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An Analysis of the Challenges Encountered by Anaesthetists when Obtaining Consent for Obstetric Epidurals

Rebecca Conlon

Royal College of Surgeons in Ireland, rebeccaconlon@rcsi.ie

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An Analysis of the Challenges Encountered by Anaesthetists when Obtaining Consent for Obstetric Epidurals

Rebecca L. Conlon
Department of General Practice
RCSI

A thesis submitted to the Department of General Practice, Faculty of Medicine and Health Sciences, Royal College of Surgeons in Ireland, in fulfilment of the degree of MSc in Healthcare Ethics and Law

Supervisor: Ms. Mary Kirwan BL

July 2018
Candidate Thesis Declaration

I declare that this thesis, which I submit to RCSI for examination in consideration of the award of a higher degree, MSc in Healthcare Ethics and Law, is my own personal effort. Where any of the content presented is the result of input or data from a related collaborative research programme this is duly acknowledged in the text such that it is possible to ascertain how much of the work is my own. I have not already obtained a degree in RCSI or elsewhere on the basis of this work. Furthermore, I took reasonable care to ensure that the work is original, and, to the best of my knowledge, does not breach copyright law, and has not been taken from other sources except where such work has been cited and acknowledged within the text.

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ABSTRACT

Background

Obtaining informed consent for obstetric epidurals is a complex area of anaesthesia. Practice among obstetric anaesthetists in this jurisdiction is widely varied. This paper provides an analysis of the ethical and legal challenges encountered by anaesthetists when endeavouring to obtain informed consent to administer the obstetric epidural and makes recommendations as to how these challenges might be lessened.

Methods

A systematic review of research papers sourced from relevant data bases and websites was conducted. Direct inquiries were also made with three Dublin Maternity Hospitals regarding the practice of obtaining consent for epidurals as well as with the State Clams Agency regarding the incidence of litigation in this area.

Results

The study demonstrates the onerous legal duty now placed upon clinicians when obtaining informed consent as well as the ethical quandaries that can arise. The legal expectation is that the clinician has or ought to have an awareness of the risks associated with any given procedure / treatment which his patient will attribute significance to and that his patient will be advised accordingly. This presents challenges in the context of the administration of the obstetric epidural including ethical dilemmas, demands on resources, moral distress and potential litigation.
Conclusion

In order to lessen the incidence of such challenges the following recommendations are made:

• A national standard governing the process of obtaining informed consent to obstetric epidurals is implemented across the nineteen public maternity units in this jurisdiction.

• This includes the introduction of a nationalised patient information card regarding obstetric epidurals which is first presented in the antenatal period and re-introduced on admission for delivery.

• Ante-natal classes includes a class given by the obstetric anaesthetist regarding the effects, side effects and risks associated with obstetric epidurals.

• Obstetric anaesthetists are provided with better guidance from their professional bodies in respect of the doctrine of informed consent.

• Annual group sessions with an ethicist and a medico-legal specialist whereby anaesthetists gain better understanding of their legal and ethical obligations in this context should also be facilitated.

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ACKNOWLEDGMENTS

I would like to thank Mary Kirwan BL who supervised this dissertation and whose expertise and words of encouragement proved invaluable to me. I would also like to thank Ciaran Breen, Director of the State Claims Agency who facilitated this opportunity. I am also grateful to the National Treasury Management Agency for funding this work and to the RCSI for their guidance and accessibility throughout. I would also like to express thanks to the three Masters of the three Dublin Maternity Hospitals, each of whom ensured that I was provided with relevant information for the purposes of this paper.

For their personal support and to whom this paper is dedicated, I would like to thank my mother, Stella Murray, for her words of wisdom and reassurance, my wonderful children, Niall, Eoin, Aislinn and Darragh for their patience, love and forbearance and finally, my husband and best friend Paul, for his endless support.
CHAPTER ONE

Introduction

Objective of Dissertation:

While much research has been carried out into the area of informed consent and obstetric epidurals there is currently no national standard in this jurisdiction specifically aimed at governing this process so as to achieve best practice. The purpose of this paper is to provide an analysis of the legal and ethical challenges which obstetric anaesthetists encounter in this scenario. This in turn will assist in establishing if a national standard, along with any other measures, would assist in minimising such challenges thereby affording the obstetric anaesthetist better protection and support in this context.

The administration of obstetric epidurals is an extremely complex area of medicine from both a legal and ethical perspective. The challenge which the anaesthetist faces can be summarised as follows:

A woman in labour, who is in significant pain, has possibly had opiates and is undoubtedly anxious is requesting the anaesthetist to insert a catheter into her spinal canal, administer drugs via this catheter causing temporary numbness with the intention of rendering her pain free during childbirth. This procedure is associated with a number of complications ranging from minor to very significant and possibly life changing.
Research indicates that there is major variation in practice among obstetric anaesthetists in this jurisdiction when obtaining informed consent for obstetric epidurals, particularly in terms of information given to patients in respect of associated risks [1]. This is undoubtedly indicative of the raft of issues which the obstetric anaesthetist must consider at a challenging time, some of which are described below and illustrate the complexities involved.

- Prior to the onset of labour did the patient have any knowledge as to the effects, side effect and risks associated with obstetric epidurals?
- Has the patient capacity to give informed consent to the procedure?
- How will the anaesthetist go about obtaining informed consent?
- What risks should the patient be advised of in these circumstances and what risks are of particular significance to this patient?
- Will the patient be able to make a voluntary decision based on the information provided to her by the anaesthetist?
- Is the patient a suitable candidate for an epidural and not suffering from any contraindicating condition?
- Is there sufficient time to administer an epidural or is labour so far advanced that to administer an epidural at this stage could be considered an unnecessary medical intervention?
- Are there sufficient resources in place to administer the epidural and provide the appropriate level of care and monitoring thereafter?
This is therefore an area deserving of further guidance, leadership and governance in an effort to minimise litigation as well as support the anaesthetist when managing ethical dilemmas arising in this setting.

To assist in establishing if the obstetric anaesthetist would benefit from the implementation of a national standard along with any other relevant measures, the ethical challenges which the anaesthetist can encounter in the administration of obstetric epidurals are considered in this paper. Separately, the legal obligations which both case law and legislation such as the Assisted Decision Making (Capacity) Act, 2015 impose on the obstetric anaesthetist are also analysed.

Having considered both the ethical and legal challenges arising, recommendations are made as to how the implementation of a national standard would further support and protect the obstetric anaesthetist when obtaining informed consent for epidurals during labour, with the intention of lessening the incidence of litigation and ethical dilemmas in this area. Additionally, other relevant issues where further research or measures are warranted are identified.
REFERENCES


CHAPTER TWO
Methodology

This thesis is divided into four main sections. The first section provides an overview of the cause of pain in labour, the mechanism of the obstetric epidural, national and international rates of obstetric epidurals and a review of information provided to pregnant women in respect of epidurals. The second section examines the ethical issues arising in the context of the administration of the obstetric epidural. The third section examines the legal issues arising and in the fourth section recommendations are made on measures to be put in place to assist and protect the obstetric anaesthetist when obtaining informed consent to administer an obstetric epidural. An overview of the methodology applied to research these sections is provided below.

PICO
The PICO process has been utilised to provide a framework to this research. PICO is an acronym for Population, Intervention, Comparison and Outcome. Its aim is to facilitate a focused methodological approach to research. As outlined above, the objective of this research is to make recommendations to lessen litigation and ethical dilemmas for the obstetric anaesthetist in the context of administering epidurals. The PICO framework has therefore been implemented as follows:

- **Population:** The obstetric anaesthetist.
- **Intervention:** The expectant mother requesting the obstetric anaesthetist to administer an epidural in labour.
- **Comparison:** The different practices among obstetric anaesthetists in relation to obtaining informed consent for obstetric epidurals
- **Outcome:** Measures to be put in place to facilitate and protect the obstetric anaesthetist when obtaining informed consent in this situation.

The PICO framework has facilitated focus and direction in the conduct of this research. For the most part, a review of qualitative research has been conducted for the purposes of this paper. The rationale for this approach is to garner subjective views among anaesthetists as to what constitutes informed consent and to consider the factors which influence the obstetric anaesthetist’s practice in the administration of obstetric epidurals. A review of qualitative research has also been conducted to examine the factors which influence expectant mothers to choose epidurals as a form of pain relief in labour and to consider the extent to which their consent is informed. Quantitative research has been reviewed to determine the rates of the administration of obstetric epidurals as well as the incidence of litigation in various jurisdictions.

**Systematic Review**

In the first section, to establish the reasoning behind the request for an epidural in labour, a systematic review of relevant qualitative studies on the causes of pain in labour was conducted. Searches of PUBMED, Google Scholar and the Cochrane Database of Systematic Reviews were undertaken using a combination of key search terms to include “pain in labour”, “pain relief in labour”, “childbirth and pain” and “epidural and labour”. No limitation was put on the time period searched, the
rationale being the cause of pain in labour remains the same regardless of the time period. These searches produced a variety of international qualitative studies which were systematically reviewed for the purposes of establishing their relevance. This included screening of abstracts and full texts. The relevant articles were critically appraised with a view to identifying the ethical and legal dilemmas that can arise for the obstetric anaesthetist in the context of the obstetric epidural.

When researching the ethical dilemmas for the purposes of the second section of this thesis, key terms searched included “expectations in labour”, “childbirth and ethics”, “obstetric anaesthetists and epidurals”, “informed consent for epidurals in labour”, “autonomy and childbirth”. This particular search spanned a period of fifteen years, the rationale being that this time period would garner the most up to date research in this area. To confine this to a lesser period, for example five years, would not yield adequate information for the purposes of this thesis due to the limited number of research papers in this field.

The objective of this review was to identify existing research on the practice of obstetric anaesthetists when obtaining informed consent for epidurals in labour. When identifying such research studies the inclusion criteria required the obstetric anaesthetist to be the participant for the purposes of the study. It was established early on in this review that the numbers of studies in this regard are limited. There are significantly more studies in establishing the mother’s experience of furnishing consent in labour as opposed to the obstetric anaesthetist’s experience and practice in obtaining consent. None the less, relevant studies where the anaesthetist was
the participant were identified and analysed. Relevant studies where the mother was the participant were also reviewed on account of their affiliation to the subject matter of this paper.

Due to the limited research available, this search was not confined by geographical location despite the fact that the aim of this research is to make recommendations for implementation in the Irish jurisdiction. A limitation to this search was that relevant studies produced in Japan and France were excluded on account of the fact that they were not written in English and hence a language barrier existed.

