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EVALUATION OF MEAT AS A FIRST COMPLEMENTARY FOOD FOR BREASTFED INFANTS: IMPACT ON IRON INTAKE & GROWTH

K. Michael Hambidge, MD, ScD[1], **Nancy F. Krebs, MD, MS**[1], **Xiaoyang Sheng, MD**[2], **Tianjiang Jiang, MD**[2], **Manolo Mazariegos, MD**[3], **Ana Garces, MD, MPH**[3], **Dinghua Li, MD**[2], **Jamie Westcott, MS**[1], **Antoinette Tshefu, MD, PhD, MPH**[4], **Neelofar Sami**[5], **Elwyn Chomba, MBChB, DCH, MRCP**[6], **Omrana Pasha, MD**[5], **Adrien Lokangaka**[4], **Norman Goco, MHS**[7], **Albert Manasyan, MD, MPH**[6], **Linda L. Wright, MD**[8], **Marion Koso-Thomas, MD, MPH**[8], **Carl Bose, MD**[9], **Robert L Goldenberg, MD**[10], **Waldemar A Carlo, MD**[11], and **Elizabeth M McClure, MS**[7]

[1]University of Colorado Denver, Aurora, CO, USA

[2]Shanghai Jiao Tong University, Shanghai, China

[3]San Carlos University, Guatemala City, Guatemala

[4]Kinshasa School of Public Health, Kinshasa, Democratic Republic of Congo

[5]Aga Khan University, Karachi, Pakistan

[6]University Teaching Hospital, Lusaka, Zambia

[7]RTI International, Research Triangle Park, NC, USA

[8]Eunice Kennedy Shriver National Institute of Child Health and Human Development, Bethesda, MD, USA

[9]University of North Carolina, Chapel Hill, NC, USA

[10]Drexel University, Philadelphia, PA, USA

[11]University of Alabama, Birmingham, AL, USA

Abstract

The rationale is considered for promoting the availability of local, affordable, non-fortified food sources of bioavailable iron in developing countries. Intakes of iron from the regular consumption of meat from the age of six months are evaluated with respect to physiological requirements. The paper includes a description of two major randomized controlled trials of meat as a first and regular complementary food that are currently in progress. These trials involve poor communities in Guatemala, Pakistan, Zambia, Democratic Republic of the Congo and China.

Keywords

iron; meat; complementary feeding

Corresponding author: K Michael Hambidge, MD University of Colorado Denver, 12700 E 19th Avenue, Box C225, Aurora, CO 80045 Michael.Hambidge@ucdenver.edu Phone: 303.724.3261 Fax: 303.724.3206.

Objectives

The principal objective is to provide an overview description of two major efficacy trials currently in progress to evaluate the use of meat as a first and major complementary food for older infants and toddlers. Though designed with providing adequate dietary zinc as a principal objective and with linear growth velocity as the primary outcome, the magnitude of the effects on iron status in populations at high risk from iron deficiency is a major secondary outcome measure. The paper will consider the magnitude of the theoretical benefits to the quantity of iron absorbed and the extent to which these are sufficient to meet iron requirements.

Rationale for Promoting the Availability of Affordable Sources of Non-fortified Food Sources of Iron

Much has been gained, though not without some risk and unresolved challenges, from judicious use of iron supplements, iron-containing sprinkles and iron-fortified food staples in both low-income and more affluent populations. However, even at a time of rapid scaling-up of these programs in low-income countries, recognition has been given to the fundamental importance of promoting the availability of locally-available, affordable food sources of all essential nutrients including iron.[1] However, in times of severe food insecurity, emphasis on dietary diversity may need to give ground to the immediate threat of energy inadequacy, although recognizing that dietary diversity is essential for successful reliance on non-fortified/supplemental foods. The outstanding challenge in achieving adequate food diversity in young children is the provision of animal products, especially meat. Iron deficiency itself remains the single most prevalent nutrient deficiency globally. Biofortification of local food staples may eventually offer a partial alternative to meat as a local source of iron, especially in vegetarian communities, but this is not a current reality.

