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ABSTRACT

Objective To determine the attitudes of Egyptian patients regarding their participation in research and with the collection, storage and future use of blood samples for research purposes.

Design Cross-sectional survey.

Study population Adult Egyptian patients (n=600) at rural and urban hospitals and clinics.

Results Less than half of the study population (44.3%) felt that informed consent forms should provide research participants the option to have their blood samples stored for future research. Of these participants, 39.9% thought that consent forms should include the option that future research be restricted to the illness being studied. A slight majority (66.2%) would donate their samples for future genetic research. Respondents were more favourable towards having their blood samples exported to other Arab countries (62.0%) compared with countries in Europe (41.8%, $p<0.001$) and to the USA (37.2%, $p<0.001$).

Conclusions This study shows that many individuals do not favour the donation of a blood sample for future research. Of those who do approve of such future research, many favour a consent model that includes an option restricting the future research to the illness being studied. Also, many Egyptians were hesitant to have their blood samples donated for genetic research or exported out of the Arab region to the USA and European countries. Further qualitative research should be performed to determine the underlying reasons for many of our results.

Recent advances in genetics, molecular biology and biomedical technologies have increased the scientific value of research on stored biological samples and have spurred the development of genetic databases and biobanks.[1] Research on biological samples has led to the development of diagnostic and therapeutic agents and has identified genetic mutations that increase the risk of certain diseases.[2] Genetic research also generates commercial value for companies with interest in the area of personalised medicine and pharmacogenomics.

The collection, storage and use of biological samples in future research raise unique ethical and policy issues that have resisted consensus among several national and international documents.[3–5] Chief among these ethical issues include questions regarding confidentiality, ownership and the commercialisation of stored biological samples. There has also been a lack of consensus regarding the type and quality of informed consent needed to collect and store samples for future, unspecified research.[6] Differing opinions have included: offering research participants up to six separate choices regarding their prospective consent for future research[1]; re-contacting participants each time new research on their biological samples is proposed[1]; and re-contacting participants only for research that poses greater than minimal risk.[7]

Finally, as research has become increasingly globalised, ethical issues also arise from collaborative international research in which samples are collected in developing countries and then exported for analysis to developed countries. Such international research raises concerns of exploitation, the validity of informed consent from vulnerable populations, appropriate benefit-sharing between sponsors and participants, and guidelines for regulating types of future research.[8–11]

Because of the complex ethical and policy issues that arise in research with human biological materials, particularly in the international setting, it is important for researchers, ethicists, policy makers and oversight organisations to work together to form appropriate policies governing this research. The principle of respect for persons would entail that such policies be informed by the opinions of those who donate their biological samples.

As such, several studies have elicited public preferences regarding stored biological samples. For example, the public's willingness to contribute their biological samples for research is relatively high according to several American and European studies.[12–18] Such attitudes might not be generalisable to other cultures and countries, as the perception and familiarity of health research might be different in developing countries compared with developed countries. Currently, there is limited empirical research involving the perspectives of individuals from developing countries.[19] Accordingly, the objectives of this study were to determine the attitudes of Egyptian patients (potential research participants) regarding participation in research and the collection, storage and use of blood samples in future research and to identify sociodemographic factors associated with these attitudes.

METHODS

Study design

The study consisted of a cross-sectional survey in which data were collected between June and December 2007.

Study population

Participants were adult Egyptian patients who were receiving medical care at different hospitals/clinics at the time of the survey. Such patients are proxy participants of research, as they might be asked—at any time—to provide their informed consent for the collection and storage of biological samples for research purposes. Participants were recruited from rural and urban areas and from public and private medical care centres. Patients attending private clinics are often of higher socioeconomic status. Our planned recruitment strategy ensured the inclusion of a wide range of socioeconomic statuses.

Participants were enrolled from the following sites in Cairo, Egypt: Cairo University Hospitals; National Research Center, Cairo University; Central Laboratories, Ministry of Health and Population (MOHP); National Hepatology and Tropical Medicine Research Institute and two private clinics in Cairo.

Participants were also recruited from the following sites outside of Cairo: Menia University Hospitals, Menia; Beni Suif University Hospital, Beni Suif; Menofeya University Hospitals, Menofeya; Suez Canal University Hospitals, Ismalia; Assuit University, Assuit; and one private clinic in Ismalia.

We excluded patients who might have found it difficult to participate, for example, those who were critically ill or with diminished decisional capacity.

