Comprehensive Follow-up Care and Life-Threatening Illnesses Among High-Risk Infants: A Randomized Controlled Trial

R. Sue Broyles; Jon E. Tyson; Elizabeth T. Heyne; et al.

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Comprehensive Follow-up Care and Life-Threatening Illnesses Among High-Risk Infants

A Randomized Controlled Trial

R. Sue Broyles, MD
Jon E. Tyson, MD, MPH
Elizabeth T. Heyne, MS, PA-C
Roy J. Heyne, MD
Jackie F. Hickman, RN
Michael Swint, PhD
Sally S. Adams, MS, RN, CPNP
Linda A. West, RN, CPNP
Nancy Pomeroy, PhD
Patricia J. Hicks, MD
Chul Ahn, PhD

Context Inner-city high-risk infants often receive limited and fragmented care, a problem that may increase serious illness.

Objective To assess whether access to comprehensive care in a follow-up clinic is cost-effective in reducing life-threatening illnesses among high-risk, inner-city infants.

Design Randomized controlled trial.

Setting and Participants A total of 887 very-low-birth-weight infants born in a Texas county hospital between January 1988 and March 1996 and followed up in a children's hospital clinic. One hundred four infants who became ineligible or died after randomization but before nursery discharge were excluded from the analysis.

Interventions Infants were randomly assigned to receive routine follow-up care (well-baby care and care for chronic illnesses; n=441) or comprehensive care (which included the components of routine care plus care for acute illnesses, with 24-hour access to a primary caregiver; n=446).

Main Outcome Measures Life-threatening illnesses (ie, causing death or hospital admission for pediatric intensive care) occurring between nursery discharge and age 1 year, assessed by blinded evaluators from inpatient charts and state Medicaid and vital statistics records; and hospital costs (estimated from department-specific cost-to-charge ratios).

Results Comprehensive care resulted in a mean of 3.1 more clinic visits and 6.7 more telephone conversations with clinic staff ($P<.001$ for both). One-year outcomes were unknown for fewer comprehensive-care infants than routine-care infants (9 vs 28; $P=.001$). Identified deaths were similar (11 in comprehensive care vs 13 in routine care; $P=.68$). The comprehensive-care group had 48% fewer life-threatening illnesses (33 vs 63; $P<.001$), 57% fewer intensive care admissions (23 vs 53; $P=.003$), and 42% fewer intensive care days (254 vs 440; $P=.003$). Comprehensive care did not increase the mean estimated cost per infant for all care ($6265 with comprehensive care and $9913 with routine care).

Conclusion Comprehensive follow-up care by experienced caregivers can be highly effective in reducing life-threatening illness without increasing costs among high-risk inner-city infants.

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NEONATAL FOLLOW-UP PROGRAMS were originally developed to survey the outcome of high-risk infants, assess the effects of perinatal insults and care, and identify infants needing referral for care of ongoing problems. Unfortunately, this approach has often been associated with a substantial loss to follow-up among families of lower socioeconomic status.[1,2] Moreover, this approach does not address the needs of very-low-birth-weight infants of any socioeconomic situation who lack access to a physician skilled in managing the pulmonary, gastrointestinal, nutritional, neurological, developmental, and other problems common among these infants.[1-5] Some follow-up programs now provide well-baby care and care for chronic illnesses. However, care for acute illnesses typically is not provided. Without prompt, effective treatment, minor illnesses or complications may quickly become life-threatening in these vulnerable infants. This problem is likely to contribute to their increased mortality, morbidity, and cost of care throughout infancy.[1,4-7]

See also Patient Page.

