

The Abecedarian Approach to Social, Educational, and Health Disparities

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Published online: 11 April 2018 © Springer Science+Business Media, LLC, part of Springer Nature 2018

Abstract

This paper places the Abecedarian Approach in theoretical and historical context and reviews the results from three randomized controlled trials that have tested an experimental protocol designed to prevent cognitive disabilities and their social consequences. Results affirm that cognitive disabilities can be prevented in early childhood and subsequent academic achievement enhanced via a multipronged comprehensive approach that contains individualized and responsive early childhood education starting in early infancy, coupled with pediatric health care, good nutrition, and family-oriented social services. Additional important findings reveal that the most vulnerable children benefited the most and that cognitive gains were not at the expense of children's socioemotional development or relationship to family. In general, mothers derived benefits in education and employment and teenage mothers especially benefited from their children participating in the early education treatment group. On the whole, the overall pattern of results supports a multidisciplinary, individualized, and long-term longitudinal perspective on human development and prevention science. Recent structural and functional brain imaging in the fifth decade of life shows persistent effects of intensive early educational treatment. Independent recent cost-benefit analysis in adulthood reveals a 7.3:1 return on investment with a 13.7% average annual rate of return. The paper concludes with a discussion of implications of the Abecedarian Approach to today's high-risk population in the USA

Keywords Early development · Early childhood education · Disparities · Prevention · Conceptual framework

The Abecedarian Approach to Early Childhood

Some questions about human existence are so basic as to require experimental scientific address, if ethically possible. The broad question of human malleability is one such question. Can the course of human development be significantly and practically altered by intentional and directed acts? If

abe·ce·dar·i·an \, \bar{a} -bē-(,)sē-'der-ē-ən\ n [ME *abecedary*, fr. ML *abecedarium* alphabet, fr. LL, neut. of *abecedarius* of the alphabet, fr. The letters a + b + c + d]: one learning the rudiments of something (as the alphabet). The idea behind the name was to provide a broad knowledge base to prepare children for success in school.

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¹ Distinguished Research Scholar, Virginia Tech Carilion Research Institute, Professor of Psychology, Neuroscience, Human Development, and Pediatrics, Virginia Tech, VTCRI, 2 Riverside Circle, Roanoke, VA 24016, USA so, through what systematic interventions and by how much? To what theoretical and social ends should systematic efforts be focused?

This question of human malleability has a long and controversial history in the USA and around the world. The issue of human malleability began, in the USA, with racial and social class assumptions that predate the founding of the Republic and that became cornerstones of public polices including slavery, education, housing, health care, employment, and marriage. The assumptions about malleability pro and con—have shaped and continue to shape public policy debates, civil conflict, and practical politics.

Scientists have contributed to the malleability controversies with some individuals taking strongly predetermined and unalterable genetic views, such as Galton (1883), Jensen (1969), and Herrnstein and Murray (1994), while others have favored an experiential and/or environmental view point including Hunt (1961) and Bijou and Baer (1961), particularly with respect to cognitive performance and social and economic consequences. What became clear to me and others beginning in the mid to late 1960s was that this basic controversy needed an experimental approach. It simply could not be adequately addressed via correlational analyses of naturalistic observations no matter how complex and sophisticated. To me, the most basic question became whether individuals from highly vulnerable populations could benefit significantly if given more adequate resources for fuller development of cognitive abilities and socioeconomic status. Chief among these resources were health care, good nutrition, family-oriented social services, and early childhood education. These are factors that we attempted to control experimentally to make our understanding of variations in early childhood education more precise.

This paper deals with some of the experimental work that I began at the Frank Porter Graham Child Development Institute of the University of North Carolina at Chapel Hill almost five decades ago. I realize there are practice, policy, and ethical implications of these basic questions, but this paper is primarily about the research that I, and my many colleagues, have been privileged to conduct on human malleability.

The social and political contexts that contributed to my thinking leading to the creation of the Abecedarian Approach can be captured by acknowledging five megatrends: First was the Brown vs. Board of Education decision in 1954 that declared separate but unequal school systems for blacks and whites to be unconstitutional. Second was the Civil Rights Legislation in 1965 and 1967 that outlawed racial discrimination in voting, employment, housing, and interracial marriage. Third was the War on Poverty proposed by President Lyndon B. Johnson in 1964 with an emphasis on community action that included Head Start and later Early Head Start. Fourth was the creation of Welfare Reform now known as Temporary Assistance for Needy Families (TANF) proposed by President Clinton in 1997 with its work and educational requirements for mothers. Fifth was the creation and expansion of second wave feminism from roughly the 1960s through the 1980s with its emphasis on women's equality of opportunity and pay. Collectively these and other trends continue to influence public policy with regard to social, educational, and health disparities.

Epidemiology of Social Disparities

Poverty has a profound effect on brain development (Farah 2017), school readiness, and later school performance according to recent data from the Early Childhood Longitudinal Study—Birth Cohort (ECLS-B). More than 25% of children from poor families score more than one standard deviation below average at age 5 on early math and reading skills compared to 7% of children from moderate and high-income families (Isaacs and Magnuson 2011). The deeper a family lives in poverty and the more generations that it has persisted, the more that poverty results in educational and health disparities for the next generation.

This paper provides an overview of the Abecedarian Approach developed and used in the Abecedarian Project (e.g., Ramey et al. 1976) and its replications, Project CARE (e.g., Ramey et al. 1985; Wasik et al. 1990) and the Infant Health and Development Program (e.g., Infant Health and Development Program (e.g., Infant Health and Development Program 1990; Ramey et al. 1992). The word "approach" is used to indicate the main Abecedarian concepts and procedures that have been used as tools in a series of randomized controlled trials (RCTs). In that sense, the Abecedarian Approach summarized briefly in Table 1 and in much greater detail in Ramey et al. (2012) is a set of standards, curriculum resources, and practices that were used in the interventions conducted for the Abecedarian Project, Project CARE, and The Infant Health and Development Program (IHDP).

The immediately relevant research that drove the creation of the Abecedarian Project came out of basic behavioral research that clearly established that even young infants were capable of learning, remembering, and generalizing from environments that were responsive to their behaviors (e.g., Watson and Ramey 1972; Ramey et al. 1975; Ramey and Finkelstein 1978). The three main experiments to be described in this paper sought to determine whether the provision of a theory-guided set of active learning experiences could produce significant benefits in language and learning for young children from highly impoverished, multi-risk families (who were known from an epidemiological perspective to be at risk for poor school achievement and subsequent life difficulties) and, later, for children with known biological risks at birth for poor cognitive developmentspecifically low birth weight and prematurity. The control groups of children who did not attend the specially developed experimental child development centers received support for health care, free and unlimited nutritional supports, and active social work services for their families, as well as timely referrals and follow-up when any developmental problems were detected or suspected. Because the control groups received these multiple supports, the research findings provide an even stronger basis than traditional untreated controls for concluding that the educational component of the Abecedarian Approach produced the documented positive differences between children in the experimental groups versus the control groups.