Recruitment methods

From each university/institutional site, our goal was to recruit 50 patients, half from the inpatient general surgery and the internal medicine departments, and the other half from the outpatient clinics. We used a random process for the selection of patients in each department to ensure age, gender and socioeconomic diversity. At the inpatient departments, the registration files of the general surgery and the medical departments were reviewed and three to five patients were chosen randomly from one department each day for recruitment. At the outpatient clinics, three to five patients were randomly selected from the orthopaedic, ear, nose and throat, dermatology and ophthalmology clinics for recruitment. Patients from the three private clinics were recruited by a 'first-come, first selected' basis with a maximum of five patients per day and a total of 50 patients from each clinic.

Data collectors

We recruited data collectors for each specific site. Data collectors were responsible for recruiting participants from among the patients attending the hospitals/clinics and they were responsible for helping the participants to complete the surveys, by ensuring their comprehension of the information in the survey. To enhance the consistency of the data collected and to minimise intrapersonal variations, only one data collector was assigned for each site. Also, to ensure the integrity of recruitment methods and data collection, we conducted a training session for these data collectors that included: the theoretical and practical aspects of obtaining informed consent; principles of research ethics; and techniques to explain to patients concepts of research, informed consent and genetics in a value-neutral manner.

Study tool

We developed a survey that included mostly closed-ended and a few open-ended questions. The survey was developed in English and then translated into Arabic. The survey instrument was pilot tested at the National Cancer Institute, Cairo University and the Cairo University Hospitals to ensure that the questions were comprehensible and clear. The study tool was finalised after necessary modifications based on the pilot testing.

The survey tool consisted of the following domains: (1) demographic and socioeconomic variables; (2) previous research experiences and attitudes regarding future research participation; (3) attitudes regarding informed consent for the collection of blood samples for future research; (4) attitudes regarding the storage and use of blood samples in future research; (5) attitudes regarding the use of blood samples in genetic research and (6) attitudes regarding the exportation of blood samples to foreign collaborators.

To enhance the understanding of the research participants regarding the concepts of research, informed consent and genetic issues, we provided a short paragraph explaining these concepts before each of the domains in the survey tool. The data collectors were also prepared to provide additional explanations of these concepts. For example, the following introductory paragraph was stated before eliciting the respondents' views regarding previous research experiences and future research participation:

> 'Research means an experiment or investigation done to discover new facts or get additional information. Medical research can consist of the following types of activities:
> - Drug trials (a new drug is compared with a drug that is currently used by doctors)
> - Blood sampling (obtaining a teaspoon of blood to see the prevalence of high blood sugar (diabetes) and high cholesterol levels among Egyptians)
> - Solid tissue sampling (a study performed on surgically removed specimens, eg, a study done on appendices removed after an operation to determine the degree of their inflammation)
> - A survey only (similar to the one we are performing).'

The following introductory paragraph was stated before eliciting the respondents' views regarding informed consent for future research involving stored blood samples:

> 'In some cases, individuals who are enrolled in a research study may be given the option to give informed consent for the use of their blood samples to be stored for future research. The storage of these blood samples is not part of the present study. In such cases, the blood samples would be stored with a code that links the blood samples to information that can identify who is the patient. There is a debate about the type of options, if any, that should be offered to individuals when they provide informed consent for the storage of blood samples for future research. Some commentators believe that individuals should not be allowed to consent to future research on their stored blood samples that is not yet defined. Others argue that individuals should be allowed to provide consent for the storage of blood samples to be used in future research. Some think that if individuals are given the option to consent to have their blood samples used in future research, then they should be given the option as to whether future research is limited to research that involves the illness of the present study or unlimited in the sense that the blood samples could be used to study any illness, related or not related to the present illness.'

Following this informational paragraph, respondents were asked whether informed consent forms should provide individuals with the opportunity to give consent to the collection of a sample of their blood for future research. Respondents who gave an affirmative response to this query were then asked whether the consent forms should provide an option as to whether future research should be limited to the illness being studied or whether such an option is unnecessary.

The next section of the survey contained the following paragraph before eliciting respondents' views regarding the storage and future use of blood samples in research:

> 'Assume you have given your informed consent to have your blood samples stored for future research. You also know that these blood samples do not have any information on it that can identify you. There is a code that links your blood samples to your name, but this code is kept in a locked and secure place and only the investigators and their research staff have access to this code. Hence, there are strong measures to assure the confidentiality of your blood samples. Also, if blood samples are given to other investigators, they will not have the code that links your blood samples to you.'

Following this paragraph, respondents were asked for their views regarding access to their blood samples by researchers unrelated to the study that collected the blood samples, whether there should be a time limit for storage of the blood samples, their right to withdraw their blood samples, their right to share in commercial profits, and whether there should be notification of results relevant to their health.

