Specimen plastic containers used to store expressed breast milk in neonatal care units: A case of precautionary principle

Mélissa Blouin, PhD, Martin Coulombe, MSc, MAP, Marc Rhainds, MD, MSc, FRCPC

ABSTRACT

Breast milk is the only milk that meets both the nutritional and immunitary needs of infants. Since breastfeeding is widely promoted, public health measures to preserve the nutritional qualities of expressed breast milk (EBM) should be applied in hospital care settings. The Health Technology Assessment Unit (HTAU) of the Centre hospitalier universitaire de Québec was requested by the Neonatal Care Unit to assess the acceptability of a plastic specimen container, designed to harvest tissues and body fluids, for storing collected EBM. An evidence-based public health perspective approach was taken to evaluate the safety of the specimen container. The HTAU recommended that plastic specimen containers no longer be used for storing EBM and that other options should be evaluated for neonatal care units. These recommendations are in accordance with the public health precaution principle and with legal considerations.

KEY WORDS: Expressed breast milk; storage; plastic container; neonatal care unit; safety and chemical innocuity; precautionary principle

La traduction du résumé se trouve à la fin de l'article.

Can J Public Health 2014;105(3):e218-e220.

Breastfeeding is widely recognized as the optimal infant feeding method. This practice is also strongly promoted and encouraged in hospital care settings. For various medical or other reasons, some mothers cannot breastfeed after childbirth, and sometimes for indefinite periods of time. However, they may still express their milk to feed their infant. In order to preserve the nutritional qualities (variation in energy, macronutrient or micronutrient content) and chemical safety (contamination of milk by substances that migrate or that may be expected to migrate from plastic into milk) of expressed breast milk (EBM), it is important to apply standards in hospitals regarding its storage and conservation.

A question was raised in the Neonatal Care Unit of the Centre hospitalier universitaire (CHU) de Québec regarding the chemical safety of a plastic specimen container, designed to harvest tissues and body fluids, for storing EBM. The hospital's Health Technology Assessment Unit (HTAU) was asked to review from different perspectives the use of this container for storing EBM. An evidence-based HTA process was then conducted, including consideration of the characteristics and chemical safety of the container, as well as laws and regulations that may apply to storing collected EBM. The full technical report, including all methodological aspects, is available elsewhere.¹ HTA is a multidisciplinary area of applied research that produces high-quality information about health technologies – drugs and health interventions. The main purpose is to provide objective information to support health care decisions in order to improve the quality and cost-effectiveness of health care.²

According to the information gathered from the HTA process and in accordance with the precautionary principle, the HTAU made recommendations to the CHU de Québec to protect neonates: 1) to stop using the plastic specimen containers for

storing collected EBM; 2) to use the remaining EBM that is already stored in the former specimen container only after informing and obtaining consent from the parents; and 3) to evaluate potential alternatives to replace the former specimen container and implement the most appropriate scenario according to the operational practices of neonatal care units and available resources of the hospital.

What is known about containers used to store EMB in hospital care settings?

In the literature, many articles aim to help health professionals promote and support breastfeeding. Some organizations and experts in the field provide recommendations for the conservation of EBM and specify which types of containers should be used. These recommendations are addressed to different care settings (hospitals, home or human milk banks) and sometimes designed according to the specific needs of preterm or full-term infants. Only six clinical guidelines suggesting which types of containers should be used to store EBM in hospital care settings were retrieved from our literature search.³⁻⁸ Major recommendations from these clinical guidelines were that the containers should be made of rigid plastic (polypropylene) without bisphenol A (BPA), sealed, sterile,

Authors' Affiliation

Health Technology Assessment Unit, Department of Evaluation, Quality and Strategic Planning, Centre hospitalier universitaire (CHU) de Québec, Québec City, QC

Correspondence: Dr. Marc Rhainds, Health Technology Assessment Unit, Department of Evaluation, Quality and Strategic Planning, CHU de Québec – Hôpital Saint-François d'Assise, 10, rue de l'Espinay, room D7-729, Québec City, QC G1L 3L5, Tel: 418-525-4444, ext. 5-4683, E-mail: marc.rhainds@chuq.qc.ca

Acknowledgements: The authors thank the CHU de Québec interdisciplinary group of experts who took the time to review the manuscript. Their comments and revisions were much appreciated. Funding was provided by the CHU de Québec.

Conflict of Interest: None to declare.

labelled for personal identification, graduated and easy to store. Regarding chemical safety, no definitive research results aimed at clarifying the most suitable plastic containers to store EBM in hospital care settings were found. Some organizations mentioned that EBM should be kept in containers made of food grade materials to ensure that migration of chemical substances from the plastic container to EBM does not represent a health risk and will not affect its nutritional and immunologic content. However, it remains unclear whether these recommendations are based solely on legal considerations or scientific evidence in humans.

