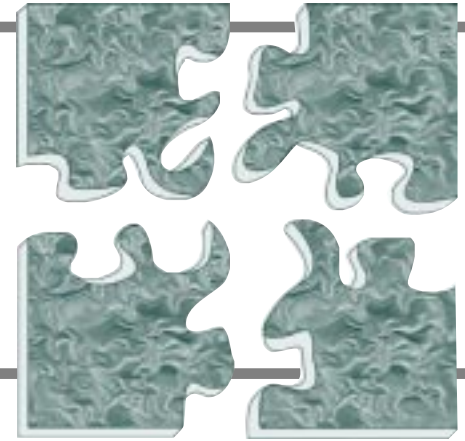


BEST PRACTICE BRIEFS



PUTTING THE PIECES TOGETHER

EVALUATIONS CAN BE
INCONCLUSIVE DUE TO

- characteristics of randomized trials
- low-risk population
- high attrition
- some in control group receive service
- measured outcomes not related to services
- service model not implemented
- flawed service model

USE MULTIPLE
APPROACHES
TO ASSESS
EFFECTIVENESS



OUTREACH
PARTNERSHIPS

MICHIGAN STATE
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ISSUES IN COMMUNITY-BASED EVALUATION: EARLY INTERVENTION HOME VISITING

*During the last 30 years, early interventions have been undertaken by researchers and community agencies concerned with promoting good outcomes for at-risk infants and toddlers. The extent to which various projects have accomplished this goal has been tested through evaluation protocols. A recent report in *The Future of Children* the results evaluations of six home visiting models. This **BRIEF** explores possible reasons why these clinical trials of home visiting models were deemed to be inconclusive. The conclusions have a broader application to evaluations of other community-based interventions.*



INTRODUCTION

The Future of Children, a publication of the David and Lucille Packard Foundation, recently raised questions about the effectiveness of home visiting interventions in accomplishing change for at-risk families. Conclusions resulted from a review of evaluations of six examples of nationally known home visiting programs, five of which were randomized clinical trials repeated in more than one location.¹

¹ D.S. Gomby & P.L. Culross, Eds., (1999), Home Visiting: Recent Program Evaluations, *The Future of Children*, David and Lucille Packard Foundation, vol. 9 (1). The report reviews five programs with results from randomized clinical trials:

- Nurse Home Visitation Program (NHVP), a research project undertaken by David L. Olds, Ph.D., in two locations—Elmira, New York, and Memphis, Tennessee (subsequently replicated in Denver, Colorado)
- Healthy Start (the predecessor of Healthy Families), an ongoing service in three locations in Hawaii
- Comprehensive Child Development Program (CCDP), a five-year research project in 21 locations underwritten by the U.S. Administration for Children, Youth, and Families
- Parents as Teachers (PAT)
- Home Instruction Program for Preschool Youngsters (HIPPY) and one model evaluated in multiple sites using different methods:
- Healthy Families.



In summarizing the results from these six different service models, the reviewers concluded that *Home visiting is a fragile intervention, dependent upon other community agencies for any success in case management, and dependent upon parents for any success with children.... When program benefits were demonstrated, they usually accrued only to a subset of families..., they rarely occurred for all of a program's goals, and the benefits were often quite modest in magnitude.*²

This **BRIEF** explores the characteristics of the randomized clinical trial in community-based interventions that may make for inconclusive results. Future **BRIEFS** will discuss the possible outcomes that home visiting might accomplish, the variations among home visiting models, and the characteristics of effective interventions.

POSSIBLE REASONS FOR INCONCLUSIVE RESULTS

THE NATURE OF RANDOMIZED CLINICAL TRIALS IN THE COMMUNITY

The randomized clinical trial used in these evaluations derives from a research model used in agriculture, medicine, and psychology in situations where a treatment can be controlled and the impact clearly defined. **The prototypic clinical trial** has the following characteristics:

- A sufficiently large population to achieve statistical significance is assigned randomly to an experimental or control group.
- A standard protocol assures that all experimental or control persons get the same treatment.

- Positive results are determined by a statistically significant difference between the two groups in a measurable outcome.
- The relation between a single intervention and the outcome is assumed to be causal.

