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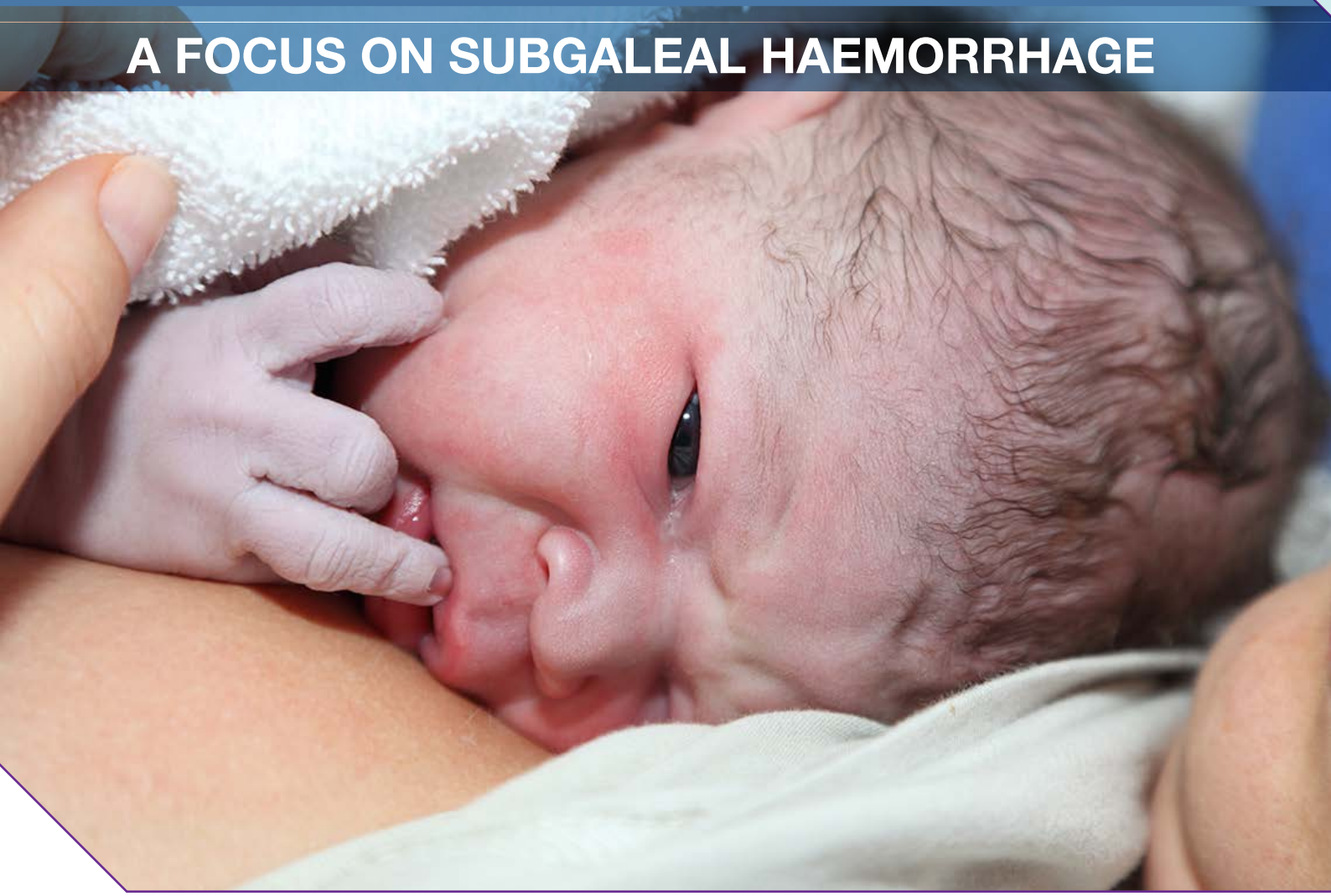
CLINICAL FOCUS REPORT

Vacuum Assisted Births – Are We Getting it Right?

A FOCUS ON SUBGALEAL HAEMORRHAGE



NSW KIDS + FAMILIES

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Foreword

The role of the Clinical Excellence Commission is to promote and support improved clinical care, safety and quality across NSW.

Analysis of aggregated information from the NSW Incident Information Management System (IIMS) is one of the best sources of information to identify potential gaps in the delivery of quality care that is currently available. Combining this information with data obtained from other sources like ICD-10-AM coding, coroners reports and event reporting from agencies such as Therapeutic Goods Administration further assists in identifying evolving trends affecting patient safety. This report is one of a series developed from this process. It provides a snapshot of issues identified during vacuum assisted births where there has been harm to the neonate. The report aims to promote an awareness of the issues identified and trigger system-wide improvements based upon the recommendations cited.

The analysis was prepared by the Clinical Excellence Commission in collaboration with NSW Kids and Families and in consultation with HETI. Key contributors were Dr Tony Burrell, Ms Vicki Fox and Ms Bronwyn Shumack, CEC Patient Safety Team; Centre for Epidemiology and Evidence; Associate Professor Michael Nicholl and Ms Deborah Matha, NSW Kids and Families; and Ms Vanessa Clements, Pregnancy and Newborn Services Network.

The report has been endorsed by the state Clinical Risk Action Group and Royal Australian and New Zealand College of Obstetricians and Gynaecologists.

Information contained within the report has been de-identified and analysed with reference to the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) College Statement on the Prevention, Detection and Management of Subgaleal Haemorrhage in the Newborn, and where applicable, the classification sets used by the Clinical Excellence Commission Maternal and Perinatal Root Cause Analysis Review Sub-committee.

We commend this report and invite those that are involved in the delivery of care to women and newborns to take the time to read it carefully. We appreciate your interest and look forward to your feedback.

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Background

CASE

A primipara woman who had experienced an uncomplicated pregnancy presented to a birthing unit post dates in spontaneous labour. Due to a non-reassuring trace and a failure to progress a vacuum assisted birth was conducted. Following three pulls with associated detachments and not achieving a significant degree of descent the procedure was abandoned. The neonate was delivered spontaneously during the next contraction with Apgars scores of 5 at one minute, 4 at five minutes and 7 at ten minutes. The baby girl was blue, floppy with poor respiratory effort. Resuscitation was initiated and the baby was transferred to the Neonatal Intensive Care Unit (NICU) for ongoing management. It was noted that the baby was irritable when handled and had a 'boggy' swelling in the occipital area of her scalp. The baby initially appeared to stabilise but subsequently deteriorated developing seizures and multi organ failure despite supportive measures. At two days of age supportive measures were withdrawn.

The Coroner stated that death was related to hypoxic ischaemic encephalopathy (HIE) following hypovaleamic shock and multi-organ failure due to a large subgaleal haemorrhage* probably associated with the vacuum extraction delivery.

