Safety aspects of local anaesthesia for intraocular surgery

Thesis submitted for the degree of Doctor of Medicine at the University of Leicester

by

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Bibliography
Safety aspects of local anaesthesia for intraocular surgery

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ABSTRACT

Purpose: The main objectives were: (i) to describe the current usage of local anaesthesia (LA) for intraocular surgery in the United Kingdom, (ii) to assess the incidence and severity of adverse events in patients who had LA, (iii) to audit the extent to which national LA safety Guidelines were being followed, (iv) to provide background information for a review of these Guidelines. Methods: A large, prospective observational study. All ophthalmology operating theatres in the National Health Service of the United Kingdom were invited to participate. During the initial week, participants were asked to complete an anonymous Report Form for every LA administered for intraocular surgery. Reporting of complications only continued for a total of three months. To validate the response rate, the theatre records of randomly-selected hospitals were inspected. Results: In the initial week, 2,827 correctly completed forms were returned. Participation rate was calculated to be 72.8% (95% Confidence Intervals: 56.4%, 96.3%). Anaesthesia techniques were: 70% LA alone, 5.8% LA with sedation, and 24.2% general anaesthesia. LA techniques were: 65.6% peribulbar, 16.9% retrobulbar, 6.7% sub-Tenon's, 4.4% subconjunctival, 2.9% topical, and 2.3% combinations. In this week, reported incidence of all adverse events within the orbit was 2.7%, and for 'systemic' adverse events it was 0.9%. In three months, an estimated 65,100 LA's were given (95% CI: 48,500, 81,700). Reported incidence of serious 'systemic' adverse events was similar for all LA techniques. 18 events were described as "life-threatening", 3 further patients had epileptic fits, and one patient's subsequent death was attributed to LA. The study
design introduces some bias from under-reporting, making it difficult to assess the true incidence of severe events. **Conclusions:** Local anaesthesia, using various techniques, is frequently used for intraocular surgery in the United Kingdom. Serious complications are rare, but at least 100 “serious systemic” adverse events occur annually.

**Summary**

**Background:** Local anaesthesia (LA) is commonly used for intraocular surgery. The LA is usually given by means of a periocular injection, which can be administered by an ophthalmologist or an anaesthetist. LA is generally safe, but life-threatening or sight-threatening complications may rarely occur. In order to encourage safe administration of LA for intraocular surgery, Guidelines were published, jointly by the Royal College of Anaesthetists and the College of Ophthalmologists, in 1993 (Anon. 1993). These Guidelines state that all patients undergoing intraocular surgery under LA should have a thorough pre-operative assessment, similar to that for patients who are to have general anaesthesia (GA). Patients should be closely monitored, intravenous access should be obtained, and an anaesthetist should be present in case resuscitation is required. These recommendations were not universally accepted, for several reasons: some have suggested that the guidelines are over-cautious, in view of the rarity of life-threatening complications. Some hospitals were unable to provide enough anaesthetists to cover all ophthalmology surgery. In view of the controversy surrounding the Guidelines, the two Royal Colleges agreed to perform a national audit. The aims were to “audit the guidelines”, and provide background information for a revised edition of the Guidelines.

**Purpose:** The main aims of the Survey were:

- To describe the current usage of LA for intraocular surgery in the United Kingdom.
- To assess the extent to which the 1993 Guidelines were being followed.
• To assess the incidence and severity of complications of LA.
• To provide background information for a revised edition of the Guidelines.

Methods: This was a large, prospective observational study. The Survey involved all ophthalmology operating theatres in the National Health Service of the United Kingdom. The main period of data collection took place over three months in late 1996. During the first week of the Survey, participants were asked to complete a Report Form for every LA administered for intraocular surgery. The forms included questions on patient demographics, LA technique, adherence to the Guidelines, and complications. For the remainder of the three-month data collection period, respondents were asked to report only those LA’s which had complications. This strategy was chosen because it was likely to give a high participation rate, while still providing enough information to estimate the incidence of rare complications. All aspects of the Survey, including the validation protocol, were designed to ensure anonymity for those respondents did not wish to be identified. Validation of the response rate involved inspection of the theatre records of a representative sample of hospitals, for the initial week of the survey.

Data from the initial week were used estimate the prevalence of LA, and the relative usage of the different LA techniques. These data also allowed estimation of incidence for the more common complications, and the degree to which the Guidelines were being followed. Figures from the initial week were extrapolated, to estimate the number of LA’s given in the three-month Survey period. These data, along with adverse event reports from all three months, were used to estimate the incidence of rarer complications.

Results: In the initial week, 2,827 correctly completed forms were returned. Participation rate in this initial week was calculated to be was 72.8% (95% Confidence Intervals: 56.4%, 96.3%). Anaesthesia techniques for intraocular surgery were: 70% LA alone, 5.8% LA with sedation, and 24.2% general anaesthesia. LA techniques were: 65.6% peribulbar, 16.9% retrobulbar, 6.7% sub-Tenon’s, 4.4% subconjunctival, 2.9% topical, and 2.3% combinations. Of patients who were given LA, 96% were monitored, 84% had an anaesthetist available in theatres in case of a
problem, and intravenous access was established in 60%. In 7% of cases, the Guidelines for pre-operative assessment and per-operative management were complied with in full.

In the three months of the survey, an estimated 65,100 LA’s were given (95% CI: 48,500, 81,700). There was a bias toward under-reporting of minor adverse events, in that the reported incidence in the second part of the Survey was much less than was predicted from the initial week. There appeared to be less under-reporting of the more serious adverse events, in that the incidence in the second part of the Survey was within the range predicted by the first-week returns. In the initial week, the incidence of orbital haemorrhage was 1.4%, and the overall incidence of adverse events affecting intraorbital structures was 2.7%. Incidence of “systemic” adverse events in this week was 0.9%. In three months, there were 22 reports of “severe” systemic adverse events (Defined as either: (i) described as “life-threatening” by the respondent, (ii) epileptic seizure in a patient who was not taking anti-epileptic medication, (iii) patient transferred directly to an Intensive Therapy Unit post-operatively, (iv) death attributed to the adverse event). Serious adverse events were associated with all LA techniques. Analysis of safety precautions (eg placing of an intravenous canula) suggested that most of these adverse events had not been anticipated.

**Conclusions:** Local anaesthesia (LA) is frequently used for intraocular surgery in the United Kingdom. A variety of techniques are used, and safety precautions are taken in most cases. Only a minority of cases complied fully with the 1993 Guidelines. Serious complications of LA are rare, but at least 100 “serious systemic” adverse events occur annually in the United Kingdom.
1. Introduction:

Local anaesthesia (LA) is frequently used for eye surgery. LA is highly acceptable to the majority of adult patients, and there is a general perception that LA is safe. However, serious complications can rarely occur, particularly when LA is injected into the orbit. For example, the needle may penetrate the globe or optic nerve, and this may result in blindness. If the needle enters the optic nerve sheath, anaesthetic may track back to vital centers in the brainstem, and cause the patient to stop breathing. If the patient is not managed properly by artificial ventilation, death may occur.

Early recognition of these serious complications, accompanied by prompt, appropriate action, may save the patient's eyesight or life. It is therefore important for clinicians to be alert to the possibility of such complications, and to be prepared to take any remedial action that is required. The ideal LA would be 100% effective and free of all complications, and the pursuit of this ideal has led to the refinement of established LA techniques, and the development of new techniques.

In order to encourage safe administration of LA for intraocular surgery, a working party was set up, comprising representatives of the Royal College of Anaesthetists and the College of Ophthalmologists. Guidelines were published in 1993 (Anon, 1993). These Guidelines state that all such patients should have a pre-operative assessment of general health, including blood tests in most cases. During the operation, the patient should be monitored by pulse oximetry, electrocardiography, blood pressure measurement, and verbal contact. Intravenous access should be obtained, and an anaesthetist should be present in case resuscitation is required. These recommendations have not been universally accepted, partly due to the shortage of anaesthetists in some hospitals, and partly due to the perception that LA is generally safe.

It was against this background that the National Survey of Local Anaesthesia for
Ocular Surgery was conceived. The main aims of the Survey were:

- to measure the usage of general and local anaesthesia for ocular surgery in 1996
- to measure the prevalent usage of the different LA techniques
- to assess the prevalent practices regarding LA safety
  \((e.g.\) pre-operative testing, monitoring and involvement of anaesthetists)\)
- to audit the extent to which the 1993 safety guidelines were being followed
- to estimate the incidence and severity of adverse events associated with LA
- to provide the basis of a review of the published Guidelines

These aims were addressed by a three-month, prospective survey that involved all operating theatres in the National Health Service of the United Kingdom.

2. Background and Literature review

2.1 What is local anaesthesia (LA)?

Local anaesthesia (LA), also known as regional anaesthesia, is anaesthesia for a certain region of the body. LA is used in most surgical specialties. The main objective of LA is for the region to be free of pain (analgesia). Often it is desirable to prevent voluntary movement (akinesia).\(^{(Johnson 1994a)}\) In certain circumstances, it may appropriate to give the patient a sedative. Many sedative agents will also induce amnesia, so that the patient does not remember the procedure. The alternative to LA is general anaesthesia (GA), which affords analgesia, akinesia, and amnesia. LA is generally considered to be safer than GA, and has many advantages for the patient, surgeon, anaesthetist and hospital manager.\(^{(Atkinson 1961; Campbell et al 1993; Dixon 1996; Forrest 1994a; Sharrock 1999)}\)

Local anaesthetic agents work by blocking transmission of action potentials in nerve. In principle, an LA will block any nerve it comes into contact with (motor, sensory, autonomic), so the effect of an LA will depend to a large extent on the anatomical
location at which the LA is given. The various LA drugs have different properties in terms of potency, speed of onset and duration of effect, differential sensory/motor effects, and adverse event profiles. (Johnson 1994a)

There are a variety of ways of getting the LA agent to the desired site. LA may be injected into the area to be anaesthetized, or the relevant nerves may be targeted at any point along their path. Anaesthetic may be applied directly to skin or membranes (topical anaesthesia), or LA agents may be used to irrigate during surgical procedures. All of these strategies have been used for intraocular surgery. Techniques for eye surgery range from topical anaesthesia (anaesthetic eye-drops alone, providing analgesia only), to deep injections which block all sensory, motor and autonomic nerves of the orbit. Sedatives, if used, range from a mild anxiolytic to deep sedation which is similar in many ways to GA.

2.2 History of local anaesthesia for intraocular surgery

Anaesthesia for intraocular surgery has a long history (Atkinson 1934; Atkinson 1961; Greenbaum 1997). Around 2,600 years ago, the Indian surgeon Susrutra described a technique for couching of cataracts, and outlined the use of inhalational anaesthesia. Later, surgeons in northeast Africa used carotid compression to induce transient cerebral ischaemia prior to couching. In the first century AD, the Greek physician Dioscorides used a soporific sponge, containing an extract of mandrake boiled in wine. (Greenbaum 1997) The use of narcotic “sleep-sponges” (spongia somnifera) continued through the Middle Ages, though their use was limited by the small difference between an effective dose and a life-threatening overdose.

There were few developments in cataract surgery until the 18th century. Extracapsular cataract extraction was described by Daviel in 1748. (Hubbell 1902) and five years later Sharp described a planned intracapsular extraction. These procedures used a large corneal section, and little was available for anaesthesia, except for soporific drugs. Surgeons needed strong assistants to restrain their patients, and had to perform the surgery in as little time as possible. Not surprisingly, most cataract surgery continued to be performed by couching, and many patients preferred to avoid surgery altogether.
The discovery of general anaesthesia (GA) was to transform surgery. Around the turn of the 18th/19th century, several anaesthetic agents were discovered, including nitrous oxide, ether and chloroform. However, it was not until 1846 that GA, using ether, was successfully demonstrated. (Garrison 1922) Almost immediately, the first cataract extractions were performed under GA, using either chloroform or ether. (Atkinson 1934) General anaesthesia solved the problem of intra-operative pain, but it brought its own problems. GA involved some risk to life, and postoperative coughing or vomiting could damage the operated eye.

The age of local anaesthesia began in the second half of the 19th century. The hollow needle, invented in 1853, made it possible to inject an agent into a specific part of the body. (Brown 1886) Cocaine was isolated from coca leaves in 1860, and its numbing effect on the tongue was described that same year. (Neimann, 1860 #2772) The anaesthetic effect of cocaine on the skin (von Anrep 1880) and eye (Coupard and Bordereau 1880) was described in 1880. In 1884, the use of cocaine for retrobulbar, (Knapp 1884) sub-tenon’s (Turnbull 1884) or topical (Knapp 1884; Koller 1884; Turnbull 1884) anaesthesia was first described. Knapp’s 1884 paper in Archives of Ophthalmology gives a dramatic account of the speed with which this new concept spread among the surgical community, and also gives insight into the difficulties of operating without a local anaesthetic. Soon afterwards, cocaine’s potential for systemic toxicity was realized, with reports of syncope, hyperstimulation, hallucinations, and even death. (Greenbaum 1997) An additional problem was corneal epithelial toxicity, drying, and prolonged anaesthesia leading to exposure keratopathy and ulceration. (Grant 1974; Greenbaum 1997) These problems limited the usefulness of cocaine LA for intraocular surgery.

Cocaine continued as the only available LA agent until the early part of the 20th century, when safer alternative LA agents were developed. (Atkinson 1961) Procain (Novocaine®, a synthetic derivative of cocaine) was the first synthetic LA to be described, in 1905 (Atkinson 1961). Adrenaline, a potent vasoconstrictor, was isolated in 1901. (Takamine 1901) By reducing blood flow to the anaesthetised area, adrenaline was found to enhance the efficacy of an LA injection (Krohn et al 1995), and reduce the risk of systemic LA toxicity. The use of the new, safer LA agents, given in conjunction with adrenaline, led to a revival of interest in LA.
The concept of a nerve block was described in 1884, when it was observed that injecting LA around a nerve led to anaesthesia in the region supplied by that nerve. (Hall and Halsted 1884) However, it was not until 1914 that van Lint first described a method of blocking the facial nerve supplying the orbicularis oculi muscle. (van Lint 1914) Several other facial nerve blocks have since been described. (Atkinson 1953; Nadbath 1963; O'Brien 1929; Schimek and Fahle 1995; Spaeth 1987) Most involve blocking branches of the nerve as it courses from the ear to the eyelid, but Nadbath's technique (Nadbath 1963) is an injection at the stylomastoid foramen. Injecting LA into this area carries the risk of also blocking the vagus, glossopharyngeal and accessory nerves, with potentially serious consequences. (Feibel 1988; Koenig et al 1988; Lindquist et al 1988; Wilson and Ruiz 1985) Injections at the stylomastoid foramen were still used by around 10% of UK consultant ophthalmologists in 1989 (Campbell and Spalton 1992), but this technique appears to have declined significantly since then. The O'Brien (mandibular ramus) and van Lint (eyelid) type blocks remain in common usage.

Another milestone in the evolution of ocular LA was the use of hyaluronidase. In 1949, Atkinson reported that the addition of hyaluronidase to the LA mixture aided the diffusion of LA, giving better anaesthesia and akinesia. (Atkinson 1949) The need for hyaluronidase remains a subject of controversy, and there are still several publications each year on the subject.

The use of sedation has continued into the 20th century. It is particularly common in the United States, where the majority of patients have an intravenous sedative for surgery under LA. (Norregaard et al 1997) In Britain, sedation is less common: a 1991 survey showed that 45% of responding ophthalmologists preferred sedation when using LA, and less than a quarter used the intravenous route. (Hodgkins et al 1992)

For most of the 20th century, the most common method of giving LA for intraocular surgery was the retrobulbar injection. (Atkinson 1934; Atkinson 1961; Greenbaum 1997) (see following section for description of techniques). Peribulbar injections were first used in the early 1970's (Kelman 1997), and were popularized by a publication in 1986 (Davis and Mandel 1986) Both of these methods carry the risk of needle
perforation of the eyeball, or inadvertent subdural injection giving brainstem
anaesthesia. Thus, new and safer methods were sought. Sub-Tenon's anaesthesia,
though described in 1884,(Turnbull 1884) was largely forgotten until the 1990's
(Furuta et al 1990; Greenbaum 1992; Hansen et al 1990; Stevens 1992). Sub-
conjunctival anaesthesia was also rediscovered around this time.(Furuta et al 1990;
Petersen and Yanoff 1991; Smith 1990) These 'new' methods were more acceptable
because of advances in surgical technique. The development of small-incision cataract
surgery gave a more controlled operating environment, so that surgeons were more
tolerant of eye movements. The logical next step for modern surgery was topical
anaesthesia,(Grabow 1993) in some cases with the addition of intracameral
anaesthetic.(Koch 1997) Some surgeons are now performing small-incision
phacoemulsification without any anaesthesia at all.(Pandey et al 2000). All of these LA
techniques remain in current use.

The refinement of LA techniques has been paralleled by improvements in general
anaesthesia (GA). For the earlier part of the 20th century, LA was used for the majority
of intraocular surgeries,(Elliott and Morrison 1975) mainly because GA caused ocular
problems due to postoperative retching, straining etc. With improvements in drugs and
techniques, use of GA became more widespread, and a 1975 British textbook stated
that, for intraocular surgery, “standard techniques of balanced general anaesthesia are
now used in the vast majority of cases”.(Elliott and Morrison 1975) Recent
questionnaire surveys have documented the decline of GA for cataract surgery in the
UK. In 1984, 63% of responding consultant ophthalmologists used GA exclusively for
cataract surgery,(Wong and Steele 1985) though by 1991, only 37% stated that they
used GA ‘frequently’ (more than 75% of cases).(Hodgkins et al 1992) This return
toward LA is due to a variety of factors: LA has been shown to be highly acceptable to
patients and hospital staff (Dixon 1996; Sharrock 1999), and allows more efficient use
of staff and theatre time(Konovitch 1997). Rapid recovery from surgery means that LA
is the favoured technique for day-case surgery (Dixon 1996; Sharrock 1999)[Strong,
1991 #2840]. Improvements in surgical technique, particularly the development of
small-incision surgery, afford a more controlled operating environment and therefore
allow the use of minimal anaesthesia.
The development of new LA techniques was largely driven by a desire for increased safety, improved acceptability for the patient and the surgeon, and efficient use of theatre time and other resources. The drive to improve standards of care has included the development of patient monitoring methods, and of clinical audit. This study was performed in order to contribute to yet higher standards of safety for patients undergoing LA for intraocular surgery.

2.3 Brief description of the different LA techniques, and their possible complications.

2.3.1. Introductory comments
The following descriptions are of "standard" methods for each of the LA techniques. Each technique may have several variants, and virtually all the possible anatomical sites for giving an LA have been described. In some cases, there are several names for what is essentially the same technique. In addition, there is some controversy as to nomenclature: certain LA techniques may be described as a "retrobulbar" by some practitioners, and as "peribulbar" by others.

2.3.2. Retrobulbar anaesthesia
Syn. Cone injection, intraconal anaesthesia

2.3.2.1 Technique and history: Retrobulbar anaesthesia was first described in 1884,(Knapp 1884) and has been in common usage throughout the 20th century.(Atkinson 1961; Hodgkins et al 1992) Essentially, it is an injection of LA behind the globe, though definitions vary between authors and most do not attempt to define what they mean by "retrobulbar". Generally, the needle enters the "cone" formed by the four rectus muscles and their fascial attachments(Atkinson 1936; Hamilton 1996), so the LA can block pain, motor, autonomic and visual nerves in the orbit. Usually, the injection is made via the inferotemporal orbit, as this is the quadrant that has fewer large blood vessels and other important structures.(Johnson 1995) When the technique was originally described in 1884, it did not meet with immediate approval, probably due to the toxic effects of a strong (4%) solution of cocaine.(Atkinson 1936) Safer methods of retrobulbar anaesthesia, using weaker solutions of cocaine, or procaine and adrenaline, led to the popularisation of the technique before 1910.(Lowenstein 1908; Seidel 1911; Siegrist 1907)
Atkinson has done much to promote the technique in the English literature, (Atkinson 1934; Atkinson 1936; Atkinson 1961) and the technique has been the most popular method of local anaesthesia for intraocular surgery for the majority of the 20th century.

2.3.2.2 Effectiveness: Retrobulbar anaesthesia gives good analgesia, and akinesia of the extraocular muscles (Hamilton et al 1988; Weiss and Deichman 1989). However, the orbicularis oculi muscle may not be well blocked, so blepharospasm can sometimes be a problem (Martin et al 1986). For this reason, retrobulbar anaesthesia is often combined with a separate injection to block the facial nerve.

2.3.2.3 Needle length and type: Special “Retrobulbar needles” have been in widespread use for many years. They have a length of 35 mm, and are dull rather than sharp. These are also known as “Atkinson needles”, named after the surgeon who popularized the technique (Atkinson 1961). In the past, needle lengths of up to 50 mm have been used (Atkinson 1936; Atkinson 1961), and these are still available from some suppliers. (1997) The needle must be long enough to enter the muscle cone, but an over-long needle may reach the orbital apex and damage important structures. Because the optic nerve is fixed at the foramen, it can easily be pierced by a very long needle. Further forward in the orbit, the nerve is more mobile, so piercing is less likely. A study of cadavers, published in 1920, indicated that inserting a needle over 35 mm was more likely to damage apical structures. (Duverger 1920) A more recent study looked at the variation in dimensions among 120 cadaver orbits, and concluded that 31 mm was the safe maximum. (Katsev et al 1989)

Atkinson advocated the use of a ‘blunt’ needle, which he felt was less likely to pierce the optic nerve sheath or blood vessels. (Atkinson 1961) However, there is evidence that a blunt needle is likely to do more damage if there is an inadvertent scleral perforation (Grizzard et al 1991; Vivian and Canning 1993). For this reason, as well as for patient comfort, most authorities now advocate the use of shorter (31 mm or less), sharp needles for periocular injections. (Forrest and Johnson 1994; Hamilton 1998a)

2.3.2.4 Position of gaze during injection: For much of the 20th century, it was standard practice for the patient to look “up and in” (the Atkinson position). (Atkinson 1936) This
position was mooted because it made it easier for the needle to penetrate the fascial sheath and enter the muscle cone. However, this position will also tighten the optic nerve, and bring it towards the path of the needle, thus making optic nerve damage more likely. The Atkinson position also brings the posterior pole (macula) of a long myopic eye into the path of the advancing needle. This was elegantly demonstrated in a study of computerized tomography images of cadaver eyes, which received retrobulbar injections whilst held in different postions of gaze (Unsold et al 1981). Another cadaver study demonstrated that the Atkinson position allowed for direct injection into the nerve or the surrounding subarachnoid space, with the injected material tracking back to surround the brainstem (Drysdale 1984). For this reason, the modern retrobulbar injection is performed with the eye in the primary position (looking straight ahead). (Hamilton 1996)

2.3.2.5 Overview of complications of retrobulbar anaesthesia

Retrobulbar injections may have sight-threatening or life-threatening complications. (Hamilton 1999) These are summarised in the table, and the more important complications are discussed in detail below.

