

# Socio-Cultural, Legal and Ethical Issues Related to Gene Banking in Oman

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**Abstract:** Establishment of genetic databases has socio-cultural, ethical and legal implications particularly in developing countries. However, there are no available data in Oman about the community knowledge and understanding of genetic database and gene banking. Thus, this study was conducted with the aim of investigating Omani public awareness on socio-cultural, ethical and legal aspects of gene studies (with consideration to regional variations) and to assess the public acceptance of initiating gene banking. This study was conducted using self-completed questionnaires by a sample of adult Omani population invited to participate in the study, from 14 health centers, a school and a university. For illiterate subjects, structured interviews were conducted. There were a total of 1,702 participants with nearly equal numbers of males and females. The mean age of respondents was 31 ( $\pm$  12) years for males and 28 ( $\pm$  10) years for females. In general, 9% of the studied population were illiterate and a total of 29% were preparatory school level and below, classified as the uneducated. While, 60% of the respondents were unemployed. The awareness on the genetic disposition of some common diseases was generally higher than 80% with the highest on sickle cell anemia. Only 17% of the participants had knowledge of genetic databases, 95% of whom were from the educated group. Public opinion on acceptance of gene banking, participation in genetic research and setting protection laws in those aware and non-aware, achieved good scores, indicating public acceptance of the above.

**Key words:** Genetic databases, public acceptance, socio-cultural, legal, ethical and religious aspects.

## 1. Introduction

Genes are blueprints composed of detailed strands of deoxyribonucleic acid (DNA), which serves as basic units of heredity present in every living cell of plants, animals and humans. These can be conserved for ages in frozen vaults as back up for the future. Gene banks therefore are type of repositories, which preserve genetic materials stored and made available for use if need arises.

The human genetic databases, also referred to gene banks, databanks or biobanks, refer to collections of genetic samples, namely human biological materials, such as, extracted DNA, body fluids example blood, isolated cells and sections of tissues together with genetic and other health and lifestyle information. These biobanks are valuable for the purpose of human

research, and have moved in line with scientific developments particularly in the area of genomics from small clinical and research tools to large-scale collections of material for population and common complex diseases studies [1, 2]. Although expensive to build and maintain, their potential benefits justify their establishment. However, possibility of their misuse raises debates over specific socio-cultural, legal and ethical aspects, thus imposing medical regulations and protection of the research subjects' interests. Issues therefore raised in use of these biobanks are related to consent, confidentiality, privacy, accessing, individual and community autonomy. Genetic discrimination in insurance and employment is another sensitive area that gathered significant interest of the public and policymakers worldwide. Further concerns over commercialization of these biobanks raised questions on benefit sharing, ownership of research findings and the need of

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establishment of property rights. In order to get support for developing such genetic banks, dealing with societal concerns and consideration of public involvement and partnership are therefore of paramount importance [3-7].

Unlike the diversity in Western populations, inbreeding is deep rooted in the Arab communities, including Oman [8-10]. The large families and high level of consanguinity result in unique socio-cultural cohesion, as well as an increased frequency of genetic disorders with specific recognizable pattern. So far, genetic research in Oman is fragmented, being largely based on case reports and series. Establishment of genetic research databases is therefore of major importance for wide scale genetic research. However, the unresolved socio-cultural, ethical and legal issues on the development of such biorepositories are not so far extensively studied or explored.

Socio-cultural issues that may have implications include awareness of the public on genetic information and their attitude and response. Other areas of concerns that will need to be addressed are the sharing of the research findings, benefits of the results to individual health or the community and stigmatization of individuals or groups of the society, who may experience discrimination, thus unfairly or inequitably treated. Ethical implications entail confidentiality of personal data and the informed consent. Informed family consent rather than individual consent particularly in extended families is important as in such cases where the genetic material is shared by many individuals in the family [11]. Therefore, specific legal procedures will have to be passed enabling the future utilization of gene data banks. Authorization of the use of genetic material and information following collection of samples is therefore a major legal and political issue [11-14].

