Haut Conseil de la santé publique

ADVICE

on defining indications for the unavoidable use of sterile bottles and teats when feeding hospitalised infants and newborns

December 2, 2011

On November 22, 2011, the French Directorate-General for Health consulted the Haut Conseil de la santé publique (French High Council for Public Health/HCSP) about the media coverage regarding use of feeding bottles and teats sterilised with ethylene oxide, with a view to defining formal indications for the unavoidable use of such sterile equipment to feed hospitalised infants and newborns.

The recommendations presented in this advice have been drawn up by a specific working group bringing together experts from the HCSP (Patient safety and Infectious diseases Comittees), paediatric experts, neonatologists, managers of breast milk banks and/or milk kitchens, hygienists and sterilisation specialists. Several paediatricians and hygienists in charge of this situation in their health centres were also contacted. The coordinator of the working group brought together under the authority of the French Food Safety Agency (Afssa) in 2005, which issued the recommendation "sterile feeding bottles for infants with immune deficiency", was also interviewed by the leader of this working group.

The HCSP recalls the conditions for feeding hospitalised infants and newborns:

- While newborns and infants in the community or local nurseries are fed in line with practices that have been subject to recommendations[1], this is not altogether the case in hospitals[2]. For healthy newborns not on breast milk (via breastfeeding or a breast milk bank), "nourettes", or mini ready-to-use bottles of formula, are routine; since these are not sterilised with ethylene oxide, they are not concerned by this opinion.
- The feeding products used are not sterile in the strict sense of the term (theoretical probability of a viable microorganism being present is less than or equal to 10^{-6})[3]. Breast milk is either used raw or treated by a breast milk bank – in which case it undergoes microbiological checks before and after pasteurisation[4]. Infant and follow-on formula is made up by mixing non-sterile powder[5],[6],[7] with non-sterile natural mineral or spring water[8] that

[1] SFHH. Avis concernant l'entretien des biberons et tétines en crèche « de ville ». 18 August 2004. http://sf2h.net/publications-SF2H/SF2H_recommandations-biberons-2004.pdf (consulted on 30/11/2011).

[2] Afssa. Recommandations d'hygiène pour la préparation et la conservation des biberons. July 2005. http://www.anses.fr/Documents/MIC-Ra-BIB.pdf (consulted on 30/11/2011).

[3] Standard NF EN 556-1 – February 2002.

[4] Afssaps. Guide de bonnes pratiques de fonctionnement des lactariums. JO of 5 January 2008. Annexe à l'arrêté du 3 décembre 2007 relatif au fonctionnement des lactariums.

[5] Van Acker J, de Smet F, Muyldermans G, et al. Outbreak of necrotizing enterocolitis associated with *Enterobacter sakazakii* in powdered milk formula. J Clin Microbiol 2001;39:293-7.

[6] Coignard B, Vaillant V, Vincent JP et al. Infections sévères à *Enterobacter sakasakii* chez des nouveau-nés ayant consommé une préparation en poudre pour nourrissons, France, October-December 2004. BEH 2006;(2-3):10- 3.

[7] Brouard C, Espié E, Weill FX et al. Epidémie de salmonellose à *Salmonella enterica* sérotype Agona liée à la consommation de poudres de lait infantile, France, January-May 2005. BEH 2006;(33):248-50.

nevertheless meets the quality criteria of Afssa's 2003 advice[9]. These different types of formula also come in liquid form which is poured into feeding bottles for administration.