<table>
<thead>
<tr>
<th>COMPLICATION</th>
<th>SIGNS &amp; SYMPTOMS</th>
<th>MECHANISM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brain-stem anaesthesia</td>
<td>Very variable, includes: Cranial nerve palsies, Loss of consciousness Apnoea Death if not treated (see text)</td>
<td>Spread along sub-meningeal pathways</td>
</tr>
<tr>
<td>Globe penetration and perforation</td>
<td>Pain, change in intraocular pressure, vitreous haemorrhage, retinal tear and detachment</td>
<td>Needle stab through the sclera</td>
</tr>
<tr>
<td>Orbital haemorrhage (arterial)</td>
<td>Rapid-onset haematoma Often, retinal ischaemia</td>
<td>Damage to artery in orbit</td>
</tr>
<tr>
<td>Condition</td>
<td>Description</td>
<td>Cause</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>Orbital haemorrhage (venous)</td>
<td>Slow-onset haematoma</td>
<td>Damage to vein in orbit</td>
</tr>
<tr>
<td>Optic nerve damage</td>
<td>Permanent loss of vision, Visual field defects, Optic nerve head swelling, Optic atrophy</td>
<td>Needle damage to axons, Nerve sheath haematoma, Damage to ciliary arteries, Pressure effect</td>
</tr>
<tr>
<td>Damage to other orbital nerves</td>
<td>Atonic pupil, Neuropathic pain, Extraocular muscle problem</td>
<td>Needle trauma (ciliary ganglion, sensory or motor nerve)</td>
</tr>
<tr>
<td>Globe ischaemia</td>
<td>Loss of vision, retinal ischaemia</td>
<td>Various causes: Pressure from injectate, Pressure-lowering devices, Previous pathology, Adrenaline?</td>
</tr>
<tr>
<td>Oculocardiac reflex</td>
<td>Bradycardia, Nausea, Increased blood pressure, Cardiac arrest</td>
<td>Muscle stimulation from rapid injection, dull needle</td>
</tr>
<tr>
<td>Complications of facial nerve block</td>
<td>Permanent facial palsy, Swallowing or breathing difficulty</td>
<td>Trauma or myotoxicity to facial nerve, Block of other nerves near main trunk of nerve</td>
</tr>
<tr>
<td>Allergic reaction</td>
<td>Skin rash, Flushing, Hypotension, Bronchospasm</td>
<td>True allergy (very rare)</td>
</tr>
<tr>
<td>Intravascular injection of local anaesthetic</td>
<td>Loss of vision, Convulsions</td>
<td>Retinal embolisation, Intravascular injection</td>
</tr>
<tr>
<td>Extrocular muscle malfunction after surgery</td>
<td>Postoperative ptosis, Diplopia</td>
<td>Myotoxicity of anaesthetic, Trauma to muscle</td>
</tr>
</tbody>
</table>
2.3.2.6. Complications: brain-stem anaesthesia:

As mentioned above, it is possible for a retrobulbar needle to pierce the dural sheath of the optic nerve, and thus enter the subarachnoid space. Anaesthetic can then track backward to the brain-stem, where it can effectively anaesthetise vital centres. If the respiratory centre is affected, this can cause respiratory depression or apnoea. Ventilatory and other support must be maintained until the anaesthetic wears off, otherwise serious consequences, including death, could result.


The typical clinical picture (Hamilton 1992) commences within 2-10 minutes of injection, and may include signs in the cranial nerves and central nervous system. Spread of anaesthetic across the chiasm may cause loss of vision in the fellow eye, or there may be other cranial nerve signs in the contralateral orbit. Lower cranial nerves may also be affected, causing tinnitus or difficulty swallowing, speaking or breathing. Signs in the central nervous system include confusion or agitation, shivering, neck weakness, hemiplegia, paraplegia or quadriplegia, nausea or vomiting, unresponsiveness or unconsciousness, convulsions, respiratory depression or apnoea. The cardiovascular system may show instability, with hypertension/ tachycardia, hypotension/ bradycardia, pulmonary oedema, or cardiac arrest. The signs can present in various combinations, with varying degrees of severity. The presence of any of these symptoms or signs should alert the clinician that rescuscitation may become necessary. (Hamilton 1992) There were no
deaths among the many cases reported above, but deaths have been reported in association with LA for intraocular surgery (see section 2.3.2.9 and 2.3.12).

There is little doubt that brain-stem anaesthesia is a genuine phenomenon, though other mechanisms such as inadvertent intra-arterial injection of local anaesthetic, toxic or allergic reactions have been suggested in the past (Feibel 1985; Javitt et al 1987) Radiographic studies of cadavers have demonstrated that the retrobulbar needle can pierce the nerve sheath (Drysdale 1984; Unsold et al 1981) with injection of contrast medium to the brain stem (Drysdale 1984) Sub-dural or subarachnoid injection of contrast medium has also been described as a complication of orbitography in living patients, for whom the contrast medium was given by retrobulbar injection (Lombardi 1967) (Kaufer and Augustin 1966; Reed et al 1969) Another case report describes a relatively high concentration of lignocaine in the cerebrospinal fluid of a patient who suffered a respiratory arrest after retrobulbar anaesthesia: the concentration could only be explained by a direct injection into the cerebrospinal fluid (Kobet 1987)

2.3.2.7 Oculocardiac reflex
The oculocardiac reflex is characterised by bradycardia in response to pressure, torsion or traction of the extraocular muscles. There may be sinus bradycardia (usually defined as a 20% reduction in heart rate below baseline), nodal rhythm, ectopic beats or cardiac arrest (Forrest 1994b) This can be a particular problem in paediatric squint surgery, and has been the cause of death in non-atropinised patients (Averbukh and Minnebaeva 1969; Bietti 1966; Kirsch et al 1957) It is a trigemino-vagal reflex, and the afferent pathway can be blocked by retrobulbar anaesthesia (Jedeikin 1977; Kiefer et al 1997; Kirsch et al 1957) prior to commencing surgery for squint or retinal detachment. In some cases, retrobulbar anaesthesia may itself stimulate the oculocardiac reflex (Berler 1963; Pontinen 1966). The mechanism is probably either direct muscle stimulation from the needle, or muscle stretch caused by rapid injection of a large volume of anaesthetic (Hamilton 1999) This appears to be a rare phenomenon, with a zero incidence in case-series of over 40,000, (Hamilton 1999) over 8,000, (Wong 1993) and 6,000 (Nicoll et al 1987) retrobulbar and peribulbar blocks. A reported case of "oculocardiac reflex" after retrobulbar anaesthesia and haematoma is more easily explained by brain-stem depression (Negrutiu et al 1988) Slow
injection has been suggested as a means of avoiding stimulating this reflex. (Hamilton 1999)

2.3.2.8 Intravascular injection of local anaesthetic causing cardiorespiratory depression
At one time, intravascular injection was thought to be the mechanism for many cases of cardiorespiratory depression. (Beltranean et al 1981; Rosenblatt et al 1980) though it is now apparent that most cases were in fact due to subarachnoid injection. (Hamilton 1992) However, two cases of seizure immediately after retrobulbar injection (Meyers et al 1978) are perhaps more easily explained by intravascular injection than by subarachnoid spread. Forcible injection into an artery could induce retrograde flow of the LA agent into the carotid artery, with subsequent delivery to the brain once the pressure on the syringe is released.

2.3.2.9 Incidence of life-threatening complications, and death
It appears the majority of life-threatening complications are due to brain-stem depression. (Hamilton 1992; Hamilton 1999; Hamilton et al 1988; Javitt et al 1987) Several large case-series have indicated a low incidence of “life-threatening” complications of retrobulbar anaesthesia. Two large studies of retrobulbar anaesthesia found the incidence of brain-stem anaesthesia to be 0.27% (16 of 6,000, or 1 in 375) (Nicoll et al 1987) and 0.15% (8 of 5,230, or 1 in 650). (Hamilton et al 1988) Another observational study found the incidence of respiratory arrest to either 0.09% (2 of 2,235), or 0.79% (7 of 888), depending on the concentration of lignocaine in the mixture (overall incidence 1 in 350). (Wittpenn et al 1986) Another ten-year series of “subarachnoid injection” found a similar incidence (8 of 3,000 or 1 in 375). (Ahn and Stanley 1987) A study of 6,000 retrobulbar blocks found evidence of brainstem anaesthesia in 16 cases (1 in 375), though the authors considered the condition to be “life-threatening” in only half of the cases (1 in 750). (Nicoll et al 1987)

Despite this incidence of life-threatening complications, there are no direct reports of death attributable to retrobulbar anaesthesia. This does not mean that deaths do not occur. In 1993, a questionnaire survey was sent to 500 British ophthalmologists asking about their personal experience of complications of LA. The 334 respondents identified 12
cases of death which was felt “might have been the result of local anaesthesia.” (Haider 1994) Eleven of these deaths occurred “on the operating table” (Haider SA, pers. comm.). It is likely that most of these cases would have involved retrobulbar or peribulbar anaesthesia.

Section 2.3.12 discusses deaths associated with any LA technique. One chart review identified two cases of death on the operating table, in patients who were given large volume (presumed retrobulbar) anaesthesia. (Petruscak et al 1973) The report has insufficient detail to ascertain whether the LA itself could have contributed to the patients’ death. The issue of LA-associated death is further explored in the Survey.

2.3.2.10 Sight-threatening complications: globe penetration or perforation

The term ‘penetration’ is used to describe a single entry wound into the eye; ‘perforation’ implies an entry and exit wound(s). In the literature, these two terms are often used interchangeably.

In the majority of cases, the needle penetrates the sclera to cause a retinal hole(s) or tear(s). This may go unrecognised at the time, or may present with pain, hypotony, or altered red reflex due to vitreous haemorrhage or retinal detachment. (Duker et al 1991; Grizzard et al 1991; Hay et al 1991; Wearne et al 1998; Wong 1993) Injection of anaesthetic into the eye may cause retinal toxicity,(Lincoff et al 1985) or raise the intraocular pressure sufficiently to rupture the globe. (Bullock et al 1998; Magnante et al 1997) Milder cases of penetration/perforation may settle with simple observation or prophylactic laser or cryotherapy,(Rinkoff et al 1991) but retinal detachment generally requires vitreoretinal surgery. Despite modern surgical approaches, visual outcome is often poor. (Duker et al 1991; Gillow et al 1996a; Wearne et al 1998)

There is some evidence that abnormally-shaped eyes or orbits increase the risk of penetration/perforation. Risk factors include: increased axial length due to myopia or previous scleral buckling(Duker et al 1991; Hay et al 1991; Ramsay and Knobloch 1978), posterior staphyloma,(Edge and Navon 1999) abnormal orbital anatomy (e.g. enophthalmos). (Schneider et al 1988) Myopic eyes are not only longer than average, but may also have a larger equatorial diameter, making perforation more likely. The Atkinson
“up and in” position increases risk by bringing the posterior pole of an elongated eye into the needle path, and also by making any perforation more likely to involve the macula. (Liu et al 1992; Unsold et al 1981) Dull needles (see above) probably do not significantly reduce the risk of a perforation, (Hamilton 1999; Waller et al 1993) but they do appear to cause more damage if a perforation does occur. (Grizzard et al 1991; Vivian and Canning 1993)

### 2.3.2.11 Sight-threatening complications: optic nerve damage

The optic nerve may be damaged by direct trauma in the form of needle damage to the axons, or pressure/ischaemic from a nerve sheath haematoma. (Jindra 1989; Kelman 1997; Morgan et al 1988; O'Day et al 1986; Sullivan et al 1983) The mechanism is the same as for subarachnoid injection (see Brainstem anaesthesia, section 2.3.2.6) and it is not surprising that the two conditions may occasionally coexist. (Brod 1989; Dorey et al 1998) Deep injections at the orbital apex are more likely to damage the optic nerve, and this method is now outmoded (see Needle length and type, section 2.3.2.3). Raised pressure from an orbital haemorrhage may cause optic atrophy in the absence of an obvious intraocular vascular occlusion (see section 2.3.2.13), presumably as a result of optic nerve ischaemia. (Anderson 1981; Carroll 1982) Optic nerve trauma may coexist with retinal vascular occlusion (see next section). It is possible that vasoconstriction due to adrenaline may cause ischaemic damage to the optic nerve, and this may be particularly noticeable in nerves which have already sustained significant damage from glaucoma. (Costa et al 1993)

### 2.3.2.12 Sight-threatening complications: occlusion of retinal or choroidal vessels

A retrobulbar needle may inadvertently enter a branch of the ophthalmic artery. If the pressure if injection exceeds the systemic blood pressure, the injectate will be forced back into the ophthalmic or carotid artery, then embolise to the retinal, choroidal or other vessels once pressure on the syringe is released. (Morgan et al 1988) Occlusion of arteries or veins supplying the eye or optic nerve may also occur secondary to elevated pressure from nerve sheath haematoma or injection. (Brod 1989; Hersch et al 1989; Mieler et al 1990; Morgan et al 1988; Pautler et al 1986; Sullivan et al 1983) secondary to elevated intraorbital pressure with orbital haemorrhage (Carl 1993; Feibel 1985; Goldsmith 1967; Kraushar et al 1974) (see 2.3.2.13 below), or in apparent isolation. (Klein et al 1982)
2.3.2.13 Orbital haemorrhage (Retrobulbar haemorrhage)

Orbital haemorrhage (OH, also known as retrobulbar or periocular haemorrhage) occurs when the LA needle damages a blood vessel in the orbit. Arterial haemorrhage can cause a sudden rise in intraorbital pressure, sufficient to cause closure of the central retinal artery. (Kraushar et al 1974) There have been several reports of visual loss following OH, due to observed or presumed occlusion of vessels in the nerve or globe. (Anderson 1981; Carl 1993; Carroll 1982; Feibel 1985; Goldsmith 1967; Kraushar et al 1974; Sullivan et al 1983) Another case appears to document simultaneous OH and intra-arterial embolisation of anaesthetic. (Morgan et al 1988)

Large studies of retrobulbar anaesthesia have estimated the incidence of OH to be between 0.1% and 3.5%. Atkinson's paper of 1934 cites data on approximately 15,000 retrobulbar injections, in which there were 15 cases of OH, an incidence of 0.1%. (Atkinson 1934) Another series of 12,000 retrobulbar and peribulbar blocks was prospectively recorded by a single anesthesiologist. “Periocular ecchymoses” occurred in 2.3–3.5%, depending on the technique used, but there were no cases of “severe” OH, and no surgery was cancelled because of OH. (Hamilton et al 1988) A retrospective review of 3,530 retrobulbar blocks defined OH as a combination of proptosis, subconjunctival hemorrhage, and increased orbital pressure. There were 60 cases of OH, giving an incidence of 1.7%. (Cionni and Osher 1991) Another retrospective review looked at 12,500 retrobulbar blocks. There were 55 cases of OH, an incidence of 0.44%. Criteria for definition of OH were not given, though 5 cases had a canthotomy, and surgery was cancelled in 41. (Edge and Nicoll 1993)

There is a low incidence of permanent visual impairment following OH after retrobulbar anesthesia. In three of the above studies (Atkinson 1934; Cionni and Osher 1991; Edge and Nicoll 1993) all 130 patients with OH made a full visual recovery. Another study reviewed 28 cases of OH, and found that two patients (7%) had permanently reduced visual acuity. This was ascribed to arterial occlusion resulting from the elevated intraorbital pressure. (Kraushar et al 1974) Another study of 2750 cataract operations under retrobulbar anaesthesia found two cases of optic nerve atrophy, from an unspecified number of haemorrhages. (Klecker 1956) Central retinal artery occlusion has been observed directly in patients who had OH with elevated intraorbital pressure following retrobulbar injections. In a report of three cases, ocular circulation was quickly re-
established, and there was no permanent visual impairment. (Kraushar et al 1974) In other cases, the arterial occlusion was not recognized until later, with a poor visual outcome. (Goldsmith 1967) Various authors have stressed the importance of active management for cases of OH. The intraocular circulation should be monitored by ophthalmoscopy or indirect methods, and the intra-orbital pressure should be lowered as necessary. Techniques include massage, medications and surgical decompression. (Cionni and Osher 1991; Feibel 1985; Hayter and Sugar 1991) In a series of 60 cases of OH after retrobulbar anesthesia, managed according to such a protocol, no patient lost vision because of OH. (Cionni and Osher 1991)

2.3.2.14 Incidence of sight-threatening complications
Sight-threatening complications of retrobulbar injections are rare. The incidence of globe penetration/perforation during retrobulbar LA has been reported to be 0% (0 of 4,000), (Kimble et al 1987) 0.02% (1 of 5,230), (Hamilton et al 1988) and 0.075% (3 of 4,000). (Ramsay and Knobloch 1978) Hamilton’s personal experience of 32,350 retrobulbar, peribulbar and combined blocks to 1998 included two perforations and one penetration (around 1 in 11,000 or 0.009%) (Hamilton 1998b) Abnormally shaped eyes, such as those with previous scleral banding, or large myopic eyes, are at increased risk due to the abnormal position of the sclera relative to the advancing needle. Duker estimated that the incidence of penetration/perforation may be up to 1 in 140 (0.7%) in myopes with an axial length of over 26mm (Duker et al 1991) but the assumptions made in reaching this estimate are open to question. In a prospective series of 50,000 retrobulbar and peribulbar blocks in Saudi Arabia, high myopes with posterior staphyloma had penetration/perforation risk of 0.13% (7 of 5350) whereas there were no such injuries in almost 45,000 non-staphylomatous eyes (Edge and Navon 1999). The other sight-threatening complications, discussed above, appear to be less common in that they are the subject of fewer case-reports and series.

2.3.2.15 Myotoxicity & damage to extraocular muscles
Local anaesthetics are toxic to muscle. (Foster and Carlson 1980; Rainin and Carlson 1985; Yagiela et al 1981) There have been numerous reports of ptosis and extraocular muscle malfunction following ocular surgery under retrobulbar anaesthesia. (Capo et al 1996; Corboy and Jiang 1997; Esswein and von Noorden 1993; Hamed 1991; Hamilton et al 1998b)
In some cases, post-operative diplopia can be ascribed to surgical factors, such as trauma to a muscle from a bridle suture (Catalano et al. 1987) or antibiotic injection, (Kushner 1988) or pre-existing conditions such as thyroid eye disease. (Hamed 1991) Haemorrhage into a muscle may cause an ischaemic contracture of the Volkmann type. (Hamed 1991) Many cases appear to be due to a true myotoxic effect, (Carlson et al. 1992; Rainin and Carlson 1985; Yagiela et al. 1981) and several authors have emphasized the need to avoid traumatizing the extraocular muscles when giving periocular injections. (Hamilton 1996; Hamilton 1999; Ong-Tone and Pearce 1989; Rainin and Carlson 1985)

2.3.2.16 Avoidance of complications of retrobulbar anaesthesia

In order to minimize the incidence of complications of retrobulbar anaesthesia, the following guidance is recommended: (Hamilton 1999) Rationale is discussed in the above sections.

- Use primary gaze, not the “Atkinson position”
- Learn the anatomy before attempting a block
- Measure the axial length
- Extreme caution if high myopia, staphyloma, coloboma or scleral buckle
- Align needles tangentially to globe
- Inject via avascular sites
- Inject no deeper than 31mm from orbital rim
- Use fine, sharp needles
- Aspiration check before injection
- Inject slowly
- Avoid extraocular muscles
- Be prepared to carry out cardiorespiratory resuscitation if required

The other approach to avoiding the complications of retrobulbar anaesthesia is to develop new techniques which seek to avoid or minimise these complications. These are discussed in the following sections.
2.3.3. Peribulbar anaesthesia (periconal anaesthesia, also referred to as parabulbar anaesthesia in some German translations)

2.3.3.1 History of peribulbar anaesthesia
The first known use of peribulbar anaesthesia was around 1970. Charles Kelman, one of the early advocates of phacoemulsification, is said to have developed the technique after a patient was blinded by a retrobulbar injection which entered the optic nerve (Kelman 1997). A detailed description of the technique was not published until 1986 (Davis and Mandel 1986). The authors of this paper, Davis and Mandel, shared Kelman’s view that peribulbar anaesthesia “affords a reliable alternative to retrobulbar injection by achieving the same degree of anesthesia and akinesia while reducing or eliminating many of the complications” (Davis and Mandel 1986). This report popularised the technique, and it is in common use in many countries (see section 2.3.13).

2.3.3.2. Technique of peribulbar anaesthesia
The technique involves making one or more injections around the globe. Most authors would consider the term “peribulbar” to mean that the anaesthetic is placed outside the muscle cone. Davis and Mandel’s technique involved placing around 9ml of anaesthetic solution above and below the globe and muscle cone. This was achieved using two transcutaneous injections, one above and one below the globe (Davis and Mandel 1986). There have been numerous variations of Davis and Mandel’s original technique, in terms of the number and site of the injections, and agents used (Apel and Woodward 1991; Arnold 1992; Bell and Butt 1995; Bernard and Hommeril 1997; Demirok et al 1997; Hamilton et al 1988; Henderson and Franks 1996; Hendrick et al 1997; Kishore et al 1991; Loots and Venter 1988; Teichmann 1992; Xifaras 1995) (Bloomberg 1986; Hamilton 1995; Ripart et al 1996; Whitsett et al 1990, Gills 1993) A recent literature review concluded that retrobulbar and peribulbar techniques both afford equivalent degrees of anaesthesia and analgesia (Friedman et al 2001).

2.3.3.3. Complications of peribulbar anaesthesia
Davis and Mandel stated that the risks associated with retrobulbar anaesthesia were “greatly minimized in peribulbar anesthesia, because the injection is deposited entirely outside the muscle cone, the muscles themselves are not engaged, and the needle is far..."
from the globe, optic nerve, and dural sheaths”. However, virtually all of the complications of retrobulbar anaesthesia have now been described with peribulbar anaesthesia. (Hamilton 1999; Hamilton 2000) Serious complications of peribulbar anaesthesia include globe penetration/perforation (Duker et al 1991; Edge and Navon 1999; Gentili and Brassier 1992; Gillow et al 1996a; Grizzard et al 1991; Hay et al 1991; Holekamp and Wax 1998; Joseph et al 1991; Kimble et al 1987; Mount and Seward 1993; Zaturansky and Hyams 1987) or globe rupture, (Bullock et al 1998; Nagpal and Nagpal 1998; Rathi et al 1997) and it appears that multiple injections are more likely to cause this problem. (Duker et al 1991; Rinkoff et al 1991) Injection into the nerve causing brain-stem depression, (Davis and Mandel 1994; Edge and Davis 1995; Gomez et al 1997; Singer et al 1997) visual loss, (Vindhya and Sheets 1992) or both, (Dorey et al 1998) has been reported. Other serious complications include blindness after orbital haemorrhage, (Puustjarvi and Purhonen 1992) and acute pulmonary oedema. (Kumar and Lawler 1999) The potential for globe perforation (Ortiz et al 1995) and optic nerve trauma with intradural injection (Zahl et al 1991) has been demonstrated radiographically, using a cadaver model of peribulbar injection.

2.3.3.4. Is peribulbar anaesthesia really safer than retrobulbar?

There is some evidence to suggest that peribulbar anaesthesia may be safer than retrobulbar injections. The randomised trials have been too small to comment on safety, in view of the rarity of severe complications. (Demediuk et al 1995; Edge et al 1995; Feibel et al 1993; Friedman et al 2001; Hessemer 1994; Murdoch 1990; Saunders et al 1993; Whitsett et al 1990). To properly answer this question would require a prospective randomised trial so large that it could probably never take place.

