



Review

Vaccine injection technique and reactogenicity—Evidence for practice

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ABSTRACT

There are inconsistencies in recommendations and practice with regards to how best to administer vaccines. This review evaluates the literature on intramuscular vaccine administration technique in primarily paediatric populations and concludes from available evidence which aspects of vaccine administration are associated with reactogenicity. Variables with best evidence to support practice to reduce reactogenicity were: Site of injection – less reactogenicity has been noted when the buttock is used rather than the thigh; tissue (muscle or subcutaneous) – less reactions are noted when vaccine is administered intramuscularly rather than subcutaneously; length of needle – longer needles are associated with less reactogenicity. Angle of injection—a 90° angle is associated with less reactogenicity than a reduced angle. Despite a need for more empirical studies, there appears to be several vaccine administration techniques relating to needle angle, length, site and depth of injection that result in fewer reactions and these could be considered for public health policy, in conjunction with immunogenicity.

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1. Background

Pain on injection and common reactions such as post vaccination local pain and inflammation are generally expected and considered an acceptable, albeit unpleasant, part of the immunisation process. Clinical trials of vaccines often report differing rates of reactogenicity for the same vaccine. Other than assumed variations in the population under study there does not appear to be any literature addressing the factors influencing these results.

Prior to 2002 there were almost no published studies investigating the optimal technique for delivering intramuscular injections. This has led to inconsistencies in recommendations and practice as well as disagreements as to how vaccines should best be administered [1]. Current recommendations are still based almost exclusively on expert nursing opinion and commentary with a virtual absence of randomised controlled trials for many of the variables in injection technique, needle size and site [1,2].

Although there is some evidence that aspects of injection technique are important including needle length, choice of site and angle, a 1996 review of 83 vaccine studies reported that of those using intramuscular technique only 24% reported the needle length used, 59% reported anatomical site and only 10% reported the injection technique used [3].

Current techniques from several countries and agencies are summarised in Table 1, illustrating the wide variation in recommendations.

2. Objectives

The objectives of this review were to:

- Review and summarise literature on intramuscular vaccine administration technique.
- Discuss the literature that considers vaccine administration technique and reactogenicity.
- Present and discuss the variables and different approaches to administering vaccines intramuscularly.
- Conclude from available literature which aspects of vaccine administration are associated with lower reactogenicity.

3. Method

A review of vaccine clinical trials and studies reporting on injection technique and reactogenicity was conducted as part of a larger study. Databases searched included:

- Cochrane Database of Systematic Reviews (CDSR).
- Medline 1966 to May 2007.
- Embase 1980 to May 2007.

The terms searched under were: vaccin*, immuni*ation, intramuscular, injections technique, reactogenicity, adverse reactions.

Additional studies were identified by hand searching the reference lists of retrieved papers.

Papers not published in English and not relating to humans, were excluded.

4. Results

4.1. Intramuscular vs. subcutaneous

Although the majority of guidelines and articles about intramuscular injection state inadvertent administration into subcutaneous tissue is undesirable as it risks more frequent and more serious local

adverse reactions, there are few studies that look directly at the rate of reactions in subcutaneous compared with intramuscular administration and reference is usually made to other guidelines [4]. It is no doubt important to administer vaccines according to the manufacturer's instructions as these will reflect the methods used in the clinical trials, not to do so could compromise immunogenicity.

Existing data comparing subcutaneous administration with intramuscular administration, as per the WHO technique, suggests reactogenicity is increased when the subcutaneous route is used [5–8]. See Table 2. It is also worth noting that some reactions such as erythema and induration may be less clinically visible with intramuscular delivery for anatomical reasons.

5. Site of injection

5.1.1. Overview

Most recommendations for intramuscular injection involve the deltoid (for over 12–15 months) and the thigh in younger infants. Some vaccinators prefer to use the buttock believing it results in lower reactogenicity. The origin of the recommendation to avoid the buttock region appears to originate from a 1961 case series of post injection sciatic palsy in infants and children. Penicillin and tetracycline were directly implicated. The authors suggested the buttock be abandoned as a site of injection in infants and children [9].

5.1.2. Buttock

It appears the reasons for avoiding this site originates in a few case reports and expert opinion including the contention that infants' gluteal area is composed mainly of fat, therefore vaccination into this site would result in administration into subcutaneous tissue and hence increased reactogenicity [10,11]. In contrast to this several studies have shown that immunisation in the buttock may result in lower local reactogenicity, notably pain and swelling [12–15]. There are no studies indicating an increase in reactogenicity when using the buttock compared with other sites (see Table 3). An ultrasonic study comparing the tissue composition of the ventrogluteal area with the thigh in children aged 2, 4, 6 and 18 months of age found that the ventrogluteal area is well muscled with a comparable subcutaneous layer to the thigh in terms of thickness suggesting there is no greater risk of administering into subcutaneous tissue [11].

The studies comparing buttock and thigh as sites for intramuscular injection of vaccine consistently show that vaccine administration into the buttock results in reduced local and systemic reactogenicity. It is important however to consider potential decreases in immunogenicity compared with other sites [15].

5.1.3. Deltoid and thigh

Generally after 12 months of age, recommendations for injection site move from the thigh to the deltoid. One study which has looked at reactogenicity between the deltoid and thigh in 18-month-old children found fewer local reactions when the deltoid was used and no significant difference in systemic reactions [16].

5.2. Length of needle

Studies using ultrasound have been conducted to determine the length of needle required to penetrate muscle [17].

The optimal needle length depends on the technique being used. Angle of injection impacts on the depth of penetration and unless a longer needle is used there is a risk of not administering the vaccine

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