It is well documented that vacuum assisted births are becoming the mode of choice to expedite birth compared to forceps, due to ease of application and low incidence of maternal trauma.[1] The Cochrane Review, Choice of instruments for assisted vaginal delivery (2010) supports the use of vacuum extraction as the first line method for assisted birth.[2]

Nationally, instrumental or assisted vaginal births (vacuum and forceps) account for 11 per cent of births[3] and this rate has been stable over the period 1990-2009.

From a New South Wales (NSW) perspective there has been a slight increase in rate of instrumental vaginal births. The rate has increased from 10.1 per cent in 2006 to 11.5 per cent in 2010.[4] Specifically, the proportion of babies delivered by vacuum assisted birth in 2006 was 6.87 per cent increasing to 7.39 per cent in 2010. From 1991 to 2001, Canada reported an increase in the rate of vacuum use from 6.8 to 10.6 per cent.[5] The United States also reported an increase of vacuum births compared to forceps, with 68 per cent of all instrumental vaginal births being vacuum assisted births in 2007 – an increase from 41 per cent in 1990.[6]

Vacuum assisted birth does not come without risks to both the woman and neonate. These must be weighed against the consequences of awaiting vaginal birth, or alternatively performing a caesarean section with the head deep in the pelvis.[3] Maternal complications include cervical and vaginal lacerations, vaginal haematoma, postpartum haemorrhage and third and fourth degree perineal tears. Complications for the neonate vary in severity, ranging from minor trauma to facial or scalp lacerations, chignon/cup markings on the scalp and cephalohaematoma. More serious outcomes include jaundice/hyperbilirubinaemia, retinal haemorrhage and facial nerve palsy. Potentially fatal complications include subgaleal haemorrhage, intracranial haemorrhage/fractures and cervical spine injury.[7] The risk of injury from vacuum assisted birth is estimated to be around five per cent.[8]

Subgaleal haemorrhage* can occur during any birth, including normal vaginal birth and caesarean section, but is frequently associated with vacuum assisted births.

In a retrospective ten year review of all neonates born in a Taiwanese hospital, the subgaleal haemorrhage incidence rate was 0.6/1,000 of all births and 4.6/1,000 of vacuum births.[9] In 2003, Uchil[10] reported a similar rate of 0.4/1,000 spontaneous vaginal births and 5.9/1,000 vacuum assisted births. Both make reference to the difficulty of diagnosis and point out that symptoms are often insidious.[9] These factors result in a potential underestimation of incidence rates of subgaleal haemorrhage. Reported mortality from subgaleal haemorrhage varies from 2.8 per cent[1] to 12 per cent.[9]

*Subgaleal haemorrhage is a rarely reported condition of the neonate and is often associated with instrumental birth. It is a potentially fatal condition that is often under reported and under diagnosed.

In 1998 the U.S. Food and Drug Administration (FDA) distributed a Public Health Advisory: *Need for CAUTION when using Vacuum Assisted Delivery Devices*[11] to provide guidance and raise awareness of the potential risks associated with this method of birth. In 2009, NSW Health also distributed a Safety Notice 016/09 *Safe Instrumental Birth*,[12] in response to growing concerns about adverse outcomes related to vacuum assisted births.

In late 2012 the Maternal, Child and Family Health Team from NSW Kids and Families started to receive anecdotal reports from across the state of increased rates of neonatal trauma, specifically subgaleal haemorrhages, following vacuum assisted births. In collaboration with the Clinical Excellence Commission Patient Safety Team, an initial review of clinical incidents notified into the Incident Information Management System (IIMS) during the period January 2012 to February 2013 was undertaken to ascertain if there was an issue of concern. Fifteen per cent of the IIMS notifications related to vacuum assisted births cited maternal or neonatal trauma. Twenty eight per cent of these were subgaleal haemorrhages.

After this initial review it was agreed that a wider analysis would be conducted to systematically assess the extent of neonatal trauma associated with vacuum assisted birth within NSW. The period of review was limited to January 2001 to December 2012. Information was sourced from: IIMS; International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification (ICD-10-AM) coding; Newborn and paediatric Emergency Transport Service (NETS) retrieval data; device information from the Therapeutic Goods Administration (TGA); Root Cause Analyses (RCA); and available reports from coronial inquiries. The following commentary outlines the findings from this analysis, identifies key contributing factors to neonatal trauma and makes recommendations for system improvement.

What we found

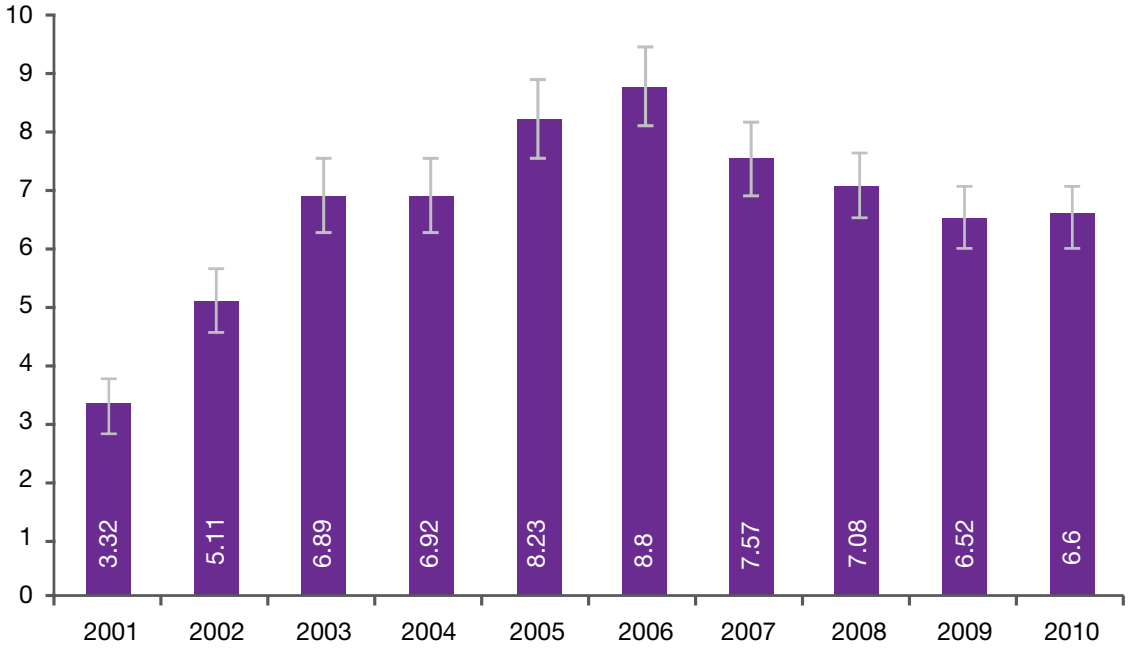
The extent of neonatal trauma from vacuum assisted birth in NSW was ascertained from two primary data sources: ICD-10-AM coding and IIMS notifications. Both ICD-10-AM and IIMS data have limitations. The accuracy of both is dependent upon the diligence of clinicians documenting outcomes in the patient's health record, and/or completing an electronic IIMS notification. These issues are not unique to maternity care. The review was further limited as ICD-10-AM linked data (maternal and neonate) were only available for the period 2001–2010 while IIMS data were available from 2006 to 2012.

