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COMMENTARY

Minimizing shoulder injury related to vaccine administration

Ian F. Cook

School of Public Health and Medicine, University of Newcastle, Callaghan, Australia

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Shoulder injury related to vaccine administration[1] is generally mild and transient with medically attended events being uncommon, most often reported by the vaccine recipient.

Medically attended events range from any condition for which medical attention is sought and include serious events such as those associated with persistent disability, hospitalization and death. These can be divided into three groups;[1] nerve palsies (radial and anterior branch of the axillary nerve); musculoskeletal injuries (bone, articular injury, subacromial/subdeltoid bursitis, and rotator cuff tendinopathy) and cutaneous reactions (subcutaneous nodules, localized lipoatrophy, sterile abscess, local sepsis – cellulitis, abscess, and pyomyositis, infectious subcutaneous emphysema and embolia cutis medicamentosa – Nicolau syndrome). A musculoskeletal syndrome termed SIRVA (Shoulder Injury Related to Vaccine Administration) characterized by the rapid onset of shoulder pain and persisting dysfunction after deltoid muscle vaccination has been reported.[2] This is considered[2] to be an immune-mediated inflammatory reaction resulting in bursitis, tendonitis and adhesive capsulitis. However, the National Vaccine Injury Compensation Program[3] now considers that this syndrome results from "improper – that is, negligent – administration technique".

Mandatory evidence-based guidelines (EB) are required to be propagated by National Immunization Technical Advisory Groups (NITAGs) to minimize these injuries and maintain public confidence in COVID-19 vaccination programs. Evidence-based medicine (EBM) has provided strong recommendation[4] for selection of deltoid injection site,[5] needle length,[6] route[7] and technique of injection[8] and aspiration before injection.[9]

However, clinical equipoise,[10] defined as "genuine uncertainty in the expert medical community about the preferred treatment" exists for skin disinfection prior to injection and the gauge of needle to be used for intramuscular injection in adults.

There is no consensus on skin disinfection prior to vaccine administration among NITAGs.[11] In Australia, an ex-cathedra statement by Del Mar et al.[12] based on tangential data not involving intramuscular injection of vaccines resulted in the recommended cessation of this practice. A similar recommendation was made in Canada as a consequence of an underpowered study[13] with multiple different vaccines, with different routes of administration, using injection site reaction (ISR) as a surrogate measure of infection.

However, a case for skin disinfection prior to vaccine administration can be made. Sherman et al.[14] reported that 70% isopropyl alcohol swabbing prior to ultrasound guided musculoskeletal injection reduced skin flora contamination by 95%. In their study of 26 patients, 21 were culture positive before swabbing and only 1 remained culture positive after swabbing. Moreover, it has been postulated[12] that a 66% reduction in skin flora with 70% Isopropyl alcohol swabbing would be cost-effective in the prevention of vaccine-related cellulitis occurring at a rate of 1 per 2363 injections. Consequently, it may be difficult to defend a case of skin sepsis if skin disinfection was omitted prior to vaccine administration.[15]

Uncertainty also exists for the gauge of needle to be used in adult vaccination, 23 or 25 gauge. The skin has horizontal neural plexuses at the dermato-epidural junction[16] and its penetration at the different angles (IM injection at 90°, SC injection at 45°) may account for the greater pain immediately after SC compared with IM injection of anthrax vaccine.[17] This can be explained on the basis of the longer tract $\sqrt{2}$ through the neural plexus with SC injection (45°) compared with IM injection at 90°. Consistent with this mechanism of injection pain, narrower gauge needles have been shown[1819] to significantly reduce pain during injection compared with wider gauge needles.

Consequently, a 25-gauge, 25-mm long needle should be favored over a 23-gauge, 25-mm long needle for vaccine administration in adults.

There are limited pediatric data on needle gauge for intramuscular vaccine administration. In a study of infants aged 2, 3, and 4 months, Diggle et al[20] reported slightly lower rates of ISRs with 25-gauge, 25-mm needles compared with 23-gauge, 25-mm long needles. However, Pathak et al.[20] reported higher pain scores (7.3 points) for 25-gauge, 25-mm long needles compared with 23-gauge, 25-mm long needles in children up to 24 months old. The latter study did not specify the site of injection and independent review[21] noted that "differences of less than 10 points on the 100 mm VAS may not be clinically significant".

Strict formulation of vaccine administration practice will prevent inadvertent misadministration of COVID-19 vaccine as reported by Ng.[22] An evidence-based protocol for vaccine administration is:

(A) Skin disinfection with 70% isopropyl alcohol swabbing.

CONTACT Ian F. Cook drifcook@bigpond.com School of Public Health and Medicine, University of Newcastle, University Avenue, Callaghan, New South Wales 2308, Australia

(B) Selection of the deltoid injection site as the mid-point of the deltoid muscle (between the acromion and deltoid tuberosity) with the arm abducted by placing the hand on the hip.
(C) Vaccine administration with a 25-gauge, 25-mm long needle at 90° to the skin surface of the deltoid muscle.

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No potential conflicts of interest were disclosed.

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