Large observational case-series should be interpreted with caution, because they are susceptible to bias. For example, patients who are perceived to be at high risk of complications may be given the anaesthetic which is perceived to be safer. Results may be influenced by factors in the local population (e.g. the high incidence of posterior staphyloma in a series from Saudi Arabia). (Edge and Navon 1999) In institutions where several practitioners give the anaesthetic, personal preference may bias outcomes in that clinicians with an interest in safety may use different techniques, and be more willing to report any complications that occur. In single-practitioner series, changes in anaesthetic
technique over time may be accompanied by other confounding changes, such as better follow-up to screen for complications. In addition, some case-series are carried out by practitioners who wish to promote the safety of a certain technique, (Davis and Mandel 1994) and such series tend to originate from centres with a particular interest in LA safety. These concerns, coupled with the multiple variations in technique and the controversy over nomenclature (see section 2.3.1) mean that these studies may not reflect LA safety in the ‘real world’.

Hamilton’s single-practitioner case-series documents the reduction in complications as his technique evolved from retrobulbar to peribulbar, to a combined technique of peribulbar anaesthesia with retrobulbar top-up if necessary (Hamilton et al 1988). Brain-stem anaesthesia was only seen in the patients who had retrobulbar blocks. Hamilton now uses a combined retrobulbar/peribulbar technique, and reports no significant complications in over 8,500 cases. (Hamilton 1996; Hamilton 1998a; Hamilton et al 1988) Other large case-series tend to concentrate on one LA technique, and do not mention the reasons for choosing this technique for the individual patients, or what anaesthetic was given to those patients who were not included in the study (another potential source of bias). Brain-stem depression and globe perforation have been evaluated by a few large series. (Ahn and Stanley 1987; Arnold 1992; Duker et al 1991; Kimble et al 1987; Meyers et al 1978; Nicoll et al 1987; Ramsay and Knobloch 1978; Wittppen et al 1986) (see above, sections 2.3.2.6 and 2.3.2.10). Comparison with peribulbar anaesthesia is difficult, because there are few series for comparison (Ahmad et al 1993; Davis and Mandel 1994; Edge and Navon 1999), and they relate to different populations and times. One large series (Davis and Mandel 1994) may be biased toward ‘safety’ in that it is authored by Davis and Mandel, the original proponents of the technique. (Davis and Mandel 1986) The other large series (Edge and Navon 1999) has the problem that clinical judgment was used in the choice of anaesthesia technique. Therefore, extreme caution should be used when comparing the safety of these techniques.

Attempts to extrapolate the relative incidence of a complication (e.g. globe perforation) from a group of cases generally fail because of a lack of data regarding the current usage of the different LA techniques. The National Survey of Local Anaesthesia for Ocular
Surgery was designed to give more information in this subject, by simultaneously recording the relative usage, and complication rates, for the two techniques.

2.3.4. Subconjunctival anaesthesia (limbal anaesthesia)

2.3.4.1. History and technique of subconjunctival anaesthesia

Subconjunctival injections of cocaine were first used for surgery in 1884,(Knapp 1884) and the concept was reintroduced in the 1950’s in an effort to reduce the risks of retrobulbar injections.(Swan 1956) In recent times, the technique was popularised by publications in British and American journals in 1988(Smith 1988) and 1990(Petersen and Yanoff 1990), each of which bore the title “Why retrobulbar anaesthesia?” The British author, Redmond Smith, stated that “it is almost as easy to carry out cataract extraction without retrobulbar anaesthetic… a few drops of amethocaine followed by 1ml of subconjunctival 2% lignocaine injected under direct vision in the region of the superior rectus insertion are all that is required.”(Smith 1988) Two years later, he published a case-series of 175 extracapsular cataract extractions using subconjunctival anaesthesia, with good results. He further stated that, as a surgeon approaching retirement, he had always performed peripheral iridectomies and fistulising glaucoma surgery using a similar technique. Further case-series were published by other authors around this time (Furuta et al 1990; Petersen and Yanoff 1991; Redmond and Dallas 1990) More recently, randomised studies have compared the efficacy of subconjunctival anaesthesia against peribulbar(Azuara-Blanco et al 1997; Maclean et al 1997) or retro/peribulbar anaesthesia,(Shammas et al 1997) and demonstrated similar or superior clinical effect and patient acceptability for cataract surgery(Maclean et al 1997; Shammas et al 1997) and trabeculectomy.(Azuara-Blanco et al 1997)

2.3.4.2. Safety of subconjunctival anaesthesia

The technique was introduced in an effort to improve safety of local anaesthesia. Because the needle remains under direct vision at the front of the globe, optic nerve damage and brain-stem injection are impossible. However, globe perforation has been described.(Yanoff and Redovan 1990) The smaller volume of injectate means that there is less potential for drug toxicity.
The lack of akinesia may make surgery more risky, particularly in “open” operations such as conventional extracapsular cataract surgery, when contraction of the extraocular muscles may cause extrusion of the ocular contents. For this reason, the technique is better suited to small-incision surgery such as phacoemulsification and trabeculectomy. (Azuara-Blanco et al 1997; Shammas et al 1997) Surgical complication rates were compared among 402 patients who were randomly assigned to subconjunctival or retro-peribulbar anaesthesia: the vitreous loss rate was 0% with subconjunctival, and 2.9% with retro-peribulbar, and this was ascribed to the positive vitreous pressure secondary to the latter technique. (Shammas et al 1997) Thus, minimal anaesthesia may in fact lead to fewer surgical complications.

2.3.5. Sub-Tenon’s anaesthesia (parabulbar anaesthesia, episcleral anaesthesia)

2.3.5.1. History and technique of sub-Tenon’s anaesthesia

Sub-Tenon’s anaesthesia was first used in 1884, the year that local anaesthesia for eye surgery was first described. Turnbull dropped 4% cocaine into a cut made through conjunctiva and Tenon’s prior to enucleation. (Turnbull 1884) The technique appears to have received little attention until recent years, though Kirby in 1950 reported taking up sub-Tenon’s anaesthesia in an effort to reduce the risks associated with retrobulbar anaesthesia for cataract surgery. (Kirby 1950) In 1956, the technique was described again. (Swan 1956) but it did not gain popularity until it was rediscovered around 1990. (Friedberg et al 1991; Fukasaku and Marron 1994a; Greenbaum 1992; Hansen et al 1990; Stevens 1992)

The technique requires topical anaesthesia. A small incision is made through conjunctiva and Tenon’s capsule, exposing the bare sclera. A canula is introduced and 1ml or more of local anaesthetic is injected into the sub-Tenon’s space. To reduce the likelihood of trauma, a blunt, rounded or flexible canula is used, and the initial incision is made 2-3 mm posterior to the limbus for ease of injection. As with other techniques, there are numerous published variations in the exact location of injection, number of sites, composition and amount of injectate, and cannula type. (Azmon et al 1999; Behndig 1998; Bergman et al 1996; Briggs et al 1997; Buys and Trope 1993; Chittenden et al 1997; Friedberg et al 1991; Fukasaku and Marron 1994a; Greenbaum 1992; Guise and Laurent
1999; Guise 1996; Hansen et al 1990; Kapran et al 1996; Khoo et al 1996; Kumar et al 2000; Kwok et al 1999; Li et al 2000; Nielsen and Allerod 1998; Ripart et al 1998b; Roman et al 1997; Rous 1999; Rowley et al 2000; Stevens 1992; Stevens 1993; Tokuda et al 1999) Greenbaum’s technique uses an anterior injection with a short, wide, plastic canula,(Greenbaum 1992; Greenbaum 1997) and is perceived to be low-risk but causes chemosis in a large proportion of cases. Stevens described a posterior approach, using a smooth-ended metal canula.(Stevens 1992; Stevens 1993) This seems to be more likely to cause chemosis, but the posterior approach is more likely to cause bleeding from a vortex vein. Ripart’s technique (Ripart et al 2000; Ripart et al 1998a) uses a sharp needle for sub-Tenon anaesthesia, and is therefore more likely to cause a globe perforation.

2.3.5.2. Effectiveness of sub-Tenon’s anaesthesia
Several randomized trials have demonstrated good efficacy and acceptability when compared to peribulbar(Azmon et al 1999; Ripart et al 2000) and retrobulbar (Buys and Trope 1993; Kapran et al 1996; Khoo et al 1996; Tokuda et al 1999) anaesthesia. Other non-randomised studies support these findings,(Briggs et al 1997; Guise 1996; Kollarits et al 1998; Ritch and Liebmann 1992; Roman et al 1997; Tokuda et al 2000) and several authors claim that the sub-Tenon approach is superior in terms of speed of onset, safety and patient acceptability. Because of good akinesia, the technique allows for successful large-incision cataract surgery.(Ntim-Amponsah 1998; Roman et al 1997; Tokuda et al 2000) Friedman’s review of the literature to April 1999 concluded that there was fair evidence that sub-Tenon was less painful to administer, and gave better pain control than retrobulbar anaesthesia, and that there was insufficient evidence to say that sub-Tenon provided less akinesia than retrobulbar blocks.(Friedman et al 2001)

2.3.5.3. Safety of sub-Tenon’s anaesthesia
The use of a soft or round-ended canula makes globe penetration almost impossible with this technique. Likewise, one would not expect optic nerve trauma or brain-stem depression. However, there are some risks inherent to sub-Tenon’s anaesthesia. A posteriorly-placed canula can damage a vortex vein where it crosses the sub-Tenon space, and cause severe haemorrhaging.(Olitsky and Juneja 1997) This risk is virtually eliminated by using a short canula, as in Greenbaum’s technique.(Greenbaum 1992; Greenbaum 2000) The importance of using a blunt cannula is emphasised by the report of
inadvertent intraocular injection during attempted sub-Tenon injection of corticosteroid using a sharp needle. (Gomez-Ulla et al. 1993) One other perforation has been reported: this occurred during dissection with scissors, prior to sub-Tenon injection, in an eye that had previously undergone surgery for retinal detachment. (Frieman and Friedberg 2001)

A series of 3000 sub-Tenon blocks found no cases of globe perforation, haemorrhage or central nervous system complications, and a 0% need for supplemental block. (Fukasaku and Marron 1994a) Another series of over 2000 sub-Tenon blocks, including 1500 as the 'default' anaesthesia (over 99% of cataract extractions) showed no regional or systemic complications, and no severe pain. (Tsuneoka et al. 1993) Guise's original series of 300 cases (Guise 1996) has recently been updated to cover 6000 consecutive sub-Tenon's blocks: there were no sight-threatening complications, one case was cancelled because of a marked subconjunctival haemorrhage, and there were 5 systemic adverse events. (Guise 2001) Greenbaum, who has patented a sub-Tenon's cannula, states that "roughly 300,000 blocks have been given, with no complication reported in the literature other than subconjunctival hemorrhage or chemosis". (Greenbaum 2000) The National Survey of Local Anaesthesia for Ocular Surgery assessed the safety of sub-Tenon anaesthesia in the "real world".

2.3.6. Topical anaesthesia

2.3.6.1. Technique and history

The introduction of cocaine in 1884 revolutionised ophthalmic surgery. Knapp (Knapp 1884) summarised the considerable number of reports that were made between September and December 1884, most of which concerned the topical use of cocaine. It was found that one drop of 2% cocaine effectively anaesthetized the cornea, and that deeper structures such as the iris could be anaesthetized to some extent by repeated instillations (e.g. every 5 minutes for half an hour before surgery). Topical anaesthesia does not block the extraocular muscles, so it is not well suited to large-incision intraocular surgery in which eye movement could cause vitreous loss. However, many surgeons felt that this was a better option than the systemic complications (Atkinson 1934) frequently associated with Knapp's retrobulbar injection of 4% cocaine. (Knapp 1884) or general anaesthesia. For example, Hirschberg in 1910 reported using topical 2% cocaine for thousands of
intracapsular cataract extractions (Gills et al 1993). With the introduction of new and safer techniques of retrobulbar anaesthesia in the early 1900's, (Atkinson 1934; Atkinson 1936) the technique received little further attention until the 1990's.

The advent of small-incision phacoemulsification and the self-sealing wound led to a revival in interest in topical anaesthesia. The first cases of clear-corneal phacoemulsification using topical anaesthesia (3% cocaine) were reported by Shimizu in 1986 (Shimizu 1986). In 1993, Fichman, Fine and Grabow described the use of 0.5% amethocaine (tetracaine) drops, and emphasized the importance of “constant coaching” of the patient to maintain proper position of the globe (Fine et al 1993; Grabow 1993). Various minor variations of the technique have been described, including the use of topical lignocaine 4% drops, (Dinsmore 1995) bupivacaine drops, (Gills and Williams 1993; Novak and Koch 1995) proxymetacaine drops, (Hamilton and Claoue 1998) and lignocaine jelly (Koch 1999). Using an anaesthetic-soaked sponge, either surrounding the limbus (Bloomberg and Pellican 1995) or in the conjunctival fornix, with a Honan balloon to enhance diffusion, has been claimed as a superior technique (Rosenthal 1995).

2.3.6.2. Acceptability of topical anaesthesia

Several studies have looked at patients' perceptions of topical anaesthesia for cataract surgery. Overall, topical anaesthesia is acceptable to patients, though there does appear to be more surgical discomfort than with other techniques (Friedman et al 2001). Patient satisfaction rates are high. (Maclean et al 1997; Spiritus et al 2000) Pulse rate and blood pressure do not change significantly during phacoemulsification under topical anaesthesia. (Fichman 1996) The visual experience is generally not unpleasant. (Newman 2000) though in one series 8% of patients found their visual experience frightening. (Au Eong et al 2000) Prospective randomized trials have looked at the experience of receiving the anaesthetic, and of having the surgery. Comparing pain score during surgery, randomised studies found that topical anaesthesia was inferior to sub-Tenon's (Chittenden et al 1997; Manners and Burton 1996; Nielsen and Allerod 1998) inferior to peribulbar, (Aziz and Samra 2000; Virtanen and Huha 1998) and inferior (Nielsen and Allerod 1998) or similar (Patel et al 1996) [Jacobi, 2000 #372] to retrobulbar. These results should not be taken out of context, as the per-operative pain scores are generally low for
phacoemulsification, and other factors should be taken into account. In a prospective, study of 66 patients having simultaneous bilateral cataract surgery, eyes were randomized to have topical, sub-tenon’s or retrobulbar anaesthesia. Per-operative pain scores were highest for topical and lowest for retrobulbar, but the retrobulbar was the most painful to administer. 40% of patients said they would not have retrobulbar anaesthesia again, compared with 19% for topical, and 16% for sub-Tenon.(Nielsen and Allerod 1998)

Another randomised trial of bilateral surgery had similar findings, with 62% of patients preferring topical over peribulbar anesthesia.(Roman et al 1996) The administration of topical anaesthesia is more comfortable for the patient than an injection.(Johnston et al 1998) A further prospective trial of bilateral cataract surgeries differed in that patients were sedated. 96 of the 98 patients were unaware of the anaesthetic being injected, though all had some awareness of surgery. Combined retro/peribulbar anaesthesia was preferred by 71% of patients, 10% preferred topical and 19% had no preference (Boezaart et al 2000)

2.3.6.3. Safety of topical anaesthesia

Topical anesthesia has its advantages and disadvantages. As discussed above, it is best suited to small-incision surgery because of the problems associated with co-contraction of the extraocular muscles in an ‘open’ eye. Because the patient must be asked to gaze in the required direction, topical anaesthesia may not be suitable for patients with nystagmus, deafness, dementia, or those who do not speak the same language as the surgeon.(Dinsmore 1995; Novak and Koch 1995)

No large case-series has been published to demonstrate the safety of topical anaesthesia. Most authors seem to assume that topical anaesthesia is safe, because there is no injection and only a small amount of anaesthetic is used. This ‘no needle’ technique may be particularly desirable for anticoagulated patients.(Hall 1996) However, it could be argued that there are some risks which are inherent to topical anaesthesia. Unlike periocular injection techniques, topical anaesthesia will not block the oculo-cardiac reflex (see section 2.3.2.7, above), the oculo-respiratory reflex or the oculo-emetic reflex.(Forrest 1994b) This does not appear to be a practical problem, in that these problems were not encountered in a series of around 1000 cases.(Claoue and Lanigan 1997) There is an endocrine stress response to cataract surgery under general anaesthesia, which is not
observed when retrobulbar or peribulbar anaesthesia is used. (Barker et al 1994; Barker et al 1993; Barker et al 1991) When general anaesthesia is supplemented with retrobulbar anaesthesia, there is no stress response until the patient is emerging from general anaesthesia, implying that there are separate stress responses to the surgery and to general anaesthesia itself (Barker et al 1994) The endocrine stress response to cataract surgery under topical anaesthesia has not been fully studied. The author's own observations suggest that there is similarly small endocrine stress reaction when phacoemulsification is performed under topical or peribulbar anaesthesia (Dalgleish, Eke et al, unpublished results). Thus it appears that the phenomenon is a reaction to general anaesthesia, rather than to cataract surgery per se.

Another concern is regarding surgical complications. Because topical anaesthesia does not prevent eye movements, it has been suggested that the technique predisposes to sight-threatening surgical complications, such as capsule rupture and vitreous loss. Because of the low incidence of these complications (often 1-2%), most series are not large enough to identify anything other than a large increase in complication rate. A comparison of 476 patients who were randomised to receive either topical or retrobulbar anaesthesia found similar rates of surgical complications overall, but a significantly lower rate of vitreous loss in the topical group. [Jacobi, 2000 #372] Similar results were found in a comparison of topical-subconjunctival anaesthesia against the retrobulbar technique. (Shammas et al 1997) Thus, it may be that the lack of vitreous pressure may make this technique safer than traditional methods, at least in the hands of an experienced surgeon.

2.3.7. Topical with intracameral anaesthesia

2.3.7.1. History and technique

In Knapp's 1884 overview of the first few months' experience with cocaine anaesthesia, it is apparent that cocaine was a good anaesthetic for the cornea, but topical application did not fully anaesthetise the iris or other intraocular structures. Knapp quotes a Dr D.C. Cocks of New York, who published in the Medical News of Dec. 13th, 1884: "[He] anaesthetizes the iris after the corneal section either by injecting the solution with a syringe, or let it run along a spatula introduced into the wound." Dr E. Smith of Detroit published a similar method in the Medical Record of the same day. (Knapp 1884)
Intracameral anaesthesia was reintroduced in modern times as an adjunct to small-incision phacoemulsification (Koch 1997). Most surgeons use unpreserved lignocaine, though mepivacaine (Malecaze et al 2000) and bupivacaine (Anderson et al 1999) have also been used effectively. Normally, around 0.1-0.5 ml of anaesthetic is injected into the anterior chamber using an intraocular cannula (Gills et al 1997; Koch 1997) or the anaesthetic solution is used for hydrodissection (Tan and Burton 2000).

Effectiveness of intracameral anaesthesia

Intracameral anaesthesia is helpful if the iris is to be manipulated (Crandall et al 1999; Tseng and Chen 1998) or if the patient complains of pain (Malecaze et al 2000). An early controlled trial (Gills et al 1997) and case-series (Koch 1997) popularized the technique. However, several studies have questioned its role in routine phacoemulsification surgery. Several large, well-designed randomised controlled trials have concluded that the routine addition of intracameral lignocaine has no significant effect on pain (Boulton et al 2000; Gillow et al 1999; Tan and Burton 2000). Other studies found a small effect: slightly higher pain scores, but similar patient satisfaction score, (Carino et al 1998) and similar pain scores but patients less bothered by tissue manipulation (Crandall et al 1999). Friedman’s review of the literature to April 1999 concluded that there was ‘good evidence’ that pain control during surgery was better using intracameral lignocaine, than with topical anaesthesia alone (Friedman et al 2001). Many surgeons now believe that topical anaesthesia alone should be sufficient, but that intracameral ‘top-up’ is helpful if iris manipulation is expected, the surgeon is learning the technique, or if the patient complains of discomfort during surgery (Malecaze et al 2000).

Safety concerns

In addition to the concerns related to topical anaesthesia (section 2.3.6.3), intracameral anaesthesia has the additional risk of toxicity from the intracameral anaesthetic. The small volumes injected do not represent a significant systemic dose (Wirbelauer et al 1999) but concern has been raised regarding toxicity to the corneal endothelium and other intraocular structures (Judge et al 1997). Amethocaine (tetracaine) has been reported to cause endothelial toxicity if inadvertently injected into the anterior chamber (Fraunfelder 1982). Bupivacaine’s high lipid solubility may make endothelial toxicity more likely.
though this did not seem to occur in a small clinical study. (Anderson et al 1999) In a randomised controlled study with 50 eyes, mepivacaine had no significant effect on endothelial cell count, postoperative inflammatory activity or intraocular pressure. (Malecaze et al 2000) Similar randomised (Carino et al 1998; Garcia et al 1998) and non-randomised (Iradier et al 2000) studies indicated no effect of lignocaine on endothelial cell parameters of anterior chamber inflammation.

2.3.8. No anaesthesia
In an attempt to improve safety of local anaesthesia, minimalist techniques have been developed. A ‘logical’ extension of this is to perform surgery with no anaesthesia at all. In the United States, where sedation is commonplace, (Norregaard et al 1997) Rand and Stein reported performing cataract surgery using only ‘very low-dose, titrated, intravenous alfentanil’, a short-acting opioid analgesic. (Rand et al 2000) In India, Dr Agarwal has pioneered phacoemulsification with no anaesthesia of any sort. (Pandey et al 2000) The surgical technique is similar to standard phacoemulsification, but extra care is taken to avoid grasping the conjunctiva, the microscope light is low, as is the phaco power. Patients do feel the sting of the initial iodine wash, but surgery generally proceeds without undue discomfort (Agarwal A, pers. comm.) In a double-blind, randomised trial, the no anaesthesia technique was compared with topical and topical-intracameral anaesthesia. There was no significant difference in patient’s assessment of pain or discomfort, though the surgeon’s stress score was significantly higher for the no anaesthesia group (Pandey et al 2001a; Pandey et al 2001b). It is possible that local factors, such as trachomatous corneal changes or a particularly stoic population, may contribute to these remarkable findings. The personal experience of the author and others indicates that this approach would not be acceptable to British patients, who are accustomed to having topical anaesthesia for tonometry at every outpatient visit.

2.3.9. Other problems with local anaesthesia
There are some other problems that may occur with ocular surgery under local anaesthesia of any type (Konovitch 1997) The block may be inadequate, resulting in pain and/or sub-optimal operating conditions. The patient may fall asleep, then wake with a start, and this sudden movement may cause surgical complications. Some patients find the idea of eye surgery under local anaesthesia very stressful, and the anxiety may make them un-
cooperative, or cause cardiovasacular problems. Older patients may become confused
while lying under the surgical drapes in a darkened room. Exhaled carbon dioxide may
accumulate under the drapes, causing hypercapnia and associated hyperventilation and
possible surgical complications (Schlager et al 1998; Schlager and Staud 1999). Others
may experience claustrophobia while under the drapes, and may panic. Most of these
problems may also occur with general anaesthesia, though probably to a lesser
extent (Forrest 1994a; Sharrock 1999). Adequate pre-anaesthetic discussions with the
patient, and careful blocking technique will minimise these problems. It is important to
remember that patients can die as a result of retrobulbar or peribulbar anaesthesia,
particularly if there are no facilities or staff for resuscitation (1993; Haider 1994; Mayer
and O'Connor 1993; Morgan 1990).

