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Medico-legal considerations and operative vaginal delivery

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A B S T R A C T

Women undergo operative vaginal delivery (OVD) as an alternative to caesarean section when complications arise in the second stage of labour. The perinatal mortality associated with OVD is very low, and most of the perinatal morbidity is minor. However, when serious adverse events occur, such as traumatic birth injury, shoulder dystocia, cerebral palsy and perinatal death, there are medico-legal implications. There is also the potential for litigation in relation to maternal pelvic floor injury, which is increased with OVD. Obstetricians performing and supervising OVDs need to be aware of the potential pitfalls and minimise the risk of adverse outcomes. Given that most obstetricians will be involved in adverse birth-related events, it is important that they are aware of the legal processes that may ensue. It is also important when reviewing adverse OVD-related outcomes that association is differentiated from causation. These issues are addressed in the current chapter with attention drawn to the Montgomery ruling, which redefines the legal standards expected in relation to informed consent.

Background

Operative vaginal deliveries (OVD) account for 10–15% of all births in the United Kingdom and Ireland and up to a third of births amongst first-time mothers [1,2]. The perinatal mortality following OVD is very low, although incident data are lacking. Published cohort studies from a number of UK and Irish settings report few or no perinatal deaths in association with vacuum- and forceps-assisted births

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[3–7]. A study from the United States of America (USA) of more than a million vacuum- or forceps-assisted births reported a neonatal mortality of 5 per 10,000 births compared to 3.7 per 10,000 spontaneous vaginal births [8]. There is an increased incidence of perinatal morbidity in association with OVD. Forceps delivery is associated with an increased incidence of facial bruising or superficial skin lacerations (common), facial nerve palsy (uncommon) and skull fractures or intracranial haemorrhage (rare) [9]. Vacuum-assisted delivery is associated with cephalhaematoma and superficial skin abrasions (common), retinal haemorrhage (uncommon) and subgaleal haemorrhage/haematoma (rare) [9].

Some OVDs are performed in the context of significant foetal compromise, such as prolonged foetal bradycardia and complicated foetal tachycardia. In these circumstances, the neonate may be born following a significant hypoxic-ischaemic insult that may result in seizures, encephalopathy, perinatal death or cerebral palsy [10]. OVDs are also performed in the context of prolonged second stage of labour due to foetal malposition and/or relative cephalopelvic disproportion (CPD), which may be followed by shoulder dystocia and brachial plexus injury (BPI). Finally, OVD with or without episiotomy is associated with an increased incidence of obstetric anal sphincter injury (OASIS) and pelvic floor trauma, which may lead to incontinence, prolapse and dyspareunia [11]. Most appropriately counselled women cope well with the minor traumatic injuries associated with OVD, but when serious birth-related adverse events occur, medico-legal action may be initiated. Intrapartum care providers need to do everything possible to minimise the risk of adverse birth-related events and also need to have an understanding of the processes involved when litigation occurs.

Legal basis for medical litigation

Legal principles

Most medical negligence cases will come through a civil court and be heard by a judge with no jury [12]. There may be a delay of some years between the birth-related event, the notification that a negligence case is being pursued and the final scheduling of a case for court, assuming that the case is not withdrawn or a settlement cannot be reached. A woman with pelvic floor injury or a young adult with a BPI may pursue a case on their own behalf, but most birth-related injuries including cerebral palsy will be brought by a parent or guardian on behalf of the child. The legal basis for a medical negligence claim in different jurisdictions is outlined in Table 1.

In general terms, medical negligence is based on three principles: i) that there is a duty of care, ii) that the duty of care has been breached and iii) that harm has resulted as a direct result of the breach of duty [12]. In the case of obstetrics, an obstetrician who attends a woman in the second stage of labour has a duty of care; if they advise assisted delivery and deviate considerably from practice-based guidelines for OVD, then they would be in breach of their duty of care, and if, for example, the baby had a brain injury as a result of failure to adhere to widely accepted safety criteria, then they would be found negligent. In practice, only a small subset of adverse birth-related events reach court, as the burden of proof for breach of duty and causation can be difficult for the plaintiff to establish.

