How strong is our evidence for effective management of wasting? A review of systematic and other reviews

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Abstract

A need for improved empirical evidence for the effectiveness of interventions used in the management of child wasting (moderate and/or severe acute malnutrition) has recently been highlighted. There is no lack of published studies in this field, but when examined through the lens of systematic review protocols, few of these studies stand up to rigorous methodological critique. This paper summarizes the current state of knowledge, as supported by high-quality research included in multiple systematic reviews. It also elaborates on the criteria and standards used in such reviews. The paper highlights the weaknesses of many studies that could, with more care during study design and reporting, result in a larger body of evidence being available to policy makers and program implementers dealing with child wasting.

Key words: Empirical evidence, nutrition interventions, systematic reviews, wasting

Introduction

The International Symposium on Understanding Moderate Malnutrition in Children, held in Vienna in 2014 under the auspices of the International Atomic Energy Agency, was organized in part because "more evidence on effective programmatic approaches to manage moderate wasting is needed" [1]. This is acknowledged in the World Health Organization (WHO) 2013 updated guidelines on the treatment of severe wasting, which notes that "the evidence, available for the development of recommendations, was in general of very low quality. . . . This was due to the limited availability of randomized controlled trials, trials comparing existing WHO recommendations with new treatment options, or trials documenting comparisons of diagnosis and treatment methods identified by the guideline development group as requiring review"[2]. The same applies to evidence on the management of moderate wasting, as was noted by the 2013 *Lancet* Series on nutrition, which concluded that "high-quality programmatic research" is needed to help improve the design and outcome of nutrition interventions where wasting is a prime concern [3].

Policy makers and donors have increasingly called for evidence-based options for managing wasting as the scale of the problem has become more widely acknowledged. Recent estimates suggest that in least developed countries, roughly 1 in 10 children under 5 years of age is wasted (less than, or equal to, minus 2 SD from the median weight-for-height of WHO child growth standards) [4]. Importantly, there is growing recognition that it can be counterproductive to see wasting as a distinct problem from chronic manifestations of undernutrition (such as stunting or micronutrient deficiencies), since such problems often coexist among affected vulnerable communities and "this 'divide' in interests can in turn lead to a separation in policies and programming" [5]. That said, the unit costs associated with conventional interventions to manage wasting have often caused national governments to question the budgetary commitments needed to fully engage with this aspect of the global nutrition challenge. Thus, evidence of cost-effectiveness of alternative interventions, and programmatic costs versus unit costs of products used, are at the top of many policy makers' wish lists.

This paper reviews the current state of evidence relating to moderate wasting (moderate acute malnutrition [MAM]) and acute wasting (severe acute malnutrition [SAM]). It focuses specifically on the rigorous standards applied by systematic review protocols used to distinguish between good study methodologies and high quality of reported data and analyses. It does not,

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therefore, include an assessment of knowledge derived from realist or other forms of evidence review. It recommends a series of elements that authors of future research papers should keep in mind if they aspire to meet the high standards of research design required by the formal review systems that contribute the highest standards of rigor to the evidence base for action.

Evidence for what works

The body of research dealing specifically with the treatment of SAM has grown rapidly since the early 2000s, prompted in large part by the wide adoption of community-based interventions (compared with facility-based inpatient models) using newly developed products (such as lipid-based packaged foods that mimic older milk-based liquid treatments) [6]. The effect of SAM on child mortality played a large role in the modeling exercises reported in the 2008 *Lancet* Series on Maternal and Child Undernutrition, although moderate wasting was not considered [7]. However, 5 years later, the second *Lancet* Series included the management of both SAM and MAM among 10 "proven" interventions that should be scaled up (to 90% coverage) in countries with the highest burdens of malnutrition [3]. Indeed, it was argued that actions to address maternal wasting, not just child wasting, would have significant benefits in reducing mortality and morbidity across developing countries in development settings, not only in emergency contexts.

The evidence on which the *Lancet*'s influential recommendations were made was based on an assessment of the quality of evidence from earlier reviews—which were found to be wanting in terms of "limitations of analysis and variable quality of studies" [3]; review of more recent individual studies (mainly comparing various products used in treatment protocols in community interventions) and a pooling of data, where possible, for analysis of combined datasets; and synthesis of findings from recent systematic reviews that have dealt with various aspects of MAM and SAM management. Certain conclusions were drawn from this body of research and programmatic evidence, but less was possible than had been hoped, because the nature of the evidence was often of low quality and statistical differences reported "were for the most part small and . . . had substantial heterogeneity" [3]. Thus, although there was (just about) sufficient evidence to promote the treatment and management of wasting in the *Lancet* Series, more recent assessments still argue that while the need to act is clear, "the evidence base is sparse" [8].

