Editorial

Balance and Threats of Mandatory Micronutrient Fortification of Foods in India

The idea of mandatory fortification of foods with micronutrients is not new. However, it is troubling when the fortifying nutrient is already present in variable quantities in the food chain, when the same nutrient is also offered through additional supplementary programmes and other fortified foods, when not all sections (such as men) need the extra intake, and when there are clear risks. An example is the recent policy of mandatory iron fortification of rice for public health programmes in India.

The motivation for this policy comes from at least four strands of thought. First, that there is a wide, unbridgeable gap between the requirement and daily intake of specific micronutrients. Second, that clinical problems, such as the apparent persistence of anaemia, demand a 'fix', which only fortification can provide. Third, that food fortification is technologically simple and does not require behaviour change. Fourth, that fortification is safe, as 'tiny' amounts of extra nutrient are given daily, which could not pose any harm.

With evidence that was available in the first and second decades of this century, these strands of thought coalesced with the setting of regulatory standards for food fortification by the Food Safety and Standards Authority of India (FSSAI).[1] However, in the current decade (the 20s), new evidence on nutrient requirements, risks of excess, and operational problems of rice fortification have become available. This has begged the following questions: 'Did we jump the gun?' and 'Is a regulatory mechanism in place to stop mandatory fortification after operationalization?' We discuss the new evidence below.

First, is there an unbridgeable gap in the iron intake? At the turn of this century, the Indian Council of Medical Research (ICMR) mandated requirement of iron was 30 mg/day for men and non-pregnant women of reproductive age (WRA). Since the Indian diet has a low iron density of about 8–9 mg iron/1000 kcal, there was just no way this requirement could be met by diet alone. In 2010,[2] the situation eased when the iron requirement was set at 21 mg/day for WRA, but even this would not be met with the normal diet intake of 1600–1800 kcal/day. However, in 2020,[3] the iron requirement was again revised downward considerably. For WRA, this was now 15 mg/day and could be met by the daily diet alone. The dietary gap was not overwhelming or unbridgeable with normal diverse diets.

Second, clinical conditions such as anaemia have been the fire-alarm that necessitate urgent need for action: in this case, fortification. However, the estimation of anaemia in national surveys[4] by capillary blood is error-prone. A rigorous Indian study of simultaneous capillary and venous blood draws in WRA showed that capillary blood had lower haemoglobin (Hb) concentration by 1 g/dl.[5] This lowered the anaemia prevalence by half in that study. Another issue is the diagnostic Hb cut-off for anaemia. This needs revisiting, since a rigorous re-examination of this cut-off in Indian children showed that it was 1–2 g lower[6] and if applied, it would also lower the prevalence of anaemia significantly. Then, is iron fortification the 'fix' for anaemia? The short answer is 'no', particularly when all anaemia is not due to iron deficiency. In a recent national survey of 1–19-year-old children,[7] only 28%–54% of all anaemia was found to be specifically due to iron deficiency. That tells us that a lack of dietary iron is probably not likely to be the only, or the major, cause of the decadal persistence of anaemia. Then, iron fortification alone will not work for prevention of anaemia. This has been echoed in a Cochrane review of rice fortification,[8] which concluded 'Fortification of rice with iron…may make little or no difference in the risk of having anaemia…' There are even

more troubling recent data. In 2021, an accurate isotope-based evaluation of long-term iron supplementation in Gambian toddlers[9] unexpectedly showed that iron excretion/loss increased with iron absorption, such that the net body iron balance was not much enhanced by supplementation. This explains the lack of clear efficacy of fortification but is troubling, because body iron loss was thought to be invariant and low, except when blood loss occurred. If losses increased in toddlers, there must have been some epithelial exfoliation, along with microscopic blood loss, but this is speculative. More investigation is required.

Third, does food fortification require no behavioural/diet modification? The cereal portion of the Indian plate[10] has rich diversity with different varieties, where the 'rice' intake is one quarter (~60 g) of the total daily cereal intake. Yet, the rice fortification policy will perversely make the cereal portion of the Indian plate less diverse, as 300 g of rice intake required for the target (10 mg/day) iron intake.[1] It is more than the entire recommended cereal portion of the Indian plate. Whither diversity? Another technical problem is that the fortified rice grain (kernel) must be exactly matched to the rice it fortifies, in terms of shape, size, colour and density. If not, it will get 'picked out' during cleaning or washing; that behaviour will need change. There are also many varieties of rice in India: creating matching kernels for each will be extremely difficult, if not impossible.

Fourth, is fortification safe? This depends on the intake value at which the risk of adverse effects occurs. If this is close to the right-hand tail of the distribution of normal intakes, then, in a person whose iron intake is normal, a fortified intake could cross into the excess intake or unsafe zone.[11] This is even more likely when many are on other supplementary policies or pills for perceived benefits. For iron, there are risks of chronic metabolic disease such as diabetes associated with higher serum ferritin values. This has been observed in surveys by NHANES (National Health and Nutrition Examination Survey),[12] but also in a recent analysis of Indian children,[13] and is a price that will be paid in the long run. Mandatory fortification is a blunt tool that targets the nutrient-deficient and sufficient population alike. By that act, it becomes inappropriate if there are 'sufficient' people in the population, particularly when fortified intakes run the risk of crossing into excessive intakes, and this can be potentially forever, since there is no 'stop' indicator identified for fortification. That is the situation in India, and serious thought should be given to more precise ways to improve population nutrient intake. A recent study shows that dietary diversity can be improved in aspirational districts[14] and must be given a chance.

Finally, the ethics of mandatory public health actions come to mind. 'Mandatory' equates to coercion, which is doubtlessly required when there is greatest good for the population. Seatbelts while driving, vaccinations, even the pandemic lockdown come to mind. But with coercion comes loss of autonomy and agency for the individual as well as the population. Then, for mandatory rice fortification for the entire population, the benefits must be crystal clear for the entire population. If contextual evidence indicates that iron fortified food would be the best option for a particular population group as an interim short-term measure, then the utmost care should be exercised to ensure that the risk of excess iron intake, particularly through the layering of multiple iron interventions,[11] is minimal. Otherwise, for the entire population, holism and diversity are better bets.

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