ICD-10-AM coding

ICD-10-AM code P03.3 is allocated when it is suspected that a 'fetus or newborn is affected by delivery by vacuum extractor (ventouse)'.

Of the 71,396 vacuum assisted births (2001 - 2010) coded, 6.7 per cent were allocated a P03.3 code. Figure 1 shows that there has been an increase in coded P03.3 events since 2001 peaking in 2006 at 8.8 per cent and then declining to a rate of 6.5 per cent by 2010.

Figure 1: Proportion of babies affected (with 95% confidence interval) by vacuum assisted birth (ICD-10-AM code P03.3) between January 2001 and December 2010



Data Source: Perinatal Linked data (PERI1) and Admitted Patients Dataset (APDC)

Incident Information Management System (IIMS) notifications

The IIMS database was implemented across NSW public health facilities in 2005. The associated Incident Management Policy - PD2005_634 (now PD2014_004) mandates that all adverse events or near misses are entered into the reporting system.

The initial search of IIMS included all clinical incidents notified between January 2006 to December 2012 regardless of allocated actual severity assessment code, specific service or principal incident type. The following broad search terms were used in an endeavour to capture all relevant obstetric events: "vac", "vacuum", "kiwi", "mityvac", "haem", "subgaleal", "laceration", "fracture" and "scalp".

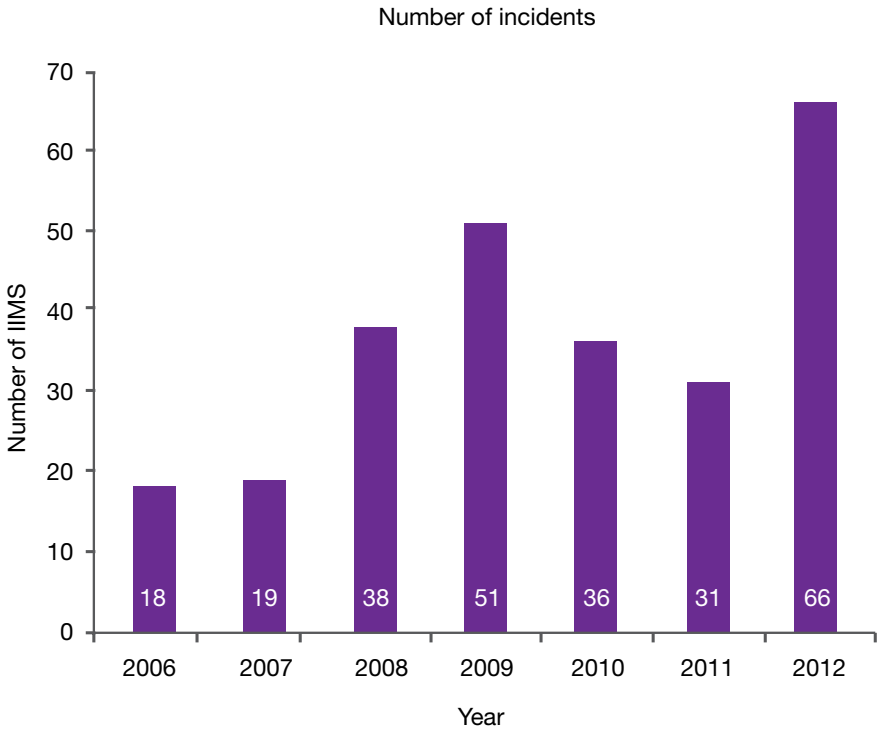
A total of 6,245 incidents were identified and screened further for obstetric relevance. It was determined that 1,245 incidents were pertinent. They were then reviewed by an expert group of maternity and obstetric clinicians. There were 259 incidents (21 per cent) that were of interest in

relation to the overall practice of vacuum assisted birth. The reasons for exclusion were that many of the IIMS notifications relating to vacuum assisted birth were entered as trigger reports as required by the Maternity - Clinical Risk Management Program policy (PD2009_003); and notifications were excluded if it could not be substantiated that the neonatal trauma/compromise was directly related to the mode of birth by the description given in the notifications. The main clinical indications to undertake a vacuum assisted birth are to expedite birth where fetal compromise or delay in second stage of labour are suspected.[3] Analysis to determine if the birth mode contributed to, or was indicated because of a compromised neonate proved to be difficult and may have resulted in either inclusion or exclusion of relevant notifications.

All maternal complications following vacuum assisted birth were excluded as they were not in the scope of this report.

Figure 2 shows that there has been a rising trend in vacuum assisted birth IIMS notifications from January 2006 to December 2012, the absolute number of notifications was higher than the previous year (s). Possible reasons for this will be explored further in the report.

Figure 2: IIMS notifications concerning vacuum assisted birth from 2006 to 2012



Neonatal trauma as recorded by ICD-10-AM coding

Within ICD-10-AM coding, there are six specific codes for birth trauma (P10-P15). Review of these six ICD-10-AM codes shows that code P11 'other birth trauma to central nervous system' accounted for the smallest number of events (0.19 per cent), while P12, 'birth trauma to the scalp' was the most common (86.59 per cent). Table 1 shows the breakdown of the six trauma subgroup codes.

Table 1: ICD-10-AM coding subgroups depicting birth trauma associated with birth by vacuum 2001 – 2010 in NSW

Code	Description	Number*	%
P10	Intracranial laceration and haemorrhage due to birth trauma	21	0.45
P11	Other birth trauma to central nervous system	9	0.19
P12	Birth trauma to scalp	4,080	86.59
P13	Birth trauma to skeleton	219	4.65
P14	Birth trauma to peripheral nervous system	71	1.51
P15	Other Birth trauma	312	6.62
Total		4,712	100

*Individual neonates may have more than one trauma coded.

The actual term subgaleal haemorrhage is not found in the coding descriptions. The most relevant reference in the coding descriptors is epicranial subaponeurotic haemorrhage (P12.2). Therefore subgaleal haemorrhage could be coded as either a P10 or P12. Table 2 and Table 3 show the yearly coding profile of P10 and P12. The proportion of neonates sustaining an intracranial laceration and haemorrhage due to birth trauma (P10) or a birth trauma to scalp (P12) has progressively increased over the period being reviewed. These cannot be attributed specifically to an increase in subgaleal haemorrhage.

