Evidence-Based Immunisation Practice

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Practical aspects

- Preparation
- Aspiration
- Speed
- Route
- Injection site
- Needle size
- Simultaneous injections
- Parental/Nurse demeanour

Preparation

- Warming prior to injection does not reduce incidence of pain[1]
- Pre-cleansing of injection site? No need for alcohol wipe[2, 3]
- Change the needle between drawing up and injecting?

  Practitioners have always felt this glides needle through skin

  DoH Green book now recommends[4]

1. Maiden, M. J., Benton, G. N. & Bourne, R. A. (2003) Effect Of Warming Adult Diphtheria-tetanus Vaccine On Discomfort After Injection: A Randomised Controlled Trial. Med J Aust, 178**,** 433-6.

2. Dann T, (1969)Routine skin preparation before injection, an unnecessary procedure. Lancet 2:96-98

3. Del Mar CB, Glasziou PP, Spinks AB, Sanders SL. Is isopropyl alcohol swabbing before injection really necessary? Med J Aust 2001;174(6):306

4.Dept of Health, Immunisation procedures chapter www.dh.gov.uk/

Aspiration

Pulling back on the syringe plunger before injection to check for blood return

- Entrenched in nursing textbooks since 1930's
- No evidence to document necessity[1,2]
- DoH advise this is not needed

1. Dept of Health, Immunisation procedures chapter www.dh.gov.uk/
2. American Academy of Paediatrics.

Does speed of injection affect pain?

- RCT: two techniques in 113 infants
- Standard care: slow aspiration, injection & withdrawal

  Pragmatic care: no aspiration, rapid injection & withdrawal
- Immediate infant pain measured by Modified Behavior Pain Scale (MBPS), Crying, Parent/paediatrician VAS
- Pragmatic rapid injection technique was less painful than slow standard of care technique
- Rapid injection technique is recommended

Ipp, M., A. P. Taddio, et al. (2007). "Vaccine related pain: Randomized controlled trial of two injection techniques." Arch Dis Child **8**: 8. PMID: 17686797

Simultaneous injection by two practitioners

- When two injections are required, some practitioners have chosen to give both injections simultaneously
- Studies showed ‘no detectable decrease in discomfort in the child’ compared with administering the injections sequentially[1,2]
- However, this is effective in reducing anxiety in older children (need to inform parent in advance)

1. Bogin et al (2004) A comparison of the pain associated with simultaneous(SIM) vs.sequential (SEQ) immunization injection given at the 9 and 12 month well child visits. Pediatric Research, 55, 210A.

2. Horn et al. (1999) Children's responses to sequential versus simultaneous immunization injections. J Pediatr Health Care, 13, 18-23.

Which route for vaccination?

Intramuscular

- DTaP/Hib/IPV
- MenC
- Pneumo conjugate
- Pneumo polysaccharide
- Hep A, Hep B
- Influenza
- Typhoid (Vi vaccine)
- Rabies

Intradermal

- BCG

Subcutaneous

- MMR (SC or IM)
- Varicella
- Yellow Fever

Oral

- Rotavirus
- Cholera
- Oral typhoid

Injection route

Technique determines where vaccine is placed (ID, IM, SC)

- Angle of the injection
- Whether the tissue is stretched or bunched up
- Depth of needle insertion

Route: Intradermal delivery

- BCG into left arm
- Insert needle at 10-15° angle
- Bevel upwards, place just under epidermis
- Should be able to see the bevel through skin
- Should feel resistance
- Injection should raise a bleb

Immunisation handbook
www.dh.gov.uk

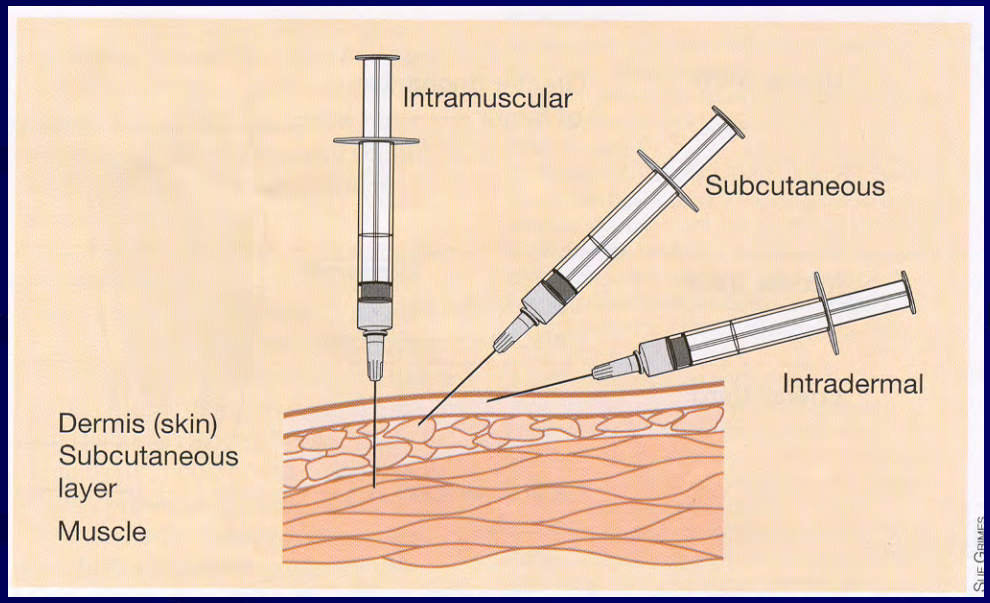
Route: Intramuscular

- Why are most given IM?
- Most contain aluminium adjuvant
- Adjuvants help stimulate an immune response (are less reactogenic in muscle)
- Muscle has a better blood supply
- Quicker mobilisation & processing of antigens
- Optimises antibody production
- IM delivery minimises local side effects

Zuckerman JN, Cockcroft A, Zuckerman AJ. Site of injection for vaccination. BMJ 1992;305(6862):1158.

