Returning Results of Stored Biological Samples and Biobanks: Perspectives of Saudi Arabian Biomedical Researchers

Ghiath Alahmad,^{1,2} Haneen Alzahrany,^{1,2} and Adel F. Almutairi^{1,2}

Scientific medical research involving human samples often leads to improved diagnosis, the discovery of treatment modalities, or the identification of possible risk factors for many diseases. Some findings, including incidental findings, may be important to donors, and some may require intervention. This study aimed to explore the perspectives of health care professionals in their use of stored biological samples for biomedical research regarding the concept of the research results and the challenges of informing donors regarding the results. This qualitative study involved 19 medical researchers doing research with stored biological samples and biobanks. The data were gathered during face-to-face interviews in English using a semistructured interview technique. The participants provided rich and illuminating experiences, framed in the following themes: the professional duty of researchers to return the research results and the right of donors to know; factors affecting informing donors of results (e.g., severity of disease; impact of the provided information; reliability of the research results; and donor approval); challenges to physically returning the results; and the nature of the informed consent, as well as the elements required in the informed consent documentation. Although the majority of researchers agree on the importance of returning research results, some have contradictory views such as that returning research results is not the researcher's responsibility. The study results also support the view that a number of elements should be included in the informed consent, such as the intention of informing the donors of the results as well as the benefits and risks.

Keywords: research results, incidental findings, return of results, actionable or nonactionable, informed consent, right to know

Introduction

BIOBANKS CONSIST OF LARGE numbers of samples and data, creating an environment for numerous research projects and offering benefits in diagnosing disease, identifying predisposing factors, and other related factors. Such research may result in major contributions, and can provide results important to the patients, donors, or the community; or on the contrary, the results may not have any importance to them.¹ The results may be useful scientifically and not yet part of current practice, being classified as “actionable results” or “nonactionable results.”² Actionable results are those for which an intervention or treatment to slow or cure the disease is available. Research often has unexpected re-

sults, known as “incidental results,”³ which are those that were not part of the original hypothesis or aim, but outside the original purpose for which a test or procedure was conducted. These incidental results may be important or not important, and actionable or nonactionable. Moreover, it is important to consider both clinical validity and clinical utility of any result.⁴

Two more points should be considered, although they are not directly connected to the return of results, but rather to biobanking. First, the return of results is sometimes impossible due to the use of blinded coded samples, especially in the context of biobanks built for generating generalizable information and not to return individual results.⁵ Second, there can be delays in the turnaround of samples in

¹King Abdullah International Medical Research Center (KAIMRC), Riyadh, Saudi Arabia.

²King Saud bin Abdulaziz University for Health Sciences (KSAU-HS), Riyadh, Saudi Arabia.

biobanking, that is, a delay between collection of the sample and when the testing occurs. Depending on the study design, months or even a decade or more can elapse.

The issue of returning research results to donors raises many ethical challenges, the topic of many research studies. One aspect is the definition of the concept of research results, whether they are limited to the research goals or whether they include incidental findings. Among the challenges are the ethical responsibility of the researcher and research institutes to inform donors of the results of the study, and the right of the donor to know or not to know the results, and whether the donor should consent before the research in terms of the possibility of returning any results. Many donors may prefer to receive the results of research conducted with their samples and data, especially when these results have clinical significance for the donor or his family. From another perspective, informing donors of the research results may cause negative effects, for example, anxiety and stress, as well as violation of privacy and confidentiality. Moreover, participants may not wish to receive their results and should be given the right to know or not to know these results accordingly.

The vast number and diversity of research results generated by biobanks, as well as their varying importance and practical value, complicate the ethical challenges experienced by the researchers in returning research results. Many researchers have been interested in investigating and studying the ethical challenges of returning research results, using both quantitative and qualitative approaches. For instance, a qualitative study was conducted by Barazzetti et al. with groups of doctors and citizens in Switzerland.⁶ They reported that the doctors generally agreed on the benefits of returning research results, after considering the potential study associated psychosocial impact. The citizens, however, expressed ambivalent attitudes with mixed feelings between the “right not to know” and the “responsibility to know.”

