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FEATURE

FORMULA MILK

Overdiagnosis and industry influence: how cow's milk protein allergy is extending the reach of infant formula manufacturers

The condition may be helping the baby milk industry to form relationships with the paediatric profession, finds **Chris van Tulleken—** with potential for harm to mothers and children

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Allergy to cow's milk protein may be acting as a Trojan horse for the $50bn (£40bn; €44bn) global formula industry to forge relationships with healthcare professionals in the UK and around the world.[1] Experts believe these relationships are harmful to the health of mothers and their children, creating a network of conflicted individuals and institutions that has wide ranging effects on research, policy, and guidelines. Potential overdiagnosis of the allergy can also have negative effects on breast feeding.

Between 2006 and 2016, prescriptions of specialist formula milks for infants with cow's milk protein allergy (CMPA) increased by nearly 500% from 105 029 to over 600 000 a year,[2] while NHS spending on these products increased by nearly 700% from £8.1m to over £60m annually.[3] Epidemiological data give no indication of such a large increase in true prevalence[4 5]—and the extensive links between the formula industry and the research, guidelines, medical education, and public awareness efforts around CMPA have raised the question of industry driven overdiagnosis.

Nigel Rollins from the World Health Organization's department of maternal, newborn, child, and adolescent health tells *The BMJ*, "It's reasonable to question whether these [prescription and spending] increases reflect a true increase in prevalence."

Guideline proliferation and competing interests

Clinical guidelines propose two main types of CMPA,[6-9] which can overlap. Immunoglobulin E (IgE) mediated reactions have rapid onset symptoms and the diagnosis can be confirmed with testing. In non-IgE mediated CMPA, symptoms are slower onset and non-specific so diagnosis can be made only with a trial of dietary exclusion followed by reintroduction.[9] Many clinicians who spoke to *The BMJ* are concerned that these factors make non-IgE mediated allergy vulnerable to industry exploitation.

Bob Boyle, a consultant paediatric allergist at Imperial College, points to the number of guidelines. "There are many more milk allergy guidelines published than for other food allergies. Many have direct or indirect support from industry, which has a lot to gain from increased specialised formula use."

The first international guideline for primary care was developed in 2007[10] and followed by another in 2010.[7] Both were funded by formula manufacturers, with many authors declaring conflicts of interest. Five of the 11 authors of the 2011 food allergy guidelines from the National Institute for Health and Care Excellence (NICE),[6 11] 10 of the 12 authors of the 2012 European Society for Paediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) guidelines,[12] all five authors of the 2013 Milk Allergy in Primary Care (MAP) guideline,[8] and all 12 authors of the 2017 iMAP guideline[9] declared interests with infant formula manufacturers either at the time of writing or subsequently. In the case of the NICE guidance no authors were excluded from discussions on any topic (see supplement on bmj.com and box 1).[11]

Box 1: Why conflicts of interest matters

Conflicts of interest describe an objective extant condition, regardless of their actual effect on an individual.[13]

The scientific literature shows that physician contact with drug industry representatives leads to increased cost and reduced quality of treatment.[14-24] Trials funded by industry are more likely to produce results that favour the sponsor.[21-23]

The literature also shows that bias is often unconscious and unintentional[18-21] and that disclosure may have the perverse effect of exaggerating bias rather than mitigating it.[22]

Guideline modifications can create large new markets for industry and escalate costs of treatment by billions of dollars; this has been seen in hypertension, diabetes mellitus, composite cardiovascular risk, depression, rheumatoid arthritis, and gastro-oesophageal reflux.[4 5]

Instances have been reported of industry influence over guidelines seeming to contradict best evidence to the potential detriment of patient care.[18 20]

The BMJ attempted to contact all the authors of these guidelines and received six replies from authors with declared conflicts of

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interest. These acknowledged concerns about the influence of industry but said that there was no direct influence over the guidelines or their practice.

ESPGHAN guideline author Steffen Husby said, "These links may be harmful, and that bias may be subconscious. To the best of my knowledge my practice has not been influenced by these conflicts." Fellow ESPGHAN guideline author Sibylle Koletzko said that ESPGHAN has adopted codes of conduct requiring all members of guideline development groups to declare conflicts of interest and if relevant they may be excluded from discussions.

