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Improving Immunization Rates for Inner-City Infants: The Effectiveness of Parent Education in the Office Setting

Christopher Joseph Stille

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IMPROVING IMMUNIZATION RATES FOR INNER-CITY INFANTS: THE EFFECTIVENESS OF PARENT EDUCATION IN THE OFFICE SETTING

Christopher Joseph Stille

Sc.B., Brown University, 1987
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IMPROVING IMMUNIZATION RATES FOR INNER-CITY INFANTS: THE EFFECTIVENESS OF PARENT EDUCATION IN THE OFFICE SETTING

presented by

Christopher Joseph Stille, M.D.

Major Advisor

David Gregorio

Associate Advisor

Paul H. Dworkin

Associate Advisor

Bruce Bernstein

University of Connecticut

1999
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INTRODUCTION

Since the early part of this century, immunization of children against dangerous infectious diseases has been one of the primary missions of public health in the United States, and indeed has become one of its triumphs. Smallpox and polio have been eradicated completely from this country, and measles is at an all-time low\(^1\). This has been achieved through campaigns to immunize all susceptible children at an early age, surveillance for vaccine-preventable diseases in the community, and early identification and isolation of outbreaks. However, in order to preserve this success and continue to add to the list of diseases which have been eliminated, these efforts must continue.

During recent years, outbreaks of pertussis and an epidemic of measles have illustrated that the success we have achieved is fragile. Research over the last ten years has identified many factors that must be addressed in order to prevent further epidemics. Some of these factors, such as lack of access to care and fear of immunization, contribute directly to underimmunization; others, like increased mobility of the population, contribute to both underimmunization and the spread of disease, and a few, such as immigration of infected persons, contribute to the spread of disease directly. Many of these factors are modifiable, and those that are not are at least identifiable; recent efforts to change these factors have led to a remarkable resumption of the success in eliminating vaccine-preventable disease. Some deficiencies remain, however.

This paper will address some of the recent factors contributing to childhood underimmunization, and will focus specifically on the problem of timely immunization of infants, which has been identified as one of the persistent problems in inner-city
populations. I will review recent research investigating the current status of childhood immunization in the United States, factors contributing to immunization delay, and the impact of interventions on these factors. I will then evaluate the role of education of families by the physician in changing health behavior, incorporating the Health Belief Model, and discuss how it may be applied to childhood immunization. After that, I will describe a study I undertook during 1997 and 1998 which investigated the utility of a parent education intervention to boost immunization rates during the first year of life in an inner-city population. I will report on the results of the study, and consider implications of the results which may be used in both policy-making and clinical decision-making.
BACKGROUND

The problem of childhood underimmunization in the United States

Prior to the 1980s, immunization of young children in the United States was relatively simple. Children were routinely immunized during the first year of life with combined diphtheria-tetanus-pertussis (DTP) and polio vaccines, and a dose of measles-mumps-rubella vaccine was given during the second year of life. Boosters of DTP and polio vaccines were given at 18 months and 5 years of age. Reported levels of vaccine-preventable diseases declined steadily, although small pertussis outbreaks continued to occur because of waning immunity in adulthood and the lack of complete effectiveness of the vaccine in infants until the full three-dose series was completed. Immunization rates were not routinely recorded on a nationwide level until 1991, although the absence of epidemics seemed to make this unnecessary.

During the 1980s, immunization of preschool children became more of a problem. Public fears about pertussis immunization, boosted by prominent media attention, contributed to a crisis in which many vaccine manufacturers stopped producing pertussis vaccine because of fears of lawsuits. This led to a decrease in preschool immunization rates in several states, accompanied by an increase in pertussis cases. In 1984, the immunization rate of preschoolers in Hartford was only 52%, far less than the 90% rates generally accepted as sufficient to prevent transmission.

From 1989 through 1991, the United States experienced a large epidemic of measles, with more than 55,000 cases, 130 deaths, and 11,000 hospitalizations reported. In Connecticut, 454 cases were reported, with a significant number of cases in
unimmunized adults and underimmunized preschoolers\textsuperscript{7}. This epidemic awakened the public as well as policymakers to the problem of underimmunization, and prompted the Clinton Administration to start the President’s Childhood Immunization Initiative in 1993\textsuperscript{8}. This initiative specified actions to be taken at a national level to improve immunization delivery services, reduce costs to parents, improve vaccines, conduct surveillance both for disease and immunization coverage, and build community partnerships. The further publication of the \textit{Healthy People 2000} objectives specified 90\% coverage with a full series of five vaccines (diphtheria-tetanus-pertussis (DTP), polio, \textit{Haemophilus influenzae} type B (HiB), measles-mumps-rubella (MMR), and hepatitis B) for all preschoolers by the year 2000 \textsuperscript{9}. Research sparked by this initiative has identified barriers to the adequate immunization of children, as well as strategies to overcome these barriers.

During recent years, new challenges have arisen which may make timely immunization even more difficult. Poverty among children has increased steadily during the past 20 years, as has the proportion of single-parent households. Immunizations may well become less of a priority to families where providing enough food is a daily struggle\textsuperscript{10}. With the changes brought about by welfare reform, the guarantee of Medicaid coverage for all children eligible for welfare assistance may not exist as it has in the past; this may further limit the access of poor children to immunizations. As our success in inventing new vaccines increases, immunization schedules have grown steadily in complexity; over the past 12 years, the number of immunizations given in the first five years of life has risen from 10 to 19, creating challenges for parents and child health
providers alike. The cost of immunizing children has naturally increased as well; although poor children now have their vaccines paid for by the federal Vaccines for Children (VFC) program, budget cuts may threaten this program in coming years\textsuperscript{11}. Finally, increased travel, both domestic and foreign, affects the susceptibility of the population to vaccine-preventable disease outbreaks. All cases of measles in the United States are now imported\textsuperscript{12}, and in fact, a large contributor to the measles outbreak in Connecticut from 1989-91 was the presence of a population of unvaccinated adults from Puerto Rico\textsuperscript{7}.

The renewed focus on childhood immunizations by public health officials in the last ten years has produced dramatic results. Current immunization rates of preschoolers nationwide are at an all-time high; 1997 figures indicate that 76% of children aged 19 to 35 months had received all indicated immunizations. In Connecticut, 85% of children were up-to-date in the nationwide survey\textsuperscript{13}. Data from the state registry show a similar increase for children enrolled in Medicaid; immunization rates of two-year-olds in Hartford has gone from 52% in 1984 to 79% in 1997\textsuperscript{14}. However, the year 2000 goal of 90% complete immunization nationwide has not yet been reached, and there exist populations of children whose immunizations remain delayed. One such group is that of infants in the first year of life. Infants routinely receive more immunizations than older children, as they achieve immunity with the “primary series” of immunizations between birth and 6 to 9 months of age. Delays can easily occur if even one routine appointment is missed by the family, or if one opportunity for immunization is missed when the infant
comes to the health provider for care. As a baseline, only 41% of infants nationwide in 1988 \(^2\) and 45% of infants in Hartford in 1993 were up-to-date for their primary series; by 1995, the Hartford figure had increased only to 52%, and remains below 60% at this time\(^3\). Since completion of the primary series is necessary to develop adequate immunity, these delays leave infants vulnerable to vaccine-preventable diseases at a time when they are least able to fight them adequately due to their immature immune systems. Clearly, although progress has been made, much work remains to be done.

**Causes of missed or late immunization**

Recent research has identified a number of factors as important in the problem of immunization delay. Problems with the system of delivering immunizations, such as inability to obtain timely appointments, office policies prohibiting immunization without an appointment, failure to immunize children at “sick” visits, and inconvenient office hours, have been identified\(^{10, 15-17}\). Poverty itself has been identified as a factor; poor children are at high risk for underimmunization\(^{18}\), and this problem has persisted even after the establishment of the VFC program\(^1\). Knowledge gaps and misconceptions about the safety and timing of immunizations are also important; this problem affects both parents and providers\(^{15, 16, 19-21}\). Lack of an accurate immunization history from previous health care providers can also impact immunization rates, leading both parents and providers to believe falsely that children are fully immunized\(^{20, 22-24}\). Finally, many of these factors can come together, creating the problem of “missed opportunities”, when children who present to their health care provider are not immunized although they
are due to receive immunizations. This problem, primarily the responsibility of providers, has been identified as one of the most important factors, responsible for delay in 20 to 25% of children in some studies\textsuperscript{19, 25}.