A qualitative study conducted by Salvaterra et al. used the answers of 31 respondents who responded to open-ended questionnaires sent to a selected group of 57 researchers about biospecimens banking. Only 18 researchers answered the questions related to return of results, which reported that diagnostic information was communicated to parents ($n=9$) or to patients and parents ($n=5$), and to health professionals by letter ($n=4$). However, as determined by responses from researchers, patients did not derive any direct benefit from the use of their biospecimens and/or data in research.⁷

A study conducted in India included ethics committee members and researchers, who agreed that results considered “actionable” or having “clinical significance” should be returned to donors, as it is seen as an ethical obligation and a moral duty on the side of the researchers. The researchers mentioned, as well, some challenges related to cost, ownership, altruism, and mutual benefits.⁸

The risks associated with breaching donors’ confidentiality were a concern for many family decision makers, as indicated in the Siminoff et al. study where 85 family decision makers were interviewed regarding donor confidentiality in biobanks.⁹ Donor families understood that the researchers using biological samples from a biobank would not have access to the donor’s identity-related information. Richards et al. conducted 15 interviews on return of results and the allocation of resources for communicating summary results with researchers and lawmakers.¹⁰ Verlinden et al.

interviewed 28 informants in Benelux and Scandinavia about the custodianship of human biological material and data stored in biobanks and data access, including the return of research results.¹¹

Along the same line, Siminoff and Heather conducted a study using a questionnaire and telephone interviews with 55 U.S. family decision makers about returning research results in biobanks. Most of the family decision makers wanted genetic results to be returned. Results related to treatable diseases or diseases that could affect children were highly regarded, in contrast to results related to untreatable diseases.¹² Similar findings were reported by Bacon and others in terms of the factors determining families’ preferences in receiving the results of genetic tests of their children. Two factors, severity and preventability of the disease, influenced their decision.¹³ Botkin et al. interviewed 11 parents about storing the leftover blood from their children’s samples.¹⁴ Dove et al. examined different issues in pediatric consent forms across Canada, including a theme about whether the return of research results includes individual results and/or incidental findings and the processes involved therein.¹⁵

A review of the medical literature indicates that there is only one quantitative study in Saudi Arabia and the Middle East investigating returning the results. In that study, the perspectives of three different groups, doctors, researchers, and the public, were explored.¹⁶ The authors reported a general agreement that important results should be returned, taking in consideration the right of the donors to refuse to learn about their results. However, their study did not provide a clear definition of the “research results” concept, and whether incidental results were included with the results. The study did not clearly distinguish between actionable and nonactionable results. Given the importance of this topic in a country such as Saudi Arabia and the fact that the first national biobank facility was recently established and operating, it is important to explore this topic deeply using qualitative research methods. The importance is highlighted, as neighboring countries in the Gulf region are moving toward establishing national biobanks. The research location for this study is a governmental institution that offers full free treatment to all National Guard staff and their families. The context of the study is a region that shares common norms and similar social, familial, cultural, and tribal structures, which are built on extended families with strong relationships, a high percentage of consanguinity marriages, respect of old people, solidarity, commitment to the tribe’s opinion, and sacrifice for it.¹⁷

This study aimed to explore the perspectives of health care professionals, mainly physicians, in terms of research results, returning research results to donors, and the complexities associated with this process. The clinical information that was not derived from research (e.g.: from clinical diagnosis or treatment) was not included in this study.

Methods

Research design

Due to the nature of the topic, a qualitative research approach was adopted to explore the perspectives of health care professionals who have been conducting biomedical

research with stored biological samples and the biobank. The study explored the participants' understanding of the concept of research results and the challenges to return the results to the donors. The qualitative design was appropriate due to the fact that this topic is poorly understood in the Saudi Arabian context, with very distinct cultural and social norms. A qualitative design supports an in-depth exploration to develop a complex picture of the phenomenon under investigation and understand a notion that cannot be easily measured.¹⁸

Data collection

The participants were chosen using a sampling technique that refers to deliberate selection of people with knowledge and experience of the phenomenon being investigated.¹⁷ The inclusion criteria were researchers employed by the Ministry of National Guard-Health Affairs in Riyadh or Jeddah, who conducted research using stored samples, and who consented to participate. Potential participants were identified using the research center database and invited to participate by the research team. The participants were informed regarding the importance, purpose, and method of the study before they signed the informed consent.

The data were collected using a semistructured interview technique with a set of open-ended questions written in the English language, giving the participants the chance to speak about their educational and professional background and their relationship and experience with storing samples. Then they were asked in detail about the ethical challenges and their perspectives and thoughts. The open-ended questions used in the interviews are listed in the Table 1. The advantage of this technique is that it gives the researcher the flexibility to probe more based on participants' responses and to focus the interview on the topic. The principle of saturation, a stage where data redundancy is observed, was used to determine the sample size.¹⁹ The interviews were conducted individually, face to face, and audio recorded. The duration for each interview was approximately from 30 to 60 minutes.