On the other hand, **work in the community** lacks many features of a controlled experiment. Home visiting and other human services interventions are complex, multiple services are provided, and the relation between services is synergistic. Under these circumstances, the randomized clinical trial is prey to a number of discrepant conditions:

- Some outcomes to be prevented, e.g. child abuse and neglect, are relatively small incidence events. A large sample is required to show significant differences. To overcome the small numbers in home visiting sites, data from multiple sites are sometimes combined, as in the Comprehensive Child Development Program (CCDP), despite site variability in implementation.
- The desired outcomes are multiple and diverse.
- Changes in outcome may depend on inputs from health or other human services in addition to the home visit; availability and quality of other services vary among communities.

Other aspects of the implementation of randomized trials in the community—the characteristics of the population, attrition, and service receipt by the control group—also affect the results. These are discussed in the next sections.

² P.L. Culross, & R.E. Behrman, (1999), Home Visiting: Recent Program Evaluations—Analysis and Recommendations, *The Future of Children*, pp. 23, 6.

APPROACHES TO EVALUATION

Information about the effectiveness of home visiting comes from four types of sources:

- **Case study** of the process and results of intervention with an individual child and parent(s). This approach is informative about techniques and dynamics of change, but is not necessarily representative of all persons receiving services. Case studies generally reflect success stories.
- **Summary** of standardized observational assessments, structured reporting from parents and providers, and/or community data for the group of children and parents served. Summaries present what happened to those receiving service. There is no way of knowing whether the results would have occurred in any case without intervention.
- **Quasi-experiment** comparing outcome information about the group receiving services to that for a group presumed to be comparable. The actual comparability of the two groups can be questioned.
- **Randomized clinical trial** assigning persons randomly to a service group or to a control group. Any differences in out-

come between the two groups can be attributed to the intervention.

PURPOSES FOR EVALUATION

- **To determine whether the intervention was more effective than no service, or another service**, in accomplishing the desired outcomes
- **To inform practice** by providing feedback information to staff and to other interested persons concerning
 - **the characteristics of participants** who were most successful in accomplishing outcomes
 - **the context or conditions** under which the intervention was most effective in accomplishing outcomes
 - **the characteristics of the intervention process** that were most successful in accomplishing outcomes

Evaluations that provide information about the characteristics of participants, the context, and the process that relate to why or how outcomes were or were not achieved are most useful to practitioners and policy makers.

RECRUITMENT AND REFERRAL BY ELEMENTS OF RISK

SELECTION OF PARENT

- Poor
- Single
- Adolescent and/or
- Lacks support, isolated
- Depressed
- Inadequate prenatal care
- Unprepared for infant
- Anxious about care of infant
- Infant not wanted
- Disturbed/ambivalent relationship with infant
- History of
 - mental illness
 - anti-social behavior
 - developmental disability
 - out of home placement
 - losses/abandonment
 - experience of abuse

SELECTION/REFERRAL OF INFANT

- Low birth weight/premature
- Physical impairment
- Exposed to toxins prenatally
- Difficult to care for
- Feeding, sleeping disturbances
- Depressed affect
- Withdrawn, unresponsive
- Failure to thrive
- Developmental delay

SELECTION BY NEIGHBORHOOD

- Unsafe neighborhood
- Poor outcomes
- Limited access to services

THE POPULATION SERVED IS NOT HIGH RISK

Home visiting programs may select populations by easily identifiable characteristics of the parent (low economic status, adolescent) or of the infant (low birth weight). If the selection process does not capture a population with a high probability for poor outcomes, then there is less likelihood that a significant change in outcomes between the experimental and the comparison group will be recorded.

Many home visiting programs select participants during pregnancy or at birth because they are poor or adolescent. Although poverty is strongly associated with other risk factors, poverty alone is not a sufficient predictor. Similarly, the infant of an adolescent with a supportive extended family may not be at risk. It is not surprising that the strongest outcomes have been recorded for populations and subgroups with multiple risk factors reflected in low psychological resources or high deprivation.³ An analysis of 43 early intervention programs found that interventions were most effective when they focused on children who had an identifiable problem or were at risk for other than poverty alone.⁴ Home visiting programs that use multiple risk factors or rely on referrals based on a service provider's assessment of need are more likely to access a high-risk population.