**Parent knowledge and perceptions as a factor in underimmunization**

The impact of parent knowledge and attitudes about immunization on the immunization rates of their children has been well described. Early work with focus groups conducted with poor parents identified lack of knowledge of vaccine timing and misperceptions about vaccine safety as reasons for underimmunization from the point of view of parents\textsuperscript{15}. Other focus groups have identified immunization as a low priority among inner city parents, and have described concerns about vaccine efficacy as a reason that parents do not get their children immunized\textsuperscript{26}. In a more affluent population, parental misperception of minor illness as a reason for delaying immunizations was identified as important in parental questionnaires\textsuperscript{27}. More quantitatively, several studies have identified faulty parental knowledge about timing\textsuperscript{28} and safety\textsuperscript{21} of vaccines as statistically associated with low immunization rates in their children's first year of life.

Recently, a study conducted primarily among inner-city families in Hartford reinforced these findings, identifying low parent knowledge as a strong predictor of low infant immunization rates even after controlling for multiple potential confounders\textsuperscript{29}. It also found that faulty parent knowledge about the safety and efficacy of immunizations was quite prevalent in the Hartford population; for instance, 76% of parents surveyed stated that babies should not receive shots if they have a cold, and 31% worried that some
babies are too small to withstand their shots. An ongoing study being conducted on a larger scale by the American Academy of Pediatrics Pediatric Research in Office Settings (PROS) network has found a similar pattern, finding that fears over side effects of immunizations rank first among parents as a perceived barrier to immunization, and are a significant predictor of underimmunization 30.

One important article, which looked specifically at attitudes of poor parents about immunization rather than knowledge of factual information, conflicted with some of these findings, finding parent attitudes about self-efficacy in immunizing their children and efficacy of vaccines in preventing disease to be unrelated to immunization status of their children. However, most knowledge issues were not addressed by this article, and in fact faulty parent knowledge about the safety of receiving multiple simultaneous immunizations was found to be associated with low immunization rates 31.

**Strategies to boost immunization**

Since many of the factors that have been identified as reasons for immunization delay are theoretically changeable, many studies in the last five years have evaluated the effectiveness of strategies to increase childhood immunization rates. Although it is generally agreed that improving system-related factors such as appointment scheduling, office policies, and cost reduction for families may be helpful, these measures have not been studied in isolation. In 1991, the Centers for Disease Control and Prevention (CDC) issued its Standards for Pediatric Immunization Practices (SPIP), an 18-point plan incorporating these and other changes applicable in an office setting. One study looking
at the effect of implementing these standards in an office setting found them to be effective; however, the standards included several practices such as education which cannot easily be classified as system changes32. Another study evaluated the effect of changing specific office policies on missed opportunities to immunize33. The interventions used involved changing practice policy to have office nurses screen for immunization status at all visits, to have nurses place a reminder card for the provider on the chart, and to eliminate the requirement for a legal guardian’s signature at the time of immunization. The interventions produced no beneficial effect on immunization rates, although they did help to decrease missed opportunities.

Another strategy linking part of the child health system for poor families, the United States Department of Agriculture’s Women, Infants and Children (WIC) program, to immunizations, has been very successful. Several interventions linking WIC services to immunizations have been tried; the most popular one has used voucher restrictions as an incentive to boost immunization rates34. Normally, WIC participants are required to visit the program monthly to receive coupons for food assistance. In studies evaluating this intervention, caregivers were offered the opportunity to visit the program bimonthly, with two months’ worth of coupons given, if they could produce evidence that their child is up-to-date on his or her immunizations. These studies resulted in increases ranging from 19% to 32% in immunization rates for 24-month-old children, and showed that material incentives can serve as a strong booster for immunization rates in poor populations.
Interventions directed at improving the data access problems associated with lack of an accurate immunization history are just now being evaluated. Tracking of immunizations for individual children and outreach to those found to be delayed has been shown to be very effective at the local level in improving immunization rates\textsuperscript{35}, although the impact of larger systems has yet to be described. This information will likely come during the next few years, as regional and state immunization registries become fully functional.

From the standpoint of short-term knowledge, mailed reminder cards and telephone messages to parents whose children are due for or delayed in their immunizations have been shown to be effective “triggers” for immunization visits, with significant improvements shown in multiple studies. Furthermore, these interventions have been shown to be highly cost-effective\textsuperscript{36, 37}. While parents have identified education as a potentially effective method of helping them immunize their children on time\textsuperscript{38}, few studies on its effectiveness have been done. Education of parents about immunization has been evaluated primarily in studies considering the outcome of improved knowledge, rather than immunization rates; one study found both video and oral teaching to be effective, though there was no difference between the two methods\textsuperscript{39}. The effect of education on immunization rates has been investigated in only one small study, where mothers of newborns in the nursery were given a short talk about immunizations and a paper handout reinforcing this information, followed by a reminder letter at two weeks of age. Rates in the first year of life were not different between the
two groups, although they were abnormally low compared to nationwide figures\textsuperscript{40}.
Discussion of patient/parent education in other contexts, and of education of adult
patients about immunization, will be covered in the next section.

The impact of education of providers has not been described in the literature,
although interventions aimed at increasing immunization rates through provider feedback
about immunization patterns in the office have been successful at raising rates
significantly\textsuperscript{41}.

**Patient education in the primary care setting**

Patient and parent education in primary care has been identified as one of the
major reasons for health supervision visits by both the American Academy of
Pediatrics\textsuperscript{42, 43} and the United States Government's *Bright Futures* guidelines\textsuperscript{44}.
Counseling patients and parents provides many benefits, including the opportunity to
exchange useful information in order to promote child safety and development, answer
questions related to parental or patient concerns, elicit questions that might not otherwise
arise, and promote healthy behavior change. As increasing childhood immunization rates
may require behavior change on the part of the parent, educating parents about
immunizations may play a key role in this process. In this section, I will describe the
rationale for patient and parent education in the context of the Health Belief Model
(HBM), report on studies evaluating the impact of this education, and discuss briefly how
immunization education may use the dimensions of the HBM to achieve its goals.
**Education and the Health Belief Model**

The Health Belief Model has been used for many years as a model by which health behavior change may be explained. Originally developed in the 1950s by Hochbaum to explain behaviors surrounding tuberculosis screening, it is widely used in situations where acute, short-term behavior change is desired. The components of the HBM have changed somewhat during the years, but there are basically five elements:

1) perceived susceptibility: does a person feel they are susceptible to a disease, and if so, how susceptible do they feel?
2) perceived severity: how severe will this disease be if this person contracts it?
3) perceived benefits: what does this person view the benefits of behavior change to be in avoiding this disease?
4) perceived barriers: what barriers to accomplishing behavior change stand in the way of this person?
5) self-efficacy: does this person feel that he or she is capable of achieving the necessary change?

The HBM theorizes that behavior change is likely to occur if perceived susceptibility, severity, benefits of change, and self-efficacy are relatively high, and perceived barriers are relatively low. It does not work well for long-term changes, as factors which help maintain change, such as environmental factors, are not considered.

Education can address many aspects of the HBM. Altering perceptions of disease susceptibility and severity, benefits of change, and barriers to change in a way that favors healthy changes is a key function of health educators. Counseling by educators may also be a powerful tool for boosting self-efficacy, empowering patients and/or parents to
accomplish changes. The task, then, is to create educational programs that effectively influence perceptions to the greatest degree.

