

ASSESSING THE ATTITUDES AND UNDERSTANDING OF CLINICAL TRIAL PARTICIPANTS IN THAILAND TO BIOBANKING

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ABSTRACT:

Background: Attitudes and understanding of clinical trial participants regarding biobanking are not fully understood. This study explored the baseline understanding of biobanking amongst clinical trial participants in Thailand, to determine factors and attitudes which may affect an individuals' decision to consent to involvement in biobanking studies.

Methods: Using qualitative research methodology, clinical trial participants (n=24) who were already enrolled in clinical research studies at the Hospital for Tropical Diseases were given an information sheet explaining biobanking. An in-depth interview was then conducted along with a demographic questionnaire. The results were analyzed using NVIVO 10 software.

Results: Fifty four percent felt they had a clearer understanding of biobanking after reading the brochure. All the respondents were willing to donate a blood sample to a biobank, and 22/24 were positive towards the concept of biobanking, citing an altruistic desire to help future medical research efforts, potential benefits for their family and prospect of learning more about their own health from future studies such as genetic projects. There was an inverse relationship between the level of education / income of participants and their desire to receive direct financial compensation for donating a sample. Sixty two percent agreed that their sample could be stored and used indefinitely even after their death. Interviewees wishing to have clear structures of consent, protection of confidentiality of personal information, and fifty four percent wished to be contacted to specifically consent for future studies using their sample. They felt governance structures should involve researchers, a specific biobank committee and Government organizations. Whilst most responses were positive, including the potential for Thai samples to be used by researchers in other countries, the level of agreement was markedly lower if samples might be used by commercial companies such as pharmaceutical industry (73% neutral or disagreed).

Conclusions: Most respondents have a clearer understanding and positive attitude towards the concept of biobanking. This study suggests that researchers should provide both written and oral information during enrollment for biobanking studies, giving time for participants to better understand the purpose of biobanking studies prior to signing a consent form. They have implications for the planning and establishment of biobanking facilities in Thailand.

Keywords: Biobanking, Clinical trial participant, Qualitative research, Informed consent

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INTRODUCTION

A biobank is a repository that stores biological samples and their associated data for use in medical/scientific research and diagnostic purposes, and organizes them in a systematic way for use by

others [1]. Biobanks have become a key resource for the medical research community, supporting many

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types of contemporary research such as genomics and personalized medicine [2, 3]. The organization of these specimen collections and their governance in Thailand are at an early stage and it is not a concept familiar to many Thai people. This limitation of understanding may lead to difficulties explaining research methodology and obtaining adequate informed consent from patients for participation in biobanking based research projects. Little research has been done on this issue in Thai patients and clinical trial participants, or Thai researchers.

Biobanks raise many questions of research and medical ethics. Because people have not heard of the concept of sample sharing, and retention for use in different studies to that which they have given their initial consent for, they may not understand what is involved. So informed consent for donating a sample to a biobank cannot be assumed but must be preceded by explanation, especially in developing as opposed to developed countries [4]. While viewpoints on what constitutes appropriate biobanking ethics diverge, consensus has been reached that relying on biobanks without carefully considered governance principles and policies could negatively impact communities participating in biobank programs [5]. Biobanking often raises concerns both from patients donating samples, regarding their use, the information which may result and confidentiality. In some cases they may have religious, cultural or personal objections to their samples being kept for an extended period, or used after their death, or may have different views on their potential use.

Importantly such attitudes vary according to country and culture and there is little information about the potential factors influencing patient understanding of biobanking in Thailand [6]. Gaining data on the attitudes to and understanding of biobanking research, which affect patient participation in research trials, is a key process [7]. Qualitative research is needed to understand patient's attitudes, to allow preparation of information sheets and discussion with patients in gaining proper informed consent [8]. We therefore performed a study examining the attitudes of clinical trial participants in Thailand to determine the factors influencing their understanding of biobanking research and likely to affect consent processes in the future.

