Healthy Steps in an Integrated Delivery System

Child and Parent Outcomes at 30 Months

Brian D. Johnston, MD, MPH; Colleen E. Huebner, PhD, MPH; Melissa L. Anderson, MS; Lynda T. Tyll, MS; Robert S. Thompson, MD

Objective: To test the effects of the Healthy Steps for Young Children program (HS) (which supports parents managing children’s developmental and behavioral issues)—with and without a prenatal component—on child health and development, parenting practices, and parental well-being.

Design: A concurrent comparison with clinic-level assignment to intervention or usual care status. Nested in the intervention arm, a randomized trial compared HS with and without a prenatal component.

Setting: Five primary care clinics in an integrated delivery system in the Pacific Northwest.

Participants: A consecutive sample of 439 pregnant women (80% of eligible) were enrolled. Follow-up data were obtained for 78% when the child was 30 months old.

Intervention: Families in intervention clinics received HS services, including developmental and behavioral advice and risk factor screening. In addition, those randomized to prenatal services received 3 home visits during pregnancy.

Main Outcome Measures: Assessed by telephone interview in the 3 domains of child health and development, parenting practices, and parental well-being.

Results: Intervention was associated with positive outcomes in timely well-child care, immunization rates, breastfeeding, television viewing, injury prevention, and discipline strategies. Prenatal initiation of services was associated with larger expressive vocabularies at age 24 months. Mothers who received the intervention reported more depressive symptoms, but there was no increase in the proportion with clinically significant depression.

Conclusions: For members of an integrated delivery system, the HS intervention was associated with positive effects on children’s health and parenting practices. There was little evidence of any additional benefit of HS services initiated during the prenatal period.

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The Healthy Steps for Young Children program (HS) was designed to support families of young children using a new type of health care provider, the HS specialist (HSS), in a practice-based intervention. The HS consists of risk reduction activities and universal components, including developmental screening, anticipatory guidance, and follow-up services, offered to all families receiving care. Expected benefits of HS include improved parental promotion of child development, parenting practices, child development, and health care utilization. Evaluation of the program to date has demonstrated improved timeliness and quality of pediatric services, parenting practices, and parent satisfaction with services.

In this trial, we investigated pediatric usual care (UC) vs HS implemented with and without PrePare (PP), a prenatal component designed to begin the therapeutic HSS-parent relationship during pregnancy. PrePare was delivered as 3 home visits. The objective was to introduce the HSS to the parents as a knowledgeable and caring resource, helping them prepare for the arrival of their newborn. The content of the prenatal visits included information about fetal and infant development, home safety, and the material needs of newborns and infants. Families who received PP services continued to receive the standard HS intervention from the same HSS during the postnatal period.

Our tests of this intervention package found no incremental benefits of PP (compared with HS only) on parental well-being, knowledge, or parenting practices when the infants were 3 months of age. However, families who received PP were more satisfied with their pediatric care and were less likely to disenroll from the health plan in the 12 months following the child’s birth. We hypothesized that organiza-
tional bonding might explain these positive effects of the prenatal intervention and theorized, in turn, that benefits for children and parents would become apparent during infancy and toddlerhood.

Herein, we report results of tests for intervention effects on child health and development, parenting practices, and parental well-being when enrolled children were 30 months old. A quasi-experimental design was used to compare intervention families with families who received the health plan’s usual complement of pregnancy and pediatric services. Within intervention clinics, a nested randomized trial compared PP + HS with HS only.

SETTING AND DESIGN

This clinical trial was conducted from July 20, 1998, through November 7, 2003, in a large integrated delivery system that provides services to approximately 550,000 people located in the Pacific Northwest. Three clinics received the intervention while 2 other geographically distant clinics served as comparison sites. Within intervention clinics, enrolled families were individually randomized to receive services beginning prenatally (PP + HS) or postnatally (HS only). Data analysis was performed in 2004.

RECRUITMENT AND ENROLLMENT

Recruitment was by review of obstetrical records in the second trimester, followed by a letter of invitation, telephone screening, and an enrollment visit with study staff. To be eligible, pregnant women had to be at least more than 22 weeks' gestation at study enrollment, younger than 45 years, English speaking, and planning to use a study clinic for pediatric care. Enrollment occurred from July 20, 1998, through September 29, 2000. Individual randomization was performed centrally, stratified by clinic, and blocked in groups of 4.

