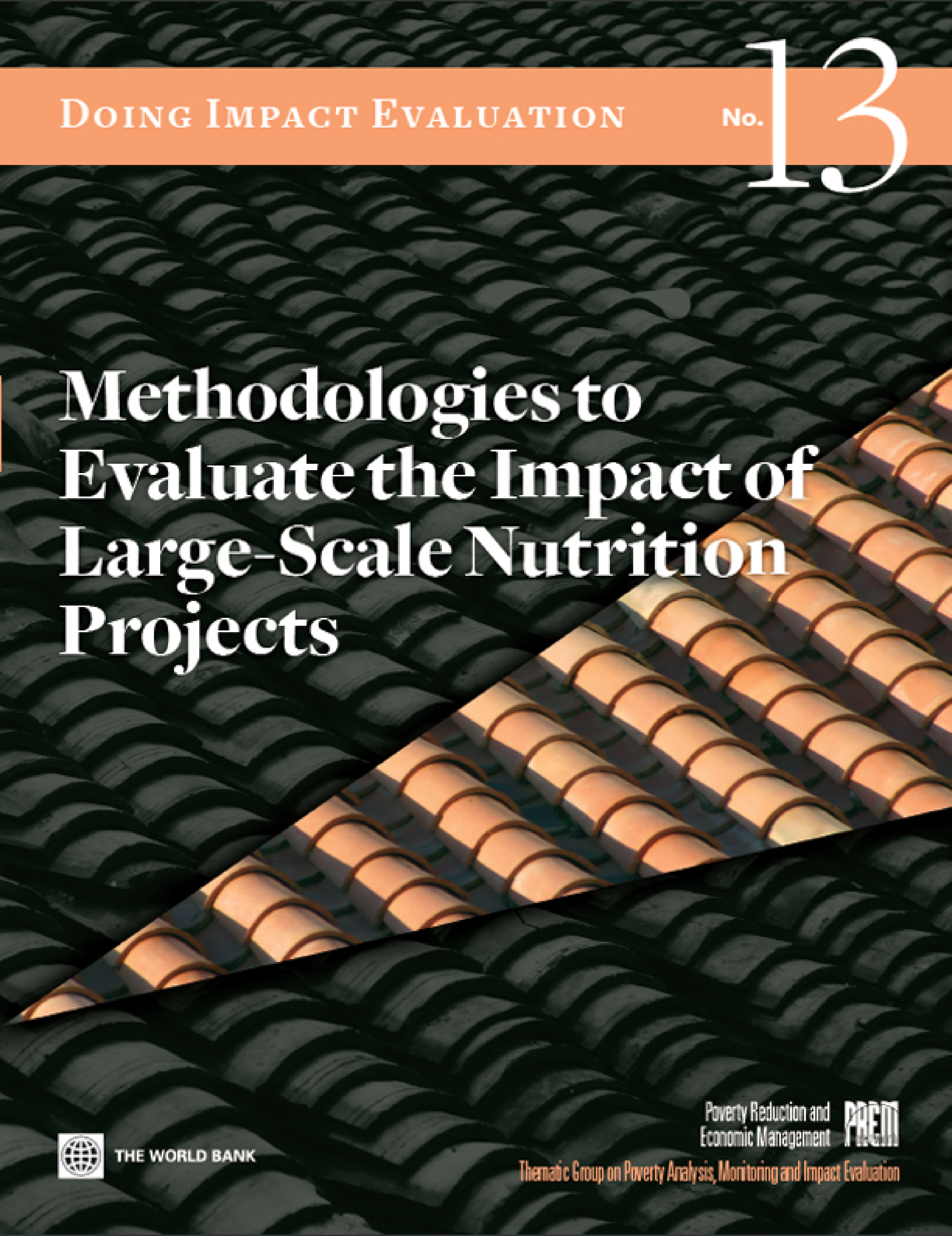

Doing Impact Evaluation No. 13

Methodologies to Evaluate the Impact of Large-Scale Nutrition Projects

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Methodologies to Evaluate the Impact of Large Scale Nutrition Programs

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Executive Summary

Recent evaluations of large scale social interventions have used randomized control trial (RCT) designs that require the identification of comparable areas before the intervention is initiated so that some areas can be randomized to receive the intervention, while others serve as controls. An RCT begins with a baseline survey to collect data before the program is implemented and then a follow-up survey is conducted after the program has run long enough to have an impact. RCTs are not only technically, programmatically, and financially difficult, but also delineating between treatment and control groups can be politically challenging. RCTs also require lag times that are long enough (3-5 years) to ensure that impact can be validly measured.

RCTs are used to establish the efficacy of interventions at several levels, from the clinic to the field. RCTs of large-scale programs should be reserved for ascertaining the highest level of program efficacy. Under certain conditions, they can also be used to assess program effectiveness. Effectiveness evaluation refers to the examination of the results of a program under usual operational conditions, in contrast to efficacy evaluation, in which the program is undertaken under more ideal conditions. There are several prerequisites for determining whether an RCT design is appropriate for the evaluation of a large scale public health intervention that is intended to improve health outcomes: (1) there has already been confirmation of the social, behavioral and biological theories that support the intervention and the development of these theories into an integrated "program theory", which is the basis of the program design and evaluation; (2) the expected impact and criteria of adequacy are defined; and (3) pilot testing has confirmed that the intervention can be implemented. Although there are situations in which large scale programs need an RCT to confirm efficacy for legitimate political purposes, this report recommends that, in general, program efficacy RCTs should be reserved for evaluations of large scale social and public health programs. These provide not only evidence of one time impact, but also are aimed at determining that the impact can be replicated in the future and in other settings within usual public health or social programmatic environments.

The prerequisites for an RCT for large-scale programs go beyond probability designs, which are aimed at assuring internal validity through testing the probability that the program had an impact. In a public health evaluation, the design must also ascertain that the impact was plausibly due to specific components of the intervention. The probability analysis of an RCT results in a higher standard of internal validity than that obtained with plausibility analyses. An RCT also could, in principle, separate out the important components, although this is unlikely to be either theoretically useful, much less feasible. Moreover, careful plausibility analyses can identify the important components of the interventions by confirming the pathways through which these are implemented (program delivery factors) and mediated through families and individuals (utilization factors) to produce biological or behavioral outcomes. Plausibility analyses require added design features and data collection, embedded within an RCT. These do not necessarily add significantly to the costs of the evaluation. Plausibility analyses should also identify which recipients of the program were responsible for the impact. This information is

useful for improving program targeting and also improves the internal validity of the analysis. Most importantly, it is essential for inferring the generalizability (external validity) of the impact.

This report recommends that RCTs of inadequately implemented programs should be aborted. This would save more than half of the cost of a full RCT and, more importantly, avoid inappropriate inferences about the potential of similar programs. Coming to a conclusion about the quality of program implementation requires operations research that need not be costly, but must be timely to be useful. The findings from such research can be fed back to the program to improve it. Operations research should also ascertain whether the economic and social circumstances are changing. Both changes in the program and in the environment need to be carefully documented and taken into account in interpreting the RCT findings.

Non RCT evaluation designs should follow the same principles described above, except that they must also demonstrate plausible causality of the overall impact. In these cases, plausible demonstration of causality may be less costly than an RCT because of savings from reduced data collection. This report explains why these potentially much less expensive and timelier evaluations are adequate for most program and policy decisions.

The remaining part of the report discusses the technical aspects of design and analyses for RCTs of nutrition interventions and for the plausibility and the adequacy investigations. It presents technical information for evaluating nutritional interventions, including types of interventions and their beneficiaries, as well as indicators to assess nutritional impact. A final section discusses ethical principles and related legalities that evaluations must consider.

1. Introduction

This report is designed to provide guidance on evaluating the impact of large scale nutrition intervention programs that are aimed at preventing and/or curing undernutrition. We review the requirements for evaluating by means of a probability design, ie. randomized control trials (RCTs), and discuss under what circumstances evaluating for plausible impact and for adequate impact are sufficient and should be the methods of choice because their designs are operationally more feasible (Habicht et al, 1999). We discuss the various uses of data from evaluation studies and the requirements to meet these uses. Regardless of the type of design that is selected, most of the material that we cover is pertinent for all evaluations of nutrition intervention programs.

Undernutrition. The term "*undernutrition*" is used to refer to micronutrient [vitamin and mineral] and macronutrient [energy and protein] deficiencies, and we will cover both aspects in this report. The term "malnutrition" is also commonly used to refer to undernutrition, but as this includes obesity and other nutritional pathologies, it is preferably to use the more specific designation.

Undernutrition is one of the most important public health problems in the developing world, the source of serious short-term and long term consequences. Undernourished children die from common infectious diseases that well nourished children survive (Caulfield et al, 2004). The case-fatality rate is two fold for children who are mildly undernourished, rises to three fold for moderate undernutrition and eleven fold for severe (Pelletier et al, 1993). Since even mild to moderate undernutrition increases mortality risk, and very significant proportions of children in developing countries suffer from mild to moderate undernutrition, this insidious condition is responsible for over half of post-neonatal deaths (Bryce et al, 2005 a). Apart from the mortality toll, children who are undernourished usually experience developmental delays that affect cognitive performance (Grantham-McGregor et al, 1999) not only in childhood, but also into adolescence and adult life (Malucio et al, 2006). Mild to moderate undernutrition is not immediately evident to clinicians, much less to the lay public. This feature makes it difficult to motivate research allocation for nutrition programs compared to programs that are directed to overtly fatal and crippling diseases. The fact that undernutrition produces health and developmental problems at every level along the continuum from mild to severe also has implications for evaluations of nutrition interventions.

Impact. In this report, we define "*impact*" as the effect of an intervention on the biological outcomes that are the objective of a large scale nutrition intervention program. By definition, nutrition interventions are explicitly intended to produce improvements in nutritional status, in addition to what ever other goals and consequences are intended. Thus the final impact measures have to include indicators of biological status.

In simplest terms, we can define "impact" as the difference in outcome measures that can be ascribed to the intervention. The different types of research designs that can be utilized to evaluate the impact of an intervention vary with respect to the certainty with which one can ascribe a difference to the intervention. They vary in the degrees of plausibility and probability about whether there was an impact, the magnitude of the impact, and whether this magnitude was adequate (Habicht et al, 1999). Our discussion in this paper is based on present practice in evaluation of nutrition programs. It is informed by evaluation (Rossi et al, 1999) and statistical approaches (Murray, 1998) augmented by perspectives from an epidemiological point of view.

Certain methodologies, such as those that are used to measure “nutritional outcomes”, are so central to nutritional sciences that there are text book-length treatments of their measurement. We have not summarized the various measuring methods (and their advantages and disadvantages), but we provide references to excellent sources where both general and specific guidance on the use of these methods can be found.

Nutrition Interventions. In this report, we use the conventional definition (adapted from McLaren, 1976) in which “*nutrition interventions*” are defined as: “... planned actions that introduce new goods and/or services into the existing food [and /or health] system for the explicit purpose of improving the nutritional well-being of designated groups.”

For the preparation of this report, we conducted a literature review that permitted us to bring together a corpus of material. The intent was not a definitive description of nutrition program evaluations, but a body of information that would provide substantive examples of evaluations of nutrition intervention programs and an overview of current practice.

We used two types of sources to identify evaluations of large scale nutrition interventions that address undernutrition: (1) peer reviewed journals and (2) agency and NGO reports. In addition to materials that were available in printed form, we also searched agency web sites and contacted authors of agency bulletins, reports or unpublished manuscripts for additional documentation for more details about methodologies, data sources and research designs. Finally, we drew on other relevant information from research and practitioners when the information in the papers was, in our view, too limited, particularly with respect to outcome.

Appendix B lists all of the interventions in our corpus and Appendix A contains a set of tables that provide information on characteristics, variables, and other features of evaluations of large scale nutrition interventions, keyed to the specific studies that we utilized in the preparation of this report. For example, if a reader is interested in evaluations of interventions that involved iron, Table 1 (Appendix A), in the section on micro-nutrients, row labeled "iron”, has references to 3 studies, and a 4th study is listed further down in the table, in the section on food fortification, row labeled iron. Similarly, in Table 4, in the section on biochemical indicators, there are references to 10 studies that evaluated impact of an intervention on hemoglobin, regardless of whether an iron intervention was an explicit input into the intervention.

Evaluations. Adequacy evaluations require benchmarks of attainment or change to compare to performance. Plausibility and probability evaluations require control groups to compare with the treatment group to assess impact. Depending on the situation, it is often methodologically, politically and/or ethically necessary to institute new activities in the control group. Thus, it is appropriate to use the term "intervention" to refer to both the treatment and the control group activities. The selection of the interventions in the control groups is crucially important in assessing the cause of the impact and its generalizability to other situations. Probability evaluations also require that the treatment and control interventions are allocated randomly to the recipients or groups of recipients.

The number of impact evaluations of nutrition programs that use an RCT design is growing, but the majority of studies that have been conducted to date are not RCTs. Therefore, we have drawn on both RCTs and non-RCTs to provide examples of techniques, experiences and other issues that we cover in succeeding sections.

2. The Context of Impact Evaluations: Technical and Social Issues

This section takes up some general issues and questions that are pertinent for the decision to undertake an evaluation and for the interpretation of results. We begin with the reasons for undertaking an evaluation of a nutrition program; we then discuss the logic of evaluation research and the scientific rationale for plausibility and probability (randomized, controlled) trials. This section also examines the issue of what makes an evaluation "trustworthy".

A. Why evaluate nutrition intervention programs?

In the final analysis, the utility of an evaluation depends on its ability to provide information for making decisions addressed to the purpose for which the research was undertaken. Program evaluations fall into two general categories:

(a) evaluations to improve an on-going program
(b) evaluations to assess the impact of a program

The first category, research to improve an on-going program, is often referred to as "formative evaluation”, while the latter is often called "summative evaluation" (Rossi et al, 1999).

In this report we use the phrase "impact evaluation" for research in the second category. One can distinguish four main purposes for which the information from an impact evaluation is used: (1) deciding to continue the program, (2) deciding to expand or diminish the size of the program, (3) deciding to implement it elsewhere, or (4) deciding to stop the program.

All of the project reports we reviewed for this paper were impact evaluations of large-scale programs, and the majority of the reports state that the purpose for undertaking the research was to "assess impact". None of the studies were undertaken for the sole purpose of improving an on-going nutrition program, although some investigators reported that as a second purpose. Only 3 authors from the more than 60 reports we reviewed mentioned extension of a current program, or using the impact evaluation as a source of information to design a new program, as a reason for doing the research. However, the information that is generated by evaluations is often useful for improving programs. An evaluation that focuses exclusively on the measurement of impact may be sufficient for a decision to continue a program or to stop a program that is not having an adequate impact and for which there is no interest in improving it or in determining the reasons for lack of impact. However, an evaluation that focuses exclusively on impact cannot yield insights on why a program is failing to achieve its goals or whether this failure is due to problems in implementation or incorrect assumptions about the biological and behavioral mechanisms of action.

Often the decisions that will follow from an evaluation are not clearly articulated, and the importance of including information on why a program is failing to achieve its full impact is not clearly specified when the evaluation is being planned. It would be naive to assume that the sole, or even the primary, reason for establishing a nutrition intervention program is always to improve the nutritional well-being of the population in which the program is situated. Other social, political and economic motivations are often involved. Similarly, the decision to evaluate the nutritional impact of an intervention may also be motivated by several factors in addition to a desire to assess whether there are improvements in biological outcomes. Regardless of what other motivations might be involved, an appraisal that is concerned with determining a program's impact on nutrition needs to attend to the steps through which a program can achieve its intended outcome, and ascertain that each of these steps is adequate before evaluating for impact.