Implications for Practice

- Intervention resources should be matched to level of need. The most intensive home visiting intervention should be reserved for those parents who show disengagement from the infant, who lack informal supports, and/or

who have risk factors most likely to impair the infant's attachment and development.

Service Refusal. Regardless of selection factors, the highest risk families are the most likely to refuse service. Refusal ranged from 10% to 25% in the home visiting programs profiled in *The Future of Children*. Initial refusal can run as high as 38% of eligible poor pregnant women (NHVP in Colorado).⁵

Initial refusal characterizes

- those who do not see the need for service (primarily those with supportive extended families),
- those who do not understand the service being offered, and
- those for whom outside contact with agency staff is perceived as a threat (those who are directly or indirectly involved in substance abuse or criminal activity, or have had prior experience with protective services or institutional care).

³ NHVP found that the most significant differences in outcomes between served and unserved groups occurred for poor, single adolescents as a whole and for those women with low psychological resources, *The Future of Children*, p. 61. Interventions with highly deprived populations overseas have also shown positive results.

⁴ S. Heverly, F. Newman, and S. Forquer, (1982), Meta-analysis and Cost Analysis of Preventive Intervention Programs, *Report to the National Center for Clinical Infant Programs*, Systems Research Unit, Philadelphia.

⁵ *The Future of Children*, p. 16; and J. Korfmacher, R. O'Brien, J. Hiatt, & D. Olds, (December 1999), Differences in Program Implementation Between Nurses and Paraprofessionals Providing Home Visits During Pregnancy and Infancy: A Randomized Trial, *American Journal of Public Health*, vol. 89 (12), p. 1849.

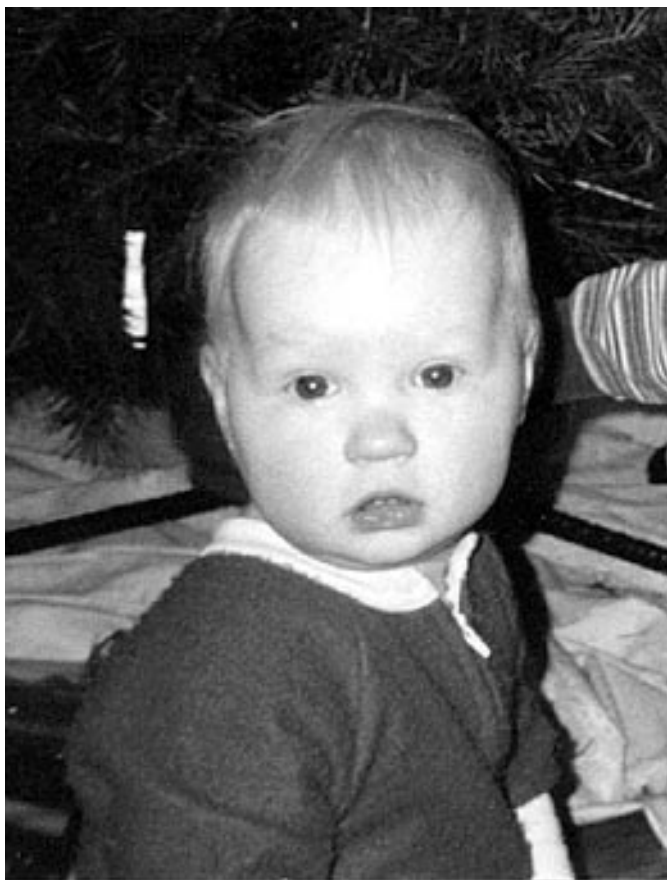
Implications for Practice

A high rate of initial refusal suggests that the recruitment approach is flawed—possibly stigmatizing (implying that the parent is incompetent), unintentionally threatening for women who have had previous aversive experiences with community agencies, or without rationale for the offer of assistance. Using a positive approach, the recruiter should

- note that parenthood is a period of transition,
- suggest that other mothers have found a home visitor helpful in terms of child care and the infant's development,
- give some idea of the time involved, the content, and what will be expected of the parent.

