

A Critique of Theory, Process and Evaluation in *Pathways: a school-based, randomized controlled trial for the prevention of obesity in American Indian schoolchildren*

Introduction

The Pathways prevention trial, published in 2003 in the *American Journal of Clinical Nutrition*, had a straightforward goal: to reduce preemptively the prevalence of obesity in American Indian school children in schools in several states through a multi-component intervention. As a randomized control trial, with rigorous planning, and some theory based components, the intervention showed a great deal of potential. While there is much to learn from how the implementers of Pathways carried out the planning and implementation of this large-scale trial, the intervention was ultimately not successful. After three years, there was no difference in markers of weight gain or obesity between children in the intervention and control schools.

Pathways was a sizable, multidimensional undertaking. Rather than seeking to reduce weight gain exclusively among overweight and obese children, the goal of Pathways was to prevent additional obesity across the board starting at a young age. The project took place in two three-year phases. In phase I of the intervention, all components of the intervention and its methodology were researched, tested, and published. In phase 2, the intervention itself was implemented.

The intervention focused on 1,704 Native American schoolchildren in 41 schools over a three-year period from third through fifth grades. There were four components: reduction of fat in school meals (breakfast and lunch), classroom-based education, family involvement, and increased exercise. The model was ecological in nature, with some elements focused on the individual children's behavior and others focused on the school and family environment.

The remarkable level of detail in the reports from phase I shows that this intervention was not undertaken heedlessly. In 1999, four years prior to the publication of the final intervention, the researchers published twelve articles in the *American Journal of Clinical Nutrition* (Volume 69, Issue 4, Apr 1, 1999) outlining aspects of the proposed intervention. These articles discussed:

- The prevalence of the obesity problem among Native American children
- The importance of cultural relevance and culturally-appropriate participatory research in collaborating with Native American communities
- Statistical analysis and intervention design, including theoretical and practical planning
- Development, pilot-testing, and appropriateness of questionnaires
- Portion-size and physical activity assessment techniques
- A model for reducing fat in school meal diets
- A plan for process evaluation.

Clearly, this intervention involved a significant amount of planning. And yet, after three years, the children in the intervention did not show improvements in body fat percentage, weight, exercise or BMI compared to their counterparts in the control schools. It seems the primary philosophy of change, that a low-fat diet would lead to increased weight loss, did not achieve the intended outcome. An in-depth analysis will allow us to examine the theory, strategy, and evaluation process of this intervention to determine its strengths and weaknesses, and what we might learn to apply to future studies.

Role of Theory in the Intervention

The theoretical model used in Pathways combined a number of different elements. These include social learning theory, cultural relevance theory, an ecological model combining personal, behavioral, and environmental changes, a balance of quantitative and qualitative assessment, formative assessment prior to the actual intervention, and a preventative approach. This intervention makes a case for its own theoretical and practical basis, but the report does not always explain exactly how the theoretical models were applied. This is particularly the case for social learning theory.

The strengths of the intervention included its assiduousness, the selection of a topic of real concern to the community it addressed, its intended emphasis on working collaboratively with the target community, and its ability to change dietary habit. Its weaknesses stem largely from components of the intervention in which researchers may not have met their own high standards, as well as from weaknesses in design methodology, a lack of direct evidence that a low-fat diet intervention successfully reduces obesity, and a limited acknowledgment that the intervention was not successful by its own measures. Additionally, although phase I discusses in detail the importance of cultural relevance, it is unclear that the study was carried out in a strongly culturally relevant manner.