MATERIALS AND METHODS

Study design

Following agreement to participate in this study, an information sheet was given to the

participant who was allowed at least 30 minutes to read this. Following this a demographic questionnaire (to gather personal information) was filled in, and an in-depth interview was conducted by a qualified researcher (duration typically 40-45 minutes). The interview was conducted in Thai and digitally recorded and transcribed and responses translated into English. The Interview format included a brief introduction of the content and aims of this study to the participant, initial feedback on the information brochure given to enable clarification of any points which they did not understand, and then a series of specific set questions designed to explore their attitudes and understanding of biobanking research and their views on different scenarios involving the potential use of biobank samples.

Study population and sampling

The sample population for this phase (n=24) were recruited using purposive sampling for study with specific type of knowledge or skill [9], from the population of all clinical study participants at the Hospital for Tropical Diseases, Mahidol University between August-November 2014. This included patients between 20-60 years old, involved in clinical trials for diseases including malaria and dengue hemorrhagic fever, who were able to write, read and speak the Thai language. They were participating in a clinical research trial which specifically involved collection and storage of a blood sample at enrollment visit, and subsequent follow up visits. Individual patients were invited to participate and recruited according to eligibility criteria having given written consent. The aim was to get a range of patients with different points of view, which required a range of demographics such as age, gender, marital status, religion, education, occupation and income level.

Several authors have suggested that the minimum requirements for sample size in a qualitative study needs to be between twenty and thirty [10, 11]. This qualitative study used purposive (criterion-based) sampling, that is, a sample that has the characteristics relevant to the research question [12]. Sampling continues until the researcher recognizes no new data were forthcoming – a point of data or information redundancy [13].

Content validity

The questionnaire was evaluated prior to use using the index of item objective congruence (IOC) test on 3 trial responses. This process allows experts to rate individual questions on the degree to which they do or do not measure specific objectives listed by the test developer [14]. Thereafter, 3 professional

Table 1 Summary demographics of Participants:

Characteristics N=24		
Gender	Male 12(50%)	Female 12 (50%)
Age (yrs)		
20-30	2 (17%)	2 (17%)
31-40	7 (58%)	2 (17%)
41-50	2 (17%)	7 (58%)
51-60	1 (8%)	1 (8%)
Education		
Primary school	1 (8%)	1 (8%)
High school	5 (42%)	3 (25%)
Diploma/ vocational education	2 (17%)	1 (8%)
Bachelor degree	3 (25%)	3 (25%)
Above bachelor degree	1 (8%)	4 (34%)
Income (THB)		
5,000-10,000	1 (8%)	2 (17%)
10,001-20,000	8 (67%)	7 (58%)
20,001-30,000	2 (17%)	0 (0%)
Above 30,000	1 (8%)	3 (25%)
Occupation		
Public servant/ employee in public sector	4 (33%)	6 (50%)
Temporary worker	4 (33%)	4 (33%)
Employee in private sector	4 (33%)	2 (17%)
Marital status		
Single	6 (50%)	4 (34%)
Married	6 (50%)	6 (50%)
Divorce/ separate	0 (0%)	1 (8%)
Widowed	0 (0%)	1 (8%)
Religion		
Buddhism	11 (92%)	11 (92%)
Christian	0 (0%)	1 (8%)
No religion	1 (8%)	0 (0%)

experts reviewed and examined each item of questionnaires for consistency, accuracy and content. The IOC score of more than 0.5 was considered to indicate good content validity [15]. The final measure of IOC for the Demographic questionnaire in this study was 1.0 and interview questionnaire was 0.66.

Data analysis

Qualitative data: Computer-assisted qualitative data analysis used NVIVO version 10 software (QSR International; Australia) for data coding, management, and analysis.

Quantitative data: The completed demographic questionnaires was coded and entered for analysis by the SPSS software version 17 (IBM, Thailand, licensed version at Chulalongkorn University).

Ethical considerations

Ethical permission to perform this study was given by Ethics Review Committee for Research Involving Human Research Subjects, Health Science group, Chulalongkorn University (ECCU) (ref 138.1/57), Faculty of Tropical Medicine (FTM),

Mahidol University (TMEC 14-029) and OxTREC; Oxford University (542-14).