Data analysis

The audio recorded data were transcribed by a professional transcriptionist in a Microsoft Word document. The data were analyzed using an inductive approach, namely the thematic analysis technique. It is used to identify and interpret the patterned meanings across the participants' responses. The technique consists of a number of phases. The first phase is data familiarization; the data are read repeatedly to have the sense of the whole. In the second phase, the data are coded, which refers to creating concise labels based on the important features of the data and then followed with categorization. The third phase is related to theme development in which the patterned meanings are identified.²⁰

Ethical considerations

Ethical approval was obtained from the Institutional Review Board at King Abdullah International Medical Research Center (KAIMRC; Reference No.: RC17-002-R). Respect for privacy and confidentiality was observed before, during, and after interviews. No personal information was collected without the participants' knowledge and approval.

TABLE 1. THE LIST OF OPEN-ENDED QUESTIONS

First part	(1) Could you please introduce yourself, including your current work position and research background? (2) Please describe your experience with stored biological samples in terms of collection and purpose? (3) What kind of diseases are you investigating? (4) From whom do you collect those samples? (5) What type of associated data do you collect? And how? Why? (6) For how long do you usually keep your stored biological sample? Why? (7) What do you think about the current practice of storing biological samples? (8) What do you think about the current regulations that govern research?
Second part	(1) How do you define "research results?" (2) What do you think about the right of participants to know research results? (3) How do you differentiate between actionable and nonactionable results? What is the importance of each? (4) Would you share research findings with your participants? (5) How certain must the results be to be shared? (6) What would you do if the patient is unable to understand for any reason? (7) What if a patient decides not to know? (8) If your participants were children, how would you share the results with them? (9) Are you familiar with the term, "incidental findings?" (10) During the analysis of your samples, what would you do if you find incidental findings? (11) Do you think the incidental findings should be seen as part of the research findings? (12) What do you think of the difference between Saudi Arabia and Western countries in terms of sharing research results with participants?

Results

Participants' characteristics

Individual interviews were conducted with 19 researchers; most worked at KAIMRC or its collaborators, in Riyadh and Jeddah. Despite their diverse research disciplines, they all share an interest in genetic research results, directly and indirectly. Four were specialists in genomic research and three engaged in biobanking. Three were researchers in the field of research ethics, in particular an Ethics Committee, with the duty to review and approve research, including genetic research. Three researchers were from the field of experimental medicine, one from nanomedicine, and two from epidemiology. The gender distribution was almost equal (10 males and 9 females) and 50% of the sample was Saudi nationals (Table 2).

Part I: factors affecting the return of research results

The duty of the researcher and the right of the donor. A general tendency related to the importance of returning results, where possible, was observed in the sample, falling

TABLE 2. CHARACTERISTICS OF THE INTERVIEWED PROFESSIONALS

<i>Variable</i>	<i>No.</i>
Gender of interviewees	
Male	10
Female	9
Nationality	
Saudi	9
Algerian	1
Egyptian	2
Indian	3
Jordanian	1
Lebanese	1
Pakistani	1
Syrian	1
Religion	
Islam	17
Christianity	2
Location of interviewees	
Riyadh	16
Jeddah	3
Main specialties of interviewees	
Genomic research	4
Biobank	2
Nanomedicine	1
Experimental medicine	3
Research core facility	2
Developmental Medicine	2
Bioethics	3
Epidemiology	2
Type of interview	
Live	19

within the ethical duties of the researcher. A participant explained,

The moral duty, the trustworthiness between the donors and the medical staff makes it imperative that we inform them of the consequences that can affect their health.

Another participant explained that returning research results is a professional duty imposed by the nature of medical research conducted on humans:

Reporting results that may benefit donors is a moral, professional and humanitarian duty.

However, another participant had a completely opposite view stating that returning research results is not the researcher's responsibility and is not consistent with medical research goals and objectives, as explained,

It is not the task of the researcher to give the results, since the research differs from the treatment, in its objectives and methods.

Some researchers indicated that they believe it is the responsibility of donors to ask for information about the research findings, and to what extent they want to know, as highlighted by the following quote:

We should respect donors wish to be aware of their future results, the same degree of respect for their wishes to know.