2.3.10. Sedation
Intravenous sedatives are commonly used in the United States, but less so in the UK.
Sedation is so common in US practice (Norregaard et al 1997) that many North American
studies fail to mention whether or not sedation has been used. The author's personal
experience shows that American patients expect to be sedated for their surgery, whereas
British patients do not. An American book chapter emphasises the advantages of sedation:
good patient co-operation, increased acceptance of the procedure, and decreased
sympathetic response (Konovitch 1997). A British chapter is more cautious, pointing out
the need for patient selection and good technique in order to minimise the risks of
respiratory depression, loss of airway control, confusion, and lack of co-operation from the
patient (Johnson 1994b).

One of the main advantages of sedation is that most sedative agents induce relaxation and
amnesia (Johnson 1994b; Konovitch 1997). If patients are sedated prior to local
anaesthetic injection, the procedure is likely to be well tolerated (Boezaart et al 2000).
Some surgeons perform cataract surgery using sedation alone, without any LA (Rand et al
2000) (see section 2.3.8).

2.3.11. Is local anaesthesia safer than general anaesthesia?
A few randomised trials have attempted to compare LA against general anaesthesia for
cataract surgery (Barker et al 1993; Barker et al 1991; Campbell et al 1993; Cheng et al
Local anaesthesia is associated with a lower stress response, as measured by serum catecholamines and other stress hormones (Barker et al 1993; Barker et al 1991). A study of myocardial ischaemia in the 24 hours after surgery found significantly fewer episodes of intra-operative and post-operative ischaemia, in the group that were randomised to receive LA (Glantz et al 2000). None of the foregoing studies is large enough to compare all possible adverse events, so it is not proven that LA is safer.

Observational studies have compared death rates after ophthalmic surgery. A series of surgical cases carried out at Wills Eye Hospital in 1952-72 (Quigley 1974) found that the death rate after LA was GA was almost identical (p < 0.6), although the patients who had LA were generally older and thus at higher risk of death from a pre-existing condition. None of the 25 LA-associated deaths were thought to have been due to local anaesthesia, but 3 of the 20 GA-associated deaths were directly attributed to complications of anaesthesia. The paper concluded that while the observed death rates were similar, GA appeared to have an increased risk. A questionnaire sent to members of the American Association of Ophthalmology in 1968 came to similar conclusions (Duncalf et al 1970). General anaesthesia was used for about 36% of ophthalmic surgery. The death rate after GA was 6.5 per 10,000 cases, compared with 6.22 per 10,000 with LA. LA patients tended to be older; 15% of 46 GA-associated deaths occurred “on the operating table”, whereas none of the 79 LA-associated deaths occurred intra-operatively. In both papers, it was felt that the majority of deaths were unrelated to surgery or anaesthesia. Needless to say, safety aspects of general and local anaesthesia practice have improved markedly since these studies were carried out.

There can be little doubt that most cataract patients in the UK would prefer local anaesthesia. LA also allows for more efficient throughput in operating theatres, and more rapid recovery from surgery, allowing the majority of cases to be carried out on a day-case basis (Forrest 1994a; Konovitch 1997).

2.3.12. How often does death occur in association with LA for intraocular surgery?

Many patients who have ocular surgery are elderly (Desai et al 1999; McKibbin 1996) and thus may be at risk of death from natural causes. This makes it difficult to assess the
excess mortality associated with LA surgery. LA appears to have a low risk of causing death.

A review of 17,259 LA’s given at the Wilmer Eye Institute between 1952 and 1972 found no deaths that could be attributed to LA (Quigley 1974). A similar study from Pittsburgh (Petruscak et al 1973) found 2 cases of intra-operative death associated with LA, of around 7,000 LA blocks given between 1962 and 1966. These patients were both ASA grade 3 (“severe systemic disturbance due to general disease or surgical condition”), had large volumes (9 and 15 ml) of LA for cataract surgery, presumably given by the retrobulbar technique. Little detail is given, and cause of death for both cases was given as ventricular fibrillation. Thus, is not clear whether these deaths were caused by local anaesthesia, the stress of having surgery, or unrelated causes. In the subsequent 5-year period, the same paper reports no intra-operative deaths among 8,703 local anaesthetics.

This subject was addressed in a questionnaire, mailed to 500 British consultant ophthalmologists in July 1993. Of the 334 respondents, 12 reported “deaths which they felt might have been the result of local anaesthesia” (Haider 1994). All but one of these deaths occurred ‘on the operating table’ (Haider SA, pers. comm.) There have been numerous reports of life-threatening complications, and deaths, associated with LA (sections 2.3.2.6-9, 2.3.3.3, 2.3.12). While none of the reports of death are sufficiently detailed for the death to be unquestionably attributed to an LA complication, it is likely that some deaths have occurred as a direct result of brain-stem anaesthesia or other complications of LA.

2.3.13. What proportion of all intraocular surgery is currently performed using LA?
Current information is not readily available. The Department of Health collates data on operations performed in England and Wales, coded by operation. Weekly totals are available for every different eye operation, but no information is available as to the type of anaesthesia used (Department of Health, pers. comm.). Surveys from abroad are not particularly helpful in estimating UK practice, given the wide international variation in anaesthesia practice (Norregaard et al 1997).
In the United States, local anaesthesia (usually accompanied by sedation) has been the norm for several decades. Atkinson, one of the great proponents of local anaesthesia, stated in 1956 that 93.2% of US ophthalmologists used LA. (Atkinson 1956) This may be an overestimate, as he does not state his survey methods and the sample could have been biased in favour of LA. More recent figures for LA usage in the United States have been compiled by Leaming et al. Annually since 1985, he has sent a postal questionnaire to members of the American Society of Cataract and Refractive Surgeons (ASCRS). (Leaming 1986; Leaming 1987; Leaming 1988; Leaming 1989; Leaming 1990; Leaming 1991; Leaming 1992; Leaming 1993; Leaming 1994; Leaming 1995; Leaming 1996) The figures are unlikely to be representative of US practice as a whole, partly because membership of the ASCRS may indicate a desire to keep up with the latest techniques, and partly because of low (24%-46%) response rates. However, these annual reviews do document the gradual demise of retrobulbar anaesthesia for cataract surgery, from 92% in 1985 to 39% in 1996. ‘Periocular’ anaesthesia rose from less than 10% in 1985 to a peak of 38% in 1995, following which it has gradually declined due to the increasing popularity of newer techniques. Topical or topical/intracameral anaesthesia was first included in 1993 (4%) and had risen to 10% by 1996. Topical/subconjunctival blocks rose from 1% to 4% in this same period. Leaming has no category for sub-Tenon’s anaesthesia, and it is unclear whether this technique is included in ‘periocular’ or ‘other’. ‘Other’ LA techniques have consistently been below 3% of blocks, and general anaesthesia was used by 4% in 1985, 2% in 1986, and 0-1% thereafter. Sedation and monitoring are not discussed in Leaming’s papers. The low usage of GA in the United States and Canada has been confirmed by other studies (Bellan et al 1997; Norregaard et al 1997)

In Japan, similar annual surveys are carried out, with questionnaires sent to members of the Japanese Society of Cataract and Refractive Surgery. The style is very similar to the US surveys, and Leaming is again a co-author. As with Leaming’s American studies, results are unlikely to be representative of the country as a whole. (Oshika et al 2000; Oshika et al 1998; Oshika et al 1993; Oshika et al 1995; Oshika et al 1996) The 1996 survey had a 51% response rate, and indicated that retrobulbar anaesthesia was in decline, and sub-Tenon and topical techniques were increasing in popularity. (Oshika et al 1998) Retrobulbar anaesthesia was used by 90% of respondents to the first survey 1992.
et al 1993) but this had declined to 30% in 1996. Peribulbar anaesthesia was used by a relatively small proportion of respondents, around 5-9%. Sub-Tenon blocks were used by 6% of respondents in 1992, and this increased steadily to 38% in 1996. Topical anaesthesia increased from 0% to 22% over the same time period. (Oshika et al 1998)

The British literature has the advantage that most studies have attempted to include all consultant ophthalmologists, rather than members of a special interest group. However, British studies have the disadvantage that they tend to concentrate on the question of whether general or local anaesthesia is used, rather than looking at the different LA techniques. A 1984 postal survey of UK consultants had a 67% response rate, and found that approximately 63% used general anaesthesia for cataract surgery, 18% used local, and 19% used either. Sedation was not mentioned. (Wong and Steele 1985) A similar postal survey in 1988 had a 78% response rate: 13.9% always used general anaesthesia for cataract surgery, 3.1% routinely used local anaesthesia, and most (82.9%) used either. (Beckett and Rosen 1989) Another postal survey of British ophthalmologists, in 1989, concentrated on the issue of local anaesthesia for cataract surgery. (Campbell and Spalton 1992) Response rate was 80%. Local anaesthesia was used by 95% of responding surgeons, though 15% only used LA if the patient was unfit for GA, and 68% rarely or never used LA as a matter of surgical preference. Asked whether GA or LA was preferable overall, 75.5% of surgeons favoured GA. The authors state that these results “reinforce the impression that most surgeons do not operate under LA as a matter of choice”. Preferred LA techniques were retrobulbar (83.5% of surgeons), peribulbar (8.1%), both (6.1%), and topical (1.4%). Sedation was used by 61.4%. 87% of surgeons had a designated person to “look after” the patient during surgery, though 22% used no monitoring equipment. The 1990 National Cataract Surgery Survey found that 54% of patients had a general anaesthetic, and 46% had local. (Courtney 1992) A further postal survey in 1991 had an 83% response rate. 37% of respondents stated that they used GA ‘frequently’ (more than 75% of cases), and 20% used LA ‘frequently’. When operating under local anaesthesia, 45% preferred their LA patients to be sedated. Retrobulbar anaesthesia was used by 54%, peribulbar by 33%, combinations by 8%, and the remaining 5% used a variety of topical and subconjunctival approaches. (Hodgkins et al 1992)
None of these data were particularly useful when designing the Survey and estimating the sample size needed. Publications from the previous 12 years confirmed that the use of anaesthesia for ocular surgery was changing rapidly. The Survey was designed to provide a “snapshot” of LA use in the UK in late 1996, and to document the adverse events which occurred.
3. Methodology

3.1 Introductory comments
The National Survey of Local Anaesthesia was a large, prospective, observational study. The protocol was designed to get as much information as possible about current usage and complications of LA. Because complications are rare, the Survey had to include a large number of LA’s. Ideally, the Survey would have collected data prospectively, for tens of thousands of LA’s. However, it would have been impractical and probably counterproductive to request such a vast amount of information from clinicians. As a compromise, participants were asked to report every LA administered for intraocular surgery during a single week, then to report adverse events only for the remainder of a three-month period. This strategy was designed to get a good participation rate, and also allow for reasonable estimates of complication rates to be made.

Not all of the following questions could be answered fully or with certainty. Despite its large size, the Survey could not make accurate estimates of the incidence of rare complications. Because it was an observational study, safety profiles for the different LA techniques could not be directly compared. However, it was felt that the Survey design was the best compromise of methodological purity and “real world acceptability”. Despite these limitations, the Survey was able to provide full or partial answers to all of the following questions.

3.2. Questions to be answered:

3.2.1. Epidemiology questions

- What proportion of all intraocular surgery is currently performed using LA?
- Of intraocular surgery performed using LA, what is the relative frequency of usage of the different LA techniques?
• Of intraocular surgery performed using LA, what is the relative frequency of pre-operative assessment, monitoring, and other practices intended to maximise safety of LA?
• Of intraocular surgeries performed using LA, what proportion have an anaesthetist involved, and what is the extent of this involvement?
• In normal practice, what is the incidence rate of retrobulbar haemorrhage, globe perforation, brain-stem depression, and of various other complications of LA?
• What is the incidence of these complications, for each of the different LA techniques?
• How often does death occur in association with LA for intraocular surgery?

3.2.2. Clinically important questions:

• How often can we expect a “severe” (life-threatening) complication to occur, during intraocular surgery using LA?
• What sort of “severe” (life-threatening) complications can be expected?
• Are some LA techniques safer than others?
• Is there such a thing as a “totally safe” method of giving LA?
• Do we need to have an anaesthetist standing by when using LA?

3.2.3. Audit questions:

• To what extent are the current LA safety Guidelines (Anon. 1993) being followed?
• Are the current LA safety Guidelines (Anon. 1993) appropriate?

3.3. The prospective, observational study: rationale, and summary of methodology

The prospective, observational study was the chosen methodology for the Survey. Because serious complications of LA are rare, it would not have been practical to perform a retrospective review of case-notes. A retrospective review may also have missed many complications, as they are not always recorded adequately. Prospective reporting of adverse events alone would not have given any information on the incidence of LA.
complications, as the number of LA's given by each technique (the denominator) was not known. The prospective nature of the Survey also allowed for an audit, looking at the extent to which the Guidelines were being followed.

The prospective study was divided into two parts: an initial single week, followed by further 12-week period (3 months total). In the initial week, respondents were asked to report details of every LA given for intraocular surgery. This gave a good estimate of the relative frequency of the different LA techniques. It also gave a good estimate of the frequency of the more common adverse events. Data from the initial week were extrapolated to give estimates of the number of LA's given in the entire 3-month study.

For the second part of the Survey, respondents were asked to only report those LA's that were associated with adverse events. Hence, the incidence of rarer adverse events could be estimated. Importantly, it did not represent an onerous additional workload for clinicians, so that the amount of extra work generated by the Survey was not large.

Validation of the response rate involved inspecting the theatre records of a representative sample of hospitals. This allowed a calculation of the response rate, and also a calculation of the relative frequency of LA and GA.

The methodology is described in detail below.

3.3.1. "Ownership" of the Survey

It was important that all clinicians involved in the Survey felt that it was "their" survey. Because of the multidisciplinary nature of providing LA, it was important that the Survey was perceived to involve ophthalmologists and anaesthetists equally, and that other members of the theatre team were involved in the Survey. A survey or audit that originated exclusively from ophthalmologists would be regarded with suspicion by many anaesthetists, and vice versa.

"Ownership" of the study is thus an important concept. A non-partisan, group project is much more likely to be accepted than one which appears to be "imposed" by a single
group. (Ferris 1996; Williams 1996). This will be reflected by the participation rate, and the extent to which the results are accepted.

Because the Survey was so large, it was not possible for the investigators to meet all of the potential participants beforehand. Ophthalmologists and anaesthetists were therefore contacted by letter. The strategies used to encourage a sense of “ownership” included the following:

- The Survey was overseen by the Clinical Audit Subcommittee of the Royal College of Ophthalmologists, and the quality of Practice Committee of the Royal College of Anaesthetists.
- Introductory letters were sent to all consultant ophthalmologists, to all heads of department of anaesthesia, and to the nurse in charge of eye theatres, for all NHS hospitals. These introduced the author as the principal investigator, explained the reasons for the survey, and gave an opportunity to ask questions before the Survey commenced.
- Prior to commencement of the Survey, articles were published in the audit newsletters of Royal College of Ophthalmologists and the Royal College of Anaesthetists.
- All forms and posters for the survey included the names and crests of the two Royal Colleges.
- The Survey methodology gave total anonymity for all respondents who wanted it. Thus, all respondents could make free and frank reports of what happened, without fear of being “policed” by the Royal Colleges. This should have encouraged cooperation with the Survey.

3.3.2. Anonymity for respondents, and validation

Anonymity is very important to the Survey. The Survey was part clinical audit, part epidemiological research. In order to minimise bias from under-reporting of adverse events, it was very important that all reports could be anonymous. If a procedure did not comply fully with the safety Guidelines, and an adverse event occurred, the clinician
should be able to send in a full and frank report, without fear of reprisal. Anonymity was vital for the Survey, in terms of overall participation rate, reporting of adverse events, and reporting of cases which did not fully comply with the safety Guidelines.

Anonymity did cause some methodological difficulties. It was desirable to obtain follow-up data on patients who had certain adverse events (e.g. life-threatening events). If the survey were totally anonymous, such data would be unavailable. Having an optional section in the Adverse Event Report Form, in which clinicians could enter their contact address if they wished, circumvented this problem.

Anonymity also posed some problems in validation of the response rate. An easy way to validate the response rate would be to select representative hospitals, and to put an identifying code or mark on all of the Report Forms that were sent to each of these hospitals. By comparing the number of Forms returned in the first week with the number of LA procedures in the theatre record, participation rate for that hospital could be exactly calculated. For reasons outlined above, it was important that there were no identifying marks on any form that would link it to a particular hospital. Therefore, a different method of validation had to be chosen. The method used is described in full below (section 3.4.1.). Briefly, the theatre records of representative hospitals were inspected, and the number of LA's used in these hospitals was extrapolated to estimate the number of LA's given in the country for that week. Participation rate was then estimated, by dividing the actual number of returns by this figure.

3.3.3. Sample size, and compromises to improve participation rate

In order to estimate the incidence of rare complications of LA, it is necessary to look at a large number of procedures. A very large sample should, in an ideal world, give the best estimate of incidence. However, such a sample is not always practical, particularly for this sort of study. Requesting very large amounts of data would adversely affect the participation rate, paradoxically reducing the certainty of the estimate. As discussed above (section 3.3), the Survey protocol was a compromise that was designed to give a good participation rate, and be only a small burden on clinicians. This strategy was adopted in order to get a reasonable estimate of the incidence of severe complications.
To calculate the sample size required, it is necessary to have estimates for the following:

(i) Approximate incidence of the event to be studied
(ii) Expected participation rate for the survey
(iii) The degree of certainty that is required

If there is no previous estimate of incidence, then it is necessary to have estimates of:

(i) Numerator (ie number of complications occurring, in a given time-period and area)
(ii) Denominator (ie the number of LA’s given, in this same time-period and area)

LA has a low incidence of “life-threatening” or “sight-threatening” complications (see section 2.3, particularly sections 2.3.2.9, 2.3.2.14, 2.3.12). Two large studies of retrobulbar anaesthesia found the incidence of brain-stem anaesthesia to be 0.27% (16 of 6,000)(Nicoll et al 1987) and 0.15% (8 of 5,230).(Hamilton et al 1988) Another study found the incidence of respiratory arrest to either 0.09% (2 of 2,235), or 0.79% (7 of 888), depending on the concentration of lignocaine in the mixture.(Wittppenn et al 1986) With peribulbar anaesthesia, incidences of any “life-threatening” complications of 0.006% (1 in 16,224) (Davis and Mandel 1994) and 0% (0 of 5704)(Hamilton et al 1988) have been reported. A series of 3000 sub-Tenon’s blocks found no systemic complications.(Fukasaku and Marron 1994b) The incidence of globe penetration/perforation during retrobulbar LA has been reported to be 0% (0 of 4,000),(Kimble et al 1987) 0.02% (1 of 5,230),(Hamilton et al 1988) and 0.075% (3 of 4,000).(Ramsay and Knobloch 1978) During peribulbar LA the reported incidence is 0.006% (1 of 16,224), or 0% (0 of 5,704).(Hamilton et al 1988) A prospective survey of 50,000 retrobulbar and peribulbar blocks in a large Saudi teaching hospital found seven needlestick injuries (0.014%).(Edge and Navon 1999) A 1994 survey of UK ophthalmologists found 39 ocular perforations in one year, an estimated incidence of 0.114%.(Gillow et al 1996b) Thus, the expected incidence of “severe” complications is in the order of 0.1% (1 in 1,000)

Information on the number of intraocular surgeries performed each week under the National Health Service (NHS) is available from government sources. In 1995, the Department of Health could supply data on the number of intraocular surgeries performed each week in England and Wales, but not for Scotland or Northern Ireland. Data are
available for each surgical procedure in the coding book, (Anon. 1990) though there is a delay of at least two years in accessing data for any particular week. Unfortunately, the method of anaesthesia (LA or GA) is not recorded. This source indicated that 190,032 intraocular surgeries were performed in England and Wales in the fiscal year 1991-2 (Department of Health, personal communication). Data held at the Royal College of Ophthalmologists indicated that 563 of the 685 UK consultant ophthalmologists (82%) worked in England and Wales. Of the 178 UK hospitals that have ophthalmology departments, 155 (87%) are in England and Wales. The number of NHS intraocular surgeries performed in the UK in the year 1991-2 was therefore estimated to be (190,032) \( \div \) (about 85%) = 223,500. Because of service expansion, the true figure for 1996 could be nearer to 250,000.

The proportion of these surgeries that use LA was estimated using previous published data, and our own observations. British surveys had indicated a decline in GA usage over the preceding decade. (Beckett and Rosen 1989; Courtney 1992; Hodgkins et al 1992; Wong and Steele 1985) (see section 2.3.12). In 1996, the general perception among ophthalmologists was that LA use was becoming more widespread. For the purposes of estimating the sample size required for the Survey, it was assumed that around 75% of intraocular surgery was performed using LA.

The Survey method was a compromise between what could be expected of ophthalmologists and anaesthetists who were asked to complete the forms, and an ideal which would have involved reporting of all anaesthetics for many months (section 3.1). 250,000 intraocular surgeries per year is equivalent to around 5,000 a week. If 75% of these are performed using LA, this would give around 3,600 LA's per week. Previous national audits carried out through the Royal College of Ophthalmologists (Bailey et al 1998; Courtney 1992) indicated that a 75% response rate could be expected, giving around 3,000 reports per week. If the actual incidence of a complication is 3%, then a sample size of 3,000 can be expected to estimate the complication rate with an accuracy of -0.6% to +0.7%, assuming that the sample is representative (Estere et al 1994).

Given the low incidence of ‘severe’ complications of LA, it was apparent that the Survey would not be able to get an accurate estimate of incidence. To ask for detailed reports of
every LA given for several months would have been unacceptable, and would have resulted in a poor response rate. Thus, the sample used was a compromise that was felt to be most likely to give a good reporting rate: reports of all LA’s for one week only, then reports of complications only for the remainder of a 3-month period.

3.3.4. The Hawthorne effect

The Hawthorne effect is “the effect (usually positive or beneficial) of being under study upon the persons being studied; their knowledge of the study often influences their behaviour” (Last 1983). The name is derived from a series of experiments that were carried out in the 1930’s in the Western Electrical Plant, in Hawthorne, Illinois. This effect is evident in clinical audit, in that practice may change in anticipation of an audit taking place (Ferris 1996).

In designing the Survey, there was concern that some Eye units might alter their practice for the initial week of data collection. For example, pre-operative assessments could be performed in a different way to better comply with the Guidelines, or anaesthetic departments might find more anaesthetists to cover ophthalmic LA surgeries in that week. To minimize this possible source of bias, the actual dates of the Survey were not announced until 1-2 weeks before data collection commenced. The other likely manifestation of the Hawthorne effect would be for stricter compliance with the Guidelines on the day of surgery. Guaranteed anonymity for all respondents should have minimized the Hawthorne effect as far as is practicable.