RESULTS

The demographic results of the study participants are summarized in Table 1. There were an equal number of male and female participants, with a preponderance of young - middle aged (18/24 between the ages of 31-50). There was a mix of income, occupation and education with some bimodal distribution of the level of education in the female participants with 7/12 having a Bachelors degree or above. The participants were overwhelmingly of Buddhist religion 22/24.

Attitudes toward clinical trials participation

In terms of their involvement in the original clinical trial which led to them being asked to participate in the biobanking questionnaire, the responses were very positive, with all participants either 'feeling good' about participating in clinical studies 22/24 or 'neutral' 2/24. They gave a number of reasons for these positive attitudes (Figure 1). No respondents felt "Negative" about clinical research.

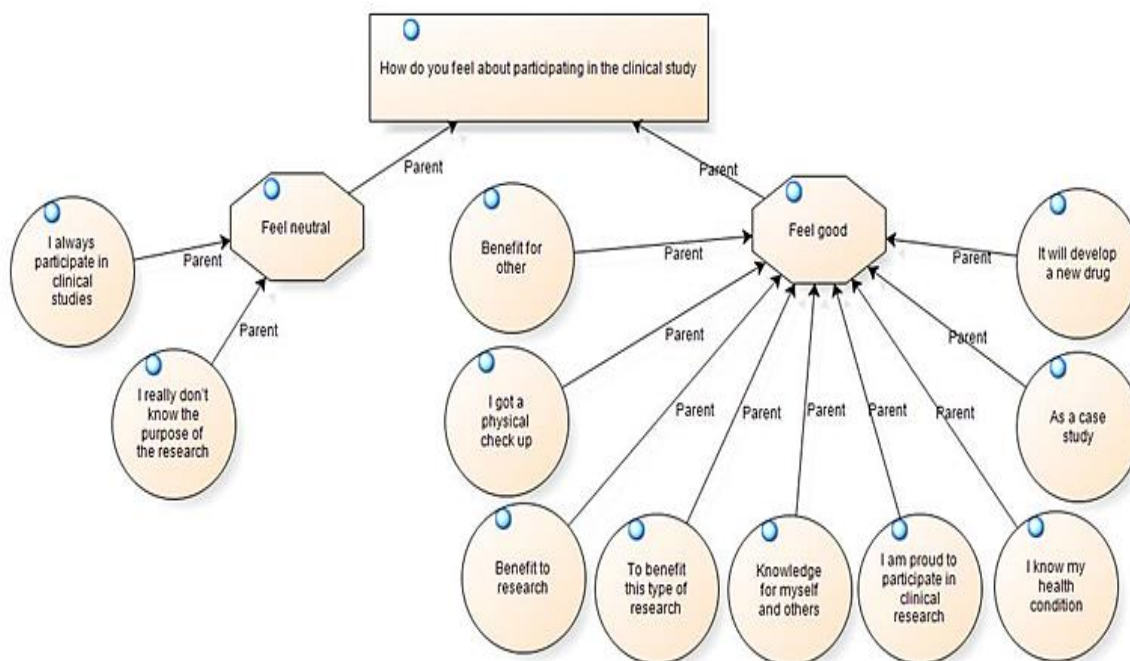


Figure 1 Summary of responses to the question “How do you feel about participating in a clinical study?”

Were there particular factors influencing this decision?

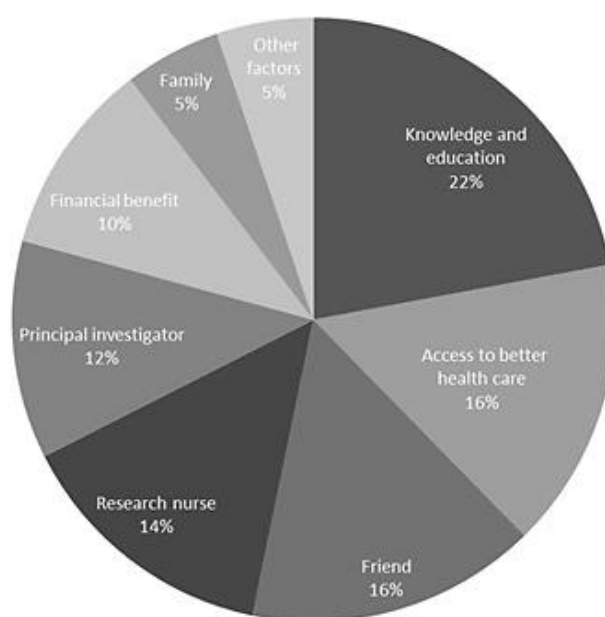


Figure 2 Pie chart illustrating factors listed as influencing decision to participate in clinical trials

