

HARM MODULE

Intussusceptions and Oral Rotavirus Vaccine.

Objectives:

After working through this packet, you should be able to:

1. Apply the validity criteria for harm studies to an article concerning a question of adverse events.
2. Understand the methodology, strengths and weaknesses of a case-control study.
3. Understand the meaning of an odds ratio and how to apply it to a clinical case. .
4. Understand the principle of confounding and be able to generate examples of possible confounders in this example.

Assignment:

Review the clinical scenario and the enclosed paper and decide:

1. Read the attached scenario.
2. Read the attached guidelines for reading articles concerning harm.
3. Critically appraise the attached article using the accompanying worksheet.
4. Describe how you would address the patient's concerns and management options taking into account your review of the article.

Clinical Scenario:

You are a primary care physician and updating your patients' immunization schedule. On your appointment lists of next morning, there are infants who will be coming for regular three-month check-up. You know that it is a good point of time to immunize them rotavirus vaccination, however, you remember that there were news on TV that infants with oral rotavirus vaccine intussusceptions were at higher risk of intussusception several years ago. Some mothers still insist that they do not want their infants to take the new vaccine due to problems with the old one. You would like to study more what happened in the past and learn about how the problems with the rotavirus vaccination were determined.

Enclosed Materials:

1. Levine M, Ioannidis J, Haines AT, Guyatt G, Chapter 14 Harm (Observational Studies) Ch 14 Pgs 301 - 314 In Guyatt G, Roman Jaeschke, Mark Wilson, Victor Montori, and Scott Richardson. What is evidence-based medicine. In Guyatt G, Rennie D, Meade MO, Cook DJ. Users' Guides to the Medical Literature: A Manual for Evidence-based Clinical Practice. 3rd ed. New York, NY: McGraw-Hill; 2015.
2. Murphy TV, Gargiullo PM, Massoudi MS, et al. Intussusception among infants given an oral rotavirus vaccine. N Engl J Med 2001;344:564-72.
3. Worksheet for the evaluation of a harm article.

For further studies:

1. CDC. Intussusception among recipients of rotavirus vaccine-United States, 1998-1999. *MMWR* 1999; 48:577-81.
2. Zanardi LR, Haber P, Mootrey GT, Niu MT, Wharton M. Intussusception among recipients of rotavirus vaccine: reports to the Vaccine Adverse Event Reporting System. *Pediatrics* 2001; 107:E97.
3. CDC. Rotavirus vaccine for the prevention of rotavirus gastroenteritis among children: recommendations of the Advisory Committee on Immunization Practices. *MMWR* 1999; 48(No. RR-2).
4. Kramarz P, France EK, Destefano F, et al. Population-based study of rotavirus vaccination and intussusception. *Pediatr Infect Dis J* 2001; 20:410-6.
5. Haber P, Chen RT, Zanardi LR, et al. An analysis of rotavirus vaccine reports to the Vaccine Adverse Event Reporting System: more than intussusception alone? *Pediatrics* 2004; 113:e353-9.
6. Verstraeten T, Baughman AL, Cadwell B, et al. Vaccine Adverse Event Reporting System Team. Enhancing vaccine safety surveillance: a capture- recapture analysis of intussusception after rotavirus vaccination. *Am J Epidemiol* 2001; 154:1006-12.
7. Rhodes PR, DeStefano F, Chen RT, MCO RRV-TV Safety Cohort Study Group. Long-term risk of intussusception following Rhesushuman reassortant rotavirus tetravalent vaccine (RRV-TV). Presented at the 43rd Interscience Conference on Antimicrobial Agents and Chemotherapy, Chicago, Illinois, September 17, 2003.
8. Glass RI, Bresee JS, Parashar UD, Jiang B, Gentsch J. The future of rotavirus vaccines: a major setback leads to new opportunities. *Lancet* 2004; 363:1547-50.
9. Robinson CG, Hernanz-Schulman M, Zhu Y, Griffin MR, Gruber W, Edwards KM. Evaluation of anatomic changes in young children with natural rotavirus infection: is intussusception biologically plausible? *J Infect Dis* 2004; 189:1382-7.