This feeling, however, is not consistent among donors and their families. Some researchers explained that some donors

trust their doctors to decide which information they should or should not know.

Often they prefer to leave the doctor to choose what results he wants to deliver to them, he knows their interest.

Factors affecting the reporting of results

Exploring the factors affecting the need to inform donors of the results of their donated sample, several factors were highlighted. These factors include the possibility of using the samples in a practical way to treat disease, the usefulness or potential harm to donors and family, the validity and reliability of these results in terms of disease or science, and finally, the requirement of emphasizing returning the results in the informed consent the donor signs. Table 3 summarizes the factors influencing returning of results with explanations. A participant verbalized his negative attitude regarding returning the research results as follows:

Reporting the results to donors is nothing more than a waste of time and effort.

However, when there is a practical benefit that could be obtained due to a result, the participants agreed that reporting the results is an important duty:

When results are useful, we have to tell the results, especially when they are related to a serious disease like cancer.

However, if the information is related to mild illness based on the researchers' best judgments, some viewed it as not important and worth ignoring.

If information about a symptom or disease is simple, it is not wise to inform the patient unless he or she insists on knowing it.

Balancing benefits versus potential risks is one of the factors raised by participants.

The main factor in the matter of reporting the results is the overriding of the expected benefits on potential risks.

Another factor expressed as important was the reliability of the results.

TABLE 3. FACTORS AFFECTING THE RETURN OF RESULTS

<i>Factors</i>	<i>Explanations</i>
Responsibility of researcher or institution	Professional duty Moral duty
Donor approval	The right to know The right not to know The wish to know
Severity of disease	Serious illness Slight illness
Effects of information	The possibility of its usefulness Expect damage Balance benefits and risks
The reliability of results	Reliable results Potential results Low probable results
Intention	Intentional results Incidental results

Only the explicit results can be communicated to the donors, contrary to the potential results.

Participants had different views related to the reporting of incidental results. Some stated that useful incidental findings should be reported, although other participants did not find this necessary. A third group did not even consider incidental results to be research results.

Incidental information cannot be considered a part of the research results unless it is very serious, which is rare.

Part II: challenges to return results

Reporting the results to the donors is not always easy. A number of challenges were described and were grouped in two categories (Table 4). The first concerns the donors themselves and the second is related to the information to be delivered. There may be barriers preventing researchers to find the donors. Some explanations were as follows:

It's not possible to communicate information to people when they change their addresses and we lose contact with them.
If we get a result about a withdrawn patient, it's a dilemma about how to tell him about that,
When a donor dies, too.

However, loss of contact with the donor is not the only obstacle; there are barriers that make reporting the results very difficult, such as a young age or donor's inability to understand the information.

When a donor is too young or unable to understand the information even if it is streamlined to the fullest extent possible, reporting the results becomes useless.

A donor may have a psychological or emotional state preventing him from fully understanding the information, and in itself is a challenge to communicate the results. The nature of the findings also presents a challenge. It may not be possible to know the donor's identity due to coded samples, which may not be linked to personal details.

Biobanks often use encryption to protect the confidentiality of information, but that's a two-edged code.

TABLE 4. CHALLENGES ASSOCIATED WITH REPORTING OF RESULTS

<i>Category</i>	<i>Type</i>
Challenges related to donors	Lack of communication with the patient Ability to understand information Psychological state Age of the patient Withdrawal of the donor Death of the donor
Challenges related to information	Certainty about the degree of danger and benefit Reversible and nonreversible encoding Disease carrier status Tribal structure and extended families Method of returning the results Cost of returning the results

Using double coding can make researchers unable to know when the results are to be returned.

A challenge mentioned by the participants is that the results of the research may be too large, such as genomic results causing reporting to be very difficult, as well as the inability to be certain of the importance and effectiveness of these results.

It is not often possible to accurately estimate the degree of harm or benefit expected from reporting the results, since the whole thing may depend on intuition and experience.

In some instances, the donor does not have the disease that the information refers to, but may be just a carrier without his health being affected.

I find it awkward to report results that do not directly affect the donor's health, such as being a carrier.

The fact that the results may be related to other people, whether in the family or elsewhere, is also a cause for concern.

The information, especially genetic, is related not only to the person and his family, but sometimes to the whole tribe or to a branch, especially that the tribal structure and extended families is the common structure in our society.