Program Theory. The value or importance of explicating the logical sequence of steps that link inputs to outcomes cannot be stressed enough, in part because it rarely receives the attention it deserves - either in the initial design of programs or in their evaluation. In the evaluation literature, this set of steps or linkages is often referred to as "program theory". Epidemiologists commonly couch this in terms of "causal pathways". "Proof of construct" is another phrase that is used to refer to input-outcome linkages. Each of these phrases refers to the set of assumptions (articulated or implicit) that underlie the decision to undertake a particular intervention with the aim of producing an outcome. Common to all of these concepts is the recognition of the sequential nature of the steps that are required to achieve a desired outcome. Programs can fail to achieve their goals because of a failure in one of the steps and/or because some part of the "construct" ("theory") was wrong. In the case of nutrition program evaluations, where impact is assessed as a change (improvement) in a biological measure, there are several steps at which either implementation issues or constructs (or both) may lead to reduced impact.

The basic pathway that underlies many nutrition interventions begins with a focus on the food sources that are available to a household and concludes with the biological outcomes from the consumption of those foods (see 6. Types of Interventions). There are various ways in which programs may be designed to increase household food availability, and each of these pathways contain a set of steps that link program inputs through program activities to increased household availability. Improved household food available requires a series of steps before there is improved food intake by young children. The greater the level of specification in the program theory, the easier it is to identify what features of the intervention - implementation or constructs or both - reduced or supported its impact.

One of the most difficult challenges for program impact evaluation is that, in the usual case, one is simultaneously testing the adequacy with which the intervention has been operating and the underlying social and biological constructs at the same time. Even when the biology is thought to be well-understood, the assumptions about the intermediate programmatic delivery and utilization steps that link the "input" (biological agent) to the "outcome" (biological response) may be incomplete or incorrect. As it is difficult in an impact evaluation to completely avoid the problem of distinguishing implementation problems from problems in the underlying assumptions, we will discuss, below, strategies for reducing the challenges this poses for the interpretation of results of an impact evaluation. To set the stage for that discussion, the next section provides an overview of the research steps that have employed randomized controlled trials to progressively assess interventions to improve nutrition in populations. Our presentation is clearer if we concentrate on RTC’s because we avoid having to deal with the uncertainties that occur in plausibility trials.

B. From biological agent to biological impact in a population: steps in the process of assessing nutritional interventions

Clinical trials in the field

Testing the biological efficacy of a prescribed regimen in a field setting is the first step for assessing a potential public nutrition intervention after laboratory and clinical human studies have shown its potential. Such studies require strict control of the intervention. An example is an ongoing zinc supplementation trial in Guatemala. This trial, which is being conducted in schools, randomizes children within the class rooms to receive zinc or a placebo. Tablet intake for each child is observed, and, through careful record-keeping, investigators can be assured that the intervention (zinc) was biologically delivered to (ingested by) the individuals in the treatment group and was not delivered to individuals in the control group.

Another variant of a clinical field trial is one in which all the individuals in a cluster (e.g. classroom or village) receive the agent. There is no difference between cluster level and individual level trials in the rigor with which one ensures the delivery of the biological agent. The famous studies that provided the proof of the life saving properties of vitamin A, conducted by Sommer and colleagues, used both individual and cluster level clinical trials (Sommer and West, 1996). The implementation of such studies is not compatible with implementing a large scale public health intervention and only a research study can adequately control the ingestion of the biological agent (food or nutrient supplement).

Utilization efficacy trials

Once nutritional regimen efficacy is established, and one is sure that the biological context is similar enough to justify the assumption that it will have similar biological efficacy in another context, the next step is to evaluate utilization efficacy on the biological outcome. Utilization refers to the uptake of the intervention by the intended “target unit”. Sometimes the food or biological agent is given to an individual who takes it home to consume (Ekstrom et al, 2002). Often the utilization pathway is more complex and involves sequential target units. For example, the ultimate target may be an infant or young child, but the responsibility for delivering the agent to the child is assigned to the household, or more specifically (although often ambiguously) to the child's caregiver. (Bonveccio et al, 2006). In some cases, the “target unit” is a community (Chen et al, 2005).

The purpose of a utilization efficacy trial is to determine whether the target units will actually accept and use the intervention in a manner that leads to biological impact. Thus, the strategy in this type of efficacy trial is to ensure that the intervention is adequately delivered to the targeted unit (e.g. individual, household, community), which then permits one to assess response, along the pathway from participation to biological outcome.

Several steps need to be examined in utilization trials: (i) participation of the intended beneficiaries; (ii) "adherence", which is compliance with the appropriate use of a service or good provided by a treatment intervention, and (iii) biological impact.

"Adherence" is a term that covers the range of behaviors that mediate between delivery and ingestion. For example, when the intervention is a nutrient supplement that is added to foods to increase micronutrient intake in young children (Menon et al, 2006), "adherence" involves the set of behaviors that a caregiver needs to carry out to ensure that the preparation is correctly mixed, added to foods for the child and not given to other family members, fed to the child, accepted by the child and actually ingested. Utilization efficacy trials require measures of both adherence and impact.

Food and nutrients are not the only deliverables in nutrition programs. Information and motivation are usually also necessary, and sometimes these non-nutrient bearing interventions are delivered without food or supplements. Randomized assignment in a utilization trial of these interventions is only warranted if the availability of the prerequisite economic, food and social resources that are necessary to act on information have already been examined, and there is reasonable assurance that these are in place.

Utilization efficacy studies are difficult to interpret if there is a negative finding because the absence of effect could be due to false expectations about adherence (compliance) or to confounding biological factors that were not adequately revealed in the clinical trials. It is therefore essential to know whether adherence was adequate by assessing all the steps from participation in receiving the intervention until the ingestion of the food or nutrient. Because this data collection requires special expertise, utilization trials are best conducted by a research agency, not a programmatic agency, although it is often feasible to embed the study within a public health operation.

Program efficacy trials

The randomized control efficacy trials described above are designed to ensure that the intervention is capable of producing a biological outcome when it reaches its intended biological beneficiary. When one is sure that the biological and household contexts are similar enough to guarantee efficacy if the intervention is delivered, one can then test its efficacy when it is delivered through a program. This is still an efficacy trial because the program delivery system is set up to function as envisioned and planned. Program inputs, including design according to correct program theory, training, supervision, and supplies are assured (Penny et al, 2005; Menon et al, 2002) but the actual program delivery to the intended target unit is not assured. Thus, this type of trial is a test of the full set of constructs (program theory) on which the intervention is based, including the constructs about bureaucratic behavior. A program efficacy trial may assess the impact of a new program, or of an addition to a program, or a change to a program.

Other parts of the pathway from biological agent to impact, including compliance, should be well established before a program efficacy trial is envisaged. However, even when one is confident that these are in place, it would be improvident to measure only biological impact and not collect information on intermediate steps.

If the purpose of the program efficacy evaluation is to design future large scale programs, it would be wise to ensure that the program is administered in the same manner as the future program will be. However, impact evaluation of program efficacy also requires concurrent formative program evaluation, not only for use in the interpretation of the results, but also to improve program performance (Loechl, 2004). In a true efficacy study, it is essential to correct situations that interfere with achieving the delivery, as planned. Efficacy studies that include formative research also present a challenge to program administration, which must be willing to implement required changes in a timely and effective manner.

Program effectiveness trials

In contrast to efficacy trials, effectiveness evaluations study the impact of a program under usual, not ideal, conditions. Programs in which all the effort is concentrated on delivering a single intervention (or package of interventions) to individuals, such as vaccination campaigns, can be easily evaluated for effectiveness using an RCT. This type of evaluation was done for vitamin A supplementation campaigns following after the clinical trials (Sommer and West, 1996). These campaigns deliver the vitamin A directly into the mouths of the beneficiary, and thereby avoid the utilization step completely. They resemble a military campaign rather than a public health program in that all the staff, energies and the program hierarchy are concentrated on a single activity. In many ways, they resemble a program efficacy trial more than an effectiveness trial in the quality control exercised over the program bureaucracy. Major uncertainties relate to coverage more than to delivery. This participation component warrants evaluation, but it is rarely done even though it does not require an RCT for relevant program decisions.

In the past, effectiveness has usually been judged in relation to expected adequacy as measured by coverage and by whether the public health outcomes are evolving over time in the expected direction. Impact has been examined by plausibility analyses in which investigators compare outcomes in those who participated with those who did not, taking into account factors that affect both participation and the outcome. The recognition that randomized trials might be used to assess effectiveness of more complex programs is relatively recent. Most of the nutrition intervention RCTs we identified pertained to nutrition education and conditional cash transfer programs that depend on complex household and bureaucratic response behaviors for their success.

C. Trustworthiness: the credibility of an intervention

Decision makers must believe the inferences made in an evaluation report. This trust depends on how the evaluation is conducted and how its quality is judged. It also depends on the position and perspectives of the users/readers. Program managers tend to trust a report that is intended to be useful for improving an ongoing program if they have been intimately involved in setting the evaluation objectives, understand how the design helps to meet those objectives, and are involved in the interpretation of the results.

Many people believe that the prerequisites for a good impact evaluation are incompatible with the prerequisites of a useful formative evaluation of an ongoing program. There are two elements to this belief:

1) The assumption that involving program implementers in an impact evaluation may bias the measuring and reporting of the results that are used to assess outcomes.

2) The assumption that involving program implementers in the evaluation may change the intervention so that it is no longer the original intervention that was to be the object of the evaluation.

This report focuses on impact evaluations that are intended to provide information that is useful for policy makers, who generally tend to base their assessment of the quality of a report on technical expert opinion. Technical experts define quality according to a combination of their judgment of the logic of the presentation and the algorithms that have been used in the evaluation design (sampling, data collection and analysis). These experts' judging standards are rarely made explicit, and often are unrecognized by the experts themselves. They depend in large part on the disciplinary training and experience of the expert (McCloskey, 1998).

Many readers of this report depend on the opinion of experts who are economists. Until recently, economists believed that they could determine impact without taking the step of allocating the intervention to the recipients, provided they could estimate the characteristics of those who received the intervention sufficiently well that they could compare them with others with identical characteristics who did not receive the intervention (see instrumentalization in Judge et al, 1980). This is similar to the position taken by many epidemiologists when they control, through statistical analysis, for factors that may be different between those who do and those who do not receive an intervention (Rothman, 1998).

Recently, many economists started to think differently (e.g. Ravallion, 2005) and concluded that a randomized control trial (RCT) approach has technical advantages that other designs lack. The statistical approach used in the randomized control trial method was described by Fisher in the 1930's for agricultural research and adopted for drug testing in the early 1950s (Cochrane, 1972), culminating in a canonical methodology (see Appendix C). It has been applied to populations by epidemiologists, beginning in the late 1960s (Habicht and Martorell, 1993; Sommer and West, 1996), and social scientists (for examples see Savidoff, 2006; and Rossi, 1999). It is increasingly widely seen across a range of disciplines as the "Gold Standard" of evaluation design for impact studies because it is the only procedure that is capable of providing a probability statement that the observed impact was caused by the intervention (Habicht et al, 1999).

However, it is wise to remember that the quality that is defined as" adequate" at one time may not be judged as adequate at another time, even in the same discipline. We believe that the present wisdom about the appropriateness of using randomized control trials to provide impact information in populations will be found wanting (Victora et al, 2004). In part this is because the "Gold Standard" only specifies the procedures that improve the certainty of the impact and its magnitude. This certainty is important in some circumstances, but not in others. And this certainty of impact is insufficient for many decisions. Thus one needs to ask: for what decisions are impact evaluations warranted, or even essential? For what decisions are impact evaluations not warranted? For what decisions do impact evaluations, as presently conceived, fail to provide the necessary information?

3. Deciding to undertake an evaluation to assess nutritional impact of a program

The issues discussed in this section are pertinent to any impact evaluation. They are especially pertinent to an RCT because the difficulty and cost of implementing an RCT is so great that deciding when an impact evaluation is not warranted is more important than for other evaluation designs.

A. Explicit purpose

Before undertaking an impact evaluation, the purpose of the study should be examined to be sure that this type of evaluation is necessary to achieve the intended purpose. High plausibility or probability evaluations are required to:

1. Provide evidence through a program efficacy trial that an intervention or set of interventions can work when it is fully implemented under ideal conditions.

2. Provide evidence that a program that has already been shown to work in an efficacy trial is effective when it is brought to scale.

3. Provide evidence that a successful program can be extended to situations that are similar in those in which effectiveness has already been demonstrated.

> This purpose requires knowledge about the conditions that are thought to be the reasons for success. Again, this requires an examination and testing of the program theory at each the of the pathway steps between intervention and impact.

4. Provide evidence that an effective program can work when it is extended or replicated in new areas or situations that are different from those in which effectiveness has been demonstrated.

> Extending a successful program to another situation requires program theory about the barriers and facilitating circumstances that need to be taken into account in extrapolating impact from one situation to another. This means that the planning for the evaluation must identify likely synergisms or antagonisms (effect modifications) of the new conditions so that effect modifiers are examined.

Plausibility evaluations are warranted for the following decisions:

1. Deciding to stop the implementation of a potentially damaging program. Setting up a probability evaluation (RCT) for this purpose of demonstrating causality of pernicious impact would be unethical. Other methods should be used.

> Sometimes it is necessary to know the magnitude of the beneficial impact to weigh against the damaging impact for a program that has already been implemented. Other methods that do not endanger future recipients of the program can give answers that are plausible enough to make these decisions. These methods involve the use of rapid non-longitudinal and non-randomized evaluations of the present program.

2. Deciding to stop a program for which there is no interest in improving it.

B. First steps

The decision to plan for any evaluation should be made before an intervention is mounted. A baseline survey needs to be conducted in the population where the program will be sited. If an RCT is to be used, a randomization procedure must assign communities or areas to intervention and control groups.

This early stage of planning for a potential impact evaluation is the time to examine the program theory that underlies the intervention. As discussed above, every intervention has a theory which underlies its planning and implementation. This "program theory" explains why the intervention is supposed to produce the desired results (e.g. Bryce, 2005b). If it is wrong, it is less likely that the intervention will have any impact, even if it is well implemented. Getting program theory "right" is particularly important for nutrition interventions because these usually involve complex biological and psycho-biological interactions as well as all the social factors and interactions that are at work in social-behavioral interventions.

Assessing the adequacy of the program theory requires multi-disciplinary inputs from the spectrum of disciplines that are involved in the pathway from input to nutritional impact. Tracing the pathway requires substantive knowledge about the diseases and conditions being addressed by the intervention and about the causal pathways. For example, in a food intervention, one needs to trace the pathway from the source of the food to the program, from the program to the household, and from the household to the beneficiary in the family to be sure that the program theory assures that the food will reach the beneficiary. As part of the assessment of the program theory for the intervention, it is also important to identify other pathways that could explain how the intervention might function, including synergistic (facilitating) and antagonistic (blocking) conditions and processes. Tracing the pathways is also necessary to identify intermediary outcomes and processes that should be measured during the evaluation to be sure that the pathway is actually followed.

None of the evaluations reviewed for this report had adequate descriptions of program theory, and it is probable that the explanation for some of the evaluations that failed to show an impact can be traced back to basic problems in the assumptions about how the program was expected to achieve an impact; that is, to problems in the program theory. This prerequisite step of tracing pathways and the critical review of the program theory is likely to change an intervention considerably, so enough time must be given to this step for the consequences of this effort to be incorporated into the program design. Program theory is as important for program effectiveness evaluations as it is for program efficacy evaluations.

C. Ascertaining the quality of the implementation

Prior to undertaking the follow-up study to obtain data on impact, the quality of program implementation should be ascertained. This is most efficiently done in steps (Mason, 1984). Each step carries increased costs in time and resources; however, all of these costs are a fraction of the cost of follow-up surveys for a probability or plausibility evaluation.

Even a well planned intervention based on correct program theory will not be successful if the resources allocated to it are patently inadequate, or if its administration is obviously inadequate to provide staff, resources and supervision. These matters can be ascertained relatively quickly and inexpensively from documents that are available at a central level (e.g. project monitoring data), or from the absence of such documentation.

If all is well at the central level, the next issue is implementation in the field, which may be so inadequate that no impact could be expected. Ascertaining the quality of implementation in the field is also most efficiently accomplished in steps. The first step is field visits by experts who know how to ascertain adequate implementation of the specific intervention or program through appropriate sampling and investigative methods. They can quickly decide if implementation is grossly inadequate. Less gross inadequacies in implementation require more careful investigation and more expertise in qualitative operations research.