Conceptual Framework: Biosocial Developmental Contextualism

On the basis of my 50 years of research on early experience I view a conceptual framework as essential to make the many relevant factors coherent to a broad range of colleagues from

Table 1 Major features of the Abecedarian Approach

An education program that began in early infancy

A structured curriculum grounded in developmental theory and research findings

- A highly trained and actively monitored teaching staff committed to implementing the curriculum and documenting each child's progress with biweekly summaries
- Provision of high-quality health and safety practices including active health/safety monitoring of all children within an environment that emphasized nutritious food, lots of exercise and play, and health promotion (good hygiene, appropriate rest)

Low adult to child ratios (1:3 until babies were walking, 1:4 for toddlers and twos; 1:6 for ages 3 and 4)

- Ongoing professional development from the child development center director and other learning specialists, with weekly meetings and frequent monitoring and in-classroom supports for teachers. All teachers received active instruction and supervision to implement the curriculum daily and to document each child's engagement in specific games that were part of the educational program
- Individualization of pace in the curriculum and attention to special needs of the child and family, including provision of social work services in a timely manner with follow-up supports
- Provision of transportation to children as needed from their homes to center and back
- Full-day, full-week, year round program (center open from 7:30 a.m. to 5:30 p.m., operating 5 days a week, 50 weeks per year) with major emphasis on full attendance by all children
- Parent engagement component, including group meetings and special topic sessions as well as teacher meetings with parents about their own children's progress
- Referral of children to specialists when any problems were detected or suspected based on systematic and frequent assessments in language, cognition (intelligence), social-emotional progress, and health
- Provision of a well-supplied book and toy lending library for families, including many of the same materials available to children during their center experiences
- Stable and stimulating adult–child interactions with a central commitment to ensuring that each child engaged daily in many rich and varied language and learning activities (The primary place for ensuring that these activities occurred was a child development center that implemented educational activities, known first as *LearningGames*[®] (Sparling and Lewis 1979, 1984, 2008) and later modified as *Partners for learning* (Sparling et al. 1984/1995))
- A planned transition program in the summer before kindergarten that was a preview or pre-exposure to what the known public kindergarten classrooms were like. (Note: this applied only to The Abecedarian Project and Project CARE)
- A commitment to using objective data as a basis for observing, documenting, and monitoring the delivery of the educational intervention and relating children's development in multiple domains (cognitive, language, social/emotional, physical) to their participation in a structured, research-informed early educational program

different disciplines, practitioners, and the general public. Over the years my framework has evolved as I and the relevant disciplinary perspectives have become more detailed and as assessment techniques have become both more sophisticated and scientifically applicable to young children and families. (See the following papers for examples of my own development: Ramey and Gallagher 1975; Ramey and Haskins 1981; Ramey et al. 1985; Ramey and Ramey 1998a, b; Ramey et al. 2006; Bickel et al. 2014; Ramey and Ramey, in press).

In this section I summarize a general conceptual framework for clarifying the goals, components, and developmental outcomes of early intervention programs. This framework is an intergenerational one that emphasizes both child and parent development. Figure 1 depicts salient sources of influence on the cognitive, social, and emotional development of children and their primary caregivers and specifies broad categories of potential intervention services and support. Within this framework, the current biological and behavior status of children and adults reflects the cumulative effects of their personal histories. These influences include developmental epigenetics, genetics, the prenatal environment, pervasive sociocultural norms and practices, and special characteristics and resources of local communities. In addition, each family and child have particular supports and stressors from within and outside the family that affect the quality and quantity of behavioral transactions among members; these transactions are the primary mode of learning for young children.

Within this general conceptual framework, changes in child and family developmental status are mediated by specific *psychosocial developmental priming mechanisms* (described below). That is, the early intervention supports and services are hypothesized to have their effects by altering the experiences and behaviors of individual children and family members. Social transactions, both within and outside the family, and their cognitive interpretation and memories are construed as the primary mechanisms of inducing developmental change.

Changes in very young children's cognitive, social, and emotional development are, of course, interrelated and neurobiologically mediated. Important developmental neurobiological mediators currently hypothesized to be implicated in early experience include neurotransmitter

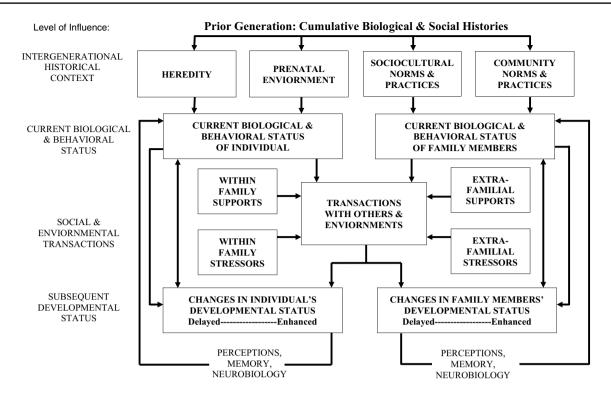


Fig. 1 Biosocial Developmental Contextualism. Reproduced with permission from Ramey and Ramey (1998a, b)

changes (such as in the serotonin and dopamine levels and the endorphin system), synaptic pruning as a function of experience (particularly use-dependent neural network development), and gene activation associated with experience (e.g., Shore 1997). In Fig. 1, the provision of early care and education activities can be construed as an extra-familial support system and includes monitoring the participants' progress and adapting and modifying interventions when needed to optimize individual development.

Biobehavioral transactions of young children with their environments are construed to be mechanisms that induce, maintain, and expand a child's behavioral repertoire. I consider these to be Developmental Priming Mechanisms of which 6 are especially prominent for young children and which were emphasized in Abecedarian education. The six developmental priming mechanisms elaborated by Ramey and Ramey (1998a, b) are (1) encouragement to explore the environment, (2) mentoring in basic cognitive and social skills, (3) celebrating new skills, (4) rehearsing and expanding new skills, (5) protection from inappropriate punishment or ridicule for developmental advances, and (6) stimulation and support in language and symbolic communication. These priming mechanisms are hypothesized to be critical to normal development and must be present in children's everyday lives on a frequent, predictable basis.

The Three Abecedarian Randomized Controlled Trials

The Abecedarian Approach was employed in three independent longitudinal Abecedarian studies—two single-site and one multi-site randomized controlled trial. The protocol was applied in these studies with some variations as Table 2 summarizes.

We assume that children are potentially learning all the time, starting at birth (and perhaps even earlier). The overall Abecedarian program and the specific educational practices and curricula were designed to be highly engaging, fun, and active—with learning occurring throughout the day in various activities including daily caregiving, transitions, physical play, and exploration, as well as more structured learning experiences. Activities included many adult–child individualized interactions construed as developmental priming mechanisms as well as small group activities as babies became older.

