

Conflicts of interest

The World Health Assembly Resolution 49.15 of May 25, 1996 urges member states "to ensure that the financial support for professionals working in infant and young child health does not create conflicts of interest". But what is a conflict of interest? This is one of the accepted definitions: "A set of conditions in which professional judgment concerning a primary interest tends to be unduly influenced by a secondary interest".¹ There is no doubt about the primary interest of a health professional: to act for the maximum benefit and do the minimum harm to the individual and the community he or she serves. But what is a secondary interest and where does it come from?

A health professional can have a political, academic, religious or personal conflict of interest, but very often the nature of a secondary interest is financial. Sixteen different forms of financial entanglement between health professionals and companies have been described: acceptance of direct and indirect gifts to attendance at sponsored dinners and social or recreational events, ownership of stock or equity holdings to conducting sponsored research, funding of academic chairs or medical associations to paid consultancies and ghost-writing of "scientific" articles...² From this short list it is clear that a financial conflict of interest can be individual and/or collective; i.e. a health professional may have no individual entanglement with a company, but may belong to an association or attend an event that does.

Collective conflicts of interest may involve huge amounts of money. In 2001-03, for example, the American Academy of Pediatrics (AAP) sold a total of 600,000 copies of "The New Mother's Guide to Breastfeeding" to Abbott Ross, for an undisclosed amount of money. Abbott Ross distributed the book to mothers of newborn infants, with its name and logo, through doctors and nurses. More recently, Nestlé paid for each AAP member (more than 60,000 in total) to receive a copy of the "Pediatric Nutrition Handbook". Both instances are good examples of "image transfer", a strategy to enhance image by association with respected professional bodies. Similar links between health professionals and their associations, and industry, are common. The magnitude of financial conflicts of interest is even larger when drug companies are involved. A recent analysis of 37 biomedical research articles from major medical journals found that a third of the lead authors had financial conflicts of interest: for example, patents, shares, or remuneration for being on advisory boards.³ Infant food and drug companies do not reveal the amount of money they spend on health professionals, individually or collectively, but they spend 10-15% of their budget on marketing, and a large proportion of this could be used for such funding.

It is often said that conflict of interest is a "condition", not a "behaviour". As a consequence, the suggested solution is transparency: health professionals and their associations should disclose and declare competing financial interests. Unfortunately this does not happen. Most health professionals do not declare their conflict of interest because they think they are honest and unbiased.³ It is probably true that most health professionals are honest but at the same time, they are very likely to be biased, i.e. unconsciously influenced by their funders. Both social science and medical research show this. For example, when the results of studies sponsored by industry were compared with those of non-sponsored studies, results more favourable to industry were almost four times more likely to be found in sponsored studies than in non-sponsored ones.⁴ The reason is that "even when individuals try to be objective, their judgments are subject to an unconscious and unintentional self-serving bias".⁵ Disclosing one's financial attachments is not only difficult to enforce, but more seriously, it does not eliminate the influence of industry funding on research or doctors' behaviour. Putting limits to the amount of funds given to individuals or associations, as recently done by the American Medical Association, does not solve the problem: even small gifts feed an unconscious and unintentional self-serving bias. More radical proposals, such as recommending that health professionals should receive no payment of any kind from industry, are unlikely to be accepted: most medical conferences would be cancelled!

There is no simple solution. The first thing to do is to recognise that the problem exists, that it is huge, and that it is complex. All health professionals should then ask themselves the following questions: what would our patients, the people we are serving, think if they were aware that part of our income comes from the manufacturers of the products we prescribe, and that the cost is retrieved in the price of these same products? What would they think if they knew that our advice is not based on independent judgment, but that indeed it is biased? Failure to give an adequate individual and collective response to these questions will progressively undermine the image of health providers and the confidence of users.