The next section of the survey elicited respondents' preferences for their blood samples to be used for future genetic research and was preceded by the following paragraph:

> 'The genes in someone's body govern their physical make-up (eg, the colour of their eyes and hair) and what illness they might get in the future. Genetics refer to how certain traits of an individual (eg, how one looks, their likelihood of getting a disease) are inherited or passed on from families to their children. Genetic research involves the testing of the genes in the blood sample that is responsible for the inheritance of these traits. These research activities might include understanding whether the effects of certain drugs are related to the genetic make-up of an individual.'

Respondents were asked for their attitudes regarding whether 'it would be acceptable to have their blood samples used for genetic research' both before and after being told the information in this paragraph.

The final section of the survey enquired about respondents' views regarding the exportation of their blood samples to foreign collaborating scientists and was preceded by the following introductory remarks:

> 'Scientists in different countries often collaborate on research involving the collection of human samples. For example, blood samples collected and stored in Egypt might be sent to another country This is sometimes done because the equipment or the knowledge needed to analyse the blood sample do not exist in Egypt. Sometimes the blood samples are sent to investigators in another country so that different types of research can be done, even though Egyptian scientists are able to analyse the blood samples for their own studies.'

Except for questions that had narratives for choices, response categories to the other closed-ended questions included either 'important', 'not important', or 'don't know', or 'yes', 'no' and 'don't know'.

Statistical analysis

Data from completed surveys were entered in Microsoft Access and then converted to SPSS version 13.0 for the purpose of statistical analysis. Simple descriptive statistics and cross-tabulations were used to profile the data with regard to the collected demographic data that included age, gender, healthcare settings (inpatient/outpatient and public/private), geographical area (rural/urban), average monthly expenses, educational level and employment type. Logistic regression analysis was used to compare the independent variables (preceding list of demographic categories) against dependent variables (survey questions eliciting respondents' attitudes). Each covariate was adjusted for all of the others. Variables associated with non-significance ($p<0.05$) were removed from individual models. We report in percentages the positive responses of the available choices (eg, 'yes' as opposed to 'no' and 'don't know', 'important' as opposed to 'not important' and 'don't know'). OR and CI are reported in the narrative for associations that demonstrated significant differences. We set the significance level at a p value of less than 0.01 due to the number of variables tested.

Human subjects protections

Informed consent

A cover sheet providing information about the survey study accompanied the survey. The respondents' informed consent was indicated by their completing and returning the survey.

Confidentiality

Identifying information was initially linked to the participants' response sheets by a code number. During data collection, the response sheet was kept separate from the identification code sheet in a locked, secure location. After data collection was completed, the data were anonymised by destroying the identification sheets.

RESULTS

A total of 600 surveys was collected from the study sites. Table 1 shows the demographics and socioeconomic characteristics of the respondents. The mean age was 41.0±14.3 years and 82% of the respondents were above 25 years of age. The study sample had almost equal proportions with respect to gender and geographical area (urban vs rural), while a greater proportion of the respondents was recruited from the public compared with the private sector (72% vs 28%) and a greater proportion consisted of outpatients compared with inpatients (61% vs 39%). Regarding education, 38% classified themselves as being illiterate, whereas slightly more than a quarter of the respondents held university degrees. Using monthly expenses as an indicator of economic status, 37% stated that they spend less than 500 Egyptian pounds/month (approximately US$90/month). As for employment, 48% reported their status as being unemployed, while slightly less than 20% were professionally employed. More than 90% of the participants had an electricity and water supply.

When asked about previous research participation, 94% of the participants stated that they had never been asked to participate in a research study. Of those who had been approached for participation (n=36), 78% (n=28) agreed to enrol in research; 31% (n=11) of those studies involved the collection of tissue/blood samples. Table 2 shows the respondents' attitudes towards the different types of medical research. Most of the participants felt that all types of research are important. Logistic analysis revealed that public patients compared with private patients (OR 9.80; 95% CI 2.20 to 43.48) were more likely to think that research involving blood samples was important; whereas rural compared with urban patients (OR 4.18; 95% CI 1.47 to 11.91) were more likely to think that solid tissue sampling research was important. In contrast to attitudes regarding the importance of different types of medical research, a lower percentage of the respondents would not volunteer for research involving solid tissue samples and clinical drug trials compared with research involving surveys and blood sampling. Logistic analysis revealed

Table 1 Demographics and socioeconomic characteristics of the study population (n=600)

Characteristic	% of Total
Age (years)	
≤25	18.0
26–45	43.2
≥46	38.8
Gender	
Men	49.2
Women	50.8
Healthcare setting	
Inpatient	39.0
Outpatient	61.0
Public	72.0
Private	28.0
Geographical area	
Urban	52.8
Rural	47.2
Education	
Illiteracy	38.0
Below university	34.3
University and higher	27.7
Average monthly expenses (Egyptian pounds)	
≤500	37.3
501–1000	35.9
>1000	26.9
Employment	
Unemployed	48.2
Manual	10.2
Skilled	15.2
Semi-professional	7.7
Professional	18.8
Electricity	
Yes	94.3
No	5.7
Water supply	
Yes	99.5
No	0.5

that men compared with women patients (OR 1.63; 95% CI 1.13 to 2.36) were more likely to volunteer for clinical drug trials.