Author Affiliations: Department of Pediatrics, University of Texas Southwestern Medical Center, Dallas (Drs Broyles, Tyson, and Hicks and Ms Hickman); University of Texas-Houston School of Public Health (Drs Swint and Pomeroy); Children's Medical Center of Dallas (Mss Heyne, Adams, and West and Dr Heyne); and Department of Internal Medicine, University of Texas Houston Medical School (Dr Ahn). Dr Tyson is now director of the Center for Population Health and Evidence-Based Medicine, University of Texas-Houston.
Corresponding Author and Reprints: Jon E. Tyson, MD, MPH, University of Texas-Houston Medical School, 6431 Fannin St, MSB 3.228, Houston, TX 77030-1503 (e-mail: jtyson@ped1.med.uth.tmc.edu).

Based on our experience in caring for high-risk inner-city infants,[1,8-10] we developed a comprehensive follow-up program to augment continuity of care and provide ready access to highly experienced caregivers. Unfortunately, many health care programs with similar goals have increased costs substantially with little or no demonstrated improvement in outcome.[11-13] The funding provided to traditional follow-up clinics has been quite limited[9,14] and is declining or curtailed in managed care programs. It is important to demonstrate that the costs of any new follow-up programs are justified by the benefits, so we conducted a large randomized trial of comprehensive follow-up care provided by experienced caregivers. Our purpose was to assess whether providing access to such care is cost-effective in reducing life-threatening illnesses (illnesses that result in death or admission to a pediatric intensive care unit) among high-risk inner-city infants.

METHODS

Hypotheses

Our primary hypotheses were that comprehensive care given to high-risk infants by experienced caregivers would decrease deaths between nursery discharge and 1-year adjusted age (1 year past term) by 50% and reduce admissions to a pediatric intensive care unit and total days in such a unit by 33%. (No reduction in hospitalizations was hypothesized because increased access to care might increase admissions for all illnesses warranting hospitalization.) We also hypothesized that comprehensive care would reduce total emergency department (ED) visits by 33%, reduce the number of infants failing to attend our clinic at 1 year by 75%, and offset the increased costs for follow-up care by reducing costs for pediatric intensive care.

Infant Enrollment and Randomization

Infants born at Parkland Memorial Hospital (the public hospital for Dallas County, Texas) were eligible if they were born to a Dallas County resident and either weighed less than 1000 g at birth or weighed between 1001 and 1500 g and received mechanical ventilation in the first 48 hours after birth. Infants were enrolled within a few days of birth because obtaining parental consent before the mother's discharge reduces loss to follow-up in the population.[1,8,10] Informed consent was obtained for all participants as approved by our institutional review board. Sequentially numbered, sealed, opaque envelopes stratified by birth weight (≤800, 801-1000, and 1001-1500 g) were used to randomize infants to receive routine or comprehensive follow-up care (if they survived to nursery discharge and remained eligible for the follow-up clinic). The envelopes were prepared using a random number table by a person who did not participate in enrollment or randomization.

Infant Care

The follow-up clinic was located in Children's Medical Center, a private hospital adjoining Parkland Hospital. Both groups received care from the same personnel in this clinic: 2 pediatric nurse practitioners and a physician's assistant, each supervised by both a pediatrician and a neonatologist trained in follow-up care. These were highly experienced personnel who had a mean of 11 years' service in our clinic. In each group, infants whose parents spoke only Spanish were assigned to a bilingual caregiver. In addition to other responsibilities in the clinic, provider caseloads did not exceed 20 to 30 infants in each group at any time.

Routine Follow-up Care. Routine follow-up care was available 2 mornings per week and included care for chronic illnesses as well as standard well-baby care (eg, immunizations, anticipatory guidance, social services, and developmental assessment). All mothers were taught the signs of acute illness needing prompt evaluation and told to seek care for these illnesses in neighborhood clinics or the Parkland Hospital Acute Care Clinic on weekdays or in the Children's Medical Center ED at other times. (Infants rarely received care in the offices of private practitioners.) All these sites are staffed by board-eligible or board-certified pediatricians employed by Parkland Hospital or the University of Texas Southwestern Medical Center. The neighborhood clinics are part of a well-developed system of community-based care.[15]

Measures to maintain contact with the family and encourage attendance at the follow-up clinic included (1) discussing the clinic with the mother at study enrollment and shortly before the infant's discharge; (2) scheduling the first clinic visit within 1 to 2 weeks after nursery discharge; (3) enrolling the mother and infant in Medicaid before nursery discharge and reenrolling infants whose coverage had lapsed at any clinic visit; (4) collecting detailed contact information (including addresses and telephone numbers for the mother and 2 close friends or relatives) at enrollment that was updated at nursery discharge and each clinic visit; and (5) contacting the mother to reschedule any clinic visit that was missed.