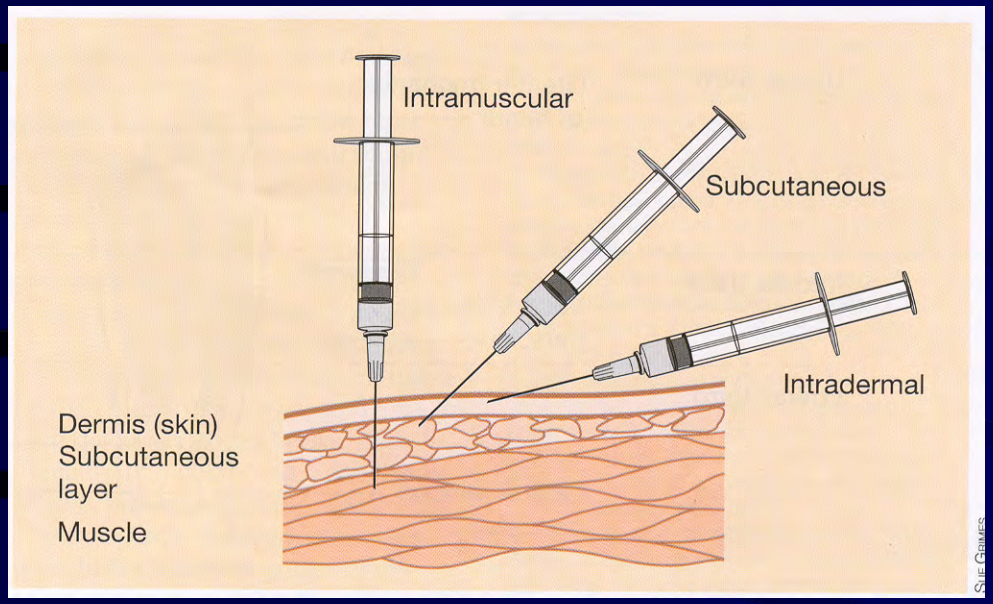
Intramuscular injection technique

- Skin stretched flat between thumb & index finger
- Optimize insertion deep into muscle
- Inserted at 90° angle
- Needle length long enough to reach muscle



Source: Diggle L. Injection technique for immunisation. *Practice Nurse* 2007; 33 (1).

Route: Subcutaneous



- Skin is bunched up
- Ensures insertion into fatty tissue just below skin
- Inserted at 45° angle
- Needle length shorter to reduce chance of insertion into muscle

Source: Diggle L. Injection technique for immunisation. *Practice Nurse* 2007; 33 (1).

Why not SC?

- Poorer drainage channels in fat
- Lack of antigen presenting cells
- SC fat retains injected material for longer
- More susceptible to any adverse effects of injection[1]
- Used for live virus vaccines requiring a slow, sustained release into the capillary network

1. Shaw et al. (1989) Effect Of Anatomic Injection Site, Age And Smoking On The Immune Response To Hepatitis B Vaccination. Vaccine, 7 (5), 425-30.

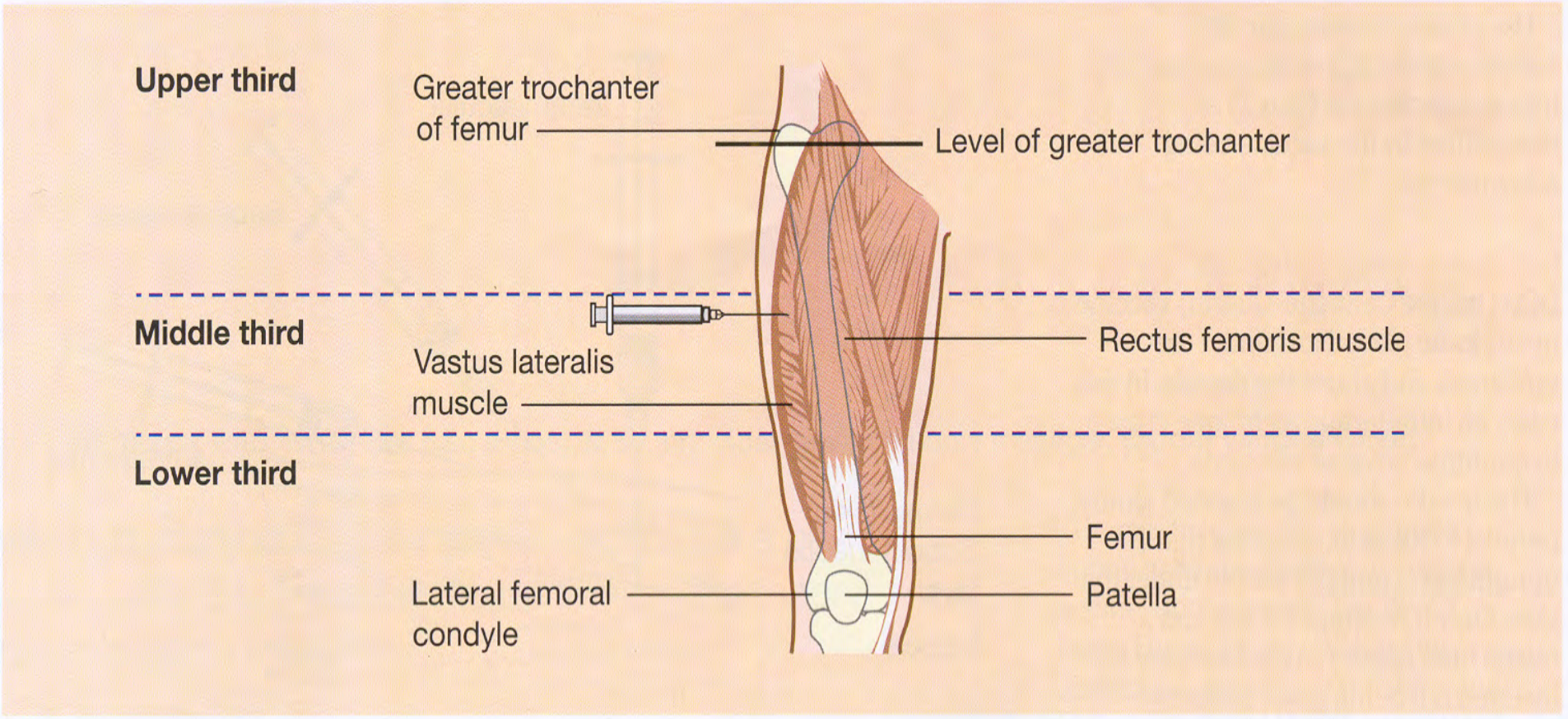
Injection site?

- Determined by - route to be used
  - amount of vaccine to be injected
  - age & size of the patient

- IM injection to Pre-schooler/Adolescent/Adult
  Deltoid (antero-lateral aspect of thigh)

