Telephone Subsidy

An Effective Incentive for Successful Participation in Home Memory Monitor Study

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Context: The Collaborative Home Infant Monitoring Evaluation (CHIME) study enrolled healthy term infants and 3 groups of infants considered to be at increased risk for sudden infant death syndrome to evaluate apnea and bradycardia events in the home. Mother-infant pairs without a telephone were ineligible for enrollment.

Objective: To determine whether mother-infant pairs who were offered a telephone subsidy would agree to enroll in CHIME and achieve protocol compliance rates comparable with those of matched subjects able to afford telephones.

Design: Thirty-one telephone subsidy subjects were retrospectively compared with 55 control subjects matched for study group, site, birth weight, and maternal race, age, and education.

Setting: Collaborative Home Infant Monitoring Evaluation clinical research centers in Honolulu, Hawaii, and Toledo, Ohio.

Intervention: Provision of telephone subsidy to otherwise eligible enrollees for CHIME.

Main Outcome Measures: Frequency of compliance with protocol requirements for follow-up evaluations and for extent of home monitoring.

Results: Subsidy subjects achieved protocol completion rates that were comparable with those of control subjects, for developmental assessments at 56 and 92 weeks postconceptional age (PCA), and for the polysomnogram. Unexpectedly, however, subsidy subjects were more likely to have a developmental assessment at 44 weeks PCA ($P = .02$), as well as a cry analysis ($P = .04$). They were also more likely to use the CHIME home monitor for more hours during weeks 2 through 5 ($P = .004$), have a higher percentage using the monitor for 10 or more hours per week during weeks 2 through 5 ($P = .009$), and have a higher total number of days of monitor use throughout 6 months ($P < .001$). Mean cost of the subsidy was $3.25 per day of monitor use, and monitor use per day was directly related to total cost of the subsidy ($P = .02$).

Conclusions: Telephone subsidy is an effective financial incentive. At least within the context of the CHIME study, telephone subsidy enhanced access to health care, and in some categories it resulted in enhanced protocol compliance.

SUBJECTS AND METHODS

Comprehensive demographic and medical information, including maternal and infant medical history, was obtained at enrollment. The home monitor developed for CHIME (Non-Invasive Monitoring Systems, Miami, Fla) recorded cardiopulmonary, oxygen saturation, and position and movement whenever the recording threshold for apnea or bradycardia was reached. The monitor recorded the time turned on or off, and stored all physiological signals taking place 75 seconds before an event, during an event, and 30 seconds following the event. Parents were instructed to use the monitor during sleep time and during unsupervised time when the infant was awake. The number of hours of monitor use during each day of monitoring was stored in the monitor memory. The first week of home monitoring was defined as beginning with midnight of the first night of monitoring, and it included 7 consecutive 24-hour periods. Compliance during weeks 2 through 5 was used to calculate initial monitor compliance so as to exclude home monitor problems causing limited use during the first week of monitoring. Total days of monitor use were an additional measure of monitor compliance.

At entry into the study, there was standardized training in the operation and use of the monitor. There was 24-hour availability of CHIME staff for questions related to study protocols or clinical care, and caregivers were contacted at least weekly by telephone to complete a scripted interview. Home visits, including replacement of the memory cartridge in the monitor, were scheduled for the first week of monitoring, at 1 month of use, and every 4 weeks thereafter. If review of the most recent memory cartridge indicated monitor use for less than 8 hours per day, additional support or intervention was provided. The intended duration of home monitoring was through 66 weeks of follow-up visit. Compliance during weeks 2 through 5 was used to calculate initial monitor compliance so as to exclude home monitor problems causing limited use during the first week of monitoring. Total days of monitor use were an additional measure of monitor compliance.

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have characteristics that would lead to early dropout or to unsatisfactory protocol compliance. We hypothesized, however, that providing a subsidy to establish and maintain telephone service would be a cost-effective and successful strategy for enrolling mother-infant pairs with very high risk for adverse health outcomes (including SIDS), and that once enrolled, telephone subsidy subjects would achieve protocol compliance rates comparable with those of the mother-infant pairs with low SES who were selected as controls.