Example quotes explaining the attitudes of participant included:

Positive: Male, age (41-50 years)

“I feel good to know about my health and proud to be a part of research”

Female, aged (51-60 years)

“I feel good and proud to be participating in clinical research, it means I am strong and am able to help research for others (who have this disease) after using the drug treatment that I am involved in”

Neutral: Male, aged (51-60 years)

"I fell neutral because I really don't know the purpose of the research"

Female, age (41-50 years)

"I feel neutral because I often participate in clinical studies"

Factors influencing the decision to participate in clinical trials

Interviewees listed a number of factors as impacting on their decision to participate in the original clinical study (summarized in Figure 2) including wanting to have more knowledge and education about their own condition (22%) from the study. Access to better health care (16%) and the advice of friends (16%) were other factors influencing their decision to participate or because the opportunity to participate in the study arose whilst they were a patient, and they wanted to know or learn more about a particular clinical study.

Level of understanding of participation in clinical trials

Half of participants (50%) felt they understand the aim of clinical study based on the information given by researcher before signing the consent form, but 50% stated that this was only a 'partial' understanding.

Understanding of the concept of biobanking and the influence of the information sheet

Similar to the original clinical trial, the level of understanding of a biobanking study following access to the patient information sheet was about half of all participant (13/24). Those who felt they only partial understood the concept of biobanking after reading the information brochure 11/24 requested more details about how their sample might be used in future studies, and others said that they would prefer more "lay" language or non-technical term to be used in leaflet to help increase their understanding of the process. Comments as to why they did not feel they fully understood included:

Female, aged (41-50 years)

"I partially understand, this is new knowledge and the pamphlet needed to add more information"

Male, aged (31-40 years)

"I understand it involves stored tissue samples for research, but need time to understand fully"

Factors influencing the decision to participating in biobanking a blood sample

All patients mentioned their desire to help with future studies through biobanking as this may help their children or relatives in the future (24/24). There was also agreement amongst all participants for an altruistic 'Humanitarian' motivation, contributing to future medical research which might help other people (24/24). In particular they felt that potential future research projects involving genetic testing might benefit themselves or their family. Others mentioned the possibility of monetary benefit, with (8/24) stating that compensation would influence the decision to donate a blood sample

Attitudes toward biobanking studies - advantages and disadvantages

All of interviewees were willing to share their blood sample or donate it to biobank for future use. Example quotes detailing participants views as to the potential benefit of biobanking included:

Male, aged (31-40 years)

"I would like to share my blood sample or donate it to a Biobank if they have a good system and confidential process"

Female, aged (41-50 years)

"Yes, I would like to share my sample, but it depends on the criteria and process of the study"

Female, aged (31-40 years)

"My blood will useful for studying rare diseases"

Female, aged (20-30 years)

"It for developing research for prevention and treatment of disease"

Female, aged (41-50 years)

"It for social benefit and it would be benefit drug producing process"

Participants gave a number of different perspectives on the potential benefits and problems of biobanking research (Figure 3). All participants felt it would benefit future research and treatments, and some felt there was an advantage in keeping samples for future research projects because it is saved research costs, reduced time for blood collection and had broader social benefits. Others had personal reasons such as knowledge of their