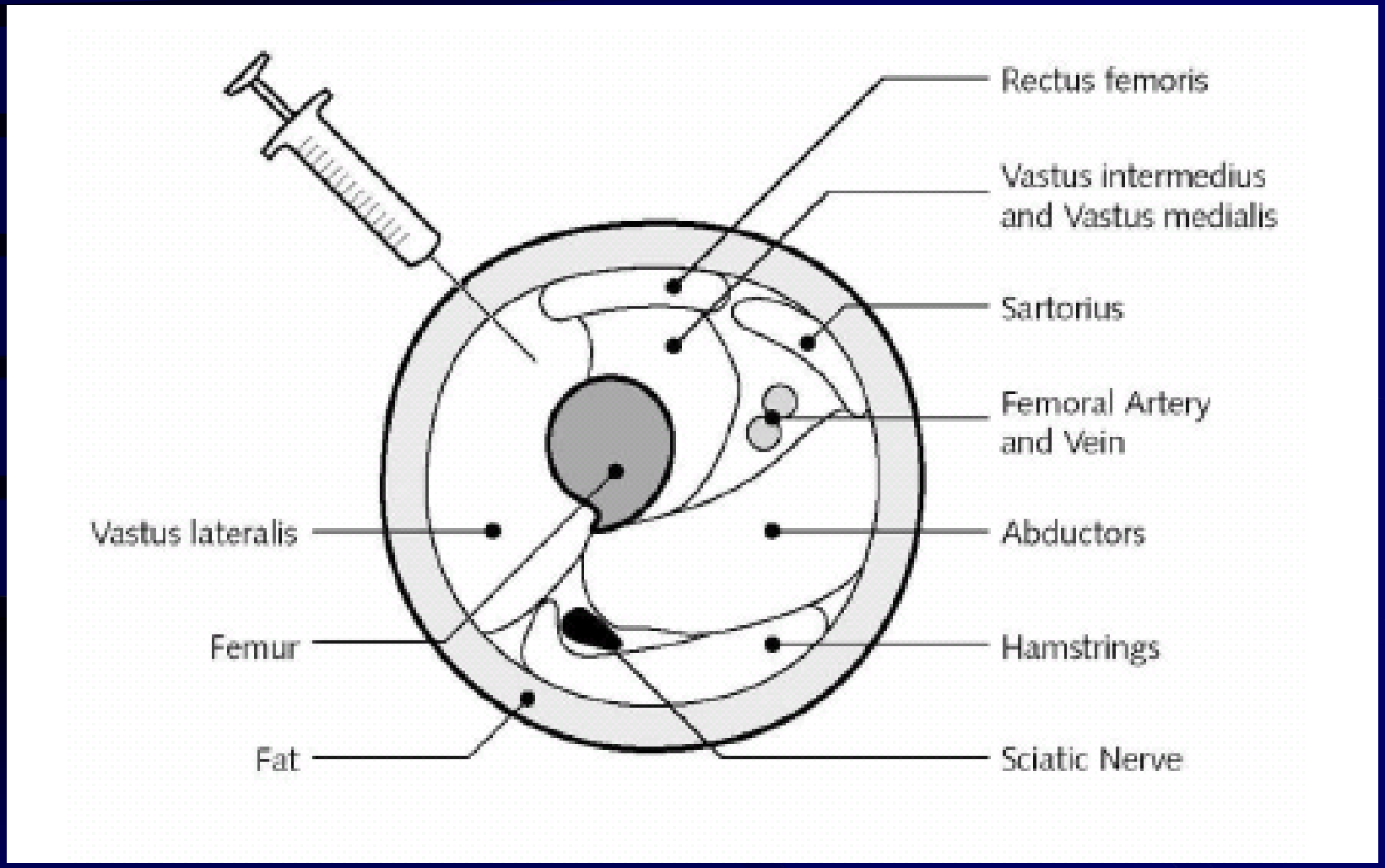
- IM injection to 2, 3, 4 month old infants
  Antero-lateral aspect of thigh
  Away from neurovascular bundle: femoral nerve, artery, vein

Antero-lateral thigh



Source: Diggle L. Injection technique for immunisation. *Practice Nurse* 2007; 33 (1).

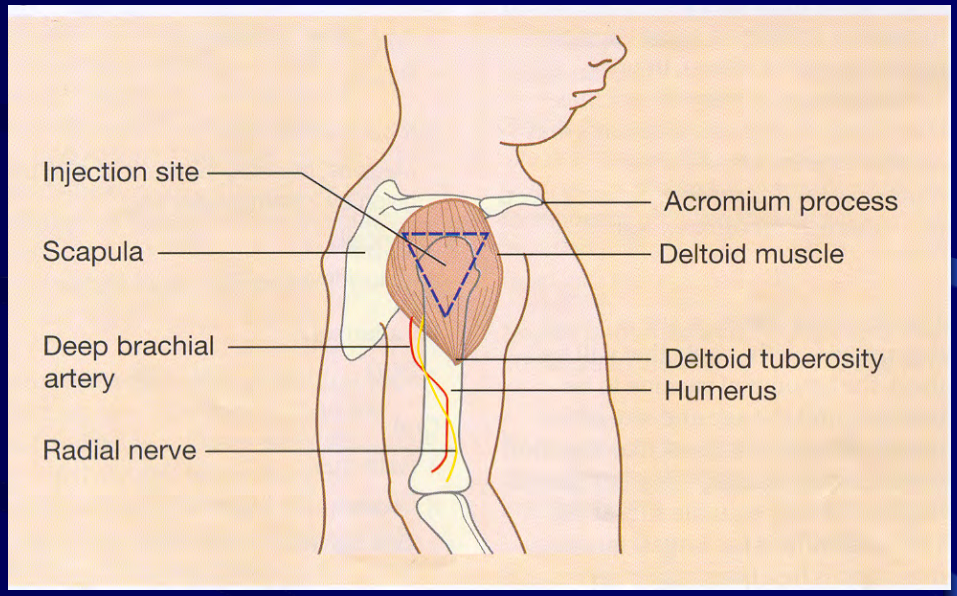
Cross-section of the left thigh



National Health and Medical Research Council (2003) The Australian Immunisation handbook (8th edition), Canberra, Australian Government Printing Service.

Site at age 12/13 months

- Usually thigh is used
- Deltoid is probably large enough for an IM injection after 12 months[1,2]
- WHO state 15 months[3]