3.3.5. Other strategies to encourage participation:

Attempts were made to maximize participation at all stages of the Survey, particularly for the main period of data collection. Efforts were made to make all concerned feel that it was “their” Survey (ie ownership, section 3.3.1), and the amount of extra work for clinicians was designed to be minimal. The Survey was overseen by representatives of both Royal Colleges, which should have reassured participants regarding possible bias towards the interests of either anaesthetists or ophthalmologists. Other strategies used to encourage participation were:
• The Survey was referred to as a “survey”, rather than an “audit”. The term “survey” is more neutral, and does not carry any implication of being “policed” by the Royal Colleges.
• All letters were kept to a single side of A4 paper
• All letters were personally signed by the author
• Participants were promised that the results would be made available to them
• Anonymity was guaranteed
• Data collection periods were kept as short as possible
• All forms were piloted before being circulated
• Forms for the initial Survey week were short (one piece of A4 paper)
• Forms for the initial Survey week had simple questions, so that any member of theatre staff could complete them, at the time of surgery
• All Survey forms, envelopes, instructions etc. were presented together in a free-standing plastic dispenser (of the type used to offer advertising leaflets at “point of sale”).
• Posters were produced, to remind staff of the Survey dates, and inclusion criteria
• Survey Packs, comprising a pre-filled dispenser, posters and covering letter were mailed directly to each individual Eye Theatre.

3.3.6. Ethical considerations:

Any hospital-based, interventional must have prior approval from the appropriate Local Ethics Committee. The protocol for the present Survey was discussed with the chair of the local Committee. It was agreed that, because this was a purely observational study, formal Ethical approval was not required. This opinion was confirmed by a representative of the Department of Health, who had encountered a similar query the previous year regarding a survey carried out by the Royal College of Obstetricians Gynaecologists.
3.3.7. The introductory questionnaires to Consultant Ophthalmologists.

Questionnaires were sent to all consultant ophthalmologists in the UK. Names and addresses of 685 ophthalmologists were obtained from a database, held by the Royal College of Ophthalmologists. The questionnaires served to introduce the survey, gather baseline data, and also to assess previous experience and attitudes to anaesthesia. A copy of the questionnaire appears as Appendix 1.

The questionnaire had the following aims:

- To introduce the Survey
- To provide an estimate of the number of intraocular surgeries performed each week, and the proportion of LA and GA used
- To give an estimate of the extent to which some aspects of the 1993 LA safety Guidelines (Anon. 1993) were being followed
- To estimate how many surgeons would sometimes operate without backup (anaesthetist or cardiac arrest team) in the hospital
- To assess personal preferences for anaesthesia techniques (GA or LA, use of sedation, LA techniques)
- To assess opinions regarding the need for the routine presence of an anaesthetist during LA surgery
- To assess the incidence of deaths related to LA for intraocular surgery. This is a very rare complication of LA, (Haider 1994) but it is likely that any consultant would remember a case that occurred under their care.

Because of the sensitivity of some of the questions, it was decided that this questionnaire, like the rest of the Survey, should be anonymous.

3.3.8. The introductory questionnaires to Heads of Department of Anaesthesia.

Questionnaires were sent to all Heads of Department of Anaesthesia, for hospitals that had at least one consultant ophthalmologist. There was no data available as to which
consultant anaesthetists covered ophthalmology lists, therefore the questionnaires were sent to Heads of Department only. The aims of the questionnaire were very similar to those of the consultant ophthalmologists' questionnaire, and many of the questions were identical. The anaesthetists' questionnaire also aimed to find out the reasons for incomplete provision of anaesthetists to cover ophthalmology lists (Appendix 2).

3.3.9. The introductory questionnaires to Nurse in Charge of Eye Theatres

Letters were sent to the Nurse in Charge of Eye Theatres, for hospitals that had at least one consultant ophthalmologist. These served to introduce the Survey, and request help in the form of putting up posters and survey packs. A short form was included, (Appendix 3), on which respondents were asked to enter the name and address of each operating theatre in which surgeons from their hospital performed intraocular surgery under the National Health Service. This had the following benefits:

- Survey packs (forms, posters, etc.) could be mailed direct to each appropriate theatre, thus facilitating a good participation rate
- The number of theatres used by each unit was known, which allowed for more accurate calculations when validating the response rate (section 3.4.1)
- Theatre staff could anticipate the Survey, be reassured about the minimal workload, and encourage their colleagues to participate

3.3.10. Contents of the Survey Pack

A Survey Pack was mailed to each individual eye theatre. Each pack contained everything needed for participation in the main period of data collection (the initial week, and the remainder of the three-month Survey).

The contents of the Survey Pack are illustrated as Appendix 4. Each pack contained:

- A covering letter
- A poster, detailing survey dates, and instructions (Appendix 5)
A free-standing plastic dispenser, pre-filled with the following:

- A laminated card, printed with instructions for the Survey (Appendix 6)
- Copies of the Local Anaesthetic Report Form (Appendix 7)
- Copies of the Adverse Event Form (Appendix 8)
- Pre-printed, pre-paid envelopes, addressed for return to the author at the Royal College of Ophthalmologists

### 3.3.11. The Local Anaesthetic Report Form

The Local Anaesthetic Report Form comprised a single sheet of yellow A4 paper, with 12 questions (Appendix 7). The LA Report Form had several features designed to encourage participation: there were no marks of any kind, thus ensuring anonymity for respondents. Questions were simple, so that any member of the theatre staff could complete the Form at the time of surgery, without having to refer to the patient’s case-notes. The questions were chosen so that the Form could be completed in theatre, at the time of surgery. Questions covered patient and hospital demographics, the type of surgery and LA technique, the person giving the LA, use of anticoagulants, safety precautions, and any adverse events.

The format of the Forms, while designed to maximize participation in the Survey, also had several disadvantages. Because the forms were anonymous, the participation rate could not be calculated as accurately as if each hospital could be identified (see section 3.4.1, Validation). The simple questions meant that there was no information about the pre-operative tests that took place on patients who had uneventful surgery (this data was requested on the Adverse Event Form). Completing the Forms at the time of surgery meant that any late Adverse Events (occurring after the patient had left the theatre) would be missed by the Survey. The format of these Forms was thus a compromise, but the advantages (particularly a good participation rate) were felt to outweigh the disadvantages.

For the initial week of the Survey, theatre staff were asked to complete a LA Report Form for every case in which LA was administered to a patient, for the purpose of intraocular surgery. If an adverse event occurred, an Adverse Event Report Form was to be
completed in addition. For the remainder of the three-month Survey, forms were only to be completed for cases in which an adverse event occurred in association with LA.

3.3.12. The Adverse Event Form

The Adverse Event Form was printed on pink A3 paper, folded to give 4 sides of A4 (Appendix 8). It was to be completed, along with a LA Report Form, for cases in which an adverse event occurred in association with LA. For the purposes of the Survey, an Adverse Event was defined as “something which made you observe the patient more closely, or take action”.

The 20 questions asked for detail on the Adverse Event, its management and immediate outcome. The Form also asked detailed questions about the pre-operative testing, LA drugs and sedatives used, and more detail on monitoring. Ideally, these latter data would have been sought in the LA Report form, but it was felt that to ask for this data on every case would be too cumbersome, and adversely affect participation. The Form ended with an optional section, in which consenting ophthalmologists could enter their contact details to allow for follow-up of Adverse Events.

3.3.13. Piloting

The forms were piloted prior to printing and distribution. Piloting took place at the Leicester Royal Infirmary, and at the Croydon Eye Unit. The main aims of piloting were to ensure that the questions could be understood and answered easily, and that the forms themselves were of acceptable size and format. This required several rounds of consultation and piloting.

3.4. Data interpretation.

3.4.1. Validation of the participation rate: initial week

The participation rate for the initial week of the Survey can be defined as the proportion of eligible LA’s for which a properly completed LA Report Form was actually received. A validation protocol was designed, to allow calculation of the participation rate, and the
total number of GA’s and LA’s given. Validation involved inspecting the theatre records of a representative sample, and comparing their results with the completed forms received.

Because the larger Eye Units can be expected to have a larger surgical workload, the 178 Eye Units were grouped into three categories, and a representative sample was taken from each group. This was done in order to get a sample that was likely to reflect the true workload. The 178 Eye Units were classified into three categories: major academic units, other units recognised for basic specialist training in ophthalmology, and units without recognition. A sample of hospitals from each category were selected at random to be “validation units”.

It was anticipated that surgical workload would be highest in the “major academic units”, and lowest in the “non-recognized” units. It was decided to sample around 20% of the “major academic” units, and 10% of the other categories. Thus, 5 of the 26 “major academic”, 15 of the 136 “other, recognized” and 2 of the 16 “non-recognized” units were selected at random, giving a total of 22 prospective “validation units”. These 22 units were then asked to participate in validation. A letter was sent to the consultant ophthalmologist with responsibility of audit, as identified from the database held at the Royal College of Ophthalmologists. The letter explained the need for validation, and asked for co-operation. 21 of the 22 units agreed (one of the “other, recognized” units declined). Validation units were asked to participate in the Survey as for all other units, but were asked in addition to send a copy of the operating theatre records from all eye theatres, relating to the initial week of the Survey.

Responses to the theatre nurses’ mailing (section 3.3.9) confirmed that the “major academic” units did indeed have more theatres. Inspection of the theatre records, sent in by the Validation Units, showed that surgical workload was also higher in the “major academic” units. When extrapolating the Validation Unit data to estimate national figures, appropriate corrections were made for the different surgical workload in the three categories of Eye Unit.

An attempt was made to further verify the response rate from the validation Units, while maintaining anonymity for the hospitals and clinicians involved. This involved the use of
colour-coded forms. The Survey Packs that were sent to the Validation Units contained Report Forms of a darker shade of yellow. Thus, it was possible for the investigators to tell whether a Report Form had been completed in one of the 21 Validation Units, or (if pale yellow) one of the 157 other units. The only other difference between Validation Units and other units was that we had requested permission from the ophthalmologist with responsibility for audit. This request for permission was made via a letter, followed up by a reminder letter and telephone calls if required. This strategy allowed an exact calculation of the overall response rate from the 21 Validation Units: inspection of the theatre records showed that 535 eligible LA operations were performed in the initial week, and a total of 515 dark yellow forms were received for this period. This gives a response rate of \( \frac{515}{535} = 96.2\% \) for Validation Units, which is far in excess of the expected overall participation rate for a national survey of this type (Bailey et al 1998; Courtney 1992). It was concluded that this high response rate in Validation Units must have been due to increased enthusiasm for the Survey as a result of personal contact from the principal investigator.

Because the colour-coded forms system appeared to be a source of bias (see previous paragraph), we used a more standard method of estimating the national participation rate. To estimate the total number of eligible LA’s given in the initial week, we extrapolated the figures from the theatre records of the Validation Units. For each of the three categories of surgical unit, we knew the number of operating theatres (data from theatre nurses’ questionnaire, section 3.3.9). For each category, total number of theatres was divided by the number of Validation Unit theatres, and this figure was multiplied by the number of eligible LA’s given in the validation units. This gave a reasonable estimate of the number of eligible LA’s given nationally, in the initial week.

3.4.2. Estimation of the ratio of general anaesthesia to local anaesthesia

The ratio of GA to LA was calculated from the theatre records of the Validation Units. The method was similar to that used to calculate participation rate in the initial week (section 3.4.1), in that actual figures from the Validation Units were extrapolated, for each of the three categories of unit.
3.4.3. Estimation of the number of LA’s given in three months, and one year

The number of LA’s given nationally in the initial week was estimated as described above. This figure was extrapolated to give an estimate of the number of LA’s given nationally in the entire three-month Survey, and a one-year estimate. In making these calculations, it was necessary to make a correction for the weekly variation in surgical workload.

Department of Health figures show that national surgical workload varies from week to week, and is significantly affected by such factors as school holidays and the national holiday at the end of August. The Department of Health can provide weekly totals for intraocular operations performed in England and Wales, but does not record the type of anaesthetic used. As 1996 figures were not expected until late 1998, data from the financial year 1991-2 were used instead. 1991 was chosen because September 1st fell on a Sunday, the same day as in 1996. In 1991-2, 1.586% of eye operations were performed in the first week of September, and 26.58% in the period 1st September-30th November (Department of Health, pers. comm.) This factor (i.e. 26.58/1.586, or 16.76 x first week) was used to correct for workload. Standard errors and confidence intervals were calculated on a log scale using the delta method so as to combine the uncertainty in the validation study, the first week and the reported events over 3 months. In this way, estimates were made for the total number of intraocular operations performed in the whole United Kingdom, and the total number of LA’s given.

3.4.4. Estimation of adverse event rates: initial week

It was simple to calculate the reported adverse event rate for the initial week. The number of adverse event reports was divided by the total number of reports for this week. However, this calculated rate may not reflect the true rate. It is likely that the degree of under-reporting for ‘routine’ LA’s was different to that for LA’s associated with adverse events. Thus the true rate of adverse events may have been higher or lower than the rate that was calculated from first-week returns.

It was not possible to estimate the degree of under-reporting for adverse events. Because adverse events are rare, any attempt at validation would require the inspection if a very large number of case-notes, from many hospitals. This would be very difficult to organise, particularly as it would be necessary to examine 100% of the case-notes in any sample.
(patients who experienced severe adverse events are more likely to have been transferred to another specialty, or died, and this would make their case-notes more difficult to locate for review). Additionally, many adverse events may not have been recorded adequately.

A further problem was that, in order to encourage full and frank participation, none or the LA Report Forms contained data to link them to a particular hospital. Attempts at validation of the adverse event reporting rate would thus cause an enormous amount of extra work, and would have added little to the conclusions of the Survey.

3.4.5. Estimation of adverse event rates: second phase of Survey

In the second phase of the survey, respondents were asked to report only those LA’s which were associated with adverse events. This made under-reporting more likely, as respondents would have to make more effort to remember the Survey, and complete the forms. Because of this, we expected a higher degree of under-reporting in this second phase.

The rate of reported adverse events for the second phase was calculated, by dividing the number of Adverse Event Reports by the estimated total number of LA’s given. This calculation would only give a true rate if all Adverse Events were reported (i.e. 100% participation for adverse events). Because we expected a degree of under-reporting, we attempted to estimate this effect by comparing the reported adverse event rates in the two phases of the Survey. This was done separately for ‘minor’ and for “severe’ adverse events.

3.4.6. Follow-up of patients who had adverse events

It was desirable to get follow-up data on patients who had experienced certain adverse events, in order to evaluate any long-term effects of Adverse Events. In order to get follow-up information, it was necessary for the investigators to contact a clinician who had managed the patient, and to have some way of identifying the patient. This meant a loss of anonymity. Because anonymity was felt to be vital for a good response rate, it was decided to make the Follow-up section optional. The Adverse Event Form (Appendix 8) included a section in which clinicians could enter their name, address, and the patient’s identification number, only if they consented to be contacted for follow-up. This strategy
allowed total anonymity for those who wanted it, while still allowing for follow-up data to be sought.

Ideally, the Survey would have sought follow-up data on all patients who had LA. This would have been so cumbersome as to seriously reduce the participation rate. The above strategy was chosen as a compromise that allowed follow-up information for the majority of patients who experienced adverse events, while still maintaining anonymity for those who wanted it. This strategy was felt to be the best way of balancing the needs for full and frank reporting, with the need for follow-up information.

Follow-up was sought for all patients who experienced orbital haemorrhage, and Systemic adverse events. Follow-up was not sought for other adverse events, generally because there were few patients in each category, and/or the outcomes for these events was well known.

The Follow-up Form for orbital haemorrhage appears as Appendix 9. The Follow-up Form for Systemic Adverse Events appears as Appendix 10. Follow-up questionnaires were mailed to clinicians about 6 months after the end of data collection. They were designed to get the following information:

- Full description of the Adverse Event
- Management of the Adverse Event
- Long-term outcome

### 3.4.7. Dissemination of results

It was important to disseminate the results of this Survey to ophthalmologists and anaesthetists, for the following reasons:

- The Survey addressed an ongoing controversy in patient management, with implications for service provision, manpower and patient safety
- The Survey had been anticipated in British ophthalmology (Rubin 1997) and anaesthesiology journals (Rubin 1995), and also in non-peer reviewed publications (including the audit newsletters of each of the Royal Colleges).
• The Survey results were to be used in the preparation of revised LA safety guidelines, hence the need for peer-reviewed publication.
• Ophthalmologists and anaesthetists were promised feedback, in an effort to improve the participation rate.

Initial outcomes were presented at several academic meetings, including the Annual Congress of the Royal College of Ophthalmologists, the European Society of Regional Anaesthesia, and the British Ophthalmic Anaesthesia Society (see Appendix 11 for full list). The main peer-reviewed papers were published in *Eye*, which is circulated to all Members and Fellows of the Royal College of Ophthalmologists. Anaesthetists were informed of impending publication, via the Quality of Practice Committee of the Royal College of Anaesthetists.
4. Results/discussion

4.1. The initial questionnaires to consultant ophthalmologists

**Summary**

Initial contact questionnaires (*Appendix 1*) were sent to all 685 UK consultant ophthalmologists on the Royal College of Ophthalmologists' database. The forms were anonymous and unmarked, hence individual reminders could not be sent: 510 ophthalmologists (74.5%) returned completed questionnaires. Not all respondents answered all questions, but each of the questions was answered by at least 465 respondents. With the exception of a few ophthalmologists who never performed intraocular surgery, no respondent indicated a refusal to participate in the main part of the Survey.

This response rate compares favourably with similar postal surveys of British consultant ophthalmologists: previous questionnaires on related subjects have had response rates of 67%, (Wong and Steele 1985) 71%, (Gillow et al 1996) 78% (Beckett and Rosen 1989) and 86%, (Hodgkins et al 1992) though it is unclear whether reminders were sent to non-responders in these studies.

The initial questionnaire showed that most consultant ophthalmologists preferred LA over GA when performing cataract surgery, and that this trend is stronger among younger consultants (see below for full discussion). Ophthalmologists were asked about the availability of anaesthetists to cover their LA intraocular surgery in NHS hospitals. 49% of respondents stated that an anaesthetist was always available to cover their LA lists, and overall 72% of cases were said to be covered. Forty-nine ophthalmologists (9.6%) stated that they never had an anaesthetist in theatres when performing intraocular surgery under LA. Sixty-four (12.5%) stated that they sometimes operated under LA when there was no anaesthetist in the hospital, and 31 (6%) stated that they sometimes operated when there was neither an anaesthetist nor a cardiac arrest team available on site.

There were ten reports of patient death "as a result of local anaesthesia for intraocular surgery". This reported death rate is equivalent to one LA-associated
death per twenty 25-year consultant careers. The questionnaire did not ask about other serious complications, but several respondents described cases in which patients might have died were it not for the intervention of an anaesthetist.

The actual questions are reproduced below (surrounded by boxes), followed by results and discussion.

4.1.1. Ophthalmologists' Question 1 (workload)

Oq 1. In total, how many “intraocular” operations are performed by your surgical firm in an average week? This means cataract, trabeculectomy, retinal reattachment, corneal grafting and related surgery, but not lasers, squints or lid work.

About ................ operations per week

There were 501 responses. The mean was 10.2 intraocular operations/week, with standard deviation (SD) of 6.05 and the mode was 10 (chart Oq 1.1).

Fifteen respondents gave an answer above 20 (see table). It is likely that most or all of these 15 had misunderstood the question, and had given the weekly total for their hospital (unit), rather than for their personal consultant firm.

Six respondents (1.2%) stated that the number of such operations was “zero”.
4.1.2. Ophthalmologists' Question 2 (use of general and local anaesthesia)

Oq 2. Of these operations, what is the usual frequency of the different types of anaesthesia? (Percentages should add up to 100%)

<table>
<thead>
<tr>
<th></th>
<th>% General</th>
<th>% Local alone</th>
<th>% Local + sedation</th>
</tr>
</thead>
</table>

Pooling all responses, the majority of cases (66%) used LA alone, 27% used GA and 5% LA with sedation (Pie chart Oq2.1). Individual responses are grouped in deciles in the bar chart Oq2.2, which demonstrates that some practices use mainly GA, some use mainly LA, and some use mainly LA with sedation. For each of the three techniques, there are a few consultant firms that use it exclusively, or eschew it (table Oq2.3).

These results illustrate a continuing trend away from general anaesthesia in the last decade. Wong's 1984 postal survey of UK ophthalmologists found that 66%
of respondents used GA exclusively for cataract surgery. (Wong and Steele 1985) A similar survey in 1988 gave a figure of 13.9%, (Beckett and Rosen 1989) and the current Survey (table Oq2.3) found that only 3 of 490 respondents (0.6%) used GA exclusively.

**Oq2.1. Overall usage of GA, LA, LA + sedation**  
(pooled results from all respondents)

- GA: 27%
- LA alone: 66%
- LA + sedation: 5%

**Oq2.2. Frequency of use of GA, LA, LA + sedation**
Oq2.3. Exclusive use or non-use of anaesthetic techniques.

<table>
<thead>
<tr>
<th></th>
<th>General</th>
<th>Local alone</th>
<th>Local + sedation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never used (0%)</td>
<td>5.3%</td>
<td>5.2%</td>
<td>76.5%</td>
</tr>
<tr>
<td>Always used (100%)</td>
<td>0.6%</td>
<td>3.2%</td>
<td>0.2%</td>
</tr>
</tbody>
</table>

4.1.3. Ophthalmologists’ Question 3 (ophthalmologists’ place of work)

Oq 3. Type(s) of hospital where your firm performs intraocular surgery

- [ ] Teaching Hospital (General)
- [ ] Teaching Hospital (Eye Specialist)
- [ ] District Hospital (General)
- [ ] District Hospital (Eye Specialist)
- [ ] Cottage Hospital
- [ ] Other: please specify .......................

This question was asked in order to perform sub-group analysis on the other questions (see results for q. 7, 8, 10). Forty-one of the 491 respondents (8.3%) operated in more than one category of hospital, and this is why the totals in table Oq3.1 sum to more than 491. These 41 consultants were assigned one hospital as a “main place of work”, assuming the following priorities: Teaching (general) > Teaching (eye) > District (general) > District (eye). These combined data were used to produce the 491 “Main places of work” in table Oq3.2.

Oq3.1: All places of NHS surgical work

| Teaching Hospital (General) | 109 |
| Teaching Hospital (Eye Specialist) | 76 |
| District Hospital (General) | 280 |
| District Hospital (Eye Specialist) | 64 |
| Cottage Hospital | 6 |
| Other: | 6 |

Oq3.2. “Main place of work”:

| Teaching Hospital (General) | 109 |
| Teaching Hospital (Eye Specialist) | 64 |
| District Hospital (General) | 261 |
| District Hospital (Eye Specialist) | 54 |
| Other: | 3 |
4.1.4. Ophthalmologists’ Question 4 (monitoring of LA patients)

The following questions refer to your firm’s LOCAL ANAESTHETIC practice.

