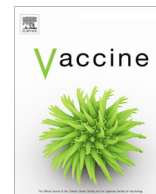


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Immunizations under sedation at a paediatric hospital in Melbourne, Australia from 2012–2016

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ABSTRACT

Background: Sedation for immunizations is of particular importance in a subset of paediatric patients with anxiety disorders, needle phobia, developmental or behavioural disorders. The Royal Children's Hospital (RCH) Melbourne offers a unique *immunization under sedation* service for these patients. We aimed to evaluate the number and types of patients using inpatient sedation for immunizations, distraction and sedation techniques used, and outcomes of these procedures.

Methods: A medical record review was conducted on all patients who had immunization under sedation between January 2012 to December 2016 in the RCH Day Medical Unit (DMU).

Results: A total of 139 children and adolescents had 213 vaccination encounters. More than half of the vaccination encounters involved multiple vaccines. A total of 400 vaccines were administered. One third of patients (32.3%) had multiple DMU admissions for vaccinations. The median age of patients was 13 years. There were only 10 (4.7%) failed attempts at vaccination; all due to patient non-compliance with prescribed sedation. The majority of patients (58.9%) had a diagnosis of needle phobia.

Sedation was most commonly adequately achieved with inhaled nitrous oxide (54.7% sole agent). Midazolam was often used as an adjunct therapy (42.8%). Local anaesthetic cream or play therapy, were used in only 5.9% and 3.9% of patients respectively, although this may reflect poor documentation rather than actual practice.

Conclusions: For a subset of paediatric patients for which standard immunization procedures have failed, distraction techniques and conscious sedation enable immunizations to be given safely and effectively. Future research will develop protocols to streamline immunization procedures under sedation.

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1. Introduction

Pain and anxiety associated with vaccine administration can be a source of distress for children and their families. If not addressed, this can sometimes lead to long-term consequences such as needle phobia, which may contribute to health care avoidance and therefore impact on the success of immunization programs [1]. Both pharmacological and non-pharmacological techniques and

strategies to reduce pain and anxiety have been trialled and employed in a wide range of age groups with varying success [2].

Existing research has focused predominantly on infants and young children [2]. Parental and child information on preparation as well as positioning in the upright position are well-established techniques to minimize pain and anxiety [3]. The use of distraction and coping strategies including play/music therapy, technology devices and vibrational instruments have mixed results, although have been generally beneficial [4–8]. Swaddling techniques and oral sucrose solutions have also been shown to be effective in infants [9].

Likewise, there is varying success surrounding the use of vapocoolant sprays (eg. ethyl chloride), with recent studies showing only minimal benefit in reducing pain and anxiety [10]. Topical anaesthetic creams, such as Eutectic Mixture of Local Anaesthetics (EMLA[®]) or amethocaine (AnGel[®]), have been shown to be easy

Abbreviations: EMLA[®], eutectic mixture of local anesthetics; N₂O, nitrous oxide; ASD, autism spectrum disorder; NIP, National Immunization Program; DMU, Day Medical Unit; RCH, Royal Children's Hospital Melbourne; EMR, electronic medical record; ADHD, attention deficit hyperactivity disorder.

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to use and efficacious in pain reduction [2,11], however its usefulness is limited by the significant time required to produce dermal anaesthesia.

There is currently no data on the use of conscious sedation agents in paediatric immunizations [2]. However one agent, nitrous oxide (N₂O) is optimally suited for this purpose. N₂O provides fast onset, fast offset, conscious sedation as well as anxiolytic, amnesic and analgesic properties, and is used routinely in paediatric emergency departments for fracture manipulation and minor surgical procedures [12,13]. N₂O when inhaled at concentrations below 50% maintains protective reflexes and does not require fasting or post procedure monitoring. A combination of 50% N₂O in combination with EMLA[®] anaesthetic cream has been shown to be superior to either monotherapy for pain reduction in intramuscular injections and venous cannulation [11,14].

Oral midazolam is also used for conscious sedation and has anxiolytic and amnesic but no analgesic properties. Its maximal effect is within 15–20 min; however it can last for up to two hours. Midazolam has been shown to be effective for conscious sedation and to control anxiety in children undergoing dental treatment, especially in combination with N₂O [15]. However, Luhmann et al. have shown that N₂O is more effective than oral midazolam in reducing distress, adverse effects and recovery times when used for repair of lacerations in young children presenting to an emergency department [16].