INTERVENTIONS

Four master’s-level trained HSSs provided most of the intervention program’s services. Two HSSs had backgrounds in nursing, one in social work and one in mental health practice. All received additional training and ongoing education in early child development and in specific aspects of HS. Key clinicians and other personnel from intervention clinic sites also received intervention-related training. Enrollees randomized to HS were eligible to receive prenatal home visits from an HSS; developmental advice and parent-initiated telephone support; developmental assessments conducted in tandem with scheduled well-child care. The PP participants began the intervention by receiving 3 home visits with their HSS when they were at approximately 20, 27, and 34 weeks' gestation. The conceptual framework for PP drew on findings of the psychological transition to parenthood, in which adjustment to the maternal role requires renegotiation of the current family structure to incorporate the unavoidable changes that accompany the birth of a baby. In keeping with this framework, the 3 home visits were structured to help parents create a safe, knowing, and welcoming environment for their newborn. In addition, the PP participants received screening and intervention for targeted risk factors, such as smoking, depression, and domestic violence. The HSS who provided prenatal services continued to provide the standard package of HS services following the birth of the infant. Comparison clinic enrollees received the health plan’s standard package of well-child pediatric care, outreach, and support services.

The Group Health Cooperative Human Subjects Review Committee reviewed the study. Informed consent was obtained from all participating families.

DATA COLLECTION

Most outcome data were collected by telephone interview of mothers at enrollment to the study (at 16-20 weeks’ gestation), at 7 to 10 days post partum, when enrolled children were 3 months of age, and again when these children were at 30 months of age. Data on language acquisition were obtained by mailed questionnaire at age 24 months. Health plan utilization data were extracted from administrative databases.

The overall intervention goal was to improve child health and developmental attainment by supporting appropriate parenting practices. Herein, we present findings grouped into the following 3 domains: child health and development, parenting practices, and parental well-being.

OUTCOME MEASURES

Child Health and Development

We used immunization delivery and attainment of timely age-appropriate well-child care as intermediate health outcomes. Well-child visits occurring within 60-day windows centered around the health plan’s recommended visits at 2, 4, 6, 10, 15, and 24 months were counted as “timely” preventive care. Among those continuously enrolled for the first 2 years of life, the health plan’s standard Health Plan Employer Data and Information Set measure was used to identify children whose immunizations were up-to-date at age 24 months (4 diphtheria and tetanus toxoids and pertussis vaccines [or diphtheria and tetanus toxoids with acellular pertussis vaccines], 3 oral polio vaccines or inactivated poliovirus vaccines, 1 measles-mumps-rubella vaccine, 2 Haemophilus influenzae type b vaccines, and 3 hepatitis B vaccines). When enrolled children were 24 months old, parents completed a questionnaire that included elements of the short and long forms of the MacArthur Communicative Development Inventories assessing single-word expressive vocabulary, word combining (≥2 words), use of 3 or more word endings, and mean length (in morphemes) of the child’s 3 longest phrases.

Parental perception of child behavior problems was assessed at 30 months by telephone using 3 subscales from the Child Behavior Checklist. These included aggressive behavior, sleep problems, and symptoms related to an anxious or depressed mood.

Parenting Practices

The PP and HS interventions promoted parental knowledge of child development, self-efficacy, and developmentally supportive parenting practices. The 2003 gives an overview of the continuous measures used to assess these constructs. For parenting practices, we used established scales of nurturing behavior and parenting sense of competence. We developed and used a brief measure of self-efficacy for pediatric health care (Table 1). Other measures of parenting practices reported herein include frequency of activities to promote child development (including reading or playing with the child), maintaining routines around bedtime and meal times, and limiting television viewing. The proportion of mothers initiating breastfeeding and engaging in any breastfeeding beyond 6 months is reported.
Mothers’ reports of child injury prevention practices were summed to create a 5-point index that reflected the presence of a functioning smoke detector (1 point), regular use of a car seat (1 point) in the correct position (1 point), and absence of firearms in the home (2 points) or safe storage of any firearms reported (1 point). We also asked about the use of 4 common household safety items (safety latches, electrical outlet covers, stair gates, and poison control center telephone number).

Mothers were asked about specific discipline strategies. The proportion reporting any unusually harsh discipline (i.e., slapping on the face or spanking with an object) is reported.

