Constructing the Biobank as a Health Place

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Biobanks have been established from the beginning of the millennium as relevant infrastructures to support biomedical research. These repositories have also transformed the paradigm of collecting and storing samples and associated clinical data, moving these practices from the healthcare services and research laboratories to dedicated services. Biobanks collect a wide range of samples such as blood, tissues removed in surgeries or biopsies, saliva, hair, teeth, and feces, among others, and these would be, in most of the cases, given by donors voluntarily aiming to contribute for the advancement of biomedical research. Regardless of their health status, every person could be a biobank donor with different attributes or functions. Biobanks store these large amounts of medical information and biological samples collected in healthcare services to be used in biomedical research. These two contexts—healthcare services and research laboratories—have a significant role in determining the chain of procedures through which samples are collected and organized.

Keywords: biobank ; health ; human biological samples ; biomedical research ; ethnography ; caring practices ; illness narratives ; Portugal (study context)

1. Introduction

1.1. Setting the Scene for the Emergence of Biobanks for Health and Biomedical Research

Medicine has always made use of bodies and body parts for studying, teaching, and research. However, in recent decades there has been an increasing need to draw on large sets of human biological samples and produce data in a systematic way to cope with the growing needs of biomedical research.

In order to understand these changes, it might be worth reflecting on the work of Clarke et al. ^[1]. The authors argued that the turn into biomedicine and biomedicalization was due to a number of transformations that have marked the way of performing, learning, and presenting medicine. In the name of health, life has become an object and an end in itself ^{[1][2]}. These transformations were connected mostly to technological developments, such as the appearance of powerful computers and informatics. Computer technology has facilitated the collection and the use of larger amounts of data and the refinement of statistics applied to life sciences. Although these changes began to insinuate themselves after World War II, it is possible to recognize several initiatives of considerable scales, such as the end of the 20th century that this way of investigating and producing medical-scientific knowledge gained greater visibility through the Human Genome Project. For this reason, it was after this moment that the appearance of more and larger repositories of biological samples to support the intensification of this form of research was rendered more evident. Current research uses large amounts of systematic information, aggregated in databases, as a way to ensure the robustness of scientific evidence in biomedicine and requires an increased storage capacity, both samples and information, requiring technological devices that allow accessing and managing these data ^[3]. Moreover, it stresses the biological understanding of the disease processes by applying the logic of biology to medical research.

However, the approximation of Medicine to Biology, which had already been hinting since the beginning of the 19th century, had become more evident through the sharing of the laboratory ^[4]. In this line, Jewson ^[5] noted that people were no longer the object of medicine; however, the human body has maintained its value as a resource for developing medical knowledge. The influence of Biology progressively extends to language and the way of investigating the body ^[6]. Against this backdrop, the use of data science becomes more recurrent, as biology has also come to incorporate an important strand of biostatistics and bioinformatics ^[Z]. Statistics as a source of scientific knowledge had already been used in medicine since the early 18th century by collecting information about the state of populations ^{[8][9]}. This was even more pronounced in the transition to biomedicine, which brought with it the normality of the body based on statistics. Statistics are produced by comparison with the population considered healthy ^[9], becoming criteria for defining disease status ^[10]. The *medical gaze* ^[11] is now transformed, in the words of Rose ^[12], into a *molecular gaze*. As noted by Sharp ^[13], the

increased claims for body parts by biomedical researchers contribute to the fragmentation of the medicalized body and, at the same time, promote their commodification. Thus, body parts, namely human biological samples, are still quite useful for the study of physiology and cellular mechanisms, helping to understand disease in biomedical research. The body is, in this paradigm, seen as a complex organization of molecules to be studied. In some cases, genetic testing (both in clinical contexts and self-performed, e.g., direct-to-consumer tests) is defining new ways of dealing with one's body and disease [14], reconstructing self-identity [15], and even mediating the relationship between the nation state and citizens [16] [17][18].

Another important transformation of medical research within this period, signaled by Rose ^[12], was the emergence of nonmedical research professionals conducting research in life sciences. This approach to the life sciences implied an integration of knowledge from other scientific areas and the incorporation of research practices that were not so common in medical practice until then. In this line, the crescent specialization of biobanks is seen by the construction of a specific body of knowledge reflected in scientific articles dedicated to the topic, a scientific journal dedicated to biobanks, and best practices in samples' preservation is a recurring theme at biobanks conferences.

This changing paradigm of biomedical research set the scene for the emergence of greater repositories of samples and clinical data. Biobanks such as deCODE in Iceland and the UK Biobank in the United Kingdom were two big biobanks storing millions of biological samples and clinical data. The appearance of networks such as BBMRI-ERIC (*Biobanking and Biomolecular Resources Research Infrastructure—European Research Infrastructure Consortium*) at the European level that gathers biobanks from all over Europe are also signals of the recent developments in this field.