Legal Research

In order to examine the evolution of the doctrine of informed consent it was necessary to examine relevant case law, its jurisprudence as well as primary legislation. Case law searches were conducted using www.westlaw.ie and www.westlaw.co.uk. Written judgements were sourced from either www.westlaw.ie or directly from www.courts.ie/Judgments. Legal text books were consulted for an analysis of the relevant case law and sourced through a search of the Law Library database, Google Scholar and PUBMED. Relevant articles commenting on the doctrine of informed consent were sourced via PUBMED and www.westlaw.ie using searches of key phrases to include “informed consent in labour”, “obstetric anaesthesia and consent”, “childbirth and epidurals” and simply “informed consent”.
In terms of primary legislation, www.Irishstatutebook.ie was searched for an analysis of relevant statutory provisions such as the Assisted Decision Making (Capacity) Act 2015. Additionally, relevant healthcare guidelines were sourced via the following:

- Health Services Executive’s website at www.hse.ie,
- The College of Anaesthetists of Ireland’s website at www.anaesthesia.ie,
- The Association of Anaesthetists of Great Britain and Ireland’s website at www.aagbi.org and
- The National Institute for Health and Care Excellence at www.nice.org.uk/guidance

Primary research whereby direct inquiries were made with three Dublin maternity hospitals as to their current practice in respect of obtaining informed consent to administer obstetric epidurals was also carried out.

On account of the repeal of Article 40.3.3¹ of the Irish constitution in May 2018 a review of recent parliamentary questions via www.oireachtas.ie was also conducted to establish if any relevant plans are afoot to amend legislation such as the Assisted Decision Making (Capacity) Act 2015 in light of this repeal which may have a bearing on the assessment of capacity in pregnancy.

¹ The state acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and as far as practicable, by its laws defend and vindicate that right
Statistics

Statistics on litigation arising as a consequence of obstetric epidurals, were researched via PUBMED and Westlaw using a combination of key word searches including “regional”, “anaesthesia”, “litigation” and “obstetric”. This yielded results pertaining to Canada and England.

Further primary research whereby direct inquiries were made with the State Claims Agency which manages all clinical negligence claims taken against state healthcare enterprises, hospitals and clinical, nursing and allied healthcare practitioners in Ireland. However, data relating to claims arising specifically as a consequence of epidurals was not automatically retrievable for the time period requested. This is not an indication that such claims do not exist. It is simply an indication of the manner in which such claims are classified. Depending on the Plaintiff’s cause of action, a claim relating to an obstetric epidural may be classified as for example, an “obstetric” claim, an “administration of medicines” claim or a “nerve injury” claim. It is therefore a limitation of this study that the number of actual claims arising in Ireland as a direct consequence of obstetric epidurals claims is not retrievable at this point in time. However, of note, specific medications were added to the National Incident Management System in 2017, therefore any claims finalised in the future which involve medications used in epidurals will be retrievable.

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2 The State Claims Agency (SCA) operates the National Incident Management System (NIMS), a confidential, highly secure end-to-end risk management tool that the HSE and relevant funded services use, to report incidents [1].
3 This information was obtained via direct inquiries with the State Claims Agency
REFERENCES

CHAPTER THREE
Childbirth and the Epidural

Childbirth

Manglesdorf et al opine how:-

“One of the most impactful events across the life course of a woman is giving birth to a child” [1].

Experiences of childbirth vary greatly as does the intensity of pain which women suffer. Among the main objectives of maternity care is making childbirth a positive experience which requires effective management of labour pain [2]. This necessitates an understanding of the cause of labour pain and methods of pain relief, both pharmaceutical and non-pharmaceutical, on the part of healthcare staff working in the delivery suite.

The purpose of this paper is to focus on epidurals as a method of pain relief in labour and consider the challenges encountered by anaesthetists when obtaining informed consent to administer an epidural in such circumstances. Before considering this issue it is important to understand why childbirth is painful, how an epidural can relieve this pain and what are the advantages, disadvantages and risks associated with epidurals.
Pain in childbirth

Lowe observes how pain experienced in labour is affected by multiple physiological and psychosocial factors including the mother’s obstetric history, her educational background, culture and ethnicity as well as her ability to cope [3].

Labor et al describe the experience of labour as complex and subjective, with often pain scores being higher in the nulliparous⁴ woman compared to the multiparous⁵ woman [6]. Labor et al describe the mechanism of labour pain as:

“The active process of delivering a foetus ….. characterised by regular painful uterine contractions which increase in frequency and intensity” [7].

They observe two components to labour pain, namely visceral pain and somatic pain.

1. Visceral pain occurs during the first and second stage of childbirth⁶. With each contraction pressure is transmitted to the cervix causing stretching and distension.

2. Somatic pain occurs in the late first stage of labour and the second stage caused as a result of stretching, distension, ischaemia and injury of the pelvic floor, perineum and vagina [7].

The transmission of each pain differs, with visceral pain occurring in the lower abdomen, sacrum and back while somatic pain occurs nearer the time of delivery characterised as sharp and localised to the vagina, rectum and perineum [7].

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⁴ Having never borne children [4]
⁵ Having given birth to more than one child [5]
⁶ The first stage of childbirth is when the cervix dilates fully, to approximately 10 centimetres in diameter [8]. The second stage of childbirth is from the full dilatation of the cervix until the baby is completely out of the birth canal [9].
When considering the causes of pain in labour it is important to also understand the psychological challenge which labour presents to women [10]. Beigie et al conducted a qualitative study aimed at considering the different factors which affect women’s experiences of pain during childbirth [11]. They concluded that assessing women’s experiences can assist in understanding the delivery pain phenomenon. In conducting their research they asked participating women to describe their labour pain. Responses varied. One participant described labour pain as being:

“The sweetest pain in the world, I love it so much, of course it is hard to endure but it is sweet” [12],

whilst another participant described it as

“Really hard to endure, it is not similar to other pains…. The most severe pain that I’ve ever tolerated is labour pain” [12].

Thus demonstrating how mothers’ life experiences and cultural differences impact on their experiences during childbirth.

**Labour epidurals**

As Labor et al opine, the aim of pain relief in labour is to render mothers relatively pain free [13]. Mothers have a number of options to consider when deciding upon pain relief during childbirth. These include, though are not limited to, complementary therapies such as acupuncture, transcutaneous electrical nerve stimulation, inhalation therapies such as Entonox (oxygen and nitrous oxide), opioids and epidurals. Studies indicate that epidural analgesia is the most effective form of pain relief [14]. The Irish Maternity Indicator System National Report of 2015 indicates
that the national rates for women receiving labour epidurals in the nineteen Irish public maternity units were 40.8% in 2014 and 40% in 2015 – see Table 1 below [15].

This data demonstrates that in 2014 and 2015 obstetric anaesthetists in Irish public hospitals obtained consent to administer an epidural from women in labour in approximately 4 out of every 10 deliveries. In 2011 a study carried out in 27 states in the US indicated that 61% of women in labour used epidurals for pain management [16] while in Canada in the same year a study indicated that 56.7% of women used epidural analgesia during labour [17].
The challenge for the anaesthetist in such circumstances is to ensure that consent to this type of pain relief is informed. But can a woman in the throes of labour, who may not have attended antenatal classes where an explanation regarding the pros and cons of epidurals is provided, furnish an informed consent to an epidural? It is arguable that the only concern she will have at that point in time is pain relief. Even if the woman has attended antenatal classes and has been advised of the risks associated with epidural, she may have complete disregard for this information when faced with reality of pain in labour. This is the challenge for the obstetric anaesthetist when obtaining consent and the core issue which this paper seeks to explore.

**Is enough information available to pregnant women in respect of obstetric epidurals?**

In 2003 the National Institute for Clinical Excellence (NICE) pointed to a gap in the knowledge of healthcare professionals in supporting pregnant women in making informed decisions during labour [18]. Similarly, in 2008 Lally et al identified a gap between pregnant women’s expectations of pain in labour and their actual experiences of pain [19]. They concluded that health care professionals needed to ensure that pregnant women are appropriately prepared for “what might actually happen to limit this expectation–experience gap and potentially support greater satisfaction with labour” [20].

More recent guidelines published by NICE indicate that:-

“Giving pregnant women relevant information to allow them to make an informed decision remains a challenge to all healthcare professionals. The
use of media other than leaflets needs to be systematically studied, and the current available evidence is limited” [21].

This use of leaflets was considered by Munro et al in 2018 [22]. Munro sought to assess change in knowledge and preference for epidural associated with the use of an information pamphlet and to explore women’s decision-making and information needs regarding pain relief in labour. They found that an illustrated information pamphlet regarding epidural analgesia in labour increased women’s knowledge of benefits and risks of epidural analgesia and preference for epidural use. However, it was not associated with a change in preference regarding pain relief in labour. In conclusion they found that women prefer to receive comprehensive information prenatally to support informed choices in labour.

Can we therefore conclude that the optimal situation for the obstetric anaesthetist when obtaining consent for an epidural is that his patient, at the very least has received written information regarding the epidural in the antenatal period, and at most, has attended antenatal classes where information regarding the epidural is discussed and relevant information leaflets distributed? What protection does this afford the obstetric anaesthetist in terms of exposure to legal liability when complications arise? What ethical implications arise for the anaesthetist and his patient when administering an epidural to a patient who has neither attended antenatal classes nor received information leaflets regarding epidurals? What ethical implications arise for the anaesthetist when administering an epidural to a patient who has attended antenatal classes and / or has been furnished with
information leaflets but has no regard for the information contained therein when in labour?

These issues, which will be explored further in this paper, highlight the vulnerabilities for the anaesthetist in the context of obtaining informed consent for epidurals during labour. To appreciate the implications of this it is important to understand what an epidural is, its effects, side effects and complications.

**What is an epidural?**

An epidural is the injection of regional anaesthetic into the epidural space which in turn blocks pain signals. During labour it is injected into the lumbar area of the back – see diagram below:

![Diagram of epidural space and related anatomy](image)

(Courtesy of Institute for Quality and Efficiency in Health Care (IQWiG) [23]).

As demonstrated in the diagram above, a catheter is usually left in the epidural space throughout labour. This allows for intermittent top-ups by midwifery staff, or
alternatively, continuous infusion of patient-controlled epidural analgesia during the course of childbirth. The rational for this is a single injection is often not sufficient to last for the entirety of childbirth [24]. Epidural anaesthetic drugs include local anaesthetics such as bupivacaine or lidocaine frequently delivered in combination with opioids for example, fentanyl. This in turn decreases the required dose of local anaesthetic [25].

Side Effects of Epidurals in Labour

The side effects associated with epidurals include:

1. A transient drop in blood pressure, drowsiness, shivering and fever
2. Urinary retention
3. Inadequate pain relief
4. Itchiness
5. Puncture to the dura causing leakage of cerebrospinal fluid leading to headaches
6. A prolonged second stage of labour and an increased need for instrumental vacuum / forceps delivery.
7. Temporary nerve damage
8. Permanent nerve damage
9. Injection of local anaesthetic into a vein in the spine causing dizziness, fits and heart problems. [14], [16], [26]

7 This can be remedied by an epidural blood patch (EBP), a procedure in which a small volume of autologous blood is injected into a patient’s epidural space to stop a leak of cerebrospinal fluid (CSF) [26].
8 This in turn carries an increased risk of perineal tear / laceration [27]
While some of these side effects can be described as minor and of a transient nature others are more serious thereby compounding the requirement for an informed consent. Given the context of the administration of an obstetric epidural and the important legal and ethical issues arising for the anaesthetist, it is important to address these issues separately. Ethical issues may arise which, while not necessarily legal issues, are still testing for the anaesthetist and vice versa. In the next chapter the ethical challenges encountered by the obstetric anaesthetist when administering epidurals during labour will be examined.

