

“Respect to participants and communities:
Education with cultural adequacy to conduct
researches in indigenous Peruvian communities
about shared data and bio banking”



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I. BRIEF DESCRIPTION OF THE RESEARCH PROJECT

Indigenous populations of Peru have a great ancestral cultural richness, but they also suffer from native environmental diseases and have genetic and genomic components that need to be researched. Collecting and bio banking samples from this population could be a great alternative for such research. This case study describes research with 40 Aymaras and Quechuas leaders of both genders from the Peruvian Highland and an educative intervention about biobanking.

- ✓ The first research objective was to study indigenous leaders' attitudes and perceptions about using bio banking for research with their communities, and the ethical safeguards that indigenous communities would require before accepting such uses of biological material.
- ✓ The second objective was to assess the impact of an educative program, which used booklets with drawings, videos and socio dramas to provide information about the use of bio banking to find the cause of diseases, improvement of diagnoses and treatment for their communities and about the extraction of ethic aspects, storage and samples' use.



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II. METODOLOGY

The first step was made a Focus Group for know the attitudes and perceptions about using bio banking for research with indigenous communities, and the ethical safeguards that indigenous communities would require before accepting such uses of biological material and bio banking.

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Results about the more frequent opinions in the focus groups

✓ Own definition of biobanks
✓ I do not have information about biobanks
✓ Place where blood is stored
✓ Place where organs are stored
✓ Place where human biological material and associated information is stored, for one or more research purposes
✓ Place where human biological material is stored
✓ Place where organs and blood are kept for when an emergency happens

The benefits of biobanks
✓ No idea
✓ Use of biobanks to find the cause of diseases
✓ Diagnostic improvement
✓ Appropriate treatment alternatives for their communities
✓ Investigate to heal in the future
✓ Investigate to save lives
✓ Investigate to create new medicines
✓ Investigate to know the diseases or Investigate how to prevent diseases of indigenous peoples
✓ No benefits

Risk of biobanks
✓ They do not identify higher risk
✓ That the samples are stored badly and donated in vain
✓ That the sample be lost and donated in vain
✓ That they use the data for other topics that are not research
✓ Risks when extracting samples with bad technique that hurt them (punctures, wounds, infections)
✓ Loss of privacy

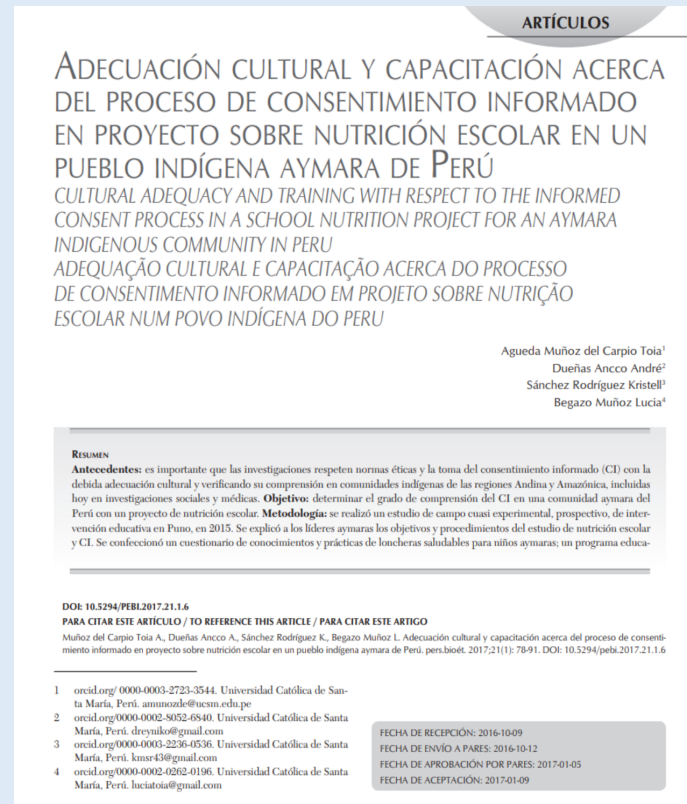
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About the Information that was given to human subjects,
about the different types of informed consent

A similar experience:

Preference of informed consent

- ✓ Specific informed consent: A consent for each study
- ✓ Broad informed consent, which proposes the use of human biological and genetic
- ✓ General informed consent, is known by different names such as, sheet, broad consensus, generic
- ✓ Dynamic informed consent: modality in which the patient has the possibility of permanent traceability
- ✓ Waiver of informed consent
- ✓ Staggered consent.



http://www.scielo.org.co/scielo.php?script=sci_arttext&pid=S0123-31222017000100078

