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A Stepped Intervention Increases Well-Child Care and Immunization Rates in a Disadvantaged Population

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KEY WORDS
child health services, community pediatrics, immunization, randomized, controlled trial, well-child care

ABBREVIATIONS
CI—confidence interval
DH—Denver Health
OR—odds ratio
WCV—well-child visit
ICD-9-CM—International Classification of Diseases, Ninth Revision, Clinical Modification

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WHAT'S KNOWN ON THIS SUBJECT: Previous studies of reminder/recall/outreach to increase infant preventive health care in urban settings showed mixed results.

WHAT THIS STUDY ADDS: A stepped intervention of tracking and case management improved infant immunization status and receipt of preventive care in a population with low socioeconomic status, at a cost of $23.30 per infant per month.

abstract

OBJECTIVE: To test a stepped intervention of reminder/recall/case management to increase infant well-child visits and immunization rates.

METHODS: We conducted a randomized, controlled, practical, clinical trial with 811 infants born in an urban safety-net hospital and followed through 15 months of life. Step 1 (all infants) involved language-appropriate reminder postcards for every well-child visit. Step 2 (infants who missed an appointment or immunization) involved telephone reminders plus postcard and telephone recall. Step 3 (infants still behind on preventive care after steps 1 and 2) involved intensive case management and home visitation.

RESULTS: Infants in the intervention arm, compared with control infants, had significantly fewer days without immunization coverage in the first 15 months of life (109 vs 192 days $P < .01$) and were more likely to have ≥5 well-child visits (65% vs 47% $P < .01$). In multivariate analyses, infants in the intervention arm were more likely than control infants to be up to date with 12-month immunizations and to have had ≥5 well-child visits. The cost per child was $23.30 per month.

CONCLUSION: This stepped intervention of tracking and case management improved infant immunization status and receipt of preventive care in a population of high-risk urban infants of low socioeconomic status. *Pediatrics* 2009;124:455–464

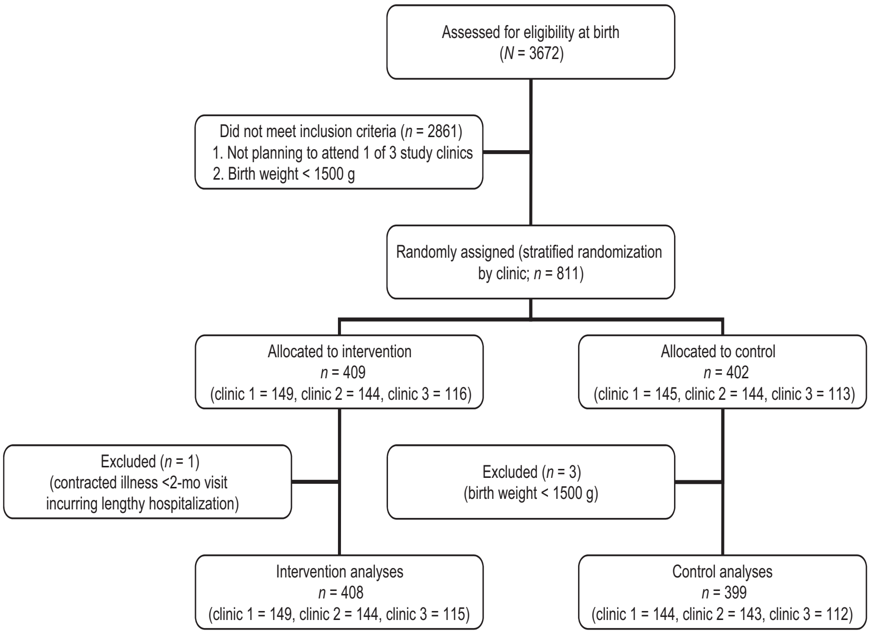

FIGURE 1
Study flow and randomization.