Comprehensive Follow-up Care. Comprehensive follow-up care was provided in our clinic 5 days per week and included care for acute illnesses as well as all components of the routine follow-up care. The nurse practitioner or physician's assistant who was responsible for the infant was also available by telephone or pager at all hours to address acute problems. The primary care clinician contacted 1 of the 2 physician supervisors as needed and also contacted the ED staff for infants needing immediate care outside clinic hours. If needed, transportation by taxi was provided to the ED. On the morning after an ED visit, the mother was called to assess the need for further evaluation.

To augment rapport, our personnel met with the mother at enrollment and before the infant's discharge home. A home visit was routinely attempted except when considered unsafe for our personnel. Mothers thought to have the greatest need for parenting education and support were offered a trained foster grandmother of the same ethnic and socioeconomic status.

Follow-up clinic staff did not manage hospitalized infants, determine who

received intensive care, or participate in decisions affecting duration of intensive care or hospital stay. Study infants were admitted to the hospital from a variety of sites (the ED, the Parkland Acute Care Clinic, a specialty clinic, or the follow-up clinic). Whether hospitalization was warranted was determined by the attending physician. If the infant was seriously ill, this physician contacted the attending intensivist who was responsible for all decisions to admit infants to or discharge infants from the pediatric intensive care unit. Attending physicians were generally not aware of the study, did not know which infants attending the follow-up clinic were participants, and were not told the treatment group of study infants.