NICE, MAP, and iMAP guideline author Adam Fox said, "MAP has been published in multiple journals, all with independent peer review process. None of the peer reviewers raised any concern of bias."

The guideline content and the allergy itself are widely promoted by industry to healthcare professionals and patients using campaigns, leaflets distributed in primary care, educational courses, and information on websites, including parent forums.

The iMAP guideline is promoted on the website of Allergy UK, a charity providing information to patients that lists formula manufacturer Danone Nutricia as a partner. isitcowsmilkallergy.co.uk is a website maintained by Mead Johnson. It was used in a 2014 campaign, involving MAP and NICE guideline authors, to highlight the allergy. The website was promoted on parent forums as part of this campaign.[25] Another website, cowsmilkallergy.co.uk, is sponsored by Danone Nutricia and has videos for the public of Fox discussing CMPA.

Formula sponsored education

Much patient and medical education around CMPA is provided by bodies that may seem to be independent but that receive funding from the formula industry. As well as Allergy UK, these include the British Society for Allergy and Clinical Immunology (BSACI, the UK's professional society of allergists), which accepts £100 000 a year from the formula industry,[26] and the Allergy Academy, a collaborative initiative run from the department of paediatric allergy at King's College London, which provides education on allergy to healthcare professionals and patients and their families, and is sponsored by formula manufacturers Abbott, Mead Johnson, and Nutricia.

BSACI says in a statement, "'Until the number of healthcare professionals able to treat allergies matches demand for allergy treatment, we believe we have a responsibility to do all we can to provide training to GPs and others. As with all other specialist societies and royal colleges, we work with industry in a responsible way to help us fulfil our aims and objectives ensuring healthcare professionals are able to treat patients as effectively as possible."

Neena Modi, a professor of neonatology at Imperial College and the immediate past president of the Royal College of Paediatrics and Child Health (RCPCH), has declared that she has received unrestricted funds from Nutricia, Abbott, and Nestlé. She tells *The BMJ* that corporate sponsorship of medical education is not unusual: "Many people who object to formula industry sponsorship don't object when the pharmaceutical industry does the same thing."

While drug industry sponsorship of medical education is common, sponsorship by formula manufacturers is regulated by a code of practice: the International Code of Marketing of Breast-milk Substitutes.[27] The code was adopted by WHO in 1981 after egregious marketing practices to mothers in the developing world were exposed in the 1970s. It requires marketing restrictions for breastmilk substitutes and states that companies should not create conflicts of interest, sponsor educational events, or advertise in health facilities or throughout health systems.[27]

But there have been frequent and widely reported allegations of code violations, including the *Breaking The Rules Report* from the International Baby Food Action Network and reports in the mainstream press. The *Guardian* and Save the Children published an investigation in early 2018 that found that formula companies were offering doctors, midwives, and local health workers gifts, in violation of Philippine law and the international code.[28] Unicef estimates that, in the Philippines alone, there are 16 000 deaths a year due to formula feeding.[29] A *Lancet* paper estimated that scaling up breastfeeding to a near universal level could prevent 823 000 annual deaths in children younger than 5 years.[30]

Baby friendly?

The code is not fully adopted into UK law, but some hospital trusts—including Guy's and St Thomas', which runs allergy education courses—have Baby Friendly status, a Unicef accreditation that requires full compliance.

On its website, Guy's and St Thomas' NHS Foundation Trust reaffirms this commitment.[31] It also tells *The BMJ* that it is "committed to being a Baby Friendly trust and [we] believe that breastfeeding is the healthiest way for a mother to feed her baby ... Our specialist breastfeeding midwives on the postnatal ward work hard to support mothers with feeding."

The Allergy Academy, which is sponsored by three infant formula manufacturers, delivers courses on Guy's and St Thomas' premises. These are described by the trust as private "evidence-based training days for healthcare professionals."

Asked whether these courses violate the WHO code or Baby Friendly standards, a spokesperson for Guy's and St Thomas' says, "We do not display or distribute any materials produced by the manufacturers of breastmilk substitutes within our hospitals. Sponsors of the event are only allowed to speak to attendees in the exhibition area and in the context of … hypoallergenic formula for infants with a diagnosis of milk allergy, which are designated as foods for special medical purposes."