RESULTS

The telephone subsidy was implemented in Toledo 6 months after the CHIME study was started and then 11 months later in Honolulu. Among the 64 mother-infant pairs screened in Honolulu and Toledo after the subsidy was implemented who were ineligible for CHIME because of absence of a home telephone, 31 (48%) accepted the telephone subsidy and enrolled in CHIME. Among the 33 families (52%) who were eligible for the subsidy but who did not enroll, the primary reason was inability to contact mothers in a timely and effective manner to explain the subsidy and seek consent. In a few instances, however, we could not offer the subsidy because of unresolved issues regarding place of residence. At the time of prospective matching for analysis, only 1 match could be found for 7 subsidy infants before overlapping with a control for another subsidy infant. This resulted in a total of 55 controls for the 31 subsidy infants.

Compared with telephone subsidy subjects in Toledo, Ohio, subsidized Pairs

Table 1. Subject Characteristics and Data∗

<table>
<thead>
<tr>
<th>Variable</th>
<th>Toledo, Ohio (n = 21)</th>
<th>Honolulu, Hawaii (n = 10)</th>
<th>Total (N = 31)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Healthy term</td>
<td>6 (16.2)</td>
<td>2 (11.1)</td>
<td>8 (14.6)</td>
</tr>
<tr>
<td>SIDS-sibs</td>
<td>8 (21.6)</td>
<td>4 (22.2)</td>
<td>12 (21.8)</td>
</tr>
<tr>
<td>ALTE</td>
<td>5 (15.3)</td>
<td>10 (55.6)</td>
<td>15 (27.2)</td>
</tr>
<tr>
<td>Premature</td>
<td>18 (48.7)</td>
<td>2 (11.1)</td>
<td>20 (36.4)</td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>15 (48.4)</td>
<td>27 (73)</td>
<td>42 (68.1)</td>
</tr>
<tr>
<td>Black</td>
<td>7 (22.6)</td>
<td>7 (18.9)</td>
<td>14 (22.6)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>1 (3.2)</td>
<td>1 (2.7)</td>
<td>2 (3.2)</td>
</tr>
<tr>
<td>Asian</td>
<td>6 (19.4)</td>
<td>25 (41.9)</td>
<td>31 (50.8)</td>
</tr>
<tr>
<td>Other</td>
<td>12 (38.7)</td>
<td>11 (16.1)</td>
<td>23 (37.4)</td>
</tr>
<tr>
<td>Mean (SD) maternal age, y</td>
<td>22.8 (4.0)</td>
<td>25.4 (5.4)</td>
<td>24.6 (5.2)</td>
</tr>
<tr>
<td>Maternal education &lt;12th grade</td>
<td>23.1 (4.4)</td>
<td>25.4 (5.4)</td>
<td>24.6 (5.2)</td>
</tr>
<tr>
<td>Mean (SD) maternal education, y</td>
<td>11.8 (1.0)</td>
<td>11.7 (1.1)</td>
<td>11.8 (1.1)</td>
</tr>
</tbody>
</table>

All data are presented as numbers (percentages) unless otherwise indicated. SIDS-sibs indicates siblings of infants who died of sudden infant death syndrome; ALTE, apparent life-threatening event; 44-wk, 56-wk, and 92-wk, 44, 56, and 92 weeks’ postconceptional age; BSID-II, Bayley Scales of Infant Development–Revised; and PSG, polysomnogram. For completed assessments, P value for totals in the 44-week BSID-II completed assessment is .02; for the cry analysis, P = .04; for all other assessments, P was not significant. As determined by matching, baseline characteristics were similar. No protocol compliance rate was lower in the subsidy group than in the control group.

likely to be preterm but more likely to be in the apparent life-threatening event group, and less likely to be African American, but more likely to be Asian (Japanese, Filipino) or of other ethnicity (Hawaiian, part Hawaiian, mixed). As defined by the matching requirements, the subsidy subjects and control group subjects are similar for birth weight, maternal age, gestational age, group, race, and maternal education (Table 1, “Total” columns).

