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The distribution of environmental pressures from global dietary shift

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The distribution of environmental pressures from global dietary shift

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**Abstract**

The production and consumption of food is one of the main drivers of environmental change globally. Meanwhile, many populations remain malnourished due to insufficient or unhealthy diets. Increasingly, dietary shifts are proposed as a means to address both environmental and health concerns. We have a limited understanding of how dietary shifts could alter where food is produced and consumed and how these changes would affect the distribution of environmental pressures both globally and across different groups of people. Here we combine new food flow data linking producing to consuming country with environmental pressures to estimate how a global shift to each of four diets (Indian, EAT-Lancet, Mediterranean, and mean Food Based Dietary Guidelines (FBDGs)) could affect environmental pressures at the global, country income group, and country level. Globally, cumulative pressures decrease under the Indian, EAT-Lancet, and Mediterranean scenarios and increase under FBDGs. On average, low income countries increase their cumulative consumption and production pressures while high income countries decrease their consumption pressures, and typically decrease their production pressures. Increases in low income countries are likely due to the nutritional inadequacy of current diets and the corresponding increases in consumption quantities with a shift to our diet scenarios. Despite these increases, we believe that three out of four of our simulated dietary shifts can be seen as a net benefit by decreasing global pressures while low income countries increase pressures to adequately feed their populations. Additionally, considering principles of fairness applied, some nations are more responsible for causing historical environmental pressures and should shoulder more of the change. To facilitate more equitable shifts in global diets, resources, capacity, and knowledge sharing of sustainable agricultural practices are critical to minimize the increases in pressures that low income countries would incur to adequately feed their populations.

1. Introduction

The food system continues to be a dominant driver of environmental change, contributing nearly a third of global greenhouse gas (GHG) emissions, disturbing

or degrading substantial portions of arable land and fishable waters, using over 70% of freshwater resources, and adding the majority of nutrient pollution into streams, rivers, lakes and coastal waters [1–3]. The magnitude and spatial distribution of

these environmental pressures and their impacts are determined to a large extent by what people eat (their diets), and how and where this food is produced. Foods differ enormously in the environmental pressures that their production generates, both among food categories and across geographies for a single food category [4]. The pressures of food production are often remote from the location of consumption, given that about a quarter of food is traded internationally [5]. While there are considerable benefits to international food trade, including economic efficiencies, and increased supply and diversity of food supply [6, 7], it has also raised concerns about the outsourcing of environmental pressures to lower income countries [8–10].

Diet is a major determinant of health. The consensus of public health agencies and researchers is that diets in many countries are becoming increasingly unhealthy for a majority of their citizens, with some unhealthy food categories overconsumed (e.g. sugars, starchy staple crops, red meat) while healthy foods are underconsumed (e.g. vegetables, seafood, legumes, nuts) [11, 12]. Moreover, food production and distribution systems supporting these diets are increasingly environmentally unsustainable and socially unjust with higher rates of nutritional deficiency found among lower income countries and individuals [13]. Diet related diseases are among the highest causes of morbidity and mortality worldwide [14]. These diseases disproportionately affect people living on lower incomes, who have become over-reliant on cheap energy-dense foods, with risks of micronutrient deficiency and overconsumption of calories [14, 15].

Diets, and dietary shifts, therefore have profound implications for the environment, for human health, and for issues of distributional equity. While many governmental diet recommendations (e.g. Food Based Dietary Guidelines, (FBDGs)) are focused on health outcomes [16, 17], the last 10 years have seen increased research assessing the environmental consequences of diets, and combining both health and environmental impacts [2, 11, 18, 19]. More recently, there have been calls for explicit consideration of the justice implications of these dietary shifts and broader food system transformations [13, 20].

However, these past analyses have been limited by the coarse resolution of environmental pressure data (e.g. global or regional averages), their focus on a limited set of environmental pressures (thereby obscuring trade-offs between pressures, or synergies in the benefits of responses), their focus on a single 'realm' of food production (i.e. not linking terrestrial and marine foods), non-standardized pressure data across food categories, and challenges associated with linking production location to consumption locations through international trade [4, 21, 22]. As a result, calls for large scale diet shifts tend to focus on the global environmental changes that would arise from consumption patterns without the ability to examine

how diet shifts will change the environmental pressures of countries producing said diets. They have also largely ignored how environmental pressures of current and idealized diets may be distributed among different countries and income groups as both consumers and producers [13].

Motivated by these knowledge gaps and newly available data that combine high-resolution information on the global pressures of food production [4] with trade flow data [21], we explore how universal shifts to widely-recommended reference diets will change the consumption pressures of countries and how these changes will ultimately alter the distribution of environmental pressures of food production across nations. The data used standardized methodologies of environmental pressures and tracks their trade across a variety of food items from the producer to the consumer. This allowed us to calculate country to country specific environmental pressures per gram of food for more accurate consumption pressure calculations and trace changes in consumption to estimate changes in production. We also use World Bank (WB) country income groups to explore the distributional implications of these changes. With this high-resolution data, we were able to examine which country income groups would decrease or increase their environmental pressures as both consumers and producers and explore why these patterns may be occurring.