Table 2: Proportions of neonates sustaining intracranial laceration and haemorrhage due to birth trauma (P10) between January 2001 and December 2010 in NSW

Year	Number of Neonates Sustaining Trauma (P10)	Total Number of Vacuum Extractions or Failed Vacuum Extractions	%	Lower 95% confidence interval	Upper 95% confidence interval
2001	1	6,196	0.02	0.02	0.04
2002	4	6,574	0.06	0	0.12
2003	0	6,483	0	0	0
2004	2	6,504	0.03	-0.01	0.07
2005	1	7,002	0.01	-0.01	0.04
2006	1	7,045	0.01	-0.01	0.04
2007	1	7,719	0.01	-0.01	0.04
2008	4	7,778	0.05	0	0.1
2009	1	8,181	0.01	-0.01	0.04
2010	6	7,914	0.08	0.02	0.14
Total	21	71,396	0.03	0.02	0.04

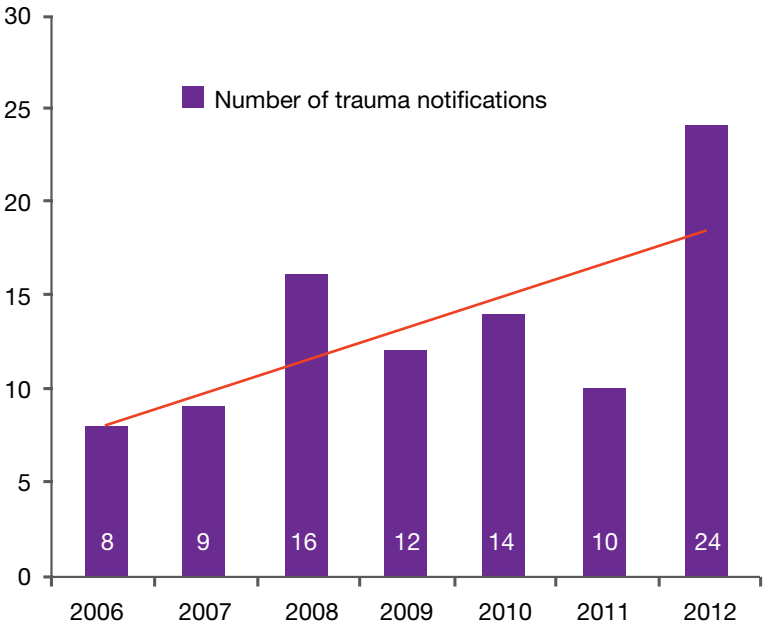
Table 3: Proportions of neonates sustaining birth trauma to scalp (P12) between January 2001 and December 2010 in NSW

Year	Number of Neonates Sustain Trauma (P12)	Total Number of Vacuum Extractions or Failed Vacuum Extractions	%	Lower 95% confidence interval	Upper 95% confidence interval
2001	166	6,196	2.68	2.27	3.09
2002	265	6,574	4.03	3.55	4.52
2003	378	6,483	5.83	5.24	6.42
2004	382	6,504	5.87	5.28	6.46
2005	502	7,002	7.17	6.54	7.8
2006	544	7,045	7.72	7.07	8.37
2007	509	7,719	6.59	6.02	7.17
2008	453	7,778	5.82	5.29	6.36
2009	431	8,181	5.27	4.77	5.77
2010	450	7,914	5.69	5.16	6.21
Total	4,080	71,396	5.71	5.54	5.89

Neonatal trauma as recorded in IIMS

Of the 259 IIMS notifications identified as relevant, 93 specifically described trauma to the neonate in the notification. Figure 3 shows an increased number of reports of trauma relating to vacuum assisted births – a three-fold increase in incidents/IIMS notifications since 2006.

Figure 3: Neonatal trauma associated with vacuum assisted births as notified in IIMS



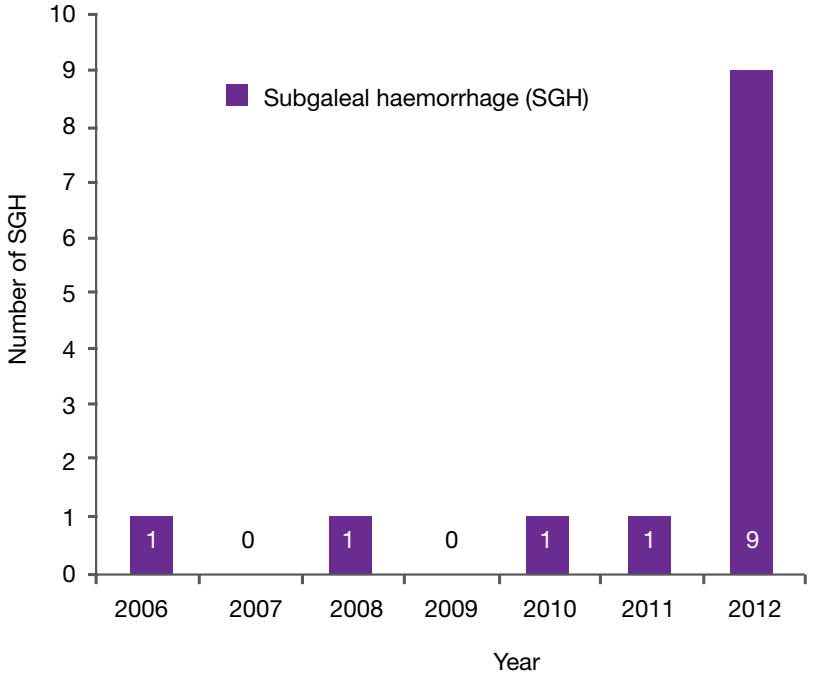
The trauma described in the IIMS notifications ranged in severity from minor (e.g. lacerations and bruising) to major, inclusive of subgaleal haemorrhage. Some notifications documented multiple injuries. Table 4 shows the breakdown of trauma as described by the notifying clinicians. The most frequent trauma type notified was lacerations to the scalp (35 per cent). The second most frequent notification was subgaleal haemorrhage (14 per cent). Due to the limitations of some of the descriptions, the category of 'boggy head', 'trauma', and 'multiple' may be more significant than suggested.

Table 4: Categorisation of trauma as stated in IIMS following vacuum assisted births

Trauma Description	Number Notified (n=93)	%
Laceration	33	35
Subgaleal haemorrhage	13	14
Cephalohaematoma	7	8
Multiple injuries	6	6
Trauma (no other descriptor)	6	6
Abrasion	4	4
Excessive caput, moulding, chignon	4	4
Boggy head	4	4
Bruising	4	4
Mark - head	4	4
Cephalohaematoma plus other trauma (skull fracture/lacerations)	3	3
Haematoma	2	2
Avulsion of skin of the head	1	1
Subcutaneous bleed	1	1
Subdural haemorrhage	1	1

The frequency of subgaleal haemorrhage notifications from 2006 to December 2012 is shown in Figure 4. There were a large number of subgaleal haemorrhages reported in 2012 but it is uncertain from the data whether this represents a real increase in trauma rates or improved ascertainment and reporting through screening and investigation of neonates following vacuum assisted birth.