In other words, although many existing studies have a lot to offer (in terms of practical insights and description of field experiences), most do not meet the requirements of inclusion in formal systematic review processes. As such, their potential to contribute to the evidence base is impaired; they remain largely hidden to the policy community because the findings are not included in synthesis publications that underpin global guidance and standard-setting agendas. That is, most study findings on wasting are not included in systematic reviews that tend to serve as the foundation for most critiques of evidence quality.

The power of systematic reviews

The term "systematic review" refers to a literature search using a formal protocol for defining evidence quality and degree of confidence in the results presented. In other words, it is not simply a search through the literature resulting in a narrative summary. Originating in the health sciences disciplines to add rigor to assessments of the clinical efficacy of interventions or drugs, systematic reviews seek to make potential biases in the selection of publications, data, and findings explicit and transparent, and to minimize such biases to the extent possible in order to make conclusions and policy recommendations based on evidence that is deemed to be credible and "the best there is."

The approach typically involves a comprehensive search strategy (with carefully defined "search terms"), with the goal of identifying, appraising, and synthesizing relevant studies on a narrowly formulated topic. For example, Bhutta et al. applied search guidelines defined by the Child Health Epidemiology Reference Group (CHERG) [9], while others turn to Cochrane guidelines [10] or those provided by the Campbell collaboration [11]. In all cases, search terms are run through various electronic libraries and databases using combinations of keywords. Some reviews include unpublished data if it is deemed to be of appropriate quality and pertinence. Electronic searches of this kind throw up large numbers of paper titles and abstracts that are screened for eligibility by more than one researcher. Full texts of apparently eligible studies are similarly assessed, with only those meeting clear inclusion criteria retained for full review. For example, Picot et al. screened 8,954 records of potentially useful papers, of which 74 articles (describing 68 studies) met the inclusion criteria [12]. Often, the authors of studies retained for analysis are contacted by the reviewers with a request for any missing information and for access to the data (for potential meta-analysis).*

To reduce the risk of overlooking relevant papers,

* Some, but not all, systematic reviews include a meta-analysis of data. This involves pooling datasets or computed results from the set of included studies to synthesize outcomes into a single quantitative estimate or summary effect size. Meta-analysis is a way to combine and compare the results of separate studies and reach conclusions on the overall effects being researched. To allow inclusion of a study in meta-analysis requires good documentation of the database.

some reviews search the bibliography contents of important studies and apply the "forward citation" function of some Internet search engines to identify papers cited in those studies. The opposite risk also holds true, in that application of the most rigorous screening criteria risks leaving out papers of potential value. Although the so-called gold standard for experimental design in public health is the double-blind, placebo-controlled, randomized control trial, that type of study design is not always possible or even appropriate for answering questions about program interventions in humanitarian settings or in nonemergency contexts where wasting is widely prevalent. Therefore, reviewers make a choice of how high to set the exclusion bar in terms of study design. Some focus on studies with randomized control designs (such as Picot et al., who highlighted that "only the best available evidence was reviewed and . . . this meant that only randomized, controlled trials and CCTs were included" [12], while others accept cohort-with-control or prospective case-control studies [13–15], and others still may broaden out the search to impose no rigid restriction on study design but pay extra attention to the quality of analysis and information presented [16]. In other words, a range of designs can (and should) be considered in a review of evidence, but the search approach, inclusion or exclusion criteria, and quality assessment used should be as transparent as possible.

For example, Picot et al. acknowledge in the case of their systematic review of SAM treatments, "in focusing on evidence from controlled studies with the most rigorous designs that were published in the English language, the systematic review may have excluded other forms of evidence" [12]. The value of "other forms of evidence" is acknowledged by Kerac and Seal [8] in their review of a 2014 paper by Langendorf et al. [17] on uses of cash and/or food in the management of wasting in Niger. The reviewers noted that despite the large number of children included in the study, it was not a randomized trial and since it was "more akin to an observational study . . . findings could equally be due to inter-site differences resulting in bias or unmeasured confounding." That said, they concluded that the study still had many methodological strengths that should not be ignored, including "rigorous and detailed reporting and analysis." Indeed, even small qualitative studies or focus group interviews can generate valuable information to a project implementer about local context, cultural constraints, or political concerns. However, when seeking to generalize findings across settings and promote a consensus position among scientists on evidence-based recommendations, minimum criteria are needed to establish credible norms.