When creating programs, the importance of the type of message, the method of delivery (written, verbal, or other), and the deliverer (physician, other professional, or peer) must be considered. In a review of HBM studies, Glanz 45 reports that “perceived barriers” was the most important dimension of the HBM for predicting behavior; perhaps, then, messages emphasizing the ease and safety of behavior changes might be most effective. This agrees with the findings that faulty parent knowledge about the safety and timing of immunizations has been associated with lower immunization rates in their children. Glascoe 46 argues that when the method of instruction is considered, written instructions are more effective than oral for parents, although a combination of specific written instructions along with supportive counseling are the best. Another study 47 found that use of preventive services in adults could be increased by a combination of written and oral presentation, but that written instruction alone had no effect. Now that video has worked its way into the world of health education, strategies incorporating this medium will need to be evaluated as well. The role of the deliverer of information is also important. In a number of studies, patients have preferred the physician as the educator of choice, citing the physician’s increased expertise and valuing the physician’s credibility 48-50.

The effectiveness of physician education of patients and families on health behavior change has been studied in many different situations. It is quite variable, and it depends highly on the type of topic as well as the nature of the outcome desired. In
general, physician education is more effective for specific problems or diseases, like heart disease, and short term behavior changes; on the other hand, it is less effective for more broad-based preventive behaviors and longer-term behavior changes. In adults, it has been found to be effective in short-term dietary change for heart disease patients\textsuperscript{51} and for patients with hypercholesterolemia\textsuperscript{52}, short-term exercise for middle-aged and older patients\textsuperscript{53, 54}, and medication compliance for patients with depression\textsuperscript{55}. It has not been effective for compliance with long-term preventive medication use in splenectomy patients\textsuperscript{56} or long-term diet change for patients with hypercholesterolemia\textsuperscript{57}. In the pediatric population, it has been found to be effective in promoting anonymous HIV testing in adolescents\textsuperscript{58}, and short-term seat belt use\textsuperscript{59}, but not in bicycle helmet use\textsuperscript{60, 61}. Osborn\textsuperscript{62} argues that behavior changes that do not require individualized counseling for a situation unique to the patient or family being seen by the physician are probably best addressed through a variety of community resources rather than by the physician, since such resources are much more pervasive than episodic counseling.

One could argue that immunization behavior is a prime candidate for application of the HBM, since it involves relatively simple, short-term action on the part of parents. In fact, it has been included in previous evaluations of the applicability of the HBM\textsuperscript{63, 64}, where postcard reminders designed to address elements of the HBM were found to be effective in increasing influenza immunization in adults. On the other hand, the behavior of parents obtaining immunization for their children has a few features that may make application of the HBM less than ideal. It is a somewhat repetitive behavior, requiring at
least five visits in the first two years of life for completion of required immunizations. Additionally, all of the measures of the HBM must be applied “by proxy”, as caregivers consider how their child fits into the categories of the model. Some of the elements take on multiple dimensions as well; for example, barriers perceived by the parent might comprise both caregiver-specific factors (such as ability to get transportation to appointments) and child-specific factors (such as being too ill to receive immunizations). Thus, while immunization behavior might be described well by the HBM, the scope of the elements of the model might need to be expanded somewhat.

A few studies have been done in adults to evaluate the role of education in ensuring immunization. One study found that influenza immunization rates were increased among patients given a reminder card to carry to their visits65, and another found that while an informational handout was not effective alone in increasing rates, a handout with physician counseling was effective66. A third found that a combination of verbal education in the waiting room (by unspecified staff) and written information was very effective at increasing immunization in the elderly67. Handouts available in the waiting room, by contrast, were not found to have an effect in adult women47. Studies evaluating the usefulness of telephone and mail reminders have showed mixed results; while most show that they increase immunization68, 69, others do not70. One problem in evaluating these studies is that they do not explicitly separate brief reminders, which serve more as cues to action, from education, in which verbal or written information is used to alter health beliefs. The few data which exist seem to show that some counseling
by either a physician or other staff member is necessary to make educational handouts work to change behavior.

Finally, when written material is prepared for use to educate patients or families, attention must be paid to the reading level at which it is written, to ensure that a low reading level does not serve as a barrier to education. For families with a low educational level, as is found in many public clinics, one article suggests that a fifth grade level may be ideal; another, which specifically looked at education about immunization, found that while a pamphlet at a sixth grade reading level was preferred by families in both private and public clinics, its comprehension was somewhat low in the public clinic. The second article recommended that a third to fourth grade reading level may be the best for literature distributed in public clinics.
EDUCATIONAL INTERVENTION STUDY

Since current literature supports the theory that a low level of parental knowledge and beliefs against immunization may adversely affect infant immunization rates, but few data exist to evaluate whether providing education to change knowledge and beliefs may help improve rates, an obvious question arises: Might educating parents about their children’s immunizations help boost on-time rates? In late 1997 and early 1998, I undertook a study, with help from personnel at the Connecticut Immunization Registry and Tracking System and primary care providers affiliated with the University of Connecticut School of Medicine, to investigate whether infant immunization rates could be favorably affected by parent education. The hypothesis that I tested was:

An educational intervention given at the two-week well-child visit and reinforced at subsequent visits, focusing on the importance of immunizations in the first year of life, will increase on-time immunization rates for the infant’s primary series.

Utilizing the elements of the Health Belief Model, I theorized that since perceived barriers, such as concerns over the safety, timing, and side effects of immunizations, are involved, and since self-efficacy issues, such as knowing when to bring children for immunizations, seem to be important, then education targeted at lowering perceived barriers and boosting self-efficacy might be useful. The design of the intervention focused specifically on these elements. The timing of the intervention was very deliberate as well. During the immediate newborn period, families are typically more concerned with basic infant care such as feeding and bonding; by the infant’s routine two-week visit, they are recovered from the immediate stresses of delivery, and should be more receptive to information. The only similar study in the literature utilized an
intervention delivered while the infant and mother were still in the hospital, and did not report a positive effect. However, the two-week visit occurs before the first set of immunizations, so families can make full use of the information given. Reinforcement of the education at subsequent visits may serve as a reminder to busy families, especially in the inner-city setting where single-parent families are the rule and scheduling appointments may be a low priority. I chose the seven-month age cutoff since that is the age at which delayed immunization is a problem for the highest number of infants.

In the following pages, I will describe the methods of the study, with the rationale for different aspects interspersed throughout, then report on the results of the intervention. Finally, I will discuss conclusions that I drew from the results, and suggest some implications for both further research and clinical practice.

**Methods**

**Study Population and Subjects**

The families in this study were taken from the population of Hartford, Connecticut, a city with a largely low-income population with a significant representation of mainland Puerto Ricans and African-Americans. At present, all infants born in Hartford are enrolled in the Connecticut Immunization Registry and Tracking System (CIRTS) unless a parent provides a written refusal at the time of the child’s birth. Infants and their caretakers were considered eligible for enrollment at the time of the first health-supervision (also called “well-child” or WCC) visit if the infant was born in Hartford, was under 28 days of age, and was with the primary caretaker (typically the mother) at
the time of the visit, and if the primary caretaker’s preferred language was either English or Spanish.

Setting

Enrollment and intervention was conducted at three inner-city pediatric primary care sites, staffed by pediatric faculty, staff, and residents from the University of Connecticut School of Medicine. The sites were: the Primary Care Center of the Connecticut Children’s Medical Center, a very large hospital-based site serving primarily low-income families from a predominantly Puerto Rican Hispanic neighborhood; the Pediatric Clinic of St. Francis Hospital and Medical Center, a medium-sized hospital-based site serving primarily low-income African-American and Hispanic families; and the St. Francis/Mount Sinai Burgdorf Pediatric Clinic, a free-standing clinic with primarily African-American families. All sites serve as teaching sites for University of Connecticut residents and students; although medical students and non-pediatric residents participate in the care of children, enrollment and intervention was done only by pediatric faculty and resident physicians, nurse practitioners, and physician assistants. The three sites provide primary care for over 90% of uninsured and Medicaid children in Hartford. Approval for the study was obtained from the institutional review boards of both Connecticut Children’s Medical Center and St. Francis Hospital and Medical Center.