None of the impact evaluations reviewed for this report indicated that preliminary work was undertaken to determine the quality of implementation prior to mounting the impact evaluation. Had this been done, some of the program evaluations would not have been conducted because the preliminary investigation would have revealed inadequate implementation.

We believe that a primary reason that these necessary preliminary steps are not usually taken is that their relevance is not widely understood. Typically, experts with skills in conducting RCTs do not have the type of program experience that sensitize them to the importance of assessing quality of implementation prior to impact evaluation. Also, they often do not have the type of field research expertise to conduct the "quality of implementation" research.

In some of the evaluation reports, one can surmise that an impact RCT was the only study that was bureaucratically and politically feasible, and that the funds for the RCT evaluation were not fungible for a formative evaluation to improve the program. This last possibility means that the agencies that fund RCTs must have a larger vision about how to allocate funds for evaluation than seems to be the case presently.

D. Ascertaining appropriateness of timing

The appropriate timing of an evaluation depends on three lag times:

1. The time until a program can achieve the quality of implementation necessary for adequate coverage with adequate quality. This is the effective starting time for judging impact. This decision is as important for program effectiveness studies as it is for program efficacy studies.

2. The time it takes an individual to respond to the interventions, and whether that response changes over time. For example, an individual with vitamin A deficiency manifest as night blindness will show improved night vision in less than a week. On the other hand, the response of hemoglobin to iron takes a month (Gibson, 2005), but it usually takes three months before one can identify an adequate response to a public health intervention. In young children, the effect of a nutritional intervention on growth in height is about a month, but the effect is small. The impact increases over time because growth in height is accretionary, so

that maximum effect is seen at two years of age, after which there is usually no more effect. The effect of nutritional interventions on birth weight takes months if the intervention improves the nutrition of pregnant women. It takes years to achieve the incremental effect that is brought about by improving nutrition status of women before pregnancy, and it takes two generations when a still greater incremental effect is sought because the mother is taller due to better intra-uterine and childhood nutrition.

3. The time until an adequate sample size can be amassed for impact. The larger the sample, the easier it is to determine that there is an impact and the smaller the magnitude of impact that can be identified. The magnitude depends on the distribution of coverage at different levels of magnitude of the intervention, and the responses of individual to the intervention at those levels.

There is a trade off between waiting for maximum effect and sample size. Smaller, incomplete effects can be identified earlier if one has a large enough sample. It is best to wait for maximum response by individuals because that permits one to distinguish between an optimal versus an adequate and a partial response. The magnitude of the response and its lag time should be part of the program theory so that they are incorporated into program objectives. This would prevent unrealistic goals and prevent evaluations that are undertaken too early, both of which result in evaluations that conclude erroneously that a program is ineffective. Thus, good program theory provides the guidance necessary to decide when an evaluation should be done.

4. Designing impact evaluations for nutrition interventions

In earlier sections we presented the theoretical rationale for ascertaining the conditions for an impact evaluation. In this section we discuss design issues that are relevant once one has decided to undertake an impact evaluation.

A. Describing treatment and treatment pathways

A full description of the treatment, including the steps in the pathway to biological impact, is an essential prerequisite for an impact evaluation, not only to identify the inputs, processes and outcomes that need to be measured, but also to provide a basis for generalizing to other situations. Most of the evaluations we reviewed for this report were spare in their description of interventions. The more steps that were required between the intervention and the outcome, the less complete was the specification, and few of the RCTs had sufficient description of the assumptions to guide data collection for validating the assumptions or for external validity. We believe that detailed flow charts are necessary to identify the assumptions, and to decide which ones need to be measured. Setting up dummy tables for the appropriate analyses is also useful to identify appropriate statistical methods and examine their feasibility. Reports of impact results need to review the assumptions that were considered, note which ones were found to be true, and give major attention to the discussion of those found to be wanting.

Control and placebo activities

In evaluations, the impact is probabilistically or at least plausibly due to whatever is different between the treatment and the control groups. Program assumptions must be precise about what this difference is supposed to be and design the treatment and control interventions so that the only difference between the two is the treatment or combination of treatments of interest. The most rigorous implementation of this principle is in a clinical trial in which a biological agent is being examined. The control group receives exactly the same "pill" or other nutrient carrier as the treatment group except that the biological agent is absent. Furthermore, all contacts with treatment staff are identical in kind and amount. In these trials, the control intervention is called a placebo, which makes it clear that only the treatment is different. In program effectiveness studies in nutrition, a simple placebo (given to a "negative control group") is often difficult to establish.

Another type of control is a “positive control” group. The “positive control” group receives the same intervention (ie. the same nutrient) but in a different form, one that has been shown to be efficacious in other settings. For example, giving an iron tablet that has been shown to be efficacious against iron deficiency anemia to compare with an unproven iron fortification intervention. Having both negative and positive controls is useful because it provides information on the range of potential response (see further discussion about adequacy of impact in 5.C below).

Sometimes only a positive control is used because it is thought to be unethical not to give a treatment, and one presumes that the "efficacious treatment" that is to be used as the "positive control" is universally applicable. The danger with this use of a "positive control" design, without also having a negative control, is that one makes the inference that the treatment shows adequate impact if the results in the treatment group are as good as the “positive control” groups results. However, equal outcomes in the two groups could occur if the positive control is inefficacious in the new setting, which would be the case, for example, if anemia in the new setting was not due to iron deficiency. The iron intervention literature is bedeviled by a continuing production of such studies resulting in false inferences of effectiveness (cf. Ekstrom et al, 2002). These problems would have been avoided with the use of negative controls.

Describing the treatment context to assess external validity

With respect to an intervention trial, the phrase "external validity" refers to the potential to generalize the results to other populations. This potential depends on the biological and social characteristics of the other populations relative to the population in which the evaluation was carried out. For example, what is the similarity in the distribution of the nutritional deficiency? For equal treatment, the greater the nutritional deficiency the greater will be the biological capacity to respond (Rivera, 1991). Other determinants of the outcome also have to be taken into consideration. For example, when malaria is endemic in an area, the impact of iron supplementation is much less for equivalent average levels of anemia.

Sometimes an adjunct to a nutrition intervention changes conditions in both intervention and control groups in a fashion that can affect external validity. For example, deciding to give basic, but effective, medical treatment to both treatment and control groups in a nutrition supplementation trial in Guatemala made sense given the objectives of the intervention (INCAP, 1993). However, this feature clearly changed the environmental context.

The external validity of a program evaluation should examine the range of responses, not only in relation to biological capacity to respond, but also in relation to household, programmatic and bureaucratic characteristics. Will the program be able to deliver the intervention as effectively in another setting? Will households participate at similar levels and take up what the program offers? Will households use the program inputs similarly? The description of the program that is being evaluated needs to have sufficient information about the program setting, staff deployment, training and supervision, logistics and other factors that affect delivery so that these issues can be examined in new settings. Similar information is required about household access to program services, the factors that determine their uptake of the services, and the factors that determine how these inputs are transferred to the biological target persons.

B. Blinding

Because recipients' knowledge that they are receiving an intervention is, in effect, an intervention in its own right, an important principle in randomized trials is that the recipients are blinded (ignorant) about whether they are receiving the treatment or the placebo. Without blinding, the potential for a biased response is even more likely if the outcome of interest is behavioral (Westinghouse effect). A second principle is that the measurers of the outcomes must also be blind to what the recipients received in order to avoid biases in measurement associated with the measurers’ expectations.

In some nutrition evaluations, double blinding is impossible. For example, an intervention to improve breastfeeding, which involves a behavioral component, cannot be readily paired with a placebo behavior. The breastfeeding mother is aware that she and her infant are receiving an intervention, which may affect other aspects of her behavior toward her infant. In such cases, one develops placebo interventions that expose mothers to the same amount and intensity of an educational intervention, but on another subject (Kramer et al, 2003). Keeping the recipients and the measurers blinded is done by physical separation so that treatment and control groups are unaware of each others' activities. This presents a challenge for the standardization of measurements because the two groups have different measurers. It also provides challenges in developing meaningful informed consent procedures.

Setting up an appropriate placebo is particularly challenging when there is a possibility that the placebo intervention affects a determinant that is synergistic or antagonistic with the treatment in producing an outcome. A good example is the matter of breastfeeding, which is most effective in preventing infant deaths where environmental sanitation is poor (Habicht et al, 1988). A placebo that substitutes cleaning up the environment for an intervention that uses breastfeeding counseling to change mothers behaviors would not give information on the impact of breastfeeding among those living in poor environments, and would impair the external validity of the evaluation for many relevant situations.

Delivering behavioral change interventions in programmatic contexts also involves developing or changing the organizations that deliver the intervention, and designing blinded organizational behavior placebos is very difficult. It is clear that double blinding of recipient and measurer becomes more difficult as one moves from the biological pathways upward to program delivery. Double blinding in program efficacy trials is difficult, but still possible, if the intervention and control groups are sufficiently geographically separated. Double blinding is nearly impossible in program effectiveness evaluations, so one must appeal to plausibility to conclude that an impact is not affected by lack of blinding.

Two placebo problems that can occur in every impact evaluation - including RCTs - are felt to be particularly pernicious:

1. Field activities, including the activities of program staff, are not equally distributed between treatment and controls. Ideally every staff member in the program and every measurer should spend the same amount of time in treatment and control areas. At the least one should be sure that the identity of the individuals who are collecting data are recorded the data set so that this can be examined in the analysis.

2. The vehicle of the biological agent appears different or contains different ingredients in the treatment and control groups.

All program evaluations can endeavor to avoid the first problem, and program efficacy evaluations should endeavor to avoid the second.

C. Allocations of interventions

Allocation to clusters to assess overall impact

Probability and plausibility evaluations must allocate the treatment and control interventions to individuals or clusters of individuals. Allocating to clusters of individuals must take into account that, apart from exposure to the intervention, the individuals in a cluster also have common characteristics that are not shared by individuals in other clusters. This means that clusters are less similar to each other than are the individuals within a cluster. Consequently, each individual provides less information about impact than would be the case if they were less similar. This feature produces a trade-off for investigators between having more clusters with fewer individuals or fewer clusters with more individuals. Part of the decision about the best trade-off is made on feasibility and financial grounds. Part of the decision is made on whether or not one is looking for overall impact or for differential impacts related to different population characteristics, such as examining the effect of iron fortification in higher and lower hook worm-infected areas. The latter requires more clusters and more total individuals.

Characterizing clusters

Before allocation, the clusters (e.g. villages) that are potentially available for the evaluation must be examined to: (a) assess their feasibility for a study and (b) characterize them in relation to conditions that are likely to affect the final outcome.

In an ideal world, all clusters would be eligible for inclusion, but some conditions are so daunting that the cost of including them is prohibitive. For example, access to some villages may be too difficult or the political situation is likely to prevent participation initially or in the longer run. Evaluations of nutrition interventions are often of longer duration than other kinds of evaluations, so that the feasibility for the longer run is important. An example of long-term feasibility problems was encountered in the Progresa evaluation (Rivera, 2004), which required two years to evaluate the impact on growth, while it was politically impossible not to extend the program to the control villages earlier. Of course excluding areas from the sampling frame means that conditions in those areas that may affect the impact of the intervention will impair the external validity of the evaluation. But poor internal validity destroys external validity. Thus, it is better to have strong internal validity in a well implemented program, than poor internal validity in a program with more external validity, so long as the limitations of external validity are well described.

Characterization of the clusters to ascertain conditions that are likely to affect the final outcome is important, particularly to ensure that these conditions are adequately measured. Initial values of the variables that will be used to measure impact usually affect the outcomes. An area with a higher initial value is likely to have a higher outcome value too. The more similar the initial values are among the areas (homogeneity), the more likely that they will be similar on final evaluation except for the effect of the intervention. This increases statistical power, which makes the evaluation cheaper. A good procedure to improve initial and predicted homogeneity across the intervention and comparison groups is to pair clusters according to similarities of initial characteristics most likely to affect the outcome.

However, one also has to pay attention to the problem of contamination between paired treatment and control clusters. Having a thorough program theory will help identify potential areas of future associations of outcomes within pairs. For example, if the same team of front-line health workers delivers the intervention to the treatment group cluster and the control intervention cluster, the likelihood of an association is increased. A program theory that specifies the importance of front line worker motivation and skill for the quality of intervention delivery and utilization would flag this potential problem and the threat it poses for analysis and interpretation.

Assessing comparability of intervention and control groups after randomization

The probability design requires randomization to allocate the treatment to the intervention and control intervention units according to a random process, analogous to flipping a coin. The theory underlying the probability design does not require knowledge of initial values. Only the final results need be used to ascertain impact. However, baseline information is essential for determining the success of the randomization process. Additionally, one can also use the baseline information to look at longitudinal (before-after) changes within the treatment groups and show impact by comparing the within group changes across the treatment groups.

Homogeneity across clusters diminishes the likelihood of large initial differences between the intervention and control groups that occur by chance in the randomization process. However, neither randomization nor relative homogeneity guarantee comparability of treatment and control groups. Therefore, it is crucial to examine the difference between the initial, particularly predictive, characteristics after randomization, but before the intervention is initiated, and do more randomizations until the differences between crucial initial values are statistically very similar between intervention and control groups. Some believe that repeated randomization until an initial condition of no statistical difference between randomized groups is attained (constrained randomization) impairs statistical probability testing for impact. This belief is certainly not true if the criteria to accept a randomization are predefined. Failing to perform constrained randomization can result in initial values being better for the intervention group, which impairs the plausibility of inferring that the final effect is due to the intervention or, conversely, that the initial results were worse for the intervention group, which might cancel out an effect. When inadequate comparability occurs prior to initiation of the intervention, investigators have to deal with the problems raised through plausibility analyses, thereby forfeiting the benefit of the probability design, the only reason for doing an RCT in the first place.

Randomization to identify the impact of specific interventions within a program

Often it is desirable to obtain information about the relative magnitudes of impact of separate interventions in a multiple intervention program. This requirement may be motivated by the need to prioritize the interventions with most cost-effective impacts. The most efficient strategy is to add a new treatment group that excludes the intervention component that is thought to be least cost effective. This would increase the sample size by 50%. Other comparisons to parse out the relative contributions of the separate interventions would cost many times more. Simple designs that test additive impact would still add substantially to the cost but can result in seriously erroneous conclusions because of the likelihood that multiple interventions have synergistic (non-additive) effects. Designs that test for interactions would cost even more. On the other hand, some answers to the question of relative impact may be suggested by plausibility analyses if appropriate data are collected in the RCT, but these conclusions will be tenuous.

D. Data Sources for Evaluations

There are three main sources of data for evaluations of nutrition intervention programs: (a) survey data, (b) data collected by the program, and (c) data collected by other programs or agencies, including routine administrative information. Table 1 shows the types of data sources utilized by evaluations. Many of the evaluations we reviewed used national nutrition surveys for pre and post intervention assessment of impact. None of these were RCT evaluations. The RCT evaluations collected their data by special surveys. Very few evaluations used data from other programs. These consisted primarily of routinely collected health clinic data.

Table 1: . Sources of Data for Nutrition Evaluations

(a) Survey data
"General Purpose" Survey Data (e.g. NHAINES, MICS) Special Purpose Survey Data (e.g. CDD, Morbidity, special marketing surveys) Survey for the Evaluation
(b) Data collected within the program
Administrative Data 1) input data i) supplies ii) training iii) distribution 2) output (beneficiary) data i) delivery/coverage ii) growth and health status Specialized data collected within program being evaluated
(c) Data collected in other programs
Administrative Data (hospitals and health facilities) 1) input data i) supplies ii) training 2) output (beneficiary) data i) delivery/coverage ii) growth and health status Specialized data collected within other programs

5. Probability and plausibility analyses for RCT program evaluation

In this section we deal with analyses for an RCT, which are necessary to establish probability of impact.

A. Probability analysis for intent-to-treat

The appropriate analyses for a probability design require that impact be assessed in all of the individuals whom one intended to treat, whether or not they were actually treated. The counterfactual of interest in this analysis is the comparison of the "state of the world in the presence of the program" to the "state of the world if the program did not exist" (Heckman and Smith, 1995). This is different from the counterfactual for the "effect of the treatment on the treated", which is the "state of the treated in the presence of the program" compared to the "state of the treated if the program did not exist".