Table 3 shows respondents' attitudes towards the options that should be provided in informed consent forms regarding the collection and future use of blood samples. Slightly less than half of all of the respondents stated that informed consent forms should provide research participants the option to have their blood samples stored for future research. Of these respondents (n=334), almost 40% felt that prospective consent should include an option to restrict future unspecified research to the illness that is the focus of the present research, whereas a slight majority thought that such an option was not necessary.

Logistic analysis revealed that younger individuals (OR 2.46; 95% CI 1.39 to 4.32) and inpatients (OR 1.97; 95% CI 1.19 to 3.38) were more likely to think that informed consent forms should provide an option for research participants to donate blood samples for future research. Regarding preferences for options to limit future research to the illness being studied, logistic analysis revealed that there were no significant associations between the responses and any of the sociodemographic variables.

Table 4 shows respondents' attitudes regarding conditions that should be associated with the storage and use of blood samples for future research. Overall, slightly more than 50% of the respondents believed that blood samples can be given to other investigators (ie, those not related to the original study that collected the samples) without participant re-contact, provided that an independent research ethics committee gave its approval. Logistic analysis revealed that younger individuals (OR 0.398; 95% CI 0.225 to 0.703) and men (OR 0.378; 95% CI 0.255 to 0.560) were less likely to hold this attitude, whereas those spending between 500 and 1000 Egyptian pounds/months (OR 2.15; 95% CI 1.25 to 3.68) were more likely to share this attitude.

Less than a quarter of the study population felt there should be a time limit for the storage of blood samples. Logistic analysis revealed that outpatients (OR 2.02; 95% CI 1.17 to 3.51) and rural residents (OR 2.90; 95% CI 1.72 to 4.89) were more likely to share this attitude.

Less than a third of the respondents believed there should be: a right to withdraw the blood samples or a right to share in any commercial profits. Logistic analysis revealed that rural residents (OR 1.69; 95% CI 1.14 to 2.50) were more likely to believe there should be a right to withdraw blood samples. Regarding the attitude that there should be a right for participants to share in commercial profits, logistic analysis revealed that men compared with women were more likely to share this attitude (OR 1.92; 95% CI 1.34 to 2.75).

A large majority of the respondents (>85%) believed that research participants should be made aware of subsequent results that are relevant to their health. Logistic analysis revealed that rural residents (OR 5.17; 95% CI 2.35 to 11.38) were more likely to share this attitude.

Table 4 also shows that almost two-thirds of the study population would donate a blood sample for future genetic research. Logistic analysis revealed that women compared with men (OR 1.84; 95% CI 1.21 to 2.79) and inpatients compared with outpatients (OR 3.19; 95% CI 1.90 to 5.38) were more likely to donate a blood sample for genetic research. Table 5 shows the respondents' responses towards donating blood samples for genetic research both before and after receiving an explanation regarding genetics. Focussing on the 'I don' know' responses (which might be reflective of a lack of comprehension of concepts in genetics), this table shows that for the aggregate group, the percentage of 'I don't know' responses before and after receiving clarifying information decreased from 30.7% to 10.5%; whereas for the 'illiterate' group, the 'I don't know' response decreased from 53.1% to 18.9%. These differences for both the aggregate responses and when divided according to the education level were statistically significant ($p<0.001$).

Table 6 shows respondents' attitudes regarding issues with the exportation of blood samples. Overall, respondents were more favourable towards having their blood samples exported to other Arab countries compared with countries in Europe ($p<0.001$) and to the USA ($p<0.001$). Logistic analysis revealed that women compared with men (OR 2.12; 95% CI 1.30 to 3.45) and rural compared with urban residents (OR 1.76; 95% CI 1.15 to 2.69) were more likely to favour sending their samples to another Arab country. There were no significant associations between the responses involving the exportation of blood samples to foreign countries and any of the socioeconomic variables.