Montgomery 2015

The legal situation for obstetricians has been redefined as a consequence of the Montgomery ruling in 2015 [13]. The Montgomery *v* Lanarkshire case drew attention to informed consent in terms of what the patient is entitled to expect. Nadine Montgomery, a woman with diabetes and short stature, had a vaginal delivery complicated by shoulder dystocia, exposing her son to a hypoxic insult and subsequent cerebral palsy. Her obstetrician had not disclosed the increased risk of shoulder dystocia, despite Montgomery asking whether the baby's large size was a potential problem [14]. Montgomery sued for negligence, arguing that, if she had known of the increased risk of shoulder dystocia, she would have requested a caesarean section. The Supreme Court of the UK announced judgment in her favour in March 2015, overturning a previous decision by the House of Lords [15].

Previously, the Bolam test [16] in England and the Hunter *v* Hanley test [17] in Scotland were used to determine what should be disclosed when counselling patients (Table 1). These tests ask whether a doctor's conduct would be supported by a responsible body of clinicians. The Montgomery case firmly

Table 1
Legal principles.

Tort law	English tort law concerns the compensation for harm to people's rights to health and safety. A 'tort' is a wrong in civil law rather than criminal law, and tortshttps://en.wikipedia.org/wiki/Tort like other civil cases are generally tried in front of a judge without a juryhttps://en.wikipedia.org/wiki/Jury.
Medical negligence	Medical malpractice is a specific subset of tort law that deals with professional negligence. Medical negligence is proved if all components of the three-part test are established on the balance of probabilities (civil suit) or beyond reasonable doubt (criminal prosecution). 1. A person is owed a duty of care. 2. A breach of that duty of care is established. 3. As a direct result of that breach, legally recognised harm has been caused. Negligence arising from medical acts may result in a civil action by the injured party (claimant/pursuer) or a criminal prosecution by the state. Successful civil actions result in monetary compensation to the injured party or dependents, which may be paid by the employing trust or the doctor's defence organisation. Successful criminal prosecutions may result in a custodial sentence for the doctor and an additional GMC fitness to practice hearing.
Duty of care	Duty of Care is defined simply as a legal obligation to Consider next line 1. Always act in the best interest of individuals and others. 2. Not act or fail to act in a way that results in harm. 3. Act within your competence and not take on anything you do not believe you can safely do.
Breach of duty	The defendant is in breach of duty towards the claimant if their conduct falls short of the standard expected under the circumstances.
Causation	In English law, causation proves a direct link between the defendant's negligence and the claimant's loss and damage.
Bolam test	*Bolam v Friern Hospital Management Committee* [1957] is an English tort law case that lays down the typical rule for assessing the appropriate standard of reasonable care in negligence cases involving doctors**.** The Bolam test states that "*If a doctor reaches the standard of a responsible body of medical opinion, he is not negligent*". Note: Bolam was rejected in the 2015 Supreme Court decision of *Montgomery v Lanarkshire Health Board*.
Hunter v Hanley	*Hunter v Hanley* [1955] SC 200 is the Scottish equivalent to Bolam. It sets out a slightly different test applicable to professional negligence cases under the law of Scotland. To establish liability in circumstances where deviation from normal practice is alleged, three facts have to be established: 1. It must be proved that there is a usual and normal practice; 2. It must be proved that the defender has not adopted that practice and consider next list 3. Most importantly, it must be established that the course the professional had adopted is one which no professional person of ordinary skill would have taken if he/she had been acting with ordinary care.
Montgomery ruling	The 2015 *Montgomery v Lanarkshire Health Board* ruling clarified UK law and set new standards for consent, stating that doctors have a duty to ensure that patients understand the material risks of any medical intervention and the risks of any reasonable alternatives.
Time limits	In England, an individual must start their legal claim within 3 years from when the incident happened or when they first realised they would have suffered an injury. In the case of children, the 3-year limit does not start to apply until their 18th birthday. If the claim is about a patient who cannot manage their own affairs because of a mental disability (e.g. cerebral palsy), the 3-year period does not apply. In both these cases, a parent or another person close to them can make a claim on their behalf.
No-fault compensation	No-fault compensation refers to a compensation scheme based on the principle that injured persons are entitled to receive compensation for their injuries, without proving fault against the opposite party. A no-fault medical compensation scheme has been in place in New Zealand since 2005.