Defining the problem: Obesity incidence, vs. correlation between obesity and dietary fat

The researchers clearly and accurately define one aspect of the problem: that childhood obesity is an issue of significant concern in Native American communities. As the discussion from phase I of the study points out, obesity and associated diseases of metabolic syndrome, particularly diabetes mellitus, are even more prevalent in Native American communities than in other communities in the United States. Precise comparative figures are difficult to establish, since tribal communities are excluded from NHANES data on obesity, but the trend is widely recognized. NHANES demonstrated that 11% of children ages 6-19 in the general population in the time period preceding this study (1988-1994) were obese. A study from a similar time (1990-1991) indicated that 39% of Native American children were obese (J Am Diet Assoc Volume 93, p. 1136-40). In some tribes, over half or three-fourths of members are overweight or obese (AJCN, Volume 69, p. 749S). As established in phase I, tribal representatives are invested in addressing and preventing obesity,

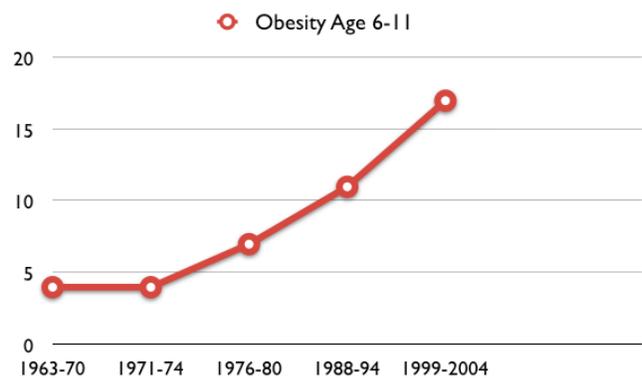
although it is not clear from the report whether any of the Native American communities have specifically requested this intervention as opposed simply to being amenable to it.

However, when one delves into the research in phase I, it appears this intervention is not evidence-based. While the research establishes the prevalence of the problem, explanations about why this disparity occurs are weak. The researchers suggest that environmental, economic, and dietary factors are all relevant, but they fail to establish causality between any one dietary factor and incidence of overweight. Additionally, while their research cites dietary factors other than fat (e.g. sugar), the only specific dietary component of the intervention was fat reduction. The researchers cite genetics as a potential factor, but admit a lack of correlation with obesity. Finally, there is an argument that Native American diets were not originally high in fat, but not only does this inaccurately lump together all Native American traditional diets, but traditional diets ranged significantly in their fat intake and composition, with some accessing a majority or sizable portion of calories from saturated fat. Instead, what is consistent among indigenous groups which have seen a rise in obesity is not a rise in fat, but a change in the composition of fat in the diet, away from monounsaturated and saturated natural sources to polyunsaturated refined vegetable oils and trans fats. Another consistent factor is an introduction of inexpensive refined carbohydrates such as sugar and white flour.

The authors do not show that a reduction in dietary fat will lead to decreased obesity. Phase I cites three sources on this issue. One (Dattilo, *Nutr Today* 1992;53:13–9) based its conclusion that dietary fat affected body weight on *another* study which, in turn found a weak association between fat and obesity, relied on self-reporting and did not look at other dietary variables like sugar intake. The second study (Flatt et al, *J Clin Invest* 1985;76:1019–24) looked at short-term post-prandial effects rather than weight gain, and used margarine rather than natural saturated fat. The third study (Schutz, *Am J Clin Nutr* 1989;50:307–4) looked at simplified energy intake and expenditure rather than long-term weight gain or obesity. This study did not specify the type of fat ingested. Even this study on energy expenditure was refuted by another study, also in the *American Journal of Clinical Nutrition* (Saltzman, *Am J Clin Nutr* 1997; 66; 1332-1339) which showed that dietary fat content did not affect energy expenditure in twins consuming otherwise matched diets.

USDA data, when coupled with obesity statistics from NHANES, show no population-wide association between saturated fat intake and obesity. The obesity problem in the United States increased significantly between 1969 and 1999 (Table 1). In this same period, saturated fat intake decreased, overall fat intake remained level, and only vegetable oil and hydrogenated fat intake

TABLE 1
Obesity (≥95th percentile) children ages 6-11. NHANES data.



increased (Tables 2 & 4). Consumption of red meat and high fat dairy decreased, while intake of poultry, fish, and low-fat dairy increased.