Enrollment

Providers were asked to enroll all eligible infants born between October 1, 1997, and May 8, 1998, at their first WCC visit. Verbal informed consent was obtained from
all caretakers in their preferred language, and a brief sociodemographic questionnaire (Figure 1 - enrollment sheet), including attributes identified previously as risk factors for underimmunization, was administered to all families.

Families consenting to participation were randomized to either intervention or control groups based on the week they were enrolled; before the study started, a calendar specifying alternating weeks for “intervention” or “control” enrollment was given to each practice site.

**Intervention**

Caretakers in the intervention group received a brief educational intervention administered by the primary care provider, in addition to the normal education about immunizations given at the first WCC visit. The intervention consisted of two components: 1) a two-sided interactive graphic card (Figure 2) with spaces for stickers to be applied when immunizations were given, with accompanying informational text, and 2) explanation of the card and its message by the provider. The intervention was designed to be administered easily by the provider within the normal context of a brief health supervision visit, and took about three minutes to administer during pilot testing. At the end of the visit, caretakers were given the card, were encouraged to keep it and refer to it during the infant’s first year of life, and were told to bring it back at subsequent WCC visits, normally done at two, four, and six months of age. The stickers were placed in the clinic chart for future use, along with a sheet for providers to record when parents brought the card back (Figure 3- follow up sheet). At the infant’s subsequent WCC visits, if caretakers returned the card, stickers corresponding to the immunizations given
were applied; if they did not return it, a new card was given with appropriate stickers.
This intervention was continued through the infant’s six-month WCC visit, although the
card was designed to be used throughout the first year.

Elements of the intervention

The card was designed to be eye-catching and colorful, as one of our primary
goals was to encourage caretakers to keep the card, rather than throw it out. The graphic
on the front side, composed of a teddy bear with “balloons” where stickers for
immunizations could be applied, was designed to both attract the eye and serve as a
memory aid for caretakers. Immunizations given at each visit were represented by a
cluster of balloons; each balloon represented one immunization, and there was space for
one sticker in each balloon. Next to each cluster was a small box where due dates for
immunizations could be written by the provider. When all balloons were filled,
caretakers could be sure that their baby had received all necessary immunizations for the
first year. There was also a space provided where caretakers could attach a photograph of
the child, in order to personalize the card further and minimize the chance of discarding
it.

The text of the card was written at a fourth-grade reading level, and was designed
to be culturally appropriate; it was reviewed for appropriateness and reading level by an
educational psychologist with experience in education of inner-city populations. It was
translated into Spanish, then independently back-translated for accuracy by a native
Caribbean Spanish speaker. Text on the front side, accompanying the graphic, was
designed to be primarily motivational, attempting to bolster the self-efficacy of caretakers with the emphasis that caretakers can play an important role in securing the health of their infant through on-time immunization. On the reverse side, the text was targeted to address deficiencies in parent knowledge identified by the literature, to reduce perceived barriers to immunization. Specifically, it emphasized:

- the importance of immunizations in the first year of life
- the timing of immunizations
- the necessity of providing immunizations in a complete series
- which immunizations are needed at each visit
- common misconceptions, including the lack of need to postpone immunizations during a minor illness.

The text was broken into small “bullets” of information to make it easy to read, and was worded positively so as to further motivate parents. A picture of a happy, healthy African-American mother and baby was included with the words “YOU can help keep your child healthy!” at the end of the text, to make inner-city families feel accepted and motivated.

Child health providers were told to explain the card and its message in their own words, as they would any educational handout. I decided not to include a scripted dialogue for two reasons. Although it may decrease the consistency of the intervention, each provider giving his or her own explanation is consistent with what happens in everyday practice and makes the intervention more generalizable, assuming that providers at the three sites give similar explanations as a group to providers in other locations. Also, I was concerned that neither caretakers nor providers would accept a scripted explanation as part of “normal” anticipatory guidance. I did feel, however, that some sort
of verbal reinforcement by the provider was necessary to ensure the effectiveness of the card, as several studies quoted earlier have shown. The goal was to create an educational intervention which could be incorporated within the normal course of health supervision visits.

**Data collection**

Data collection was accomplished at two times: sociodemographic data were collected at enrollment, and outcomes data were collected after the infants turned 7 months of age. 7 months of age is the age defined by the CDC\(^72\) at which infants are defined as delayed in their immunizations if they have not received three doses of diphtheria-tetanus-pertussis (DTP) vaccine, two doses of polio vaccine, three doses of *Haemophilus* influenzae type B (HiB) vaccine, and two doses of Hepatitis B (HBV) vaccine. After infants became 7 months old, their clinic charts were reviewed for immunization dates, WCC appointment dates, dates of appointments missed either because of no-show or cancellation by the family, and missed opportunities for immunization (Figure 4- outcomes sheet). A missed opportunity was defined as any visit (WCC, sick, or follow-up) at which an infant was due to receive an immunization but did not receive one, and at which a valid contraindication to immunization, as defined by the AAP Red Book\(^73\), did not exist. For infants in the intervention group, data were also collected on parent compliance with returning the card at well-child visits, and provider compliance with checking for and using the card.
For infants determined to be delayed in their immunizations by chart review, data from the CIRTS database were also gathered, to determine whether infants had received immunizations from sites within Connecticut other than their primary site. CIRTS compiles their data by extracting immunization dates from provider billing records; the record of any infant thought to be delayed in his/her immunizations after this data is collected is flagged at 7 and 19 months of age. Any providers that the infant has seen are identified from insurance records. The providers are contacted by CIRTS staff, and any new immunization data from the providers’ charts are recorded.

CIRTS data were then combined with the chart review data to provide the best estimate of immunization status for each infant. Data from the combined method of chart and registry review were compared with those from chart review alone, to determine how much of an advantage the combined technique could provide over the traditional method. Additionally, infants who had changed providers according to the CIRTS database were noted, to determine if changing providers had an impact on immunization status.

**Data analysis**

The primary outcome measure was immunization completeness at 7 months of age. Intermediate outcomes measured were the number of cancelled and no-show WCC appointments during the first 7 months of life, the number of missed opportunities in the first 7 months, and on-time receipt of the first DTP immunization (by 3 months of age). Differences in outcomes between intervention and control groups were assessed; sociodemographic data and registry data about transfers of infants between providers
were then included to determine predictors of up-to-date status among all infants enrolled.

Sociodemographic data and outcomes data were entered and analyzed using the SPSS statistical package, Version 6.1. Associations between categorical data were determined using the Pearson $\chi^2$ statistic, between categorical and ordinal data using the Mann-Whitney U test, and between categorical and numerical data using Student’s t test. For the primary outcome, univariate associations were determined for intervention status, all sociodemographic variables, and intermediate outcome variables. Significant predictors were then entered into a logistic regression model to adjust for confounding by other predictors; stratification was also used to assess for confounding. For intermediate outcomes, associations between intervention status and outcome were determined by univariate analysis alone. Significance was reported at a level of $\alpha \leq 0.05$.

Results

Demographics

During the period of the study, a total of 846 newborns were seen for their initial well-child visit at the three sites. Although providers were asked to approach all families for enrollment, factors such as time pressures, individual providers’ comfort with the study, and failure of office staff to place enrollment packets on each infant’s chart limited the number who were approached. Thus, 364 families, or approximately 43% of newborns seen, were approached for the study. Of these, 348 were eligible for enrollment. 323 (93% of eligible) caretakers consented to enrollment and were enrolled
into the study. Eight were later dropped from the study. Six of these had the intervention administered improperly when their provider kept the handout in the chart instead of giving it to the caretaker, and the other two were enrolled in a special clinic for drug-exposed infants which incorporated multiple educational interventions; thus, they were considered not to be comparable to the other children in the study. 315 families were included in the final analysis: 156 in the intervention group, and 159 in the control group.

Demographic characteristics of families in each group are shown in Table 1. The demographics are reflective of a poor, inner-city population with a large mainland Puerto Rican Hispanic component, as is seen in Hartford. 56% of caretakers described themselves as Hispanic, 29% as African-American, 4% as Caucasian, and 1% as Asian; the rest were mixtures of these. Mean maternal age was 22.4 years, 44% of infants in the study were firstborn, and 75% of mothers were single. 86% of families received Medicaid assistance; this figure may actually be artificially low, as many families apply for Medicaid during the first month of their infant’s life. 53% of caretakers had completed high school or equivalent education.