rejected the application of Bolam to consent, establishing a duty of care to warn of material risks. The test of materiality defined in the Montgomery ruling was whether 'a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it [13].' Legal opinions have described the ruling as 'the belated obituary, not the death knell, of medical paternalism [18]," while others have argued that the standard imposed by the Montgomery decision merely reflected good practice as already specified by the GMC [19,20].

Procedures

In the first instance, a medico-legal case will be based on a review of the medical records, which highlights the importance of clear, accurate and complete contemporaneous documentation. For a child with cerebral palsy the obstetric, midwifery, neonatal, paediatric, developmental and neuro-imaging records will be relevant, and the child may be assessed by an independent paediatric neurologist or developmental paediatrician. Statements may be required from members of staff involved in the care of the mother (and baby) and this will include recall, reflection on what was documented and a description of their usual practice for the given circumstances. The case records will be provided to relevant experts by the solicitors for the plaintiff, and based on the reports received, the plaintiff's legal team will determine whether they have a strong case to pursue. If at this point a case is initiated, usually by way of a legal summons, the defenders legal team will instruct experts to provide independent reports on the standard of care (duty, breach of duty) and causation. This is likely to include experts in obstetrics, midwifery, neonatology, paediatric neurology/developmental paediatrics and paediatric neurology. A pathologist will be involved in perinatal deaths or if the placental histology is of relevance. The case may be withdrawn based on a strong defence, or where the strength of the case is uncertain, there may be a settlement in advance of court proceedings.

Where the case goes to court, the health professionals involved in the patient's care will be called as 'witnesses to fact' and will be cross-examined on their evidence by senior council. The mother (and her partner) may be called to describe her recall of the birth events and what she was told afterwards, and she will be cross-examined by the senior council for the defendant (clinicians/health organisation/ medical defence organisation). The experts for each side will be called on to share their specialist expertise with the court and will be cross-examined by both senior council. It may be some months before the judge will issue his/her judgement.

Less commonly, for example in the case of a perinatal death that is perceived to have resulted from gross medical negligence, the doctor may be accused of manslaughter and the case will be heard in a criminal court. In the event that a doctor is convicted of manslaughter the case will be referred to the relevant Medical Council in terms of fitness to practice.

Association versus causation

Clinical perspective

When an adverse birth-related event occurs, the mother and her family will want to know what caused it and whether it could have been prevented. The death of an infant or a subsequent diagnosis of cerebral palsy may occur in the context of delivery by vacuum or forceps (association) but this does not necessarily imply that the mode of delivery was causative (causation) [21]. It is very important that when counselling bereaved parents, particularly in the immediate aftermath of a tragic event, health professionals do not draw conclusions and provide erroneous answers based on incomplete information. This is not to say that clinicians should not be open, transparent and honest in their dealings with bereaved parents but that they should explain that it can take some weeks to have a complete picture of what led to the tragic outcome, and that a fully informed discussion will be facilitated at a later date. The difference between association and causation is complex and not always appreciated by either patients or healthcare staff (see Table 2). It requires careful information gathering, reflection and, ideally, discussion in a multidisciplinary team (MDT) setting. Examples of the complexity involved in differentiating between association and causation are described in Table 3.

