

SOUTH PACIFIC REGIONAL PROJECT HUMAN MILK SURVEY PROTOCOL 2009

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SUMMARY INFORMATION ON THE WHO HUMAN MILK SURVEY FOR THE SOUTH PACIFIC REGION 2008-2009

Since 1976 the World Health Organization through its GEMS/Food Programme has collected and evaluated information on levels of persistent organic pollutants in foods, including human milk. Over the period 1987-2003, it has coordinated three international studies of human milk to assess the levels and trends of polychlorinated dibenzodioxins, polychlorinated dibenzofurans and dioxin-like polychlorinated biphenyls. Analysis of human milk, maternal blood and adipose tissue are all relevant matrices for assessment of body burdens for persistent organic pollutants. However, human milk is recognized as the preferred matrix because has several important advantages. Biomonitoring of human milk data can provide information on the exposure of the mother as well as the infants. Furthermore, such information provide guidance on the need for measures to reduce levels of this substances in food, which is the main source of exposures for most people. More recently, it has been recognized that human milk is an ideal matrix to generally monitor levels of persistent organic pollutants in the environment.

In 2004, the Stockholm Convention on Persistent Organic Pollutants was ratified by governments to decrease environmental and human exposure to twelve priority substances in this class. The revised WHO guidelines for developing a national protocol describe the basic study design that can be used to monitor human exposure over time in order to, among other things, see if the Stockholm agreement is actually effective in reducing the release of these chemicals into the environment.

These guidelines continue to support the monitoring of persistent organic contaminants for human health and food-chain contamination purposes. The protocol guidelines were designed based on the advice of experts in the field and on extensive experience of certain countries in undertaking similar surveys using human samples, including human milk. In order to promote reliability and comparability, participating countries are encouraged to adhere as closely to this protocol as possible. Ethical issues, including informed consent of donors and confidentiality, are major considerations in this protocol. Given that breastfeeding reduces child mortality and has health benefits that extend into adulthood, every effort has been made to protect, promote and support breastfeeding in the context of these studies.

Based on previous surveys, mothers should be reassured that the breast milk is a naturally superior food for infants. This survey is intended to monitor the effectiveness of a new international agreement to reduce the levels of certain chemicals in our environment and which appear in human milk. In ratifying this agreement, countries have signaled their commitment to assuring that present and future generations will enjoy safe and wholesome nutrition and other benefits that only pure breast milk can offer.

Persistent organic pollutants (POPs) are a group of chemicals that have been intentionally or unintentionally introduced and widely distributed in the environment. Due to their stability and fat solubility, they have a capacity to accumulate in many fat containing foods as well as the human body where traces of POPs can be found in human milk. The most commonly encountered POPs are organo-chlorine pesticides, such as DDT, industrial chemicals, most notably polychlorinated biphenyls (PCBs) and industrial by-products, especially dioxins and furans (PCDDs and PCDFs). These chemicals as a group have been of public health concern. For many years, the World Health Organization (WHO) has collaborated with countries in the development of data on levels of POPs in food as well as human breast milk. These data have been used to assess the risks to human health posed by exposure to various POPs. In 2004, an international agreement, the Stockholm Convention on POPs, was adopted by a large majority of the world's countries to reduce the amount of these substances in the environment and in people.

Meeting under the auspices of the United Nations Environment Program (UNEP), parties to the Convention have identified human milk as one of the core matrices to be monitored to evaluate the impact of the Stockholm Convention in reducing emissions of POPs. In conducting this survey of POPs in human milk. This survey will also promote human milk as the optimal food for infants and will include samples from all regions of the world and will reflect different consumption patterns. This survey will also support and where feasible strengthen the national capabilities for the monitoring and sound management of POPs in food and the environment.

Selection of Donors

The criteria for selection of donors presented below are designed to reduce the variability in the individual samples due to factors that are known to have influence on the levels of POPs in human milk. Because the two collection periods for this survey may be only four or five years apart, the reduction in variability is of particular importance. On the other hand, overly stringent criteria in the selection of donors may give rise to an insufficient number of qualified donors. Consideration of available statistics on primiparae mothers and experiences from other studies involving mothers may be of assistance.