So far, there are no available data in Oman on the community's knowledge and understanding of genetic database and there are no conducted prospective epidemiological studies of public opinion on this topic.

Public awareness of the scientific implications and future use or abuse of genetic information on the individual, family and community as a whole is also not known. The impact of education on knowledge and awareness is also an important aspect worth studying to identify the need for educational program in genetic sciences and gene banking. Thus, the aim of this study was to investigate Omani public awareness on socio-cultural, ethical and legal aspects of gene studies (with consideration to regional variations) and to assess the public acceptance of initiating gene banking. The data gathered can be utilized in identifying areas that contribute positively or negatively to the future implementation of genetic studies in Oman.

Furthermore, Omani researchers and institutions will acquire knowledge on the society's perception and reaction to the idea of gene banking. It will help to address concerns of the society, thus building trust and cooperation with the people in carrying out meaningful work in genetic sciences. Finally, the socio-cultural and ethical attitude to gene banking practices and genetic studies will contribute to the government policies and framework on establishing genetic databases for future research.

## 2. Methodology

The objectives of this study were met using self-completed questionnaire by a sample of adult Omani population comprising of various sections of the society. For illiterate subjects, structured interviews were conducted. Data collectors were trained through an organized workshop and supervised by co-investigators. Suitable briefing sessions were arranged for all the subjects before questionnaires were filled.

### 2.1 Questionnaire

The questions were chosen to explore the basic knowledge of the studied population in the field of genetics and gene data banking. It also investigated

the socio-cultural, ethical and legal interpretation of the population to the concept of genetic studies and gene bases. It was composed of four parts, of which the majority were close question of 5-point rating scale and few were open-ended questions to give the studied sample the opportunity to report their own views on the subject.

After developing the questionnaire, face validity was assured prior to its translation into Arabic by one of the researchers and backed by an independent translator. The questionnaire was piloted for the following reasons: (1) to assess the appropriateness and understanding of the public to the questions, thus making appropriate revisions to it; (2) to train the assistant researchers on using the questionnaire and interviewing participants in a standardized format; (3) to calculate sample size. All assistant researchers attended a training workshop, which oriented them to the study tool, data collection using the questionnaire and the interview process. Following the pilot study, the questionnaire was edited and changed accordingly to fulfill the study objectives.

## 2.2 Sample

Three sample subgroups were randomly selected. Sample of general population was randomly selected from different sections of the society, including the final year students from all faculties at the public university and a representative sample of final year secondary school students from a private school in the capital.

As the studied topic is new and there are no previous data available, it was decided to conduct a pilot study on 100 subjects, 25 from each sub-sample and 50 from the general population sub-sample. Accordingly, a sample size of 1,500 was estimated to be adequate for the study purpose.

Data were collected from the two largely populated regions in the Sultanate of Oman, namely Muscat and Al Dakhiliya, which consisted of six and eight "Wilayats" (districts), respectively. The distribution of

the studied population was from 14 health care centers of the "Wilayats". The utilization of the regional health centers in the "Wilayats" as focuses for collecting the data was achieved with the collaboration of the Directorate of Research Studies at Ministry of Health Oman.

## 2.3 Ethical Consideration

Ethical approval of the study was obtained from WHO regional office and Medical Ethics Committee of Sultan Qaboos University. Written consent was obtained from the final year university students and the general public. Informed written consent was also taken from the parents of the secondary school students and verbal consent from the students themselves. Confidentiality of the data collected was assured by the anonymity of the responders and proper storage of all filled up questionnaires, which were accessible only to the investigators.

## 2.4 Statistical Analysis

Data were analyzed using SPSS version 21.0. The qualitative variables were expressed as number and percentage, and the quantitative variables were expressed as mean and standard deviation (SD). The association between socio demographic and the dependent variables, such as gene banking acceptance etc., were analyzed by chi-square test with Yate's correction. The categories "strongly disagree and disagree" as well as "strongly agree and agree" were combined to avoid issue of small numbers when doing the chi-square test.

