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OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

The Dummies' Guide to Risk-Benefit Analysis of Vaccines

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Pediatrics 2002;110:193-

DOI: 10.1542/peds.110.1.193-b

This information is current as of July 9, 2006

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<http://www.pediatrics.org/cgi/content/full/110/1/193-b>

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American Academy of Pediatrics

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tial number of children over 6 years of age without the performance of confirmatory radiographs may have resulted in the inclusion of children without sinusitis. The antibiotic doses that were used were low (by 2002 standards) and may have been inadequate for a subgroup of children infected with resistant organisms. These two factors alone could easily have obscured the 20% to 30% difference in outcome that is expected between treated and untreated children.

Garbutt and her colleagues have performed a very important study.⁶ It is essential that we continue to do systematic investigation of this issue so that we can determine which children with respiratory symptoms are most likely to benefit from antimicrobial therapy and whether imaging procedures can be omitted in all age groups.

ELLEN R. WALD, MD, FOR THE AAP SUBCOMMITTEE
ON MANAGEMENT OF SINUSITIS AND COMMITTEE ON
QUALITY IMPROVEMENT

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To the Editor.—

In her article 'The Rotavirus Vaccine Story: A Clinical Investigator's View' (*Pediatrics* 2000;106:123-125), Dr Margaret B. Rennels asks, "How many children are required to satisfy us that a vaccine is safe to licence and recommend?" In the case of rotavirus vaccine the excess risk of intussusception was 1 per 5000 vaccinated children. She says the risk-benefit decisions such as "how many serious adverse events are acceptable to save a life" are difficult to make. The author feels strongly about a vaccine she has helped develop and thinks "although the ACIP and AAP have withdrawn recommendations for use of the vaccine, the vaccine may still be indicated in other areas of the world." The issues raised are not as difficult as it is made out to be. The risk-benefit calculations used by health economists are actually quite easy to comprehend.

1. Let a represent the lifetime risk of an individual getting the disease in the community (usually given as a fraction, say 1 in a 1000).
2. Let b represent the fraction of those with disease likely to develop a serious complication (usually given as fractions say 1 in 100 or 1 in 1000 etc).
3. Let x represent the fraction of those vaccinated who develop a serious complication attributable to the vaccine.

4. Then a multiplied by b represents benefit and x represents the risk.

If x is greater than a multiplied by b, the vaccine should not be used as the risk of vaccine-related-complication is more than the risk of acquiring the disease in the community and getting a serious complication from it.

Assume that 1 in 10 of the population develops measles and assume 1 in a 1000 of those with measles develop subacute sclerosing panencephalitis (SSPE). Then the chance of SSPE is 1/10 (a) multiplied 1/1000 (b) = 1/10 000. Suppose 1 in a 100 000 of those who receive measles vaccine develops SSPE then the risk x is 1/100 000. The benefit is higher than the risk.

The factor x remains constant for any given vaccine. The factor b remains constant for a given illness. However, the factor a is different in different populations and changes with time.

x, a and b could also be reckoned in terms of economic costs of the disease and side effects.

The chance of contracting hepatitis A is much lower in Europe than in Asia. Thus, with its good sanitation, the vaccine risk may be too high for Europe but acceptable for its benefits in Asia. Smallpox risk is an example of how time alters the risk-benefit ratio. As long as smallpox was epidemic, the risks of disease were more, compared with the risks of vaccination. However, after smallpox was eradicated, the risks of continuing with the vaccination program became unacceptably high compared with risk from the disease. The same is the problem with vaccine-induced polio in developed countries, where the risk of acquiring wild polio is now nearly eliminated.

Refinements may be incorporated to this simple formula. For a vaccine that has a very limited duration of protection (for example viral-influenza vaccination that must be given each year) instead of lifetime risk, the risk of the acquiring the disease each year may be considered.

A vaccine does not protect all those vaccinated. Suppose the vaccine protects 1 in 2 of those vaccinated, the benefit is reduced, and must be multiplied by a fraction c = 1/2 in this case. a multiplied b, multiplied c must be greater than x.

The risk-benefit ratio is thus a dynamic mathematical solution to the question of, "Is the cure (prevention) worse than the disease?"

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Politics and Reading

To the Editor.—

I am writing to express my concerns about the commentary by Strauss printed in the January 2002 issue of *Pediatrics*. First, in Dr Strauss' commentary he misquoted Dr Reid Lyon in 1 of the 3 quotes. The other 2 quotes were taken out of context. Second, this commentary was written in a manner that questions the credibility of the work of the National Institute of Child Health and Human Development with an important portion of the medical community. It is critically important that pediatricians are informed about reading difficulties and how to recognize the warning signs so we can identify children early.

In this 1-page commentary, Dr Strauss states that Dr Lyon represented the NICHD at the hearing to discuss President Bush's proposals for yearly testing and for accountability. He then argues that the NICHD's criteria for funding only reading research proposals that meet rigorous scientific standards is narrow, given the acceptance of descriptive research among educators. He raises questions about whether any scientific evidence exists to demonstrate that testing and accountability improves student achieve-

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