The intent-to-treat analysis requires measurements of the impact variables even in those who dropped out or did not participate in the treatment. Only intent-to-treat analysis permits one to ascribe causality to the probability of the statistical test. Unmeasured drop-outs might not have shown an impact or might have shown a negative impact so that not including them in the analyses would have biased the results. The theory underlying the probability analyses does not permit drop-outs.

B. Analysis of effect of the treatment on the treated

Once the intent-to-treat result is in hand, one can estimate a mean treatment effect in the participants by dividing the intent-to-treat impact by the proportion of those who actually received the treatment (Nitsch et al, 2006). These estimates of individual impact are unbiased and cannot be due to other confounding factors that independently affected the outcomes. However, it is important to be clear that this estimate of impact cannot be extrapolated to those who did not participate because the impact, although unbiased, nevertheless includes synergisms and antagonisms that the participants had, which the non-participants might not have had. Conversely, the participants may have lacked synergisms and antagonisms that the non-participants might have had, had they received the treatment.

C. Assessing adequacy of impact

Two of the main reasons for assessing adequacy of impact are as follows:

1. A primary purpose for estimating the adequacy of an intervention with respect to its nutritional impact is to determine its cost-effectiveness. Impact must be assessed relative to absolute change from baseline for cost-effectiveness analyses.

2. Impact may also be assessed for adequacy relative to a predefined expectation, such as diminishing malnutrition by half. When expectations are pre-defined, evaluation planning needs to take into account the fact that nutrition interventions often involve a lag time before they are effective in changing biological status. (see 3.D above).

All of the reports we examined used expectations of inadequate impact as the basis for calculating sample sizes. Logically, these should be less ambitious than the impact one hopes to achieve. The degree to which the expected impact is met is a definition of adequacy. This can be measured as the ratio of the improvement from baseline divided by the difference between baseline and the expected impact.

The most common nutritional impact variables are measured in individuals (these are presented in section 8 below). For the assessment of adequacy, these measures are compiled into summary measures that describe the impact on populations. In clinical studies, these summary variables are often presented in terms of the prevalence of clinical symptoms. For some variables, those that can be meaningfully examined as a continuous distribution, the treatment and control summaries are presented as means. For some variables, it is more common to show prevalence in relation to cut-off points, such as the number of children who fall below a cut-off for serious growth faltering in weight-for-age or height-for-age. In general, public health decisions, including cost-effectiveness measures, are made on the basis of differences in prevalence. Problems are defined as the difference in actual prevalence from some desired prevalence, and impact is assessed as a difference in prevalence. The value of concern in public health is the absolute difference, not the relative difference, which is the usual focus of attention in clinical medicine. Thus, analyses of differences in prevalence, which are performed by logistic analysis, must be transformed from relational to absolute differences.

Another way to measure adequacy of impact is to compare the results to a standard. The standard is usually derived from a healthy population (Rivera, 2004) and can be expressed as the ratio of the improvement divided by the difference between baseline and the standard (Habicht & Butz, 1979). Sometimes the standard that is employed is derived from a “Golden Standard” intervention. For example, Zlotkin and colleagues (2001) compared the results on anemia reduction of a new intervention (Sprinkles) to the results of drops containing iron (a gold standard measure).

D. Longitudinal “before and after” analyses: estimating the “difference of the differences”

As previously noted, the probability theory underlying the RCT approach does not require that baseline information be taken into account in the analysis. However, all RCTs collect initial values before the interventions or program is implemented because this information is required for randomization. Most studies collect the same information in the baseline and the final survey. If the methods of data collection are identical in the baseline and follow-up studies - as they should be - one can take the initial values into account in the impact analyses. The simplest approach to calculate the difference over time is by simple subtraction, and this is usually satisfactory. Rarely are more complicated methods necessary, although they are required if "regression towards the mean" might bias the estimate.

One can use these differences over time to estimate impact by obtaining a second difference through subtracting the first differences between the treatment and control groups. This second difference is referred to as "the difference of the differences". One reason for using the difference of the differences is to improve statistical power in order to achieve greater statistical significance for a same impact. However, the procedure does not guarantee this result. It only occurs if the initial and final measures have moderately high correlations, e.g. of r >.250. High correlations are usual for measures over time within individuals, such as measures of hemoglobin or anthropometry.

In many evaluations, investigators need to assess the impact on clusters, not individuals, and the measures that are compared are cluster prevalences or cluster means. These are not necessarily correlated over time. One scenario is that they are not correlated at all, in which case one needs twice as large a sample size to obtain the same statistical significance. This is a large two fold loss of statistical power. Loss of statistical power is even greater when there is no correlation at baseline, but the matches between treatment and control are correlated at the end of the evaluation. This can happen, for example, when there are differences in the quality of delivery a program as a result of differences in frontline workers, and the same workers are operating in both intervention and control group clusters. In this case, there can be even larger losses of statistical power. In one recent study, the loss was over three fold (Menon et al, 2006).

A correlation between treatment-control matches at the end of an evaluation that was not there at the beginning may indicate leakage of the treatment into the control group. This determination must be made by plausibility analyses. If such is the case, the impact will be greater than estimated by the probability analyses and can be adjusted. The adjustment is a plausibility analysis and cannot appeal to the statistical significance of the probability analysis.

Another reason for using the differences of the differences is to increase the plausibility of the results, especially for consumers of evaluation results who do not understand the premises of the probability analyses. This is a legitimate use, so long as it does not destroy the statistical significance of the probability analyses, which, again, is the only reason for doing an RCT in the first place.

E. Plausibility evaluation within an RCT

The fact that an evaluation uses a randomized design does not obviate the need for plausibility analyses. In this section, we review several issues for which plausibility analyses are essential.

Accounting for loss of randomization

Ascribing a statistical probability statement that the intervention actually caused the impact outcome is the only reason to do an RCT, and this ascription depends on successful randomization. During the design phase, the statistical similarity between the intervention and comparison groups should have been guaranteed by constrained randomization. However, this cannot guarantee that events after completion of randomization also occurred in a random fashion. In an RCT where randomization is at the cluster level and not the individual level, a serious threat is that whole clusters will be affected differentially by unexpected happenings. For example, some clusters might drop out of the study because of political or social events. Alternatively, events such as epidemics, floods, new roads, or increases in income opportunities may be more frequent in control or in treatment villages. All of these events can affect food availability and food intake and thus influence nutritional status. When this happens, the effects of the beneficial events may be wrongly ascribed to the intervention, resulting in a false inference that the intervention caused the impact. Careful monitoring of these events is important so that their effects can be estimated. This effect is a confounding effect and should be taken into account in the estimates of impact. It can never be completely taken into account because it is never perfectly measured, especially when the effects are mediated by dietary changes. However, it is plausible that the event did not cause the impact if the estimate of the magnitude of the impact increases or does not change.

At the individual level, there are three ways in which some participants may stop participating in the study: (1) they die, or leave the study area and cannot be found for follow-up measurement; (2) they refuse to cooperate with the evaluation measurements; or (3) they cooperate with the evaluation measurements but do not participate in the intervention (treatment or placebo). It is crucially important to obtain the final measurements of impact outcomes by tracking down those who have left the area, by persuading the reluctant to participate at least in the measurement of the most important outcome, and by continuing to measure those who stop participating in the treatment so that they can be included in the intent-to-treat analyses. The reason why this is important is because those who drop out of the treatment group may be different than those who drop out of a control group. For instance, those in the treatment group who most need the treatment because they are the poorest remain while those in the control groups leave to seek work elsewhere. An effect of the treatment would then be to retain the poorest diminishing the impact on final outcome, but possibly spuriously increasing the impact on change measurement.

One can include in the intent-to-treat analyses those drop-outs for whom there is no final data by imputing a final value that is the equivalent of "no impact”. Making this decision depends on the plausibility that these individuals would not have suffered a negative impact. Imputing the "no impact" values also involves plausibility analyses.

Another approach is to make a plausible case that omitting unmeasured drop-outs did not bias the results. Two conditions are required to make the case: (1) there is no difference in the number of dropouts, separated into reasons for dropping out; and (2) there is no difference in the initial characteristics of the drop-outs, compared to those who remained in the program. In the final analysis, one must appeal to plausibility that omitting these data does not impair the conditions for applying probability analyses through intent-to-treat comparisons.

Validating the causal relationship of the treatment to the intervention impact

Among the most serious threats to concluding that the intervention was responsible for an impact is the possibility that the activities and biological factors associated with the intervention were not identical between the intervention and control groups. The better the placebo and the blinding, the less this is a problem. However, as discussed above, it is difficult to develop a good placebo for programs, the blinding of recipients is also difficult, and the blinding of measurers is almost impossible. There are several measures that can be taken to strengthen plausibility analyses and arguments. For example, one can conduct interviews with intervention and control group participants to support a claim that they did not realize that they were receiving or not receiving a special program. One can develop evidence to support the claim that a "Hawthorn effect" was not a significant factor (Behrman and Hoddinott, 2001). The Hawthorn effect is named after a classic study, conducted in the 1930s, which showed that simply the knowledge that one is participating in a study or being observed by researchers changes people's behavior. One can correct the data for measurer biases, but other arguments are required to plausibly compensate for inadequate blinding of measurers.

The strongest plausibility argument is the demonstration that the behaviors and activities that were required by the program theory actually occurred at the crucial links between the intervention and the outcome. For instance, records of program delivery can be shown to correspond to reports from those to whom the delivery was targeted; the movement of foods and nutrients through the household occurred as predicted; the targeted biological beneficiary ingested the nutrients or food; and the intermediary or ancillary biological responses were as expected, given the impact. An example of the latter (ancillary biological response) is the demonstration that ferritin increased in an iron intervention that improved hemoglobin.

Estimating dose-response

Plausibility that the intervention delivered by a program was responsible for the impact is improved if one can show that the impact is related to the intervention in an expected fashion. In addition to following program theory expectations, dose response analysis is another way of validating the intervention. Dose response requires knowledge about individuals' participation and utilization of the intervention. (Other uses of this data are to describe coverage, and to make extrapolations about the effects of changing coverage on impact).

Estimations of dose response must differentiate between actual dose response and unconfounded dose response. Actual dose response is most important for establishing a plausible argument that the impact is due to the intervention. However, actual dose response may include confounding influences associated with participation. Estimating unconfounded dose response is achieved by matching those who participated in the treatment with similar individuals in the control group. The more transparent these analyses are, the more plausible are the results.

The distribution of participation with a placebo will be similar to the distribution of participation with a treatment, so one can match on similar levels of participation or ingestion. Less good placebos may result in unequal distributions, but one can match on ranked distributions, assuming that the ranks have similar confounding determinants. Other matching procedures are less satisfactory because factors that foster participation and that confound impact may not be measured or may be poorly measured. Some matching methods are so sophisticated that they hide this uncertainty. Analyses that show an “unconfounded” dose response in an RCT for which no intent-to-treat impact can be shown is, on the face of it, so implausible that it requires a plausible explanation that can be demonstrated by data. Such an explanation might be that randomization was destroyed by external events, which worsened the outcome results in the treated group relative to the control group. This example reemphasizes the importance of measuring the impacts of these external events.

Another issue that dose response analysis can address is the matter of the optimal dose that is necessary to observe an impact. In nutrition, the "optimal dose" that is required for a response can be difficult to identify, given the influence of dietary interactions on biological absorption and utilization. An RCT design provides an ideal condition for examining optimal dose response. For example, in Bangladesh, Ekstrom and colleagues (2002) showed that the optimal dose of iron to prevent iron deficiency anemia was half of the WHO recommendations. Further such analyses, embedded in RCTs, are desirable to determine the generalizability of these results.

In addition to the influence of synergistic and antagonistic biological characteristics, it is also important to examine potential behavioral synergisms and antagonisms that might be associated with participation. Unfortunately, such relationships are likely, particularly in nutrition interventions. For example, mothers who have a greater level of participation in a food distribution program may also see to it that their children eat a higher proportion of the food than mothers who participate less. Given the importance of caregiver behaviors in realizing the benefits of greater food availability, it is possible that the provision of more food to those who participated less would not have changed impact.

Identifying "potential to benefit" as a means of strengthening plausibility

Plausibility is increased by the demonstration that the impact was affected by the synergisms and antagonisms (interactions) predicted by program theory. These and other unexpected interactions are also necessary for extrapolating dose response information, and the RCT impact information to other situations. These analyses permit investigators to identify those with a potential to benefit from the interventions. From the perspective of future program targeting, this is more relevant than the usual descriptions of likely impact that are based on "risk of poor outcome”. For example, a case-control subanalyses, embedded within an RCT for iron-fortified soy sauce in China, identified the characteristics of women who responded to the intervention with improved iron status (Du, 2005). Comparing responders and non-responders in the treatment group in an RCT is a statistically efficient method to identify those with potential to benefit, much more efficient than also using the control group in the analyses.

6. Types of Interventions

There are several different options for organizing a typology of nutrition interventions, including: (a) according to how the intervention was delivered, (b) according to what is delivered, (c) according to the recipient, (d) according to changes in intermediary outcome behaviors (e.g. breastfeeding), (e) according to the impact sought (e.g. improved health), and (f) according to whether the intervention is viewed as preventative or curative. Usual typologies are a mix of these options. The typology we have created for this report is organized by (a) and (b) because this is more relevant for programmatic interventions, and because their program theories can be described as a flow of goods and services thru the program into the household, into the biological beneficiary and leading to a biological outcome (Figure 1). Nutrition relevant interventions occur at various places along this pathway as described below.

Figure 1: Pathway from food sources available to a household to biological outcomes

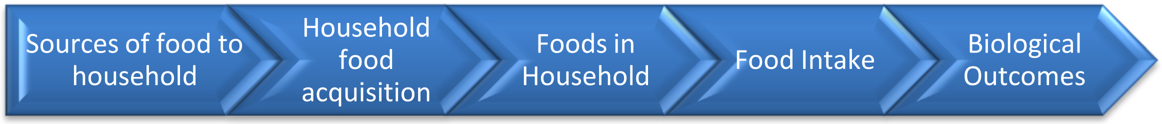


Figure 2 concentrates on the program theory of the programmatic part of the pathway from the inputs through program outputs to household, either by direct delivery, facilitated purchase or by improving own production. All the interventions mentioned below function according to this schemata except for the direct delivery to the biologically targeted beneficiary, such as the child who is given a vitamin A dose directly into the mouth. For this direct delivery and the delivery modes depicted in Figure 2, the quality of the program delivery, of the coverage and of the focus (targeting) are important determinants of the availability of food and nutrients. It is not enough that the food and nutrients be available, they must also be accessed, which depends on knowledge, motivation and resources that determine household nutrition seeking behaviors.