Information gathering requires a thorough review of the maternal and family history, antenatal course, intrapartum care and birth-related events. The foetal heart rate pattern in labour, whether by intermittent auscultation (IA) or continuous electronic foetal monitoring (EFM) using cardiotocography (CTG), will need to be reviewed. The neonatal resuscitation needs to be reviewed and the subsequent neonatal course including imaging. Paired cord blood samples should have been analysed at the time of delivery and the placenta should be sent for histological examination. In the case of a perinatal death, additional aetiological blood tests and microbiological samples need to be sent, the

Table 2
Association versus causation.

A multiparous woman labours following a previous caesarean section and while pushing in the second stage of labour a foetal bradycardia is recorded which fails to recover. Uterine rupture is suspected, and the obstetrician is summoned urgently. The foetal head is OA position spines+1 and the obstetrician applies a direct traction forceps and delivers the baby with 2 pulls. Bradycardia duration 19 min; Apgar scores 1^{1}, 3^{5}, 5^{10}; pH_a6.9, BE_a-14.5, pH_v7.0, BE_v-12.6; seizures/encephalopathy; cerebral palsy (CP).	Forceps association with CP Forceps not causative of CP Uterine rupture causative
A nulliparous woman develops a pyrexia and foetal tachycardia in the second stage of labour. The obstetrician assesses a large baby, 0/5th palpable abdominally, OA position, at spines+0 with caput+. The woman is very keen for a vaginal delivery and consents to trial of forceps±proceed to caesarean section. She is moved to an operating theatre where the obstetrician applies direct traction forceps and notes minimal descent with one pull. The procedure is abandoned in favour of caesarean section. The baby is flat at birth; Apgar scores 1^{1}, 3^{5}, 7^{10}; pH_a 7.06, BE_a −11.2, pH_v7.12, BE_v −9.6; seizures, Group B Strep meningitis; cerebral palsy (CP).	Failed forceps association with CP Forceps on causal pathway GBS sepsis causative
A nulliparous woman is pushing for almost 2 h in the second stage of labour. The foetal head is thought to be OA at spines+0 to +1 and suitable for OVD. The obstetrician applies a vacuum and exerts traction over 5–6 contractions with 2 'pop-offs'. Delivery is still not imminent and direct traction forceps are applied. The foetal head is delivered over 2 further pulls in an OP position. At 4 h of age, the baby collapses and is diagnosed with a subgaleal haemorrhage. Care is withdrawn the following day due to poor prognosis, and the baby dies. A post-mortem examination confirms subgaleal haemorrhage/haematoma in an otherwise normal baby as the cause of perinatal death (PND).	Vacuum association with PND Forceps association with PND Vacuum likely causative of PND Forceps on causal pathway
A nulliparous woman has been pushing in the second stage of labour for an hour with variable decelerations on the CTG. The obstetrician advises OVD based on maternal fatigue. The position is OA with station+2 and caput visible. There is sub-optimal maternal effort, and the vacuum cup comes off on the second pull. Delivery is completed with one pull of a direct traction forceps. The neonate is born in a poor condition, and neuroimaging reveals a skull fracture and intracranial haemorrhage. The assumption is that this is a traumatic birth-related injury, and the baby dies. A subsequent diagnosis of osteogenesis imperfecta (OI) is made at post-mortem.	Vacuum/Forceps association with PND Vacuum/Forceps on causal pathway OI causative factor
A nulliparous woman has been pushing for 40 min in the second stage of labour when late decelerations are noted on the CTG. The obstetrician recommends OVD based on suspected foetal compromise. The procedure is conducted with local anaesthetic to the perineum. A vacuum delivery of a healthy 4.2 kg male infant is completed over three contractions. A second degree tear is repaired and the woman is discharged on the following day. She subsequently presents with faecal incontinence, and a complete rupture of the external and internal anal sphincter (OASI) is diagnosed on endoanal ultrasound.	Vacuum association with OASI Vacuum and Fetal size causative

placenta should be biopsied for karyotyping and a full post-mortem examination of the baby should be encouraged. In some cases, it will be appropriate to refer the case for an independent review by the coroner (England and Ireland) or procurator fiscal (Scotland). Parents should be informed that this is an important part of quality assurance procedures even though it may result in delays providing information.