Using average diets from each country and the trade flow of food production pressures data, we map each nation's current diet and where the environmental pressures for that diet are generated. We model a shift from each nation's average baseline diet to one of four recommended diets and estimate the changes in environmental pressures that would occur at national and global levels. To assess environmental changes, we use an established cumulative pressure value calculated from four pressure categories: GHG emissions, nutrient pollution, land/sea disturbance, and water use [4]. We use these pressures specifically because the methodologies have been standardized and spatialized for global production pressures in a single data source and because they are the dominant classes of pressure focused on by global food sustainability research [4, 19, 23]. To understand the distributional implications of the cumulative pressure changes we examine how they vary among countries in different WB income groups and with different nutritional deficiency profiles.

2. Methods

2.1. Current (baseline) diets

We used data on current diets from Our World in Data (OWID), which simplifies food supply data from the United Nations Food and Agriculture Organization (FAO), to estimate baseline diets. OWID data provide the average grams consumed per

person per day for each country of 13 food categories: cereals, roots and tubers, vegetables, fruits, dairy (in milk equivalents), red meat (including pork), chicken, eggs, fish, legumes, nuts, oils, and sugars. Fish supply data from OWID were reported in live weight rather than edible weights. We therefore converted these values to edible weights by multiplying live weight of fish supply values from FAO by a taxon-specific conversion factor and summing these values across all species ([24]; supplementary table 1). For countries that had environmental pressure data but no data on current diets from OWID, we calculated regional averages for food categories with regional definitions from WB Development Indicators to gap-fill the missing countries consumption. Each country with no diet data was assigned the regional grams per person per day calculated for each food category. In total 14% of countries that had missing diets but had pressure data were gapfilled (see supplementary table 2).

2.2. Environmental pressures of production and consumption

We used data from [21], building on [4], which quantifies the cumulative environmental pressures of food production and then tracks that production to the consuming country. These data measure within-farm-gate pressures and exclude the pressures from activities like processing, transportation, or manufacturing equipment. Specifically, we used data on GHG emissions (CO₂eq), freshwater use (m³), disturbance (km²eq), and nutrient emissions (tonnes excess of N and P). Importantly, these pressures account for the inputs, processes and outputs of food production and do not directly measure environmental impacts, which are highly dependent on local context [4, 21, 25]. For example, we estimate freshwater use from cereal production but do not explore how withdrawal of freshwater from the environment impacts specific species or ecosystems where the production occurs.

Food traded commodities and the associated pressures, from [21], were categorized into the 13 food categories from OWID. We confirmed that apparent consumption disaggregated by source country adds back up to apparent consumption reported in the FAO Food Balance Sheets, as presented in OWID (supplementary figure 1). All pressures associated with animal feed were included with the corresponding animal food category. For each food category in each country, we calculated the pressure per gram of food consumed from a given producer. We also calculated the proportion of each food category that was imported and locally produced by a consuming country. These calculations allowed us to generate unique pressure efficiencies for each country's food consumption based on where their food comes from. We capped these pressure efficiencies for each food category at the third standard deviation above or

below the global mean pressure efficiency for that category to minimize the effects of outlier pressure efficiencies that are potentially unrealistic. Only 2.2% of country and food category specific pressure efficiencies were changed from this process and results were largely insensitive to this cap (see supplementary table 3). In the instances where a country had consumption data and no associated trade of pressures were available for a country, we calculated a global average efficiency for each food category and used this to fill in the pressure value; this represented less than 0.01% of the data.

2.3. Diet scenarios

We examined four widely recommended diets in our scenarios: the EAT-Lancet diet [11], the Mediterranean diet [26], dietary recommendations issued by Indian government/health organizations [16, 17], and a global mean diet of FBDGs [17]. The EAT-Lancet grams per person per day values were developed by the EAT-Lancet Commission and was chosen as a scenario because it was developed for beneficial health outcomes [11]. The Mediterranean diet was chosen because it is a distinct and popular cultural diet that has been promoted, in North America and Europe, as healthy and the values for it, in grams per person per day, are from a literature review of Mediterranean diets [26]. The Indian recommended diet was chosen for being a distinct cultural diet with low meat consumption. Many diet assessments include vegan or vegetarian options in their assessment and the Indian diet was selected to represent these types of diets as it is a country that supports a large population with lower consumption rates and lower recommendations for meat consumption in its national dietary guidelines. Its consumption quantities were obtained from a FBDGs study and the published FAO FBDGs [16, 17] (supplementary table 4). FBDGs are country or region specific documents and endorsed by political or government entities; they provide recommendations and advice on healthy diets [17]. To generate the FBDGs recommended quantities we used data from [17], harmonizing the food categories with our other diets' categories and the data from OWID. Harmonizing involves making sure the same sub-categories make up a food category, for example ensuring beef and pork gram recommendations are included under red meat. Some country guidelines were reported as proportional increases or decreases; in these instances we used consumption quantities from OWID as a baseline and adjusted according to the guidelines. Some countries were missing food categories from their recommendations; we gapfilled these through literature review (supplementary table 4). These FBDGs were included to calculate mean grams per person per day quantities to apply to all countries for the diet scenario. A summary of each diet's recommended grams per person per day quantities are summarized in table 1.