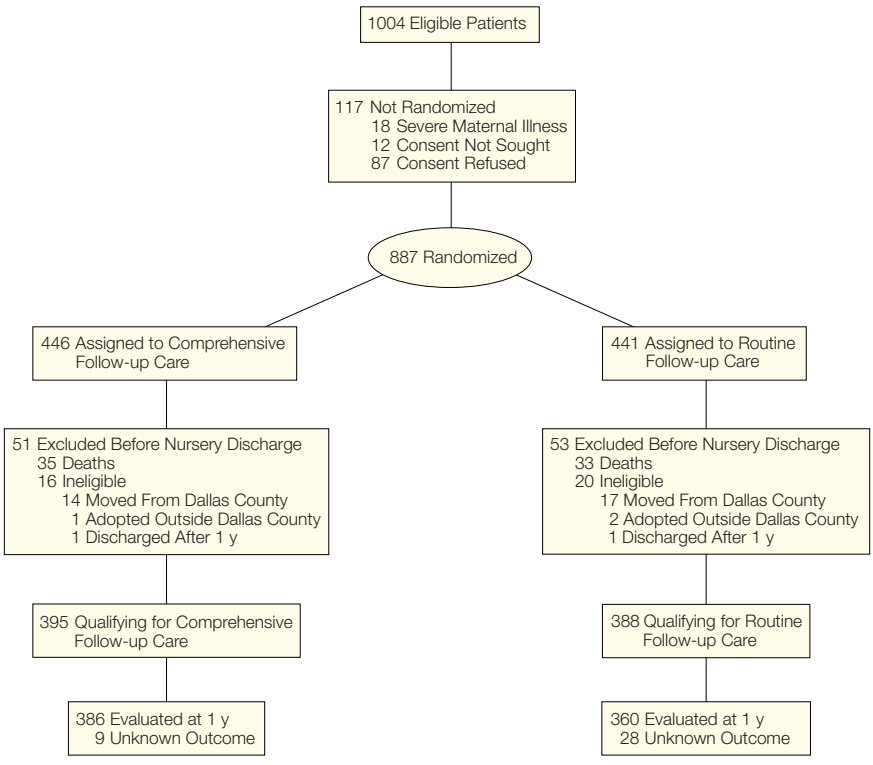
Evaluation of Outcome

Admission for pediatric intensive care was used as a marker for the development of a life-threatening illness. To assess whether an infant died or received pediatric intensive care before 1-year adjusted age, evaluators masked to treatment group assessed inpatient medical records for Parkland Hospital and Children's Medical Center, Texas Medicaid billing records, and Texas vital statistics records. We were unable to identify whether some infants had died or survived to 1-year adjusted age because neither a death certificate nor a record of medical services at or beyond this age was identified. For these infants, all of the above searches and a search of the outpatient records were repeated annually in an attempt to find records indicating whether they had survived beyond 1 year.

Evaluation of Care

Except for 1 hospitalization in another city that was identified through our clinic records, masked evaluators identified and assessed all inpatient care using Texas Medicaid and hospital records. Evaluators who could not be masked to treatment group assessed outpatient care from clinic records at Children's Medical Center and Parkland Memorial Hospital. Records for the small proportion of outpatient visits that occurred outside our center were not reviewed, in part because such visits could not be identified in an accurate or unbiased manner from Medicaid records or other sources.[14]

Figure. Patient Flow Diagram



Evaluation of Costs

As described previously,[14] inpatient costs were estimated by multiplying hospital charges by department-specific cost-to-charge ratios from the hospital's annual Medicare Cost Report.[16-18] Outpatient costs also were estimated using hospital charges and the cost-to-charge ratio for clinic services. These estimates were adjusted for the increased time that the comprehensive-care group received from the nursing and physician staff of our clinic. The salary supplements given primary caregivers for taking telephone calls after clinic hours also were included in the costs of comprehensive care.

Our analyses were designed to provide a conservative estimate of the cost savings from a societal perspective if, as hypothesized, comprehensive care substantially reduced life-threatening illnesses and admissions for intensive care. We anticipated that a net cost savings could be verified without evaluating some costs that would simply reinforce this finding and be difficult and expensive to assess. For this reason we did not assess indirect costs to the family, intangible costs (eg, pain and suffering), costs for physician services outside the follow-up clinic, and costs in the community clinics.

We did assess hospital reimbursements as well as hospital costs. All estimated costs and reimbursements were inflation-adjusted (using the Consumer Price Index for Hospital and Related Services), discounted at 3% per annum[18] and expressed in 1997 dollars.

Sample Size and Study Periods

The prespecified sample size was 760 infants in the primary analysis group to allow adequate power to assess the hypothesized effect of comprehensive care on each primary outcome. The power to assess a 50% reduction in mortality

was 80% ($\alpha = .05$; expected mortality with routine care, 10%). Enrollment lasted from January 1, 1988, to March 31, 1996. Hospital costs were assessed for all infants born after December 31, 1992, when complete costs could first be obtained for both Children's Medical Center and Parkland Hospital. Time devoted by clinic personnel to all aspects of care was prospectively assessed during 6 months (March, April, July, August, and November 1995 and February 1996) considered to be representative of an entire year.

Statistical Analysis

To assess follow-up care between nursery discharge and 1-year adjusted age, we excluded from the primary analysis group infants who were enrolled but died before nursery discharge, were discharged after 1 year, or became ineligible for our clinic because the mother moved out of the county or the infant was adopted by an out-of-county mother before nursery discharge. These criteria were considered unlikely to bias the results in favor of our hypotheses, were selected a priori, and would have been used as exclusion criteria had enrollment occurred at nursery discharge. All other infants were analyzed as randomized. None were excluded after nursery discharge.

A 2-tailed Fisher exact test was used to assess categorical variables. A 2-tailed Wilcoxon rank-sum test was used to assess clinic and ED visits, admissions, hospital stay, intensive care days, life-threatening illnesses, costs, and reimbursements. We calculated 95% confidence intervals for the relative risk of outcomes specified in our hypotheses. Differences between groups in continuous variables (eg, intensive care days, costs) were not assessed with confidence intervals because the data were skewed.