Immunizations and preventive health care visits are central to high-quality infant health care. Many areas of the United States are approaching the immunization goals outlined in Healthy People 2010.[1–4] Despite these successes, pockets of underimmunization persist in many of the same inner-city areas that were the primary sites of the measles epidemic in the 1990s.[5–10] Because immunizations are associated with receipt of other childhood preventive health services, many inner-city children who are underimmunized also are not receiving adequate well-child care.

Numerous studies identified risk factors for childhood underimmunization, whereas others tested interventions to increase immunization rates.[11–32] A smaller number of studies examined risk factors for lack of receipt of well-child visits (WCVs) or tested interventions to improve WCV rates.[11,23,31,33] We conducted a randomized, controlled, practical, clinical trial of a stepped intervention of reminder/recall/outreach in a socioeconomically disadvantaged, majority-Hispanic population, to increase both immunization rates and WCVs in the first year of life.

METHODS

Setting and Subjects

Denver Health (DH) is the largest vertically integrated, community health center system funded by the Bureau of Primary Health Care (Section 330) in the United States.[34] This study used the DH Medical Center and 3 of its affiliated community health centers. In 2005, these 3 health centers served 2174 patients <15 months of age, with a total of 7605 visits. Ninety percent of these children were eligible for Medicaid. The racial/ethnic status of all children seen in these 3 health centers in 2005 was 19% black, 74% Hispanic, 3.5% non-Hispanic white, and 3.5% other.

Study Population and Randomization

All 3672 infants who were born at DH Medical Center between February 1, 2004, and January 31, 2005, were assessed for eligibility (Fig 1). This clinical trial was approved by the institutional review board of the University of Colorado School of Medicine and the research review committee of DH. Because this study was determined by the institutional review board to be a minimal-risk study, consent was not required. We used the newborn nursery log to identify eligible infants. This log records all births, birth weights, and primary health care center assignments for the infants (determined on the basis of the home address). Of the total birth cohort, 811 infants met the inclusion criteria (family planning to attend 1 of 3 study health centers and infant birth weight of >1500 g). Infants who weigh <1500 g at birth usually are hospitalized for prolonged periods and are not seen in primary care clinics until many months of age. All eligible infants underwent block-randomization, with stratification according to clinic, using random blocks of 2, 4, or 6 infants, to ensure similar numbers of control and intervention-treated infants in each clinic. Randomization was implemented by using numbered nontranslucent envelopes; the research assistants who were responsible for opening the envelopes and assigning the treatment arm were blinded to the randomization sequence. The randomization sequence was generated by an analyst who was not otherwise involved in the study and it was maintained by the principal investigator (Dr Hambidge), who was not involved in the actual random assignment of patients. Of the 409 infants who were allocated to the intervention arm, only 1 infant was excluded from the final analysis (because of contracting, before 2 months of age, a vaccine-preventable disease that resulted in a lengthy hospitalization). In the control arm, 3 infants (of a total of 402 infants) were excluded from the final analysis because they had birth weights of <1500 g (these infants should not have been eligible for random assignment but were assigned in error). All children were monitored through 15 months of life. Therefore, the first infant entered the study on February 1, 2004, and the last infant was monitored through April 31, 2006.

Study Design and Intervention

We conducted a randomized, controlled trial of a stepped intervention to assist families in obtaining preventive health care for their infants. The trial was practical in design,[35] to maximize its measure of effectiveness and external generalizability. Case managers/patient navigators (described in detail below) established early contact with mothers in the intervention arm, using a scripted dialogue to assess individual barriers to care. Of the parents representing infants enrolled in the study, 186 (46%) were met in the hospital, 182 (44%) were met by telephone, 8 (2%) were met at a home visit, and 32 (8%) were not met for this initial scripted encounter. Mothers were interviewed to assess risk factors for underimmunization and were provided with a refrigerator magnet with direct telephone contact information for case managers, an immunization schedule, and a bag containing educational materials from the Colorado Bright Beginnings Warm Welcome program (information available at www.brightbeginningsco.org).