**Oq 4. How are patients routinely monitored?**

<table>
<thead>
<tr>
<th>Option</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood pressure</td>
<td></td>
</tr>
<tr>
<td>Electrocardiography</td>
<td></td>
</tr>
<tr>
<td>Pulse oximetry</td>
<td></td>
</tr>
<tr>
<td>None of these</td>
<td></td>
</tr>
</tbody>
</table>

The vast majority of respondents (98.4%) stated that their patients had some sort of monitoring during LA surgery, though 8 respondents (1.6%) stated that no monitoring was performed (pie chart Oq4.1). Almost 60% stated that they routinely used all three modalities of monitoring, therefore complying with the 1993 College guidelines (Anon. 1993).

A similar survey of British consultant ophthalmologists was carried out in 1989, 4 years before to the publication of the Colleges’ guidelines. It found that 22% of respondents used no monitoring for their LA patients (Campbell and Spalton 1992). Electrocardiographic monitoring was done by 42%, blood pressure by 29%, and 87% had a “designated member of staff to look after the patient”. The present Survey therefore demonstrates that there has been a significant increase in the use of monitoring for LA patients.
Oq 4.1 How are patients routinely monitored?

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Monitoring Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>2%</td>
<td>No monitoring</td>
</tr>
<tr>
<td>60%</td>
<td>Pulse oximetry, Blood pressure, Electrocardiography</td>
</tr>
<tr>
<td>9%</td>
<td>Pulse oximetry, Blood pressure</td>
</tr>
<tr>
<td>10%</td>
<td>Pulse oximetry, Electrocardiography</td>
</tr>
<tr>
<td>2%</td>
<td>Blood pressure, Electrocardiography</td>
</tr>
<tr>
<td>15%</td>
<td>Pulse oximetry alone</td>
</tr>
<tr>
<td>2%</td>
<td>Blood pressure alone</td>
</tr>
<tr>
<td>1%</td>
<td>Electrocardiography alone</td>
</tr>
</tbody>
</table>

4.1.5. Ophthalmologists' Question 5 (use of intravenous cannula)

Oq 5. Is an intravenous cannula routinely sited? [ ] Yes [ ] No

Over two-thirds of respondents stated that they complied with the College Guidelines (Anon, 1993) and routinely sited an intravenous cannula for LA surgery.
Oq5.1. Is an intravenous cannula routinely sited?

[Diagram showing 31% No i.v. cannula and 69% routine i.v. cannula]

4.1.6. Ophthalmologists' Question 6 (presence of anaesthetist for LA surgery)

Oq 6. For what proportion of your LOCAL anaesthetic intraocular operations is there an anaesthetist in the theatre? (Present in case there is a problem with a local anaesthetic, not necessarily to give the LA itself.)

..................% of these LA operations

In the majority of cases, an anaesthetist was available in case of a problem (bar chart Oq6.1). An anaesthetist was in theatres all (100%) of the time in 54%, some of the time in 36%, and none (0%) of the time in 10% (pie chart Oq6.2).

Of the respondents stated that there was never an anaesthetist in theatres when they performed LA surgery, 11 were in teaching (general) hospitals, 7 were in teaching (eye) hospitals, and 28 were in district general hospitals.
Oq6.1. For what proportion of your LOCAL anaesthetic intraocular operations is there an anaesthetist in the theatre?

![Bar graph showing percentage of LA cases covered by an anaesthetist.]

Oq6.2. Anaesthetic cover for LA surgery (pooled results)

- 10% None covered
- 36% Some covered
- 54% All covered
4.1.7. Ophthalmologists' Question 7 (LA surgery when there is no anaesthetist in the hospital)

Oq 7. Does your firm ever do intraocular surgery when there is no anaesthetist in the hospital?

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>65</td>
<td>87</td>
</tr>
</tbody>
</table>

Sixty-five of 494 respondents (13%) said that this sometimes happened. (pie chart Oq7.1). Analysis of responses to q.9 indicated that this situation arises in the experience of about 5% consultants working in general hospitals, 16% of consultants in eye hospital, and 50% of those working in cottage hospitals (table Oq2.2). This fits with the general perception that there is usually at least one ‘on-call’ anaesthetist at a district general hospital or teaching hospital, but free-standing eye hospitals and cottage hospitals may not have a resident anaesthetist.

Oq7.1. Does your firm ever do intraocular surgery when there is no anaesthetist in the hospital?

- 13% sometimes
- 87% Never

Oq7.2. In what type of hospitals does this happen?

<table>
<thead>
<tr>
<th>5% of consultants in:</th>
<th>Teaching Hospitals (General)</th>
<th>(6 / 109)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15%</td>
<td>Teaching Hospitals (Eye Specialist)</td>
<td>(11 / 76)</td>
</tr>
<tr>
<td>6%</td>
<td>District Hospitals (General)</td>
<td>(16/280)</td>
</tr>
<tr>
<td>19%</td>
<td>District Hospitals (Eye Specialist)</td>
<td>(12 / 64)</td>
</tr>
<tr>
<td>50%</td>
<td>Cottage Hospitals</td>
<td>(3 / 6)</td>
</tr>
<tr>
<td>50%</td>
<td>Other</td>
<td>3 / 6</td>
</tr>
<tr>
<td></td>
<td>Not stated</td>
<td>14</td>
</tr>
</tbody>
</table>
4.1.8/9. Ophthalmologists’ Question 8 (LA surgery when there is no anaesthetist or cardiac arrest team in the hospital). Question 9 (further detail)

Oq 8. Does your firm ever do intraocular surgery when there is no anaesthetist and no cardiac arrest team in the hospital?

[ ] Yes  [ ] No

Oq 9. If you answered “Yes” to questions 7 or 8, in what type of hospital does this happen?

[ ] Teaching Hospital (General)  [ ] Teaching Hospital (Eye Specialist)
[ ] District Hospital (General)  [ ] District Hospital (Eye Specialist)
[ ] Cottage Hospital  [ ] Other: please specify...........................

This question looked at whether ophthalmologists ever operated without any formal “back-up” in case resuscitation was required. This situation occurred to 32 consultants, comprising 6.5% of respondents (*pie chart Oq8.1*). Analysis of the type of hospitals where this occurs (q.9) indicated again that specialist eye hospitals and cottage hospitals are more likely to have poor back-up in case of an emergency (*table Oq8.2*).

Oq8.1. Does your firm ever do intraocular surgery when there is no anaesthetist and no cardiac arrest team in the hospital?

- 6.5% Sometimes
- 93.5% Never
Oq8.2. In what type of hospitals does this happen?

<table>
<thead>
<tr>
<th>0% of consultants in:</th>
<th>Teaching Hospitals (General)</th>
<th>(0 / 109)</th>
</tr>
</thead>
<tbody>
<tr>
<td>11%</td>
<td>Teaching Hospitals (Eye Specialist)</td>
<td>(8 / 76)</td>
</tr>
<tr>
<td>1%</td>
<td>District Hospitals (General)</td>
<td>(4 / 280)</td>
</tr>
<tr>
<td>17%</td>
<td>District Hospitals (Eye Specialist)</td>
<td>(11 / 64)</td>
</tr>
<tr>
<td>50%</td>
<td>Cottage Hospitals</td>
<td>(3 / 6)</td>
</tr>
<tr>
<td>50%</td>
<td>Other</td>
<td>(3 / 6)</td>
</tr>
<tr>
<td>Not stated</td>
<td></td>
<td>3</td>
</tr>
</tbody>
</table>

4.1.10. Ophthalmologists’ Question 10 (personal preference for LA or GA)

The following questions refer to your personal opinions and preferences.

10. All other factors being equal, do you prefer your patients to have cataract surgery under Local or General anaesthesia?

- [ ] General
- [ ] Local alone
- [ ] Local with sedation

The overall, pooled results for personal preference were similar to the pooled results for actual practice (q.2), in that 66% preferred LA alone, 27% GA, and 7% LA with sedation (pie chart Oq10.1). These results represent a significant change in opinion since a 1989 postal survey of British consultant ophthalmologists, which found that over 75% “thought that GA was preferable overall” (Campbell and Spalton 1992)
Contemporaneous studies from other countries have showed a much lower usage of GA for cataract surgery. The 1996 survey of members of the American Society of Cataract and Refractive Surgery indicated that only 0.1% of respondents used GA, (Leaming 1997) and the 1996 survey of Japanese Society of Cataract and Refractive Surgery members does not even mention general anaesthesia. (Oshika et al 1999) It should be remembered that these surveys were mailed to special interest groups within ophthalmology, and may not be representative of the national picture as a whole. However, they do indicate that general anaesthesia is much less commonly used in these countries.

Results were analysed according to place of work, to look for a possible difference in attitude among the four main types of hospital. When analysing by place of work, surgeons who operated in more than one category of hospital were excluded. Results indicated similar preferences among consultants in the four main types of hospital, though general anaesthesia was slightly more popular among those who worked in teaching hospitals (eye specialist) (bar chart Oq10.2).
Analysis by age was made, to look for a possible cohort effect. Recent literature has documented the decline in popularity of GA,(Beckett and Rosen 1989; Elliott and Morrison 1975; Hodgkins et al 1992; Wong and Steele 1985) so it was hypothesised that younger consultants would be more likely to prefer LA. Using the responses to q14 (number of years worked as consultant ophthalmologist) as a substitute for chronological age, ophthalmologists were categorised into three groups. As expected, the younger consultants had a higher preference for the LA techniques. This trend is illustrated in bar chart Oq10.3.
Oq10.3. Consultant preferences for anaesthesia, grouped by age

![Bar chart showing preferences for anaesthesia grouped by age](chart)

- **Years as consultant**
  - 0-10
  - 11-20
  - 21-30

- **Percentage of respondents**
  - 0%
  - 20%
  - 40%
  - 60%
  - 80%
  - 100%

- **Anaesthesia types**
  - GA
  - LA
  - LA + sedation
4.1.11. Ophthalmologists’ Question 11 (who should give LA)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ophthalmologists</td>
<td>20%</td>
</tr>
<tr>
<td>Anaesthetists</td>
<td>23%</td>
</tr>
<tr>
<td>Either</td>
<td>57%</td>
</tr>
</tbody>
</table>

Pooling all 477 responses gave 20% “Ophthalmologists”, 23% “Anaesthetists” and 57% “Either”. This question was asked in view of the unresolved controversy over safety (whether complications such as globe perforation are more likely when a non-ophthalmologist anaesthetist is giving the block) (Boase 1996; Duker et al 1991; Grizzard et al 1991; Rubin 1997; Tighe 1997), though some ophthalmologists may have considered the issue of service provision (efficiency and safety in theatre) when making their choice.

**Oq11.1. In your opinion, who should give the local anaesthetic for intraocular surgery?**

![Pie chart showing the distribution of responses]

- 20% Ophthalmologists
- 23% Anaesthetists
- 57% Either
4.1.12. Ophthalmologists’ Question 12 (favourite method of giving LA)

Oq 12a. Please describe your most favoured method of giving LA for cataract surgery:

- [ ] retrobulbar
- [ ] peribulbar
- [ ] subtenon
- [ ] subconjunctival
- [ ] topical
- [ ] other local (please specify)

Oq 12b. Is a facial nerve block given?

- [ ] Yes
- [ ] No

The most popular choice of the 488 respondents was peribulbar anaesthesia (62%), followed by retrobulbar (22%). Supplemental blocks of the facial nerve were favoured for 8% of peribulbar and 59% of retrobulbar blocks. In 1996, when the questionnaire was circulated, less than 20% of ophthalmologists preferred any of the other, “new” methods of LA (pie chart Oq12.1).

Oq12.1. Ophthalmologists’ most favoured method of LA for cataract surgery

Responses were classified according to age of respondent (again using number of years as consultant as an indicator of chronological age), in graph Oq12.2.
Results of question Oq10 had shown that older consultants were more likely to prefer GA than younger consultants. However, the choice of LA technique showed no particular age-related trend. Graph Oq12.2 shows that the ‘older’ and ‘newer’ LA techniques are used in similar proportions by ophthalmologists of all ages.

These results are not strictly comparable to surveys from other countries, because other studies are more selective in their sampling. The major foreign questionnaire studies by Leaming et al deal exclusively with members of the American (Leaming 1997) and Japanese (Oshika et al 1998) Societies of Cataract and Refractive surgery, whereas this survey was sent to all UK consultant ophthalmologists. In addition, these surveys have a much lower response rate. These considerations should be borne in mind when comparing the results (Table Oq12.3)
Table Oq12.3. Comparison of responses to q 12 against the 1996 surveys of ASCRS and JSCF IS members

<table>
<thead>
<tr>
<th>Authors</th>
<th>Eke (Present study)</th>
<th>Leaming et al</th>
<th>Oshika et al</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who surveyed</td>
<td>All UK consultant ophthalmologists</td>
<td>Members of American Society of Cataract &amp; Refractive Surgery</td>
<td>Members of Japanese Society of Cataract &amp; Refractive Surgery</td>
</tr>
<tr>
<td>Response rate</td>
<td>74.5%</td>
<td>26%</td>
<td>50.7%</td>
</tr>
</tbody>
</table>
| Results          | 6.6% Retro.  
9.5% Retro/facial  
42% Perib. alone  
3.6% Perib/facial  
3% Topical  
0.7% Subconj  
6.8% Subtenon alone  
0.7% SubT/facial  
27% GA | 18% Retrob. alone  
27% Retrob/facial  
34% Peribulbar  
12% Topical  
4% Subconj  
3% Other  
0.1% GA | 13% Retrob. alone  
17% Retrob/facial  
6% Peribulbar  
22% Topical  
30% Subtenon alone  
8% Subtenon/facia | (no mention of GA) |

4.1.13. Ophthalmologists’ Question 13 (opinion regarding anaesthetist cover for LA)

13. What is your personal opinion regarding the need for an anaesthetist to cover intraocular surgery under local anaesthetic? (tick the opinion nearest your own)

- [ ] Anaesthetist should be present, with no other responsibility than the current list
- [ ] Anaesthetist should be available in the theatre complex in case of problems, but could also be attending to another list
- [ ] Anaesthetist need not be in theatres, but should be available in an emergency
- [ ] No need for anaesthetist involvement at all, provided there is a cardiac arrest team
- [ ] No need for anaesthetist, even if there is no cardiac arrest team

The 1993 College Guidelines (Anon, 1993) state that “an anaesthetist should be present in order to give resuscitation, should it be required, and to arrange for monitoring [which could be performed by a trained nurse, or an ODA].” This
corresponds with options 1 and 2 in the above list. Most of the respondents (79%) agreed with this statement (Pie chart Oq13.1).

Oq13.1. Ophthalmologists’ opinion as to need for anaesthetist to cover intraocular surgery under LA

- 40% Dedicated anaesthetist for the list
- 39% Anaesthetist in theatre complex, attending another list
- 11% Anaesthetist available in emergency (need not be in theatres)
- 9% No need for anaesthetist, provided there is a cardiac arrest team
- 1.5% No need for anaesthetist, even if there is no cardiac arrest team

Interestingly, 7 of the 474 respondents (1.5%) felt that there was “no need for an anaesthetist, even if there is no cardiac arrest team”. The ‘most favoured method of giving LA’ (q.12) for these 7 respondents was retrobulbar (1), peribulbar (2), subtenon’s (2) and topical (2).

Previous studies have asked the opinion of UK ophthalmologists regarding this issue. Haider’s 1993 survey indicated that 55% ‘thought that an anaesthetist should be present’. (Haider 1994) Thus, there appears to have been a shift of opinion in favour of the presence of an anaesthetist to cover LA surgery.
4.1.14/15. Ophthalmologists' Questions 14 & 15 (years as a consultant, and deaths due to LA)

Some final questions on your personal experience

Oq 14. How long have you been a consultant ophthalmologist? ....... Years

Oq 15. Since you became a consultant, have any of your patients ever died as a result of local anaesthesia for intraocular surgery?

[ ] No       [ ] Yes, ................(number) of my patients have died

The 510 respondents had a total of 4915 years' experience as consultant ophthalmologist (range 0-30 years). There were ten reports of patient death, attributed to LA complications, in this period. This is equivalent to approximately one LA-associated death per twenty 25-year consultant careers.

The questionnaire did not ask about other serious complications, but several respondents described cases in which patients might have died if it were not for the intervention of an anaesthetist. For example, an ophthalmologist with 23 years experience answered 'no' to q15, but commented that patient death had occurred "very nearly on at least 6 occasions; on each occasion, bailed out by anaesthetist".

These results are similar to those of a 1993 questionnaire, which was mailed to 500 UK ophthalmologists. The 334 respondents identified 12 cases of LA-associated death, (Haider 1994) all but one of which occurred 'on the operating table' (Haider SA, pers. comm.). 78 (23%) of the respondents 'had encountered what they had interpreted as life-threatening complications which they felt were attributable to LA'. The LA techniques were not recorded by Haider or in the present study. However, as the vast majority of LA's given prior to 1993 were by retrobulbar or peribulbar infiltration (Campbell and Spalton 1992; Hodgkins et al 1992), is it likely that most or all of the reported life-threatening events occurred in association with these LA techniques.
4.2. The questionnaire to Heads of Department of Anaesthesia

This questionnaire was mailed to the Head of Department of Anaesthesia, in all 178 hospitals in the UK that had been identified as having an ophthalmology department. As with the questionnaire to ophthalmologists, all questionnaires were anonymous and unmarked, so individual reminders could not be sent to non-responders. There were 138 responses (77.5%).

The eight questions are reproduced verbatim below, along with a summary of the responses.

4.2.1. Anaesthetists’ Question 1. (Type of hospital)

Aq 1. Type(s) of hospital where your anaesthetists work

- [ ] Teaching Hospital (General)
- [ ] Teaching Hospital (Eye Specialist)
- [ ] District Hospital (General)
- [ ] District Hospital (Eye Specialist)
- [ ] Cottage Hospital
- [ ] Other: please specify

Aq1.1: All places of NHS anaesthetic work

<table>
<thead>
<tr>
<th>Hospital Type</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Teaching Hospital (General)</td>
<td>21</td>
</tr>
<tr>
<td>Teaching Hospital (Eye Specialist)</td>
<td>11</td>
</tr>
<tr>
<td>District Hospital (General)</td>
<td>96</td>
</tr>
<tr>
<td>District Hospital (Eye Specialist)</td>
<td>12</td>
</tr>
<tr>
<td>Cottage Hospital</td>
<td>1</td>
</tr>
<tr>
<td>Other:</td>
<td>4</td>
</tr>
</tbody>
</table>

The above table summarises all responses: in many departments, anaesthetists worked in more than one hospital, which is why the total number of responses in table Aq1.1 is greater than 137, the number of respondents. In table Aq1.2, the “main place of work” for the 137 respondents is summarised: this information was used in analysis of the other questions.
Aq1.2: "Main place of work" for responding anaesthetists

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Teaching Hospital (General)</td>
<td>21</td>
</tr>
<tr>
<td>Teaching Hospital (Eye Specialist)</td>
<td>9</td>
</tr>
<tr>
<td>District Hospital (General)</td>
<td>98</td>
</tr>
<tr>
<td>District Hospital (Eye Specialist)</td>
<td>8</td>
</tr>
</tbody>
</table>

4.2.2. Anaesthetists’ Question 2/2a. (anaesthetist cover for LA lists)

Aq 2. For what proportion of your unit’s LOCAL anaesthetic INTRAOCULAR operations is there an anaesthetist in the theatre?  
(Present in the operating theatre or an adjacent theatre, in case there is a problem with a local anaesthetic, but not necessarily to give the LA itself.)

About .................% of these LA operations

Figure Aq2.1 shows that two-thirds of respondents stated that all of their unit’s LA surgery was covered by an anaesthetist. However, 5% of respondents stated that none of their unit’s LA surgery was covered. The actual percentages (as estimated by respondents) are tabulated in table Aq2.2.

This question was designed to find out the extent to which the 1993 Guidelines(1993) were being followed. If the unit were complying fully with these Guidelines, then the response should have been ‘100%’. Thus, 66% of Heads of Department of Anaesthesia felt that their units were complying with this aspect of the Guidelines.
Aq2.1 Proportion of LA intraocular operations for which there is an anaesthetist in theatres

- None: 5%
- Some: 29%
- All: 66%

Aq2.2 Proportion of LA intraocular operations for which there is an anaesthetist in theatres

Percentage of LA surgery that is covered by anaesthetists
Forty-six of the 137 respondents (34%) did not have 100% cover for intraocular surgery (see Aq 2, above). Reasons are summarised in bar-chart Aq 2a.1, and are subdivided by respondent’s “main place of work” in table Aq2.2.

Aq 2a.1: Reasons why some units do not cover 100% of LA lists

Lack of anaesthetic personnel to staff LA lists was the commonest reason given for incomplete cover (26 respondents or 19% of all replies). “Other” reasons given for incomplete LA cover included: personal wish of an individual ophthalmologist or anaesthetist, “a waste of anaesthetic time” and “surgeon uses eye drops only.”
Aq2a.2: Reasons for incomplete LA cover, classified by responding anaesthetists' "Main place of work"

<table>
<thead>
<tr>
<th></th>
<th>Teaching (general)</th>
<th>Teaching (eye)</th>
<th>District (general)</th>
<th>District (eye)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staffing problems</td>
<td>3</td>
<td>2</td>
<td>19</td>
<td>2</td>
</tr>
<tr>
<td>Anaesthetic policy</td>
<td>4</td>
<td>1</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Ophthalmology policy</td>
<td>4</td>
<td>1</td>
<td>8</td>
<td>-</td>
</tr>
<tr>
<td>Management Policy</td>
<td>-</td>
<td>-</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>-</td>
<td>11</td>
<td>-</td>
</tr>
</tbody>
</table>

In table Aq2a.2, reasons for incomplete LA cover are classified by the responding anaesthetist's main place of work. This table should be interpreted with caution, as many Heads of Department oversaw anaesthetists who worked in more than one category of hospital, and the questionnaire design made it impossible to tell which category of hospital had incomplete LA cover.

Seven respondents had answered "0%" to question Aq2, meaning that none of the LA intraocular surgery in their unit was covered by an anaesthetist. All 7 were in District General Hospitals. Reasons given were: lack of staff (3 respondents), policy of the ophthalmologists (2), 'a waste of anaesthetic time' (1); one respondent did not give a reason.

4.2.3. Anaesthetists’ Question 3. (hospital policy regarding anaesthetist cover for LA)

Aq 3. Does your hospital have a policy regarding provision of anaesthetists to cover intraocular surgery done using LA?

[ ] Yes       If "Yes", please state policy or append a copy, if possible
[ ] No
[ ] Don't Know

In most units (57%), there was a policy regarding cover of LA lists. Responses are summarised in pie-chart Aq3.1. Respondents were asked to state what the policy was, and responses were classified in accordance with the 5 categories.
used in the anaesthetists' question Aq7 and ophthalmologists' question Oq13. Policies are summarised in table Aq3.2.

Aq 3.1: Does hospital have a policy regarding anaesthetic cover of intraocular surgery using LA?

