



Biobanking: A Challenge Facing Pathologists in Egypt

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Authors' contributions

This work was carried out in collaboration between all authors. Author WESAEA developed the ideas presented in the article, wrote the protocol and wrote the first draft. Author NFA revised the draft and authors SLES and MAEMB managed the literature searches. All authors read, discussed and approved the final manuscript.

Article Information

DOI: 10.9734/BJMMR/2016/21583

Editor(s):

(1) Divya Kesanakurti, Department of Cancer Biology and Pharmacology, University of Illinois College of Medicine, USA.

Reviewers:

(1) Anonymous, University of Florence, Italy.

(2) Anonymous, Abubakar Tafawa Balewa University, Nigeria.

(3) Sanjay K. Pandey, Awadhesh Pratap Singh University, Rewa, India.

(4) Mario Bernardo-Filho, Universidade do Estado do Rio de Janeiro, Brazil.

Complete Peer review History: <http://sciencedomain.org/review-history/12716>

Review Article

Received 24th August 2015
Accepted 1st December 2015
Published 17th December 2015

ABSTRACT

Background: Biobanking today plays a key tool in biomedical research. Establishment and proper running of biobanks in developing countries is confronted with a number of challenges of legal, ethical, and financial nature. Considering that there are no guidelines or regulations to control biobanking in Egypt; major ethical issues arise and are often managed by research ethics committees (RECs). Pathologists are the custodians of tissue samples in different universities and hospitals; they have an important role in advancement of scientific research. So, they have to equip themselves adequately to manage the evolution of pathology work towards integration of biomarker analysis in clinical research and to deal with the ethical and legal issues of biobanks in Egypt.

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Objective/Aim: The purpose of this review is to highlight the current situation of human tissue research and biobanking in Egypt with Comparative policy of other countries. We will address the role of pathologists and the difficulties and challenges facing the process of initiating biobanks and give some recommendations that might help different stakeholders for biobanking in Egypt.

Conclusion: Egypt is one of the developing countries which are in need to implement biobanks to improve the quality of research. The review highlights the different challenges facing biobanks in Egypt, mainly: lack of legislations, consent form, public trust, tissue transfer and commercialization. It also discuss the role of pathologists and research ethics committees in establishing and maintaining the work in these biobanks; and to make every effort for the interests of the participants, community and scientific progress, hopefully for good future biomedical research in Egypt.

Keywords: Tissue biobanks; research ethics; pathologists; Egypt.

1. INTRODUCTION

Written codes of ethics for doctors had existed in Egypt 3,550 years ago. There are Egyptian medical papyri (such as *Ebers* and *Smith*) that described the accepted medical practices and codes of ethics dating from about 2000 to 1090 BC. Imhotep is the earliest recorded name of a physician. When Imhotep died, he was defined as the Egyptian "God of Medicine", and later as a universal God of Medicine. He was so important to the early Egyptians that in honor they built the Temple of Imhotep, the "first hospital", and engraved his picture on the walls [1].

During the twentieth century, there were remarkable advances in medical science in relation to human tissue. For more than 100 years, tissue has been derived from human bodies, stored, distributed and used for educational and research purposes. Gradually such collections have become known under various names such as biobanks, biolibraries, tissue repositories, genetic databases, or DNA banks [2]. Pathology biobanks are vital assets for medical care and treatment of current and future patients. In association with good clinical data they are also useful for biomedical research regarding the underlying mechanisms of human disease [3]. Future studies using biobanked biospecimens should describe in detail the preanalytical handling of biospecimens and analyze and interpret the results with regard to the effects of these variables [4].

In the last decade, the number of biobanks has increased significantly. The top 6 countries according to the number of large-scale biobanks are the United Kingdom (UK), United States (US), Sweden, France, Netherlands, and Italy [5,6]. In China; hospitals and research institutes set up and operate most of the biobanks to support

clinical and scientific research [7] and in Korea; project phase II (2013–2015) is preparing a biobank accreditation program and an on-line application system for the distribution of their biospecimens to researchers [8].

