

Routine primary immunization using a longer needle resulted in fewer local reactions in infants

Diggle L, Deeks J. Effect of needle length on incidence of local reactions to routine immunisation in infants aged 4 months: randomised controlled trial. *BMJ*. 2000 Oct 14;321:931-3.

QUESTION

When giving routine immunizations to infants, does needle length affect the incidence of local reactions?

DESIGN

Randomized (allocation concealed*), blinded (outcome assessors)*, controlled trial with follow-up to 3 days.

SETTING

8 general practices in Buckinghamshire, England, United Kingdom.

PARTICIPANTS

119 healthy infants attending routine immunization clinics. Exclusion criteria were those applicable to children receiving primary immunizations. 92% of infants (58% boys) completed follow-up.

INTERVENTION

58 infants were allocated to receive their third dose of diphtheria, pertussis, and tetanus and *Haemophilus influenzae* type-b vaccines (due at 16 wk) given with a 23-gauge, 25-mm (longer) blue-hub needle; 61 were allocated to vaccine administration with a 25-gauge, 16-mm (shorter) orange-hub needle. Practice nurses were instructed to inject into the

anterolateral thigh, stretching the skin taut and inserting the needle at a 90° angle to the skin up to the hub.

MAIN OUTCOME MEASURES

Parent recording of redness, swelling, and tenderness at 6 hours and at 1, 2, and 3 days after immunization.

MAIN RESULTS

Infants who were vaccinated with the longer needle had lower rates of any local reaction than did infants vaccinated with the shorter needle; specifically, infants vaccinated with the longer needle had lower rates of redness and swelling at 6 hours and at 1, 2, and

3 days (Table). The groups did not differ for tenderness at any time point.

CONCLUSION

Infants who had their 16-week primary immunization given with a longer needle had lower rates of local redness and swelling for up to 3 days than did those who had immunizations given with a shorter needle.

*See Glossary.

Source of funding: Smith and Nephew Foundation.

For correspondence: Ms. L. Diggle, Oxford Vaccine Group, University Department of Paediatrics, John Radcliffe Hospital, Oxford OX3 9DU, England, UK. FAX 44-186-522-1068. ■

Longer vs shorter needle for giving routine immunizations to infants†

Outcomes	Longer needle	Shorter needle	RRR (95% CI)	NNT (CI)
Any local reaction up to 3 d	62%	84%	26% (7 to 43)	5 (3 to 19)
Redness at 6 h	40%	60%	34% (3 to 56)	5 (3 to 81)
At 1 d	28%	63%	55% (30 to 73)	3 (2 to 7)
At 2 d	9%	39%	76% (43 to 90)	4 (3 to 8)
At 3 d	4%	28%	87% (51 to 96)	5 (3 to 9)
Swelling at 6 h	23%	58%	61% (35 to 78)	3 (2 to 6)
At 1 d	28%	63%	55% (30 to 73)	3 (2 to 7)
At 2 d	19%	51%	63% (34 to 80)	4 (3 to 7)
At 3 d	13%	40%	67% (33 to 85)	4 (3 to 10)

†Abbreviations defined in Glossary; RRR, NNT, and CI calculated from data in article.

COMMENTARY

Diggle and Deeks report on the reactogenicity of a vaccine that has since been replaced in many countries by newer vaccines that produce only about one third of the local reactions (1). This fact, however, should not detract from the importance of their observation: To achieve high vaccination rates, acceptance of immunization still needs to be improved, especially by minimizing adverse events.

The choice of an appropriate injection site and the use of needles that are long enough to ensure complete intramuscular vaccine deposition will reduce the number and severity of local reactions (2). Ultrasonographic data suggest that a needle length of 16 mm is sufficient to reach the middle of the muscle layer and yet short enough to avoid damage to the bone, vessels, and nerves in an infant's thigh (3). A short needle should be adequate when using the World Health Organization (WHO)-recommended injection technique: Skin and soft tissue are left in place when inserting the needle at a right angle to the femur. A longer needle may be required if it is inserted at an angle of 45° in the compressed muscle. Unfortunately, no studies have compared the safety of these needles and injection techniques with respect to damage of deep anatomical structures.

Diggle and Deeks showed that the 25-mm needle was the better choice, even for the WHO injection technique. Manufacturers

should consider including longer needles in their vaccine kits. Continued use of the shorter needle may be advisable for premature infants with birthweights < 1500 g who are vaccinated, as recommended, according to their chronologic age.

Johannes Forster, MD
St. Josefskrankenhaus
Freiburg, Germany

References

- Dagan R, Igbaria K, Piglansky L, et al. Safety and immunogenicity of a combined pentavalent diphtheria, tetanus, acellular pertussis, inactivated poliovirus and *Haemophilus influenzae* type b-tetanus conjugate vaccine in infants, compared with a whole cell pertussis pentavalent vaccine. *Pediatr Infect Dis J*. 1997;16:1113-21.
- Ipp MM, Gold R, Goldbach M, et al. Adverse reactions to diphtheria, tetanus, pertussis-polio vaccination at 18 months of age: effect of injection site and needle length. *Pediatrics*. 1989;83:679-82.
- Groswasser J, Kahn A, Bouche B, et al. Needle length and injection technique for efficient intramuscular vaccine delivery in infants and children evaluated through an ultrasonographic determination of subcutaneous and muscle layer thickness. *Pediatrics*. 1997;100:400-3.