Background: Research must respect ethical norms and informed consent (IC), with appropriate cultural adaptation and verification of its understanding in indigenous communities of the Andean and Amazonian regions, including social and medical research. **Objective:** Determine to what extent IC is understood in an Aymara community in Peru, specifically as concerns a school nutrition project. **Methodology:** A prospective, quasi-experimental field study of an educational intervention was conducted in Puno Peru during 2015. The objectives and procedures of the school nutrition project in question were explained to the local Aymara leaders, and a questionnaire was prepared on knowledge and practices regarding healthy lunch boxes for Aymara children. An educational nutrition program and two IC formats (simple and culturally appropriate) were drawn up. The documentation was evaluated by a research ethics committee. **Results:** Seventy (70) Aymara villagers participated in the research project. The extent to which they understood the IC was modified to a statistically significant degree subsequent to the educational intervention and adaption for cultural appropriateness. **Conclusion:** Aymara indigenous communities understand the IC procedure when this It has the appropriate cultural adaptation. This requires engage in participatory relationships, mutual trust, respect and dialogue with the indigenous community.

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The second step was develop an educational intervention:

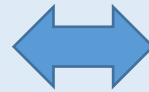
For the education with cultural adequacy to conduct researches in indigenous Peruvian communities, we began with the review of information on cultural aspects of pre-Inca culture and Inca medicine to share this information with the indigenous population

It was necessary to develop processes respecting the sensitivity and customs of the indigenous culture.

The indigenous community, until now, has preserved its ancient cultural traditions, such as agriculture, spirituality or the use of traditional medicine for therapeutic purposes, the saving of food for times of drought and misfortune, in a life beyond the earth, in the wisdom of their ancient Inca priests and their current shamans and midwives.

One of the Inca customs that still persists, is the saving of food in the dairy farms. The Tambos, were enclosures located next to an important road and were used as shelters and as a collection center.

The Inca Trail had tambos 20 or 30 km (a day's walk) from each other. Its main function was to house emissaries of the empire who traveled these roads and were collection centers for a variety of foods, wool, firewood or other basic materials for food. In this way, in times of climatic hardship or natural disasters, the tambos fed and provided some materials for the population of the villages closest to the round. As agriculture was the main source of food for the Incas, the administration of the Inca Empire established these places as a warehouse where food could be stored in case of emergency, this ensuring the good living of the population



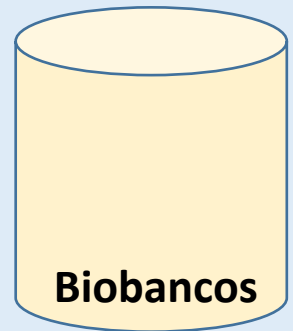
The indigenous populations of Peru suffer from native environmental diseases and have genetic and genomic components that need to be researched.



Tambo



Seed storage



Biobancos

WE FOUND THE IDEA FOR THE EDUCATIONAL INTERVENTION: ONE OF THE INCA CUSTOMS THAT STILL PERSISTS, IS THE SAVING OF FOOD IN STORAGE THAT CAN SAVE THE LIFE OF THE COMMUNITIES

TAMBOS AND MUHU QOLQA: SEED STORAGE

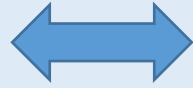
- ✓ The target population received training in analogy with information from the Biobanks, which are similar to the Muhu Qolqa and Tambos, which for centuries have functioned as storehouses for seeds and food that have served indigenous populations. The biobanks would be the reservoirs of storage of biological samples and the “seeds” would be the biological samples, useful for the investigation of diseases of indigenous populations.
- ✓ The study population also received information on how doctors from the pre-Inca and Inca cultures investigated and treated the diseases, without causing harm to the population.
- ✓ The biobanks would be the reservoirs of storage of biological samples and the “seeds” would be the biological samples, useful for the investigation of diseases of indigenous populations.
- ✓ The study population also received information on how doctors from the pre-Inca and Inca cultures investigated and treated the diseases, without causing harm to the population. Similar as investigations with biobanks and treated the diseases, without causing harm to the population too)
- ✓ Culturally appropriate educative interventions can be effective tools in this context and can have a favorable impact on the acceptance of the use of bio banking in indigenous communities.



QOLQA and TAMBOS SIMILAR AS BIOBANKS:

In the old Inca empire, QOLQA and the Tambos were the granaries, where the corn, seeds, dehydrated meat, forage of the animals were deposited.

It was necessary to develop processes respecting the sensitivity and customs of the indigenous culture.