Part III: informed consent and return of results

In discussing the reporting of results in the informed consent before the research, most agreed that it is important. Table 5 summarizes the responses in terms of the elements of informed consent about reporting research results. The following description highlights the participants' views related to importance:

Stating in the informed consent the return of results is important; it is a reflection of the principle of human respect.

Concerning the specific results to be reported and stated as such in the informed consent resulted in a range of points, including the possibility of reporting the results or not, and what specifically to report, the benefits and risks expected, as well as how and who will report.

The researcher must tell the donor before he or she is involved in the research about the possibility of telling him about the results, and how.

Return of research results lead to potential risks, the donor should be made aware about that before the donation and before the return of these result.

TABLE 5. INFORMED CONSENT IN REPORTING RESULTS

The purpose	Importance of returning the results Respect of donor
Elements	Decision related to returning the results Expected benefits of returning results Expected risks of returning results The means of communication What information will be returned The person or entity
The process	Voluntary Simplicity and ease Suitable time Suitable place Level of return of results

Regarding the importance of reporting results, one participant explained the following:

You should explain to the donor the benefits expected from the results and what to do next.

The participants highlighted the importance of describing the means of communication between the donor and the researcher or the research center in the informed consent. As for how to return the results, participants mentioned respecting donors' voluntary decisions, as well as using understandable and simple language.

You should choose the right time and place, and the results should be reported by your doctor.

Participants stressed the importance of stating what specifically should be reported to donors in the informed consent and this should be classified based on significance:

It is preferable to have a multiple levels of consenting of outcomes that the donor wishes to know and to be classified according to their clinical significance.

Discussion

Views of participants interested in genetic research, and biobanks, of returning results to donors were explored. The study highlighted a sense of moral responsibility toward donors, especially when the results are useful or actionable. The findings of this study are supported by studies conducted elsewhere, such as Vaz and Vaz,⁸ Murphy et al.,²¹ Bollinger et al.,²² and others, who reported that giving back the results to the people who participated in research is seen as an ethical obligation and a moral duty from the viewpoint of the researchers. It is also consistent with the rules governing Saudi biobank operations,²³ while Knoppers et al. presented different modalities of regulations and policies in regard to whether or not to return results.²⁴

In addition to having a moral duty, the fact that a donor has a genuine right to know his findings was accepted by the majority of the participants. This supports the results of a previous Saudi Arabian study, in which more than half (56%) of the participants agreed with the donors' rights to know their results.¹⁶ This finding is also mentioned in international studies, such as by Jarvik.²⁵ The researchers' duty to return the results is not only based on the principle of moral responsibility but also on the right of the donors to know the results, based on the right of autonomy, which is a translation of the principle of respect of persons, corresponding to a previous study in Saudi Arabia.¹⁶

However, participants highlighted a number of factors influencing the return of results, especially in terms of functional effectiveness and the clinical usefulness of the results to the donor, which make results more logical and feasible. This is also in line with what other researchers have found in their studies, pointing to the validity of the results to be more actionable and clinically significant.^{26,27} However, the field of actionability has differed in its identification, especially in terms of its limitation to clinical aspects or its adaptation to other nonmedical areas.²⁸

One of the factors affecting whether or not results are to be returned, is reliability. The more reliable the information is, the higher the likelihood of it being returned.^{21,29,30} Results that are not reliable could cause a real dilemma in practice. Knowing the degree of reliability of results will

help researchers in making the most correct decision about returning results to patients. The utility of these reliable results should be judged against different diseases, which could be classified in three categories: preventable and treatable; nonpreventable or treatable; and unclear whether they are preventable and treatable.³¹

Another factor influencing the reporting of donors' research results is the severity of the disease, as return of results is seen as less important in diseases that cause mild or minimal discomfort compared with fatal or disabling diseases.¹³ When results are associated with serious illnesses, reporting is more important. This is consistent with the results of other studies. In a previous study, only 30% of researchers agreed that nonimportant results should be returned compared to 80% for important information associated with the serious diseases.¹⁶ This is also consistent with other studies.²⁸

The researchers also took into consideration the issue of harm and negative effects that may result from the return of results, including the characteristics of the donor, the quality of the information, and the importance of the intended benefits being greater than the potential risks. In practice, this is one of the ethical principles governing medical research.^{9,15,32,33}

