PROSPECTIVE OBSERVATIONAL STUDY OF POSTOPERATIVE EPIDURAL ANALGESIA FOR MAJOR ABDOMINAL SURGERY.

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Submitted in Partial Fulfilment of the Requirements of the Degree of Doctor of Philosophy, January 2009
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Acknowledgements

I would like to express my sincere thanks to everyone who has supported me in studying over the past four years. Thank-you to the University of Salford for accepting me as a student and offering me a bursary. I would particularly like to thank Professor Carol Haigh, my supervisor throughout, for your commitment and friendship.

Thank-you to the ‘Sisters of Pain’ at work, my good friends Jo, Paula, Tracy and Angela. You gave me the time I needed, made me laugh, and picked up my share of the work when I had just too much to do.

Thank-you to my family, particularly you Peter, for the encouragement and very practical support. To Meg, Ian and Jane, my three wonderful grown up children (when did that happen?), just don't follow my example! Ian, thank-you for the encouragement, advice and love.
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<td>ACE inhibitor</td>
<td>Angiotensin-converting enzyme inhibitors</td>
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<tr>
<td>APS</td>
<td>Acute Pain Service</td>
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<tr>
<td>ASA</td>
<td>American Society of Anaesthetists</td>
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<tr>
<td>β blocker</td>
<td>β-adrenoceptor antagonists</td>
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<td>BURP</td>
<td>Bupivacaine Research Project</td>
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<td>IASP</td>
<td>International Association for the Study of Pain</td>
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<td>IM</td>
<td>Intramuscular</td>
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<td>IT</td>
<td>Information Technology</td>
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<td>JCAHO</td>
<td>Joint Commission on Accreditation of Healthcare Organizations</td>
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<td>Medical search headings</td>
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<td>MRC</td>
<td>Medical Research Council</td>
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<td>MRI</td>
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<td>National Patient Safety Agency</td>
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<td>NSAID</td>
<td>Non Steroidal Anti-Inflammatory Drug</td>
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<td>PDSA</td>
<td>Plan Do Study Act cycle</td>
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<td>PONV</td>
<td>Post Operative Nausea and Vomiting</td>
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<tr>
<td>PROSPECT</td>
<td>Procedure Specific Postoperative Pain Management</td>
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<tr>
<td>PRN</td>
<td>Pro Re Nata (as required)</td>
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<td>Patient Reported Outcome Measures</td>
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<td>RCA</td>
<td>Royal College of Anaesthetists</td>
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<tr>
<td>SCI</td>
<td>Spinal Cord Infarction</td>
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<tr>
<th>Acronym</th>
<th>Full Form</th>
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<tr>
<td>SPC</td>
<td>Statistical Process Control</td>
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<td>VAS</td>
<td>Visual Analogue Scale</td>
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<td>VNRS</td>
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Abstract

Prospective observational study of postoperative epidural analgesia for major abdominal surgery.

Background

The number of surgical procedures is increasing worldwide. The Audit Commission set a target that only 5% of patients should experience severe post-operative pain. Major abdominal surgery is a cause of severe post-operative pain. Epidural analgesia is regarded as the “gold standard” for treating this category of post-operative pain. A randomised controlled trial conducted by the author suggested that it was possible to have 95% of patients pain controlled, but with a high incidence of hypotension. Hypotension can restrict rather than enhance a patient’s recovery after surgery. Building on this work, this thesis will explore whether it is possible to provide good analgesia without serious side effects in the workplace.

Methods

This study reports the results of a prospective observational study (n = 480) designed to both describe the technique and examine the association of various factors with pain scores and the incidence of hypotension. Classical statistics and statistical process control methods, a unique feature of the study, were employed to analyse and learn from the data.

Results

Twenty-eight percent of patients reported severe pain. Lower pain scores were associated with female gender and elective surgery. An association exists between increasing age and decreasing pain scores on the first day. The incidence of hypotension was 56%. Low pain scores strongly correlated with hypotension. Many failures occurred due to technical problems.
Recommendations

It is important for nursing professionals to know the true risk/benefit profile of postoperative epidural analgesia as it is ward nursing staff who are primarily responsible for monitoring the effectiveness of the technique, the patients’ safety, and intervening to improve poor quality pain control. The results of this study suggest that epidural analgesia is far from the gold standard for postoperative analgesia. An urgent debate needs to take place to establish its true place in the management of postoperative pain.
1 Chapter 1 Pain after Surgery

1.1 Introduction

This prospective observational study focuses on the quality of epidural analgesia, a technique used for the relief of pain after surgery. A major fear for patients before they have surgery is the amount of pain they might be expected to cope with after their operation (Hansson et al. 2006; Powell et al. 2004; Bruster et al. 1994). This is a realistic fear as publications in the first decade of the 21st century indicate that up to a third of patients may suffer a period of severe pain after both daycase and more extensive surgery (Macrae 2008; Gramke et al. 2007; McLeod et al. 2006). An increasing body of evidence exists to support the fact that, if pain is not controlled in the immediate postoperative period, there are several deleterious consequences such as delayed wound healing, extended hospital stay and chronic pain syndromes (Bonnet and Marret 2005; Macrae 2001).

Epidural analgesia is a technique used to control pain for several days after major surgery. The technique is perceived by anaesthetists to be the ‘gold standard’ for postoperative pain control (Australian and New Zealand College of Anaesthetists and Faculty of Pain Medicine 2005; Block et al. 2003; Rodgers et al. 2000). The problem is that, to date, there is conflicting or insufficient evidence that epidural analgesia is effective for the majority of patients, despite being the analgesic technique recommended to patients before major surgery (Low et al. 2008; Marret et al. 2007). The Audit Commission (1997) has proposed a standard whereby less than 5% of patients should suffer severe pain following surgery. This may prove to be an unrealistic goal, as the results of more pragmatic trials that have been published highlight the complexity of delivering effective analgesia to every patient. For
example, McLeod et al. (2006) reported that only 30% of patients in their study of epidural analgesia ($n = 1359$) received high quality pain relief. In addition, it is difficult to maintain good pain relieving epidurals, as a higher incidence of side effects was associated with the longer duration of pain relief.

The first difficulty is that there is a gap in the evidence about what is achievable in everyday practice with the resources available in the work place. Second, there is a need to understand more about the context in which the technique does work. Such knowledge is not available from Randomized Controlled Trials (RCT), as their very nature mandates adherence to strict protocols, involves the exclusion of whole groups of patients and requires additional resources of time or people who regularly visit participants. This study seeks to fill a part of that knowledge gap, and describes the characteristics of 480 patients receiving epidural analgesia for postoperative pain relief. The incidence of side effects, particularly hypotension, and factors associated with the success or failure of the technique are explored. This will add new knowledge to the body of knowledge emerging about the effectiveness of the technique considered the “gold standard” for postoperative pain relief. The information gathered was analysed using both traditional statistical methods and statistical process control charts to describe the variability in the data. Control charts are a more advanced version of a run chart used in time series designs. The use of control charts to display Acute Pain Service (APS) data is a unique feature of this study.

It has been stated that ‘No side effect will be uncovered unless someone thinks to look for it’ (Anon 1967 p 278). Similarly, the effectiveness profile of an epidural has not been fully uncovered. This introductory chapter summarizes the background to the topic, including definitions, the incidence of side effects and the current state of
knowledge about epidural pain management. The key reasons why this research is warranted are introduced; they are then expanded upon in the following two chapters. The establishment and development of APSs are described in Chapter 2. The effectiveness profile of epidural analgesia is debated in Chapter 3 in order to contextualize the contribution this study will make to the current body of knowledge. The specific reasons for the design of the study to address the study questions are justified in Chapter 4. The results of the study are presented in Chapters 5 and 6. The results are interpreted in the final chapter. In addition, strategies for measuring and improving the quality of postoperative pain relief are proposed in Chapter 7.

1.2 Background

1.2.1 Pain

Everyone at some point in his or her life will experience pain. Pain is a very personal experience, which responds to constantly changing physical, psychological and environmental circumstances. Acute pain is generally a symptom that signals tissue damage from injury or inflammation and has a useful biological function. ‘Pain is a teacher and without it every childhood experience becomes a danger instead of a joy’ (Fleetwood 2008 p 1). This is a quotation from the mother of a child born with no perception of pain, a condition called ‘sensory neuropathy type four.’ It is an extremely rare condition; there were only 32 survivors in the world in 2007. Children do not survive to adulthood because there is no warning of injury and infection. Thus, it is clear that feeling pain is necessary for the survival of humans. Yet pain can and does cause suffering and distress. More than 50% of the population will consult a doctor about an episode of acute pain during their life; it is the most
common reason in the UK for individuals to attend an appointment with a General Practitioner (Colvin and Lambert 2008). In a survey by the British Pain Society (2005), it was estimated that almost 10 million people were suffering pain at the time of the survey. Pain not only has an impact on an individual’s quality of life, it has a financial cost to society, too. For example, back pain alone has been estimated to cost the UK treasury £5 billion per annum (The British Pain Society 2008). Approximately 80% of people in the world do not receive adequate treatment for pain. Severe undertreatment of pain is a problem documented in 150 countries worldwide (Taylor et al. 2008). The core reasons for this gross deficit in the management of pain were grouped by Taylor et al. into three key areas. First, there are legal factors. With the fears of addiction and the potential for misuse, prescriptions for opioid drugs are so tightly regulated that patients do not receive adequate pain relief in many countries. Obtaining opioids for patients with cancer pain and for children can be particularly difficult. These barriers to obtaining adequate pain relief are magnified in poorer countries. Second, there is a lack of access to common drugs, such as morphine. While morphine is relatively cheap in the developed world, it is prohibitively expensive in the developing world. Finally, staff attitudes contribute to the undertreatment of pain. This problem is not confined to the developing world; this attitudinal issue also continues in the developed world, including the UK (Brennan et al. 2007).

1.2.2 Definitions of pain

The International Association for the Study of Pain (IASP) has defined pain as 'an unpleasant sensory and emotional experience associated with actual or potential
tissue damage or described in terms of such damage’ (IASP 1979 p 250). Thus, pain involves a significant psychological component. Descriptions of ‘pain’ have been further subdivided into three categories – acute, chronic and cancer. Acute pain has been defined as ‘pain of recent onset and probable limited duration. It usually has an identifiable temporal and causal relationship to injury or disease’ (Ready and Edwards 1992). When pain is described as ‘chronic’ there may not be an obvious cause, with pain continuing long after an injury, such as trauma or surgery, has healed. These definitions are not, however, mutually exclusive. Patients with chronic pain undergo surgery for other conditions. The surgical population commonly includes those with cancer pain. Nowadays, pain is considered as being somewhere along a continuum rather than being categorized as acute or chronic (Australian and New Zealand College of Anaesthetists and Faculty of Pain 2005).

1.2.3 Pain after surgery

Pain after surgery is of particular concern to patients (Terry et al. 2007; Audit Commission 1997). An increasing number of patients undergo surgery worldwide, with an estimated 234 million major surgical procedures per year (World Health Organization 2008). This equates to one operation per 25 humans. The poorest third of the world’s population receive just 3.5% of all the surgery undertaken across the globe. Surgical complications resulting in disability or a prolonged hospital stay affect between 3 to 25% of hospitalized patients, according to the World Health Organization (WHO 2008). Major complications are not confined to the Third World countries; there are major complications in an estimated 3 to 16% of all surgical inpatients in the developed world, nearly half of which are preventable (Weiser et al.
2008; Bickler and Speigel 2008). Surgical complications are now considered a public health concern worldwide and a growing emphasis has been placed on monitoring and improving patient safety during and after surgery. Post-operative analgesia has to be considered an important factor in the surgical pathway. Too much or too little analgesia can result in harm. High technology infusion devices used to deliver pain relief can fail and highly invasive techniques like epidural analgesia can provide good pain relief while having the potential to cause catastrophic harm. The potential risks and benefits of epidurals are the focus of this study and will be described in Chapter 3.

There are approximately 7 million operations per year in the UK, utilizing 4,338,709 bed days, based on data from Hospital Episode Statistics (2007). Thirty-eight percent of patients were admitted as emergencies. Nineteen percent of the overall total were over 75 years of age in the 2006 – 2007 period. In theory, the vast majority of those 7 million patients undergoing surgery annually should have adequate pain management provided by medical and nursing staff on the inpatient wards or the daycase environment. Nevertheless, it is extremely difficult to know if this is achieved. There is just one national source available to hospitals about the effectiveness of pain management. The NHS Health Commission surveys, run by the Picker Institute, have been conducted annually since 2002. The Picker institute is a charity that is a leading authority on the patient’s experience of health care. Approximately 76,000 adults from 165 trusts responded to the 2007 inpatient survey. Two of the 72 questions about health care were related directly to pain. Patients were asked, ‘Were you ever in any pain?’ The second question was, ‘Do you think the hospital staff did all they could to control your pain?’ Sixty-six percent of patients reported they had experienced pain when an inpatient; of those, 71% felt that staff had done all they could to relieve the
pain (Picker Institute 2008). The Picker reports are all that is available to Trusts to monitor what is happening with pain control in their units. Nevertheless, it is a useful first step in finding out directly from patients how much pain they experienced and how patients rated the pain management they received while in hospital.

1.2.4 Pain after abdominal surgery

It is the patients undergoing major thoracic and abdominal surgery who have the most painful incisions (Macintyre and Ready 2001; McQuay and Moore 1998) and so frequently require more ‘high tech’ analgesic techniques. Those patients are also reviewed regularly by teams with expertise in pain management. If the pain is not controlled, some patients will suffer significant morbidity. For example, pain after abdominal surgery can restrict the patients’ ability to take a deep breath, cough, or sit out of bed. These are all important aspects of an event free recovery. The length of time people stay in hospital is influenced by side effects, such as nausea and vomiting, persistent ileus, fatigue, the presence of drains, stress-induced organ dysfunction, uncontrolled pain and postoperative complications (Delaney et al. 2001). Particularly relevant is the fact that severe acute post surgical pain is followed by persistent pain in 10 to 40% of patients, and this can have a major effect on the patients’ quality of life (Nielsen et al. 2007).

Older people are surviving longer and increasingly undergoing major surgery. It has been estimated that, by 2031, the number of people over the age of 75 will increase from 4.7 million to 8.2 million (Darzi 2008). As we live longer, we are also more likely to have developed one or more long-term conditions, such as heart disease or diabetes. Surgical interventions with increasing age are more likely, too. For example,
the incidence of colorectal cancer increases sharply with age; 41% of affected patients are over 75 years of age. Approximately 80% of these patients will undergo open surgical resection with up to 30% presenting as emergencies (National Institute for Health and Clinical Excellence 2006). Studies have reported a decrease in quality-of-life scores during the first few months after bowel surgery, which is followed by improvements three to six months after surgery (Arndt et al. 2004; Rauch et al. 2004). It is known that pain is under recognized by health professionals in older people (Kumar and Allcock 2008). Daily pain has been reported by over 50% of those over the age of 65. The incidence of pain is higher for those cared for in institutions (Cairncross et al. 2007) for several reasons, including the ‘stoicism’ of the elderly and because pain is viewed as an inevitable part of growing older.

1.2.5 Measuring pain

However, pain must be assessed expertly; otherwise, any treatment is unlikely to succeed. Pain is a subjective experience. There is no objective measure of pain; therefore, the only yardstick that can be used is the patients’ own reporting of the severity of the pain they are experiencing. Nevertheless, if pain is measured properly, the results have proved to be sensitive and consistent (McQuay and Moore 1998). The most common measurement tools are categorical and visual analogue scales, which will be described in detail later in the study. The pain scores function best when quantifying the patient’s pain in the present (Breivik et al. 2008). In terms of research, pain scoring is a concept that has been relatively amenable to research over the years. There is a large evidence base for the use of pain scores in postoperative pain management studies such as this.
'From the research point of view the outcome measures and the necessities of paying attention to trial design, randomization, double-blinding and comparators were resolved and emphasized many years ago, so that the rules for pain trials were clear much earlier than in other areas of medicine which also use subjective measures.'

(McQuay and Moore 1998 p 2)

As will be discussed in Chapters 3 and 4, the rules alluded to above are not always followed, so the quality of papers that use pain scores as an outcome is very variable. One reason for this is that techniques such as patient controlled analgesia (PCA) and epidural analgesia, which will be described later in the study, can continue after surgery for up to seven days. Such a long time-span can mean that the measurement of pain and the recording of the side effects of treatment pose many challenges for researchers and clinicians. There is much potential information to collect and report on, so the context in which the research is undertaken is increasingly important. Effective pain management can be measured from a number of different perspectives. For example, the department manager may be interested in the number of patients an APS visits every day, and in whether the service is cost effective. The anaesthetist may want to count the number of adverse events. Specialist nurses might focus on measuring the impact of a patient or staff education programme. However, from the patient's point of view, the outcomes are more important than the process of care (Australian and New Zealand College of Anaesthetists and Faculty of Pain Medicine 2005). The patient is generally not in a position to judge whether an epidural is positioned higher or lower in the epidural space, but will be in an ideal situation to judge whether it is effective.
Nurses traditionally identify those in pain, and instigate adjustments or ask for help from others when pain relief strategies are not effective. Nurses are essentially 'the gatekeepers' to additional expertise if a patient is in pain because an analgesic technique has failed. Therefore, nurses are in the ideal situation to identify important variables to be considered in a study to measure epidural effectiveness. Yet there are few epidural studies conceived and published by nurses; it is still the domain of the anaesthetists and surgeons, albeit with the support of a multidisciplinary team. This is interesting because the majority of the analgesia given after the patient has left the recovery room is supervised or controlled by nurses.

1.2.6 The purpose of pain control after surgery

Promising any patient a pain-free recovery gives the patient unrealistic expectations and is generally not achievable. One reason why it is difficult to deliver 'pain free' care for any length of time is that all drugs given also result in side effects and there is a fine balance between delivering effective analgesia and preventing harmful side effects. Opioid analgesia is a good example of this balance; too much drug will lead to respiratory depression, a poor cough and, in extreme cases, respiratory arrest. Therefore, the primary aim of postoperative pain management is to provide continuous uninterrupted dynamic pain relief that will allow postoperative rehabilitation with a minimum number of side effects (Breivik et al. 2008; Nielsen et al. 2007; Viscusi 2005). In order to achieve this degree of pain relief, the side effects and adverse events of any pain treatment must also be measured and minimized in clinical practice.
Clinically meaningful outcome measures in acute pain management can be either desired or adverse and reflect both how a patient feels and the quality of recovery (Australian and New Zealand College of Anaesthetists and Faculty of Pain Medicine 2005). For example, a desired outcome is good pain relief; an adverse outcome is the number of epidural haematomas. A distinction is made between different types of outcome measures, such as clinical or surrogate. Not all outcomes are important to the patient. Statistically meaningful reductions in pain may not in fact be clinically meaningful to the patient (Low et al. 2008; Liu and Wu 2007). Furthermore, the measurement captures only a snapshot of the patient experience, which again may not be the most important aspect to the patient of their overall pain experience. There are also very rare serious complications associated with anaesthesia and pain management. Individual studies are generally not powered to detect rare complications, and national databases are required, and indeed, are being developed to quantify this (Royal College of Anaesthetists 2007). The power of a study is the ability of the design to detect a relationship between variables. Thus getting the delivery of good pain relief right for every patient after surgery is an important balance between providing good pain relief and avoiding harmful side effects. The challenge is to obtain evidence of exactly what ‘getting it right’ is for the majority of patients in everyday practice and this will be discussed throughout this study.
1.2.7 A brief history of pain

Modern day anaesthetists have become the champions of pain control, but their skills did not leave the operating theatre until relatively recently (Loeser 2000). Perioperatively, the early advances in anaesthesia were much greater. The first public administration of an anaesthetic for major surgery was by William Morton in 1846 in Boston. The first anaesthetic in England, using ether, occurred in the same year (Churchill-Davidson 1978). In the same period, chloroform, cocaine and nitrous oxide were introduced.

This was a great advancement, as before this time 'surgery was a terrible last resort in a final attempt to save life' (Wilkinson 2008 p 1). In essence, the progress in surgery was dependent on developments in anaesthesia. Other inhalational agents were introduced over the following decades. The next advance was cocaine local anaesthetic in 1877, followed by nerve infiltration techniques, including epidurals in the 1900s. The patients' breathing was more controlled with tubes placed in the trachea in the early decades of the 20th century. Sir D'Arcy Power (1923), describing the history of anaesthesia in the first edition of the British Journal of Anaesthesia, documented that, in 1923, the following procedures did not warrant an anaesthetic:

- Avulsion of a toenail
- The opening of an acute abscess of the breast
- The incision of a whitlow
- The removal of enlarged tonsils

Anaesthesia is now a very safe technique with fewer than 1 in 200,000 deaths related directly to anaesthesia (Wilkinson 2008).

The sensation of pain has intrigued and challenged both philosophers and doctors for thousands of years. It is only very recently that there has been any understanding of
the physiological basis of pain (Sinatra et al. 1992). Several theories of pain have been proposed over the centuries, including Descarte’s description of nerves as tubes connecting the skin and brain in 1664. The publication of Melzack and Walls’ gate control theory of pain in 1965 had a profound effect on the understanding of the mechanisms of pain (Loeser 2000). The gate control theory of pain attempted to correlate the physiological and psychological components of pain. Melzack and Wall proposed that the substantia gelatinosa in the spinal cord acted as a ‘gating site’ where afferent input is modulated before transmission to higher centres in the brain. For example, the large fibres can stimulate the substantia gelatinosa cells and close the gate (Melzack and Wall 1965). Thus, emotions, memory, and acupuncture can modify the system and open or close the gate. Since this time, there have been significant advances in the understanding of pain in the fields of neurobiology and the genetics of pain (Colvin and Lambert 2008).

Before the 1960s, there were no specialists in pain management, and only one textbook had been written – Bonica’s *Management of Pain* in 1953 (Loeser 2000). The pioneers in the 1940s and 50s were, amongst others, Beecher and Dr William Livingston, who ran a pain laboratory. Dr Harry Beecher was the clinician who identified the lowered analgesic requirements of those soldiers injured in battle compared to civilians (Loeser 2000).

Professor Bonica, in 1953 (Loan and Morrison 1967), listed a variety of factors that could be related to the severity of pain. He included the patients’ age, sex, personality, the site of the operation and surgical management. Severity of pain in those early studies was based on the need for analgesia rather than on any type of measurement documented on observation charts. Major medical texts rarely mentioned pain management. In nursing books, the basis for postoperative pain control was expert
nursing care. Pain relief in the form of drugs was limited. Pearce (1946), in her general textbook of nursing, devotes several pages throughout her text to pain, which illustrates the nursing skills involved in both recognizing and controlling a patient’s pain. In a section entitled ‘discomforts following an abdominal operation’ she wrote that:

‘a certain amount of pain will follow an abdominal operation because of the handling of the intestine and the incision made in the anterior abdominal wall. The nurse in charge should see that pain and discomfort are not in any way contributed to by having the patient in an uncomfortable position ... The bandage should not be too tight; the top bedclothes should be light and rather loosely arranged, pressure across the abdomen, thighs and knees should be avoided ... the patient should be carefully handled and the bed should never be jarred or shaken as all such movements will cause the patient to contract involuntary his abdominal muscles and this would pull on the stitches holding the tissue together and give rise to pain. As pain is likely to keep the patient awake, and this would delay his recovery from shock, the doctor will usually order an opiate on the first night.’

(Pearce 1946 p 638)

Evelyn Pearce appreciated the subjective nature of pain, and gave a very accurate description of different types of pain in other chapters of her book. It was, and still should be in the first part of the 21st century, the nurses’ role to both identify those in discomfort, pain, or distress and treat them swiftly and effectively.

It is clear from Pearce’s text that she recognized the multiple factors contributing to patients’ distress. Pat Benner, in her influential work ‘From Novice to Expert’ (1984)
identified seven domains of nursing practice. One domain, the helping role, was further broken down into eight competencies. Benner entitled one of those eight competencies as 'Interpreting kinds of pain and selecting appropriate strategies for pain management and control' (Benner 1984 p 62). She identified that selecting the appropriate strategy at the right time was a nursing judgement. Benner recognized that such competencies were difficult to quantify, but that nurses should strive to excel at listening to patients and understand what the illness means to the patient. Those who stood back and did not get involved with their patients could struggle with the helping role. At a time when pain scoring was not practised routinely, both Pearce in the 1940s and Benner in the 1980s, acknowledged that it was the nurses’ role to pick up the cues from the patient about comfort and pain control. It could be hypothesised that, with the presence of APS members, today’s ward nurses may have abdicated a degree of that intuitive understanding, described by Pearce in the 1946 text, about when patients are in pain (Haigh 2008).

The first pain research programmes gained funding in the 1960s (Loeser 2000). The International Association for the Study of Pain (IASP) was launched as a multidisciplinary professional organization in 1973, after which specialist journals, conferences, and research began to flourish. By the 1980s, the importance of controlling pain after surgery had been recognized by health care professionals and concerted efforts were made internationally to ensure suffering for patients was a thing of the past. This was the remit of the Acute Pain Services, introduced in the majority of UK hospitals in the 1990s, based on a model of service introduced by Ready in Seattle (Sinatra et al. 1992; Ready et al. 1988).
1.2.8 1990 Working Party Report

The publication of a joint working report by the colleges of surgeons and anaesthetists in the UK heralded the start of an enthusiastic movement in the National Health Service (NHS) to improve pain relief after surgery. Solutions to the problem of ineffective pain relief after surgery were proposed in the report and included the establishment of multiprofessional pain teams to educate clinical staff and patients and oversee the introduction of 'high tech' pain relief methods. The summary recommendations of the 1990 Working Party Report stated,

'Research into pain relief after surgery should be encouraged and intensified. There is a need for powerful, safe analgesics, and long-acting non-toxic local anaesthetics. If these were available, it is likely that postoperative pain would cease to be a major problem.'

(Royal College of Surgeons of England, College of Anaesthetists 1990 p 1)

Unfortunately, postoperative pain has not ceased to be a major problem. Education of health professionals about managing pain has not resulted in the expected improvements for patients after surgery (Justin 2008; Taylor 2007). Effective analgesic strategies are available to practitioners. For example, acute pain services have learnt over the years to use many of the drugs, which have been available for a long time, more effectively. It is now common practice to combine different classes of drugs, such as opioids, Non Steroidal Anti-Inflammatory Drugs (NSAIDs), local anaesthetic drugs and inhalational drugs to achieve effective postoperative analgesia. Despite these improvements, services are struggling to provide evidence of their effectiveness (McDonnell et al. 2003). This decade has seen a proliferation of national
and international documents, standards and guidelines published to guide practitioners (Australian and New Zealand College of Anaesthetists and Faculty of Pain Medicine 2005; International Association for the Study of Pain 2005; Royal College of Anaesthetists 2004; Scottish Intercollegiate Guidelines Network 2004). The evidence is available in print, but regrettably, the expected improvements have been modest (Cleeland et al. 2003).

Chapter 2 describes in more detail, and offers a critique of, the development of APSs up to 2008 so that the circumstances and challenges of how pain relief is delivered are understood before moving to a detailed description of epidural analgesia in Chapter 3. A brief description of epidural analgesia is documented in the next section.

1.2.9 Epidural analgesia

Controlling pain after major thoracic and abdominal surgery is particularly important to enable the patient to cough and start mobilizing after surgery. If patients are unable to do this because pain is not controlled adequately, they are at increased risk of significant morbidity and mortality (McIntyre and Ready 2001). Opioid drugs (a term used to describe both naturally occurring and synthetic drugs), such as morphine, fentanyl and diamorphine have side effects, including nausea, hallucinations and drowsiness when used at the higher doses needed to control pain after major surgery. An alternative is epidural analgesia, which has been advocated as a method for reducing some of the deleterious effects of postoperative pain (Rodgers et al. 2000). It has been proposed that opioids and local anaesthetics administered into the epidural space can reduce myocardial ischaemia by controlling the stress response to surgery (Heard and Harper 2002). Epidural drugs can blunt the motor and sympathetic
response to abdominal surgery resulting in improved analgesia and respiratory function. Epidurals can also reduce the risk of pulmonary embolism by increasing venous blood flow, and so ameliorate the surgical stress response (Sinatra 1992).

Postoperative pain and gastrointestinal dysfunction are the two main reasons patients stay longer than planned in hospital (Marret et al. 2007). These two factors are interrelated, as opioid drugs, such as morphine, used to relieve pain can delay the recovery of colonic (bowel) mobility. Paralytic ileus is defined as ‘a state of atony of the intestine’ (Ellis et al. 1998 p 229). Epidural analgesia may reduce the incidence of postoperative ileus (Liu et al. 1995) because high-dose opioids are avoided. The clinical features of paralytic ileus are vomiting, constipation, abdominal distension and colicky pain (Ellis et al. 1998), so it is an extremely unpleasant complication for the patient. Yet despite this presumed benefit of epidurals, there is currently no evidence that epidural analgesia reduces the length of hospital stay (Marret et al. 2007).

In order to establish epidural analgesia, a fine catheter is positioned in the epidural space before surgery starts, and a continuous infusion of analgesic runs for several days after surgery. It is a highly skilled and complex intervention; the technique is described in more detail in Chapter 3. For the technique to be successful, a range of both technical and communication skills are needed by all those involved in the care of the patient including the anaesthetists, physiotherapists, surgeons and others, but fundamentally, it is the nurse who has the 24-hour responsibility for the management of epidural analgesia after surgery. Therefore, the topic is an important focus for nursing because nurses are responsible for measuring pain, recognizing and responding to side effects and complications, and making the decision to contact other professionals if greater expertise is needed at the bedside.
The epidural technique has gained in popularity over recent years; it has been described by some as 'the gold standard' for pain relief after major abdominal surgery (Rodgers et al. 2000; Ballantyne et al. 1998; Liu et al. 1995). Unfortunately, as experience using the technique has increased, so has the evidence that it is not effective for all patients. Up to 30% of the population of patients with epidurals experience severe pain in everyday clinical practice (McLeod et al. 2006; Wickstrom 2005; Rigg et al. 2002a). Defining exactly what 'effective' or 'quality' is varies, or is not transparent, in many studies. Certainly, relief of pain is only one aspect of the technique; reducing the incidence of side effects and complications are important, too. A reduction in pain scores at the expense of an increase in side effects may not be acceptable to the patient (Liu and Wu 2007).

A second concern is that when epidurals do work, there is mounting evidence that one particular side effect, namely, hypotension, occurs in over one-third of patients (Low et al. 2008; Duncan et al. 2005). When this hypotension occurs, patients are often not able to sit out of bed. Yet a compelling reason for advocating the technique is early mobilization. Mobilizing the patient after surgery is a key factor in postoperative recovery, particularly since the introduction of rapid recovery programmes (Alcorn and Renwick 2008; Kehlet 1997). Rapid recovery (also called enhanced and fast-track recovery) programmes are designed to achieve a rapid and uncomplicated recovery from surgery and will be described in greater detail in Chapter 3. Protocols combine a number of interventions, such as fluid management, epidural analgesia and early mobilization. The hypotension can result in serious morbidity for some patients. However, preventing this hypotension related to epidurals is not a simple task. Some of these patients may need to be cared for in a critical care bed so that drugs such as vasopressors (drugs used to maintain blood pressure) can be administered in a
monitored environment. Hypotension is not a complication associated with other postoperative analgesic techniques such as PCA (Marret et al. 2007; Macintyre and Ready 2001).

To summarize, the epidural technique provides good pain relief for some patients, based on outcomes considered important to patients, but not the 95% advocated by the Audit Commission (Dolin et al. 2002), and when it does work there can be potentially harmful side effects. If this is the reality in clinical practice, then the widespread use of epidural analgesia must be questioned. First, patients are consenting to an analgesic technique that cannot be delivered effectively to the majority of patients. Secondly, there may be a shift in the risk benefit scales as the technique is not without side effects and can have rare but significant complications. Third, evidence is mounting that severe pain after surgery is associated with an increased risk of chronic pain (McCrae 2008; Kehlet et al. 2006). Thus, a patient nursed with an ineffective epidural may be at increased risk of suffering chronic pain.

It will become evident in the next couple of chapters that providing good quality evidence of the effectiveness of epidural analgesia in everyday practice has been a challenge for APSs. There are gaps in the current literature about both the effectiveness or quality of the technique, and factors that could predict those in whom it could provide good analgesia for the majority of the time. For example, patients admitted as emergencies for a laparotomy are a group of patients normally not recruited to epidural research trials because of co-morbidities; they are too sick to approach for consent or the recruiting investigators are not available. Yet a technique is administered for which there is little evidence in this group of patients. Chapter 3 explores the evidence in greater detail.
1.2.10 The foundations for this research

This study is not starting from scratch, but building on both evidence from the literature and a previous Randomized Controlled Trial (RCT) designed and conducted by this researcher with the support of a multidisciplinary group, which will be introduced in the next section. Anaesthetists in Dundee (McLeod et al. 2006) published the results of the analysis of a database (n = 1359) measuring the quality of epidural analgesia over a period of 8 years. McLeod et al. concluded their paper by suggesting that there is a need to ‘determine which independent factors predict prolonged pain relief and side effects.’ They considered the following might be predictors of quality: age, sex, site of needle insertion, duration of surgery, experience of the anaesthetist and surgeon, composition and mode of the epidural solution and prior chronic pain, and depression or anxiety. The aim of the Dundee study was to measure, not to predict. This study has been designed to both measure and predict the factors associated with both pain relief and side effects. Specifically, patient factors, including the age and gender of the patient, together with clinical factors, such as the position of the epidural, are investigated to identify the properties of effective analgesia.

1.2.11 Previous research – BUpivacaine Research Project (BURP)

The original study from which this present thesis was developed, sought to identify the optimum concentration of a drug to be administered for postoperative epidural analgesia. This was a collaborative research study supported by a research award (Duncan et al. 2005). All members of this research group are acknowledged in the references. The primary aim of the BURP study was to maintain effective analgesia,
but reduce the incidence of side effects by reducing the concentration of local
anaesthetic administered via the epidural catheter. The primary endpoints were the
effect of the epidural on dynamic pain relief (pain on movement) and the incidence of
hypotension. Five percent of the patients overall (n = 100) reported high pain scores
on the first day after surgery, which met the Audit Commission standard (1997). Over
50% of patients were hypotensive on the first morning after surgery, which restricted
patient mobility, despite optimum fluid management. We also interviewed 71 patients
after discharge to understand more about the experience of epidurals from the
patients’ perspective. We found that patients will not explain how they feel unless
directly asked. For example, patients are not aware, unless told, that side effects, such
as hallucinations, sore heels, or feeling light-headed might be related to the epidural
analgesia. A number of patients had pain before the surgery and took regular
painkillers, but this was not formally measured in the BURP study. This has been
rectified in this current study. Patients were asked to quantify the pain they had, if
any, before surgery in order to look at any correlations between preoperative pain and
postoperative experience.

The patient-reported outcomes reported in the BURP study have pre-empted a
national healthcare initiative. Lord Darzi, Parliamentary Under Secretary of State at
the Department of Health, was tasked with conducting a wide-ranging review of the
NHS. In Lord Darzi’s report (2008), ‘High Quality Care for All’, there is a
commitment to measure and publish information about the quality of care received by
patients in the UK. The promising aspect of the Darzi report is the desire to measure
more than mortality figures and waiting times. Measures are to include the patients’
own views on the success of their treatment, which is to be measured through ‘Patient
Reported Outcome Measures’ (PROMS). This will include patients’ view of their pain
management amongst other aspects of care. Therefore, this study will provide important information about how such measures can be collected routinely from patients in the future.

In designing and undertaking the BURP study, it became apparent that an RCT had limitations, particularly the problem of translating the results of such studies into everyday practice. This current study is both the progression from the BURP study and the uptake of the recommendations from the McLeod et al. paper (2006). These two previous studies took two very different approaches to study design, but both left a remarkably similar question in their conclusions, namely, that when epidural analgesia is effective, the incidence of hypotension is high despite optimal fluid management. Patients, therefore, might need to be nursed in a high dependency bed so that they can be administered drugs to control their blood pressure. This has a cost implication. Patients nursed with an epidural are the biggest acute pain investment in terms of theatre time and critical care facilities.

The RCT formed a strong knowledge base on which to build this thesis. For example, it was not necessary to design a database from scratch; rather, variables were improved and added to the original database. Some fields had not proved to be worthwhile in the BURP study so they were deleted. Thus, this current study has been designed to be complementary to the original RCT. This study is observational in design in order to answer the research questions, which will be clearly stated in the next section. We already have some knowledge of what appears to work from the BURP study in which less than 5% of patients suffered severe pain measured on the first day after surgery by both investigators and physiotherapists. This study is about the effectiveness of treatment as opposed to efficacy research. Both types of research might measure the same parameters, but effectiveness research focuses on the
outcomes of treatments carried out in everyday clinical practice so the results are more generalizable than are those of strictly controlled trials (Wittink and Carr 2008). This current study explores whether similar results can be achieved in practice and challenges the assumption that it is possible to deliver effective epidural analgesia to the majority of patients in everyday practice. The advantages of the design for this study are that, after collecting a large amount of data, it is possible to examine which characteristics are associated with pain and the incidence of hypotension and it is acceptable to explore a large number of interrelationships in a short time (Polit and Beck 2008). It is not possible to explore multiple relationships in a controlled study. Classical statistics were used to compare the means of the two study groups in the BURP study. However, presenting an aggregated pain score, which is common in pain studies, does not offer much information about the quality of pain relief. Therefore, methods used in quality improvement research were used in this study in addition to classical statistical methods to learn more from the data. Statistical Process Control (SPC) is a tool used by researchers of Quality Improvement (QI) and is the key tool used in this research (Batalden and Davidoff 2007; Thor et al. 2007). The NHS Institute for Innovation and Improvement, the Institute for Healthcare Improvement in Boston, and the NHS Quality Improvement Scotland advocate the use of SPC methods in a drive to persuade clinicians and managers to use data to guide quality improvement. SPC is rapidly becoming a major tool in healthcare quality improvement. The tools of SPC will be used to explore data over a specific time, rather than presenting an aggregated pain score for the whole sample. Thus, the research sought to understand more about the characteristics of those patients in whom the epidural analgesia works measured by both process measures and patient report of pain and side effects. If we do not learn more about the
technique, patients will continue to suffer pain, may be nursed in inappropriate clinical areas and may suffer long-term chronic pain problems. If we do not look critically at what we provide, nurses, surgeons and anaesthetists may not be able to answer their patients’ questions about the quality of pain relief offered. Furthermore, patients are now able to find information about treatments on the Internet, a resource not readily available to patients in the past. By 2012, 74% of UK homes are expected to have broadband internet access (Darzi 2008). Nurses need to be able to respond to patients’ questions as they become more informed about their options for treatment. It is important for nurses to take the debate about the effectiveness of epidural analgesia forward because nurses prepare patients for theatre and are responsible for delivering effective analgesia with minimal side effects when the patient leaves the operating theatre.

1.2.12 Measuring quality and effectiveness

So far, both the terms ‘quality’ and ‘effectiveness’ have been used almost interchangeably and thus need explanation. Quality in healthcare was high on the UK political agenda in 2008 with the publication of ‘High Quality Care for All’ (Darzi 2008). Quality, according to Ara Darzi, consists of patient experience, effectiveness of care, and patient safety. The Department of Health’s definition of quality is ‘doing the right things, at the right time, for the right people, and doing them right – first time’ (Belamothe 2008 p 1280). The definition used in this current study, borrowed from Dolin and colleagues (2002), encompasses these aspects, but is specific to pain management. In order to achieve a comprehensive review of pain management, Dolin et al. suggest looking at the following three broad areas of outcomes; the effectiveness
of a technique, which can be inferred from pain scores; the tolerability as measured by the incidence of a variety of factors, such as nausea, pruritis, and hallucinations; and, finally, the safety of a technique, which can be measured by the incidence of, for example, hypotension and respiratory depression.

It must, however, be acknowledged that this study was not designed to capture all aspects of the quality of the technique, such as a patient satisfaction score. Patient satisfaction is not a reliable indicator of the quality of pain relief. There is a significant body of evidence to support the view that patient satisfaction and pain intensity do not correlate (Jain et al. 2007; Roth et al. 2005). In other words, patients can report strong pain without feeling dissatisfied. German investigators (Roth et al. 2005) published the results of an investigation using a modified questionnaire of the American Pain Society. The aim was to estimate the influence of variables on dissatisfaction; the results showed that the most important factor for dissatisfaction was the patient’s feeling that a complaint about pain had not been taken seriously. During a telephone interview a month after surgery, satisfaction with pain management was obtained from 71 patients in the BURP study, which was useful for understanding more about the patients’ experience of epidural analgesia. This knowledge was used to support the design of this study.

1.2.13 Information technology

On completion of the BURP study, the APS worked towards collecting data, including pain scores, side effects and patient mobility, on every patient visit. To collect this information on all patient visits as a routine was a massive undertaking. There are often several visits to an individual patient, and this resulted in a database
with up to 200 fields. Therefore, the opportunity was taken in the design of this current study to plan to use computer technology in the future, that is, simultaneously collecting and entering information into a handheld computer at the bedside. It was anticipated this study would make it much clearer which aspects of the patient assessment were worthwhile collecting. Handheld data collection systems have great potential to improve the care of patients (Jamison et al. 2007) in the future and will be explored in greater detail in the final chapter.

1.2.14 Research question/problem

Epidural analgesia is not effective in up to 30% of patients in everyday clinical practice, but the quality of data obtained thus far from published papers varies. When epidurals do work, a high incidence of orthostatic hypotension may restrict immediate postoperative mobilization. Therefore, this observational study was designed to determine whether the severity of pain after surgery, and the incidence of hypotension, are associated with certain patient characteristics, the technique itself, and the quality of postoperative management.

The research questions are as follows;

- Research Question 1: What is the incidence of pain, hypotension, and other epidural-related side effects on the first day after major abdominal surgery?
- Research Question 2: What factors are associated with effective analgesia and postoperative hypotension?

Answering the research questions will help establish a baseline for identifying the characteristics of those patients in whom the epidural is effective, particularly on the
first day after surgery. An effective analgesia produces good pain relief without significant side effects.

The aims of the current study are to describe the incidence of pain, hypotension and other epidural-related side effects after major abdominal surgery and to identify factors associated with effective analgesia and postoperative hypotension in everyday clinical practice.