## 3. Results

### 3.1 Participants Demographic Data

Out of 1,702 subjects approached, 1,034 were in Muscat and 668 in Al Dakhiliya with some missing data in the variable responses. There were nearly equal numbers of males and females (53% and 47%, respectively). The mean age of respondents was 31 ( $\pm$  12) years for males and 28 ( $\pm$  10) years for females.

Among the respondents, 57.6% were married, 38.7% not married and the remaining divorced or widowed. Nearly 9% of the studied population were illiterate and 29% were preparatory school level and below, classified as the uneducated group. Out of the educated group, 36% of the respondents were at secondary school level and 35% were college or university level and degree holders. Two-thirds (60%) of the respondents were not employed, including 11% unemployed and the rest were housewives, retired persons and students (Table 1).

A good number of respondents (72%) owned home computers and 54% used internet to access information. The 99% had television and a large majority watched scientific, cultural and health programs. The 93% listened to home or car radios, while 52% were reported to read general and scientific books. The 57% attended medical seminars or talks.

### 3.2 Knowledge of Genetic Diseases and Gene Banking

The awareness on genetic disposition of some common diseases was generally higher than 80% with the highest on sickle cell anemia. Only 17% had knowledge (aware) of gene databases, of whom the majority (71%) were from Muscat and 29% from Al Dakhiliya. The source of information on gene data banking for the aware group was from the media, mainly television and radio (67%). Ninety-five percent of the aware group was educated, that is from secondary level and above, irrespective of those who suffered chronic diseases or have a family member with a genetic disorder. About half of the aware group respondents found no disadvantages in gene banking. Amongst those, none of the uneducated ones found any disadvantage in gene banking. The results were nearly the same with both genders and from the two regions.

**Table 1** Socio demographic characteristics by gender wise.

Variable	Male (n = 880)		Female (n = 783)		Total (n = 1,702)	
	n	%	n	%	n	%
Age	Mean ± SD 30.97 ± 12.10		Mean ± SD 28.17 ± 9.97		Mean ± SD 29.66 ± 11.24	
Religion						
Mascat	560	55.4	451	44.6	1,011	60.8
ADakhiliya	320	49.1	332	50.9	652	39.2
Educational status						
Illiterate	64	45.1	78	54.9	142	8.6
Read and write	59	67.0	29	33.0	88	5.3
Primary	24	28.9	59	71.1	83	5.0
Proparatory	88	51.8	82	48.2	170	10.4
Secondary	275	46.7	314	53.3	589	35.9
College (graduate)	96	63.2	56	36.8	152	9.2
University	268	63.8	152	36.2	420	25.5
Occupation						
Government employee	279	72.3	107	27.7	386	23.6
Private employee	174	75.3	57	24.7	231	14.1
Business	24	70.6	10	29.4	34	2.1
Retired	44	86.3	7	13.7	51	3.1
Unemployed	71	39.7	108	60.3	179	11.0
House wife	59	13.9	366	86.1	425	26.0
Student	212	64.8	115	35.2	327	20.0
Marital status						
Milka	14	46.7	16	53.3	30	1.8
Married	460	48.6	487	51.4	947	57.7
Divorced	1	9.1	10	90.9	10	0.7
Widowed	7	35.0	13	65.0	13	1.2
Never married	391	61.7	243	38.3	243	38.6

3.3 Attitude towards Gene Banking

Acceptance of gene banking, participation in genetic research and setting protection laws among the aware participants was high. The majority agreed or strongly agreed with no difference in gender, except in opinion on setting protection laws ( $P < 0.001$ ). There was a statistical difference in the public acceptance and participation in genetic research scores in the aware group, as compared with the non-aware after given explanation on gene banking by the data collectors. The educated group scored significantly

better than the uneducated ( $P < 0.05$ ). In public acceptance and participation in genetic research, Muscat region scored significantly better than Dakhiliya region ( $P < 0.01$ ) (Table 2).

