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NUTRITION REVOLUTION BY REDUCING HEMOGLOBIN CUT-OFFS?

ANEMIA IS NOT A NUMBERS GAME

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Endorsed by: 260 signatories listed from Pages 3-8

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01 INTRODUCTION

In a recent article titled '*Anaemia, a weak case*' published in the *Economic Times* on the 13th of April 2023, two economists, Sanjeev Sanyal and Chirag Dudani (Sanyal & Dudani, 2023) express disbelief that in spite of India's economic prosperity, the prevalence of anemia in India has not shown a decline. Instead of looking at clinical outcomes, they question the biochemical cut-offs and standards used to define anemia, which, according to them, exaggerate numbers and show India in a poor light while also diverting resources that they feel could be better spent. Their whole argument relies on a single paper titled "*Haemoglobin thresholds to define anaemia in a national sample of healthy children and adolescents aged 1–19 years in India: a population-based study*" by Sachdev et al. (2021) (henceforth called '*The Paper*').

This note offers a critique of *The Paper* by Sachdev et al. (2021) which argues for change in haemoglobin thresholds for Indians.

A BRIEF DESCRIPTION OF THE ARGUMENTS MADE BY SACHDEV ET AL.

In *The Paper* published by Sachdev et al in the Lancet Global Health, they question current hemoglobin cut-offs in India. They claim that these cut-offs are based on World Health Organisation's (WHO) haemoglobin cut-offs which are drawn from five studies done more than 50 years ago on predominantly White adult populations.

Sachdev et al. (2021) suggest that these cut-offs be re-examined based on hemoglobin values of 'representative healthy populations' of children and adults. *The Paper* argues that such data is scarce in low and middle-income countries, and analyses data from the Comprehensive National Nutrition Survey (CNNS, 2019) to assess age and sex specific percentiles of hemoglobin levels and cut-offs to define anemia for the Indian population.

The methodology used in *The Paper* is to apply exclusion criteria to the pre-existing CNNS data to filter it down to a 'healthy population'.

02

Based on these arbitrary exclusion criteria (discussed below), the authors identify a primary analytical sample of 8,087 individuals from the larger CNNS sample of 49,486 individuals and conclude that the findings from this sample supports the re-examination of the WHO hemoglobin cut-offs to define anemia in India.

ERRONEOUS (AND DANGEROUS) ASSERTIONS ABOUT ANEMIA CUT-OFFS IN INDIA

Following objections and concerns raised by clinicians (specifically pediatricians and obstetricians), nutritionists, activists and public health professionals to the suggested changes in Hb cut-offs, the current note has been put together to highlight several issues of concern. Some of these are discussed in more detail later.

- In order to be applicable to a country, anemia cut-offs by definition, have to be arrived at based on hemoglobin levels of 'healthy' populations with no social, economic or nutritional constraints to hemoglobin synthesis. This means that the methodology should yield a study population that has access to all the macro and micro-nutrients necessary for hemoglobin synthesis. This population should be identified using clearly defined inclusion and exclusion criteria. A sub-sample from a survey such as CNNS cannot be used to set standards.
- Anemia has serious clinical consequences especially in pregnancy, and includes heavy bleeding during and after child-birth resulting in the death of the mother or child or both. 20-30% of all causes of maternal mortality can be traced to anemia. So, decisions about cut-off can only be made with an assessment of clinical impact and definitely not by looking only at datasets.

> ***Anaemia is a really difficult problem in India. In my own practice at our super-speciality hospital, I still see 30-40 percent of children with anaemia. All research papers, NFHS studies done so far has shown it increasing year by year in almost all places. It is mainly affecting growing children, adolescents, young women, mothers, pregnant women, and adult males too.***
>
> **-Dr. Selvan, Pediatrician and Researcher, Erode, Tamil Nadu**

03 ***The Comprehensive National Nutrition Survey (CNNS) on which The Paper by Sachdev et al. is based is not a healthy population and therefore unsuitable for devising cut-offs.***

We elaborate on these concerns in the remainder of the note.

IS THE CNNS SUITABLE FOR DEVISING CUT-OFFS?

To obtain a 'healthy' population, *The Paper* excluded participants with serum iron, folate, vitamin B12, and retinol deficiencies; inflammation; variant haemoglobins (haemoglobin A2 and haemoglobin S); and history of smoking. Sensitivity analyses after further excluding participants with high total cholesterol, high glycosylated haemoglobin, high serum creatinine, zinc deficiency, stool parasitic infestation, and hypoalbuminaemia yielded almost identical results. It is significant that they have relied completely on biochemical indicators rather than the nutritional (heights, weights, dietary intakes, serum proteins to name a few), socio-economic and other constraints to hemoglobin synthesis. The hemoglobin levels of this 'healthy' population were compared with WHO thresholds and were found to be lower throughout 1-19 years, usually by 1-2 gms.

Incidentally, the CNNS itself has warned on page 34 of their report that their survey was cross-sectional, provides information on the associations between indicators and outcomes and cannot be used to conduct analyses of causality. Household level information was only collected to provide background information on children and adolescents, and is not appropriate for calculation of household level estimates. Importantly, they state that their sample provides state level estimates and that there is not enough statistical power to make valid conclusions below the state level.