While in the past, tissue collection was performed by local pathology departments dealing with local operating procedures. Tissue biobanks now work with stringent SOPs for procurement, processing, storage of annotated specimens, application of a wide range of new technologies, validation of molecular patterns of disease, stratification of patient groups for implementation of novel cellular and molecular biomarkers into clinical trials "personalized medicine" [9]. As a result, there has been the emergence of groups such as the Biobank and BioMolecular Resources Research Infrastructure (BBMRI) [10], the Public Population Project in Genomics (P3G) [11] and others. Despite these groups, difficulties in international collaboration have emerged where there are still differences in guidelines [12].

Activities in a pathology department are mainly concerned with supplying physicians with diagnoses of specimens from their patients. Pathology tests are an essential part of the healthcare system, used to aid medical practitioners in the diagnosis of disease, assist in preventive health, acute care, management of chronic conditions and more recently genetic research [13]. Recent progress in the field of molecular biology, genetics, and pathology presents extraordinary research opportunities for the better understanding of diseases, and for subsequent prevention and treatment. Much of this progress would have been impossible without access to human biological specimens and associated patient data [14].

With the growing biomedical industry, there has been a sudden increase in requirement for human tissues, both fresh and archival, for research, validation and even commercial purposes [15]. Because of several gaps in knowledge regarding the standard of operative procedures for the procurement, storage, and quality assessment of cytology specimens, further studies as well as national conferences and workshops are needed not only to create awareness but also to facilitate the use of cytopathology specimens for biobanking [16].

Often the pathology department is approached by agents from biomedical companies for requests of blocks of common cancers such as those of breast, colon and lung. These requests are put forward under the general category of "research" when actually they may be used for commercial purposes such as constructing tissue microarrays. As pathologists we must be fully aware of the exact purpose for which the tissues are used [15].

So, how is it still possible that human tissue can be rightly used for biomedical research? [17]. This article explains the role of pathologists in establishment of biobanks in Egypt, the challenges and recommendations for providing ethical framework for biobanks in Egypt.

2. CURRENT SITUATION IN EGYPT

Egyptian scientists are eager to adapt and apply the latest scientific advances to their country [18]. For the last ten years, there were increasing capacity building for research ethics and strengthen the infrastructures through the Middle East Research Ethics Training Initiative (MERETI) which was established in 2005 between Egypt and Maryland University in US and since then more than 50 Egyptian have received advanced training in Research Ethics [19].

Considering that there are no guidelines or regulations to control biobanking in Egypt; major ethical issues arise and are often managed by research ethics committees (RECs). At present, over 55 RECs are well organized in different universities and research centers in Egypt. The Egyptian Network of Research Ethics Committees (ENREC) established in 2008 to raise the harmonization between Egyptian RECs in reviewing of research proposals and to augment sharing of information and intellectual resources, policies and review strategies. Thirty-

three Egyptian RECs from different universities and institutes are members of ENREC [20].

In comparison to other North African countries; the Committees Registered in Office for Human Research Protections (OHRP) are as follows, Egypt 45 RECs, Algeria 7 RECs and Tunisia 3 RECs [21]. For Other African countries; Gambia was the first country to establish a national DNA bank, and the Africa Centre in South Africa has built up an extensive collection of biological samples over the past decade. In the Middle East; many countries are starting to establish biobanks; examples are Qatar, Saudi Arabia and Jordan [5].

Very recently, in 2014 and 2015, there have been initiatives for establishing biobanks in Egypt by the International Agency for research on Cancer (IRAC) in France, The Low- and Middle-Income Countries (LMICs) Biobank and Cohort Building Network (BCNet) to share information between BCNet members and partners about ongoing and planned activities and programmes; to provide a medium for sharing guidelines, protocols, and standard operating procedures (SOPs); and to inform the public and the international scientific community about the goals of BCNet in order to identify and encourage new opportunities and foster collaboration [22]. Three biobanks have been established in Egypt, the first is in Tanta University, the second in the National Cancer Institute and the third is in Children's Cancer Hospital Egypt (CCHE-57357).