Figure 2: Pathways from program inputs to household food availability

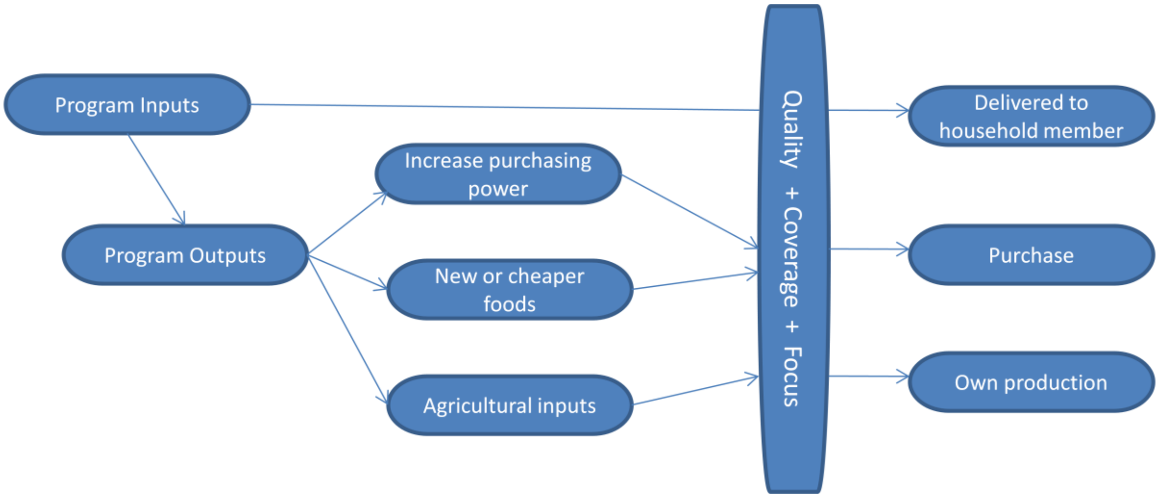
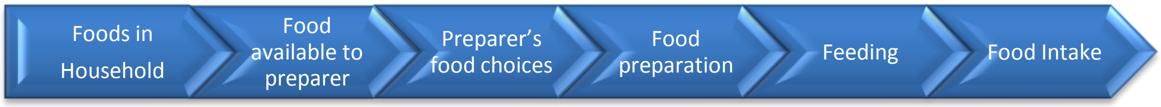


Figure 3 shows the steps that a household must take to obtain a household input and deliver it to the biological beneficiary. Each of these steps depends on knowledge, motivation and resources (e.g. time, cooking materials) although these are different from those required for Figure 2. Finally, Figure 3 depicts the "program" theory of how foods and nutrients are translated into a biological outcome. Again there are many determinants that affect each of these steps - absorption may be impaired by parasitic infections or by inadequate fats (Jalal et al, 1998). Movement from storage to the cell and cellular response to improved nutrient availability may be decreased by concomitant deficiencies and diseases. Usual childhood diseases do not impair nutritional status enough to affect biological outcomes if dietary intake and absorption are satisfactory (Lutter et al, 1992). However, these diseases potentiate poor nutrient intake, so that when a program has less than complete success in improving intake, the impact will be reduced even further. Moreover, concomitant nutritional deficiencies often behave synergistically. The interventions we reviewed for this report did not explicitly address these antagonistic effects, which depend on the pattern of their determinants in the population. Considering this pattern (context) in the program theory is therefore as important as consideration of the simple linear program theory of the interventions, as depicted in the figures. This consideration may lead to complementary interventions, such as de-worming, or increasing fat intake.

Figure 3: Pathway from foods in household to food intake of a young child



The figures and the following discussion are very schematic, and should be expanded by using, for example, the information in Austin and Zeitlin (1981) and further developed to be effective as a tool for planning a program and for developing its evaluation.

A. Supplementation

This type of intervention involves the provision of supplemental foods or specific nutrients to the normal diets of high risk populations (preschool and school age children, pregnant and lactating women). Foods and supplements are most often provided at no cost to the recipient, and directly to the individual or to the household. In the former case, the direct provision of supplementary foods (e.g. in a recuperation center) short cuts the household behaviors except for those that bring the child to the centers.

A.1 Micronutrient Based: The commonly supplemented micronutrients in intervention programs are vitamin A, iron, iodine and micronutrient combinations (that often include zinc and B vitamins). This is often given directly to the child by program personal (e.g. vitamin A campaigns). Sometimes it is provided as a condiment-like add-on, as is the case with spreads and "Sprinkles" (Menon et al, 2006).

A.2 Food Based: These may consist of nutritious foods that are added to the diet (e.g. milk provided for school lunch) or the provision of special formulated, nutrient dense foods (e.g. "Nutramix" for complimentary feeding to infants).

A.3 Food For Work: This involves the provision of food stables (e.g. cornmeal, millet, legumes) paid in exchange for work by recipients. Recent literature indicates that this sometimes improves the diet of the most nutritionally vulnerable in a household, but often does not because of countervailing household behaviors. The reasons for these discrepancies are unclear, and need to be better elucidated for program theory to best inform how these interventions should be implemented and evaluated.

B. Fortification

This type of intervention is designed to introduce deficient or inadequately available nutrients into the diet by adding them to commonly consumed foods (e.g. iodization of salt). World wide this approach has been successful, particularly in societies with good food distribution and either highly centralized food processing (e.g. for the iodinization of salt) or enforceable legislation for fortification. One crucial concern, for which there is often inadequate attention, is the price accessibility of fortified foods compared to their non-fortified equivalents (Du, 2005).

C. Nutrition Education

This intervention strategy focuses on educating population groups about the importance of and means to increase intake of locally available, nutritious foods. Often the education is specifically directed to high risk sub-populations (e.g. educating mothers about providing locally accessible beta-carotene rich foods to young children). Education techniques are often used in conjunction with other interventions (e.g. education regarding the importance of vitamin A may be carried out concurrently with a vitamin A supplementation program or a home gardening program). This intervention is synergistic with almost every step of the program theories in Figures 1- 3. These synergisms should be explicit and their effects measured. A major concern for some of these steps is resource availability. For example, research into the effects of level of maternal schooling (education) on child nutrition shows that better maternal knowledge and motivation as proxied by maternal education are only beneficial if resources are sufficient (Reed et al, 1996).

D. Home/Community Based Horticulture

This type of intervention may also be referred to as Homestead Food Production (HFP). These interventions target households for education and support toward household based production of foods for home consumption and, in many cases, for the provision of additional income.

D.1 Home Gardens: Home garden programs teach household members how to produce nutrient-rich (e.g. beta carotene containing) vegetables and fruits. Household members are also usually educated on the value of consuming nutritious, home-produced foods. Often, the required inputs (seedlings, tools, fertilizers) are provided as well.

D.2 Animal Husbandry: These programs target households for the production of animal based foods for household consumption and market sale. Eggs, poultry, fish-ponds and other animal foods are among those subsidized for home production at the program level.

Program theory is poorly developed in the planning and evaluation of these interventions, and therefore it has been difficult to show convincing evidence of their effectiveness. This paucity of evidence may be more due to imperfect program theory than to ineffectiveness.

E. Food Price Reduction Interventions

This intervention can be brought about by decreasing the costs of food production, processing, and distribution, or by direct food subsidies. Program theory for all of these possibilities is complicated because these interventions may result in more unintended side effects than other types of interventions. Decreases in food prices may be attained at the expense of those who produce process and distribute the foods, whose nutrition may therefore deteriorate.

General food subsidies are so expensive that they are being abandoned. The evaluation of targeted food subsidies (e.g. direct cost reduction of foods, food stamps) requires more attention to evaluating programmatic and household fraudulent behavior than with other interventions, not because they are necessarily subject to greater fraud but because of political concerns about such behaviors in the context of nutrition interventions.

F. Conditional Cash Transfers

These interventions consist of demand side incentive money transfers provided to very low income families, often specifically families with infants, young children and/or pregnant or lactating women. Health-related cash transfers require that families (usually mothers and children) attend prescribed health care programs. Recent large scale trials of coupled education, health and nutrition conditional transfer programs have shown excellent correspondence to the economic program theory of conditional transfer on demand (e.g. school and clinic attendance), but much less impact on nutritional status than would be expected from the improved demand. In general, neither the programs not the evaluations included adequate program theory of household behavior. Implicit assumptions were made about household behaviors, which were only discovered after the RCT evaluation results were not as expected, and implicit expectations were made explicit and investigated. Had assumptions about household behaviors been investigated through formative research, program planning could have taken these into account and the program would have been undertaken differently.

G. Integrated Nutrition Programs

Historically “integrated nutrition programs” referred to nutrition education and/or supplementation organized around growth monitoring directed to younger and high risk children. These programs have fallen into disrepute because of poor evaluation results, which is not surprising, given the inadequacy of the program theory underlying these interventions. To the very limited degree that any plausible program theory has been investigated, it tends to support some of the basic assumptions about mothers' comprehension of child growth and uptake of the educational information associated with growth monitoring activities (Ruel et al, 1990, 1992).

H. Other

Many other child health, environmental or other programs specify improved nutrition as a goal but do not institute any specific nutrition intervention activities. These include diarrheal disease control programs, anti-helminthic programs, sanitation programs and water improvement programs. These are not included in Table 2, which presents a full list of nutrition interventions, organized according to the foregoing typology.

Table 2: Types of Interventions

Supplementation	1) Micronutrient-Based Vitamin A Iron Zinc Vitamin C Iodine Multiple Micro-nutrient 2) Food-Based Formulated and Special Food Preparations Donated Foods Nutrient Rich Food Staple Foods Food-for-Work
Fortification	Iron Iodine Vitamins Multiple Micro-nutrients
Nutrition Education	Information about Breastfeeding Information about Complementary Feeding Information about Pregnancy Information about Family Diets Information about Micronutrient and Food Based Supplements Other information
Home/Community-Based Horticulture	Home Gardens Livestock/Animal Husbandry
Interventions to Reduce the Price of Food	Food Vouchers Food Subsidies
Conditional Cash Transfers	
Integrated Nutrition Programs	

7. Beneficiaries

In this section, we consider beneficiaries of interventions from two perspectives: (1) categories of individuals who can benefit biologically, and (2) categories of recipients who are targeted for the delivery of goods and services. By “goods” we mean the items that carry the potential for nutritional benefit and that must be ingested to have a biological effect. “Services” refer to the social and behavioral inputs that are expected, ultimately, to lead to ingestion.

Table 3: Types of Beneficiaries

Infants 0-6 Months for Exclusive Breastfeeding
Breastfeeding with Complementary Feeding
Complementary Feeding without Breastfeeding
Children Under 5 Years of Age
Children 5-12 Years of Age
Pregnant Women
Lactating Women Or Postpartum
Women of Reproductive Age
Elderly
Other Household Members

A. *Targeting those with a potential to benefit*

Nutrition interventions to address undernutrition are undertaken with the expectation that they benefit the recipients biologically. An obvious, but often under appreciated, precondition for the effectiveness of interventions is that those who receive them must have a potential to benefit biologically from the intervention for it to have a biological effect. The recipients must have a nutritional deficiency that can be remedied by the intervention. This is more likely to be the case in infancy and the second year of life, and among pregnant and lactating women, because these are the periods of life when nutrient requirements are greatest. Moreover, in poor populations world-wide, these are the population sub-groups that are least likely to consume adequate and appropriate foods when food is not sufficient.

The available evidence suggests that after age 2 many children, even in deprived populations, do not benefit from nutrition interventions that are designed to improve their growth in height and weight. However, this may not be uniformly the case across the world. Therefore, it is essential to establish a profile of nutritional status across age groups before the design of an intervention. If this has not been done prior to designing the intervention, it is essential to do so before designing an evaluation of the intervention. Cross sectional national data is widely available for height-for-age, the best overall population indicator of general undernutrition, and for hemoglobin, the usual indicator for iron deficiency. If such a profile reveals that children 2-5 years of age are not likely to benefit from the intervention even though they are included as stated beneficiaries, then those children who were exposed to the intervention only after they reached 2 years of age should not be evaluated for impact. They can be included as a control group to children over 2 years who had received the intervention at younger ages.

Some socio-economic factors differentially affect the availability of appropriate foods for those with specific needs. Availability of breast milk, first as an exclusive food to age 6 months and then as part of the diet when the child is consuming complementary foods, is particularly subject to socio-economic and cultural factors. The types of foods that are fostered by interventions are usually designed to be appropriate for at-risk groups. One common exception is neglecting the lactating mother, particularly when the aim is to promote exclusive breastfeeding for 6 months. For an undernourished woman to sustain lactation, nutritional support is essential (Cassio-Gonzalez et al, 1998), and it is also essential that interventions to promote exclusive breastfeeding do not leave undernourished nutritionally depleted as a consequence of accepting program advice. Improving maternal nutrition is important not only for the production of breast milk, but also for the mother herself, and for her next infant. These considerations extend to all women of child bearing age if they are malnourished because they are poorly prepared for pregnancy and lactation. In order to obtain an adequate interpretation of biological impact, attention to these considerations should enter into the design of evaluations of interventions to improve breastfeeding, as well as those that are aimed at improving birth weight.

Old age is also thought to be a period when interventions might improve nutrition in poor populations. This group is rarely an object of nutritional interventions. Children over age 2 and non-elderly adults are often targeted beneficiaries for nutritional interventions. They usually suffer less from general malnutrition, although profiles may reveal otherwise in specific populations. In developing these profiles, it is important to take into account non-nutritional influences on the profile measures. For example, hemoglobin is depressed in areas with malaria, and this depression must be considered in judging the profile. Other non-nutritional influences on hemoglobin, such as some hemoglobinopathies, restrict the potential for hemoglobin to respond to a nutritional intervention to such an extent that there is actually no potential to benefit.

Another type of benefit from nutritional interventions can be characterized simply as "improved diet”, without the specification of particular biological benefits. This is an appropriate outcome to evaluate if it has been shown that a similar intervention in a similar setting had a biological impact that is mediated through diet. In this case, the diet is a proxy measure for a biological impact. However, this assessment is most appropriately used for monitoring. Monitoring dietary improvement is much less onerous than evaluating for biological outcome, in large part because those who have the potential to improve their diet are more prevalent than those who have a biological potential to benefit. However, as discussed below, dietary information should not be used as a proxy for nutritional impact in evaluations.

B. Targeting for Delivery of Goods and Services

Many nutrition intervention programs use multiple levels to reach their target. In practice, there appear to be three levels of selection for receiving goods and services: communities, households and individuals. This may be done for only one category or for combinations of categories, sequentially. For example, poor communities may be selected, and within those communities households may be selected for screening, and within households only some individuals (e.g. undernourished children) are selected (e.g. for supplementary feeding in feeding centers). Alternatively, all households in poor communities may be selected or all children under 2 years of age may be targeted.

Targeting for goods and services is sometimes made from the perspective of biological potential to benefit. However, this is not always the case. Sometimes the targeting includes recipients who do not have a biological potential to benefit, but who will assure that the nutritional intervention reaches those with the potential. Feeding a mother who breastfeeds benefits both mother and child. Nutrition education to a mother is meant to lead to improved diet for the child.

Sometimes targeting for the delivery of goods and services is done on the basis of feasibility from the perspective of the agency that is charged with delivering them. For example, food is sometimes delivered by one agency (e.g. government) to another agency (e.g. non-governmental agency) or to a community representative. Evaluations should assess the coverage of the delivery system at each of these levels. Coverage includes both availability and accessibility. These are not synonymous. Availability is usually defined geographically in relation to the population being served. As previously mentioned, accessibility refers to whether the available source is readily or reasonably accessible. For example, a food distribution center may be available within easy walking distance, but going to it requires passing through a dangerous or forbidden neighborhood. In some cultures women may not go alone to a center, and appropriate male companions may not be routinely available.

Table 4 shows the categories that are reported for targeted delivery of goods and services and the types of indicators that are used to assess impact.

Table 4: Categories of targeting and types of indicators used to assess impact

Categories of recipients	Indicators
Community Level	Community development indicators
Household level	Household wealth and demographic indicators
Individual level	Demographic and need-based indicators

8. Impact Indicators

Impact indicators are used in RCTs to ascertain the impact of the intervention. This is accomplished by subtracting the indicator results in the treatment group from the values in the control group. These same indicators are also necessary for describing the context of the program, for ascertaining the population's potential to benefit from the program, and for ascertaining whether the program met adequacy goals related to these standards and criteria.

A. Indicators of dietary intake

A review of the types of interventions and types of beneficiaries above shows that many nutrition interventions are designed to provide nutrients directly to beneficiaries. These are delivered in two main forms: (a) capsules or pills or (b) mixtures and food-derived supplements (e.g. dried milk powders, micro-nutrient enriched powders, specialized "snack foods”, spreads, etc).

Other interventions aim at improving nutrition through improved dietary intake of foods. When the intervention is focused on improving dietary intake of specific foods or categories of food, such as "green leafy vegetables”, measures of intake of the foods that are being promoted could be considered as outcomes. However, as biological theory and program theory make clear, they are always intermediary to biological outcomes and cannot be regarded as proxies. For example, in the case of promoting green leafy vegetables, increased consumption does not translate unit for unit into better vitamin A status because conversion of beta-carotene to biologically usable vitamin A depends on a complex of issues, including the characteristics of specific vegetables, other dietary factors and other biological characteristics of individuals.