The systematic educational curriculum and the professional development associated with it was based on the identification of multiple types of learning processes in infants, toddlers, and young children (Ramey et al. 1996)—and was paced to be appropriate for a child's development to continuously provide positive challenges that were individualized for each child. The Abecedarian Approach strongly

Intervention components	The Abecedarian project 1972	Project CARE 1977	Infant Health and Development Program (IHDP) 1984
Criteria for inclusion in the sample	Multi-component socioeconomic risk (high risk score > 11)	Multi-component socioeconomic risk (high risk score > 11)	Low birth weight (≤ 2500 g) and premature (≤ 37 weeks gesta- tional age)
Duration of the child development center program	Age 6 weeks to age 5 years	Age 6 weeks to age 5 years	12 to 36 months corrected age
Amount of child development center program offered	Full day ^a , 5 days/wk., 50 weeks per year	Full day, 5 days/wk., 50 weeks per year	Full day, 5 days/wk., 50 weeks per year from 12 to 36 months
Visits in homes	As needed, for social support ^b	Weekly educational visits (<i>Learn-ingGames</i> [®] , 1979, 1984)	Weekly educational visits first 12 mos, then twice a month (Spar- ling et al. 1984/1995)
Health care	On-site with nurses and MDs	On-site with nurses and MDs	By family's own provider
Transportation to center	Provided by program	Provided by program	Provided by program
Parent education group sessions	Several per year	Several per year	Every other month
Educational program	Abecedarian Approach	Abecedarian Approach	Abecedarian Approach

Table 2 Three longitudinal applications of the Abecedarian Approach

^aMost children received approximately 8 h/day

^bFor the Abecedarian Project, 50% of the child development center children and 50% of the preschool control also received a home-school liaison follow-up program with a summer educational program for the first 3 years of public school that included both home and school visits

acknowledged the centrality of communication to the development of cognition and intelligence (cf. McGinness and Ramey 1981; Ramey et al. 1981). Thus, the planned activities included many ways to use signs, symbols, sounds, words, sentences, stories, and interactive conversations— starting early in the first year of life. Even conversational reading and play began in infancy with specially written picture/word books. Teachers were encouraged to use varied, complex, and informative language throughout the day and to use Standard English in the child development center. (Note: no children or families in Abecedarian Project or Project CARE spoke a language other than English.)

The Commitment to High Quality in the Abecedarian Approach

In the Abecedarian Approach, there were four broad areas that were considered especially critical to help children to grow and thrive. These areas recently have been described in detail as "The Four Diamond Model of High Quality Early Care and Education" (Ramey et al. 2012) and were used for ongoing professional development and support for staff:

- *Health and Safety Practices* Behaviors that seek to prevent accidents and promote physical and mental health and safety, consistently implemented at all times.
- *Adult–Child Interactions* Frequent, warm, and responsive transactions with individual children.
- Language and Learning Activities Adapted for the child's age and developmental level to maintain high interest and motivation. These were designed to be frequent, enjoy-

able, and to promote new and more advanced levels of child competence and independence.

• *Caregiver-Family Relationships* Respectful, supportive, and informative. These were designed to facilitate frequent communication between adults in the program and parents and other family members and to be socially positive.

In the Four Diamond Model there are many other important environmental influences (such as staffing ratios and an enriched physical environment) but these are considered distal rather than proximal influences on the child.

The Abecedarian Study Samples

The Abecedarian Approach was applied in three separate longitudinal investigations while I was at Frank Porter Graham Institute from 1971 to 1990. Following are some details on the study samples in these research projects:

- *The Abecedarian Project*: The sample consisted of 111 poor, high-risk families in Orange County, NC, whose children were born between 1972 and 1977. 98% of the families in the Abecedarian Project were African-American, 76% were headed by single mothers, and the mothers had an average educational level of 10th grade and a mean IQ of 84 (approximately 1 standard deviation below national average).
- *Project CARE*: The sample consisted of 64 poor, highrisk families in Orange County, NC, whose children were born between 1978 and 1980. 91% of the CARE families were African-American/Black.

• *The Infant Health and Development Program*: The sample was comprised of 985 premature and low birth weight infants from eight cities. The families were from all socioeconomic classes and were 38% white/non-Hispanic, 51% African-American/Black, and 11% Hispanic/Latino.

These three are the longest-term and most extensively published Abecedarian Approach studies, but there have been many other shorter-term research studies that employed all or parts of the Abecedarian Approach. In the listing of experiments in Table 3, we identify the 8 sites of the Infant Health and Development Project, because each was independently randomized and was about the size of the original Abecedarian Project. In total, this list identifies 10 samples that have been studied in randomized controlled trials that tested the efficacy of the Abecedarian Approach.

Admission Criteria for the Longitudinal Studies

Before launching the Abecedarian Project, we created a High Risk Index (Ramey and Smith 1977) to establish eligibility for admission of children into the research study. We used epidemiological data concerning the demographic factors linked to developmental delay, cognitive impairment, and poor school achievement. We assigned weights to these variables based on the best available evidence about their predictive importance as listed in Table 4.

In the Abecedarian Project and in Project CARE, the criteria for inclusion were a High Risk Index score of 11 or greater and being healthy at birth. The population in Orange County was screened to identify eligible families. Then children were randomly assigned to either the experimental or the control group via use of a computer program.

In the 8-site Infant Health and Development Project, the only criteria for inclusion were being low birth weight (<2500 gm) and premature (<37 weeks gestational age). Children were randomly assigned within two strata: birth weight between 2500 and 2000 g and birth weight lower than 2000 g via use of a computer program.

Highlights of the Longitudinal Studies

The children in the Abecedarian Project were randomly assigned to two groups: an experimental treatment group (57 children) or a control group (54 children). (Note: due to twins and a child later deemed ineligible, group size was not identical). Their family characteristics included:

- Very low incomes (well below 50% of the federal poverty line, adjusted for family size),
- Very low levels of maternal education (approximately 10 years),
- Low intellectual test scores for mothers (average Intelligence Quotient was near 84),
- Single parenthood (in approximately 75% of the families), and
- Unemployed mothers (almost all at time of study recruitment).