RESULTS

Study Population

During enrollment, 1004 infants met eligibility criteria; 117 could not be enrolled or randomized (FIGURE). Before nursery discharge we excluded 51 infants from the comprehensive-care group and 53 infants from the routine-care group. Thus, the primary analysis group included 395 infants given comprehensive care and 388 infants given routine care.

The groups were at similar high risk (TABLE 1). More than 80% of the mothers were black or Hispanic, and their mean education was less than 11 years. The infants had a variety of major neonatal problems. The comprehensive- and routine-care groups had the same mean duration of mechanical ventilation (12 days) and virtually the same mean hospital stay (66 and 65 days, respectively).

Outpatient Care

On average, the comprehensive-care group had 3.1 more visits to hospital clinics and 6.7 more telephone contacts with our clinic staff before 1-year adjusted age than did the routine-care group (TABLE 2). A foster grandmother was provided for 70 infants given comprehensive care.

Infants given comprehensive care were less likely than those given routine care to cease attending the follow-up clinic by 1-year adjusted age (10.9% vs 31.4%; $P<.001$). Moreover, the comprehensive-care group had fewer total ED visits (597 vs. 730; $P=.03$).

Hospitalizations

The comprehensive-care group and routine-care group were similar in total hospital admissions (273 vs 283; $P=.77$) and hospital days (2358 vs 2949; $P=.52$) (Table 2). All but 5 hospitalizations and 1 admission for pediatric intensive care occurred at Parkland Hospital or Children's Medical Center.

Unknown Outcomes and Deaths

Despite extensive efforts to contact the families and repeated searches of medical, Texas Medicaid, and vital statistics records, we could not track 37 infants (4.7%) to 1-year adjusted age and determine whether they survived. With the increased contact with families, the comprehensive-care group had fewer such infants than did the routine-care group (9 vs 28; $P=.001$) (TABLE 3).

There were 11 deaths identified in the comprehensive-care group and 13 in the routine-care group ($P=.68$). The groups

Table 1. Study Population Characteristics

	Comprehensive-Care Group (n = 395)	Routine-Care Group (n = 388)
Maternal Characteristics		
Age, mean (SD), y	23 (6)	23 (6)
Single marital status, No. (%)	214 (54)	213 (55)
Education grade level, mean (SD)	10.7 (2.8)	10.8 (3.0)
Race, No. (%)		
Black	218 (55)	202 (52)
Hispanic	124 (31)	121 (31)
White	45 (12)	52 (13)
Asian or other	8 (2)	13 (3)
Infant Characteristics		
Birth weight, median (25th-75th percentile), g	1125 (880-1324)	1085 (890-1295)
Selected diagnoses, No. (%)		
Respiratory distress syndrome	239 (61)	227 (59)
Congenital pneumonia	36 (9)	48 (12)
Acquired pneumonia	30 (8)	44 (11)
Sepsis	112 (28)	108 (28)
Necrotizing enterocolitis (surgically treated)	17 (4)	13 (3)
Intracranial hemorrhage, grade III or IV	55 (14)	45 (12)
Ventilator therapy, No. (%)	383 (97)	368 (95)
Mean (SD), d	12 (16)	12 (14)
Oxygen therapy at 36 wk postmenstrual age, No. (%)	93 (24)	84 (22)
Hospital stay, mean (SD), d	66 (35)	65 (35)

were similar in age at and cause of death. Death was unexplained or attributed to sudden infant death syndrome for 5 infants given comprehensive care and 4 infants given routine care. Death was attributed to infection for 3 infants given comprehensive care and 4 infants given routine care. Various other causes were noted for 3 infants given comprehensive care and 5 infants given routine care.

