (45.2)	167 (54.8)	305 (21.6)
Refused potential transfer of samples and/or data to third parties in Europe	5 (23.8)	16 (76.2)	21 (4.6)	35 (55.6)	28 (44.4)	63 (6.6)	40 (47.6)	44 (52.4)	84 (6)
Refused potential transfer of samples and/or data to third parties outside Europe	7 (20.6)*	27 (79.4)*	34 (7.4)°	60 (58.8)	42 (41.2)	102 (10.7)°	67 (49.3)	69 (50.7)	136 (9.6)
Refused giving access to electronic medical records (EMRs)	NA	NA	NA	3 (30)	7 (70)	10 (1.1)	3 (30)	7 (70)	10 (0.7)

* significant difference between males and females with $p<0.05$

° significant difference between HV and NP with $p<0.05$

informed of research results, compared to patients (HV: 43%; NP: 11.3%; $p<0.0001$)(Fig. 1).

No differences by sex were observed in terms of consent refusal percentages, neither among HV ($p=0.385$), nor among patients ($p=0.488$), nor in the overall sample ($p=0.369$).

When donors wished to know potential test results, personal contacts (telephone number, email, etc.) were recorded. For those who did not want to know potential test results, personal contacts were not collected. This did not compromise participation in the biobank, nor affected other choices within the consent.

Attitudes towards sharing within and outside EU

The GDPR sets rules on the processing of personal data and data concerning health for individuals within and outside the European Union (EU), but different regulations may be adopted in other countries. Therefore, we asked donors for authorization to transfer their samples and/or data to other research institutes, both within the EU or non-EU countries. Only a minority did not consent to sharing to third parties within EU (HV: 4.6%; NP: 6.6%) (Table 1), whereas we found NP significantly were most likely to not allow transfer to extra EU countries (HV7.4%; NP: 10.7%; $p=0.050$) (Fig. 1).

Amongst respondents not consenting to data sharing in EU countries, we found no sex-related differences (NP: $p=0.606$; HV: $p=0.190$), while among HV, women significantly preferred to limit sharing with non-EU countries ($p=0.036$) (Fig. 2); no such gender differences were observed in the patients' group ($p=0.170$).

Attitudes towards using data from medical records

All patients were asked for consent to use data from the EMR for the biobank database, which can lead to potential sharing with other researchers in other institutions. Among patients, only ten of 952 denied consent (1.1%). This option was not given to HV, as they did not have an EMR. No sex differences were observed in terms of consent refusal percentages ($p=0.154$).

Discussion

Collecting consent for the donation of material for research purposes is crucial for biobanking and biomedical research studies that use biological material of human origin. Different interests come together in consent: on one hand the researcher prefers wide availability of use and sharing of the material; on the other the donor must receive all the necessary information and be free to decide on the use and limitations, according to the requirements established by the GDPR. Here, we focus on the choices of patients with neurological diseases and donors who decide to participate in the neurological biobank.

A significant body of literature focuses on donor perspectives regarding biobanking, attitudes to participating, sharing, etc. However, most studies are conducted on data obtained using focus groups and/or telephone surveys as sources. These tools are very useful for reaching a large number of heterogeneous individuals from different centers, but nevertheless they reflect general personal opinions of the interviewers and do not represent official documents where a choice about one's future is required, even though informed consent is by definition dynamic, modifiable and revocable over time.