3. ETHICAL ISSUES AS CHALLENGES FOR BIOBANKS IN EGYPT

3.1 Lack of Legislations and Laws for Human Tissues Use in Research

There are no guidelines or legislations regarding the use of human tissue in research. RECs in Egypt usually depend on international guidelines such as Declaration of Helsinki [23]. A draft for law of medical research in Egypt have been written 3 years ago but due to political unrest and the absence of a People's Assembly, the law has not yet been issued. At present, a committee of members of the Ministry of Health in collaboration with the Ministry of Higher Education and the Ministry of Scientific Research is working on passage of the law of medical Research and clinical trials in Egypt.

Inconsistent national laws contribute to confusion and inhibit collaborative research efforts, but

conflicting ethical, cultural, and religious perspectives will continue to make international regulatory harmonization a highly difficult challenge [24]. Maintaining biobanks and producing effective scientific outcomes based on the biobanking resources are not easy without a proper framework and the capacity to manage biobanks [25].

In a study done in the NRC of Egypt about the perceptions of physicians and researchers in the National Research Center (NRC) to applications of research ethics in their Investigations issue of ownership of biological samples, the majority (72%) mentioned that the patients are the owner, while 16% mentioned that it is owned to the hospital or the institute [26].

3.2 Consent Form

Consent form represents the most difficult challenge facing biobanks in Egypt, pathologists usually have no direct contacts with patients; they are responsible for diagnostic tests on tissue samples and writing reports to the clinicians. So, obtaining consent form will be the duty of the clinicians who are not interested in archiving surplus or tissue for future research. We think that this is also the situation in many other countries, it is important to understand that consent for use of archival pathology material is almost never obtained [27]. The decision to allow consent to be waived is given to a Human Research Ethics Committee (HREC) and requires that they carefully consider items such as the difficulty or obtrusive nature of obtaining consent, as well as the likely risk to benefit ratio of permitting a restricted and carefully monitored invasion of an individual's privacy [27].

The need to adequately obtain informed consent prior to research involving human participants is a fundamental ethical principle [28]. The Human Tissue Act makes the removing, storing or using of human tissue without consent and the taking and testing of DNA without consent illegal [29]. Although the signing of informed consent documents is frequently mandated by U.S. regulations, many individuals in Middle Eastern countries are opposed to signing such documents, because they strongly believe that giving their verbal agreement should be sufficient [30]. Currently there is a great deal of heterogeneity in the approaches to informed consent taken by different countries [31].

Consent allows individuals to protect their right to decide whether and how their body parts will be

used in research. Before obtaining consent, all participants must be well-informed and understand the purpose of research with its expected benefits and risks. Only after that, a voluntary consent can be obtained from each participant [32].

Consent should be required for research using clinically derived, identified samples, but waived for additional research using research derived, anonymized samples. Research risks and benefits must be disclosed to research participants. It is important to maintain a balance between the potential benefits for diagnosis and treatment and the need to safeguard those participants [24].

There is an important unanswered question regarding the issue of consent form, thousands or millions of tissues specimens are archived in our hospitals and pathology labs in Egypt and as consent cannot be obtained retrospectively, what rules should be applied to these existing archives?

3.3 Privacy and Confidentiality

In tissue biobanks, the confidentiality of the patients is maintained by coding all material specimens. Access to patient identification must be restricted to the authorized personnel at the institution. The Privacy Rule requires specific written permission from a patient before anyone may use or disclose "protected health information" (PHI) about that person for non-routine purposes such as research [24].

In human tissue research, genomic technology has not only increased the demand for human tissue, but it has also increased the potential for tissue donors to be subjected to both psychosocial and economic harms [33].

Because possible unfair discrimination against an individual by a present or potential employer, insurer, educator, or other party on the basis of genetic information derived from a scientific analysis of the individual's tissue specimen is a major risk of allowing one's tissue to be available for research purposes, it is necessary to consider the confidentiality implications of collecting and storing tissue to be used in the research context [24].

3.4 Role of RECs in Biobanks

RECs are safeguards of participants' interest and thus have a very important role in the process, As RECs play such a critical role, we believe that

there should be more literature that could provide guidance and help improve the quality of their contribution in the process of reviewing biobanking activities [25].

Special concerns in review included research design, informed consent, risk/benefit assessment, selection of subjects and privacy. In REC of the National Research Centre of Egypt, a model of consent form was put in Arabic language containing all the elements of informed consent and distributed to researchers as a guide to how to write a consent form; however, some researchers might introduce very short consent with incomplete information given to the participants, so modifications may be recommended by the committee to write details about objectives, methodology or side effects and how to deal with them [34].