An overwhelming majority (>80%) believed that the source country of the blood samples should have access to drugs derived from the analysis of the blood samples and that government approval should be required for the exportation of samples. Logistic analysis revealed that individuals spending less than 500 Egyptian pounds/month were less likely to think that the source

Table 2 Respondents' attitudes towards the different types of medical research (n=600)

	Which type of medical research is important?				Which type of medical research would you volunteer for?			
Characteristic	Survey	Blood sample	Solid tissue sample	Clinical drug trial	Survey	Blood sample	Solid tissue sample	Clinical drug trial
Aggregate	87.5	89.0	83.2	87.5	88.2	81.7	69.0	49.5
Age (years)								
≤25	91.5	89.4	89.4	89.4	93.6	87.2	61.7	42.6
26–45	87.1	89.2	82.8	87.6	88.8	81.1	69.7	50.0
≥46	87.3	87.3	81.7	85.9	80.3	81.7	69.0	50.7
Gender								
Men	88.8	87.1	83.1	90.2	87.5	81.4	71.2	55.9*
Women	86.2	90.8	83.3	84.9	88.9	82.0	66.9	43.3
Healthcare setting								
Inpatient	94.0	94.9	90.2	87.6	92.7	85.9	75.2	58.5
Outpatient	83.3	85.2	78.7	87.4	85.2	79.0	65.0	43.7
Public	91.0	91.4*	86.1	88.0	89.4	82.2	67.6	53.9
Private	78.6	82.7	75.6	86.3	85.1	80.4	72.6	38.1
Geographical area								
Rural	93.3	91.5	88.3*	89.0	91.9	84.8	71.0	42.9
Urban	82.3	86.8	78.5	86.1	84.9	78.9	67.2	56.9
Average monthly expenses (Egyptian pounds)								
≤500	89.8	91.2	85.1	87.4	87.9	80.5	66.0	53.0
501–1000	88.9	89.4	84.5	90.8	87.4	85.5	72.5	51.7
≥1001	84.5	86.5	80.0	85.8	89.7	80.0	70.3	45.2
Education								
Illiteracy	89.5	92.1	84.6	84.6	88.2	82.5	71.5	55.7
Sub-university	87.4	84.5	81.6	87.4	86.4	77.7	64.6	49.5
University	84.9	90.4	83.1	91.6	90.4	85.5	71.1	41.0
Employment								
Unemployed	88.2	90.3	82.4	85.1	89.6	82.4	68.9	48.8
Manual	86.9	86.9	83.6	86.9	88.5	83.6	78.7	50.8
Skilled	85.7	83.5	79.1	89.0	81.3	74.7	62.6	62.6
Semi-professional	87.0	91.3	89.1	93.5	89.1	89.1	78.3	54.3
Professional	87.6	90.3	85.8	90.3	89.4	81.4	65.5	38.1

*$p<0.01$.

country should be able to have access to derived drugs (OR 10.12; 95% CI 2.52 to 41.2).

DISCUSSION

This is the first extensive study coming from a country in the Middle East (Egypt) that elicits the opinions of a diverse group of patients regarding research participation and the collection, storage and use of blood samples for future research. Regarding medical research in general, a large majority of our sample population thought that all types of research studies (survey, blood sampling, solid tissue sampling and clinical drug trials) were important. However, a lower percentage expressed a desire to participate in research involving solid tissue samples and clinical drug trials compared with participation in survey and blood sampling research. Similar results were obtained in a qualitative research study involving Egyptian individuals and that study revealed that concerns with risks associated with studies involving solid tissue samples and clinical drug trials accounted for the observed difference in the desire to participate.[20]

Our study also elicited the attitudes towards the donation of blood samples for future research. Previous studies performed predominantly in western countries (eg, USA, UK, Sweden, Japan) and one from a resource-limited country in Africa (Uganda)[19] showed that most individuals (more than 80%) are willing to donate a blood sample for future research.[12–17 19 21] Our results contrast with those previous studies in that less than a majority of the Egyptian patients (44.3%) thought that informed consent forms should provide research participants with an option to donate a linked blood sample for future unspecified research.