Protecting the confidentiality of information and the privacy of donors is a challenge related to returning research results. This has been reported by several researchers.^{8,9,24,31} This aspect is even more complicated, due to the sharing of information with others. Returning medical and genetic results poses particular challenges because of cultural specificity and social structure, due to the tribal nature and extended families characteristic of Saudi Arabia and neighboring countries in the region.^{34,35} Any violation of confidentiality and privacy will affect not just the narrow individual range, but would extend to a family-wide and tribal range for the reason that people are seen as a part of wider context due to many factors, such as strong connections and relationships among families and tribes. In addition, there is a percentage of consanguinity that makes genetic diseases more likely. If stigma occurs, the risk for extended effects, especially in genetic diseases reflected in social and other relationships, is significant. This corresponds to the governance of a Saudi biobank, which insists on preventing any kind of discrimination or stigma³⁶; and to the results of previous studies related to medical confidentiality reporting similar results.^{16,34} Although return of results reflects the right to know on a personal level, information is shared with relatives. This is an issue that raises questions about the limits of independence of genetic information to which any person is entitled.

The process of returning results to donors also faces a number of challenges such as lack of communication due to several reasons, including change of address, loss of contact, or the death of a donor. In addition, sometimes, the psychological impact of returning results and varying degrees of awareness of the donors will raise questions about the potential utility of returning research results to some people, and make communication of information impossible and futile. All of this makes learning communication skills very important in creating a culture of trust with donors.³⁷

The withdrawal of the donor from a study also exacerbates reporting the results. Many of the biobanks use varying degrees of withdrawal to enable them to continue to

use prestored data and samples that are often irreversibly anonymized, making return of results impossible. Should the data be kept in a reversible coding scheme, the return of results is possible and affordable.^{38,39}

An aspect affecting the reporting of findings is “being a carrier” of a disease, a matter that has been investigated in a number of research studies. In a study done by Klitzman et al., the donors were satisfied to be informed, should they be a carrier. Information regarding their carrier status for a disease can have implications for the behavior and decisions of donors and their families, including reproductive decisions.²⁷ However, when a carried disease is classified as a moderate normal risk, the return of the results does not have a tangible benefit, for example, reporting BRCA1 mutation to a 70-year-old patient,⁴⁰ although such information might benefit other family members.²⁷ However, another study showed more negative emotional responses among relatives than donors themselves.⁴¹ Some researchers believe that recessive status may be reported if the gene is more than 1% and the incidence of the disease is more than 1/40,000.⁴²

Cost is another challenge inherent in the process of returning research results, especially when coding is broken and when there are consequences for the reporting process. Returning results is costly and requires adequate financial investment and establishing an infrastructure for dealing with the increasing number of results that will be returned, as well as the increasing number of research proposals. Moreover, there are difficulties related to the source of funding, such as who will cover expenses, including but not limited to, insurance and health coverage in the case of positive results. Many researchers have emphasized the issue of cost and its impact on reporting results.^{25,43}

The relationship between informed consent and returning the results to donors, as well as the importance of stating them explicitly in the informed consent document, has been researched and supported by the views of the participants in our study. It must be stated clearly that the decision to have results returned is entirely voluntary, as the right of donors to not know is a stable right and a sound ethics practice.^{31,44} It is necessary to indicate whether partial or complete results will be returned, and which results are expected to be returned.

Returning results may have benefits, whether clinically, psychologically, communicatively, or even scientifically, which should be clarified to the donor, and similarly potential harm, to enable the donor to make an informed decision. Because genetic information is not always individual information, it may be familial or even tribal; its effects can be extended to others. The law may require notifying certain parties, so this must be clear in the informed consent signed by the donor, for an autonomous and correct decision.

The researchers noted some points related to the informed consent as well as how they are performed and obtained, insisting that returning research results ensures the voluntary nature of the decision, in simple, easy, and understandable language at the right time and place. This is in accordance with the requirements essential for ethical practice in any scientific research, as stipulated in local and international research ethics regulations.

Conclusion

This study presents the perspectives of a group of researchers in genetics and biobanks in the Kingdom of

Saudi Arabia, regarding returning research results to the donors. While the group generally agreed, they highlighted a number of challenges experienced when returning results generated during the research process, both in terms of the donors and the information. The study noted that the concerns of the researchers in Saudi Arabia are similar to what has been reported in other regions of the Western world, despite the differences in customs, traditions, and the family and social system. The study also emphasized the need for further research to manage these challenges, and the importance of coordinating with other biobanks.