With respect to nutrient composition of the diet, the value of including meat as a complementary food from the age of six months is indisputable. Among the micronutrients of key public health importance this applies especially to zinc, iron and, frequently, vitamin B12. The concentrations of zinc in meat are especially favorable. One ounce of beef provides approximately 2 mg of zinc with favorable bioavailability.[2] If provided daily, this leaves only 0.5 mg bioavailable zinc/day from all other dietary sources to meet the Estimated Average Requirement or 1 mg zinc/day to meet the RDA.[3] The selection of linear growth as the primary outcome measure for each of these studies was influenced heavily by the strong association between linear growth and morbidity/mortality globally.[4] Linear growth may benefit from multiple nutritional improvements resulting from diversifying complementary feeding of breast fed infants from the age of 6 months with the addition of meat on a regular basis. However, the association between zinc nutrition and linear growth[5] and the inadequate zinc intake in the diet of the populations being studied was one outstanding factor. Of relevance to the four-country study to be described, pilot growth and diet studies in toddlers at these four sites revealed a statistically significant positive association between linear growth Z-scores and consumption of meat or/and eggs at least × 3 weekly.[6]

Though anemia and indices of iron status are only secondary outcomes in these two studies to be described, this should not detract from the interest and importance attached to them. Iron concentrations in beef are no more than half of those of zinc[2] and one ounce of beef per day provides approximately 1 mg iron/day. To get this figure in perspective, 70% of that iron needs to be absorbed to meet the physiologic requirement of 0.69 mg iron/day determined by the Institute of Medicine[3] for infants 6-11 months of age and a little over 60% iron absorption by toddlers. This appears to be an unlikely achievement with the EAR set at 7 mg iron/day for older infants.[3] However, the EAR was based on the assumption that the diet of older infants did not include meat; it was, therefore, based on the absorption of inorganic iron for which a figure of 10% absorption was applied. The iron derived from meat is heme iron, absorption of which in adults is very favorable[3] in contrast to that of inorganic iron. Data on absorption of heme iron specifically in later infancy would be invaluable. Other factors that merit discussion in considering the above iron absorption calculations include the fact that these calculations were based on the assumption that the beef would be the only dietary source of iron. A modest downward adjustment of these calculations is, therefore, reasonable. Furthermore, important physiologic gains may be achieved even if absorption is less than estimated requirements. Even 1 mg of inorganic iron/day given in a wheat product increased the hemoglobin in young children.[7] This is consistent with the hypothesis that even smaller quantities of beef will have beneficial physiologic effects in iron-deficient older infants/toddlers even if not achieving optimal iron stores. This could be especially relevant when feeding other sources of meat. Lean pork and chicken leg has only about half of the iron concentration of beef, and white meat from poultry even less.[2]

The importance of including animal source foods (ASF) including meat in complementary feeding has been emphasized by investigators;[8-12] by international organizations including WHO;[13-15] by national ministries of health as in Guatemala;[16] and by national committees including those in the US.[17-19] Meat consumption is positively associated with psychomotor outcome in UK children up to 24 months of age[20] and with iron status in late infancy.[21] Beef has been shown to improve growth and cognitive function in Kenyan school children.[22, 23] Though this concept appears foreign to so many people today, there is little doubt that ASF including meats, perhaps pre-masticated,[24] were fed to older infants and toddlers at the time of development of the human genome when the lifestyle was that of the hunter-gatherer and that the change to an agrarian lifestyle has been an important contributory factor to iron deficiency in young children today.

An earlier study in Denver[25, 26] demonstrated that the acceptability of beef as a first complementary food by exclusively breast fed infants at age 5-6 months is identical to that for infant rice cereal. By age 7 months, the average intake of pureed beef was 2 oz/day. Informal acceptability studies in the Western Highlands of Guatemala indicate the ready acceptance of cooked, minced liver by infants aged 6-12 months (Krebs et al, unpublished data). Acceptance of meat and liver by infants has also been confirmed by formal testing in Peru,[7] despite the mothers' preferences for non-meat containing porridges.

Though there is broad-based recognition of the importance of ASF, including meats, the evidence base to justify major programmatic efforts to promote meat as a major complementary food remains inadequate. This has essentially provided the rationale for two major trials by our group. It has also dictated a focus on efficacy trials, fully recognizing that effectiveness in different populations will demand further study(ies) in different populations. These trials have been accompanied by a more intensive metabolic study in Denver, which is also nearing completion at this time (Krebs et al, unpublished data).