Tambos and MUHU QOLQA were a place where food could be stored in case of emergency, this ensured the survival of the population

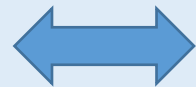


Currently the indigenous population of Peru, preserves the habit of storing food and seeds for the future

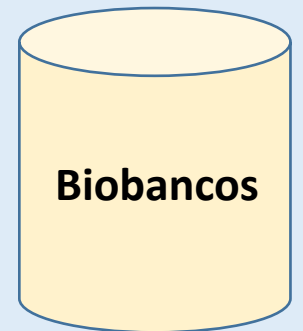


Seed warehouse

The indigenous populations of Peru suffer from native environmental diseases and have genetic and genomic components that need to be researched.



Collecting and bio banking samples from this population could be a great alternative, to find the cause of diseases, improvement of diagnoses and treatment and in case of emergency, for their communities this ensuring the good living of the population.



Do you agree with the storage and use of your biological sample for research?



YES



I do not know



NOT

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III. RESULTS

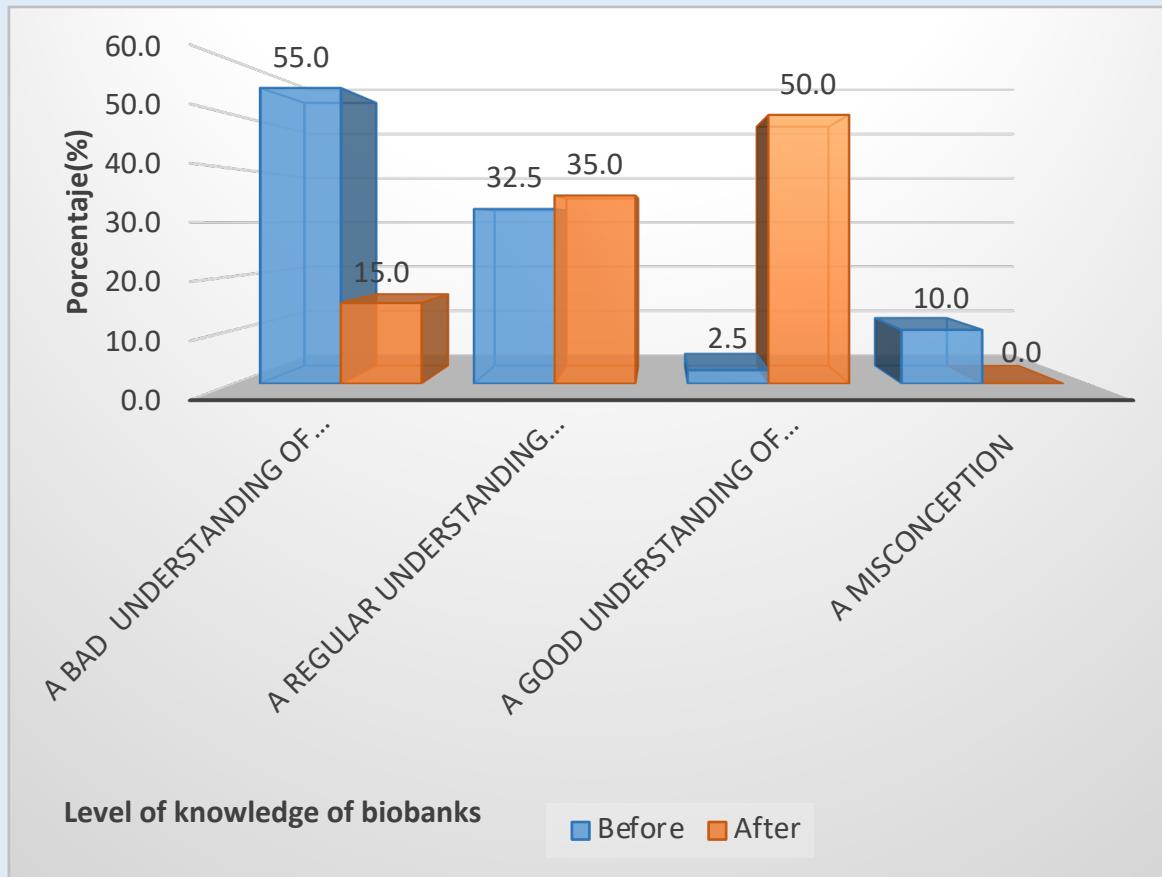
Aymaras and Quechuas leaders were interviewed before and after the educative program, to assess its impact. Before the intervention, 96% of the leaders had objections about their samples' confidentiality, 92% were afraid about who could have access to their samples, 93% about how their information should be used by the researchers, 99% about the access rights of the obtained results in the research, 89% about how the process of informed consent should be conducted, and almost everyone had several questions about the final destination and destruction of their tissues.

After the educative intervention, the leaders improved their attitudes and perceptions about bio banking and its potential use in research into causes of diseases prevalent in the Aymaras, which could lead to an improvement in diagnoses and treatments for their communities.



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Results:



According to the test of Chi cuadrado ($X^2=30.37$) shows that the level of Knowledge about biobanks before and after educational intervention presented significant statistical difference ($P<0.05$).

