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Controversy over the Regulations of Infant Milk Formula Marketing from 1970s to 2000s: A Theoretical Analysis on the Use of Evidence in Health Policymaking

Marselia Tan[1]

[1]London School of Economics and Political Sciences, Department of Health Policy, London, UK, marseliatan@gmail.com

Introduction

Driven by the assumption that objective and scientifically sound evidence instead of values should inform policy decision-making, many politicians, academics, and professional bodies have supported the use of evidence-based policymaking in various public policy fields, including healthcare (1-3). However, an emerging view among scholars claims that the creation, selection, and interpretation of evidence related to public policies are inherently subjective and reflect the political interests of various stakeholders (2). Aligned with this view, this commentary focuses on how evidence has been used by different actors in the health system to influence the health policymaking process related to the marketing of infant milk formula (IMF). While the IMF industry's controversy has been studied before, the existing literature has focused on business ethics and corporate social responsibility implications of the policy-influencing activities of industry actors (4-6). Hence, past research had utilised analytical frameworks most relevant to the critical discourse on the IMF industry's corporate actors. While actors with substantial financial stakes in the industry –most notably the market leader Nestlé– have indeed defended their interests by strategically creating, selecting, and interpreting evidence, activists and other interest groups have also strategically utilised evidence to challenge the legitimacy of IMF companies and to promote stricter regulations on IMF marketing in the developing world (7,8).

By tracing controversial IMF cases that occurred worldwide from the 1970s to the 2000s (4,9,10) and using Kingdon's multiple streams model of policy change (11), this commentary argues that the strategic and agenda-driven use of evidence at crucial moments in the policymaking process has allowed both groups of actors to attain some success in influencing policy changes throughout the years. As this approach calls for analysing the IMF controversy in a chronological manner, Kingdon's multiple streams model is deemed the most appropriate framework as it "emphasises the time dimension in evidence use and recognises that evidence may influence policy at key moments or alternatively only after long periods of time." (2: p.26) The commentary concludes that the body of evidence involved in health policymaking on IMF products has grown and is likely to continue expanding, shaped by the intense contestations over values and ideologies between two diametrically opposed groups. The approach used in this commentary may be applied to analyse the strategic and political use of evidence in other ongoing health policy controversies.

A short description of Kindgon's multiple streams model

Kingdon argues that for a key change in policymaking to take place, three separate "streams" -problem stream, policy stream, and politics stream- must converge to enable a "window of opportunity" for influential policy change to open (11). In the *problem stream*, a particular policy issue receives the attention of policymakers, often due to how it is framed by interested stakeholders or due to an emerging focusing event or crisis around the problem, instead of solely due to any objective indicators. Certain groups of stakeholders may come into favour by capitalising on the crucial moment when a problem captures attention. The *policy stream* emerges with different policy entrepreneurs proposing viable policy solutions, developed in anticipation of certain problems receiving major attention. Lastly, in *politics stream,* policymakers are compelled by the national or international feedback on the particular problem's magnitude and the existence of policy proposals to address it, to select the policy solutions and enact the change (11).

The 1970s

Infant milk formula was developed in the 19th century as a substitute for breastfeeding (4), but only gained a wider market during the period after World War II. Journalists noticed that the widespread marketing campaigns by IMF companies had framed the product as a desired "status symbol" especially among lower-income women, misled consumers to perceive it as a "modern" replacement to natural breast milk, and created a false impression of doctors' endorsement (12,13). These campaigns were argued to contribute to the declining breastfeeding rate in both developed and less developed countries from the 1940s to the 1970s (9,14-16). In response to the allegations, IMF companies and their supporters explained that IMF's popularity was merely due to the increasing trend of women in Western countries entering the workforce without any mechanism in workplace to support them for exclusive breastfeeding (4,9,13,17). Thus, IMF products became an attractive and convenient infant feeding choice. This showcases how a strategic *interpretation of evidence* was utilised to shift the responsibility of in IMF product preference solely on a broader socioeconomic trend, instead of as a direct result of the companies' marketing activities.