Table 1. Summary of food category quantities recommended by each diet scenario in grams per person per day.

Food category	EAT-Lancet (gram per person/day)	Mediterranean (gram per person/day)	Indian (gram per person/day)	FBDGs (Mean) (gram per person/day)
Cereals	232	305	431	333
Eggs	13	23	21	31
Fish	28	50	21	34
Fruits	200	225	100	237
Legumes	75	35	45	59
Milk equivalents	250	215	300	497
Nuts	50	4	0	22
Oils	52	45	29	39
Poultry	29	84	0	32
Red meat	14	21	0	54
Roots/Tubers	50	125	200	164
Sugar	31	0	45	53
Vegetables	300	250	300	294

2.4. Baseline environmental pressures and pressures from diet shifts

To calculate the pressures generated by a country for its baseline diet and each diet scenario, we multiplied each country-food combination's unique pressure per gram by the scenario's grams per person per day consumed and the consuming country's population. This produced an estimate of the consumption pressures per day for each food category and country (see supplementary figures 2 and 3 for baseline diet patterns and production efficiencies). The resulting value for each food category was then multiplied by the proportion coming from each country so that dietary scenario changes in pressures could be traced back to the country of production. This assumes that each country would continue to import/export the same proportional quantity of a given food category in the baseline diet and alternate diet scenarios. This assumption is a simplification of global food economic markets, however it allows us to compare how consumption and production pressures change for each country.

Following methods outlined in [4], we calculated a cumulative pressure index for baseline diets to allow the direct comparison of pressures across food categories, countries, and diet scenarios. For each food category, we calculated the total daily pressure, for each of the four pressures, from the baseline diet for each food category at both the country and global scale. We then divided each country's total pressure (c) for each food category (f) by the global total pressure (equation (1)). This method weights each pressure's contribution equally and the total global cumulative pressure from current diets would be equal to 4,

$$\text{Cumulative}_{c,f} = \frac{\text{water}_{c,f}}{\sum \text{water}} + \frac{\text{GHG}_{c,f}}{\sum \text{GHG}} + \frac{\text{nutrient}_{c,f}}{\sum \text{nutrient}} + \frac{\text{disturbance}_{c,f}}{\sum \text{disturbance}}. \quad (1)$$

To calculate cumulative pressure values for each different country, food category, and diet scenario, we used the same method as the baseline diets but

divided each country's (c) food category (f) total diet scenario pressure (d) by the baseline global total (b) (equation (2)),

$$\text{Cumulative}_{c,f,d} = \frac{\text{water}_{c,f,d}}{\sum \text{water}_b} + \frac{\text{GHG}_{c,f,d}}{\sum \text{GHG}_b} + \frac{\text{nutrient}_{c,f,d}}{\sum \text{nutrient}_b} + \frac{\text{disturbance}_{c,f,d}}{\sum \text{disturbance}_b}. \quad (2)$$

Cumulative pressures in the baseline and alternative diet scenarios were used to understand how environmental pressures would change with each diet for each country. For each country, we estimated the proportional cumulative pressure changes, compared to the baseline diet as a producer and consumer (equation (3)),

$$\text{Proportional Cumulative Pressure Change}_{c,d} = \frac{\text{Cumulative}_{c,d} - \text{Cumulative}_{c,b}}{\text{Cumulative}_{c,b}}. \quad (3)$$

2.5. WB groups and nutritional deficiency prevalence for distributional implications

We used WB income groups to understand the distributional implications of the diet scenarios and baseline diets on different country income groupings. WB income groups are calculated by the WB using, 'gross national income (GNI) per capita data in US dollars,' [27], and categorize a country into one of four categories: high income, upper middle income, lower middle income, and low income. We used WB data from 2015 to 2019 to coincide with the trade and pressure data [21], and if a country moved between income categories during this period, the most frequent classification was used. Only 28 countries out of 218 changed categories during this time (supplementary table 5).

We aggregated production and consumption cumulative pressures for each WB income group for baseline diets and each diet scenario by summing the cumulative pressure values of countries within each group. To calculate the per capita cumulative pressures across income groups, we divided the

total cumulative pressure of the income group by the population of that income group. These calculations allowed us to compare pressures across diet scenarios, food categories, income groups, and production versus consumption.

To further explore the distributional implications of dietary change across different income groups we used nutritional deficiency data. We used data from the Institute for Health Metrics and Evaluation (IHME) to compare each country's prevalence of nutritional deficiency and proportional change in consumption pressure for each diet scenario. Cumulative consumption pressure was used because the consumption of a diet is more directly tied to health outcomes than food production. The IHME nutritional deficiency metric, 'incorporates death and disability due to nutritional deficiencies including protein-energy malnutrition, iodine deficiency, vitamin A deficiency, iron deficiency, and other nutritional deficiencies' [28].