The objectives of the study were as follows;

- To design a data collection form for every visit
- To collect pain scores, side effects and critical incidents for all patients consenting to an epidural for postoperative pain relief over a period of 18 months
- To identify the characteristics associated with the quality of postoperative epidural analgesia and the incidence of hypotension using both classical descriptive and correlational statistics and SPC methods
- To compare the extent to which the results achieved in an RCT (BURP) mirror those in everyday practice
- To identify the important measurements of acute pain assessment in preparation for computerized data collection
- To identify the characteristics associated with the quality of postoperative epidural analgesia and the incidence of hypotension using both classical descriptive and correlational statistics and Statistical Process Control (SPC) methods.
The underlying assumption throughout the thesis is that there is a benefit to providing effective analgesia after major surgery. The next chapter describes in detail the development of Acute Pain Services, national and international policy documents and the context within which the technique is delivered both nationally and locally. This is necessary to appreciate the multidimensional aspects of delivering the technique, the unique role of nurses in a specialist service, and the role of the nurses at the bedside monitoring the effectiveness of the technique in day-to-day practice.
2 Chapter 2: Acute Pain Services (APS)

‘Advances in knowledge do not necessarily lead to the same degree of progress in patient care’

(Macintyre et al. 2006 p 2)

2.1 Introduction

It is clear from the overview in Chapter 1 that pain and pain relief is a complex topic. The degree to which an individual experiences acute pain is known to vary according to a multitude of factors, such as the type of injury, the location and extent of tissue involvement and the general health of the patient (Gil 1992). In addition, there are important psychological factors that influence an individual’s perception of pain, for example, fear, expectations, values, and the degree of family support (Morley 2008). The psychological factors are important because, when admitted to hospital, patients rely on the skills of ward staff, particularly nurses, to understand such multiple factors when measuring pain and responding with appropriate treatment. For patients nursed with an epidural for postoperative pain relief, this skill is particularly essential because failure of the technique, or not recognizing complications, could seriously harm individual patients. The challenges and frustrations faced by clinicians in attempting to improve pain relief after surgery are presented in this chapter.

2.2 Acute Pain

As mentioned previously, acute pain is defined as ‘pain of recent onset and probable limited duration. It usually has an identifiable temporal and causal relationship to
injury and disease' (Australian and New Zealand College of Anaesthetists and Faculty of Pain 2005 p 1). Acute pain after surgery is predictable, and is generally managed by ward nurses and junior surgical doctors, often with the support of an Acute Pain Service. The first formal pain services were introduced in the United States of America (USA) and Germany in 1985 (Werner et al. 2002). The United Kingdom (UK) and Australia did not lag far behind. A 1990 joint working party report published by the Royal College of Surgeons and College of Anaesthetists was the catalyst for the introduction of APSs in the UK. The authors of the report, a multiprofessional group, used a list of studies published over the previous 40 years to highlight the high incidence of severe pain suffered by patients after surgery. The authors stated, 'the treatment of pain is inadequate and has not advanced significantly for years' (Royal College of Surgeons and College of Anaesthetists 1990 p IV). This quotation might still have relevance late in the first decade of the 21st century because recent evidence indicates that treatment of postoperative pain is still inadequate for some groups of patients (Wickstrom et al. 2005; Dolin et al. 2002; Svensson et al. 2000). For example, 80% of patients (n = 250) responding to a postoperative telephone survey in the USA reported moderate or severe pain after surgery (Apfelbaum et al. 2003). Poor pain management after surgery is a global problem. Chinese nurse researchers reported that 62% of patients had inadequate treatment of pain when measured on the second day after surgery (n = 388). However, consistent with other studies, patient satisfaction with treatment of pain was high (Shen et al. 2008). This chapter describes in more detail the background to the introduction and development of pain services, and concludes by detailing the challenges currently faced by those services.
2.3 Search strategy

Electronic searches were undertaken to identify the volume of literature on Acute Pain Services (APS), limited to English language publications. The search strategy comprised the following main elements;

- Search of electronic databases
- Scrutiny of bibliographies of retrieved papers
- Monthly scan of key journals online

The following keywords and medical subject heading (MeSH) terms were selected; ‘acute pain teams’, ‘acute pain services’, ‘critical incident reporting in anaesthetics/acute pain services’, ‘quality improvement’ ‘pain management standards’, and ‘satisfaction with postoperative pain relief.’ Reference lists were searched and several authors were contacted directly by letter and email. The Cochrane Database of Systematic Reviews and the Database of Abstract of Reviews of Effects (DARE) were searched. The National Research Register was also searched for current projects.

In addition, recent conference proceedings were scanned to identify additional potentially relevant studies. The table of contents from key journals were searched online, namely, Acute Pain, Pain, the British Medical Journal, the New England Journal of Medicine, the European Journal of Pain, Anaesthesia, and the British Journal of Anaesthesia. Additionally, websites connected with pain were browsed, including the British Pain Society and the International Association for the Study of Pain. There were no date restrictions.

The literature search started in May 2005 and was ongoing throughout the study.
2.4 Pain after Surgery

The seminal report, ‘Pain after Surgery,’ published jointly by the Royal College of Surgeons of England and the Royal College of Anaesthetists in 1990, provided the impetus for the rapid developments in postoperative pain management in the UK. The authors of the report were influenced by the work of Brian Ready, an anaesthetist in Seattle, who had already established a multiprofessional Acute Pain Service in 1986. He had published promising reports of improvements in pain management after surgery (Ready et al 1988). Members of the joint Working Party group envisaged that similar improvements could happen for patients in the UK. The report was aimed at a wide audience, including all health care professionals, managers, and the general public.

Table 2.1 is the list of papers published in the original Working Party report as evidence of the undertreatment of pain. Table 2.2 is a small sample of references of papers published since 1990 documenting the percentage of patients in severe pain. The purpose of the tables is to illustrate the problem of poorly treated pain after surgery, which is expanded on in the next paragraphs, showing the comparison between research conducted in very different contexts spanning almost 60 years.
Table 2.1 Incidence of postoperative pain (Royal College of Surgeons of England and the Royal College of Anaesthetists 1990 p 5)

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<th>Failure of conventional treatment of postoperative pain</th>
<th>‘insufficient analgesia’</th>
<th>‘moderate or severe pain’</th>
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<td>Reference</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td>Papper et al. 1952</td>
<td>33</td>
<td></td>
</tr>
<tr>
<td>Lasagna and Beecher 1954</td>
<td>33</td>
<td></td>
</tr>
<tr>
<td>Keats 1965</td>
<td>26 – 53</td>
<td></td>
</tr>
<tr>
<td>Keeri-Szanto and Heaman 1972</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Cronin et al. 1973</td>
<td>42</td>
<td></td>
</tr>
<tr>
<td>Banister 1974</td>
<td>12 – 26</td>
<td></td>
</tr>
<tr>
<td>Tammisto 1978</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>Cohen 1980</td>
<td>75</td>
<td></td>
</tr>
<tr>
<td>Tamsen et al. 1982</td>
<td>38</td>
<td></td>
</tr>
<tr>
<td>Donovan 1983</td>
<td>31</td>
<td></td>
</tr>
<tr>
<td>Weis 1983</td>
<td>41</td>
<td></td>
</tr>
<tr>
<td>Donovan 1987</td>
<td>58</td>
<td></td>
</tr>
<tr>
<td>Seers 1989</td>
<td>43</td>
<td></td>
</tr>
<tr>
<td>Owen et al. 1990</td>
<td>37</td>
<td></td>
</tr>
</tbody>
</table>
Table 2.2 Sample of studies published since 1990 indicating incidence of postoperative pain

<table>
<thead>
<tr>
<th>Reference</th>
<th>% 'insufficient analgesia'</th>
<th>% 'moderate or severe pain'</th>
</tr>
</thead>
<tbody>
<tr>
<td>Miasowski et al. 1994</td>
<td>43</td>
<td></td>
</tr>
<tr>
<td>Oates et al. 1994</td>
<td>34</td>
<td></td>
</tr>
<tr>
<td>Svensson et al. 2000</td>
<td>43</td>
<td></td>
</tr>
<tr>
<td>Dolin et al. 2002 (systematic review)</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>Apfelbaum et al. 2003</td>
<td>39</td>
<td></td>
</tr>
<tr>
<td>Wickstrom et al. 2005</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>Moss et al. 2005</td>
<td>60</td>
<td></td>
</tr>
</tbody>
</table>

The early reports by Papper et al. in 1952, listed in Table 2.1, and others such as Jaggard et al. (1950) and Parkhouse et al. (1961) used data of ‘patient demand’ for analgesia as a guide to the incidence of significant pain after an operation rather than pain scores per se (Loan and Morrison 1967). It is salutary to note that, even after major surgery, 36% of patients in the Jaggard report, and 23% of Papper’s group required no analgesia in the postoperative period. At the time of their studies, analgesia was not prescribed regularly; rather it was prescribed ‘as required’ or ‘pro re nata’ (PRN). The onus was placed on the patient to request analgesia.

In addition, Parkhouse et al. (1961) described the correlation of patients who had different surgical incisions with demands for pain relief. Gastric and gall bladder surgery topped the list with 95% of patients requesting analgesia. Interestingly, there has been a relatively recent initiative to return to procedure-specific treatment, with
pain control one aspect of the patient recovery plan (Schug et al. 2007). The PROSPECT (procedure specific postoperative pain management) group have worked to bring together procedure-specific guidelines for practitioners (Schug et al. 2007). In 2008, guidance was available for eight types of surgery including bowel surgery. The recommendations, developed by an international group of surgeons and anaesthetists, were thought to be needed to complement existing national guidelines because there is now good evidence that different surgical procedures result in different types and intensities of pain. Therefore, different risk benefit ratios for the techniques used to control the pain for each class of procedure follow (Schug et al. 2007).

Parkhouse et al. also found that the group of patients requiring less pain relief were the over 50s. It is difficult to know if the patients did indeed experience less pain, were more stoical or were more reluctant to request pain relief. The requirement to request pain relief has subsequently been found to be a barrier to effective pain relief in older age groups (Schofield 2007). Other factors for disparity between age groups in pain relief administered could also be related to the fear of addiction in the older patients (Jairath and Kowal 1999). Furthermore, it was common until recent times to give patients a premedication of either an opioid or barbiturate. Premedication could exert quite an influence on postoperative pain by sedating the patient, both making them appear comfortable and reducing their ability to request analgesia. It was no longer common practice to give premedication in 2008 with the trend towards daycase surgery and admission on the day of surgery, even for major operations (Alcorn and Renwick 2008).

The studies listed after the introduction of the APS in Table 2.2 are a small sample of those that indicate the percentage of patients in severe pain after surgery. Between 1990 and 2008, there was a significant increase in the number of pain publications.
The studies before the introduction of APSs generally used similar analgesic techniques. The conventional method of treating pain after surgery was an intramuscular injection of an opioid, usually morphine, prescribed on an 'as required' basis. It was given at the discretion of the nurse. Routine pain scoring was not practised.

Further, there are many differences between the delivery of surgical services in the 1990s and 2008. Many more patients attend preoperative clinics run by nurse practitioners, and are admitted to hospital on the day of surgery. Surgical and anaesthetic techniques have undergone a revolution too, with the advent of such techniques as laparoscopic surgery and anaesthetic agents with rapid recovery, such as remifentanil and desflurane (Rang et al. 1999).

Since the introduction of APS, the evidence about the effectiveness of postoperative pain relief has been much harder to interpret and collate, as different techniques to manage pain are used, with different measurements of pain, and widely different research outcome measures. However, the quality of individual peer-reviewed papers greatly improved over the same period (Macintyre et al. 2006).

The largest review published after APSs were firmly established was by the UK team of Dolin, Cashman and Bland in 2002. Dolin et al. undertook a review of the evidence of the incidence of severe pain after surgery representing the experience of nearly twenty thousand patients. They looked at the three main modes of pain relief delivery. The first to be examined was intramuscular injections, which was the conventional technique before the publication of the Working Party report. Patient Controlled Analgesia Systems (PCA) and postoperative epidural analgesia were the second and third techniques introduced with enthusiasm in the early 1990s in the UK. Dolin et al. were particularly interested in looking at the evidence for the Audit Commission
standard that less than 20% of patients by 1997 and less than 5% by 2002 would suffer severe pain (Audit Commission 1997). The review authors made the point that effectiveness is more than a reduction in the measured pain scores. The safety and incidence of side effects of any analgesic technique is an equally important measure of effectiveness. They noted that psychological effects, such as hallucinations, may be important negative aspects of analgesia that affect effectiveness. Patients are unlikely to know whether what they are experiencing is a side effect of their treatment unless we let them know what to expect and directly question them (Duncan et al. 2005).

Because any side effect or complication of treatment can limit effectiveness, the importance of including side effects in addition to the level of pain has been embedded in the design of this research project and will be described in greater detail in the later chapters.

Dolin et al.'s (2002) methodology is open to criticism, which the authors themselves acknowledge, as they did not grade papers on quality and retrieved evidence from cohort studies and audits. Despite this study weakness, it is worth taking note of the findings. The overall incidence of severe pain was 11%; the incidence of moderate to severe pain was 30%. Patients who received intramuscular (IM) analgesia fared the worst with 29% of patients suffering severe pain. Nevertheless, the literature contains very few prospective studies of IM analgesia. Several authors have hypothesised that if the strict protocols, guidelines and monitoring applied to epidural analgesia and PCA were applied to other techniques such as IM analgesia the evidence for the superiority of these two techniques would not be so good (Svensson et al. 2000). This would then lead clinicians to question whether the well-documented disadvantages, particularly of epidural analgesia, are worth the risk. Dolin et al. (2002) concluded following their review of the literature that the target that only 5% of postoperative
patients should experience severe pain, as suggested by the Audit Commission, was probably not achievable in clinical practice.

Jeffrey Apfelbaum et al. (2003) assessed patients’ postoperative pain experience by conducting a national telephone survey. Eighty percent of patients (n = 250) experienced acute pain after surgery, of whom 86% experienced an episode of severe or very severe pain. Apfelbaum acknowledged the problems with patient recall bias in the study design, but, not unsurprisingly, still concluded that further efforts were needed to improve the situation despite the wide availability of both local and national guidelines.

Wickstrom et al. (2005) had concerns similar to those of Apfelbaum. Pain relief was not adequate after surgery despite the availability of drugs, new technologies and guidelines and protocols. Wickstrom, a nurse researcher, designed a study to identify predictors and barriers to effective pain relief in a group of patients after a radical prostatectomy (n = 90). The primary analgesic technique used to control the pain was epidural analgesia. Thirty-nine percent of patients experienced moderate pain, and 30% suffered severe pain for one or more days after surgery. The author concluded that the failure rate was related to the treatment regime and an inadequate response in general by nurses to high pain scores. Wickstrom suggested that staff may believe that the patient cannot be in pain because the epidural is in situ. This hypothesis was supported by the fact that patients received higher amounts of systemic opioids on day 3 after the epidural had been removed than in the first 48 hours after surgery. This thinking has been proposed by other researchers. Schafheutle et al. (2001) studied barriers to effective pain relief in nursing practice and found one factor was the presence of ‘high tech’ analgesic techniques.
Moss et al. (2005) conducted an audit of 14 hospitals in the north of England to describe the incidence of postoperative pain \((n = 522)\) and patient satisfaction with pain relief. In general, the majority of patients were comfortable immediately after surgery when pain was measured in the recovery room. However, only 40\% of patients had effective analgesia when measured on movement 24 hours after surgery, and 25\% described severe pain (defined as 8 – 10 on an 11-point visual analogue scale). In common with other studies (Jain et al. 2007), Moss found that patient satisfaction was high despite relatively poor pain control. The evidence for this paradox was reported in the first chapter. Not all the hospitals in Moss’s study had a pain service, so it was possible to compare those that did with those that did not. There appeared to be no correlation between the presence of an APS and improved performance in acute pain management.

Thus, taking into account all the work highlighted above, it would be reasonable to conclude that APSs have had a negligible impact on the incidence of postoperative pain. If a 2008 follow up Working Party report had been written in a similar format to the original report, based only on a comparison of the published percentage of patients in moderate, or moderate and severe pain after surgery, it would have shown that little has changed. However, in reality, the papers in Tables 2.1 and 2.2 can be compared only when reviewed superficially. It will be contested in this chapter that such comparisons are too simplistic because of the complexity of the service developments that have occurred over the years. This introduces complexity as a factor, which is hard to measure. It is considered more difficult to conduct a review of health care service interventions than of drug interventions because of the greater heterogeneity of interventions and methods (Zimmermann 2008).
A more productive approach is to consider the main Working Party recommendations in more detail. The pioneers in APS development might not have predicted that improving postoperative pain management for all patients would be so complex. The purpose of an APS, as described in the 1990 Working Party report, was to improve the treatment of postoperative pain in all hospitals. The authors of the report made recommendations regarding how this improvement could be accomplished. In the following sections of this chapter, the key recommendations from the Working Party report will be taken in turn and achievements in progress towards implementing the recommendations will be discussed in light of current knowledge. This will put into context the complex tasks APSs face when trying to deliver a technique such as postoperative epidural analgesia, which is the focus of this research.

2.4.1 Recommendation 1
*Establish acute pain teams in all major hospitals*

This recommendation has almost been attained with some major limitations. The number of UK hospitals with a formal APS increased rapidly from 3% in 1990 to 43% in 1994 (Windsor et al. 1996). According to the 1997 Audit Commission report, 57% of hospitals had an acute pain team and reported that their presence improved pain management. Austin (2002) conducted a survey of pain services, specifically looking at the provision of postoperative epidurals, and reported that a formal acute pain team existed in 92% of hospitals.

The Working Party members recommended that membership of an APS include medical, nursing, pharmaceutical and psychological expertise. Yet few hospitals have followed the exact constitution of an APS as described in the document. There is a wide diversity of APS structures (Australian and New Zealand College of
Anaesthetists and Faculty of Pain (2005). For example, some are anaesthetic led, others nurse led, with many working only 9 to 5 on weekdays. As part of a review of services 10 years after their introduction, Nagi (2004) reported that anaesthetists were represented in 99% of services, nurses in 81%, pharmacists in 47%, physiotherapists in 12% and psychologists in 4.9%.

Very few surgeons were involved in the work of APSs, despite the fact that the surgical team are responsible for the postoperative care of the patient. A multidisciplinary approach was considered essential by the authors of the working party report for the success of APSs.

One reason most services did not develop as anticipated may be funding (Powell et al. 2004; Nagi 2004). Advice about how to fund this new service in 1990 was less prescriptive at a time when most hospitals managed their funding differently. The Pain Society in partnership with the Royal College of Anaesthetists published guidance on the components of service provision, contents of a business plan, financial considerations and recommendations for education, audit and research in 1997. By this time, many services were struggling to be established without adequate funding. In section 3.5 of the 1997 report the following guidance was given:

'There is no definitive pattern for the structure and funding of an acute pain service. Each unit must consider its individual requirements and constraints. Start-up grants may be sought from local or regional bodies and audit money may be available. The cost effectiveness of an acute pain service can be estimated by assessing changes in length of hospital stay and patient mobility.'

(The Pain Society and The Association of Anaesthetists of Great Britain and Ireland p 4) 42
In truth, there has been a paucity of cost effectiveness studies in the 10 years since the above report. Yet there have been significant ongoing cost issues with the introduction of PCA and epidural analgesia, including the cost of equipment, pharmacy costs and staffing (Carr et al. 2005). One reason may be that it has not been possible to demonstrate a reduced length of stay with improved pain management as suggested in the 1997 recommendation. Again, this is because delivering effective pain strategies is a complex intervention. Length of hospital stay is influenced by many other factors in the postoperative recovery period, such as surgical rituals, the length of time drains are kept in, the timing of the reintroduction of nutrition, physiotherapy, and whether the staff have the appropriate skills. According to Powell et al. (2004), who explored the extent to which APSs have developed in line with recommendations, service provision nationally falls far short of that proposed in national policy documents.

A shortfall in service provision was a conclusion reached also in a relatively recent systematic review and meta-analysis (McDonnell et al. 2003). Eighteen years after the establishment of APSs, 'there is insufficient robust research to assess the impact of acute pain teams on postoperative outcomes of adult patients or on the processes of postoperative pain relief' (McDonnell et al. 2003 p 261). More recent publications have supported this view (Breivik and Stubhaug 2008). McDonnell et al. were particularly searching for evidence of measurable outcomes to support funding for APSs from purchasers. She postulated that teams might not be functioning optimally because APSs are under resourced. The need for measurable outcomes was a shrewd observation by McDonnell because, as mentioned in Chapter 1, Patient Reported Outcome Measures (PROMs) are now high on the political agenda with the publication of Ara Darzi's report 'High Quality Care for All' (2008). It may become
mandatory for all types of service to publish measurable patient outcomes. McDonnell was able to conclude her review on one positive note. There was no evidence that APSs were ineffective.

2.4.2 Recommendation 2
*Assess and record pain systematically, involving the patient whenever possible*

The Working Party members recognized that pain has to be assessed before it can be treated. Prior to the introduction of pain services, patients were not routinely asked about their level of pain; they had to request analgesia. Yet pain is a very subjective experience. There is no objective measure of pain; only the patient can measure their pain in the majority of circumstances (McQuay and Moore 1998). The patient’s description of pain can also be a useful diagnostic tool. For example, nerve, or neuropathic pain, may be described by the patient as ‘burning’ or ‘shooting’ in nature. The simplest tools are single-dimensional, matching pain to a scale, either visual or verbal (Australian and New Zealand College of Anaesthetists and Faculty of Pain 2005). Specialist books and journals provide a mass of information on pain scores. Each individual hospital tends to find a system to suit their needs. The key points are that the tool must be quick and easy to use, the assessment should be made by the patient both at rest and on movement and the result should be the control of pain. A patient’s pain should be assessed and documented on arrival in casualty or admission to the ward, and should continue to be carried out routinely at regular intervals, coinciding with other observations, such as respiratory rate, blood pressure, heart rate and temperature. After major surgery, patients should be comfortably able to take a deep breath, cough and mobilize in order to recover function. ‘Pain as the fifth vital sign’ (Joint Commission on Accreditation of Healthcare Organizations 2001) was an
American initiative to make pain scoring mandatory for all patients. The Joint
Commission standards were centred on the right of patients to receive good pain
relief. Few studies have looked at the impact of those standards.

It is common practice that there is regular assessment of the patient’s level of sedation
at the same time as pain scores are reported in order to identify those at risk of
respiratory depression from treatment with opioids. This is because the best early
clinical indicator of respiratory depression is increasing sedation (Macintyre and
Ready 2001). It is important to document and acknowledge that there are specialist
techniques for quantifying pain in young children, those with communication
difficulties, and patients in intensive care, but a detailed description is beyond the
scope of this research.

Verbal Numerical Rating Scores (VNRS) and Visual Analogue Scales (VAS) are
well-validated tools used in pain research because they are considered sensitive to
small changes in pain and have ratio properties; thus, they are easy to use for
statistical analysis (Campbell and Patterson 1998). It is important to make the point
that a modest reduction in pain scores in a clinical trial considered statistically
significant, may not be considered a meaningful reduction in pain for the patient (Liu
and Wu 2007). Patients might also be influenced by the side effects of the treatment
when reporting a pain score.

Thus, one role of the APS was to train staff (medical and nursing) in how to measure
pain routinely using simple scores for every patient as described above. In general,
this aim of the Working Party has been achieved. Evidence that pain scoring per se
has improved patient outcomes is harder to decipher. There is published evidence that
the regular assessment of pain has resulted in improved pain management, although
the paper used to support this in the most recent international guidance (Australian
and New Zealand College of Anaesthetists and Faculty of Pain (2005) is relatively old (Gould 1992). In the Gould study, conducted in a Welsh university teaching hospital, the introduction of pain scoring was just one of five interventions initiated in a before-and after-study design. Rawal, writing an editorial in 2002, suggests that problems with pain management continue because both medical and nursing staff believe that patients who do not report pain do not feel pain. Therefore, the conclusion that pain scoring improves pain scores is open to debate.

Unfortunately, the problem with many studies published in the 18-year period after the establishment of APSs is that pain is measured only at rest or at one point in time, or that there is no indication of how the pain was measured (Dolin et al. 2002). There is even disparity between measures of what constitutes moderate and severe pain. Assessment of pain only at rest does not distinguish between optimal and barely adequate analgesia when thoracic epidurals are used (Breivik et al. 2008). As mentioned earlier in the text, presenting data in research papers as an aggregated score misses important aspects of patients' pain experience. This will be discussed in detail in the next chapter in relation to epidural analgesia.

Rawal (2002), in a paper discussing progress made by APSs in reducing postoperative pain, makes a case for defining a maximum pain score that triggers treatment. He suggests 3 as the trigger for treatment on an 11-point VNRS scale, but this would not be practical in the postoperative setting, as a percentage of patients will have a score higher than 3 before surgery. It would be more effective to have individual parameters for pain scores for those patients admitted to hospital with chronic pain before surgery.

Patients may also limit the use of painkillers, and not verbalize how much pain they are suffering, for reasons such as the side effects of the painkillers, which can be
worse than the pain. Nurses and doctors are known consistently to underestimate a patient’s level of pain (Wickstrom 2005). For example, Idvall et al. (2002) found that nurses and patients differed in their assessment of quality of care in postoperative pain management. Therein lies the problem: pain control, including the side effects of the treatment, and safety, is such a complex topic it is hard to disentangle from the other aspects of illness and recovery.

It was established early in APS development that patients receiving more ‘high tech’ analgesia would be closely monitored. In general, the use of epidurals and PCAs for postoperative pain relief is discussed with patients before surgery starts, and patients are closely followed in the following days by anaesthetists and APSs (Royal College of Anaesthetists 2004). This is not true for the majority of patients in hospital, who do not receive the more ‘high tech’ interventions to manage pain. Patients can experience pain at anytime and unless nurse specialists can give 24-hour cover, one of their roles should be to support, teach and empower the ward nurses to both measure and treat pain effectively (Duncan 1999).

In conclusion, this recommendation has been achieved in the sense that pain is documented, the first stage needed before treatment. The evidence for whether this results in the right treatment for every patient is less convincing.
2.4.3 Recommendation 3

*Improve hospital staff education and challenge traditional attitudes to postoperative pain relief*

The traditional attitudes to postoperative pain relief, which were thought to limit the administration of adequate analgesia, were summarized by Macintyre and Ready (2001) as;

- A belief that pain is not harmful to the patient or that it is a normal consequence of surgery or injury
- Concerns that giving pain relief will obscure a surgical diagnosis
- A tendency to underestimate a patient’s pain
- A lack of regular assessment
- Fears of addiction
- A high risk of respiratory depression
- Poor preoperative patient information
- A lack of awareness of pharmacology
- Dosing for four hours or longer
- A lack of accountability.

There was evidence that both fear of addiction and respiratory depression stopped staff from administering adequate analgesia (Cartwright 1985). Fear of addiction was, and is, a real concern for patients, too (Hansson et al. 2006). Patients also believed that pain was natural after surgery and were unaware of the potential harmful effects of under treated pain.

The Working Party report used Cartwright’s paper (1985) involving interviews with 302 qualified nurses in the northwest of England to highlight the problems with staff attitudes to pain relief. Essentially, beliefs identified as contributing to the problem
were that nurses believed the patients would prefer surgical pain rather than an injection, that there was a maximum number of injections they could give after surgery, and that no injections could be given after a certain period such as 48 hours postoperatively. In addition, staffing levels had an influence on the under treatment of pain if there were not enough staff to administer adequate pain relief.

There was little teaching for either medical staff who prescribed or the nurses who made judgements about when to give pain relief about how drugs worked, as the majority of prescriptions were traditionally on an as required basis. Much of this problem with prescribing and administering adequate analgesia was thought to be due to the understanding caregivers had of basic pharmacology (Collins 1992). Teaching about pharmacology was seen as a prime role for the APS and one reason the working party group recommended that a pharmacist should be an essential member of APSs. Therefore, education has formed a vital part of the work of APSs and has been directed at all health professionals (within the hospital and community) and the public. A survey conducted at the beginning of this decade (Austin 2002) found that over 80% of the hospitals who replied had a formal training programme for nurses caring for patients with epidurals.

Thus, when pain services started, it was assumed that by teaching the principles of pain management and working alongside colleagues on the ward nurse specialists would effectively do themselves out of a job relatively quickly (Duncan 1999). It was taken for granted that the new generation of medical and nursing students would be much better informed about the importance of pain management and would not have the beliefs and attitudes of their older colleagues. The reality has been very different. The old fears of addiction and overdose still linger (Australian and New Zealand College of Anaesthetists and Faculty of Pain 2005).
Several studies, of varying quality, have been published over the years describing the impact education delivered by an APS has had on an assortment of study outcomes. In early pain service publications (Harmer and Davies 1998), guidelines and education were reported to decrease pain levels, but this is not the case in a more recent report (Dahl et al. 2003). A quality improvement programme, evaluated by patients, nurses and physicians, did not improve patients' expectations of pain intensity in a 2006 study (Hansson et al. 2006). It is difficult for some of these study designs to avoid the pitfalls of before and after, also known as pre-test/post-test study designs. The primary pitfall is that factors other than those under investigation cause or affect the outcomes. Nurse researcher Wickstrom and her colleagues (2008) reported a discrepancy in pain scoring between patients and nurses in a study of male patients on a urology ward who had undergone major surgery. After the establishment of an educational programme, 40% of nurses still did not assess pain both at rest and on activity, and 25% did not evaluate the effects of the pain treatment they administered. McCaffrey and Robinson (2002) undertook a snapshot study of the attitudes and knowledge of 3000 subscribers to a nursing journal. Only 42% of nurses passed the online test. However, the group of nurses responding to the survey might not have been representative of the nursing population. Twycross (2007) explored the association between paediatric nurses' knowledge about pain (n = 13) and their actual clinical practice. She concluded that the nurses did not routinely apply their knowledge, and it was perhaps over simplistic to presume that theoretical knowledge would lead to improved practice.

Patient factors have an influence, too, on any outcome measures in clinical trials. For example, patients have different tolerances to different types of side effects, such as nausea, sedation or constipation. In one small study (n = 50) of patient preference for

50
acute pain management, it was observed that patients generally place equal importance on pain relief and on side effects (Gan et al. 2004). The authors of this pharmaceutical-sponsored study concluded that different patients have different relevant preferences for different side effects. In other words, patients are willing to ‘trade off’ pain to reduce unpleasant side effects.

There continues to be a wide variety of training in pain for all healthcare professionals in the UK with little up-to-date information about undergraduate training (Justins 2008). There is a trend towards nursing students in the UK doing a pain module only as an option, rather than pain being taught to all nurses as part of a core curriculum (Taylor 2007). The result is that both junior nurses and doctors, who are the main providers of pain relief out of hours, are perhaps not equipped with the skills to deliver effective postoperative pain management. These skills are particularly important in order to care for patients with more ‘high tech’ methods of pain relief, especially epidural analgesia.

### 2.4.4 Recommendation 4

*Responsibility for the management of pain relief policy after surgery in each hospital is given to a named member of staff.*

At the time of the 1990 Working Party report, it was unclear which members of staff were responsible for pain management. Anaesthetists tended to prescribe analgesics, but responsibility for both the measurement and administration of this was passed on to the junior medical and nursing staff once the patient had left the operating theatre. There were concerns that enthusiastic anaesthetic colleagues were keen to introduce new techniques, such as PCA and epidural analgesia, but this would have been
potentially hazardous if not monitored closely by a named member of staff responsible for the delivery of postoperative pain management. Anaesthetists were the obvious choice for this role, mainly because of their knowledge of pain relief techniques and their complementary roles already established in both critical care and chronic pain clinics.

Nagi, in a survey of service provision published in 2004, noted that in 37% of UK hospitals there was no dedicated medical session for the APS. Many of those surveyed commented on the lack of funding for such sessions. Nagi considered that the multidisciplinary nature of the APS, as described in the Working Party report, had failed to be adopted at that time.

In retrospect, perhaps the role of managing postoperative pain relief should have been a joint responsibility with a named surgeon. Rawal (2002) postulates that an APS without surgeons is ‘doomed to fail,’ at least in the USA. This is because, in Rawal’s opinion, surgical participation is required for the development of protocols and or analgesic techniques for all patients, pathways for rehabilitation, and improved ward nurses’ compliance with pain scoring and treatment. There is no reason to believe the UK situation is different.

2.4.5 Recommendation 5

Introduce new methods and utilize existing methods more effectively giving due regard to safety

The administration of intramuscular (IM) injections of an opioid, prescribed ‘as required,’ was the standard method of pain relief after surgery throughout the world at the time of the Working Party report. It was recognized at that time that utilizing
existing techniques more effectively had the potential to make significant improvements in postoperative pain management. There is now clear evidence that clinicians are using the available drugs more effectively. For example, soon after the establishment of APSs, several centres published encouraging results based on the introduction of simple prescribing guidelines. Subcutaneous catheters replaced IM injections, and drugs were prescribed regularly rather than as required (Humphries et al. 1997; Gould et al. 1992). The concept of ‘multimodal’ analgesia was promoted successfully. Multimodal is the combination of a variety of different analgesics acting at different target sites in the body. Since 1990, there has been a long list of international and national bodies who have published guidelines in an attempt to improve postoperative pain management (Breivik and Stubhaug 2008).

It was seen as particularly important to establish APSs in order to facilitate the introduction of the more ‘high tech’ techniques – PCA and epidural analgesia. Epidurals and PCA can provide excellent pain relief, but have rare and potentially serious side effects. The potential for harm was recognized in the Working Party report; the safety of the patient was paramount in the recommendation for APS development. Nevertheless, ‘due regard to safety’ is quite a task when there is not a complete understanding of the incidence, impact and risks of epidurals in particular, which are only now being fully recognized by clinicians. This will be discussed in more detail in Chapter 3.

Lanigan and Luffingham (1998), an anaesthetist and nurse, conducted a two-year audit of PCA and epidural analgesia in a London hospital (n = 1781). They described sequential improvement in epidural and PCA pain control after the introduction of an APS. The incidence of patients experiencing severe pain dropped from 35 to 11% but this was measured in only approximately 10% of the surgical population. The focus of
Lanigan and Luffingham’s study did not include side-effects other than vomiting. This could reflect clinicians’ inexperience, and therefore, lack of awareness of complications, when APSs were established, and this would be reflected in the design of studies at the time. It could also be hypothesised that better pain relief would have occurred without the presence of the APS, as there was a greater awareness of pain management in the 1990s.

Barak et al. (2006) used the increased use of PCA and epidural analgesia as evidence of improved postoperative pain management. The problem with Barak’s approach to finding evidence of improved pain relief is that the increased use of techniques does not consistently provide effective and safe analgesia. Thus, adoption of ‘high tech’ analgesia should not be used as a surrogate outcome for improved pain relief after surgery.

**2.4.6 Recommendation 6**

*Audit and continuous appraisal of activity*

There are regular audits of activity published by APSs (Popping et al. 2008; Goldstein et al. 2007; McLeod et al. 2006; Tsui et al. 1997). However, the problem with local audits is that they are a snapshot in time and may not truly reflect performance. This difficulty will be discussed in greater detail when describing the design of this current study. Continuous appraisal of activity is a real challenge to any service. This is because managing pain after surgery is a complex process. A survey in Canadian hospitals found that only 32% of APSs collect and use ongoing data (Goldstein et al. 2004). Of those who did collect continuous data, few apparently used the data for either measuring quality or conducting research.
The ability to measure performance is fundamental for any audit and appraisal of activity. Nevertheless, this can be hampered by a lack of information systems. Real life data sets are large and thus time consuming to analyse. For example, the APS at this researcher’s hospital made 3755 visits to patients in 2006. Monitoring only service activity, such as counting the different techniques employed to deliver pain relief, the type of surgery, or the surgical team involved in patient care, tells little of the quality of pain relief. In addition, problems with techniques can be uncovered only if they are looked for. This is the reason for identifying the key characteristics of a pain assessment by an APS, a secondary objective in the study presented here. Identifying exactly what demographic and clinical measurements an APS ideally needs to collect on a daily basis will guide future service evaluation. Specifically, in this study, one objective is to identify the component parts of safe and effective epidural analgesia.

Stomberg and Haljamac (2003) emphasised the importance of the overall organization of an APS, which must include a Quality Assurance component because education and the introduction of new techniques do not necessarily result in improved pain management. The evidence for the effectiveness of epidural analgesia, therefore, may be lacking due to the shortage of funding and time required for the collection of such evidence.
Establish appropriate facilities for the provision of adequate postoperative pain relief in all hospitals. Provide properly trained staff and resources for these services

‘Appropriate facilities’ has turned out to be a difficult recommendation to define. Each hospital pain service has developed both to suit their own need and based on facilities and funding available at the time. Indeed, this service heterogeneity was encouraged in a joint Association of Anaesthetists and Pain Society document (1997). This aspect of service development has added to the problems for clinicians and researchers when attempting to provide generalizable evidence of service effectiveness. At the time of the report’s recommendations, it would not have been clear what the costs would be for the establishment of an APS with a named consultant, providing cover 24-hours a day, 7 days a week plus medical and resuscitation support. In addition, there were costs attached to regular patient monitoring where there had been none in the past, education programmes for staff, and the production of printed protocols. The reality has been that there have been significant ongoing cost issues with the introduction of PCA and epidural analgesia (Carr et al. 2005).

Early proponents of the epidural technique published reports supporting the safe use of epidurals on surgical wards (Wheatley et al. 2001; Wheatley et al. 1991). At the time of Nagi’s study at the beginning of this century, 73% of patients with an epidural were nursed on a general surgical ward (Nagi 2004). There was a relationship between the presence of an APS and the ward care of patients with an epidural. The clinical area of care for patients with an epidural has, and continues to be a contentious issue (Low et al. 2008; Chilvers et al. 2007; Walton et al. 2006).
reasons for this will become transparent in the next chapter and the debate will continue throughout this study. Interestingly, the safety of the technique has been justified through the years if it is supervised by an APS; yet, in the majority of hospitals, the responsibility for epidurals devolves to an anaesthetic trainee out of hours (Austin 2002). It was described earlier that the training for junior anaesthetists in pain management is still not optimum (Justins 2008).

There was little mention of how to access resources to pay for new equipment, drugs and specialist staff, as discussed earlier in relation to the establishment of new services. This was compounded by the fact that it was unclear which individual practitioner was responsible for the management of a patient’s pain. Providing properly trained staff was a further issue, as it took several years to build links with universities and establish a career pathway in acute pain for both nurses and anaesthetists.

2.4.8 Recommendation 9

To continue and intensify research into the development of better and safer drugs to relieve pain

The Working Party report hoped that a pain relief drug would be developed that was as effective as morphine, but had fewer of the side effects, particularly respiratory depression. This has proved not to be such a concern over the years, as APS practitioners have learnt to use the available drugs more effectively including monitoring and treating the side effects of pain relief. Pain-related research has advanced in the past decade with, for example, a promising new understanding of the
effects of local anaesthetics on the spinal cord and greater understanding of the genetics of pain (Colvin and Lambert 2008). Since 1990, there have been great developments in molecular biology enhanced by imaging techniques, such as Magnetic Resonance Imaging (MRI), giving a greater understanding of the transmission of nociceptive information (Loeser 2000). In the future, the abolition of pain may be possible with the greater understanding of pain mechanisms, but as described in the introduction, may not be desirable, as serious complications such as anastomotic leak would be masked.

2.4.8.1 Safety and efficacy of new methods of pain relief

There was particular enthusiasm in 1990 for introducing two new methods of pain relief. The Working Party report acknowledged this could not be done safely unless monitored in the context of an APS. The first was Patient Controlled Analgesia (PCA) – a technique that allows the patient to control their pain through self-administered small incremental doses of a pain-killer, usually an opioid. The second was epidural analgesia, which is the focus of this research study. The safety and efficacy of epidurals will be discussed in detail in the next chapter.

New pain relief delivery systems are on the horizon, but not yet in routine use. For example, transdermal fentanyl (an opioid) delivered by iontophoresis allows for the delivery of charged molecules across the skin (Polomano et al. 2008). It is a needle-free system and is attached to the skin by an adhesive backing. It has been reported that nursing time is saved, as there are fewer interruptions for alarms, blocked intravenous lines or syringe changes compared to PCA. However, this is a questionable advantage if nurse time with patients is further reduced.
2.4.8.2 Monitoring of patients after surgery

It was envisaged in 1990 that a monitor would be developed to monitor patients more accurately particularly in regards to respiratory depression, which at the time of the report had been identified as the greatest concern for patient safety. This perhaps reflected the lack of experience with managing epidurals where, with time, the risk from other side effects and complications has proved to be much more common.

2.4.9 Counselling and psychological methods of pain relief

It was recommended in the Working Party report that, ideally, a nurse with training in psychological methods should be on duty on the wards. This was because relaxation and distraction therapies are known to reduce pain. Other evidence presented in the Working Party report related to information for patients and the use of information leaflets. The evidence for the benefits of preoperative information in general is conflicting. Now, patients are no longer passive receivers of information. They can and do arrive asking for different pain relief techniques. Problems can occur if patient expectations, gained from unreliable sources on the internet, are not met.

It was envisaged in 1990 that psychologists would play a key role in the APS team, but there is little evidence that this has happened (Nagi 2004). The APS can educate the medical and nursing teams about the impact of psychological factors on the pain experience, such as distraction for young children (Gil in Sinatra et al. 2002). Loeser (2000) suggested that increased strategies to reduce anxiety and fear would reduce postoperative pain. This is particularly challenging, as patients who are admitted to hospital on the day of surgery will not meet the staff who will look after them until discharged from theatre after surgery. Terry et al. (2007), in an exploratory study of
patient anxiety and pain ratings, reported that higher levels of anxiety were associated with reports of more severe pain following surgery. Terry et al. stress the importance of reducing patient anxiety in the clinical setting whenever possible. The recommendation that nurses on the ward would have additional counselling skills has not been achieved.