The recruiter should assure confidentiality (but indicate that she/he is legally obligated to report observed abuse or neglect).

Because some parents who refuse initially will change their minds later or will be identified by other service providers and referred, community programs should have mechanisms for enrollment at a later date.



RESULTS ARE ATTENUATED BY ATTRITION

Random clinical trials include all those who have been enrolled and who can be located regardless of the amount of service received (i.e., the evaluation, following standard statistical procedure, is based on “intent to serve,” not actual service). In most programs, a substantial number of families that are initially enrolled drop out of service prior to the term of service anticipated in the model. For example, the Comprehensive Child Development Program projects reported a constant 1% per month rate of dropout over the life of the projects,⁶ and attrition among the three Hawaii Healthy Start sites varied from 40% to 65% after one year (51% across the three sites), with 10% overall dropping out by three months.⁷

Some portion of those who withdraw from service are also dropouts from the evaluation.

However, comparative outcome data, using the “intent to serve” approach, invariably includes some proportion of families who received little

⁶ R.G. St. Pierre, J.I. Layzer, B.D. Goodson, L.S. Bernstein, (June 1997), National Impact Evaluation of the Comprehensive Child Development Program: Final Report, Abt Associates Inc., pp. 2-13.

⁷ A.K. Duggan, et. al., (1999), Evaluation of Hawaii's Healthy Start Program, in *The Future of Children*, pp. 73-76, 198.

or no service and who therefore have outcomes no different than those for the control group. Thus the Hawaii Healthy Start, keeping attrition from the evaluation to 12% after two years, included data for 39% of families who received less than the full term of service.⁸ In the studies covered in *The Future of Children*, 20% to 67% of families left before the expected term of service, while researchers kept the attrition from the evaluation data at 10% to 48%.⁹

Generally, the proportion of families who accomplish service objectives increases with the length of service.

Implications for Practice

Evaluations should include an analysis by length of service, including the characteristics of persons at various levels.

PERCENT OF FAMILIES COMPLETING ACCORDING TO PLAN GOES UP AS LENGTH OF SERVICE INCREASES

DURATION OF SERVICE AT TERMINATION	% COMPLETING ACCORDING TO PLAN
3 months or less28%
4-6 months46%
7-12 months33%
13-18 months55%
19-24 months59%
25-36 months72%

Data from Objectives/Problems Checklist analysis quoted in Michigan Department of Mental Health, (May 1995), A Review of Infant Mental Health Services in the Context of Systems Reform, Lansing, MI.

Types of Attrition¹⁰

Pulling away after enrollment can be described as

- **Refusal of service** (from 25% to 34% of enrollees)
 - passive refusal: cannot be located or are unresponsive
 - active refusal of service
- **Move** out of the program area (from 8% to 11%)
- **Death or removal** of a child (from 3% to 4%)

There is some evidence that the less educated, less competent families are those most likely to pull away from service,¹¹ and that adolescents who pull away from service are younger and have less healthy babies.¹²

Participant reasons for active or passive refusal are varied:

- Parent or significant others fear a **potential threat** of protective services or police involvement.

- Parent or significant others perceive home visiting content as **unnneeded or unwanted**.
- Parent cannot fit a home visit into a **crowded schedule**. Under welfare reform, movement to employment will increasingly be a reason for premature termination as parents faced with escalating demands on their time find it too difficult to meet with a home visitor.
- Home visitor touches on **issues** that the parent does not wish to confront.
- Parent has **accomplished her perceived objectives** for home visiting.

⁸ *The Future of Children*, p. 198.

⁹ *The Future of Children*, pp.16, 42.

¹⁰ Percentages come from the experience in Hawaii Healthy Start, *The Future of Children*, p.74; and NHVP in Colorado, Korfmacher, p. 1849.

¹¹ K.N. Barnard, et al., (1985), Prevention of Parenting Alterations for Women with Low Social Support, *Psychiatry*, vol. 5, pp. 248-253.

¹² J. Osofsky, N.M. Culp, & L.M. Ware, (1988), Intervention Challenges with Adolescent Mothers and Their Infants, *Psychiatry*, vol. 51, pp. 236-241.