1. Green Book - procedures chapter
2. 2003 Australian Immunisation Handbook
3. WHO 2005

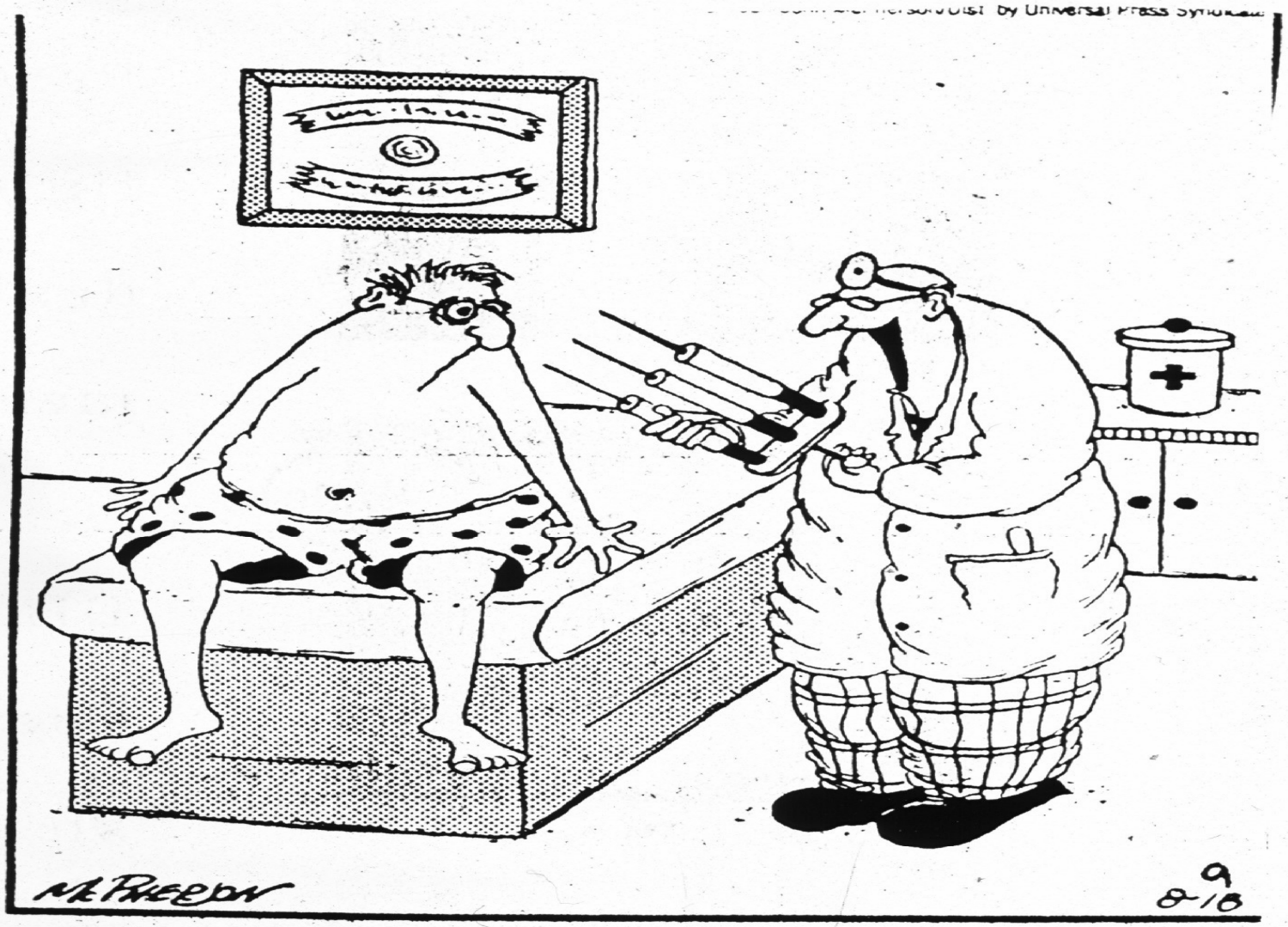
Source: Diggle L. Injection technique for immunisation. *Practice Nurse* 2007; 33 (1).

Why not use the buttock?

- Infants: sciatic nerve position variable
- Reduced immunogenicity of Hep B[1] & rabies[2] vaccines
- Adults: amount of S/C fat necessitates a needle >35mm (1½ inch)

1. MMWR (1985) Suboptimal response to hepatitis B vaccine given by injection into the buttock; 34:105-8,113.

2. Shill et al (1987) Fatal rabies encephalitis despite appropriate post-exposure prophylaxis: a case report. NEJM; 316:1257-8



"Fortunately, medical researchers have been able to combine tetanus, smallpox and rubella vaccinations into one shot."

Needle size for adults?

Men

- 25mm for deltoid (60-118 kg)

Women

- 25mm for deltoid (60-90kg)
- At least 38mm for weights over 90kg (>14 stone)

Poland, G. A., Borrud, A., Jacobson, R. M., Mcdermott, K., Wollan, P. C., Brakke, D. & Charboneau, J. W. (1997) Determination Of Deltoid Fat Pad Thickness: Implications For Needle Length In Adult Immunization. *JAMA*, 277 (21), 1709-11.

Needle size for infants?

- Needles vary in length & diameter
- Blue 25mm
- Orange 16mm
- Not known if this mattered

4 mnths of age: Blue 25mm needle gave less local reaction

Diggle L, Deeks J. Effect of needle length on incidence of local reactions to routine immunisation in infants aged 4 months:
BMJ 2000; 321: 931-933

Effect of needle length on incidence of local reactions to routine immunisation in infants aged 4 months: randomised controlled trial

Linda Diggle, Jonathan Deeks

Abstract

Objective To compare rates of local reactions associated with two needle sizes used to administer routine immunisations to infants.
Design Randomised controlled trial.
Setting Routine immunisation clinics in eight general practices in Buckinghamshire.
Participants Healthy infants attending for third primary immunisation due at 16 weeks of age: 119 infants were recruited, and 110 diary cards were analysed.
Interventions Immunisation with 25 gauge, 16 mm, orange hub needle or 23 gauge, 25 mm, blue hub needle.
Main outcome measures Parental recordings of redness, swelling, and tenderness for three days after immunisation.
Results Rate of redness with the longer needle was initially two thirds the rate with the smaller needle (relative risk 0.66 (95% confidence interval 0.45 to 0.99), P = 0.04), and by the third day this had decreased to a seventh (relative risk 0.13 (0.03 to 0.56), P = 0.0006). Rate of swelling with the longer needle was initially about a third that with the smaller needle (relative risk 0.39 (0.23 to 0.67), P = 0.0002), and this difference remained for all three days. Rates of tenderness were also lower with the longer needle throughout follow up, but not significantly (relative risk 0.60 (0.29 to 1.25), P = 0.17).
Conclusions Use of 25 mm needles significantly reduced rates of local reaction to routine infant immunisation. On average, for every five infants vaccinated, use of the longer needle instead of the shorter needle would prevent one infant from experiencing any local reaction. Vaccine manufacturers should review their policy of supplying the shorter needle in vaccine packs.

Introduction

As part of the UK childhood immunisation schedule, infants routinely receive diphtheria, pertussis, and tetanus (DPT) vaccine and *Haemophilus influenzae* type b (Hib) vaccine at 2, 3, and 4 months.[1] Nationally available guidelines advise practitioners to administer primary vaccines to infants by deep subcutaneous or intramuscular injection using either a 25 or 23 gauge needle but give no recommendation regarding needle length.[1] The question of optimum needle length for infant immunisation has not previously been addressed in Britain, despite calls from nurses for evidence on which to base immunisation practice. We conducted a randomised controlled trial of the two needle sizes currently used by UK practitioners to determine whether needle size affects the incidence of redness, swelling, and tenderness.

Participants and methods

Participants
Eight of 11 general practices approached in Buckinghamshire agreed to participate in the study. Practice nurses recruited healthy infants attending routine immunisation clinics. Parents received written information about the study when attending for the second primary vaccination and were asked if they wished to participate when they returned for the third vaccination. The only exclusion criteria were those normally applicable to a child receiving primary immunisations.[1]

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BMJ 2000;321:931–3

Unanswered questions

- Did the size of needle matter for local reactions at ages 2 & 3 months?
- Was it length or gauge that made the difference to local reaction incidence?
- Did the size of needle make a difference to protection ?

Source: World Health Organisation

BMJ, doi:10.1136/bmj.38906.704549.7C (published 4 August 2006)

RESEARCH

Effect of needle size on immunogenicity and reactogenicity of vaccines in infants: randomised controlled trial

Linda **Diggle** [1*], Jonathan J Deeks [2], Andrew J Pollard [1]

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[2] Department of Public Health and Epidemiology, University of Birmingham, Birmingham

[*] Correspondence to: linda.diggle@paediatrics.ox.ac.uk.