A third type of nutrition intervention, which is still relatively rare, but likely to become more common, particularly in conjunction with other nutrition interventions, is aimed at changing feeding behaviors. For example, there is evidence that frequency of feeding is important to protect young children from undernutrition during the period of complementary feeding, and that inadequate number of feeding episodes per day is associated with growth faltering (WHO/UNICEF, 1998, Dewey and Brown, 2003). When a complementary feeding intervention includes advice to feed more frequently or to feed a supplement at a particular time of day (as is the case with the supplement distributed by Oportunidades - formerly Progresa- cf. Bonvecchio et al, 2006), assessment of beneficiary response should be part of impact assessment. However, as with the promotion of specific foods, these cannot be regarded as proxies for biological impact.

Nonetheless, measuring at least selected aspects of diet is important in nutrition intervention evaluation for several reasons:

1) At baseline to describe the "dietary" context for purposes of program planning and external validity.

2) At follow-up for plausibility analysis to ensure that the intervention did not merely displace nutrient sources. This is particularly important when impact is less than expected. Dietary information may also be used to identify other dietary factors that may be acting synergistically with the intervention.

3) As indicators of intermediary outcomes that are the most proximal in the social/behavioral chain that leads to biological impact.

From the inception of nutritional sciences as a field of study, the measurement of dietary intake has claimed substantial amounts of attention. Given the repetitive, but variable, nature of dietary intake (which can be seen as requiring sampling from a "behavioral stream") plus the fact that measurement of quantity is necessary to make assessments of nutrient intake, and that diet is deeply embedded in a variety of social and cultural processes, it is not surprisingly that methods for precise measurement have eluded even the sharpest methodological minds.

Over the years, a variety of techniques have been developed, each of which has strengths and weaknesses (see Gibson, 2005, for an excellent summary). The most common techniques for obtaining estimates of total dietary intake of individuals are:

1. A 24 hour recall (or multiple 24 hour recalls)

2. A food frequency questionnaire (typically covering a week)

3. Direct observation (with or without weighing of portions)

4. Dietary history (over a month or longer)

The first two methods are those usually used in evaluations.

When investigators are concerned about specific categories of foods, such as animal source foods, iron rich foods, vitamin A rich foods or complementary foods for infants, the general techniques can be modified to focus exclusively on the foods and feeding behaviors of particular interest (Blum et al, 1997). This is essential to interpret the biological impact of interventions that deliver specific foods and nutrition education related to foods and feeding behaviors.

A number of different techniques have been developed to convert dietary data about food into nutrient and energy content. Commonly, the dietary data are converted into estimates of nutrient intake using food composition tables (USDA, 2006), and the profile is then compared to nutrient reference levels. Several different reference values of evaluation of nutrient intakes and diets are available, including guidelines jointly issued from FAO/WHO/UNU (1985), FAO/WHO (2002) and the Institute of Medicine (2000). Collecting and analyzing dietary data in a fashion that yields reasonable estimates of nutrient intake requires substantial time, skill and economic resources.

For contextual purposes, dietary information is necessary to describe the diet, but it is inadequate to identify undernutrition. Identifying undernutrition requires anthropometry for protein-energy undernutrition, clinical signs for iodine undernutrition, and biochemical indicators for other nutritional deficiencies. Dietary information is essential to explain the reasons for undernutrition identified by these other means. For similar reasons, dietary information is inadequate to assess the biological nutritional impact of an intervention, but it is essential in explaining why impact did or did not happen.

Recently, dietary data have been used without conversion to nutrients. Within a population, individual intakes can be compared by means of scales or composite measures created from food intake records (Ruel, 2003; Hoddinott, 2002). The potential for using these measures is still under investigation.

B. Biochemical and clinical indicators of nutritional status

An indicator of nutritional status is a measure of a biological variable that is affected by nutrition. Table 5 provides a comprehensive list of the indicators of micronutrient and macronutrient status that are currently used by the nutrition community. These indicators reflect nutritional status. Dietary intake is a determinant of nutritional status but is not an indicator of nutritional status, and some of the considerations that are important for indicators of nutritional status do not pertain to dietary intake. For instance, the determinants of dietary intake only affect nutrition through the diet, while indicators of nutritional status are also affected by many non-nutritional influences. Moreover, these influences also affect the nutritional interpretation of these biological outcomes.

All indicators of nutritional status can be defined at the individual level. Individuals whose indicators fall below (or above) some level are declared deficient (see “Individual cut-offs for estimating population prevalences” in Table 6). The prevalences of these deficiencies are an expression of the nutritional status of the population. Table 6 presents some standards that are used in the assessment of severity and prevalence of specific nutrient deficiencies. The data provided are for the evaluation of populations only. Assessment of nutritional status in individuals requires more information.

Table 5: Indicators of Micro-nutrient and Macro-nutrient Status

Health Outcomes	**Biochemical and Clinical Outcomes, continued**
Pregnancy outcomes	Conjunctival Xerosis
Pre-term	Xerophalmia
Low birth weight	Corneal lesions
Premature	Serum/plasma
Intra-uterine growth retardation	*Other Vitamins*
Miscarriage	B vitamins levels in blood
Morbidity Indicators	Urinary B vitamins excretion
Self-reported	*Iron*
Clinic Records	Unspecified "anemia" assessment
Other	Hemoglobin (Hb)
Cognitive/Behavioral and Developmental	Hematocrit (Hct)
Mortality Rates	Serum iron (SFe)
Growth and Body Composition	TIBC
Weight/Age	Transferrin saturation
Height/Age	Serum ferritin
Weight/Height (BMI)	Erythrocyte Protoporphyrin
Knee height	Red cell indices (MCV,MCH,MCHC)
Head circumference	*Zinc*
Middle upper arm circumference	Serum/plasma zinc concentration
Middle upper arm muscular area	Erythrocyte zinc
Skinfold thickness	Leukocyte and Neutrophil zinc
Somatic and visceral protein status	Urinary zinc
Physical Strength	Hair zinc
Work capacity	Salivary zinc
Biochemical and Clinical Outcomes	*Iodine*
Vitamin A	Urinary Iodine
Serum retinol (SR)	Serum/plasma Iodine
Serum carotenoids (SC)	Thyroid hormone
Serum Retinyl Ester (SRE)	Goiter size or volume
Relative dose response (RDR)	
Modified Relative Dose Response (MRDR)	*Protein*
Rapid dark adaptation (RDA)	Indices of somatic protein status
Breastmilk retinol	Indices of Visceral Protean status
Night blindness	Metabolic changes
Bitot’s spots	Immunological function

Table 6: Cut-offs to estimate prevalence and prevalence criteria of population undernutrition for frequently used biological outcome measures.

	Individual Cut-offs			*Population*	
Indicator	*Individual cut-offs*		*Gibson 2005 page*	*Prevalence of inadequacy*	*Gibson 2005 page*
Vitamin A					
Serum Retinol (umol/L)		>0.70		2- 10% - mild 10-20% - moderate > 20% - severe	p.496
Modified Relative Dose Response (ratio)		>0.060		20-30% - moderate >30% - severe	
Night blindness				<1% - mild 1-5% - moderate >5% - severe	
Iron	Age/gender based cut-off criteria				p. 447
Hemoglobin (g/L)	*Age in Yrs*. *g/L* 0.5-5 <110 5-11 <115 12-13 <120 Men <130 Non-preg. Women <120 Preg. Women <110			≥ 40 - severe 20-39.9 - moderate 5.0-19.9 - mild ≤ 4.9 - normal	p.17
Serum Ferritin (ug/L)	*Age in Yrs*. *ug/L* 1-2 <10 3-5 <10 6-11 <12 12-15 <12 ≥ 16 <12			>20% indicates a population with iron deficiency (WHO 2004)	

Table 6: Cut-offs to estimate prevalence and prevalence criteria of population undernutrition for frequently used biological outcome measure (continued)

Indicator	Age and gender based cut-off criteria	Prevalence	Gibson Pg.
Iodine	Prevalence		
Goiter	*Grade 1*- goiter palpable but not visible. *Grade 2*- visible goiter	*Total Goiter Rate= % of goiters > grade 1* 5.0 - 19.9 Mild 20.0 - 29.9 Moderate ≥ 30 Severe	p.755
Urinary Iodine Excretion		No more than 50% should have a urinary iodine concentration < 100ug/L, and no more than 20% of the population should have a urinary iodine concentration below 50ug/L.	p.759

There is some suspicion that high prevalences of hemoglobin below 90 g/L may reflect other reasons for anemia besides iron deficiency (Stoltzfus, 1997), so it is worth reporting the prevalences below 90 g/L separately from the prevalences of those below the cut-offs in Table 6.

The cut-offs to describe iron deficiency in the population have been changed recently. Transferrin receptors now replace transferrin. Iron deficiency and depletion are now differentiated within those who have low ferritin levels as follows: low ferritin and low transferrin receptors are classified as depleted; low ferritin but normal transferrin receptors are classified as deficient (WHO, 2004). Indicators of iron undernutrition are explained by the fact that lower hemoglobin is the expression of an iron deficiency that is severe enough that the formation of hemoglobin is affected. Iron deficiency is described both by the amount of iron in stores (which is reflected in ferritin levels), and the avidity of transferrin to bind iron (reflected by the transferrin receptors). Transferrin transports iron from storage to the cells and more transferrin receptors for iron become available when iron becomes deficient. Measures of ferritin and transferrin receptors are each affected by other factors than iron, but their combination deals with this confounding.

C. Anthropometry: indicators of growth in children

The WHO publication (1995), “Physical status: The use and interpretation of anthropometry”, describes the uses of anthropometry to identify and quantify undernutrition for specific purposes, including describing nutritional status in a population and responses to nutritional interventions. In addition to the extensive guidelines in this document, Gibson (2005) provides further information about measurement issues and techniques. Appendix D contains the WHO recommended protocol for standardizing the anthropometrists, the people who will do the measuring. This protocol is used extensively in this or adapted form.

Anthropometry is widely used in clinical practice to manage pregnancy. At the population level, inadequate weight gain during pregnancy is an important indicator of population undernutrition. Maternal anthropometry is used to ascertain the prevalence of maternal energy undernutrition, as well as to assess the impact of interventions to improve maternal diet.

In public health research and evaluation, the most common use of anthropometry is with children. In undernourished populations, child growth in stature falters from about 3 months to about two years. Stature is considered the best overall measure of undernutrition in children in this age range. There is no significant catch-up in growth of stature thereafter. Because stunted growth is accretionary over the 3-24 month period, its full impact is only visible at two years of age and thereafter. Consequently, the height of children from two to five is a good, and statistically powerful, indicator of previous malnutrition, which occurred during their first two years of their life.

When evaluations are conducted at a point at which a sufficiently large number of children in the intervention group have reached 2 years of age, and been in a program during the period that is most sensitive to growth faltering, relative smaller sample sizes are required compared to evaluations that seek to identify impact before the period of maximum effect can be observed (Shen et al, 1996).

In contrast to height and weight, other anthropometric indicators, including upper arm and calf circumferences, skin fold thickness, weight-for-height and body mass index (=kg/height^2) are not accretionary and therefore reflect current undernutrition rather than previous malnutrition. These are less statistically powerful for use in program evaluations that address general undernutrition. They are also somewhat more difficult to interpret, except in conditions of near starvation when they are the best measures - especially upper arm circumference. The ambiguity of these indicators of current nutrition derives from the fact that children who are growing better in stature tend to be thinner than those who are experiencing growth faltering. Weight takes into account both faltering in stature and thinness and is therefore the most widely used anthropometric measure, although it is statistically less powerful than stature to identify impact.

There are two ways to summarize anthropometric status of children in a population: (1) the prevalence of growth stunting and 2) mean stature.

The prevalence of growth stunting

A stunted child is one whose recumbent stature or standing height falls below the 2.5 percentile according to age and sex specific standards. This cut-off corresponds to -2 of the difference in cm from the 50th percentile divided by the standard deviation. This standardized difference is a Z-score. So the cut-off for counting the stunted is -2Z-score. A population with no undernutrition will have a prevalence of 2.5% "stunted" children, all of whom are, however, well-nourished and healthy. In moderately and severely undernourished populations half or more of the children are stunted by 2 years of age. The prevalence of stunted children is less at younger age groups because of the dynamics of stunting described above.

The specification of undernutrition as height or weight below -2 Z is serious flawed because, in a population with a high prevalence of undernutrition, many undernourished children will be taller than -2 Z cut-off. However, if they had received adequate nutrition, they would have been taller, and the extent of undernutrition they suffered may be equal to those of children who are shorter, but began life with a lower genetic potential to achieve a greater height. One can deal with this by distributional analyses, but the prevalence results depend on assumptions about the distributions (cf. Figure 26 p220 of WHO, 1995). On the other hand, for ascertaining a difference between intervention and control groups or in a population measured over time, the difference between the -2 Z score prevalences is still a powerful method.

Mean stature

Another way to summarize anthropometric data at the population level is by mean stature. Mean indicators of nutritional status can be compared to the mean of a standard. A mean Z-score of 0 indicates no malnutrition. A mean Z-score of -2Z is approximately equivalent, by construction, to a stunting prevalence of 50%. One can also compare the means across populations and across time. Comparing means is more statistically powerful for anthropometry than comparing prevalences.

Standards for indicators of nutritional status can only be constructed if the distributions of indicators of nutritional status are similar across healthy well-nourished populations. This is the case for anthropometry (Martorell and Habicht, 1986) even though there is a large variability within populations that is due to the genetic factors: tall parents have taller children than shorter parents in healthy populations. However, the means and distributions are fairly consistent within healthy, well-nourished populations. Age and sex make such significant contributions to anthropometry that it is necessary to have age and sex specific standards. On the other hand, the effects of "racial" background and altitude are so minor relative to the effects of undernutrition that a universal standard is scientifically appropriate.

D. Other indicators in nutrition intervention evaluations

Table 7 illustrates some of the other, non-biological outcomes that were evaluated in the nutrition intervention reports we reviewed. These outcomes are grouped as changes in behavior of program participants, institutional level behaviors, such as training of health workers or delivery of supplements, and evidence of feedback of information within the program to make adjustments in operations.

Table 7: Indicators of Social, Behavioral and Psychological Outcomes

Behavioral Outcomes	**Institutional Outcomes**
Community	Quality of goods and services
Availability of food in local markets	Training
Delivery coverage	Supervision
HC/Program utilization	
Household	Quantity of goods and services being delivered
Food expenditure	Coverage
Availability of food in the household	Delivery (e.g. doses per capita)
Program utilization	Availability (e.g. distance to supplementation centers, field workers per capita, facilities per square mile
Individual	i)Individual
Food intake behavior (e.g. No. of meals per day, share of valued foods)	ii)Household
Breastfeeding	iii)community
Knowledge, attitude and practice	
Program utilization (e.g. attendance)	**Inputs (Feedback)**
	Evidence of changes in policy and program planning during the intervention

9. Ethics

There are legal issues involved in the designation of impact evaluations as research. This is important for US institutions because research involving human subjects must meet US government requirements for protection of human subjects (See information from Office for Human Research Protections (OHR) at < http://www.hhs.gov/ohrp/>). When the data that are being analyzed for impact are routine program records that are collected for programmatic purposes, the relationship to "protection of human subjects" research regulations is arguable. However, when an evaluation has a baseline and other information collecting activities, such as operational research, the data collection would often require "protection of human subjects" procedures. Furthermore, when an evaluation includes a control group, the program may be considered part of the evaluation. These issues are best resolved by having an established institutional review board that can help delineate the human protection responsibilities of the evaluation, as distinct from those of the program.

In general, there are four basic principles that need to be taken into account in protecting human subjects: (a) autonomy, (b) non-malfeasance, (c) beneficence and (d) justice. These principles have evolved out of clinical trials and are well conceptualized for that context (c.f. Beauchamp and Childress, 1983). Translating the principles to a public health setting is challenging because they only address the protection of individuals. The injunction of non-malfeasance is the least ambiguous, and should be specifically addressed. Protection of autonomy is essential for some cultures, including the US, and is strongly protected by US regulations, and implemented through the concept of "informed consent". This concept includes freedom to choose not to participate in parts of an intervention, or its evaluation, without losing any of the other benefits.

