Randomized Controlled Trial of an Immunization Recall Intervention for Adolescents

WHAT’S KNOWN ON THIS SUBJECT: Immunization recall systems have been found effective in increasing immunization rates in younger children and adults, however, there have been only a few studies in adolescents and they have produced mixed results.

WHAT THIS STUDY ADDS: In this randomized controlled trial, immunization rates were significantly higher 4 weeks after a recall intervention in which both the adolescent’s parents and the adolescent were contacted, but this effect did not persist 1 year after the intervention.

abstract

OBJECTIVE: Determine if adolescent immunization rates can be improved by contacting the parents or by contacting both the parents and adolescents.

METHODS: Thirteen- to 17-year-olds overdue for at least 1 of 3 immunizations were randomized to (1) a control arm (Control), (2) telephone calls to the parent/guardian (Parent Only), or (3) telephone calls to the parent/guardian and the adolescent (Parent/Adol). Immunization records were assessed 4 weeks and 1 year after the intervention. Two-sided χ² tests and logistic regression models were used to compare receipt of immunizations by study arm.

RESULTS: The intention-to-treat analysis showed improved immunization rates at 4 weeks (adjusted odds ratio 2.27, 95% confidence interval 1.00–5.18), but not at 1 year, in the Parent/Adol group compared with controls. There was a trend toward increased immunization in the Parent Only group (odds ratio 2.02, 95% confidence interval 0.89–4.56). However, phone contact was not achieved for many parents and adolescents in the intervention groups. A post hoc analysis of the impact of actual phone contact showed significant improvement in immunization rates both 4 weeks and 1 year after the intervention among those who were reached successfully.

CONCLUSIONS: Improvement in immunization rates was seen in the short term but not the long term after contacting both the parent and adolescent. Although telephone interventions may be effective when rapid immunization is necessary, the difficulty in reaching parents and adolescents by phone highlights the importance of up-to-date contact information and a need to assess the effectiveness of alternative means of communication. Pediatrics 2012;130:507–514
Adolescent immunization rates are well below the Healthy People 2020 goals for the meningococcal conjugate vaccine (MCV4); tetanus, diphtheria, and acellular pertussis vaccine (Tdap); and varicella vaccine (VAR).\textsuperscript{1,2} There are many barriers to immunization in adolescents, including lack of reminder and recall systems.\textsuperscript{3,4} Client reminder/recall interventions are strongly recommended by the US Task Force on Community Preventive Services, the Advisory Committee on Immunization Practices, and the American Academy of Pediatrics as a way to increase vaccination rates.\textsuperscript{5,6} Immunization reminder and recall systems have been found to be effective for younger children,\textsuperscript{7-17} but studies in adolescents have produced mixed results.\textsuperscript{18,19} Adolescents should assent to receive an immunization,\textsuperscript{20} and studies have shown that youth prefer to be involved in medical decisions.\textsuperscript{21} We hypothesized that immunization rates could be improved by contacting adolescents and/or their parents about vaccination, and that the improvement might be greater when both the parent and adolescent are contacted. Therefore, we conducted a randomized controlled trial to examine the effect of an immunization recall intervention involving parents alone or involving both parents and adolescents on adolescent immunization rates.

METHODS
Participants
This study was performed at the Adolescent Medicine Practice at Boston Children’s Hospital. Hospital billing and immunization databases were examined to identify adolescents 13 through 17 years of age with a billing code for a physical exam within the 3 years before May 13, 2010, at the Adolescent Practice and who met 1 or more of the following criteria: had not received MCV4; had not received Tdap in the past 5 years; or had received only 1 VAR but did not have a documented history of chickenpox. All 3 of these vaccines are routinely recommended for adolescents.\textsuperscript{22-24} Exclusion criteria included being in the custody of the Department of Children and Families (DCF) or the Department of Youth Services; having a sibling enrolled in the study; or having no record of any immunizations or only influenza vaccines, implying that immunization data had not been entered in the electronic medical record. If multiple siblings were identified, the sibling with the most recent physical was enrolled, and all other siblings were excluded.