Parental Well-being

The PP and HS interventions offered screening and referral for maternal depression along with general social support from the HSS. Maternal depressive symptoms were assessed using a modification of the Center for Epidemiological Studies Depression Scale17 (Table 1); the scores are reported herein along with the proportion of respondents who reported “feelings of sadness” that were discussed with someone in the pediatric practice.

Other measures of maternal well-being included self-reported use of any illicit drug and the presence or absence of significant physical domestic violence in the preceding 12 months (“Did your partner hit you, shove you, or kick you?”). “Problem drinkers” were identified according to accepted definitions based on reported alcohol consumption.18 Exposure to environmental tobacco smoke was assessed as the proportion of households with current smokers.

SAMPLE SIZE

Sample size estimates indicated that 100 enrollees per study group were needed for analysis of our primary outcomes at 30 months. For example, with a total sample of 300, we could detect (with 80% power at α = .05) a difference of 0.28 SD when the outcome measured was continuous.

STATISTICAL ANALYSIS

We based all analyses on initial group assignment and made adjustments to minimize differences due to the quasi-experimental design. We used generalized linear models with robust variance estimates to account for within-clinic clustering effects. To identify a parsimonious and consistent set of covariates for use in adjusted analyses, we examined all demographic data collected. No enrolled family had missing data at baseline for these variables. One variable was selected from any highly correlated pairs. Covariates were included if they differed statistically between the intervention and comparison groups at baseline or if inclusion in an analytic model caused point estimates of effect size to vary by more than 10%. Based on these criteria, maternal education, family income, and status as a first-time parent were used as covariates in our adjusted analyses. To account for norms used in scoring language outcomes, these were also adjusted for the child’s sex and age at the time of the assessment. For all outcomes measured at baseline, we used statistical adjustment for these baseline scores, providing a test of the intervention’s effect on change after enrollment.

For dichotomous outcomes, rate ratios (RRs) from Poisson models are presented. For continuous outcome variables, we report adjusted linear regression coefficients. All estimates are reported with 95% confidence intervals (CIs). All analyses were performed using Stata 8.0 (StataCorp LP, College Station, Tex).

RESULTS

STUDY RESPONSE AND DEMOGRAPHICS

Women who agreed to participate in the study (N = 439) represented about 80% of those who were eligible.10 Participants in the intervention groups (PP + HS vs HS only)
differed from those in the UC group on 2 potential confounds, maternal education and maternal age (Table 2). Therefore, we report unadjusted and adjusted comparisons for intervention vs comparison group outcomes.

The telephone interview at 30 months was completed by 77% of enrollees assigned to HS only, 81% of those assigned to PP/HS, and 77% of those assigned to UC (Figure). Nonrespondents at 30 months had less maternal education and lower family incomes compared with respondents. Nonrespondents in the intervention group were more likely than comparison group nonrespondents to be first-time parents (67% vs 53%) and be without a spouse or partner (13% vs 3%). The mailed paper survey was completed at 24 months by 71% of the HS-only group, 74% of the PP+HS group, and 68% of the UC group.

OUTCOMES BY DOMAIN

Throughout this article, intervention vs UC comparisons are presented first. These are followed by results of the randomized contrast between the PP/HS and HS-only groups.

Child Health and Development

Receipt of well-child care within specified time intervals was more likely among intervention recipients than comparison enrollees at 4, 6, and 15 months (Table 3). Among the intervention recipients, the PP+HS group was more likely than the HS-only group to make a timely 24-month visit (adjusted RR, 1.17 [95% CI, 1.08-1.27]). At 24 months, more intervention recipients than comparison enrollees were up to date for immunizations (90% vs 85%; adjusted RR, 1.06 [95% CI, 1.02-1.09]); among intervention recipients, full immunization was significantly more common in the PP+HS group (92%) than in the HS-only group (88%).

Attainment of developmentally appropriate language skills at 24 months did not differ between the intervention and UC groups for vocabulary size, sentence length, the proportion of children using 3 or more word endings, or the proportion combining 2 or more words (Table 3). Within the intervention group, the vocabulary score of PP+HS children, on average, exceeded that
of HS-only children by 4.08 (95% CI, 0.69-7.74) words, and the proportion combining more words in the PP + HS group exceeded the proportion in the HS-only group (93% vs 89%; adjusted RR, 1.05 [95% CI, 1.02-1.08]).