There are several types of criteria used to screen papers into or out of a systematic review. First, study design: most reviews will automatically include randomized, controlled trials (RCTs), including cluster-randomized controlled trials (cRCTs) and nonrandomized controlled clinical trials (CCTs). Some, such as the study by Lazzerini et al. of specially formulated foods for treating children with MAM, included controlled before-and-after studies (CBAs), but only if they met the additional criteria of contemporaneous data collection (data in the experimental and control sites were collected in the same time frame) and inclusion of appropriate control sites (that are comparable to the intervention site in terms of setting and population characteristics) [15]. Nevertheless, even if the research design appears to be sound, studies can be excluded if they do not offer sufficient detail on the interventions considered and on potential mitigating or confounding factors, if they do not have an appropriate counterfactual as part of the study, or if the sample size is too small to allow for inference of statistical significance.

For example, one review of nutrition surveys carried out in Ethiopia between 2003 and 2008 (more than 340 surveys) concluded that too few surveys provided sufficient detail on the representativeness of the study population, contextual concerns, baseline conditions, trend data, and potential confounders (such as previous or contemporaneous interventions), nor were there always plausible links made between program components and expected outcomes [18]. In other words, many potentially useful studies are excluded because insufficient information was provided by the authors, even when the study design was of a high quality. If the reviewers cannot obtain full answers about potential sources of bias (and hence the quality of the study) from the paper itself or from the authors, they cannot have full confidence in the interpretation of the reported findings. Thus, information gaps downgrade the perception of study quality.

There are several major categories of bias risk commonly assessed in the screening of study quality [10, 11, 19, 20]:

Random selection of study participants (called random sequence generation), which entails ensuring that some element of randomization is included in sample selection. Convenience or purposive sampling carries at least an unclear risk, if not a high risk, of bias.

Avoiding bias in participant access to interventions (allocation concealment). This requires the provision of adequate information to assess any bias in treatment (those who were supposed to get it did get it, there was no systematic exclusion of certain categories of population, etc.).

Complete outcome data provided (no missing findings). Many studies report positive impacts without presenting full data on, for example, default rates, people lost to follow-up, and mortality or relapse rates. Even if these data are provided, information is needed on the distribution of such outcomes across intervention groups to be able to assess any introduced bias by subgroups.

Selective reporting. It is important to avoid "cherry-picking" results to the exclusion of findings that do not support the study's hypotheses. Reviewers consider whether prespecified primary outcomes are all reported and analysis methods proposed in a research protocol were actually applied.

Additional sources of risk could include leakage of intervention effects into control groups, and baseline confounders (systematic differences between intervention and control groups not specified). Each of these elements is graded as having "low risk of bias" (hence a study element of high quality), "high risk," or "unclear risk" (with researchers often referring to the GRADE working group recommendations on how to determine the quality of evidence) [19]. Reviewers will also consider the risks of bias inherent in the study design used (relative to the primary questions posed), whether an assessment of sample population heterogeneity was conducted, if sensitivity analysis was pursued on analysis specifications and results, and whether appropriate analytical methods were applied to the data [21]. Researchers seeking to ensure that their studies, even if published, will contribute to building the body of evidence on which policies are made must take each of these risks of bias into account at the design stage of their studies and address them directly in the text in sections explaining methodology and/or study limitations.

Existing evidence from systematic reviews on wasting

Between 2011 and 2015, roughly half a dozen systematic reviews were conducted on the management of wasting (SAM and MAM). (Not all are included here, since several remain unpublished at the time of writing.) They did not all apply identical exclusion criteria, include the same papers, define the same cutoffs for the range of publication years considered, or focus on the same types of research designs or interventions. Key findings of the five most cited reviews are briefly summarized here, as well as their common conclusions.

Picot et al. examined the effectiveness of interventions to treat children under 5 years of age with SAM [12]. Based on the 68 studies that were retained for review, they concluded that community (home-based) care of SAM was at least comparable to inpatient care in terms of effectiveness, but that for most important questions "evidence was lacking or inconclusive" [12]. The reviewers made a strong case for a need for more research on most aspects of the management of SAM in children.