The study was designed to test the effects of a high-quality, supportive educational program over the first 5 years of life. We sought to address the hypothesis that comprehensive educational services for children from highly disadvantaged families beginning at birth for initially healthy children could be instrumental in preventing cognitive impairment prior to entry into public school in kindergarten, while ensuring that both treatment group and control

Randomized samples	Location	Ν	Duration of program	Type of program	Oldest age of follow- up
Abecedarian 1 (The Abecedarian Project)	Chapel Hill, NC	111 children	Birth to age 5 years	Center + social work + home visits + health care	40
Abecedarian 2 (Project CARE)	Chapel Hill, NC	65 children	Birth to age 5 years	Center + social work + educa- tional home visits + health care	21
Infant health and development program	m (IHDP)				
Abecedarian 3	Boston, MA	138 children	Birth to age 3 years	Center+educational home visits	18
Abecedarian 4	New Haven, CT	112 children	Birth to age 3 years	Center+educational home visits	18
Abecedarian 5	Bronx, NY	138 children	Birth to age 3 years	Center+educational home visits	18
Abecedarian 6	Philadelphia, PA	101 children	Birth to age 3 years	Center+educational home visits	18
Abecedarian 7	Miami, FL	100 children	Birth to age 3 years	Center+educational home visits	18
Abecedarian 8	Little Rock, AK	128 children	Birth to age 3 years	Center+educational home visits	18
Abecedarian 9	Dallas, TX	137 children	Birth to age 3 years	Center+educational home visits	18
Abecedarian 10	Seattle, WA	131 children	Birth to age 3 years	Center+educational home visits	18

Table 4 High Risk Index for the Abecedarian Project and Project CARE. Source Ramey and Smith (1977)

Mother's educational level (highest grade of school completed)	Weights	Father's educational level (highest grade of school completed)	Weights	Total annual family income (\$)	Weights
6th grade	8	6th grade	8	≤1000	8
7th grade	7	7th grade	7	1001-2000	7
8th grade	6	8th grade	6	2001-3000	6
9th grade	3	9th grade	3	3001-4000	5
10th grade	2	10th grade	2	4001-5000	4
11th grade	1	11th grade	1	5001-6000	0
12th grade	0	12th grade	0		
Other indications of high risk and po	int values				
Pts. (Weights)					
3	Father absent from child's life for reasons other than health/death				
3	Absence of maternal adult relatives in local area (i.e., no parents, grandparents, or brothers or sisters of majority age)				
3	Siblings of school age who were one or more grades behind age-appropriate grade, or who scored equivalently low on school administered achievement tests				
3	Payments received from public assistance or welfare agencies within the past three years				
3	Record of father's work indicated unstable and unskilled, or semi-skilled labor				
3	Record of mother's or father's IQ score of 90 or below				
3	Records of one or more siblings with IQ scores of 90 or below				
3	Relevant social agencies in the community indicate that the family is in need of assistance currently				
1	One or more members of the family has sought mental health counseling or professional help in the past 3 years				
1	Special circumstances not included in any of the above which are likely contributors to cultural or social disadvantage				
1	Special circumstances not included in any of the above which are likely contributors to cultural or social disadvantage				
Criterion for inclusion in high-risk sa	mple is a score	greater than or equal to 11			

group children recevied essential health and social services. Table 5 summarizes the services received by the treatment and control groups.

- Thus, both groups received: Adequate nutrition (i.e., free, unlimited supply of iron-fortified formula) since none of the mothers chose to breastfeed.
- Supportive social services via designated social workers for the family with referrals as needed (e.g., for housing, job training, mental health and substance abuse problems) over the first 5 years of life.
- Free or reduced-cost medical care (consistent with the highest levels of professionally recommended pediatric care) for the children's first 5 years of life.

Table 5 The AbecedarianProject: comparison ofeducational treatment andcontrol groups	The Abecedarian treatment group	Control group	
	Adequate nutrition via formula and meals while in child devel- opment center	Adequate nutrition via formula	
	Supportive family social services	Supportive family social services	
	Low-cost or free primary health care	Low-cost or free primary health care	
	Transportation	Transportation	
	Early care and education program at child development center		
	Intensive (full day, 5 days/week, 50 weeks/year, 5 years)		
	Abecedarian Approach including learning games, conversa- tional reading, language priority, and enriched caregiving		
	Individualized pace for learning activities in curriculum		

With this design, the control group was not untreated. Rather, the basic nutrition, health, and social service needs of the families and children were addressed systematically during the children's first 5 years of life. This design allows for the most stringent test of early childhood education as a causal change agent of any early childhood program reported in the scientific literature so far.

The key factor distinguishing the treatment group from the control group was being enrolled in our child development center, starting as early as 6 weeks of age, and lasting until the children entered public kindergarten. The Abecedarian program was provided full day (7:30 a.m. to 5:30 p.m), 5 days a week, 50 weeks per year. Children attended whether they were healthy or ill. Transportation was provided to ensure attendance. Almost all children participated fully.

Health Studies Embedded in the Abecedarian Project

Since all of the families were living in poverty and had limited transportation options, we provided on-site pediatric care by university faculty who were pediatricians and nurse practitioners. In the process of providing this free health care, the medical team of the Child Development Institute was able to study important issues regarding health and illness in a group child care setting. At the time, infant and toddler group care outside the family's home in the USA was new and highly controversial. Reasonably, there was serious concern about the spread of infectious diseases and other health and safety risks, including the potential disruption of mother-infant attachment relationships.

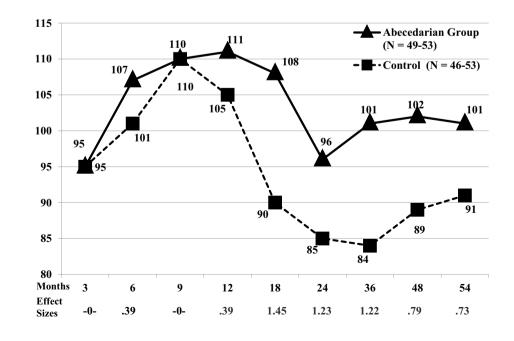
Studies of the Abecedarian children produced many journal articles and book chapters that added new knowledge to the field of young children's health. For example, contributions to knowledge were made on basic lung growth and functioning, (Collier et al. 1978; Williams et al. 1979), otitis media (Etzel et al. 1992; Henderson et al. 1982), the role of mycoplasma and viral infections (Fernald et al. 1975; Henderson et al. 1979), and other infectious diseases (Carson et al. 1985). Overall, the careful monitoring of the daily health of the Abecedarian children provided first-ever evidence that an early childhood program did not result in poor health outcomes if the program consistently followed good hygiene practices, and provided prompt care for illnesses and injuries. Data from the Abecedarian Project and Project CARE contributed to later guidelines established by the American Academy of Pediatrics regarding infant and toddler group care.

Results

In the Abecedarian Project, we measured many aspects of the children's growth and development at frequent intervals in their first 5 years. The assessments included cognitive, linguistic, and social-emotional measurements for children and educational and employment status of mothers.

Qualified clinical psychologists who had no involvement in children's treatment individually administered and scored standardized developmental and cognitive assessments for children in both groups between 3 and 54 months of age. The key findings before kindergarten entry are presented in Fig. 2.

Fig. 2 Mean intellectual scores and effect sizes for educational treatment and control groups in The Abecedarian Project from 3 to 54 months old



- For the first 12 months, the treatment and control groups performed similarly and essentially at the national average.
- Starting at 18 months, the control group's mean scores declined significantly. At 24 months of age the control children were performing at the low end of the normal range with a mean Developmental Quotient of 85 on the Bayley Scales of Infant Development—one standard deviation below the national average of 100.
- For the remaining preschool years, the treatment group scored an average of 10–17 IQ points higher than did the control group, on three different types of cognitive and developmental assessments (Ramey et al. 1999).