1.2. The Emergence of Portuguese Biobanks

In Portugal, biobanks are in their early stages. In 2021, there were 16 initiatives: some of them were already in place, and others were just an intention to open a biobank in the near future. Organizing a biobank demands a wide range of resources alongside institutional support. Nevertheless, the low level of recognition of biobanks within the scientific community makes biobanks to be projected by small teams of researchers or medical doctors that mobilize their own resources to organize their own biobanks. Although the growth of initiatives possibly points to a crescent recognition, the existent biobanks are still underused by researchers. In many cases, there is no solid institutional support or a strategic mission that informs the constitution of a new biobank. The absence of a legal framework or a national strategy for biobanks is also problematic—not only because their scope of action is unclear but also because it limits their development. Since biobanks are neither a research project nor a research institution, nor are they considered a health service, they cannot benefit from grants or apply for the more common funding opportunities in the field of healthcare ^[19]. The lack of specific funding has been seen as a lack of investment in health research. To date, there are some fragmented strategies to stimulate healthcare research, but there has never been a true scientific health research policy in Portugal ^[20].

In the last 30 years, health research in Portugal has had an impulse through the establishment of relevant research institutions that try to settle upon the intersection of medicine and fundamental research. However, this is a recent and circumscribed phenomenon, and its impact is not yet visible in the biobanks landscape. The investment in health research is poor, with the Health Authorities recognizing the low level of interest in health research ^[21]. This opened the way for life sciences researchers to develop their research in the health domain. In 2010, it was already clear that doctoral and post-doctoral scholarships in the field of medical and health sciences have come to value mainly biomedical research, where there is no involvement of patients ^[22].

The management of the biobank itself demands knowledge of laboratory procedures and is mainly carried out by technicians with training in life sciences, and not so much by doctors since many of them do not have the knowledge to operate at this level. This fact is noteworthy since if, on the one hand, doctors seem to be increasingly distant from laboratory research, on the other hand, they still hold leadership positions in these infrastructures ^[19].

Doctors are still indispensable when it comes to collecting samples through the recruitment of donors. Additionally, considering the legal framework into force that might relate to collecting samples for research ^[23], only medical doctors could request samples to be used in clinical research. Medical doctors still have a relevant presence in Portuguese society, and they are considered authorities when it comes to health matters ^[24]. Interestingly, this fact is in line with the expectations of Portuguese citizens reported by Gaskell et al. ^[25], where 45% place the physician as being an adequate person responsible for protecting the public interest in this field (the highest value of the 27 countries surveyed), followed by researchers (13.2%).

In 2018, there was an attempt to produce an updated legal framework for biomedical research, where biobanks could be included and where the most relevant funding agency in Portugal excluded biobanks from its scope of activities, pushing biobanks to the jurisdiction of health authorities. The bill did not come into force; however, these discussions among the possible authorities in charge of biobanks illustrate how difficult it has been to define the domain to which biobanks belong.

Despite these difficulties, some biobank projects have succeeded. However, the heterogenous nature of local and national-level initiatives, and the profusion of actors with changing roles and interests, make it difficult to understand what the biobank attributions are.

2. A Medical Framework to Classify Samples

Biobank staff was responsible for the organization and storage of samples. In this regard, classifications recurring to health and illness frameworks were common and central to the work organization. Other management decisions, such as the ones concerning the quality of the samples, the samples to be discarded due to technical conditions, or decisions about sample viability, only depend on the biobank staff's judgment. Samples could, for example, be labeled as infected, diseased, or healthy.

Biological samples were classified according to the part of the body from which they are taken: a bladder, a kidney, a testicle, a carotid artery, a synovial membrane, even if the sample is only part of these organs or anatomical structures. In other cases, they are DNA, RNA, tumors, and cells, according to their typology. These simple classifications reveal different classification systems—some favoring body anatomy, more frequently used in the healthcare sphere, while others are more commonly used in the laboratory sphere. The imposition of reasonably stabilized classification grids also rendered the donor's body into a sample object, which is simpler and easier to manage.

In the day-to-day work, questions about the nature of the samples arise: alive, dead, animal, human, healthy, sick, infected, or not infected are classifications that arise with a certain regularity and that are determinant in or determined by the daily practices of the Biobank. These classifications are, for the most part, changeable and not always obvious. Their complexity is, in many cases, interconnected with essential categories such as dead/living, mortal/immortal, animal/human, or even infected/non-infected, stable/unstable, visible/invisible, healthy/sick. These sets, which apparently constitute opposites, are commonly used in day-to-day life, and throughout the ethnographic observation, it became more evident that they were not necessarily configured as opposing poles but could even coexist in the same sample or in the same reality. This complexity of classifications and articulations also refers to the symbolic domain of the body, to a set of other possibilities that are being created through the biological samples ^{[2][26]}. Sometimes the classification of biological samples is clearly determined by the donor; sometimes, it is determined by the analysis of the biological sample itself and its use.

