Explaining the Risks and Benefits of Vaccines to Parents

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n increasing number of vaccines are available and recommended for routine use in children. Pediatricians must keep up-to-date as new vaccines are added to the schedule and the recommendations for older vaccines are revised. No vaccine is 100% safe or 100% effective. However, the benefits of vaccines far outweigh the risks. Not only do parents want and need to know about these vaccines, communication about their risks and benefits is legally mandated and ethically necessary to enable parents to make informed decisions.

What specific vaccine information needs to be communicated and who must provide it are problematic decisions for many pediatricians to make. However, neither the law nor the American Academy of Pediatrics (AAP) Red Book is explicit about what must be included in vaccine communication. A recent national survey found a mismatch among legal mandates for vaccine risk–benefit communication, providers' perceptions of what parents needed to know, and the actual vaccine risk–benefit communication practices of providers. The survey also indicated that vaccine communication need not be costly in time or effort.

There is no gold standard for vaccine risk–benefit communication. This article reviews the legal requirements, the Red Book recommendations, and research findings regarding current practice patterns among pediatricians, family physicians, and immunization nurses. Recommendations from parents across the United States are also described.

WHAT IS THE LAW?
The National Childhood Vaccine Injury Act of 1986 indicates that "Each health care provider who administers a vaccine set forth in the Vaccine Injury Table shall provide a copy of the current Centers for Disease Control and Prevention (CDC) Vaccine Information Statement (VIS) supplemented with visual presentations or oral explanations. Such materials shall be provided prior to the administration of (each) vaccine." The law does not specify what oral explanation is needed.

WHAT DOES THE AAP RED BOOK RECOMMEND?
The most recent edition of the Red Book recommends risk–benefit communication as follows:

The ... parent ... should be informed about the benefits to be derived from the vaccine in pre-
ventating disease in individuals and the community and about the risks of these vaccines. Questions should be encouraged so that the information is understood. When a parent initiates discussion about a vaccine controversy, the health care professional should discuss the specific concerns and provide factual information, using language appropriate for parents. Some vaccines may be acceptable to the resistant parent. Their concerns should be addressed in the context of this information. Health care professionals can reinforce important points about each vaccine, including vaccine safety, and emphasize the risks encountered by unimmunized children. Parents should be advised of state laws pertaining to school or child care entry, which may require that unimmunized children stay home from school during outbreaks.

Documentation of such discussions in the patient's record may help to reduce any potential liability should a vaccine-preventable disease occur in the unimmunized patient.

WHAT ARE PHYSICIANS WHO IMMUNIZE ACTUALLY DOING?

A recent national survey of private practice primary care pediatricians and family physicians who provided immunizations found that they valued immunization risk-benefit communication. Providers tended to tell parents what they thought parents needed and wanted to know. This generally included practical information about common side effects and how to treat them, when to call the clinic, and the schedule for the next vaccine. Almost all of the providers (97%) said they believed parents needed information on immunizations.

However, responses disclosed poor performance when it came to discussing benefits or severe risks and in screening for contraindications. Provider responses also disclosed a gap between the legal mandate and actual practice; approximately 40% self-reported they were not giving the VIS with every vaccine dose. Survey respondents cited lack of time as the main barrier to risk-benefit communication. Providers estimated that 4 to 5 minutes were needed to discuss immunizations.

WHAT DO PARENTS WANT?

We studied this issue by conducting 12 focus groups among parents in 6 cities. Similar to Clayton and others, we found that parents desired verbal information from their pediatrician, even if they were given the VISs and had little uncertainty about the vaccines. Parents in our 12 focus groups saw this communication as a matter of respect and trust that they expected from their pediatrician’s staff in general and their pediatrician in particular.

Parents were most interested in information they deemed relevant and practical (eg, management of common side effects and what to expect in the immunization schedule) (Table 1). Parents desired specific information about what side effects to expect, how long such symptoms would last, and whether the child would miss day care or they would miss work.

Specific management questions included how to best care for the child after injections (eg, giving acetaminophen or massaging the leg) and under what conditions to call the pediatrician or return to the clinic. Specific information desired about the immunization schedule consisted of the overall schedule and the time to return for the next vaccine. Parents of all income levels wanted to know about risk, but did not require much detail. Statistical probability and rates and numbers were not helpful to parents with less than a college education. An example of a risk statement acceptable to parents was “There is a very small chance something bad could happen, such as brain damage.”