Group differences in the Child Behavior Checklist subscales showed that parents in the intervention group reported higher scores than those in the UC group on the aggressive behavior subscale (7.4 vs 6.80; adjusted β, 0.83 [95% CI, 0.37-1.30]), although neither group reached a subscale score of clinical significance (the cutoff for this age is 22 years) (Table 3).11 There were no group differences in reports of sleep problems or problems with depression or anxiety. Although children in the PP + HS group were reported to have more anxious or depressed behaviors than those in HS-only group (β level, 0.40 [95% CI, 0.07-0.73]), the mean scores were well below the range of clinical significance.

Parenting Practices

Within the intervention group, 97% of mothers initiated breastfeeding compared with 91% in the UC group (adjusted RR, 1.06 [95% CI, 1.00-1.11]) (Table 4). Intervention recipients who initiated breastfeeding also breastfed their infants longer on average than the UC recipients (13.9 vs 11.2 months; adjusted β, 1.30 [95% CI, 0.18-2.43]). The proportion of intervention mothers who breastfed for 6 months or longer18 was higher (82%) than that of UC mothers (64%). No difference was found between the PP + HS and the HS-only groups.

There were no group differences in parents' nurturing behavior or self-efficacy for pediatric health care. Parenting sense of competence was slightly lower among intervention recipients (β level, −0.92 [95% CI, −1.40 to −0.44]), an effect driven by lower scores on the satisfaction subscale rather than by differences in self-efficacy (Table 4).

Parents in the intervention group were more likely to report the use of routines in the home (adjusted RR, 1.12 [95% CI, 1.03-1.22]) and were 25% less likely than those in the UC group to allow more than 1 hour of daily television viewing (34% vs 50%; adjusted RR, 0.75 [95% CI, 0.62-0.91]). Within the intervention group, recipients of PP + HS reported that they were less likely to read to their child daily (88% vs 95%) and were more likely to allow more than 1 hour of television viewing (39% vs 28%) compared with recipients of HS only.

Respondents in the intervention group were almost 20% more likely than those in the UC group to score the full 5 points on the index of injury control behaviors (smoke detector function, car seat use, and gun safety items). Intervention families were also more likely to use stair gates (adjusted RR, 1.19 [95% CI, 1.15-1.23]) and to have access to the local poison control center's telephone number (adjusted RR, 1.08 [95% CI, 1.03-1.12]), but they were less likely to report having safety
latches on cabinets (Table 4). Intervention families were 54% less likely to report the use of extreme disciplinary measures (ie, slapping the child's face or spanking with an object) than UC families (adjusted RR, 0.46 [95% CI, 0.29-0.73]).

Parental Well-being
When the study children were 30 months old, maternal depressive symptoms scores on the Center for Epidemiological Studies Depression Scale were generally low (Table 5). The intervention respondents reported slightly more distress than the UC respondents on these measures (adjusted RR, 0.75 [95% CI, 0.20-1.31]) but were no more likely to score above the clinical cutoff for an affective disorder. The elevated 30-month Center for Epidemiological Studies Depression Scale scores in the intervention group were driven by a higher prevalence of depressive symptoms among the PP-only group (a difference not present at baseline). Among those who were self-identified as having problems with depression or sadness, 53% in the HS-only group and 49% in the PP-only group said that they had discussed these concerns with someone in the pediatric practice, compared with only 35% of those in the UC group (adjusted RR, 1.45 [95% CI, 0.95-2.21]).

Only a small proportion of respondents reported any use of illicit drugs or exposure to significant physical domestic violence in the preceding year. No group differences in these outcomes were detected. Although screening and referral for smoking cessation services were included in both arms, the low proportion of house-