The intervention consisted of 3 steps, with each more-intensive step targeted to the progressively smaller number of children who had not responded to less-intensive interventions. In step 1, all infants in the intervention arm received language-appropriate reminder postcards before every WCV. In step 2, all high-risk infants received a telephone reminder before all WCVs, with postcard and telephone recall for all missed WCVs or immunizations. An infant was classified as being at high risk on the basis of either missing a WCV or immunization or having characteristics known from previous work with an earlier birth cohort of infants in this same safety-net health care system to be associated with lower immunization rates.[23,24] These characteristics included having a mother who was non-Hispanic (for the population served by DH, we showed that non-Hispanic white and black infants had worse immunization rates than did Hispanic infants[23]), who intended to bottle feed (not breastfeed), who was uninsured, or who had a history of poor prenatal care or smoking.[24] In addition, infants were included in the high risk group if the mother had a history of street drug use or domestic violence. In step 3, only the infants who were still missing WCVs or behind on immunizations after step 2 received intensive outreach and home visitation. The timing of the intervention was as follows: 10 days before the age due for a WCV, reminder postcard (step 1) and telephone call (step 2); 10 and 21 days overdue for a WCV or immunization, recall postcard and telephone call (step 2); 30 days overdue, home visit (step 3). The intervention continued through 16 months of age (May 31, 2006, for the youngest child in the cohort). Once children were classified as being at high risk and received more-intensive intervention, they continued to receive the more-intensive intervention for the duration of the study. We did not intervene or track patients once they left the DH system.

All telephone contacts and home visits were conducted by 1 of 3 patient navigators or *promotoras* ("health promoters"), all of whom had master's degrees and lived within the defined service area of a DH community health center. Two of the navigators were fluent in Spanish (1 spoke Spanish as her first language); the non–Spanish-speaking navigator worked only with English-speaking families. The navigators conducted reminder/recall activities on weekends and evenings, as well as weekdays. In addition to reminders/recalls, the navigators provided assistance with a broad array of nonbiomedical issues, including transportation, insurance problems (especially Medicaid reenrollment), billing issues, child care referrals, Social Security problems, and in some cases obtaining food on an emergency basis.

Data Sources

Immunization Registry

The DH electronic immunization registry is the system-wide legal repository for pediatric immunizations. This registry captures >97% of immunizations given in the DH system,[36] and it recorded ~1 700 000 vaccines for 140 000 children by February 1, 2004 (Michele Berg, MBA, written personal communication, 2007). These data were used to assess all immunization outcomes for this study.

Medical Record Review

Medical chart review was conducted to obtain measures of maternal prenatal care, risk behaviors, race/ethnicity, language, birth country, and breastfeeding intent. Three trained research assistants abstracted these data from maternal prenatal and peripartum records. They also abstracted information from the newborn nursery log, including infant medical record number, date of birth, birth weight, and intended site for primary care.

Administrative Data

All relevant billing and diagnosis data were downloaded from the DH computer system, including insurance status (updated at each visit), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnoses, hospital service codes, and charges; these data sources also provided supplemental information regarding birth dates, race, and ethnicity. Immunization data (from the electronic registry) and WCV data (from billing records) were downloaded weekly into a research database, to allow reminder/recall activities to be performed in real time.

Measures

Primary Outcome Measures

The primary outcomes for this study were immunization and well-child care receipt, measured as both dichotomous and continuous variables. Immunization receipt was determined by using the immunization registry, with duplicate immunizations or invalid doses being removed according to the minimal ages and intervals set by the Centers for Disease Control and Prevention for the time at the inception of our cohort.[37] The primary immunization measure was the continuous outcome of days underimmunized in the first 15 months of life. We used the method described by Luman et al[38] to determine days underimmunized. Days underimmunized is a more-sensitive measure of infant underimmunization than up-to-date rates, because it reflects the time at risk for vaccine-preventable disease in the first year of life. For the dichotomous outcome, up-to-date status was defined as receipt of the following immunizations: 4 diphtheria-tetanus-pertussis, 3 poliovirus, 1 measles-mumps-rubella, 3 *Haemophilus influenzae* type B, 3 hepatitis B, 1 varicella, and 2 conjugated 7-valent pneumococcal vaccine doses by 15 months of age. These were all of the vaccines recommended for this age group at that time; only 2 pneumococcal vaccine doses were included because a transient national shortage affected our cohort and resulted in DH administering only 2 infant conjugated 7-valent pneumococcal vaccine doses until the shortage was resolved.