Aq 3.2: Summary of hospital policies

<table>
<thead>
<tr>
<th>Policy Description</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaesthetist should be present, with no other responsibility than the current list</td>
<td>31</td>
<td>22%</td>
</tr>
<tr>
<td>Anaesthetist should be available in the theatre complex in case of problems, but could also be attending to another list</td>
<td>20</td>
<td>16%</td>
</tr>
<tr>
<td>Anaesthetist need not be in theatres, but should be available in an emergency</td>
<td>2</td>
<td>1%</td>
</tr>
<tr>
<td>No need for anaesthetist involvement at all, provided there is a cardiac arrest team</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>No need for anaesthetist, even if there is no cardiac arrest team</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Policy not stated, or not possible to categorise</td>
<td>25</td>
<td>18%</td>
</tr>
</tbody>
</table>

Table Aq3.2 shows that at least 38% of anaesthetic departments had a policy that agreed with the 1993 Guidelines, that an anaesthetist should be present for all intraocular surgery using LA. The figure may be as high as 56%, as the policy was either not stated, or ambiguously stated, in a further 18% of 'yes' respondents. All policies stated that an anaesthetist should be available, though in 2 cases (2.6%) this was as part of the on-call or emergency cover team. Of the
units that had a stated policy, all but two (97%) had a policy that agreed with the 1993 Guidelines.

4.2.4. Anaesthetists' Question 4. (training policy for LA)

4. Does your department have a policy or programme for training anaesthetists to cover LA eye lists?

- [ ] Yes  
  "If "Yes", please state policy or append a copy, if possible"
- [ ] No
- [ ] Don't Know

The majority (57%) of respondents did have a training policy (pie-chart Aq4.1). In most cases, this took the form of on-the-job training with an experienced consultant (table Aq4.2). Only five respondents (4%) indicated that eye LA was part of a modular training system.

**Aq4.1: Does your department have a policy or programme for training anaesthetists to cover LA lists?**

![Pie chart showing 57% Training policy and 43% No]

**Aq4.2. Types of training policy or programme in use**

<table>
<thead>
<tr>
<th>Training Type</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>On-the job training</td>
<td>28</td>
<td>21%</td>
</tr>
<tr>
<td>Modular training</td>
<td>5</td>
<td>4%</td>
</tr>
<tr>
<td>Not stated</td>
<td>25</td>
<td>18%</td>
</tr>
</tbody>
</table>
4.2.5. Anaesthetists’ Question 5. (ocular LA specialists)

5. In your unit, is there an anaesthetist(s) with a special interest or responsibility for LA eye lists?

- [ ] Yes
- [ ] No
- [ ] Don’t Know

Just over half of the respondents stated that there was an anaesthetist with special interest or responsibility for LA eye surgery (pie-chart Aq 5.1).

**Aq5.1: Is there an anaesthetist with special interest or responsibility for LA eye lists?**

- "Eye anaesthetist" 55%
- No 45%

4.2.6. Anaesthetists’ Question 6. (who should give LA)

6. In your personal opinion, who should give the local anaesthetic for intraocular surgery?

- [ ] Ophthalmologists
- [ ] Anaesthetists
- [ ] Either

The majority thought that LA for intraocular surgery should be given by either anaesthetists or ophthalmologists, though 11% thought this was the remit of the ophthalmologist, and 26% felt that LA should be given by the anaesthetist (table Aq 6).
This question was asked, in exactly the same form, of consultant ophthalmologists (section 4.1.11). The responses of the two groups are compared in table Aq6.2. Responses were similar, though ophthalmologists were more likely to say that their profession should be giving LA blocks. There is an unproven perception that anaesthetists may be more likely than ophthalmologists to cause a globe perforation (Duker et al 1991; Grizzard et al 1991), and this has been reflected in the recent literature (Blumenthal 1997; Boase 1996; Bywater 1997; Coombes and Mawer 1997; Percival 1997; Rubin 1997; Tighe 1997).

<table>
<thead>
<tr>
<th>Aq 6.2.</th>
<th>Who should give LA? Comparison of ophthalmologists' and anaesthetists' responses</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Responses from Ophthalmologists</td>
</tr>
<tr>
<td>Ophthalmologists</td>
<td>20%</td>
</tr>
<tr>
<td>Anaesthetists</td>
<td>23%</td>
</tr>
<tr>
<td>Either</td>
<td>57%</td>
</tr>
</tbody>
</table>
4.2.7. Anaesthetists’ Question 7. (opinion regarding anaesthetist cover for LA)

7. What is your personal opinion regarding the need for an anaesthetist to cover intraocular surgery under local anaesthetic? (tick the opinion nearest your own)

- [ ] Anaesthetist should be present, with no other responsibility than the current list
- [ ] Anaesthetist should be available in the theatre complex in case of problems, but could also be attending to another list
- [ ] Anaesthetist need not be in theatres, but should be available in an emergency
- [ ] No need for anaesthetist involvement at all, provided there is a cardiac arrest team
- [ ] No need for anaesthetist, even if there is no cardiac arrest team

This is another question that was also asked of consultant ophthalmologists. The responses from Heads of Anaesthesia are summarised in pie-chart Aq7.1, and the responses from the two groups are compared in table Aq7.2.

Aq7.1: Personal opinion regarding need for anaesthetic cover for LA intraocular surgery
Two of 134 Heads of Anaesthesia gave answer no. 4, that there is no need for an anaesthetist, provided there is a cardiac arrest team. One gave answer no. 5, that there is no need for an anaesthetist, even if there is no cardiac arrest team. These three respondents were all based in District General Hospitals, and none had an anaesthetist with an interest or responsibility for LA eye lists.

Table Aq 7.2 compares responses to those of ophthalmologists (section 4.1.13). Heads of Anaesthesia are more likely to believe that an anaesthetist is required in theatres when LA intraocular surgery is taking place. This could be because most ophthalmologists do not have personal experience of a life-threatening complication of LA (Haider 1994).

Aq 7.2: Personal opinion regarding the need for anaesthetic cover for LA intraocular surgery: Comparison of responses from ophthalmologists, and Heads of Anaesthesia

<table>
<thead>
<tr>
<th>Degree of cover</th>
<th>Responses from Ophthalmologists</th>
<th>Responses from Heads of Anaesthesia</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Present, dedicated</td>
<td>40%</td>
<td>49%</td>
</tr>
<tr>
<td>2. In theatre complex</td>
<td>39%</td>
<td>41%</td>
</tr>
<tr>
<td>3. Emergency anaes.</td>
<td>11%</td>
<td>7%</td>
</tr>
<tr>
<td>4. No need, if crash team</td>
<td>9%</td>
<td>2%</td>
</tr>
<tr>
<td>5. No need, even if no crash team</td>
<td>1.5%</td>
<td>1%</td>
</tr>
</tbody>
</table>

4.2.8. Anaesthetists’ Question 8 (personal preference for GA or LA)

8. All other factors being equal, do you prefer patients to have cataract surgery under Local or General anaesthesia?

| [ ] General                      |
| [ ] Local alone                  |
| [ ] Local with sedation          |

This question was also asked of consultant ophthalmologists. Responses from Heads of Anaesthesia are summarised in pie-chart Aq8.1.
An identical question was asked of consultant ophthalmologists, as question Oq10 (section 4.1.10). Results are compared in table Aq 8.2. Comparison shows that surgeons are more likely to want GA for their patients. This is probably because GA is more likely to provide ideal conditions for surgery and teaching. The anaesthetists’ preference for LA probably reflects a desire for uncomplicated procedures with rapid recovery, high patient acceptability and efficient throughput in theatres.

Table Aq8.2. Overall preference for anaesthesia for cataract surgery. Comparison of responses from ophthalmologists, and Heads of Anaesthesia

<table>
<thead>
<tr>
<th></th>
<th>Responses from ophthalmologists</th>
<th>Responses from Heads of Anaesthesia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local alone</td>
<td>66%</td>
<td>79%</td>
</tr>
<tr>
<td>Local + sedation</td>
<td>7%</td>
<td>9%</td>
</tr>
<tr>
<td>General anaesthesia</td>
<td>27%</td>
<td>11%</td>
</tr>
</tbody>
</table>
4.3. Forms sent to Nurse in Charge of Eye Theatres

Forms were mailed to Nurse in Charge, Eye Theatres, in all 178 NHS hospitals that had an ophthalmology department (see Methods, section 3.3.9, and Appendix 3 for a copy of the form). The accompanying letter served to introduce the Survey, and request co-operation with data collection. The Form asked for the addresses of all operating theatres where surgeons from the unit performed intraocular surgery under the NHS. Because this data was required in order to mail out the Survey Packs, the forms were numbered, and non-respondents were contacted by telephone. In this way, a 100% response rate was achieved.

Responses from theatre nurses showed that surgeons from the 178 units operated in a total of 200 NHS hospitals. These 22 additional hospitals comprised nearby General or Cottage hospitals. A total of 306 operating theatres were identified. For the purposes of validation, the 178 main units had been classified into three categories: major academic units, other units recognised for basic specialist training in ophthalmology, and units without recognition (see Validation, methods section 3.3.3 and 3.4.1). The distribution of the 306 eye theatres is summarised in table T1, below.

Table T1. Number of UK operating theatres performing intraocular surgery under the NHS

<table>
<thead>
<tr>
<th></th>
<th>Theatres</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major academic units</td>
<td>76</td>
<td>26</td>
</tr>
<tr>
<td>Other units recognised for basic specialist training</td>
<td>210</td>
<td>136</td>
</tr>
<tr>
<td>Units without recognition</td>
<td>20</td>
<td>16</td>
</tr>
<tr>
<td>TOTAL</td>
<td>306</td>
<td>178</td>
</tr>
</tbody>
</table>

Twenty-one units had been assigned as “Validation Units” (see methods section 3.4.1). Theatres in the Validation Units are summarised in table T2.
Table T2. Validation Units

<table>
<thead>
<tr>
<th></th>
<th>Theatres</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major academic units</td>
<td>19</td>
<td>5</td>
</tr>
<tr>
<td>Other units recognised for basic specialist training</td>
<td>21</td>
<td>14</td>
</tr>
<tr>
<td>Units without recognition</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>43</strong></td>
<td><strong>21</strong></td>
</tr>
</tbody>
</table>

Tables T1 and T2 demonstrate that the ‘major academic’ units had a higher number of theatres per unit (mean 2.92 theatres per unit), when compared with ‘other recognised units’ (mean 1.54 theatres per unit) and ‘non-recognised’ units (mean 1.25 theatres per unit).
4.4. Results section 2: the Survey itself

For the initial week of the Survey, packs of report forms were available in all NHS eye theatres in the United Kingdom. Ophthalmologists were requested to complete a report form for every case in which LA was administered with the intention of performing intraocular surgery (see Methods, section 3.3).

In the initial week, 2827 correctly completed local anaesthetic report forms were returned. A further 128 forms were excluded, either because the date had not been entered, or the procedure did not fulfil the entry criteria. The actual number of LA’s given was calculated using data from the Validation Units, as described below.

4.4.1. Validation: number of operations performed in the initial week, and GA/LA profile

The validation protocol has already been described in detail (section 3.4.1). A representative sample of eye units was identified, comprising 22 units. For each of these 22 units, we wrote to the consultant ophthalmologist with responsibility for clinical audit. The letter introduced the survey, and asked for co-operation with validation. For validation, each of these units was asked to send the investigators a copy of the theatre record(s) for the initial week, with description of anaesthesia (LA or GA) for each procedure. 21 consultants agreed, and all 21 subsequently provided the required information. These Validation Units, and their number of theatres, are summarised in tables T1 and T2 (section 4.3).

Theatre records from the Validation Units showed that not only did the ‘non-recognised’ units have fewer theatres, but the workload per theatre (number of cases per list) was also lower. This trend is summarised in table V1. A proportionate correction was made for this when calculating participation and LA usage rates.
Table V1. Theatre workload in Validation Units (initial week)

<table>
<thead>
<tr>
<th></th>
<th>Number of Theatres</th>
<th>Number of intraocular cases</th>
<th>Cases per theatre per week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major academic units</td>
<td>19</td>
<td>320</td>
<td>16.8</td>
</tr>
<tr>
<td>Other units recognised</td>
<td>21</td>
<td>368</td>
<td>17.5</td>
</tr>
<tr>
<td>for basic specialist</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>training</td>
<td>3</td>
<td>25</td>
<td>8.3</td>
</tr>
<tr>
<td>TOTAL</td>
<td>43</td>
<td>713</td>
<td>16.5</td>
</tr>
</tbody>
</table>

Validation calculations

Validation unit data was used to calculate the LA/GA ratio, to estimate the participation rate and hence the total number of LA’s actually given.

To calculate the LA/GA ratio, we used the data supplied by the Validation Units. These data are summarised in table V2. The LA and GA totals for each theatre were used to estimate the ratio of LA’s and GA’s given nationally during this week. The number of LA’s and GA’s was calculated by extrapolating the data from each of the theatres in the Validation Units, taking into account the variability of theatre usage within units.

The number of LA’s performed nationally in the initial week is estimated to be 3884 (95% confidence intervals: 2895, 4873) (see table V3 on following page). The number of GA’s in this week was 1127 (95% CI: 631, 1621). Thus, local anaesthesia accounted for 3884/(3884 + 1127) = 77.5% of all intraocular surgery in the initial week. This figure is slightly different to the published figure (Eke & Thompson 1999a), because some validation data were still awaited at the time this paper was prepared.
Table V2. Use of LA and GA in the initial week. Data from theatre records of the 21 Validation Units.

<table>
<thead>
<tr>
<th></th>
<th>Number of LA cases</th>
<th>Number of GA cases</th>
<th>Number of Theatres in Validation Units</th>
<th>Number of theatres overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major academic units</td>
<td>247</td>
<td>75</td>
<td>19 theatres 5 Units</td>
<td>76 theatres 26 Units</td>
</tr>
<tr>
<td>Other units recognised for basic specialist training</td>
<td>274</td>
<td>82</td>
<td>21 theatres 14 units</td>
<td>210 theatres 136 units</td>
</tr>
<tr>
<td>Units without recognition</td>
<td>24</td>
<td>1</td>
<td>3 theatres 2 units</td>
<td>20 theatres 16 units</td>
</tr>
<tr>
<td>TOTAL</td>
<td>545</td>
<td>158</td>
<td>43 theatres 21 units</td>
<td>306 theatres 178 units</td>
</tr>
</tbody>
</table>

The response rate was calculated by comparing the number of returned forms against the number of eligible LA’s that were given in the initial week. This latter figure was estimated by extrapolating the data provided by the validation units, as explained above. In the initial week the number of LA’s was 3884 (95% CI: 2895, 4873). The number of correctly completed forms for this week was 2827. Therefore, the calculated response rate was 3884/2827, or 72.8% (95% Confidence Interval: 56.4-93.9%).

4.4.2. Extrapolating the initial week’s figures to three months & one year

To calculate the number of LA’s given in the three-month period, a correction was made for workload. Department of Health figures show that the total number of operations performed nationally varies from week to week, and is significantly affected by such factors as school holidays and the national holiday at the end of August. The Department of Health can provide weekly totals for intraocular operations performed in England and Wales, but does not record the type of anaesthetic used. As 1996 figures were not expected until late 1998, data from the financial year 1991-2 were used instead. 1991 was chosen because September 1st fell on a Sunday, the same day as in 1996. In 1991-2, 1.586% of eye operations were performed in the first week of September, and 26.58% in the period 1st September-30th November. Therefore, the totals for the three-month study were estimated by multiplying the initial week totals by 26.58/1.586.
Similarly, annual estimates were made using the factor 100/1.586. Standard errors and confidence intervals were calculated on a log scale using the delta method so as to combine the uncertainty in the validation study, the first week and the reported events over 3 months. In this way, estimates were made for the total number of intraocular operations performed in the whole United Kingdom. Results are shown in table V3. The totals for each of the LA techniques are shown in table V4.

Table V3. Estimated total number of intraocular operations performed in the UK. Calculated using initial week data from the validation units, corrected for workload using 1991 data from Dept of Health.

<table>
<thead>
<tr>
<th></th>
<th>Initial week</th>
<th>3 months</th>
<th>1 year</th>
</tr>
</thead>
<tbody>
<tr>
<td>LA</td>
<td>3884</td>
<td>65,100</td>
<td>245,000</td>
</tr>
<tr>
<td></td>
<td>(95% CI: 2895-4873)</td>
<td>(95% CI: 48,500-81,700)</td>
<td>(95% CI: 182,500-307,000)</td>
</tr>
<tr>
<td>GA</td>
<td>1127</td>
<td>18,900</td>
<td>71,000</td>
</tr>
<tr>
<td></td>
<td>(95% CI: 631, 1621)</td>
<td>(95% CI: 10,600, 27,200)</td>
<td>(95% CI: 39,800, 102,300)</td>
</tr>
<tr>
<td>total</td>
<td>5011</td>
<td>84,000</td>
<td>316,000</td>
</tr>
</tbody>
</table>
Table V4. Use of the various LA techniques for intraocular surgery in 1996.

<table>
<thead>
<tr>
<th>LA technique</th>
<th>Number of reports (week 1)</th>
<th>Relative frequency</th>
<th>Estimated Number of LA's given in 3 months (95% confidence intervals)</th>
<th>Proportion of patients given facial block</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peribulbar</td>
<td>1854</td>
<td>65.6%</td>
<td>42,700 (33,000-55,100)</td>
<td>2%</td>
</tr>
<tr>
<td>Retrobulbar</td>
<td>479</td>
<td>16.9%</td>
<td>11,000 (8,400-14,400)</td>
<td>13%</td>
</tr>
<tr>
<td>Subtenon's</td>
<td>190</td>
<td>6.7%</td>
<td>4,380 (3,280-5,840)</td>
<td>3%</td>
</tr>
<tr>
<td>Subconjunctival</td>
<td>124</td>
<td>4.4%</td>
<td>2,860 (2,100-3,880)</td>
<td>2%</td>
</tr>
<tr>
<td>Topical alone</td>
<td>81</td>
<td>2.9%</td>
<td>1,870 (1,340-2,600)</td>
<td>1%</td>
</tr>
<tr>
<td>Intracameral</td>
<td>2</td>
<td>0.07%</td>
<td>46 (11-188)</td>
<td>0%</td>
</tr>
<tr>
<td>Combinations</td>
<td>63</td>
<td>2.3%</td>
<td>1,450 (1,020-2,060)</td>
<td>0%</td>
</tr>
<tr>
<td>Not stated</td>
<td>34</td>
<td>1.2%</td>
<td>780 (510-1,190)</td>
<td>3%</td>
</tr>
<tr>
<td>Total</td>
<td>2827</td>
<td></td>
<td>65,100 (48,500-81,700)</td>
<td></td>
</tr>
</tbody>
</table>

4.4.3. Are the calculated figures correct?

Table V3 shows that the total number of intraocular operations performed in the year 1996-7, as estimated in the Survey, was in the order of 300,000, but with broad confidence intervals for the estimate. This figure is for the entire United Kingdom (England, Wales, Scotland, Northern Ireland). The Department of Health is able to provide annual totals for intraocular operations performed, but only for England and Wales. England and Wales have 155 (87%) of the 178 units, and 255 (83%) of the 306 operating theatres.

Department of Health figures indicate that 190,032 intraocular operations were performed in the financial year 1993-4, in England and Wales (department of Health, pers. comm.). Multiplying by a factor of 1/0.85 (see previous paragraph), this would give approximately 223,500 intraocular operations per
annum in the entire UK. The amount of intraocular surgery performed in the NHS is steadily increasing (Desai, 1999). Thus, the calculated figures for 1996 (table V3) are in broad agreement with other measures of surgical activity in ophthalmology.

4.4.4. Calculating the participation rate.

None of the report forms had any identifying codes or marks, so it was not possible for the investigators to know from which hospital any form originated. This guaranteed anonymity was felt to be an important factor in encouraging full and frank reporting (See Methods, section 3.3.2). Therefore, it was not possible to calculate the participation rates for any particular hospital. Instead, overall participation rate was estimated, by comparing the estimated number of eligible LA’s in the initial week (calculated using Validation Unit data, see section 4.4.1 above) against the actual number of returns for this week. The estimated number of eligible LA’s was 3884 (95% CI: 2895, 4873). The number of correctly completed forms for this week was 2827. Therefore, the calculated response rate was 3884/2827, or 72.8% (95% Confidence Interval: 56.4-93.9%). (i.e. of all eligible LA’s given in the UK in the initial week, a calculated 72.8% resulted in a correctly completed form received by the investigators).
4.5. Responses to the individual questions on the report Form

The individual questions are reproduced below, each with a summary of the responses. As mentioned above, there were 2827 correctly completed report Forms for the initial week, giving an estimated response rate of 72.8% (95%CI 56.4-93.9%) nationally.

4.5.1. Report form question 1 (patient details)

<table>
<thead>
<tr>
<th>1. Patient details:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of operation: .................................../1996</td>
</tr>
<tr>
<td>Year of birth [ ] 1890’s [ ] 1900’s [ ] 1910’s [ ] 1920’s</td>
</tr>
<tr>
<td>[ ] 1930’s [ ] 1940’s [ ] 1950’s [ ] 1960’s [ ] Other ...</td>
</tr>
<tr>
<td>Sex: [ ] Male [ ] Female</td>
</tr>
<tr>
<td>Planned Admission type: [ ] Inpatient [ ] Daycase</td>
</tr>
</tbody>
</table>

The Initial Week of the Survey ran from Sunday 1 September to Saturday 7 September, inclusive. As would be expected, most surgery took place between the Monday and Friday (bar-chart R1.1, below). This chart shows that daily returns were approximately equal for the Monday to Thursday, indicating that participants commenced the Survey “on time”. The lower number of returns for the Friday is probably due to reduced surgical workload on that day, as many units have their academic half-day session on Fridays.
Patient age was ascertained from the decade of birth. Decade of birth was used in preference to age, in order to make the questionnaire easier to complete and thereby to further encourage participation. A patient born in the 1900’s would have been aged between 85 and 96 in the autumn of 1996. Patient ages are summarised in bar chart R1.2.

Chart R1.2 shows that over 70% of patients were aged between 65 and 86. Three patients were born in the 1970’s (aged 15-26 years in 1996), of whom two had retinal detachment repairs using retrobulbar and peribulbar anaesthesia. Thirteen patients were born in the 1890’s (aged 95-106 years). One patient may have been aged over 106 years: manual extracapsular cataract extraction was performed using peribulbar anaesthesia, and the ‘other’ box was ticked but date of birth was not entered. There were no reports of adverse events in patients of these extreme ages.
Gender distribution followed the expected pattern, with more women than men having surgery (pie chart R1.3). This is consistent with the longer life expectancy of women (Desai et al 1999).

**Pie Graph R1.3: Gender distribution in initial week**

<table>
<thead>
<tr>
<th></th>
<th>Male</th>
<th>Female</th>
<th>not stated</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>35.7%</td>
<td>59.2%</td>
<td>5.2%</td>
</tr>
</tbody>
</table>
Data on planned admission type was not of direct relevance to the Survey. However, it was felt that the College may find such information useful, which is why it was collected. Local anaesthesia had already been shown to be eminently suitable for day-case surgery (Strong, 1991, Cooper, 1996), and the figures in bar-chart R1.4 confirm that the majority of LA intraocular surgery in 1996 was performed as day-case.
4.5.2. Report form question 2 (planned operation)

2. Planned operation (If a “combined” procedure, tick more than one box.)

- [ ] Cataract (extra- or endocapsular)
- [ ] Phacoemulsification
- [ ] Cataract (other, specify)
- [ ] Trabeculectomy
- [ ] Retinal Reattachment
- [ ] Corneal Graft
- [ ] Other operation (specify) .................................................................