Infected and non-infected is an obvious example of categorization of biological samples, determined a priori by the infected or non-infected status of the donor and imply the medical definition of infection. The classification regarding the infection of the sample is perhaps one of the most obvious and has a direct impact on the processing of biological samples at the Biobank. This classification precedes the entry of the biological sample into the Biobank and is determined by the patient's laboratory tests and then conveyed by the physician. An infected sample designates, in a very general way, samples that may carry in themselves the potential of infecting laboratory technicians in their manipulation, which may lead to the contraction of a certain disease. Thus, biological samples from patients with HIV and hepatitis are considered in this group of infected biological samples. This classification does not depend on systematic verification. Some health services tend to have more patients with these pathologies are unknown, the sample is not classified as infected. Therefore, the infection status of the biological sample is not always known to the techniques at the time of entry into the biobank.

On these occasions, the work of the Biobank is completely determined by the categorization attributed in the clinical context to the biological samples. In these circumstances, the encounter with the physician is determinant in the definition of these categories ^{[27][28]}. Infection is not macroscopically visible and is not always implicated in disease pathology; therefore, it is necessary to rely on the assessment that is performed in a medical context, admitting that it is not always possible to be in possession of such knowledge.

The contact with biological products, either by spilling fluids or by cutting with the same blade that has already been used in the manipulation of biological material, exposes the Biobank staff to risk, bringing them momentarily closer to the patient's bodily reality.

Another essential category in everyday life is whether the sample is precisely "healthy or diseased". Although this category refers primarily to the status of the donor, it is commonly used to refer to biological samples—a healthy sample is a frequent terminology.

In the health care context, only samples from patients are collected, whereas on days organized by the Biobank, samples are collected from *healthy* people. This option is often called into question as the health status of the healthy is often corrupted with various pathologies.

"We ask the responsible researcher what kind of control he wants, and they give us the criteria of what is healthy for them. Usually, the ones that are healthy are the ones that don't have the disease under study." Biobank technician, Fieldnotes.

The categorization of healthy or sick seems to refer more to the comparative function that certain biological samples may play in scientific research. Moreover, underlying this classification is the place where the biological sample is collected. If the sample is collected in health care units, it is considered a patient sample, and it is included in collections dedicated to certain projects. If, on the contrary, the biological sample is collected as part of an action for the dissemination and promotion of the Biobank, as happens in the aforementioned open days, that sample is considered healthy. Moreover, it sometimes happens that the declaration of healthy is contradictory to what is considered "healthy" at the laboratory level, reminding researchers that there are several ways to materialize the disease ^[29].

"Look, it was a sample that came supposedly from a healthy control and when I went to do the cell count, there were almost none. That person couldn't be healthy." Fieldnotes.

The healthy and diseased category is often decided a priori, usually not depending on a laboratory analysis for diagnosis or for assignment of such category. Thus, donors who come into contact with the Biobank on open days are naturally integrated into the sample collection of "healthy controls". There is no prerequisite in this case except wanting to donate the biological sample. Various categories are assigned using a medical classification system, which often includes the samples in collections with the name of the pathology "they carry". The medical categories are then transported to the laboratory, and there is not necessarily an immediate or direct correspondence in the classification that is assigned in the Biobank. It should also be added that these categories are not necessarily stable, being regularly redefined in the process of laboratory treatment of the biological samples. Even if the sample is subject to unforeseen conditions, it may still meet the criteria to be used in another way.

Even technical procedures carry medical categories. For example, the implemented system of color classification, with the goal of quickly identifying to which biobank collection a particular sample belongs when opening the freezers. The colored caps of cryogenic tubes indicate, e.g., red for cardiac pathology, black for cirrhosis, transparent for healthy donors, orange for tumors, etc. This is also referred to by Palmer ^[30] as a way of objectification; it was crystallized in the idea expressed by a journalist who visited the biobank in the news headline "In the biobank, diseases have the colors of the rainbow" (published on 14th October 2017, in a widely read Portuguese newspaper). The metaphor continued throughout the text, enforcing the idea of the absence of the donor and the diseases as being relevant subjects. These classifications enabled a link between health and illness context; additionally, they reduced the multidimensional aspects of the ill-health status of the donor.

The categorization of biological samples often carries the categories assigned to donors, such as infected or non-infected. In other cases, the classifications assigned to the donor and to the sample may be dependent or independent, displaying the donor and sample against each other in the coincidence or mismatch of the categories assigned. Medical categories are thus essential to classify and organize not only samples but to define the work in the biobank.