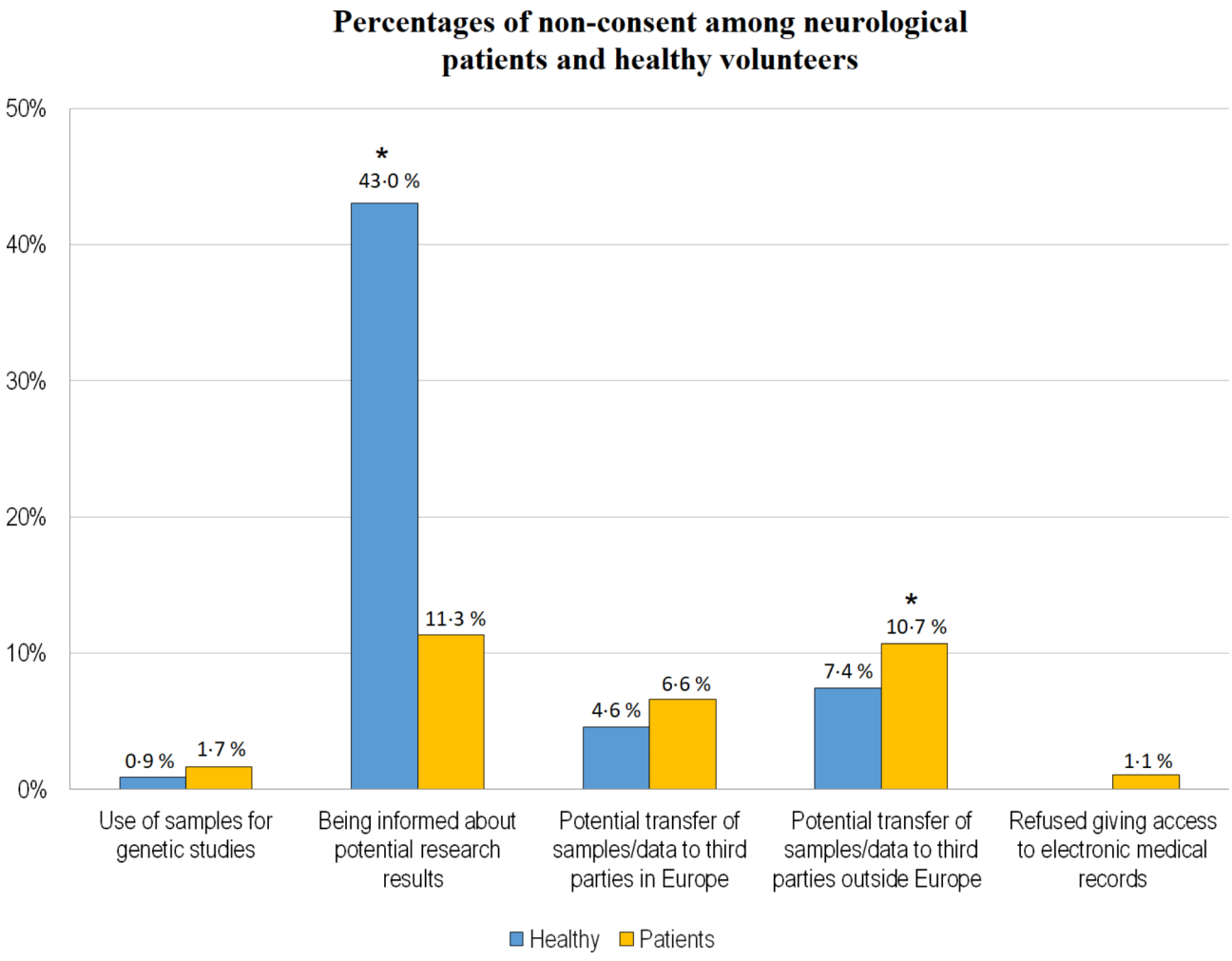

Fig. 1 Relative frequencies of non-consent among neurological patients and healthy volunteers
* significant difference between neurological patients and healthy volunteers ($p < 0.05$)

Because of the increasing access to high volumes of data through EMR, laboratory information systems, digital applications, etc., the promises and expectations related to data science and AI are growing exponentially [12–14], along with the risks of unauthorized or uncontrolled use, as well as cyber attacks and data leaks [15]. Such possible threats could affect the perception of patients and donors regarding the research conducted on data and biological samples, therefore hampering the donation of biological material, data use and sharing. In our study, we analyzed the participation of 1410 donors and patients in biobanking and the choices about limitations on the use of biological material and data for research purposes. In the discussion, we will put our findings for each of the subdecisions participants have to make in light of the existing literature. Firstly, we recruited a population of 502 healthy volunteers, who underwent blood collection for other diagnostic or screening purposes, by asking them to participate in biobanking. Almost all volunteers (91.2%, $n=458/502$) gave consent and therefore additional sample collection was performed to store for future research studies, while only a small number of volunteers (8.8%) denied. Our results confirm that participation in the biobank is generally well accepted by the population. This is in accordance with results of previous studies, which have investigated the knowledge and perception about biobanks and their associated activities [16]. Recently, a survey of 17,758 students and personnel of an Italian University reported that people recognize the importance of research biobank activities for the progress of biomedical research. Results also showed a remarkable will of the donors to provide biological samples to biobanks for research activity in order to contribute to scientific research, increase in knowledge in science for future generations, out of a sense of duty. Mostly, participants stated that the benefits of biomedical research far outweigh the risks [17]. In many cases, however, individuals also think that biobanks should offer benefits to donors, namely information on