Further they say that disaggregated analysis by, for example socio-economic status of CNNS biochemical indicators cannot be done even at the state level and only valid at the national level due to limitations in sample size. They also say that there can be variation between states and at different seasons. For e.g. retinol levels can

04

vary depending on the seasonal availability of Vitamin A rich fruits such as mangoes. *The Paper* not only used a non-representative sample, it presumes that biochemical factors are the only criteria for exclusion.

BOX - DEMOGRAPHY OF CNNS

- The majority (~ 80%) of respondents were Hindus, followed by Muslims (16%), Christians (3%) and Sikhs (1%).
- Food consumption patterns improved with increased household wealth.
- ~75% of participants were from rural areas.
- More than half (~55%) consumed a vegetarian (without egg) diet and around 38% reported to consume a non-vegetarian diet.*
- Approximately 40% of respondents belonged to 'other backward classes' (OBC), 23% and 12% belonged to scheduled castes (SC) and scheduled tribes (ST), respectively. 25% were Other category.

**Non -vegetarian diet mean different things to different people in India. In most households, it is only a weekly delicacy where approximately 250-400 gms of flesh foods are bought to feed a family of 4-5. Detailed diet surveys provide actual food intakes in grams, while the frequency method used in the CNNS provides at best a qualitative picture.*

The Paper has ignored an important study by Khusun H et al. (1999) where volunteers in Indonesia were selected based on strict exclusion and inclusion criteria, using venepuncture rather than capillary blood and found to be comparable to the WHO cut-offs.

As can be seen in Box above, the CNNS survey population seems to be comprised of the very same population that the WHO identifies as disproportionately affected by iron-deficiency anaemia – 'the most vulnerable, poorest and least educated groups'.

05 It is surprising that the authors of this much-quoted paper have failed to recognise that such a far from healthy population is likely to have a lower mean hemoglobin compared to the WHO standard cut-off. Some of specific points to note from the CNNS report are

- Many nutritional outcomes are positively correlated with mother's education. As per the CNNS, around 42% mothers never attended school. Only around 13.5% of the mothers had completed 12 or more years of schooling, and only 4-10% children have received a minimum acceptable diet. The consumption of milk or curd, fruits, eggs, and fish or chicken or meat increased with higher levels of maternal schooling and household wealth.
- Across the wealth quintiles and mothers education, only 3-9% children received a minimum acceptable diet or iron rich foods. Consumption of iron rich foods was substantially higher among Christian children (30%), followed by Muslim children (16%). Sachdev et al. make no mention of how, if at all, they have factored this variable into their effort to select a 'healthy' population to devise cut-offs for the country.
- As should have been obvious, the frequency method used in diet surveys does not give accurate measurements of protective foods. Using this method to conjure up a 'healthy' population is alarming and could explain the lower hemoglobin levels in T*he Paper*.

The authors of *The Paper* have used some biochemical parameters as exclusion criteria, but have not specified whether children who are stunted, underweight or with other nutritional deficiencies have been excluded. In the CNNS report, of under-5 children, 35% were stunted and 33% underweight. 24% of adolescents were thin for their age. Stunting and undernutrition have a multifactorial causation and protein deficiency is one of the important contributors. In such undernourished children, it stands to reason that good quality protein would be absent or inadequate even for hemoglobin synthesis.

06 DO LOWER CUT-OFFS IMPROVE OR WORSEN MANAGEMENT OF ANEMIA?

As early as 1968, a WHO Scientific Group (WHO, 1968), averred that "anemia is a late manifestation of nutritional deficiency, and even mild anemia is not the earliest sign of such a deficiency." This essentially means that people can as well have nutritional anemia even before it is picked up by tests. They also go on to state that "the object of therapy is to correct the underlying deficiency rather than its mere manifestation."

In the case of anemia, clinically it would be okay to over-diagnose anemia than miss out someone who actually does have anemia. The sensitivity of a screening test is its ability to pick up true positive and specificity is the ability of a test to pick up true negative. In the specific context of screening tests for anemia and from a programmatic or preventive point of view, one would be okay with false positives but would want fewer false negatives. Ironically, in rushing to provide optimistic figures of the decline in anemia, the authors run the real risk of missing out on those women who have mild or moderate anemia and thus delaying or denying them preventive and primary care. Nutritional anemia, which is what most Indian women suffer from, is interesting in that the spectrum of management always includes a good quality and quantity diet.

As the severity of anemia increases from mild to moderate to severe, the treatment additionally includes iron supplements, iron injections and blood transfusions.

If a woman presents to the healthcare system with mild to moderate anemia (9-11gm), ideally, a doctor would advice her to increase her intake of iron rich foods (organ meat, red meat, dark green leafy vegetables, other meats), deworming and prophylactic iron tablets. With the lower cut-offs suggested by Sachdev et al., an entire population of women will now get labelled as NORMAL.