The Boston Children’s Hospital Committee on Clinical Investigation approved this study and granted a waiver of written informed consent.

Interventions
This randomized controlled trial had 3 study arms: (1) a control arm in which no specific outreach was made regarding vaccinations and in which adolescents received usual clinical care, including potentially receiving vaccinations at clinic visits at the provider’s discretion (Control); (2) an intervention arm in which the parent or guardian was called to inform him or her that the adolescent was overdue for immunizations (Parent Only); and (3) an intervention arm in which both the parent or guardian and the adolescent were called to inform them that the adolescent was overdue for immunizations (Parent/Adol). Subjects were prospectively followed for 1 year after the intervention. Immunization records were assessed for receipt of any vaccines at 4 weeks and 1 year following randomization. Intervention subjects were contacted sequentially by study ID and follow-up time began at the time of the first phone call. As no call was made to control subjects, follow-up time started for control subjects at the same time as the participant most recently randomized to an intervention.

In the Parent Only group, a study investigator called the parent/guardian of the adolescent overdue for a vaccine, using a telephone script that included a brief description of the vaccine-preventable illness(es) derived from the Centers for Disease Control and Prevention Vaccine Information Statements. Initially, if the parent/guardian stated that the adolescent had received this vaccine elsewhere, the script prompted the caller to instruct the parent/guardian to have a record mailed or faxed to the Adolescent Practice; however, owing to clinic flow concerns, partway through the study the script was modified such that all parent/guardians were asked to have any records of immunizations given at other practices mailed or faxed to the Adolescent Practice. Any records received were incorporated into the adolescents’ medical records. The caller offered to schedule an appointment for the adolescent to receive the vaccine(s). Clinical questions about the vaccines or vaccine-preventable infections were referred to practice nurses. Up to 4 telephone calls within 1 week were made to each subject’s parent/guardian, until the vaccination content was delivered or the parent/guardian asked not to be contacted again. No voicemail messages were left.

In the Parent/Adol group, the parent/guardian was called using a telephone script similar to the one used in the Parent Only group, but at the end of the call, the parent/guardian was asked for verbal consent to contact the adolescent as well. If consent was given, telephone calls were made to the adolescent using a similar script, differing only from the parent script in the scheduling of appointments to receive a vaccine. If the parent/guardian had
scheduled an appointment, the adolescent was informed. If no appointment had been scheduled, the adolescent was asked to discuss the vaccines with the parent/guardian and given the telephone number for the Adolescent Practice to schedule an appointment. Up to 4 telephone calls were made to each adolescent, until the vaccination content was delivered or the adolescent asked not be contacted again.

The interventions were performed from May 13, 2010, through July 19, 2010. Phone calls were made between 9 AM and 7 PM on weekdays only. Medical interpreters were used if the parent/guardian or adolescent did not speak English.

Outcomes
The primary outcome was a new record of 1 or more of the 3 vaccines of interest (Tdap, MCV4, or VAR) within 4 weeks after the first phone call attempt had been made to the parent in either intervention group or within 4 weeks after enrollment in the control group. This follow-up timeframe has been used in previous research.15 Immunization status was assessed by using the Boston Children’s Hospital electronic medical record; it was not possible to assess whether vaccines listed in the medical record were received in the clinic or incorporated from outside records.

Secondary outcomes included (1) receipt of 1 or more of the 3 vaccines of interest within 1 year after the intervention; (2) receipt of any vaccines other than the 3 vaccines of interest by the 4-week and 1-year follow-up dates.