Accurate, timely communication is even more important because of the issues currently being
EXPLAINING THE RISKS AND BENEFITS OF VACCINES TO PARENTS

TABLE 2
The 8 Cardinal Rules of Vaccine Risk Communication

| 1. Involve the parents. |
| 2. Listen nonjudgmentally. Do not argue with parents. |
| 3. Be empathetic and respectful of parents’ need to protect the child. |
| 4. Layer information given. |
| 5. Be honest. |
| 6. Be empathetic. |
| 7. Speak clearly and simply. |
| 8. Check for understanding. |

Modified from Covello and Allen.18

raised about vaccine safety, lack of firsthand experience with the vaccine-preventable diseases, and the inaccurate information available to parents through a variety of sources, including the Internet.9,10 A recent national telephone survey of parents found that 25% had important misconceptions about immunizations.14 These misconceptions can arise from a variety of nonscientific sources, such as the media, the Internet, and persuasive stories from friends and neighbors. Pediatricians must be aware of the misinformation so that parental concerns can be adequately addressed in a minimal amount of time.

There are always gaps in our knowledge about vaccines. When efficacy trials are performed, we learn about the common side effects and risks of vaccines. Random events associated with a vaccine may not be identified until the vaccine is given to a much larger number of children. In addition, epidemiologic studies must be completed to distinguish whether the event is truly associated with that vaccine or has occurred temporally by coincidence with the vaccination. When gaps in knowledge exist, parents must be made aware of the uncertainty. Our focus groups and the literature indicate that when uncertainty exists, parents rely on information from a trusted physician.2,6,8,15-17

HOW TO COMMUNICATE
Besides the content of communication, the manner in which a physician communicates the risks and benefits of vaccines is also important. The Environmental Protection Agency wrote rules for communicating environmental risk to the public, which we have modified for communicating childhood vaccine risk (Table 2).18,19

Parents in the focus groups universally emphasized the importance of the physician–patient relationship and that the physician was a trusted source of information.5,15 Parents wanted physicians to know (and respect) that “My child is the most important thing to me.” Parents wanted the highest level health care provider to briefly tell them about the most serious issues, such as risk. Nurses and other staff were acceptable for discussing routine issues such as common side effects and scheduling. Interestingly, parents in the focus groups indicated that they wanted immunization visits to be timely and efficient just as much as the health care providers did.

Effective Communication in a Busy Practice
Most pediatricians develop brief, informative messages that are to be repeated on a daily basis to address child health management topics. The same can be done for vaccine risk–benefit communication. We recommend that pediatricians “layer” vaccine risk–benefit messages by giving simple information first. Given the opportunity, parents who want more complex, detailed information will ask for it. We recommend that each pediatrician develop a simple, direct message that fits his or her personality, practice, and patient population. Finally, pediatricians or staff must check for understanding.20,21

How Much Time to Spend
How much time is enough? Only two studies to date have quantified this for immunization or immunization risk–benefit communication in pediatric offices. In a time and motion study from Rochester, New York, physicians spent a median of 1.9 minutes discussing vaccination. Staff in these practices spent a median of 1.6 minutes administering vaccines, and a median of 0 minutes discussing them. However, this study did not indicate the content of vaccine discussions.22 A second time and motion study was conducted in private pediatric and public immunization clinics in Shreveport, Louisiana. Less than 1 minute was spent discussing vaccine risks and benefits in both public and private clinics (13 seconds and 36 seconds, respectively).23 Neither
study assessed parents' understanding of or satisfaction with what was discussed.

A national survey of physicians and nurses working in pediatric and family practice offices also obtained self-report estimates for time spent and time needed. When asked how many minutes on average they currently spend discussing immunizations with parents, physicians and nurses estimated that they spent significantly less time (average 3.5 minutes) than they believed was actually needed (average 4.5 minutes). The national survey results showed that they feel pressured to spend more time than they do. In any event, the time spent by physicians and nurses on risk–benefit communication is brief.

**How to Set Up the Office**

The office nursing staff is an underrecognized asset that physicians can capitalize on to increase compliance with the law while reducing time demand. Physician and nurse respondents to the national survey were asked to indicate any staff (eg, nurses, physicians, or clerks) who gave or discussed immunization materials. Responses indicated that physicians were most likely to discuss materials but not give them, whereas nurses were most likely to both give and discuss materials.

The national survey indicated that office nurses felt they had a high investment in immunization; they had more training in risk–benefit communication and desired more training than did physicians, and their role, the content of their immunization discussion, and the amount of time they spent differed significantly from that of physicians. Nurse–parent communication was an important aspect of immunizations. This was often unrecognized by physicians. Respondents were asked to rate how confident they were in knowing what the rest of the clinical team said when discussing the risks and benefits of immunization with parents. Health care providers of all types were only moderately confident. This indicates that improvement can occur by organizing and streamlining this communication process.

**Immunization Materials Requested by Health Care Providers and What Is Under Development**

Health care providers participating in the national survey were asked what materials would be useful for them and their patients' parents. The most commonly requested item was a pre-immunization booklet for parents (80%). The second most common request was for screening sheets about contraindications. Foreign language materials were requested by many providers and nurses. These materials have been developed with funding from the Health Resources and Services Administration and under the guidance of representatives from 15 agencies, including the AAP and others. They are currently undergoing implementation trials.