The woman and her family may need to attend on more than one occasion to fully comprehend the information provided and to ensure that all of their questions have been answered. Verbal meetings should be supported with additional written information outlining everything that has been discussed using terminology accessible to a lay person. A copy should be provided to the woman's general practitioner (GP) who will be able to offer additional support and advice. If the woman and her family are not happy with the explanations provided or they have been provided with information suggesting shortcomings in the care received, they may, at this point, contact a solicitor for legal advice. Failure to provide a family with support, information and an honest appraisal of the care provided is more likely to result in legal intervention, even where there has been no breach of duty or causation is unlikely to be proven.

Table 3
Areas of potential medical negligence.

When to deliver	The decision-making about when to deliver by vacuum/forceps is often disputed in medical negligence cases. CTG interpretation in the active second stage of labour poses particular difficulties.
Where to deliver	The decision-making about where to perform an OVD warrants careful consideration. Failed OVD in a labour room rather than an operating theatre will be subject to criticism
Who performs the procedure	The operator needs to have the required competencies for the chosen procedure particularly when senior support is off-site. Errors in assessment rather than technical ability often underlie failed attempts at OVD.
Who supervises the procedure	The senior supervising clinician needs to establish what support a trainee requires and be available when needed. Trainees who lack insight into their own limitations pose a particular challenge.
Which instrument to use	The choice between vacuum and forceps should balance the benefits and risks of each instrument for the circumstances, and the woman should be counselled accordingly.
When to abandon a procedure	Operators should refer to evidence-based guidelines (RCOG) on when to abandon an attempt at OVD. Practice that deviates from guideline recommendations is commonly cited in relation to adverse outcomes.
Sequential use of instruments	The use of more than one instrument increases the incidence of both perinatal and maternal trauma; however, this may be more appropriate than a difficult second stage caesarean section.
Failed OVD	The obstetrician should have stopping rules in keeping with clinical guidelines and be cognisant that the risk of intra- and extra-cranial neonatal haemorrhage is increased.
Shoulder dystocia and OVD	Shoulder dystocia occurs more commonly in association with OVD and obstetricians should prepare accordingly. Brachial plexus injuries (BPI) that persist are likely to result in litigation.
Maternal trauma and OVD	Obstetric anal sphincter injuries (OASI) occur more commonly with OVD. Careful recognition, management and aftercare will reduce the likelihood of complications.
Informed consent	Informed consent is challenging in the active second stage of labour, particularly with CTG abnormalities. Operators should refer to guidelines (RCOG) on consent issues.
Documentation	Adverse birth-related events occur even when care has been beyond reproach. The standard of documentation determines whether or not a robust defence is possible
Aftercare	Open transparent communication with a women and her family is essential when adverse events occur.

Legal perspective

CTG poses a particular challenge, as there is a well-recognised tendency to over-interpret abnormal findings where an adverse outcome is known [22]. Additionally, the criteria for CTG interpretation are subjective and prone to inter- and intra-observer variation. This leads to a great deal of dispute at internal reviews, independent external reviews and when experts present their opinions in court [23]. Despite these shortcomings, there is an undue reliance on CTG interpretation in court, presumably because it is the only continuous recording of the foetus available for scrutiny. It is important to note from the recent INFANT randomised controlled trial that a computer-based decision support system for CTG interpretation had no impact on adverse birth-related events, highlighting the shortcomings of our current reliance on heart rate-based monitoring to assess foetal well-being and compromise in labour [24].