Additional information was obtained from the product manufacturer regarding the characteristics of the specimen container used to store EBM at the CHU de Québec. The specimen container is intended to be used for collecting tissues or body fluids. It is sterile and graduated, and has a screwed cover (hermetic) and an identification label. It is made of polypropylene, and the cover is made of high-density polyethylene and an orange dye. According to the manufacturer, the container and cover do not contain BPA or diethylhexyl phthalate. The container's characteristics appear to be in accordance with major recommendations retrieved from clinical guidelines. However, since this container is not marketed for infant feeding (breast milk and breast milk substitutes), the manufacturer has no legal responsibility to ensure that the product is chemically safe with regard to human health.

What do we know about the use of specimen containers to collect or store EBM in hospitals? A small-scale consultation was done during the HTA process with representatives of neonatal care units of university hospitals in Quebec (n=3) and Ontario (n=1) in order to document their practices. Except for one hospital that uses plastic storage bags marketed for infant feeding, the results revealed that the same plastic specimen containers were used to collect or store EBM in other neonatal care units.

The chemical safety of containers used to store EBM appear to be in a legal vacuum

Given that the information gathered from the literature search did not clearly indicate whether the plastic specimen container currently used is chemically safe for human health, information on legal considerations about food packaging and consumer product safety was retrieved from governmental sites (Government of Canada, Health Canada and Canadian Food Inspection Agency). From a legal perspective, the chemical safety of containers marketed to store EBM appears to be in a legal vacuum. Since EBM is not a food freely available from grocery stores, containers used for infant feeding (storage bags and bottles) do not need to be in compliance with the *Food and Drugs Act* regulations regarding food packaging and chemical safety.^{9,10} However, according to the *Canada Consumer Product Safety Act*, manufacturers of containers marketed for infant feeding have a legal responsibility to ensure that their products do not represent hazards to human health,¹¹ although, as opposed to food packaging, the chemical innocuity of these containers is not systematically evaluated and approved by Health Canada.¹²⁻¹⁵

In addition to applicable laws and regulations, a legal opinion was sought from the Department of Ethics and Legal Affairs of the CHU de Québec to determine whether it was acceptable to

continue using this type of container in hospital settings to store EBM. According to the legal opinion, hospitals must ensure that the health of infants under their responsibility is not threatened by the use of any container to store EBM whose chemical safety is unknown. Furthermore, hospitals cannot assume the legal responsibility, and the manufacturer of the specimen container has no legal obligation to do so when the container is used to store EBM. Because the chemical safety of such containers is unknown in humans, it is desirable to consider other avenues.

Potential avenues regarding containers used to store EBM

Several containers are available to collect and store EBM in neonatal care units (storage bags and bottles). Even if these containers are not systematically evaluated and approved by Health Canada with regard to chemical safety before marketing, manufacturers have a legal responsibility to ensure that their products do not pose a hazard to infants. The unit cost of the specimen container is about 8 to 15 times lower than the cost of the bottle marketed for infant feeding (\$0.12 versus \$1.00 to \$1.84). The approximate unit cost of bags marketed for storage of EBM varies between \$0.05 and \$0.30, depending on the manufacturer (see the full technical report for more details¹).

In addition to the safety issues and the financial impact, other aspects related to the alternative containers must be taken into account in the decision-making process. From the experience of the CHU de Québec, it appears that the contribution of an interdisciplinary workgroup, including experts from different health care specialties (pediatrics, nursing, dietetics, lactation), is an essential factor in the development of feasible scenarios. For example, discussions on logistical aspects related to the storage and handling revealed that it would be useful for containers to be rigid in order to facilitate their stacking in refrigerators and freezers or to facilitate supplementation with fortifiers. Throughout the HTA process, the interdisciplinary workgroup assisted the HTAU in identifying relevant clinical and organizational issues and other dimensions that should be considered in the decision-making to implement changes in clinical practice regarding storage containers for EBM.

CONCLUSION

Review of the evidence indicates that the plastic specimen container used to store EBM in hospital care settings meets most of the characteristics recommended in clinical guidelines, but there is insufficient evidence regarding its chemical safety and effects on infants' health. Moreover, since the specimen container is not marketed for infant feeding, the manufacturer has no legal responsibility to ensure that this product is chemically safe for infants. Children are known to be more vulnerable to a variety of exposures, particularly because they receive greater exposure to the chemical per unit of body weight than adults. In this context and particularly since newborns are a vulnerable population, health care facilities should adopt the precautionary principle to manage containers used to store EBM.