3. Results

Global cumulative pressures decrease with shifts from baseline diets to three out four diet scenarios. A global switch to the Indian diet led to the largest total reduction in global cumulative pressure (-20.9%). The FBDGs diet is the only diet that increased total global pressures from current diets (35.2%). The Mediterranean diet scenario resulted in the smallest cumulative pressure change from current diets but still decreased pressures overall (-3.6%). The EAT-Lancet diet had the second largest decrease in global cumulative pressures (-8.7%).

Under current diets, low and high income countries account for the lowest total cumulative consumption pressures (10.5% and 14.5% of total pressures, respectively), while upper middle and lower middle income countries account for the greatest total cumulative consumption pressure (32.8% and 42.2%). These consumption pressure percentages are comparable to the total population percentages in each income group (table 2). Across each of the four diet scenarios, low income countries increase their total cumulative environmental pressure for production and consumption (figures 1(a) and (c)). High income countries decrease their cumulative environmental consumption pressure in all four diet scenarios and decrease their cumulative production pressure in three out of four scenarios. Upper middle and lower middle income groups have mixed results of decreasing or increasing cumulative pressures depending on the diet scenario.

After adjusting for population size, low income countries' have the highest environmental pressures per capita of the country income groups under baseline consumption and each diet scenario (figure 1(b)). Per capita cumulative consumption pressures decrease as income increases with high

income countries the most efficient. Compared to high income countries, upper middle income countries' cumulative consumption pressure per capita is 1.5% higher, lower middle income countries' is 15.5% higher, and low income countries' is 17.6% higher. This result varies when examining individual pressures compared to cumulative pressure per capita. For GHG, high income countries have the highest pressure per capita and low income countries have the lowest pressure per capita. Low income countries have the highest nutrient pressure per capita and disturbance pressure per capita compared to other country income groups, which contributes to its higher cumulative pressure per capita (see supplementary figures 4–7 for figure 1 with individual pressures).

Among baseline diets, the difference between the higher and lower income groups in per capita consumption pressure appears to be driven by cereals and red meat (figure 2). Cumulative production pressures per capita have a different pattern, with lower middle income countries producing the most pressures per capita and upper middle income countries having the lowest (figure 1(d)). Low income countries' food consumption was associated with more pressures, per capita, than their production (difference of 9.1%), suggesting there is a net displacement of dietary pressures to other countries. Conversely, high income countries produced more per capita pressures than they consumed (difference of 4%), suggesting they, overall, incur pressures for food that is consumed elsewhere (figures 1(b) and (d)). These patterns appear to be driven by cereals (figure 2), with low income countries consuming more cereal-based pressures per capita than they produce, while the opposite is true for high income countries. Upper middle income countries and lower middle income countries had the smallest difference between consumption and production pressures per capita (0.7% and 0.3% respectively) (figures 1(b) and (d)).

To understand if overall trends in the changes in cumulative pressure for income groups were driven by a few countries, we plotted each countries' proportional cumulative pressure change as producers and consumers under each diet scenario (figure 3). Using the marginal plots and 50% confidence interval ellipses, we observe that low income countries tend to increase their consumption and production pressures while higher income countries, on average, decrease their pressures or have smaller increases. Under each diet scenario there are multiple high income countries that decrease their consumption pressure but increase their production pressure. Under these diet scenarios these high income countries would be incurring the pressures for food that is consumed elsewhere. Overall, the patterns observed at the aggregate, income group level (figure 1), appear to be present for most of the countries within each income group (figure 3).

Table 2. Income groups makeup summary and baseline pressure contribution to global total.

WB country income group	Number of countries	World pop. (%)	Consumption contribution to baseline cumulative pressure (%)
High income	80	15.9	14.5
Upper middle income	58	34.7	32.8
Lower middle income	46	39.7	42.2
Low income	34	9.7	10.5