The total cost of providing home telephone service for all participants was $12132 and included preenrollment delinquent bills plus monthly service charges. The mean total cost was $402 (SD, $342), and the median was $359. The total cost was greater than $700 in only 3 subsidy subjects, and the highest cost was $1794. Total costs in excess of monthly charges for routine service were primarily related to delinquent accounts that had to be paid before telephone service could be reinstated, but also included occasional malfunction of the long-distance block or placing calls to 1-900 numbers or acceptance of collect calls. The mean cost of the subsidy was $3.25 per day of home monitor use. The subsidy was continued until all follow-up components of the protocols were completed or until voluntary withdrawal of a subject from the CHIME study. The subsidy was never discontinued, however, for failure to complete an individual protocol requirement or failure to reach any specified minimum extent of home monitor use.

As expected of subjects with low SES, the subsidy control subjects seemed to be less compliant with the CHIME protocols than CHIME enrollees in total. Among all 1079 CHIME enrollees, the 44-, 56-, and 92-week PCA BSID-II assessments were obtained from 65%, 47%, and
Providing a home telephone subsidy to mother-infant pairs unable to afford a telephone eliminated the barrier to participation in CHIME and resulted in enrollment of additional subjects with low SES. We confirmed our hypothesis that these additional enrollees would achieve protocol compliance rates comparable with those of the matched control infants with low SES. Unexpectedly, however, subsidy subjects were actually more likely than controls to have a cry analysis and return for the first BSID-II assessment at 44 weeks PCA, and to use the home monitor for almost twice as many total days.

There was a direct relationship between total subsidy and total days of home monitor use. Among the telephone subsidy subjects who received a total subsidy of either less than $250 (n = 12), $250 to $500 (n = 14), or more than $500 (n = 5), the mean (SD) total number of days of monitor use was, respectively, 82 (64), 126 (65), and 212 (123) days. Using analysis of variance, the overall P value was .02.

<table>
<thead>
<tr>
<th>Table 2. Monitor Use Data*</th>
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<tbody>
<tr>
<td>Monitor Use Variables</td>
</tr>
<tr>
<td>-----------------------------</td>
</tr>
<tr>
<td><strong>Weeks 2-5</strong></td>
</tr>
<tr>
<td>Total hours of use</td>
</tr>
<tr>
<td>% Using monitor ≥10 h per week</td>
</tr>
<tr>
<td>Days used in 6 mo</td>
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</table>

*All data are presented as means (SDs) unless otherwise indicated.

Our study was not designed to document reasons for absence of a home telephone. These mothers, however, tended to be young, single, and to have less education than control group mothers, including almost one third of mothers with less than 12 years. Our study was also not designed to determine why some families without a home telephone did not receive the telephone subsidy. In general, however, mothers without home telephones did not have an established home or were not accessible to CHIME personnel.

The CHIME study required considerable parental motivation to achieve high protocol compliance rates. This was especially true for healthy term infants, SIDS-sib infants, and preterm infants who otherwise would not have been using a home monitor. As a consequence, only 16% of all mothers of infants eligible for CHIME consented to enroll, varying from the 65% range in infants with idiopathic apparent life-threatening events and SIDS-sib infants, to 28% in the preterm group, and only 7% in the healthy term group.

The number of subsidy subjects is too low to permit site-specific analyses, especially considering the additional variability associated with clinical group (Table 1). However, the ability to discern significant differences between subsidy and control subjects, despite combining enrollees from 2 diverse populations, may be indicative of a more robust benefit of the subsidy and greater potential generalizability.

We found no precedent for use of a financial incentive to satisfy a threshold eligibility requirement. Although other studies have utilized a financial incentive to enhance protocol compliance, we found no precedent for use of a financial incentive to enhance home monitor use.