Sweetener consumption increased, almost exclusively due to a triplicate increase in corn sweeteners (Table 3). In short, these data do not support the intervention's use of a low-fat diet to reduce or prevent obesity.

The researchers acknowledge that other interventions of this sort were not successful:

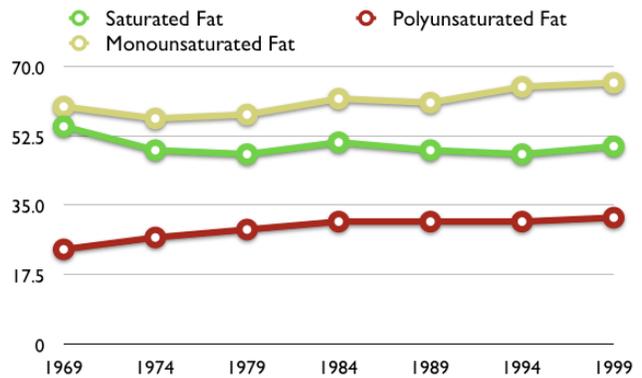
“The results from true primary prevention interventions that included at least a dietary and a physical activity component show that most interventions were able, to a variable degree, to reduce dietary fat intake, increase physical activity during school time, increase consumption of fresh fruit and vegetables, and reduce television viewing (23, 31–34). However, these studies also indicate the resiliency of body weight and adiposity in this age group: virtually none of these interventions, which ranged in duration from 1 to 4 y, significantly reduced average body weight or adiposity in interventions.” (p. 1035)

All five studies referenced in this paragraph had been published at the time Phase I was completed.

Selecting desired outcomes

The researchers selected a reduction of percentage body fat percentage compared to the control group as the primary outcome for this intervention. This is relevant and measurable, although it is not clear why %BF is chosen as the primary outcome rather than reduction in weight or BMI, which were also measured. Including all three as primary outcomes may have been more logical. Secondary outcomes included increased knowledge about nutrition information based on the education

Table 2 (USDA)
Fat consumption 1969-2004 (grams)



Does not include data on fat in meat and dairy consumption, which USDA did not tabulate as fat. However, in the period 1970-1999, consumption of high fat dairy and of red meat **decreased**, while consumption of low-fat dairy, fish, and poultry **increased**. Thus, the period 1969-1999 still represents a fairly stable level or a decrease in saturated fat consumption in the American diet.

Table 3 (USDA data)
Sweetener consumption (teaspoons) 1969-1999

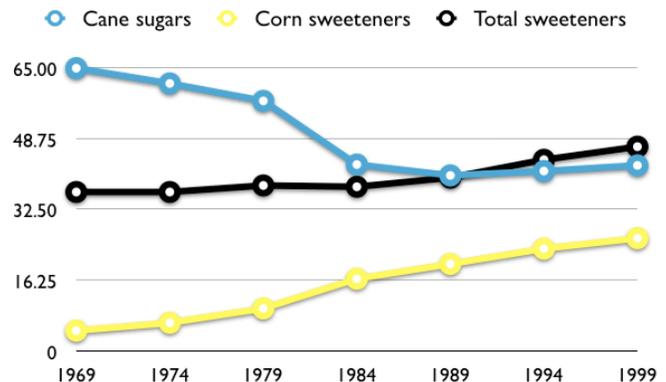
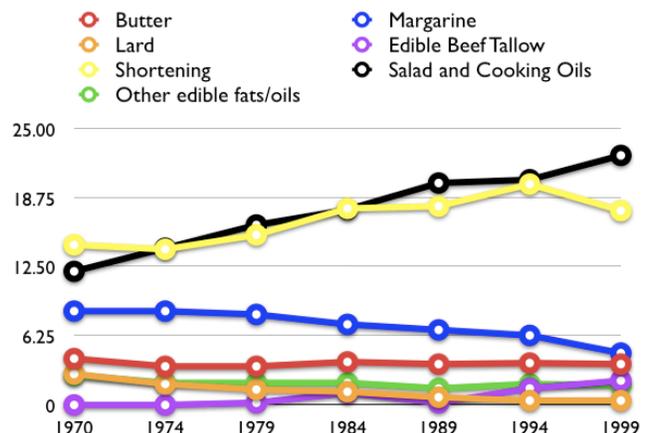