Life-Threatening Illnesses and Pediatric Intensive Care

The comprehensive-care group had 47% fewer infants who developed life-threatening illnesses (33 vs 62; $P=.001$) and 56% fewer infants who received pediatric intensive care (23 vs 52) than did the routine-care group ($P<.001$; Table 3). The comprehensive-care group also had 48% fewer total life-threatening illnesses (33 vs 63; $P<.001$), 57% fewer admissions to a pediatric intensive care unit (23 vs 53; $P=.003$), and 42% fewer total days in a pediatric intensive care unit (254 vs 440; $P=.003$). In a subgroup analysis excluding infants who moved from Dallas County after nursery discharge (and were therefore unable to attend our follow-up clinic), the comprehensive-care group had 70% fewer days of pediatric intensive care than did routine-care infants (127 vs 418 days; $P<.001$).

To assess whether the benefits of comprehensive care changed during the study, we compared the periods before and after May 1, 1992, with respect to the difference between groups in the proportion of infants with life-threatening illnesses. In the first period, the routine-care group had 6.7% more infants with life-threatening illnesses than did the comprehensive-care group ([28/207 infants] – [15/220 infants]). In the second period, the routine-care group had 8.5% more infants with life-threatening illnesses ([34/181 infants] – [18/175 infants]). To prevent 1 infant from developing a life-threatening illness required provision of comprehensive care to 13 infants (calculated as the inverse of the difference between groups in the proportion with such illnesses[19]).

Table 2. Outpatient Care and Hospitalizations

	Comprehensive-Care Group (n = 395)	Routine-Care Group (n = 388)	*P* Value
Clinic visits and contacts with caregivers at follow-up clinic, mean (SD), No.			
Clinic visits	9.4 (5.4)	6.3 (4.0)	<.001
Telephone calls*	7.6 (11.1)	0.9 (2.2)	<.001
Home visits†	0.7 (1.0)	0 (0)	<.001
Contacts before nursery discharge	2.4 (1.4)	0 (0)	<.001
Total contacts	20.0 (14.9)	7.2 (5.0)	<.001
Infants failing to attend the follow-up clinic at 1-y adjusted age, No. (%)‡	43 (10.9)	122 (31.4)	<.001
Total emergency department visits, No.	597	730	.03
Hospital care			
Infants hospitalized, No. (%)	163 (41)	160 (41)	.98
Total hospital admissions, No.§	273	283	.77
Total inpatient days, No.‖	2358	2949	.52

*Not counting contacts made in scheduling visits or rescheduling missed appointments or conversations with foster grandmothers.
†Not counting home visits by foster grandmothers.
‡Relative risk (95% confidence interval), 0.35 (0.25-0.48).
§Mean (SD) = 0.7 (1.1) for comprehensive-care group and 0.7 (1.2) for routine-care group.
‖Mean (SD) = 5.3 (16.5) for comprehensive-care group and 6.5 (19.9) for routine-care group.

Table 3. Deaths, Life-Threatening Illnesses, and Pediatric Intensive Care*

	Comprehensive-Care Group (n = 395)	Routine-Care Group (n = 388)	Relative Risk (95% Confidence Interval)	*P* Value
Total infants unknown whether alive at 1-y adjusted age	9	28	0.32 (0.15-0.66)	.001
Total known deaths	11	13	0.83 (0.38-1.83)	.68
Total infants with life-threatening illnesses	33	62	0.52 (0.35-0.78)	.001
Total infants admitted for intensive care	23	52	0.43 (0.27-0.70)	<.001
Total life-threatening illnesses	33	63		<.001
Total admissions for intensive care†	23	53		.003
Total intensive care days‡	254	440		.003

*Life-threatening illness resulted in death or admission to a pediatric intensive care unit.
†Mean (SD) = 0.06 (0.23) for comprehensive-care group and 0.14 (0.40) for routine-care group.
‡Mean (SD) = 0.6 (6.6) for comprehensive-care group and 1.1 (4.4) for routine-care group. Excluding infants who moved outside of Dallas County after discharge, total days in the pediatric intensive care unit were 127 for comprehensive care and 418 for routine care ($P<.001$).