WCVs were defined as age-appropriate encounters associated with ICD-9-CM diagnosis code V20.2. A previous study conducted in the same health care system[23] supported the validity of this measure, with 10 782 WCVs being identified through chart review and 10 494 being identified on the basis of ICD-9-CM codes alone (excellent agreement, $\kappa = 0.941$). The dichotomous up-to-date well-child care outcome was defined as receipt of >5 WCVs by 15 months of age, of a possible 6 visits (at 2 weeks, 2 months, 4 months, 6 months, 9 months, and 12 months). This number of WCVs in the first 15 months of life is now a benchmark quality measure for managed-care plans.[39]

Secondary Outcome Measures

Secondary outcome measures included (1) receipt of influenza vaccine (which was not part of the standard immunization series but was increasingly recommended over the course of the study), (2) number of children with no health insurance, and (3) health care visits and charges attributable to hospitalization or emergency department or urgent care visits in the first 15 months of life.

Covariates

Maternal prenatal records provided the following covariates: language, parity, gravidity, total number of prenatal visits, date of first prenatal visit, intent to breastfeed, history of domestic violence, and any use of tobacco, alcohol, or illicit drugs. Maternal postnatal visits or infant WCVs provided breastfeeding information when prenatal information was not available. Data extracted from the newborn log were supplemented with data from the infant's medical record when needed, so that complete information was obtained regarding infant date of birth, birth weight, and clinic where the infant's care would be obtained. Administrative data supplemented the data from the medical chart and newborn nursery log to provide maternal race and ethnicity, insurance status, date of birth, and marital status. Insurance status was analyzed as the dominant insurance for each child over the course of the study. Poor prenatal care was defined as initiation of prenatal care after the first trimester or a total prenatal visit count of <7 visits. Because the number of people reporting any personal risk behavior was small, we created a maternal risk covariate that was positive if there was a history of any alcohol or drug abuse or domestic violence.

Analyses

We used intent-to-treat analyses throughout this study, enrolling all infants who were intending to receive care at any of 3 preselected primary care clinics within DH and randomly assigning all infants at birth. Comparisons of the intervention and control groups were assessed by using bivariate techniques, including χ^2 analyses for all categorical variables, *t* tests for normally distributed, continuous variables, and Wilcoxon tests for non–normally distributed variables. In a secondary analysis, we examined outcomes for infants who were active users of the health care system, excluding those defined by clinic staff members (who used standard methods[40] to identify infants who had moved or gone elsewhere) or research case managers as having left the health care system.

All covariates that differed between the intervention and control branches ($P < .20$) were included in multivariate models. In addition, clinic site was entered in all multivariate models as a fixed rather than random effect, because rates varied according to clinic but randomization was performed at the individual rather than clinic level. The multivariate model chosen for analysis was determined on the basis of the distribution of the outcome variable; logistic regression was used for bivariate outcomes (immunization up-to-date status and WCV up-to-date status), and ordinary least-squares regression was used to model days underimmunized. Time (in days) to the fifth WCV was modeled with Cox regression techniques for multivariate analyses and with Kaplan-Meier analyses for graphing of unadjusted outcomes. We used standard statistical software to conduct all analyses (SAS 9.01; SAS Institute, Cary, NC).