2.5 Discussion

It is evident from the concise review in this chapter that it has been a challenge to find the optimal structure and delivery of pain management services to increase the safety and efficacy of pain relief and patient satisfaction. The debate continues, as evidenced by the following titles to published papers;

‘Management of postoperative pain – still a long way to go!’ (Breivik and Stubhaug 2008)

‘Challenges of pain management for the 21st century’ (Seers et al 2006)

‘Postoperative pain management – still not optimal’ (Haljamae and Stomberg 2003)

‘The acute pain service: effective or expensive care?’ (Tighe et al. 1998)

The ideal research design to measure the impact of a postoperative pain service would have been a comparison between several hospitals with and without a pain service when they were first introduced in the early 1990s. However, in reality, the opportunity was missed. APSs are not alone in struggling with providing such evidence. For example, there has also been scant evidence to support the effectiveness of specialist palliative care services (Zimmermann et al. 2008).
The Sheffield team of McDonnell, Wilson and Goodacre (2006) wrote that new services should be evaluated before full-scale implementation:

'Evaluation should be sequential, moving from theory to modelling, explanatory trials, pragmatic trials, and ultimately long term implementation'

(McDonnell et al. 2006 p 109)

The reality is that this stepwise approach to implementation does not generally happen. McDonnell et al. (2006) use examples of new services implemented without evaluation, and compare these with the results of introducing a service with a more measured approach. NHS Direct, critical care outreach, nurse consultant roles and Acute Pain Services are examples of services introduced without robust evidence of their effectiveness, according to McDonnell et al. (2006). Without evidence, our perceived impressions of what works could be wrong. In contrast, a more measured approach to service development and evaluation could result in more rigorous evidence of service effectiveness. McDonnell et al. (2006) uses the example of stroke services, which were first introduced in the 1950s. Stroke services have evidence of effectiveness, which is much more robust because the stroke services were properly evaluated.

As McDonnell et al (2006) acknowledge, organizational change can be challenging and laboriously slow, and needs the drive and enthusiasm of clinicians to initiate developments. However, this enthusiasm can blind motivated clinicians to the negative results of their innovations, or perhaps the unintended effects on other services. In addition, busy clinicians, particularly those without university affiliation,
may not have either the time or resources to evaluate rigorously a service or analgesic
technique, such as epidurals.

Without rigorous evidence of effectiveness, APSs, critical care outreach and NHS Direct could be disbanded in the future. It is worth considering the potential effect this would have. There are few anaesthetists involved full time in acute pain (Loeser 2000). According to Loeser, the anaesthetists could ‘retreat back’ to theatre lists and chronic pain services. The nurse specialists have most to lose, as they have only one job. Even here, some services are combining the APS with critical care outreach, another service with little evidence of effectiveness. McDonnell et al. (2006 p 110) describe this situation as ‘the momentum overtaking the evidence.’ Intuitively, it could be hypothesised that if APSs are abolished, the patients could suffer increased pain, side effects and complications after surgery. The routine use of epidural analgesia after major surgery could then change. The risk/benefit scales could tip away from the acceptable use of epidurals on the wards because the expertise required to monitor safety and optimise analgesia would not be available outwith critical care facilities.

There is a totally different perspective on this debate about providing evidence of service effectiveness. Donald Berwick, President of the Institute for Healthcare Improvement and a respiratory physician, has championed quality improvement research (Berwick 2008; Berwick 2007). Berwick argues that, to improve systems of care, the uneasiness between different methodologies in healthcare research must be eliminated. He uses evidence for the effectiveness of emergency medical teams, established to identify and improve the care of patients who were deteriorating on hospital wards, to illustrate the superiority of evidence from quality improvement over RCTs in nonlinear complex interventions. The UK Medical Research Council defines a complex intervention as ‘built up from a number of components, which may act both
independently and interdependently’ (2000 p 2). Berwick describes the emergency medical teams as a complex social group. The publication of the Medical Early Response Intervention and Therapy Study (MERIT) in 2005 was used by sceptics of medical emergency teams to urge caution in their development, but in fact, according to Berwick, the trial results were inconclusive rather than negative.

APSs could also be described as a complex social group, with effectiveness related to a multitude of factors, such as leadership, organizational history, and changing environments. Acute Pain Services might well have made a difference in various ways, such as introducing PCA and epidural analgesia, routine pain scoring, education, and increased patient satisfaction. Unfortunately, how this was achieved is not in the public domain. Berwick believes that understanding the context in which services are delivered is very important in order to learn and improve the quality of patient care. This aspect of measuring quality will be returned to in later chapters.

Powell et al. (2006) surveyed APSs in the UK and followed this up with in-depth interviews of three pain services. She concluded that APSs are struggling to develop because the challenges lie with tackling the organization and delivery of services rather than lack of treatment options. Whatever the cause, pain services must look to their role in the future, as they may not be the most cost effective way to improve pain management for patients after surgery (McDonnell et al. 2003). Several services are changing their direction with the amalgamation into critical care or chronic pain services (Powell et al. 2004). The organizational aspect of an APS is an international problem, too (Breivik and Stubhaug 2008; Rawal 2001). In the USA, there is a trend towards downsizing formal services and developing quality improvement teams. Currently, a team continues to monitor epidurals, but only approximately 10 to 15% of patients will receive this technique (Rawal 2001). There is a direct cost issue for
services in the USA and Australia that is not currently relevant in this country, though the situation could change in the future.

Powell et al. (2006), from the research unit in Dundee, analysed the reasons for the struggle to improve pain management in the U.K. Apart from the organizational barriers, they identified major psychological barriers. Surgeons and other health care providers viewed acute pain as self-limiting; the most important aspect of the patient recovery was that the surgery was successful. The patient's pain would be forgotten (Breivik and Stubhaug 2008). Investment in APSs and more 'high tech' interventions were not, therefore, necessary.

In summary, APSs have been established in the majority of hospitals in the UK. It has not been possible to separate the effects of greater awareness about pain, improvements in treatment, and improvements in surgical technique from the introduction of APSs (Werner and Nielson 2007). Acute Pain Services are struggling to provide evidence of improved care in a complex system (McDonnell et al. 2003). In healthcare, the workforce is fragmented, and there are many departments, each doing different tasks (Morgan and Murgatroyd 1994). The success of acute pain strategies is dependent on the interlinking of many people, departments and other factors. In addition, the challenges for APSs have changed over time. Evidence-based guidelines are readily available to APS practitioners. There is no shortage of evidence about techniques or drugs that work to control pain; however, there are problems delivering such techniques safely and effectively in the real world to the majority of patients. In order for services to survive in the 21st century, Loeser, past president of the IASP, states that APSs must produce outcome data (2000). Yet producing outcome data is a difficult task for under resourced services.
It is important to note at this point that, despite the problems with acute pain delivery highlighted throughout this chapter, there have been tremendous achievements, too (Justins 2008; Australian and New Zealand College of Anaesthetists and Faculty of Pain 2005). However, it was necessary to highlight the problems rather than the achievements in this background chapter in order to describe the complexity of delivering postoperative pain relief. The achievements will not be explored further because this research focuses on epidural analgesia, one technique used by the majority of APSs to control pain after major surgery, rather than acute postoperative pain relief \textit{per se}. The introduction of epidurals was rapid in the 1990s at a time when the quality of evaluation was extremely variable. Epidural analgesia for pain relief after major abdominal surgery is described in detail in the next chapter.
3 Chapter 3: Epidural Analgesia

"The time has come. The problem is clear. Pain is a major public health issue throughout the world. The gap between an increasingly sophisticated knowledge of pain and its treatment and the effective application of that knowledge is large and widening."

(Brennan and Cousins 2004 p 1)

3.1 Introduction

The introduction of APSs has led to an increased use of specialized pain relief methods, as recommended in the 1990 Working Report. These methods have the potential to improve patient wellbeing and reduce postoperative morbidity (Werner et al. 2002). One of those specialized techniques is epidural analgesia. In theory, an epidural block will produce complete analgesia. However, the gap in knowledge described above by Brennan and Cousins between the theory and practice of successful epidural analgesia has not yet been bridged.

Epidural analgesia is the provision of pain relief by the continuous infusion of pharmacological agents into the epidural space via an indwelling catheter (Australian and New Zealand College of Anaesthetists and Faculty of Pain 2005). Epidural analgesia has become the 'gold standard' technique for the management of postoperative pain, particularly in the 'high risk' patient undergoing major abdominal surgery (Australian and New Zealand College of Anaesthetists and Faculty of Pain 2005; Duncan and Counsell 2002). It is important to recognize that optimizing pain management in the 'high risk' patient may prevent costly admission to critical care.
beds, improve mortality rates, and reduce the length of hospital stays due to complications, such as paralytic ileus or pneumonia.

Nevertheless, the evidence base for the relatively rapid development in the use of epidural analgesia from the early 1990s to 2008 is not robust (Low et al. 2008). Several authors have questioned the relevance of statistically significant improvements in pain scores that have been used to support the use of epidurals in the past, as they do not represent clinically meaningful improvements. For example, Liu and Wu (2007) report that, for regional anaesthetic techniques, including epidurals, there is little clinically significant data to support the claim of their superiority over conventional techniques. They suggest that if patients receive increased side effects along with reduced pain, patients may not view this as an improved benefit.

Evidence about the safety and side effects of epidural analgesia is also conflicting (Chilvers et al. 2007; Ballantyne 2004; Rigg et al. 2002a). Epidurals can work well in clinical trials, but the technique is not without associated problems, such as hypotension, respiratory depression and rare serious adverse events. For example, one estimate of the risk of persistent neurological sequel after an epidural is 1 in 5000 (Bandolier 2008). Thus, their safe administration requires skilled monitoring. This skilled monitoring must be available 24 hours a day, 7 days a week. As highlighted in Chapter 2, few APSs have had the resources to provide expertise 7 days a week (Powell et al. 2004) and, therefore, rely on educating ward staff to play this skilled monitoring role and to fill the gap. Trainee anaesthetists also provide pain service advice out of hours.

The side effects of pain relief matter, as it is known that some patients do not like the technique for a variety of reasons despite good pain relief after surgery, and would not choose to have an epidural again in similar circumstances (Duncan et al. 2005). Other
patients are reluctant to accept an epidural, even without previous experience of the technique (Wijeysundera 2008). Measuring the effectiveness of the technique is time consuming and complex, particularly for services struggling with inadequate resources. This will become clear when describing the amount of data required for a snapshot of the patient experience.

There is also an economic debate. As discussed in Chapter 2, there was much discussion when APSs were established in the early 1990s about the role of high dependency units in postoperative epidural pain relief. Enthusiasts for the technique were keen to show that patients could be safely nursed on a general surgical ward (Wheatley et al. 2001; Wheatley et al. 1991). The debate is relevant in the first decade of the 21st century, as the recognition of the complexity of the epidural management grows. The technique has side effects, such as orthostatic hypotension, which are difficult to manage on a general surgical ward and may harm the patient. This debate about safety on general surgical wards appears to be led mainly by anaesthetists and surgeons. Primary nursing research focusing on, and challenging, the care of patients nursed with an epidural is scant. This is interesting, as nurses are responsible for the ongoing care of patients with an epidural, treatment of side effects, and recognition of complications. Nurses are in a unique position to observe and publicise problems with the technique.

This chapter documents and debates the evidence for the use of epidural analgesia for pain relief after major abdominal surgery. The gaps in knowledge are discussed and the problems of knowing what data to collect and how are highlighted.
3.2 Search strategy

Electronic searches were undertaken to identify the volume of literature on epidural analgesia, limited to English language publications.

The search strategy comprised the following main elements;

- searching electronic databases
- scrutiny of bibliographies of retrieved papers
- monthly scan of key journals online.

Keywords and MeSH terms selected included 'postoperative analgesia', 'epidural analgesia', 'continuous infusions', 'epidural opioids', 'critical incident reporting in APS', 'quality improvement', and 'satisfaction with postoperative pain relief.' Reference lists were searched and several international authors were contacted directly by letter and email. Three replies were received, including advice and additional papers not highlighted in the literature review. The National Research Register was also searched for current projects.

In addition, recent conference proceedings were scanned to identify additional potentially relevant studies. The table of contents from key journals were searched online; Acute Pain, Pain, the British Medical Journal, New England Journal of Medicine and the European Journal of Pain. In addition, websites connected with pain were browsed, including the British Pain Society, and the International Association for the Study of Pain. There were no date or publication type restrictions.

3.3 Acute surgical pain

In order to understand the role of epidural analgesia in postoperative pain control, it is useful to describe briefly the mechanisms of acute pain. The emotional aspect of pain
is clearly included in the definition of pain by the International Association for the Study of Pain (IASP) - ‘an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage’ (1979 p 250). Thus, pain is a human response, but many pain studies are conducted on animals. Therefore, ‘nociception’ is a term used in scientific papers because studies are performed on animals, which are unable to communicate the emotive experience of pain. Nociceptive stimulation results from the activation of peripheral sensory neurons by, for example, a surgical incision (Kehlet et al. 2006).

Three interrelated factors lead to postoperative pain. First, the impulses from the nerve fibres that have been injured innervating the surgical wound site; second, the inflammatory mediators, which are increased at the wound site and sensitize both the injured and uninjured nerve fibres; and thirdly, a sensitization of the spinal cord with increased response to noxious stimuli (Strichartz 2008).

The surgical procedure will induce impulse firing in peripheral neurones. Inflammatory pain is the heightened sensitivity that occurs in response to the tissue injury and resulting inflammation. This function is protective in that it allows healing and repair to occur (Woolf 1995). The injury is followed by the classical response of increased blood flow, tissue oedema and the sensitization of nociceptors. A great variety of substances are released in response to cell damage with others synthesised as a result of tissue injury; For example, the surgical incision is accompanied by the rapid release of serotonin and bradykinin. The release of bradykinin in turn activates the production of numerous other compounds, such as prostaglandins.

The detection of the noxious stimuli requires that there is activation of nociceptors and transduction into electrical signals for onward conduction to the central nervous system (Australian and New Zealand College of Anaesthetists and Faculty of Pain...
The nociceptive afferents are distributed throughout the body. The skin has a numerically large and specialised system of fast-conducting afferent fibres. It is activity in the A delta fibres that causes a sensation of sharp, well-localised pain and C-fibre activity causes a dull, burning pain. The A delta and C fibres convey information to specific areas of the dorsal horn of the spinal cord. The spinothalamic pathway ascends from the lamina of the dorsal horn to the thalamus and then the somatosensory cortex. The sensation of pain is also subject to descending control from higher centres. The main neurotransmitters implicated are serotonin, noradrenaline, and the endogenous opioids. Neuropathic pain is a result of injury to nerves or to the sensory transmitting systems in the brain and spinal cord (Kehlet et al. 2006). In addition, there can be direct nerve injury as a result of surgery. The mechanisms and treatment of neuropathic pain is different from that of nociceptive pain and is beyond the scope of this research.

The result of these changes is primary hyperalgesia, which means that the intensity of the pain sensation induced by the noxious stimuli is greatly increased (Sinatra 1992). The clinical picture is that the patient will experience flares of pain at the operation site and surrounding tissues. This flare can be evoked by touching the wound site, movement, coughing and gastrointestinal motility (Strichartz 2008). Inflammatory pain continues until a surgical wound has healed. The purpose of postoperative analgesia is to reduce the pain experienced on movement to a minimum so that the patients can move comfortably. In theory, this can be achieved by epidural analgesia using local anaesthetic drugs and opioids in combination. The beneficial effects are related to the attenuation of the stress response and the provision of effective analgesia (Nimmo 2004).
Pain has specific effects on the organ systems of the body, as described in the following section.

3.3.1 Cardiovascular system

In response to painful stimuli, such as movement after surgery, increased sympathetic tone results in increased cardiac work and oxygen consumption. This may result in ischaemic myocardial events in the 'high risk' surgical patient. In addition, the risk of surgical wound infection is increased, as pain induces peripheral vasoconstriction with resulting decreased tissue perfusion (Haljamae and Stomberg 2003). Postoperative epidural analgesia can reduce the incidence of myocardial infarction after surgery as a result of a reduction in sympathetic activity (Nimmo 2004). Pain can restrict movement so patients are unwilling to mobilize, a key factor in postoperative recovery. This can result in the development of deep venous thrombosis (blood clots). Compounds released as part of the surgical stress response can lead to a hypercoagulable state. Epidural analgesia after surgery is thought to reduce these deleterious effects by a combination of factors. Better pain relief allows the patient to mobilize, provides increased lower limb blood flow, blocking of the reflexes that inhibit diaphragmatic function and reduction of the stress response to surgery (Nimmo 2004).

3.3.2 Respiratory system

Postoperative lung complications, such as atelectasis, pneumonia and hypoxia are common after upper abdominal and thoracic surgery. This is because pain can stop the patient taking a deep breath and coughing effectively. The result is that secretions are
retained. Retained secretions become infected leading to pneumonia. An effective epidural is particularly useful for the treatment of pain associated with coughing and movement (Macintyre and Ready 2001).

3.3.3 Gastrointestinal

Pain can result in delays in gastric emptying and a reduction in gut motility. This is important, as the development of paralytic ileus is a major factor in extended hospital stay for patients after abdominal surgery (Werner et al. 2005). Epidural analgesia can potentially reduce the incidence of postoperative ileus by blocking sympathetic reflexes and avoiding the use of high dose opioids, which themselves slow gastric emptying.

3.3.4 Central Nervous System

There are also adverse psychological effects of uncontrolled pain after surgery, such as anxiety, lack of sleep, fear and aggressive behaviour.

It is, therefore, clear that there are potentially important advantages to the use of epidural analgesia after major surgery. Clearly, though, for the patient to benefit, the epidural must achieve analgesia. Evidence to date indicates that the failure to work in everyday practice is unacceptably high.

The next sections describe the history of epidurals and the commonly used drugs.
3.4 History of epidurals

An epidural (extradural) block is a technique to block the nerves outside the dura mater. The brain and spinal cord are covered by three membranes and the outer membrane is called the dura mater. Between the spinal dura and the vertebral canal is the epidural space, which has an average diameter of 0.5cms and includes the spinal nerve roots, lymphatics and fat, veins and spinal arteries. Thirty-one pairs of spinal nerves cross the epidural space and then exit at the intervertebral foramina (Atkinson et al. 1993). The cerebrospinal fluid around the spinal cord was discovered by Domenico Cotugno in 1764. Fernand Cathelin (1873 – 1929) was the first to describe the blocking of sacral nerves by an anaesthetic solution in 1901 (Goerig et al. 2002). Curbelo was the first worker to insert an epidural catheter into the epidural space in 1949. In an article describing sacral epidurals in 1923, Blomfield wrote that;

'When no hypodermic injection is used beforehand, injection into the sacral canal may cause considerable pain as well as a good deal of uneasiness and restlessness. It has always appeared to me paradoxical that there should be any pain associated with a process intended mainly for its prevention. To hurt a man while providing him with anaesthesia is ridiculous. Consequently, I have always employed preliminary narcotics freely before sacral analgesia. As a general rule omnopon gr. 1/3, scopolamine gr. 1/100, atropine gr. 1/200, have been given in one injection an hour and a half before the time of operation, and omnopon gr. 1/6 half an hour before. These injections have rendered some patients drowsy and quite indifferent to the sacral injection.'

(Blomfield 1923 p 7)
In the 85 years since Bloomfield’s description, the use of spinal and epidural analgesia has had a chequered history. Just after the Second World War, the use of spinal and epidural techniques lost favour in the United Kingdom as a result of several high profile reports of serious complications related to the technique (Cook et al. 2008). Clinicians in the 1980s and 1990s (Ballantyne et al. 1998) revived the popularity of epidural analgesia supported by the introduction of APSs, which allowed their use to be continued into the postoperative period.

Two classes of drugs are generally used for epidural analgesia: local anaesthetics and opioids.

### 3.4.1 Local anaesthetic drugs

For centuries, inhabitants of South America chewed the leaves of the shrub Erythroxylum cocca for the effects of reducing fatigue and appetite (Churchill – Davidson 1978). The effects, including numbing of the oral mucosa, were primarily due to the plant’s principal alkaloid, cocaine. Cocaine was first isolated in 1860 and used as a local anaesthetic in 1884. Also in the 1880s, Sigmund Freud used cocaine to treat morphine addiction, but unfortunately, the patient became the first cocaine addict (Churchill – Davidson 1978). The use of cocaine as a local anaesthetic expanded quickly, but the effects were found to be both toxic and addictive. Several synthetic local anaesthetics were developed in the first half of the 20th century, including procaine and lignocaine. Bupivacaine was synthesised in Sweden in 1957 and is still the preferred local anaesthetic for use in epidural analgesia infusions. It has a long duration of action – between 5 to 16 hours.
The local anaesthetics exert their effect by bonding to the internal mouth of the sodium channel on nerves' cell membranes. Local anaesthetics are lipid soluble bases that penetrate the lipoprotein cell membrane (Macintyre and Ready 2001). The thicker the diameter of the nerve fibre, the greater the concentration of the local anaesthetic required. When local anaesthetic drugs are injected into the epidural space, the small unmyelinated sympathetic fibres are blocked first (Freise et al. 2008). The sensory fibres transmitting temperature, pain, touch and pressure are then blocked. The largest fibres to be blocked are motor and proprioceptive fibres, although this effect is not desirable when epidurals are used for postoperative pain management, as mobilization is impaired. The evidence for the attenuation of stress response and effective analgesia is related to thoracic rather than lumbar epidural catheters (Wheatley et al. 2001).

Local anaesthetics can attenuate all three factors described earlier that lead to postoperative pain. After surgery, the 'stress response' is characterized by the increased release of catabolic hormones such as cortisol, glucose and catecholamines, and the inhibition of anabolic mediators, particularly insulin and testosterone (Sinatra 1992). Epidural blockade with local anaesthetic can suppress some neuroendocrine responses accompanying surgical trauma, as the local anaesthetic works on a broad range of targets. The afferent impulse coming into the spinal cord is reduced, minimizing central sensitization. It has also been found that local anaesthetics in the systemic circulation can alter the perception of postoperative pain. It is possible that local anaesthetics that have been infused into the epidural space are also present systemically due to vascular uptake (Strichartz 2008).
3.4.2 Opioids

The quality of pain relief produced by low dose infusions of local anaesthetics is enhanced by the addition of an opioid (Australian and New Zealand College of Anaesthetists and Faculty of Pain 2005; Curatolo 1998). In 1973, opioid receptors were discovered in the brain and spinal cord. Opioid receptors in the spinal cord are key sites in the production of analgesia. The epidural opioids can modulate the sympathoadrenal aspects of the stress response to surgery described earlier. Diamorphine, the opioid used in this study, is highly lipid-soluble, penetrates the lipophilic nervous system and thus acts rapidly. It is commonly used in the UK, but is not licensed in the USA or Australia, where major trials of epidural analgesia are carried out. Therefore, there is not an international evidence base for its use. Other centres, both nationally and internationally use epidural fentanyl in combination with bupivacaine. Fentanyl is also a lipophilic opioid. Epidural infusion of a local anaesthetic and opioid has the potential to provide excellent postoperative pain relief, particularly on movement, for ‘high risk’ surgical patients (Australian and New Zealand College of Anaesthetists and Faculty of Pain 2005; Macintyre and Ready 2001).

3.5 Surgery

The universal efficacy of epidural analgesia has been well demonstrated in comparison with conventional techniques (Australian and New Zealand College of Anaesthetists and Faculty of Pain 2005). Epidural analgesia is used for postoperative pain relief in orthopaedic, gynaecological, and cardiac surgery. The evidence base for
effectiveness is more robust for the aforementioned surgery, but the inclusion of patients who have had this type of surgery in meta-analyses in trials of epidural analgesia may distort, or mask, the effectiveness profile for the use of epidural analgesia in gastrointestinal surgery. There have been an increasing number of reviews limited to this group of general surgical patients.

A confounder to be considered when reviewing the literature is that recently there has been a change to laparoscopic techniques in surgery. Many of the studies on epidural analgesia were conducted at a time when surgeons used large surgical incisions often with wound drains and nasogastric tubes. Open resection is still the standard procedure for emergency patients. The open procedure requires a long incision through the abdominal wall. Approximately 30% of colorectal cancer patients will present as emergencies (Hospital Episode Statistics 2005). Surgical techniques for elective surgery have advanced since the establishment of APSs with the use of laparoscopic surgery for different types of surgery including bowel resections in some UK centres. It is worthwhile briefly describing these changes, as they are predicted to affect the requirement for the use of epidural analgesia in the 21st century.

3.5.1 Enhanced recovery

The advantage of laparoscopic surgery is that it is less invasive and, in theory, should lead to a more rapid postoperative recovery (Alcorn and Renwick 2008). In addition to changes in the surgical technique, there has been a move towards rapid recovery, or enhanced recovery programmes. Epidurals have been advocated as part of enhanced recovery programmes (Carli et al. 2005). However, epidural analgesia is just one of 17 elements contributing to the recovery programme. The aim of the programme is
both to reduce the trauma of surgery and plan an event-free recovery, which results in a shorter stay and an enhanced experience for the patient (Alcorn and Renwick 2008). The main target for improvement in abdominal surgery outcomes is to maintain normal gut physiology.

The 17 key elements, which act together to minimize the effect of surgery on the gut, are listed in Table 3.1 on the following page.
Table 3.1 The 17 key elements of enhanced surgical recovery programme (Alcorn and Renwick 2008 p 1)

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<td>Preoperative feeding</td>
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<td>Perioperative high oxygen concentration</td>
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<td>7</td>
<td>Active prevention of hypothermia</td>
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<td>8</td>
<td>Epidural analgesia</td>
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<td>9</td>
<td>Minimally invasive incisions</td>
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<td>10</td>
<td>No routine use of NG tubes</td>
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<td>11</td>
<td>No routine use of drains</td>
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<td>12</td>
<td>Enforced postoperative mobilization</td>
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<td>No systemic morphine use</td>
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<td>Standard laxatives</td>
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<td>Early removal of urinary catheters</td>
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<td>16</td>
<td>DVT prophylaxis</td>
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<tr>
<td>17</td>
<td>Enhanced nutrition with supplements</td>
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The epidural is recommended in enhanced recovery programmes because the sympathetic block helps with gut homeostasis and may reduce the need for morphine, which does adversely affect gut function. It is recommended in the programme that the epidural be maintained for 48 hours.

There are several potential problems with this approach, particularly if the anaesthetist, APS and ward nurses are not involved in planning and delivering the recovery programmes. Early mobilization is one of the key elements of recovery, but orthostatic hypotension related to epidurals will restrict mobilization. Second, fluids
are routinely given on general surgical wards as a bolus to optimize fluid management and reduce the incidence of hypotension related to epidural analgesia and hypovolaemia. This conflicts with the fifth element in the table – fluid restriction. The early removal of a urinary catheter (see Table 3.1) might not be possible, as urinary retention can occur as a result of epidural opioids and local anaesthetic drugs. In addition, some patients may experience significant pain if alternative analgesia is not given when the catheter is removed at 48 hours. The success of the epidural technique is in itself dependant on many more factors. Therefore, research reports about pain management techniques are being published against a background of significant shifts in surgical technique, which have undoubtedly rendered the results of some epidural studies as only of historical interest.

3.6 Complications

As mentioned in the introduction, there are rare complications of the technique that can result in serious morbidity and mortality. There is a lack of good evidence to assess the complication rate (Royal College of Anaesthetists 2008; Low et al. 2008; Cook et al. 2008). The risks of the technique have to be balanced against the benefits of improved pain control for each individual patient, and have limited the widespread adoption for all major surgical patients.

The following are the complications listed in the Association of Anaesthetists and British Pain Society publication ‘Good practice in the management of continuous epidural analgesia in the hospital setting’, published in 2004 (p 1).

1. Epidural Haematoma or abscess
2. Neurological damage
3. Respiratory depression
4. Hypotension
5. Pressure sores
6. Inadequate analgesia
7. Post dural puncture headache
8. Pruritus
9. Motor block
10. Urinary retention

3.6.1 Epidural haematoma or abscess

This section is necessarily detailed because an epidural abscess or haematoma can cause serious complications due to pressure on the spinal cord. There are several risk factors for the development of an epidural haematoma including coagulation disorders, the number of epidural needle attempts, and the administration of anticoagulants. Epidural abscess has been associated with epidural insertion site infection, longer duration of insertion and upper body procedures (Cameron et al. 2007). The symptoms are increased severe back pain, and neurological dysfunction as the abscess or haematoma presses on nerve roots or the spinal cord. Therefore, neurological monitoring should be standard practice after surgery. The onset of signs and symptoms may be delayed for days or weeks, when the patient is at home in some instances.

The estimates of the rate of epidural abscess or haematoma vary enormously. Very large numbers are needed in studies in order to quantify such rare events (Cameron et al. 2007). The results of an epidural haematoma/abscess can be devastating for the
patient and costly for hospitals. For example, there was a lot of publicity when the actress Leslie Ash sued the Chelsea and Westminster hospital because she developed a permanent disability as the result of an epidural abscess. She was admitted to hospital for several days after a rib and lung injury in 2004. A thoracic epidural was inserted for pain relief. After removal of the epidural and apparent recovery from her injuries, Ms Ash went home and woke up paralysed the next day. The problem was that the patient was unaware of the symptoms of an abscess; therefore, she was slow in presenting to casualty with the symptoms. In January 2008, she was awarded £5 million in compensation (Sanderson and Gibb 2008). The national papers reported that she ‘contracted MSSA from an epidural needle which came loose’ (Mills 2008). There was a lot wrong factually with the newspaper reports regarding the epidural technique; for example, the needle is not left in the patient. Nevertheless, the result was negative publicity for epidural analgesia and illustrates the high economic impact of cord compression. Early recognition and treatment of an epidural abscess or haematoma is critical for avoiding long-term morbidity.

In a cardiothoracic editorial, Glenn Gravlee (2003) describes the dilemma involved in adopting a procedure such as epidurals where the benefits are known and documented but where risks exist, though these are less well known. He comments on a large prospective study where the authors believe that positioning an epidural for cardiac surgery (coronary artery bypass grafts) is safe in terms of the risk of epidural haematoma (Canto et al. 2003). Nevertheless, it seems the cardiothoracic community in general is not convinced of the benefits versus the risks, as the procedure significantly adds to theatre time, thus affecting costs, and multimodal analgesia does work in this group of patients. Shortening length of stay would be worth the risks of the technique, but this was not shown. Gravlee concludes that perhaps the technique
should be reserved for those high risk patients most likely to benefit – patients with poor pulmonary function or chronic opioid dependency. The same reservations may be true for general surgical patients, particularly as general abdominal surgery is associated with greater risk for insertion site infection than in orthopaedic or vascular surgery (Cameron et al. 2007). Therefore, it is important to ascertain in which groups of patients the benefits outweigh the risks. This information is still not available to clinicians.

3.6.2 Neurological damage

Injury to nerves or to the spinal cord is uncommon, but the exact incidence is not known (Macintyre and Ready 2001). Spinal cord infarction (SCI) presents as paraplegia and loss of pain. SCI occurs because of occlusion of the anterior spinal artery. The mechanism by which epidural analgesia is associated with SCI is multifactorial in general surgical patients, but a risk factor is intraoperative hypotension (Hobai et al. 2008), which is described in detail later in this section.

3.6.3 Respiratory depression

Sudden onset respiratory arrest, sedation and respiratory depression have been related to the rostral spread of the epidurally administered opioid. The incidence is related to the water solubility of the opioid and is less common with the use of lipophilic fentanyl or diamorphine.
3.6.4 Hypotension

An effective epidural induces a sympathetic blockade (Freise et al. 2008). The sympathetic nerves lie in the epidural space and so are blocked before the sensory nerves in the epidural space are – this is unavoidable if analgesia is to be achieved. The normal response to a drop in blood pressure, a common occurrence during and after surgery, is the constriction of arterioles, a response initiated by the sympathetic nerves. Monk et al. claim, ‘Every minute of hypotension in the operating room increased the risk of dying in the first year after surgery’ (Monk et al. 2005 p 8).

Inadequate postoperative fluid management in major surgery is exacerbated by the use of epidural bupivacaine (Atkinson et al. 1993; Cheam and Morgan 1994). Hypovolaemia is the loss of intravascular volume. There is a reduction in pulmonary perfusion with the risk of arterial hypoxaemia (Forrest et al. 1990). Sub clinical hypovolaemia is enough to cause organ dysfunction (Webb 1997). Avoidance of hypotension is also important for patients at risk of spinal cord infarction (Hobai et al. 2008).

The definition of hypotension varies between published epidural studies. It is important to take into account a patient’s normal blood pressure rather than using a minimum systolic pressure for all patients. This is because, increasingly, patients undergoing major abdominal surgery are elderly and, as described in the introduction, are likely to be taking anti-hypertensive drugs. Thus, a definition of hypotension as a drop of more than 30% of normal systolic blood pressure is more accurate.

Measuring the blood pressure when the patient sits out of bed is important too. Patients will maintain a relatively normal blood pressure until sat out of bed. Their inability to compensate for the change in posture leads to a fall in blood pressure, that is, orthostatic hypotension. The recognition and management of a low blood pressure
tends to be under the control of the nurses and the surgical team. If the hypotension is not managed swiftly and effectively, there can be deleterious effect, such as patient collapse. Anastomotic leak occurs in 3 to 15% of patients after bowel anastomosis and accounts for a third of the mortality rate after colorectal surgery (Glendall et al. 2008). In order to heal, the bowel requires a good blood supply and oxygenation, which could potentially be compromised if hypotension is not treated. This may require inotropic support, which is available only in critical care beds.

A common response to hypotension related to epidural analgesia is to give a fluid bolus. Gould et al. (2002), in a study of the effects of thoracic epidural on colonic blood flow, suggest that it is difficult to restore colonic blood flow using fluids alone, and susceptible patients may develop cardiac failure. They recommend prompt treatment of hypotension with vasopressors if there is not a response to a fluid bolus. In addition, Gould et al. hypothesise that a reduced mean pressure, and reduced blood flow to the bowel for a sustained period could lead to an ischaemic reperfusion injury. The resultant sequence of bacterial translocation and the absorption of endotoxin from the bowel could then trigger a systemic inflammatory response syndrome.

In contrast, Glendall et al. (2007) state that hypovolaemia can be managed on general wards with simple fluid replacement. This current study challenges such a contention. Optimal fluid management has been practised at the author’s hospital for several years (Duncan et al. 2005), yet problems with hypotension continue, particularly when patients have mild rather than severe pain.

3.6.5 Pressure sores

Post-operative epidural analgesia is associated with a higher risk of developing heel pressure sores. Pressure sores are a direct result of pressure when soft tissue is
compressed between bone and a resistant surface. Such pressure normally results in discomfort or pain, producing movement that relieves the pressure. Epidural analgesia may contribute to a change in the sequence of events because of sensory loss, motor blockade, sympathetic block and lowered capillary pressure (Duncan et al. 2002).

### 3.6.6 Inadequate analgesia

Epidural failure may be related to a number of factors, such as the insertion of the catheter, catheter displacement, drugs used, and patient factors, which will be discussed in more detail in the next section. There is evidence that the intensity of acute postoperative pain correlates with the risk of chronic postoperative pain (Macrae 2001; Perkins and Kehlet 2000). The evidence has become more compelling over recent years, and the message needs to go beyond APSs and anaesthetists to reach the wider surgical community and primary care.

Henry Kehlet et al. have stated that iatrogenic neuropathic pain is possibly the most important cause of long term post surgical pain and may occur in 10 to 50% of patients after a variety of operations (Kehlet et al. 2006). Neuropathic pain is different from pain after surgery. It is damage to the nervous system, for example, injury directly to the nerves or transmitting systems in the spinal cord or brain. The pain is often described by patients as ‘burning’ or ‘shooting’ in nature. This is because major nerves cross the field of surgery and, therefore, potentially are damaged in most types of surgery.

Kehlet et al. (2006) hypothesise chronic pain develops because of two major reasons: continuing inflammation or surgical injury to major peripheral nerves. Local anaesthetic blocks, and epidural analgesia in particular are used to block the afferent
neural pathways thus inhibiting the nociceptive impulses. Therefore, epidural failure may contribute to longer term pain suffered by the patient.

3.6.7 Post dural puncture headache

A headache following the inadvertent puncture of the dura can occur. The incidence is between 0.4% and 24% (Australian and New Zealand College of Anaesthetists and Faculty of Pain 2005). Gendall et al. (2007) describe an incidence of approximately 0.15% to 1.3% of accidental dural puncture. A subsequent headache develops in up to 86% of patients.

3.6.8 Pruritus (itch)

Pruritus is an unpleasant, but rarely serious, side effect of the epidural opioids, and can be treated by adjusting the dose of opioid or administering naloxone intravenously. The incidence is reduced with the use of fentanyl or diamorphine instead of morphine. The incidence is also much lower in older age groups and in patients with chronic pain (Chung and Harris 1992).

3.6.9 Motor block

Motor block is rare with the use of low concentrations of local anaesthetic and with thoracic epidural placement. However, numbness and weakness are often the first signs of the rare but devastating complications of epidural abscess and haematoma.
3.6.10 Urinary retention

Urinary retention is a possible complication of the technique, but in this study, all patients had a urinary catheter in order to monitor urine output.

There are other potential dangers associated with the technique, for example, drug errors, pump programming errors and the lack of skilled personnel to monitor the safety and effectiveness of the technique. If accidentally given intravenously, the epidural drug can cause severe cardiac depression and death can occur. There were three deaths as a result of the inadvertent injection of bupivacaine into an intravenous infusion between 2000 and 2004 (National Patient Safety Agency 2007).

It is assumed that the complications described in this section are included in the risk versus benefit judgement each anaesthetist makes when deciding whether to offer the technique to a patient (Royal College of Anaesthetists 2004). Thus, the benefits of the technique, that is, excellent pain relief and an associated reduction in serious morbidity, must outweigh these rare but serious side effects described above. Yet it is very hard to give patients a true incidence of failure and complication rates because currently the numbers are not yet known. This is because there has been no denominator; professionals were not aware how many epidurals were undertaken nationally. A study is currently in progress to establish that figure, and to encourage all APSs to report any adverse events to a confidential database (Royal College of Anaesthetists 2007). Safety of the technique, therefore, relies on adequate monitoring in order to identify and treat any adverse events.

As discussed in the introduction, the delivery of effective epidural analgesia is influenced by a multitude of factors. Delivery of effective postoperative epidural analgesia is a complex intervention that may last for up to seven days in an individual patient. The Medical Research Council (MRC) defined a ‘complex intervention’ as
several components that combine to produce a desired outcome (MRC 2000). The following section highlights the complexity of the treatment by describing the 'ideal' sequence of events for patients undergoing epidural analgesia for major abdominal surgery where the level of epidural catheter must be correct, the drugs used effective, and the postoperative environment and surveillance be optimum (Barrington and Scott 2008). The multiple occasions at which the technique may fail/succeed, as debated in the literature, will be illustrated at relevant points. The reasons for the choice of data collection in the study will be clarified.

3.7 Epidural analgesia – from preparation to planned removal

3.7.1 Before surgery

Patients admitted for elective surgery (not an emergency) usually attend a nurse led preoperative clinic (Kinley et al. 2002) and, at this time, should receive information about pain relief after surgery. The technique is contra indicated in patients with local or generalised sepsis or coagulation disorders. Patient rejection is also an absolute contraindication, as is the lack of staff skilled in monitoring the epidural for the planned duration of its use. However, this last contra-indication is extremely difficult to investigate and monitor on a day-to-day basis.

Patient information leaflets, which include a section on understanding risk, are freely available to patients on the UK Royal College of Anaesthetist’s website (Royal College of Anaesthetists 2008). Interestingly it has been estimated that approximately 17% of patients do not have the numeric and literary skills to understand risk probability and severity (Moore et al. 2008). The patient will be seen at the preadmission clinic or on admission to hospital by an anaesthetist whose decision it is to
offer epidural analgesia. Understanding risk is important, as the anaesthetist should clearly state the incidence of minor and major adverse events associated with the technique. It is now common practice for the anaesthetist to either document the discussion or ask the patient to sign a separate consent form (Royal College of Anaesthetists 2004). However, it is known that patients respond differently to acceptance of medical interventions depending on how the risks versus the benefits are presented (Moore et al. 2008).

3.7.2 Emergency patients

Emergency patients do not receive the information and preparation provided in a preoperative assessment or on the web. Further, they are not usually recruited to clinical trials. It is not clear if outcomes related to pain management are different for this group of patients. Studies from as far back as the 1940s and 1950s recognized that pain experience is altered by factors such as fear, anxiety and suggestion (Loan and Morrison 1967). This was also alluded to in the introduction with excerpts from Pearce's 1946 nursing textbook. Keats paper, published in 1956, noted the different amounts of analgesia administered to those in public and private wards. Terry et al. (2007) found that higher levels of preoperative anxiety were associated with expectations of greater amounts of postoperative pain and with reports of more severe pain after surgery. Therefore, pain scores and side effects will be compared between elective and emergency patients in this study.
3.7.3 Chronic pain

There is much evidence to show that preoperative chronic pain is a predictor of postoperative pain (Macrae 2008; Kehlet et al. 2006). It was highlighted in the first chapter that a high percentage of patients have long-term pain before admission for surgery. To take account of that fact, in this study, all patients were asked if they had experienced pain before surgery. Other patient factors that may have an influence on postoperative pain scores and the incidence of hypotension are gender and age.

3.7.4 Gender

There is evidence that women have higher sensitivity to pain and postoperative pain than do men (Keogh 2008; Vincent and Tracey 2008; Gotoda et al. 2001). The reasons for gender differences in medication response are obviously multifactorial. Gender may be a significant factor for the development of adverse drug reactions, with almost a twofold increase in women compared to men (Snidvongs and Holdcroft 2008). This is due to gender differences in body structure and physiology (Gotoda et al. 2001), which affect drug pharmacodynamics and pharmacokinetics. As knowledge from clinical trials grows, Snidvongs and Holdcroft suggest that there will be individual treatment strategies with the addition of gender to other physiological variables for anaesthetic drug treatments. Conversely, Greenspam et al. (2007), in a detailed consensus report of gender differences in pain studies, state that there is not yet enough evidence to warrant gender-specific pain interventions. Greenspam et al. does recommend including gender as a factor in clinical trials and reporting any differences in outcome, as there is a lack of research in this area.
3.7.5 Age

As mentioned in the introduction, there is currently a major shift in the age distribution of the world’s population (Gibson 2006). The percentage of the population aged over 65 is predicted to rise from 17.5% to 36.5% by 2050 while the percentage aged over 80 will more than triple. The incidence of chronic pain increases with age, with at least 80% of those in elderly care suffering. The highest rates of surgery are also in the elderly group (Gibson 2006). With advancements in surgical techniques, anaesthesia and critical care (Veering 2006), surgical intervention is now possible in older groups. The over-65s have surgery four times more often than do the rest of the population so understanding what works or causes harm is particularly important in this group of patients.