The principle of beneficence causes the most confusion both within the US government guidelines, and for policy makers and the lay public. In part the confusion is one of terminology, because it should be called bene-feasance. The issue is whether one should always "do good" if one knows that there is a need. The "should" is, of course, constrained by what is feasible, but that constraint is so ill-defined that the beneficence principle is difficult to codify for useful practice. Beneficence is commonly confused with non-malfeasance. This is a disastrous confusion because non-malfeasance is an imperative that can be met, while guidance on beneficence is ambiguous.

One of the major obstacles to implementing RCTs for programs is the need for control groups. Confusing beneficence with malfeasance often precludes this possibility. One cannot, according to the rules for protection of human subjects, appeal to a greater good to override harm done to an individual. However, only malfeasance causes harm. Failure of beneficence does not cause good, but it causes no harm - a crucial ethical differentiation.

The principle of justice is the most ambiguous, even at the individual clinical level (Beauchamp and Childress, 1983). It is even more complicated in a public health setting.

10. Conclusions

In this section, we briefly summarize the results that emerged from our overview of current evaluation practice in nutrition intervention impact research. We then outline some issues that, in our view, need attention in future research on the impact of nutrition evaluations. We focus particularly on recommendations about the organization and conduct of nutrition evaluations, rather than on specific substantive nutritional topics.

Results

Impact evaluations of nutrition interventions use a range of methodological approaches, from randomized intervention/control designs, with careful analysis of counterfactuals, to simple "before/after" studies, with inadequate attention to the methodological threats to concluding that impact could be plausibly attributed to the intervention.

The strongest demonstration that nutrition interventions can have major impacts on biological well-being come from evaluations of well-run programs that deliver drugs, food or nutrients directly to the intended biological beneficiary.

Small-scale, well-designed efficacy trials have demonstrated clear biological impact for interventions that depend on behaviors of intermediaries in the pathway from intervention to the biological beneficiary impact. Moreover, some program evaluations have documented solid impact on non-biological intermediary outcomes, particularly appropriate response to economic incentives in conditional cash transfer programs.

However, in large scale programs, which involve complex delivery and utilization pathways from the intervention to the biological beneficiary, there is usually less biological impact than would have been expected given the inputs. It is not clear whether this is due to inadequate program implementation, quality and coverage of program delivery, the food and nutrition-related behaviors and uptake of program delivery of goods and education by households, and/or the household "translation" of information into practice and foods or other goods into nutrition of beneficiaries.

As disturbing as these findings are, what is equally cause for concern is that, with rare exceptions, the studies do not reveal why programs are less effective than well-designed research trials suggest they should be. There is a tendency for investigators to use sophisticated analyses to remedy the lack of impact findings or to fall back into a discussion of "lessons learned". What is strikingly absent is the use of an explicit program theory that would have focused attention on the measurement of variables that provide critical information on where and why the system is weak or failing, including an understanding of emic conceptual structures that program staff and household behaviors.

Outstanding issues for evaluation

In recent decades, there have been important advances in all of the sciences that are necessary for effective evaluation of nutrition programs. Understanding of research designs and statistical procedures for data analysis has matured, and the armamentarium of tools and techniques is impressive. Methods for feasible measurement of biological impact in populations have also made strong advances. Methods and techniques for quantitative and qualitative measurement of program delivery and household utilization processes have equally advanced. In short, while there is still much to be learned about "how to do it better", there is a wealth of knowledge and skill that is not being adequately tapped for nutrition program evaluations.

To remedy the present situation, which is not making use of the potential to use existing resources to address critical questions, it is required a re-orientation in the organization of nutrition evaluation research. To that end, we have outlined a set of recommendations for discussion:

- Restructure nutrition evaluations so that the development of program theory for the evaluation is undertaken concurrently with program planning.

- Promote multidisciplinary attention to developing the program theory within every nutrition evaluation and operationalizing the measurements to assess the components identified by the theory.

- Provide adequate funding for operational research within evaluations and link the results to the impact evaluation findings.

- Give priority to program efficacy evaluations over program effectiveness evaluations for complex nutrition interventions until there is sufficient knowledge about how to improve programs enough to warrant effectiveness evaluations.

- Restructure funding of impact evaluations so that they are implemented in a logical sequence with clear criteria for ceasing further activities if they are not warranted, and establish bureaucratic incentives to stop evaluations in a timely fashion.

- Foster RCTs for program efficacy.

- Reserve RCTs for nutrition programs that have enough external validity (and define the conditions for this validity) that the results are widely applicable.

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Appendix A. Examples of characteristics, indicators and other features of nutrition intervention impact evaluation reports

The tables in this appendix are keyed to the bibliography of evaluations that were gathered for this report. The numbers in the columns labeled "relevant studies" refer to the report number in the bibliography. The bibliography is presented alphabetically, and the reference number can be found at the end of the entry in parentheses. For example, the first entry in the bibliography is: Aguayo V.M., Baker S.K., Crespin X., Hamani H. “Maintaining high Vitamin A Supplementation Coverage in Children. Lessons from Niger” HKI-Africa, Nutrition in Development Series, Issue 5, Nov. 2003(55). The reference number for this item is 55.

To illustrate: if you are interested in evaluations of interventions that involved iron, go to Table 1 to the section on micro-nutrients. The row labeled "iron” has references to 3 studies, and a 4th study is listed further down in the table, in the section on food fortification, in the row labeled iron. If you are interested in studies that used hemoglobin (a measure of iron status), go to Table 4 to the section on biochemical indicators, and you will find reference numbers for 10 studies that evaluated hemoglobin as an impact indicator.

Items that appear in the tables in the text but that do not appear in the tables in the appendix are items for which we found no reference to their use in the reports we reviewed.

Table 1. Types of Interventions

Intervention Type	**Relevant Studies**
Supplementation	
1) Micronutrient-Based	
Vitamin A	46,55,40,47,56,26,28,25,23,15,11,16a,51b,53 42,**36.**
Iron	51b, 53, 16b
Vitamin C	53 w/Fe
Iodine	51c, 30, 31,21
Multiple Micro-nutrient	43
2) Food-Based	
Formulated and Special Food Preparations	74, 62, 38
Donated Foods	School feeding **61**, **62**, **63**, 41
Nutrient Rich Food	65, 77,4,22
Staple Foods	**1**,60,6
Food-for-Work	**1**,7
Fortification	
Iron	29
Iodine	46, 31, 21, 20, 16c,51c,43
Vitamins	29, 12
Multiple Micro-nutrients	74 (Fe, Zn, Cu) 29
Nutrition Education	
Information about Breastfeeding	77
Information about Complementary Feeding	77
Information about Pregnancy	77
Information about Family Diets	**10** (child feeding),22
Information about Micronutrient and Food- Based Supplements	55,23
Other information	39 (farming)
Home/Community-Based Horticulture	
Home Gardens	39, 23,37, 24
Livestock/Animal Husbandry	23, 24, 18
Interventions to Reduce the Price of Food	
Food Vouchers	**1**,7
Conditional Cash Transfer	**2,3,5,8**
Integrated Nutrition Programs	77,**67**,69,78, **32**
NCDDP	68
Anti-helminth	**76, 10, 9**

Table 2. Types of Beneficiaries Targeted by Nutrition Interventions and Assessment of Utilization by Those Expected to Benefit Biologically

Type of Beneficiary	**Relevant studies**	**Relevant studies that assessed utilization**
Breastfeeding & complementary Feeding	22	22
Children Under 5 Years of Age	**67**,31,**73**,39,68,55,40,25,11,**10**,24,13,38,60,53,47,65 56,**2,3,5**,7,26,28,15,12**,9**,18,31,69,1,23,14,16,72,74,**8** 4,6,22,36,77, 33, 22, 78	68,28,14,37**,9**,47, **10**,39,7,**3**,12,65,26 22,36,55
Children 5-12 Years of Age	**61**,62,**63**,41,46,73,51,21,20,76,**7**,**8**,24,16,14,**2**(teens),29 **76,** 30	14,41**,7,2**,46,**76**
Pregnant Women	72,**73**,74,31,69**,5,8**,23,16,22,51b,46,55, 32, 22, 78	22,51b,55,78
Lactating or Postpartum Women	**73**,69,**5,8**,23,32,12,16,22,46,78	12,22,78
Women of Reproductive Age	15,14,18,13,37, 32	14,37
Other Household Members	**3**,14,32	14
Households	46,**73**,**1,2**,39,**3,5**,37,13,16,7,51c, 78	46,37,**3**,51c,78
Communities	46,21	

Table 3. Targeting for Delivery of Goods and Services, and Assessment of Coverage and Delivery

Categories of Recipients	Programs	Coverage Assessed	Delivery Assessed
Community Level	**1,2**,4,**9,10**,12,14,15,16c,20,36 38,39,74,60,62,**67**,69,30,	4,10,15,16c,62,78	69,15,20,12,**9,2,10**, 78
Household Level	**1,2,3,5**,7,13,18,20,24,39,46(I) 65,32,33,30	**1,2,3,5**,18,20,39,46	46,**1,2,5**,65,78
Individual Level	6,8,11,16a,16b,21,22,23, 25,26,28,29,31,36,38,40,41,51b, 51c,47,53,46(VAC),55,56,60,**61** 62,**63**,65,68,69,**76,**77, 30	55**,8**,11,16a,16b,22,23, 25,26,28,36,40,41,51b 51c,47,46,60,62,68,69 **76, 78**	55,40,32,56,69**,9**,16b 28,51c,65,68, 78

Table 4. Indicators of Micro-nutrient and Macro-nutrient Status

Indicator	Relevant studies
Health Outcomes	
Pregnancy outcomes	
Low birth weight	31, 78
Morbidity Indicators	
Self-reported	68,67,**3**,25
Clinic Records	68,**3**
Other	
Mortality Rates	68,56,15
Growth and Body Composition	
Weight/Age	7,4,31,60,**63a**,38,65,**67**,69,2,7,26,25,14,10,24,9, 22
Height/Age	73,74,31,65,**76**,67,**1,2**,7,26,25,14,24, 78, 33
Weight/Height (BMI)	31,**67,2**,24, 33
Middle upper arm circumference	31b,**67**
Skinfold thickness	74
Biochemical and Clinical Outcomes	
Vitamin A	
Serum retinol (SR)	46,26,28,25,15,24,16a,12
Plasma Retinol	47
Modified Retinol Dose Response (MRDR)	25,12
Breastmilk retinol	16a
Bitot’s spots	39,46,25,23
Conjunctival Xerosis	23
Xerophalmia	23,16a, 36
Corneal lesions	46,25,23
Iodine	
Urinary iodine (UI)	46,21,20,16b, 30
Thyroid hormone	21
Goiter size or volume	46,51b,21, 30, 20
Iron	
Unspecified "anemia" assessment	16b, 13
Hemoglobin (Hb)	**73**,74,62,**76**,29,53,**2**,26,14,24
Serum ferritin	72,74,**76**,29,26,14,24
Hair zinc	72,74
Other outcomes	21 (TSH), **76**

Table 5. Indicators of Social, Behavioral and Psychological Outcomes

Indicators	Relevant studies
Behavioral Outcomes	
Community	
Food Accessibility	12
Delivery Coverage	11,55,60,56,23,15,41,20, 3, 32, 33, 22, 36, 78
HC/Program Utilization	11,20, 32, 3, 42
Household	
Food Expenditure	**2,8**,18, 32, 3
Food Accessibility	39,7,**2**, 30, 5,23,18
Program Utilization	7,**5**,20,**10**,37
Individual	
Cognitive/Behavioral and Developmental	**61**,62,**63**,23,**10**
Food Intake Behavior	**67**,39,60,53,58,23,**10**,37,24,18,16c, 33, 3, 78
Knowledge, Attitude and Practice	**67**,39,53,77,23,**10, 30, 78**
Program Utilization (eg; attendance)	39,60,77,56,7,26,41,**10,** 42
Institutional Outcomes	
Quality of Goods and Services	
Training	**67**,68,40,60,53,69,12, 30, 3, 42, 78
Supervision	46,68,60,**67**,69,28,15,11,12, 30, 42
Quantity of Goods and Services Being Delivered	
1)Coverage	
Delivery (e.g. doses per capita)	46,68,42, 40,**67**,3, 69,28,23,15,11
Availability (e.g. distance to supplementation centers, field workers per capita, facilities per square mile	68,55,69,7,15,11, 3, 42
i)Individual	40
ii)Household	46,65,37, 30, 3
iii)community	42
Inputs (Feedback)	46,55,60,15,11,12,37, 3
Evidence of Changes in Policy and Program Planning During the Intervention	60,28,15

Table 6. Types of Research Designs Used in Evaluations of Nutrition Intervention Programs

Types of Designs	Relevant Probability Studies	Relevant Plausibility Studies	Relevant adequacy studies
Randomized Controlled Trials			
With Blinding	63b, 36		
Without blinding	73,2,3,5,8,10,24		
Blinding not specified	1, 61,62, 63a, 32, 17, 76,67,9		
Intervention Trials without randomization			
Control/Baseline		26,19,36,47,77,57	
Control/No Baseline		37, 65b	29
No Control/Baseline		7,18,16, 20,29,74	21,38,53 46i, 23,15,39 11,14
No Control/No Baseline		72,6	74
With Blinding		None are blinded	
Cohort Study			
Closed Prospective		65,26,60	53
Open Dynamic		68,40	29
Cross Sectional/Prevalence		31,40,56, 7,28,25, 37 22, 72, 46a, 30, 78, 33	21,47, 69 23,41,20 13, 55,12,51, 22
Case Control		24	

Table 7 Controlling for non-nutritional components of the intervention and for confounding

Strategies to improve plausibility	Relevant studies
Attempts to make comparison groups similar initially	**67,61,63ab,1**,65,**76,67,3,8,1**,41,12,**10**,24,**9,** 30, 32, 33, 36, 78, 33
Blinding or other control for knowledge	**63b interviewer, 36**
Statistical control for initial confounding	72,31,68,**63ab**,40,65,**76,67**,69,**1**,7,**3**,26, 32
Design control for initial confounding	72**,67**,74,**61**,68,**63ab**,38,**67**,56,69**,3,** 30, 32, 33, 36, 78
Expected response in those with a potential to benefit	**67**,73,**61,63ab**, 3, 32, 33, 21,40,38,56,69,**1,2**,26,20,12, 30
Dose response	73,31,**76**,26, 36

Table 8. Linking the delivery of the intervention to its utilization by the beneficiary who can benefit biologically: relevant studies

Delivered to whom	Links examined	Utilized by whom
46,60,55,65,47,56,11 30, 3, 32, 42, 22	46,55,65,60,47,56,11 30, 3, 42, 22, 32	46,55,65,60,47,56,11 30, 3, 42, 22, 32

Table 9. Sources of Data for Nutrition Evaluations

Source of Data	Relevant studies
Survey Data:	
"General Purpose" Survey Data (e.g.NHAINES, MICS)	31,68,55,46,47,56**,1,**28,13,16
Special Purpose Survey Data (eg; CDD, Morbidity, special marketing surveys)	46,68,56,**1**,11,41,20,12,14,**10,** 30
Survey for the evaluation	46,**67,61**,29,77,**5,**23,12**,10**,37,18**,9**
	39,**76**,53,56**,2,8**,41,20,14,24, 3
Data Collected within the Program:	
Administrative Data	68,11
1)input data	
i)supplies	46,39,68,40,65,56,69,23,14,37,30,3,42,78
ii)training	**67,**39,40,60,69,23,14,37,30,3,42,78
iii)distribution	68,40,65,60,56,37,23,30,3,42
2)output (beneficiary) data	
i)delivery/coverage	46,39,68,40,65,37,56,69,**1,3,5**,26,23,11,41 30,3,32,22,42
ii)growth and health status	39,74,63ab,21,40,38,22,78,33,65,60,53,56, 69,**1,3**,26,23,30,3,32
Specialized data collected within program being evaluated	61,21,22,78,60,56,23
C) Data collected in other programs:	
Administrative Data (hospitalization data, health facility	
2)output (beneficiary) data	
i)delivery/coverage	31,56,3
ii)growth and health status	74,31,56,69,23

Table 10. Evaluations mentioning ethical considerations

Type of Ethical Consideration Mentioned	Relevant studies
Received approval from appropriate human protection review board(s)	72,74,21,65,7**6,**26
Explicitly addresses the principles of:	
Autonomy	39,74,65,26
Non-malfeasance	**67,76**
Beneficence	46,**67,76,5,**25,**36**
Justice	**2**

Appendix B. Impact Evaluation Reports Compiled for this Report

The references are given in alphabetic order. The coding key is in parenthesis at end of citation.

