

**EVIDENCE BASED GUIDELINES**  
**FOR**  
**VACCINATION PRACTICE**

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## **DECLARATION**

I hereby certify that the work embodied in this thesis is the result of original research and except for the work on the ventrogluteal site (dimensions and tissue composition) and the whole cell pertussis vaccine site comparative study which were submitted for a Masters in Family Medicine (Monash) 1998, has not been submitted for a higher degree to any other Institution.

Ian Cook

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Finally, I wish to thank the patients, and parents of patients, who took part in the thesis studies, their willingness to undertake ultrasonography, blood testing and to present for analysis of vaccine adverse effects has allowed for valid conclusions to be drawn from clinical studies.

## SUMMARY

Vaccination programs have been so successful that concerns about sequelae of vaccine preventable disease have been replaced by concerns about the safety of vaccines. This context mandates the development and use of the best vaccines and the best vaccination practice (site and route of administration of vaccines).

Evidence based medicine has been championed as a way of improving the quality of medical care.

Assessment of vaccination guidelines from twelve countries, nine states/provinces and two counties reveals that recommendations for vaccination practice are largely based on expert opinion.

In this thesis, clinical studies are presented on:

- The preferred route for administration of vaccines (intramuscular or subcutaneous).
- The needle length required for intramuscular injection.
- The technique for intramuscular injection of vaccines.
- The site for intramuscular injection of vaccines

These studies have resulted in the following publications in refereed journals:

1. Cook IF, Barr I, Hartel G, Pond D, Hampson AW. Reactogenicity and immunogenicity of an inactivated influenza vaccine administered by

- intramuscular or subcutaneous injection in elderly adults. *Vaccine* 2006; 24: 2395-402.
2. Cook IF, Pond D, Hartel G. Comparative reactogenicity and immunogenicity of 23 valent pneumococcal vaccine administered by intramuscular or subcutaneous injection in elderly adults. *Vaccine* 2007; 25: 4767-74.
  3. Cook IF. Evidence based route of administration of vaccines. *Human Vaccines* 2008; 4: 67-73.
  4. Cook IF. Sexual dimorphism of humoral immunity with human vaccines. *Vaccine* 2008; 26: 3551-5.
  5. Cook IF, Murtagh J. Needle length required for intramuscular vaccination of infants and toddlers: an ultrasonographic study. *Aust Fam Phys* 2002; 3: 295-7.
  6. Cook IF, Murtagh J. Paediatric vaccination practice in a division of general practice. *Aust Fam Phys* 2001; 30: 1185-9.
  7. Cook IF, Murtagh J. Ventrogluteal area – a suitable site for intramuscular vaccination of infants and toddlers. *Vaccine* 2006; 24: 2403-8.
  8. Cook IF, Williamson M, Pond D. Definition of needle length required for intramuscular deltoid injection in elderly adults: an ultrasonographic study. *Vaccine* 2006; 24: 937-40.
  9. Cook IF, Murtagh J. Optimal technique for intramuscular injection of infants and toddlers: a randomised trial. *Med J Aust* 2005; 183: 60-3.
  10. Cook IF, Murtagh J. Comparative immunogenicity of hepatitis B vaccine administered into the ventrogluteal area and anterolateral thigh in infants. *J Paediatr Child Health* 2002; 38: 393-6.

11. Cook IF, Murtagh J. Comparative reactogenicity and parental acceptability of pertussis vaccines administered into the ventrogluteal area and anterolateral thigh in children aged 2, 4, 6 and 18 months. *Vaccine* 2003; 21: 3330-4.
12. Cook IF. Sex differences in injection site reactions with human vaccines. *Human Vaccines* 2009; 5: 1-9.

These studies allow evidence based guidelines to be formulated for vaccination practice which should help to maintain public confidence in vaccination programs by minimizing the adverse reactions of vaccines whilst maintaining their efficacy.

It is noteworthy in this context that some recommendations made in this thesis have been translated into Australian Government policy in the 9<sup>th</sup> edition of “The Australian Immunisation Handbook” 2008, albeit a long time after their publication.

This work also raises questions about contemporary clinical practice and identifies sex as a determinant of immune response and adverse reaction with some vaccines. Further studies in the area of vaccination practice and sex-difference in immune response to vaccines are suggested.