Table 4 (USDA data)
Specific fats 1970-1999



Note that Salad/Cooking Oils and Shortening are the only increases, and that the major sources of natural saturated fats have decreased.

provided as part of the intervention, improved attitudes and behaviors about nutrition, and lower intake of fat. While the inclusion of dietary fat intake is problematic for the reasons stated above, it makes sense to measure changes in dietary fat intake as part of this intervention, to establish any correlation or lack thereof between changes in body fat and dietary fat intake.

While percentage body fat was an acceptable outcome focus, percentage visceral fat measured by waist-to-hip ratio would have been a strong additional outcome to measure. Phase I acknowledges (p. 749S) that midsection fat is more strongly associated with long-term health outcomes such as diabetes than overall body mass index. Other data support this claim (Mason, Obesity; 2008; Dec; 16(12):2690-5).

Intervention design

Strengths

The Pathways intervention was designed with a number of factors that might have set it up to succeed. This was a randomized, controlled trial, with the level of randomization occurring at the school level rather than the individual level, a logical choice given both logistical feasibility and the benefits of keeping control and intervention participants separate in a social learning theory study. The approach was preventative and inclusive, by working with children of all weights rather than just children who are already obese. The age population was selected logically; although there is obesity prevalence at this age, there is the opportunity to prevent some incidence of obesity from developing, to set eating and exercise habits early, and to mediate existing cases of obesity before they develop into larger-scale chronic health issues. By situating the intervention in the school, there is an opportunity to combine personal, behavioral, and environmental intervention components, to directly affect what is eaten at two meals per day, and to take advantage of an educational structure and social setting for both formal learning and application of social learning theory. The broad range of schools (41 including intervention and control) mediated the location-specific biases that might develop in a smaller pool. The three-year period of the intervention allowed researchers to determine whether their intervention had an effect.

The ecological approach not only explored four possible intervention strategies in one setting, it allowed for examination of whether these components might have an exponential helpful effect on one another (e.g. increased exercise encourages participants toward a healthful diet promoted in educational aspects of the intervention).

Weaknesses

Some aspects of the intervention design may have limited or skewed the data. While what children eat at school during the day is measurable, their diet at home is not controlled, and data regarding the home diet rely on self-reporting. The intervention only focused on willing schools, which will not necessarily reflect how

feasible it would be to encourage schools to use similar education and intervention programs in other, less-willing communities. Also, since the approach measured four factors, it can be difficult to determine causality. Had the students actually lost weight, would the changes have been necessarily attributable to all four aspects of the intervention? Only one?

The intervention followed an approach developed by Parcel et al (1988) that included six major guidelines:

- Components related to energy intake and expenditure
- Dietary intervention with family, behavioral and environmental factors
- Physical education focus should have lifelong, self-management focus
- Involvement of food-service personnel
- Self monitoring
- Peer involvement to build a supportive environment for diet and exercise

These recommendations fit with the intervention's ecological approach and value of cultural relevance and family involvement, but, in practice, application of these ideas seemed strong in some areas and limited in others. For instance, the intervention worked closely with food service personnel and focused on family, behavior and environmental factors, but there was limited information in the study about peer involvement to build a supportive environment, or the type of physical education used.

Numerous components of the study were tested comprehensively for logistical feasibility (questionnaires, age appropriateness, etc). However, the intervention's ability to prevent obesity was not evidence-based or pre-tested. The researchers acknowledge this, "Relatively few health education interventions directed at preventive health behaviors in American Indians have been reported in the literature, and none specifically on primary prevention of obesity."