The cases described in Table 3 also highlight the challenge of interpreting the relative contributions of multiple factors in the aetiology of adverse outcomes. For example, a growth-restricted foetus may not tolerate prolonged pushing in the second stage of labour and if subsequently delivered in poor condition by sequential use of instruments (vacuum followed by forceps) due to incorrect diagnosis of a malposition, it may be difficult to differentiate the antenatal (foetal growth restriction), intrapartum (decelerative CTG) or procedure-related (failed vacuum followed by forceps) contributors to the neonatal condition at birth.

Research perspective

The difficulty in differentiating association from causation is also a challenge for epidemiological research, particularly large population-based studies of OVD where sample size takes precedence over

data quality. This may result in an unduly negative view of OVD. For example, population-based studies that address perinatal mortality and cerebral palsy following OVD may not take account of prenatal or intrapartum aetiological factors at the individual level, independent of the mode of delivery [8]. It is also important to highlight that when outcomes are compared following vacuum- and forceps-assisted delivery, the relevant comparators are either an extended second stage of labour resulting in spontaneous vaginal delivery (with ongoing potential compromise to the foetus/maternal pelvic floor) or second-stage caesarean section, both of which are associated with significant morbidity [5,25]. In many cases, comparisons are made with uncomplicated spontaneous vaginal births or elective caesarean sections, neither of which is relevant to the woman who has encountered delayed progress or suspected foetal compromise in the second stage of labour [8,26].

Strategies to reduce OVD-related morbidity

Clinical guidelines

Every woman experiencing an OVD has a right to expect care from a skilled obstetrician who communicates well and acts professionally from the first assessment to the final documentation. In practice, obstetricians vary in their abilities and many women will be delivered by doctors in training. Evidence-based practice guidelines are an important element in setting standards for staff involved in patient care. The guidelines of the Royal College of Obstetricians & Gynaecologists (RCOG) [27] provide recommendations on all aspects of OVD and similar guidelines are available in Canada and Australia, with more conservative practice in the US [28–30]. Guidelines are designed to reduce unnecessary practice variation and enhance safety across all settings. Audit standards are provided to facilitate service-level evaluation of care.

There are a number of potential pitfalls with OVD that health professionals need to be aware of as outlined in Table 3. When to deliver, where to deliver and who should conduct the delivery, either independently or with supervision, are everyday decisions on the labour ward. It is very important that the decision-making processes together with accurate timings are documented clearly. When to deliver is often subjective balancing a range of care elements including the preferences of the mother and the interpretation of the CTG. The frustrating issue at a medico-legal level is that an expert may assert that the intervention was too soon when the outcome is a traumatic instrument-related injury, and that the intervention was too late when the outcome is cerebral palsy, despite basing their opinion on virtually identical CTGs. This highlights the importance of careful assessment, discussion and documentation by all health professionals, for all cases, at a time when the final outcome is unknown [31,32].

Training/supervision

Training is central to patient safety initiatives. Obstetric trainees need to familiarise themselves with the theoretical knowledge required for the technical and non-technical skills of OVD. A wide range of resources are available, including guidelines, clinical skills taxonomy lists based on expert obstetric practice [31–34], manuals [35] and online training resources (for example, StratOG provided by RCOG). These should be supplemented with initial training in a simulation setting. Trainees will then need to be taught and observed in the clinical setting and have their technique corrected and adjusted by a senior operator until they are ready for independent practice (Table 4). It should be made clear to the labouring woman that a trainee operator is working under direct supervision of an experienced operator. Inexperienced doctors should seek advice and support in all but the most uncomplicated cases, and midwives have an important role to play in cross-monitoring of performance.

Competence should be assessed using a structured approach, such as the OSATS [objective structured assessment of technical skills] form designed for OVD by the RCOG [36]. The minimum number of supervised procedures necessary before competence is achieved is unknown, and this is likely to vary at the individual level. Each unit should have specified trainers responsible for training and assessment, and ideally, there should be some continuity in terms of assessing progression. Local and specialist courses in labour ward management can contribute to the development and maintenance of operative birth expertise.