Sample Size
Previous studies of pediatric reminder/recall interventions have demonstrated effect estimates ranging from no statistically significant improvement in immunization rates to as high as a 34% increase.12,16 We decided a priori that a 15% difference between groups would justify replicating this intervention. As statistical power for a 15% difference varies depending on the base rate, we chose the most conservative 15% difference (an increase from 42.5% to 57.5%) for sample size calculations. To detect this 15% difference between groups with 80% power and α of 0.05 would have required 174 participants in each group. Because the number of eligible participants was smaller than anticipated (138–141 per group), a post hoc power calculation performed by using actual participant numbers and the actual control response rate of 7.1% at 4 weeks demonstrated that our study had 80% power to detect a 12% difference between the control and intervention groups.

Randomization
Due to a shortage of VAR in the year previous to the study, subjects were stratified into two groups by VAR status to address the potentially different reasons for being overdue for VAR than being overdue for Tdap or MCV4. Subjects who had record of only 1 VAR vaccine and no record of having varicella were considered eligible for a second VAR and randomized in 1 stratum; all other subjects were randomized in the other stratum.

Before the start of the trial, randomization software (SciRan, Boston Children’s Hospital, Boston, MA) was used by the Clinical Research Program at Boston Children’s Hospital to develop randomization assignment lists. Assignments were designated in randomly permuted blocks of 6 or 9. All subjects were assigned a confidential study ID at the time of enrollment. Once eligibility was confirmed by 1 investigator (K.B.), VAR stratum for each subject was determined and the next sequential randomization ID was assigned. This trial was not blinded to investigators.

Statistical Methods
Differences in demographic variables between study arms were assessed by using 2-sided χ² tests for categorical variables and 1-way ANOVA for the continuous variable.

The primary analysis was performed on an intention-to-treat basis. We performed 2-sided χ² tests to look for a difference in proportions receiving additional immunizations in the 3 study arms. We calculated univariate odds ratios (ORs) and 95% confidence intervals (CIs) comparing each of the intervention groups to the control group. We used multivariate logistic regression models to predict the odds of receiving an immunization, controlling for the stratification factor, demographic factors, and the script used (pre- or post-modification). In these multivariate models of treatment effect, we also examined the influence of these factors on the outcome.

Post hoc as-treated analyses were also performed by using actual telephone contact made, regardless of randomization arm, as a predictor of vaccine receipt. Fisher’s exact test was used to assess for differences in proportions receiving an immunization. We calculated univariate ORs and 95% CIs comparing the effect of type of treatment received. We used multivariate logistic regression models to predict the odds of receiving an immunization, controlling for the stratification factor, demographic factors, and the script used.

Analyses were performed by using PASW Statistics 18.0.0 (IBM Corporation, Somers, NY) and SAS 9.2 (SAS Institute Inc., Cary, NC).

RESULTS
A total of 1099 individuals between the ages of 13 and 17 years had a billing code within the previous 3 years for an annual physical exam. Of those, 424 met
criteria for the study and were stratified and randomized. After the intervention, 3 subjects were subsequently excluded from analyses (Fig 1). There were no adverse events in any group.

Control and intervention groups were similar with respect to age, sex, race/ethnicity, insurance type, and vaccine (s) needed (Table 1). Most participants were minority youth and nearly all had health insurance (the vast majority of minors have health insurance in Massachusetts).

Intention-to-Treat

Four weeks after the intervention, there was a nonsignificant trend toward increased immunization rates in both intervention arms, as compared with the control group (7.1% for Control, 14.4% for Parent Only, and 14.5% in Parent/Adol, $P = .09$). The unadjusted odds of receiving 1 or more vaccines during the 4-week follow-up period were 2.20 times higher (95% CI 0.99–4.89) in the Parent Only group and 2.22 times higher (95% CI 1.00–4.94) in the Parent/Adol group compared with controls (Table 2). When the stratification and demographic factors were adjusted for, the odds of receiving an immunization were higher in the Parent/Adol group (OR 2.27, 95% CI 1.00–5.18) and there was a nonsignificant trend toward increased likelihood of receiving an immunization in the Parent Only group (OR 2.02, 95% CI 0.89–4.56) (Table 2). In the multivariate model, age was the only variable independently associated with immunization, with
older adolescents being less likely to receive an immunization than younger adolescents.