If a woman in this category gets pregnant, her hemoglobin is expected to drop during the course of the pregnancy, pushing her into further anemia. Clinical intervention at this stage of pregnancy would be either too little or too late (or both). So effectively, by lowering cut-offs, the authors delay or deny preventive and primary care to women with mild or moderate anemia. The other advantage of treating early anemia with diet is that other nutritional deficiencies such as that of Vitamin A, zinc, protein etc. can be prevented/managed simultaneously. This advantage is also lost.

WHAT IS THE BASIS FOR URGENT REVISION OF CUT-OFFS WITHOUT INVOLVEMENT OF CLINICIANS?

The authors do not explain where the need for this urgent revision of hemoglobin cut-offs came from. One would assume that the only group with a genuine interest in revising cut-offs would be the clinicians (Shankar, 2023) or public health professionals. Have clinicians, comprising pediatricians, obstetricians, nutritionists and general practitioners articulated to the authors that the current cut-offs are adversely affecting their patient care and leading to poor quality care? Alternatively, have public health professionals argued that higher cut-offs are contributing to issues of public health concern? It seems that science is not the primary drivers behind *The Paper*. A possible reason for the urgency to reduce cut-offs could be to reduce, on paper, the prevalence of anemia from being a severe or moderate public health problem to a low or no public health problem (WHO, 2021).

If the WHO cut-offs are being criticised for being based on five studies done 50 years ago in a predominantly Caucasian population, is the data from a single cross-sectional survey of a primarily rural, vegetarian, and lower socio-economic population more nationalist and reliable? Does replacing one purportedly bad evidence base with another (even worse) one makes any research sense?

08 Anemia is important not just as statistical data, but because of its clinical consequences, as can be attested by clinicians and obstetricians working in remote rural and tribal health facilities; where there are limited blood banks; when women come in labour with bleeding and or heart failure; and when faced with the daunting task of shifting women to tertiary hospitals and blood banks that are kilometres away.

It is shocking that the CNNS survey specifically excludes pregnant adolescents, given that teenage pregnancies and anemia are a huge concern in this age group. It is even more shocking that Sachdev et al. (2021) still went ahead to declare that their "*...haemoglobin reference percentiles, derived from healthy participants in a large representative Indian survey, are suitable for national use in India*."

It seems that researchers such as Sachdev et al (2021) and economists such as Sanyal and Dudani (2023) seem to be in a tearing hurry to reduce hemoglobin cut-offs for anemia without regard to due diligence and basic research protocol. Economists in India getting alarmed about clinical and biochemical cut-offs is not a new phenomenon. In 2013, Panagriya (2013) was concerned that the stunting figures in India based on International growth standards were showing the country in poor light. His contentions and the very premise of his argument was effectively challenged (Gupta et al, 2013).

"I am shocked by the plans to reduce anemia cut-offs in the country. In my experience of 20 years of OBG practice in a rural area of Mysore, I have seen plenty of tragedies with Hb lower than 11 gms.

Our women are not able to tolerate even a little more than average blood loss during labour – they go into hemodynamic shock. We have seen a lot of this in our labour rooms. These catastrophes have almost disappeared ever since we started maintaining hemoglobin at 11 gms. I therefore strongly reject this proposal of lowering Hb cut-offs."

-Dr. Sr. Hilda Rita Lobo, Obstetrician, St. Mary's Community Health Centre Trust, HD Kote, Mysore, Karnataka

09

A recent study by Dasgupta et al. (2023) find that banning the sale or possession of beef is associated with relative increase in anemia among women in minority groups that traditionally consume beef. Bans reduce women's hemoglobin and increase the incidence of severe anemia by as much as 27% of the mean level in communities that traditionally eat beef. The spate of cattle slaughter bans across the country could as well be one of the reasons for the low mean hemoglobins in *The Paper*.

The authors of this note, as well as all the endorsing clinicians, public health professionals and health activists request the World Health Organisation (WHO), Indian Council of Medical Research (ICMR), National Institute of Nutrition (NIN), United Nations International Children's Emergency Fund (UNICEF), Indian Academy of Pediatricians (IAP), The Federation of Obstetric and Gynaecological Societies of India (FOGSI) to put out official statements on their position on this paper by Sachdev et al.

We would also like to unequivocally register our dismay that the Lancet Global Health has published this article which, on the one hand, fails to meet research standards and, on the other hand, can lead to devastating health consequences on some of the most vulnerable communities in India.

"When normal range for biological values are being decided, social, environmental and nutrition factors have to be considered. Lowering cut-offs may reduce the prevalence of anemia but will it reduce clinical complications due to anemia such as chronic infections , heart disease, abortions, premature/still births, decreased scholastic performance among students? These will definitely increase. If cut-offs are lowered will people be able to donate blood at even lower levels? This decision will have the worst impact on public health in India and exclude many people who are eligible for interventions.

With the new proposed hemoglobin cut off, will the categories of mild, moderate and severe anemia change? Will treatment aspects change?

Long term follow-up of clinical signs and symptoms of anemia have to be an essential component of any attempt to revise cut-offs."

-Prof .Dr. Sunil Kumar Dodderi , Epidemiologist and Public Health Specialist, Bangalore and President, Indian Association of Adolescent Health- Karnataka Chapter

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