The strictly applied and well-standardized mode of anonymization of tissue serves to prevent any harm to the patients and helps to avoid that each and every unproblematic protocol must be individually reviewed and approved by the review board [17]. Despite the current challenges with the REC system, many interviewees were of the view that RECs should be given the needed logistic and training support to enable them serve as effective gate-keepers of research samples [35].

3.5 Public Concerns about the Use of Human Tissue

The most important prerequisite for successful biobank-related research is ensuring the public trust. This can be achieved through continuous education of people and protection of privacy [15]. In order to assure the public's trust, policy makers charged with setting best practices for governance of biobanks and access to electronic health records should leverage critical access points to engage a diverse public in joint decision making [36].

As a result of a number of tissue-related "scandals" and increasing concern about ownership and privacy, the requirements to obtain consent from tissue donors are becoming increasingly stringent [37]. Consent symbolizes the trust invested in researchers and research institutions to use the biobank for the public good [38]. The governance of biobanks emerges as an integral part of the ethical responsibilities of institutions. It also makes the implementation of national guidelines possible, and helps to

enhance the trust and confidence of local contributors in biobank research [39]. Depletion of public trust can have damaging consequences in biobanking, but the main victims are the people who expect improvements from medicine and health systems [40].

3.6 Transfer of Tissue

The importing and exporting of biological samples constitutes an ethical dilemma in Egypt and many other developing countries. Egypt is an African country, and as bad experiences had occurred in some African countries in the past, this was reflected on public trust in international biomedical research. In 2010, a survey of patients in Egypt found that most patients (62%) preferred to have their samples exported to other Arab countries compared to Europe and USA [41]. Two qualitative studies conducted in Nigeria [42] and South Africa [43] reported general community support for the storage and reuse of samples but on condition that the appropriate structures are in place to protect the interests of participants.

There is a pressing need for a number of practical ethical concerns to be addressed in order to ensure high standards of practice and maintain public confidence in international research collaborations, particularly those involving the collection, export and reuse of human biological samples [35]. The practice of exporting and sharing human biological samples from Africa has led to questions about appropriate mechanisms to safeguard the interests of sample donors; that is research participants and their communities [44]. In India, although the government issued regulations against biopiracy in 2002, this was poorly implemented and biological samples are still shipped abroad for studies without the proper approval from authorities [45].

Irrespective of where research takes place, the interests of the less dominant partners in the collaboration (host African institutions, participants and communities) will be adequately protected, against the background of inevitable sample export. This can also be achieved through clear, transparent and fair research agreements [35]. To guarantee fairness in research agreements, the samples must be de-identified before they are shared and RECs review must be conducted in both institutions before the data and samples are shared with application of Material Transfer Agreement (MTA)

to ensure that materials will not be transferred to third parties.

3.7 Benefit Sharing

Benefit-sharing issues at community level forms an important challenge in Egypt. There are issues with data sharing – such as who owns the data, which third parties can benefit and who decides what can be shared [25].

Compared with the situation in high-income countries, where the ethical, legal and social issues of biobanks have been debated, researchers in low- and middle-countries are less experienced in coping with these issues. The fear of exploitation – i.e. unfair distribution of risks and benefits – makes many low- to middle-income countries hesitant about foreign researchers accessing and using their human biological samples and associated data. These issues may have a negative impact on international research collaborations.

Benefit sharing is a very sensitive issue and it is rarely discussed [25].

Benefit from the research results, especially the financial benefit, could be shared among participants, communities that take part in research, researchers, and their institutions. There is a substantial interest from the industry in this research, so that generation of intellectual property and benefits over time is not unlikely. In terms of benefit sharing, biobanks must strike a balance between many competing interest from various stakeholders in the process [44].

Unfair benefit-sharing with local participants and communities may constitute exploitation, and contribute to a public distrust of biomedical research [25].

3.8 Commercialization

Commercialization is a serious and contentious issue worldwide, studies carried out in Norway, the UK, Australia and New Zealand indicate that while participants appeared to trust individual researchers, the specific institutions housing the biobank and the government systems regulating the biobanks, there was skepticism about and fear and distrust of “for-profit organizations”, industry and commercial entities [46,47].