Overview of Two Efficacy Trials of Meat as a First Complementary Food

The field studies for our two international trials of meat as a complementary food are nearing completion, but results are not yet available. The primary purpose of this paper therefore is to provide an overview description of the two trials. One trial is a common protocol shared by four sites of the NICHD Global Network for Women's and Children's Health Research, with organizational, data management and statistical support from RTI International. The four sites are located in Guatemala (small town, Western Highlands), Democratic Republic of the Congo (DRC, rural Equateur); Zambia (rural) and Pakistan, (peri-urban Karachi), with leadership of the University of Colorado Denver in collaboration with the NICHD.

The other trial, supported by the Thrasher Research Fund, covers virtually the entire county of Xichou (population approximately 250,000), Wen-Shan Canton, Yunnan Province, S.W. China, and is a mix of rural and small town rural with leadership provided by a collaboration between the University of Colorado, Jiao Tong University, Shanghai, and the Head of Women's and Children's Health Program for Xichou County.

Both studies are testing the primary hypothesis that daily feeding of meat from the age of 6-18 months will result in significantly greater linear growth velocity compared to that achieved by daily feeding of an equi-caloric micronutrient-fortified, cereal-based supplement (rice-soy for the Global Network, rice for Xichou). The Xichou trial has a third arm of non-fortified rice supplement. Among the secondary hypotheses and pertinent to this paper are that the meat group will have adequate indices of iron status.

Both trials were designed as cluster-randomized, non-masked, controlled efficacy trials. For unavoidable logistical reasons the Xichou study randomization had to be modified and additional data analyses planned as a consequence.

Staff Training—The Global Network study utilizes a 'train the trainer' model with senior members of each of the participating sites receiving comprehensive training, both at Network Steering Committee meetings and in Colorado, and are provided with the necessary materials, including a Manual of Operations to train the country and community coordinators and others at their sites. The Colorado team and RTI provide follow-up training/advice in subsequent site visits.

The training in Xichou has been preceded by Colorado planning/training visits to work with their senior investigator at Jiao Tong University in Shanghai (Professor Sheng), including development of a Manual of Operations, and on-site visits in Xichou County. Dr. Sheng, with limited assistance from Shanghai colleagues, is responsible for training the leaders of the Xichou Women's and Children's Health Services who then trained the directors of the seven County Hospitals. The latter, with limited staff, have a vital role in distribution of the interventions and data collection.

Pilot Studies—The Global Network undertook a four-country pilot study to attain supervised experience in accurate anthropometry measurements under field conditions. The pilot studies included 1685 toddlers with equal gender distribution, approximately equal site distribution and a mean age of 17 months. Major dietary staples were maize, potato, and rice in DRC; maize, followed by rice in Zambia; maize, rice, and potato in Guatemala; rice and potato in Pakistan. Stunting (length-for-age Z scores <2 SD) rates were approximately 60% in DRC and Guatemala and 40% in Zambia and Pakistan in these convenience samples unselected for SES, diet or previously known growth. Relevant to our planned trial, a General Estimating Equation model revealed a significant inverse relationship between stunting and meat consumption, a relationship that was significant even after controlling for all covariates of potential interest ($p < 0.01$). Eating meat significantly reduced the likelihood of stunting (OR −0.61, Cl 0.43-0.85).[6]

In Xichou, a detailed zinc homeostasis study has been undertaken recently.[27] Observations pertinent to this study were a stunting rate of 30% for toddlers, without any toddlers underweight for length and no significant difference in zinc intake between the rural and small town study groups. Intake of flesh foods was very low in both groups. Results of homeostasis studies indicated that dietary zinc did not meet requirements.

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Study Subjects and Enrollment—Breast fed infants were enrolled at 3-5 months of age in each trial, allowing time for nutrition education including support of exclusive breastfeeding before intervention commencement at age 6 months. Subjects at all sites are low-income. Comparison data on SES between sites is not yet available. Important exclusion criteria are the feeding of or intent to feed infant formula and/or micronutrient-fortified commercial complementary foods, a special challenge in Guatemala. All participants were encouraged to continue exclusive breast feeding until 6 months. Studies received ethical approval by the Colorado Multiple Institutional Review Board and also from the local in-country review boards. Participants gave written informed consent before enrolling in the project.