Table 4
Strategies to reduce medical negligence claims.

Simulation training	Chapters 2, 4
Observed/assessed practice	Chapters 2, 3, 4
Supervision/support	Chapters 2, 3, 4, 7
Team work/fire drills	Chapters 2, 3
Evidence-based guidelines	RCOG [12]
Incident reporting	RCOG [12]
Structured documentation	RCOG [12]
Patient advocacy procedures	RCOG [12]
Organisational learning culture	Chapters 2, 3, 7

Errors of judgement

Errors of judgement are inevitable in clinical practice and do not automatically amount to breaches of duty. They only do so where the doctor has not acted with a level of care that would be expected from a reasonably competent professional. For doctors in training, this is of particular relevance, as the standard is that expected of the doctor in the same grade of that specialty [12]. There is an expectation, however, that supervisors will only allow trainees to do work that they believe them to be capable of doing. The onus therefore is as much on the supervising consultant/department to reassure themselves of the trainee's abilities to do the case or procedure as it does for the trainee to seek support. The biggest challenge is a lack of insight among inexperienced or over-confident trainees and a reluctance to attend among less conscientious senior clinicians. The senior midwife on the labour ward has an important safeguarding role in these circumstances and her contribution to organisational safety should not be under-estimated. Evidence suggests that where appropriate supervision is available 24 h a day, OVD morbidity outcomes are similar at both day and night [6].

Strategies to reduce OVD-related litigation

Complex procedures

The choice between mid-cavity rotational OVD and second stage caesarean section is particularly challenging as failed or abandoned OVD is often implicated in adverse birth-related outcomes [5]. Where there is any uncertainty about successful OVD, an experienced operator should assess the patient to ensure that the correct decision has been made to attempt OVD and that this is being conducted with the most appropriate instrument in the most appropriate setting [32]. For a trial of OVD in theatre, an experienced operator should attend in person or should be immediately available if the trainee on duty has not been assessed and signed-off as competent [37]. Detailed guidance on when to abandon an attempt at OVD is available in the latest RCOG Guideline [27].

A multicentre prospective cohort study in the UK of 393 women transferred to theatre in the second stage of labour reported a higher incidence of maternal haemorrhage and neonatal unit admission following caesarean section, but a high incidence of pelvic floor morbidity and neonatal trauma with OVD [5]. The incidence of pelvic floor morbidity following OVD was threefold higher at six weeks, but this attenuated at one and three years [11]. Women who gave birth by OVD were far more likely to have a vaginal birth in a subsequent pregnancy (80% vs 30%), and there were no differences in neurodevelopmental outcomes at five years [38,39]. This evidence summary highlights the complexity of decision-making for clinicians, and the challenge when counselling women on OVD in keeping with the Montgomery ruling.

Consent

The midwife and obstetrician need to have an ongoing dialogue with the woman to ensure that she understands the risks and benefits of the decision-making processes during labour and that she can make informed choices. By the very nature of OVD, consent will need to be obtained at the end of labour when women are emotionally and physically exhausted, and there is often a degree of urgency.

Therefore, women should be informed as much as possible about OVD as part of routine antenatal education, particularly when having their first baby, where the chance of requiring forceps or vacuum assistance is highest. This information should include strategies known to be effective in reducing the need for OVD and an explanation of the comparative morbidities for expectant management, vacuum or forceps and second-stage caesarean section. The birth plan of the mother, including any preferences or objections to a particular instrument, should be taken into account and discussed on labour ward rounds [40]. The principles of obtaining valid consent during labour as outlined by RCOG guidance should be followed [41,42]. The ability to present risk-based information in a time-sensitive manner appropriate to the clinical circumstances is essential to achieve informed consent and optimal clinical outcomes.