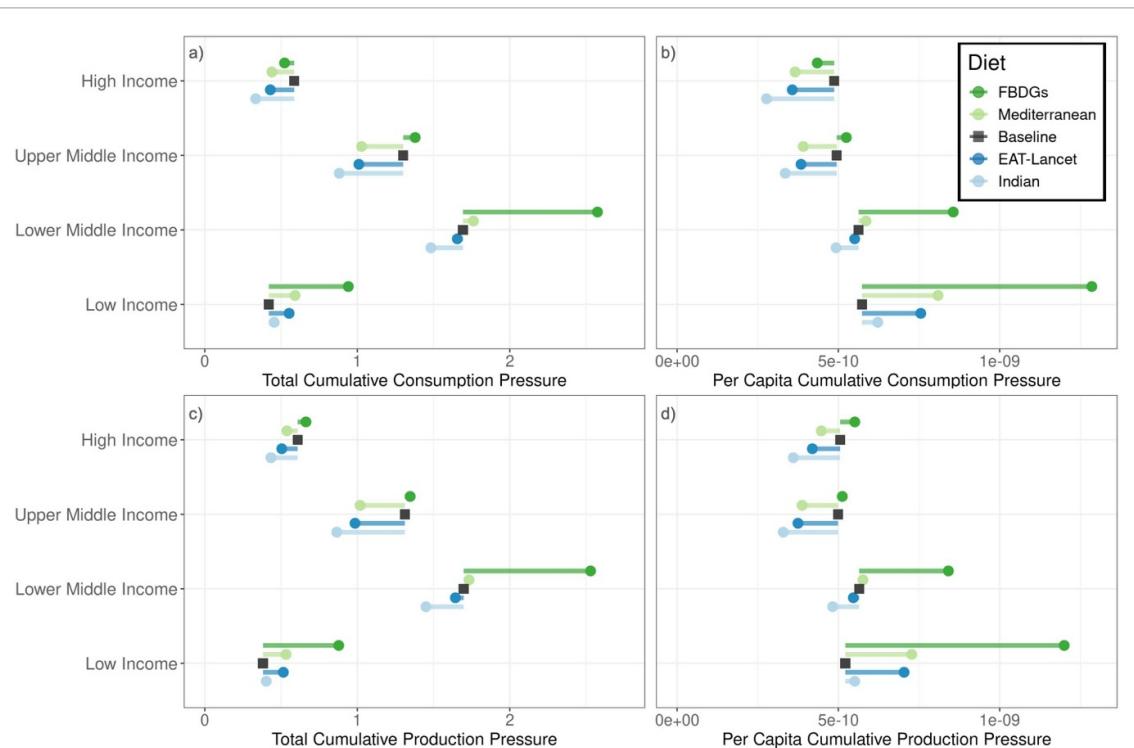


Figure 1. Total and per capita consumption and production cumulative pressure of income groups for baseline diets and each diet scenario. Figures (a) and (c) are the total cumulative pressures as consumers and producers, (b) and (d) are the per capita cumulative pressures as consumers and producers. The horizontal lines show the change from the baseline diet to each diet scenario value. See supplementary figures 4–7 for the same figure with individual pressures.