Although changing the containers used to store EBM may have significant financial impacts, legal aspects should also guide the choice of these containers in Canadian hospitals. In fact, according to Accreditation Canada, health care facilities have the responsibility, from the legal perspective, to provide high-quality

services to their patients. Consequently, in the present case they must ensure that the health of infants under their responsibility is not threatened by the use of a container whose chemical safety is unknown. Because hospitals cannot assume this responsibility, it is therefore desirable to consider other avenues regarding containers used to store EBM.

This case is a good illustration of the value of the local HTA process to support evidence-based decision-making in hospitals. In this instance, because there are sufficient concerns about the use of specimen containers to store EBM in the neonatal care setting, Canadian hospital decision-makers should address this public health issue.

REFERENCES

1. Blouin M, Coulombe M, Rhainds M. Full technical report (in French): Évaluation des contenants utilisés pour la conservation du lait maternel exprimé en milieu hospitalier. Health and Technology Assessment Unit (HTAU), CHU de Québec, 2013. Poster (in English) presented at the 2013 Cochrane International Colloquium, Québec City, Québec, September 2013. Available at: http://www.chuqcca.fr/evaluation/uetmis/publications_uetmis/.
2. Gagnon MP. Opportunities to Promote Efficiency in Hospital Decision-Making Through the Use of Health Technology Assessment. Canadian Health Services Research Foundation, 2011.
3. Chantry CJ, Howard CR. Clinical protocols for management of breastfeeding. *Pediatr Clin N Am* 2013;60(1):75-113.
4. Cossey V, Jeurissen A, Thelissen MJ, Vanhole C, Schuermans A. Expressed breast milk on a neonatal unit: A hazard analysis and critical control points approach. *Am J Infect Control* 2011;39(10):832-38.
5. Eglash A, Bunik M, Chantry CJ, Howard CR, Lawrence RA, Marinelli KA, et al. ABM clinical protocol #8: Human milk storage information for home use for full-term infants (original protocol March 2004; Revision #1 March 2010). *Breastfeed Med* 2010;5(3):127-30.
6. Jones F. Best Practice for Expressing, Storing and Handling Human Milk in Hospitals, Homes and Child Care Settings. Human Milk Banking Association of North America (HMBANA). 3rd edition, 2011.
7. Lawrence RA, Lawrence RM. The collection and storage of human milk and human milk banking. In: *Breastfeeding: A Guide for the Medical Profession*. 7th edition, Elsevier Health Sciences, 2001.
8. Robbins ST, Meyers R; Pediatric Nutrition Practice Group. *Infant Feedings: Guidelines for Preparation of Human Milk and Formula in Health Care Facilities*. 2nd edition. Academy of Nutrition and Dietetics, 2011.

9. Ministry of Justice. *Food and Drugs Act* (R.S.C. 1985, ch. F-27). Ottawa, ON: Government of Canada.
10. Ministry of Justice. Food and Drug Regulations (C.R.C., ch. 870). Division 23 : Food Packaging Materials. Ottawa: Government of Canada.
11. Ministry of Justice. *Canada Consumer Product Safety Act* (S.C. 2010, ch. 21). Ottawa: Government of Canada.
12. Health Canada. Information Requirements for Food Packaging Submissions. Ottawa.
13. Health Canada. Health Products and Food Branch Packaging Materials Assessment Process. Ottawa.
14. Health Canada. Lists of Acceptable Polymers for Use in Food Packaging Applications. Ottawa.
15. Canadian Food Inspection Agency. Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products. Ottawa.

Received: November 27, 2013

Accepted: March 29, 2014

RÉSUMÉ

Le lait maternel est le seul lait qui comble à la fois tous les besoins nutritionnels et immunitaires du nourrisson. Puisque la pratique de l'allaitement est fortement encouragée en milieu hospitalier, il importe d'appliquer correctement les mesures de santé publique en vigueur en matière de conservation du lait maternel exprimé. L'Unité d'évaluation des technologies et des modes d'intervention en santé (UETMIS) du CHU de Québec a été sollicitée par des cliniciens de l'unité néonatale afin d'évaluer l'acceptabilité d'utiliser pour la conservation du lait maternel exprimé, un contenant de plastique normalement prévu pour la collecte des tissus ou des fluides corporels. Dans cette démarche, une évaluation systématique des données probantes disponibles a été réalisée. L'UETMIS a recommandé de cesser l'utilisation du contenant actuel et d'envisager d'autres options pour la conservation du lait maternel exprimé à l'unité néonatale. Ces recommandations sont cohérentes avec l'application du principe de précaution utilisé en santé publique de même que des considérations d'ordre légales.

MOTS CLÉS : lait maternel exprimé; conservation; contenant de plastique; unité de soins néonatale; sécurité et innocuité chimique; principe de précaution