In the education field, an effect size of 0.25 and higher is widely accepted as a sufficient basis for changing practice and policy. In the Abecedarian Project, the effect sizes ranged from a low of 0.73 up to 1.45 for children from the ages of 18 months to 4.5 years, with a mean effect size of 1.08 during the toddler and preschool years.

A clinical perspective offers another view. Figure 3 shows the percentage of children in each group who scored in the normal range of intelligence (i.e., earning IQ scores of 85 or higher on tests that have a national average of 100 and a standard deviation of 15 or 16 depending on the test) from 6 months to 4 years (Martin et al. 1990)

- For the control group, 93% were in the normal range at age 6 months, but this dropped to 45% by age 4 years—consistent with the hypothesis of a cumulative toll due to insufficient cognitive, language, and social-emotional learning opportunities for these control children.
- For the early educational treatment group, 95–100% scored in the normal range at all the ages tested. This pattern of consistent and large differences between the

groups supports the hypothesis that high-quality early education can prevent cognitive declines and clinically low IQ scores among children from very high-risk families living in poverty.

Maternal Outcomes

For parents in the treatment group, the most likely important aspect of support provided by the Abecedarian early childhood program was 5 years of free, full-time, high-quality educational childcare. Thus, a major question is did this confer measurable benefits for the mothers whose children received it? We examined the effects of the early educational treatment of the children on maternal educational advancement and employment. The biological mother was the custodian of record for all child participants at study entry. Subsequent examination of gains in maternal education was necessarily confined to mothers for whom data were collected. (Note: several mothers died young and some others relinquished parental rights to others.)

Figure 4 shows the percentage of mothers in the educational treatment and control groups who continued formal education beyond high school after their child's birth and at three later points—4, 8, and 15 years of age. The figure also displays maternal education gains separately for teen mothers (aged 17 or younger) and adult mothers. The teen mothers whose children received the educational treatment and adult mothers were significantly more likely to obtain post-high school education by the time their children were age 15 (80%) than were control mothers (28%). Further, rates of maternal employment for adult mothers were 84% in the educational treatment and 74% in the control condition; for teen mothers, their employment rate was 92% in

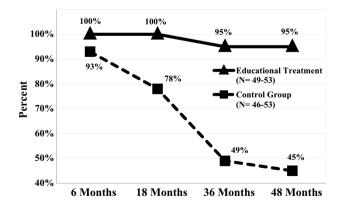


Fig. 3 Percent of children in normal IQ range (>84) by age and treatment groups in the Abecedarian Project. *Source* Martin et al. (1990)

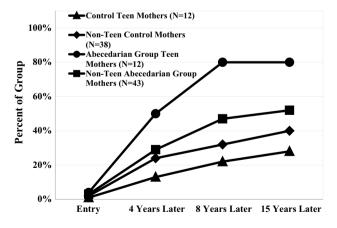


Fig. 4 Percent of total group and teenage mother subgroups who obtained post-high school education beginning when their infant entered The Abecedarian Project. *Source* Ramey et al. (2000)

the educational treatment group versus 66% in the control group by the time their children were 15 years. These data (from Ramey et al. 2000) are presented graphically in Fig. 4.

Finally, a most unanticipated long-term group difference concerns maternal longevity (survival rates): significantly more mothers in the control group died before their children were 40 (29%) compared to mothers whose children received the educational treatment (10%). This recent finding (Sonnier-Netto et al. 2017) has stimulated pursuit of additional data collection to help understand plausible mediating mechanisms to account for differential maternal death rates.

Replications—Project CARE (Carolina Approach to Responsive Education) and IHDP (The Infant Health and Development Program)

A hallmark in science is demonstrating replicability of findings as well as fidelity of treatment interventions. The Abecedarian Project was replicated in two additional longitudinal studies conducted in nine sites:

- Project CARE (Ramey et al. 1985; Wasik et al. 1990) initiated in 1977 in North Carolina.
- Infant Health and Development Program (IHDP 1990) initiated in 1984 and conducted at eight sites (Little Rock, Arkansas; New Haven, Connecticut; Miami, Florida; Boston, Massachusetts; New York, New York; Philadelphia, Pennsylvania; Dallas, Texas; and Seattle, Washington).

Children in the early education and control groups of Project CARE served as a true replication for the Abecedarian Project, with the same educational program at the same site (the FPG Child Development Institute) using the same curriculum, staffing ratios, staff training and professional development plus supportive services (nutrition, health care, and social services to the family). In Project CARE 65 families who met the same high-risk enrollment criteria as those in the Abecedarian Project were randomly assigned at the time of the child's birth to 1 of 3 groups: the Abecedarian education group, a control group, and a new intervention known as "Home Visiting Education Group." This new intervention group offered the same educational curriculum but sought to have mothers deliver this directly to their infants from birth to age 5. Home visitors were trained and established positive working relationships with families. Initially, visits were once every week until age 3; then the frequency of home visits was designed as a function of parental preference from weekly or biweekly to monthly or every 6 weeks. Mothers were given supplies, games, books, and toys to support the home-based curriculum. To assess the cognitive outcomes, The Bayley Scales of Infant Development were administered at 6, 12, and 18 months; the Stanford-Binet Intelligence Test at 24, 36, and 48 months; and the McCarthy Scales of Children's Abilities at 30, 42, and 54 months. This schedule was similar to the assessment in the original Abecedarian project.

On each test after the 6-month assessment, scores of children in the Abecedarian educational treatment group were significantly higher than those in the family visiting and control groups. No positive cognitive intervention effects were detected for the home visiting education group at any age. Further, the magnitude of the group differences between the controls and educational treatment closely replicated the findings from the Abecedarian Project. We, and many colleagues in the fields of early education and developmental psychology, had hypothesized that children in the home visiting group would show significant benefits, perhaps in-between the performance of children in the child development center receiving the curriculum from qualified, actively supervised teachers and assistants and those in the control group. To find NO benefits in any outcome was not only surprising, but led us to think more carefully about the "dosage" of developmental priming mechanisms hypothesized in the guiding conceptual framework (see above). That is, we speculate that even if mothers learned a lot from the home visiting program, they still may be less adept and consistent (for a myriad of reasons) at providing a full 8 h of educational caregiving, 50 weeks per year, than the professional staff at the university-based child development center.