The BMJ has confirmed that materials produced by formula manufacturers were displayed and distributed at events at St Thomas'. The trust states that Allergy Academy courses will not take place in St Thomas' hospital in the future: "The Allergy Academy supports the Baby Friendly status of the hospital and has decided that it will no longer host events within trust facilities where any infant formula manufacturer is present."

Sue Ashmore, director of Unicef's Baby Friendly initiative, says that the organisation lacks the budget to police violations but will investigate St Thomas' and the Allergy Academy.

Guideline author Fox is a director of the Allergy Academy as well as a consultant allergist at St Thomas' and the president of BSACI. He has declared research funding, consultancy, and lecture fees from Abbott Nutrition, Danone, Mead Johnson, and Nestlé.[32]

He says, "There is an important debate to be had on how best to manage the risk of influence. Specialists must work with industry in a transparent, open, and ethical way. While industry provides financial support, it does not set the agenda. Leadership in this area is provided by the RCPCH."

The RCPCH accepts funding from Danone and Nestlé, two of the largest formula manufacturers, but according to its website it will only accept advertising or conference stands providing information about specialist formulas, not breastmilk substitutes.

Defining formula

This distinction is one that St Thomas', Fox, and the RCPCH have all made in correspondence, saying that their sponsorship relates only to specialist formulas.

Yet Rollins confirms that specialist formulas are unequivocally breastmilk substitutes in the eyes of WHO and are thus covered by the code.

The belief that specialist formulas are exempt from the code may be enabling manufacturers to justify this network of links with clinicians and institutions to pursue a wider agenda. Larry Grummer Strawn, a technical officer at WHO, is concerned that these links affect breastfeeding rates. "The influence that the formula industry has on young health professionals is likely an important reason for the lukewarm support for breastfeeding that we often encounter," he says.

Fox says, "Across the board, specialists very much support breastfeeding as the optimal form of infant nutrition, which is reflected in the MAP and BSACI guidelines."

Overdiagnosis and maternal exclusion diets

Clinicians and patients who spoke to *The BMJ* are concerned at the wide availability of industry funded online information promoting non-specific symptoms potentially indicating cow's milk allergy as a diagnosis in exclusively breastfed infants. Although there is evidence that cow's milk and other food proteins can be transferred from mother to infant in breastmilk, the quantities transferred are likely to be too small to cause symptoms in most infants.[33]

Gary Marlowe, City and Hackney Clinical Commissioning Group vice chair and principal general practitioner at de Beauvoir Practice, is concerned that the symptom list in the iMAP guideline (box 2) is so broad it may lead to a concern about allergy in healthy babies: "Virtually every single infant could potentially be diagnosed using these symptoms." Boyle agrees, "It would be hard to find an infant who doesn't have any of these symptoms."

Box 2: Diagnosis of mild to moderate non-IgE mediated CMPA[9]

Usually several of these symptoms will be present.

Treatment resistance—eg, to atopic dermatitis or reflux, increases likelihood of allergy.

Gastrointestinal

- Irritability—"colic"
- Vomiting —"reflux"— gastro-oesophageal reflux disease
- Food refusal or aversion
- Loose or more frequent stools
- Constipation–especially soft stools, with excessive straining
- Abdominal discomfort, painful flatus
- Blood or mucus in stools in an otherwise well infant

Skin

- Itching, flushing
- Non-specific rashes
- Moderate persistent atopic dermatitis

The iMAP guideline is not specific about symptom severity, number, or duration, although text on the website states that the diagnosis should be considered only where "symptoms are multiple, significant, persistent as well as resistant to medical treatment."[9]

A diagnosis can be made only by excluding cow's milk protein from the maternal diet, observing symptoms, and then reintroducing, although clinical trial evidence for advising maternal dietary exclusions to treat non-specific symptoms in breastfed infants is weak.[33]

Marlowe says that most of the women he sees who are worried about cow's milk allergy are exclusively breastfeeding. "They have searched for symptoms online, and the top hits are industry funded sites relating to CMPA. Most have already excluded dairy from their diet."

Ruby Abiss, a journalist, became concerned about CMPA in her exclusively breastfed daughter after an online search. "The first websites I found, which I didn't realise were linked to industry, seemed to describe my child: up in the night, colicky, and windy," she remembers. "You assume that these behaviours indicate a problem and everything online gives CMPA as the answer. In online breastfeeding groups it is the first thing to be suggested for symptoms of any kind. People think it's really common."