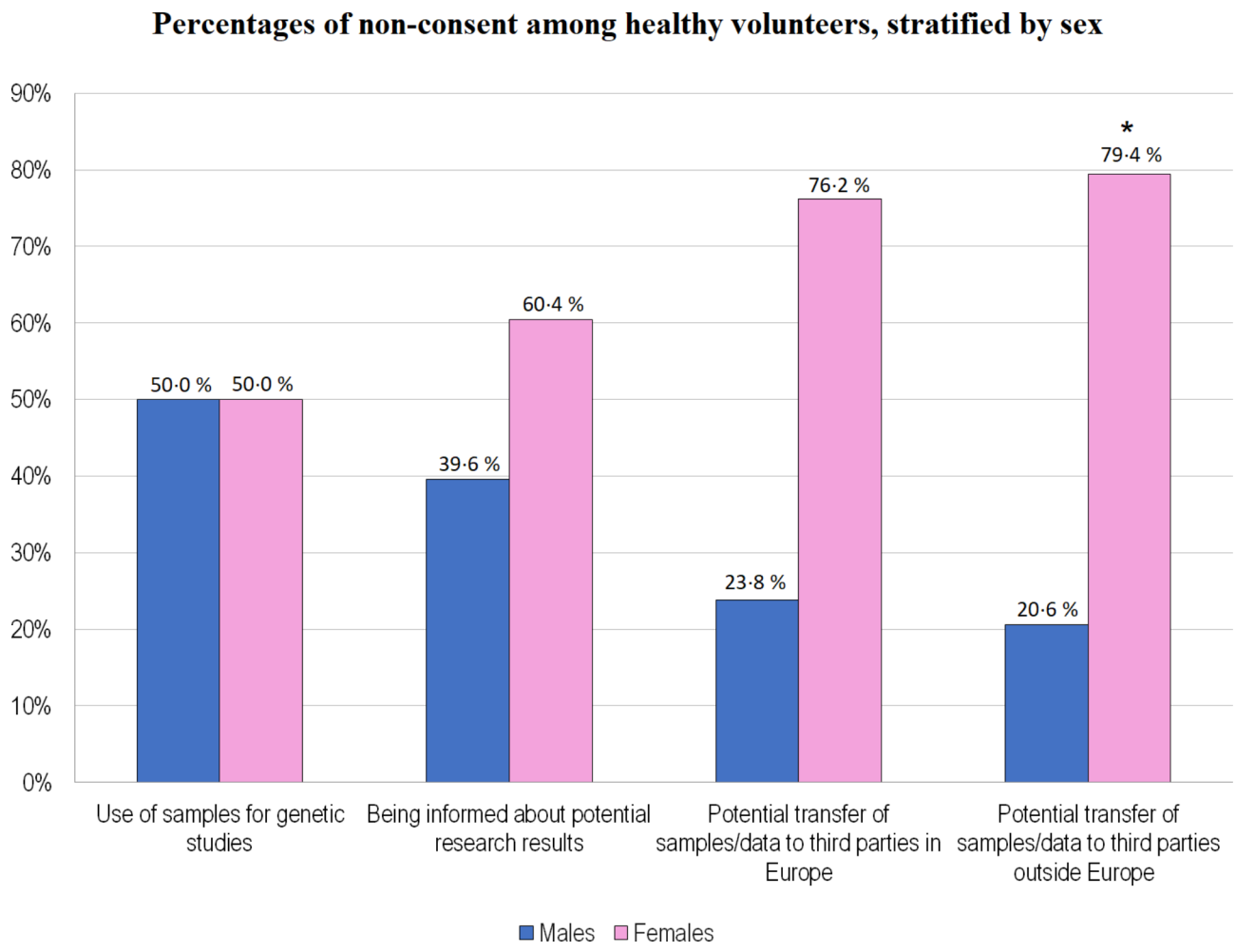

Fig. 2 Relative frequencies of non-consent among healthy volunteers
* significant difference between female and male among healthy volunteers ($p < 0.05$)

blood and metabolite concentrations (e.g. cholesterol), and other health risks [17].