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The obstetric anaesthetist encounters practical, legal and ethical challenges on a daily basis. These are wide in variety and range from issues such as resource management, prioritisation of patients and endeavouring to obtain informed consent in often difficult circumstances. In this chapter the ethical challenges which are encountered by obstetric anaesthetists when administering obstetric epidurals are explored.

A recent study carried out at the National Maternity Hospital in Dublin indicated that 0.8% of nulliparous mothers had a “practically perfect birth” [2]. Of note, 12.54% of this cohort had an epidural. The authors of this study drew attention to its limitations in that the definition given to a “perfect birth” for the purposes of the study was an objective one and did not include any of the mothers’ perceptions of a perfect birth. It also excluded deliveries involving the following:

1. Delivery less than 37 weeks
2. Induced/Pre labour Caesarean section
3. Artificial rupture of Membranes
4. Oxytocin
5. Foetal Blood Sample
6. Emergency Caesarean section/Forceps Delivery/Ventouse Delivery
7. Perineal Outcome: first degree tear plus / minus sutures, Second degree tear plus / minus sutures, 3rd degree tear, episiotomy plus / minus sphincter damage, labial tears

8. Neonatal Outcome: Apgars of less than 9 at 1 or 5 minutes

None the less, this study demonstrated a significantly low chance of a perfect birth. The authors described the result as “astonishing”. In their view, the question which now has to be asked is:-

“Would imparting this information to first time mothers evoke fear of labour or provide realistic expectations?” [2]

According to Lally et al, appropriate preparation and education for childbirth leads to more realistic expectations and “supports greater satisfaction with birth” [3].

In addition to a healthy baby, maternal satisfaction with birth is arguably the ultimate goal for both healthcare staff and mothers. Should as much information as possible therefore be given to mothers in the antenatal period? To examine this contention in the context of the labouring mother requesting an epidural, it is necessary to consider the ethical challenges this presents for the obstetric anaesthetist and examine the four ethical principles espoused by Beauchamp and Childress [4] in this scenario, namely respect for autonomy, non-maleficence, beneficence and justice.

**Paternalism versus Respect for Autonomy: An Historical Perspective**

In 1871 American physician Professor Oliver Wendell Holmes Sr advised a group of graduating medical students that:
“Your patient has no more right to all the truth then he has to all the medicine in your saddle bags… He should only get so much as is good for him” [5]

This was indicative of the culture of benign paternalism which existed in medicine at the time. However, by 1914 a gradual shift from this position was emerging as demonstrated by Justice Benjamin Cardoza when he stated:

“Every human being of adult years and sound mind has a right to determine what shall be done with his own body: and a surgeon who performs an operation without his patient’s consent commits an assault for which he is liable in damages” [6]

Following the travesty of the Nuremburg trials [7] ethical principles began to evolve and be applied in research involving human subjects. These were eventually crystallised in the Declaration of Helsinki9. Patients’ right to self-determination and bodily integrity gradually became the accepted norm in modern day healthcare. Theorists such as Jotterand et al now advocate for autonomy as the overriding principle of the four ethical principles arguing that patients should be empowered…

“through patient education which enhances their autonomy and encourages them to become full healthcare partners as opposed to objects of clinical intervention” [9].

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9 The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects. This Declaration was first adopted in 1964 and was most recently updated in 2013. [8]
The position in obstetric anaesthesia

However, is this always a realistic goal for patients under the care of the obstetric anaesthetist? If the obstetric anaesthetist is asked by a woman in labour to administer an epidural, particularly in circumstances where she has no prior knowledge of its effects, side effects and risks, or indeed has no regard for such information, what challenges does this present and how does this affect the anaesthetist’s approach to her care?

Torres et al [10] highlight how the terms “good” and “bad” are regularly used to make moral judgments in obstetrics. Torres explains how for some, the “good” mother is one who listens to her doctor, arrives at the hospital promptly when labour begins and follows her obstetrician’s plans for a safe birth. This category of “good” undoubtedly includes knowledge as to the effects, side effects and risks associated with the obstetric epidural. In contrast, Torres explains how for others the “good” mother is the one who takes charge of her birthing experience, does not simply accept a clinician’s opinion and has a birth plan. It is foreseeable that a “good” mother in this category may not have knowledge of and / or regard for the effects and side effects of an epidural particularly if her plan is to have a natural childbirth.

Torres therefore demonstrates how the morality of motherhood is subjective. It is this subjectivity which arguably poses ethical dilemmas for the obstetric anaesthetist in the delivery suite. Does the anaesthetist proceed and administer the epidural to the woman in labour who, prior to this point had not considered this option and / or had no knowledge of its associated risks? Does his approach to this woman differ
to the approach he would adopt towards a well-informed and decisive labouring mother? If the anaesthetist endeavours to obtain consent at that point how can he guarantee that the consent is informed and that the woman has capacity in circumstances where she is in severe pain, stressed and has possibly had pain relieving medication? Does he proceed in any event and if so on what basis? The timing of the administration of an epidural is crucial. If it is administered too late it can be futile. The obstetric anaesthetist does not have the luxury of time to consider this dilemma. He must make a decision swiftly and act upon it.

In contrast with Jotterand et al [9], Torres expresses concern about an approach to bioethics that revolves around autonomy. Whilst this may appear surprising in today’s society where there has been a dramatic shift from paternalism to respect for autonomy over recent decades, Torres’ rational for this contention is arguably well founded. In Torres’ view, emphasis on autonomy can often result in the “abandonment of patients by healthcare professionals [11]”. He points to Orfali and Gordon’s research [12] by way of illustration. Orfali and Gordon compared the treatment of French and American parents in NICUs 10 and found that French parents treated paternalistically felt cared for. In contrast, American parents who were given plenty of information and autonomy felt abandoned. Corrigan summarises this theory as follows:

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10 Neonatal Intensive Care Unit
“However noble the goal of patient autonomy, this is sometimes experienced by patients as abandonment. Informed consent is premised on an equitable doctor/patient relationship that cannot always be realised” [13].

Should the obstetric anaesthetist be cognisant of Orfali and Gordon’s theory of abandonment and Corrigan’s realism when treating the woman in labour? Are there times in this context when paternalism trumps respect for autonomy? What ethical options are open to the obstetric anaesthetist when he encounters the labouring mother requesting an epidural who has no knowledge or regard for its risks and side effects? Should he use his clinical and ethical judgement and administer the epidural in the pursuit of a pain free childbirth, provided it is not clinically contraindicated? Whilst he can endeavour to explain the effects and side effects associated with an epidural, the extent to which a labouring mother will consider this in her decision making at that point in time is questionable.

Black and Cyna [14] conducted a survey in 2006 among consultant obstetric anaesthetists in Australia to identify and compare risks of regional anaesthesia which they discussed with women prior to and during labour and to inquire into the type of consent obtained. Of significance, seventy percent of the respondents indicated that they believed that active labour inhibits a woman’s ability to give fully informed consent. Twenty percent of respondents were of the view that a primigravida¹¹ was incapable of giving antenatal consent as they believed that the

¹¹ A woman pregnant for the first time [15]
unknown, namely the experience of labour pain, prevented a woman from being fully informed.

Does this therefore mean that this latter cohort of anaesthetists believe that it is impossible to obtain informed consent from a patient in respect of a procedure a patient is undergoing for the first time? Paech points to an endorsement of this view by highlighting how some commentators opine that a final decision about choice of pain relief can only be made once the pain of labour is experienced [16].

This view has also been reflected in Fröhlich et al's study which showed that out of 100 mothers who had an obstetric epidural only 65 had planned to have epidural analgesia prior to the onset of labour [17] thus demonstrating that 35 out of 100 mothers had a change of plan when faced with the reality of child birth.

In contrast to this, Saunders et al [18] conducted a survey among 885 anaesthetists based in the United States to establish their views on informed consent in relation to epidurals. Of this group 46% worked as part of an obstetric anaesthesia team. Sixty-eight percent of respondents were of the opinion that women in active labour, despite their painful and stressful circumstances, are able to give informed consent for epidural analgesia and 13% recommended that women inquiring about epidurals in the antenatal period should have an antenatal appointment with an anaesthetist.

Similarly, Jackson et al surveyed sixty actively labouring women immediately after requesting an epidural [19]. The majority of the participating women wanted all
complications disclosed to them but not their incidences. Of note 46% of the women surveyed had received an opioid before the study. Jackson concluded that:

“labouring patients are as able to give informed consent as are other members of our patient population” [19].

In recognition of Jackson’s work and taking comfort from its conclusions, Smedstad observed how:

“In the real world however, women arrive on the labour floor without the benefit of previous discussion. It is therefore helpful to know that such discussion can take place while in labour” [20].

Brooks and Sullivan also observe that while pain, distress and drugs may inhibit a woman’s capacity, evidence suggests that if a woman had capacity before labour she usually maintains it in labour [21].

However, these findings are at odds with Fröhlich et al’s study which showed that 79 out of 100 women who had undergone epidural analgesia for labour felt that their decision making was compromised as a result of labour pain [17]. Significantly, 96 of the women believed consent should be obtained prior to the onset of labour.

Such conflicting findings are indicative of the ethical complexities encountered by obstetric anaesthetists in this context. Indeed, Paech observes how:-

“Ethical issues pertinent to this rather difficult and complex clinical situation continue to be the subject of detailed and often emotive discussion in forums”
Beneficence versus Non-maleficence

The strained relationship which can occur between respect for autonomy and paternalism in the context of the request for an obstetric epidural is also reflected in the relationship between beneficence and non-maleficence. Beneficence has been defined as a moral obligation to act for the benefit of others [23]. The moral obligation associated with administering an obstetric epidural is to relieve pain. In terms of non-maleficence which asserts an obligation not to inflict harm on others [23], the goal is to avoid the occurrence of complications. However, neither can be guaranteed hence the requirement for informed consent. Further, the definition of beneficence and non-maleficence is subjective in this context as demonstrated by Callister et al who identified one mother who commented:

“The doctor encouraged me to have an epidural. Afterward I thought, ‘This isn’t childbirth. There’s got to be more to it than just laying there with a numb body’” [24].

Trumble et al conducted an observational study in an Australian maternity unit of obstetric anaesthetists when obtaining informed consent to epidurals and advising patients of the risks and benefits associated with epidurals [25]. A wide range of practice was observed among practitioners with regards the numbers and types of risks explained to patients. The average number of risks mentioned to patients was seven. Only one fifth of participating anaesthetists mentioned the benefit of an
epidural to patients. The study demonstrated an assumption among practitioners that a patient requesting an epidural understood its purpose. However, this was not necessarily the case. It was noted that family members and healthcare staff could be unduly influential with regards choice of pain relief and that once an epidural was requested alternatives to same, which arguably carried less risk, were rarely discussed.