For example, a sturdy, 5 × 7-in "baby shot resource book that can survive a baby bag" has been developed (Fig. 1). The book, written at a fourth-grade reading level, notifies parents of the risks and benefits of vaccinations and also informs them of how to manage common and
EXPLAINING THE RISKS AND BENEFITS OF VACCINES TO PARENTS

Screening Questions for Child Vaccines

Designed for Nurses and Health Care Support Staff.

Some children should not get a particular shot or should wait. These questions and tips will help you decide which vaccines should be given today.

1. Is your child very sick today?  
Tip: Common illnesses (e.g., diarrhea, ear infection) are NOT a contraindication.

2. Has your child developed hives or breathing problems as an allergic reaction to
   a) a vaccine in the past? If so: what vaccine:__________________________
   b) to anything else? If so: what:__________________________

Tip: Here are some common contraindications to specific vaccines:

Gallbladder MMR, Varicella, Poliovirus
Dilated pupils, chills B, IPV
Mumps, B, IPV

3. Has your child had a seizure or a brain problem?
Tip: Consider deferring Pertussis vaccine in children with progressive, evolving, or untreated neurologic disorders.

4. Have any of your child's parents or brothers or sisters had a seizure?
Tip: Family history of seizure is not a contraindication to vaccination.
If family history is positive, you may want to prevent fever.

5. Is your child's immune system weakened by cancer, HIV/AIDS, leukemia, cortisone, prednisone, other high dose steroids, anticancer drugs, or x-ray or other treatments?
Tip: Children with weakened immune systems should not receive MMR or Varicella.

6. Has your child received a transfusion of blood, plasma, or a medicine called
immune globulin in the past year?
Tip: Depending on the product, timing or dose the child may not be eligible for MMR or Varicella.

7. For Pre-adolescent, teen and adult females only: Are you pregnant or at risk for
   becoming pregnant within the next three months?
Tip: These women should not receive MMR or Varicella vaccine.

If in doubt, seek medical guidance.

Parent Signature ______________________ Date ___________ Witness ______________________ Date ___________

Based on the "Screening Questionnaire for Child and Teen Immunization" by the Immunization Action Coalition (www.immune.org) and the Red Book.
This project was supported by funding from the Health Resources and Services Administration (HRSA), through Cooperative Agreement #U76 AP 0301 to the Association of Teachers of Preventive Medicine (ATPM).

Figure 2. Contraindication screening sheet for child immunizations.

severe side effects. The book also provides instructions for how to reach the National Vaccine Injury Compensation Program and the Vaccine Adverse Event Reporting System.
EXPLAINING THE RISKS AND BENEFITS OF VACCINES TO PARENTS

Figure 3. A poster to prompt vaccine risk-benefit communication.

Similarly, a child immunization contraindication screening sheet to be completed by the parent has been developed (Fig. 2). Finally, a poster listing seven questions parents should ask about vaccines has been created for display in the examination room to prompt questions and discussion (Fig. 3).

CONCLUSION

The findings described here imply that simple steps can be taken to improve compliance without burdening anyone, by building on the capacity of all members of the immunization team and incorporating practical materials designed to automate the risk-benefit communication process.

We recommend that the entire office staff function as a team to develop a vaccine risk-benefit communication plan that works (Table 3). Several professional immunization web sites are available that are appropriate for both providers and

| TABLE 3 |
| Ways to Involve the Entire Office Staff in Vaccine Risk–Benefit Communication |
| 1. Physicians should use up-to-date risk-benefit messages and materials. |
| 2. Office staff should be empowered to use those messages to provide competent risk-benefit communication. |
| 3. Vaccine communication tasks should be assigned to immunization nurses and staff. |
| 4. Nurses and physicians need to develop succinct messages for parents. |
| 5. Vaccine Information Statements should be provided before vaccines are administered. |
| 6. Booklets and contraindication screening sheets should be used to streamline communication. |
| 7. Proper documentation should be obtained. |
EXPLAINING THE RISKS AND BENEFITS OF VACCINES TO PARENTS

<table>
<thead>
<tr>
<th>TABLE 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Additional Information Resources for Physicians and Parents</td>
</tr>
<tr>
<td>Immunization information web sites for physicians</td>
</tr>
<tr>
<td>American Academy of Pediatrics</td>
</tr>
<tr>
<td>Centers for Disease Control and Prevention, National Immunization Program</td>
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<tr>
<td>National Network for Immunization Information</td>
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<tr>
<td>Immunization information web sites for parents</td>
</tr>
<tr>
<td>Immunization Action Coalition</td>
</tr>
<tr>
<td>Vaccine Education Center</td>
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<td>Vaccine Page</td>
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parents (Table 4). Within the office system, the immunization nurse may need a stronger voice in vaccine risk–benefit communication.

REFERENCES

Explaining the risks and benefits of vaccines to parents.