Study limitations

Although our participants were experts in biobanks and stored samples, we are not sure whether their answers reflect actual experience in returning results. Moreover, only three participants have a bioethics background, which may not be sufficient to represent all bioethicists' points of view, or show real differences with other participants.

Author Disclosure Statement

The authors declare no conflict of interests.

Funding Information

This research is funded by King Abdullah International Medical Research Center. Grant Number: RYD 17-417780-30903.

References

1. Halverson CM, Ross LF. Engaging African-Americans about biobanks and the return of research results. *J Community Genet* 2012;3:275–283.
2. Burke W, Evans BJ, Jarvik GP. Return of results: Ethical and legal distinctions between research and clinical care. *Am J Med Genet C Semin Med Genet* 2014;166:105–111.
3. Cho MK. Understanding incidental findings in the context of genetics and genomics. *J Law Med Ethics* 2008;36:280–285.
4. Burke W. Genetic tests: Clinical validity and clinical utility. *Curr Protoc Hum Genet* 2014;81:9–15.
5. Wallace SE, Kent A. Population biobanks and returning individual research results: Mission impossible or new directions?. *Hum Genet* 2011;130:393–401.
6. Barazzetti G, Cavalli S, Benaroyo L, et al. “Still rather hazy at present”: Citizens' and physicians' views on returning results from biobank research using broad consent. *Genet Test Mol Biomarkers* 2017;21:159–165.
7. Salvaterra E, Giorda R, Bassi MT, et al. Pediatric biobanking: A pilot qualitative survey of practices, rules, and researcher opinions in ten European countries. *Biopreserv Biobank* 2012;10:29–36.
8. Vaz M, Vaz M. The views of ethics committee members and medical researchers on the return of individual research results and incidental findings, ownership issues and benefit sharing in biobanking research in a South Indian city. *Dev World Bioeth* 2018;18:321–330.
9. Siminoff LA, Wilson-Genderson M, Mosavel M, et al. Confidentiality in biobanking research: A comparison of donor and nondonor families' understanding of risks. *Genet Test Mol Biomarkers* 2017;21:171–177.