On this point, Paech comments how he has never encountered a woman in labour who has changed her mind about having an epidural once advised of its effects and risks. Paech is of the view that there is little point in offering alternatives given the epidural is the most effective form of pain relief [26]. However, as will be explored further in this paper, Braun et al warn that a patient who is not advised of different anaesthetic options may have grounds for an action in negligence if she suffers from a complication and is able to prove that she would have opted for the alternative had she been so advised [27]. This could arguably be an uphill battle for the patient but none the less not unforeseeable in today’s litigious society.

Of note, Paech describes his experience of encountering a distraught woman in labour requesting an epidural. When he began the process of obtaining an informed consent she yelled “Stop patronising me, just put it in!” He proceeded “without further discussion on the basis of the ethical principle of beneficence” and his belief that a patient such as this has “every right to refuse to discuss these topics especially when in extreme pain” [28]. It would not be incorrect to assume that an element of common sense also prevailed here. The reality is that this type of scenario is undoubtedly common in delivery suites. An obstetric anaesthetist can justify
administering the epidural in pursuit of beneficence. However, as referred to above, this is not without risk as will be explored further in the next chapter.

**Justice**

Beauchamp and Childress define justice as “*fair, equitable, and appropriate treatment in light of what is due or owed to persons* [29]”. In essence this means that a woman requesting an epidural in labour should receive it provided this is clinically indicated. However, overstretched delivery suites means that this may not always be possible. A question of fair and prioritised distribution of resources arises. Additionally, anaesthetists may not have the luxury of time to advise mothers of the benefits and risks associated with an epidural thereby foreseeably causing moral distress.

Well thought out birthing plans devised in the calmness of the antenatal period where perhaps a woman has stipulated she does not wish to have an epidural can lead to challenging and time consuming encounters for the obstetric anaesthetist if she changes her mind when faced with the reality of child birth. Aside from the informed consent dilemma which this can present, this situation can also cause the anaesthetist practical difficulties in the busy delivery suite impinging on his ability to prioritise his work and attend to other patients thus creating a situation where autonomy and its concomitant issues trump justice arguably unfairly, as illustrated below.
It is not unforeseeable that a birthing partner will be of the view that he/she is acting in the labouring mother’s best interests when endeavouring to dissuade her from having an epidural if she has indicated in her birth plan that she does not wish to have one. Indeed, it could be a stipulation of the birth plan that in the event of her requesting an epidural the partner should interject and prevent this from happening. What is the busy obstetric anaesthetist to do in this situation? Scott describes the experience of a partner threatening physical violence against an anaesthetist when this very issue arose. “Don’t let me change my mind” had been included in the mother’s birthing plan [30]. Clearly this partner took his responsibility extremely seriously when he was prepared to commit crime to fulfil his duty. This sense of duty on the partner’s behalf was arguably misguided but trying to manage this scenario undoubtedly creates moral distress for the anaesthetist and his obstetric and midwifery colleagues. If the anaesthetist considers it his moral duty to administer the epidural in pursuit of beneficence, Scott warns that “in such circumstances (the anaesthetist) is wide open to a complaint and potential litigation for assault” [30]. Whilst this warning dates back 20 years it is perhaps all the more stark in today’s litigious society.

It would therefore appear that the key message to be drawn from these observations is that both the expectant mother and her partner should keep an open mind with regards pain relief in childbirth. Mothers wishing to prepare birth plans should be encouraged to do so in the knowledge that eventualities in childbirth may necessitate changes to the birthing plan for the benefit of both mother and child. Caton illustrates the polarised positons within which an obstetric anaesthetist must manage
the ethical dilemmas as explored above by describing a conversation he overheard between two midwives one of whom was pregnant. The pregnant midwife..

“wished she could have an epidural sometime in the seventh month and carry it through delivery while the other responded that she had chosen to have no anaesthesia for either of her pregnancies as she wanted to experience ‘everything’ ” [31].

**Four Principle Ethics versus Virtue Ethics**

One of the fundamental key points which can be drawn from this discussion is that the four ethical principles as championed by Beauchamp and Childress [4] conflict considerably in this situation. Each scenario brings with it its unique challenges for the obstetric anaesthetist.

Research such as that of Saunders [18] and Jackson’s [19] offer some comfort to the anaesthetist endeavouring to obtain an informed consent from the labouring mother. However, this research is not without challenge. Gardiner opines that when “the four principles conflict it is not always easy to decide which should dominate” [32]. He observes how the four principles approach has limitations and does not take into account “the emotional element of human experience” [32]. Gardiner is therefore an advocate of the virtue ethics approach as an ethical framework in healthcare rather than the four principles approach. He explains how virtue ethics focuses "on the character of the moral agent rather than the rightness of his or her
action” [32]. This would therefore allow for the human experience to be considered when confronted with ethical dilemmas such as those described in this chapter.

Braun et al also observe how virtue ethics are less constrained by principles and “more accommodating of the complexity of the ethical challenges often faced in healthcare” [33]. In light of the conflicts which arise in the context of the four principles approach and the challenges these present for the obstetric anaesthetists, this is perhaps an avenue worth exploring.

Regardless of the ethical framework adopted, the obstetric anaesthetist must always endeavour to administer the obstetric epidural to the labouring mother in accordance with the law. This presents further challenges which are perhaps even more worrisome for the obstetric anaesthetist. Such challenges will be explored in the next chapter and will again demonstrate the testing nature of this area of anaesthesia.
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As indicated in the previous chapter, in recent decades there has been a shift away from the paternalistic nature of the doctor / patient relationship to one of partnership between the doctor and his patient. Donnelly opines that the reason for this shift is twofold [1]. Firstly, it originated in the developing mistrust in the medical profession among citizens as a result of research studies such as the Tuskegee Syphilis Study\textsuperscript{12} where abuses of vulnerable members of society at the hands of medical researchers occurred and secondly, on account of a growing awareness of civil rights and a rise in feminism in the 1960s.

According to the Medical Protection Society it is the duty of the clinician to respect his patient’s right to self-determination and, where this is not possible, to act in his patient’s best interests [3]. In Irish maternity hospitals the HSE’s National Consent Policy [4] governs the doctrine of Informed Consent. Based on this policy the

\textsuperscript{12} This study was conducted by the U.S. Public Health Service (PHS) from 1932 to 1972, and examined the natural course of untreated syphilis in African American men. A group of 399 infected patients and 201 uninfected control patients were recruited for the program. The subjects were all impoverished and were not told that they had syphilis or that the disease could be transmitted through sexual intercourse. Instead, they were told that they had “bad blood”. Treatment was initially part of the study. Some patients were administered arsenic, bismuth, and mercury. But after the original study failed to produce any useful data, it was decided to follow the subjects until their deaths, and all treatment was halted. Penicillin was denied to the infected men after it became available in the mid-1940s. It was still being withheld from them 25 years later. It is estimated that more than 100 of the subjects died of tertiary syphilis. The study finally came to an end in 1972 when the program and its unethical methods were exposed in the press. A class action suit against the federal government was settled out of court for $10 million in 1974. The same year the U.S. Congress passed the National Research Act, requiring institutional review boards to approve all studies involving human subjects. In 1997 President Bill Clinton issued a formal apology for the study [2].
expectation is that the obstetric anaesthetist will enter into a partnership with his patient premised upon openness, trust and good communication [5].

In accordance with the National Consent Policy, for consent to be valid the patient must:

- have received sufficient information in a comprehensible manner about the nature, purpose, benefits and risks of an intervention/service or research project:
- not be acting under duress; and
- have the capacity to make the particular decision [6]

The obstetric anaesthetist foreseeably encounters challenges in meeting these requirements when asked by a woman in labour to administer an epidural. In this chapter the legal consequences of such challenges and how the shift from paternalism to partnership has been reflected in the law are examined.

**The Doctrine of Informed Consent**

To understand the rationale behind the evolution of the doctrine of informed consent it is necessary to conduct an analysis of relevant case law. A prudent starting point is Daniel v Heskins, 1954 where the paternalistic approach was adopted in the Supreme Court by Kingsmill Moore J when he stated:-

“An attempt to substitute a rule of law or even a rule of thumb or practice for the individual judgement of a qualified doctor doing what he considers best for the particular patient would be disastrous [7].”
When comparing this theory to today’s partnership approach one commentator described this as “undoubtedly the high point of medical paternalism recognised in Irish jurisprudence [8]”.

In contrast with Kingsmill Moor J, in more recent times Madden opines that

“Decisions about what form of treatment to undergo….are not simply technical medical judgements to be made by medical professionals [9].”

Madden references Dworkin in support of this view who observed that

“To suppose that these are matters of expertise, decisions to be taken by experts represents a denial of autonomy [10].”

Such opinion was beginning to emerge in case law in the UK by the late 1950s. In the landmark English case Bolam v Friern Hospital Management Committee 1957 [11] the Plaintiff sustained injuries during electro convulsive therapy. He alleged that he had not been warned of the risks involved in this therapy as a result of which he was deprived of the opportunity of deciding whether he wanted to take those risks. Justice McNair directed the jury that they had to decide that:

“When the defendants adopted the practice they did (namely, the practice of saying very little and waiting for questions from the patient) they were falling below a proper standard of competent professional opinion on the question of whether or not it is right to warn” [12].

After a retirement of forty minutes the jury found in favour of the hospital. It was established that it was not common practice among the medical profession to warn
of such risks at that time and as such the hospital had acted in accordance with a practice accepted as proper by a responsible body of medical men.

This became known as the “Bolam principle” and was subsequently applied in the case of Sidaway v Board of Governors of Bethlem Royal Hospital 1985 [13] where a patient was left severely disabled after an operation on his spine. It was held that the doctor had not acted in breach of his duty for failing to disclose the inherent risk of paraplegia as not disclosing this risk was consistent with medical practice in the speciality at the relevant time.

In essence, the Bolam principle meant that it was for the doctor to decide what a patient should be told, balancing this with the patient’s right to information to make a decision. Cases such as these became persuasive authority in the Irish Jurisdiction. However, it should be noted that Lord Scarman in his dissenting judgement in Sidaway observed:

‘The doctor’s duty arises from his patient’s rights. If one considers the scope of the doctor’s duty by beginning with the right of the patient to make his own decision whether he will or will not undergo the treatment proposed, the right to be informed of significant risk and the doctor’s corresponding duty are easy to understand: for the proper implementation of the right requires that the doctor be under a duty to inform his patient of the material risks inherent in the treatment [14]’

Lord Scarman’s views were indicative of the growing awareness and respect for patient autonomy and the gradual evolution of the patient centred approach to informed consent.
In 1989 the basic principles of medical negligence in the Irish jurisdiction were established in Dunne v National Maternity Hospital 1989 [15] where it was held by the Supreme Court that in order to prove negligence the Plaintiff must prove that the defendant clinician had been:

“guilty of such failure as no medical practitioner of equal specialist or general status and skill would be guilty of if acting with ordinary care” [16].

This test is more commonly known as “the reasonable doctor” test. It was endorsed by Finlay CJ in Walsh v Family Planning Services, 1992 [17] where a patient suffered from severe pain following a vasectomy operation not relieved by further surgery. The Court held that the fact that this surgery was elective placed a more onerous duty on the clinician to warn of the possible harmful consequences in the clearest language. However, it found that the hospital had fulfilled its duty in this regard by telling the patient there was a small risk he would suffer pain as a result of the surgery.