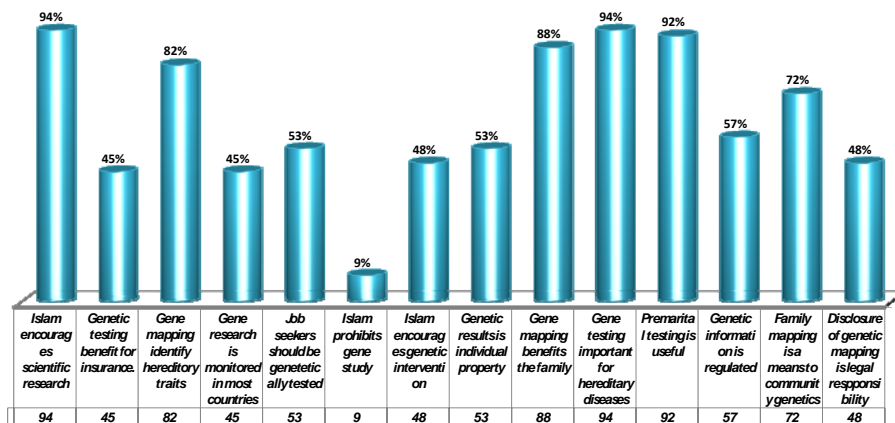
3.4 Attitude on Socio-Cultural, Ethical and Legal and Aspects of Gene Banking

Opinion on the various social, cultural, ethical and legal and aspects of gene banking was highly positive with ratings as shown in Fig. 1. This was irrespective of region, gender, education or known associated

**Table 2 Attitude towards gene banking by region, gender and education for the aware group.**

Variable	Attitude towards gene banking in Oman										P value
	Strongly disagree		Disagree		Not sure		Agree		Strongly agree		
	n	%	n	%	n	%	n	%	n	%	
<b>1. Public acceptance of initiating:</b>											
<b>Region</b>											
Muscat	1	0.5	4	2.0	13	6.6	98	50.0	80	40.8	$P < 0.01$
A'Dakhiliya	1	1.3	2	2.5	11	13.8	36	45.0	30	37.5	
<b>Sex</b>											
Male	2	1.1	5	2.8	14	8.0	87	49.4	68	38.6	NS
Female	0	0.0	1	1.0	10	10.0	47	47.0	42	42.0	
<b>Education</b>											
Uneducated	0	0.0	0	0.0	4	26.7	7	46.7	4	26.7	$P < 0.05$
Educated	2	0.8	6	2.3	20	7.7	127	48.7	106	40.6	
<b>2. Agree to participate in genetic research: What is your attitude?</b>											
<b>Region</b>											
Muscat	2	1.0	19	9.9	32	16.7	121	63.0	18	9.4	$P < 0.01$
A'Dakhiliya	0	0.0	8	10.0	22	27.5	31	38.8	19	23.8	
<b>Sex</b>											
Male	0	0.0	21	12.2	35	20.3	91	52.9	25	14.5	NS
Female	2	2.0	6	6.0	19	19.0	61	61.0	12	12.0	
<b>Education</b>											
Uneducated	0	0.0	4	28.6	0	0.0	8	57.1	2	14.3	$P < 0.001$
Educated	2	0.8	23	8.9	54	20.9	144	55.8	35	13.6	
<b>3. What do you think about setting laws &amp; regulations in gene banking to protect people?</b>											
<b>Region</b>											
Muscat	8	4.2	5	2.6	13	6.8	80	42.1	84	44.2	NS
A'Dakhiliya	4	4.9	3	3.7	10	12.3	28	34.6	36	44.4	
<b>Sex</b>											
Male	10	5.8	6	3.5	13	7.5	74	42.8	70	40.5	$P < 0.001$
Female	2	2.0	2	2.0	10	10.2	34	34.7	50	51.0	
<b>Education</b>											
Uneducated	0	0.0	0	0.0	5	33.3	8	53.3	2	13.3	$P < 0.05$
Educated	12	4.7	8	3.1	18	7.0	100	39.1	118	46.1	