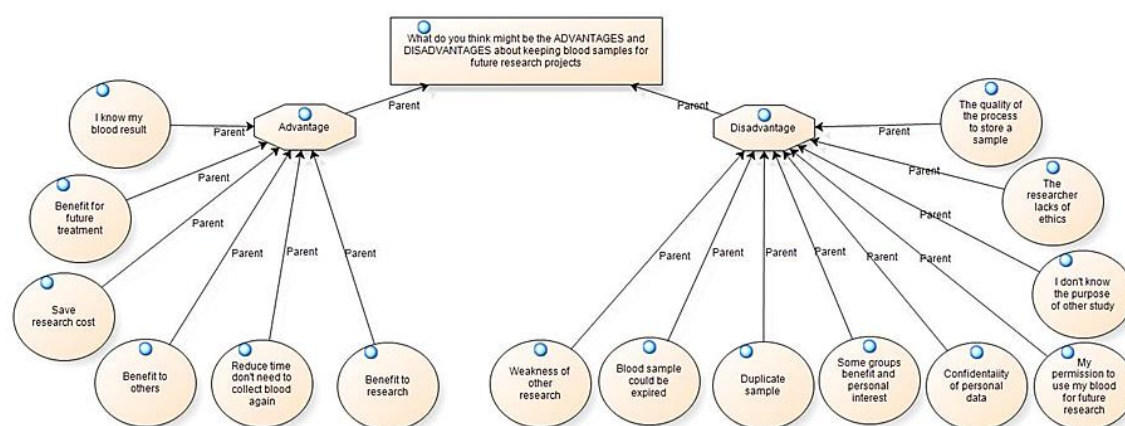


Figure 3 Participants views on the advantages and disadvantages of biobanking studies

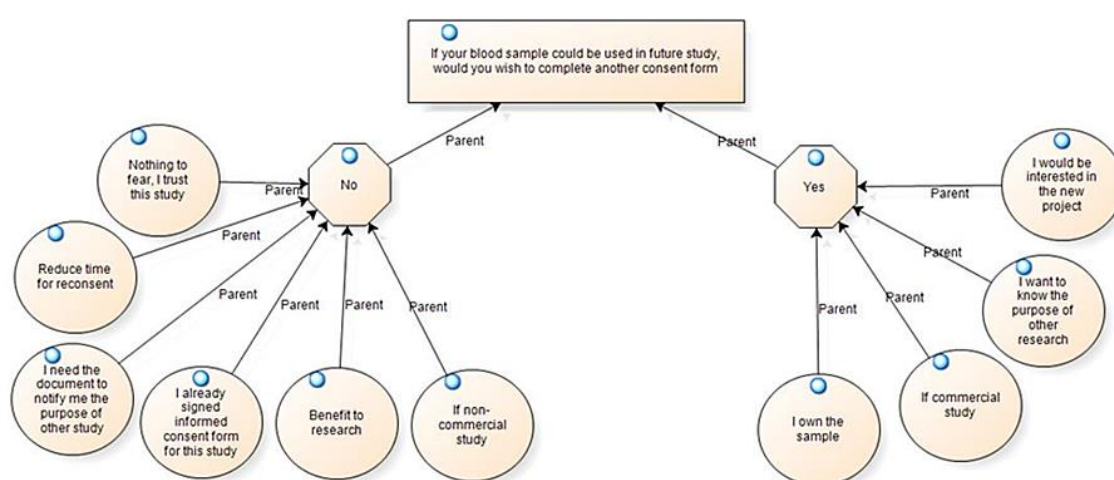


Figure 4 The issue of re-consent for subsequent studies using a biobanked sample

own blood result (and potentially future genetic information derived from it) for themselves or their children / family.

Others (9/24) mentioned potential disadvantages such as blood samples expiring or being used up, lack of ethics of some researchers, confidentiality of personal data, and need to ensure the quality of storage processes. There were specific comments regarding some way to ensure the quality of future research, protect against personal interests being derived from the biobank, ensure consent was granted for each subsequent study, and the problems of donating duplicate samples.

Most of participants were positive about the convenience of being asked to use their blood sample in another study by research team (22/24) because it had a wider benefit to society and medical research, and it saved time. None were against this and (2/24) felt neutral.

All participants agreed that a decision to share

their sample depended on the sample type – All of interviewees prefer blood because it easy to collect, but a majority would be willing to donate a sample from tissue/ organ (18/24) or DNA (13/24), if they were involved in a study which allowed collection of these types of sample.