In the landmark case of Geoghegan v Harris, 2000 [18] the Court took a different approach to that in Dunne in respect of informed consent and established “the reasonable patient” test, again reflective of the shift from the paternalistic approach to the partnership approach. In this case the Plaintiff underwent a dental implant requiring retrieval of a bone graft from his chin. The Plaintiff suffered nerve damage as a consequence of the procedure leaving him with long term pain. He alleged that he was not advised of this risk. In his defence the dentist explained that he did not advise the Plaintiff of this risk as there was a less than 1% chance of the risk occurring. In response the Plaintiff indicated that he would not have undergone the
operation had the risk been even 0.1%. The court held that provided the risk carried grave consequences it ought to be disclosed. Statistical frequency was irrelevant in the Court’s view. Nonetheless, the Court found that the evidence indicated that the Plaintiff was eager to have the surgery even if this risk had been disclosed and that a reasonable person in his position would have proceeded with the surgery. The Plaintiff’s action therefore failed.

Geoghegan v Harris established that it is for the patient to prove that he would not have undergone the operation had he been advised of the said risk. Two important points arise as a consequence:

1. The clinician must disclose a material risk associated with the procedure regardless of its remoteness
2. A patient must prove that had he been informed of that risk he would not have undergone the procedure.

In Madden’s opinion this case represented “an important indication of judicial willingness to move in the direction of greater recognition of patient autonomy” [19].

Case law since Geoghegan v Harris has endorsed and reinforced this approach. In Fitzpatrick v White 2008, Justice Kearns said in the Supreme Court:-

“The patient centred test is preferable and ultimately more satisfactory from the point of view of both doctor and patient a like than any “doctor centred approach” [20].

One of the points in issue in this case was whether informed consent could be obtained in circumstances where the Plaintiff was advised of a risk thirty minutes
before surgery. While the Plaintiff was not successful in his claim Mr Justice Kearns warned how:

“There are obvious reasons why, in the context of elective surgery, a warning given only shortly before an operation is undesirable. A patient may be stressed, medicated or in pain in this period and may be less likely for one or more of these reasons to make a calm and reasoned decision in such circumstances” [21].

Mr Justice Kearns observed how associated risks could have been explained to the Plaintiff at outpatient appointments prior to the surgery. His observations regarding a patient’s ability to make a decision when “stressed, medicated or in pain” are comparable to the woman in labour requesting an epidural. Of note, Mr Justice Kearns went on to say:

“...While I have noted the views of a number of the experts to the effect that this practice of warning day patients on the day of their operation had its advantages, it seems to me that the disadvantages were far greater, including the possibility of an embittered patient later asserting that he was too stressed or in too much pain to understand what was said or to make a free decision and that he was thus effectively deprived of any choice.” [21]

Such observations could be equally applied to and relied upon by a Plaintiff pursuing a claim in negligence for damages in respect of a complication suffered as a consequence of an epidural, which she consented to in labour.

This patient centred approach was taken one step further by the UK Supreme Court in Montgomery v Lanarkshire 2015 [22] where the court held that a woman had a
right to information about any material risk in order to make an autonomous decision about how to give birth. The case related to a woman with diabetes who was pregnant with her first child. The plan was to give birth vaginally. However, she was not told of the associated risk of shoulder dystocia\textsuperscript{13}. During vaginal delivery complications arose as a result of which the baby was born with severe disabilities consequent upon oxygen deprivation at birth.

The Plaintiff issued proceedings against the hospital and claimed that she ought to have been advised of the risk of shoulder dystocia and that if she had she would have opted for an elective caesarean. In her defence the obstetrician argued that the possibility of vaginal birth causing a problem for the Plaintiff’s baby was small and that she did not advise diabetic women of this risk routinely as in her view this would lead to all such women in these circumstances requesting a caesarean section which was not in the maternal interest. The Supreme Court held that a doctor is under a duty to take reasonable care to ensure that the patient is aware of any “material” risk which could / would arise from their treatment and that the risk is “material” if a reasonable person in the patient’s position would be likely to attach significance to it or if the doctor is or should reasonably be aware that the patient would be likely to attach significance to it.

Legal commentators have described this decision as “\textit{a long awaited affirmation of a woman’s rights to personal autonomy in child birth}” [24]. It has raised the bar in

\textsuperscript{13} Shoulder dystocia is defined as a vaginal cephalic delivery that requires additional obstetric manoeuvres to deliver the foetus after the head has delivered and gentle traction has failed. Infants of diabetic mothers have a two- to four-fold increased risk of shoulder dystocia compared with infants of the same birth weight born to non-diabetic mothers [23]
terms of the enquiries the obstetric anaesthetist is expected to make with his patient for the purposes of obtaining informed consent. The words “should reasonably be aware” creates an expectation that the anaesthetist must be familiar with his patient to such an extent that he would have an awareness of the risks she would attach significance to and the risks she would not.

Whilst this undoubtedly poses challenges in terms of resource allocation in a busy delivery suite this has become the legal expectation none the less. This was demonstrated in a recent UK case Hassell v Hillingdon Hospitals NHS Foundation Trust 2018 [25]. In this case a patient made a successful claim for damages for failing to be adequately advised of the risks of spinal surgery. During cervical disc surgery she suffered damage to her spinal cord rendering her tetraplegic. She was awarded £4.4 million by the Court. She alleged negligence in respect of the surgical technique employed during surgery as well as the hospital’s failure to obtain her informed consent having not advised her of alternative treatments or warned her of the risk of spinal cord injury. She claimed that with adequate advice she would not have agreed to the surgery.

With regards her allegations relating to surgical technique the court found that the surgery was performed to a reasonable standard. However, in relation to the allegation of failing to obtain informed consent the court found that the Plaintiff had not been warned of the risk of spinal cord injury or of alternative treatments. Mr Justice Dingemans in his judgement observed that:
“Montgomery makes it clear that there must be dialogue and if there had been
dialogue Mr Ridgeway would have known that Mrs Hassell had not yet had
physiotherapy for the neck and upper arm problems” [26]. “Had (the Plaintiff)
been given information about material risks and conservative treatment (she)
would not have agreed to the operation” [27].

This is reflective of Lord Scarman’s dissenting judgement in Sidaway v Board of
Governors of Bethlem Royal Hospital, 1985 [13] thirty years previously which
planted the seed to a patient centred approach when obtaining informed consent.
Case law such as Hassell v Hillingdon is reflective of the germination of this seed.

Significantly, Mr Justice Dingemans also found that although the plaintiff was told on
the day of surgery of the risk of cord damage, a warning at that late stage was not
sufficient. This is in keeping with the warning given by Mr Justice Kearns in
Fitzpatrick v White 2008 [20], regarding the timing of advising of risks. Legal
commentators have observed how in light of this decision patients must be given
choice. “It is not enough to advise of the risks and benefits of a recommended
treatment. Patients must be told of the risks and of any reasonable alternative” and
“Warnings on the day of surgery are risky” [28]. This poses further challenges for
the obstetric anaesthetist when administering an epidural to a patient he is meeting
for the first time in the delivery suite.

In 2016 in the Irish High Court case Health Service Executive v B and Baby B [29] a
woman’s capacity during and at the end of pregnancy was the central issue. The
Health Service Executive sought an order to force a pregnant woman to have a
caesarean section against her will in order to vindicate the right to life of the unborn child. The woman had had three previous caesarean sections and now wished to have a vaginal delivery with her fourth child. This was contrary to medical advice due to the risk of uterine rupture which could lead to the death of the baby and/or the mother. The High Court ruled that the woman could not be forced by the court to undergo a caesarean section. While the court indicated that it could not understand why she would not follow the medical advice, it would not make an order whereby she would be forced to:

"have her uterus opened against her will, something which would constitute a grievous assault if it were done on a woman who was not pregnant" [30].

Of note, when assessing capacity the court heard evidence in respect of the dialogue between the treating obstetrician and the mother during the course of her pregnancy in respect of the risks of a vaginal birth in these circumstances, thus echoing the judgement in Montgomery v Lanarkshire [22]. Justice Twomey in his judgement said:

"For his part, Dr. A confirmed that Ms. B was an articulate person and understood the risks involved. There was no suggestion that she suffers from any psychiatric condition ...."[31]

The court found that the mother had full decision making capacity and that she therefore had a right to make a decision of this sort14.

14 It should be noted that after this judgement was delivered the mother’s waters broke and she in fact decided to follow medical advice and undergo an elective caesarean section giving birth to a healthy baby girl [32].
In 2017 in an unreported Irish Circuit Court Case [33] the issue of capacity arose again, this time during labour. The Plaintiff sought damages for distress caused by the videoing of the insertion of an epidural during labour for educational purposes. The hospital in its defence said that the Plaintiff had consented to the procedure being filmed for these purposes. The Plaintiff’s barrister argued that it was not sufficient for the doctor to say that he perceived that she had capacity to consent, noting that the Plaintiff had only been asked for her consent to film the insertion of the epidural after she requested the epidural while in labour. The judge found in the Plaintiff’s favour and awarded her €30,000 in damages. It was the Judge’s view that while the doctors had not done anything wrong there was fault with the consent process. The judge held that because of her level of stress at that time she may not have been in a position to make a calm, reasonable decision.

Whilst this is in keeping with Mr Justice Kearn’s judgement in Fitzpatrick v White 2008 [19] the rationale behind the judge’s decision was not documented as a written judgement was not handed down in this case. This is unfortunate in terms of the evolution of the law in this area. None the less, this case highlights the probability of the Court being sympathetic towards a Plaintiff who raises concern regarding the consent process in labour. As a consequence the obstetric anaesthetist must take every measure to protect himself when obtaining consent in this situation.

**Litigation Statistics**

In this section two research studies relating to litigation arising as a consequence of regional anaesthesia in England and Canada are reviewed. The Canadian study in
particular demonstrates that if litigation is to be minimised there must be an effective process in place in relation to obtaining informed consent for epidurals by obstetric anaesthetists.

**England**

In 2010 Szypula et al undertook a study of all claims from the NHSLA’s database relating to regional anaesthesia and analgesia that occurred between 1995 and 2007 [34]. The number of claims analysed was 366. Of these claims 186 related to obstetric regional anaesthesia. The types of claims arising from obstetric anaesthesia were recorded as follows:

- Needle insertion into wrong position during spinal anaesthesia for removal of retained placenta
- Paraplegia following labour epidural analgesia
- Neurological damage following combined spinal-epidural anaesthesia
- Pain and weakness in leg and back following damage to nerve roots during epidural via “needle through needle technique”
- Spinal infarct after prophylactic saline infusion for dural puncture following labour epidural
- Spinal anaesthetic complicated by cord damage leading to permanent disability
- Labour epidural complicated by dural puncture, leading to ongoing backache and hearing problems

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15 National Health Service Litigation Authority is responsible for handling clinical and non-clinical claims on behalf of NHS bodies in England.
- Nerve damage following spinal anaesthetic for elective caesarean section
- Nerve damage during combined spinal-epidural anaesthesia

Neuraxial block accounted for all of the obstetric claims. The most frequent damaging events for obstetric neuraxial claims were inadequate block (57 claims), nerve damage (39 claims) and back pain (19 claims). The total cost of obstetric claims relating to regional anaesthesia was £5,433,920 and for non-obstetric claims £7,290,097.