Objectives To assess the immunogenicity of vaccines for infants and to investigate whether the incidence of reactogenicity is reduced after each immunisation dose using needles of varying lengths and gauges.

Design Randomised controlled trial.

Setting 18 general practices within two UK primary care trusts.

Participants 696 healthy infants vaccinated at 2, 3, and 4 months of age, with follow-up to 5 months of age.

available at www.bmj.com

Comparison of 3 needle sizes

1. **Blue wide long needle**

   23G 25 mm (1-inch)
2. **Orange narrow short**

   25G 16 mm (5/8 inch)
3. **Orange narrow long**

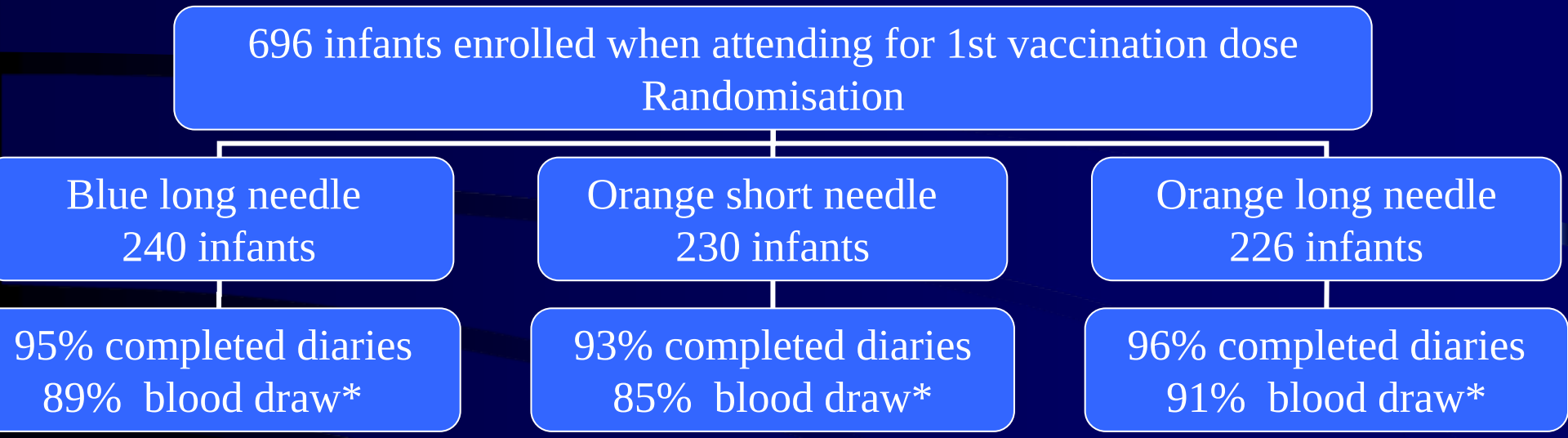
   25G 25 mm (1-inch)

Needle gauge diameters:

23G =0.6mm

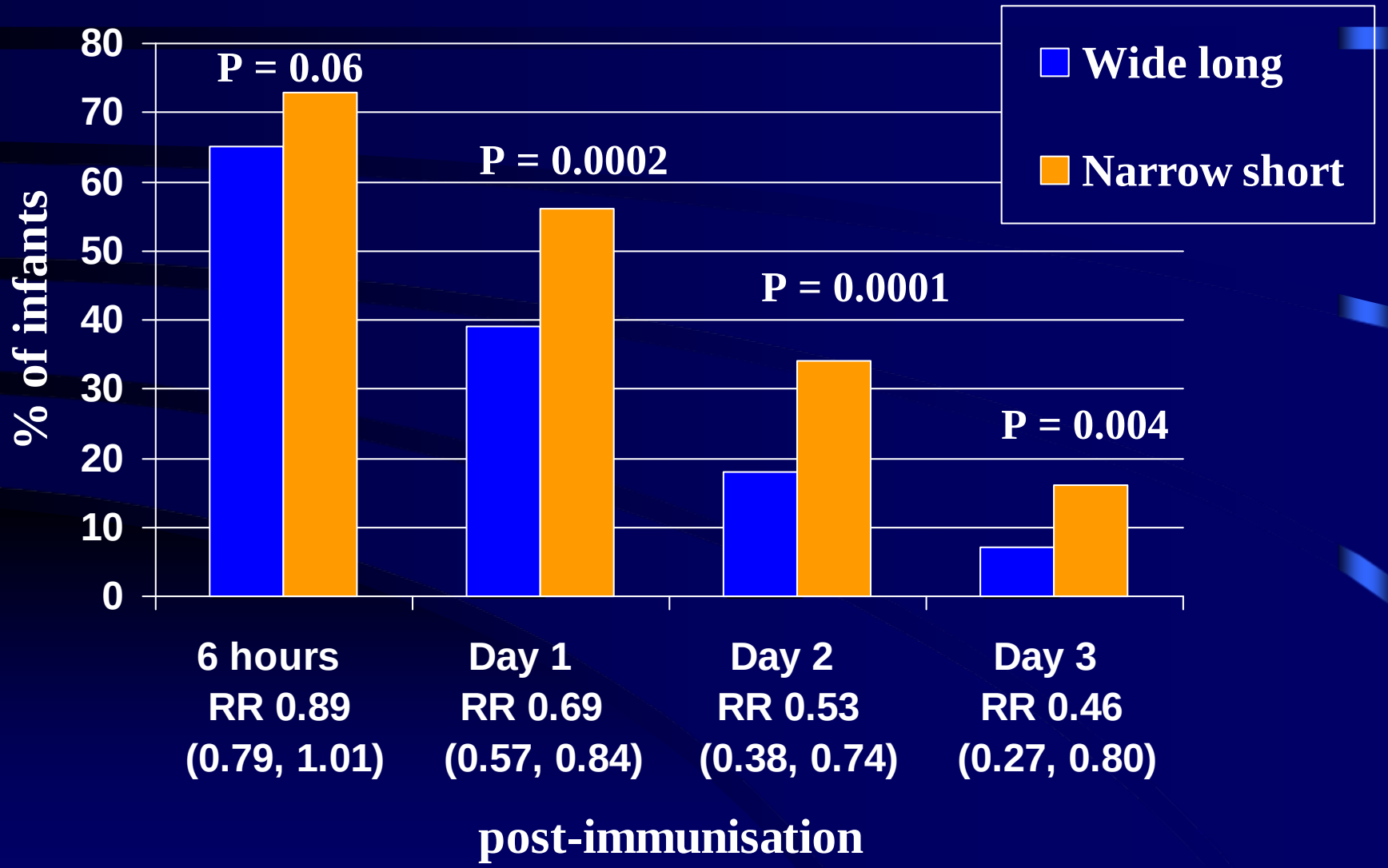
25G= 0.5mm

Study design

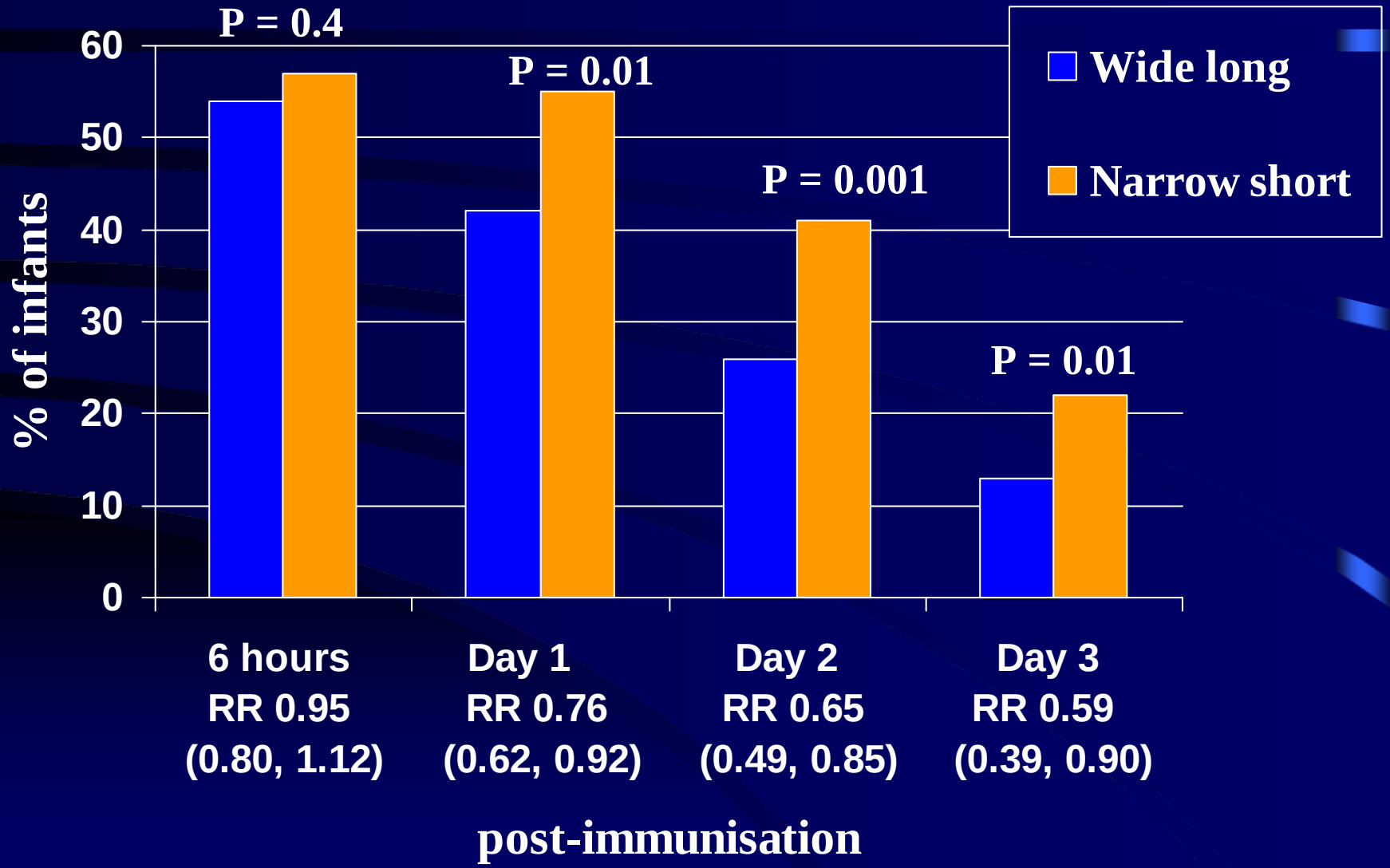


*Blood draw at 28-42 days after 3rd dose DPT/Hib and Men C

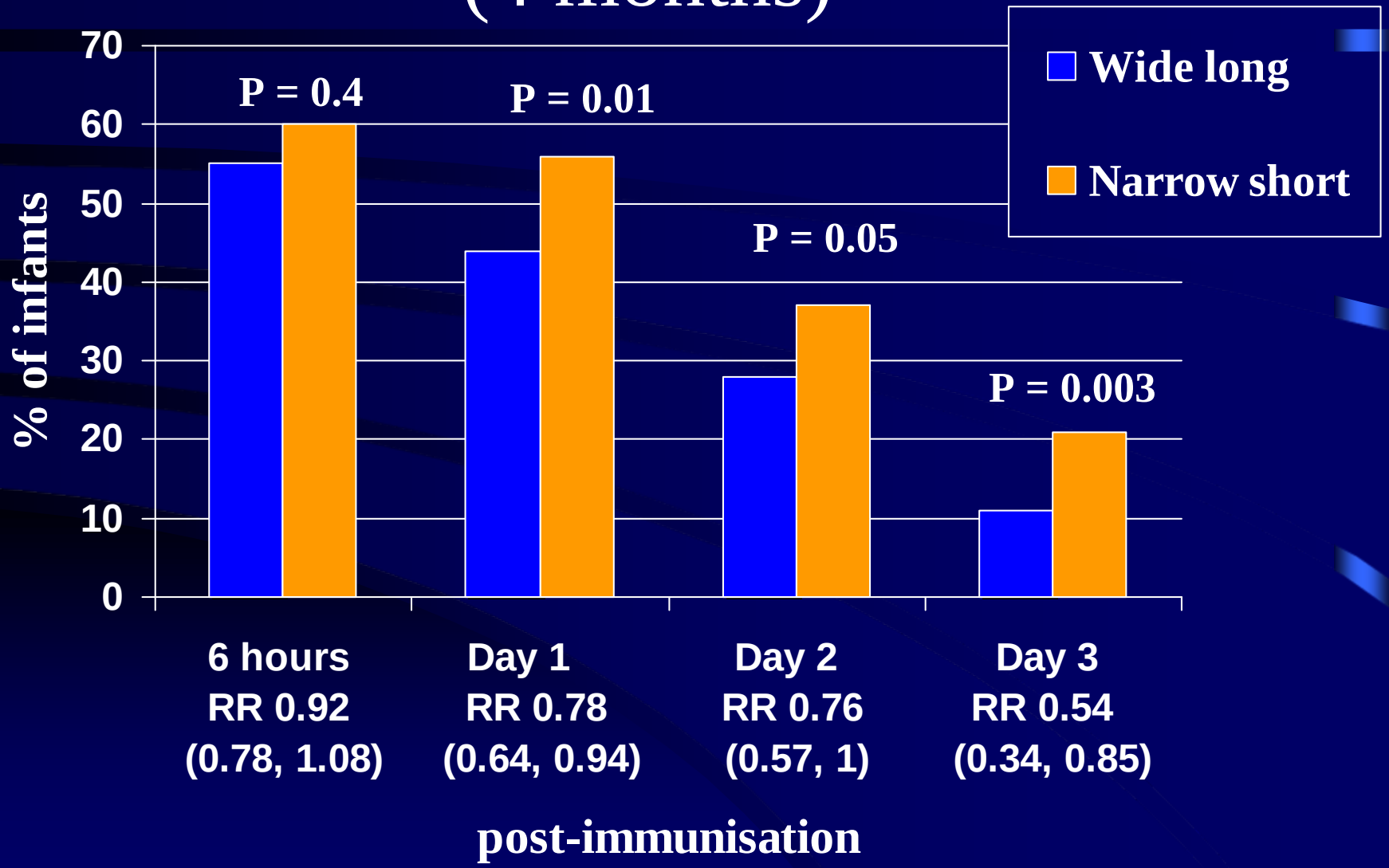
Any local reaction 1st dose DTwP/Hib (2 months)