The Infant Health and Development Program (IHDP) was an unprecedented multi-site RCT concerning malleability of infants born prematurely and low birth weight. The replication of the Abecedarian educational treatment was limited to only the first 3 years of life, with the rationale being this was a sensitive developmental period for these biologically vulnerable children, and that many services and preschool supports would be available for ages 3-5 (given the demographic shift to most children in the 1980s being cared for outside the home by this age, in contrast to the early 1970s when the Abecedarian Project was launched). IHDP included some accommodations for the infants' low birth weight, premature conditions including not beginning the group-based child development component until the infants were 12 months of age (corrected for degree of prematurity) due to concerns about infections and lung vulnerability. At age 36 months, the education treatment group had significantly higher mean IQ scores than the follow-up group in each of the eight sites. Mothers in the educational treatment group reported fewer behavior problems in their children.

Targeted Versus Universal Programs

A pressing policy issue has to do with whether all young children need early educational enrichment in a child development center. For instance, do all premature and low birth weight infants need a special early educational program?

The findings from the Infant Health and Development Program (IHDP), which focused on 985 low birth weight, premature infants are informative. The findings support the well-established association of maternal education on children's intellectual and cognitive performance in the control group condition as depicted in Fig. 5.

Among the control group of 608 children, those whose mothers had not graduated from high school performed at the lowest mean level (i.e., had the lowest IQs), followed next by those whose mothers graduated from high school, mothers who had some college, and those who were college graduates. This stepwise pattern reflects the well-recognized positive correlation of maternal education with their children's IQ scores. The children who scored the lowest had an average IQ at age 3 years of 85—one standard deviation below normal (100)—the same as reported in many schools with a large percentage of children from poor and undereducated families.

In the treatment group of 377 children, the pattern was significantly different. Essentially, the Abecedarian educational program in the first 3 years of life "leveled the playing field" for these low birth weight, premature children and enabled them to perform at levels slightly higher (IQs of 104–107) than the national average at these years of age (Ramey and Ramey 1998a, b). In other words, the early educational treatment produced outcomes that overcame the cognitive "disadvantage" associated with low maternal education.

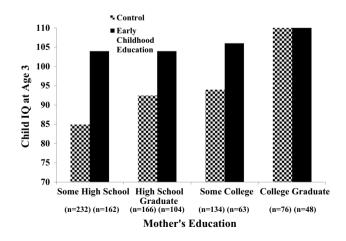


Fig. 5 Children's IQ at Age 3 as a function of maternal education (Infant Health and Development Program). Reproduced with permission from Ramey et al. (2012)

For children whose mothers were college graduates, the early education program neither increased nor decreased their tested intelligence at age 3. We speculate that the highly educated parents of these low birth weight, premature infants were able to provide opportunities for learning that were comparable in quality, quantity, and content to that in the IHDP child development centers. These children performed well above the national average-in spite of being born prematurely and low birth weight. These results support our inference that there is an array of ways that young children can receive the developmental priming mechanisms needed to support healthy cognitive (and socioemotional) development. The Abecedarian Approach is one way, but not the only way. Further many families have the skills, time, and resources to support their children's early development often combining within-family and extra-familial resources. In contrast, for infants whose families have markedly lower resources, as estimated by maternal education, in this case, they show large and significant benefits from receiving systematic extra-familial support in the form of enriched learning opportunities in full-day, year round child development center educational programs.

Levels of Participation are Related to Child Outcomes

In the Infant Health and Development Program, linking the process of early education to outcomes provides important insights. The extensive data collected on implementation of the IHDP point to a variety of process factors that are predictive of a child's developmental progress. The factors include, for example:

- Level of children's participation
- Amount of curriculum activities
- Rate of delivery of curriculum activities
- Degree of active participation for parents

To explore a possible relationship between children's IQ levels and the level of children's participation in the program, we devised a Participation Index. This index was the sum number of contacts with each family, as measured by number of days a child attended the child development center, the number of home visits completed, and the number of group meetings parents attended.

Figure 6 shows the percentage of children who had borderline intellectual performance (IQ < 85) and intellectual disabilities (IQ < 70) at age 3 according to three levels of program participation (low, medium, and high), compared to children in the control group.

The differences in the percent of children at borderline or lower IQ at 3 years across the three levels of participation were dramatic (Ramey et al. 1992). These differences took

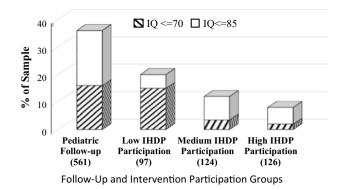


Fig. 6 Percentage of borderline (IQ ≤ 85) and impaired intellectual performance (IQ ≤ 70) (Infant Health and Development Program). *Source* Ramey et al. (1992)

into account parent, family, and child variables that may have influenced participation levels.

Rate of Curriculum Delivery and Active Experience

In an analysis of the year by year levels of participation of individual children and families, Blair et al. (1995) discovered a clear association between participation levels and cognitive progress at ages 2 and 3. For each year from ages 1-3, the days attended by the child in the IHDP Abecedarian Approach Center, the number of home visits, and the number of parent meetings attended predicted cognitive advances above and beyond the child's background characteristics such as maternal education and low birth weight. That is, early educational experiences exerted an effect that served to overcome the usual negative toll of low parent education, low family income, and prematurity. Further, these effects were not influenced by parent or family variables. This represented the first strong evidence that treatment dosage related directly to magnitude of treatment benefits on a yearly basis.

School-Age Results from the Abecedarian Project

The long-term outcomes from the Abecedarian Project are informative. The children in the educational treatment group continued to display benefits associated with their participation in the early childhood program—lasting throughout their school years and well into their adulthood. During the school years the children who participated in the educational treatment had:

• Significantly higher achievement scores in reading and math at all tested ages specifically, 8, 12, 15, and 21 years (Campbell et al. 2001)

- Significantly lower rates of grade retention (i.e., failing at least 1 grade): 30% of the Abecedarian education group vs. 56% of the control group children (Ramey et al. 2000)
- Significantly lower rates of placement in special education: by age 15, 12% of the treatment group versus 48% of the control group that received no Abecedarian education services. (Ramey et al. 2000)

The reduced need for grade repetition and special education are particularly important outcomes, with both fiscal implications for governments and personal consequences for children and families. The cost of special education programs is approximately 2.5 times the cost of regular education. Children in special education are entitled to free public education until age 22 (approximately four additional years compared to students in regular education). The US average for placement in special education programs is approximately 11%. For many children, the embarrassment and personal stigma associated with attending a special education program are considerable.

Adulthood Results

Age 21 Outcomes

In the Abecedarian Project, we had the opportunity to follow the children into adulthood. At age 21, the children who participated in the education treatment still showed multiple signs of positive outcomes compared to the control group (Campbell et al. 2002), including:

- In the treatment group, 67% were engaged in a skilled job or were enrolled in higher education, in contrast with only 41% of the control group.
- The young adults in the treatment group were three times more likely to have attended, or to be attending, a 4-year college than were those from the control group (35.7 vs. 13.7%).
- The percentage of teen parents (defined as having a first child at or before age 19) was significantly reduced in the treatment group compared with the control group (25 vs. 45%).
- Young adults who had received the Abecedarian early education treatment reported fewer symptoms of depression at age 21.
- The use of illegal substances (e.g., marijuana within the past 30 days) was significantly lower for the treatment group compared to the control group (18 vs. 39%, respectively).