In early 1970s, the dissidents of IMF marketing practices expressed their concerns more vocally. The Director of Carribean Food and Nutrition Institute at the time, Dr Jelliffe, was the first to claim in a public forum (12,18) that IMF companies' aggressive marketing tactics, such as offering free samples to mothers, over-incentivising doctors, and employing sales representatives dressed like nurses in maternity wards (7,12) were directly associated with the soaring rates of mortality and morbidity among infants in third-world countries (4,18). Other scientists subsequently presented studies indicating a link between IMF companies' aggressive marketing of IMF and infants' health problems in developing countries, where women lacked access to proper sanitary conditions, literacy, and financial means required to properly follow instructions about bottle-feeding their infants (6,12). Many third-world mothers used contaminated water to prepare IMF products or overly diluted the formula to make the expensive product last longer. These practices led to infants' malnutrition, diarrhoea, gastroenteritis, and deaths (19,20). Nestlé's countered these accusations by presenting a contrasting evidence implying a link between IMF consumption and the decrease in infant mortality rates, as observed in some countries from 1940 to 1970 (13). This claim provoked nutritionists and scientists to accuse Nestlé of a *technical bias in the interpretation of* the statistical evidence –the declining infant mortality in some countries at that period was more likely to be caused by a combination of systematic factors like the improved health care system, vaccination, and better standards of living rather than due to increased IMF consumption (21,22).

The movement against IMF companies at this juncture can be explained as a manifestation of an *advocacy coalition framework* (3), where individuals form coalitions to turn their beliefs into policies and to oppose the beliefs and policies of competing coalitions. Indeed, in calling for the establishment of an international health policy for IMF marketing, various actors such as religious groups (Interfaith Center on Corporate Responsibility (23), the U.S. Methodist Church (24)); activist groups (Infant Feeding Action Coalition (25)); International Baby Food Action Network (26)); paediatrics; nutritionists; and scientists coordinated to vigorously utilise and expand the body of evidence supporting their cause, guided by the same underlying *'policy core' belief* that "breast is best" (7,8). The controversy reached its tipping point and gained worldwide attention after the 1974 ground-breaking publication of "The Baby Killer" (27), an exposé of damages caused by IMF companies in the developing world. This sensationalist publication marks the coalition's exercise of power by framing evidence to discredit IMF companies, to the extent of "demonising" them (3). In response to the scathing pamphlet, Nestlé, the primary focus of the public's negative sentiment, sued the authors for libel and won (7,12). Capitalising on the public momentum from this lawsuit, the Infant Formula Action Coalition (INFACT) in 1977 launched a successful international boycott on Nestlé's products (4,12). To this day, the INFACT boycott continues to galvanise other boycotts by other NGOs and activists worldwide (28).

Pressured to react to these forces, IMF industry leaders employed various uses of evidence to maintain their legitimacy, such as creating the International Council of Infant Food Industries (ICIFI) in 1975, an industry association consisting of Wyeth, Ross-Abbott, Danone, Cow & Gate, four Japanese IMF companies, and Nestlé (12). The purported objective of this association was to be recognised as a self-regulatory body and to sponsor research studies in various areas, including topics such as infant feeding patterns and the extent to which breast milk alone can suffice an infant's needs (12,29,30). Such research topics can be construed as an attempt to orient the process of *creating new evidence* to favour the industry. The IMF industry also criticised its opponents for promoting the misconception on breastfeeding substitutes (12,17) and for campaigning to make IMF available only on medical prescription (29). The industry accused its opponents of *issue bias in their selection of evidence* (2) by neglecting some important social concerns, such as the benefits of IMF for women unable to naturally breastfeed and in preventing the use of less suitable alternatives like sweetened condensed milk or gruel for infants whose mothers were unable to breastfeed (17,29).

The 1980s to 1990s

The struggles between IMF industry and opposition groups culminated in 1981 with the establishment of the WHO International Code of Marketing Breast Milk Substitutes (the Code), a nonbinding code that restricts the promotional activities of IMF products (31). The events leading up to the creation of this Code can be analysed using multiple streams analysis (3,11). Kingdon captures the importance of time dimension in evidence use and posits that when *problem stream*, *policy stream,* and *politics stream* converge at the optimal time, a *window of opportunity* opens to enable a policy change (11). In the IMF controversy, a *problem stream* emerged as the evidence compiled in "The Baby Killer" and the worldwide attention it received made the issue of IMF marketing practices salient in agendas of policymakers such as the WHO and national governments. By the time the controversy reached its boiling point of Nestlé's lawsuit and the INFACT boycott, a *policy stream* had emerged, with a number of doctors, advocates of breastfeeding, and NGOs revealing proposals for restricting IMF companies' marketing practices especially among the vulnerable populations. Popular support for these proposals consequently enabled a *politics stream*, allowing policymakers to act in a

politically correct course. These three streams ultimately opened up a window of opportunity for the development of the WHO Code.