There has been a growing concern about the poor pain management of this vulnerable group of patients. They may receive inferior pain relief compared to younger members of society for a number of reasons, such as communication problems, and concerns about interactions between pain relief medication and drugs for other conditions (Kumar and Allcock 2008). Members of this elderly population were born at the beginning of the 20th century, long before the birth of the NHS and before current attitudes to pain were formed. Older people are not well represented in clinical trials, usually because of arbitrary age restrictions and the presence of comorbidities. For example, a 70-year-old living in the community takes an average of seven medications for an average of three comorbidities (Gibson 2006). In England, more drugs are prescribed for hypertension and heart failure than for any other condition (Cole 2008). This is important, as cardiac drugs can affect the treatment response to hypotension related to an epidural.
Yet epidural analgesia is particularly recommended for the older, high risk patient (Veering 2006). It is already known that advancing age alters opioid dose response (Preble et al. 2002). There is some evidence that elderly patients may be more susceptible to hypotension (Simon et al. 2002). The elderly group in Simon’s study of the influence of age on haemodynamic changes with an epidural were over 61, and the increased hypotension was thought to be caused by the high thoracic spread of analgesia and a diminished haemodynamic homeostasis (n=54). Veering (2006) advises that marked hypotension in the elderly may be particularly harmful, as the elderly have a limited cardiac reserve. Serious postoperative complications are a consistent independent predictor of a longer recovery time. There is evidence that, after major surgery, elderly patients can look after themselves at three months, but it takes at least six months for full strength to return (Lawrence et al. 2004). It is, therefore, clear that there are several factors related to the patient that may be predictors of the quality of postoperative analgesia.

3.7.6 In the anaesthetic room

Some surgeons do not favour epidural analgesia because the patient spends increased time in the anaesthetic room (Wijeysundera 2008). When the patient arrives in theatre, the epidural is usually positioned in the anaesthetic room before the start of surgery under full aseptic conditions. The general consensus is that this should be done with the patient awake, although some patients request to be asleep (Meek 2004). The reason the patient is awake is to detect any problems with catheter position. The experience of the operator may be one of several predictors of an effective epidural at
this stage. Anaesthetists with five years’ experience or more have significantly greater success at positioning an effective epidural (Meek 2004).

During the procedure, the patient sits on the edge of a trolley as in the following picture (Figure 3.1).

![Image of epidural catheter positioning](image)

Figure 3.1 Positioning an epidural catheter using a Tuohy needle in the anaesthetic room (Barrington and Scott 2008 p 515). Reprinted from The Lancet with permission from Elsevier

Local anaesthetic is used to infiltrate the skin and the anaesthetist uses a Tuohy needle to identify the epidural space. A Tuohy needle is a hollow needle, shown in the picture above, which is slightly curved at the end. The thin epidural catheter is threaded through the needle after which the needle is removed. It is important that the epidural be sited at a level corresponding to the dermatome in the middle of the anticipated incision in order to provide effective pain relief. Yet it has been suggested
that the ability of an anaesthetist to identify the correct interspace may be off by four spaces (Broadbent et al. 2000). Ready (1999) reported that approximately 50% of ineffective epidurals were not sited in the position the anaesthetist believed. Occasionally, the needle punctures the dura, or hits a vein and the technique is abandoned in some cases. Multiple attempts at positioning the epidural catheter are associated with complications (Meek 2004). In addition, the higher up the spinal column, the technically more difficult the technique becomes.

Some trials do not report the failure to site epidurals in their results; therefore, the technique appears more successful than it is when applied to the whole population. Similarly, patients can awaken in the recovery room with severe pain and the technique is then discontinued. Thus, failure can happen at a number of stages before the patient leaves the operating suite.

Figure 3.2 Distribution of cutaneous nerves

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When the space has been identified, a fine catheter with graduated markings is threaded through the Touhy needle. The needle is removed and the epidural catheter is held in position with dressing and tape. A test dose of local anaesthetic is given, with continuous monitoring of the effect to ensure correct positioning has occurred. At this point, the patient is prepared for general anaesthetic. Intraoperatively, there is a diversity of anaesthetic and analgesic techniques. Some anaesthetists choose to use the epidural at a high dose and concentration as part of the anaesthetic, some run it at the lower rate and concentration used postoperatively. Few epidural studies standardize the anaesthetic technique; this is a major flaw but one that mirrors practice in the real world.

The type of dressing used to secure the epidural catheter is important, as the incidence of epidural failure due to the catheter falling out is high. In a large Australian trial (Rigg et al. 2002a), 42.5% of epidurals did not last the 72 hours intended in the study protocol. The Australian scientific evidence publication (Australian and New Zealand College of Anaesthetists and Faculty of Pain 2005) reported that, overall, 22% of patients have premature termination of the technique.

Therefore, there is bias in these studies with an artificially high rate of perceived success of the technique, as several studies did not use an intention-to-treat design and withdrew patients from data analysis if the epidural failed. For example, Richman et al. (2007), in a study of epidurals for gynaecological surgery, experienced a high failure rate before discharge to the ward and analysed data from only 88 patients rather than the 103 women recruited to the trial. Similarly, Nightingale et al. (2007), in a double blind randomized trial to establish the most efficacious agents to use for an epidural infusion, did not analyse data for patients with failure to site or early dislodgement. Nightingale et al. did not recruit patients who took painkillers before
surgery, yet in their discussion proposed that their results added evidence to the superiority of epidural analgesia over other techniques. Dolin et al., in their 2002 meta analysis (n = 13,629), reported an incidence of 5.75% premature epidural dislodgement.

The technical failure may be as high as 18.7% in the first 72 hours after surgery. Cameron et al. (2007), in an analysis of epidural data over a period of 16 years, found a consistent 9.9% ‘accidental displacement rate’, which was higher in thoracic than in lumbar epidurals. Werner et al. (2007) reported that the epidural catheter had to be reinserted due to inadequate analgesia in 9% of patients (n = 91). This figure is remarkably similar across published reports. Ballantyne et al. (2003) reported a catheter dislodgement rate of 9.84% in a study of 5,628 surgical patients. While dislodgement is bad enough, this is not the only cause of failure. In an American survey of 26,000 patients, 32% of thoracic epidurals failed (Ready 1999). This failure rate included inadequate analgesia and unacceptable side effects.

To summarize this section, the catheter failure includes fall outs, occlusions, kinks, leaks or working on only one half of the abdomen (unilateral block). Thus, it is important to collect data on the grade of the anaesthetist, any technical problems experienced positioning the catheter, and the site of the catheter, as these factors are all predictors of the success or failure of the epidural.

3.7.7 Drugs used

As described earlier, the general consensus is that a combination of a local anaesthetic and opioid results in a synergistic analgesic action and reduces the side effects associated with either drug used alone (Australian and New Zealand College of
Anaesthetists and Faculty of Pain 2005). The drugs must be of a sufficient concentration and volume that the afferent input from the area of surgery, which can be extensive, is blocked. This block of the entire surgical field must last until the wounds are healing and the intensity of pain is much less (McLeod and Cummings 2004).

3.7.8 Recovery

Recovery nurses are responsible for ensuring the patient is comfortable before the patient leaves theatre. The continuous infusion is established, using a pump that is programmed with a variety of parameters. Pumps can malfunction frequently, which consumes health care providers’ time (Viscusi 2005). This high incidence of malfunction means that all staff must be skilled at managing the technology. Drug errors and pump programming errors can occur (National Patient Safety Agency 2008) leading to patient harm.

Chris Pasero is a nurse consultant and ‘pain management educator’ who has several publications in the field of pain, including promoting the benefits of epidural analgesia (2005). He wrote that perioperative nurses have led the way in managing epidural analgesia, and he appears to be a strong proponent of epidural use. In his paper about improving outcomes with epidural analgesia, Pasero omitted the two large multicentre trials (Rigg et al. 2002a; Park et al. 2001) designed to investigate adverse outcomes in high risk patients. The results of both studies showed no overall difference in mortality or major morbidity. Therefore, by omission, he did not present an unbiased argument for the risks and benefits of epidural analgesia.
3.7.9 Ward or high care

On return to the ward, standing orders, protocols and the support of an APS or anaesthetist are required to optimize the safety of the technique. All observations should be documented at regular intervals. Several authors have suggested that this vigilance in recording may inflate the perceived effectiveness of the technique (Gravlee 2003; Dolin et al. 2002). In other words, patients receiving multimodal analgesia could potentially receive just as effective pain relief if they were monitored as closely as are patients with an epidural. According to an Audit Commission report, ‘Anaesthesia under examination’ (1997), 30% of patients with an epidural were nursed in an intensive care or high dependency unit. Those hospitals without sufficient access to such facilities were under pressure to introduce the technique and provide evidence it was a safe technique when managed on general surgical wards. This issue was discussed in Chapter 2.

The epidural may stay in situ for several days after surgery depending on a variety of factors. During this time, patients will start to mobilize on the first postoperative day in order to optimize their recovery. Patient safety is clearly paramount. Good practice recommendations state that patients must ‘always be under the close supervision of nurses competent in the management of continuous epidural analgesia and able to be with the patient within seconds of being summoned’ (Royal College of Anaesthetists 2004 p 3). In addition, nurses must have 24-hour access to anaesthetic advice and support. McLeod and Cummings (2004) have suggested that the lack of trained staff rather than the lack of critical care facilities has limited the expansion of epidural services for patients.

The minimum monitoring for all patients involves regular monitoring of the following:
- Pain scores on movement
- Haemodynamic variables, including blood pressure (BP), heart rate (HR) and central venous pressure (CVP)
- Pump function and the rate of epidural drug infusion
- Temperature
- Pressure areas
- Epidural site
- Side effects, including sedation, hallucinations, motor block

(Royal College of Anaesthetists 2004 p 1)

Bird and Wallis (2002), in a study of nursing knowledge of epidurals in an Australian hospital, were concerned that there was only a weak correlation between nursing knowledge and actual skill performance. The authors concluded that the education for nurses should develop nurses' 'clinical decision making skills' and 'autonomous critical thinking.' This is an important aspect of epidural management to research in the future. However, it was beyond the scope of this study to investigate nursing knowledge of epidurals.

3.8 The debate in 2008

Relatively recent large randomized controlled trials (Peyton et al. 2003; Rigg et al. 2002a; Park et al. 2001) have not been able to reproduce the results of earlier meta analyses (Beattie et al. 2001; Rodgers et al. 2000; Ballantyne et al. 1998) that reported a reduction in the incidence of pulmonary, cardiac and infectious complications associated with epidural analgesia (Viscusi 2005). In the 1990s, the incidence of perioperative myocardial ischaemia was a concern to surgeons and anaesthetists.
Epidurals appeared to reduce this risk (Beatie et al. 2001). The assumption was made in several reports (Nimmo et al. 2004; de Leon-Casasola 2003) that the improved pain management and reduced cardiac and pulmonary complications would reduce hospital stay. Clearly, the time a patient spends in hospital is subject to many factors and there is no objective evidence that this was due to the epidural per se. In fact, none of the studies reviewed have unequivocally shown a relationship between reduced length of stay and postoperative pain scores. Nevertheless, the converse is perhaps more realistic. Ineffective pain relief can extend a patient’s stay in hospital because of the complications described earlier in the chapter.

Early RCTs and systematic reviews reported significantly improved postoperative outcomes. These papers have been criticised since then for a variety of methodological problems (Nimmo 2004; Rigg et al. 2002b). The majority of the studies used in the meta analysis published at the start of the century were in fact investigated or undertaken in the 1980s and first part of the 1990s at a time when services were being established, and experience of what were the correct questions to ask the patient were lacking. Small RCTs at that time were very positive about the benefits of the PCA and epidurals (Yeager et al. 1987); the Yeager et al. trial in particular has been excluded from more recent reviews because of its limitations, including early study termination, and poor analgesia in the control group (Viscusi 2005).

With the benefit of hindsight, it has been suggested that there were improved outcomes for patients with epidurals separate from the epidural (Marret et al. 2007). The monitoring was superior; therefore, other problems that delayed recovery were discovered quickly and treated. Some centres routinely nursed epidural patients in a high dependency unit with monitoring and cardiovascular support not available on
general wards. Epidurals were compared to conventional analgesia. The evidence base for conventional analgesia was built mainly before the 1990 Working Part report and the development of APSs. There has been little subsequent evaluation of optimal systemic multimodal analgesia in combination with the increased level of monitoring that is routine with epidural analgesia. Pain scores and the management of side effects might not have been optimal for those patients receiving systemic analgesia. A more recent study found that changing from epidural analgesia to optimal systemic analgesic resulted in comparable analgesia (Chilvers et al. 2007). There was a reduction in theatre time, stay in critical care and side effects and complications with optimal systemic analgesia compared to epidurals. Methodological problems were present with the design of the study, but the results have been among those of several studies recently to suggest that the risk benefit scales for epidural analgesia are shifting (Low et al. 2008; Rigg et al. 2002a).

Cardio-oesophagectomy is a particularly high risk surgical procedure with a high morbidity and mortality rate compared to other surgery. A prospective observational study conducted over a six-year period in a Swedish hospital found superior analgesia for patients receiving epidural analgesia (n = 201). However, epidural treatment was stopped earlier than planned in 37% of patients due to insufficient analgesia, and to side effects of the epidural and catheter displacement (Rudin et al. 2005).

The publication of the multicentre Australian study of epidural anaesthesia and analgesia in major surgery (MASTERS) trial (Rigg et al. 2002a) marked the shift in the level of enthusiasm for epidural analgesia. In Australia, the technique is used less frequently, and in the UK, the debate about effectiveness is resulting in increased controversy (Barrington and Scott 2008; Low et al. 2008). The initial increase in the use of epidurals throughout the 1990s and the decline since 2001 has also been
reported by Canadian authors publishing the results of a large cohort study (Wijeysundera et al. 2008). The MASTERs trial was designed to reflect everyday practice, but controlling all the variables in the multicentre trial was difficult. The study was powered to detect a 20% difference in morbidity and mortality (n = 888), but there was no overall difference between an epidural group and a conventional analgesia group. Again, the design of the trial has been called into question, but empirically, it is the most rigorous trial design to date. Critics opposed the intention-to-treat study design because of the lack of study control over the type of anaesthetic, grade of anaesthetist or type of major abdominal surgery to name but a few. One perspective is that this calls the results into question (de Leon-Casasola 2003). A different perspective is that the study reflected real life, and may even underestimate the problems of delivering effective epidural analgesia in the ‘real world’, as patients were recruited by enthusiasts of the technique. Many of the earlier studies, such as Jaeger in 1987 advocating the use of the technique, were underpowered (Low et al. 2008). Failure rates and the incidence of side effects were not reported. The Canadian observational study reported borderline overall benefit on 30-day survival despite very large numbers with a number needed to treat of 477 (Wijeysundera et al. 2008).

It has been argued that the use of the technique is still worthwhile if the patient experiences reduced postoperative pain, particularly on movement (Barrington and Scott 2008). Yet up to 50% of epidurals failed in the MASTERS study. In clinical practice, a failed epidural means that the patients will then suffer poor pain relief unless ward staff are able to respond rapidly with appropriate alternative pain relief.

There is a growing awareness of the limitations of the technique (Viscusi 2005).

In an evaluation of a multimodal surgical programme for colonic resection using thoracic epidural, the rate of severe pain was approximately 20% (Werner et al. 2008).
The results are not robust, as a simple 0 to 3 score was used and pain scores were measured at only two points in a 48-hour period. The only other relevant published study is McLeod et al.'s (2004) report of the initial quality of an epidural after theatre and the effect on overall quality of pain relief (n = 1359). They measured time to the first experience of pain over a nine-year period from 1993. During that time the service developed, the drugs used changed and the level of skill improved. They used crude scores on a 0 to 3 scale. All patients were nursed in a critical care bed with the advantages of increased monitoring and nurse staffing. The scores were not collected by the investigators, but were copied from charts. Side effects and complications were not published with the data. McLeod et al. (2006) reported technical problems in 10% of patients, which is similar to other studies (Ballantyne et al. 2003).

In an update of the Australian scientific evidence document (Australian and New Zealand College of Anaesthetists and Faculty of Pain 2007), there is still unequivocal support for the use of epidural analgesia. Specifically, the international report uses several more recent meta-analyses to support the superiority of epidural analgesia over conventional methods in abdominal surgery (Marret et al. 2007; Nishimori et al. 2006; Werawatganon 2005). Interestingly, there is no mention of the MASTERS trial in this publication of best available evidence. Marret et al. (2007) conducted a systematic review of RCTs which was designed to compare epidural analgesia and intravenous opioid analgesia after bowel surgery. They concluded that the epidural analgesia had adverse effects, and did not shorten length of stay despite lower pain scores and a reduced incidence of ileus. The reduction in the incidence of ileus is important from the patient comfort aspect. The review did not include emergency surgery. In addition, the surgical technique changed after 2000; the majority of the studies recruited patients undergoing enhanced recovery programmes. Once again,
Marret and co-authors report that, in one study, almost 40% of patients had the epidural catheter removed prematurely.

The debate about the use of epidural analgesia in the UK is escalating. Supporters and critics of the technique exist, but Walton et al. (2006) point out that the literature available supports either argument. What was clear as a result of a national survey of epidural practice is that UK anaesthetists in 2006 still favoured the use of epidurals despite problems with the lack of provision of a bed in critical care. Sixty percent of those who took part in the survey had difficulty accessing such beds. Three UK anaesthetists from Derby brought the debate to the fore in an editorial in 2008 aptly titled ‘Epidural analgesia; first do no harm’ (Low et al. 2008). They question the routine use of the technique in major abdominal surgery. This is based on a greater appreciation of the complexity of managing epidural-induced hypotension. Fluid boluses alone may not be enough to correct this and, as discussed earlier, can lead to significant morbidity. The BURP study supports this argument with a high incidence of hypotension recorded despite optimum fluid management (Duncan et al. 2005). Low et al. suggest that patients may have a routine need for vasopressors, which has large resource implications.

In summary, research focusing on epidural analgesia for pain relief after major surgery is an important topic because there is still no strong evidence in favour of a procedure that could potentially harm patients. An incidence of 30% failure rate is not acceptable on humanitarian grounds. The high incidence of orthostatic hypotension limits the early mobilization because patients feel light-headed and this may increase surgical morbidity if the patient collapses. The incidence of side effects and complications is not clear, particularly in different patient populations, such as emergency patients. The fact that most controlled trials did not mirror the real patient
population and environment underpins the core research problem with postoperative epidural analgesia presented in this thesis. Epidural analgesia is not a single entity – it can be used for different operations and involve different drugs, and even the insertion site in the epidural space is variable (Australian and New Zealand College of Anaesthetists and Faculty of Pain 2005). The delivery spans up to seven days and involves the skills of several members of the multidisciplinary team. Thus, the results of efficacy trials are difficult to interpret. This chapter has highlighted the fact that few trials match the population who routinely undergo major abdominal surgery. This study contributes to the epidural versus non-epidural debate by describing the population and identifying factors associated with both the success and failure of the technique.

In addition, all APSs must collect data on outcomes related to epidural analgesia. This is a mammoth task for under-resourced services. Thus, one objective of this study was to design a database to gather information prospectively on all patients and capture events that are important to patients and clinicians. The design of the study is explored in the next chapter.
Chapter 4: Methodology

'The challenge is to discover what we need to know that we do not know now in order to create much more effective systems of care'

(Berwick 2005 p 317)

4.1 Introduction

As discussed in the previous chapter, the challenge for APSs is to discover what we need to know that we do not know now about the quality of epidural analgesia. From the review of the literature and the description of the epidural from start to planned removal in Chapter 3, it was possible to identify key factors that may influence the effectiveness of the technique, such as patient and nursing factors. This prospective observational study of adult patients undergoing major abdominal surgery was designed to describe the incidence of pain, hypotension and other epidural-related side effects after major abdominal surgery and to identify factors associated with effective analgesia and postoperative hypotension.

In this chapter, the development of the research questions will be presented. The following section will justify the methodology underpinning the research design.

4.2 Developing the study design

As described in the introductory chapters, the genesis of this current research developed from the experience of designing, conducting, and publishing a double-blind randomised controlled trial (BURP) over a three-year period starting in 2001 (Duncan et al. 2005). The aim of the BURP study was to reduce the incidence of
hypotension related to effective epidural analgesia by comparing two strengths of bupivacaine for epidural infusion. When the BURP study was designed, overwhelming support for epidural analgesia existed internationally (Australian and New Zealand College of Anaesthetists and Faculty of Pain 1999). This universal confidence in the technique has waned over the intervening seven years.

There were several experiences related to the BURP study that have usefully informed this study. The consent procedure of the BURP study, rather than the study protocol per se, excluded many of the patients routinely reviewed by an Acute Pain Service. Therefore, the results were not generalizable to all patients consenting to an epidural.

The BURP study took approximately three years to complete. Practice was changed for only a very small group of patients because the focus of the controlled trial was on only one aspect of the epidural. The study was not designed and conducted as part of research training so the researcher was not constrained by deadlines. It was a mammoth task to design and load data for a large number of patients, yet only the main outcomes could be reported. Nevertheless, it did help to identify factors that were measurable and relevant to this current study. It is clear from the introductory chapters that there is potentially a significant amount of information to be collected from each patient visited by an APS over days rather than hours. Fortunately, different studies, for example, effectiveness and efficacy studies, can measure similar parameters and endpoints (Wittink and Carr 2008) and complement one another. The results of this present study will be compared where relevant to the results of the BURP study in order to provide greater understanding about the different study samples.

Measuring patient satisfaction is beyond the remit of this current study. Whilst the topic is important, measuring patient satisfaction will, it seems, nearly always show
high levels of satisfaction for pain relief after surgery, and it is not a particularly discriminating measure of the success of a pain service (Dolin et al. 2002). There is a significant body of evidence to support the statement that patient satisfaction and pain intensity do not correlate, as presented earlier in this study.

There were several positive aspects of planning and conducting an RCT, as evidenced by publication of the BURP study in a peer-reviewed journal aimed at a multiprofessional audience. It was one of the first papers to identify the problem of hypotension related to epidural analgesia for major abdominal surgery. The high incidence of hypotension in effective epidurals has since been supported by other publications (Low et al 2008; McLeod et al. 2006). Hypotension after major abdominal surgery can harm the patient due to the reasons explained in Chapter 3 and this has rekindled the debate about the routine use of epidural analgesia for all general surgical patients. Further, controversy exists about whether patients can be nursed effectively, and crucially, safely, on a general surgical ward rather than in a critical care bed. In order to advance this debate about the safety and effectiveness of epidurals, more information needs to be analysed about the technique in everyday clinical practice.

Specifically, it was clear that a randomized trial, with the emphasis on a single intervention and single endpoint, was appropriate for finding the most efficacious local anaesthetic to use for epidural analgesia. However, an RCT is not the most appropriate or cost-effective methodology for learning about care in real clinical settings. Strict study entry criteria can mean that little is learnt about the analgesic techniques given to, for example, emergency or elderly patients. When strict protocol controls are removed, the technique or drug may perform in a different way (Pronovost et al. 2004). Alternative means of investigation exist that can be as robust
as an RCT. Observational research is more suitable for detecting adverse events related to treatment, and to providing an indication of what can be realistically achieved in clinical practice (Vandenbrouke 2008; von Elm et al. 2007). This current observational study is the next phase of epidural research, and is complementary to the RCT, rather than being a study designed in isolation.

Understanding how epidurals function in real life situations that are more relevant to other centres requires a more pragmatic study design. Pragmatic studies seek to address practical research questions, such as the benefits and risks of an intervention undertaken in routine clinical practice (Polit and Beck 2008). Knowledge of this could shift the understanding of the risk/benefit profile of epidurals in the group of patients described in this study. If epidurals are not effective for all patients undergoing major abdominal surgery, there may be subgroups of patients who do benefit. In order to discover who they are, measurements need to be taken under day-to-day conditions, and should include, for instance, those patients normally excluded from controlled trials and the large number of health care professionals involved in caring for patients. Polit and Beck (2008) suggest clearly stating the research questions as it “invites an answer” and thus guides the researcher to focus on the most appropriate type of data to collect for a research study. Thus, to reiterate the research questions;

- What is the incidence of pain, hypotension, and other epidural-related side effects on the first day after major abdominal surgery?
- What factors are associated with effective analgesia and postoperative hypotension?

It was anticipated that answering the research questions would help establish a baseline for identifying the characteristics of those patients in whom the epidural is
effective, particularly on the first day after surgery. An effective analgesic produces good pain relief without significant side effects.

This prospective observational study was designed to determine if the severity of pain after surgery, and the incidence of hypotension, is associated with patient characteristics, with the technique itself, or with the quality of postoperative management.

The aims of the current study were to describe the incidence of pain, hypotension and other epidural-related side effects after major abdominal surgery and to identify factors associated with effective analgesia and postoperative hypotension on the first day after surgery.

The objectives of the study were;

- To design a data collection form for every visit
- To collect pain scores, side effects and critical incidents on all patients consenting to an epidural for postoperative pain relief over a period of 18 months
- To compare the extent to which the results achieved in the BURP study mirror those in everyday practice
- To identify the important measurements of an ideal acute pain assessment in preparation for computerized data collection.
- To identify those characteristics associated with the quality of postoperative epidural analgesia and the incidence of hypotension using both classical descriptive and correlational statistics and Statistical Process Control (SPC) methods.

The research questions are supported by the existing body of research evidence presented in Chapter 3. In a single centre study such as this, it is not feasible to look at
the reduction in mortality, as it has been estimated that approximately 55000 participants would need to be recruited. Consequently, research studies need to look at the quality of the epidural (Wijeysundera et al. 2008). Cashman and Dolin (2002) proposed focusing on the quality of the epidural and the incidence of respiratory depression and hypotension as an indication of the safety of epidural analgesia. Barrington and Scott (2008) proposed that the level of the epidural catheter must be correct, the drugs used effective, and the postoperative environment and surveillance optimum. Walton et al. (2006) concluded that little is known about the association of epidural analgesia with the site of epidural insertion, choice of drugs, and postoperative management. The Dundee team (McLeod et al. 2006) echoed this need to determine if effective epidural analgesia is associated with demographic, preoperative, clinical or surgical factors. McLeod et al. specifically suggest further work be undertaken to determine if the following are independent predictors of the quality of the epidural block: age, sex, site of needle insertion, duration of surgery, amount of experience of the anaesthetist and surgeon, the drugs used, and prior chronic pain. It is clear that there is potentially a huge amount of information to be collected from each patient over days rather than hours in order to describe fully epidural analgesia.

Little guidance is available from the published studies about how to design such a study. Without clear guidance from current literature, the research question must guide the choice of study design, or methodology. All research requires a methodology, that is, a systematic way of generating knowledge, in order to reach conclusions (Haralambos and Holborn 1991). Pope and Mays (1995) state that much healthcare research is driven by a specific practical problem that is turned into a
research question. The choice of research design to provide the most robust evidence possible about epidural analgesia will be further justified in the next section.

4.3 Methodology

The BURP study was an experimental study, designed to establish cause and effect relationships. The conditions were tightly controlled with randomization and blinding. This present study was a prospective observational study. It is not possible to assign cause and effect in this type of design. Rather, the aim is to identify associations, or correlations, between variables. In clinical practice, several interrelated factors combine to result in effective pain relief after surgery. Thus, it is an effectiveness trial rather than efficacy trial; these can be the most useful type of studies because other clinicians can apply the results to their own practice as the study reflects ‘real life’ (Rigg et al. 2002b). However, one feature preserved from the BURP study in this current study is the intention to treat approach of controlled trials so that any evidence for effectiveness is not inflated.

A second insight from previous studies (Duncan et al. 2005; Duncan and Haigh 2003) is the under-reporting of side effects by patients. For example, during follow-up interviews after discharge, patients reported a number of side effects that they did not communicate to the nursing or medical staff whilst in hospital. Patients are not versed in the side effects associated with therapy, are not aware that what they experience is not intended, and will not tell a clinician unless directly asked. Therefore, it was important that all members of the APS asked patients about every variable of interest.

‘Observational’ means that the research is non-experimental; there has been no intervention or manipulation of variables. It is a quantitative study not a qualitative study. It is a prospective study, which is more rigorous than a retrospective study.
The outcomes, or dependent variables of interest, were identified, namely, pain scores and hypotension. In controlled trials, side effects and complications are generally secondary outcomes, with as many as half the trials reviewed considered inadequate in the reporting of adverse events (Australian and New Zealand College of Anaesthetists and Faculty of Pain 2005). The key message from the Australian best practice report was that ‘multiple outcome measures are required to adequately capture the complexity of the pain experience and how it may be modified by pain management interventions’ (Australian and New Zealand College of Anaesthetists and Faculty of Pain 2005 p 29). The independent variables or predictors in this study were also identified and were operationalized in the methods section.

Correlational studies explore relationships between variables. The data for a correlational study, therefore, must be quantitative in order that statistical testing can be applied to identify relationships between variables. A correlational design is used when a researcher has good reason to believe a relationship exists among variables and can support this with past research and/or a literature review (Wood and Brink 1989). There is no control over variables, which are measured as they exist. It has already been highlighted that postoperative epidural pain relief is a complex intervention. It is common in a correlational study to have several dependent and independent variables in a single study. The advantage of correlational research is the ability to collect a large amount of data and look at more than one relationship between variables in the same study. Whittink and Carr (2008) suggest that the methodological rigour lacking in effectiveness studies of pain management is compensated for by the size of the population under study, the duration of observation, and the reliance upon statistical techniques to control for confounding
variables. This is an important point because the disadvantage of progressing from a tightly controlled experimental design to a non-experimental study is the greatly increased threat to internal validity. In other words, other potential confounders, not identified in the study, could influence the pain scores and/or incidence of hypotension. In the current study, the threat to internal validity has been limited as far as possible by measuring potential confounders identified from a variety of sources as presented in the background chapter. In addition, statistical process control (SPC) was used for data analysis to further increase the rigour of the study.

An additional way to classify the research is by the type of question asked. The study question in this research sought to find out more about relationships between a variety of factors (variables) in addition to simply describing the characteristics of the epidural patients. Every variable had to be operationalized or defined in order to be measured (Polit and Beck 2008).

Reliability is the ability of a measure to produce consistent results when measured repeatedly under the same conditions (Field 2005). Validity is particularly concerned with the tools used to measure the outcomes in the study, such as pain scores, that is, the degree to which the pain tool measures what it is intended to measure. Yet pain is a subjective multidimensional experience and so there is no objective way of measuring it. Although subjective, pain measurement tools are robust (McQuay and Moore 1998). There is a large evidence base for the use of pain scores in postoperative pain management studies such as this. In order to compare data between studies, the standardization of outcomes, mainly pain measures, will increase the validity of comparisons. Validity is the degree to which inferences made in the study are well founded (Polit and Beck 2008).
Limiting a study to changes in pain score alone is very unlikely to give a clear picture of the effectiveness of epidurals. As stated before, the drugs used to control pain have a variety of effects, which can be more intolerable than the pain. Achieving effective pain relief using large doses of drugs can be associated with an unacceptable incidence of side effects, which may contribute to patient morbidity and mortality (Australian and New Zealand College of Anaesthetists and Faculty of Pain 2005) and extended stay in hospital.

A large sample is crucial in a correlational study in order to ensure a true representation of the patient population is achieved. Relationships between variables should be generalised from the study sample to the population. The sample size is also related to the number of variables being studied (Wood and Brink 1989). In other words, the sample must be large enough to contain all the variables and their full range of variance. There is natural variability in biological data, which may be due to random variation, a real effect or a combination of the two. It is the job of the researcher to establish which variation is due to a real effect (Campbell and Machin 1993). The statistics used need to reflect the design of the study and type of data.

Quantitative methods require an in-depth knowledge of the topic in order that the appropriate tools are selected and so are available for measurement (Brink and Wood 1989). Four different levels are described for the measurement of data. This guides the type of data analysis performed. Nominal data are data that can be named. For example, 'either or' categories such as male/female. The numbers assigned to this data have no meaning. With more than two categories, it is possible to categorize data in rank or categories. Numbers are assigned to the data, such as the grade of anaesthetists, but the data cannot be treated as having a numerical value. It is common to dichotomize continuous data to make them into nominal data for ease of analysis.
In this study, a systolic blood pressure less than 30% of normal is the discriminator of hypotension and normotension.

Continuous data can be divided into interval and ratio scales. In an interval scale, the difference between the measurements has meaning. The distances between the points are equal. In a ratio measurement, the distances between points are equal, but in addition, the value of zero has real meaning. The advantage of using interval and ratio scales is that data can be averaged meaningfully.

The majority of the measures used in acute pain research are at nominal or ordinal level and have been used as outcomes in studies similar to this present study. One unique measurement that was used in this study was developed by this author as part of a team (Counsell and Duncan 2000). Thirst scores are routinely documented with other postoperative scores to identify patients who are hypovolaemic. The reliability of the instrument has not been formally evaluated.

The intensity of pain can be measured in a reliable and valid way by patient self-rating (Carecini et al. 2002). Pain scores in published studies are measured in a variety of scales (0-10, 0-7, 0-100) and are usually treated as interval scales. There is controversy about the characteristics of such scales because they are ordinal data, as they do not represent equal distance between scores. O'Connor and Tennant (2008) object to the aggregation of essentially ordinal data and the subsequent presentation of the data as interval data with decimal points, and suggest it is a misuse of data. However, many publications in pain research recommend that the visual analogue pain scales are treated as interval data (Sinatra et al. 1992). The VAS is more sensitive than a simple 4-point categorical rating scale (none, mild, moderate, severe) in measuring pain (Caraceni et al. 2002), but it is commonly used clinically. Variability in outcome measures in clinical trials can hinder the evaluation of the effectiveness of
treatments. It has been recommended that investigators should use both the VAS and the 4-point categorical scale as pain outcome measures in order to be able to compare results with other studies (Dworkin et al. 2005).

The 4-point categorical score described above is the scale used by ward nurses routinely in the researcher's institution. The VAS and the 4-point categorical score are known to be well-correlated (Dworkin et al. 2005). In this study, the patients were asked to imagine that '0' represents 'no pain' and '10' represents the 'worst pain imaginable.' This verbal numerical rating scale (VNRS) is equally as sensitive as the VAS in assessing pain after surgery (Breivik et al. 2008). Because acute pain is a complex emotion, it needs to be recognized that factors, such as the way a pain score is presented to a patient, the side effects experienced or the time of day, will have an influence on the patient response. Nevertheless, this study was designed as a pragmatic study with no study intervention; thus, it was necessary to use the type of information that patients receive in everyday practice where it is not possible to educate all patients in pain scoring.

Descriptive statistics support the external validity or generalizability of the study by clearly presenting the characteristics of the patients in the study. Exploratory data analysis has been described as a philosophy that directs the researcher to use the data for the greater understanding of the subject of the research – in this case epidural analgesia (Cramer and Howitt 2004). Correlation is used to measure the degree of linear association between two variables. The correlation coefficient lies between +1 for a perfect positive relationship and -1 denoting a perfect negative relationship. The word 'linear' means relating to a line. The correlation coefficient equals zero when the variables are totally unrelated.
To increase further the understanding of epidurals used in everyday clinical practice, Statistical Process Control (SPC) methods were also adopted. SPC is a tool used by researchers of Quality Improvement. SPC is a branch of statistics equal in rigour to traditional statistical methods (Benneyan et al. 2003). In this study, SPC was used to enhance the rigour of the trial. SPC has a long and successful history in the manufacturing industry. More recently, the NHS Institute for Innovation and Improvement, the Institute for Healthcare Improvement in Boston, and the NHS Quality Improvement Scotland have advocated the use of SPC methods in a drive to persuade clinicians and managers to use data to guide quality improvement. SPC is rapidly becoming a major tool in healthcare quality improvement. The founder of SPC was Walter Shewhart, a physicist and engineer. Shewhart developed SPC methodology in the 1920s. His theories are based on the fact that every process displays variation. As an example, he suggests writing the letter a, then repeating it, up to 10 times: ‘You try to make all the ‘a’s alike. But you don’t and you can’t’ (Shewhart 1931 p 5).

In order to help distinguish between types of variation, Shewhart developed the statistical process control chart, which will be referred to as a ‘control chart’ from this point on. The emphasis in SPC is on stabilizing systems to improve the understanding of cause and effect. Shewhart identified two types of variation, and these form the basis of an understanding of the control charts.

4.3.1 Assignable/common cause variation

This is the variation inherent in any process. Other terms are ‘noise’ and ‘random variation’. Shewhart concluded that the multitude of causes that interacted to produce the variation must be continuously present in the system. 

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4.3.2 Unassignable special cause variation

Data in this situation vary in an unpredictable manner; something else is going on apart from the underlying process. Shewhart concluded that these outlying values or the sudden shift in average performance were caused by specific circumstances, a special cause of variation. He also hypothesised that a frequent observer of the control chart, such as a pain nurse specialist or ward nurse, would be able to identify the special cause of the variation.

One advantage of the SPC approach to data analysis is that the participants of the study reflect the population for which treatment is intended. Secondly, the use of control charts avoids the pitfalls of before and after, also known as pre-test/post-test study designs. The error in such designs is that conclusions are based on the belief known as ‘post hoc ergo propter hoc’, that is, after this, therefore, because of this (Speroff and O’Connor 2004). For example, in a hypothetical pain study before-and-after design, data are collected for 12 months, followed by an intervention, such as an education programme, which in turn is followed by further data collection. Pain scores are aggregated, and the average scores are compared using a t test, which may or may not show significance. In fact, no valid conclusions should be drawn without anything being known about the underlying process. A variety of confounding variables may have been responsible for the different scores. In contrast, using SPC, it is possible to detect statistically significant signals from patterns in data more quickly than in controlled trials (Benneyan et al. 2003). The unknown or confounding factors become less of an issue using SPC methods. In classical controlled studies, data fishing, or post hoc subgroup analysis is not recommended. In SPC, it is possible, in fact advantageous, to ‘drill down’ into aggregated data (Carey 2004). For example, data can be displayed for different anaesthetists, departments, or age groups. The
effects of natural history are taken into account by multiple measurements. Data have to be collected for a reasonable period without interventions for patterns in the data to be interpreted. Enough data points need to be collected to identify the 'underlying secular trend' (Eccles et al. 2003). Recommendations are that between 20 and 28 data points are collected (Carey 2004). In this current study, there are 30 points, which is the reason the data presented in Chapter 6 are bi-monthly.

One criticism of observational studies is that authors selectively report their findings after 'multiplicity of analysis' (Tuma 2007). Therefore, all the factors tested, including those that failed to show a significant association, are reported. A further criticism of observational studies, reported by Tuma, is the lack of detail in the methodology description and a clear statement of the study objectives. In addition, it is known that if too many hypotheses are tested at once, there is the risk of false positive results. Adjusting the p-value for significance would not solve the problem. This is the reason Tuma recommends that researchers look for biological plausibility before the study begins. This was the approach taken in this current study.

So far in this chapter, the background to the development of the research questions and the methodology chosen to answer the questions have been discussed. The justification for the choice of study design was based on the researcher's 'assumptions about reality that we bring to our work' (Crotty 1998 p 2). Such assumptions are our beliefs about what exactly human knowledge is, that is, the theoretical perspective behind the methodology. This is discussed further in the following section.
4.4 Theoretical perspective

The methodology is more than a detailed description of the study design and of how data were collected and analysed; it is concerned with the more general philosophies on which the study design is based (Haralambos and Holborn 1991). It is clear from the description in the introduction that this study is quantitative. Positivism is a theoretical perspective that is one approach to making sense of the real world. Positivist methodology has traditionally formed the basis for quantitative studies. Founders of sociology in the 18th century believed that the principles of the natural sciences could be applied to society. The viewpoint, simplistically, is that the behaviour of humans can be measured objectively, in line with scientific discovery. Those measures can be counted and statistics produced, making it possible to make statements about cause and effect (Haralambous and Holborn 1991).

Polit and Beck (2008) state that nurse researchers still tend to operate within two broad paradigms: positivist and naturalistic. Paradigms are a view of the world based on philosophical questions and they guide a researcher’s approach to study. Shanks and Parr (2003) and Lipscombe (2008) list three dimensions related to a paradigm: the ontological question asks what the nature of reality is; the epistemological question asks about the relationship between the researcher and that that can be known; the methodological question asks how best to obtain knowledge. Polit and Beck (2008) add a fourth dimension: the axiologic question is the role of values in the research. In contrast to the positivist assumptions of independence and objectivity, the naturalistic researcher interacts with the subjects under study and does not seek to quantify experiences. However, the ultimate aim of both positivist and naturalistic paradigms is to gain greater understanding of a problem.
Empirical evidence is a term commonly used to describe evidence rooted in objective reality. In other words, the measurements are grounded in reality rather than in the researcher’s own beliefs. Yet it is virtually impossible for the researcher to design a study objectively. Robson (2002) lists features, considered by researchers themselves, which characterize successful research projects. Specifically, success develops from:

1. Frequent contact with those in the field
2. Convergence of two or more activities
3. Intuition, feeling that the project is timely
4. Real world value, and
5. A concern for theoretical understanding.

In this study, the belief in an objective reality means the assumption is made that there are identifiable and measurable factors related to whether the epidural works for an individual patient. This research most certainly fits the positivist methodology, as counts are used to produce statistics, and there is a search for a correlation relationship between variables, for example, the age of the patient and pain scores.

In the positivist view, the patients have no choice about how they respond when asked about pain or side effects. The assumption is made that patients do not attach a meaning to the level of pain. However, it is known that patients do attach meaning to the concept of pain. The side effects of treatment, age of the patient, the environment patients are nursed in, and the time of day, are just a small example of influences that can affect the response of a patient when s/he is asked to quantify their level of pain at one point in time. The assumption is also made that patients both understand and can articulate a response to questions. The alternative is clinician or nurse observer scores. However, it is recognized that clinicians underestimate pain intensity (Paige and Cioffi 1992). Therefore, studies into postoperative pain management are not truly
objective; the researcher must acknowledge that quantitative measures are only an approximation of peoples' subjective feelings (Crotty 1998).

