HUMAN MILK BANKING - A PUBLIC HEALTH ISSUE

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Abstract: *Objectives: The article's aim is to focus on the epidemiological particularities of our country and the impact they have regarding the protocols of human milk banking. Materials and methods: We documented the most recent scientific articles about the infectious risk that can impact the donation of the human milk and we compared the results with international protocols. Results: We found that the screening for the human milk donor needs to address the risks for different infectious diseases: by introducing to the interview specific questions; by serological testing; by clinical examination. Conclusions: Even though at an international level many protocols from countries with a big legacy in the field of human milk banking are available, there is the need to adapt the recommendations to the local reality, especially in a country with a specific epidemiological situation.*

INTRODUCTION

The benefits of breastfeeding are well known. In the situation in which breastfeeding is not possible or is not enough, the first option is to use donor human milk.

World Health Organization (WHO) recommends human milk banks as the first choice that may be used when a mother's milk is not available.(1)

The first human milk bank was established in 1909, in Viena.(2) Since then, human milk banks appeared worldwide, but the concern about being involve in transmitting blood born viruses like HIV, led to the closure of many human milk banks in 80's.(3)

The re-establishment of human milk banks could be possible because of new screening protocols for donors that took into account these risks and also because the donor human milk is pasteurized.

At this moment, the European country with the most human milk banks is Italy, 37 human milk banks.(4)

In Italy, the first human milk bank was established in 1965 and the first Italian Guidelines for The Establishment and Operation of a Donor Human Milk Bank, in 2002.(5) Italy is a very good model for other countries in the field of human milk banking because it is one of the few European countries with specific legislation and guidelines.

Also the Italian Association of Donor Human Milk Banks (Associazione Italiana Banche del Latte Umano Donato, AIBLUD) was founded in 2005.(6)

Romania is one of the few European countries with no active human milk bank.

Historically, the country had human milk banks, but, probable, the HIV epidemics with its particularities in Romania led to the closure of all human milk banks in 80's. Since then, in Romania have not appeared any other milk banks and until recently, there was not any specific legislation.

The Health Minister Order number 1461/2017 regarding the modification and the completion of the Public of Health Minister Order number 914/2006 published in the Official Gazette of Romania in January 2018 states that human milk banks can be organized inside the hospitals with units that take care of neonates <34 weeks gestational age. Human milk banks should be located in a dedicated structure with a consultation room, a room for the expression of donated human milk, a room to deposit raw donated human milk, an authorized and accredited laboratory for medical analyses, a room to pasteurize and to deposit the donated human milk ready to use. In the order, there are also mentioned the technical norms, the procedures of self-control, traceability and the data and documents that are needed to be kept, the basic equipment.

This order is being implemented.(7)

PURPOSE

The article's aim is to focus on the epidemiological particularities of our country and the impact they have regarding the protocols of human milk banking.

MATERIALS AND METHODS

The study is a descriptive, documentary study, based on scientific evidences end existing scientific articles and reports related to human milk banking operationalization recommendation and best practices examples from other European countries. We also take into account Romania's specific particularities regarding the screening of the possible human milk donor. Consequently, we compared the international protocols and models of human milk banking systems with our situation.

RESULTS

International recommendations state that the human milk donor needs to be in a good health condition and with a healthy life style.(8)

Similar to donated blood, using donor human milk can have risks. These risks include the transmission of viruses (e.g. HIV, HTLV, hepatitis B and C), bacteria and other infectious agents such as prions (like in Creutzfeldt Jacob Disease). These risks need to be addressed even though the transmission through breast milk is rare and appears at a lower rate compared to

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blood. Donor screening is important to reduce these risks.(9)

Human Milk Banking Association of North America (HMBANA) recommends serological testing for HIV 0,1,2, HTLV 1 and 2, Hepatitis B and C, Syphilis.(8)

The Italian Guideline states that the donors should be serologically tested for hepatitis B and C and HIV. Regarding CMV, the positive donors can donate because the Holder pasteurization method of heat treatment for the donated milk is considered sufficient. Regarding syphilis and tuberculosis, the clinical examination and anamnesis is considered sufficient.(10)

There is a difference between these guidelines (Italian and HMBANA) regarding the various infectious diseases. This aspect underlines the idea to document these situations for every country taking into account their epidemiological specificity.

In 2013, the Italian Association of Donor Human Milk Banks performed a survey with the purpose of evaluating the operational procedures of Italian human milk banks in order to identify both areas of strength and room for improvement.

Nearly all of the human milk banks (96%) screened donors for smoking, alcohol, drugs, medicines, and the hepatitis and human immunodeficiency viruses.

Implementing the guidelines and monitoring the activity of the human milk banks in a framework of safety and research is the most important factor that led to the establishment of new human milk banks in Italy through the years.(6)

Romania's epidemiological characteristics.

All the protocols from the countries where human milk banks are operating integrated the screening for smoking, alcohol, drugs, medicines, lifestyle. The aspects about different infectious disease that can impact the donation of human milk need to be documented for every country because general or international recommendations must be adapted to the local reality.