Some authors have suggested that payment of subjects is never ethical, but financial incentives are in fact frequently offered and sometimes considered necessary. Prospective payments are more likely to be ethically acceptable than poststudy financial rewards provided to participants having achieved predetermined compliance goals. In a review of financial incentives offered in 11 US studies, with a wide array of disciplines and a wide variation in type and magnitude of incentives, all but 1 study demonstrated improved compliance when a financial incentive was provided.

Providing economic vouchers to offset out-of-pocket expenses in women with low SES has been shown to moderately improve compliance with follow-up requirements, but offering a financial incentive to low SES subjects may create excessive pressure to participate owing to financial need. Lower SES has been associated with the willingness of parents to enroll a child in an...
Consenting mother-infant pairs in this treatment study were less educated, less likely to have professional or administrative jobs, had less social support, displayed greater health-seeking behavior, and consumed more habit-forming substances. Owing to the influence of greater financial need, the concern has been expressed that financial incentives result in disproportionately higher enrollment of subjects with low SES in research studies, and hence in subjects with low SES bearing an unduly large share of the risks and burdens of clinical research.8

Before implementing our telephone subsidy for potential CHIME enrollees without a home telephone, we considered the aforementioned factors related to the ethics and nature of financial incentives. We did not consider a telephone subsidy to mother-infant pairs with low SES as imparting an undue clinical research burden because these infants were at a significantly higher risk for adverse outcomes, including SIDS, and there was hence a greater potential health benefit to participation. Parents of all potential enrollees who were offered the subsidy were fully informed and subjected to no pressure to consent to participate in CHIME.12 The telephone subsidy was not a reward for having participated in the study, but rather an incentive provided “up front” to be eligible for enrollment and to hopefully lead to protocol participation that would be comparable with that of otherwise equivalent mother-infant pairs with low SES.8 Individual subsidy amounts were directly related to financial need and were not excessive relative to the time, effort, and inconvenience caused by enrollment. Hence, amounts were not considered to represent undue coercion.13 Finally, by diminishing the social or medical isolation in mother-infant pairs of low SES that is associated with the additional burden of having no home telephone, the telephone subsidy had the potential for enhanced health-seeking behaviors and improved access to health care that was independent of any perceived or actual direct benefit as a result of enrollment in CHIME.

There are potential limitations to this study. This is not a study of the factors causing or associated with an inability to afford a home telephone, nor is it a comparison of demographic and other characteristics of mother-infant pairs (with low SES) who were able vs those who were not able to afford a home telephone. These would be informative studies, however, especially knowing the results of this study. Second, this is not a randomized study of the effects of a telephone subsidy to mother-infant pairs with and without financial need for the subsidy. Although such a study might lead to useful insights, the subsidy would not be comparable between groups because of variable needs for “up-front” payment of delinquent accounts among pairs unable to afford a telephone.

In summary, providing a telephone subsidy to satisfy eligibility requirement for CHIME was effective in increasing enrollment of mother-infant pairs with low SES, and it resulted in protocol compliance that was equivalent or better than that of the controls. Significant reductions in social and medical isolation achieved by the subsidy may have been perceived as having a value-added benefit outweighing the actual cash value of the subsidy. It is unknown to what extent these results might be generalizable to other research settings or to nonresearch settings in which absence of a telephone adversely affects access to health care.

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REFERENCES


What This Study Adds

Subjects with low SES may not have sufficient access to clinical research, including studies of disease conditions for which they are at high risk. We sought enrollment of families across the full range of SES in a study of home memory monitoring in infants at increased risk for SIDS because low SES infants are at increased risk for SIDS. The families with the lowest SES, however, were ineligible because of the absence of a home telephone. The telephone subsidy is an effective financial incentive leading to enhanced study enrollment, and in some instances, enhanced protocol compliance. The reductions in social and medical isolation achieved by the subsidies were perceived as having value or added benefit beyond the actual cash value. These results may have implications for other clinical research settings and for nonresearch settings in which the absence of a home telephone adversely affects access to health care.