It has been argued that positivist research paradigms are not suited to the practical discipline of nursing. Hart (1995) documents the increasing criticism of positivist research in the 1990s in comparison to action research in nursing because people are not active participants in the research and there is no account of meaning or context in research. Yet nurses are inextricably linked to the quality of care received by patients: ‘Measures are the lenses through which we quantitatively determine quality’ (Pronovost et al. 2004 p 1062). Crotty (1998) points out that research is presented in positivist or non-positivist terms rather than quantitative or qualitative terms, which is a feature of the underlying methodology. Positivist research has the features of objectivity, validity and generalizability.

Much research in acute pain management is undertaken by multiprofessional teams; therefore, concerns about paradigms suited to one profession are not so compelling. The pragmatic paradigm inherent in quality improvement is the most relevant to a study such as this, but appears not yet to have a high profile in nursing studies that aim to measure whether interventions are effective in routine practice (Eccles et al. 2003). In this type of study design, withdrawals are treated and are included in an intention-to-treat analysis. The population was predefined so even if it were not possible to position an epidural, data would still be analysed, as the intention was to carry out the procedure.

The next section describes the study methods, defined as the technical means by which data are identified, collected and analysed (Lipscomb 2008).
4.5 Methods

The plan was to collect data from every patient visit made by the APS, not just epidural visits, over a period of 18 months between January 2006 and June 2007. A large sample size was planned in order to reduce the risk of error in reported results due to any undefined factors. Data were collected and recorded on paper when patients were reviewed, then entered onto a database by the researcher. All variables measured needed to be operationalized to minimize variation in the data collection before the data collection started. There were strict definitions of variables to ensure uniformity, which will be described in detail later in this methods section. However, as noted by Andy Field (2005), using such terms is inappropriate because this is a correlational research rather than a controlled study. Therefore, independent variables are referred to as ‘predictors’, and the dependent variable as the ‘outcome.’

After all the data had been loaded, a new database, with only epidural patients, was created. Data are presented from the larger database to compare groups of patients where relevant.

4.6 Context

Approximately 27,000 operations are performed annually at the District General Hospital where the researcher is based. The APS, established in 1991, provides a pain relief service to postoperative and trauma patients. The team consists of 2.6 whole-time equivalent nurse specialists who work with the support of a consultant anaesthetist, supplemented by ward-based link nurses. A number of different pain relief techniques are employed, including intravenous Patient-Controlled Analgesia (PCA) and continuous epidural infusions. Members of the APS visit major
postoperative surgical patients daily, except on Sundays. Twenty-four hour cover is provided by an on call anaesthetic trainee doctor service.

Best practice recommendations for epidural analgesia (Royal College of Anaesthetists 2004) have been fully implemented. The day-to-day management of an epidural is the responsibility of the ward nurses caring for the patient. It is the responsibility of the nurse to call for assistance when deemed appropriate.

To place this study further in context, the APS visited 1153 patients in 2006, with a total of 3755 patient contacts. Five hundred and sixty-two patients were male (53%), and 32% of patients were emergencies. Sixty-two percent of patients were under the care of general surgery, 23% of patients had cardiothoracic surgery. The remainder of the patients were from a mixture of specialities, including urology, orthopaedic, gynaecology, trauma and medical. All nurses looking after a patient with an epidural attend mandatory teaching sessions annually.

4.7 Sample

Table 4.1 summarizes the data collection on the APS ward round. Each factor will then be described in more detail in the following section.
Table 4.1 Summary of data collected at patient visit by the APS

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Gender</th>
<th>Age in years</th>
<th>Type of surgery</th>
<th>Elective or emergency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Co-morbidities</td>
<td>Anti-hypertensive drugs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain before surgery</td>
<td>0 to 10 VNRS score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Epidural technique</td>
<td>Grade of anaesthetist</td>
<td>Awake or asleep</td>
<td>Site of insertion</td>
<td>Failure</td>
</tr>
<tr>
<td></td>
<td>Site of insertion</td>
<td></td>
<td>Number of attempts</td>
<td>Dural puncture</td>
</tr>
<tr>
<td></td>
<td>Number of attempts</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain scores</td>
<td>Pain scores</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Side effects</td>
<td>Side effects</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypotension</td>
<td>Urine output</td>
<td></td>
<td>Dizzy or light-headed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dizzy or light-headed</td>
<td></td>
<td>Central Venous Pressure monitoring</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Central Venous Pressure monitoring</td>
<td></td>
<td>Sat out of bed</td>
<td></td>
</tr>
<tr>
<td>Adverse events</td>
<td>Free text</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4.7.1 Demographics

Demographic data collected included the patient’s age in years, gender, type of surgery, whether elective or emergency, and the American Society of Anaesthesiologists (ASA) classification (Table 4.2).

Table 4.2 American Society of Anaesthesiologists definitions (2008)

<table>
<thead>
<tr>
<th></th>
<th>A normal healthy patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>A patient with mild systemic disease</td>
</tr>
<tr>
<td>3</td>
<td>A patient with severe systemic disease</td>
</tr>
<tr>
<td>4</td>
<td>A patient with severe systemic disease that is a constant threat to life</td>
</tr>
</tbody>
</table>
4.7.2 Co-morbidities and drugs

It was noted whether the patient took drugs to control high blood pressure (antihypertensive drugs). Specifically, it was recorded if the patient took one or both of the following groups of drugs – β-adrenoceptor antagonists (β-blockers) and angiotensin-converting enzyme inhibitors (ACE inhibitors). This information related specifically to hypotension is described in more detail in the next section. It was also documented whether the patient was diabetic and/or took steroids, which related to the increased risk of epidural site infections.

4.7.3 Pain before surgery

All patients were asked if they had pain before the surgery. If the answer was yes, patients were asked to use numbers from 0 (no pain) to 10 (worst possible pain) to describe their pain (VNRS). It was documented whether the patient was under the care of a chronic pain service or palliative care service. This information was collected because there is an association between chronic preoperative pain and the severity of postoperative pain, as described in the introductory chapters.

4.7.4 The epidural technique

The following details about the anaesthetic technique were collected. The name and grade of the anaesthetist was collected, and coded in three categories as ‘consultant’ ‘staff grade’ or ‘trainee.’ Details of the epidural technique included whether the patient was awake or asleep, the number of attempts to position the epidural and the documented site of insertion. It was also recorded whether intrathecal analgesia was
administered. Intrathecal analgesia, usually morphine or diamorphine, is given through a spinal needle into the cerebrospinal fluid. The use of intrathecal morphine has become more popular in anaesthetic practice and it is used to supplement analgesia in the first 24 hours after surgery.

The composition of the epidural infusion, specifically the concentration of bupivacaine with the amount of opioid added, and whether a PCA was added to the analgesic regime was recorded. All details were completed on the front of the epidural chart at the time of surgery, and a duplicate sheet with this information collected by a member of the APS. The day of surgery was defined as day 0. The front page of the observation chart with instructions for staff is shown in Figure 4.3 at the end of the chapter.

4.7.5 Observations

4.7.5.1 Pain Scores

When the patient was awake in the recovery room, their pain was assessed using a four-point verbal rating score as none (0), mild (1), moderate (2) and severe (3). If the pain score was 2 or above, a recovery nurse increased the epidural rate until the pain score was below 2. If this was not achievable, the anaesthetist returned to review the patient. All patients had a postoperative epidural care chart, which allowed intravenous fluids to be prescribed for maintenance and to be given in boluses in response to a low systolic pressure, low urine output or a falling central venous pressure (see Figure 4.3 at the end of this chapter).

A simple pain intensity scale described above is also used on the wards. Moderate to severe pain is the criteria used by the ward nurses as an indication of inadequate analgesia. Ward nurses are able to adjust epidural infusion rates and set up a morphine
PCA as 'escape analgesia'. Individual fluid requirements were calculated and simple algorithms provided to guide individual patient management. Paracetamol (one gram 6 hourly) was prescribed regularly for all patients unless contra-indicated.

In addition, members of the APS routinely use a verbally administered numeric rating scale because it is continuous and approximates a ratio scale. All patients were asked to use numbers from 0 (no pain) to 10 (worst possible pain) to describe their pain. Pain was measured during a stimulating activity, such as coughing or movement rather than at rest. The team also documented whether the patient was unable to use this technique, or was too ill to ask.

4.7.5.2 **Hypotension**

Hypotension was defined as a fall of 30% of the patient’s pre-operative systolic blood pressure, a fall in blood pressure affecting urine output (< 0.5mls/kg/hour), or a symptomatic low blood pressure restricting the patient’s ability to mobilise postoperatively. It was considered more relevant to choose a dichotomous variable in this instance because it was more meaningful than documenting an individual’s blood pressure. In addition, the infusion of noradrenaline to treat hypotension was documented as yes/no. A functional measure of effective pain relief is whether a patient can sit out of bed on the first postoperative morning. Therefore, it was noted whether the patient was sat out of bed.

4.7.5.3 **Motor block**

Motor block was assessed using the modified Bromage scale where

0 = No weakness

1 = Cannot straight leg raise, can flex knees
2 = Unable to flex knee, able to flex ankle
3 = Paralysed legs.

### 4.7.5.4 Other side effects

Nausea and vomiting pruritis (itch) and thirst scores were all measured on a 0–3 score where 0 = no side-effect, 1 = mild, 2 = moderate and 3 = severe. Patients were asked about other side effects, namely, visual disturbances and hallucinations (0 = no, 1 = yes). Other data collected included average infusion rates, and the time (in days) the catheter remained in situ. In addition, details of adverse events, (e.g. pump problems, tender back), and severe adverse events (e.g. cardio-vascular collapse), were collected.

### 4.7.5.5 Epidural removal

Data were collected about epidural catheter removal and whether the epidural was removed as planned. If not removed as planned, it was recorded whether the catheter leaked, kinked, was pulled out accidentally by the patient, or removed because ineffective. All these factors would contribute to the overall effectiveness of the technique.

All the observations described in the previous section are an integral part of epidural monitoring at the researcher’s hospital and the observation chart is shown in Figures 4.3 – 4.5 at the end of the chapter.
4.7.5.6 Data analysis

The software used was Statistical Package for the Social Sciences (SPSS for Windows Version 14 Chicago IL; Version 16 after February 2008).

4.7.5.7 Statistics

Patient and epidural characteristics were assessed using descriptive statistics. The average values of continuous data are described by means and standard deviation. Categorical data are described by frequencies. A numeric code was created to represent missing values (Table 4.3)

<table>
<thead>
<tr>
<th>333</th>
<th>Discharged from APS</th>
</tr>
</thead>
<tbody>
<tr>
<td>666</td>
<td>Not applicable</td>
</tr>
<tr>
<td>999</td>
<td>Not documented</td>
</tr>
</tbody>
</table>

Graphs are used where appropriate to display data. Histograms and box-whisker plots are used to display continuous data, as the data set is large (Campbell and Machin 1993). Categorical data are displayed using bar charts. Tables are used to display numerical information in more detail.

Inferential statistics were used as a framework to make a judgement about the relationships between variables based on the laws of probability (Polit and Beck 2008). The Kolmogorov-Smirnov test was applied to continuous data to determine whether distributions were normal. If the test was non-significant (p > .05), the sample was considered not to be significantly different from a normal distribution.
(Field 2005) and parametric tests were used if indicated. Pearson’s correlation coefficient was used only on interval and normally distributed data. Spearman’s correlation coefficient was used for non-normally distributed data. The correlation coefficient was used to measure the strength of the relationship between variables. The effect size is an objective and standardized measure of the magnitude of an observed effect (Field 2005). Pearson’s correlations coefficient \( r \) is used as an effect size, with 0 meaning no effect and 1 as a perfect effect. The following were used in this study as effect size; \( r = \pm .1 \) represented a small effect, \( r = \pm .3 \) a modest effect and \( r = \pm .5 \) or greater a large effect. With a small effect, 1% of total variance is explained, medium accounts for 9% of total variance and large accounts for at least 25% of the variance (Polit and Beck 2008; Field 2005). Two-tailed tests were used when the direction of the relationship could not be predicted.

To compare groups of patients, Student’s \( t \) test was used for continuous variables, the Mann-Whitney \( U \) scale for ordinal scale variables and the Chi-square for dichotomous variables. Multivariate analysis was used to support the understanding of this large and complex data set. It was postulated that greater sense could be made of the data using multivariate procedures because they would provide greater insight into relationships that more closely mirror the real world. The purpose is to predict group membership. For example, in this study it was considered useful to understand factors associated with both low and high pain scores. Sample size is particularly important in multivariate analysis in order to avoid type 2 errors. Type 2 errors occur when a researcher concludes that no relationship between variables exist when in fact a relationship does exist (Polit and Beck 2008). Tabachnick and Fidell (2006) recommend a minimum ratio of predictors to number of samples of 20:1 for hierarchical regression. Polit and Beck (2008) recommend performing a power
analysis. Field (2005) discusses this at length, and recommends using graphs. Overall, Field recommends that a sample size of 200 will suffice for a medium effect size and up to 20 predictors. The size of the sample reported in this study is over 200 and the predictors are much less than 20, which fulfils the recommendations of both Field and Tabachnick and Fidell.

One of the two dependent variables is the presence or absence of hypotension after surgery. This is a dichotomous variable, and it was important to explore the characteristics associated with this, some of which are also categorical data, such as gender. Clearly, it was not possible to use any statistical tests associated with the mean. To examine such relationships, the chi-squared test was used. There are only two important assumptions with this test. First, it cannot be used in a repeated measures design. Second, the expected frequencies must be greater than five (Fields 2005).

One-way analysis of variance is the usual choice for testing for differences between multiple groups (SPSS 2008), but the assumption is made that the mean is a valid estimate of centre, and there is a normal distribution. In this study, no such assumptions could be made about a majority of the data; therefore, nonparametric tests were used.

It has been suggested that where there are a large number of correlation coefficients reported, a conservative type 1 error rate value (p = .01) should be adopted to reduce the possibility of significant findings being observed by chance alone. However, a stricter level increases the risk of a type 2 error, which is a false negative conclusion, as described earlier. The significance level was set at .05 in this study, and the exact p value produced by SPSS is documented throughout the results chapters. In general,
the results are reported as the test statistic, its degree of freedom and the probability of that test statistic. Table 4.4 summarises the statistical tests employed.

<table>
<thead>
<tr>
<th>Statistical test</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kolmogorov – Smirnov test</td>
<td>To test whether a distribution is normal</td>
</tr>
<tr>
<td>Levene’s test</td>
<td>Testing for homogeneity of variance. Used to test if the variances in groups of patients are equal, particularly when exploring data.</td>
</tr>
<tr>
<td>Bivariate Correlation</td>
<td>To measure size and direction of the linear relationship between two variables. Used for interval or ratio data</td>
</tr>
<tr>
<td>Pearson product moment correlation coefficient, r</td>
<td>Used for ordinal measures</td>
</tr>
<tr>
<td>Spearman’s rho</td>
<td></td>
</tr>
<tr>
<td>The Jonckheere-Terpstra Test</td>
<td>To test the difference between the medians of groups that are in a meaningful order</td>
</tr>
<tr>
<td>Chi-square analysis</td>
<td>To explore the relationship between 2 categorical variables</td>
</tr>
<tr>
<td>Odds ratio</td>
<td>To explain, in an easily understood way, an effect size. The odds of an event occurring in one group compared to another</td>
</tr>
<tr>
<td>Independent samples t test</td>
<td>Comparing means of groups</td>
</tr>
<tr>
<td>Logistic regression</td>
<td>Used to predict a score on one variable from a score on another.</td>
</tr>
<tr>
<td></td>
<td>Used when predictors are a combination of continuous and nominal data. The goal of analysis is to create a linear combination of the log of the odds of being in one group</td>
</tr>
</tbody>
</table>

Table 4.4 Summary of statistical tests employed
4.7.6 Control chart

The control charts are used to complement the descriptive and correlation statistics described above. The visual data display developed by Shewhart is the control chart, a more advanced version of the run chart used in time series designs. The centre line of the control chart is the mean of all subgroups. The X, or horizontal axis, is the unit of time, in this study bi-monthly because the literature recommends approximately 20 to 25 data subgroups in order to apply tests on the data. The Y, or vertical axis, is the quantitative measure, the pain scores, and percent of patients with hypotension and side effects. Control charts also have two further lines, that is, the upper and lower control limits, which are traditionally set at plus and minus 3 standard deviations from the average. These control limits would be expected to include 99.73% of the data points in a normal distribution.

There are several different types of control chart available and the choice of chart depends on the type of data collected. In this study, measurement data, such as the 11-point VNRS for pain is on a continuous scale. Count data are dichotomous, or binomial, for example, the presence or absence of hypotension. Thus, a P-chart, described below, would be used to plot hypotension, and an X-bar chart would be used for mean pain scores.

4.7.7 The charts

4.7.7.1 P chart

The p chart stands for the percentage. This is the simplest and most commonly used control chart. In this study, it is used for count variables, specifically side effects, and the percentage of patients with a high pain score. The ‘p’ value is found by dividing
the count of interest, sometimes called the special outcome or nonconforming units, by the total count (the denominator).

4.7.7.2 I chart

The I-chart, also called an ‘XMR’ chart, is used on the Department of Health website, and involves using every individual observation. The X stands for the individual value and MR for moving range.

4.7.7.3 X-bar and S-chart

X-bar stands for average (or mean) and S-bar for standard deviation. The control limits on this chart are derived from the standard deviation of the subgroup. In this study, the X-bar chart is used for displaying the mean pain scores. Each subgroup has more than one observation, which is appropriate with pain scores. However, the statistical average could well obscure important effects on some patients, which is the reason for also using the p-chart to display the percentage of patients in severe pain. The S-chart that accompanies the X-bar chart examines the variation within each subgroup, whereas the X-bar examines the variation between the subgroups over time (Carey 2003).

There are several rules to identify special causes in a control chart; the main rules are displayed in Table 4.5. Most software packages tend to follow these tests for the existence of non-random influence (Hart and Hart 2002).
Table 4.5 Definitions of special cause variation

<table>
<thead>
<tr>
<th>A special cause is indicated when;</th>
</tr>
</thead>
<tbody>
<tr>
<td>One point falls above 3 sigma – the upper control limit on the chart or one point below the lower control limit</td>
</tr>
<tr>
<td>8 points in a row above the centreline or 8 points in a row below the centreline</td>
</tr>
<tr>
<td>6 points in a row trending up or 6 points in a row trending down</td>
</tr>
<tr>
<td>14 points in a row alternating up and down</td>
</tr>
<tr>
<td>2 out of 3 successive points are on the same side of the centreline and more than 2 standard deviations from the centreline.</td>
</tr>
</tbody>
</table>

Figure 4.1 provides an example of a basic control chart that uses the example of Scottish immunization data in a paper by Guthrie et al. (2005). The control chart shows the percentage of Scottish children with completed primary tetanus immunization at one year. The central line in the chart shows the mean for the four-and-a-half-year period from June 1996. Control limits are set at both 2 and 3 standard deviations from the mean. There are obvious special cause variations in the 4 quarters from March 2001. On investigation, the reduced percentage was thought to be caused by a vaccine shortage.
Figure 4.1 Example of a P-chart (Guthrie et al. 2005 p 451)

4.7.7.4 Pareto charts

The Pareto charts show the counts of various occurrences in descending order of frequency and are used to find out the key factor for the failure or success of any process. The 'Pareto principle', also known as the 80 – 20 rule, is based on a fact that 80% of problems are based on 20% of the occurrences. This theory originated from the findings of an economist, Vilfredo Pareto, who found that approximately 85% of the wealth was owned by 15% of the population (Hart and Hart 2002). Figure 4.2 shows an example of a Pareto chart.
Figure 4.2 Example of a Pareto chart (Institute for Healthcare Improvement 2004)

In summary, both classical statistical methods and control charts were employed in order to answer the research question. The advantage of the control charts is that complex data can be summarized and understood without any need for an understanding of the underlying statistics (Guthrie et al. 2005).

4.7.8 Ethics

NHS Local Research Ethics Committee (LREC) approval was granted for this project (Appendix 1). It is a statutory requirement that all research involving NHS staff, patients or resources must be assessed by a research ethics committee. Fully anonymised data can be used in research. This means that by omitting information, such as date of birth or hospital number, data cannot be linked to a
patient. This study did not involve any additional data being collected or anything being done to patients beyond their normal clinical management.

The patient outcomes used in this study are exclusively physiological in nature. They are grounded in health data such as Blood Pressure, Nausea and Vomiting score and Pain score, which are routinely collected by nurses at the bedside. These measurements are already used to review service delivery and are a key part of the safe operation of the Acute Pain Service. Therefore specific patient consent was not required for this study. To undertake a formal consent process for the use of routinely collected information may be burdensome to people who are already suffering ill health. To protect patients further, the data were fully anonymised.

Consent was obtained from all members of the Acute Pain Service who took part in this study (Appendix 2).

In summary, the challenge for APSs is to discover what they need to know that they do not know now (Berwick 2005). This observational study was designed to discover more about the incidence of pain, hypotension and other epidural-related side effects after major abdominal surgery and to identify factors associated with effective analgesia and postoperative hypotension in everyday clinical practice. Gaining more knowledge about this is important in order to improve the quality of postoperative epidural analgesia. The results of the study are presented in Chapters 5 and 6.
### POSTOPERATIVE CHART FOR EPIDURAL ANALGESIA

<table>
<thead>
<tr>
<th>Date:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Site:</td>
<td>WOE</td>
</tr>
<tr>
<td>Epidural depth at:</td>
<td>AWAKE/ASLEEP</td>
</tr>
<tr>
<td>Catheter inserted to:</td>
<td>WOE</td>
</tr>
<tr>
<td>Number of attempts:</td>
<td></td>
</tr>
<tr>
<td>Other comments:</td>
<td></td>
</tr>
</tbody>
</table>

### Write patient details or affix identification label

- **Hospital Number:**
- **Name:**
- **Address:**
- **Date of Birth:**
- **NHS Number:**

### TARGET PARAMETERS

This is a guide to perioperative management, use clinical judgement and ask for advice early if there are any concerns about the patient's condition. Ensure there is a nurse on duty proficient in the management of epidurals.

**Humidified Oxygen at:** 0%. Continue at night for at least 72 hours or the duration of Diamorphine via epidural.

**Heparin:** Remove epidural catheter a minimum of 12 hours after last administration of low molecular weight heparin. Contact APS for advice if epidural catheter falls out within this 12 hour period and continue neurological observations. Contact anaesthetist or Acute Pain Service if increasing motor block.

**Epidural Diamorphine:** No systemic opioids or sedatives to be given except as ordered by the anaesthetist.

**Blood Pressure:** Maintain systolic between 120-140 mmHg or above 100% systolic. Monitor every 10 minutes for minimum 40 minutes when the patient sits out of bed. Nausea and light-headedness are usually first indication of postural hypotension. Do not give ACE inhibitors, or β Blockers unless B.P. greater than 50% systolic. If on two antihypertensive drugs, give 3 hours apart.

**Urine output:** Maintain above 0.5mls per hour or 0.5mls per kg per hour.

**Central Venous Pressure:** Maintain between 6 and 10 cm H2O or ________

Duration of Epidural infusion and catheter removal: Palpate catheter site for tenderness daily and monitor body temperature. Continue epidural for 3-5 days or until chest drain removed. Stop epidural in the morning and give oral analgesia. If analgesia satisfactory, remove catheter. Send swab from catheter exit site and tip for C.S.

**Recommended Bolus Fluids:** In response to low urine output, hypotension (low CVP if recorded) and high thirst score:

- Give _________mls of 0.9% saline or ____________

**No response to fluid challenge?** Check CVP after fluid challenge and instigate the following: SpO2 monitoring, ABGs and Senior review. Increase frequency of observations.

For advice contact Acute Pain Team on 434/403/495.

On-call Anaesthetist bleep number: 704.

**Signature:** ___________________________ **Date:** ___________________________

Junior Medical Staff must review initial fluid therapy by 6-8 hours postoperatively. Take FBC and U&Es first postoperative morning and act on results.

---

**Figure 4.3 Epidural observation chart with target parameters to guide treatment**
Monitor all observations at least hourly for first 4 hours and then 4 hourly if stable. Increase frequency of observations if any score 2 or greater. Take action if 2 or greater.

<table>
<thead>
<tr>
<th>Assessment Score</th>
<th>Pain</th>
<th>Nausea</th>
<th>Sedation</th>
<th>Motor block</th>
<th>thirst</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No pain on movement</td>
<td>No nausea</td>
<td>None (Faint)</td>
<td>No leg or arm weakness</td>
<td>No thirst</td>
</tr>
<tr>
<td>1</td>
<td>Mild pain on movement</td>
<td>Mild nausea</td>
<td>Mild (Easy to nauseate)</td>
<td>Cannot straight leg raise</td>
<td>Mod. thirst</td>
</tr>
<tr>
<td>2</td>
<td>Moderate pain on movement</td>
<td>Moderate nausea and occasional vomiting</td>
<td>Moderate (Crowed or aspex but can be woken)</td>
<td>Unable to flex knee</td>
<td>Moderate thirst</td>
</tr>
<tr>
<td>3</td>
<td>Severe pain on movement</td>
<td>Severe nausea and frequent vomiting</td>
<td>Severe (Bemoment or difficult to raise)</td>
<td>Paraplegic legs</td>
<td>Severe thirst</td>
</tr>
</tbody>
</table>

If both arms/legs become increasingly heavy or weak and hand grip/legs paralysed following surgery:
Stop the epidural pump.
Contact the APS or on-call anaesthetist.
Continue hourly observations.

If the patient complains of severe back pain:
Commence neurological observations and contact APS or on-call anaesthetist.
Epidural abscess or haematoma are very rare but potentially devastating complications of epidurals.
Spinal cord compression causes severe back pain and sensory loss.
Early identification and MRI scan are crucial to avoid permanent paraplegia.

If the respiratory rate is low and the patient very drowsy:
Stop the epidural pump.
Ensure a clear airway and give oxygen. Monitor EWS. Record oxygen saturation.
Constantly supervise the patient and contact APS or covering anaesthetist.
Ensure that Nilposetine is available and consider administering intravenous naloxone in 50micrograms aliquots (1ml bolus of 400 micrograms diluted in 5mls).

If the blood pressure drops suddenly:
Open the IV fully
Elevate legs if sat up, ie flat if possible
  * Check: Is BP low with tachycardia (Tachy. Tachy.
  * Is BP low with bradycardia (Effect of Local Anaesthetic)
  * Is BP low with posture?
  * Check: Height of block
CONTACT on-call anaesthetist if considered an emergency. Ensure ephedrine is available.

Inadequate analgesia - Pain score >1:
Assessment must first consider causes other than site of operation e.g. pain from postoperative complication, shoulder tip pain.
Check epidural pump on, ensure the patient has a bolus handset which is working.
Consider increasing epidural infusion rate per prescription.
Add regular paracetamol.
If no improvement or pain score 3, remove diamorphine from epidural and start PCA. Contact APS or anaesthetist.

Figure 4.4 Epidural observation chart with guidance for pain scores and management of complications
Figure 4.5 Routine observations on epidural observation chart
5 Chapter 5 Results

5.1 Introduction

This chapter and Chapter 6 report the results of this prospective observational study designed to both describe the epidural technique and examine the association of various factors with pain scores and the incidence of hypotension. Classical statistics and statistical process control methods, a unique feature of the study, were employed to analyse and learn from the data.

5.2 Results

Data were collected prospectively from 480 consecutive general surgical patients between 1 January 2006 and 30 June 2007. It was not practical to review every patient at a specific point in time after surgery, as the APS was not available 24 hours, 7 days a week. Out-of-hours cover was provided by the on-call anaesthetist, to manage inadequate pain control and complications of the technique. Thus, 34% of patients (n = 163) were first reviewed on the day of surgery. Data collection started on a further 48% of patients (n = 227) on the first postoperative day. Eighteen percent of patients (n = 90), who had had surgery late on a Friday or during the weekend, were not reviewed until the second or subsequent days.

Missing data occurred for a variety of reasons over the 18-month period; therefore, the total number of observations in each section of data analysis varies. It was possible to review notes and collect some missing data about adverse events and about whether the epidural was removed as planned. However, it was not considered
appropriate to collect retrospectively much of the clinical information, which involved the patients' own description of pain scores and side effects because this would have reduced the rigour of the study.

Data were first screened to identify outliers, using histograms and boxplots. Basic descriptive data were produced for different groups using the 'split file' option in SPSS. The 'explore' option in SPSS was used to determine whether the statistical techniques for data analysis were appropriate.

5.3 Clinical area

One hundred and seventy-one patients (35.6%) were discharged from recovery to a high dependency unit (HDU) bed. It was beyond the resources of the study to record how long patients stayed on the HDU before discharge to a general ward. A further 276 (57.7%) patients were discharged to a Surgical High Care Unit (SHCU), which opened at approximately the same time as the start of this current research. The remaining 29 patients (6.7%) returned directly to a general ward.
Figure 5.1 Histogram of number of visits to individual patients by the APS

The pattern of APS visits to patients can be seen in the histogram above (Figure 5.1). The number (frequency) of visits by a member of the APS (Table 5.1) demonstrates that approximately 67% percent of first visits (n = 476) were routine checks and were completed in less than 15 minutes. The remaining third of visits involved more direct pain management interventions and additional interventions, including the following; fluid management, oxygen therapy, stabilizing a sick patient, administering alternative analgesia or anti-emetics, patient support, palliative care and referral to critical care or the surgical team.
Table 5.1 Length of review by APS on first visit to patient (n = 476)

<table>
<thead>
<tr>
<th></th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - 15 minutes</td>
<td>318</td>
<td>66.8</td>
</tr>
<tr>
<td>16 - 30 minutes</td>
<td>112</td>
<td>23.5</td>
</tr>
<tr>
<td>31 - 60 minutes</td>
<td>22</td>
<td>4.6</td>
</tr>
<tr>
<td>1 - 2 hours</td>
<td>19</td>
<td>4.0</td>
</tr>
<tr>
<td>&gt; 2 hours</td>
<td>5</td>
<td>1.1</td>
</tr>
<tr>
<td>not documented</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>476</td>
<td>100</td>
</tr>
</tbody>
</table>

5.3.1 Demographic and clinical characteristics

Two hundred and fifty-six (53%) patients were male. The mean age (SD) of the patients was 66.6 years (14.3). The mean age of males was 65.6 (13.9), and 67.6 (14.7) for females. The following chart (Figure 5.2) displays the age frequency table; the subsequent chart (Figure 5.3) displays the age range grouped in decades. The age range was wide – from 17 to 93 years old. Eighty-nine percent of patients were over 50 years of age.
Figure 5.2 Age distribution of patients with an epidural

Figure 5.3 Age range of patients with an epidural
A normal Q-Q plot was produced using SPSS (Figure 5.4). The deviation from normality is clear because the dots on the chart do not fall along the straight line. The Kolmogorov–Smirnov test confirmed that the age distribution was significantly non normal, \( D(479) = 0.08, p = .000 \). This information was important for future analysis, as nonparametric tests are used when data is not from a normal distribution.

### 5.3.2 Type of surgery

Bowel surgery, including planned and emergency laparotomy, accounted for 362 (75%) of cases. There were 43 oesophagogastric procedures, 32 vascular, and renal and gynaecological surgery accounted for seven patients. The remainder were a
variety of procedures, such as incisional hernia repair. Figure 5.5 illustrates the spread of surgery as documented in the medical notes.

5.3.3 Anaesthetist and surgeon

There were 17 surgeons who operated on patients over the 18-month period of this study. Four general surgeons and one vascular surgeon undertook the majority of the cases. Overall, 15 consultant anaesthetists and 5 staff grades were involved in 87% of operations. The remaining 62 procedures (13%) involved a number of trainee anaesthetists. It was further documented that 80% of emergency operations were consultant anaesthetic led, 15% were trainee anaesthetists, and 5% were staff grades.
Operation description

Figure 5.5 Bar graph of counts of surgery in order of frequency
5.3.4 Diabetic and steroids

Ten percent of patients (n = 46) were diabetic. Thirty-three patients (7%) took steroids regularly. Two patients in their sixties were both diabetic and took steroids. Patients who are diabetic or take steroids are at a higher risk of infections, including epidural site infections. To examine the relationship between the patients’ ages and taking steroid medication, the point-biserial correlation coefficient was computed. Pearson and Spearman both require ordinal interval or ratio level data. The prescription of steroids is a discrete dichotomous variable; the patient either takes, or does not take, steroids. The age of the patient showed a moderate negative correlation with the taking of steroids, $r = -0.344$, which had a two-tailed significance value of $p = 0.000$. In other words, the younger patients were more likely to have a prescription for steroids, which may be related to the number of patients with inflammatory bowel disease (IBD) in the study population. Crohn’s disease manifests itself during early adulthood with the peak onset between 15 and 30 years of age with a higher incidence in women (Ehlin et al. 2003). Conventional treatment can involve long-term steroid treatment. The mean age for a laparotomy for Crohn’s disease in this study was 33.5 years. All other surgical operations had a mean age of above 53, as can be seen documented in Table 5.2.
Table 5.2 Operation and mean age

<table>
<thead>
<tr>
<th>Operation description</th>
<th>Mean age (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cystectomy</td>
<td>65.4 (7.8)</td>
</tr>
<tr>
<td>Anterior resection</td>
<td>68.8 (11.4)</td>
</tr>
<tr>
<td>Right hemicolectomy</td>
<td>70.0 (13.0)</td>
</tr>
<tr>
<td>Left hemicolectomy</td>
<td>69.1 (14.2)</td>
</tr>
<tr>
<td>Colectomy</td>
<td>58.5 (19.3)</td>
</tr>
<tr>
<td>Laparotomy (for bowel obstruction)</td>
<td>72.9 (10.3)</td>
</tr>
<tr>
<td>Hartmann’s</td>
<td>75.6 (12.4)</td>
</tr>
<tr>
<td>Gastrectomy</td>
<td>63.9 (10.8)</td>
</tr>
<tr>
<td>Cholecystectomy</td>
<td>59.3 (11.9)</td>
</tr>
<tr>
<td>Incisional hernia repair</td>
<td>59.9 (12.2)</td>
</tr>
<tr>
<td>Laparotomy – Crohn’s</td>
<td>33.5 (13.1)</td>
</tr>
<tr>
<td>Laparotomy – appendicectomy</td>
<td>65.9 (13.0)</td>
</tr>
<tr>
<td>Formation defunctioning colostomy</td>
<td>71.5 (7.7)</td>
</tr>
<tr>
<td>Ivor-lewis oesophagectomy</td>
<td>64.6 (10.5)</td>
</tr>
<tr>
<td>Gastrojejunostomy</td>
<td>66.2 (9.3)</td>
</tr>
<tr>
<td>Laparotomy</td>
<td>66.7 (14.3)</td>
</tr>
<tr>
<td>Reversal of Hartmann’s</td>
<td>60.9 (14.2)</td>
</tr>
<tr>
<td>Reversal of ileostomy</td>
<td>53.0 (12.7)</td>
</tr>
<tr>
<td>AP resection</td>
<td>69.0 (11.4)</td>
</tr>
<tr>
<td>Vascular surgery</td>
<td>67.2 (10.7)</td>
</tr>
</tbody>
</table>
The ASA physical status scores (n = 377) documented on the anaesthetic chart were as follows:

I 38 (10%)
II 180 (47.7%)
III 141 (37.4%)
IV 18 (4.8%)

One hundred and twenty-four patients, that is, 26% of patients, were emergencies. Table 5.3 describes the epidural and anaesthetic characteristics of the patients. Data from 76 patients’ charts were either missing or illegible.

Table 5.3 on the next page shows that the majority of patients were awake when the epidural was positioned in the anaesthetic room. More than two attempts were recorded in 20% of patients. The incidence of documented dural tap was low (1.3%) and the majority of catheters were positioned at T10 and above. The procedure was abandoned in 35 patients. No statistically significant association was found between failure to position the epidural with either the gender or emergency status of the patients.
Table 5.3 Characteristics related to epidural procedure in the anaesthetic room (%)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Awake for sitting epidural</td>
<td>348 (83.1)</td>
</tr>
<tr>
<td>Asleep for sitting epidural</td>
<td>71 (16.9)</td>
</tr>
<tr>
<td><strong>Number of attempts at positioning epidural</strong></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>221 (54.7)</td>
</tr>
<tr>
<td>2</td>
<td>102 (25.2)</td>
</tr>
<tr>
<td>3</td>
<td>46 (11.4)</td>
</tr>
<tr>
<td>&gt;3</td>
<td>35 (8.7)</td>
</tr>
<tr>
<td><strong>Dural tap</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>6 (1.3)</td>
</tr>
<tr>
<td><strong>Catheter site</strong></td>
<td></td>
</tr>
<tr>
<td>Above T6</td>
<td>7 (1.6)</td>
</tr>
<tr>
<td>T6</td>
<td>14 (3.2)</td>
</tr>
<tr>
<td>T7</td>
<td>61 (13.7)</td>
</tr>
<tr>
<td>T8</td>
<td>168 (37.8)</td>
</tr>
<tr>
<td>T9</td>
<td>78 (17.6)</td>
</tr>
<tr>
<td>T10</td>
<td>46 (10.4)</td>
</tr>
<tr>
<td>T11</td>
<td>27 (6.1)</td>
</tr>
<tr>
<td>T12 and below</td>
<td>26 (5.9)</td>
</tr>
<tr>
<td><strong>Failure to insert or removed in recovery</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>35 (7.4)</td>
</tr>
</tbody>
</table>

Failure was associated with the following patient and anaesthetic characteristics. There was a weak positive statistically significant relationship between failure to site an epidural and the patient being asleep when the epidural catheter was positioned in theatre, $r = .102$, $p = .012$. It was unclear whether the patient being asleep before the
procedure was a request by the patient or an anaesthetic decision. The failure rate was highest in the 60 to 69 age group (Table 5.4). Of the 35 failures, 63% were men, and one anaesthetist had a higher rate of failure compared to that of colleagues.

Table 5.4 Number (%) of successful v failed epidurals by age groups (n = 439)

<table>
<thead>
<tr>
<th>Age in decades</th>
<th>Successful</th>
<th>Failed</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 - 19</td>
<td>3 (7)</td>
<td>0</td>
</tr>
<tr>
<td>20 - 29</td>
<td>10 (2.3)</td>
<td>0</td>
</tr>
<tr>
<td>30 - 39</td>
<td>10 (2.3%)</td>
<td>2 (5.7)</td>
</tr>
<tr>
<td>40 - 49</td>
<td>27 (6.2)</td>
<td>2 (5.7)</td>
</tr>
<tr>
<td>50 - 59</td>
<td>63 (14.4)</td>
<td>8 (22.9)</td>
</tr>
<tr>
<td>60 - 69</td>
<td>116 (26.4)</td>
<td>13 (37.1)</td>
</tr>
<tr>
<td>70 - 79</td>
<td>126 (28.7)</td>
<td>6 (17.1)</td>
</tr>
<tr>
<td>80 - 89</td>
<td>80 (18.2)</td>
<td>4 (11.4)</td>
</tr>
<tr>
<td>90 - 99</td>
<td>4 (0.9)</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>439</td>
<td>35</td>
</tr>
</tbody>
</table>

The next stage in the data analysis was to compare the mean pain scores of patients who received an epidural and those in whom it failed in theatre. The error bar graph in Figure 5.6 is a useful graphic display of the observations related to the two groups.
Figure 5.6 Error bar graph of mean VNRS for success/failure to site epidural catheter

In the middle of the error bars in Figure 5.6 is a dot, which represents the mean of each group; the vertical bars illustrate the confidence intervals around the mean. The error bars in Figure 5.6 above do not overlap, so it is clear that the samples are different. The independent t-test was computed to establish whether the means differed significantly between the two groups.

Table 5.5 Independent samples t test of mean pain scores of successful and failed epidurals (n = 383)

<table>
<thead>
<tr>
<th></th>
<th>Group Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Failure to site epidural</td>
</tr>
<tr>
<td>VNRS 0 - 10 on</td>
<td></td>
</tr>
<tr>
<td>movement</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>
Levene’s test, shown in Table 5.5, is non-significant for the mean pain scores, which indicates that the variances are not significantly different. Therefore, the test result from ‘equal variances assumed’ can be used. The descriptive table above demonstrates a difference between the mean scores of 2.5. On average, patients experienced higher pain scores when the epidural failed before discharge to the ward (M = 6.34, SE = .46) than did patients discharged with an epidural in situ (M = 3.99, SE = .15) where M is the mean and SE is the standard errors. This difference was statistically and clinically significant t(381) = -4.37, p = .000. The 35 patients who had a failed epidural procedure in theatre were included in all subsequent data analysis. Alternative analgesia, usually a morphine PCA, was established before the
patient was discharged from theatre. This intention-to-treat design was justified in the methods section.

Other anaesthetic characteristics that may influence the effectiveness of epidural analgesia include the position of the epidural catheter. The majority of catheters were positioned, theoretically, in the correct position. In order to check any association between level of pain and the position of the epidural catheter, a boxplot was created to give a graphical representation of the different catheter positions (Figure 5.7).

![Boxplot of 11 point VNRS and site of epidural](image)

Figure 5.7 Boxplot of 11 point VNRS and site of epidural

The centre line in the boxplot (Figure 5.7) shows the median, the interquartile range and the range of scores for pain scores associated with each documented position of the epidural chart. It is also clear from the boxplot that all distributions are skewed, because the ‘whiskers’ on either side of the box are not equal. No statistically significant differences were found between the mean pain scores and the position of
the epidural catheter. The mean pain score (VNRS) for each group is shown in Table 5.6 below.