The authors of the study hoped that its findings would assist in the development of guidelines for safe practice and risk avoidance and would act as a useful tool for clinicians in demonstrating the type and nature of cases that lead to litigation. Of note 10% of the claims, to include obstetric and non-obstetric, pleaded allegations relating to failure to obtain informed consent. It was anticipated that this finding would:

"act as an impetus to anaesthetists to consider how best to deliver and document information about the risks and benefits of regional blocks" [35].

Canada

Peng et al, conducted an analysis of closed claims relating to regional analysis between 1990 and 1997 [36]. Although dating back some 21 years this study provides useful information. Within this period 7909 legal actions were closed by the Canadian Medical Protective Association. Three hundred and ten of these cases named the anaesthetist as the defendant to the proceedings; 61 of these cases related to regional anaesthesia given between 1982 and 1996; 42 of these cases
were associated with neuraxial block and 34 of these 42 cases related to perioperative or obstetric settings.

The reason for the claims relating to obstetric cases were documented as follows:
- Post dural puncture headache
- Cardiorespiratory arrest
- Paraplegia
- Pain
- Catheter shear
- Viral meningitis
- Poor baby outcome

The legal outcome for malpractice claims relating to regional anaesthesia were as follows:
- 79% dismissed
- 11% settled
- 8% judgment for the Defendant
- 2% judgement for the Plaintiff

The authors of the report concluded that anaesthetists can protect themselves by documenting assessments, consent discussions, pre-existing conditions, details of procedures and monitoring, as well as vital signs. In terms of neuraxial blocks they advised that well recognised complications and material risks should be discussed before obtaining a verbal or written consent. Untoward reactions should be documented contemporaneously. In conclusion the authors warned;
“Good communication before, during and after the procedure may prevent malpractice claim” [37].

Of note, Chattopadhyay et al warn how “litigation has a very grave impact on obstetric anaesthesia practice” [38]. They describe this as

“The physician having one eye on the courts of law instead of both eyes on the patient. This leads to defensive practice by doctors increasing the burden of investigations, raising the pressure on health care system, infrastructure and expenses” [38].

Whilst measures can be taken by obstetric anaesthetists to avoid litigation, Chattopadhyay observes how “Litigation cannot be totally prevented” [38]. However, if obstetric anaesthetists follow Peng et al’s advice by maintaining good documentation and communicating effectively with patients in a timely manner, this will be undoubtedly stand to their benefit when defending litigation.

**Capacity**

The assessment of capacity is often a difficult exercise for a clinician, frequently requiring the assistance of the Court to determine. Prior to Fitzpatrick v FK 2008 [39], a status based approach was taken to assessing capacity in law. This meant that a person’s capacity was determined by the category of person to which he / she belonged. For example, a person suffering with dementia or a mental health condition would be considered as incapable of making decisions about his / her medical treatment.
Fitzpatrick v FK changed this status approach to one of a functional approach. In this case a Congolese national suffered a massive post-partum haemorrhage. She refused a blood transfusion. Her friend and interpreter explained that she was a Jehovah’s Witness and could not have a transfusion. Despite alternative treatment her condition deteriorated. The patient was advised of the risk of death if she did not receive a blood transfusion. However, she responded by asking for ‘Coca Cola, tomatoes and eggs’ [39]. The hospital made an application to the High Court stating that, they were concerned about the patient’s capacity. The court granted the order on the grounds that the welfare of the newly-born child of the patient was paramount and that the baby should not be left an orphan. The patient received the blood transfusion and survived.

The matter went to the Supreme Court. It was the patient’s case that her bodily integrity had been violated. The Supreme Court held that for the patient to have the necessary capacity she would have had to believe that a blood transfusion was necessary and that without it she might die. It further held that the hospital was justified in doubting that she had capacity as she had undergone a prolonged labour, a challenging delivery and a post-partum haemorrhage. The court concluded that the Plaintiff did not have capacity and that the hospital had acted lawfully in administering the blood transfusion.
Of note, the presumption of capacity which currently exists now has statutory footing in the form of the Assisted Decision Making Capacity Act 2015\textsuperscript{16}. The essence of this act is that a person’s capacity shall be assessed on the basis of his / her ability to understand at the time that a decision is to be made, the nature and consequences of the decision in the context of the available choices at the time.\textsuperscript{17} Importantly this means that a pregnant woman is presumed to have capacity and that her capacity should not be called into question unless there is a sufficient trigger. This in turn means that with a woman in labour there is a presumption of capacity, not a presumption that she lacks capacity simply because she is in labour. This is of particular importance for the obstetric anaesthetist when obtaining consent for epidurals.

However, the act also arguably bestows on a pregnant woman a status akin to a second class citizen. Section 85 (6) of the act provides a mechanism to ensure that the interests of the unborn are safeguarded even if this involves overriding the mother’s right to autonomy. It provides that where a pregnant woman who makes an advanced care directive lacks capacity but her directive does not state whether or not she intended a specific refusal of treatment set out in the directive to apply if she were pregnant, and complying with the refusal would have an adverse effect on the unborn, there shall be a presumption that treatment shall be provided. This in

\textsuperscript{16} Of note, at the time of writing this act has been implemented but not yet commenced in its entirety. Commencement orders – which were signed in October 2016 – mean that some parts of the Capacity Act have been brought into effect. These orders mean that the Decision Support Service (DSS) can be established and the working group to establish the code of practice for Advance Healthcare Directives can also be convened [40].

\textsuperscript{17} Section 3, Assisted Decision Making (Capacity) Act 2015.
essence prioritises the welfare of the unborn over the mother’s right to bodily integrity and right to self-determination.

Of note, parliamentary questions have been put to the Minster of Health by Claire Daly TD in June 2018 [41] to determine if plans are afoot to repeal section 85(6) of the Assisted Decision Making (Capacity) Act 2015 in light of the result of the 2018 referendum to repeal the 8th Amendment of the Constitution of Ireland\(^\text{18}\). The response has been that once legislation regulating termination of pregnancy has been passed by both Houses of the Oireachtas then at that stage consideration will be given to potential amendments to the Act. It therefore remains to be seen the extent to which the repeal of the 8th amendment will protect a woman’s right to self-determination and bodily integrity in pregnancy. This is a “watch this space” scenario and an important issue for obstetric anaesthetists to keep under review.

It is foreseeable that in light of the 2018 referendum result Section 7.1.1 of the HSE National Consent Policy which provides for refusal of treatment in pregnancy as set out below, will also be reviewed:

“The consent of a pregnant woman is required for all health and social care interventions. However, because of the constitutional provisions on the right to life of the “unborn”, there is significant legal uncertainty regarding the extent

\(^{18}\) The Eighth amendment of the Constitution Act 1983 amended the Constitution of Ireland by inserting a subsection (Article 40.3.3) which recognises the equal right to life of the pregnant woman and the unborn — “The state acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect, and as far as practicable, by its laws defend and vindicate that right”. The 2018 Irish referendum repealed this. Statutory implementation of this repeal is pending at the time of writing.
of a pregnant woman’s right to refuse treatment in circumstances in which the refusal would put the life of a viable foetus at serious risk. In such circumstances, legal advice should be sought as to whether an application to the High Court is necessary”. [42]

In summary, this chapter has demonstrated how the shift from paternalism to partnership in the doctor / patient relationship has been reflected in case law. It has also highlighted the risk of litigation in the area of obstetric anaesthesia as well as deficiencies in current legislation and the National Consent Policy as to how the pregnant woman’s right to self-determination is protected and in need of review, particularly in light of the repeal of the 8th Amendment of the Irish Constitution. All of these issues demonstrate the need for protection of the obstetric anaesthetist when obtaining consent from the woman in labour. What measures can be taken in this regard will be explored in the next chapter.
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12. Bolam v Friern Hospital Management Committee 1957 I [WLR] 582 at pg 590

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14. Sidaway v Board of Governors of Bethlem Royal Hospital [1985] AC 871 at pg 888

15. Dunne v National Maternity Hospital [1989] IR 91


17. Walsh v Family Planning Services [1992] IRR 496

18. Geoghegan v Harris [2000] 3IR 536


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CHAPTER SIX

Recommendations and Conclusion

In 1987 Nancy Rhoden, having conducted an observational study on informed consent in obstetrics, formed the view that “the prognosis for shared decision making in obstetrics is grim” [1]. Having observed the effects of the threat of medicolegal litigation, value judgements and potential conflicts in obstetrics, such was Rhoden’s pessimism that she concluded:

“In obstetrics informed consent may soon pass from being a necessary illusion to an illusion that is not necessary at all [2]”

The purpose of this paper has been to analyse the challenges encountered by anaesthetists when obtaining informed consent for epidurals during labour. Having considered both the ethical and legal complexities of this situation, has Rhoden’s prophecy come to fruition more than thirty years on? Is consent for obstetric epidurals simply an illusion and not truly informed or, has this paper demonstrated that consequent upon changes in practice in medicine, an evolving jurisprudence, a shift from a culture of paternalism to partnership in the doctor / patient relationship and a heightened respect for women’s right to bodily integrity and self-determination, consent for obstetric epidurals is informed? The aim of this chapter is to consider this question and to make recommendations as to what measures might be put in place to further protect the obstetric anaesthetist when legal and ethical issues arise in this scenario.
As explored in chapter three, pain associated with labour is an inevitability for physical, psychological and social reasons [3]. It has been demonstrated in chapter four that there are two schools of thought as to whether the pain of labour and stress impact on a patient’s ability to give consent. There are those whose research demonstrates how labour does not affect a patient’s capacity to give consent, nor indeed does the administration of opiates in labour [4], and there are those whose research demonstrates that labour does affect a patient’s capacity to give consent [5].

**Litigation**

This dichotomy is of questionable comfort to the obstetric anaesthetist faced with a civil claim for damages for personal injury wherein allegations of negligence are made in relation to the failure to obtain informed consent for an obstetric epidural. While research papers which demonstrate that labour does not impact on a patient’s capacity to give informed consent may be of some support to the anaesthetists’ position, the presiding judge will also examine case law and legislation when determining if the anaesthetist has fulfilled his duty of care in this regard. In doing so the judge will consider the persuasive authority of case law such as Montgomery v Lanarkshire [6] and look for evidence in respect of the dialogue which has taken place between the anaesthetist and his patient regarding the effects, side effects and risks associated with the epidural and the extent to which the anaesthetist has ensured that his patient is aware of the material risks which she would attach significance to.
As examined in chapter five, it is important to bear in mind that the presumption of capacity exists currently and will be put on a statutory footing with the commencement of the Assisted Decision Making (Capacity) Act 2015. The obstetric anaesthetist is therefore entitled to presume capacity, even in labour, in the absence of any triggers to the contrary.