-
1. Thompson DF. Understanding financial conflicts of interest. *N Engl J Med* 1993;329:573-6
 2. Moynihan R. Who pays for the pizza? Redefining the relationships between doctors and drug companies. *BMJ* 2003;326:1189-96
 3. Hussain A, Smith R. Declaring financial competing interests: survey of five general medical journals. *BMJ* 2001;323:263-4
 4. Bekelman JE, Li Y, Gross CP. Scope and impact of financial conflicts of interest in biomedical research. A systematic review. *JAMA* 2003;289:454-65
 5. Dana J, Lowenstein G. A social science perspective on gifts to physicians from industry. *JAMA* 2003;290:252-5

As pointed out by law professor Mark A. Rodwin, disclosing financial links is only a first step: "Disclosure can help address conflicts of interest, but only if it is a part of a coordinated policy that sets high standards of conduct, clearly delineates the permissible from the unacceptable, develops institutions to monitor behaviour and imposes meaningful sanctions to ensure compliance."⁶ And as noted by Dana and Lowenstein, "Because bias induced by monetary interests is unconscious and unintentional, there is little hope of controlling it when monetary interests exist. The implication for industry gifts is straightforward: they should be prohibited."⁷

6. Rodwin MA. *Medicine, money and morals: physicians' conflicts of interest*. New York and Oxford, Oxford University Press, 1993

7. Dana J, Lowenstein G. *op. cit.*

Breastfeeding why...

Hospitalization for respiratory disease

Galton Bachrach VR, Schwarz E, Bachrach LR. Breastfeeding and the risk of hospitalization for respiratory disease in infancy: a meta-analysis. *Arch Pediatr Adolesc Med* 2003;157:237-43

The risk of hospitalization for lower respiratory tract diseases in healthy, full-term breastfed infants with access to modern medical care is lower even in high income countries. Data from 33 studies were analysed. Infants who were not breastfed had a more than three times higher risk of hospitalization for severe respiratory illness compared with those who were exclusively breastfed for 4 months. This effect remained stable and statistically significant after adjusting for the effects of smoking or socio-economic status.

Asthma and allergy

Kull I, Wickman M, Lilja G, Nordvall SL, Pershagen G. Breast feeding and allergic diseases in infants—a prospective birth cohort study. *Arch Dis Child* 2002;87:478-81

Allergy has been consistently related to artificial feeding among children. To investigate the effect of breastfeeding on allergic diseases up to 2 years of age, a birth cohort of 4,089 infants was followed prospectively in Stockholm. Children exclusively breastfed during 4 months or more had about 30% less asthma, 20% less atopic dermatitis, and 30% less suspected allergic rhinitis by 2 years of age. There was also a significant 30% risk reduction for asthma if partial breastfeeding had been maintained 6 months or more.

Da Costa Lima RC, Victora CG, Menezes AMB, Barros FC. Do risk factors for childhood infections and malnutrition protect against asthma? A study of Brazilian male adolescents. *Am J Public Health* 2003;93:1858-64

This article contradicts the previous one, but it was carried out in a different environment, with different methods and for a different age group. About 18% of a birth cohort of 2,250 male 18-year-olds reported having asthma. Several childhood factors were found to be significantly associated with increased asthma risk: being of high socio-economic status, living in an uncrowded household, and being breastfed for 9 months or longer. These results are consistent with the "hygiene hypothesis", according to which early exposure to infections provides protection against asthma. Should breastfeeding more than 9 months be confirmed as a risk factor for asthma, the policy implications would be unclear

given its protective effect against other serious childhood diseases.

Brain development

Wang B, McVeagh P, Petocz P, Brand-Miller J. Brain ganglioside and glycoprotein sialic acid in breastfed compared with formula-fed infants. *Am J Clin Nutr* 2003;78:1024-9

The concentration of sialic acid in the brain has been linked to learning ability in animal studies. Human milk is a rich source of sialic acid. In this study, the sialic acid concentration in the brain of breastfed and formula-fed infants was compared in 25 samples of frontal cortex derived from infants who died of sudden infant death syndrome. Higher sialic acid concentrations in infants fed human milk suggest an increased potential for brain development.