Contextual conditions contribute to active or passive refusal:

- **Home visitors lack skill in establishing a relationship** with families and accomplishing objectives. Home visitors may not receive sufficient training and supervision for adequate support and direction.
- **Discontinuity in service providers.** Parents with experiences of loss seldom can weather the transition to a new home visitor when the person with whom they have established a relationship decides to move on. A substantial number of home visited families experience this type of disruption in service—50% of families in NHVP in Memphis as a result of a nursing shortage in the community; 11% for nurses and 35% for paraprofessionals in Nurse Home Visiting Program in Colorado.¹³
- **Agency's explicit or implicit policy.** Home visitors are not explicitly encouraged to persist in callbacks after no shows. Families who move out of the service area—even for short distances—are automatically dropped from service. High caseloads encourage attrition.

Implications for Service

- Attrition figures should be monitored and possible reasons explored to see whether changes need to be made in policies, procedures, training, or supervision.
- Special procedures should be used to bridge the transition from one home visitor to another when staff disruption occurs.
- Agency and staff flexibility in work schedules may be required under welfare reform to allow for evening and Saturday visits.
- Agencies in neighboring jurisdictions can reduce attrition by interagency agreements to reimburse each other for services to families moving within a reasonable distance that wish to continue services.

THE COMPARISON GROUP RECEIVED SERVICES

If a portion of the control group in fact received comparable services from other sources, the comparison understates the impact of the intervention. Although most studies do not obtain this information, the Hawaii Healthy Start evaluators noted that

28% of the control group received home visiting from other sources.¹⁴ Despite evaluation designs, in most communities referral sources make every effort to get high-risk families served in some way.¹⁵

Projects that utilize a case management model, emphasizing access to and integration of services, are particularly vulnerable to this problem because service coordination is commonly available to high-risk families through multiple systems. The Comprehensive Child Development Program, linking low income families to community services in 21 sites, showed little difference overall between service and control groups in access to services and both groups showed similar changes in child's verbal ability and parental employment, except in one site that, among other differences, had no competing services.¹⁶

Implications for Practice

The proliferation of home visiting services and other interventions for at-risk populations in larger communities during the 1990's suggests that it is no longer possible to have a comparison group that is totally unserved. Under these circumstances, a realistic evaluation should

- exclude those receiving service outside the evaluation group from the analysis, or
- document that outcomes were no different for those controls receiving or not receiving services.

Assessing the results of alternative interventions would be more productive than comparison with a control group that has in fact received services in some measure.

MEASUREMENT, DELIVERY, AND DESIGN OF THE INTERVENTION

MEASURED OUTCOMES ARE NOT RELATED TO SERVICES

Measured outcomes are unlikely to be significant if there is a disconnect between the service rendered

¹³ *The Future of Children*, p. 58; Korfmacher, p. 1849.

¹⁴ *The Future of Children*, p. 75.

¹⁵ In Grand Rapids, Michigan, for example, in addition to the CCDP project, Project Focus, the following home visiting services were available in the community for at-risk infants/toddlers and their parents: Kent County Health Department—Maternal Support and Infant Support Services; Spectrum Hospital—MOMs Program; Child and Family Resource Council—Healthy Start; Arbor Circle—Infant Mental Health Services; MSU Extension—Building Strong Families; and HIPPY.

¹⁶ *The Future of Children*, pp. 143-144.

and the measured objective. The measured outcome must be

- appropriate to the **characteristics of the population** served.

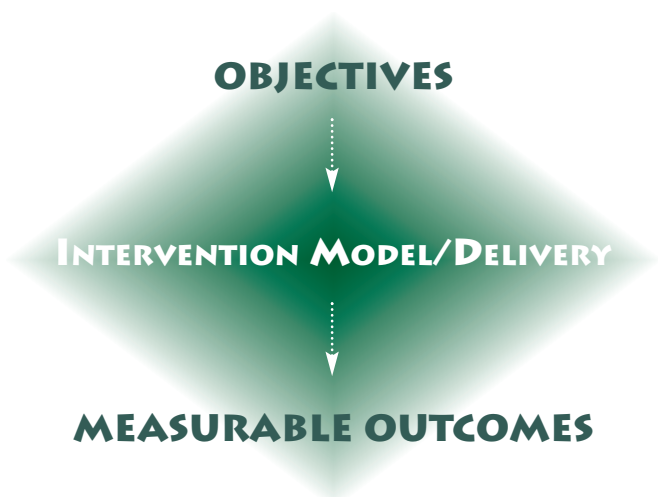
The Nurse Home Visiting Program in Elmira achieved a reduction in smoking and consequent reduction in the number of low birth weight babies. In Memphis no impact on smoking and low birth weight occurred because a very small proportion of Memphis adolescent mothers smoked and low birth weight was a result of other conditions.