Sedation for immunizations is of particular importance in a subset of paediatric patients with anxiety disorders, needle phobia, developmental or behavioural disorders (such as autism spectrum disorder (ASD)). Children and adolescents with extreme anxiety or needle phobia may miss/avoid or refuse immunizations due to fear of the procedure. Attempting to vaccinate children with extreme developmental or behavioural disorders may trigger physical aggression, combative or distressed behaviour that particularly in older children and adolescents, may endanger themselves, their families or immunization providers.

Children refusing to be vaccinated or exhibiting difficult/endangering behaviours is often juxtaposed against a strong parental desire for their child to complete their vaccination schedule, as well as recent Australian legislation known as “No Jab No Pay”, which restricts access to financial welfare incentives for families if their child has not completed their vaccine schedule as per the National Immunization Program (NIP) [17]. Within this legislation, there is currently no specific exemption for children who are unable to be immunized unless sedated. Having failed to have vaccinations in general practice, school or local council healthcare settings, these patients either remain unvaccinated or have to wait for opportunistic immunization during a general anaesthetic for an unrelated procedure.

The immunization service at the Royal Children’s Hospital Melbourne, Australia (RCH) has developed a unique service to the aforementioned subset of paediatric patients. Children and adolescents who have had confirmed via phone discussion, that they have failed immunization in the community using standard distraction and minimally invasive techniques, are then booked to be seen by an Immunization Paediatrician and admitted as day patients to the Day Medical Unit (DMU), where they receive their immunizations in conjunction with a combination of distraction and sedation. These methods aim to address the anxiety surrounding the immunization process. Most importantly, they are relatively easy to use and can be titrated and administered by qualified medical or nursing staff. They are fast acting and their effects wear off relatively quickly – ensuring minimal adverse outcome and facilitating same day discharge.

This review aimed to evaluate the RCH immunization under sedation service, including the number and types of patients using

inpatient sedation for immunizations, the distraction and sedation techniques used and outcomes of these procedures.

2. Patients and methods

Patients are able to access the RCH immunization under sedation service after being referred by a primary care provider or paediatrician. Prior to booking a clinic appointment, an immunisation nurse has a phone discussion with the child’s parent/guardian. Details of previous failed immunisation attempts in the community are obtained and information on the distraction/sedation options are provided. Additionally, parents/guardians are emailed a comprehensive preparation package (www.mvec.vic.edu.au/immunisation-references/needle-phobia/) on the available options for distraction including play therapy and sedation medications. If the family are keen to attend and immunisation nurse confirm that the child is suitable, a clinic appointment is arranged. The immunization specialist takes a thorough medical and immunisation history, the risks and benefits of distraction/sedation procedures are explained and an individualised immunization under sedation plan is written. Children of any age and with/without underlying medical conditions may be referred. There are no specific age or underlying medical conditions for referral to this clinic, however sedation is contraindicated in patient’s less than 2 years of age (due to risk of airway obstruction). Patients with pre-existing co-morbidities were not treated any differently from other patients unless there were specific contraindications to sedation techniques (eg. Previous reactions to midazolam and/or Nitrous oxide).

At RCH, there is an organisational policy for procedural sedation relevant to ambulatory areas [19]; and whilst not specific to immunisation, does provide a structured and standardised approach for the delivery of procedural sedation. Nitrous oxide is the first-line agent of choice in the majority of cases (titrated to a maximum percentage of 70% as required with a minimum oxygen percentage of 30%). Quick recovery after nitrous oxide use is induced with the inhalation of 100% oxygen at the conclusion of the immunization procedure. Other adjunctive therapies including oral midazolam (0.3–0.5 mg/kg per dose, maximum of 20 mg) and play or distraction therapy are added as needed.

A medical record review was conducted on all patients who had immunization under sedation in the RCH Day Medical Unit between January 2012 to December 2016. Data was collected from scanned medical records and the integrated Electronic Medical Record (EMR) system. De-identified demographic data from each patient including associated medical diagnoses and conditions was collected. Vaccines administered, sedation techniques used, adverse effects and outcomes post vaccination were also noted. Ethics approval was obtained from the RCH Human Research Ethics Committee (#DA001-2016-93).

Descriptive statistics were used to characterize cases. Data analysis was conducted via Stata 12 (Statacorp, TX, USA) and Microsoft Excel (Microsoft, Seattle, WA).

3. Results

There were 213 vaccination encounters identified, with a total of 139 patients and a male majority (59.7%). The overall number of patients has increased over the study time period (Fig. 1). The majority of patients with developmental or behavioural problems were male (87.5%); in contrast to the female predominance in patients with needle phobia or anxiety (52.8%). The median age of patients was 13 years (Table 1). There were only 10 (4.7%) failed attempts at vaccination; all were first-time patients to our service

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