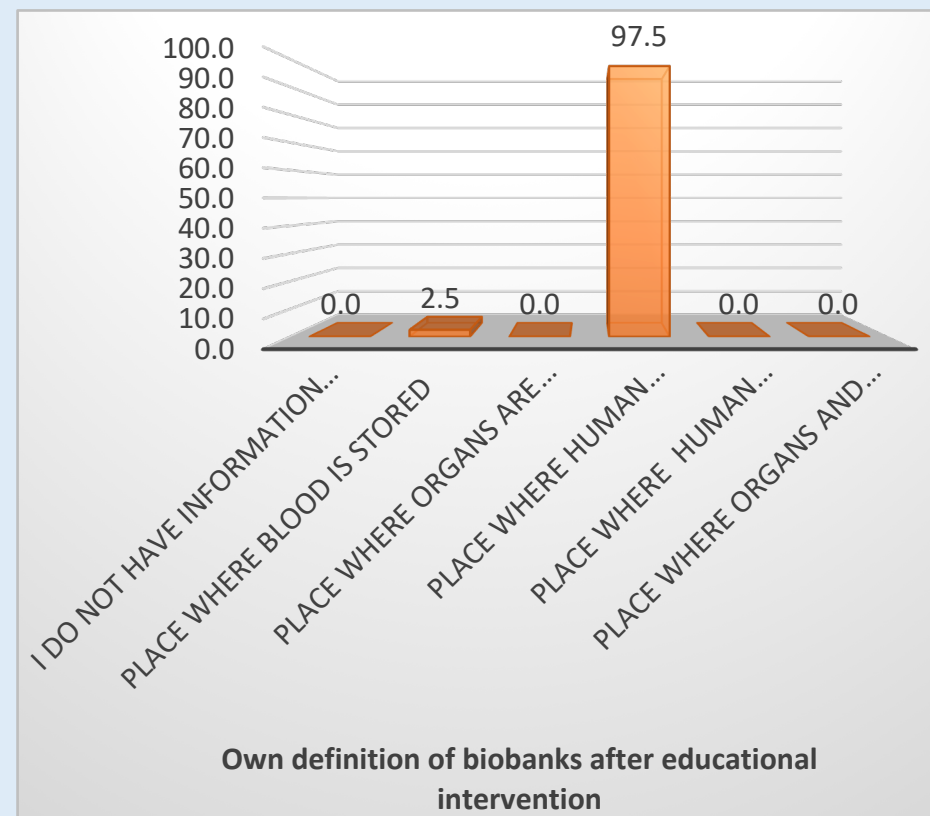
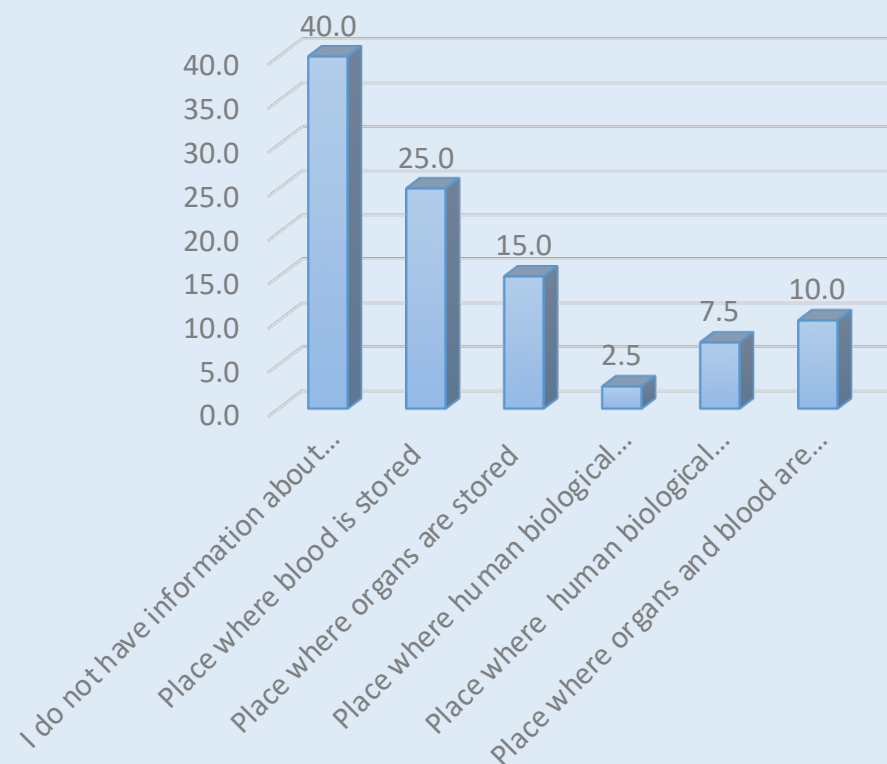
It is also observed that 55.0% of the surveyed population before educational intervention have a bad understanding of biobanks, while 50.0% have a good understanding of biobank after educational intervention.