The only statistically significant demographic difference between intervention and control groups was in maternal education, with intervention families having slightly more education than control families (Mann-Whitney U test: $Z$ score= -2.03; $P=0.04$). The effect of this, and investigation for possible confounding, will be discussed in detail in the discussion section. Demographic features of families refusing consent for the study ($N=25$) were not significantly different from those consenting.
Outcomes

Effect of intervention

Differences in immunization outcomes between intervention and control groups are described graphically in Figure 5. There were no significant differences between intervention and control groups either for the primary outcome of immunization completeness at 7 months of age or for the intermediate outcome of receipt of the first DTP vaccine by 3 months of age. However, the pattern of a dramatic decrease in immunization rates between 3 and 7 months of age is evident, with a decrease overall from 86.7% to 58.1% during this time. The overall completeness rate of 58.1% at 7 months of age is consistent with the rate for all 7-month-old infants attending the three sites for primary care in 1996-7, which was 55% according to CIRTS data. (CIRTS, unpublished data, 1999). Since maternal education was higher in the intervention group, groups were stratified according to education status (high school graduates or greater vs. all others) to investigate any potential negative confounding; within each stratum, the effect of the intervention was similarly absent.

Differences in appointment-keeping behaviors between intervention and control groups are described in Figure 6 and Table 2. In the United States, there are four recommended WCC visits during the age range of study patients: at zero to two weeks, two months, four months, and six months of age. Figure 6 shows the mean number per infant of appointment cancellations and no-shows for WCC visits in the first 7 months of life, and the significance of differences between intervention and control groups.
Intervention group infants had 77% more cancelled appointments than control infants (0.23 vs. 0.13, p=.04), and a non-significant increase in no-show appointments (0.74 vs. 0.63, p=.30). When these were added together to produce the total number of missed WCC appointments per child, the intervention group had 28% more missed appointments per child (0.97 vs. 0.76) than the control group; however, the difference dropped just below the level of significance (p=.09).

Appointment-keeping data were also analyzed by dichotomizing outcomes according to presence or absence of missed appointments in each category, in order to determine relative risk figures. Table 2 shows differences between the two treatment groups with respect to this analysis; relationships are similar to those found in the numerical analysis above, with intervention group infants having a higher risk of any cancelled well-child appointments during the first 7 months of life (RR=1.72 compared with controls).

Data describing missed opportunities to immunize according to intervention status are described in Figure 7. Intervention group infants had significantly fewer missed opportunities during the first seven months of life using either method of analysis. The mean number of missed opportunities in the intervention group was half that of the control group (0.18 vs. 0.36, p=.01), and the relative risk of any missed opportunities in the intervention group was 0.61 compared with controls (p=.04).

For families in the intervention group, providers checked for the card and used the stickers provided at 75% of visits; data were missing for 17 families (11%). Parent compliance with returning the card was much lower, with cards being returned at only
54% of visits for which parent compliance data were recorded. Data on parent compliance were not recorded by providers for 52% of families, however.

**Predictors of immunization delay in all infants**

Univariate analysis

Associations between sociodemographic variables and immunization status, and between intermediate outcomes and immunization status, are described in Table 3. Sociodemographic variables associated with delayed immunizations were a low level of maternal education, high birth order, and type of provider seeing the child. Within provider type, children seen by resident physicians were at highest risk for underimmunization, followed by children seen by mid-level practitioners and then by attending physicians. When intermediate outcomes were examined between provider types to identify the source of this difference, missed opportunities emerged as a significant difference between groups, with children seen by midlevel practitioners having a higher mean number of missed opportunities than either attending physicians (.39 vs .09, p<.001) or resident physicians (.39 vs .18, p=.008). However, children seen by resident physicians were not found to have any unfavorable differences in intermediate outcomes to account for their poorer immunization status. Variables not predictive of immunization status included insurance type, language, ethnicity, marital status, maternal age, or the number of other children in the household. Several of the intermediate outcome variables were predictive of immunization delay; a higher number of no-show and missed appointments and delay for the first DTP immunization were all associated
with delay, and a higher number of missed opportunities also showed a trend toward predicting delay, although the difference did not reach statistical significance (p=.06).

Multivariate analysis

To investigate relationships between predictors of immunization status, logistic regression models were constructed using sociodemographic and intermediate outcome predictors (Table 4). Numerical independent variables were dichotomized for purposes of analysis, as described in the table. In the sociodemographic model, all univariate predictors remained independently significant predictors of immunization status. Provider type had the strongest effect; infants seen by attending physicians had an odds ratio for delayed immunization of 0.36, and infants seen by mid-level practitioners had an odds ratio of 0.52 when compared with resident physicians. Infants who were not firstborn had an odds ratio for delay of 1.80 as compared with firstborn infants, and infants whose mothers had less than a high school education had an odds ratio of 1.65 as compared with those whose mothers were high school graduates.

In the outcomes model, total missed appointments could not be included because they were a composite of other outcomes; cancelled appointments were not a significant predictor of immunization status, while no-show visits and on-time receipt of the first DTP were. Delay for the first DTP immunization was the strongest predictor of delay at 7 months, with infants delayed for DTP1 having an odds ratio of 9.74 for delay compared with infants receiving DTP1 on time. Infants having any no-show appointments had an odds ratio of 3.29 compared with infants who had none. Adding the variable of intervention status did not change any of the relationships in either model.
Utility of the CIRTS registry

Of the 315 infants in the study, 168 infants (53.3%) were found to be on time for their primary series by chart review at the primary site of care. When the CIRTS database was used to inquire about additional care and immunizations received within the state for children apparently delayed (AD) in their immunizations, 44 children (30% of AD children, or 14% of the total) were recorded as having changed providers within the state during their first 7 months of life. 28 of these children (19% of AD children; 95% CI, 12.7 to 25.3%) had documentation of additional immunizations given at their new providers, and 15 (10% of AD children; 95% CI, 5.3 to 15.1%) were determined to be on time when these new data were added to those from chart review. (Figure 8). This increased the total up-to-date rate to 58.1%, an overall 4.8% (95% CI, 2.4 to 7.2%) increase over chart review. No data were available about infants moving out of state, as the CIRTS registry does not record this.

Provider change was also examined as a risk factor for underimmunization. Infants who changed providers within the state were almost twice as likely to be delayed in their immunizations ($RR = 1.81$, 95% CI= 1.41, 2.33; $p=.0001$) as compared with infants who had no documented provider change. This remained a significant predictor of underimmunization when it was added to the regression model with the other risk factors.
DISCUSSION

This study attempted to build on earlier research which identified deficiencies in parent knowledge as an important contributor to delayed immunization. Unlike earlier studies, it evaluated the usefulness of a brief, practical office-based intervention to improve infant immunization rates through improving parent knowledge and beliefs about immunization. It utilized an innovative educational tool, a reusable graphic handout, which was intended to serve both as a reminder to parents and an educational resource for immunizations during their infant’s first year. The handout was targeted toward an inner-city population with a low reading level, and addressed knowledge deficiencies identified by a local study to be associated with immunization delay in this population. It was administered by the child’s primary care provider, a person with whom families develop an ongoing relationship, as one of the first of many pieces of anticipatory guidance offered to the family during their child’s health supervision visits. It was also designed to be reinforced at each visit as a reminder to families, as are many other important anticipatory guidance topics.

While I designed this intervention in order to optimize the chances of providing the most useful information to parents, I also designed it in a way that was generalizable for further use in the office setting. With the limited time available to pediatric primary care providers during health supervision visits, any intervention involving providers that lasts longer than a very few minutes is not likely to be acceptable to providers, and may cut into time needed for other health supervision functions. Longer, more elaborate interventions may have greater capability to affect parent behavior, but are not practical
for inclusion by child health providers as part of routine anticipatory guidance.