Economic Findings

The comprehensive- and routine-care groups had similar median hospital costs for outpatient care ($2165 vs $1944, respectively) and for all care ($2608 vs $2662, respectively). The median value for inpatient costs was $0 for both groups because less than half of the infants in each group were hospitalized between nursery discharge and 1-year adjusted age.

Mean rather than median costs were used as the appropriate measure of overall program costs because they indicate the cost impact of reducing infrequent but highly expensive events. As expected, comprehensive care increased mean costs for follow-up care ($P<.01$). However, this increase was more than offset by the reduction in mean costs for intensive care beds ($P<.03$; TABLE 4). With the hospital accounting methods used, other costs incurred in the intensive care unit aside from bed costs (eg, laboratory, radiology, and pulmonary costs) could not be fully separated from corresponding costs outside the intensive care unit. For all care between nursery discharge and 1 year, the estimated mean cost per in-

fant was $6265 for comprehensive care and $9913 for routine care.

Total costs exceeded total reimbursements by an average of $1070 per infant given comprehensive care and $2997 per infant given routine care. However, the only statistically significant differences between groups in the economic analyses were intensive care bed costs and follow-up clinic costs.

COMMENT

In this large randomized trial, access to comprehensive follow-up care from highly experienced caregivers significantly reduced life-threatening illnesses and total days of pediatric intensive care by more than 40% among high-risk inner-city infants. On average, 1 of every 13 infants given comprehensive care was prevented from developing a life-threatening illness. This finding indicates a much more favorable "number needed to treat" than for many widely used medical interventions.[19] The benefits were achieved without increasing total costs. The mean estimated cost per infant for outpatient and inpatient care between nursery discharge and 1-year adjusted age was $9913 for routine care and $6265 for comprehensive care.

Adverse outcomes and costs are more likely to have been fully identified in the comprehensive-care group because these infants had greater contact with our staff, fewer infants who could not be tracked, and higher maintenance of Medicaid enrollment[14] than in the routine-care group. Thus, our findings may provide a conservative assessment of the cost-effectiveness of comprehensive care for the population studied.

No effect on mortality was shown, which may reflect the absence of an effect, an inadequate sample size to identify the effect, or an inability to identify all deaths. Despite use of clinic, hospital, and Texas Medicaid billing records and extensive efforts to contact families, we could not locate 28 infants in the routine-care group and 9 in the comprehensive-care group. Even in populations at lower risk than in our study, infants who are difficult to track have a high risk of adverse outcomes.[20-22] The infants in our study were at particularly high medical and social risk in a population previously shown to have a high prevalence of maternal drug abuse.[23] With no ongoing source of medical care, some infants who could not be found may have died as a result of untreated illness, unintentional injuries, neglect, or even homicide.[24,25]

The better outcome with comprehensive care did not result from inattention to the routine-care group. The routine-care group (including those who ceased attending the clinic) had an average of 6.3 clinic visits during infancy and received care for chronic illnesses as well as standard well-baby care in the clinic. Care for acute illnesses was available in a well-developed community-based system of clinics,[15] the Parkland Acute Care Clinic, and Children's Medical Center ED. Thus, access to care for the routine-care group is likely to have exceeded that for most inner-city infants in the United States. For such infants, the benefits of a comprehensive-care program might be greater than we identified. However, it may be difficult to achieve these results with a less extensive program of comprehensive care or with less experienced caregivers than in our study.

The difficulty in overcoming adverse socioeconomic factors[11,26] was apparent in the finding that 31% of the routine-care group ceased attending the follow-up clinic. Similar problems occur in other centers serving a similar population.[27] When there has been extraordinary funding for the follow-up program, low rates of attrition have been achieved in this population[10] and other similar populations without offering special programs of care. Our findings indicate that providing comprehensive care can reduce both attrition and adverse outcomes without increasing total expenditures.