Figure 4: IIMS reporting of subgaleal haemorrhages by year



Both data sets have identified scalp trauma (minor lacerations) as the most frequently occurring neonatal trauma following vacuum assisted birth – a finding supported by the literature.[13]

The remainder of this report will focus on information contained within the IIMS notifications, inclusive of RCA reports, NETS data and TGA Device Incident reports. This commentary aims to analyse the complex issues identified in the reported incidents, by identifying themes and causative factors, and highlighting gaps in practice which present the greatest opportunity for improvement.

Please note that the vignettes in this report have been extracted directly from the IIMS notifications and were de-identified where appropriate. The language and grammar used in the vignettes is that of the reporting clinicians.

Severity Assessment Code (SAC)

The allocated SAC for the 93 notifications are listed below in Table 5. The SAC reflects the clinician's interpretation of the level of risk associated with an incident. An actual SAC was allocated to 98 per cent of incidents. An actual SAC score of 3 was allocated by the appropriate manager to 60 per cent of the incidents which represents moderate to major harm.

Table 5: Allocated Severity Assessment Codes

Actual SAC	Number Allocated (n=93)	%
SAC1	1	1
SAC2	14	15
SAC3	55	60
SAC4	21	23
No SAC applied	2	2

Neonatal and paediatrics Emergency Transport System (NETS) data

NETS retrieval data were utilised as a secondary data source. The clinical manifestations of subgaleal haemorrhage can be varied. They may range from a small bleed which does not compromise the neonate haemodynamically to a large bleed with haemodynamic compromise requiring resuscitation and transfusion. The latter, if occurring in a small facility, would require transfer by NETS to a tertiary facility for ongoing management. Consequently, NETS data does not capture subgaleal haemorrhages occurring in tertiary facilities and those not serious enough to warrant transfer to a tertiary facility. NETS retrieval data suggest an increase in transfers of neonates with subgaleal haemorrhage in 2011 and 2012 (Table 6).

Table 6: shows a comparison of the number of IIMS notifications and NETS retrievals for subgaleal haemorrhage.

Year	Number of NETS retrievals for subgaleal haemorrhages	Number of subgaleal haemorrhages notified in IIMS
2006	1	1
2007	1	0
2008	2	1
2009	0	0
2010	0	1
2011	3	1
2012	3	9

Issues

The safe conduct of vacuum assisted birth relies on careful patient selection, good technique and the setting of appropriate procedural limits. The 93 notifications were categorised based upon the variables detailed in Table 7. Many of these variables are included in the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) College Statement on the Prevention, Detection and Management of Subgaleal Haemorrhage in the Newborn.[14] Some incidents describe multiple factors while others contain minimal description. The latter have been included in the total numbers but excluded from further analysis.

Table 7: Selected variables related to subgaleal haemorrhage prevention

Patient Selection	Procedural Technical Aspects	Clinical Governance Aspects
• Standard prerequisites for instrumental birth present	• Vacuum cup placement	• Scope of practice of medical officer
• Adequate maternal effort	• Appropriate traction	• Scope of practice of midwife
• > 36 weeks gestation	• Adequate descent	• Training and Supervision
	• Duration of traction	
	• Number of pulls / time to birth	
	• Number of cup detachments	

Analysis

Multiple instrumentation and /or persistence with the procedure following failure of the initial attempt

The Royal College of Obstetricians and Gynaecologists (RCOG) state that the use of sequential instruments is associated with an increased risk of trauma to the neonate and cite that the risk of intracranial haemorrhage is 1 in 256 deliveries for two instruments, versus 1 in 334 for failed forceps proceeding to caesarean section.[15] Towner concurs that subdural or cerebral haemorrhage incidence is greater with the combined use of instruments.[16] In a study by Demissie, frequency of complications were also increased with sequential use of vacuum and forceps.[6] Multiple instrumentation by its inference means that one or multiple instruments have failed to provide the anticipated outcome, and as such is a significant risk factor. Use of a second instrument is deemed to not only add to the risk associated with that instrument, but increases the risk beyond the sum of risks associated with each instrument.[17] These risks must be contextualised as it is recognised that in some circumstances it may be safer to use multiple instrumentation rather than proceeding to caesarean section.

Multiple instrumentation was described in 34 per cent of all the IIMS notifications. Of these multi-instrument births, 15 per cent described subgaleal haemorrhage as a neonatal outcome. Of all births with sequential instrument use, 72 per cent successfully achieved a vaginal birth. Below are two IIMS notifications depicting the use of multiple sequential instruments and the subsequent neonate outcomes.

CASES

A woman at 40^{+6} weeks gestation had spontaneous rupture of membranes however labour did not establish in the following twelve hours. Subsequently it was decided to induce labour and a Syntocinon infusion was commenced. At full dilation the woman was instructed to push. There was little descent and a ventouse was applied with three pulls - there was still no descent, but increasing amounts of caput and moulding. The medical officer decided that a forceps birth would be attempted. Forceps were applied and the first pull resulted in no movement. The fetal heart rate through these interventions was overall satisfactory, but there were some decelerations with contractions. The forceps were tried another three times with no descent noted. The decision was made for emergency caesarean section. The baby was born crying with excessive caput and moulding present.

A woman 40^{+1} weeks went into labour and the cervix fully dilated within one hour. Due to the mother's exhaustion the decision was for instrumental birth. The ventouse was applied, but pulled off 12 minutes later after seven pulls; it was re-applied and two more pulls performed, there was descent of the head. Five minutes later attempted application of forceps with unsatisfactory outcome. The ventouse was re-applied and one more pull performed. The Consultant attended and re applied forceps, delivering the fetal head. The registrar completed the delivery, 39 minutes after initial application of ventouse. A live male infant was delivered with Apgars of 2:4:5:8. A subgaleal haemorrhage was immediately diagnosed.

Number of pulls* performed by the proceduralist

Of the 93 notifications, 42 (45%) quantified the number of pulls performed by the proceduralist. The literature states that a maximum of three pulls during a vacuum assisted birth is associated with a lower risk of fetal injury,[15,18] and there is an increased risk of scalp injury after the third pull.[18] With respect to a non-occipito anterior position, Vacca concludes that the acceptable number of pulls is three in the descent phase and three in the perineal phase, as long as there is some descent observed during each pull.[18] The notifications below describe how in some instances, the number of pulls exceeded best practice.

* The term pull in this context is used to mean the application of traction force upon a device that is attached to a fetal head during a maternal expulsive effort.

CASES

Prolonged second stage and ventouse birth in birthing unit decided. Kiwi cup applied. Baby delivered over eight pulls with kiwi cup coming off three times. Apgars were 8 at 1 minute and 9 at 5 minutes. Baby sustained a graze to back of head where kiwi cup was placed.