Additionally, I felt that it was important for parents not to be presented with a large volume of information that might overwhelm their ability to absorb other education presented to them at their newborn’s important first well-child visit.

This study was also one of the first to utilize a large-scale immunization registry to determine immunization outcomes. Many others have used review of medical charts as the “gold standard” for accuracy in determining immunization rates; with a large, mobile inner-city population where provider change is common, this tends to underestimate rates even more than it would in a more stable population. While telephone contact with families may help boost the accuracy of immunization records, this has been shown to overestimate rates$^{22}$, and is not feasible for families without a working telephone, as is the case for many inner-city families. A registry that records all immunizations given within the state can help overcome these problems, although families that move out of state will still be missed.

**Interpretation of results**

The results of this intervention study with respect to the primary outcome demonstrate clearly that with the techniques and sample size used, no benefit of the intervention in increasing overall immunization rates for the primary series at 7 months of age could be found. The percentage of infants fully immunized in each group was almost identical, and was very similar to the baseline group of all infants seen at the participating primary care centers during 1996-7. When enrollment data were examined to search for
any source of bias that may favor negative results, the only difference found was that mothers in the intervention group were more highly educated than mothers in the control group; since more highly educated mothers also had children with higher immunization rates, any bias resulting from this would tend to skew the data toward finding a positive effect of the intervention. Furthermore, no differences in primary outcome between intervention and control groups were found when the groups were stratified according to education status. Since there was so little difference in immunization rates between groups, the possibility of a Type II error also seems unlikely, as the small difference in rates found would not only require a very large sample size to detect statistical significance, but also is not clinically significant.

There are many possible reasons for the apparent lack of effect of the intervention on the primary outcome. Several may stem from the design and implementation of the intervention. The intervention may simply have been too weak to cause a significant change in the knowledge or attitudes of the families enrolled. The brief intervention was included by providers as part of their routine anticipatory guidance, and although the handout was designed to be used by families over time, the explanation itself typically took two to three minutes to administer, far shorter than many other types of educational programs. The scope of the project did not permit a detailed evaluation of the impact of the intervention on immediate knowledge or belief change, so this effect is unknown. Another reason may be that since the explanation of the intervention was not standardized, variations between providers in their administration of the intervention blunted any positive effect. However, the lack of standardization was deliberate, as
providers in the community at large seldom standardize the anticipatory guidance that they give to families. Additionally, the intervention, although it may have worked to change knowledge and attitudes initially, may not have been used by families in the longitudinal fashion recommended to achieve long-term behavior change; the low level of parent compliance with returning the card at well-child visits makes this possibility likely.

Although faulty parent knowledge and beliefs have been related to low immunization rates both epidemiologically and through evaluation of parent interviews\(^\text{29, 74}\), it does not necessarily follow that improving knowledge and/or beliefs will result in improved immunizations. Solving the problem of faulty knowledge and beliefs may be necessary, but not sufficient, to make an impact on actual immunization rates. Also, parents may blame themselves for the problem, when in reality the blame should fall elsewhere. Since parents do not see the parts of the immunization delivery system which are not directly involved in immunizing their child, they may not realize that removing barriers to knowledge may only uncover others over which they have no control. This effect may be magnified in the inner-city environment, where day-to-day functioning presents many difficult challenges not experienced in other settings. It is possible that were this intervention implemented in another setting, a more beneficial effect might have been demonstrated.

Despite a lack of effect of the intervention on the primary outcome, significant effects of the intervention were observed when outcomes more proximal to the 7-month immunization rate were evaluated. These suggest that the process of getting children
immunized was affected to some extent by the intervention. Infants in the intervention group had a small but significant increase in WCC appointments initially made, but later cancelled, as well as a trend toward a significant increase in overall missed WCC appointments during their first 7 months of life. This suggests that although caretakers were motivated by the intervention to make appointments for their infants’ immunizations, other factors intervened during the period between appointment scheduling and appointment date to negate any beneficial effect. One surprising effect also seen was a dramatic decrease in missed opportunities to immunize occurring among infants in the intervention group. Since missed opportunities to immunize are primarily influenced by the child’s health provider, this indicates that providers were positively influenced by the intervention, as they were not blinded to which infants were enrolled in the intervention group and since intervention group infants had both stickers and follow-up sheets displayed in the front of their charts. This is a significant finding, as other studies have found it difficult to cause providers to reduce missed opportunities through various interventions.

When data from all infants in the study are combined, several predictors of immunization status emerge both from sociodemographic and intermediate outcome data. These are important to examine, as they may illuminate some causes for the dramatic decrease in immunization rates between 3 and 7 months of age. Sociodemographic predictors of immunization delay were the same in both the univariate and multivariate models; these were low maternal education and high birth order, two variables which have been found previously to be predictive of delay. Another factor determined at the
time of enrollment (and therefore included in the sociodemographic model), that of
provider type, was also a significant predictor. Infants seeing resident physicians for their
primary care were more likely to be delayed than infants seeing “midlevel providers”
(nurse practitioners or physician assistants), and infants seeing midlevel providers were
more likely to be delayed than infants seeing attending physicians. In the primary care
system used at the three sites, newborn infants are assigned to providers without regard to
sociodemographic characteristics, so patient panels for different types of providers are
similar. This difference has not been reported previously, and has important implications
for medical education. Intermediate outcomes which predicted immunization delay in
both univariate and multivariate models were delayed receipt of the first DTP
immunization and the number of no-show WCC appointments; the number of missed
opportunities also fell just short of achieving statistical significance (P < .10 but > .05) in
both models. Delay for the first DTP immunization as a risk factor suggests strongly that
the process of immunization delay begins early in life; however, the majority of infants
delayed at 7 months were up-to-date for their first DTP, pointing to one or more other
factors as important contributors as well. The influence of appointment no-shows,
controlled by families, and missed opportunities, controlled largely by providers, suggest
that neither group alone, but a combination of the two, is primarily responsible for
immunization delay.

The CIRTS statewide immunization registry proved remarkably useful for this
study. All infants enrolled in the study had records in the CIRTS database, and those
who changed providers within the state were easily tracked by the system, which requires
providers statewide to report all immunizations given for children enrolled in the registry. 14% of infants in the study had changed health care providers during their first 7 months of life, and almost one in five infants thought to have immunization delay after chart review at their original site of care had additional immunizations documented by the registry. More importantly, 10% of infants thought to be delayed were actually up-to-date, boosting the overall immunization rate by about 5%. Use of the registry to track infants between sites of care also uncovered a significant risk factor for immunization delay, that of provider change during the first 7 months of life. This has significant implications for education of both parents and providers.

**Implications for practice**

The findings of this study underscore the complicated nature of the process of improving immunization delivery in an inner-city population. There is some evidence that the educational intervention was potentially helpful in motivating parents to make well-child appointments, but that any advantage was negated by factors which intervened between the time of making the appointment and the actual appointment date. This may well be due to the fact that in a poor, inner-city environment, many day-to-day difficulties such as transportation problems, ensuring adequate food, and securing safe child care make keeping appointments for well-child care more difficult, and possibly less of a priority, than in more affluent environments. Reminder and recall systems for appointments have been found to be helpful in increasing immunization rates; perhaps such a system would be helpful in combination with education if it could address the problems of poor telephone coverage and the need for a reminder very close to the day of
the appointment. Individualized outreach programs have been found by studies both locally\textsuperscript{77} and in other settings\textsuperscript{78} to be prohibitively costly, but other techniques are being developed in conjunction with immunization registries that may be more practical\textsuperscript{35}, so a combination including outreach may be a good solution. As children born into larger families are at higher risk for immunization delay, targeting these families may be a good start.

The positive impact of the educational intervention on missed opportunities to immunize, together with a significant risk of underimmunization among patients cared for by health care providers with lower levels of training, points to a definite need to educate providers about immunization delivery in order to keep missed opportunities to a minimum. Providers need to be aware of the impact of missed opportunities on immunization rates, and the rarity of true contraindications for immunization. Providers also need to be aware of the need to place infants delayed for their early immunizations on a “catch-up” schedule. When patients delayed for their first set of immunizations are not seen again until the typical two-month interval has passed, not only do they remain underimmunized, but they are at risk for further delay if the interval between visits is prolonged for any reason. Since immunizations in the primary series are safe and effective when given as little as four weeks apart, it should be relatively easy to remedy the problem of early underimmunization.