Age 30 Outcomes

The age 30 results show that those who received the Abecedarian early education, compared to controls, were almost 4 times as likely to graduate college (23 vs. 6%), more likely to be employed full time (75 vs. 53%), less likely to have used extensive welfare supports (3.9 vs. 20.4%), and more likely to report being in excellent health (69 vs. 59%) (Campbell et al. 2012). Other beneficial outcomes at age 30 with effect sizes > 0.25 include higher earned income, higher job prestige, and higher age at birth of first child. Above all, those who received high-quality early Abecedarian education were more likely than controls to have entered the middle class, rather than remain in the lower class.

Age 35 Outcomes

Collecting biomedical data, Campbell et al. (2014) found that those in the education treatment had significantly lower risk factors for cardiovascular and metabolic disease in their mid-30 s. The evidence was especially strong for males. For example, the mean systolic blood pressure among the control males was 143, compared to 126 among the educationally treated. One in four males in the control group was affected by metabolic syndrome, while none in the treatment group were. Thus, the evidence shows the potential of early education to prevent diseases and promote health well into adulthood.

Ages 39–45 Outcomes

Childhood poverty is associated with differences in cognitive function and brain structure, observable by MRI in childhood and beyond (c.f. Farah (2017) for a review). These differences have many potential causes, among them differences in cognitive and linguistic stimulation experienced by poor versus non-poor children. This suggests that providing appropriate cognitive and linguistic stimulation to children growing up in impoverished environments could alter brain development, perhaps reducing or eliminating structural and functional differences historically associated with poverty. The Abecedarian Project provided a unique experimental test of the hypothesis that limited early learning experiences comprise the primary causal mechanism for altered brain development. (Note that the earlier project description provided both control and treatment group participants had good health care, good early nutrition, and family social services.)

In their early 40s, the Abecedarian participants had structural and functional MRIs of their brains to examine whether those who experienced the early education treatment had measurable differences in their brains. (Farah et al. 2017). Forty-seven of 74 participants could be successfully scanned; 29 (15 males, 14 females) were in the early education group, and 18 (9 males, 9 females) were in the control group. Covarying sex and age, initial findings revealed larger overall cortical gray volume (p=0.035) and borderline significant larger white matter volume (p = 0.084), with no difference in overall deep grey matter volume. Five a priori regions of interest were selected to assess the effects of the program on areas related to language (L inferior frontal gyrus, L superior temporal gyrus) and cognitive control (L and R anterior cingulate cortex and R inferior frontal gyrus), covarying whole brain volume as well as the earlier covariates. Of these 5 regions, two showed significant positive effects (L inferior frontal gyrus [p=0.005] and R inferior frontal gyrus [p=0.006]) and one showed a borderline significant effect (L anterior cingulate cortex [p=0.08]). In sum, children from poor families who experienced an intensive language and play-based education starting early in life had more cortical grey matter and, in a preliminary examination of specific regions, larger inferior frontal gyrus volumes.

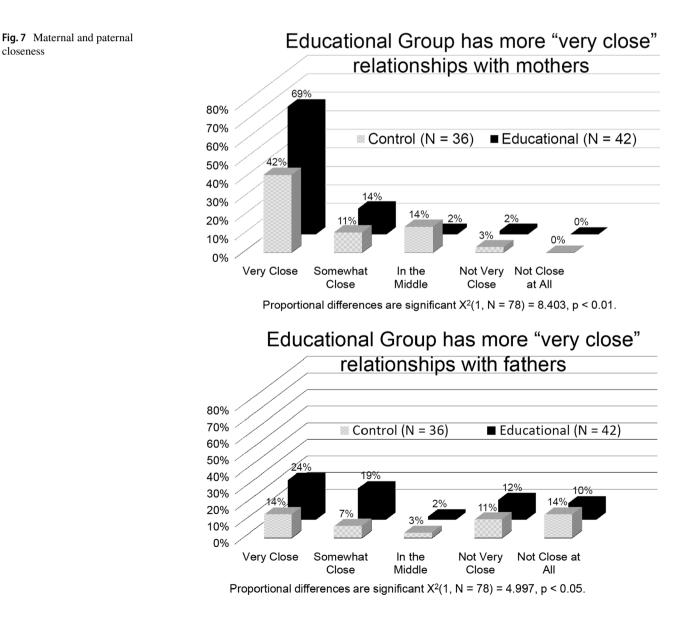
We also tested the possible impact of early childhood education on social decision-making and prosociality (Luo et al. 2017). We had participants play an Ultimatum Game (UG), a well-validated social exchange game, during functional magnetic resonance imaging (fMRI). We measured the behavioral and neural reactions to disadvantageous, equal, and advantageous ultimatum game offers from a computer partner. We also included an independent comparison group of 178 adults from Roanoke, Virginia, that did not receive any controlled treatment during their childhood. Using behavioral modeling, we estimated individual sensitivity to inequality. We used the Fehr-Schmidt inequality aversion utility function where the utility of an offer is discounted by the inequality-regardless of advantageous or disadvantageous-between the two amounts of the split. As expected from previous work that reported behavior driven by self-interest in the face of advantageous offers (i.e., low rejection rates), the Abecedarian control rejected more disadvantageous offers than equal offers but had similar very low rejection rates for equal and advantageous offers. In stark contrast, the Abecedarian treatment group rejected disadvantageous offers as well as advantageous offers more than equal offers and displayed a rejection rate pattern suggesting symmetric disutility for advantageous and disadvantageous offers. Over all it appears that the treatment group children were more bothered by inequality whether it was to their advantage or disadvantage.

Using the brain response when viewing disadvantageous unequal offers, we could predict the participants' group with high accuracy, suggesting that the two groups have distinct patterns of activity when they face such offers. Areas predictive of being in the treatment group included bilateral cuneus and the left superior frontal gyrus. Areas predictive of being in the control group included bilateral anterior insula precuneus, supramarginal gyrus, and the middle and posterior cingulate.

Some Additional Important Results

Mother-Child Attachment

Because the Abecedarian Approach had children attending a Child Development Center beginning in early infancy, we were concerned that early group educational daycare might have a negative effect on mother–child relationships and particularly attachment. That is, we were concerned that cognitive and language gains, if there were any, might be at the expense of the child's social relationships with the family. This was a particularly delicate topic since attachment theory was approaching great saliency in the early 1970s when the Abecedarian Project was launched. We chose to directly address this issue through systematic and frequent examination of mother-child interaction patterns both in the home and in laboratory situations including using the Ainsworth Strange Situation Protocol-a widely used standard measure of attachment. In a series of publications, we found no evidence of negative effects on mother-child interaction patterns or attachment, even though in both the treated and control groups there is evidence that more frequent and warmer mother-child interaction patterns do, in fact, relate positively to children's cognitive development. I refer the reader to the following journal publications for a more detailed set of presentations about this important issue (Farran and Ramey 1977; Ramey et al. 1979; Farran and



Ramey 1980; Ramey and Farran 1981; Ramey et al. 1984; Burchinal et al. 1989; Burchinal et al. 1992).