Breastfeeding fears

Amy Brown, professor of child public health at Swansea University, is concerned that dietary restriction diminishes the capacity of mothers to breastfeed. "Although some mothers will be able to restrict their diet, it is a considerable undertaking. For mothers who are struggling this is one hurdle that may lead them to make the decision to stop breastfeeding," she says.

Abiss agrees, "Excluding dairy when you're breastfeeding makes it hard to keep up calories, and that's when mothers start to falter. You're starving and exhausted and formula seems like a simpler solution. I just about managed, but I know lots of people who didn't."

Brown adds, "One of the most common reasons for stopping breastfeeding is a concern about breastmilk sufficiency or content. The promotion of cow's milk allergy to the public by industry plays to this anxiety."

Natalie Shenker, who runs Hearts Milk Bank, is concerned about maternal mental health. She receives several calls a week from women who wish to donate milk having self diagnosed their babies as having CMPA and moved to formula feeding. "Not being able to breastfeed when a mother wishes to is one of the highest risk factors for postnatal depression."

However, says Boyle, "Severe CMPA is far less common in exclusively breastfed infants, and the worst effects could be avoided by changing our national culture around breastfeeding. If breastfeeding is continued as WHO recommends, the burden of disease will be reduced."

Chi Eziefula, senior lecturer in the department of global health at Brighton and Sussex Medical School, worries that industry influence affects women most when they are working to establish breastfeeding. "Current CMPA guidelines include formula recommendations for top-up feeds for exclusively breastfed infants, which is concerning," she says.

"By definition, exclusive breastfeeding does not include the use of formula for top-up feeds. Such wording creates a guideline approved niche for the formula product that could interrupt breastfeeding."

Call for independence

Eziefula adds, "In a culture where breastfeeding rates fall off sharply after birth, there must be no risk of industry influence on guidelines or education of postnatal and paediatric caregivers. Instead, we need more infrastructure to support continued breastfeeding."

Helen Crawley, a public health nutritionist from First Steps Nutrition Trust, an independent nutrition charity, is concerned about industry funding of healthcare professionals who provide patient information. "Many paediatric dietitians also work with, or accept hospitality, [and] funding for training and events from manufacturers," she points out. The British Dietetic Association has Abbott, Mead Johnson, and Danone Nutricia as strategic partners and Vitaflo (Nestlé) and Friesland Campina (a global formula producer) as key supporters.

When asked about links between healthcare professionals and the formula industry, Fox says, "A range of specialist disciplines—led by the British Dietetic Association with input from the British Society of Paediatric Gastroenterology, Hepatology and Nutrition and BSACI—are developing a code of conduct on how [healthcare professionals] should work with manufacturers of infant formulas which goes beyond the regulatory requirements."

All of these organisations accept funding from the formula industry.

Anthony Costello, former director of WHO Maternal, Child, and Adolescent Health and now a professor of child health at University College London, calls for RCPCH to be independent.

"When the profession has conflicts of interest, whether personal or institutional, they create a form of 'political violence' within institutions which appear independent, even nurturing. In the UK we have one of the lowest breastfeeding rates in the world," he says. "The WHO code is not enforced strongly in British law so we need the royal college to stop accepting money from industry and defend the global codes set up to try to protect mothers.

"Without independent leadership by professional bodies, such as the RCPCH, it is hard to see the situation improving. If paediatricians betray the spirit of the code then we can't expect more from industry."

RCPCH president, Russell Viner, declined to be interviewed by *The BMJ*. In a statement the college says it consulted with members about formula milk company sponsorship in 2016: "The vast majority of respondents said they felt the RCPCH should accept funding with a robust set of safeguards in place. We are following the wishes of our members."

Some hospitals are trying to embrace the WHO code more fully. Sheffield Children's Hospital and Imperial College NHS Trust have started discussions to see if clinical services will be able to adopt the code to minimise the influence of the formula industry, particularly the sponsorship of educational events.

Bob Klaber, associate medical director and consultant paediatrician from Imperial College, says, "We are concerned about the nationwide influence that the formula industry has over mothers and children at the most vulnerable time in their lives. We are fully committed to embracing both the letter and the spirit of the WHO code. As well as working towards fully Baby Friendly accreditation, we will be adapting our process for declaration of interest and are particularly focused on providing independent education on infant feeding for all relevant healthcare professionals and students."