- consistent with the **content of the service delivery** as designed and delivered.

The accomplishment of most outcomes requires ongoing articulation, reinforcement, and facilitation. Cognitive development, for example, cannot be accomplished in the absence of specific content and a threshold intensity of delivery. It is likely that discussion and facilitation are required to accomplish an increase in immunizations, deferral of the next birth, or return to school.

Implications for Practice

- Program developers should assess the relevance of intervention content to the characteristics of their population.
- Program developers should be very clear about program objectives and the means proposed to accomplish them.
- Outcome measures must be relevant to the objectives and to the service delivery.
- Staff must be fully aware of the identified objectives, the means to accomplish them, and the measurements.



The Service Model Is Not Implemented

Inconclusive evaluation results may mean that the model of service, however well designed, is not

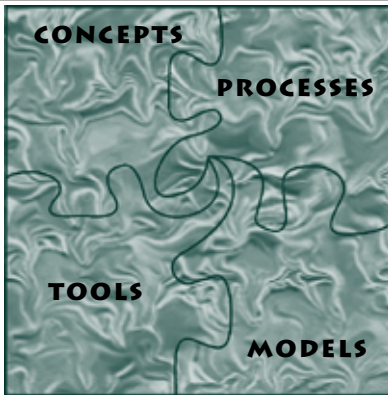
being delivered as planned. The lack of outcomes may be an issue of implementation. For example,

- **Few evaluated projects allow for a start-up period.** Under these circumstances evaluation results will capture less than optimal performance by staff. The project may change substantially after the initial period of experience in the service delivery and even in the characteristics of families served; yet the reported evaluation is based primarily on families served during the initial period.
- **The number of contacts between the home visitor and the family will be fewer than intended.** In practice, visits invariably occur less often than the model anticipates, due to no shows or caseload pressures. The Nurse Home Visiting Program in Elmira and in Memphis, for example, accomplished 53% and 55% of expected visits overall. There will be a substantial difference in the number of visits received by one family versus another.
- **Home visitors may not be following intervention content** as identified in project protocols or training. Protocols may generally or specifically outline the content of visits. However, intervention models often specify that accommodation must be made to the issues and concerns expressed by the parent. What is actually discussed depends on the wishes of the parent as well as the agenda of the particular home visitor. Moreover, it takes considerable skill to incorporate a protocol into a fluid situation directed by the parent.

The Service Model Is Flawed

Although implementation issues loom large, a more basic consideration may be the inherent viability of the home visiting model selected for accomplishing change in children and families. Although home visiting programs are presented as a generic service, in fact the content delivered and the process of delivery vary enormously depending upon the rationale for the intervention and the desired objective.

The viability of a model may be a function of the intervention itself—emphasizing support, case management, education, or relationship-based and ecological approaches. Or, the viability of the model may be a function of logistical decisions—when families are recruited, how often and how long families are visited. The background and training of the home visitors responsible for service delivery and the effectiveness of the organization in supporting them also impact outcomes. These issues will be discussed in the next **BRIEFS**.



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IN SUMMARY

Multiple hazards affect the capacity of randomized clinical trials to evaluate human service interventions in the community. The factors that have been identified in the evaluations of home visiting programs for infants/toddlers and their families are also relevant for other programming seeking to use rigorous methods to document effectiveness.

Funders, program managers, and evaluators should recognize that there are multiple ways of “knowing” the effectiveness of an intervention—some of which should be part of the ongoing monitoring and quality

management process. At the community level, the development and installation of manageable, ongoing, structured documentation and reporting processes are long overdue.

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