Any local reaction 2nd dose (3 months)



Any local reaction 3rd dose (4 months)



Severity of reaction also less with longer needle

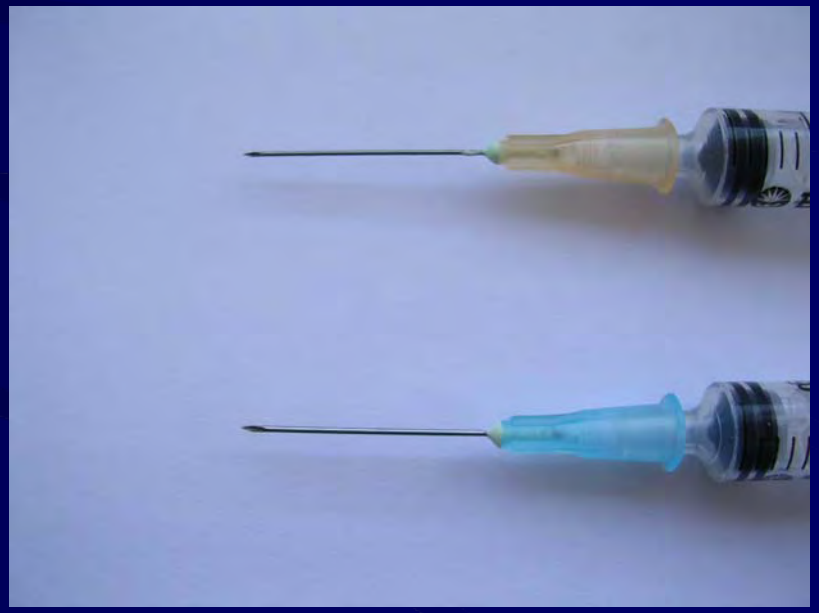
	Wide long (n=240)	Narrow short (n=230)	Narrow long (n=226)
Large local reaction contra-indicating receipt of further whole-cell pertussis containing vaccine*	1	**10**	0

$\chi 2 = 7.94$, *df* = 1, p=0.005

*As defined by Department of Health. *Immunisation against infectious diseases.* London: HMSO, 1996

Same length, different gauge?

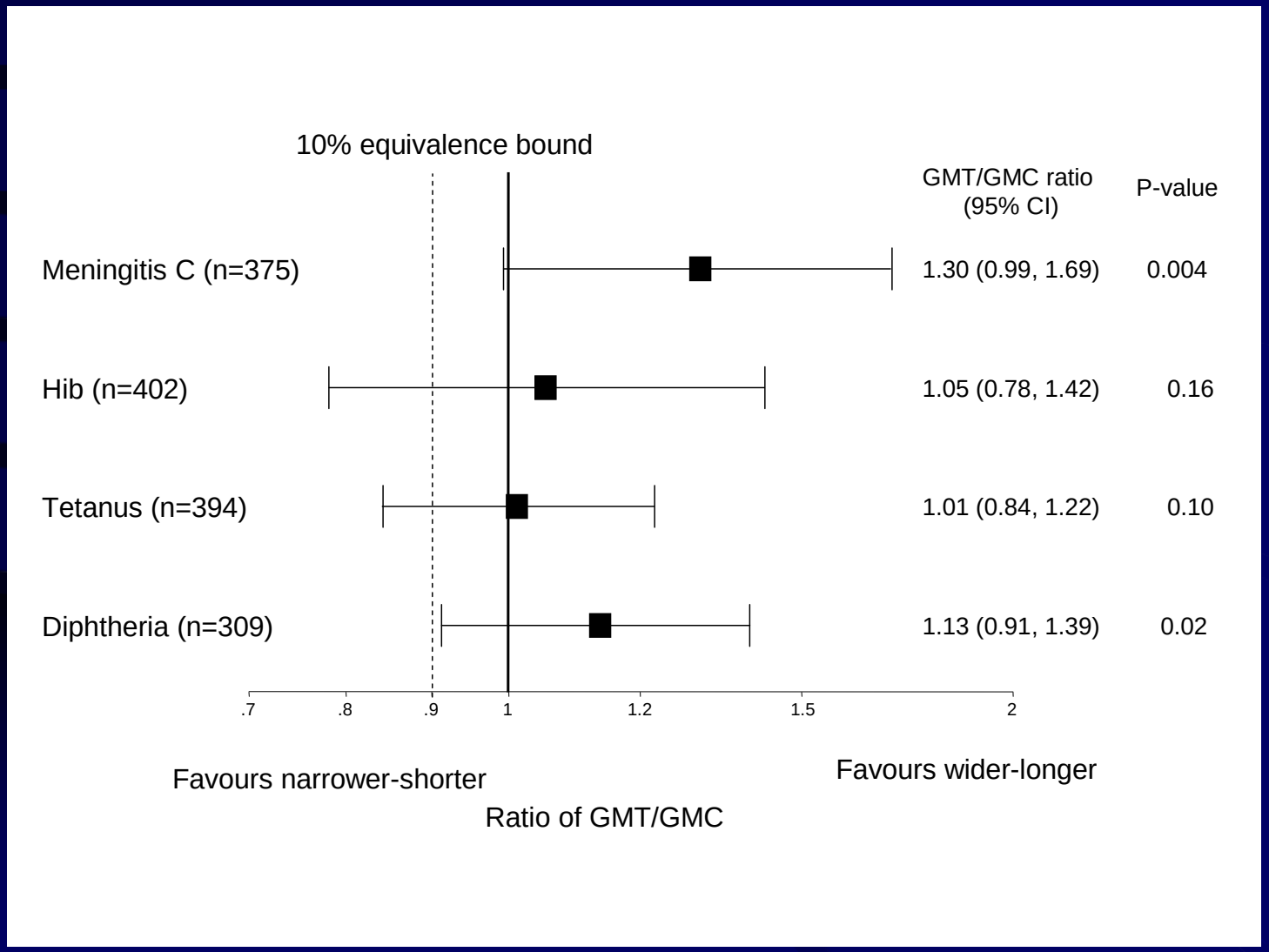
- There were no significant differences in incidence of local reactions



Did needle size affect protection?