In the United States there is acceptance of the possibility of using the human body as a capital resource, whereas European law is based on

principles that categorically prohibit selling parts of the body [48]. Allowing potential commercial uses of donated samples is controversial in some Asian countries [49].

From the perspective of justice, allowing sales of samples could be exploitive, since less affluent individuals would likely be more inclined to sell their samples [48]. Pathologists must prevent the commercial exploitation of human tissue samples. Often the pathology department is approached by agents from biomedical companies for requests of blocks of common cancers such as those of breast, colon and lung. These requests are put forward under the general category of "research" when actually they may be used for commercial purposes such as constructing tissue microarrays. As pathologists we must be fully aware of the exact purpose for which the tissues are used [15].

A typical example of commercialization in biobanking is pharmacogenomics research supported by pharmaceutical companies [50]. They support research that could eventually improve treatment, but they also hope that the results of such research could prove very profitable in the future. Also, gene patents are potentially very profitable, so many companies are willing to support such investigation to achieve future profits [44]. But, is it ethical to create such financial benefits from free donations and who has the right to a share in these profits? How should costs and benefits be balanced and how should intellectual property is shared between companies, researchers, and participants? Beier et al. [32] concluded that a certain level of commercialisation is acceptable and necessary, but that it must be harnessed within well-defined limits in order to foreclose any coercion or violation of human rights [51].

4. RECOMMENDATIONS

What is needed now in Egypt? The following recommendations may be used as guidance for implementation of biobanks in Egypt.

Recommendation 1: The government in Egypt has to encourage the establishment of tissue banks with sufficient professional staff and resources in different universities and hospitals in Egypt with generation of standard operating procedures and quality-control methods. These Tissue banks should be set up as non-profit making and not commercial for-profit biobanks.

Recommendation 2: Quality assurance in biobanks requires compliance with the ethical guidelines, accordingly, the oversight system should have additional resources to ensure its effectiveness in protecting research participants and promoting research. Government, institutions and sponsors should make these resources available.

Recommendation 3: The cultural or religious sensitivities of the donor should be considered in human tissue samples. Secure storage of the tissue to maintain confidentiality and privacy is needed specially in genomic research.

Recommendation 4: A strong system of research ethics education and training for researchers and pathologists would help ensure public trust in biobanks in Egypt.

Recommendation 5: It is the responsibility of the RECs to review and approve research that involves the collection, use, storage, and re-use of human tissue in every university or research center in Egypt. Also a good monitoring system is needed for ongoing research projects. Proper ethical review by RECs protects research subjects against harm.

Recommendation 6: Enhancement of public confidence can be obtained through programs to increase public awareness and strategies for community consultation with strict policies and regulation of commercial exploitation of human biological material. This will lead to appreciation of the importance of tissue samples for basic and clinical research and support tissue-based research in Egypt.

Recommendation 7: RECs should adopt policies to govern access to patients medical records, reuse and transfer of tissue research. Through the Material Transfer Agreement (MTA), all access to and release of samples or data from biobanks can be strictly recorded.

The use of tissue blocks to build commercial tissue arrays must be critically reviewed keeping in mind patient privacy, autonomy and intellectual property rights. It is also needed to extend the ethical principle of respect for persons to communities as well and there must be return of benefits to the community.

Recommendation 8: Establishment of an Egyptian biobank network will create the opportunity to conduct research on large

numbers of samples. This will facilitate collaboration between researchers in Egypt and attract international funding. However, in order for collaborations to be successful there should be clearly defined rules and mechanisms for sample and data access.

5. CONCLUSION

Although there are no specific regulations for biobanking in Egypt, but there is a remarkable effort to establish these biological banks in different universities and hospitals. This necessitates strong system of research ethics education and training for researchers, critical review of biobanking research with good monitoring system for on-going research projects keeping in mind patient privacy, autonomy and intellectual property rights and extends the ethical principle of respect for persons to communities. Pathologists and Research Ethics committees shared in these efforts aiming to achieve the desired progress in the field of biomedical research in Egypt.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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