TABLE 1 Maternal and Infant Characteristics

Covariate	Control ($N = 399$)	Intervention ($N = 408$)	P
Maternal characteristics			
Age, mean, y	26.0	26.2	.74
Married, *n* (%)	177 (45)	187 (48)	.43
Primiparous, *n* (%)	116 (29)	114 (28)	.72
No. of prenatal visits, mean	9.3	9.2	.76
Poor prenatal care, *n* (%)	136 (34)	144 (35)	.72
Intent to breastfeed, *n* (%)	326 (82)	321 (79)	.28
Mother born in United States, *n* (%)	110 (28)	111 (27)	.91
Hispanic, *n* (%)	358 (90)	352 (86)	.13[a]
English as primary language, *n* (%)	117 (29)	123 (30)	.80
Self-pay at delivery, *n* (%)	31 (8)	31 (8)	.93
History of domestic violence, *n* (%)	16 (4)	14 (3)	.67
Alcohol use, *n* (%)	14 (4)	28 (7)	.03[b]
Tobacco use, *n* (%)	27 (7)	48 (12)	.01[b]
Illicit drug use, *n* (%)	7 (2)	13 (3)	.19[a]
Any maternal alcohol, tobacco, or drug use, *n* (%)	36 (9.0)	63 (15.4)	<.01[b]
Infant characteristics			
Birth weight, mean, g	3274	3268	.87
Female, *n* (%)	186 (47)	218 (53)	.05[a]
All care at same clinic, *n* (%)	387 (97)	397 (97)	.79
Clinic, *n* (%)			
Clinic 1	144 (36)	149 (37)	.99
Clinic 2	143 (36)	144 (35)	
Clinic 3	112 (28)	115 (28)	

Percentages apply to the number of children after exclusion of infants with unknown or blank values for that covariate. All covariates had <3% unknown or blank data. For dichotomous variables, only 1 descriptor is shown. Percentages may not add to 100% because of rounding.

[a] $P < .20$.

[b] $P < .05$.

RESULTS

Study Flow

Of the 3672 infants born at DH Medical Center during the study enrollment year (Fig 1), 811 were eligible for random assignment because they would receive health care at 1 of the 3 intervention clinics; after 4 exclusions (3 infants with birth weights of <1500 g who were randomly assigned in error and 1 infant who underwent a lengthy hospitalization attributable to a vaccine-preventable disease that occurred before receipt of the 2-month immunizations), there were 408 infants in the intervention arm and 399 in the control arm. The randomization scheme resulted in similar numbers of infants in each study arm in each of the 3 clinics.

Study Population Characteristics

Maternal and infant characteristics are shown in Table 1. In general, these infants were from poor (>99% with public insurance or uninsured), primarily Hispanic, Spanish-speaking, urban families. Despite randomization, 2 risk factors, namely, maternal alcohol use and tobacco use, differed significantly in prevalence in the 2 study arms. In both cases, there were more women with the risk factor in the intervention arm. In addition, there were trends toward more girls, more illicit drug use, and fewer Hispanic mothers in the intervention arm than in the control arm. In our population, non-Hispanic ethnicity is a risk factor for underimmunization.[24] The risk variable that combined all risk factors (smoking, domestic violence, and drug use) was more prevalent in the intervention arm.

Intervention Exposure

Overall, we sent 4812 language-appropriate reminder or recall postcards (mean: 12 per infant), made 2675 telephone calls (mean: 6.6 per infant), and conducted 275 home visits (mean: 0.7 per infant). The telephone calls resulted in 1286 personal contacts, 624 messages left, and 765 noncontacts. Although 30 infants required no telephone calls, 8 infants required >21 calls; the majority (296 infants) required 1 to 10 calls. Step 1 of the intervention involved the 30 infants (7% of the 408 infants in the intervention arm) who required no telephone calls, step 2 of the intervention involved 228 infants (56%), and step 3 involved 150 infants (37%) who required ≥1 home visit. Of the 150 infants in step 3, 80 (53%) received 1 home visit, 59 (39%) received 2 or 3 home visits, and the rest received 4 to 7 home visits. There was no difference in intervention intensity among the 3 study clinics (data not shown). One hundred thirty infants (32%) were classified as being at high risk at birth and were placed directly into step 2 of the intervention. However, 54 infants (42%) in that group required a home visit, compared with 97 (35%) of 278 in the low-risk group (nonsignificant difference, $P = .19$).