3. Constructing Biological Samples Identities as Being Human

The collection of samples to the biobank regularly encompasses three moments—harvesting, storing, and distributing the samples to biomedical research—around which the biobanking activities are organized. The identity of samples is therefore constructed while they are progressing through this path. The construction of the samples' identity was a constant process of negotiation, and biobank technicians played a relevant role in performing this negotiation in different situations.

The sample collection was additionally accompanied by a collection of lifestyle and clinical data. Usually, medical doctors collect clinical data during medical appointments or pre-surgery procedures. Then, the biobank technicians would pick the samples and clinical data survey, and the informed consent form at the hospital. The biobank staff was rarely responsible for the data and sample collection. They were, in all circumstances, responsible for managing data and samples in the biobank space. When the samples entered the biobank, they needed to be organized and added to the computer system. Both data and samples were collected together, although they entered two different sectors in the biobank software, and the connection between the donor and the samples started to disappear.

Although the linkage between samples and the donor could be replaced, it was partially destroyed at the moment biobank staff entered sample data and donor data into the software. Additionally, pseudonymization was another essential process to silence the connection between donor and data (sample and personal/lifestyle information). The link could only be restored in case the donor asks for withdrawal or if researchers need more data and the donor has consented to be recontacted in this regard. Right before they were no longer identifiable, biobank technicians have the last opportunity to connect the sample to the donor they did not meet, avoiding immediately transforming the sample into an object. Right before they were no longer identifiable, biobank technicians have the sample to the donor the donor they did not meet, then refusing immediately transform the sample into an object.

During a technical procedure of processing samples, one technician says to another: "This cannot be like that, please cover the "ruizinho" [allusion to the donor's real name] otherwise he will get a cold." Fieldnotes.

Not only does the origin of the biological sample seem to be difficult to forget [30], but also the links to the original donor should not be forgotten, although the process of pseudonymization is about to happen. In all the cases, samples were considered to be objects but from a special kind:

"I do think it is humanization in the sense of transformation that sample in a human thing". Senior Researcher, interview.

After samples were processed and stored in the biobank were mentioned as *work material* for researchers. Furthermore, from this moment on, sample management entered a field ruled by principal investigators and medical doctors. Researchers and medical doctors were the ones deciding in which collection the samples were going to be included, in what research they were going to be used and with which researcher samples could be shared, and under which specific conditions. While the Portuguese Legal Framework ^[23] defines donors as the owners of the biological material, they were no longer responsible for the usage of the sample after they entered the biobanking circuits (unless they desired to withdraw the sample and data). Giving back the property of the samples was also something recalling for the donor—and was not only because it is enforced by law to obtain donor informed consent but also because it was embedded in technician discourses as being the natural and obvious thing to do.

To classify the tissue and cell status, biobank technicians evaluate whether the cells are viable or non-viable and which biological samples could be considered alive or dead. These classifications enable the decision about the quality of samples, type of storage, or type of laboratory analyses that could be performed. The classification relies exclusively on biological material analysis and works apart from donor status. Therefore, biological samples and donors could have different classifications, somewhat ensuring their separation as different entities.

The transformation of samples into human objects was particularly evident when denying samples of possible animal nature. This issue was central in the negotiations of samples' humanness. In some particular cases, such as the case of feces-microbiome preservation, the boundary between two categories was made clear, however allowing the combination of both natures in one entity at the same time.

"The problem is that microbiome has human and microbial material, that's why we need to ask two different entities for allowing us to store feces." Biobank technical supervisor, fieldnotes.

Metzler and Webster ^[31] mentioned the tendency to consider these entities as human subjects even though their boundaries could be difficult to be considered an asset. If in the precise situation of the microbiome, the boundaries seemed clear, usually they appeared blurred, and the human nature of samples prevails. The boundary was made obvious when the biobank workers were confronted with certain questions about the nature of the samples stored in the biobank.

"Here we only have human samples. The closest we have to animal samples are the tumors that we insert in rats and when they grow, they are removed [and kept in the biobank]. But this is still considered as human tissue.— Explained the biobank supervisor to a technician from another biobank who went for a visit." Fieldnotes.

The boundary between animal and human was again repositioned, though denying the possibility of mixing the natures of the samples again. The boundary was not that clear, but biobank-involved professionals tried, consistently, in diverse moments, to assure the biological samples were human. These biological samples seem to be what Douglas called "a matter out of place" ^[32]. In this sense, they should be forced to integrate a manageable and already existing category of objects and beings that perfectly fit the previous categorization in action. Therefore, not only the former categories were conserved, but they also enabled the removal of the particular legislation, which provided specific rules to store animal samples. Here, the legal framework does not consider both natures and to what extent these samples should be incorporated into different categories ^[33].

In addition to the constant denial of a possible animal identity of the samples or avoiding deleting the linkage between the original donor and the biological sample, there were other strategies powered in the daily routine work contributing to setting this human identity.

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