Baby born after failed ventouse. Ventouse applied three times with 11 pulls then times two pulls with forceps. Head bruised, swollen and cone shaped with forceps marks over left eye. Skin off in several areas of the head from forceps and vacuum. Baby jaundiced by day two.

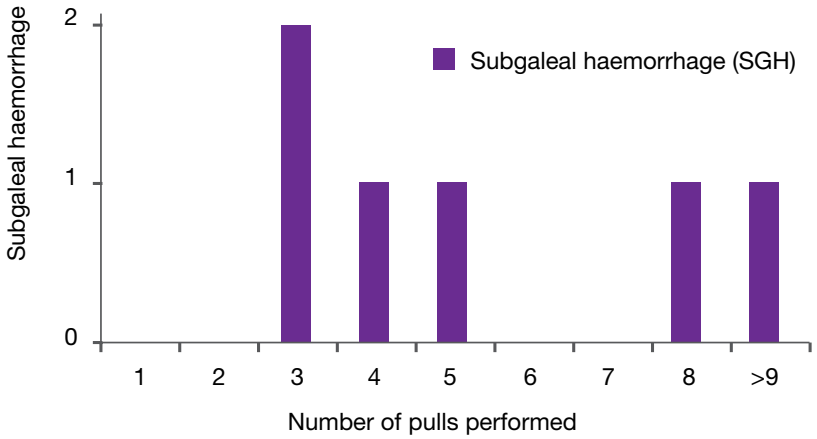
The 42 notifications describing the number of pulls stated a range of 1 to 16 pulls being performed. 29 per cent described three pulls, 19 per cent four pulls and 14 per cent six pulls. Analysis of the notifications shows no clear relationship between the number of pulls and the neonatal trauma sustained (Table 8).

Table 8: Number of pulls performed during vacuum assisted birth documented in IIMS

Number of Vacuum Assisted Pulls	%	Described Trauma
10 pulls or greater	10	Bruising, boggy head, trauma, chignon
7 to 9 pulls	14	Abrasions, lacerations, subgaleal haemorrhage
4 to 6 pulls	40	Avulsion of skin, boggy head, lacerations, trauma, subgaleal haemorrhage, subdural haemorrhage
3 pulls	29	Boggy head, bruising, cephalohaematoma, excessive caput and moulding, subgaleal haemorrhage, neurological deficit
1 to 2 pulls	7	Bruising and cephalohaematoma

Subgaleal haemorrhages were cited in six notifications where the number of pulls were described in the IIMS notification and are detailed in Figure 5.

Figure 5: Number of pulls during vacuum assisted births where IIMS notifications indicated a subgaleal haemorrhage



Poor descent or lack of maternal effort

Best practice cites that a vacuum assisted birth should be abandoned when there is no evidence of progressive descent with moderate traction during each uterine contraction.[15] The level of maternal effort is another factor in determining if a vacuum assisted birth should be performed or continued.[14] The greater the maternal expulsive effort, the less traction force is required to assist birth, thus reducing the incidence of complications.[19] The traction applied is supposed to be an adjunct to the mother's expulsive effort, not the primary force to overcome resistance to descent.[18]

Poor descent was cited in six per cent of notifications. The number of pulls in these cases ranged from three to eight, with injuries stated as cephalohaematoma (n=1), excessive caput and moulding (n=1), head mark (n=1), laceration (n=2) and subgaleal haemorrhage (n=2). The subgaleal haemorrhages occurred following three and eight pulls. Inadequate maternal effort was cited in five per cent of notifications. The number of pulls in these cases ranged from three to eleven with injuries stated as cephalohaematoma (n=1), lacerations (n=2), boggy head (n=1) and traumas/multiple injuries (n=2).

CASE

Registrar contacted regarding slow progress, decision made to perform a ventouse birth. Difficult ventouse delivery performed with progress made after three pulls and procedure continued. Cup came off once during the procedure. Six pulls required to deliver baby. Patient had poor maternal expulsive effort. Infant noted to have scalp abrasion from ventouse cup.

Traction, cup detachment, duration of procedure and cup placement

Traction

The IIMS notifications included two cases where there was a description of excessive force being used by the operator. Since 2008, the TGA has received nine device incident reports pertaining to vacuum assist devices. These incidents included:

- vacuum cup handle separating from the wire (n=4)
- vacuum cup cables snapped during birth (n=1)
- vacuum cup handles disconnected /broke off fully or partially during use (n=2)
- vacuum cup did not produce suction and easily pulled off (n=1)
- vacuum cup neck of device broke at the base of the cup during use (n=1)

The majority of the manufacturer investigations into these device incidents found that the device fault was contributed to by excessive force used. One investigation finding stated that it was estimated, based on the deformity evident in the cup, that greater than 50 pounds (22.675 kilograms) traction had been applied.

Vacca[20] states that virtually all deliveries may be completed with a traction force that does not exceed 13.5 kilograms, and at higher traction levels, there is an increase in fetal scalp injury. Technique, however, is a major influencing factor in the traction force required to be applied. There is limited information regarding neonatal outcomes in these nine TGA reports. One report stated that the neonates involved in the scenarios where the vacuum cup handles disconnected or broke off (fully or partially) during use, both suffered temporary harm with swelling to the head.

Cup detachments

Vacuum cup detachments occurred in 20 per cent of the IIMS notifications. Detachments should be avoided as they lead to rapid compression/decompression forces[5] and the rapid decompression may result in vessel damage and predispose to subgaleal haemorrhage.[14] RANZCOG[14] states that two detachments are acceptable.

The number of detachments described in IIMS ranged from one to three. One notification made reference to the number of detachments exceeding the recommended number but no numerical

value was assigned. Of the 37 per cent of notifications where three detachments were documented, none of them stated a neonatal outcome of subgaleal haemorrhage. Subgaleal haemorrhages were described in notifications where two detachments had been cited to have occurred. Correlation between number of detachments and neonate trauma is listed in Table 9. Twenty nine per cent of those with a documented detachment proceeded to a caesarean section. Those delivering vaginally had more detachments than those proceeding to caesarean section.

Table 9: Correlation between cup detachments and neonate trauma

Number of Detachments	Described Neonatal Trauma	
1	Cephalohaematoma	Laceration
	Chignon	Multiple lacerations
2	Boggy head	Multiple lacerations
	Cephalohaematoma	Subgaleal haemorrhages
3	Abrasion	Bruising
	Boggy head	Cephalohaematoma
	Chignon	Lacerations
		Trauma

Duration of procedure

Best practice states that the duration of application of the vacuum cup is up to twenty minutes,[18,14] with most vacuum assisted births being able to be concluded within fifteen minutes when there is adequate maternal effort and efficient contractions.[18] Few notifications described the time the cup was applied and of those that did specify a timeframe, the range was from 4 to 32 minutes. Below is an example of a prolonged application of the vacuum cup.