Randomization—In each of the four Global Network sites, 10 clusters (communities) were randomized by RTI to participate in either test or control groups (5 clusters in each group with 30 subjects/cluster) and pair matched on stunting rates determined from pilot data. The invitation to participate within clusters involved random sampling from cluster specific lists of births of eligible participants.

In China, randomization was initially at the Administrative Village level in the domains of six of the eight rural town areas (the remaining two were logistically inaccessible for this study). There are 70 Administrative Villages in Xichou County, each with several village-rural communities. A total of 60 villages which had > 30 births/year were selected randomly for participation. For logistical/budgetary reasons, this planned randomization had to be modified to pre-define three large domains where the provision of meat with the available resources (including transport) was realistic. All six domains were randomized to participate in one of the two cereal control groups.

Recruitment/Education—Potential participants in both projects were identified by various strategies at birth and were recruited at 3 months of age. In Xichou, a convenience sample of mother-infant dyads was recruited by the community doctors who are an integral part of each of these small communities. Early recruitment in all sites provided the opportunity to provide additional encouragement for mothers to continue exclusive breast feeding, though this was achieved in only a minority of dyads. Mothers in both studies and in both test and control groups received selected nutrition education messages.[28] These were more formalized and frequent in the Global Network study, focusing on frequency of feeds, thickened gruels, and widest possible variety of locally available foods. Hygienic preparation, feeding, and temporary storage of food were also reinforced at every contact.

Intervention—The test intervention in each study is a daily supply of meat. For the Global Network study meat is provided as a cooked, diced, lyophilized beef product marketed by Mountain House, Inc. (Albany, OR) in 17 oz cans that are stable >15 years at <100° F and for 10 days after cans are opened. Halal meat is provided for Pakistan. Typically several cans are distributed to cluster community coordinators weekly. Daily portions are weighed into small, labeled zip-lock bags, seven of which are delivered weekly to participants' homes or at the health facility. It is expected that the infant will consume the initial target quantity of 15 g (equivalent to 30g cooked meat). The daily portion is increased to 22.5 g/day starting at 12 months of age. For the first few days/weeks, the meat is fed with a minimum of others foods to maximize consumption; remaining meat may be covered and re-fed < two hours later. Initially, the lyophilized meat can be provided as a puree by crumbling the product into a powder and mixing with a little boiled water. Later on it can be mixed with other foods and/or fed as a finger food.

In China, pork is a favored meat and has been selected as the test intervention. Fresh lean cuts of pork from Department of Agriculture certified animals are purchased weekly in the local market by participating hospital directors and subsequently minced. Two ounces of the minced meat is weighed into plastic bags, stored frozen, and collected the following day by community doctors assigned to participants in the meat group. The community doctors store the packets in their freezers and distribute daily to the homes of the participants. The quantity of pork offered was twice that of beef in the Global Network trial because of the lower zinc (and iron) content of pork compared to beef. The amount of the daily serving was not increased at 12 months.

Comparison Groups—For the Global Network four-country study, there is one comparison group, a micronutrient-fortified pre-cooked rice-soy blend, but deliberately designed to require additional cooking in boiling water for final hygienic preparation. The supplement was formulated specifically for this study by Nutrica, Inc. (Guatemala City). The cereal supplement is provided in a 20 g package for ages < 12 months and then 30 g until 18 months of age. These quantities provide an equi-caloric supplement to that provided by the beef, i.e.70 kcal/day for the infant, in addition to 2.2 mg zinc/day and 5.5 mg iron/day. The 30 g packet of cereal provides 3.3 mg zinc/day and 8.3 mg iron/day. Participants in both arms were supplied with a container to store weekly supplies together with a small cooking and serving pan and plastic infant spoon. Verbal and pictorial instructions (and initial observation) for maternal-infant hand-washing, dissolving cereal in 120 ml water and gently mixing/heating for two minutes are provided.

Two comparison groups are included in the Xichou study. One comparison arm receives a commercial micronutrient-fortified infant rice cereal product. The quantity of cereal is designed to be equi-caloric to the daily supply of pork, i.e. approximately 150 kcal/day with 2 mg zinc and 4 mg iron. The second comparison group is a non-micronutrient fortified rice biscuit slightly sweetened with sugar.