Secondly, we assessed whether HV or NP were likely to set specific restrictions regarding the use and sharing of specimens and data. Although almost all participants answered positively to each posed question, a number showed different preferences with respect to specific authorizations, particularly for the employment in genetic studies, return of results, and sharing, with percentages ranging between 1.1 and 10.7%. This may have implications for those multicenter-research projects that involve human subjects, that focus on the importance of recruitment and limitations in the use of data and biological samples in scientific research. Generally, this selective consenting does not represent a drawback for researchers, whereas it constitutes the premise for a long and lasting cooperation, where the single individuals, willing to donate their biological specimen, define the limits in which they can be used, shared or transferred to keep the right to modify and to update the data, or even to revoke their consent at any time [4]. While the use of pseudonymized personal data is essential for all research activities, in some cases it is pivotal to have identifiable and patient-specific data, especially for those research studies that require long-term follow-up of patient results for a specific pathology or following a particular treatment/intervention [18]. Notwithstanding, a big issue is how to manage genetic information on disease susceptibility that comes from research projects in which donors were not informed in advance of the possibility of return of the results [19].

Third, we assessed donors' preferences regarding the return of research results. Addressing privacy and security in digital development involves careful consideration of which data are collected and how they are acquired, used, stored, and shared [20]. Although the literature often indicates that knowing one's health and risk status is a relevant incentive for participating in research, we found about 43% of HV prefer not to be informed about research results. This may be partly explained

by the fact that the Santa Lucia Foundation biobank is focused on neurological diseases, and therefore donors may be scared of receiving results with a potential negative impact on their future, e.g. the risk of developing a neurodegenerative disease. This is in agreement with the results of a survey conducted among individuals previously screened for major depressive disorder, which showed that the large majority of respondents declared they would agree to the potential collection and use of their biological samples for biomedical research purposes only if no feedback results regarding their health or predisposition to any diseases would be given to them [21]. Thus it is crucial to reflect on the potential risks of data disclosure, and on the proper and responsible method of offering individual research results. Indeed, returning the results individually to the participants may result in different outcomes [22]. For instance, subjects could receive potentially life-saving information on rare genetic mutations or conditions that were unknown before sample submission, and at the same time end up being exposed to economic harm, stress, discrimination and social alienation derived from said pathologies. It is therefore essential to define contextual and evidence-based guidance to support the implementation of ethical approaches to return individual results, in order to mitigate the impact of the absence of legal protections against damages resulting from wrong management of the return of the results [23].

Oppositely, patients highly require the return of potentially useful results, but rather prefer limiting sharing of their specimen and data. Participants' demand for research results is driven not just by the potential benefits that individuals could gain by learning about clinically actionable information, but also by their desire to learn about themselves from information that they would not otherwise have access to, for example about prevention of disease and risk factors. However, more specific guidelines are needed on which results should be reported, based on clinical significance, and how stakeholders should consider the benefits or risks, and finally the costs associated with returning, including the broad spectrum of results that may not be accurate, medically actionable, or have clear meaning [24]. The introduction of sophisticated technologies, such as databases containing genotypic and phenotypic information, laboratory tests and imaging, and growing platforms for data sharing among national and international institutions have raised new questions regarding how best to inform and protect the participants of research.

Fourth, we evaluated the choices regarding data and sample sharing. In our study, both HV as well as NP generally agree with supporting collaborative research by data and specimen sharing, even if a significant difference was observed among patients regarding Extra EU countries. Recently, the institution of a European Health Union, with a European Health Data Space (EHDS) has been under development with the aim to define rules, common standards and practices, and infrastructures for empowering individuals through increased digital access to and control of their electronic personal health data, at national level and EU-wide. In fact, the implications of sharing medical data on a continental level requires careful and calibrated communication with the donating subjects. Patients need to clearly understand the use of their data and samples, especially if it happens in another country, and to do so the IC needs to reflect these issues [25].