It is interesting to note that compared with the results regarding the collection and storage of blood samples for future research, more than 80% of our study population would participate in a study that involved blood sampling. Therefore, a reluctance to donate a blood sample for future unspecified research is probably not due to any issues involving blood sampling itself, but rather to issues surrounding storage or the undefined nature of the future research involving blood samples. Indeed, our study also showed that almost half of the respondents (40%) who would donate a blood sample for future unspecified research thought that informed consent forms for such research should give participants the option that future unspecified research be restricted to the disease being studied, in addition to an option allowing unlimited research. This preference for multiple options was not associated with any of the tested sociodemographic characteristics. These results contrast with previous research on the issue of the donation of tissue samples for future research.[21] In particular, a previous study involving Ugandan individuals who gave consent for their children to participate in a malaria study showed that more than 80% were willing to have their samples used for future research on any disease condition if an institutional review board was involved with the approval of such future research. Another study showed that a large majority of African-Americans would permit unlimited future research with their biological samples.[12]

Table 3 Respondents' responses regarding collection of blood samples for future research†

Characteristic	Consent forms should provide an option for collection of blood samples for future research (n=600)	Consent forms should include an option that future research should be restricted to the illness being studied (n=334) ‡	Consent forms do not need an option that future research should be restricted to the illness being studied (n=334) ‡
Aggregate (n=600)	44.3	39.9	54.0
Age (years)			
≤25	60.2*	48.3	45.6
26–45	39.9	43.4	50.5
≥46	41.4	30.6	63.3
Gender			
Men	46.1	41.7	52.2
Women	42.6	38.0	55.9
Healthcare setting			
Inpatient	54.3*	31.2	62.7
Outpatient	38.0	47.9	46.0
Public	47.5	37.2	56.7
Private	36.3	48.9	45.0
Geographical area			
Rural	54.4	36.1	57.8
Urban	35.3	45.3	48.6
Average expenses (Egyptian pounds/month)			
≤500	45.6	39.8	54.1
501–1000	44.9	32.4	61.5
≥1001	38.7	51.5	42.4
Education			
Illiteracy	51.3	34.4	59.5
Below university	42.2	43.9	50.0
University degree and higher	37.3	44.7	49.2
Employment			
Unemployed	43.3	40.2	53.7
Manual	47.5	42.2	51.7
Skilled	56.0	29.2	64.7
Semi-professional	32.6	33.9	60.0
Professional	40.7	51.7	42.2

*$p<0.01$.
†Data are percentage of 'yes' responses.
‡6.1% answered 'I don't know/no opinion'.

Based on these and other studies, commentators have suggested that for future research involving biological samples one only need to use a one-time 'general' informed consent process that offers only a binary choice consisting of refusing or authorising unspecified future research involving all types of diseases.[21 22]

However, our study questions whether the recommendation for a one-time 'general' consent model that does not specify a limitation on the illnesses that can be studied can be generalisable to all populations, especially to populations in the developing world. Such a 'general' and 'blanket' consent is inherently vague regarding the specification of the types of future research. A concern with studies showing that participants favoured a general model of consent that offered only the options either not to donate or to donate a sample to unrestricted future research is that the participants might not have realised that future research might include diseases associated with stigma, such as a mental disorder or a sexual problem.[23] One limitation of our results is that our narrative that preceded the questions regarding informed consent options for future research did not mention the existence of strong confidentiality measures, the ability to withdraw samples at any time, and the approval of a research ethics committee before the performance of any future research. Such safeguards might enhance the likelihood that participants would authorise future unrestricted research on their blood samples. Further qualitative research should be performed to determine whether these safeguards or other factors would enhance the willingness to donate blood samples for future, unspecified research.

Regardless of this, our results do not preclude the practice of a one-time consent procedure involving multiple options that would avoid the impractical and inefficient practice of requiring additional consent before each new research. This recommendation contrasts with several commentators who have argued that future uses of stored biological samples should require such a re-consenting procedure from participants.[1 24]

Regarding conditions associated with the storage of linked blood samples, a large majority (89%) expressed the desire that they should be notified of results that are relevant to their health. The study involving Ugandan individuals showed that 54% of the respondents wanted information retrospectively on the research done on their samples, although the study did not enquire about the type of results they would have wanted to receive.[19] In another study by Wendler and colleagues[13] involving participants from the USA, more than 80% wanted their physicians informed of research results of uncertain clinical significance. Other studies from other western countries have shown that participants' desire for study results have ranged from 26% to 54%.[21] Future qualitative research should determine participants' beliefs regarding the type of impact that results obtained from biological samples would have on their health. Such research should also determine how participants would balance their preferences for the receipt of such

Table 4 Respondents' responses regarding storage and use of blood samples in future research (n=600)†