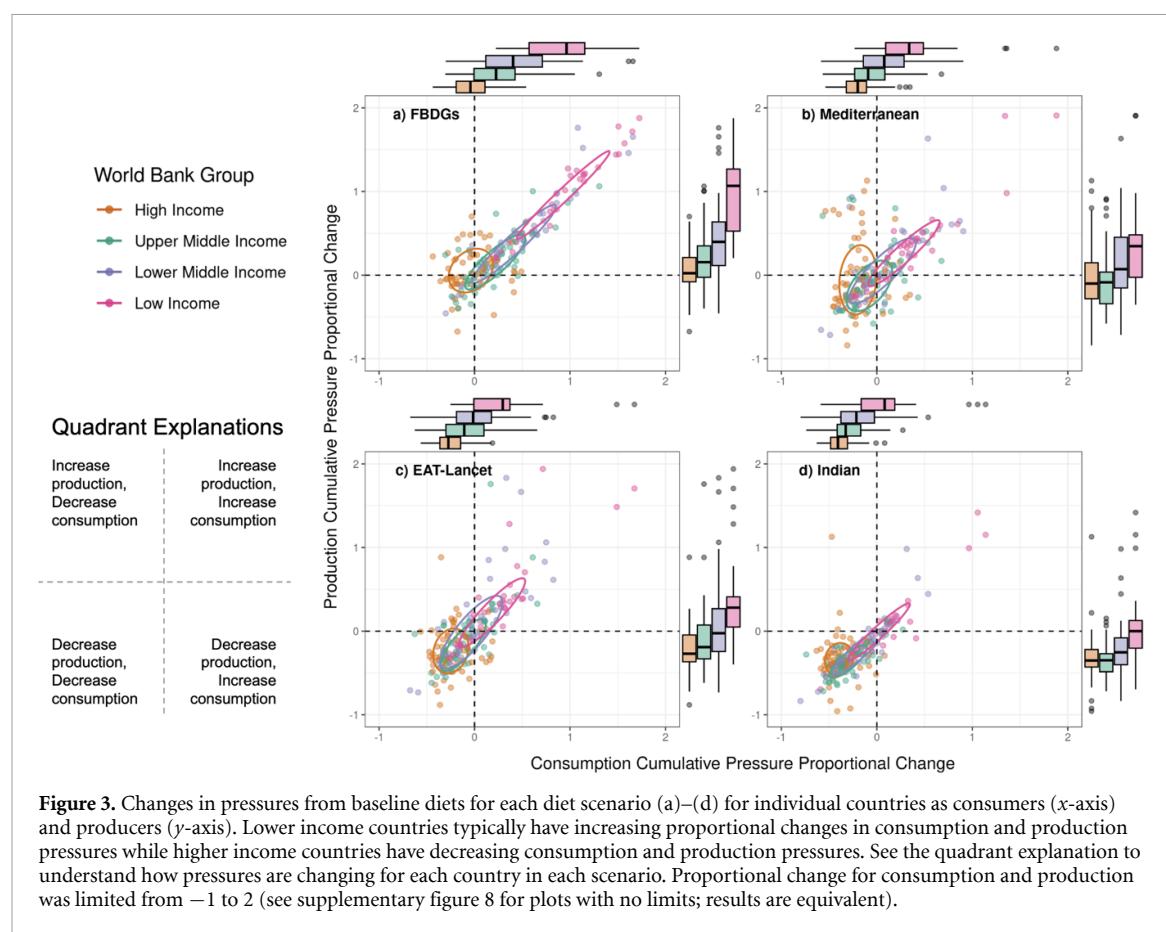
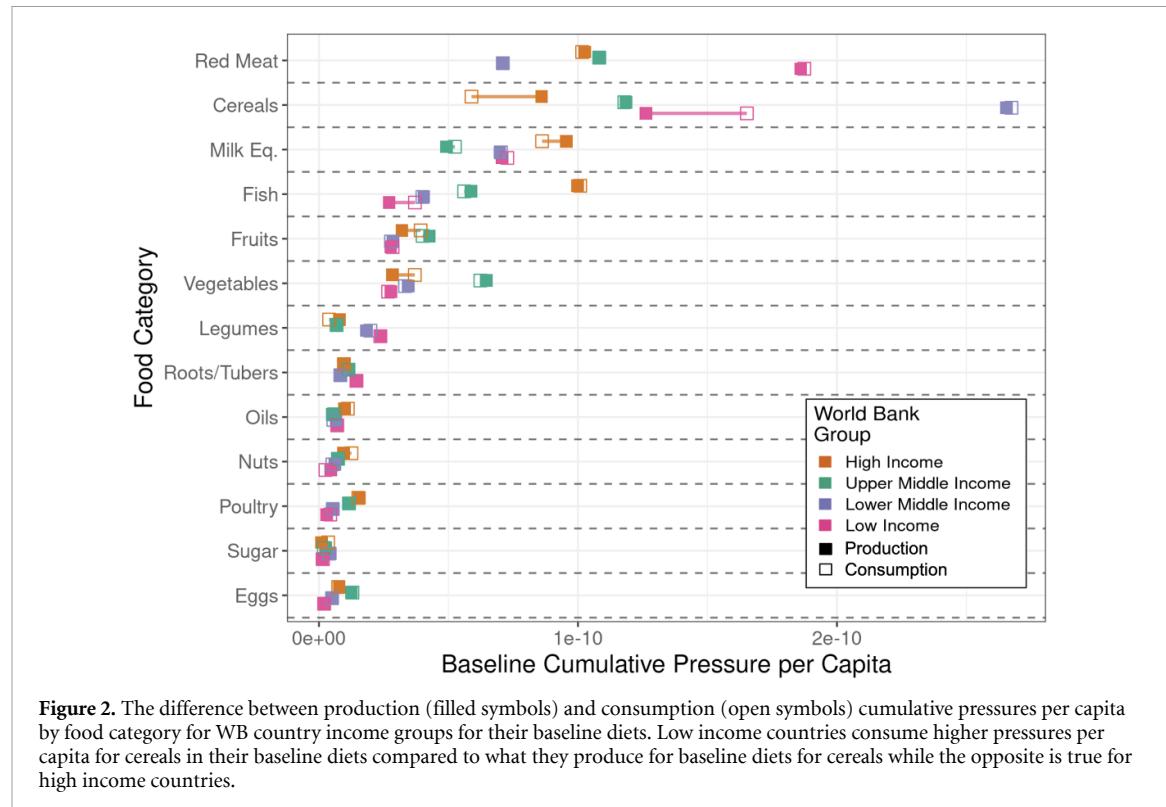
To understand why these distributional patterns are emerging from diet shifts we plotted the proportional change in consumption cumulative pressure against each country's prevalence of nutritional deficiency. Across all diet scenarios, countries that increase their consumption pressures were more often those with a higher than average prevalence of nutritional deficiency (figure 4), which are typically low income and lower middle income countries (figures 1 and 3). When comparing the average grams consumed of each food category per day of low income countries to the recommended values of our diet scenarios, low income countries are consuming less than the recommended quantities in 9 of 13 food categories (supplementary table 6). High income countries are overconsuming recommended quantities in 8 of 13 food categories.