Table 5.6 Position of epidural catheter and mean pain score (n = 347)

<table>
<thead>
<tr>
<th>Epidural site</th>
<th>Mean VNRS</th>
<th>N</th>
<th>Std. Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>above T6</td>
<td>3.3</td>
<td>6</td>
<td>3.1</td>
</tr>
<tr>
<td>T6</td>
<td>3.1</td>
<td>13</td>
<td>2.7</td>
</tr>
<tr>
<td>T7</td>
<td>4.5</td>
<td>47</td>
<td>2.8</td>
</tr>
<tr>
<td>T8</td>
<td>3.8</td>
<td>144</td>
<td>2.8</td>
</tr>
<tr>
<td>T9</td>
<td>3.6</td>
<td>61</td>
<td>2.8</td>
</tr>
<tr>
<td>T10</td>
<td>4.2</td>
<td>33</td>
<td>2.9</td>
</tr>
<tr>
<td>T11</td>
<td>5.3</td>
<td>22</td>
<td>3.1</td>
</tr>
<tr>
<td>T12 and below</td>
<td>4.5</td>
<td>21</td>
<td>3.6</td>
</tr>
<tr>
<td>Total</td>
<td>4.0</td>
<td>347</td>
<td>2.9</td>
</tr>
</tbody>
</table>

5.3.6 Epidural drugs

The study was conducted during a period when there was a shortage of diamorphine nationally. As can be seen from the next table (5.7), the most common concentration used was a concentration of 0.08% bupivacaine with 10mg diamorphine.
Table 5.7 Epidural drug at time of first visit by the APS (n = 435)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.08% Bupivacaine and Diamorphine 5mg</td>
<td>38</td>
<td>8.7</td>
</tr>
<tr>
<td>0.08% Bupivacaine and Diamorphine 10mg</td>
<td>308</td>
<td>70.8</td>
</tr>
<tr>
<td>0.08% Bupivacaine and Diamorphine 20mg</td>
<td>15</td>
<td>3.4</td>
</tr>
<tr>
<td>0.125% Bupivacaine and Diamorphine 10mg</td>
<td>4</td>
<td>0.9</td>
</tr>
<tr>
<td>0.08% Bupivacaine</td>
<td>67</td>
<td>15.4</td>
</tr>
<tr>
<td>0.125% Bupivacaine</td>
<td>3</td>
<td>0.7</td>
</tr>
<tr>
<td>Total</td>
<td>435</td>
<td></td>
</tr>
<tr>
<td>not documented</td>
<td>45</td>
<td></td>
</tr>
</tbody>
</table>

The epidural infusion was established in theatre using a Pain Manager Pump (Abbott Laboratories). Fifty percent of infusions were between 1 and 8mls per hour, with the other half between 9 and 17mls per hour. The mean rate was 8.8mls per hour. In addition, all pumps were configured to allow a patient-administered bolus dose with a setting of 2mls and lockout of 20 minutes. The lockout period is a safety feature to allow for the peak effect of the drug.

The majority of patients had a Central Venous Pressure catheter (CVP) positioned in theatre for fluid monitoring, and drug administration both during and after surgery. Only 10.8% of patients did not have a CVP line in situ from theatre. This was important because a CVP line is required for optimum measurement and management of fluid input and output after major surgery. Further, drugs to control blood pressure can be administered only via CVP catheters.
Table 5.8 on the following page is a correlation matrix of patient age, ASA status, number of attempts to position the epidural and number and length of patient visit. Spearman's correlation was chosen because the data violates the assumptions of parametric tests. It can be seen, as would be expected, that a higher ASA was significantly, but weakly, associated with the increasing age of the patient (r_s = .189, p = .000). The APS spent statistically significantly less time visiting this older higher risk group, r_s = .144, p = .002. In addition, the total number of visits to patients decreased as the age of the patients increased (r_s = .127, p = .005). Thus there was a weak negative relationship between the increasing amount of time the APS spent with a patient and decreasing age.

The correlation matrix shows a modest positive statistically significant relationship between the time spent reviewing a patient on the first visit from the APS and an increased total number of visits (r_s = .306, p = .000).
Table 5.8 Correlation matrix of patient age, ASA status, epidural attempts, number and length of visit by APS

<table>
<thead>
<tr>
<th>Spearman’s rho</th>
<th>Age</th>
<th>Correlation Coefficient</th>
<th>Sig. (2-tailed)</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td>1.000</td>
<td>.189</td>
<td>479</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td>- .144</td>
<td>.000</td>
<td>377</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td>-.015</td>
<td>.002</td>
<td>476</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td>- .127</td>
<td>.762</td>
<td>403</td>
</tr>
<tr>
<td>ASA</td>
<td>.189</td>
<td>1.000</td>
<td>.002</td>
<td>377</td>
</tr>
<tr>
<td>ASA</td>
<td>.000</td>
<td>-.062</td>
<td>.034</td>
<td>374</td>
</tr>
<tr>
<td>ASA</td>
<td>.000</td>
<td>.235</td>
<td>.541</td>
<td>321</td>
</tr>
<tr>
<td>ASA</td>
<td>.000</td>
<td>-.062</td>
<td>.235</td>
<td>477</td>
</tr>
<tr>
<td>Length of visit (approx)</td>
<td>-.144</td>
<td>-.062</td>
<td>1.000</td>
<td>402</td>
</tr>
<tr>
<td>Length of visit (approx)</td>
<td>.002</td>
<td>.235</td>
<td>.390</td>
<td>402</td>
</tr>
<tr>
<td>Length of visit (approx)</td>
<td>.002</td>
<td>.235</td>
<td>.390</td>
<td>477</td>
</tr>
<tr>
<td>Number of epidural attempts</td>
<td>- .015</td>
<td>.034</td>
<td>.043</td>
<td>404</td>
</tr>
<tr>
<td>Number of epidural attempts</td>
<td>.762</td>
<td>.541</td>
<td>.390</td>
<td>404</td>
</tr>
<tr>
<td>Number of epidural attempts</td>
<td>.762</td>
<td>.541</td>
<td>.390</td>
<td>480</td>
</tr>
<tr>
<td>Total number of visits</td>
<td>-.127</td>
<td>-.136</td>
<td>.306</td>
<td>480</td>
</tr>
<tr>
<td>Total number of visits</td>
<td>.005</td>
<td>.008</td>
<td>.000</td>
<td>404</td>
</tr>
<tr>
<td>Total number of visits</td>
<td>.005</td>
<td>.008</td>
<td>.000</td>
<td>480</td>
</tr>
</tbody>
</table>

**. Correlation is significant at the 0.01 level (2-tailed).
* . Correlation is significant at the 0.05 level (2-tailed).
5.3.7 Side effects

The five bar charts in Figure 5.8 display the scores obtained when patients were asked about the degree of nausea and/or vomiting, pruritis (itch), motor block and sedation, all measured on a 0 to 3 scale.

Figure 5.8.1 Incidence of postoperative nausea and vomiting measured on a 4-point score (n = 455)
Figure 5.8.2 Incidence of sedation measured on a 4-point score (n = 457)

Figure 5.8.3 Incidence of post-operative motor block measured on a 4 point score (n = 424)
Figure 5.8.4 Incidence of thirst measured on a 4-point score (n = 370)

Figure 5.8.5 Incidence of pruritis measured on a 4-point score (n = 446)
A weak positive association was found between an increased sedation score and PONV score \((r = .147, p = .002)\), and the thirst score \((r = .142, p = .004)\) which was statistically significant. In addition, there was a weak positive relationship between the increased sedation score and increased pain measured on the similar 4 point \((0 - 3)\) rating for pain scores \((r = .135, p = .004)\). This finding may reflect the fact that increasing amounts of opioids were given to patients with higher pain scores, and opioid-related side effects include nausea and sedation.

5.4 Hypotension

It was documented from a review of medical notes whether patients normally took antihypertensive drugs. Twenty percent of patients \((n = 91)\) were taking ACE inhibitors to control blood pressure when admitted for surgery. Eighteen percent \((n = 80)\) of patients were taking a \(\beta\) blocker. Thirty-eight patients \((8\%)\) took both drugs. Eighteen percent \((n = 79)\) of patients had noradrenaline, a vasopressor, administered to treat postoperative hypotension in the postoperative period. This was possible only because these patients were nursed in critical care facilities. Overall, (all visits first documented), 59.5\% of patients were not hypotensive on the first visit by the APS. Twenty-seven percent \((n = 119)\) had a systolic less than 30\% normal, 3\% had a urine output less than 0.5mils/kg/hour, 4\% felt faint or light-headed, and 6.7\% had 2 or more of the above symptoms, including light headedness, and low urine output. There was a weak association \((r = .157)\) between the presence of hypotension and increased thirst score \((p = .005)\).

Further useful clinical information can be gained by looking at the incidence of hypotension when the first visit was on the day of operation compared to the first day.
after surgery. Thirty-seven percent of patients \((n = 151)\) were hypotensive on the day of surgery. 56% \((n = 215)\) were hypotensive on day 1 as illustrated in the bar chart below (Figure 5.9).

![Bar Chart]

**Figure 5.9 Incidence of hypotension on operation day and day 1**

It was recorded on the first visit whether patients were sat out of bed, as early mobilization is a principle aim of treatment. Only 30% of patients sat out on the first day; this percentage increased to 70% on day 2. A similar trend was seen in the use of a vasopressor (noradrenaline) across the 48 hours after surgery; 11.3% of patients were given noradrenaline on the day of operation increasing to 24.4% on day 1. This percentage then decreased to 18.2% on day 2.
In order to analyse two sets of categorical data, hypotension (yes/no) and the sex of the patient (male/female), the crosstab command was used in SPSS and the chi-squared test, the continuity correction, and lambda tests were selected. Table 5.9 shows the SPSS output. It can be seen that 64% of men and 54% of females (n = 259) were not hypotensive. Thus, 36% of men and 46% of women were hypotensive (n = 176).

Table 5.9 Hypotension and gender crosstabulation

<table>
<thead>
<tr>
<th>Hypotension</th>
<th>Male/Female</th>
<th>Male</th>
<th>Female</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Count</td>
<td>148</td>
<td>111</td>
<td>259</td>
</tr>
<tr>
<td></td>
<td>Expected Count</td>
<td>136.9</td>
<td>122.1</td>
<td>259.0</td>
</tr>
<tr>
<td></td>
<td>% within Male/Female</td>
<td>64.3%</td>
<td>54.1%</td>
<td>59.5%</td>
</tr>
<tr>
<td></td>
<td>% of Total</td>
<td>34.0%</td>
<td>25.5%</td>
<td>59.5%</td>
</tr>
<tr>
<td>Yes</td>
<td>Count</td>
<td>82</td>
<td>94</td>
<td>176</td>
</tr>
<tr>
<td></td>
<td>Expected Count</td>
<td>93.1</td>
<td>82.9</td>
<td>176.0</td>
</tr>
<tr>
<td></td>
<td>% within Male/Female</td>
<td>35.7%</td>
<td>45.9%</td>
<td>40.5%</td>
</tr>
<tr>
<td></td>
<td>% of Total</td>
<td>18.9%</td>
<td>21.6%</td>
<td>40.5%</td>
</tr>
<tr>
<td>Total</td>
<td>Count</td>
<td>230</td>
<td>205</td>
<td>435</td>
</tr>
<tr>
<td></td>
<td>Expected Count</td>
<td>230.0</td>
<td>205.0</td>
<td>435.0</td>
</tr>
<tr>
<td></td>
<td>% within Male/Female</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td></td>
<td>% of Total</td>
<td>52.9%</td>
<td>47.1%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>
The value of the chi-squared statistic was 4.683, which was statistically significant at a p value of .032 (2-sided). This value suggested an association between hypotension and being female. The additional tests, shown in Table 5.10, were used to give an indication of the strength of the relationship because the Chi-square test does not give an indication of the strength of the relationship (Field 2005).

Table 5.10 Symmetric Measures – hypotension and gender

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
<th>Approx. Sig.</th>
<th>Exact Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nominal by Nominal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phi</td>
<td>.104</td>
<td>.030</td>
<td>.032</td>
</tr>
<tr>
<td>Cramer's V</td>
<td>.104</td>
<td>.030</td>
<td>.032</td>
</tr>
<tr>
<td>Contingency Coefficient</td>
<td>.103</td>
<td>.030</td>
<td>.032</td>
</tr>
<tr>
<td>N of Valid Cases</td>
<td>435</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The statistic displayed in Table 5.10 is .104 out of a maximum of 1, which represents a weak association. An odds ratio was calculated by first dividing the number of males who were hypotensive by those who were not; 1487/82 = 1.8. The same calculation was completed for females; 111/94 = 1.2. The odds ratio is the odds of being hypotensive as a female divided by the odds of being hypotensive and male. Females were thus 1.5 times more likely to be hypotensive in the postoperative period. This is interesting, because, as will be seen later, female patients had lower overall pain scores. Therefore, the results indicate that better analgesia is associated with a higher incidence of low blood pressure.
Data were analysed again focusing on the first morning after surgery. Data were available from 210 patients. Forty-six percent of males (n = 110), and 54% of females (n = 100) were documented as hypotensive. The output from the independent t-test produced two tables shown below (Table 5.11). The first table provides summary statistics and shows that patients who were given a vasopressor had a mean pain score of 3.3 (n = 309); those patients who were not given a vasopressor had a mean score of 4.2 (n = 55). The second table contains the test statistics.

Table 5.11 The mean pain scores of two groups – those who did, and those who did not - have a vasopressor administered to control blood pressure

<table>
<thead>
<tr>
<th>vasopressor</th>
<th>N</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>VNRS 0 - 10 on movement</td>
<td>No</td>
<td>309</td>
<td>4.210</td>
<td>2.9866</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>55</td>
<td>3.327</td>
<td>2.6109</td>
</tr>
</tbody>
</table>
Levene’s test is non-significant for the mean pain scores and incidence of hypotension, which indicates that the variances are not significantly different. Therefore, the test result from ‘equal variances assumed’ can be used. The descriptive table above demonstrates a difference between the mean scores of 0.89. On average, patients experienced higher pain scores when not administered noradrenaline ($M = 4.21, SE = .17$) than did patients who received noradrenaline ($M = 3.3, SE = .35$). This difference was statistically significant $t(362) = 2.06, p = .040$.

The next table displayed (Table 5.12) indicates the difference in mean pain scores between those patients the APS documented as hypotensive (<30 % systolic) and those who had no change or had an increase in blood pressure. The mean pain score is lower in those who were hypotensive, 3.4 compared to 4.5; the result is statistically
significant, p = .001. As before, equal variances can be assumed. There was no
difference in mean age between those who were hypotensive and those who were not.

Table 5.12 Independent t test of mean pain scores and hypotension

<table>
<thead>
<tr>
<th>Symptomatic hypotension</th>
<th>N</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>VNRS 0 - 10 on movement</td>
<td>Yes</td>
<td>142</td>
<td>3.415</td>
<td>2.7321</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>220</td>
<td>4.495</td>
<td>3.0030</td>
</tr>
</tbody>
</table>

Independent Samples

<table>
<thead>
<tr>
<th>Test</th>
<th>VNRS 0 - 10 on movement</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Equal variances assumed</td>
<td>Equal variances not assumed</td>
<td></td>
</tr>
<tr>
<td>Levene's Test for Equality of Variances</td>
<td>F</td>
<td>.200</td>
<td></td>
</tr>
<tr>
<td>t-test for Equality of Means</td>
<td>t</td>
<td>-3.460</td>
<td>-3.531</td>
</tr>
<tr>
<td></td>
<td>df</td>
<td>360</td>
<td>320.980</td>
</tr>
<tr>
<td></td>
<td>Sig. (2-tailed)</td>
<td>.001</td>
<td>.000</td>
</tr>
<tr>
<td></td>
<td>Mean Difference</td>
<td>-1.0800</td>
<td>-1.0800</td>
</tr>
<tr>
<td></td>
<td>Std. Error Difference</td>
<td>.3122</td>
<td>.3059</td>
</tr>
<tr>
<td></td>
<td>95% Confidence Interval</td>
<td>Lower</td>
<td>-1.6939</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Upper</td>
<td>-.4661</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>-.4782</td>
</tr>
</tbody>
</table>
It was shown earlier that females were more likely to be hypotensive after surgery than were males. It has also been suggested that the incidence of hypotension is higher with lower pain scores. Therefore, the test above is repeated, but with results for males and females reported separately. The descriptive table below (Table 5.13) demonstrates that female patients who were hypotensive had a mean pain score of 3.2 compared to 4.4.

Table 5.13 Independent t test of mean pain scores and hypotension by gender

<table>
<thead>
<tr>
<th>Male/Female</th>
<th>Hypotension</th>
<th>N</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Std. Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>male</td>
<td>VNRS 0 - No</td>
<td>128</td>
<td>4.594</td>
<td>3.2103</td>
<td>.2838</td>
</tr>
<tr>
<td></td>
<td>10 on Yes</td>
<td>65</td>
<td>3.662</td>
<td>2.8465</td>
<td>.3531</td>
</tr>
<tr>
<td>female</td>
<td>VNRS 0 - No</td>
<td>92</td>
<td>4.359</td>
<td>2.6995</td>
<td>.2814</td>
</tr>
<tr>
<td></td>
<td>10 on Yes</td>
<td>77</td>
<td>3.208</td>
<td>2.6325</td>
<td>.3000</td>
</tr>
</tbody>
</table>
Independent Samples Test

<table>
<thead>
<tr>
<th></th>
<th>Male/Female</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>male</td>
</tr>
<tr>
<td>VNRS 0 - 10 on</td>
<td>Equal</td>
</tr>
<tr>
<td>movement</td>
<td>variances assumed</td>
</tr>
<tr>
<td></td>
<td>2.784</td>
</tr>
<tr>
<td></td>
<td>.097</td>
</tr>
<tr>
<td></td>
<td>1.979</td>
</tr>
<tr>
<td></td>
<td>191</td>
</tr>
<tr>
<td></td>
<td>.049</td>
</tr>
<tr>
<td></td>
<td>.9322</td>
</tr>
<tr>
<td></td>
<td>.4711</td>
</tr>
<tr>
<td></td>
<td>.0030</td>
</tr>
<tr>
<td></td>
<td>1.8615</td>
</tr>
<tr>
<td></td>
<td>1.9649</td>
</tr>
</tbody>
</table>

Once again, the Levene’s test is non-significant for the 0 to 10 pain scores, which indicates that the variances are not significantly different. Therefore, the test result from ‘equal variances assumed’ can be used. The descriptive table above (Table 5.13) demonstrates a difference between the mean scores of 0.93 for males and 1.15 for females. On average, male patients experienced lower pain scores when they were also hypotensive (M = 3.7, SE = .35) than did patients who were not hypotensive (M
This difference was statistically significant \( t(191) = 1.98, p = .049 \). However, the difference in mean pain scores in the female patients is highly significant, \( p = .006 \).

In order to analyse two sets of categorical data (based on frequencies not means), hypotension (no/yes) and the occurrence of adverse events (no/yes), the crosstab command was used in SPSS and the chi-squared test and Cramer’s V were selected. Table 5.14 shows the SPSS output.

Table 5.14 Hypotension and adverse events crosstabulation

<table>
<thead>
<tr>
<th>hypotension</th>
<th>adverse event</th>
<th>No</th>
<th>Yes</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Count</td>
<td>188</td>
<td>70</td>
<td>258</td>
</tr>
<tr>
<td></td>
<td>% within hypotension</td>
<td>72.9%</td>
<td>27.1%</td>
<td>100.0%</td>
</tr>
<tr>
<td></td>
<td>% within adverse event</td>
<td>68.4%</td>
<td>44.3%</td>
<td>59.6%</td>
</tr>
<tr>
<td></td>
<td>% of Total</td>
<td>43.4%</td>
<td>16.2%</td>
<td>59.6%</td>
</tr>
<tr>
<td>Yes</td>
<td>Count</td>
<td>87</td>
<td>88</td>
<td>175</td>
</tr>
<tr>
<td></td>
<td>% within hypotension</td>
<td>49.7%</td>
<td>50.3%</td>
<td>100.0%</td>
</tr>
<tr>
<td></td>
<td>% within adverse event</td>
<td>31.6%</td>
<td>55.7%</td>
<td>40.4%</td>
</tr>
<tr>
<td></td>
<td>% of Total</td>
<td>20.1%</td>
<td>20.3%</td>
<td>40.4%</td>
</tr>
<tr>
<td>Total</td>
<td>Count</td>
<td>275</td>
<td>158</td>
<td>433</td>
</tr>
<tr>
<td></td>
<td>% within hypotension</td>
<td>63.5%</td>
<td>36.5%</td>
<td>100.0%</td>
</tr>
<tr>
<td></td>
<td>% within adverse event</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td></td>
<td>% of Total</td>
<td>63.5%</td>
<td>36.5%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>
The value of the Chi-squared statistic was 24.122 (p = .000), indicating that hypotension had a significant effect on the incidence of adverse events. An additional test, Cramer’s V, resulted in a test statistic of .236 (p = .000).

The major adverse events recorded were cardiovascular collapse in five patients, specifically, three men and two women. The patients were aged 23, 46, 56, 85 and 87. In two out of the five surgical cases, the anaesthetist was a trainee. Four of the five patients were discharged from theatre to a surgical high care ward. One patient was an emergency.

The operations were a cystectomy, anterior resection, colectomy, ivor lewis oesophagectomy and laparotomy. The 85-year-old patient, who had an ASA of 3, was the only emergency in the group, and took β-blockers and ace-inhibitors to control her blood pressure. This was the only patient in this group with a high pain score.

5.5 Pain Scores
5.5.1 Preoperative Pain Scores

Data about pain before the operation was documented for 331 (69%) of patients. Of those 331 patients, 148 (31%) were able to quantify their level of pain preoperatively. Eighty-six patients (57.7%) reported that they had no pain, and a further five patients had a pain score between 1 and 3, which equates to mild pain. Twenty-one patients described the pain as being between 4 and 6, categorized as moderate pain. Thirty-six patients (24%) had severe pain, between 7 and 10 on the verbal rating scale. A further 45 patients had long-term pain, but could not quantify it. In addition, ten patients were under the care of the chronic pain service or palliative care. There was no correlation between pain scores before surgery and the level of postoperative pain. This is an
interesting finding because preoperative pain has already been identified as a predictor of postoperative pain (Macrae 2008). Epidural analgesia works by blocking the noxious input to the spinal cord and may be effective despite a background chronic pain. Indeed nerve blocks are frequently used as a treatment option in chronic pain clinics. Thus, epidural analgesia may be a good choice for patients with chronic pain.

In order to explore this aspect further, a correlation matrix was built to look at associations with other analgesic techniques. Data were used from a larger database, which contains all visits by the APS to patients (n = 1058) in 2006. The ‘split file’ command was used to split the data file into different analgesic techniques for analysis. There was a weak positive association between increasing preoperative pain scores and an increasing level of postoperative pain for patients with a morphine PCA as the primary analgesic technique (r = .257, p = .010). There was a strong positive correlation between increasing preoperative pain, r = .843, and increasing preoperative pain (p = .004) for those patients who received intrathecal analgesia as the primary pain relief technique. This is important as the results suggest that epidural analgesia would be a good option for a patient with chronic pain.

5.5.2 Postoperative pain scores

Figures 5.10 and 5.11 in the next section illustrate both the simple 0 to 3 (none, mild, moderate and severe) pain scores and the number of patients who were able to quantify their pain on the 0 to 10 score. Table 5.15 indicates the strong correlation between the simple 0 to 3 pain score, and the 11 point VNRS (rho = .875, p = .000).
Figure 5.10 Bar chart of postoperative pain scores using 0 – 3 score

Figure 5.11 Bar chart of postoperative pain scores using 0 – 10 VNRS
Seventy percent of patients had a pain score of either 0 or 1 recorded on the 0–3 score. Nine percent of patients had a pain score of 3 documented. Data from only 19 patients were missing from this group. In the more detailed 11-point scale, 45% of patients had either no or mild (<4) pain scores. Twenty-four percent of patients had a pain score documented as severe (>6). When data were analysed for males and females separately, 29% of men (n = 60) had severe pain (> 6). This figure was much less for females with 17% (n = 31) reporting a pain score above 6.

Table 5.14 Correlation matrix of 4-point categorical and 11-point VNRS pain scores

<table>
<thead>
<tr>
<th></th>
<th>Pain score 0 - 3</th>
<th>VNRS 0 - 10 on movement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spearman's rho</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain score 0 - 3</td>
<td>Correlation</td>
<td>1.000</td>
</tr>
<tr>
<td></td>
<td>Coefficient</td>
<td>.875**</td>
</tr>
<tr>
<td></td>
<td>Sig. (1-tailed)</td>
<td>.</td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>461</td>
</tr>
<tr>
<td></td>
<td></td>
<td>.</td>
</tr>
<tr>
<td></td>
<td>VNRS 0 - 10 on</td>
<td>1.000</td>
</tr>
<tr>
<td></td>
<td>movement</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Correlation</td>
<td>.875**</td>
</tr>
<tr>
<td></td>
<td>Coefficient</td>
<td>1.000</td>
</tr>
<tr>
<td></td>
<td>Sig. (1-tailed)</td>
<td>.</td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>382</td>
</tr>
<tr>
<td></td>
<td></td>
<td>.</td>
</tr>
</tbody>
</table>

**. Correlation is significant at the 0.01 level (1-tailed).

However, data were missing from analysis in 94 patients in this group. This was usually because either the patient was too ill to be asked, or they were not able to quantify their pain using the VNRS score. This is useful information to collect because APSs need to know an approximate number of patients who cannot quantify their pain.
their pain. The 4-point categorical score was used to measure and optimize pain relief if the more accurate VNRS was inappropriate.

The advantage of 0 to 3 was that it was practical to collect and gave an indication of the quality of pain control from a higher number of patients than was possible using the verbal numerical rating score. In cases where the patient was not able to communicate, a judgement was made by a member of the APS based on other factors, such as whether the patient was able to cough, move and rest comfortably.

The pain scores were also explored based on the age of the patients. Statistically significant lower mean pain scores (3.7) were found in patients who were 70 years of age and over compared to patients below 70 (M = 4.5, p = .008). Once again, the Levene's test for equality of variance (Table 5.16) was non-significant; therefore, equal variances could be assumed.

Table 5.16 Comparison of mean score in two age groups – below 70 and 70 and above years of age

<table>
<thead>
<tr>
<th>Age</th>
<th>N</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>Std. Error Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>VNRS 0 - 10 on movement</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;= 70</td>
<td>167</td>
<td>3.731</td>
<td>2.9112</td>
<td>.2253</td>
</tr>
<tr>
<td>&lt; 70</td>
<td>218</td>
<td>4.537</td>
<td>2.9310</td>
<td>.1985</td>
</tr>
</tbody>
</table>
This difference between age groups needs to be interpreted with caution, because there are other factors that might account for the difference. For example, it was clear in the background (page 93) to the study that older patients (over 65) may be more reluctant to describe pain as severe, or they are perhaps more stoical. An alternative explanation is that the level of analgesia is more effective in older than in younger groups. This will be discussed in greater detail in Chapter 7.

In addition, age 70 is an arbitrary cut-off point; therefore, one further test was computed to look at whether the mean pain scores would decrease across the age groups. The Jonckheere-Terpstra Test (J-T) is a useful nonparametric test to show difference between several independent groups and it gives information about whether the order of the groups is meaningful. The coding variables specified (1 for aged 10 -
19, 2 for aged 20-29 and so on) were in the order in which the medians were expected to change. The output from SPSS in Table 5.17 shows the number of groups (9). The results indicate that the medians of the group descended in the order specified by the coding variable. The J-T statistic is -2.49, which is significant (p = .013) and the negative sign indicates a descending trend. This suggests that as age increases over the decades, the mean pain score reduces.

Table 5.17 Jonckheere-Terpstra Test of patient age and VNRS (n = 385)

<table>
<thead>
<tr>
<th>Number of Levels in Age in decades</th>
<th>VNRS 0 - 10 on movement</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>385</td>
</tr>
<tr>
<td>Observed J-T Statistic</td>
<td>25934.500</td>
</tr>
<tr>
<td>Mean J-T Statistic</td>
<td>28976.500</td>
</tr>
<tr>
<td>Std. Deviation of J-T Statistic</td>
<td>1218.319</td>
</tr>
<tr>
<td>Std. J-T Statistic</td>
<td>-2.497</td>
</tr>
<tr>
<td>Asymp. Sig. (2-tailed)</td>
<td>.013</td>
</tr>
<tr>
<td>Monte Carlo Sig. (2-tailed)</td>
<td>Sig.</td>
</tr>
<tr>
<td>99% Confidence</td>
<td>Lower Bound</td>
</tr>
<tr>
<td>Interval</td>
<td>Upper Bound</td>
</tr>
<tr>
<td>Monte Carlo Sig. (1-tailed)</td>
<td>Sig.</td>
</tr>
<tr>
<td>99% Confidence</td>
<td>Lower Bound</td>
</tr>
<tr>
<td>Interval</td>
<td>Upper Bound</td>
</tr>
</tbody>
</table>

185
An objective of this study was to understand more of the characteristics of effective analgesia. Therefore, characteristics of patients with three levels of pain (mild, moderate and severe) are described in Table 5.18.

Table 5.18 Characteristics associated with mild, moderate and severe pain (n = 385)

<table>
<thead>
<tr>
<th>Pain Score (0 – 10)</th>
<th>0 -3</th>
<th>4 -6</th>
<th>7 -10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Count (%)</td>
<td>172 (45)</td>
<td>122 (32)</td>
<td>91 (24)</td>
</tr>
<tr>
<td>Emergency (%)</td>
<td>18</td>
<td>18</td>
<td>28</td>
</tr>
<tr>
<td>Male/female</td>
<td>52/48</td>
<td>44/56</td>
<td>64/36</td>
</tr>
<tr>
<td>Mean age (range)</td>
<td>68 (21 – 93)</td>
<td>64 (17 – 91)</td>
<td>61 (18 – 90)</td>
</tr>
<tr>
<td>70 years and over within the group(%)</td>
<td>51</td>
<td>38</td>
<td>35</td>
</tr>
<tr>
<td>ASA 111 or IV</td>
<td>41.6</td>
<td>41.8</td>
<td>47.3</td>
</tr>
<tr>
<td>Mean preoperative VNRS</td>
<td>2.3</td>
<td>4.2</td>
<td>3.4</td>
</tr>
<tr>
<td>Infusion rate (SD)</td>
<td>8.7 (2.87)</td>
<td>9.0 (3.10)</td>
<td>9.4 (3.75)</td>
</tr>
<tr>
<td>Intrathecal analgesia (%)</td>
<td>6</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>With PCA (%)</td>
<td>5</td>
<td>11</td>
<td>23</td>
</tr>
<tr>
<td>Hypotensive (%)</td>
<td>47</td>
<td>35</td>
<td>27</td>
</tr>
<tr>
<td>Vasopressor (%)</td>
<td>19</td>
<td>13</td>
<td>10</td>
</tr>
<tr>
<td>Planned removal (%)</td>
<td>63</td>
<td>48</td>
<td>40</td>
</tr>
</tbody>
</table>

The data for the above descriptive table (Table 5.18) were from all patients (n = 386) with an 11-point pain score recorded (missing data 94). In other words, the first
patient visit varied between the day of operation and day 4 thus this data will not
capture the experiences of all patients immediately postoperatively. It can be seen that
patients with no pain or low pain scores (0 -3) were in a slightly older age group, were
less likely to be emergency patients, and had a lower preoperative pain score. Higher
numbers of patients had intrathecal analgesia, and were less likely to have morphine
PCA if their pain was categorized as mild. Moreover, patients with mild pain were
more likely to be hypotensive and to have the epidural removed as planned.
Conversely, patients with severe pain recorded were more likely to be male, with a
higher ASA score, emergencies and in a younger age group. Nearly a quarter of this
group with severe pain had a PCA and less than half had the epidural removed as
planned.

Table 5.18 gives an overall picture of some characteristics associated with the
epidurals. It is more informative to describe how patients manage on the first day and
this is illustrated in Table 5.19. It is the first postoperative day, which is the key
outcome in the study. Frequently, patients are comfortable on the day of operation for
a variety of reasons not directly related to the epidural. For example, the effects of the
general anaesthetic can last beyond the recovery room, and the patient may not be
expected to cough or sit out of bed on the evening of surgery. The level of comfort
can change on the first night and morning as the patient moves for the first time. Rates
of epidural infusions might have been reduced overnight in response to the
hypotension. Any increase in pain may not be recognized until the first postoperative
day when the patient is asked to move. This pattern of recovery was supported by the
data, as 55% of patients had no or mild pain when reviewed on the day of surgery.
This percentage fell to 43% of patients on the first day after surgery. McLeod et al.
(2006) observed in their data that the initial pain-free period after surgery was crucial
to accruing benefits from an epidural. Therefore, the following (Table 5.19) is the analysis of data collected from patients by the APS on the first postoperative morning. There should be caution in any interpretation of the results because sparse data were available for patients who had surgery on a Friday or at a weekend.

Table 5.19 Characteristics associated with mild, moderate and severe pain on first day after surgery (n = 194)

<table>
<thead>
<tr>
<th>Pain Score (0 – 10)</th>
<th>0 -3</th>
<th>4 -6</th>
<th>7 -10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Count (%)</td>
<td>81 (42)</td>
<td>69 (36)</td>
<td>44 (23)</td>
</tr>
<tr>
<td>Emergency (%)</td>
<td>19</td>
<td>23</td>
<td>38</td>
</tr>
<tr>
<td>Male/female</td>
<td>53/47</td>
<td>46/54</td>
<td>64/36</td>
</tr>
<tr>
<td>Mean age (SD)</td>
<td>71 (11.6)</td>
<td>65 (13.8)</td>
<td>60 (17.7)</td>
</tr>
<tr>
<td>70 years and over within the group (%)</td>
<td>57</td>
<td>45</td>
<td>32</td>
</tr>
<tr>
<td>ASA I II or IV</td>
<td>50</td>
<td>39</td>
<td>39</td>
</tr>
<tr>
<td>Mean preoperative VNRS</td>
<td>2.1</td>
<td>2.5</td>
<td>2.7</td>
</tr>
<tr>
<td>Infusion rate (SD)</td>
<td>9.0 (2.7)</td>
<td>8.9 (2.7)</td>
<td>9.6 (4.0)</td>
</tr>
<tr>
<td>Intrathecal analgesia (%)</td>
<td>5</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>With PCA (%)</td>
<td>4</td>
<td>11</td>
<td>25</td>
</tr>
<tr>
<td>Hypotensive (%)</td>
<td>67</td>
<td>49</td>
<td>37</td>
</tr>
<tr>
<td>Vasopressor (%)</td>
<td>29</td>
<td>20</td>
<td>12</td>
</tr>
<tr>
<td>Planned removal (%)</td>
<td>71</td>
<td>49</td>
<td>39</td>
</tr>
</tbody>
</table>
Nevertheless, the following does suggest a baseline for future causal investigations. Emergency patients, male gender and age (under 70) are characteristics of patients with severe pain on the first day after surgery. The higher ASA patients are in the mild pain group. A quarter of patients with severe pain had a morphine PCA and just over 60% of patients with severe pain did not have the epidural removed as planned; the epidural came out prematurely.

5.6 Multivariate statistics

It is clear from the results so far that there are several factors related to an effective analgesia. A more complex analysis is required to answer the research question, which was to identify predictors of two key dependent variables the pain scores and incidence of hypotension. So far, the comparison of group means has been by univariate tests, but as Tabachnik and Fidell (2001) pointed out, the results may be misleading if presented in isolation, as the variables are related.

Logistic regression was used to examine the first outcome of interest, that is, hypotension in the postoperative period. As highlighted in this chapter and in the introduction, this is the greatest clinical problem on the first day after surgery in everyday clinical practice. Therefore, the variables in the database were reviewed and the first visits identified and analysed. Three hundred and forty-three patients (52% males) were identified with data available for analysis on the first day. SPSS refers to variables in regression analysis as dependent and independent variables. However, as noted in chapter 4, using such terms is inappropriate because this is a correlational research rather than a controlled study (Field 2005). Therefore, independent variables are referred to as 'predictors', and the dependent variable as the 'outcome.'
Hypotension is a categorical dichotomous variable, and the predictors are a combination of categorical and continuous data. Logistic regression is a version of multiple regression and is used when the outcome variable is dichotomous (has only two categories). It is useful to measure the probability of an outcome. The analysis was carried out in SPSS using ‘binary regression’ from the ‘regression’ menu. There are various strategies for entering variables into regression equations. The strategy used in this research was hierarchical regression, where variables were entered in a series of steps. This was based on the fact that past research, and the results of correlations, indicated variables associated with hypotension. The first part of the output in Table 5.20 below shows a contingency table with predictor variables omitted. Overall, the model correctly classifies 56.7% of patients.

Table 5.20 Classification table for hypotension (n = 321)

<table>
<thead>
<tr>
<th>Observed hypotension</th>
<th>Predicted</th>
<th>Percentage Correct</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Step 0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>0</td>
<td>139</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>182</td>
</tr>
<tr>
<td>Overall</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percentage</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 5.21 indicates that gender significantly predicts hypotension \((p = .028)\). However, the value of the odds ratio (Exp(B) is the label that SPSS applies to the odds ratio), is crucial to the interpretation of logistic regression (Field 2005). A value less than one, as in the table below, indicates that as the predictor increases the odds of the outcome occurring decrease. In this example, as the gender changes from female to male) the odds of hypotension occurring compared to not occurring is .58.

Table 5.21 Variables in the equation for hypotension (gender)

<table>
<thead>
<tr>
<th></th>
<th>B</th>
<th>S.E.</th>
<th>Wald</th>
<th>df</th>
<th>Sig.</th>
<th>Exp(B)</th>
<th>95.0% C.I.for EXP(B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1</td>
<td>Gender(1)</td>
<td>-.539</td>
<td>.245</td>
<td>4.835</td>
<td>1</td>
<td>.028</td>
<td>.583</td>
</tr>
<tr>
<td></td>
<td>Constant</td>
<td>.539</td>
<td>.180</td>
<td>8.991</td>
<td>1</td>
<td>.003</td>
<td>1.714</td>
</tr>
</tbody>
</table>

The 11-point pain score was added in the second step as a predictor. In other words, the model used gender and pain scores to predict hypotension. Goodness-of-fit statistics help determine whether the model adequately describes the data. The Hosmer-Lemeshow statistic indicates a poor fit if the significance value is less than 0.05. It is .384 in this model; thus, the model adequately fits the data. The chi-squared statistic is reported as 24.904, which is significant at \(p = .000\). Because the chi square is less than .05, it means that the addition of one or more of the variables will significantly improve the predictive power of the model. If the probability had been greater than .05, the analysis would have been stopped. The age of the patient was added and removed from the model, as the co-efficient was not significantly different.
from zero. Table 5.22 shows the summary statistics about the new model (called ‘variables in the equation’ by SPSS).

Table 5.22 Variables in the Equation for hypotension (gender and VNRS)

<table>
<thead>
<tr>
<th></th>
<th>B</th>
<th>S.E.</th>
<th>Wald</th>
<th>df</th>
<th>Sig.</th>
<th>Exp(B)</th>
<th>Lower</th>
<th>Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1 Gender(1)</td>
<td>-.434</td>
<td>.255</td>
<td>2.910</td>
<td>1</td>
<td>.088</td>
<td>.648</td>
<td>.393</td>
<td>1.067</td>
</tr>
<tr>
<td>VNRS</td>
<td>-.197</td>
<td>.046</td>
<td>18.581</td>
<td>1</td>
<td>.000</td>
<td>.821</td>
<td>.750</td>
<td>.898</td>
</tr>
<tr>
<td>Constant</td>
<td>1.265</td>
<td>.254</td>
<td>24.830</td>
<td>1</td>
<td>.000</td>
<td>3.543</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The significance values of the Wald statistic indicate that pain scores significantly predict hypotension (p = .000). Gender is no longer a significant predictor of hypotension in this model, although Tabachnick and Fidell (2001) suggest that the criterion for the inclusion of a predictor should be less stringent than .05; a cut-off of .15 or .20 is more appropriate. Once again, Exp(B) is an indicator of the change in odds resulting from a unit change in the predictor. In other words, Exp(B) can be interpreted in terms of the change in odds (Field 2005). If a value is greater than one, the odds of the outcome increase as the predictor increases. The value of Exp(B) indicates that if the pain score increases by one along the 11-point score, the odds of hypotension decrease by .82, or 18%. The confidence intervals range from .750 to .898. As both these values are less than one, it can be predicted that the results from this sample are generalizable to the whole population. The Exp(B) for gender is less convincing at .648 and confidence intervals of .393 to 1.067. In summary, the model
now correctly classifies 63.2% of patients. This could be because gender is not able to demonstrate predictive capability in the presence of the other predictive variable.

Logistic regression was also employed to predict level of pain because it has fewer restrictive assumptions than have other analytic strategies (Field 2005). First, pain scores were divided into two groups: pain scores 0–5, and 6–10. The first part of the output in Table 5.23 below shows a contingency table with predictor variables omitted. Overall, the model correctly classifies 68.9% of patients.

Table 5.23 Classification table for pain score (n = 293)

<table>
<thead>
<tr>
<th>Observed</th>
<th>Predicted</th>
<th>Percentage Correct</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>pain dichotomous</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Step 0</td>
<td>Pain &lt;6</td>
<td>0</td>
</tr>
<tr>
<td>6 - 10</td>
<td>1</td>
<td>91</td>
</tr>
<tr>
<td>Overall</td>
<td>202</td>
<td>91</td>
</tr>
</tbody>
</table>

A sequential logistic regression analysis was performed. In the first step, gender was added to the model. The significance values of the Wald statistic indicate that male gender significantly predicts a higher pain score after surgery (p = .005) (see Table 5.24).
The age of the patient and the characteristics of the epidural technique were not obvious predictors of pain scores and were removed from analysis. The final table (5.25) documents those predictors that resulted in a final model classification of 77.7%. The significance values of the Wald statistic indicate that gender significantly predicts higher pain score ($p = .023$). The value of $\text{Exp}(B)$ indicates that male gender increases the odds of a higher pain score. In addition, emergency patients ($p = .043$), and failure to position the epidural ($p = .011$) are predictors of higher pain scores. Not being hypotensive ($p = .001$) is a predictor of higher pain scores, as the $\text{Exp}(B)$ is greater than one (see Table 5.25). The odds ratio, $\text{Exp}(B)$, indicates that as hypotension changes from yes (0) to no (1), the changes in odds of a pain score of less than 6 compared to a pain scores of 6 to 10 is 2.5.
Table 5.25 Variables in the Equation for pain score (gender, emergency, failure and hypotension)

<table>
<thead>
<tr>
<th>Step</th>
<th>Gender (Male 1)</th>
<th>Emergency (No 1)</th>
<th>Failure (No 1)</th>
<th>Hypotension (No 1)</th>
<th>Constant</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>B</td>
<td>S.E.</td>
<td>Wald</td>
<td>df</td>
<td>Sig.</td>
</tr>
<tr>
<td></td>
<td>-.648</td>
<td>.286</td>
<td>5.151</td>
<td>1</td>
<td>.023</td>
</tr>
<tr>
<td></td>
<td>-.651</td>
<td>.321</td>
<td>4.104</td>
<td>1</td>
<td>.043</td>
</tr>
<tr>
<td></td>
<td>-1.793</td>
<td>.704</td>
<td>6.484</td>
<td>1</td>
<td>.011</td>
</tr>
<tr>
<td></td>
<td>.898</td>
<td>.281</td>
<td>10.200</td>
<td>1</td>
<td>.001</td>
</tr>
<tr>
<td></td>
<td>.391</td>
<td>.768</td>
<td>.259</td>
<td>1</td>
<td>.611</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Exp(B)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Lower</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Upper</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.912</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>1.092</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3.347</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>.522</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>.278</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>.979</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>.167</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>.042</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>.662</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2.455</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.415</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>4.261</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.478</td>
</tr>
</tbody>
</table>

5.7 Epidural removed as planned

The epidural catheter remained in situ for a mean of 3.5 days, with a range from 0 to 8 days. Fifty-two percent (n = 241) of catheters were removed as planned. A more detailed description of this aspect of epidural analgesia will be reported in the next chapter. It was highlighted in the introductory chapters that various researchers have reported an unplanned stop rate of up to 50%. Therefore, it is important to understand
more about this aspect of epidural management because failure can result in increased pain and a higher risk of adverse events.