The high risk for immunization delay seen among infants who change providers within the state, even with a functional and accessible immunization tracking system, suggests that providers need to pay closer attention to the immunization status of their
newly acquired patients. The usefulness of the tracking system needs to be emphasized to providers, who may detect needed immunizations as well as avoid unnecessary repetition of immunizations, as well as policymakers, who can ensure the continued existence of the resource. Caretakers also need to be advised of the importance of maintaining continuity with their initial child health provider during the first year of their child’s life, so that immunizations (as well as other follow-up issues) remain current.

Limitations of the study

As discussed earlier, the present study was designed to examine whether a brief intervention administered by child health providers in the context of routine office visits might help improve immunizations for inner-city infants. A more intense intervention administered in a controlled setting by personnel specially trained in health education may well have produced a more positive effect, or an intervention given to families from a different environment may have proved more useful. Since parent knowledge about immunizations was not measured before and after the intervention, it is not possible to determine whether the education was effective in boosting knowledge; although this would have been a useful intermediate outcome to measure, the possibility exists that a “Hawthorne effect” might then have caused both groups to pay more attention to their child’s immunizations, further blunting any positive effect. Additionally, since providers enrolled patients from both intervention and control groups as well as administering the intervention, it is possible that the routine information they gave to control families became more intensive, and thus the difference in education given to each group was smaller than planned. However, since the overall immunization rate was not significantly
different from the baseline rate for infants seen at the study sites, this is unlikely to have had an effect.

**Future directions**

This study raises many questions that are worthy of future research. If up-to-date immunization remains a goal of public health efforts, then future work needs to continue to focus on the outcome of immunization rates; however, the impact of educating families in inner-city settings with the outcome of improved long-term knowledge and beliefs needs to be investigated as well. Other educational techniques applicable in a variety of settings, such as videotapes, should be evaluated to determine their impact on immunization rates. Combinations incorporating educational interventions and reminder/recall systems may make sense to address the combined problem of improving both health beliefs and cues to action, and these should be compared with reminders alone to determine impact on immunization delivery. Provider education is clearly an area which needs investigation; although many interventions have been unsuccessful at changing provider practices, the problem of incorrect beliefs and practices leading to missed opportunities to immunize remains. Finally, as regional and state immunization registries mature, their utility to patients and providers, and their impact on office practice, need to be evaluated.
APPENDIX I: Tables

Table 1. Demographics of families in the educational intervention study. Interval variables (maternal age, birth order, and number of other children in the house) were compared using Student’s t test; ordinal variables (education level) using the Mann-Whitney U test; and categorical variables (all others) using the Pearson $\chi^2$ test.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention</th>
<th>Control</th>
<th>P for difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of families</td>
<td>156</td>
<td>159</td>
<td>....</td>
</tr>
<tr>
<td>Maternal age (mean ± SD)</td>
<td>22.5 ± 5.4</td>
<td>22.4 ± 5.4</td>
<td>.97</td>
</tr>
<tr>
<td>Birth order of child (mean ± SD)</td>
<td>1.9 ± 1.0</td>
<td>2.0 ± 1.3</td>
<td>.36</td>
</tr>
<tr>
<td>Maternal education (mean level ± SD)</td>
<td>1.8 ± 0.8</td>
<td>1.6 ± 0.8</td>
<td>.04</td>
</tr>
<tr>
<td>Code: 1= less than HS grad</td>
<td>62</td>
<td>74</td>
<td></td>
</tr>
<tr>
<td>2=HS grad</td>
<td>56</td>
<td>49</td>
<td></td>
</tr>
<tr>
<td>3=some college</td>
<td>26</td>
<td>16</td>
<td></td>
</tr>
<tr>
<td>4=college grad or more</td>
<td>5</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Not recorded</td>
<td>7</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>Medicaid insurance (%):</td>
<td>83.4</td>
<td>88.0</td>
<td>.48</td>
</tr>
<tr>
<td>Preferred language:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>English</td>
<td>116</td>
<td>131</td>
<td>.19</td>
</tr>
<tr>
<td>Spanish</td>
<td>31</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Not recorded</td>
<td>9</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Marital status: single (%)</td>
<td>76.3</td>
<td>78.0</td>
<td>.57</td>
</tr>
<tr>
<td>Number of other children in house (mean ± SD)</td>
<td>1.4 ± 1.8</td>
<td>1.3 ± 1.3</td>
<td>.57</td>
</tr>
<tr>
<td>Ethnicity: (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>59.6</td>
<td>51.6</td>
<td>.67</td>
</tr>
<tr>
<td>African-American</td>
<td>26.9</td>
<td>30.8</td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>4.5</td>
<td>3.8</td>
<td></td>
</tr>
<tr>
<td>Provider type: (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attending</td>
<td>23.1</td>
<td>17.0</td>
<td>.35</td>
</tr>
<tr>
<td>NP/PA</td>
<td>50.6</td>
<td>57.9</td>
<td></td>
</tr>
<tr>
<td>Resident</td>
<td>26.3</td>
<td>24.5</td>
<td></td>
</tr>
<tr>
<td>Caretaker relationship to child: (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biological mother</td>
<td>100.0</td>
<td>98.1</td>
<td>.50</td>
</tr>
<tr>
<td>Grandmother</td>
<td>0</td>
<td>1.3</td>
<td></td>
</tr>
</tbody>
</table>
Table 2. Behavior of families in keeping well-child appointments. Relative risk denotes risk of intervention group infants for behavior as compared with controls. Comparisons were made using the Pearson $\chi^2$ test.

<table>
<thead>
<tr>
<th>Appointment behavior</th>
<th>Percent of infants with behavior</th>
<th>Intervention</th>
<th>Control</th>
<th>RR(95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any cancellation</td>
<td>20.5</td>
<td>11.9</td>
<td></td>
<td>1.72 (1.02,2.90)</td>
<td>.04</td>
</tr>
<tr>
<td>Any no-show</td>
<td>44.2</td>
<td>43.4</td>
<td></td>
<td>1.02 (0.79,1.31)</td>
<td>.88</td>
</tr>
<tr>
<td>Any missed appointments</td>
<td>55.8</td>
<td>48.4</td>
<td></td>
<td>1.15 (0.93,1.42)</td>
<td>.19</td>
</tr>
</tbody>
</table>
Table 3. Factors associated with immunization delay at 7 months of age in univariate analysis. Interval variables (birth order, maternal age, number of other children in the house, and appointment data) were compared using Student’s t test; ordinal variables (education level) using the Mann-Whitney U test; and categorical variables (all others) using the Pearson $\chi^2$ test.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>P for association with immunization delay</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sociodemographic variables:</strong></td>
<td></td>
</tr>
<tr>
<td>Insurance type</td>
<td>.15</td>
</tr>
<tr>
<td>Language</td>
<td>.40</td>
</tr>
<tr>
<td>Marital status</td>
<td>.42</td>
</tr>
<tr>
<td>Maternal age</td>
<td>.23</td>
</tr>
<tr>
<td>High birth order</td>
<td>.05</td>
</tr>
<tr>
<td>Low maternal education</td>
<td>.03</td>
</tr>
<tr>
<td>Number of other children in house</td>
<td>.37</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>.87</td>
</tr>
<tr>
<td>Provider type</td>
<td>.04</td>
</tr>
<tr>
<td><strong>Intermediate outcome variables:</strong></td>
<td></td>
</tr>
<tr>
<td>High number of cancelled appointments</td>
<td>.12</td>
</tr>
<tr>
<td>High number of no-show appointments</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>High number of total missed appointments</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>High number of missed opportunities</td>
<td>.06</td>
</tr>
<tr>
<td>Delay for first DTP immunization</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>
Table 4. Factors associated with immunization delay at 7 months of age in multivariate logistic regression models.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>$\beta$</th>
<th>S.E.($\beta$)</th>
<th>OR(95% CI)</th>
<th>Significance (P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sociodemographic variables:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Birth order &gt; 1</td>
<td>.59</td>
<td>.26</td>
<td>1.80 (1.08, 2.98)</td>
<td>.02</td>
</tr>
<tr>
<td>Maternal education &lt; HS</td>
<td>.50</td>
<td>.25</td>
<td>1.65 (1.01, 2.69)</td>
<td>.04</td>
</tr>
<tr>
<td>Provider type (vs. resident)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Attending</td>
<td>-1.03</td>
<td>.38</td>
<td>0.36 (0.17, 0.75)</td>
<td>.007</td>
</tr>
<tr>
<td>NP/PA</td>
<td>-.65</td>
<td>.30</td>
<td>0.52 (0.29, 0.94)</td>
<td>.03</td>
</tr>
<tr>
<td>Intermediate outcome variables:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any cancelled appointments</td>
<td>.55</td>
<td>.34</td>
<td>1.73 (0.89, 3.37)</td>
<td>.11</td>
</tr>
<tr>
<td>Any no-show appointments</td>
<td>1.19</td>
<td>.26</td>
<td>3.29 (1.98, 5.49)</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>Any missed opportunities</td>
<td>.55</td>
<td>.32</td>
<td>1.73 (0.92, 3.25)</td>
<td>.09</td>
</tr>
<tr>
<td>Delayed receipt of DTP1</td>
<td>2.28</td>
<td>.51</td>
<td>9.74 (3.61, 26.32)</td>
<td>&lt;.0001</td>
</tr>
</tbody>
</table>
Appendix II. Figures