However, a general starting point could include the following:

- **Mother should be new mothers (first time mothers).**
- **Mother should be under 30 years of age¹¹.**
- **Both mother and child should be apparently healthy, including normal pregnancy.**
- **Mother should be breastfeeding one child only (i.e., no twins).**
- **Mother should have resided in the area for at least the previous 10 years.**
- **Mother should not reside in local areas where emissions of POPs are known or suspected to result in elevated levels of POPs in the local population.**
- **Mothers should be available for sample collection within 3 to 8 weeks of delivery.**

This survey will include a proposed number/country of first time mothers whose milk samples will be analyzed for POPs. The average values for the various POPs will be used in the reports. Individual results with the names of donors are considered confidential and will not be reported. This survey will be repeated periodically every 4 or 5 years with another group of first time mothers and the average values of the two groups will be compared to give an indication of the changes, if any in the levels of POPs. It is anticipated that the levels of POPs in human milk will show downward trend as countries implement measures to reduce the emission of POPs into the environment. Your country is required to do this monitoring as a signatory of the Stockholm Convention.

On a population basis, exclusive breast feeding for six months is the recommended feeding mode for the vast majority of infants, followed by continued feeding with appropriate complimentary foods for up to two years or beyond.

GUIDANCE FOR MOTHERS COLLECTING MILK SAMPLES

Goal of sampling: The goal of this sampling exercise is to collect a sample of your milk in a way that avoids unnecessary contamination.

How to collect samples:

You may collect the sample either manually or by using a human milk pump.

You have already been given instructions on these methods but remember:

- You should not use any other vessel for collecting milk. You must not use cups or other bottles you may have at home. You should collect your milk directly into the small sampling bottle provided to you. If using a pump, you should collect the your milk into the container that comes with the pump (note that the pump will be delivered without the rubber teat).
- You should keep your breasts and hands as clean as possible but soap use should be avoided because they may contain chemicals that interfere with the analysis. When it is necessary to use soap, you should rinse your breasts and hands thoroughly with clean water.
- You should avoid using ointments on your nipples before collecting your milk. If you had used ointment that day, you should wash your nipples with soap and thoroughly rise with clean water.

The following tips are provided to make expression and collection of your milk easier, faster and more comfortable:

Breast milk pump:

You should apply the pump to your breast and continue to pump until the milk flow declines to a drop. You may wish to use the pump at the same time your infant is nursing on the breast as this helps release your milk.

Manual Method

If you wish to manually express your milk, you should collect it directly into the provided sampling bottle.

When to collect your sample

It is recommended that you collect your sample at the regular feeding time, usually two hours after the previous nursing. You should try to collect hind milk, which is milk expressed towards the end of each feeding.

Storage and transport of your sample

If you do not collect 50 ml at once, the partial sample may be stored in the refrigerator and sampling can be continued the next day. If 50ml is still not collected, the sampling may be continued the next day. However, after three days sampling should be stopped and the sample frozen if possible. The sample should be delivered to the health centre as soon as possible and protected from high temperatures during the transport. If refrigeration is not available in your home, your collection bottle will contain a tablet of chemical that will preserve the milk. However, you should collect your sample in one day if possible.

Voluntary Participation

Your participation in the WHO sampling activity is voluntary and if you agree to be part of the survey please fill in the health history form and sign the attached consent form.

Ethics

Mothers donating samples of their milk should be informed of the nature and purpose of the survey and asked to sign an informed consent form for this purpose. These guidelines for developing a national protocol have been initially evaluated by the WHO Research Ethics Review Committee. However, it is the responsibility of the National Coordinator to ensure that the national protocol that is finally adopted meets all national ethical and informed consent requirements. The results of this survey are expected to strengthen the factual basis for the health risk assessment for infants and children and to promote environmental and other measures likely to reduce the concentrations of these chemicals in human milk.