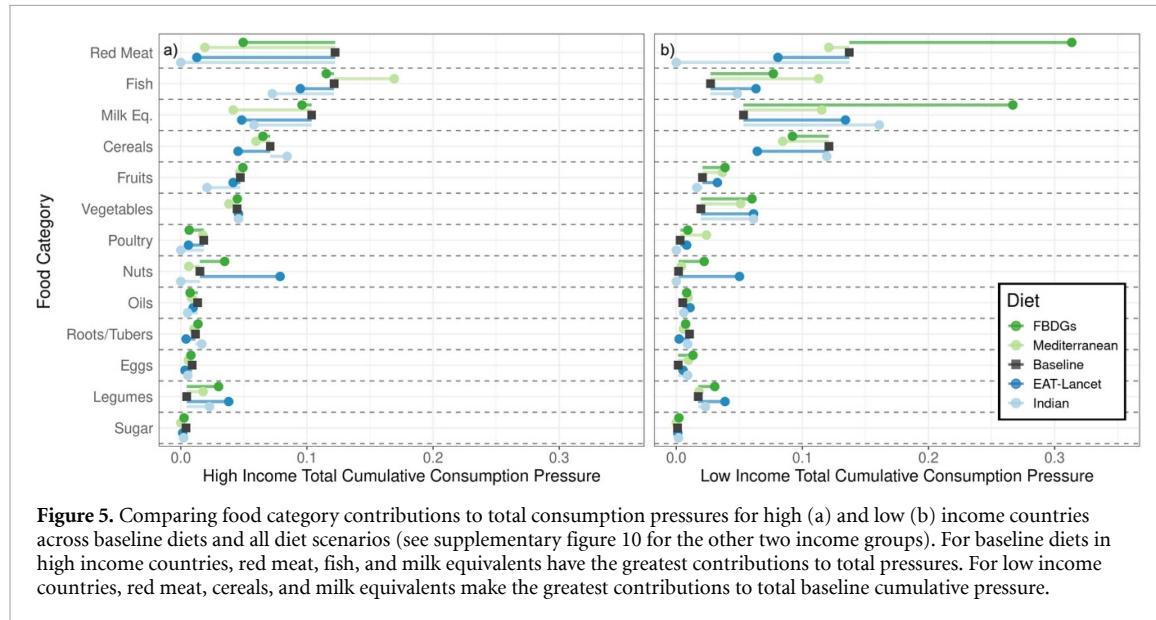
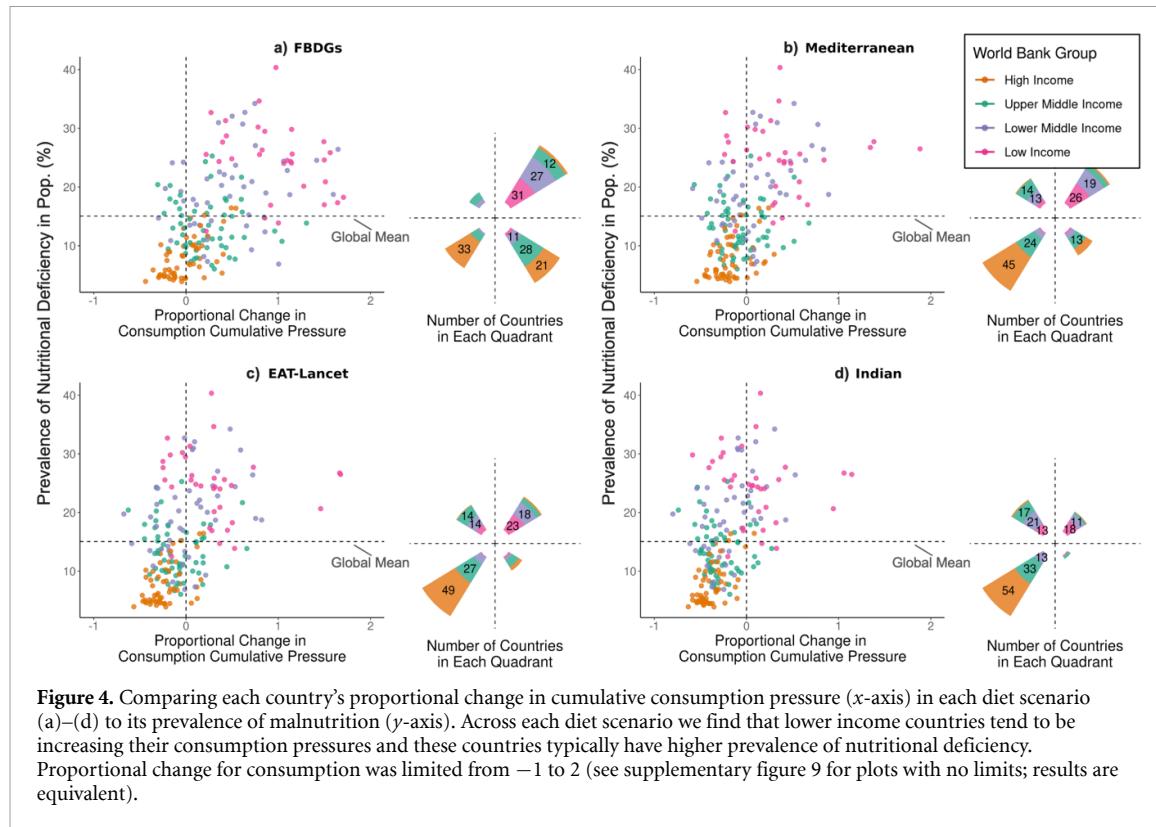
These patterns of over- and underconsumption are reflected in the cumulative impacts of different food categories (figure 5 for high and low income groups; see supplementary figure 10 for the other two income groups). In high income countries, red meat,

milk equivalents, and fish—food categories that high income countries are overconsuming compared to the simulated diets—show the greatest potential for decreasing cumulative pressures across most diet scenarios for the income group. Conversely, increased cumulative pressures for low income countries in our diet scenarios are mostly driven by greater consumption of milk, vegetable, and fish—food categories currently below recommended consumption levels in most diet scenarios (supplementary table 6).