Characteristic	Given to other investigators without re-contact?	Time limit for storage of samples?	Right to withdraw blood samples?	Right to share in commercial profits?	Notification given of results relevant to health?	Blood sample may be used for future genetic research
Aggregate	53.3	21.7	28.8	32.8	88.8	66.2
Age (years)						
≤25	46.0**	27.4	33.6	38.1	93.6	71.7
26–45	55.2	20.2	25.8	27.4	90.7	64.5
≥46	54.8	20.5	29.7	36.0	84.5	65.3
Gender						
Men	47.1**	28.8	33.6	39.3**	89.2	63.1
Women	59.3	14.8	24.3	26.6	88.5	69.2*
Healthcare setting						
Inpatient	48.3	17.9	29.5	38.5	88.9	73.5**
Outpatient	56.6	24.0*	28.4	29.2	88.8	61.5
Public	50.7	21.5	29.6	35.2	88.4	67.4
Private	60.1	22.0	26.8	26.8	89.9	63.1
Geographical area						
Rural	49.1	27.6**	35.3*	36.0	92.9**	68.2
Urban	57.1	16.4	23.0	30.0	85.2	64.4
Average monthly expenses (Egyptian pounds)						
≤500	47.9	18.1	27.0	35.3	85.1	64.2
501–1000	61.8*	25.1	30.4	31.9	89.4	66.7
≥1001	52.3	21.9	29.0	30.3	92.9	69.7
Education						
Illiteracy	44.3	22.4	34.2	36.0	85.5	61.8
Sub-university	62.1	19.9	21.8	33.0	89.8	66.5
University	54.8	22.9	30.1	28.3	92.2	71.7
Employment						
Unemployed	56.7	13.8	24.6	28.7	87.5	67.5
Manual	50.8	32.8	36.1	44.3	83.6	59.0
Skilled	37.4	35.2	39.6	41.8	93.4	60.4
Semi-professional	65.2	17.4	15.2	23.9	84.8	73.9
Professional	54.0	26.5	32.7	33.6	92.9	68.1

*p<0.01; **p<0.001.
†Data are percentage of 'yes' responses.

information against having stronger confidentiality protections, in which case re-contact would not be possible as identifiers would be deleted.

Only a slight majority of our study population (66%) were willing to have their linked blood samples used in genetic research, even with assurances of confidentiality. Studies have shown that the public willingness to donate blood samples for genetic research varies between 42% and 90%. In several studies that surveyed the American public, willingness to donate a blood sample for future genetic research ranged from 42% to 85%.[15 25–27] Swedish researchers have found that the public's readiness to contribute linked blood samples to genetic research was 86%, which increased to 89% if the blood samples were unlinked to their identity.[17] In a Singaporean population, 49% would be willing to donate blood for genetic research.[28] In a survey involving the Japanese public, participation in genetic research was approximately 85%, which was about 5–9% lower than a readiness to donate a blood sample for general research.[29] Reasons to account for a lower rate of willingness to donate a blood sample for genetic research might include concerns with stigma from the discovery of genetic information about themselves, their family, or the ethnic group to which they belong,[23] as well as concerns with the extent to which such information can be kept confidential.[14] Most of the studies assessing preferences for genetic research surveyed the general public, whereas our study recruited patients, who might have more fears regarding stigma compared with the general public. This difference in the type of study population might account for our results regarding desires to donate blood samples for genetic research being somewhat lower than many of the other studies. Alternatively, individual ethnic groups might harbour specific fears or concerns regarding genetic analysis of their blood samples. Qualitative studies are needed to explicate further the hesitation by many to have blood samples used in genetic research. Such clarifying studies involving the Arab populations are especially important, in view of the high prevalence of genetic disorders in the Arab world.[30]

Table 5 Respondents' attitudes towards donating blood samples for genetic research before and after receiving an explanation regarding the nature of genes and genetic make-up

Characteristic	Would it be acceptable for your blood samples to be used for genetic research?		
	Yes	No	I don't know
Aggregate (before explanation)*	50.7	18.7	30.7
Aggregate (after explanation)	66.2	23.3	10.5
Education (before explanation)*			
Illiteracy	34.6	12.3	53.1
Sub-university	54.4	18.0	27.7
University	68.1	28.3	3.6
Education (after explanation)			
Illiteracy	61.8	20.2	18.0
Sub-university	66.5	23.8	9.7
University	71.7	27.1	1.2

*p<0.001, χ^2 analysis when comparing aggregate responses before and after receiving an explanation regarding genetics.