However, despite the presumption of capacity, civil claims against obstetric anaesthetists wherein allegations of negligence are made in respect of a failure to obtain informed consent necessitate a close examination by the court of the documentary evidence in support of the patient’s consent, as well as the oral evidence pertaining to conversations in this regard between the Plaintiff and the Defendant anaesthetist. As also illustrated in chapter five, when deciding upon the issue of informed consent the court will examine the contents of conversations which took place during outpatient appointments as well as conversations which took place once the patient was admitted for the procedure.

Clinicians should therefore be mindful of the fact that obtaining a patient’s consent is not simply an exercise evidenced by a signed consent form. It is in fact a process which can evolve over weeks if not months depending on the circumstances of the case and which should be carefully documented on each occasion. A stand-alone consent form is simply no longer sufficient evidence of informed consent. As highlighted in Chapter 5, this was demonstrated in the 2016 High Court case Health Service Executive v B and Baby B [7].
The Need for Change

Significantly, in 2008 two anaesthetists wrote to the British Medical Journal advocating for a change in process of consent for epidurals in labour [8]. They observed how;

“The patient has nine months to anticipate this potential procedure which should allow time for a discussion of the benefits, risks and alternatives and an opportunity to consent when they are able to weigh up and retain the information. In short they have 9 months to be consented in the antenatal clinic. It is time for a change in the process of consent for epidurals in labour.”

Similarly, in recognition of a need for change, Hegarty et al [9] conducted research in 2014 which demonstrated major variation across Ireland in terms of the risks obstetric anaesthetists discussed with women and the risks quoted in relation to the obstetric epidural. In particular they found low reported discussion of the serious risks of epidural analgesia. Hegarty in turn warned:

“It is incumbent on the physician to ascertain what is reasonable and material for the patient….A risk is material when a reasonable person would be likely to attach significance to the risk in deciding whether or not to forgo the proposed therapy [9]”.

Hegarty’s research attracted a response of 88%. The participants indicated an overwhelming support for the use of a National Standardised Information Card relating to obstetric epidurals similar to that of the UK’s Obstetric Anaesthetists Association (see Appendix 1). Of significance, participants felt that the antenatal clinic was the best environment to introduce such a card to the expectant mother.
In 2003 White et al’s [10] research demonstrated how the use of an A5 laminated epidural information card by the midwifery and anaesthetic staff during labour acted as a focus point for discussion and led to significant improvement in the level of knowledge about epidural analgesia compared to women who did not have the benefit of such an information card during labour.

**A National Standard**

Hegarty’s and White’s findings [9, 10] both demonstrate how a national standard in relation to obtaining consent for epidurals is required in this jurisdiction. Their research shows that the use of an information card enhances the consent process in respect of obstetric epidurals and that the antenatal clinic would be the optimal location to introduce such a card to both expectant mothers and where possible, their partners.

Of note, in terms of practice in the three Dublin Maternity Hospitals the following is the position:

The Coombe Women and Infant’s University Hospital uses its own Patient Information Leaflet and Epidural Information Card, which is also a consent form (see Appendix 2). The Patient Information Leaflet is given to all antenatal patients and the Epidural Information Card is given to all women on admission to the labour ward. The patient signs the Epidural Information Card / consent form prior to the insertion
of the epidural\textsuperscript{19}. The hospital website also provides details of all analgesia options available to include epidurals.

In the National Maternity Hospital expectant mothers are given information about all available forms of pain relief including obstetric epidurals during the second ante-natal class (typically 30 weeks gestation). Antenatal classes at the National Maternity Hospital are midwifery led. It is estimated that approximately 55-60\% of first time mothers attend these classes and approximately 23\% of repeat mothers attend these classes. The midwives follow the information leaflet provided by the Obstetric Anaesthetist Association \textsuperscript{[11]} and while expectant mothers are not given a copy of this leaflet they receive a paper handout which includes the reference link to the leaflet should they wish to read it\textsuperscript{20}. The hospital website provides details of all analgesia options available. It also provides a link to the above Obstetric Anaesthetists Association document. Some expectant mothers will be seen by an anaesthetist at the Anaesthetic clinic. Depending on the reason for referral, there may be a discussion about obstetric epidurals. Once the patient is on the labour ward, if she requests an obstetric epidural, the midwife will give the patient and their partner a summary document from the Obstetric Anaesthetists Association \textsuperscript{[12]}. The anaesthetist then attends the patient and verbally outlines the procedure, discusses relevant risks and answers any questions before siting the epidural.

\textsuperscript{19} Information obtained via inquiry with The Coombe Women and Infant’s University Hospital
\textsuperscript{20} Information obtained via inquiry with the Department of Anaesthesia, National Maternity Hospital
As of 13th January 2018, the National Maternity Hospital maintains an electronic patient record for all obstetric patients. This is part of a national electronic patient record project for all obstetric patients known as the MN-CMS. It is currently only available in some Irish maternity units but the plan is to roll this project out to all over the coming years. This record includes a section relating to consent for obstetric epidurals and records the date and time of administration of the epidural and by whom, the antenatal information the mother received to include attendance at antenatal classes and/or information leaflets provided. It also records the type of consent given to include verbal, written or other. The anaesthetist completes this form for all patients who have obstetric epidurals.

The Rotunda Hospital hospital’s website also provides details of all analgesia options available and, like the National Maternity Hospital, also provides a link to the above Obstetric Anaesthetists Association information leaflet. Of note, the Rotunda Hospital’s website provides details of side effects associated with epidurals to include the possibility of the second stage of labour taking longer, assisted birth with forceps or vacuum may be required, backache, headaches and the risk of nerve injury. Expectant mothers booked with the hospital are given an information booklet, one page of which is dedicated to epidurals, their risks and benefits. All women are offered midwifery led antenatal classes wherein epidurals are discussed. Anecdotal evidence indicates that during antenatal classes expectant mothers can ask

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21 The MN-CMS (Maternal and New born Clinical Management System) Project is the design and implementation of an electronic health record (EHR) for all women and babies in maternity services in Ireland. This record will allow all information to be shared with relevant providers of care as and when required. [13]

22 Information obtained via inquiry with the Department of Anaesthesia, National Maternity Hospital
questions about methods of pain relief during labour, including epidurals and any question that cannot be answered is referred to an anaesthetist for clarity. A record of attendance is kept. Expectant mothers who are classified as high risk are referred to a specific anaesthetic clinic where a one to one discussion is held regarding specific anaesthetic risks and benefits. The Rotunda hospital is also involved in the MN-CMS project.

Practices such as those described above are a step forward in this complex area of anaesthesia. In light of Hegarty’s findings of the wide variation in practice [9] in Ireland regarding the practice of obtaining informed consent for epidurals, a national standard governing the consent process across the 19 public maternity units would encourage a uniform approach. This would in turn lead to expectant mothers, and where possible their partners, being furnished with important information in a timely manner allowing them time to consider and discuss the information with their loved ones in a calm environment and help lessen the legal and ethical challenges arising in this area. Such a national standard would include a nationalised information card being first presented in the antenatal period and reintroduced in the delivery suite as well as an education programme whereby the obstetric anaesthetist would participate in antenatal education by advising expectant mothers of the effects, side effects and risks associated with epidural analgesia. A record of attendees would be maintained and recorded in patient’s individual charts. However, such a national standard, while ideal will of course raise issues in respect of resources.

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23 Information obtained via inquiry with midwifery staff at the Rotunda Hospital
24 Information obtained via inquiry with the Department of Anaesthesia, The Rotunda Hospital
A Question of Resources: What to do?

As discussed in chapter three Fröhlich et al [5] have highlighted how social and legal aspects of the informed consent process have changed dramatically over recent years. They acknowledge that obtaining informed consent now presents significant logistical difficulties for the anaesthetist and that it is not always possible to inform women of the effects, side effects and risks associated with obstetric epidurals prior to labour. Nonetheless, they make the following recommendations which in their view “would improve the current situation significantly with limited resource requirements [13]”:

- All reasonable attempts should be made to provide information to women prior to the onset of labour
- Provide detailed written information regarding labour analgesia at their early antenatal visits
- Take informed consent for epidural analgesia at a subsequent visit or on admission to hospital.

These recommendations reiterate those made by Hegarty and White and are central to protecting the obstetric anaesthetist and ensuring his patient has sufficient information to make a voluntary and balanced decision. However, it is unrealistic to expect the anaesthetist to be available on every occasion in the antenatal period to achieve these recommendations. A multi-disciplinary approach to the dissemination of this information to expectant mothers would therefore be necessary involving midwifery and obstetric staff. It is for hospital management to ensure that such staff are provided with the necessary training and skills to facilitate this.
Birth Plans

The antenatal clinic is also the ideal location to discuss birth plans and encourage expectant mothers and their partners to keep an open mind in terms of pain relief in labour. While it might be reasonable in the calmness of the antenatal period for an expectant mother to stipulate in her birth plan that she does not want to have an epidural, as demonstrated in Fröhlich et al’s study [5], 35 out of 100 mothers had a change of plan regarding epidurals when faced with the reality of child birth. It would be useful to include findings such as this in antenatal education so that the gap between pregnant women’s expectations of pain in labour and their actual experience of labour as identified by Lally et al [14] and explored in chapter three, could be filled.

Professional Bodies

In 2013 the Association of Anaesthetists of Great Britain and Ireland and the Obstetric Anaesthetic Association published Guidelines for Obstetric Anaesthetic Services [15]. In relation to informed consent they provided:

“The principles of consent for anaesthesia or analgesia are set out in national guidelines. It is not usually considered necessary to obtain written consent. Brief details of the discussion that has taken place and of risks that the patient has been informed about should be recorded” [16].

Whilst it is recognised that the implication of this statement is that it should be read in conjunction with the National Consent Policy, in light of the medico-legal risk associated with obstetric analgesia as illustrated in chapter five, this guideline could be criticised for failing to provide adequate guidance in respect of the obstetric
anaesthetist’s legal and ethical duties in terms of informed consent. It provides no explanation regarding the reasonable patient test and little explanation as to expectations in terms of dialogue and/or documentation, nor does it give any indication that obtaining consent is a process rather than an exercise. At best it is reflective of a poor understanding of the doctrine of informed consent, at worst it is reflective of an indifference to the doctrine of informed consent. This guideline is due for review this year. It is recommended that it should be updated to reflect the legal and ethical expectations of the obstetric anaesthetist when obtaining informed consent and the measures which should be put in place to ensure every effort is made to meet these expectations. The obstetric anaesthetist needs reliable professional support given the complex nature of this field of anaesthesia. His professional body should make every endeavour to meet this need.

While the Guidelines for Professional Conduct and Ethics for Registered Medical Practitioners 2016 provides more detailed guidance regarding the ethical and legal obligations of the clinician when obtaining consent, it does not provide specific guidance in respect of obtaining consent during labour save for:

“You should not usually seek consent from a patient when they are stressed, sedated or in pain and therefore less able to make a calm and reasoned decision” [17].

This simply reiterates the need for a national standard for the purposes of obtaining informed consent for obstetric epidurals.
Continuing Professional Development

A final recommendation would be to include in continuing professional development for obstetric anaesthetists annual group sessions with an ethicist and a medico-legal specialist where they can gain a better understanding of their legal and ethical obligations in this difficult field creating a heightened awareness and understanding of the significant issues in relation to the doctrine of informed consent. This would assist the anaesthetist when managing such issues in the busy, ever changing, overstretched, demanding and dynamic maternity unit.