CASE

Client had been pushing for 75 minutes when the Registrar called to review client in view of assisted birth. After 75 minutes of pushing there was little fetal descent and there was concern about the position of the baby - baby in deflexed posterior position.

The registrar came into the room and explained the procedure to client. The woman was happy for an assisted birth. Prior to this the registrar had held her head forward quite forcefully and told her to push a number of times in a loud voice. Vacuum cup was put on the fetal head. Client was contracting strongly 4-5: 10 at this point with the Syntocinon IVI turned off since 2045. The epidural was running at maximum 14mls/hour but had started to be less effective in the last 30 minutes prior to placing vacuum cup in situ. The Registrar had the vacuum cup on baby's head for 32 minutes - and pulled strongly with every contraction. The woman was contracting 4-5:10 hence there was12-16 strong pulls if not more during this time. The Visiting Medical Officer contacted who said they would come ASAP. They arrived just after the birth. Throughout this procedure the fetal heart rate was satisfactory and cord blood gas results were satisfactory. The baby had a chignon from the cup on the left side of its occiput indicating asynclitism when in the pelvis.

Cup placement

Similarly, cup placement issues were not frequently cited. A pre-requisite for instrumental vaginal births include that the proceduralist knows with certainty the exact position of the fetal head so that proper placement of the instrument can be achieved.[3,8] The following are examples of inadequate identification of the position of the fetal head.

CASES

The Obstetrician stated that they had not assessed fetal position prior to applying a ventouse cup. The Obstetrician had declined a posterior cup. The baby's head birthed in a deflexed occiput transverse (OT) position and a chignon was noted to be over the anterior fontanelle.

The Registrar and Consultant were in attendance and were reviewing the patient. Both did internal assessment of the mother to ascertain baby's presentation. The assessment was difficult. The ventouse was applied on the cheek causing the bruising. The baby was born via caesarean eventually. No obvious physiological defect on the baby as a result of the ventouse being applied on the cheek.

Vacuum usage in less than 34 week gestation neonates

Vacuum assisted birth is an absolute contraindication in pregnancies that are less than 34 weeks gestation.[14] Two per cent of IIMS notifications with trauma outcomes cited that the fetus was 34^{+0} weeks gestation. Soft tissue injuries were stated to have occurred in both these instances.

Supervision, skill and knowledge

Suboptimal supervision was cited in a number of notifications resulting in trauma. Most of the references were related specifically to medical staff supervision. This information must be taken in the context of the subjective nature of IIMS notifications.

RANZCOG states that adequate training and supervision in vacuum assisted births cannot be over emphasised.[14] Supervision is an activity that has had a varied meaning and has changed over time. Point of care supervision is defined as effective leadership, support and guidance on clinical practice from senior to junior members of the clinical team, ensuring patients receive safe and appropriate care.[21] Active supervision is the ability of a supervisor to recognise opportunities for intervention to improve patient care. In the article by Dalton,[22] elements of active supervision include routine oversight (pre-planned monitoring of clinical care), responsive oversight (direct intervention by a supervisor) and backstage oversight (oversight activities of which junior staff are not directly aware). In the notifications below, deficits in the first two elements are evident to varying degrees.

CASES

Patient fully dilated at 1721hours. Fetal bradycardia evident from this point then on to baseline of 90-100 with large deep variable decelerations until birth, fetal scalp electrode put on at 1721hours. Registrar performed a vacuum extraction without supervision. Registrar stated in front of the patient and her partner "I have not used one of these before". The midwife asked if the Visiting Medical Officer was coming in, the answer was "they are on their way". As the CTG continued to show the above, the midwife suggested that another Visiting Medical Officer be called as they could arrive at the hospital sooner to get the baby birthed sooner. However the registrar continued with the case. The baby was born at 1755hours.

Well documented in notes from midwife and obstetrician that was called to assist. The labour was very long. Ventouse applied by doctor without consent. After the tenth pull on the ventouse an obstetrician from theatres was called to assist and took over delivery. Patient examined by obstetrician and verbal consent for use of ventouse obtained. A ventouse birth was performed after episiotomy extended by obstetrician. Doctor had a very poor technique on ventouse, continually pulling up and down on head regularly causing trauma to fetal head.

The registrar was unfamiliar with the vacuum extractor and used same without supervision of the obstetrician to deliver a baby who was experiencing prolonged bradycardia. The consultant was 30 minutes from the hospital.

Supervision must also be supported by appropriate clinical escalation. Escalation will depend on the clinician's scope of practice, training and level of experience. The supervisor needs to be available to discuss decisions and/or management plans in a timely and effective manner.[22] The following highlights the need for junior medical staff to liaise with senior medical staff to develop appropriate management plans.

CASE

Induction of labour for pre-eclampsia in a primiparous term pregnancy. Artificial rupture of membranes with meconium stained liquor. Syntocinon infusion commenced with epidural for pain relief. The woman developed pyrexia during labour. The continuous electronic fetal monitoring became non-reassuring with tachycardia. At +/- 0600 hours the woman was fully dilated. Ventouse was attempted at 0800hours for tachycardia CTG with a prolonged bradycardia. Five pulls with the vacuum. Two times pop offs. Procedure disbanded and decision made for caesarean section. Baby born at 0906hours and was 4570g with poor cord gases. Baby noted to have a ring shaped tear to the scalp. Transferred to special care nursery with a suspected subgaleal haemorrhage, subsequently confirmed on ultrasound. In reflection the registrar should have contacted the consultant pre-procedure to discuss appropriateness of delivery and location.

Vacuum assisted births should only be performed without senior obstetric supervision by persons who have been adequately trained and are fully competent[7] in the use of the instrument.[2,8] Inadequate training is a significant contributor to adverse outcomes.[15] The following example highlights this point.

CASE

A woman was induced at 38 weeks gestation with associated decreased fetal movements. She progressed satisfactorily and was assessed at full dilatation in the Delivery Ward by the Junior Registrar. The fetal heart rate recordings on cardiotocograph were reassuring. The fetus was in the occipito-posterior position at the level of the ischial spines. The woman was fully dilated for two hours and pushing for one hour without further head descent. A manual rotation of the head to the occipito-anterior position was attempted but unsuccessful. A trial of rotational ventouse birth was proposed to be performed in the Operating Theatre. This was discussed with the woman and the Consultant on call for the Delivery Ward. In the Operating Theatre the Junior Obstetric Registrar applied the ventouse and pulled twice over two separate contractions. There was some descent of the fetal head but there was no rotation noted. The Senior Obstetric registrar was asked to take over. Two further pulls by the Senior Obstetric Registrar resulted in descent of the fetal head of two cms below the ischial spines and a rotation of the fetal head to the occipito-anterior position. The Junior Obstetric Registrar took over and attempted two further pulls with the ventouse with minimal descent of the fetal head. The Senior Obstetric Registrar took over again and a further two pulls with the ventouse resulted in delivery of the fetal head. The number of pulls on the ventouse in total was eight. The neonate was floppy, pale and in respiratory distress at birth and required resuscitation. A subgaleal haemorrhage was identified.