Based on national requirements, National Coordinators should decide whether to provide donors with the results of individual and/or pooled samples. If such information is provided, considerable judgment must be used in drawing conclusions concerning levels of POPs. The provision of individual results should always be accompanied by an explanation giving the range of other results and a short interpretation of the health significance of the values. Once sufficient data are available, WHO will develop appropriate risk communication advice on this matter. In all cases, breastfeeding should be promoted as the best feeding mode for infants.

Analyses of Pooled Samples

The pooled sample will be analyzed by the State Institute for Chemical and Veterinary Analysis of Food (CVUA) in Freiburg, Germany, in accordance with the request of the National Coordinators. CVUA is the WHO Reference Laboratory for the fourth WHO-coordinated human milk study for POPs.

All analytical results will be reported on a fat basis. The contact email for CVUA is pops@cvuafr.bwl.de

Human Milk Sampling Survey Form

Donors Name:	Phone No: Email:	Date of Delivery:
Address		
Individual Identification Code		
Name of Collector	Date of Collection:	
Clinic of Collection	Country of Collection	
Postnatal information (to be taken at the time of sampling)		
<p>1. Are you prepared to sign the consent form? Yes: No:</p> <p> If yes, please attach the signed consent for. If no, the mother is not eligible to participate in the survey.</p>		
How old is your infant?		
< 3 weeks:	3-4 weeks:	5-8 weeks: > 8 weeks:
What is he sex of your infant?: Male: Female:		
Is your current weight different from your weight before pregnancy?		
Gained: Lost: Not Changed:		
Can you provide a sample now?		
Yes: Later: When?..... At home:		
If you want to take the sample at home, do you have a refrigerator? Yes: No:		
<p>Note: The infant has to be more than 3 weeks old (21 days). The collector should advise the mother to return, after the infant is three weeks old for milk sampling.</p> <p>Samples must be collected within 3-8 weeks after delivery. A tablet of potassium permanganate needs to be added to the sampling bottle and the mother cautioned about its potential toxicity.</p>		

Health History Questionnaire

Date of Birth:		Age:				
Height(cm)		Weight before pregnancy				
Where have you been residing in the last 10 years?						
Urban City:		Rural countryside:				
How do you describe your dietary habits before pregnancy?						
Mixed Diet:..... Vegetarian but with milk and eggs:.....Strictly vegetarian:						
Other:.....						
How often, on average, did you eat the following foods before pregnancy?						
	Fish and fish products	Marine mammals(Whales & dolphins)	Seafood other than fish and mammals	Milk and milk products	Meat & poultry and derived products	Eggs
Never						
Less than once a week						
Once a week						
Twice a week						
More than twice a week						
Everyday						
What type of fish do you consume most often?						
Fish from sea:..... Fresh Fish: Both:						
(please state species if known)						

SURVEY CONSENT FORM

Participants will only be identified by a code and that only mean results will be reported and not those of an individual.

Alternatives to participation

You do not have to take part in this research if you do not wish to do so, and refusing to participate will not affect your treatment at this centre in any way. You will have all the benefits that you would otherwise have at this centre.

You may stop participating in this research at any time that you wish until your sample has been pooled with other samples; if you choose to end your participation, you will not lose any of your rights as a patient here. Your treatment at this centre will not be affected in any way.

Contact Information

If you have any questions you may ask them now or later. If you wish to ask questions later, you may contact the following person:.....[Insert National coordinators name and address]

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have been answered to my satisfaction. I consent voluntarily to participate as a subject in this study and understand that I have the right to withdraw from the study until my sample has been pooled with others. If I choose to withdraw from the study, I understand that I can do so without in anyway affecting my medical care. I also consent that any excess sample of breast milk may be kept for related surveys in the future.

Print Name of Participating Mother **Date and Signature of Participating Mother**
.....
.....(date)

If illiterate

Print name of illiterate witness and signature with date
.....(date)

Name of research, signature and date:
.....(date)