Expectations of monetary benefit for donating a sample

Half of participants expect some direct benefit in return for sharing their blood sample with other researchers or studies. Sixty seven percent of interviewees who expected to benefit defined this as either a present or monetary payment, or benefits such as getting a free blood sample result, physical exam or treatment. However others meant only that they would like access to the results of further studies (for instance genetic information in the future) and (6/24) expected no benefit whatsoever, these patients regarded the donation as purely for social benefit. There was some variation in this

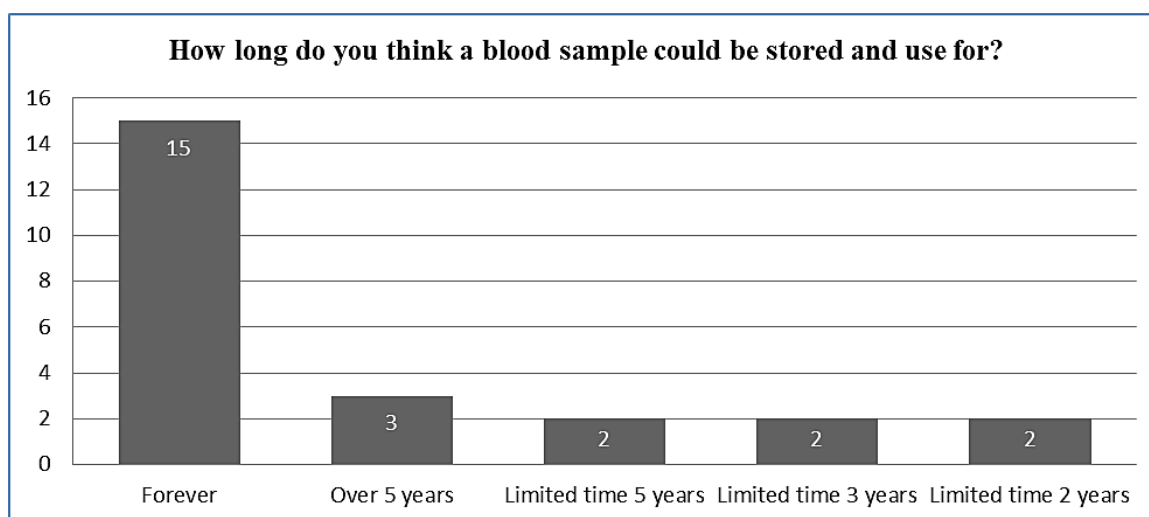


Figure 5 Variation in the time for which participants felt a sample could be kept

depending on income – in patients earning less than 20,000 THB/month (10/18) wanted payment, whereas in those earning >20,000 THB/month this was only 2/6.

Reconsent for subsequent studies utilizing biobank samples

Thirteen participants felt that each time their blood sample could be used in other research, they should be asked to consent to its use separately for each prospective study (Figure 4):

Feedback on the use of samples in subsequent studies

Most participants (19/24) wanted to be kept informed of the results of subsequent studies using their blood sample. The ways in which they preferred being informed included by letter (8/24), email (7/24), or text message (4/24).

Biobank governance

The participants were asked to suggest different possibilities as to who should be responsible for governing the use of a biobank containing multiple stored specimens from various patients in different studies. They were allowed to suggest more than one response, so they could suggest a number of different organizations who might have control. Responses included establishing a specific biobank committee (22/24), (18/24) felt the researcher should be responsible and (17/24) thought a Government organization should be involved.

Views on prospective storage time of samples

The issue of how long a specimen could be stored and used in subsequent studies led to a variety of responses (Figure 5) although most felt it could be kept indefinitely, even after the patients death (15/24).

Use of biobank samples in collaboration with Researchers in other countries outside Thailand

Most participants (21/24) were positive about the potential use of blood samples in collaborative international research, if for instance they were made available to researchers in another country.

Use of biobank samples in collaboration with commercial organizations

However, this did not extend to the unlimited use of samples for other organizations. Where this would involve a financial implication, for instance if samples were made available to researchers in Industry (like drug / pharmaceutical or commercial R&D companies) the participants felt 'neutral' (7/24) or 'uncomfortable' (15/24) with making a profit out of research, in part by using their commercial use of 'gifted' blood samples.