Conclusion

Management of the second stage of labour can be challenging. With respect to vacuum assisted births, clinicians need to appreciate that while the incidence of maternal trauma is reduced compared with forceps, neonatal trauma occurs in approximately 1 in 15 babies. While such trauma is mostly minor, potentially fatal complications such as subgaleal haemorrhage do occur. The safe conduct of vacuum assisted birth relies on careful patient selection, good technique, and the setting of appropriate procedural limits, all within a robust clinical governance framework.

It is evident from the review of cases that clinicians may perceive that the use of vacuum devices do not require the same level of rigour with respect to training, supervision and credentialing, as other forms of assisted birth. The prerequisites for instrumental vaginal birth need to be fulfilled and documented. There must be adequate maternal effort such that a clinician needs to question the use of vacuum devices where there is profound maternal exhaustion or where a neuraxial block (e.g. epidural) significantly inhibits the mother's expulsive efforts. Vacuum devices should not be used for births less than 36^{+0} weeks gestation and never before 34^{+0} weeks gestation. However, if a vacuum assisted birth is to be performed at 36^{+0} weeks gestation a consultant should be present to provide direct supervision. Professionally determined procedural limits must be adhered to and documented.

Many cases reviewed in this report indicate that clinician supervision, skill and knowledge are variable across the system. In particular, it would appear that some clinicians do not possess the full range of obstetric skills that would permit alternative options to effect birth safely. Professional obstetrical and gynaecological bodies recognise the need for clinicians to be skilled in both forceps and vacuum assisted births early in their career development. Such skills require appropriate training, supervision and credentialing.

Instrumental vaginal birth continues to have a role in modern obstetrics. It is recognised that forceps births are associated with an increase in maternal trauma. However, this report would indicate that the risk of neonatal trauma in vacuum assisted births is not fully appreciated. It is important for clinicians to recognise those elements of safe instrumental vaginal birth that are critical to minimising harm to both mothers and babies.

Recommendations

1. NSW Kids and Families develop a standard method for the documentation of vacuum assisted births to include details related to the issues identified in this report.
2. NSW Kids and Families endorse the recommendations of the RANZCOG College Statement C-Obs 28.[14]
3. The RANZCOG Training and Accreditation Committee consider further development of the current basic obstetric skills requirements to include a component specific to instrumental birth that mandates competency in obstetric forceps birth by the end of Year 2 of the Core Training Program. The competency is to be actively assessed by a supervisor, not self-reported by the training clinician.
4. Local Health Districts (LHDs) have appropriate training, supervision and credentialing arrangements in place for instrumental vaginal births. This should include limiting the use of vacuum devices to those clinicians appropriately credentialed (including non-accredited registrars) and with the procedure(s) documented in their scope of practice.
5. LHDs are required to use only those vacuum devices where traction force is measured and can be documented.
6. NSW Kids and Families consider the issues identified in this report when reviewing the Maternity Clinical Risk Management Program PD 2009_003 with a view to considering further triggers for incident reporting.
7. NSW Kids and Families should consider partnering with HETI and RANZCOG in the development of an obstetric skills module for instrumental vaginal birth.

References

1. Boo N, Foong K, Mahdy Z. Risk factors associated with subaponeurotic haemorrhage in full-term infants exposed to vacuum extraction. *British Journal of Obstetrics* 2005;112:1516-21.
2. O'Mahony F, Hofmeyr GJ, Menon V. Choice of instruments for assisted vaginal delivery (Review). *The Cochrane Library* 2010 (11).
3. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists. Instrumental Vaginal Delivery. RANZCOG College Statement:C-Obs 16 2012:1-5.
4. Centre for Epidemiology and Evidence. New South Wales Mothers and Babies 2010. Sydney: NSW Ministry of Health 2012.
5. Cargill Y, MacKinnon C. Guidelines for Operative Vaginal Birth *Journal Obstetrics and Gynaecology Canada* August 2004;26(8):747-53.
6. Demissie K, Rhoads G, Smulian J, Balasubramanian B, Gandhi K, Joseph K, et al. Operative vaginal delivery and neonatal and infant adverse outcomes: population based retrospective analysis. *British Medical Journal* 2004;329:1-6.
7. South Australian Perinatal Practice Guidelines Workgroup. Operative Vaginal Deliveries 2010.
8. Unzila A, Norwitz E. Vacuum- Assisted Vaginal Delivery. *Reviews in Obstetrics and Gynecology* 2009;2(1):5-17.
9. Chang H-Y, Peng C-C, Hsin-An K, HSU C-H. Neonatal subgaleal hemorrhage: Clinical presentation, treatment, and predictors of poor prognosis. *Pediatrics International* 2007;49:903-07.
10. Uchil D, Arulkumaran S. Neonatal Subgaleal Hemorrhage and Its Relationship to Delivery by Vacuum Extraction. *Obstetrical and Gynecological Survey* 2003;58(10):687-93.
11. U.S. Food and Drug Administration. FDA Public Health Advisory: Need for CAUTION When Using Vacuum Assisted Delivery Devices: US Department of Health and Human Services, Centre for Devices and Radiological Health 1998.
12. NSW Department of Health. Safety Notice 016/09 Safe Instrumental Birth 2009
13. Miksovsky P, Watson W. Obstetric vacuum extraction: state of the art in the new millennium. *Obstetrical and Gynecological Survey* 2001; 56(11):736-51.
14. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists. Prevention Detection and Management of Subgaleal Haemorrhage in the Newborn. 2012; C-Obs 28:1-7.
15. Royal College of Obstetricians and Gynacologists. Clinical Green-top Guideline No. 26 Operative vaginal delivery 2011:1-19.
16. Towner D. Effect of mode of delivery in nulliparous women on neonatal intracranial injury. *New England Journal of Medicine* 1999; 341:1709-14.
17. Gardella C. The effect of sequential use of vacuum and forceps for assisted vaginal delivery on neonatal and maternal outcomes. *American Journal of Obstetrics and Gynecology* 2001;185(4):896-902.
18. Vacca A. Vacuum Assisted Delivery improving patient outcomes and protecting yourself against litigation. *OBG Management* 2004(Supplement February).
19. McQuivey R. Vacuum assisted delivery: a review. *The Journal of Maternal Fetal and Neonatal Medicine* 2004;16:171-79.
20. Vacca A. Vacuum assisted delivery: An analysis of traction force and maternal and neonatal outcomes. *Australian and New Zealand Journal of Obstetrics and Gynaecology* 2006;46:124-27.
21. Clinical Excellence Commission. Patient Safety Report - Review of Clinical Incident Reports Clinical supervision at the point of care 2012.
22. Dalton S. Reflecting on clinical supervision how times change. *The Royal Australasian College of Physicians Newsletter* 2012.

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