Table 5.26 Planned epidural discontinuation (n = 480)

<table>
<thead>
<tr>
<th>Not documented for 15 patients</th>
<th>N</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>241</td>
<td>51.8</td>
</tr>
<tr>
<td>Fell out</td>
<td>62</td>
<td>13.3</td>
</tr>
<tr>
<td>Disconnected</td>
<td>8</td>
<td>1.7</td>
</tr>
<tr>
<td>Ineffective</td>
<td>50</td>
<td>10.8</td>
</tr>
<tr>
<td>Surgeon request</td>
<td>5</td>
<td>1.1</td>
</tr>
<tr>
<td>Site red/sore</td>
<td>12</td>
<td>2.6</td>
</tr>
<tr>
<td>Unable to site/removed in recovery</td>
<td>17</td>
<td>3.7</td>
</tr>
<tr>
<td>Leaking</td>
<td>24</td>
<td>5.2</td>
</tr>
<tr>
<td>Pulled out by patient</td>
<td>7</td>
<td>1.5</td>
</tr>
<tr>
<td>Hypotension and tachycardia</td>
<td>1</td>
<td>.2</td>
</tr>
<tr>
<td>Trans to ITU or terminal care</td>
<td>23</td>
<td>5</td>
</tr>
<tr>
<td>Patient request</td>
<td>1</td>
<td>.2</td>
</tr>
<tr>
<td>Catheter snapped</td>
<td>4</td>
<td>.9</td>
</tr>
<tr>
<td>Line occluded</td>
<td>1</td>
<td>.2</td>
</tr>
<tr>
<td>Transferred to a ward - can't take epidural</td>
<td>3</td>
<td>.6</td>
</tr>
<tr>
<td>Patient Unconscious</td>
<td>1</td>
<td>.2</td>
</tr>
<tr>
<td>Anaesthetist's request</td>
<td>5</td>
<td>1.1</td>
</tr>
<tr>
<td>Total</td>
<td>465</td>
<td>100.0</td>
</tr>
</tbody>
</table>
The precise reasons for the early discontinuation of the technique were collected; these are displayed in Table 5.26. Several factors are related to a deterioration in the patient's condition, while others are related directly to the care of the epidural catheter, which is the responsibility of the ward nurses. Specifically, the catheter 'falling out' is a problem common to many pain services.

It was hypothesised that the epidurals are more likely to 'fall out' when positioned for abdominal surgery rather than the higher catheter positions used in thoracic surgery, above T6.

![Figure 5.12 Bar chart of epidurals removed, and not removed, as planned with position of the epidural catheter (n= 412)](image)

Figure 5.12 Bar chart of epidurals removed, and not removed, as planned with position of the epidural catheter (n= 412)

Therefore, a bar chart was constructed to show the number of epidurals that were removed as planned for each epidural catheter site. It is clear in Figure 5.12 that the
higher rates of unplanned removal are at T7 (51%) and T9 (55%), which can perhaps be explained by the flexion and extension of the spine at these levels.

To conclude this section, it is clear from the results presented in this study to date that higher pain scores are related to a variety of factors, particularly male gender and younger age group. The epidurals can be very effective; those patients with a failed epidural in theatre had statistically and clinically significantly higher pain scores than had those with an epidural: mean difference 2.5, \( p = .000 \).

Nevertheless, an effective epidural is a predictor of hypotension on the first morning after surgery. The hypotension can restrict early mobilization and the results suggest there is an increased risk of adverse events. These results support the findings in the BURP study.

All services nationally need to have detailed data as presented in this study available routinely to make informed decisions about epidural pain management. Yet it is also clear that to collect this data as routine would be a burdensome task. One of the objectives of the study was to investigate both process and outcome data; it would be useful for all APSs to collect these data as routine. The number of fields in this study decreased over the time of the study from 165 to 90. It also became apparent that capturing the multiple visits was an impossible task even with the support of an independent research study. However, such data capture is practical and achievable with handheld computer technology and will be discussed in the final chapter.

In order to learn more from the data, and display the data in a more understandable format, the tools of SPC were used for further investigation in the next chapter. The results in this chapter have used control charts to indicate factors worth exploring, such as patient gender and age. In addition, it was not possible to investigate factors
such as individual anaesthetists and pain scores. Such analysis is possible with control charts.
6 Chapter 6 Control Charts

'In all forms of prediction an element of chance enters. The specific problem which concerns us at the present moment is the formulation of a scientific basis for prediction, taking into account the element of chance, where for the purpose of our discussion, any unknown cause of a phenomenon will be termed a chance cause.'

(Walter Shewhart 1931 p 7)

6.1 Introduction

The results of data analysis in Chapter 5 signposted key findings and relationships to be investigated further using Statistical Process Control (SPC). For example, female patients had lower mean pain scores and a higher incidence of hypotension on the first day after surgery. The mean pain scores reduced with increasing age. Furthermore, there were several factors that were not analysed using classical statistical methods because, for example, there were too many variables. The coding of a large number of anaesthetists (over 35) made it difficult to look at correlations for individual anaesthetists. Such analysis is possible using control charts and will be demonstrated in this chapter. The results of data analysis using statistical process control charts (control charts) are presented in this chapter in order to identify further factors associated with effective analgesia and postoperative hypotension.

Walter Shewhart introduced the concept of the nature of statistical process control when writing about the quality of a manufactured product in 1931. He had been commissioned to improve the quality of telephones manufactured by the Bell Laboratories in the USA. The use of statistical process control, a key tool in quality improvement research, has become increasingly popular in the past decade in health
care. The background to this was described in the introductory chapters. Essentially the control chart is a useful tool for learning more from the data than is possible using the classical statistical methods used in Chapter 5. This can be achieved by looking at data in a time series design and examining the type of variation (Carey 2003). For useful conclusions to be drawn from the data, it is important to have time-ordered data from a 'single stream process' (Hart and Hart 2002). In other words, the data need to be homogenous, that is, from the same population.

Pain scores will be explored first using control charts, followed by the second outcome of interest, hypotension. Reasons for the epidural failure will then be explored. The potential use of SPC as a tool to improve the quality of postoperative pain relief by APSs will be illustrated in the final sections of this chapter.

6.1.1 Pain scores

The control charts in Figure 6.1 show the recorded variation in the rate of mean pain score on the first morning after surgery \( n = 293 \) for patients who consented to an epidural in the 18-month period from January 2006 and could quantify their pain on a 0 – 10 rating score. Hart (2003) recommends displaying the raw data so that other readers can judge the accuracy of the charts. The raw data for Figure 6.1 are displayed in Table 6.1. The first chart displayed in Figure 6.1 is an X-chart, the second an S-chart. In this section, the \( X \) bar chart is used for the mean pain scores. The top chart shows that the mean visual analogue pain score (VNRS 0–10) was four. The centre line of the control chart is the mean of all the subgroups. The \( X \), or horizontal axis, is the unit of time, in this study bi-monthly because the literature recommends approximately 20 to 25 data subgroups in order to apply tests on the data. The \( Y \), or
vertical axis, is the quantitative measure, which is the outcome of interest, in this case, the pain scores. The control charts in Figure 6.1 also have two further lines – the upper and lower control limits, which are traditionally set at plus and minus 3 standard deviations from the average. The control limits are derived from the standard deviation of the subgroups. The S-chart tracks the standard deviation of the subgroups. The centre line in the S-Bar is irregular whenever there is a change in subgroup size. This is different from classical statistics where the overall value of S, the standard deviation, is calculated from all the data.
Figure 6.1 X-Bar and S-Chart of mean pain scores (January 2006 – June 2007)
Table 6.1 The data used to construct control chart (X-Bar) with bimonthly mean pain scores

| 5.1  | 5.2| 4.1| 3.0| 2.1| 4.9| 5.4| 3.4| 4.6| 4.9| 3.5| 1.6| 4.0| 4.2| 2.0| 1.5| 4.9| 3.5| 3.1| 2.5| 5.41| 5.6| 2.9| 5.7| 2.7| 4.5|

Table 6.2 The data used to construct the P - chart on page 208 with percentage of patients with a high pain:

last column

| 7    | 4 | 3 | 0 | 0 | 5 | 2 | 0 | 2 | 3 | 3 | 1 | 1 | 4 | 1 | 0 | 2 | 3 | 1 | 2 | 1 | 4 | 2 | 2 | 1 | 3 |
| 54   | 29| 25| 0 | 0 | 38| 25| 0 | 20| 21| 27| 20| 14| 27| 17| 0 | 29| 30| 14| 33| 14| 36| 20| 67| 12| 33|

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Both charts are ‘in control,’ that is, no points are outside the upper or lower control limits. Further, SPSS has an option to indicate a variety of ‘control rules’, which were described in Chapter 4. It is clear from the chart that no rule violations occur, that is, no points are above or below the control limits. In addition, the S-Chart is not out of control. If it were, the limits on the X-Bar would be suspect (Hart and Hart 2002).

Therefore, the process is stable and it is reasonable to predict that the pain scores for patients nursed with an epidural after surgery will continue in the future at a mean of 4 unless a special cause is introduced. In any given month, the mean pain score may be as high as 6.2 or as low as 1.6. There is a wide variation. This is the variation inherent in the process. Other terms used are ‘noise’ and ‘random variation’. Shewhart taught that the way to improve any process was to reduce any variation, which is clearly visible in Figure 6.1. The approach to improvement when a process is stable is to change the process. It is not productive to investigate individual data points.

The control chart is also useful for demonstrating why a ‘before and after’ study or snapshot audit may direct teams to make changes in response to data, which is inappropriately indicating a problem, or to make erroneous conclusions about the success of an intervention. For example, if measurement took place in only July in Figure 6.1, when the mean was 4.0, and again in August when the mean 1.5, the conclusion might be made that any change implemented in that period had been successful. However, both points are within the normal range of the variation of the process. Repeatedly responding to individual points is called tampering and actually introduces instability in a stable system (Berwick 2005). Tampering is an inappropriate and unnecessary adjustment.

The X-Bar and S-Chart is similar to the analysis of variance procedure (ANOVA). In essence, they both disclose a lack of control among means, but the advantage of the
control chart is that the results are easier to interpret and can identify trends over time (Hart and Hart 2002). There is a potential theoretical problem, which it is important to document when interpreting the trends in the data. The 11-point VNRS is positively skewed, which is clear with a mean of 4 and mode of 2. The Kolomogorov-Smirnov test was used to establish the degree to which this distribution of scores was significantly different from normal (Table 6.3). The test confirmed that the sample had a non normal distribution (p = .000). The test was repeated for separate genders because, as was clear from the last chapter, the mean pain scores were different between the groups. The distribution was significantly non-normal in this test, too (p = .000). However, the Kolomogorov-Smirnov test is prone to giving significant results with large samples even when deviation from normality is small, and this is a large sample size (Field 2005). The question is whether the assumption of normality is tenable in the group as a whole or divided by gender. The S-bar chart can guide this decision. The patterns in the X-Bar and S-bar chart are different; they do not go up and down together, and this indicates that the data are not severely skewed.

Table 6.3 Kolomogorov-Smirnov test results (VNRS)

<table>
<thead>
<tr>
<th>VNRS 0 - 10 on movement</th>
<th>Kolmogorov-Smirnov²</th>
<th>Shapiro-Wilk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Statistic</td>
<td>df</td>
</tr>
<tr>
<td>VNRS 0 - 10 on movement</td>
<td>.139</td>
<td>293</td>
</tr>
</tbody>
</table>
This issue about a normal distribution point was highlighted because Hart and Hart (2002) warn that the control limits for measurement data are derived from assuming data are normally distributed. If a special cause occurs it is impossible to know if this is due to the skewed distribution or a true special effect. However, other experts do not suggest avoiding X-Bar charts in such circumstances (Benneyan et al. 2003; Carey 2003).

The next stage in the analysis is to look in more detail at the way the pain scores are displayed on the charts. A mean pain score of four might mask the number of patients who have no pain and, more importantly, those who have moderate or severe pain.

In order to display a percentage of patients with higher pain scores, a P-chart is used. This is because the data are counted rather than measured on a scale. This type of data are called ‘attribute’ data in some texts. The P-chart is similar to the chi-squared test (Hart and Hart 2002). The P stands for percent or proportion. The unit of time is across the horizontal axis. The denominator is usually different every month, as the number and type of surgery varies from month to month. Plotting the denominator rather than the absolute number allows for the changing denominator every month.
Therefore, the upper and lower control limits are uneven or 'stair-stepped.' The centre line is the estimate of the population proportion.

![Control Chart: pain dichotomous](image)

Figure 6.2 P-chart. Proportion (percentage) of patients with pain on movement above 6 on a 0 – 10 VNRS score on first day after surgery

The raw data for the control chart in Figure 6.2 are available in Table 6.2 in section 6.1.1. Once again, only common cause variation is found in the control chart above. There are more than 20 subgroups; thus, it is reasonable to conclude that the process is stable and predictable when pain is measured on the first day after surgery. The first day was chosen, as this is the time patients need to cough and move in bed, and is a time highlighted by others as important in postoperative recovery. McLeod et al. (2006) reported that benefits started to accrue for patients if effective pain relief was provided for a minimum of 12 hours after surgery. Raymond Carey (2003) warns against using P-charts to predict process capability if there is a lot of variation in the
control limits due to different subgroup sizes. Process capability is a term used to describe how well a process is functioning. The variability is around the mean of 28% of patients with a high pain score (VNRS 7 – 10). In summary, if no changes are made to the underlying system, it can be predicted that the percentage of patients with a pain score over 6 will average around 28%, although in any given month it may be as high as 50%. This figure includes patients where the epidural failed in theatre.

The key to success with control charts, according to Hart and Hart (2002), is being able to hypothesise what might be important sources of variation in the process. A further useful tool is to produce separate control charts to compare different streams of data. When the control chart shows only common cause variation, rational subgrouping is a powerful way to analyse the source of the variation. The charts are useful in detecting special cause of variation; however, they do not find the cause. Shewhart (1931) wrote that

'Obviously, the ultimate object is not only to detect trouble but also to find it, and such discovery naturally involves classification. The engineer who is successful in dividing his data initially into rational subgroups based upon rational hypothesis is therefore inherently better off in the long run than the one who is not thus successful.'

(Shewhart 1931 p 299)

The aggregated mean pain scores could hide variation amongst various subgroups, for example, patient gender, age, co-morbidities, the ward, surgeon, and anaesthetist. The data are not presented in a time series design; it is a cross sectional comparison. The X-bar and S chart can be used not only for data in time order, but also for cross-
sectional comparisons. This is the reason the data points are no longer connected on the charts demonstrating rational subgroups.

The chart below (Figure 6.3) demonstrates clearly the mean pain scores for each age group. Once again, there is only common cause variation. The control limits are wide in the younger age group (< 50) because the subgroup numbers are small. Graphically, it supports the findings of the previous chapter that, generally, the mean pain scores are lower with increased age. This could be further analysed by producing control charts for individual age groups to check for variation, although the sample sizes in the younger age groups are too small for such an analysis.

Figure 6.3 X-Bar chart of mean pain scores by age group
Control charts in Figures 6.4 and 6.5 on the next page illustrate how useful information can be gained by drilling down into the data. The raw data are added next to each point in the chart (Figure 6.4), which represents individual anaesthetists. In order to examine different practice amongst anaesthetists, the X-bar and S-chart were constructed using 20 rational subgroups comprising aggregated pain scores from the 18-month data for each anaesthetist. The control rules are more limited than with rational subgrouping because the subgroups are not time ordered. Only the test for one or more points outside the control limits applies. The message from the first chart (Figure 6.4) is that the outcome is stable and predictable. An example of a special cause is illustrated in the second chart on the subsequent page. In Figure 6.5, which is data from a larger study group involving all general surgical epidurals, one anaesthetist is a 'special cause' and warrants further investigation. This could be done by conferring with the anaesthetist to find out what he/she does differently to produce aggregated pain scores lower than those produced by his/her colleagues.
Figure 6.4 Rational subgrouping of individual anaesthetists for general surgery – X-Bar and S-Chart
When one anaesthetist, or other subgroup, is identified as a special cause in relation to other anaesthetists, the next stage is to check if the special cause is stable when viewed separately. An Individual and moving range chart (I-Chart) was constructed for the individual anaesthetist (Dr A). The I-Chart is composed of individual observations, in this case, pain scores, and is called an XMR chart in some texts. The I-Charts require measurement data. The moving range value is the difference between the current and previous observation. The chart in Figure 6.6 shows that the mean pain score for Dr A is 2.6. There is one pain score of 10. Further investigation

Figure 6.5 X-Bar chart of rational subgrouping of anaesthetists for general surgery
revealed that the patient with the high pain score had an epidural for an emergency laparotomy, which was very effectively controlling the abdominal wound pain. However, the patient had undergone a knee replacement 3 days before the emergency laparotomy. His pain from the knee surgery was severe, as other opioid analgesia had been stopped by an ITU consultant.

As a further example of exploring data, an I-chart was constructed for trainee anaesthetists. This group was identified using classical statistical methods as being associated with higher mean pain scores. Figure 6.7 demonstrates a mean pain score of 4.5 - the centre line, with a range from 0 to 10. There is clearly a list of factors that may explain why the trainee anaesthetists have higher mean scores, including how well they are supervised, experience, and time spent in a hospital on rotation, to name but a few. All these factors could be explored separately using control charts. Further,
individual I-charts could be constructed for every anaesthetist in order to check on the stability of each subgroup.

Figure 6.7 Chart of pain scores for trainee anaesthetists

Further X-Bar and S-Charts were constructed in order to stratify data on other process variables. The data are displayed separately by gender, because there was a consistent difference between the genders when data were analysed in the previous chapter. Three factors – whether the patient was an emergency, the rate of epidural infusion and the number of attempts to position the epidural catheter – are used as examples and displayed in Figures 6.8 to 6.13.
Figure 6.8 Emergency patients (male)

Figure 6.9 Emergency patients (female)

Figure 6.10 Rate of infusion (male)

Figure 6.11 Rate of infusion (female)
Figure 6.12 Number of epidural attempts (male)

Figure 6.13 Number of epidural attempts (female)
All processes are stable; there is only common cause variation in each of the six subgroups on the previous 2 pages. Figures 6.8 and 6.9 illustrate the difference in mean pain scores for emergency patients. The mean score was 5.3 for emergency male patients and 4.4 for emergency female patients. The mean score for patients admitted for planned surgery was 4.1 for men and 3.4 for women. Because the subgroups are usually an unequal size, the centreline for the X-Bar chart is obtained by averaging all the observations.

The rate of the epidural infusion is interesting, with higher mean pain scores in both males and females, at the higher infusion rates. For example, the mean pain score in the male group is 7.5 at 13mls per hour and is 7 at 9mls per hour for females. The centre line is 4.3 for men and 3.6 for women. These data might reflect the clinical response to an ineffective epidural, namely, increasing the infusion rate. Figures 6.12 and 6.13 illustrate the variation of subgroups when data are subgrouped by the number of documented attempts to position an epidural catheter. Both gender charts clearly demonstrate the increase in mean pain scores as the number of tries increases.

The process is stable; no subgroups are outwith the control limits. It is important to present this type of information to anaesthetists – they may be unaware of the failure of the technique if they do not routinely follow up patients for the duration of an epidural. Such follow up is rarely practical, and is generally the responsibility of an APS.

It is particularly interesting to note that very low infusion rates of a low concentration of local anaesthetic can provide effective analgesia measured by an 11-point VNRS. This also supports a conclusion reached in the BURP study, in which it was hypothesised that the effectiveness of an epidural was associated with the correct
positioning and management of the epidural catheter rather than the absolute concentration of bupivacaine used.

Figure 6.14 on the following page was constructed using data from the BURP study to illustrate this point. As with the majority of charts illustrated so far, the control limits step up and down, and are wider for the smaller subgroups because there is less certainty when calculating the control limits. The centre line is lower (2.8), but once again the higher infusion rates are associated with the higher pain scores. There are two subgroups, marked in red, which are outside the 3-sigma control limits. Each point, special cause of variation, was investigated and eliminated or adopted depending on whether it was a desirable outcome in clinical practice. The first special cause variation is a mean pain score less than one at an infusion rate of 6mls per hour. The second special cause is above the control limit, with a mean pain score of 5.3 at 10mls an hour. The results were the same when separate control charts were constructed for gender. Two actions can be taken to eliminate the special cause. First, the upper pain score of 5.3 is unacceptable and needs to be investigated. Second, the lower mean score of less than 1 could also be investigated and strategies adopted, as it is a variation that is desired for all subgroups.
Figure 6.14 Rate of epidural infusion and mean pain scores using data from BURP study (n = 100)
Figure 6.15 X-Bar and S-chart for pain scores (females) by surgery
The X-Bar and S-Chart in Figure 6.15 compare pain scores and different operations for female patients. One subgroup, emergency appendicectomy, is a special cause with a mean pain score above nine. It is marked in red on the control chart. This was a small subgroup, as evidenced by the wide control limits. On further investigation, two of the epidurals had failed in recovery and on return to the ward. It would be important to find out why there is a higher epidural failure rate in this group of patients. A similar chart was constructed for men. No special cause variation was demonstrated in males; however, patient subgroups undergoing the following types of surgery all had pain scores above 5: reversal of Hartmann’s, left hemicolecotomy, emergency laparotomy and abdominoperineal resection.

Other control charts, which have not been displayed, were constructed to investigate subgroups on pain scores. There was no special cause variation when data were stratified by surgeons, clinical area, or patients who had experienced pain before surgery. There are an infinite number of other possibilities for stratification, including day of the week, the number of nurses on duty, the experience of the surgeon, and the level of postoperative monitoring, but it is beyond the scope of this chapter to explore these further. The key message is that hypotheses generated by clinicians from experiences in everyday practice suggesting factors associated with level of pain measured on the first day of surgery can be explored using control charts.

6.1.2 Hypotension

So far, the different types of control chart have been used to understand more about mean pain scores and different subgroups. The second outcome of interest in this study was to understand more about subgroup characteristics associated with
hypotension. However, it is important to reiterate that mild pain, that is, better pain control, and an increased incidence of hypotension are associated. This was demonstrated using classical statistics. Unrecognized or untreated hypotension can potentially increase the incidence of unpleasant side effects for individual patients, delay mobilization and increase adverse events associated with epidural analgesia.

First, a P-Chart was constructed of the proportion of patients who were hypotensive measured on the first morning after surgery. The data in Figure 6.16 show a stable system with only common cause variation. Thus, it can be predicted that around 57% of patients will be hypotensive on the first day after surgery in the future.

![P-Chart of proportion of patients who are hypotensive](image)

Figure 6.16 P-chart of proportion of patients who are hypotensive

In Chapter 5, it was reported that female gender was associated with a higher incidence of hypotension; thus, the data have been divided and presented by gender (see Figures 6.17 and 6.18).
Figure 6.17 P-Chart comparing the proportion of male patients who were, and were not emergencies, on hypotension

Figure 6.18 P-chart comparing the proportion of female patients who were, and were not emergencies, on hypotension
There is no evidence of special cause between the subgroups in the charts above. The difference between the proportions of hypotension for planned and emergency patients can be explained by common cause variation. In other words, the variability can reasonably be attributed to random chance. The data on the chart confirm the findings in Chapter 5, namely, that the incidence of hypotension is higher in emergency patients. The incidence is particularly high when subgrouped by gender. Seventy percent of female patients were hypotensive on the first day after surgery. The next step, which is not illustrated, could be to produce separate X-Bar and S-charts for emergency patients.

Figure 6.19 P-chart of proportion of patients who are hypotensive stratified by age

Figure 6.19 illustrates the proportion of patients who were hypotensive, the first day after surgery, stratified by age groups. The data points in Figure 6.20 represent the
proportion of hypotension for individual anaesthetists. However, there were insufficient data in several subgroups, for both anaesthetists and age groups, so it is not possible to infer that the system is stable.

![P-chart of proportion of patients who are hypotensive by anaesthetist](image)

Figure 6.20 P-chart of proportion of patients who are hypotensive by anaesthetist

Data were subgrouped by the epidural drug that was administered (Figure 6.21) and by the rate of the epidural infusion (Figure 6.22). Once again, there is no special cause of variation. Interestingly, the hypotension does not increase with the increased concentration of bupivacaine or the increased infusion rate. In the BURP study, the incidence of hypotension was reduced with the lowered concentration of bupivacaine without affecting the quality of the pain relief. The lowered incidence of hypotension with a higher concentration of the drug or higher infusion rate may be associated with higher pain scores and attempts to rescue an epidural that has failed.
Figure 6.21 P-Chart proportion of patients who are hypotensive subgrouped by epidural drug administered

Figure 6.22 P-chart. Proportion of patients who are hypotensive subgrouped by the rate of the epidural infusion in mls per hour
Figure 6.23 P-chart. Proportion of patients who are hypotensive subgrouped by pain scores from 0 - 5 and 6 and above.

Figure 6.23 shows that patients with a higher pain score, above 5 on movement, are a special cause in that the proportion with hypotension is below the lower control limit. In Chapter 5, this correlation was found to be statistically significant (p = .001) and this finding is confirmed by the P-chart above. The special cause may appear worth adopting, as the incidence of hypotension is significantly reduced. In this case, however, it would not be a desired outcome because it is associated with increased pain. Some factor inherently different in the process has led to this special cause, which is a statistically significant signal. It could be hypothesised that increased pain
results in a less sympathetic block due to a poor epidural, and the increased release of catecholamines resulting in raised blood pressure.

6.1.3 Epidural catheter

The epidural catheter must stay in place for several days until planned removal in order to provide effective pain relief. It was highlighted in the introductory chapters that this is a challenge for the majority of pain services. In an attempt to understand more about the reasons an epidural does not function for the period intended, a Pareto chart was used to illustrate the frequencies for the epidural failing before its planned removal. The Pareto chart graphs the counts of unplanned epidural discontinuation in the order of frequency. The graph demonstrates the ‘Pareto principle’, with approximately 80% of the problems caused by 20% of the types of occurrences.
Figure 6.24 Pareto Chart – reasons for premature catheter removal

In Chapter 5, it was reported that 52% of catheters stayed in situ until planned removal. Figure 6.24 shows the main problems with maintaining the technique. The aim of the chart is to highlight problems that should be examined first (Oakland 1999). The first major problem is that the catheters fall out the second is the number of epidurals that are ineffective, the third is leaking catheters. The other problems are less frequent, referred to by Oakland as the ‘trivial many.’ The results of the statistical analysis in Chapter 5 on this topic highlighted the fact that epidural catheters were more likely to fail early when positioned at T7 or T9. Therefore, in order to make the
largest impact, any improvement should focus on reducing the number of catheters falling out.

Pareto charts were also constructed to display adverse events on the first visit (Figure 6.25) and second visit (Figure 6.26) after surgery, as reported by members of the APS.

Figure 6.25 Pareto chart of adverse events on first day after surgery
It can be seen in both charts that hypotension and the epidural failure are the most common adverse events. Thirteen patients were referred to critical care because more invasive monitoring and drug treatment was required to treat low blood pressure. All these adverse events had the potential to reduce the quality and increase the morbidity associated with epidural analgesia. The Pareto charts are easy to construct and interpret, and, therefore, are a useful tool for presenting data, particularly in clinical practice.
6.2 Quality Improvement

A quality improvement initiative will be demonstrated in the next section based on the results of the prospective study presented in Chapters 5 and 6. At the end of the study in 2007, a quality improvement group was established; the group membership included ward nurses, health care assistants, theatre staff, anaesthetists and physiotherapists. Handheld computer technology was introduced to collect real time data. SPC methods were used to describe the variation in the patients’ experience graphically.

At the first meeting, the group identified the key stages in the patient journey and debated the many points at which an epidural could fail. The staff looking after the patients suggested solutions for improvement. It is imperative that all efforts are made to ensure there is a culture where problems can be discussed without individual blame or retaliation (Garland 2005).

The interventions initiated by the multidisciplinary team have been deliberate attempts to introduce special causes of variation into the data. Improvements in some processes can be seen rapidly; however, sustainable improvements in outcomes, which are important to the patient, will take much longer. Table 6.4 is an example of the ‘ideal’ patient management discussed by the group.
Table 6.4 Optimum management of postoperative epidural analgesia

<table>
<thead>
<tr>
<th>Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients who normally have pain at home are identified preoperatively</td>
</tr>
<tr>
<td>Expectations – patients know what to expect</td>
</tr>
<tr>
<td>Information - appropriate information is given to all patients</td>
</tr>
<tr>
<td>Emergency patients – referral to APS</td>
</tr>
</tbody>
</table>

<table>
<thead>
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Ward

Admitted to an appropriate clinical area
Patient comfortable on admission to ward
Staff knowledge to assess level of pain on movement
Problems first post-operative night are anticipated and avoided
Infusion rates adjusted as required
On call available for advice at all times
Epidural catheter stays in place
Rate not reduced in response to hypotension
Rapid response to a pain score above 1 (0 – 3 score)
Side effects are controlled
Weekend support from APS/on-call anaesthetist
Immediate recognition and treatment of complications

Day 1

Pain scores measured on movement
Epidural infusion rates/drugs adjusted in response to increased pain
Patient co-operation
Physiotherapy – able to co-operate, not restricted by pain
Sat out of bed
Side effects, such as PONV, recognized and controlled
Surgical team co-operation and communication with MDT
Appropriate and timely prevention and/or management of hypotension
Patient satisfied with pain and symptom control

Day 3

30 metre walk with physiotherapist
Epidural Stopped

As planned
Regular oral analgesia prescribed and given
Regular measurement of pain continues
Patient would choose to have an epidural again
Instructions if back pain etc.
Discharge analgesia – equivalent to analgesia on ward.

The group first directed their efforts towards reducing the number of epidurals that were not removed as planned, but that were falling out prematurely. A number of strategies were adopted: reporting the findings to the anaesthetists, standardizing catheter fixation and educating ward staff. In order to decrease the percentage of patients in severe pain, it was ensured that patients were asked routinely about their level of pain when admitted to hospital, as over 60% of patients took regular painkillers at home. Despite an ongoing mandatory education programme, the group believed that nurses and doctors did not monitor pain scores effectively. A pain-score card was devised by the group and attached to every non-invasive blood pressure machine. This is just a small example of the potential benefits of continuous measurement and learning from data. In addition, it avoids the pitfalls of before-and-after studies described earlier in this study. Allan Garland (2005), in a paper describing the complexity of improvement in an intensive care environment, makes the point that only 15% of problems are because of inadequate performance by individuals, and 85% of opportunities for improvement relate to flaws in the system that restrict individuals’ ability to perform their jobs well. Any quality improvement
initiative needs to be by teams, rather than nursing measuring one set of measures and surgeons tracking a different set of measures (Plesk 1999).

6.3 Discussion

The examples of data analysis presented in this chapter have demonstrated the versatility of control charts and their potential benefits if adopted by Acute Pain Services (APS). The tools of classical statistics describe only the past (Carey 2003). The time-ordered data have been used for prediction and the rational subgroups for comparison. The advantage of control charts is that they provide an opportunity not only to decide if a process is functioning at an acceptable level, but also to predict future performance. In classical statistics, researchers can be accused of ‘data fishing’ (Campbell and Machin 1993); in SPC, there are no concerns about selecting too many ways to subgroup the data (Hart and Hart 2002). SPC allows expert knowledge to be harnessed in order to hypothesise what might be important in contrast with classical statistics where objectivity is mandatory. As with classical statistical methods, it is possible to make type 1 and type 2 errors. As discussed in Section 4.7.5.7, if the chart suggests random influence, it is possible that some type of non-random pattern emerges and so a type 1 error is made. Conversely, a type 2 error occurs when a non-random influence does exist yet is not illustrated on a control chart.

When a special cause occurs, it is important to investigate it. If the special cause is considered harmful, the correct action is to eliminate it. Conversely, if the special cause is deemed beneficial, the appropriate reaction is to learn and adopt. For example, it was shown that one anaesthetist was a special cause of variation (Figure 6.5); his/her practice was inherently different from that of his/her colleagues.
However, if the process demonstrates only common cause variation, which was illustrated both with mean pain scores (Figure 6.1) and the incidence of hypotension (Figure 6.14) the whole process needs to be changed, a big undertaking for complex interventions such as epidural analgesia. In clinical practice, it is not possible for all changes to happen at once, so a clinical team or researcher needs to focus on the achievable. For example, the Pareto chart indicated the key problems with epidurals that are not removed as planned. These can be the focus for future changes. Future performance can also be predicted using the control charts. Carey (2003) recommends using control charts to indicate whether a target or goal has been achieved in clinical practice, as parametric tests are not particularly helpful for guiding improvement initiatives.

To conclude, the data presented in this chapter have formed the baseline from which to measure the effects of future changes. Data collection took place over a long period, which strengthens the ability of the researcher to attribute any future change to interventions made for improvement in the process. The key to success in the use of the control charts has been the ability to predict sources of variation. Understanding the difference between acceptable and unacceptable variability in data has the potential to improve clinical practice and generate ideas for further research.

In the next and final chapter, the results are discussed and debated.
Chapter 7 Discussion

'If we look critically at the available evidence, the generalised use of postoperative epidural analgesia in the majority of patients undergoing laparotomy has little benefit over standard opioid techniques and retains the potential to do harm.'

(Low et al. 2008 p 3)

7.1 Introduction

Without doubt, epidurals can provide excellent postoperative pain relief when evaluated in efficacy studies, but evidence is mounting to support the viewpoint in the above quotation, which was published in an editorial in a UK anaesthetic journal. It is clear that both in the UK and internationally, the anaesthetic and pain service community are becoming more divided in their views about the effectiveness and safety profile of epidural analgesia. For example, Chilvers et al. (2007) in a Tasmanian hospital changed from the routine use of epidurals for abdominal surgery to a multimodal intravenous and oral regime. They reported comparable analgesia between the two techniques with a reduction in serious complications and side effects. However, British anaesthetists Jack and Scott (2007) collected data on a cohort of 2837 cardiac surgery patients with thoracic epidurals. They reported that there were no serious complications in their cohort of patients. Jack and Scott are proponents of epidurals and firmly believe that the benefits of thoracic epidurals outweigh the risks. Nightingale et al. (2007), investigating the efficacy of patient-controlled epidural analgesia, concluded that epidurals are effective after major abdominal surgery in the elderly when patients are nursed on a general surgical ward. They did not report the incidence of adverse events. It is not difficult to find published data supporting both viewpoints. It could be hypothesised that one reason evidence questioning the value of
epidural analgesia is appearing only now is the well-known publication bias, with unpublished research papers outnumbering published papers by 4 to 1. Negative outcome studies take on average 8 years to be published rather than 4.8 years for positive results (Rowbotham 2008). The results of this current study support the views of Low et al. (2008) expressed in the quotation at the start of this chapter, particularly that patient selection is more appropriate than the generalised application of the epidural technique.

Before discussing the results of this observational study, it is important to reiterate the aim of postoperative epidurals: effective pain relief that is safe with minimum side effects. It is a complex intervention, involving a large number of healthcare professionals across a period of several days. The epidural can fail at any number of points, from planning the procedure to removal several days later. Failure can happen before the patient leaves recovery, equipment can malfunction, staff may not recognize problems and respond appropriately, adjustments of treatment are required, and, of course, the patients must be compliant with the treatment. All these variables have already been acknowledged as key factors in epidural management (Rowlingson 2005). In addition, it has been recognized that pain relief is much more than a visual analogue score measured at rest. Actively taking part in rehabilitation is now the standard for pain relief (Rowlingson, 2005). Such activity is not possible if severe pain or postoperative hypotension is inadequately treated at any point in the postoperative period. Yet, the most recent UK Royal College of Anaesthetists information leaflet about epidurals for patients (May 2008) does not reflect this complexity. For example, although epidural failure is mentioned, the true incidence of up to 30% is not made clear. Thus, it is questionable whether patients are genuinely aware of both the risks and benefits when consenting to the technique. Therefore, it is
questionable whether their consent to the technique is truly valid. It is also questionable whether nurses, anaesthetists and surgeons are fully aware of both the risks and benefits of epidural analgesia.

This study was designed to describe the incidence of pain, hypotension and other epidural-related side effects after major abdominal surgery and to identify factors associated with effective analgesia and postoperative hypotension. A full description of patient characteristics was presented in Chapter 5, which will allow other services to make an informed decision about the relevance of the results to their own practice. The type of surgery is listed, and all patients who did not have an abdominal incision were removed from any analysis. The database of McLeod et al. (2006) also included only abdominal surgery, of which the percent for bowel surgery was 55%. This compares with 75% in this study. Many of the original meta-analysis, which has been much quoted to support epidural effectiveness, included other types of surgery, such as orthopaedics, gynaecology and trauma; thus, the clinical groups were so heterogeneous that the findings may not reflect the reality of practice following abdominal surgery.

The key findings from the study are;

* There was no correlation between chronic pain before surgery and the level of postoperative pain.
* Male gender was associated with increased pain across all age groups in this research.
* Severe pain (over 6 on an 11-point scale), was associated with emergency patients, male gender, the absence of hypotension and an epidural that did not continue until planned removal.
• No statistically significant differences were found between the mean pain scores and the position of the epidural catheter.

• Significantly lower mean pain scores were found in patients who were 70 years of age and over compared to patients below the age of 70.

• Patients experienced higher pain scores when the epidural failed before discharge to the ward than did patients discharged with an epidural in situ. This difference was statistically and clinically significant.

• Fifty-six percent of patients were hypotensive on day 1. A strong correlation was found between effective epidurals and hypotension despite optimal fluid management. Low pain scores are a predictor for postoperative hypotension.

The results presented in Chapters 5 and 6 will be discussed and debated in three broad categories; first, those associated with the patient; second, those associated with the technique itself; and third, those associated with the postoperative management. It will be contended that the findings of this study support the urgent need for a national re-evaluation of epidural analgesia in this particular group of patients because it is still questionable whether the benefits outweigh the risks of epidurals for patients after major abdominal surgery.

7.2 Patient factors

7.2.1 Preoperative pain score

Good evidence has been established to show that preoperative pain is a risk factor for increased postoperative pain (Macrae 2008). In this study, preoperative pain scores
were not a predictor of higher postoperative pain. However, only 30% of patients
were able to quantify their level of pain before surgery. In addition, there was
significant room for bias, as patients were asked about pain after surgery. Stone and
Broderick (2007) suggest that memory of pain is unreliable. Furthermore, several
factors are likely to affect the accuracy of retrospective pain reports (Terry et al.
2007). Nielsen et al. (2007) propose three key reasons why there is an association
between preoperative and postoperative pain: first, there are psychological and
cultural factors, such as experience; second, the sustained nociceptive input present in
chronic pain may lead to changes in the central nervous system; and third, there may
be problems with tolerance and hyperalgesia if the patient has taken long term
opioids. However, effective epidurals differ in their action from other analgesic
techniques because they obtund, or dull central sensitisation and pain induced organ
dysfunction (Wheatley et al. 2001). Essentially, the local anaesthetic works on a broad
range of targets, including sodium, potassium and calcium channels, which can be
blocked with a resulting anti-hyperalgesic action. There may be an additional, but
unintentional benefit from the systemic uptake of local anaesthetics (Strichartz 2008).
The spinal cord is the first relay site in pain pathways from the brain to the spinal cord
(D'Mello and Dickenson 2008). Therefore, epidural analgesia may be a good choice
for patients who have chronic pain before surgery. Not to oversimplify the case, if a
patient has postoperative pain, it can be simply blocked at the spinal cord level by a
local anaesthetic. As discussed throughout this thesis, pain is a very subjective
experience and the level of pain experienced is an interpretation of the nociceptive
input influenced by genetic factors, memories, and emotional and cognitive factors
(Tracey 2008).
The results of this study were supported by the fact that higher postoperative pain scores were associated with all other analgesic techniques, namely, intrathecal and systemic opioids, and were positively correlated with preoperative pain scores. It was highlighted in the introductory chapters that chronic pain increases with age, but the results of this study suggest that older patients reported lower mean pain scores and a lower incidence of severe pain.

The presence of preoperative pain as a factor for predicting long term (chronic) postoperative pain was not assessed in this study. However, there is some evidence that epidural analgesia started before surgery and continued into the postoperative period results in significantly less pain when measured six months later compared to patients with intravenous morphine (Australian and New Zealand College of Anaesthetists and Faculty of Pain 2005). Causation of this finding is complex and beyond the scope of this study, but is potentially a fruitful area for future research. However, the shift towards shorter hospital stay may operate against such a study design in the UK.

7.2.2 Emergency patients

Emergency patients are the group of patients who are rarely recruited to randomized controlled trials. An attempt was made to recruit emergency patients in the BURP trial, but it was difficult for a number of reasons. For example, emergency patients are often too unwell to be approached to discuss consent for studies, or will not have time to read and discuss study information. In the final analysis of the BURP study, 6% of patients were emergencies; this was higher than in the majority of the published controlled trials presented in the introductory chapters. Twenty-six percent of patients
in this current observational study were emergency patients. This compares favourably with the estimation of up to 30% of patients who present for emergency surgical resection of colorectal tumours nationally as emergencies (Hospital episode statistics 2007). Therefore, the study reflects the real life patients treated by an APS more accurately than would a controlled trial with a study intervention.