Box 3: Industry response

Declan O'Brien, director general of the British Specialist Nutrition Association, which represents manufacturers including Danone Nutricia, Mead Johnson, and Nestlé, says:

"We do not believe that the WHO code precludes all interaction between healthcare professionals and industry. Instead, the code seeks to limit and define this interaction so as to manage potential conflicts of interest...

"The BSNA strongly believes that industry has a role to play both in scientific research and the education of healthcare professionals. We also recognise the need to put in place policies to ensure that potential conflicts of interest can be managed and avoided. The measures in the Infant Formula [Nutrition] Industry (INI) code are in line with the WHO code, UK regulations, the ABPI code and GMC guidance."

Parent perspectives

"I felt guilty, like I had been giving my child poison"

At three months old my son started getting eczema, particularly on his face. Our GP said he would grow out of it and prescribed steroid creams and moisturiser. During a visit to the emergency department about a separate problem, a paediatrician diagnosed cow's milk allergy. They were very quick to make the diagnosis without any questioning about diet or my son's environment.

I felt guilty, like I had been giving my child poison. They prescribed my son a specialist formula to replace his normal one. It smelt appalling and he hated it so for several weeks it was very hard to feed him, so much so that we stopped going to play groups and doing normal activities—feeding became a full time project. He's small anyway so I was worried about his nutrition and he lost weight; at 6 months old he was still in 0-6 months clothing.

After a few weeks he started to tolerate the specialist formula and we persisted for several months, but his eczema remained unchanged. So I switched him back to normal formula just before a holiday in Spain. His eczema markedly improved while we were away even on the regular formula, perhaps due to sunlight or soft water.

When we returned it worsened again. We saw a dermatologist privately who once again diagnosed cow's milk allergy despite my insistence that [my son] had improved on cow's milk and the previous hydrolysed formula made no difference. [The dermatologist] prescribed an even more hydrolysed formula but it had no effect.

We eventually saw a consultant allergist, who said that [my son] didn't have an allergy to cow's milk. Instead skin tests showed allergies to eggs, strawberries, and dog saliva. No one had ever asked about any of these things. We reintroduced normal formula and his eczema has gradually improved as we excluded the allergens from his diet.

We were put through hell, a nightmare, for what I see now as no reason. I had this diagnosis forced on me twice despite my evidence that his eczema had nothing to do with normal formula. I feel angry about how many other children these doctors may have incorrectly diagnosed: in my baby group about half of us were told we had cow's milk allergy.

Mother in south London

"I felt like a failure, that I had this precious commodity I couldn't give my child."

I found it easy to establish breastfeeding with my son. But from just [a] few weeks old he had sleep problems and constant crying. He would often vomit and arch his back after food.

We went to see several private doctors at one of London's leading private hospitals, one of whom I have since found has extensive links to one of the largest formula companies. I was told that that something I was eating was getting into my breastmilk and causing an allergy in my child. One doctor said my milk was "poison." I was surprised because he was gaining weight [and] meeting milestones.

At 3 months, after excluding wheat and dairy from my diet didn't work, I was advised to switch from breastmilk to a hypoallergenic formula which was really hard to introduce. [My son] was disgusted by the formula and I remember him reaching for the breast while I tried to turn his head toward the bottle.

I alternated formula and breastfeeding, feeling like I was cheating on either my doctors or my child. Neither seemed to help, but at six months I shut down breastfeeding completely. I found that very, very hard. I know now I had postnatal depression. I felt like a failure, that I had this precious commodity that I was told I couldn't give my child.

Stopping breastfeeding made no difference at all. At age 2 he was diagnosed with ear infections related to reflux and gradually grew out of his symptoms. Looking back is painful but I know I was vulnerable. Common sense just went out the window.

Mother in north London

Competing interests: I have read and understood BMJ policy on declaration of interests and have no relevant interests to declare. BMJ accepts advertisements for specialist breast milk substitutes provided that they are legal and honest and

meet advertising standards. We expect all claims of health benefit to be supported by published peer reviewed research evidence. BMJ co-owns *Archives of Disease in Childhood* with the Royal College of Paediatrics and Child Health.

Provenance and peer review: Commissioned; externally peer reviewed.

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