TABLE 2 Unadjusted Analyses of Preventive Health Services Measures ($N = 807$)

Outcome	Control ($N = 399$)	Intervention ($N = 408$)	P
Immunization			
Proportion up to date at 15 mo, %	33	44	<.01
Time not up to date at 15 mo, mean ± SD, d	192 ± 442	109 ± 273	<.01
Proportion with 5 WCVs by 15 mo, %	47	65	<.01

Unadjusted Outcomes

In our primary intent-to-treat analysis, the intervention reduced the number of days of underimmunization in the first 15 months of life from 192 days to 109 days ($P < .01$) (Table 2). This represents almost 3 months of better protection against vaccine-preventable disease. The proportion of children with ≥5 WCVs by 15 months of age increased from 47% in the control arm to 65% in the intervention arm ($P < .01$). Among active patients ($n = 313$ in the control arm and $n = 281$ in the intervention arm), the proportion of infants with ≥5 WCVs increased from 55% to 85% ($P < .01$).

Adjusted Outcomes

After adjustment for all significant covariates in a multivariate linear regression model, only the intervention and Hispanic ethnicity were significantly associated with the number of days underimmunized per infant by 15 months of age (Table 3). In logistic regression modeling of the proportion of infants who were up to date with the 12-month immunizations by 15 months of age, being in the intervention arm (odds ratio [OR]: 1.6 [95% confidence interval [CI]: 1.2–2.1]) and having a mother without documented risk behaviors (OR: 1.7 [95% CI: 1.0–2.7]) were independently associated with better rates (Table 4). Similarly, being in the intervention arm (OR: 2.3 [95% CI: 1.7–3.0]), having no documented risk behaviors (OR: 1.6 [95% CI: 1.0–2.5]), and being of Hispanic ethnicity (OR: 2.0 [95% CI: 1.2–3.2]) were associated with better WCV rates (Table 5). One clinic also had consistently lower immunization and WCV rates, which reflects the variability that exists even within an integrated health care system and indicates the need for appropriate randomization within clinics and adjustment for clinic-level effects in randomized, controlled trials.

Analysis of Time to Fifth WCV

The time to the fifth WCV was noticeably shorter in the intervention arm than in the control arm (Kaplan-Meier log-rank test, $P < .01$). In a multivariate Cox regression analysis of these data, the intervention ($P < .0001$), Hispanic ethnicity ($P = .003$), absence of any maternal risk factor ($P = .03$), and clinic site ($P < .001$) were positively associated with increased WCVs.

TABLE 3 Multivariate Linear Regression Analysis of Days Underimmunized at 15 Months ($N = 807$)

Covariate	Estimate	SE	P	Standardized Estimate
Intercept	423.6	59.8	<.0001	<0.01
Received intervention	−107.5	32.3	<.01	−0.12
Hispanic	−220.6	51.9	<.01	−0.16
Female	−2.2	32.3	.95	−0.00
Maternal smoking, drinking, and/or drug use	11.3	50.6	.82	0.01
Clinic (fixed variable)				
Clinic 1	39.5	40.9	.33	0.04
Clinic 2	36.3	41.3	.38	0.04

TABLE 4 Multivariate Logistic Regression Analysis of Up-To-Date Status for 12-Month Immunizations at 15 Months ($N = 807$)

Covariate	OR (95% CI)
Received intervention	1.55 (1.16–2.07)
Hispanic	1.43 (0.88–2.32)
Male	0.81 (0.60–1.08)
No maternal risk habit (smoking, drinking, or drug use)	1.66 (1.04–2.65)
Clinic (fixed variable)	
Clinic 1 vs 3	1.67 (1.15–2.43)
Clinic 2 vs 3	1.65 (1.13–2.40)