Compliance—Observation of each meal is not only impossible but undesirable. In the Global Network study, home visits by community coordinators are initially conducted 5 times per week, decreasing to a weekly visit after 3 months. The number of unused food packets is counted.

For Xichou, home visits are undertaken daily for the meat group to deliver the daily supply. For cereal groups, the visits are weekly. This study represents an additional duty for the community doctors whose commitment to the study quality likely varies.

Assessment—Initial demographic data, longitudinal anthropometric measurements, dietary data, neurocognitive development measures and blood collections are obtained by highly-trained teams of community workers (Global Network) or graduate students (from Jiao Tong University). The latter are supported and supervised by the head of maternity and child services and her deputy and staff in Xichou County. Morbidity data are collected in the homes by community health workers or community doctors on their regularly scheduled weekly visits.

Sample size estimations—Different assumptions were made for the two trials resulting in minor differences in projected final group size.

Data Processing—For both trials, data are entered and checked locally on a daily basis. Global Network data are transferred to RTI International for storage, check edits, and subsequent analyses. Xichou data are entered each evening by the graduate students, checked and stored on a memory stick which is collected monthly by Dr. Sheng for transfer to Jiao Tong. Further checking and processing are undertaken there with eventual transfer of data to Colorado for analysis.

Summary

These trials have many similarities; the rate of stunting in Xichou toddlers is lower than in other sites and, apart from very limited meat, their diet appears adequate. Though representative of poor rural Chinese communities, the pace of change is notable even in Xichou County. The study has relatively limited funds leading to limitations in the number of frontline workers and close monitoring. Of note, two control groups are included. The type of meat used in the interventions is different, with different levels of nutrients. Both studies were designed to ensure an adequate intake of bioavailable zinc. Though iron was also a micronutrient of primary interest, estimates of quantities of meat to provide were not based on calculations for ion, primarily heme iron requirements for this population.

Discussion

No results are yet available from these two projects which will be completed in 2011. Very early and incomplete hemoglobin data from the current Denver study also in progress are encouraging for the beef arm.

Neither of the two projects included liver, though the ease of preparation and infant acceptability were observed with informal acceptability testing in one of the participating Global Network sites. Liver has attractive features apart from the above including lower cost and higher iron content. The iron content is twice as high as that of beef;[2] however, much of this iron will be non-heme. The high and potentially toxic vitamin A content[2, 29] was a reason for being cautious with liver, though provided in judicious quantities along with other organs (especially lung and heart, both of which have relatively high heme iron content) and meat, its advantages are likely to outweigh its disadvantages, especially in eliminating the risk of vitamin A deficiency. It is noted that the use of liver has been promoted[28] without report of adverse effect, and it is currently widely used including on-going research projects (one of which is in a Global Network site).

At the time when our genome developed, our ancestors were hunter gatherers and there is now evidence that meat from large mammals was consumed by the hominid species *Austalopithecus afarensis* at least 3.4 million years ago.[30] It seems likely that meat was provided by hunter gatherers as a first and frequent complementary food[31-33] following maternal premastication.[24] This practice remains common in some populations, including in China, though now discouraged because of the perceived risk of vertical transfer of HIV. Foman's classic text[34] draws attention to the use of meat broth as a complementary food in the United States 200 years ago, but more recent common advice to mothers, which focuses on plant-based foods during the first months of complementary feeding, does not appear to be based on scientific validation. Without maternal pre-mastication, feeding meat at 6-9 months can be facilitated by provision of a simple grinder in addition to cooking.

The production of meat is discouraged by many because of cost in terms of agricultural land and of carbon emissions, the former also resulting in impossible purchase costs for the global poor. Though data are not available at this time that readily allow estimates of costs in terms of DALYs and Net Present Value, estimates of high costs of production have not taken into account the costs of foraging/scavenging animals subsisting largely on refuse. This issue is especially pertinent to the rural poor who cannot afford micronutrient fortified products and may also not be in reach of such commodities. Where grass is available for grazing on a community level, good animal husbandry results in very favorable carbon capture in contrast to maize-fed animals.[35] Finally, a frequent barrier, not limited to low-income populations, is that current practice is not to give the older infant and young child first, if any priority, for access to meat even when available to families. Behavioral change communication has the potential to help change current practices except when determined by genuine religious reason.

The challenges are sufficiently great to require a strong evidence base starting with efficacy trials such as these in progress.

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