There was no discussion on sustainability. Since the intervention was carried out by the school's own staff, the intervention seems more sustainable than it might be if implemented only by researchers, but the authors do not discuss this or answer questions about long-term feasibility of maintaining this intervention's changes.

While the design included family involvement, it did not do so in a way that draws on family or community knowledge, such as including families in the development of education materials. Rather, the study's family involvement was one-directional, seeking to:

"introduce families to the Pathways intervention and to assist them in creating a supportive environment for healthy behaviors. The activities also offered families an interactive forum to discuss practical aspects of the Pathways program and to extend their knowledge on healthy lifestyle and eating behaviors."

The study goes on to discuss take-home materials, "snack packs" with low-fat foods, tips for "preparing healthful snacks at home" and family events at school where family would be taught about a "healthier lifestyle." All of these strategies assume that researchers know about healthy living and families do not, which is not a respectful or culturally relevant way to treat families. Additionally, given that Native American communities

have historically led healthier lives eating a traditional diet rather than a diet of Western foods, the failure to draw on potential community knowledge about a healthy lifestyle seems problematic. This was one of several ways in which the intervention design did not meet its own standards of cultural relevance.

Measuring process & outcomes

The intervention included both quantitative and qualitative tools to measure process and outcome. Process evaluation was conducted by Pathways staff who did not play a role in the intervention. Assessment included attendance logging at classes and education events for students and families, monitoring of calendars, kitchen-visit logs, and questionnaires for students and families. These tools seem practical given the design of the study.

Food intake was measured by observation and self-reporting, both of which may have skewed data. Dietary intake based on 24-hour recall is limited by social desirability bias and recall bias, perhaps enhanced by the age of the participants. Observation of small groups' food choices, despite being described as nonintrusive, might also have affected what children chose to eat.

Activity level was measured by a combination of quantitative motion-sensor data and qualitative self-reporting data. Combining these allows for broad sampling, and, in this case, for showing a discrepancy between the quantitative data, which showed no increase in physical activity, and self-reporting, which showed an increase among the intervention group. This suggests a level of reporting bias.

Measuring for percent body fat as the primary outcome also has limitations, although comparing the results to the control group helps moderate limitations to some extent. Combining these data with BMI and weight data also strengthen the quality of quantitative outcomes.

Some quantitative measures in the intervention seemed imprecise, particularly in the process of reducing fat in school lunches. Throughout the publication, the authors refer generally to "fat" but in some of the phase I literature and again in the *discussion* section, they use the term "saturated fat" to discuss what they were trying to reduce. It is unclear whether the intervention focused on all fats, including polyunsaturated and trans fat, or only saturated fat; given the USDA data discussed previously, the lack of precision makes a difference. Additionally, while the results show a reduction in fat intake, there is no difference in energy intake, and the authors do not discuss what type of calories may have increased in the diet.

Identifying next steps

The authors keep their discussion of next steps very limited, suggesting only that, "more intense or longer interventions may be needed to modify the continuing trend toward higher adiposity in this population." If this study had shown even incremental achievements in reducing weight, BMI, or %BF, this might be a reasonable suggestion. However, given that there was no such outcome, other next steps might be more logical. These could include a follow-up at the intervention schools to determine whether there has been any

long-term or sustainable effect from the intervention. Additionally, instead of repeating the study in a more intense or longer term way, as the authors suggest, it might be more effective to replicate a similar version of the intervention with different variables in different schools (low-fat, low polyunsaturated fat, low sugar, increased traditional foods, etc). This may cross the line between research and intervention; if this is too unfeasible given a belief among some practitioners that the line should remain clearly delineated, perhaps another intervention focused only on one variable (sugar reduction or increase of traditional foods) might be more logical.