As part of the age 40 follow-up, participants used a fivepoint Likert-type scale to rate maternal and paternal closeness with "1" being "not close at all" and "5" being "very close". Figure 7 shows that the early childhood education group rated themselves as significantly more close to both their mothers and fathers than did the control group participants. (Sonnier-Netto et al. 2017). I interpret these findings to suggest, contrary to attachment theory expectations, that the influence of the early education was positive on family socioemotional closeness. One mother recently shared with us that her child taught her to be a better and more positive mother by telling her how her teachers treated her so positively and suggested that she (the mother) do the same. The mother reported she tried this new way of responding and that this was to the benefit of the whole family.

Differential Risk and Response to Treatment

The recruitment strategy for the selection of participants in all three randomized controlled trials adhered to a basic idea. That idea was to pre-specify the inclusion cutoff points, e.g., a risk score of greater than 11 in the Abecedarian Project and Project CARE and birth weight of less than 2500 grams and gestational age of less than 37 weeks in IHDP and to assume that significant variation on important other parameters would likely occur. Given that random assignment should result in initial equivalence of treatment and control groups this strategy allowed a potentially useful data analytic approach to better understand different levels of risk as expressed in assessments of control group participants and how similar individuals or families responded to the delivery of the educational treatment.

An example of this research strategy comes from the paper by Breitmayer and Ramey (1986) concerning biological nonoptimality and quality of postnatal environment as codeterminants of intellectual development. In that paper we demonstrated that nonoptimal perinatal status (1-min Apgar score of ≤ 8) had a negative relationship with cognitive scores at 4.5 years of age in the Abecedarian control group and lower than control children with scores ≥ 9 ; however, comparable test scores of children with optimal or nonoptimal Apgars did not differ within the group that received the Abecedarian Approach educational treatment and were significantly higher.

These differential risk and differential response to treatment results are similar in form and outcomes concerning mild fetal malnutrition reported by Zeskind and Ramey (1978, 1981). The general pattern has forced me to consider whether clinical cut points that have been established with general population samples need to be reconsidered by an appreciation of the social context in which a child is likely to be reared. Low resource environments may need to be taken into account when assigning risk status. In many ways these general findings parallel the results from IHDP in which the Abecedarian Approach attenuated the relationship between parental educational level and the child's cognitive performance at 3 years of age.

Benefit–Cost Analyses

Cost/Benefit analyses have become an expected feature in public policy concerning child and family programs particularly for economically poor families. This work was pioneered by Barnett (1986) using data from the Perry Preschool Project. Barnett and Masse (2007) also conducted a preliminary benefit-cost analysis of the Abecedarian program through age 21. From the age 21 results Barnett and Masse estimated the benefit-cost ratio was approximately 3:1 for every dollar invested. More recently Heckman et al. (in press) have amalgamated data from the Abecedarian Project and Project CARE into middle adulthood using a more complete dataset and refined statistical analyses that account for variations within treatment and control groups. They estimate the benefit-cost ratio to be 7.3:1 with an annualized rate of return of 13.7% for the cost of 5 years of high-quality early education year round. The main point that I draw from these perspectives is that there is no adequate substitute for longitudinal data from experimental designs that incorporate a lifespan approach and that simultaneously include information about educational attainment, employment, and health as outcomes. The economic perspective further needs to be contextualized by the interdependence of outcomes that are affected by lifestyle and opportunity for advancement.

Multifactorial Influences on Intellectual Development

By the early 1980s, it was becoming clear that simple models of human development were inadequate to describe and account for intellectual development. Multiple and interacting forces that changed over time was a more likely dynamic model. After a period of intense discussion and reconceptualization, MacPhee, Yeates, and I developed a version of General Systems Theory that applied to differential intellectual development in vulnerable populations. We illustrated this perspective with data from multiple domains of influence using Abecedarian Project data (Ramey et al. 1982).

After consolidating our new perspective we were able to pursue these ideas more fully in a series of empirical articles (Yeates et al. 1983; Ramey et al. 1984; Martin et al. 1990). In this series of papers, we documented how the correlations between maternal IQ, the cognitive stimulation quality of the home environment, and the educational treatment changed in a systematic way over the first 5 years. Specifically, for those in the treatment group, maternal IQ became less powerful while the explanatory power of the treatment increased and the home environment remained an important independent contributor. These findings have caused me to question the applicability of single point estimates of heritability. We captured these insights into an extended chapter on developmental genetics (Moser et al. 1990), along with suggested research designs and constraints.

Is the Abecedarian Approach Relevant to today's US Population and Circumstances?

The Abecedarian, CARE, and IHDP projects were launched in the 1970s and 1980s and completed the active early childhood education between 1981 and 1990. Between then and now, there have been significant changes in the US population, maternal employment patterns, and the economy. For example, the population has become more diverse in terms of ethnicity, race, and language.

The national economy has gone through major boom and decline phases with impacts on job opportunities, employment patterns, and requisite skill expectancies particularly at the entry level of the job market. Entry-level jobs now require more literacy and mathematical skills now than they did decades ago. Welfare has been reformed with time limits on eligibility and an explicit focus on mothers completing high school or obtaining a GED certification and obtaining employment. A crackdown on crime with a special focus on drug-related issues has led to a swelling prison population with an over-representation of Black males.

Finally, racial discrimination has continued to be a major characteristic of US society with predicable patterns in educational attainment, income distribution, housing, incarceration, and death rates. Given these and other trends too numerous to detail in this paper, it is germane to ask whether the Abecedarian Approach is relevant to contemporary life in the USA? I think the answer is yes for one major reason. We know even better today, from a scientific perspective, that learning and development occur early and are powerfully cumulative and consequential. Without a systematic and comprehensive approach that begins early in development, I am skeptical about later interventions being sufficient to overcome 5 or more years of social, educational, and health disparities. Consequently, starting education in infancy and paying close attention to family circumstances and dynamics seem only logical based on the empirical data. If anything the developmental expectations for literacy, mathematics, and social skills are going up not down. While we must continue to work on effective clinical treatments for socially and economically vulnerable children, we can also capitalize on what we, as a society, have learned from prevention science and make early childhood education more widely available.

Funding This program of research has been supported by grants from: The National Institute of Child Health and Human Development, The US Department of Education, The Administration on Children, Youth, and Families, The Maternal and Child Health Bureau, The National Institute of Mental Health, The Centers for Disease Control and Prevention, and The Robert Wood Johnson Foundation.

Compliance with Ethical Standards

Conflict of interest No conflict exists.

Ethical Approval All procedures performed in this program of research involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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