Organisational learning

Adverse events are inevitable in any large organisation caring for women with a range of risk profiles. The manner in which the personnel and organisation as a whole deal with these events is a marker of the standard of care. As with all healthcare professionals, obstetricians have a duty of candour; a professional responsibility to be honest with patients when things go wrong. This is described in the joint statement from eight regulators in the UK [43]. Obstetricians should contribute to adverse event reporting, confidential enquiries, and take part in regular reviews and audits. They should respond constructively to outcomes of reviews, taking necessary steps to address any problems and carry out further retraining where needed.

Unsuccessful forceps or vacuum, birth trauma, admission of a term baby to the neonatal unit, low Apgar scores (less than 7 at 5 min) and cord arterial pH less than 7.10 should trigger an incident report and review if necessary, as part of effective risk management processes [44]. Maternity units should provide a safe and supportive environment in which learning can take place from serious adverse birth-related events. Highly complex human factors are involved in OVD, and an understanding of the interplay of these in adverse events is important. Not all serious adverse events are caused by failures in care.

Documentation

Documentation for OVD should include detailed information about the assessment, decision-making and conduct of the procedure, the birth outcome and any complications, a plan for postnatal care and sufficient information for counselling in relation to subsequent pregnancies. Use of a standardised proforma, as provided with the RCOG Guideline, is recommended to prompt a thorough assessment and complete documentation of the clinical findings. Paired cord blood samples should be processed and recorded following all attempts at OVD as a marker of foetal well-being. Deviations from guideline recommendations should be documented and explained. Inevitably, the obstetrician's documentation of the procedure occurs after the event, but close attention should be paid to actual timings, which are usually recorded by the midwife who is providing assistance. The names, signatures and grade of the clinicians involved should be recorded legibly. Care should be taken to avoid inconsistencies in key elements of the procedure, particularly timings, and where a supervising doctor takes over, the time of their arrival and point at which they took over the procedure should be recorded.

Summary

The medico-legal aspects of OVD encompass duty of care, breach of duty and causation. Obstetricians who are well-trained and supervised, and who adhere to best clinical practice guidelines, are best placed to provide safe OVD care with a minimum of morbidity. This approach provides women with an alternative to caesarean section in the second stage of labour, which greatly increases the woman's chance on an uncomplicated spontaneous vaginal birth in a subsequent pregnancy. Good clinical skills include communication, team work and documentation. The importance of informed consent has been highlighted by the Montgomery ruling of 2015. Adverse birth-related events may be associated with

OVD, but this does not imply causation. A comprehensive review is required after every adverse event, and doctors have a duty of candour when dealing with patients and their families. A culture of organisational learning will serve to minimise adverse birth-related events and will provide families with a fair and effective response when adverse events occur.

Practice points

- Obstetricians performing vacuum- and forceps-assisted deliveries need to work within their capabilities and seek senior support where any uncertainty exists in relation to safe successful completion of the procedure.
- Informed consent for OVD requires that obstetricians discuss the risks, benefits and alternatives to the proposed procedure thoroughly but in a time-sensitive manner in keeping with the urgency of the situation.
- Obstetricians should contribute to adverse event reporting and confidential enquiries and take part in regular reviews and audits.
- Obstetricians have a duty of candour; a professional responsibility to be honest with patients when things go wrong.
- Obstetricians should be aware of the elements of care that commonly arise in medical negligence cases, informing strategies to reduce adverse birth-related events at both an individual and an organisational level.

Research agenda

- Foetal monitoring in labour to detect impending foetal compromise
- Ultrasound to enhance assessment prior to OVD
- Educational strategies including simulation to minimise morbidity
- Technological advances, such as disposable forceps with strain gauge to measure force applied and new devices, such as 'ODON'
- Consent procedures that inform without engendering fear

Conflicts of interest

The author has provided expert opinion on medico-legal cases of adverse birth-related events in England, Scotland and Ireland over the past 20 years, for which she has been remunerated. She is the lead author of the RCOG Guideline on Operative Vaginal Birth.

The cases described in Table 3 are fictionalised accounts based on real cases. The opinions expressed are those of the author.

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