Bouwstra H, Boersma ER, Boehm G, Dijck-Brouwer DA, Muskiet FA, Hadders-Algra M. Exclusive breastfeeding of healthy term infants for at least 6 weeks improves neurological condition. *J Nutr* 2003;133:4243-5

Might there be a minimal duration of exclusive breastfeeding necessary for optimal neurological outcome? The quality of general movements (GM), a sensitive marker of neurological condition, was assessed at 3 months in 147 breastfed, healthy, term infants followed from birth. GM were classified as normal-optimal, normal-suboptimal, mildly abnormal and definitely abnormal. Information on social and pre- and perinatal conditions, and the duration of breastfeeding, was collected prospectively. After adjustment for these factors, there was a positive association between breastfeeding duration and GM quality until approximately 6 weeks of age. In infants exclusively breastfed for 6 weeks or less (n = 55), 18% exhibited normal-optimal, 47% normal-suboptimal, and 47% mildly abnormal GM. In contrast, in infants exclusively breastfed for more than 6 weeks (n = 92), 43% exhibited normal-optimal, 45% normal-suboptimal, and 12% mildly abnormal GM.

Good night!

Horne RS, Parslow PM, Ferens D, Watts AM, Adamson TM. Comparison of evoked arousability in breast and formula fed infants. *Arch Dis Child* 2004;89:22-5

Arousal from sleep is believed to be an important survival mechanism that may be impaired in victims of sudden infant death syndrome (SIDS). In this

study of 43 healthy term infants, arousal thresholds were measured at 2-4 weeks, 2-3 months, and 5-6 months. Arousal thresholds were not different between breastfed and formula-fed infants in quiet sleep. However, in active sleep, breastfed infants were more easily arousable than formula-fed infants at 2-3 months of age, the age with the peak incidence of SIDS. There was no difference between groups of infants when the sleep period length was compared.

Breastfeeding how...

Preterm infants

Espy KA, Senn TE. Incidence and correlates of breast milk feeding in hospitalized preterm infants. *Soc Sci Med* 2003;57:1421-8

In this study, the clinical charts of 151 pre-term infants (34 weeks gestational age or less) admitted in a neonatal intensive care unit of a regional hospital in the USA were reviewed. About 51% of the infants were fed formula exclusively. On average, the remaining infants received at least one breastmilk feeding per day for 44% of their hospital stay. Higher maternal age and an Apgar score higher than 6 at 5 minutes were the two factors associated with a higher probability of breastmilk feeding.

Community-based promotion

Bhandari N, Bahl R, Mazumdar S, Martines J, Black RE, Bhan MK; Infant Feeding Study Group. Effect of community-based promotion of exclusive breastfeeding on diarrhoeal illness and growth: a cluster randomised controlled trial. *Lancet* 2003;361:1418-23

This study assessed the feasibility, effectiveness, and safety of an educational intervention to promote exclusive breastfeeding for 6 months in India. Eight pair-matched communities were randomised; one of each pair received the intervention and the other received none. In the intervention communities, health and nutrition workers were trained to counsel mothers for exclusive breastfeeding at multiple opportunities. After training, 1,115 infants were enrolled, 552 in the intervention and 473 in the control communities. At 3 months, exclusive breastfeeding reached 79% in the intervention and 48% in the control communities. The 7-day diarrhoea prevalence was lower in the intervention communities at 3 months (about 30% less) and 6 months (about 15% less). The mean weights and lengths and the proportion of malnourished infants did not differ between groups. Promotion of exclusive breastfeeding till 6 months through existing primary health care services is feasible, reduces the risk of diarrhoea, and does not lead to growth faltering.