Sguassero et al. conducted a review of community-based supplementary feeding interventions for promoting the growth of children, which updated a prior review from 2005 [14]. Although this was not exclusively focused on the management of wasting, outcomes and programs addressing wasting were included in the search. Based only on randomized, controlled trials, the review of eight studies found "high levels of clinical heterogeneity in the participants, interventions and outcome measures across studies," which prevented any formal generalization of results. Indeed, the authors were forced to state that "the scarcity of available studies and their heterogeneity makes it difficult to reach any firm conclusions" and that "future studies should address issues of research design, including sample size calculation, to detect meaningful clinical effects and adequate intervention allocation concealment" [14].

The Cochrane review by Schoonees et al. [13] was explicitly focused on evidence relating to the use of ready-to-use therapeutic foods (RUTFs) in home-based treatment of SAM. Focused on randomized and quasi-randomized controlled trials, the review sought to assess rates of recovery, relapse, and mortality as primary outcomes. After screening 2,830 records, 26 full-text articles were retained for scrutiny, which delivered just four studies meeting the defined eligibility criteria, of which three were classified as "having a high risk of bias" [13]. With such a small sample, the review was forced to conclude that "given the limited evidence base currently available, it is not possible to reach definitive conclusions regarding differences in clinical outcomes in children with severe acute malnutrition" and that there remains an urgent need for "well-designed, adequately powered pragmatic randomized controlled trials" to answer key questions in this domain.

Lenters et al. [16] were less restrictive in setting their inclusion criteria in a systematic review of the effectiveness of treatments for both SAM and MAM. More than 10,500 titles and abstracts were identified, of which 247 were included for full content review, resulting in 14 studies for analysis. These authors found that for the treatment of MAM, children receiving lipid-based food supplements were significantly more likely to recover and less likely to be nonresponders than children receiving grain-based fortified blended foods (such as corn–soy blend), but that although the differences were statistically significant, they were small and of uncertain clinical significance. The reviewers concluded that limitations to the analysis included "considerable heterogeneity in many outcomes and an inability to evaluate intervention effects separate from commodity effect" [16].

The most recent Cochrane review by Lazzerini et al. [15] focused on studies dealing with specially formulated foods used in the treatment of MAM (not SAM). The reviewers searched 13 electronic databases as well as consulting with key informants familiar with the unpublished literature on the topic. Their search generated 8,900 references for possible inclusion in the review, but of these only 298 represented studies appropriate to the analysis. The full text of these articles

was read by multiple researchers, who found that 287 had to be excluded for a variety of reasons (tabulated as an appendix to ensure transparency of reporting on the review process). Thus, only eight trials (reported in 11 of the papers) were ultimately used for the analysis. The authors concluded that there is "moderate to high quality evidence that both lipid-based nutrient supplements and blended foods are effective in treating children with MAM" and that since lipid-based products did not reduce mortality, the risk of default, or progression to SAM better than fortified blended foods, such "blended foods may be equally effective and cheaper" [15].

Although the topics, targeted papers, and tone of these reviews are quite different, they all deal with the evidence for effective management of wasting in developing countries, and a number of common conclusions stand out:

» There is evidence that food supplements of various kinds *are* effective in the treatment of SAM and MAM, where "effective" is defined as meeting minimum Sphere standards for rate of recovery and percentage of those treated exiting successfully from treatment [22]. In other words, existing food products and protocols for their use in treating wasting are "known to work."
» Lipid-based ready-to-use foods show evidence of generating faster and greater weight gains in children with MAM than grain-based fortified blended foods.
» The clinical significance of faster weight gain or time to reaching exit criteria remains to be determined in terms of sustainability of recovery (relapse rate after exit from treatment).
» There is little evidence of a statistically significant difference between types of foods used in treatment regimes in terms of mortality outcomes, default rates, or progression from MAM to SAM.
» An absence of high-quality, rigorous studies, with adequate statistical power and appropriate design, focused on answering key questions remains a major constraint to generating generalizable, evidence-based conclusions.

In other words, a range of current treatments that follow existing protocols for ensuring adequate program coverage, inclusion of those in need of treatment, and necessary quality of implementation do seem to be effective interventions where wasting is a serious threat to child mortality. However, very little else can be said with any scientific certainty about what works best, in what settings, and at what cost.