Reasonability of Intervention Strategy

Intervention strategies were reasonable and relevant for the target community. The changes proposed were simple and straightforward: schools would change what food they served in the cafeteria, what information they taught about health and nutrition, and what opportunities for physical activity were available. Children would change their behavior in response to environment and education. These strategies and outcomes were in line with what the community wished to see happen.

Behavioral outcomes

The focus on social learning theory suggests that the researchers were relying on education of students and family to result in behavioral outcomes based on knowledge and peer/community approval. However, the precise implementation of this was not clearly delineated, making it difficult to determine whether it was a plausible method to achieve desired behavior change. In addition, if the approach chosen for educational intervention (e.g. low-fat diet) was ineffective at achieving the outcome (reducing obesity), then behavioral outcomes lose relevance because they do not achieve study outcomes.

Some of the components outlined, however, do not suggest high potential for changing behavioral outcomes, particularly the one-directional form of family involvement discussed previously. To achieve behavioral outcomes, a community has to feel ownership of and buy-in for the behavioral change being proposed. This is often achieved through meaningful community input, respect for community knowledge, and cultural relevance, all of which seem somewhat, if not fully, lacking in the family involvement component.

Target community & cultural relevance

As evidenced by the in-depth discussion of cultural relevance in phase 1, and the mentions of it throughout the Phase 2 report, the researchers were deeply aware of its importance. In practice, true collaboration and cultural relevance seem vague in some components and limited in others.

Significantly, the intervention failed to draw on traditional foods and/or dietary differences between tribes, even though a phase 1 article refers to the importance of accounting for variations in culture and food preferences between Native American tribes.

Extent of inclusion of Native American members in design and implementation was vague. Researchers did get buy-in from tribal authorities, although the extent of enthusiasm is unclear. The steering committee included “2 American Indian representatives elected by all American Indian study personnel” although the role of these representatives or their tribal affiliation is not clear.

The researchers made an attempt to incorporate cultural relevance into education design using “several indigenous learning modes (eg, story telling).” However, this feels somewhat limited; from what cultures are the stories? How are they told? Does this draw on stereotypes of Native American cultures rather than subtle, complex cultural models? Additionally, were teachers who delivered lessons about healthful eating to students and families also from a Native American background?

In short, the research in phase I includes a sensitive and thoughtful analysis about cultural relevance with suggestions for respectful, collaborative interventions. While the actual intervention clearly had some buy-in, collaboration, and representation from Native American communities, it’s difficult to tell from the report itself how meaningful or extensive these were, particularly in the idea-development phase.

Evaluation

The evaluation process, discussed somewhat in the *methods and outcome* section above, examined both primary and secondary outcomes. Evaluation, as per descriptions in phase I, was qualitative, quantitative, and qualitative-quantitative. The primary question was: will a four-part intervention, including a decrease in dietary fat intake, an educational component, family involvement, and exercise, result in a change in body fat percentage? Secondly, process evaluation examined whether an intervention of this design could feasibly produce the four components being implemented. Secondary evaluation also examined whether the intervention resulted in changed attitudes, behaviors, or dietary intake. Evaluation looked at both process (annually) and outcomes, and assessed results individually and institutionally.

The goals were well-defined and measurable, and the reporting was thorough, both in the process and in the outcome evaluation. The researchers measured the extent to which their recommendations were being followed (e.g. 94% of lessons completed, or food service guidelines implemented with a progression of 51%, 80% and 87% across years 1-3). If there was follow-up from the evaluation after the study, it was not reported.

Perhaps the biggest weakness in the evaluation came in the interpretation of the findings. The results of this intervention were poor, with none of the major outcomes achieved (%BF, BMI, weight, exercise increase) other than a very modest reduction in fat intake in school. Yet, the report took somewhat of a positive focus, lauding the reduction of fat intake as an achievement. It is certainly noteworthy that such an intervention was able to make a modest dietary change in a school menu, and this information may be applied to future studies. However, an honest look at the failure of this intervention to achieve its own outcomes would have been welcome.

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