- Do the vaccines work just as well with the blue long as with the orange short needle?
- If study again showed a reduction in local reactions with the blue long needle (but the vaccines worked just as well) - this would be sufficient to recommend the longer needle as best practice for infant immunisation

Blue 25mm works just as well as the shorter needle



Our research demonstrated that:

- Local reactions were less with longer (25mm) needle at 2, 3, 4 months
- Needle gauge made no difference to reaction rates
- Evidence favoured longer needle achieving comparable, if not, superior immunogenicity
- No evidence to indicate results would be any different for other vaccines
- For best practice - use 25mm needle for term infants
- Use clinical judgement for prems/LBW infants

Needle length: 4 to 6 yrs

- US study of 1315 children aged 4-6yrs (5th dose DTaP)
- Prospective assessment deltoid injection
- 25mm needle (793 children)
- 16mm needle (381 children)
- Not randomly assigned to needle size but analyses adjusted for BMI
- Higher risk of redness & pain with shorter needle

Jackson et al (2008) Prospective assessment of the effect of needle length & injection site on the risk of local reactions to the fifth DTaP vaccination. Pediatrics, 121, e646-52.

Two injections into one leg

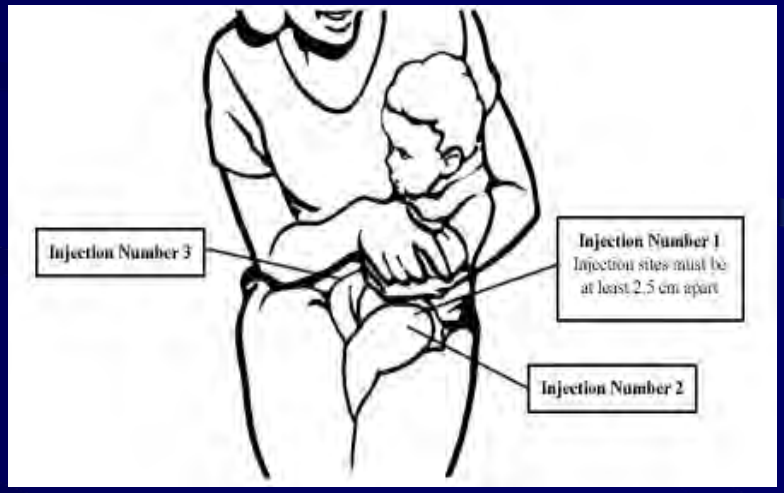
- Common practice in US[1]
- Infant A/L thigh can accommodate two IM injections
- Need to be at least 2.5cms (1 inch) apart so that reactions don't overlap[2]
- Be consistent/record which one went where

Demo at www.prevenar.co.uk

1. American Academy of Paediatrics 26th ed. 2003,
2. Dept of Health, Immunisation procedures chapter

Three injections to infants?

1. Pediacel in left A/L thigh
2. Men C in left A/L thigh (2.5cm away)
3. Prevenar in right thigh



NHMRC 2003 Australian Immunisation Handbook

Assessment Tool for Immunisation

This document can be used as a self-assessment tool for practitioners who administer immunisations. To complete it, review the competency areas below and the clinical skills, techniques and procedures outlined for each of them. Score yourself in the Self-Assessment column. If you tick **Need to Improve** you indicate further study, practice or change is needed. When you tick **Meets or Exceeds** you indicate you believe you are performing at the expected level of competence, or higher. Mentors: Use this checklist to clarify responsibilities and expectations for those who administer vaccines. Next observe their performance as they provide immunisations to several patients and provide a score in the Mentor Review columns. If improvement is needed, help the immuniser to develop a Plan of Action that will help them achieve the level of competence you expect; circle desired actions or write in others. When all competency areas meet expectations, mentors should take a copy of this document for their records; immunisers should keep this document within their PREP/CPD folder.

		Self-Assessment				Mentor Review				
Competency	**Clinical Skills, Techniques and Procedures**	Need to Improve		Meets or Exceeds		Need to Improve		Meets or Exceeds		Plan of Action
A Patient/parent education	1. Welcome patient/family, establish rapport									
	2. Check patients records, confirming with patient/parent to ascertain previous immunisation history. Verify appropriate point on the childhood schedule, if appropriate.									
	3. Explain what vaccines are to be given today, inform of any expected adverse effects answer any questions referring to DoH leaflets to aid explanations/discussion as appropriate									
	4. Use language appropriate leaflets/interpreter as appropriate to ensure patient/parent informed.									
	5. Ensure you are conforming to applicable patient group direction/prescription and be aware of scope and limitations of PGD's. For infants, ensure 8 week check has been performed.									
	6. Ensure informed consent is obtained prior to vaccination and be aware of issues applicable to competence and age of patient									
	7. Screen for contraindications (referring to Green Book chapters as appropriate)									
	8. Know who to contact for advice if unsure about vaccination schedules, spacing or compatibility of vaccines									
B Medical Protocols	1. Ensure anaphylaxis equipment is readily available.									
	2. Be aware of appropriate dosage, how to administer & when to use it									
	3. Maintain up to date basic life support skills (mandatory yearly).									
	4. Be aware of protocol to follow in case of needlestick injury									
	5. In case of an adverse incident during vaccination procedure (eg. Cold chain error, needle-stick injury), be aware of incident reporting procedure as per local protocol.									
C Vaccine preparation	1. Demonstrate an understanding of the rationale for maintaining the cold chain of a vaccine, state the correct temperature range for vaccine storage and explain the system you are using to monitor the vaccine fridge									
	2. Be familiar with local protocols for cold chain audit and action to be taken in case of cold chain failure.									
	3. Demonstrate knowledge of proper vaccine handling, eg. protection of vaccine from light.									
	4. Prior to reconstitution of vaccine, check vaccine and expiry dates.									
	5. Wash hands and correctly reconstitute vaccine as appropriate, ensuring vaccine diluent and lyophilized powder are fully mixed in vial.									
	6. Ensure informed consent is obtained prior to vaccination.									
	7. Select correct needle size according to the evidence base									

Parental demeanour

- Parental demeanour significantly influences the amount of pain & distress children experience
- Excessive parental reassurance, criticism, apology, giving control to the child were associated with increased child distress
- Humour, distraction, matter of fact, supportive non-apologetic approach tends to decrease distress

Schechter et al, Pain Reduction During Pediatric Immunizations: Evidence-Based Review and Recommendations Pediatrics 2007;119;e1184-e1198

In summary

- No need to warm, cleanse or aspirate
- Speedily is best for IM injection delivery
- Most immunisations should be IM
- Antero-lateral thigh for infants
- May use deltoid >1yr
- Use 25mm needle for infant thigh, pre-school deltoid
- At least 25mm for adult deltoid
- Parental demeanour significantly reduces child’s distress
- Practice should be evidence based

'And here's a lollipop for being so brave'

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