Secondary Outcomes

In addition to the primary immunization and WCV outcomes, the intervention had other benefits. For example, although influenza vaccination was not part of the intervention, the proportion of infants who received ≥1 vaccination to protect against influenza increased from 68% to 77% and that for 2 vaccinations increased from 31% to 43% (for both, $P < .01$). Many infants in this study, despite being eligible for Medicaid, faced barriers in enrollment, which in turn limited health care access. The proportion of infants who were never enrolled in Medicaid during the 15 months of the study decreased from 20% (81 of 399 infants) in the control arm to 14% (59 of 408 infants) in the intervention arm ($P = .03$). Overall health care charges and visits to the pediatric hospital ward or ICU, the emergency department, and the urgent care clinic did not differ significantly between study arms (data not shown).

Cost Outcomes

The total cost of the intervention, including all personnel, mailings, telephone calls, home visits, and creation of the reminder/recall database, was \$142 596. Therefore, the cost for each child in the intervention arm was \$349.50, or \$23.30 per child per month over 15 months. The cost per additional WCV was \$530, and the cost per additional child brought up to date was \$3316. The cost per additional immunization administered was \$266.

TABLE 5 Multivariate Logistic Regression Analysis of Receipt of >5 WCVs by 15 Months ($N = 807$)

Covariate	OR (95% CI)
Received intervention	2.28 (1.70–3.05)
Hispanic	1.97 (1.24–3.15)
Male	1.04 (0.78–1.39)
No maternal risk habit (smoking, drinking, or drug use)	1.58 (1.01–2.49)
Clinic (fixed variable)	
Clinic 1 vs 3	1.56 (1.08–2.24)
Clinic 2 vs 3	1.65 (1.14–2.39)

DISCUSSION

We conducted a randomized, controlled trial to evaluate a stepped intervention of reminder, recall, case management, and home visitation to increase immunization and WCV rates in a poor urban population. The intervention resulted in improved preventive health care delivery for both primary outcome measures; days underimmunized in the first 15 months of life were decreased by 43%, which resulted in almost 3 months less of underimmunization per child, on average. The proportion of children with ≥5 WCVs by 15 months of age increased by 18%, to 65% of infants in the intervention arm (85% for children who were active users of the health care system).

This study adds information to several previously published interventions to increase immunization rates for inner-city infants. There is ample evidence of the success of reminder/recall strategies in general to increase pediatric immunization rates.[15,16,19,21,29] However, there have been several negative or only marginally successful trials of reminder/recall strategies in specific inner-city locales. For example, a large-scale, registry-based, reminder/recall intervention in Atlanta, Georgia, resulted in only small improvements in immunization status.[25] A number of previous interventions in Denver have been unsuccessful or only slightly successful,[23,41,42] including an intervention that used both reminder/recall and additional clinic-based strategies.[23] Taken together, these results suggest that reminder/recall activities work to improve pediatric immunization rates but, in some economically disadvantaged areas, additional strategies (such as intensive case management) may be necessary to reach optimal vaccination coverage, to provide herd immunity for entire populations, and to meet the goals of Healthy People 2010.[1]

In our study, children who were not brought in for well-child care and immunizations after reminder/recall were targeted with more-intensive outreach, including home visitation. Slightly more than one third of our population required ≥1 home visit. Such reminder/recall/outreach has been shown to work in other settings. For example, Rodewald et al[31] demonstrated that this strategy could improve immunization rates and preventive health care visits in the Rochester, New York, area, although they used an on-treatment rather than intent-to-treat analysis. That intervention was the model for the Rochester Primary Care Outreach Program[32] and was shown to reduce disparities in childhood immunization rates.[16] The successful interventions in that study and in the current study, in 2 very different settings and populations, suggest that the reminder/recall/outreach method works to improve preventive health services in disadvantaged populations. A key to the success of both projects was the work of energized, committed, culturally proficient case managers who functioned as patient navigators to help access preventive services for families. In our study, given the majority-Hispanic population, they functioned as *promotoras*, community workers who promoted the health of infants while addressing both biomedical and social needs.