One year after the intervention, many more adolescents had received 1 or more vaccines but the trend toward increased immunization rates in the intervention groups did not persist (35.5% for Control, 41.4% for Parent Only, and 38.4% in Parent/Adol, P = .59). Univariate and multivariate analyses showed no difference in immunization rates among the groups (Table 2); however, needing a second varicella vaccine and Hispanic self-identification significantly increased the odds of immunization at 1 year:

The intervention did not significantly affect the proportion of subjects who received immunizations other than Tdap, MCV4, or VAR 4 weeks and 1 year after the intervention. The annual influenza vaccine became available between the 4-week and 1-year follow-up visits. Although the intervention did not involve education regarding the influenza vaccine, there was a trend toward increased influenza vaccination rates in the 2 intervention arms as compared with the control arm, with 21.8% of the Control group, 28.6% of the Parent Only group, and 34.8% of the Parent/Adol group receiving the influenza vaccine (P = .055).

### As-Treated Analysis

Seventy-nine (56.4%) of the parents/guardians in the Parent Only group and 70 (50.7%) of the parents/guardians in the Parent/Adol group were successfully reached. In the Parent/Adol group, only 30 (21.7%) of the adolescents had received influenza vaccination at 1 year. The most common reasons for the adolescents not being contacted were lack of contact with parents/guardians (n = 56) and parents/guardians not giving consent for the adolescents to be contacted (n = 31). In total, 270 subjects were not contacted, 119 subjects’
parents/guardians were contacted only, and 30 subjects and their parents/guardians were contacted (Fig 1).

A post hoc analysis of actual intervention received showed that 4 weeks after the intervention there was a significantly increased rate of immunization when either the parent alone was reached (24.4%) or the parent and adolescent were both reached (20.0%), as compared with no contact (5.6%, P < .001). In multivariate analysis, the odds of receiving at least 1 vaccine were 5.31 times higher (95% CI 2.66–10.63) when the parent only was reached and 4.72 times higher (95% CI 1.62–13.79) when both the parent and adolescent were reached, compared with no contact (Table 3). Similar to the intention-to-treat analysis, age was also an independent predictor of receiving an immunization, with older adolescents being less likely to receive an immunization.

One year after the intervention, the post hoc analysis of actual intervention received showed a significantly increased rate of immunization when the parent alone was reached (51.3%) and when the parent and adolescent were reached (63.3%), as compared with no contact (30.0%, P < .001). In multivariate analysis, the odds of receiving at least 1 vaccine were 2.40 times higher (95% CI 1.51–3.82) when the parent only was reached and 3.78 times higher (95% CI 1.62–8.52) when both the parent and adolescent were reached, compared with no contact (Table 3). Needing a second varicella vaccine, Hispanic self-identification, and female gender were also independent predictors of immunization.

**DISCUSSION**

To the best of our knowledge, this study is the first to examine the effect of a parent and adolescent recall intervention on immunization rates. In the intention-to-treat analysis, contacting both the parent and adolescent significantly increased the likelihood of receiving an immunization within 4 weeks but not at 1 year. This finding is consistent with the waning effect seen in a study of audiotaped telephone reminders for households of adolescents concerning immunizations and annual exams.18 In settings in which it is important for many individuals to be vaccinated quickly (such as during outbreaks of communicable infections), phone calls to adolescents and their parents may help to improve immunization rates. Our intervention may have affected only the timing of vaccination but not the adolescents’ willingness to be immunized, as similar numbers of adolescents in each arm received immunizations in the course of usual clinical care in the subsequent year.

In multivariate analyses, younger age was associated with vaccine receipt at the 4-week but not at the 1-year follow-up. Age has been found to affect immunization rates in other studies, with older adolescents being less likely than younger adolescents or children to receive vaccines.25,26 One possible explanation is that younger individuals are under more parental supervision, so after a reminder call they may be more influenced by parents to attend an extra clinic visit to be vaccinated. However, this association was not seen 1 year after the intervention, so older adolescents may be equally likely to receive a vaccine during the course of usual clinical care.