Gaps in knowledge and constraints on evidence quality

The current state of evidence on how best to address the global problem of wasting does not include rigorous data on the cost-effectiveness of a range of approaches; the potential contribution of home-based diets to improving outcomes; the effectiveness of existing products and approaches to preventing MAM (i.e., stopping mild wasting from evolving into MAM); incidence rates versus prevalence of MAM or SAM; the seasonality effects of wasting and how they affect recovery rates and relapses; subgroup analyses of effectiveness that adequately control for initial conditions (health history and comorbidities of affected children); the potential role of intensive behavior change communication and/or provision of cash or vouchers, with or without food, in the management of MAM in different kinds of market settings; cognitive versus physiological outcomes of treatment and recovery; or the relative dose–response of food treatments containing various levels of animal-source protein, specific amino acids, different forms of micronutrients, or probiotics. Indeed, the state of evidence is extremely weak, and there are many important information gaps that urgently need to be filled. Lazzerini et al. [15] clearly point to "limitations in the completeness of evidence and its generalizability," while Lenters et al. [16] express frustration with the continuing "gaps in our ability to estimate effectiveness." In other words, the need for strengthening the evidence base for action is long overdue.

Recommendations for building stronger evidence

Lowering the bar of rigor is not a solution. Although it may be appropriate to challenge many analysts' focus on randomized, controlled trials as representing the highest "quality" of evidence in all circumstances, current gaps in operationally relevant knowledge must be filled with generalizable, replicable studies that are better designed, more transparent in potential bias risks, and accommodating of the parameters that will make their inclusion in future systematic reviews more likely. Those involved in study design and the programs being studied should digest the (high-quality) literature and consult with research experts to determine appropriate study designs that will convincingly answer questions being posed. High-quality studies come at a price, but the cost of collecting poor-quality data that do nothing to enhance knowledge is far higher.

The criteria that will likely enable a study to be included in a systematic review (and perhaps meta-analysis) are not insurmountable. Careful consideration of the design and reporting elements that would make a study ineligible for review inclusion is essential. For example, a systematic review conducted by Masset et al. [23] in a different (but related) sphere of development work noted that "few studies performed a rigorous counterfactual analysis of the impact of the interventions. Most studies neglected the analysis of the characteristics of program participants. Sample

sizes were often inadequate and power calculations for determining sample size were rarely performed or presented. Most studies were based on good conceptual framework and analyzed intermediate outcomes, but often relied on inappropriate outcome indicators. Finally, all studies neglected the analysis of heterogeneity of impact and were unable to extrapolate results outside the area of the interventions considered."

In other words, fairly basic and avoidable research design and analysis flaws continue to impede the professional community's ability to find trustworthy evidence on which to pin important decisions and investment choices.

The solution lies with enhanced collaborations among practitioners and researchers to better achieve common goals, as well as greater inclusion in the prioritization of evidence needs of donors, national policy makers, and editors of the academic journals that publish even the weakest of studies. Everyone involved needs to understand the information gaps that result in an "unclear" or "high risk" of bias grading by reviewers. The writers of research grants should aim from the outset to achieve a "low-risk" assessment by ensuring that they provide as much detail as possible not just on study design but on the characteristics of the population, the setting, and the interventions considered. Less is *not* more when it comes to convincing reviewers that possible biases were taken into account. Limitations should be clearly acknowledged, and findings should not be overinterpreted for the sake of publication potential.

Conclusions

There remain a large number of evidence gaps that require priority attention for policies and programs to be appropriately designed and implemented. Although every study faces tradeoffs in terms of feasibility, cost, desirability, and rigor, poorly conceptualized or badly conducted studies should not be funded, implemented, or published. The idea that "some data must be better than no data" is false when the data collected are either not used or useless and when scarce resources could have been used in other productive ways. That said, high-quality studies are feasible, and strong evidence-based recommendations can have huge policy and programmatic significance. Many governments and nongovernmental organizations are investing in generating stronger evidence for what works in the management of MAM and SAM, but researchers need to be fully aware of where the bar has been set. As Kerac and Seal [5] put it, the publication of high-quality studies on the treatment and prevention of wasting feeds directly into improved practice on the ground; but researchers and practitioners alike should reach for appropriately high standards of rigor so that future dialogue on best practice "can be more scientific and focused on evidence rather than ideologies."

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