Graffy J, Taylor J, Williams A, Eldridge S. Randomised controlled trial of support from volunteer counsellors for mothers considering breastfeeding. *BMJ* 2004; 328:26-31

Is providing support on breastfeeding enough to help mothers to breastfeed? This randomised controlled trial was carried out in 32 general practices in London and south Essex to investigate whether offering volunteer support from counsellors would result in

more women breastfeeding. The intervention did not significantly increase the prevalence of any breastfeeding to 6 weeks: 65% (218/336) in the intervention group and 63% (213/336) in the control group. Neither duration of breastfeeding nor time of introduction of formula feeds differed significantly. However, only 20% of women in the intervention group had at least one postnatal visit, 43% had postnatal telephone contacts and 38% had no postnatal contact at all. About 73% of women who contacted (visit and phone) counsellors postnatally rated them as very helpful and said that the most helpful advice came from counsellors rather than from other sources. Person-to-person contact is the best way to maximize breastfeeding support.

In-hospital education of mothers

Labarere J, Bellin V, Fourny M, Gagnaire JC, Francois P, Pons JC. Assessment of a structured in-hospital educational intervention addressing breastfeeding: a prospective randomised open trial. *BJOG* 2003;110:847-52

Is just one session on breastfeeding education enough? To determine whether a single one-to-one in-hospital education session could increase the rate of breastfeeding at 17 weeks, a randomised trial was conducted in a maternity hospital in France. 106 mother-infant pairs were allocated to the intervention group (a structured, one-to-one in-hospital education session) and 104 to the control group (usual verbal encouragement). The rate of any breastfeeding (34.4% vs. 40.2% in the control group) and of exclusive breastfeeding (14.0% vs. 14.4%) at 17 weeks was not significantly different. Guidance provided by maternity staff should be reinforced by a long-term, multifaceted support programme in countries with a low to intermediate rate of breastfeeding.

Human milk banks

Azema E, Callahan S. Breast milk donors in France: a portrait of the typical donor and the utility of human milk banking in the French breastfeeding context. *J Hum Lact* 2003;19:199-202

One important constraint to the establishment of human milk banks is the availability of donors. While the characteristics of blood donors are well known, those of lactating women who decide to donate their milk are largely unknown. Seventeen milk banks in France were contacted and eight accepted to participate in a study examining donor characteristics. The results showed that among 103 donors, the majority were women with strong support at home; more than a half worked outside of the home particularly in health and social services. Only 11.7% reported practical problems in donating their milk. The main reasons for giving their milk were altruism and an optimistic attitude; close to 60% indicated having "too much milk". This study can give leads for the recruitment of potential donors of breastmilk.

Working mothers

Galtry J. The impact on breastfeeding of labour market policy and practice in Ireland, Sweden, and the USA. *Soc Sci Med* 2003;57:167-77

International recommendations advise exclusive breastfeeding for 6 months. There would be consid-

erable potential for labour policy and practice, particularly maternity/parental leave provisions, to positively influence breastfeeding practice. Taking the case studies of Ireland, Sweden, and the United States, this paper concludes that both socio-cultural support and labour market/health/early childhood policy are important if high rates of both breastfeeding and women's employment are to be achieved in industrialised countries.

Less pain

Carbajal R, Veerapen S, Couderc S, Jugie M, Ville Y. Analgesic effect of breast feeding in term neonates: randomised controlled trial. *BMJ* 2003;326:13

Is breastfeeding effective for pain relief during venous puncture in neonates? A study was carried out to compare the effect of breastfeeding with that of oral glucose combined with a pacifier, in 180 randomised, term newborns, 45 in each group. During venous puncture, infants were either breastfed (group 1), held in their mother's arms without breastfeeding (group 2), given a placebo (group 3), or given glucose and a pacifier (group 4). Video recordings of the procedure were assessed by two observers blinded to the purpose of the study. Median pain scores for breastfeeding, held in mother's arms, placebo, and 30% glucose plus pacifier groups were 1, 10, 10, and 3 with one pain scale, and 4.5, 13, 12, and 4 with another pain scale, with a significant difference among groups. Breastfeeding effectively reduces response to pain during minor invasive procedures in term neonates.