Table 6 Responses regarding sharing and exportation of blood samples (n=600)†

Characteristic	Samples may be sent to another Arab country?	Samples may be sent to a European country?	Samples may be sent to the USA?	Source country should have access to drugs derived from analysis?	Government approval for sample exportation?
Aggregate	62.0**	41.8	37.2	89.0	82.2
Age (years)					
≤25	65.5	42.5	31.9	94.7	83.2
26–45	62.9	41.5	38.3	87.5	83.9
≥46	59.4	41.8	38.5	87.9	79.9
Gender					
Men	55.6	41.7	35.9	92.2	85.1
Women	68.2*	42.0	38.4	85.9	79.3
Health setting					
Inpatient	66.7	43.3	38.9	87.6	77.6
Outpatient	59.0	41.0	36.1	89.9	83.6
Public	62.5	39.8	34.0	88.9	82.9
Private	60.7	47.0	45.2	89.3	80.4
Geographical area					
Rural	66.4*	41.7	36.7	89.0	82.3
Urban	58.0	42.0	37.5	89.0	82.0
Average monthly expenses (Egyptian pounds)					
≤500	64.7	33.0	30.2	82.3**	80.9
501–1000	63.8	43.5	36.7	91.3	81.6
≥1001	57.4	52.9	49.0	94.8	84.5
Education					
Illiteracy	63.2	34.2	33.8	84.6	81.1
Sub-university	59.7	41.3	33.5	90.3	84.5
University	63.3	53.0	46.4	93.4	80.7
Employment					
Unemployed	67.1	40.5	36.7	86.2	79.2
Manual	67.2	37.7	32.8	91.8	86.9
Skilled	51.6	37.4	34.1	91.2	89.0
Semi-professional	54.3	52.2	41.3	89.1	82.6
Professional	57.5	46.9	41.6	92.9	81.4

*p<0.01; **p<0.001.
†Data are percentage of 'yes' responses.

Our study population also did not believe there should be a time limit for sample storage, a right for them to withdraw their blood samples, or a right to share in commercial profits. Similarly, other studies have shown that participants do not feel that there should be a limit to the length of sample storage or that individuals are concerned about sharing in commercial profits resulting from the research.[31 32] Qualitative studies should assess whether participants understand the implications of these choices, especially as many commentators have recommended that information about these issues be specified in informed consent forms.[1 7 24 33]

Regarding the exportation of blood samples to other countries, our study population expressed less of a desire to share their biological samples with the USA and European countries compared with other Arab countries. Having said this, only 62% of our study population would allow their blood samples to be shared with other countries in the Middle East. These results contrast with the opinions of the Ugandian individuals, of whom more than 90% stated that they would allow their samples to be sent to a neighbouring country (Tanzania or Kenya) or to the UK or the USA.[19] Factors to account for the unwillingness of our study population to share their blood samples with other countries, especially those from the western world, might revolve around issues of confidentiality, commodification of the samples,[9 11] religious values, or a concern that once blood samples leave the country it might be more difficult to provide oversight on the types of research performed on them.

Our study population also expressed the importance of the source country having access to any drugs that might result from the analysis of the blood samples. This attitude reflects recommendations from several codes of research ethics,[34 35] as well as commentators emphasising concerns with justice and exploitation with research involving developing countries and the need for appropriate benefit sharing between international collaborators.[8 9 11] Our study population also expressed the need to obtain governmental clearance before transporting biological samples with another country.

Our study has several limitations. First, a large proportion of our study population was illiterate, which raises the possibility that many in our sample population might have had difficulty with comprehending concepts such as 'research', 'informed consent' and 'genetics'. To be sure, huge variations in comprehension between illiterate, literate and highly educated persons regarding scientific concepts and terms could confound the results observed in the responses between these groups. To minimise such concerns with comprehension, we instituted two measures to enhance comprehension. First, our data collectors who recruited the study participants were also available to enhance their understanding of the various concepts and terms contained in the survey. Also, we included clarifying information of the major concepts before each set of questions. That such information might have enhanced comprehension of the important concepts in the survey is implied by our results showing that a lower proportion of the respondents (aggregate group and illiterate group) chose the option 'I don't know' after

receiving information about genetics compared with before receiving such information.

Another potential limitation of our study is that although a special training session was held with our data collectors to ensure a uniform and neutral approach with completion of the surveys, framing effects might still have played a role in the responses given by the participants. A third limitation is that this survey study focused on blood samples, whereas patients might have different views on research involving other biological samples, such as tissue and bodily fluids. The strengths of our study include the large sample size and the diverse representation of individuals from different socioeconomic strata in a developing country.

In conclusion, this study shows that many individuals do not favour the donation of a blood sample for future research and of those that do approve of such research, many favour a consent model that include an option that would place limitations on the type of diseases involved with such future research. These results contrast with previous studies that support a 'general' consent model that would not place any limitations on the type of future researches. Also, many of our results suggest potential underlying concerns with the use of blood samples by other investigators, especially those from foreign countries. We recommend further studies in other developing countries, as well as the performance of qualitative research studies to explore more fully the underlying reasons and beliefs accounting for our results.

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