### Table 4. Parenting Practices Outcomes

<table>
<thead>
<tr>
<th>Variable</th>
<th>Unadjusted Estimates</th>
<th>Adjusted Analyses</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Usual Care (n = 104)</td>
<td>Intervention (n = 239)</td>
</tr>
<tr>
<td>Continuous Outcomes, Mean ± SD or ( \beta ) (95% Confidence Interval)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Breastfeeding duration, mo</td>
<td>11.2 ± 9.5 (n = 91)</td>
<td>13.4 ± 8.8 (n = 232)</td>
</tr>
<tr>
<td>Parenting behavior checklist nurturing subscale</td>
<td>59.6 ± 6.3 (n = 117)</td>
<td>59.4 ± 6.6 (n = 116)</td>
</tr>
<tr>
<td>Parenting sense of competence Efficacy subscale</td>
<td>21.4 ± 2.2 (n = 117)</td>
<td>21.1 ± 2.2 (n = 116)</td>
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<tr>
<td>Parenting sense of competence Satisfaction subscale</td>
<td>26.8 ± 3.0 (n = 117)</td>
<td>26.2 ± 3.3 (n = 116)</td>
</tr>
<tr>
<td>Total</td>
<td>48.2 ± 4.5 (n = 117)</td>
<td>47.3 ± 4.8 (n = 116)</td>
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<tr>
<td>Health care self-efficacy</td>
<td>16.9 ± 2.0 (n = 117)</td>
<td>17.0 ± 2.0 (n = 116)</td>
</tr>
<tr>
<td>Injury prevention index</td>
<td>4.68 ± 0.56 (n = 117)</td>
<td>4.84 ± 0.43 (n = 116)</td>
</tr>
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Abbreviations: HS, Healthy Steps for Young Children program; PP, PrePare.
*Statistically significant comparisons (\( P < 0.05 \)).

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The HS has been shown to improve the quality of child health services and parental satisfaction in diverse practice settings. When children in this study were 3 months old, an evaluation demonstrated that HS with or without PP was associated with improved parental knowledge, practice, well-being, and satisfaction. When the children were 30 months old, there were additional positive effects on the receipt of timely well-child care, immunization rates, duration of breastfeeding, and parenting practices to prevent childhood injury, to increase the use of household daily living routines, to minimize television viewing, and to reduce the use of inappropriate discipline techniques.

An important feature of HS is the universal nature of the intervention. Parenting support programs have been shown to have positive effects among families with young infants at high psychosocial risk. Our results suggest a benefit from the universal provision of parenting and child development support services to an unselected sample of families with health coverage, who ranged from the affluent and employed to those at greater socioeconomic and psychosocial risk. This is a meaningful result.

There was no difference in response to the intervention according to the HSS assigned (data not shown). All were experienced master’s-level clinicians. Whether paraprofessionals with other backgrounds could produce similar outcomes is unknown and should not be assumed. Dose-response analyses are an appealing strategy to identify the intensity of intervention required to elicit desired effects; however, they are not applicable in this trial. The intervention was clinic based, involving office staff, providers, and systems of care. The effect of these changes in the milieu of care cannot easily be delineated from the effect of countable visits or encounters with the HSS.

Despite the noted improvements in child health and parenting practices, the intervention was associated with some undesirable effects. Intervention recipients reported more depressive symptoms and a diminished parenting sense of competence that stemmed from less satisfaction in the parenting role. Whether this reflects an increase in symptoms or an increased accuracy and willingness to identify and report symptoms is unknown. Differences in neither baseline rates of depression nor maternal education explain these findings. Fortunately, the number of depressive symptoms in any group was low when enrolled children reached 2½ years old. Nevertheless, more investigation of the interaction among the intervention, parenting experience, and maternal mental health outcomes seems warranted.

A major objective of this study was to test a new model for delivering HS services capitalizing on the strengths of an integrated delivery system. To do so, we added a prenatal component. Despite increased member satisfaction and decreased health plan disenrollment in the early postnatal period, the only long-term health benefits from PP seemed to be (1) greater compliance with the 24-month well-child visit, with a concurrent improvement in immunization status, and (2) modestly increased vocabulary production and word combination at 24 months. Paradoxically, these developmental attainments were seen in a group that reported more depressive symptoms, more television viewing, and less daily reading to the children. These findings in the PP + HS arm cannot be explained using the data available to us.

There are several potential limitations in this trial. Although we were gratified to achieve a 78% retention rate in the study during 3 years, there remain significant differences in the demographic composition of nonrespondents in the intervention group compared with the UC group, and within the randomized treatment groups as well. The comparisons between the combined intervention and UC groups were limited by the quasi-experimental design. Although we adjusted for several
important baseline covariates and for clustering within clinics, unmeasured residual confounding likely exists.

Overall, we believe that our implementation of HS in an integrated delivery system resulted in positive effects for parents and their children. These must be weighed against costs of the intervention, its effects on utilization, provider satisfaction, and satisfaction of health plan enrollees. These outcomes will be assessed in future studies, and policy implications of the findings will be discussed in subsequent publications.

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Correspondence: Brian D. Johnston, MD, MPH, Department of Pediatrics, University of Washington, Harborview Medical Center, 325 Ninth Ave, Box 359774, Seattle, WA 98104 (bdj@u.washington.edu).

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REFERENCES