40.0% of the surveyed population are between 31-50 years old, 87.5% are from the Aymara ethnic group, 50.0% have primary education and 87.5% are from Cusco

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Results about own definition of biobanks:

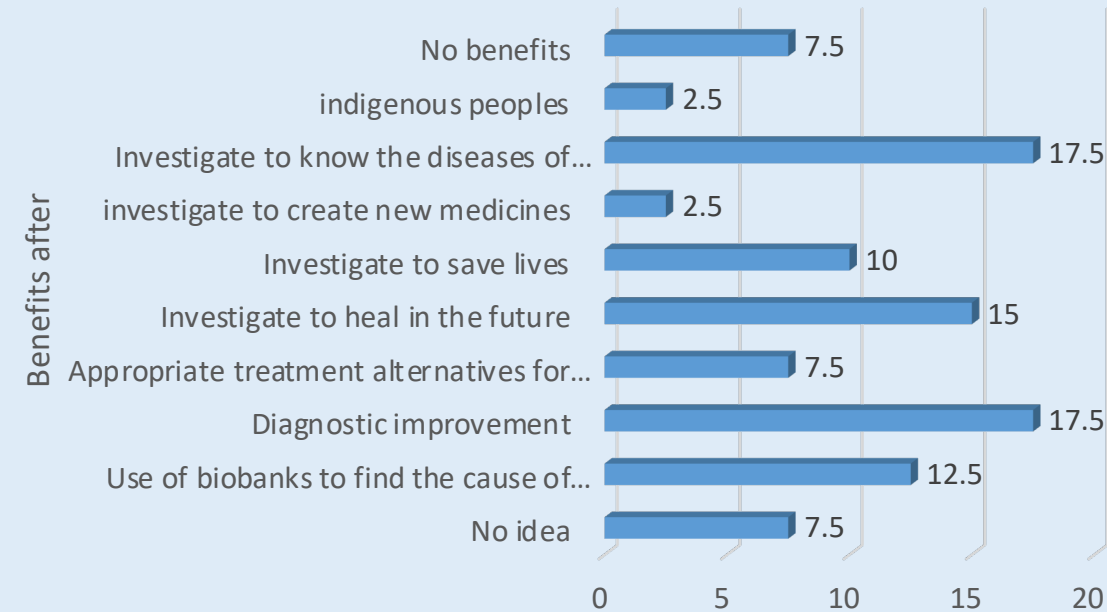
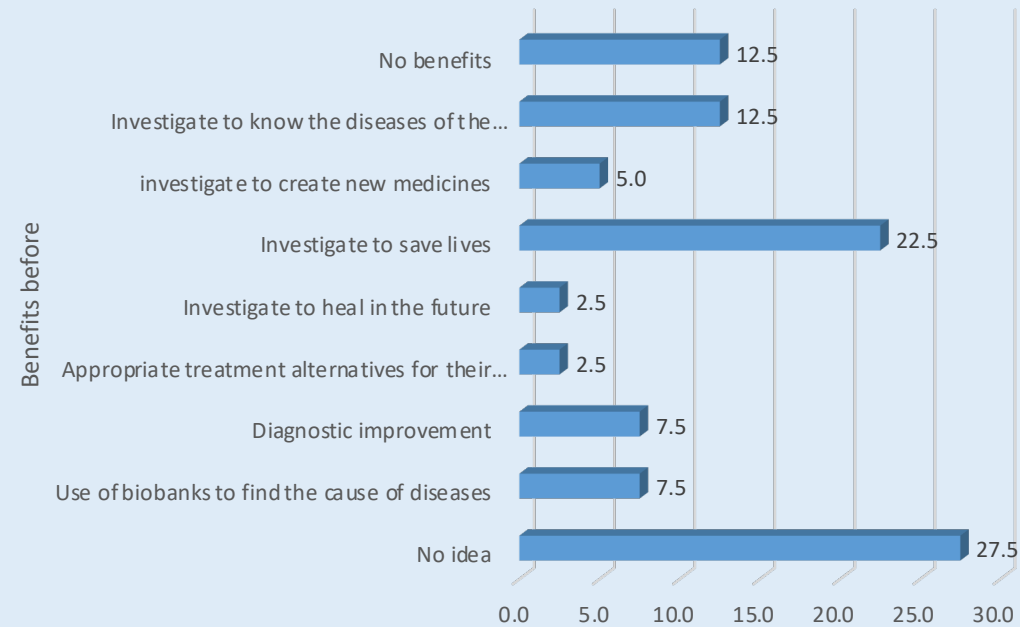
Own definition of biobank before intervention