Fifth, we evaluated the attitudes of patients in allowing the use of EMR as an additional source of data, and we found only 1.1% of patients denied permission. The high patient participation may be explained by the individuals' expectation that the study in which they participate will contribute to improving the state of medical knowledge. Although some information is usually collected directly by the physician or researcher via a medical history questionnaire, most health information is contained in the EMR, which can be created, collected and accessed by authorized physicians and staff within the healthcare organization. In the future, there is a great expectation that the use of data from the EMR will strongly improve the quality and quantity of health data for each subject, and so the potential use for large-scale studies by applying high throughput technologies, omics sciences and big data [13, 25], to investigate the impact modifiable factors on development of neurodegenerative diseases [26] or to predict the outcome after traumatic or vascular events [27–30].

To our knowledge, our analysis conducted on a large number of individuals presents for the first time, how the preferences of patients and healthy volunteers are aligned with GDPR requirements on informed consent in biobanking of their specimens, and how this affects the impact of their consent on research and donation. Our results are consistent with the literature, demonstrating that many individuals are willing to participate in biobanking and give consent for future use in research [30] and show a broad consensus for use and sharing, except for extra-EU transfer.

The study has some limitations, mainly because it was conducted in a single center, in a disease-specific biobank, which may limit the generalizability of the results. However, the study addresses essential GDPR issues that reflect patient and donor attitudes towards sharing and collaborative research. This is of great importance as it highlights the value of IC as a tool to clearly define the authorization to use and share data and biological samples, thus avoiding the risk of considering IC indiscriminately. Several networks of biobanks have been

established for standardization and sharing of methods and results. This paves the way for future studies to be conducted to assess donors choices regarding treatment authorization in a larger population.

Conclusion

Consent for the donation of material for research purposes is crucial for biobanking and biomedical research studies that use biological material of human origin. Here, we focus on the choices of patients with neurological diseases and donors who decide to participate in the neurological biobank.

We have shown that choices regarding participation ina neurological biobank and authorizations for the processing of data and samples can be different between donors and patients affected by neurological diseases, even if the benefit for research and scientific progress is recognized.

Our data suggest that (i) participation in a neurological biobank is generally well accepted by the population; (ii) HVs and NPs agree with use of samples for genetic studies; (iii)NPs have a strong interest in being informed of possible results, unlike healthy donors; (iv) HVs authorize a wide dissemination and sharing of data, while NPs limit sharing outside the EU community. We could identify a perception of greater individual or relative benefit in NPs, while HVs prefer wide dissemination and not to have the return of the results, favoring a possible benefit for society and knowledge. The results of our study underline the complexity of managing biological material and data collected in biobanks, in compliance with the GDPR and the specific requests of donors.

Abbreviations

AI	Artificial intelligence
EMR	Electronic medical records
EU	European Union
GDPR	General Data Protection Regulation
HV	Healthy volunteers
IC	Informed consent NP: neurological disease patient

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Author contributions

GS, Conceptualization, Methodology, Formal analysis, Investigation, Writing – original draft, Visualization, Project administration, EG, Conceptualization, Methodology, Data collection and analysis, writing–review & editing: SDS statistical analysis, review & editing; JMB Methodology, Formal analysis, review & editing; SB, EC, SDF, FRF, AP, VP, GP, FS, patients enrollment, data collection, review & editing; GSc, RF, MGG, SP, DDA Conceptualization, Methodology, review & editing. All authors were responsible for the decision to submit the manuscript.

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Data availability

The data collected for the study will be made available to researchers on request. Proposals should be directed to the corresponding author, accompanied by the study protocol and analysis plan and the approval by a committee of the current research. Data will be shared only after approval of the proposal by the Biobank Scientific Committee. The shared data will be de-identified participant data.

Declarations

Ethics approval and consent to participate

The Santa Lucia Foundation Neurological Biobank has been approved by the Santa Lucia Foundation Ethic Committee (CE/PROG.796 04-12-19). Informed consent to participate was obtained from all of the participants in the study.

Patient consent for publication

Not applicable.

Competing interests

SP received payment for manuscript writing from Ipsen and payment for lectures and presentations from Lundbeck. GS holds a leading role in Chair Working Group on Cerebrospinal Fluid–Italian Society of Clinical Chemistry – Laboratory Medicine (unpaid). All other authors declare no competing interests. All authors have completed the ICMJE uniform disclosure form at https://www.thelancet.com/for-authors/forms?section=icmje-coi and declare: no support from any organisation for the submitted work (except the research grants listed in funding); no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

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