4. Discussion

Switching from baseline diets to the four studied diet scenarios shows distinct changes in the distribution of consumption and production pressures across the different income groups. On average, low income countries increase their cumulative consumption and production pressures while high income countries decrease their consumption pressures, and typically decrease their production pressures, although this depends on diet (figure 1) and





country (figure 3). Upper middle income countries lower their pressures in three out of four scenarios and lower middle income countries split the diet scenarios evenly between increasing and decreasing pressures. Disaggregating global changes by income groups therefore provides an important lens to determine how environmental pressures are distributed across countries.

Low income countries were the only group to increase their consumption and production pressures in each scenario, which occurs largely because they are under consuming 9/13 food categories compared

to recommendations for most of the diets (figures 4, 5 and supplementary table 6). This underconsumption is linked to these countries having relatively high rates of nutritional deficiency [29–31]. Efforts to reduce these deficiencies will require increases in consumption, particularly of high nutritional value foods such as fish, milk, and vegetables [29–31] regardless of scenario (figure 5).

Considering that low income countries also have greater cumulative consumption pressures per capita than high income countries, they will therefore disproportionately have larger increases to meet

nutritional needs. This is in part because historical and ongoing underdevelopment of low income countries means that they have not had the same opportunities to develop more efficient technologies [32]. The Human Right to Food, Food Sovereignty and Food Security perspectives diverge in their specific goals and mechanisms for accountability and implementation but all converge around a shared recognition of the need to reduce the environmental pressures and impact of food production while ensuring food security for countries and their individual populations. In order to achieve this objective, low income countries should be supported by wealthier nations in their efforts to achieve, (i) local increases in environmental production efficiency through innovation or knowledge sharing, (ii) access to imports of efficiently produced foods, and (iii) continued economic development and growth which has been shown to improve dietary-related health while reducing the environmental pressures of food production [2, 33]. With support in these three areas, low income countries can more quickly achieve human health goals without widespread increases in environmental pressures [2, 33]. It is important to keep in mind that even without knowledge sharing or changes in trade to lower pressure foods, in most of the diet scenarios included in our study, there is a net decrease in total global cumulative pressures even while low income countries increase their cumulative pressures. This speaks to common principles of fairness applied such as 'Common But Differentiated Responsibilities' often used in the IPCC that recognize we have a common responsibility to reduce emissions, but some nations are more responsible for causing historical harms, and associated to this some nations are currently more able to shoulder the change.

Due to the documented relationship between per capita gross domestic product and consumption of empty calories and animal products, we did not expect higher income countries to have lower per capita consumption pressures [18], compared to lower income countries (figure 1). Although per capita cumulative pressures were relatively low in high income countries, the patterns among the individual pressures varied considerably among income groups. For example, high income countries had the highest GHG pressures per capita (supplementary figure 4) for production and consumption, which supports the documented increase in animal consumption with income [18]. Our study differs from previous ones, most predominantly, by using country to country specific pressure per gram of food category values, which allows us to compare diet production and consumption. Other studies develop global averages for item specific foods (e.g. trawling fishery and recirculating aquaculture vs. fish) and apply them to each country, which highlights what changes should be made in what foods people consume.

4.1. Limitations and future research

According to our results, changes in environmental pressures due to global diet shift scenarios would be unequally distributed among income groups of countries, with higher income countries decreasing their pressures and lower income countries increasing theirs. Our findings assume the consumption of baseline and diet scenarios are done equally by all of each country's population and future work could use country population data to distribute consumption within each country more accurately. Some country's baseline diet data needed to be gapfilled using regional averages, future research could also find better or more complete diet data. Our study is framed around issues of equity and justice but were unable to complete a complete assessment of these subjects due to data limitations and availability. To expand on these findings, future work should include an economic or employment perspective to explore the environmental justice of these changes in a holistic way. One way this could be accomplished is by filling agricultural jobs data gaps and including this factor in a similar study, although current data limitations precluded this for our analysis. Understanding the specific changes required in different countries, and understanding how these will affect environmental pressures and, crucially, environmental impacts, will also be essential for developing robust policies to avoid trade-offs between human and environmental health.

4.2. Conclusion

Global diet shifts are required for a healthier population and planet. Our findings suggest that global environmental pressures of food production can be reduced through specific diet shifts. Countries that have higher rates of undernutrition are frequently those with lower incomes and the countries that, on average, increase their pressures, despite the overall global reduction, due to increasing consumption compared to baseline diets. Considering principles of equity, lower income countries should not have the same expectations to lower environmental pressures as higher income countries because they are the most nutrient deficient and historically underdeveloped. Therefore, to facilitate equitable diet shifts, every effort should be made to minimize these pressure increases through the adoption of locally adapted, socially and economically equitable interventions to increase the environmental efficiency and nutritional value of food production.

Data availability statement

The data that support the findings of this study are openly available at the following URL/DOI: <https://zenodo.org/records/13001955>.

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Conflict of interest

The authors declare no competing interests.

Ethics statement

The research meets all ethical guidelines, including adherence to the legal requirements of the study country.

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