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Ayele, Z., Peacock, C. 2003. “Improving Access to and Consumption of Animal Source Foods in Rural Households; The Experiences of a Woman Focused Goat Development Program in the Highlands of Ethiopia”. J.Nutr. 133: 3981s-3986s (18)

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Hop, L.T. 2003. “Programs to Improve Production and Consumption of Animal Source Foods and Malnutrition in Vietnam”. *J. Nutr*. 133:4006s-4009s (13)

Houston, R. 2003. “Why They Work: An Analysis of Three Successful Public Health Interventions: Vitamin A supplementation Programs in Ghana, Nepal and Zambia” USAID-MOST, Jan. (11)

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Olinto, P., Flores, R., Morris, S., Veiga, A. 2003. “The Impact of Bolsa Alimentacao Program on Food Consumption”. Preliminary Report, IFPRI July. (8)

Pachon, H., Schroeder, D.G., Marsh, D., Dearden, K.A., Ha, T.T., Lang, T.T. 2002. "Effect of an Integrated Child Nutrition Intervention on the Complementary Food Intake of Young Children in Rural North VietNam". *Fd Nutr Bull,* 23(4)s: 59-75. (67)

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Yamano T, Alderman H, Christiaensen L. 2003. “Child Growth, Shocks and Food Aid in Rural Ethiopia”. Foundation for Advanced Studies on International Development, Japan, Feb.(1)

Appendix C. CONSORT Checklist for reporting a randomized control trial

From www.consort-statement.org
March 12, 2006

CONSORT **Checklist of items to include when reporting a randomized trial**

PAPER SECTION And topic	Item	Description	Reported on Page #
TITLE & ABSTRACT	1	How participants were allocated to interventions (*e.g.*, "random allocation", "randomized", or "randomly assigned").	
INTRODUCTION Background	2	Scientific background and explanation of rationale.	
METHODS Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.	
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	
Objectives	5	Specific objectives and hypotheses.	
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (*e.g.*, multiple observations, training of assessors).	
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	
Randomization - Sequence generation	8	Method used to generate the random allocation sequence, including details of any restrictions (*e.g.*, blocking, stratification)	
Randomization - Allocation concealment	9	Method used to implement the random allocation sequence (*e.g.*, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	
Randomization - Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. When relevant, how the success of blinding was evaluated.	
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses.	
RESULTS Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	
Recruitment	14	Dates defining the periods of recruitment and follow-up.	
Baseline data	15	Baseline demographic and clinical characteristics of each group.	
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat". State the results in absolute numbers when feasible (*e.g.*, 10/20, not 50%).	

Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (*e.g.*, 95% confidence interval).	
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	
Adverse events	19	All important adverse events or side effects in each intervention group.	
DISCUSSION Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	
Generalizability	21	Generalizability (external validity) of the trial findings.	
Overall evidence	22	General interpretation of the results in the context of current evidence.	

Appendix D. Standardization of Procedures For The Collection Of Anthropometric Data In The Field[4]

The procedures described here are aimed at helping a field investigator answer the following questions about the anthropometric data he is in the process of collecting:

(a) How do repeated but independent measurements of the same subject compare in precision? By this criterion, a worker may be truly precise and yet decidedly wrong at the same time - a not uncommon occurrence in other endeavors.

(b) How nearly correct and how accurate are the observers? In other words, how close do they come to the values of an accepted standard? Faced with this problem, the common advice to field workers is to use the average (mean) of measurements made by all observers. In reality, the supervisor and his staff all recognize the value determined by the supervisor as the most reliable. He has the greater experience, he is able to evaluate his own accuracy by standardizing his measurements with those of colleagues with whose measurements he will eventually compare his data. The pragmatic practice of accepting the supervisor's measures as a standard simplifies calculations and the interpretation of results.

(c) Finally, where are the errors being made? Is it just carelessness; is there a consistent error in taking the measurement or is the procedure itself fundamentally at fault?

This standardization procedure provides a prompt return of information, pinpointing errors so that correction may be made before sources of error become fixed. It signals when accomplishment has reached a satisfactory degree. Because observers analyze their own findings, they quickly learn to appreciate the virtue of care. The supervisor learns what features are necessarily stressed to assure precise and accurate measurements and what finesse that adds little, if anything is.

I. Data collection

Ten subjects constitute the usual standardization series. Each observer measures each subject twice in such a way as to avoid being influenced by the first measurement; otherwise agreement is likely to be spuriously good. The results of the initial measurement are noted on an appropriate record form and put aside until the second series of measurements is taken, to be made in the same order as before. Results of a standardization series on heights carried out in 4 year old children are shown in Table 1.

[4] From A Guideline for the Measurement of Nutritional Impact of Supplementary Feeding Programs Aimed at Vulnerable Groups, World Health Organization, (WHO/FAP/79. 1), Geneva, Nov. 1979, adapted from Habicht, J-P: Estandardizacion de methodos epidemiologicos cuantitativos sobre el terreno. Boletin de la Oficina Sanitaria Panamericana, 1974, 76 (5): 375-384

II. Calculations (see Tables 2 and 4)

Step 1 - The results of duplicate measurements are entered in the first 2 columns a and b.

Step 2 - In column d the difference of a minus b is entered with its appropriate sign.

Step 3 - In column d^2, a - b is squared. Instead of squaring results, the approximate values of $(a - b)^2$ can be read directly from a table of approximations to squares (see Table 4) with no loss in satisfactory results. Its use also eases later steps and reduces adding errors because only those digits necessary for later analysis are recorded. Directly adding the d's would also save the squaring step, but it is less sensitive and the results are difficult to interpret.

Step 4 - Pluses and minuses of (a - b) are counted. The sum of the most frequently occurring sign constitutes the number of the numerator of a fraction where the total number of signs is the denominator. Zeros are ignored.

Step 5 - In column s, the sum of a plus b is entered.

These five steps are carried out simultaneously by all observers and the supervisor.

Step 6 - The s column of the supervisor's sheet is transferred to the sheet of each observer under column S.

Step 7 - The difference between the observer's s and the supervisor's S is entered in column (s - S) with the appropriate sign, and squared in column D^2.

Step 8 - Pluses and minuses of (s - S) are counted. The sum of the most frequently occurring sign constitutes the number of the numerator of a fraction where the total number of signs is the denominator. Zeros are ignored.

Step 9 - The sums of d^2 and D^2 and the results of the sign counts are transferred to a single sheet of paper as in Table 3.

III. Evaluation of results (see Table 3)

The following general rules apply in the analysis of results:

(a) The supervisor's Σd^2 will usually be the smallest; his precision will be the greatest because of his expected greater competence.

(b) Observer's Σd^2 (inversely related to precision)[5] is arbitrarily no more than twice (this factor f should be smaller than 2.97 for theoretical reasons) the supervisor's Σd^2.

(c) Observer's ΣD^2 (inversely related to accuracy)[6] is arbitrarily no more than thrice (this factor should be smaller than 2f for theoretical reasons) the supervisor's Σd^2.

[5] Precision = ability to repeat the measurement of the same subject with the minimum variation. Ideally Σd^2 should be equal to zero for both supervisor and observers.

[6] Accuracy = ability to obtain a measurement which will duplicate as closely as possible that of the supervisor. Ideally observer's ΣD^2 should be equal to zero.

(d) The observer's ΣD^2 should be larger than his Σd^2. The opposite calls for special scrutiny of the data and recalculation (see discussion of observer F, Table 3).

The first step in the evaluation is to inspect the summary of results as they are presented in Table 3, bearing in mind the 4 rules listed above. When inadequacies have been revealed (for example an observer's Σd^2 which is more than twice the supervisor's Σd^2), the next step is to inspect the "sign" column on the worksheet (Table 2).

In theory there should be as many pluses as minuses and thus no statistically significant sign test. This is ascertained by checking the results under the "sign" column (Table 2) with the numbers given in Table 5 to see if there is any significance.

A significant sign test for the d column (Table 2) indicates a probable difference between the first and second measurements; either the observer tired or the subject changed. The latter event occurs, for example, when a nude toddler urinates unnoticed between first and second weighings. The observer often tires when many children are measured and all first heights are determined before the second measurement begins. Effort and attention tend to wane the second time around and the children may appear to have grown.

A significant sign test for the D column indicates that the performance of the observed differs from that of the supervisor, either in too large values (more pluses than minuses) or too small (more minuses than pluses); the observer has a systematic bias.

In this particular exercise, all the individual worksheets are not printed. We have drawn on the data presented in Tables 1, 2 and 3 to discuss some results.

The supervisor (Table 3) does indeed possess the greatest precision: his Σd^2 is the smallest. Three staff workers show adequate precision: their Σd^2 is less than twice that of the supervisor (588). The three other workers do not show adequate precision because their Σd^2 is more than twice that of the supervisor.

None of the sign tests for d are significant; so systematic differences between the first and second measurements were not to blame (Tables 3 and 5).

Inspection of the raw data (Table 1) reveals that Observer C's precision was not wholly satisfactory due to one poor duplicate. Hopefully this will not recur. Observer D's precision was poor throughout.

One Observer (A) was consistently accurate (ΣD^2 less than 882 [Table 3]); all others were poor (ΣD^2s too high). In part, this was because of poor precision (C, D and F), and in part because of systematic bias, as indicated by sign tests (B, D and E). Observer F's Σd^2 is larger than his ΣD^2. His performance demands special attention.

Inspection of calculation worksheets (Table 2 or raw data in Table 1) further reveals that Observers D and E were doing something basically wrong; they were systematically measuring more than 7 mm too high. Observer B had the same fault, but to a lesser degree (4 mm).

Observer F's poor accuracy was due to the first four measurements. He did not gain dependable ability until the fourth child examined on the first round; thereafter, his record was satisfactory. These faults explain the discrepancy between his $\Sigma d^2 = 1278$ and his $\Sigma D^2 = 1049$.

Observers learn eventually to interpret their own standardization results and to evaluate calculation worksheets (Table 2) as a means for improved accomplishment. Under "Observations" on Summary Table 3, the supervisor verifies such conclusions by his staff members.

The above analysis can be thus recapitulated as follows:

The summarizing figures Σd^2 and ΣD^2 of observers, when compared to the supervisor's Σd^2 yield a quick assessment of work performance. If an observer's Σd^2 is more than twice or his ΣD^2 is more than thrice the supervisor's Σd^2, individual columns are examined. A large Σd^2 indicates either careless measuring, fatigue or changes in the subject over a period of time to be determined by inspection of signs or individual d's.

A large ΣD^2 indicates either carelessness, systematic bias (inspection of the signs of the individual D's), or single differences in qualitative judgment (single large D). Once the nature of the error is identified, correction ordinarily is simple.

TABLE 1: RAW DATA IN A STANDARDIZATION TEST
FOR MEASUREMENTS OF HEIGHT OF PRE-SCHOOL CHILDREN(expressed in mm)

Child No.	Supervisor		Observer											
			A		B		C		D		E		F	
	a	b	a	b	a	b	a	b	a	b	a	b	a	b
1.	828	822	819	826	841	834	833	828	838	825	842	837	836	819
2.	838	846	846	846	842	854	849	856	850	856	861	854	860	845
3.	860	856	863	861	856	865	875	853	882	872	862	858	873	860
4.	862	860	862	850	866	855	854	864	856	869	875	865	874	854
5.	820	820	825	823	827	826	826	822	836	828	826	827	818	827
6.	856	854	857	862	855	860	856	864	862	873	864	860	858	856
7.	823	824	824	825	826	824	827	826	832	825	820	835	818	827
8.	876	876	880	875	877	875	873	878	879	887	884	882	876	874
9.	801	806	810	804	811	810	809	808	811	800	820	815	800	797
10.	853	865	858	852	859	860	857	860	856	856	866	870	852	856

a = First measurement
b = Second measurement, independently made after an appropriate interval and recorded separately.

TABLE 2: CALCULATIONS OF A STANDARDIZATION TEST

(Data of Observer E in Table 1)

Child	a	b	d	d^2		s	S	D	D^2	
	1st Measurement	2nd Measurement	(a-b)	$(a-b)^2$	Sign	Observer (a+b)	Supervisor (a+b)	(s-S)	$(s-S)^2$	Sign
1.	842	837	+ 5	25	+	1679	1650	+ 29	841	+
2.	861	854	+ 7	49	+	1715	1684	+ 31	961	+
3.	862	858	+ 4	16	+	1720	1716	+ 4	16	+
4.	875	865	+10	100	+	1740	1722	+18	324	+
5.	826	827	- 1	1	-	1653	1640	+13	169	+
6.	864	860	+ 4	16	+	1724	1710	+14	196	+
7.	820	835	-15	225	-	1655	1647	+ 8	64	+
8.	884	882	+ 2	4	+	1766	1752	+14	196	+
9.	820	815	+ 5	25	+	1635	1607	+28	784	+
10.	866	870	- 4	16	-	1736	1718	+18	324	+
Sums			+17	477	7/10			+177	3875	10/10

TABLE 3: SUMMARY OF FINDINGS FROM A STANDARDIZATION TEST OF HEIGHT MEASURES OF PRE-SCHOOL CHILDREN

Measurers	Σd^2	"Signs"	ΣD^2	"Signs"	Observations (by Supervisor)
Supervisor	294	4/8			Best precision, as expected
Observers					
A	324	6/9	524	7/10	Both precision and accuracy satisfactory
B	431	6/10	1195	8/9	Precision satisfactory. Accuracy deficient; values too great by 3.8 mm. Re-examine same children under supervision, with instruction.
C	774	5/10	1024	7/10	Poor precision due to one poor duplicate; accuracy almost adequate. With adequate precision, accuracy can be expected to be adequate.
D	893	5/9	3655	9/10	Overall poor precision; measures 7.4 mm too long, poor attitude, careless. Talk to him and re-standardize.
E	477	7/10	3875	10/10	Precision satisfactory; doing something wrong systematically; 8.9 mm too long. (Upon repeating, he stretches children while measuring them.)
F	1278	7/10	1040	6/10	Poor precision and accuracy due to first four measures. Thereafter satisfactory.

Supervisor's (2 x Σd^2 = 588)
(3 x Σd^2 = 882)

TABLE 4: APPROXIMATIONS TO SQUARES WITH LESS THAN 3.5% ERROR

Number to be squared	Approximate square	Number to be squared	Approximate square
1	1	25	625
2	4	26	675
3	9	27	725
4	16	28	800
5	25	29	850
6	35	30	900
7	50	31	975
8	65	32	1025
9	80	33-34	1120
10	100	35	1200
11	120	36-37	1330
12	140	38-39	1480
13	170	40	1600
14	200	45	2000
15	225	50	2500
16	260	55	3000
17	290	60	3600
18	325	65	4300
19	360	70	4900
20	400	75	5600
21	450	80	6400
22	475	85	7200
23	525	90	8100
24	575	95	9000
		100	10000

TABLE 5: GIVEN A PRESCRIBED NUMBER OF SUBJECTS TO BE MEASURED, HOW MANY DIFFERENCES OF THE SAME SIGN MUST OCCUR TO RECOGNIZE A DIFFERENCE[7] BETWEEN FIRST AND SECOND MEASUREMENTS (d) OR BETWEEN SUPERVISOR AND STAFF WORKER (D)

Number of subjects	Number of differences with same sign
5	At least: 5
6	6
7	7
8	7
9	8
10	9
11	9
12	10
13	10
14	11
15	12
16	12
17	13
18	13
19	14
20	15

[7] Two tailed probability, P <0.1; one tailed probability, P <0.05

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