### Opinion on gene banking from legal, religious and social aspects



**Fig. 1** Opinion on gene banking from various perspectives.

chronic or genetic diseases. Around 90% of the respondents agreed that Islam encourages scientific research, and that gene mapping as well as premarital testing is helpful and important for the understanding of hereditary pattern of diseases and thus benefits the family and the community as a whole. About half agreed it is important that there should be full privacy and confidentiality with protected laws and legal framework in gene testing. Those educated scored better than the uneducated.

#### 4. Discussion

Similar to other studies [12-14], this study revealed a low rate of knowledge on the practice of genetic database banking (17%), of whom the majority were of higher level of education. However, supportive public opinion on acceptance of gene banking, participation in genetic research and setting protection laws among the aware and the unaware groups after being introduced to the subject, achieved good results, also similar to the findings in Refs. [12-14]. So far, as public acceptance is concerned, the educated scored better than the uneducated in both aware and unaware groups. This supports the theory of growing confidence in health sciences and genetic research, as

the level of education increases. Analysis of the data did not reveal much impact on previous experience of chronic diseases or genetic diseases in the family. This positive attitude is promising, as the gene banks are potent means of providing the required genetic materials for research to improve the knowledge about diseases in our community.

It is imperative that understanding diseases in certain population depends on establishment and broad use of human biobanks and genetic research databases. However, the use and exchange of human genetic material and the information derived from it is not without some controversy. Countries need comprehensive legislative frameworks to regulate these and safeguard human dignity and human rights. Oman is no exception, and like its neighboring Arab countries, specific rare autosomal recessive diseases have been shown to be at high frequencies. A comprehensive survey of bioethical regulations in the Arab region is therefore required. Efforts have been ongoing to establish population genetic databases. The Center for Arab Genomic Studies (CAGS) has initiated a pilot project of a centralized database in Dubai for “genetic disorders in Arab populations” [15]. Saudi biobank was also established in 2010 to shed

light on common diseases by conducting a large-scale study of the combined effects of genes, environment and lifestyle. Prior opinion on public attitude towards biomedical research was undertaken at the outpatient clinics of King Abdulaziz Medical City in Riyadh, the results of which revealed a positive attitude [16].

The social values and norms of different cultural environments necessitate the need for development of ethical standards and codes. Oman has no regulations on genetic testing, but efforts have been ongoing to formulate guidelines on “collection, transfer and exchange of human genetic data and biological samples”. These are not yet in practice and therefore it is important to collect public opinion and information on cultural and social contexts with the goal of contributing to the country’s regulations and codes.

## 5. Conclusions

The result showed that only 17% of the studied population had knowledge (aware) of gene databases, of whom the majority were from Muscat. The source of information for the aware group was mainly from the media, such as television and radio. Ninety-five percent of the aware group were educated. In general, there was a positive attitude towards gene data banking, of which the main predictor was the level of education. There was a statistical difference in the public acceptance and participation in genetic research scores in the aware group as compared with the non-aware after given explanation on gene banking by the data collectors. The educated group scored significantly better than the uneducated ( $P < 0.05$ ). In public acceptance and participation in genetic research, Muscat region scored significantly better than the interior region (Dakhiliya) ( $P < 0.01$ ).

Opinion on the various social, cultural, ethical and legal aspects of gene banking was highly positive. This was irrespective of region, gender, education or known associated chronic or genetic diseases. The impact of education on knowledge and awareness identify the need of educational programs through the

media, which was demonstrated as the main source of information to the public.

For the first time, it was able to engage the public in their opinion on gene banking and this information can formulate strategic decisions and make suitable recommendations for relevant research policies and establishment of gene database banking in the country.

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