At 1 year after the intervention, participants who lacked a second varicella vaccine were more likely to have
received 1 or more of the 3 vaccines of interest than those who did not need a second varicella vaccine. This finding may reflect an underlying difference in the reason for not being fully vaccinated, as there had been a VAR shortage before the start of the study.

Despite making 4 phone call attempts, many parents and adolescents were not reached. Successful contact has been an obstacle in other studies in which outreach to adolescents has been attempted. In the post hoc as-treated analysis, successful contact with a parent alone or parent and adolescent had a robust impact on the odds of receiving an immunization at both 4 weeks and 1 year after the intervention, although the magnitude of the effect was lower at the 1-year time point. As with any as-treated analysis, unbalanced unknown confounders may influence the result; in this case, factors influencing the likelihood of successful contact may also be related to likelihood of vaccine receipt. However, our results highlight the importance of clinics maintaining up-to-date contact information for all patients and parents.

This study has several limitations. Given the small number of adolescents actually reached in the Parent/Adol group, we were not able to assess the incremental benefit of contacting adolescents. Further studies are needed to determine if involving adolescents in immunization recalls has an effect on immunization rates. Although we asked parents to have copies of their child’s immunization records at other sites sent to our practice, we were unable to track how many parents actually provided these records. In addition, it is possible that some of the subjects were no longer patients of our practice and had received these vaccines at other practices. Finally, this study was performed in a primary and subspecialty adolescent medical practice at an urban tertiary care hospital, so results may not be generalizable to all adolescent populations.

Our study adds to the literature describing obstacles to adolescent immunization. Because many of our subjects were not reached despite multiple attempts, it will be important to examine alternative techniques, including E-mail, texting, or social media platforms, or school-based outreach. It is also imperative for clinicians to review the immunization status of adolescents during all medical visits. With the increasing number of immunizations recommended for adolescents, it will take continued creativity and innovative interventions to successfully reach the Healthy People 2020 immunization goals.

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**EARLY KITCHENS:** I was at dinner with friends the other night and naturally the conversation turned to cooking: who in the family enjoyed cooking, when the interest developed, and what foods they liked to cook. The stories were fascinating and led to the question of when humans actually began cooking their food rather than eating it raw. When our human ancestors first began cooking meat over fires is not known. However, recent evidence suggests that humans, at least in what is current day China, have been using simple cooking vessels in kitchens or designated cooking areas for at least 20,000 years. As reported in The New York Times (Science: June 28, 2012), researchers examined newly discovered pottery fragments found in a cave in the Jiangxi Province. The fragments are 2,000 to 3,000 years older than any other pottery fragments ever found. The researchers suspect that the fragments are remnants of simple concave bowls that were used for steaming and cooking gathered foods. The remnants of the earliest kitchens, such as the one found in China, reveal clues about the diet of the cooks. Pottery, it seems, was or became essential for the type of food preparation practiced by ancient Chinese hunter-gatherers. In the Middle East, however, pottery was not so essential for food preparation. Foods could be cooked over pits (think barbecue), while pita bread—made by mixing ground seeds with water—could be cooked directly over the fire without the need for a container. Thus, even though domestic plant cultivation began in the Middle East 1,000 years before it did in China, pottery fragments in China far predate those found in the Middle East. While I have a zillion pots and pans kicking around the kitchen and the advantage of modern technology, I find it fascinating that we spent quite a bit of time at dinner talking about slow cooking single pot dinners. I guess those ancient Chinese cooks were onto something good.

*Noted by WWR, MD*
Randomized Controlled Trial of an Immunization Recall Intervention for Adolescents
Kathryn S. Brigham, Elizabeth R. Woods, Sarah K. Steltz, Thomas J. Sandora and Emily A. Blood

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