Mother-to-child transmission of HIV

Jackson JB, Musoke P, Fleming T, Guay LA, Bagenda D, Allen M, Nakabiito C, Sherman J, Bakaki P, Owor M, Ducar C, Deseyve M, Mwatha A, Emel L, Duefield C, Mirochnick M, Fowler MG, Mofenson L, Miotti P, Gigliotti M, Bray D, Mmiro F. Intrapartum and neonatal single-dose nevirapine compared with zidovudine for prevention of mother-to-child transmission of HIV-1 in Kampala, Uganda: 18-month follow-up of the HIVNET 012 randomised trial. *Lancet* 2003;362:859-68

From November, 1997, to April, 1999, 313 HIV-1 infected pregnant women were randomly assigned nevirapine (200 mg at labour onset and 2mg/kg for babies within 72 hours of birth) and the other 313 HIV-infected pregnant women zidovudine (600 mg orally at labour onset and 300 mg every 3 hours until delivery, and 4 mg/kg orally twice daily for babies for 7 days); 99% of babies were breastfed (median duration 9 months). The estimated risks of HIV-1 transmission in the zidovudine and nevirapine groups were 10.3% and 8.1% at birth; 20.0% and 11.8% by age 6-8 weeks; 22.1% and 13.5% by age 14-16

weeks; and 25.8% and 15.7% by age 18 months. Nevirapine was associated with a 41% reduction in relative risk of transmission through to age 18 months. The nevirapine regimen is simple, inexpensive, well-tolerated, and has the potential to significantly decrease HIV-1 perinatal transmission in less-developed countries.

Leroy V, Karon JM, Alioum A, Ekpini ER, van de Perre P, Greenberg AE, Msellati P, Hudgens M, Dabis F, Wiktor SZ; West Africa PMTCT Study Group. Postnatal transmission of HIV-1 after a maternal short-course zidovudine peripartum regimen in West Africa. *AIDS* 2003;17:1493-501

To assess the postnatal transmission risk of HIV-1 after a maternal short-course zidovudine regimen in a breastfeeding population, data were pooled from two trials conducted in Côte d'Ivoire and Burkina Faso. Consenting HIV-1 seropositive women were randomized at 36-38 weeks' gestation to receive oral zidovudine or placebo. At age 24 months, the risks for postnatal transmission were similar in the zidovudine (9.8%, n = 254) and placebo groups (9.1%, n = 225). Postnatal transmission occurred at a similar rate between arms and therefore reduced the long-term overall efficacy of this zidovudine regimen at age 24 months.

Cochrane reviews

Early skin-to-skin contact

Anderson GC, Moore E, Hepworth J, Bergman N. Early skin-to-skin contact for mothers and their healthy newborn infants. *Cochrane Database Syst Rev* 2003;(2):CD003519

To assess the effects of early skin-to-skin contact on breastfeeding, behaviour, and physiology in mothers and their healthy newborn infants, 17 studies, involving 806 participants, were included in this systematic review. Early skin-to-skin contact was found to have statistically significant positive effects: more than twice the number of infants were still breastfed at 1-3 months, breastfeeding duration increased by 42 days on average, infant temperature and blood glucose were better kept in the normal range, infant crying was greatly reduced, and the scores of maternal affectionate behaviour improved. No statistically significant benefit of early skin-to-skin contact was noted for other major clinical variables: breastmilk maturation, maternal chest circumference, and infant heart rate. Early skin-to-skin contact appears to have some clinical benefit especially regarding breastfeeding outcomes and infant crying, and has no apparent short or long-term negative effects.

Prepared by the **Geneva Infant Feeding Association (GIFA)**, a member of the **International Baby Food Action Network (IBFAN)**.

Editors: Marina Ferreira Rea, Adriano Cattaneo. Lída Lhotská, Bob Peck and Elaine Petitot-Côté revised and edited the text.

For copies of *Breastfeeding Briefs* please make request to GIFA, Box 157, 1211 Geneva 19, Switzerland

Fax: +41-22-798 44 43, e-mail: info@gifa.org, or to UNICEF country offices. Available also in French, Spanish, Portuguese and Arabic. A contribution of CHF 20.-- for a subscription to organisations in industrialised countries is gratefully accepted and can be sent by international postal order to account no. 12-17653-5