Regarding HTLV infection, the study "Epidemiological aspects and world distribution of HTLV-1 infection" concluded that Romania seems to be the only true endemic zone for HTLV in Europe with a prevalence of 5.3/10.000 blood donors.(11)

There is the recommendation for the mother infected with HTLV-1 to stop breastfeeding.(12)

That is why we recommend that the possible Romanian donor should be screened for HTLV infection.

HIV infection remains an important public health problem in Romania. HIV epidemics in 1980-1990 had serious consequences in Romania. The children infected in 1980s-1990s are now adults, in the fertile period, the infection in Romania being characterized by long term survivors.(13)

The HIV status is important when donating human milk, especially in our country, that is why we recommend that the interview with the possible donor must contain questions about the partner, lifestyle that can impact the HIV or other blood born viruses' transmission. The serological testing for HIV is a must when donating human milk.

In Romania, the incidence for syphilis is 4.79%, one of the biggest in European Union. Of the cases presented in females 12.4% were pregnant.(14) Taking into account the human milk donation process the screening should include testing for the syphilis infection with venereal disease research laboratory test (VDRL) and passive hemagglutination assay test (TPHA).

Romania has the biggest incidence of tuberculosis in the European economical zone. A number of 800 cases are reported annually with multiresistant tuberculosis.(15)

Because of these specific aspects the screening process of possible human milk donors must include questions about the bacille Calmette-Guerin (BCG) vaccination, BCG scar, tuberculosis history of the possible donor or of the family or friends, chronic cough, haemoptysis or rapid weight loss.

In all types of hepatitis, breastfeeding is not contraindicated but human milk donation is.(8,12)

Romania reported high hepatitis A virus (HAV) incidence in children and young adults. The results suggest low level of HAV transmission in most of Europe, but Romania, however, appeared as an area with intermediate transmission.(16)

The Center for Disease Control and Prevention, in 2017, recommends HAV vaccination for travellers to Romania.(17) Therefore, it is important to include in the screening clinical examination for jaundice and serological test that include transaminase levels, as other endemic countries like Taiwan do.(18)

An ECDC's- European Center for Disease Control and Prevention report from 2016 states that countries in the eastern and southern part of the European Union were found to have a higher HBV and HCV prevalence than countries in the northern and western parts. The HBV (hepatitis B virus) prevalence ranged from 0.1% in Ireland to 4.4% in Romania.(19) Screening for HBV can be done with the AgHbS test.(20)

In Romania, hepatitis C virus (HCV) infection has been identified as the main cause of chronic hepatitis (64%) and liver cirrhosis (59%) and it is the leading indication for liver transplantation. Screening strategies for HCV infection should be based on the local epidemiology. Screening for HCV infection is based on the detection of anti-HCV antibodies.(21)

The screening for human milk donors should also include questions about partner and lifestyle that can impact the transmission of viral hepatitis.

Regarding the Creutzfeldt Jacob disease, the order number 1993 from 7 July 2007 mentions the situations in which the blood donor cannot donate. These rules can be applicable also for the human milk donor and can be used in the screening process.

For other infections (viral, bacterial and fungal) the mother should be instructed to self exclude from the donation process and should announce the human milk bank regarding her condition in order to follow the best, scientific documented instructions.

DISCUSSIONS

The main objective of the article is to document the epidemiological particularities of our country and the impact they have regarding the protocols of human milk banking.

Taking into account the lack of regulations in our country regarding the screening of the human milk donor we propose to adapt the general international recommendations to the local conditions, from an epidemiological point of view.

Globalization and Romania's position at the cross roads between Asia and Europe enhance the risks of many types of infections that need to be documented in the donor's screening process.

Having in mind the various infectious risks we propose that the screening process for a possible Romanian human milk donor should include:

- an interview with specific questions regarding infectious diseases that are more prevalent in our country;
- serological testing for: HTLV, HIV, HAV, HBV, HCV, syphilis, tuberculosis;
- a clinical examination with focus for the signs of the mentioned infectious diseases.

The study made by Cohen and his colleagues found that from the 1091 possible donors who had serological tests,

3.3% had positive results: 6 for syphilis, 17 for hepatitis type B, 3 for hepatitis type C, 6 for HTLV and 4 for HIV. These findings emphasize the need for a screening protocol that includes extensive serological testing.(22)

CONCLUSIONS

The human milk donor's screening process is really important in order to guarantee the safety of human milk banks. Every infection: viral, bacterial, fungal has to be documented regarding its transmission in human milk via human milk banking. A continuous work of research needs to be done in this direction, also taking into account the particularities of every country.

In order to establish human milk banks in Romania, the safety has to be a priority.

Even though at an international level many protocols from countries with a big legacy in the field of human milk banking are available, there is the need to adapt the recommendations to the local reality, especially in a country with a specific epidemiological situation.

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