Just over 40% of patients were ASA 3 or 4 in this study, which means they were high risk patients. Emergency patients are rarely in a position to read information leaflets or attend preoperative clinics, so they are less well prepared for surgery. However, it was reported in a national French survey of acute pain that one in three patients could not remember information they were given preoperatively (Fletcher et al. 2008). The emergency patient group had higher pain scores. The higher pain scores were related to a higher incidence of side effects such as nausea and sedation, which all affect the quality of the recovery for individual patients. Therefore, emergency patients should be one focus for improving the quality of epidural analgesia, as they have not been well studied and the results suggest they experience poorer pain control.

7.2.3 Gender

The proportion of females to males was 47:53 in this study, and thus was consistent with other pain studies involving abdominal surgery (Wijeysundera et al. 2008; McLeod et al. 2006). This reflects the higher incidence of major surgery in men in general both locally and nationally. The overall incidence of colorectal cancer nationally is higher in men than in women; for example, the male to female ratio is 7:4 for rectal cancer and holds for all age groups (Card and Logan 2003). Women suffer a disproportionately greater number of pain disorders than do men. Meta
analyses of studies with experimental pain have found that women tend to be more 'pain sensitive,' that is, women report more pain to stimuli that both sexes experience as painful, but the difference is small (Derbyshire 2008).

Male gender was associated with increased pain across all age groups in this research. The Dundee group (McLeod et al. 2006) did not analyse their data separately by gender, but did recommend that gender, amongst other factors, should be investigated as an independent predictor of the quality of epidural block. The gender differences are a unique finding to this study. When data were reviewed with regard to the database of all pain service techniques in 2006, (n = 826) no difference in mean pain scores was found by gender, with a mean of 5.5 for men and 5.8 for women. The same issue was looked at in the BURP study data: mean scores were 2.7 for men and 2.9 for women. Ready (1999) looked at gender differences using a large pain service database. He found that, in a matched group, men and women reported similar pain scores on movement (6.0), but women chose to use approximately 20% less morphine via a morphine PCA. The reasons for the differences found in the current study are likely to be multifactorial, but could also be as simple as difference in body size, because the rate of infusion is similar for males and females and does not allow for women being smaller. Snidvongs and Holdcroft (2008) envisage that individual prescriptions in the future should be based on gender in addition to physiological and pharmacological variables.

7.2.4 Age

The mean age of this study population was 66.6 (range 17–93); on average, the women were slightly older than were the men. The mean age and age range are
remarkably similar between this study and the research involving 1359 patients published by McLeod et al. (2006): mean age 66.5 with an age range 22 to 97. The mean age of patients in the BURP study was 67.8 (range 29 - 89). In a study of 205 patients undergoing bowel surgery, who had an epidural for postoperative pain relief, the median age of the patients was 68.6, with an age range from 10 to 88 years (Nightingale et al. 2007). The results of this current study suggest that older patients report lower levels of pain than do younger age groups. This is particularly interesting in light of a BBC headline: ‘NHS should get tough over pain.’ This was a BBC news headline heralding a Help the Aged publication on the 14 November 2008. The report was called ‘Pain in older people; reflections and experiences from an older person’s perspective.’ The charities’ research found that 53% of people believed that health care professionals dismiss pain in older people as old age, and 47% were not confident that health professionals could offer effective pain relief. In addition, 55% of those studied wrongly believed that pain is an inevitable part of growing older. Over half thought that healthcare providers, who leave older people ‘languishing’ in pain, should be penalized. The charity is calling for the Department of Health to recognize pain as an urgent public health issue. However, this recognition is not new; the International Association for the Study of Pain (2008) has been campaigning for such a profile for several years with a Global Year against Pain in older people in 2006-2007 to raise awareness worldwide. A theme running throughout the thesis has been pain management in older patients. The results have also shown that pain experience after major abdominal surgery is more complicated than recognizing pain in older people – younger age groups suffer too, and the results suggest men experience more pain than do women. A study by a Swedish nurse researcher found a similar inverse predictor of pain: lower pain scores with increasing age. Increased
severity of pain was associated with younger age groups in patients after prostatectomy with an epidural (Wickstrom 2005). The mean age of the patients in the Wickstrom study was 62 (range 43 – 72). In a study of the effects of age on the severity of pain in patients undergoing hysterectomy (n = 77), older women reported much lower mean pain scores on movement, that is, 4.3 v 7.1. Similar findings were found in a male population (Ready 1999). Patients requiring rescue analgesia after knee replacement were in the younger age groups in a study of intrathecal morphine for postoperative pain relief (Bowrey et al. 2005).

It appears that epidurals have the potential to work on older patients (70 and over). There was no difference found between different age groups in the volume of epidural drug administered. Anatomically, the lower pain scores in older age groups could be explained by the spread of local anaesthetic in the epidural space. A given volume of local anaesthetic tends to give a higher block in the elderly than in younger patients (Atkinson et al. 1993). Infusion rates should be adjusted to reflect this. Different strengths of local anaesthetics drugs could help for different types of surgery and different age groups. Conversely, a standardized solution is recommended to increase the safety of the technique (NPSA 2007; Royal College of Anaesthetists 2004) so may not be practical on general surgical wards.

It has been suggested that the increased pain suffered by the elderly generally is in part due to poor pain assessment. In this study, a member of the APS who is skilled in pain assessment conducted all the patient assessments. Data collection in the McLeod et al. (2006) paper involved collecting epidural charts and manually transferring the data to an electronic database. Therefore, many different individuals over the period of their study, with varying experience, will have assessed the patients’ pain in a 4-point scale. Japanese investigators (Ishiyama et al. 2007) reported that elderly patients
had significantly lower pain scores on coughing in a study of patient-controlled epidural fentanyl \((n = 80)\). They also reported that patients, both young and old, chose to wait until their pain scores were reaching 40 on a 100mm scale before pressing a bolus button, and suggested that patients rarely self-medicate to achieve complete pain relief.

It is now known that older people have a diminished ability to respond to the stress of constant pain. Reasons for this include physical and cognitive impairments and altered pharmacokinetic and pharmacodynamic factors (Karp et al. 2008). It is, therefore, important to optimise pain relief in the elderly and ensure that an effective epidural stays in situ. Older patients are excluded from clinical trials without justification, and are thus underrepresented in clinical research (McMurdo et al. 2005) despite the fact that there is a greater number of elderly people alive at the start of the 21st century than at any time in history. Reasons for exclusion include comorbidities and multiple medicines, which are common in older age groups and described in the introductory chapters. The result of this disparity is that evidence from trials does not apply to the elderly.

7.3 The technique

7.3.1 Positioning the epidural catheter

It was shown in this study that there was a higher epidural failure rate perioperatively when the epidural was inserted with the patient asleep, was male and in their 60s. It was highlighted in previous chapters that most investigators do not either document or include such patients in data analysis. The Australian MASTERS study (Rigg et al. 2002a) that heralded the shift in enthusiasm for thoracic epidurals, did quantify and
include perioperative failure in the data analysis. This intention-to-treat analysis by the Australians stimulated a debate about the appropriateness of such an approach (de Leon-Casasola 2003).

Multiple attempts at positioning an epidural are associated with complications (Meek 2004); there is also the adverse affect on the patient of prolonged discomfort just before major surgery. In a prospective study of 637 patients, anaesthetists with more than 5 years experience had a significantly higher success rate at positioning an epidural. In addition, patient positioning in the anaesthetic room with good spine flexion was important for successful epidurals (Meek 2004). It is intuitive to think that positioning would be harder in the elderly. However, it was those in their 60s who had the highest failure rate in this study, and in over 20% of them there were more than two tries. Nevertheless, it was clear that when the epidural was not positioned as planned, in 35 patients in this study, the postoperative recovery was significantly and clinically more painful than for those patients with an epidural – a difference of 2.5 on the 11-point scale.

7.3.2 Experience of the anaesthetist

It can be difficult to elicit the grade of anaesthetist who positions the epidural catheter, because anaesthetic charts are completed with the consultant in charge of the case although an accompanying trainee anaesthetist may well have inserted the epidural under supervision. This was found to be true when discussing cases with consultants. Jack and Scott (2007) state that their hospital’s success in cardiac surgery with epidural analgesia is in part due to an experienced consultant positioning the epidurals. In addition, in their unit, there is continuous patient assessment by
experienced nursing and medical staff. Perhaps this relates to an anaesthetist’s ability
to site the epidural accurately and consistently. The control charts used in this current
study to look at subgroups highlighted the practice of one anaesthetist with
significantly lower mean pain scores. This would have been difficult to find using
classical statistics. Nurse specialists play a vital role in reporting both failures and
successes to their anaesthetic colleagues. One way forward may be to restrict the
operator to a few experienced anaesthetists. However, while this improves the current
patient experience, how would the next generation of anaesthetists learn to master the
technique?

7.3.3 Composition of the epidural solution

There is robust evidence that the combination of a local anaesthetic and lipophilic
opioid improves the quality of epidural analgesia compared to either alone (Wheatley
et al. 2001). Many studies in the 1990s focused on the ideal combination of drugs to
be administered rather than the effectiveness of the technique in the postoperative
period. In fact, the BURP study was designed to determine if a lower concentration of
bupivacaine could produce good quality analgesia and fewer side effects. We are still
far from identifying the ideal solution (Meek 2004), but once again, it will be argued
that it is the performance and maintenance of the technique rather than the drugs used
that is the key to success.
7.4 Postoperative management

7.4.1 Pain

Traditionally, the decision to position an epidural and the perioperative management of the patient has been the domain of the anaesthetist. Nurses are most involved in documenting and managing postoperative pain, side effects and adverse events.

In this study, severe pain (over 6 on an 11-point scale), was associated with emergency patients, male gender, the absence of hypotension and an epidural that did not continue until planned removal. Deciding on an acceptable pain score and then using this as an outcome is open to debate. Bauer et al. (2007) used a score of below 6 on movement to quantify effective epidurals in a double blind trial of epidural and PCA for thoracic surgery. The authors considered a reduction of 2.5 on an 11-point scale to be clinically relevant. Liu and Wu (2007), in a systematic review of patient-reported outcomes, documented that a change of 1.3 or 1.4 on an 11-point VNRS may be a difference that is noticeable to a patient, whilst a reduction of 2 to 2.4 may correlate to a greater and more meaningful reduction in acute pain. However, the 11-point scale is a unidimensional scale, and as such, may not capture the complexity of pain (Caraceni 2002). McLeod et al. (2006) used a large clinical database of epidurals for abdominal surgery to explore the time to first experience of pain. The Dundee anaesthetists concluded that extending this period beyond 12 hours improves the overall quality of epidurals, as benefits accrue beyond the duration of the block, but this is at the expense of an increase in side effects. Basing this assumption on scores that were not prospectively and directly collected from the patients, as occurred in the study by McLeod et al. (2006), is questionable. There is evidence that patient charts do not represent real events. For example, one study of physicians in an emergency
department found that a patient’s chart is a poor surrogate marker for pain assessment and management. The physicians underestimated pain and, although most tried to assess pain, the documentation was poor (Chisholm et al. 2008). In this study, all recorded measures of pain were collected by one of the APS members, and pain scores on the 0-3 scale took into account whether the patient was able to sit out of bed and cooperate with physiotherapy. In the BURP study, too, pain was assessed both by the APS and by the physiotherapists before and after they treated the patient.

Only 30% of patients achieved the quality marker of pain relief for at least 12 hours in the McLeod et al. study. This compares with 55% on the day of surgery and 42% on the first day with no or mild pain in this study. Nevertheless, pain relief is much more than a pain score; it is safety and the limitation of side effects, and although not examined here, acceptability to the patient. In clinical practice, it is common to record a patient’s score as above 6, but the patient is comfortable, and can sleep and cooperate with treatment. The patient can be unwilling to accept further increments in treatment, particularly if associated with an increase of side effects.

In this study, the control charts indicated that, on average, 28% of patients had a high pain score measured on movement on the first day after surgery. McLeod et al. (2006) reported that only 40% of their patients experienced pain relief for more than 6 hours after surgery. It is important that, in future studies, not only the outcomes are reported, but also the emphasis is shifted to any changes made being fully documented so that other services can learn both what does and does not improve the quality of postoperative pain management.
7.5 Blood Pressure

It is clear that many factors affect blood pressure; amongst these is pain, which is a powerful vasoconstrictor, and, as such, raises blood pressure and prevents hypotension. In effect, good analgesia contributes to hypotension by a resulting reduction in endogenous catecholamine release (Ready 1999). Mcleod et al.'s (2006) analysis of blood pressure was based on a systolic of less than 100mmHg or less than 90 mmHg, which is an arbitrary measure not related to the patient's normal blood pressure. The incidence of hypotension was not a primary outcome of their study, but McLeod found an increased incidence of hypotension with prolonged pain relief (more than 12 hours). The results of this study presented here are more specific. Data were collected about both the incidence and treatments for hypotension. Blood pressure was defined as low if it was less than 30% of the normal systolic to allow for the variation in normal pressure associated with age, co-morbidities and other factors. For example, a systolic of 95 can be normal for one patient while a systolic of 180 would be normal for a different patient. There was also routine documentation of whether the patient was sat out of bed, and of any side effects related to hypotension, such as feeling faint, light-headed, or nauseated.

A key finding in this prospective study confirmed the findings from the BURP study, that is, that low pain scores are a predicator for postoperative hypotension. Fifty-six percent of patients were hypotensive in this study; the incidence was 62% in the BURP study. This was despite a regime of optimum fluid management and observation. An obvious explanation for this high incidence of hypotension would be inadequate fluid replacement and the resulting hypovolaemia. The sympathetic block associated with epidural analgesia would then render the patient vulnerable to hypotension, as vasoconstriction, which normally occurs to compensate for
hypovolaemia, can no longer occur. All the patients in this study had a central venous catheter inserted; central venous pressures were measured on all the patients, and fluids were administered according to a long-established protocol. In this study, only 30% of patients were mobilized on the first day after surgery; therefore, it is crucial that studies on effectiveness measure this functional aspect of recovery. One of the benefits of epidurals is facilitating rapid recovery programmes, which will not be possible if the patients cannot mobilize because of orthostatic hypotension. In those patients who were hypotensive, an increased incidence of adverse events occurred. Wheatley et al. (2001) combined the results of studies in order to estimate the incidence of hypotension, and, with approximately 9000 patients, reported an incidence of only 6.8%. This depended on the concentration of local anaesthetic, on how hypotension was defined and on whether a patient bolus was used. The conclusion in the BURP study was that the incidence of hypotension has increased over time because epidurals have become more effective than when services were established. It is also hypothesised that hypotension was not a primary outcome in early epidural studies. Fluid management alone is not the answer to managing hypotension and there may be a need to consider the use of vasopressor therapy (Low et al. 2008; McLeod et al. 2006; Duncan et al. 2005). If this cannot be provided, then epidural analgesia may not be the optimum and safest method of pain management. Not all those who may benefit from noradrenaline receive it, because the facilities are not available in the majority of UK hospitals. Walton et al. (2006) conducted a postal questionnaire of UK anaesthetic departments. Sixty percent of departments reported difficulty accessing a bed on critical care for a patient with an epidural. It has been suggested that higher mortality rates of general surgical patients compared to cardiac surgical patients may in part be due to the lack of availability of critical care facilities
The mortality rate for general surgery is 9.9%, but only 3.5% for cardiac patients who are admitted to cardiac critical care units as routine. The mortality rate is much higher in some high risk general surgical groups, many of whom are never admitted to critical care beds (Goldhill and Down 2008). When APSs started, clinicians were perhaps not as aware of the problems associated with epidurals, and believed the ward environment was safe if supported by a pain service. The international best evidence document (Australian and New Zealand College of Anaesthetists and Faculty of Pain 2005) suggests this is still the case. Perhaps now is the time to learn from cardiothoracic services, where all patients return to a critical care facility as routine, and provide this level of care for all epidural patients. However, provision of additional critical care facilities has a cost implication, and without proven benefits in outcome or reduced hospital stay, the epidural technique may be judged too costly by managers. Critical care beds are a scarce resource in the UK and there does not appear to be a national consensus on which type of surgical patient should be admitted after surgery (Goldhill and Down 2008). However, there is some evidence that the higher nurse patient ratio, invasive monitoring and constant availability of anaesthetic staff should result in good pain control, and the prevention of side effects, which should improve postoperative outcome (Jack and Scott 2007). Thirty-six percent of patients were admitted to critical care in this study, but the decision for this was largely due to the individual anaesthetist and the availability of beds.

The problem with managing hypotension with intravenous fluids, particularly on a general ward, is that the treatment is often ineffective and may have deleterious effects if not monitored closely. There is an association between excess intravascular fluid volumes and increased morbidity and mortality. Excess fluid can lead to
respiratory failure, myocardial dysfunction, prolonged ileus and sepsis (Gobindram and Gowrie-Mohan 2007). Interestingly, these are the same harmful effects that epidurals have the potential to avoid and so improve outcomes. Studies now suggest that a restrictive fluid regime in the postoperative period favours a better outcome after abdominal surgery (Low et al. 2008). Conversely, hypovolaemia can result in splanchnic hypoperfusion leading to inadequate perfusion of the gut (Chappell et al. 2008). In other words, both too little and too much fluid could be harmful, so the aim must be to maintain the circulatory volume whilst not overloading the patient. The UK Intensive Care Society has published a best practice document (British Consensus Guidelines on Intravenous Fluid Therapy for Adult Surgical Patients) developed by surgeons, anaesthetists, renal physicians and researchers (Powell-Tuch et al. 2008). The document was written because of concerns about postoperative fluid overload, and it was envisaged by the authors that, with more accurate fluid therapy, patient outcomes would improve. Recommendation 20 states that ‘in high risk patients undergoing major abdominal surgery, postoperative treatment with intravenous fluid and low dose dopexamine should be considered’ (Powell–Tuch 2008 p 26). The British National Formulary (2008) recommends dopexamine and other similar drugs, which are sympathomimetic inotropes, should be confined to critical care beds where invasive haemodynamic monitoring can be undertaken. There is no evidence in this important consensus document of any nurse involvement yet nurses generally manage fluids in the postoperative period. Worryingly, no mention of managing the patient with an epidural in the postoperative period is included. The take-home message is that this debate about hypotension and how to treat it is not resolved. More importantly, treatment has to be carried out by all members of the multidisciplinary team – anaesthetists, nurses, surgeons, intensive care physicians and managers.
Epidural can provide superior analgesia, allowing early mobilization and early intake of food. In addition, postoperative epidural analgesia has been reported to provide improved health-related quality of life compared to conventional analgesia (Carli et al. 2002). This study has highlighted the problem of hypotension, which occurs despite optimum fluid monitoring and management. There is a clear and strong association between lower pain scores and the higher incidence of hypotension. An epidural that provides good analgesia is strongly associated with hypotension.

7.6 Safety

There is good evidence that ‘high tech’ pain relief can and does contribute to harmful adverse events (Bandolier 2008). The patients in this study were in the higher risk group for the development of epidural abscess or haematoma, because they had a longer duration of catheter placement, had thoracic epidurals, belonged to the older age groups or because of comorbidities, such as diabetes (Jack and Scott 2007). Several patients were identified with infection at the site. No patient had an epidural abscess or haematoma, but perhaps this was because there had been increased vigilance. Most studies documenting the incidence of these rare events had a low number of study participants and were retrospective. According to Wheatley et al. (2001), there have been no reports of an epidural abscess with a catheter in situ for two days or less. The problem with such an assumption is that all cases in the literature have been reported by individual anaesthetists and there may be many reasons for not reporting an event.

The epidural infection rate might reasonably be expected to increase with more successful epidurals because the epidural catheter stays in situ for longer than it does.
with unsuccessful epidurals. The last few decades have been notable for the gradual but consistent increase in estimates of the incidence of epidural infections. As the estimates go up, the risk benefit scales adjust. For example, a 1980s study of 50,000 epidurals reported three serious adverse events – an incidence of 0.006% (Kane 1981). A prospective French study of over 30,000 patients showed an incidence of 0.04% (Auroy et al. 1997). By 2007, Cameron and colleagues, in a report on 8000 cases in one centre, estimated the incidence of epidural abscess of 1:1368 patients and an incidence of major neuraxial complications of 0.1%. Christie and McCabe (2007) identified six cases of epidural abscess, three haematomas and three patients with meningitis (n = 8100). Importantly, the level of the catheter was associated with infection, with 2.8% for thoracic epidurals compared to 0.8% lumbar. Cameron (2007) states that measures can be taken to reduce the risk further, as one case of paralysis brings into question the advantages of the technique. For example, the use of chlorhexidine for skin preparation has the best profile for reducing the incidence of the colonization of catheters by organisms such as staphylococci (Meek 2004).

The role of the nurse in this debate is extremely important. Nurses must recognize the signs of rare complications and act quickly and decisively. Wheatley et al. (2001) stated that the introduction of APSs has facilitated the early recognition of epidural problems, but in fact what is important is early recognition by the ward nurses, as under resourcing means the APSs are not available out of hours; this equates to approximately 148 hours per week during which a patient is without immediate access to the expertise of a pain service. The 2005 UK national audit (Royal College of Anaesthetists 2007) was set up to establish the incidence of major neuroaxial injury and crucially a denominator for the number of epidurals, which was not known up to this point in time. This is because epidural abscesses/haematomas are rare and
individual studies are not powered to detect them. A news report in the Nursing Times (Taylor 2007) voiced concerns that pain management is now an ‘option’ rather than compulsory in preregistration nursing. Therefore, it is important to question whether all nurses have the essential skills to look after patients with an epidural.

7.6.1 Side effects

The incidence of all side effects with a score above one, including nausea and vomiting, pruritis, motor block and sedation was low. Thirst scores were higher and reflected the higher incidence of hypotension. An increase in side effects was related to the increased pain scores, which would reflect the higher use of intravenous morphine to control the pain. A higher incidence of nausea (25%) and pruritis (37%) was related to the use of intrathecal opioid analgesia. The problem with intrathecal analgesia is it gives only short term (less than 24 hour) pain relief. However, in this study, it was supplementary to epidural analgesia.

7.6.2 Technical problems

Problems with maintaining an effective epidural have been highlighted throughout this study. The rate of catheter-related failures was 10% in the McLeod study (2006), and a 12% failure rate was reported by Lui et al. in 1998. Rowlingson (2005) reported a 32% failure rate from a large database of epidural patients (n = 26,000). Marret et al. (2007) revealed an overall failure rate of 40%. A recently published study (Popping et al. 2008) analysed epidural data from a German APS database (n = 14,233) for the eight-year analysis to 2006. Strong proponents of epidurals, the German authors had a ‘malposition’ rate of 7%, plus major complications of three epidural haematomas and one epidural abscess. Popping et al. still concluded that epidurals were safe and
effective on general wards despite the incidence of four paralysed patients, but also concluded that close supervision by an APS was mandatory.

Omitting to present data regarding the inability to position the epidural, or not reporting technical problems with the catheter, gives a false impression of the success of the technique. This study has documented failure throughout the patient journey from the time it was decided to use an epidural. In addition, the APS documented details about the cause of failure, for example, occlusion, surgical request, leaking and so on. It will be described later in this chapter how collecting this type of information can become routine. This offers the potential for information to be shared by different services. It was also interesting to note that the catheter fell out more frequently when positioned between T7 and T9. A quality improvement initiative could work towards reducing this incidence. An epidural that fails and goes unrecognized often means no analgesia, which may lead to an increase rather than a reduction in mortality particularly with coexisting respiratory problems (Counsell 2008). Furthermore, patients will have been subjected to the risks of epidural catheter insertion without accruing any benefit.

In summary, to answer McLeod et al.’s. question about what makes an epidural work for major abdominal surgery in the real world of clinical practice, first and foremost, it is obvious that the communication and knowledge of a multidisciplinary team is needed in order to optimize the effectiveness and safety of the technique. It works better when the surgery is planned, and when the patients are female and belong to older age groups. The epidural is more effective when positioned by a consultant. In addition, there is variation in pain scores between different types of surgery. Ready (1999) reported that the type of operation has a predictive value regarding the amount of opioids used after surgery in the analysis of a large acute pain service database. It
can work well with few adjustments at low infusion rates. It is more likely to work for
the intended duration if sited above T7 or below T9, as the catheters are less likely to
fall out prematurely. Unfortunately, when the epidural does work, hypotension is
likely to limit its effectiveness, as low pain scores are highly correlated with
hypotension.

Studies comparing epidural with intravenous analgesia, including PCA, report
statistically improved analgesia. The difference is higher when the epidural catheter is
positioned appropriately for the surgery (thoracic rather than lumbar) but Liu and Wu
(2007) report that the studies do not reach clinical, rather than statistical, significance.
Higher than 2 on an 11-point visual analogue scale, or 20 on a 0-100 scale is accepted
as a clinical improvement. They also found insufficient evidence to determine if the
type of analgesic technique, level of pain and incidence of side effects influenced the
quality of recovery. To date, no studies have been uncovered that have assessed the
quality of recovery as a primary endpoint (Liu and Wu 2007). A decrease in a pain
score with an increase in side effects may not be perceived as an improved outcome
by patients. Yet this is exactly what is happening with epidural analgesia where
decreased pain scores are associated with increased hypotension and the resulting
nausea and light-headedness.

Marret et al. (2007) conducted a systematic review of RCTs designed to compare
epidural analgesia and intravenous opioid analgesia after bowel surgery. They
concluded that the epidural analgesia had adverse effects, and did not shorten length
of stay despite lower pain scores and a reduction in ileus. The reduction in ileus is
important from the aspect of patient comfort. This is interesting, as it has been shown
that ileus and pain keep patients in hospital longer. The review did not include
emergency surgery, and in the majority of the papers after 2000, a rehabilitation programme was used, which reflects the current national trend.

It was described in Chapter 3 how positive results can be inflated when an intention-to-treat design is not employed. A further example as a reminder was a comparison of epidural versus intravenous opioids after major spinal surgery (n = 72) in which the researchers excluded 14 patients from the analysis. Reasons for withdrawing patients were dural tap, inability to position the catheter, and catheter occlusion. The authors of this study reported superior analgesia for the epidural group (Schenk et al. 2006). Had the 14 patients been included in the epidural group, the results might not have been so positive.

It is perhaps the time to consider a UK multi centre trial comparing thoracic epidural analgesia to optimum systemic analgesia. In addition, primary outcomes should include the functional aspect of pain relief, and the incidence of outcomes important to patients. In controlled trials to date, side effects and complications are generally secondary outcomes, with as many as half the trials reviewed considered inadequate in the reporting of this aspect (Australian and New Zealand College of Anaesthetists and Faculty of Pain 2005). The key message from the international document was that ‘multiple outcome measures are required to adequately capture the complexity of the pain experience and how it may be modified by pain management interventions’ (p29). There is certainly a growing awareness of the limitations of epidural analgesia (Low et al. 2008) and the results of this study add more knowledge about those limitations.

One strength of this study was the focus on patient-reported outcomes as well as process measures. It has been suggested that attempts to break down a complex intervention to its component parts amounts to an ‘irretrievable loss of what makes it
a system' (Hawe et al. 2004). Essentially, Hawe et al. warn that it is hard to capture the essence of an intervention simply by collecting data on all the processes. An epidural, therefore, is more than the sum of its parts, but in order to present the results in this study each variable was presented individually. Further, APSs must revisit the debate about where to manage safely the hypotension that is inextricably linked to an effective epidural. Other services may not be aware of the true incidence unless they monitor a patient’s blood pressure at frequent intervals when they first sit out of bed. This debate may be spurred by surgeons with the move to an enhanced recovery programme and their belief that fluid restriction improves outcomes for abdominal surgery. Certainly epidural analgesia can aid recovery, but when studied in isolation, it becomes clear that it has not had the effect of reducing postoperative morbidity that was claimed in earlier studies.

The research questions have been answered, but new questions have been generated. The incidence of pain, hypotension, and other epidural-related side effects has been described using both classical statistics and control charts. Factors associated with effective analgesia and postoperative hypotension have been identified. Based on these results, the important measurements of an optimum acute pain assessment have been identified in order to prepare for computerized data collection, described later in this chapter.

This study was designed to improve understanding of current practice. One strength of this pragmatic study is that it was conducted on patients who represent the full spectrum of the population to which the treatment might apply (Godwin 2003). Essentially, the study reflects what happens in clinical practice; thus, it is strong on realism. Only major abdominal surgery was included to increase clinical homogeneity. Data collection was based on direct patient report rather than on chart
review. The functional aspect of recovery was also taken into consideration. This study has added knowledge to the debate about epidurals by identifying characteristics associated with the technique's success and failure in everyday clinical practice. The context of the study has been fully described; therefore, other APSs can interpret the data. In addition, the data has been presented in a novel way, demonstrating the use of control charts to learn from data trends over time and advance the knowledge about epidurals. This study also included outcomes that will matter to patients, such as pain and side effects. Discussing the NHS Quality and Outcome Framework, Starfield (2008) points out that outcomes that are important to patients are not yet the focus of research. Starfield uses an example from diabetes research, where outcomes that are important to patients are ascertained in only 18% of clinical trials. The majority of the focus is on the measurement of surrogate outcomes, such as blood glucose levels. Acute pain research has had similar problems, with outcomes that are important to patients not yet the primary focus of research.

7.7 Methodological constraints

This study has several methodological constraints, which were acknowledged in the planning stage. No causal relationship can be determined between the factors presented in this study. Additionally, although the number of variables collected was large, it still captured only a small part of the overall pain experience. Data were not collected for those patients who refused to consent for an epidural. This would be an interesting topic for future study. Although perhaps not generalizable to a UK population, American researchers (Ochroch et al. 2007) found that acceptance of epidurals is strongly affected by race (non Caucasian) and higher socioeconomic
status. In addition, other factors influenced acceptance. For example, those who had an epidural for childbirth were less likely to accept an epidural, and the opinion of family and friends was a further influence.

The 11-point pain score captures only a limited amount of information about a patient’s pain experience. A further limitation is that patient characteristics were considered and reported one at a time, whereas in reality, patients have multiple characteristics simultaneously (Kent and Hayward 2008). However, this problem is not unique to this current study; unknown confounding factors weaken any study of this type. Nevertheless, unknown confounding variables would have appeared as special cause variation in the long series of observations in the control charts (Diaz and Neuhauser 2005), and this has improved the rigour of the study.

The next step after this observational study, armed with information about factors associated with pain scores and hypotension, is to improve pain management in the ‘real world’ where local knowledge is relevant. The final section of this study suggests ways of doing this.
7.8 The future

'The formal methods of summative evaluation simply are not relevant when the hypotheses are many and vague; when alternatives need to evolve over time; when local knowledge is relevant and contains perhaps more transferable wisdom than bias; when the confounders are not defects that spoil our learning, but are themselves interesting and comprise the seeds of further progress; and when the effects sought are large enough that we ought not to have a hard time detecting the signal within the noise.'

(Berwick 2005 p 321)

It is important to strive to improve postoperative pain relief for a variety of reasons, including mounting evidence that ineffective pain management can lead to long term pain problems for the patients. It is particularly important to optimize epidural analgesia for both patient comfort and patient safety. Patients nursed with an epidural are the biggest acute pain investment in terms of theatre time and critical care facilities. Evidence of effectiveness is conflicting, and the failure rate is high. It is clear from the results of this study and other published research that, to date, we are not delivering the current best practice either locally or nationally due to organizational, cultural, resource and 'conflicting interest' issues (Macrae 2008). This is known. What is not currently known are the changes that can be made to improve epidural analgesia, or whether it is possible to deliver effective analgesia to every patient in clinical practice. If it is not possible to improve, the use of epidurals routinely after major abdominal surgery should be revisited. In the last section, it was suggested that a multi centre trial should be planned comparing thoracic epidural with multimodal analgesia. This will take several years to plan and conduct. In the interim,
it is proposed that all acute pain services should work towards a quality improvement programme. One way of achieving this, which can be implemented by other services, is described in this final section.

7.9 Information Technology

Dr W Edwards Deming, a student of Shewhart and a quality improvement expert, made the point that to improve the quality of the river we should not study the river itself but go upstream and study the streams that feed the river (Hart and Hart 2002). In order to understand properly more about the quality of postoperative pain relief, all services need to collect data continually rather than perform a snapshot audit. Pronovost et al. (2004) argue that the greatest opportunity for improving healthcare in the next 25 years is by learning how to deliver existing effective therapies rather than discovering new ones. This view has been echoed in the pain literature (Australian and New Zealand College of Anaesthetists and Faculty of Pain 2005; McQuay and Moore 1999). In order to do this, a way must be found of both measuring and improving the quality of postoperative analgesia as part of the everyday work of a pain service. Measurement is fundamental to any change, but it has already been established that this would be prohibitively difficult with a pen and paper system because the data sets are extremely large. It could be time consuming to analyse this large data set, which would affect an already heavy workload. However, it would, be possible to collect a large amount of data using handheld computer technology. There are potential barriers to the implementation of handheld data collection, which it is important to acknowledge first. The National Information Technology System for the English National Health Service has paradoxically hindered rather than helped
researchers developing specialised databases, particularly for quality improvement. It has been suggested that this is because the immediate needs of the policymakers and managers have prevailed over the needs of clinicians. The effect at a local level has been a reluctance to support any isolated information technology developments (Black 2008). Further, there are valid concerns about confidentiality, particularly when patient-identifiable data is collected on handheds.

Handheld computer systems are increasingly used in the medical profession in a variety of clinical settings (Chan et al. 2004; VanDenKerkhof and Goldstein 2003; Goldstein and VanDenKerkhof 2002). A wide range of software is available internationally. Computer face scales have been developed to measure paediatric pain (Fanciullo et al. 2007). Computer assessments of symptoms are being used in chronic pain clinics (Provenzano et al. 2007). Studies have been completed that report that such systems can enhance data collection and the accessing of information (Chan et al. 2004). Canadian anaesthetists have already published work on using real time data collection within an Acute Pain Service and have reported the benefits in terms of quality of data and treatment outcomes (VanDenKerkhof and Goldstein 2003). For example, when a service uses paper data collection, there is likely to be a difference between the novice and the more experienced practitioner regarding patient interaction and the quality of documented information. All members of the acute pain team and trainee anaesthetists can use a handheld computer to record patient assessments. These can be programmed to ask the same questions at every patient visit. As a result, a more consistent quality of data is produced with the use of real-time data collection (Chan et al. 2004). There is some evidence that implementation of real-time systems has had positive effects on treatment outcomes (VanDenKerkhof and Goldstein 2004). The advantages are that the results can be obtained
concomitantly with data collection, effectively eliminating the lag between data collection and data analysis. Information Technology (IT) can be used to look at the entire patient population as the database builds.

Canadian investigators David Goldstein, Elizabeth VanDenKerkhof et al. have published regularly about using IT in an APS. Their most recent publication (2007) describes the results of a 12-month data capture involving 2874 patients admitted to an APS. Over half their patients received PCA and 20% received epidural analgesia. Overall, 35% of patients reported pain scores above 5 on a 0 – 10 scale. The researchers cite the ready access to data as one of the advantages of using handheld technologies, as it offers their service a significant benefit for quality improvement initiatives. They found it is an easy task to produce a description of the APS population. Importantly, using computer technology offers researchers the potential to conduct an in depth analysis of pain outcomes associated with different pain modalities, medications and adverse events (Goldstein et al. 2007).

Once the data have been collected, the aim is to learn from the data and improve the quality of postoperative pain relief, which will be described in the next section.

7.10 Quality Improvement (QI)

Quality Improvement has a long history in the manufacturing industry. ‘Like all scientific studies, quality improvement research can be viewed as probes for knowledge that involves testing interventions by manipulating variables and observing the effect upon the variables’ (Speroff and O'Connor 2004 p 17 18). The goal of QI is to improve delivery of scientifically based care. Such care is derived as part of a system, so there has to be understanding of how the system performs.
Berwick (1996) has called the approach to system improvement, which is so difficult in a complex system, pragmatic science. The epistemology of QI is learning through trial and effect. Outcomes are the function of the process in QI, and to influence this, researchers and practitioners need to understand the influence of a multitude of factors. The researcher or nurse specialists dealing with acute pain have a role as advocates for improvement. Bias can be minimized by high standards for data collection and analysis. Hypothesis testing by a group who work in real life clinical situations, has its foundations in action research, which was traced back to Lewin in 1946. Lewin wrote that ‘theory should not only be used to guide practice and its evaluation but that, equally important, results of evaluation should inform theory in a cyclical process of fact finding, planning action and evaluation’ (cited in Iles and Sutherland 2001 p 66). The Plan–Do–Study–Act (PDSA) cycle used in healthcare quality improvement is one form of action research. A multidisciplinary group Plan a change, Do it in a trial, Study the results using control charts, and Act by either implementing, modifying or discarding the change (Carey 2003). For example, the percentage of patients in severe pain (27%) presented in Chapter 6 (figure 6.2) is a stable process, but is not acceptable. Therefore, the process needs to be changed by implementing and testing a series of changes initiated by a multidisciplinary team. It is clear that if we look at the outcome of mean pain score and hypotension, several changes in the process are needed before a change in outcome will be seen. In other words, immediate changes can be seen in process measurements, such as the number of epidurals falling out, but changes in outcome will take much longer to reveal.

The knowledge of those who contribute to a quality improvement group is crucial to an understanding of what is happening in real clinical situations. In order for a group of clinicians to learn more about what does and does not work in clinical practice,
control charts can be used because they are easily understood. Plotting the data over time, and presenting the variation graphically is a simple way to determine if the changes are making a difference. The patterns in control charts can show more than can methods reliant on averages, which can mask variation (Pronovost et al. 2004). The many confounders are a rich source of interest. The existence of a special cause in a control chart is the opportunity to create a natural experiment. For example, special causes were shown in the control charts in Chapter 6. One anaesthetist was outside the control limits with a lower mean pain score. Similarly, the Pareto charts presented in Chapter 6 can be presented to a group who can then suggest and discuss reasons why the epidurals are falling out and suggest strategies for change. The Plan-Do-Study-Act cycle supports learning in action. Promising changes are identified and others avoided (Berwick 1996). How the changes are made is generalizable, in other words, useful to other APSs. Reporting an outcome in isolation is not. Dr Seers (2007) voiced a concern that the results of RCTs into complex interventions imply results are robust, but they do not, in fact, translate into real world clinical practice. The results of this current study add weight to the argument that the promising results from early epidural studies do not translate into real world clinical practice.

7.11 Conclusion

To conclude, it is clear from the research presented that the success of an epidural for postoperative pain relief is dependent on the interlinking of multiple people, departments and other factors. The challenge for APSs is to recognize this complexity and encourage the multidisciplinary team to work together. There is no shortage of evidence about techniques or drugs that work to control pain. However, there are
problems delivering such techniques safely and effectively in the real world to the majority of patients. Epidural analgesia has to be part of a whole recovery process that is more than reducing pain scores and side effects. This study has contributed to knowledge by describing epidural pain control after major abdominal surgery, and identifying predictors associated with the level of pain and incidence of hypotension.

In addition, the application of Statistical Process Control methods has been demonstrated and shown to offer great potential to learn more about both the process of change and outcomes in an Acute Pain Service. This simple but rigorous approach to data management can potentially guide improvement, which other services could adopt. The problem of vast amounts of data collected can be overcome by the introduction of bedside data collection using handheld data technology. The use of computers in pain medicine has great potential to improve the quality of care provided for patients and their widespread use is imminent (Jamison et al. 2007). Further, the 2008 Darzi report called for measures to include ‘Patient Reported Outcome Measures’ to obtain patients’ views on the success of their treatment. This will be readily achievable with handheld computer technology. According to the National Nursing Research Unit (2008), the public is concerned about the quality of nursing care delivered to patients, and the nursing profession is keen to demonstrate the nursing contribution to the quality of patient care. In order to do this, the profession must work towards routinely measuring nursing. Ongoing measurement and improvement is vital because, ultimately, the cost of inadequate postoperative analgesia is large in both human and economic terms.
18 October 2006

Mrs Fiona Duncan  
Nurse Specialist/PhD student  
Blackpool Victoria Hospital NHS Trust  
Whinney Heys Road  
Blackpool  
FY3 8NR

Dear Mrs Duncan

Full title of study: The introduction of a continuous quality improvement programme to optimize delivery of acute pain management techniques.  
REC reference number: 06/Q1309/89

Thank you for your letter of 28 September 2006, responding to the Committee's request for further information on the above research and submitting revised documentation.  

The further information was considered at the meeting of the Sub-Committee of the REC held on 06 October 2006. A list of the members who were present at the meeting is attached.

Confirmation of ethical opinion  
On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites  
The Committee has designated this study as exempt from site-specific assessment (SSA). There is no requirement for [other] Local Research Ethics Committees to be informed or for site-specific assessment to be carried out at each site.

Conditions of approval  
The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents  

Acting Chairman: Mr J. Dunlop  
Chief Executive: Mr R. Piggiewell  
Professional Executive Committee Chair: Dr D. Dawson  
www.stockport.nhs.uk

An advisory Committee to NHS North West

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The final list of documents reviewed and approved by the Committee is as follows:

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<td>Supervisors CV Dr C Haigh</td>
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Research governance approval

You should arrange for the R&D department at all relevant NHS care organisations to be notified that the research will be taking place, and provide a copy of the REC application, the protocol and this letter.

All researchers and research collaborators who will be participating in the research must obtain final research governance approval before commencing any research procedures. Where a substantive contract is not held with the care organisation, it may be necessary for an honorary contract to be issued before approval for the research can be given.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

06/Q1309/89 Please quote this number on all correspondence

With the Committee’s best wishes for the success of this project

Yours sincerely

Dr P Wilkinson
Chair

Email: Davina.Halliday@lasca.nhs.uk

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

Standard approval conditions

Copy to: Dr M Pilloti
The University of Salford
Research and Graduate office
Faraday House,
Salford

An advisory Committee to NHS North West
CONSENT FORM

Research title: Quality improvement in an Acute Pain Service.

Name of Researcher: Fiona Duncan

1. I confirm that I have read and understand the information sheet dated ............... (Version 3[1]) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that direct quotations may be used as part of this study and that all quotes used will be anonymised.

3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason.

4. I agree to take part in the above study.

________________________  ____/____/  ______________________
Name of Participant        Date                Signature

________________________  ____/____/  ______________________
Researcher                 Date                Signature

When completed: 1 copy for participant; 1 for researcher site file.
References


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