The Code was a result of 118 WHO member countries' positive votes and one negative vote from the United States, which was under the Reagan administration at the time (5) –an administration widely regarded to be protective of private sector's agendas (32,33). Echoing ICIFI's reasoning to oppose the Code, the U.S. rejected the WHO Code for its rigidity and incompatibility with the American values of "free speech and freedom of information" (9,34). However, this statement had neglected important research findings on the perils of the absence of IMF marketing standards in the U.S., such as recorded IMF misuse in low-income American cities (9). Disregarding this body of evidence reflects the U.S. government's *cognitive dissonance aversion* (2), as the idea of negative impact caused by private sector was incongruent to the pro-market ideology that thrived during the Reagan era (33). The negative vote also suggests a government's *issue bias in selection of evidence,* ignoring parts of a larger body of evidence about the social harms of unregulated marketing of IMF products.

In 1982, to end the prolonged boycott and to claim a commitment to Code compliance, Nestlé established the Nestlé Infant Formula Commission and the Nestlé Coordination Center for Nutrition to research on the level of compliance of its marketing activities to the WHO Code, as well as to expand the knowledge on artificial feeding for infants (12,19,35,36). Unsurprisingly, the commissioned research produced only favourable results for Nestlé (36), exemplifying how an influential industry player deliberately engaged in a *confirmatory bias* (2) by commissioning strategically designed research that produce evidence confirming the firm's existing hypothesis of its compliance to the Code. In contrast to the evidence produced by these research centres, in a manner befitting the *advocacy coalition framework*, WHO, UNICEF, and various influential NGOs like IBFAN, INFACT, and Baby Milk Action (BMA) found consistent evidence of the industry's continuous violations to the WHO Code as well as to various developing countries' national laws (4,37-39).

Throughout the years of global boycott implicating even Nestlé's non-IMF products, the public perception of Nestlé and the IMF industry has deteriorated (6). However, since 1985 onward, the industry found a new turning point. A growing number of studies showed that HIV/AIDS can be transmitted from mother to baby via breastfeeding (4,8,40). Rapidly reacting to this advantageous turn of events, IMF companies launched extensive campaigns publicising evidence on dangers of breastfeeding and benefits of IMF in preventing mother-to-baby HIV infections (8,41). In a strange twist, the IMF industry could then claim the moral high ground, accusing WHO and UNICEF of slow response to the crisis and of risking the lives of at-risk infants by limiting IMF access and availability to mothers (40,42). Nevertheless, the industry also showed an *issue bias in its selection of evidence*, by disregarding the existing concern that mothers in poor living conditions are not equipped to utilise IMF in the first place. On the other hand, the revelation HIV transmission risks from breastfeeding left anti-IMF groups baffled, confronted with the uncomfortable fact that once-decried IMF products could now be an effective tool for saving third-world children from AIDS (8). This hard-to-swallow evidence of the IMF's potential benefit destabilised the coalition's *policy core belief* (3) that "breast is best".

The 2000s

In the early 2000s, the mother-to-child HIV transmission issue reignited the waning debate of "breast versus bottle", enabling a *problem stream* that made IMF marketing regulations once again an attention-grabbing issue in the policymakers' agenda. IMF industry's continuous

effort to present various pieces of evidence and its emphasis on the moral imperative in making IMF available to HIV-infected mothers had even gained support from some of its past detractors, such as UNAIDS officials and doctors in developing countries (43). From the perspective of the multiple streams model, this acceptance from former "enemies" was crucial to enable a *politics stream* for a change in the WHO Code, as amendments could now be a politically correct response to the HIV crisis and might also appease breastfeeding advocates. Alongside Nestlé, Wyeth emerged as an enthusiastic *policy entrepreneur* (44), capitalising the developing body of evidence to propose a solution: donating free IMF products to HIV-infected mothers in Africa (42,43), explicitly violating part of the WHO Code prohibiting the distribution of free IMF samples (31). Ultimately, the convergence of the three streams resulted in a *window of opportunity* for a policy change favouring the IMF industry. After years of resistance, UNICEF relented to starting a pilot project to provide IMF to HIV-infected mothers in Africa (45). It commissioned a non-controversial French dairy cooperative to provide free, plain-packaged IMF products for HIV-positive mothers (40,45,46). Although the biggest companies were excluded as potential suppliers for UNICEF's programme, the pilot programme conferred back some legitimacy on the IMF products and brought hope to the wider IMF industry on possible future amendments to the Code.