DISCUSSION

This study explored the attitudes of Thai patients and clinical trial participants towards the unfamiliar concept of biobanking. It showed that most of clinical participants had a generally positive attitude, and were willing to donate samples to a biobank given some caveats on consent, feedback and the nature of future use. This result was consistent with previous study. For instance, one study of parents attitudes on the retention and use of residual newborn screening blood samples indicated that they would be willing to permit use of their children's DBS for future research studies [16]. This finding is also similar to previous study in 2013 [17]. They found that the respondent approached, 521 (88%) agreed to participate in study use of Newborn Dried Blood Spots for Research and they preferred being asked for their consent each time their

children's blood spots would be used. They preferred that the children's identity not be linked to the blood spots and that the research will be conducted by university researchers, though these issues had less impact on attitudes than consent. However in 2014, Virgilia et al. conducted attitudes and willingness to donate biological samples for research among potential donors in the Italian Twin Register and found that more than 80% of respondents expressed willingness to donate their sample [18].

These results suggest the need to survey Thai researchers in the field to gather similar information from potential users of biobank samples [19]. They will be used to improve the quality and relevance of information given to patients, and design a standard informed consent form for research projects in Thailand involving biobanking. They also have implications for planning biobanking projects in Thailand. Such facilities are expensive in terms of staffing, specimen storage (in freezers or liquid nitrogen), administration, computerized audit systems and quality control mechanisms. There would need to be a transparent structure agreed by patient representatives and researchers with clear governance, protection of patient confidentiality and some guarantee that individual patients had access to results and opportunity to re-consent for future studies. Thai patients are willing to participate in biobanking if given the opportunity, but these results argue that a single unified national biobank may be the easiest way to start large scale biobanking trials in Thailand.

The results demonstrate some interesting points, some of them specific to Thailand as a country in which such attitudes have not been explored before. For instance, despite the overwhelmingly Buddhist demographic, the majority of patients would allow retention of a blood sample after death. This result is consistency to Virgilia et al. [18] stated that 21.2% of respondents consider donation as a religious/moral duty toward the others ("religious/moral obligation"). However, in this recent study also found that all of the participants were in favors of participating in clinical trials research, and of these (22/24) persons were positive towards biobanking studies on resultant samples. This raises the issue that the participants in this study are open to selection bias, in that their willingness to participate in clinical research might influence both their availability for biobanking trials and a positive general predisposition to being involved in research.

Sample type affected the nature of responses. Because the original clinical trials leading to them

being interviewed for this study were based on taking a blood sample, the respondents were at ease with this, and all would be positive about donating blood samples to a biobank. However they were less familiar with studies which could involve taking DNA or tissue samples. Some level of misunderstanding of the nature of biobanking was implicit in these responses. For instance all participants agreed that sharing blood samples was relatively easy, but only 50% would willingly share DNA, but this is easy to extract from a whole blood sample so such processes should be made clear to participants. This results is similar to the qualitative study of knowledge and attitudes to biobanking among lay persons in Nigeria [20] found that participants accepted biobanking once they understand it. Tissue donation was viewed differently from blood, but responses implied that some participants did not realize that they would only be asked for a tissue sample if they were involved in a clinical trial involving tissue collection (such as sampling of surgical resections of cancer tissues). It is very unlikely that a biobanking trial would be approved to allow sampling of tissues from healthy trial participants without a specific hypothesis driven research aim, as this is an invasive procedure which would only be justified by clinical, diagnostic or treatment need. Here biobanking studies are an adjuvant, not the aim of the study. The limitation of this study was conducted at a single hospital, which may not be representative of every institution.

CONCLUSION

Most respondents have a clearer understanding and positive attitude towards the concept of Biobanking. This study suggests that researchers should provide both written and oral information during enrollment for biobanking studies, giving time for participants to better understand the purpose of biobanking studies prior to signing a consent form. They have implications for the planning and establishment of Biobanking facilities in Thailand.

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