Enrollment Sheet- Immunization Education Study

Eligibility Checklist:

- First WCC visit? (Y/N)
- Age 7-28 days? (Y/N)
- With primary caretaker? (Y/N)
- English or Spanish primary language? (Y/N); if Y, which? (E/S)
- Born in Hartford? (Y/N); if Y, where? HH SFH other

(IF ANY OF THE ABOVE IS “NO”, STOP HERE; PUT SHEET IN BOX; DO NOT ENROLL)

Demographics: Please complete even if consent not OK

- Infant’s race - please circle one: Hispanic AfrAm White Asian other___
- insurance type - please circle one: Medicaid HMO Medicaid non-HMO (Title 19 etc) self pay private HMO private non-HMO
- Site - please circle one: CCMC SFH Burgdorf
- Today’s Date (MM/DD/YY) __/__/
- Number of other kids in household ___
- Caretaker’s relation to child -circle: biological mother grandmother aunt foster parent father adoptive mother other___

If biological mother:
- Age ___
- Marital status - circle: single married separated divorced widowed
- Highest education - circle or fill in - Less than HS (grade completed ___)
  HS Grad
  Some college
  College grad or higher
- Birth order of this child _____
- Type of provider seen: Resident Midlevel Attending
  (midlevel includes NP, APRN, PA) Provider’s initials (optional) ___

Verbal consent OK? (Y/N)
(IF NOT OK, STOP HERE; PUT SHEET IN BOX; DO NOT ENROLL)

If enrolled:
- Handout given? YES (every other week) NO (every other week)
- Infant’s name __________
- Medical Record # __________
- DOB (MM/DD/YY) __/__/

THANKS！！！

Figure 1. Data form used for patient enrollment.
Figure 2. Educational intervention card
2 to 6 month follow-up sheet - Immunization Education Study
(KEEP IN CHART UNTIL 6 MONTH WCC VISIT)

2 month WCC visit:

Handout brought back? (Y/N) - if “N”, please give another with appropriate stickers and explanation

4 month WCC visit:

Handout brought back? (Y/N) - if “N”, please give another with appropriate stickers and explanation

6 month WCC visit:

Handout brought back? (Y/N)

AT 6 MONTH VISIT, PLEASE TEAR THIS OUT OF THE CHART AND PLACE IN STUDY BOX - THANKS!!!

Figure 3. Data form used at follow-up well-child visits.
Immunization Study - Outcomes data sheet

ALL DATES PLEASE: (MM/DD/YY)

ID number:
Site:
Chart #:
Name: (last, first)
DOB:

In CIRTS? : (Y/N)

Dates of immunization (from CIRTS database):

<table>
<thead>
<tr>
<th>DTP/DTaP</th>
<th>Polio</th>
<th>Hib</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1 (<em><strong>/</strong></em>)</td>
<td>#1 (<em><strong>/</strong></em>)</td>
<td>#1 (<em><strong>/</strong></em>)</td>
</tr>
<tr>
<td>#2 (<em><strong>/</strong></em>)</td>
<td>#2 (<em><strong>/</strong></em>)</td>
<td>#2 (<em><strong>/</strong></em>)</td>
</tr>
<tr>
<td>#3 (<em><strong>/</strong></em>)</td>
<td></td>
<td>#3 (<em><strong>/</strong></em>)</td>
</tr>
</tbody>
</table>

Hep B:

#1 (___/___)
#2 (___/___)

From this: Complete by 7 months? (Y/N) If “Y”, skip next section

IF NOT COMPLETE BY 7 MONTHS: Dates of other immunizations (from chart)

<table>
<thead>
<tr>
<th>DTP/DTaP</th>
<th>Polio</th>
<th>Hib</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1 (<em><strong>/</strong></em>)</td>
<td>#1 (<em><strong>/</strong></em>)</td>
<td>#1 (<em><strong>/</strong></em>)</td>
</tr>
<tr>
<td>#2 (<em><strong>/</strong></em>)</td>
<td>#2 (<em><strong>/</strong></em>)</td>
<td>#2 (<em><strong>/</strong></em>)</td>
</tr>
<tr>
<td>#3 (<em><strong>/</strong></em>)</td>
<td></td>
<td>#3 (<em><strong>/</strong></em>)</td>
</tr>
</tbody>
</table>

Hep B:

#1 (___/___)
#2 (___/___)

From this: Complete by 7 months? (Y/N)

MISSED OPPORTUNITIES (from chart):

Dates: ___/___  ___/___  ___/___  ___/___  ___/___

Figure 4. Data form used to collect outcomes data (page 1).
From followup form: (if not available, look in chart for it)

Form findable? (Y/N) (If N, skip to next section)

Handout brought back at 2 mos? (Y/N/unknown)
4 mos? (Y/N/unknown)
6 mos? (Y/N/unknown)

Stickers used through ____ mos.

Appointment data: (from computer)

Dates of WCC appts kept:__/__/__ __/__/__ __/__/__ __/__/__
(usual dates): (1-2 wk) (2 mos) (4 mos) (6 mos)

Dates of WCC appts missed:__/__/__ __/__/__ __/__/__ __/__/__

Appointment data (from chart): (fill this in only if different from computer)

Dates of WCC appts kept:__/__/__ __/__/__ __/__/__ __/__/__
(usual dates): (1-2 wk) (2 mos) (4 mos) (6 mos)

Dates of WCC appts missed:__/__/__ __/__/__ __/__/__ __/__/__

Figure 4. Data form used to collect outcomes data (page 2).
Figure 5. Immunization outcomes of study infants.
WCC appointments missed by 7 months

![Bar chart showing appointment-keeping of study infants.]

- Cancelled appts: P=0.04
- No-show appts: P=0.30
- Total missed appts: P=0.09

Figure 6. Appointment-keeping of study infants.
Mean number of missed opportunities
(first 7 months)

Any missed opportunities: 14.1% of intervention infants, 23.3% of controls;
RR of intervention compared with control (95% CI) = 0.61 (0.38, 0.98); P=0.04.

Figure 7. Missed immunization opportunities of study infants.
Utility of registry for infants apparently delayed by chart review at 7 months (n=147)

Figure 8. Provider and immunization data from the CIRTS registry for infants apparently delayed for immunizations after chart review.
REFERENCES

1. Rodewald LE. Childhood vaccination successes, yes, but the job is not finished. Pediatric Annals. 1998;27:335-336.


72. Rodewald L. (personal communication); 1997.