In light of this seeming willingness of WHO and UNICEF to begin a cooperative relationship with the IMF industry, a strong advocacy coalition was re-established among the industry critics, consistently rejecting IMF companies' offers for donations and heavily relying on other evidence from emerging studies on breastfeeding's safety in HIV context (37,46-48) – particularly a pioneering study from South Africa that shows a reduction in risk of mother-to-infant HIV transmission when breastfeeding is combined with antiretroviral treatment (49). Other strategies employed by the activist groups since 2004 involve the *creation of evidence* through cataloguing IMF companies' Code violations. BMA and Interagency Group on Breastfeeding Monitoring, INFACT, and IBFAN continually monitor and report IMF companies' violations to the Code (4). In 2004, IBFAN released a report "Breaking the Rules, Stretching the Rules" (50), a documentation of purported evidence on how IMF companies idealised their products and downplayed the negative health impact of bottle-feeding. The document was put forward as evidence to the United Kingdom's House of Commons to demand the cessation of IMF marketing malpractice (42). To this day, opposition groups continue to develop the evidence base contesting the legitimacy of IMF companies by extensively cataloguing the industry's violations of the Code (4). One way Nestlé had reacted to this was by emphasising its "listed" status on the FTSE4Good Index (51) –an independent stock market instrument relied on by investors to measure corporate social responsibility performance of various companies–, framing it as impartial evidence of compliance to the Code and of its ethical operation (52). Nevertheless, critics scorned that Nestlé relied on its listing on the Index as evidence of its socially responsible activities, since the company had simultaneously pushed for the removal of Code compliance as a requirement for other companies to be included on the Index's listing (42,53).

Beyond the 2000s, the financial stake in the IMF industry continues to rise, as the global sales of IMF grow three times as quickly as the global economy (54). Given this economic incentive, it is unsurprising that IMF companies and its supporters continue to contend every World Health Assembly's resolution or amendment proposal to the WHO Code through various means. For instance, engaging in evidence creation, Nestlé sponsored a large-scale study on Chinese toddlers and found that they were lacking certain micronutrients in their diet. The company recommended that this deficiency could be supplemented with IMF products (55). Nestlé also framed the study's results as grounds to refuse further regulation on advertising on toddlers, arguing that further restriction on IMF advertisement may then increase the consumption of other less healthy, less restricted dietary alternatives such as Coca Cola (56).

Meanwhile, opposition groups have continued to present evidence on the industry's violations to the Code through new marketing channels. Save the Children cited several studies implying the IMF industry's exploit of the rise of social media for intensive behavioural targeting, for example by engaging social media influencers to promote IMF brands with a veneer of impartiality and non-sponsored endorsement (54).

Conclusion

In the long battle of "breast versus bottle", activists, scientists, physicians, and religious groups have fought in an "advocacy coalition" model to utilise evidence that advance their cause. Driven by a strong policy core belief that breastfeeding yields the best health outcomes for infants, the advocacy coalition insists that the IMF industry's values and intentions are inherently incompatible to public interests. Thus, it has continuously discredited the industry's legitimacy through persistent monitoring of its violations to the Code. While previous literature has critically examined mainly the IMF industry, by applying Kingdon's multiple streams analysis on some crucial moments in the history of IMF controversy, this commentary demonstrates that both the IMF industry and its opposing groups are capable of using evidence within ideal timeframes to allow three streams of problem, policy, and politics to converge into windows of opportunity for policy changes that suit their ideological, economic, or other interests.

As the debate on the IMF issue goes on, the body of evidence on breastfeeding and IMF continues to expand and evolve, reflecting the two polarised groups' interests, beliefs, and values. Future health policy analyses within the IMF topic may focus on the development of the controversy from 2010s onward, dissecting the roles of internet and social media as new devices of evidence creation, selection, and dissemination. As this commentary demonstrates, Kingdon's multiple streams model is suited for conducting a historical analysis on how intensely opposed groups of actors strategically influence the "evidence-based" policy making process. The model can be applied to understand actors' actions on other controversial, ideology-driven health policy cases that span across a substantial period of time, such as on the use of medical marijuana or mandatory childhood vaccinations.

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