- Very premature babies as well as hospitalised infants at times are fed using specific systems: oro- or nasogastric tubes and disposable syringes for administering breast milk or formula for low birth weight babies, prepared and packaged before administration in disposable bottles. All of these disposable, sterile materials (tubes, syringes, etc.) used in breast milk banks, milk kitchens or other departments are sterilised with ethylene oxide. This treatment results in high microbiological safety for these products. Standards specify the conditions for carrying out and validating this technique as well as the permissible maximum residue levels of ethylene oxide after desorption[10]. The ministerial instruction of November 25, 2011 asks that feeding bottles and teats treated with ethylene oxide be substituted pending the HCSP's opinion.
- The HCSP also recalls the fact that the status of bottles, teats and equipment for feeding infants and newborns meets a different classification from other medical devices[11]. It is within this context that the regulations on food contact materials and articles as well as those on biocidal products apply.

The strategies for using disposable feeding bottles and teats that are safe in infectious terms can depend on the findings of risk assessments conducted by the French Agency for Food, Environmental and Occupational Health and Safety (Anses) on the ethylene oxide sterilisation process.

It is important to remember that disposable teats and bottles have now replaced multiple-use bottles with rubber teats that used to be sterilised in an autoclave, with a view to controlling contamination and transmission of microorganisms (this transmission source has also been documented)[12],[13]. A return to such practices is out of the question.

Lastly, the HCSP is well aware that health centres are facing an uncertain future: if they cannot use the feeding bottles they currently have in stock – sterilised with ethylene oxide – a risk of feeding bottle shortages is highly likely in the short-term given the scarcity of alternative solutions proposed by manufacturers. A hurried, poorly controlled return to solutions involving reuse of feeding bottles and teats – for multiple uses – after disinfection or autoclave sterilisation, is likely to run the risk of process and/or handling errors that may well lead to the transmission of pathogenic microorganisms. This risk is much higher during autumn and winter epidemics.

In this context, the HCSP has not identified a single clinical situation for which use of a sterile feeding bottle and teat is unavoidable, with the exact definition of sterility being: theoretical probability of a viable microorganism being present is less than or equal to 10^{-6}. This recommendation applies to all hospitalised infants – very premature newborns and infants with immune deficiency alike – including those suffering from severe combined immunodeficiency who are monitored in sterile incubators.

However, the HCSP recommends:

[8] Pour les nourrissons hospitalisés, l'Afssa recommandait en 2005 {référence 2] de ne pas utiliser d'eau du réseau de distribution, mais de privilégier l'eau embouteillée voire de l'eau bactériologiquement maîtrisée.

[9] Afssa. Avis relatif à la fixation de critères de qualité des eaux minérales naturelles et des eaux de source embouteillées permettant une consommation sans risque sanitaire pour les nourrissons et les enfants en bas âge. 2 décembre 2003.

[10] Norme NF EN ISO 10993-7.

[11] Articles L. 5231-2 et R. 5231-1 du code de la santé publique.

[12] Carlos Sánchez-Carrillo, Belén Padilla, Mercedes Marín et al. Contaminated feeding bottles: The source of an outbreak of Pseudomonas aeruginosa infections in a neonatal intensive care unit. Am J Infect Control 2009, 37:150-4.

[13] Renfrew M J, McLoughlin M, McFadden A. Cleaning and sterilisation of infant feeding equipment: a systematic review . Public Health Nutrition 2008,11:1188–99.

- using disposable feeding bottles and teats presenting safety characteristics in view of the infectious risk, as defined below, irrespective of the strategy put forward to achieve this quality. This is because using feeding bottles and teats that can be reused after treatment is not recommended, unless this practice is already well-established, organised, controlled and assessed.
- asking manufacturers proposing feeding bottles and teats that have been treated to make them safe in infectious terms to furnish proof of the lack of potentially pathogenic microorganisms (*Bacillus cereus*, sporulated anaerobic bacteria, enterobacteria, *Pseudomonas aeruginosa*, *Staphylococcus aureus*) and of the control of total flora (by total aerobic microbial count and total yeast/mould count), and to guarantee the safety of such materials pursuant to the regulations on food contact materials.

Opinion drawn up by a group of experts, who may or may not be members of the HCSP, around the Patient Safety Comittee and validated by the HCSP President.

On December 2, 2011

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