Highly accurate assessments of medical costs require a labor-intensive and expensive evaluation[28] that is impractical, particularly in multiple hospitals over an extended period. The method that we used to estimate hospital costs (multiplying hospital charges by department-specific cost-to-charge ratios) is the most accurate method feasible in most US hospitals.[6,16,18] Using this method, Rogowski[6] estimated hospital costs for very-low-birth-weight infants in California that are comparable to our estimates for the routine-care group (data available from the authors).

Certain costs were not measured because we anticipated that they would be expensive and difficult to evaluate and unnecessary to verify the cost-effectiveness of comprehensive care. These included costs of physician services outside our clinic, costs for visits to community clinics, and the indirect and intangible costs (eg, pain and suffering, lost work days) to the infant or family. These costs are likely to have been systematically higher in the routine-care group—the group that received all acute care outside our clinic and had substantially more ED visits and intensive care days—than in the comprehensive-care group. Thus, our analyses are likely to provide a conservative estimate of the total cost sav-

Table 4. Estimated Hospital Costs From Nursery Discharge to 1-Year Adjusted Age*

	Costs, Mean (SD), $	
	Comprehensive-Care Group	Routine-Care Group
Outpatient costs		
Follow-up clinic	1201 (897)	917 (772)
All outpatient	2748 (2415)	2931 (3635)
Inpatient costs		
Intensive care bed costs	296 (1750)	1371 (4849)
All inpatient	3517 (14 657)	6982 (24 342)
Total cost	6265 (15 424)	9913 (25 462)

*For the 168 comprehensive-care infants and 171 routine-care infants born between January 1, 1993, and March 31, 1996. Data are presented in 1997 dollars.

ings of comprehensive follow-up care from a societal perspective.

Costs are assessed from the hospital's perspective in relation to reimbursements. In both groups, the estimated costs exceeded Medicaid reimbursements. This shortfall may discourage hospitals from developing follow-up programs for high-risk infants. However, the shortfall may be considerably greater in the absence of any follow-up program. With the effort in our clinic to maintain Medicaid coverage,[14] the estimated shortfall with comprehensive care ($1070 per infant) was less than with routine care ($2997 per infant).

Because our trial assessed the combined effects of all aspects of the comprehensive-care program, the effects of the individual components are unclear. The reduction in life-threatening illnesses was achieved without a substantial increase in outpatient visits. Indeed, the comprehensive-care group had a mean of only 3 additional visits to hospital clinics and fewer ED visits than did the routine-care group. We suspect that the success of the program was largely due to 24-hour-per-day access to primary caregivers who were highly experienced in the care of very-low-birthweight infants. The value of augmenting continuity of follow-up care and providing prompt attention to acute complications or illnesses is supported by trials in other high-risk populations.[29-31]

The value of comprehensive follow-up care might change with the improving neonatal outcome of very-low-birth-weight infants. However, there has been little, if any, change in the proportion of these infants discharged with chronic lung disease[32,33] or neurodevelopmental deficits,[5] problems that increase the likelihood of life-threatening complications or illnesses during infancy. We found no decrease over the course of the trial in the benefits of comprehensive care as measured by the reduction in the proportion of infants who developed life-threatening illnesses. With the increasing survival of very-low-birthweight neonates, the absolute number who would benefit from comprehensive care may be increasing.

For comprehensive care to be effective, follow-up clinics will need full access to high-risk infants. The best outcomes for high-risk patients are achieved in high-volume programs designed specifically to meet their needs.[34] Our findings support the development of methods to promote programs of comprehensive follow-up care and the referral of high-risk infants to these programs. This approach could help improve the outcome of these infants, reduce the costs of their care, and create better understanding of the long-term effects of perinatal care and disorders in early life.

In summary, our findings demonstrate that comprehensive follow-up care provided by highly experienced caregivers can be highly effective in reducing life-threatening illnesses without increasing the overall costs of care for high-risk inner-city infants. Follow-up clinics that serve such infants should consider developing a comprehensive-care program.

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