Of note, the identification of infants as being at low risk or high risk at birth did not differentiate successfully the infants who would eventually need a home visit. This finding adds to previous evidence[24] that it is not possible to predict accurately at birth which infants will fall behind in their preventive health care, and it emphasizes the need to target all infants in vulnerable populations.

Clearly, any prospect of translating this research into practice depends on the relative cost of the intervention per child. The Rochester group estimated their costs for tracking and outreach at $5.27 per child per month ($6.72 in 2004 dollars); our costs were 3.5 times greater, accounting for inflation.[43] This difference in cost was attributable to several factors. First, our protocol involved meeting families in the hospital when possible; this added case management time and therefore cost to the intervention. Second, more than one third of our cost was attributable to the one-time creation of a sophisticated computer database that could automatically process electronic immunization and WCV data and generate reminder/recall cards and lists. Third, and most importantly, 37% of infants in our study required a home visit, compared with 12% in the Rochester study. This threefold increase accounted for much of the increased cost and suggests that the population in Denver is less responsive to reminder/recall cards and calls than is that in Rochester.

A study using home visitation and case management to increase WCV and immunization rates for black infants in South Central Los Angeles, California, was fairly successful but at significant cost, that is, $12 022 per additional child immunized and $1587 per child in the intervention arm.[30] However, that study used home visitation for all children in the intervention group, which increased costs, and did not use a postcard and telephone reminder/recall system, which might have increased effectiveness.

From a societal perspective, vaccines are the most cost-effective pediatric health intervention, saving an average of $5 in direct costs and $11 in additional costs to society for every $1 spent.[44] In the United States, however, with its current fragmented system of health care, every health care delivery system must decide what is an acceptable cost/effect ratio for interventions that improve infant preventive visits and immunization rates.

In the most in-depth studies of home visitation of poor mothers and maternal and child outcomes to date, Olds and colleagues[45–49] demonstrated many favorable outcomes in different settings, including Denver, Colorado. Of note, those studies did not demonstrate an increase in infant immunization rates,[45] although childhood vaccines were not a target of the home visitors but only a secondary outcome. Those studies also found that nurse home visitors produced better outcomes than did paraprofessional home visitors.[47,48] Our study used case managers/home visitors who had master's degrees and were community based, which suggests that it is possible to have successful outcomes with home visitors who are not nurses. Other programs used community-based paraprofessionals successfully to demonstrate positive maternal-child outcomes,[50] although immunization rates and WCVs were not targeted specifically.

Perhaps the major limitation of our work is external generalizability, given the fact that we intervened in a large, vertically integrated, urban health care system with a population of majority-Hispanic children. It is therefore encouraging that similar strategies worked both in inner-city Denver and in Rochester, New York,[31] which had a population that was $<10\%$ Hispanic at the time of the study and more than one third black. Taken together, these 2 studies suggest that the reminder/recall/case management/home visitation strategy would work in very different settings. A second limitation is that, because certain maternal risk factors resulted in more-intensive intervention, any association of those risk factors with health care outcomes at the end of the study would be biased toward the null hypothesis. A third limitation is that few infants (7%) did not require at least some telephone reminder/recall, which suggests that future interventions in similar populations may need to begin by at least calling all infants. Finally, any assessment of the effectiveness of a longitudinal intervention requires data on sustainability. We are collecting follow-up data on our entire cohort through 2 years of age, well after the end of the intervention, and will assess receipt of preventive health care (WCVs, immunizations, and other secondary outcomes, such as screening for lead toxicity and anemia and interpartum spacing) at that time.

CONCLUSION

A stepped intervention of reminder/recall/case management/home visitation was successful in improving receipt of preventive health services in a disadvantaged population of urban infants. Implementation of this strategy on a broader scale will require additional data on cost-effectiveness and sustainability of the positive impact of the intervention.

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