- ✓ I do not have information about biobanks
- ✓ Place where blood is stored
- ✓ Place where organs are stored
- ✓ Place where human biological material and associated information is stored, for one or more research purposes
- ✓ Place where human biological material is stored
- ✓ Place where organs and blood are kept for when an emergency happens

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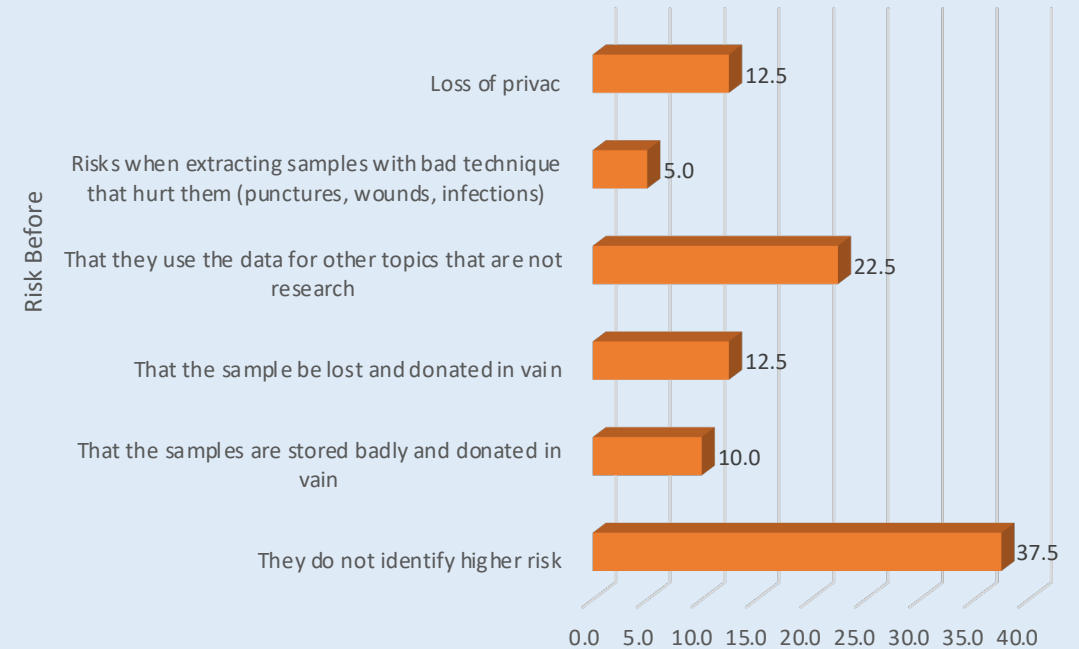
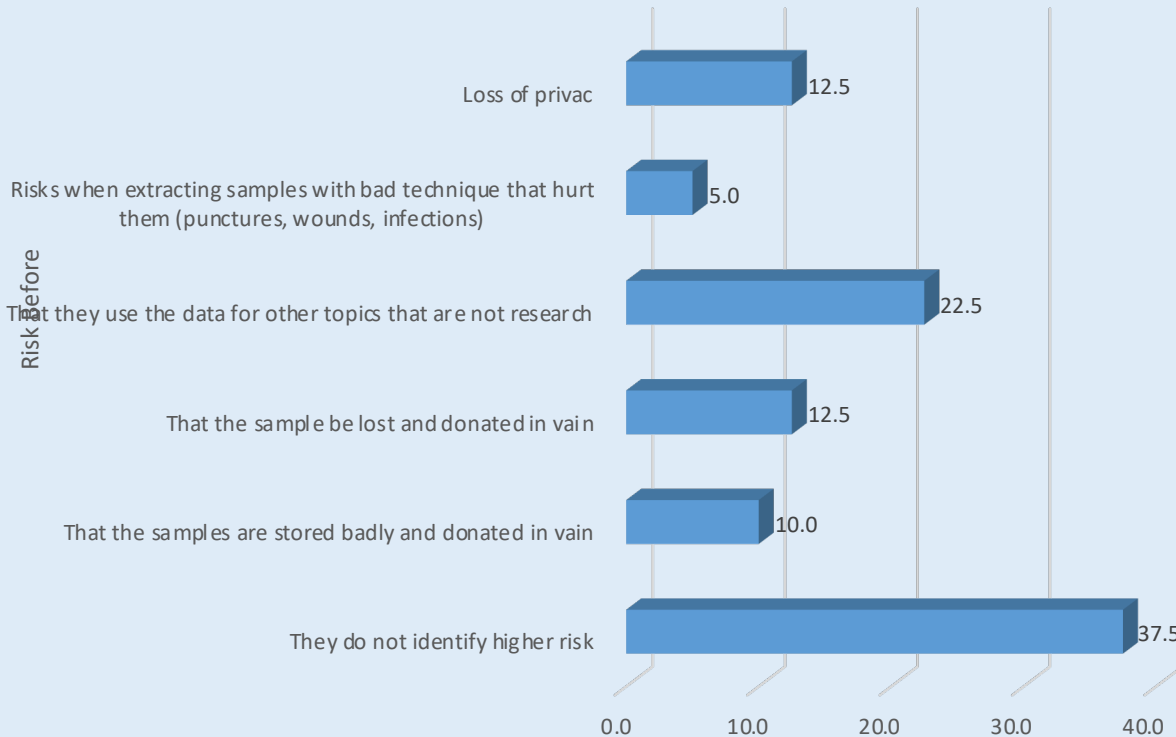
Results about benefits of biobanks:



- ✓ No idea
- ✓ Use of biobanks to find the cause of diseases
- ✓ Diagnostic improvement
- ✓ Appropriate treatment alternatives for their communities
- ✓ Investigate to heal in the future
- ✓ Investigate to save lives
- ✓ Investigate to create new medicines
- ✓ Investigate to know the diseases or prevent diseases of indigenous peoples
- ✓ No benefits

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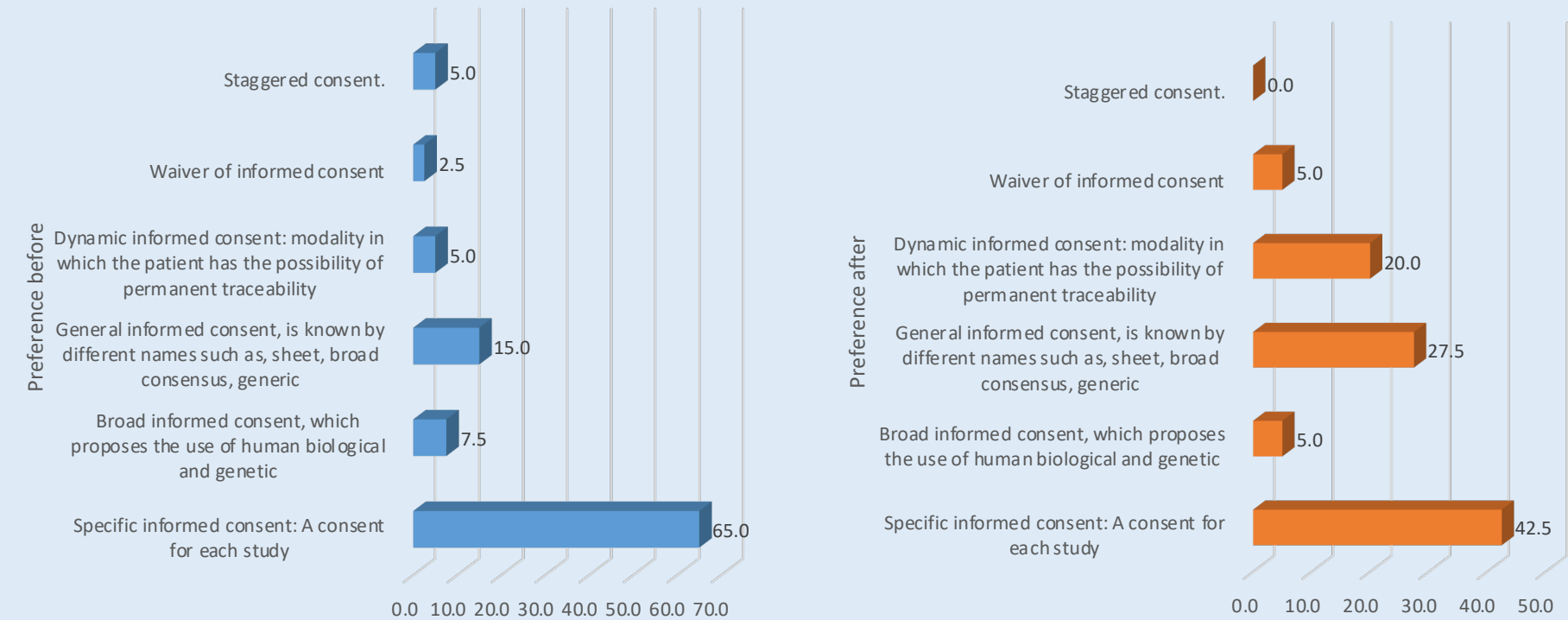
Results about risk of biobanks:



- ✓ They do not identify higher risk,
- ✓ That the samples are stored badly and donated in vain
- ✓ That the sample be lost and donated in vain
- ✓ That they use the data for other topics that are not research
- ✓ Risks when extracting samples with bad technique that hurt them (punctures, wounds, infections)
- ✓ Loss of privacy

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Results about preference of type of informed consent



65.0% of the surveyed population before educational preference of type of informed consent specific informed consent: A consent for each study, while 2.5% Waiver of informed consent. 42.5.0% of the surveyed population after educational preference of type of informed consent specific informed consent: A consent for each study, while 5.0% Waiver of informed consent

Preference of informed consent	
✓	Specific informed consent: A consent for each study
✓	Broad informed consent, which proposes the use of human biological and genetic
✓	General informed consent, is known by different names such as, sheet, broad consensus, generic
✓	Dynamic informed consent: modality in which the patient has the possibility of permanent traceability by internet for example
✓	Waiver of informed consent
✓	Staggered consent.

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IV. BACKGROUND

In Peru, more than 8 million of people are indigenous, the majority of whom are Quechuas and Aymaras, living in areas of high geographic altitude such as the Andean region and jungle areas (Amazonia). Multiple forms of research have been conducted in these communities, including social, anthropological, and medical studies, including, genetic researches; researches with medicinal plants, and vaccines, etc. Peruvian indigenous communities have a great cultural richness, traditions, their own way to conceive of the process of health and sickness. Also, two features of the indigenous populations are important to consider in the researches, the environment where our native populations live and the diseases' genetic components that still need to be researched, being the use of bio specimens a great alternative.

The indigenous communities are exposed to inadequate environmental and sanitary conditions, the presence of infectious diseases' vectors called reemergents, which affect the populations and increase their vulnerability. (In the last ten years, between 200,000 and 150,000 cases of Vector-borne diseases such as Malaria, arbovirosis, Bartonellosis, Leishmaniasis, Tripanosomiasis, Dengue, Chikungunya, Zika, Carrion Disease, and Chagas disease), have been reported. Indigenous communities also suffer of illnesses due to poverty and limited access to health services, including multidrug resistant tuberculosis, malnutrition, anemia and chronic and degenerative diseases.

Nowadays we talk of genetic components related to diseases which could make the populations resistant to treatments for the anemia. For this, it is necessary to raise awareness in the communities about the possibility of developing research that promotes knowledge based on evidences and the use of bio banking, for studies that could contribute with data that could go further than public health.

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V. ETHICAL ISSUES WITH COMMENTARY ON EACH ISSUE

During this research we conducted focus groups (with community leaders and with Peruvian researchers), to identify the ethics recommendations, for biobanking research. The proposed recommendations included:

- Inclusion of indigenous leaders in the development of research proposals for biobanking indigenous samples;
- Ensuring the cultural adequacy of the informed consent with the help of translators and representative leaders of the indigenous communities for the use of secondary samples;
- Using samples to identify solutions for population health priorities;
- Promoting active communication between researchers and the indigenous community about relevant information for the results’ return to the community and health system;
- Exchanging data with other institutions with similar indigenous populations
- Ensuring that the interests of sample donors are protected by promoting, data confidentiality, stigmatization prevention, and the right to accept or refuse participation in research with secondary samples,
- Creating organizations and regulations that ensure the ethical storage and destruction of the samples.

Collaborative research with bio banking in indigenous communities can have more benefits than risks if care is taken to promote consent, and maintain the privacy of medical and genetic data.

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VI COMMENTARY AND CONCLUSIONS

Respect for autonomy and protection of confidentiality are key considerations in research on samples from indigenous communities. Collaborative research with genomic data exchanges related to health could provide solutions to communities with fewer resources for the research. Comprises the principle of justice and equity. It is necessary for ethical oversight of genetic and genomic data links to the communities, as well as mechanisms of tissue storage and destruction, respect the beliefs, customs and rituals of a community.

Commentary: Research ethics committees can be strengthened by promoting active participation of community members and empowerment of institutions that protect shared data of bio banking internationally, and at all stages of the research process including sample collection, storage, study and destruction

Conclusions: Before implementing research data sharing and bio banking in indigenous communities, it is necessary to develop processes respecting the sensitivity and customs of each culture. Culturally appropriate educative interventions can be effective tools in this context and can have a favorable impact on the acceptance of the use of bio banking in indigenous communities.

It is also important to promote culturally appropriate educative programs, focused on indigenous communities and communities in general, about the importance of bio banking research to sensitize the population. It is also important to provide information about effective measures to protect data confidentiality in the consent process.

Thank you so much Adrienne, Claudia and Susan for your corrections, suggestions, comments and your patience.

Thanks to my co-author Lucia for the team work of always!

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Thank you Fogarty Flacso for all your support of this years

And thanks to the Peruvian indigenous who agreed to be part of the present study.

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