10. Richards JE, Bane E, Fullerton SM, et al. Allocation of resources to communication of research result summaries: biobank participant perspectives. *J Empir Res Hum Res Ethics* 2016;11:364–369.
11. Verlinden M, Nys H, Ectors N, et al. Qualitative study on custodianship of human biological material and data stored in biobanks. *BMC Med Ethics* 2016;17:15.
12. Siminoff LA, Heather MM. Family decision maker perspectives on the return of genetic results in biobanking research. *Genet Med* 2016;18:82.
13. Bacon PL, Harris ED, Ziniel SI, et al. The development of a preference-setting model for the return of individual genomic research results. *J Empir Res Hum Res Ethics* 2015; 10:107–120.
14. Botkin JR, Rothwell E, Anderson RA, et al. What parents want to know about the storage and use of residual newborn bloodspots. *Am J Med Genet A* 2014;164:2739–2744.
15. Dove ES, Avar D, Black L, et al. Emerging issues in paediatric health research consent forms in Canada: Working towards best practices. *BMC Med Ethics* 2013;14:5.
16. Alahmad G, Dierickx K. Return of research results in the Saudi Biobank: An exploratory survey. *Genet Test Mol Biomarkers* 2017;21:166–170.
17. Barakat H. *The Arab World: Society, Culture, and State*. California: University of California Press; 1993.
18. Creswell J. *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches*. 3rd ed. Thousand Oaks, CA: Sage; 2012.
19. Sugarman J, Sulmasy DP. *Methods in Medical Ethics*. Washington, DC: Georgetown University Press; 2001.
20. Denzin NK, Lincoln YS (eds.). *The Sage Handbook of Qualitative Research*. Thousand Oaks, CA: SAGE Publication; 2011.
21. Murphy J, Scott J, Kaufman D, Geller G, LeRoy L, Hudson K. Public expectations for return of results from large-cohort genetic research. *Am J Bioeth* 2008;8:36–43.
22. Bollinger JM, Bridges JF, Mohamed A, Kaufman D. Public preferences for the return of research results in genetic research: A conjoint analysis. *Genet Med* 2014;16:932.
23. The governance of Saudi Biobank. Riyadh: King Abdullah International Medical Research Centre; 2011.
24. Knoppers BM, Deschênes M, Ma'n HZ, Tassé AM. Population studies: Return of research results and incidental findings Policy Statement. *Eur J Hum Genet* 2013;21:245.
25. Jarvik GP, Amendola LM, Berg JS, et al. Return of genomic results to research participants: The floor, the ceiling, and the choices in between. *Am J Hum Genet* 2014;94: 818–826.
26. Lakes KD, Vaughan E, Lemke A, et al. Maternal perspectives on the return of genetic results: Context matters. *Am J Med Genet A* 2013;161:38–47.
27. Klitzman R, Appelbaum PS, Fyer A, et al. Researchers' views on return of incidental genomic research results: Qualitative and quantitative findings. *Genet Med* 2013;15:888.
28. Grove ME, Wolpert MN, Cho MK, Lee SS, Ormond KE. Views of genetics health professionals on the return of genomic results. *J Genet Couns* 2014;23:531–538.
29. Klitzman R, Buquez B, Appelbaum PS, Fyer A, Chung WK. Processes and factors involved in decisions regarding return of incidental genomic findings in research. *Genet Med* 2014;16:311.
30. Fernandez CV, Kodish E, Shurin S, Weijer C. Offering to return results to research participants: Attitudes and needs of principal investigators in the Children's Oncology Group. *J Pediatr Hematol Oncol* 2003;25:704–708.
31. Henderson GE, Wolf SM, Kuczynski KJ, et al. The challenge of informed consent and return of results in translational genomics: Empirical analysis and recommendations. *J Law Med Ethics* 2014;3:344–355.
32. Vermeulen E, Rebers S, Aaronson NK, Brandenburg AP, van Leeuwen FE, Schmidt MK. Patients' attitudes towards the return of incidental findings after research with residual tissue: A mixed methods study. *Genet Test Mol Biomarkers* 2018;22:178–186.
33. Avar D, Silverstein T, Sillon G, et al. Researchers' perceptions of the ethical implications of pharmacogenomics research with children. *Public Health Genomics* 2009;12:191–201.
34. Alahmad G, Al Jumah M, Dierickx K. Confidentiality, informed consent, and children's participation in research involving stored tissue samples: Interviews with medical professionals from the Middle East. *Narrat Inq Bioeth* 2015;5:53–66.
35. Alahmad G, Hifnawy T, Abbasi B, et al. Attitudes toward medical and genetic confidentiality in the Saudi research biobank: An exploratory survey. *Int J Med Inform* 2016;87:84–90.
36. Alahmad GH, Dierickx K. Confidentiality, informed consent and children's participation in the Saudi biobank governance: A comparative study. *East Mediterr Health J* 2014;20:681–689.
37. Mester JL, Mercer M, Goldenberg A, et al. Communicating with biobank participants: Preferences for receiving and providing updates to researchers. *Cancer Epidemiol Biomarkers Prev* 2015;24:708–712.
38. Wolf SM, Crock BN, Van Ness B, et al. Managing incidental findings and research results in genomic research involving biobanks and archived data sets. *Genet Med* 2012;14:361.
39. Laberge C, Kharaboyan L, Avar D. Newborn screening, banking, and consent. *GenEdit* 2004;2:1–15.
40. Antoniou A, Pharoah PD, Narod S, et al. Average risks of breast and ovarian cancer associated with BRCA1 or BRCA2 mutations detected in case series unselected for family history: A combined analysis of 22 studies. *Am J Hum Genet* 2003;72:1117–1130.
41. Hallowell N, Alsop K, Gleeson M, et al. The responses of research participants and their next of kin to receiving feedback of genetic test results following participation in the Australian Ovarian Cancer Study. *Genet Med* 2013;15: 458–465.
42. Solomon BD, Hadley DW, Pineda-Alvarez DE, et al. Incidental medical information in whole-exome sequencing. *Pediatrics* 2012;129:1605–1611.
43. Bledsoe MJ, Clayton EW, McGuire AL, et al. Return of research results from genomic biobanks: Cost matters. *Genet Med* 2013;15:103–105.
44. Pereira S, Robinson JO, McGuire AL. Return of individual genomic research results: What do consent forms tell participants?. *Eur J Hum Genet* 2016;24:1524.

Address correspondence to:

Ghiath Alahmad, MD, PhD

King Abdullah International Medical Research
Center (KAIMRC)

P.O. Box 3660, Mail Code 1515

Riyadh 11481

Saudi Arabia

E-mail: ghiathalahmad@hotmail.com;

ahmadg@ngha.med.sa