Summary

In conclusion, the purpose of this paper has been to analyse the challenges encountered by obstetric anaesthetists when obtaining informed consent for epidural in labour. Turning back to Rhoden’s view in 1987 that “In obstetrics informed consent may soon pass from being a necessary illusion to an illusion that is not necessary at all [2]”, the reality is that there remains the possibility that informed consent in some instances will be illusionary. The fact remains that labour is painful. Pain, stress and opiates may impact on a person’s capacity. Consent may be obtained none the less which may not necessarily be informed and litigation and / or an ethical dilemma may ensue. However, if the recommendations referred to above are implemented the incidence of litigation and ethical dilemmas may lessen and the obstetric anaesthetist may be provided with effective professional support. Professional bodies need to have greater cognisance of the complexities of this scenario and ensure that their members are adequately supported and furnished with appropriate advice and guidelines. Obstetric anaesthetists need to
be mindful of the evolving case law in respect of consent and the changing statutory
landscape in relation to capacity.

It should be noted that in 2016 The Health Information and Quality Authority
launched a set of National Standards for Safer Better Maternity Services [18]. A
detailed examination of these standards is beyond the scope of this paper. However,
their overriding objective is to improve the quality and safety of maternity services in
Ireland. Whilst the doctrine of informed consent is included in these standards they
do not include a standard specific to informed consent in the context of obstetric
epidurals. In light of the findings of this paper such a standard is required.

A further area worthy of research for the purposes of such a standard but beyond
the scope of this paper is obtaining informed consent for the administration of
epidurals to minors in labour. This is undoubtedly a situation which the anaesthetist
encounters and which is worthy of guidance.

Finally, what must not be lost amongst the complexities of this area is that there is
no doubt obstetric epidurals are of immense benefit to a large proportion of women
when in labour. They can enhance the experience of child birth by making it
rewarding, positive and pain free where joyful moments and happy memories are
created. This is the core objective of the obstetric epidural. Obstetric anaesthetists
should in turn be provided with optimal support when performing this function.
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Epidurals in labour – what you need to know

This is a summary. There is fuller information in the Pain Relief in Labour section. Please discuss anything that is not clear with your anaesthetist.

Setting up your epidural

- You will need to have an intravenous cannula and maybe a drip. While the epidural is being put in, it is important that you keep still and let the anaesthetist know if you are having a contraction.
- Usually takes 20 minutes to set up and 20 minutes to work. Some epidurals do not work fully and need to be adjusted or replaced.

Advantages of an epidural

- Usually provides excellent pain relief.
- Sometimes a spinal is given first for a quicker effect.
- The dose or type of local anaesthetic can sometimes be altered to allow you to move around the bed. This is a lowdose (or mobile) epidural.
- In general epidurals do not affect your baby. Can be topped up for caesarean section if required.
Possible problems with your epidural

- Repeated top-ups with stronger local anaesthetic may cause temporary leg weakness and increase the risk of forceps or ventouse delivery.
- The epidural may slow down the second stage of labour slightly. You may develop low blood pressure, itching or a fever during the epidural.
- The epidural site may be tender but usually only for a few days. Backache is NOT caused by epidurals but is common after any pregnancy.
## Risk of having an epidural or spinal to reduce labour pain

<table>
<thead>
<tr>
<th>Type of risk</th>
<th>How often does this happen?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Significant drop in blood pressure</td>
<td>One in every 50 women</td>
</tr>
<tr>
<td>Not working well enough to reduce labour pain so you need to use other ways of lessening the pain</td>
<td>One in every 8 women</td>
</tr>
<tr>
<td>Not working well enough for a caesarean section so you need to have a general anaesthetic</td>
<td>One in every 20 women</td>
</tr>
<tr>
<td>Severe headache</td>
<td>One in every 100 women (epidural) One in every 500 women (spinal)</td>
</tr>
<tr>
<td>Nerve damage (numb patch on a leg or foot, or having a weak leg)</td>
<td>Temporary - one in every 1,000 women</td>
</tr>
<tr>
<td>Effects lasting for more than 6 months</td>
<td>Permanent - one in every 13,000 women</td>
</tr>
<tr>
<td>Epidural abscess (infection)</td>
<td>One in every 50,000 women</td>
</tr>
<tr>
<td>Meningitis</td>
<td>One in every 100,000 women</td>
</tr>
<tr>
<td>Epidural haematoma (blood clot)</td>
<td>One in every 170,000 women</td>
</tr>
<tr>
<td>Accidental unconsciousness</td>
<td>One in every 100,000 women</td>
</tr>
<tr>
<td>Severe injury, including being paralysed</td>
<td>One in every 250,000 women</td>
</tr>
</tbody>
</table>

The information available from the published documents does not give accurate figures for all of these risks. The figures shown above are estimates and may be different in different hospitals. Retrieved from Obstetric Anaesthetist’s Association website at [http://www.oaa-anaes.ac.uk/home](http://www.oaa-anaes.ac.uk/home) at “Information for Mothers” at [file:///D:/Downloads/Epidural_Information_Card.pdf](file:///D:/Downloads/Epidural_Information_Card.pdf).
APPENDIX 2

Labour Epidural Analgesia
Patient Information Leaflet

Introduction

The amount of pain a woman feels during labour differs from woman to woman. Pain depends on many factors, such as the size and position of the baby, the strength of contractions and whether your labour has been induced. There are several ways of helping you cope with pain during childbirth including having an epidural.

What is an Epidural?

The epidural space is a tiny space close to the spine. Having an epidural involves placing a small plastic tube into this space, through which pain relieving drugs can be given as often as is necessary. While epidurals provide pain relief you may still be aware of pressure sensation.

What does it involve?

Only anaesthetists can administer epidurals. During busy times it may take some time for an anaesthetist to arrive to perform the epidural. You will first need a drip with fluid running into a vein, if you do not already have one. You will be asked to either curl up on your side or sit bending forwards. Your skin will be cleaned and local anaesthetic used to numb the skin. An epidural needle is used to insert a small plastic tube (catheter) into the epidural space. The needle is withdrawn once the catheter has been inserted and then the catheter is taped into place on your skin. During the insertion of an epidural extreme care is needed to avoid accidental puncture of the bag of fluid around the spinal cord as this may give you a headache afterwards. Therefore, it is most important that you keep still during the procedure. Afterwards you will be confined to bed and will need continuous monitoring of the baby's heartbeat. You will be free to move from side to side or sit up but you should avoid lying on your back. Pain relieving drugs will then be given into the catheter in one of two ways: (1) continuously by a pump with the option of you pressing a button for an extra dose if needed or (2) the midwife can give top-ups as they are needed. While the epidural is taking effect the midwife will take your blood pressure regularly and check that the epidural is working properly. It usually takes 20 minutes to work fully and occasionally needs some adjustment.
or repeating if it isn't working well. Once it is working the midwife will insert a tube into your bladder as the epidural may remove the urge to urinate.

**Who can have an epidural?**

Most women are suitable for this form of pain relief. There are some conditions that make it unsuitable for example bleeding disorders, previous spinal cord surgery and some heart conditions. If you have any questions or concerns you should discuss them with your obstetrician who may then refer you to be seen by an anaesthetist before the onset of labour.

**What are the side effects of an Epidural?**

- Occasionally (1 in 50 epidurals) it can cause your blood pressure to decrease transiently, which is why you are given fluids through a drip.

- If the covering (dura) around the spinal fluid is pierced during the insertion of the epidural you can get a bad headache that may interfere with you looking after the baby afterwards. In this hospital the risk of this is 1 in a 100 epidurals. This may just need treatment with painkillers, but sometimes you may need another epidural to treat the headache some days later.

- You may feel shivery after the epidural is inserted

- Occasionally (1 in 30 epidurals) the epidural may not provide total pain relief. This may be fixed by adjusting the catheter, but sometimes the epidural procedure may need to be repeated.

- The effects of epidural pain relief on labour have been subject to extensive research. Epidural pain relief is associated with an increased need for instrumental (vacuum/forceps) assisted delivery. It does not increase the need for a caesarean section.

- Backache is common during pregnancy and often continues afterwards too. Your back may be sore from the injection for a few days but epidurals do not cause long-term backache.

- Temporary nerve damage (eg. numb patch on your leg) is rare - 1 in 1000 epidurals.

Permanent nerve damage is extremely rare (less than 1:13,000).

**What are the serious complications?**

An epidural is the most complex method available for relieving childbirth pain, and although serious complications are very rare (1 in a 100,000 epidurals), they can occur. There is a risk of accidental injection of local anaesthetic into a vein in the spine. This can cause dizziness, heart problems and fits. This is why only trained personnel anaesthetist or midwife can administer epidural medication. The small tube can be placed into the spinal fluid compartment instead of the epidural space. This could cause temporary paralysis and affect your chest muscles making it hard for you to breathe and may cause your blood pressure to fall. Anaesthetists are equipped with skills to properly manage and treat these complications. *The anaesthetist will be happy to discuss this information and your questions.*

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1. It is important to keep still during the epidural insertion
2. It usually takes about 20 minutes for insertion and another 20 minutes for it to work
3. Some epidurals do not work fully and may need to be adjusted or repeated
4. Possible problems associated with your epidural:
   - May cause temporary leg weakness and increase risk of forceps or ventouse delivery
   - You may develop low blood pressure, high block, itching or a fever during the epidural
5. Risks of having an epidural for labour analgesia are as follows:

<table>
<thead>
<tr>
<th>Complications</th>
<th>Risk</th>
<th>How common is it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drop in blood pressure</td>
<td>1 in 50</td>
<td>Occasional</td>
</tr>
<tr>
<td>Severe headache</td>
<td>1 in 100</td>
<td>Uncommon</td>
</tr>
<tr>
<td>Nerve damage (numb patch on the leg or foot, or a weak leg)</td>
<td>1 in 1000</td>
<td>Rare</td>
</tr>
<tr>
<td>Effects lasting for &gt;6 months</td>
<td>1 in 13 000</td>
<td>Rare</td>
</tr>
<tr>
<td>Epidural abscess (infection)</td>
<td>1 in 50 000</td>
<td>Very rare</td>
</tr>
<tr>
<td>Meningitis (infection)</td>
<td>1 in 100 000</td>
<td>Very rare</td>
</tr>
<tr>
<td>Epidural haematoma (blood clot)</td>
<td>1 in 170 000</td>
<td>Very rare</td>
</tr>
<tr>
<td>Severe injury, including being paralysed</td>
<td>1 in 250 000</td>
<td>Extremely rare</td>
</tr>
</tbody>
</table>

I hereby consent to undergo the procedure of:

Epidural CSE Spinal

the nature and effect of which have been explained to me.

I have read and understood the epidural information leaflet and been given the chance to discuss the possible side effects and risks.

Date:....................................... Patient’s Signature:...........................................

Date:....................................... Doctor’s Signature:...........................................