This question was asked in order to get an idea of what sort of intraocular procedures were performed using LA, and also to remind respondents which procedures were eligible. The information was also needed to compile the series of cases for which there were complications.

As expected, the majority of intraocular procedures were for cataract (table R2.1). Cataract surgery made up 88% of the LA workload. In the initial week, 59% of LA cataract surgery was by phacoemulsification (1492 cases), and 40% by ‘manual’ extracapsular technique (1015 cases). Only one intracapsular extraction was reported, along with 27 unspecified cataract procedures.

The 90 ‘other’ operations in table R2.1 included 9 secondary lens implants, 8 implant removal, exchange or repositioning, 8 vitrectomies, 2 peripheral iridectomies, and 4 injections of intravitreal antibiotics.

Table R2.1: Operations performed using LA in the initial week.
(Numbers sum to over 2827 because some ‘combined’ procedures appear in more than one category).

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cataract (extra- or endocapsular)</td>
<td>1015</td>
<td>35.1%</td>
</tr>
<tr>
<td>Phacoemulsification</td>
<td>1492</td>
<td>51.6%</td>
</tr>
<tr>
<td>Cataract (other, specify)</td>
<td>28</td>
<td>1%</td>
</tr>
<tr>
<td>Trabeculectomy</td>
<td>204</td>
<td>7%</td>
</tr>
<tr>
<td>Retinal Reattachment</td>
<td>22</td>
<td>0.8%</td>
</tr>
<tr>
<td>Corneal Graft</td>
<td>3</td>
<td>0.1%</td>
</tr>
<tr>
<td>Other operation (specified)</td>
<td>90</td>
<td>3.1%</td>
</tr>
<tr>
<td>Not specified</td>
<td>36</td>
<td>1%</td>
</tr>
<tr>
<td>total</td>
<td>2890</td>
<td></td>
</tr>
</tbody>
</table>
4.5.3. Report form question 3 (LA technique)

3. Type of Local Anaesthetic *(Tick as many boxes as apply)*

- [ ] retrobulbar
- [ ] subtenon
- [ ] peribulbar
- [ ] subconjunctival
- [ ] facial block
- [ ] topical
- [ ] (other local please specify) ......................................

Overall, around two-thirds of LA was given by the peribulbar technique, one-sixth retrobulbar, and the other one-sixth made up of subtenon’s, subconjunctival, topical, and intracameral anaesthesia (see Table R3.1 and pie chart R3.2).

**Table R3.1. Use of the different LA techniques in the initial week.**

<table>
<thead>
<tr>
<th>LA technique</th>
<th>Number of reports (week 1)</th>
<th>Relative frequency</th>
<th>Estimated Number of LA's given in 3 months (95% confidence intervals)</th>
<th>Proportion of patients given facial nerve block</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peribulbar</td>
<td>1854</td>
<td>65.6%</td>
<td>42,700 (33,000-55,100)</td>
<td>2%</td>
</tr>
<tr>
<td>Retrobulbar</td>
<td>479</td>
<td>16.9%</td>
<td>11,000 (8,400-14,400)</td>
<td>13%</td>
</tr>
<tr>
<td>Subtenon’s</td>
<td>190</td>
<td>6.7%</td>
<td>4,380 (3,280-5,840)</td>
<td>3%</td>
</tr>
<tr>
<td>Subconjunctival</td>
<td>124</td>
<td>4.4%</td>
<td>2,860 (2,100-3,880)</td>
<td>2%</td>
</tr>
<tr>
<td>Topical alone</td>
<td>81</td>
<td>2.9%</td>
<td>1,870 (1,340-2,600)</td>
<td>1%</td>
</tr>
<tr>
<td>Intracameral</td>
<td>2</td>
<td>0.07%</td>
<td>46 (11-188)</td>
<td>0%</td>
</tr>
<tr>
<td>Combinations</td>
<td>63</td>
<td>2.3%</td>
<td>1,450 (1,020-2,060)</td>
<td>0%</td>
</tr>
<tr>
<td>Not stated</td>
<td>34</td>
<td>1.2%</td>
<td>780 (510-1,190)</td>
<td>3%</td>
</tr>
<tr>
<td>Total</td>
<td>2827</td>
<td>1.2%</td>
<td>65,100 (48,500-81,700)</td>
<td></td>
</tr>
</tbody>
</table>

The use of facial nerve blocks is summarised in table R3.1. Overall, facial nerve blocks were used in 4% of cases. The actual technique of nerve block (see
section 2.2) was not recorded, but there were no reports of Adverse Events attributed to facial nerve block.

**Pie chart R3.2: Summary of LA techniques (data from initial week)**

- **Peribulbar**: 65.6%
- **Retrobulbar**: 16.9%
- **Subtenon's**: 6.9%
- **Subconjunctival**: 4.4%
- **Topical**: 2.9%
- **Intracameral**: 0.07%
- **Combinations**: 2.3%
- **Not stated**: 1.2%
4.5.4. Report form question 4 (intravenous cannula)

4. Was an intravenous cannula sited?  [ ] No  [ ] Yes

Around 60% of LA patients had an intravenous cannula sited, in accordance with the 1993 Guidelines (1993) (pie chart R4.1). The Guidelines imply that the cannula should be sited before the LA is given. In order to keep the Report Forms concise, the question of timing of cannula insertion was relegated to the Adverse Event Form. (See section 4.6.17).

Pie chart R4.1. Use of intravenous canula.

<table>
<thead>
<tr>
<th></th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>IV canula sited</td>
<td>60.3%</td>
</tr>
<tr>
<td>No IV canula</td>
<td>38.1%</td>
</tr>
<tr>
<td>Not stated</td>
<td>1.5%</td>
</tr>
</tbody>
</table>

4.5.4.1. Intravenous access for the different LA techniques

Table R4.2 shows the use of intravenous (i.v.) access for the five main LA techniques. It shows that use of i.v. access was 64% for retrobulbar and peribulbar techniques, but for the “newer” techniques of sub-conjunctival and topical, i.v. access rates were only 19% and 22%. Chi-squared test, comparing the 5 different techniques in terms of i.v. access, gave \( p < 0.0001 \). This fits with the perception that the “newer” techniques are safer. While this is most probably true (see section 2.3 for discussion), there are still no large published case-series to back up this assumption.
Table R4.2. Use of intravenous access for the different LA techniques. Data from the initial week of the Survey.

<table>
<thead>
<tr>
<th>LA technique (number of reports)</th>
<th>i.v. access</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peribulbar (1854)</td>
<td>1191 64%</td>
</tr>
<tr>
<td>Retrobulbar (479)</td>
<td>306 64%</td>
</tr>
<tr>
<td>Sub-Tenon (190)</td>
<td>118 62%</td>
</tr>
<tr>
<td>Sub-conjunctival (124)</td>
<td>24 19%</td>
</tr>
<tr>
<td>Topical (81)</td>
<td>18 22%</td>
</tr>
</tbody>
</table>

4.5.5. Report form question 5 (monitoring)

5. Were any of these features monitored?
   [ ] Blood pressure
   [ ] Electrocardiography
   [ ] Pulse oximetry
   [ ] None of these

Monitoring took place in 96% of patients (93% had pulse oximetry, 41% blood pressure monitoring, 55% ECG), though only 35% had all three modalities, as recommended by the 1993 Guidelines (Pie chart R5.1).

4% of LA patients had no per-operative monitoring at all. These cases were analysed according to the LA technique used: 2% of retrobulbar, 2% of peribulbar, 5% of subtenon’s, 35% of subconjunctival and 24% of topical anaesthetics had no monitoring.
4.5.5.1. Monitoring for the different LA techniques

Table R5.2 shows the use of monitoring for the five main LA techniques. The overall picture is similar to that for intravenous access (section R4, above). For peribulbar and retrobulbar techniques, 98% of cases had some sort of monitoring. The "newer" subconjunctival and topical techniques had no formal monitoring in 35% and 25%, respectively. As discussed above in sections 4.5.4 and 2.2, this lack of monitoring is consistent with the perception that these newer techniques are safer.
Table R5.2. Monitoring of patients for the different LA techniques. Data from initial week.

<table>
<thead>
<tr>
<th>LA technique (number of reports)</th>
<th>Pulse oximetry</th>
<th>Blood pressure</th>
<th>ECG</th>
<th>No monitoring</th>
<th>All 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peribulbar (1854)</td>
<td>1774</td>
<td>774</td>
<td>1055</td>
<td>39</td>
<td>673</td>
</tr>
<tr>
<td>Retrobulbar (479)</td>
<td>464</td>
<td>207</td>
<td>236</td>
<td>11</td>
<td>144</td>
</tr>
<tr>
<td>Sub-Tenon (190)</td>
<td>179</td>
<td>96</td>
<td>112</td>
<td>10</td>
<td>92</td>
</tr>
<tr>
<td>Sub-conjunctival (124)</td>
<td>75</td>
<td>31</td>
<td>52</td>
<td>43</td>
<td>29</td>
</tr>
<tr>
<td>Topical (81)</td>
<td>58</td>
<td>24</td>
<td>33</td>
<td>20</td>
<td>21</td>
</tr>
</tbody>
</table>

4.5.5.2. To what extent were the Guidelines for intravenous access and peroperative monitoring followed?

Usage of intravenous access and monitoring are assessed together in table R5.3. It shows that, for all LA techniques, well under half of cases fulfilled the Guidelines and had i.v. access and monitoring by all three modalities. For retrobulbar and peribulbar anaesthesia, only 2% of cases had no i.v. access and no formal monitoring. For the “newer” techniques of sub-conjunctival and topical anaesthesia, the figures were 35% and 23% respectively. Chi-squared testing, making a comparison of the 5 different LA techniques in table R5.3, showed a high association between monitoring/i.v.access, and LA technique ($p < 0.0001$). These data should be interpreted with caution, as the newer techniques were used in relatively few cases, so the practice of a small number of centres may distort the results.

Table R5.3. Use of intravenous access and monitoring, for the different LA techniques. Data from initial week.

<table>
<thead>
<tr>
<th>LA technique (number of reports)</th>
<th>i.v access &amp; all 3 types of monitoring</th>
<th>No i.v. access, No monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peribulbar (1854)</td>
<td>556</td>
<td>32</td>
</tr>
<tr>
<td>Retrobulbar (479)</td>
<td>113</td>
<td>9</td>
</tr>
<tr>
<td>Sub-Tenon (190)</td>
<td>74</td>
<td>9</td>
</tr>
<tr>
<td>Sub-conjunctival (124)</td>
<td>22</td>
<td>43</td>
</tr>
<tr>
<td>Topical (81)</td>
<td>8</td>
<td>19</td>
</tr>
</tbody>
</table>
6. Was any premedication or intravenous sedative given as part of the PLANNED procedure?

[ ] No  [ ] Premedication  [ ] I.V. sedative

In the initial week, around 8% of LA patients had some either oral or intravenous sedation (pie chart R6.1.).

**Pie chart R6.1. Use of sedation with LA in the initial week.**

- No sedation: 88%
- Premed only: 2.9%
- IV sedation only: 4.8%
- Premed + IV sed: 0.1%
- No response: 4.2%

These data allowed calculation of the relative usage of the three major anaesthesia techniques. The figure was combined with the GA/LA ratio, which had been estimated using the Validation Unit data (section 4.4.1). An estimated 24.2% of intraocular surgery was performed using GA, 70% using LA alone, and 5.8% using LA with sedation. (pie chart R6.2)
Pie Graph 6.2. Overall usage of GA, LA and sedation for intraocular surgery. Combining data from Validation Units and the initial week's Report Forms.

- GA: 24.2%
- LA: 70%
- LA + sedation: 5.8%
4.5.7. Report form question 7 (who gave the LA)

7a. Local anaesthetic given by

- [ ] Ophthalmologist (consultant)
- [ ] Anaesthetist (consultant)
- [ ] Ophthalmologist (other)
- [ ] Anaesthetist (other)
- [ ] Other person (Please state) .....................................................

7b. This person has been giving LA’s for ocular surgery for

- [ ] Two months or less
- [ ] One year or less
- [ ] More than one year

All of the retrobulbar, peribulbar and sub-tenon blocks were performed by medically qualified personnel: either ophthalmologists or anaesthetists (Pie chart R7.1). Of the 50 LA’s administered by nurses, 47 were topical and 3 were subconjunctival anaesthesia. For ‘needle injection’ blocks (retrobulbar and peribulbar), the ratio of anaesthetist: ophthalmologist was almost exactly 50:50.

Pie Graph R7.1. Who administered the LA?

- Ophthalmologist (consultant) 26%
- Ophthalmologist (non-consultant) 27%
- Anaesthetist (consultant) 27.4%
- Anaesthetist (non-consultant) 17.3%
- Other (Nurse) 1.8%
- Other (not stated) 0.03%
- No response 0.4%

Pie chart 7.2 shows that most of the people who administered LA had at least one year’s experience of giving LA’s for intraocular surgery. Because NHS hospitals have a strong teaching role, it is to be expected that a significant proportion of LA’s are administered by ‘learners’. It was not felt appropriate for the Survey to further assess the degree of supervision of trainees.
The 1993 Guidelines (1993) imply that the LA blocks should be performed by either an anaesthetist or an ophthalmologist, although this is not explicitly stated. In some other countries, such as the United States, ‘nurse anesthetists’ are trained to give peribulbar and retrobulbar LA blocks, and also monitor the patient (Frandsen 1989; Pecka and Dexter 1997). In a prospective evaluation of peribulbar anaesthesia, running from 1988-1992, Certified Registered Nurse Anesthetists were performing all of the peribulbar blocks in some US centres (Davis and Mandel 1994). There is no such equivalent qualification in the UK. Another international study highlights the international variation in anaesthesia involvement for cataract surgery (Norregaard et al 1997). An international survey of ophthalmologists, performed in 1993, looked at who gave the LA block. In the US and Canada, 80% of blocks were given by the ophthalmologist, 16% by the anaesthesiologist (doctor), and 4% by ‘other’ personnel. In Barcelona, Spain, the figures were 75%, 24%, 1%, and in Denmark they were 86%, 0%, with the 14% ‘other’ comprising ‘mainly surgeons in training’. This variation reflects to some extent the different modes of healthcare provision in these countries.

Pie Graph 7.2. Experience of the person giving the LA.
8. Was an anaesthetist available to cover this procedure?

[ ] Dedicated anaesthetist for this list
[ ] Anaesthetist available in theatre suite, but attending to another list
[ ] Anaesthetist only available in dire emergency
  (e.g. as part of cardiac arrest team)
[ ] No anaesthetist in the hospital

Pie Graph 8.1. Anaesthetist cover for LA cases

<table>
<thead>
<tr>
<th>Anaesthetist Cover</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dedicated anaesthetist</td>
<td>60.3%</td>
</tr>
<tr>
<td>Anaesthetist in theatres</td>
<td>23.5%</td>
</tr>
<tr>
<td>Available in dire emergency</td>
<td>12.7%</td>
</tr>
<tr>
<td>None in the hospital</td>
<td>2.6%</td>
</tr>
<tr>
<td>No response</td>
<td>0.9%</td>
</tr>
</tbody>
</table>

In around 84% of cases, there was an anaesthetist available either in the theatre or nearby in the theatre suite, as recommended by the 1993 Guidelines (See pie chart 8.1).

In 2.6% of reported cases in the initial week, intraocular surgery took place with no anaesthetist in the hospital. Only one of these cases took place at the weekend; the Survey did not record whether the other cases were performed in normal working hours. Anaesthetic techniques for these 74 cases are summarised in pie chart 8.2. This chart shows that 62% of these LA's were given by retrobulbar or peribulbar anaesthesia, and 37% by the "safer" non-periocular routes. Comparison with the overall results from this initial week (section 4.5.3) suggests that there is a higher usage if these "safer" techniques when there is no anaesthetist in the hospital. Whether this is in direct response to safety concerns,
or for other reasons, is not certain. The types of hospital in which this took place
are defined by question 9, below.

**Pie Graph 8.2. Anaesthetic techniques for those LA's which were given
when there was 'No anaesthetist in the hospital'.**

<table>
<thead>
<tr>
<th>Technique</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retrobulbar</td>
<td>20%</td>
</tr>
<tr>
<td>Sub-Tenon</td>
<td>3%</td>
</tr>
<tr>
<td>Peribulbar</td>
<td>42%</td>
</tr>
<tr>
<td>Sub-conjunctival</td>
<td>27%</td>
</tr>
<tr>
<td>Topical</td>
<td>7%</td>
</tr>
<tr>
<td>No response</td>
<td>1%</td>
</tr>
</tbody>
</table>
4.5.9. Report form question 9 (hospital type)

9. Type of Hospital where the procedure took place

- [] Teaching Hospital (General)
- [] District Hospital (General)
- [] Cottage Hospital
- [] Teaching Hospital (Eye Specialist)
- [] District Hospital (Eye Specialist)
- [] Other: please specify

This question was asked in order to obtain more information about those LA’s which were given without an anaesthetist in the hospital (see q8, above). Overall data in Pie Chart R9.1 show that over half of LA’s were administered in District General Hospitals.

**Pie Graph R9.1. Type of hospital where LA was given.**

- Teaching (general) 16%
- Teaching (eye) 13.6%
- District general 53.4%
- District (eye) 14.5%
- Cottage hosp. 0.6%
- Other 0.8%
- No response 1.1%

A separate analysis was made for those LA’s which took place with “no anaesthetist in the hospital” (question 8, above). Pie chart R9.2 shows that this situation occurred in district general hospitals, eye hospitals and cottage hospitals. The only type of hospital in which this situation did not occur was Teaching hospitals (general), presumably because these hospitals are large and always have at least one anaesthetist on site at all times.
Pie Graph R9.2. Hospitals where LA was given when there was "No anaesthetist in the hospital" (see R8).

- Teaching (eye) 5.4%
- District General 24.3%
- District (eye) 60.8%
- Cottage hospital 9.5%

4.5.10. Report form question 10 (aspirin and warfarin)

10. In the last fortnight, has the patient been treated with regular Warfarin, Aspirin, or other anticoagulant or antiplatelet agent?

[ ] No  [ ] Warfarin  [ ] Aspirin  [ ] Other agent: Please specify ..................................

Warfarin patients only: Was dosage reduced or stopped because of impending surgery?

[ ] No  [ ] Yes  [ ] Yes, changed to heparin

Warfarin patients only: Was the INR checked within 24 hours of surgery?

INR is the International Normalised Ratio (Prothrombin time vs. control).

[ ] No  [ ] Yes: If Yes, please state INR .....................

This question was asked in order to perform a secondary study, which looked into the safety of LA injections in patients who were using antiplatelet or anticoagulant therapy. Results will not be discussed in detail in this thesis, but have been summarised in a paper entitled Haemorrhagic complications of local
Anaesthetic injections: the effect of warfarin and aspirin, which has been submitted for publication.

In the initial week of the Survey, 258 (9.1%) of LA patients had been taking regular aspirin, and 54 (1.9%) had been taking regular warfarin (Pie chart R10.1). Of the warfarin-treated patients, warfarin dosage was reduced or stopped because of impending surgery in around one-third of cases. Analysis of adverse event reports found no evidence that warfarin was associated with increased risk of any adverse event. Aspirin use was associated with a modest increase in risk of “severe” orbital haemorrhage (section 4.5.12 and 4.6.1.3), by a factor of 2.5 (95% CI: 1.0, 6.7).

Pie Graph R10.1. Use of warfarin, aspirin, and related agents in patients who received LA.
4.5.11. Report form question 11 (‘Systemic’ adverse events)

Adverse Events: We define an adverse event as something which made you monitor the patient more closely, or take action.

11a. Were there any Systemic adverse events?

[ ] NO SYSTEMIC ADVERSE EVENTS
[ ] Cardiovascular system problem
[ ] Respiratory or oxygenation problem
[ ] Neurological or psychiatric problem
[ ] Patient unresponsive
[ ] Cardiorespiratory arrest
[ ] Other: Please describe: ...........................................

11b. If an adverse event occurred, what was done about it?

[ ] Patient was monitored more closely
[ ] Action was taken

The yellow Report Form asked for some information about adverse events. This was partly because we expected that some adverse events would result in a Report Form being returned without an attached Adverse Event Form. More importantly, it was necessary to know the number of LA’s which were uneventful, in order to estimate complication rates.

Pie chart R11.1 shows that, in the first week, 0.9% of LA’s were associated with some sort of ‘Systemic’ adverse event. Responses to question R11 are summarised in table R11.2. These 25 adverse events are further described in table R11.3, and in the section on adverse events, below. In 10 of these 25 cases, “action was taken” to manage the adverse event.

Three of these ‘systemic’ adverse events were considered to be “life threatening” by the respondent (question 2 on Adverse Event Form, see next section). Thus, the reported incidence of “life-threatening” adverse events in the initial week was 3/2827, or 0.1%. Clinical aspects of these three cases are summarised in section 4.6.1.2, table AE0.3, as cases 5, 7, and 17.
Pie Graph R11.1. Systemic adverse events in the initial week.

No systemic adverse events 94.5%
Systemic adverse event(s) 0.9%
No response 4.6%

Table R11.2. Incidence of reported "Systemic" adverse events in the initial week.

<table>
<thead>
<tr>
<th>Adverse event</th>
<th>Number of reports</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>2671</td>
<td>94.5%</td>
</tr>
<tr>
<td>Cardiovascular system problem</td>
<td>13</td>
<td>0.5%</td>
</tr>
<tr>
<td>Respiratory or oxygenation problem</td>
<td>4</td>
<td>0.1%</td>
</tr>
<tr>
<td>Neurological or psychiatric problem</td>
<td>1</td>
<td>0.03%</td>
</tr>
<tr>
<td>Patient unresponsive</td>
<td>1</td>
<td>0.03%</td>
</tr>
<tr>
<td>Cardio-respiratory arrest</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Other</td>
<td>6</td>
<td>0.2%</td>
</tr>
<tr>
<td>No response</td>
<td>131</td>
<td>4.6%</td>
</tr>
<tr>
<td>Total</td>
<td>2827</td>
<td></td>
</tr>
</tbody>
</table>
Table R 11.2. Description of the 26 systemic adverse events, reported in the initial week. Patients given oral pre-medication or intravenous sedation are indicated in italics.

<table>
<thead>
<tr>
<th>LA Technique</th>
<th>Less severe adverse events</th>
<th>&quot;Life-threatening&quot; adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Description</td>
</tr>
<tr>
<td>Peribulbar</td>
<td>17</td>
<td>3 hypertension (1 with ventricular ectopics; <em>had pre-med</em>)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 bradycardias (1 with pulsus bigemini, 1 with panic, <em>1 sedated pre-op</em>)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 tachycardias (1 supraventricular, <em>1 sedated pre-op</em>)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 palpitations</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 vasovagal faint</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 unspecified cardiovascular system problem (<em>had pre-med</em>)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 'totally uncooperative'</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 panic only (<em>both sedated pre-op</em>)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2 deoxygenation (1 with claustrophobia, <em>1 sedated pre-op</em>)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 urinary incontinence</td>
</tr>
<tr>
<td>Retrobulbar</td>
<td>2</td>
<td>1 panic/tremor</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 panic/confusion</td>
</tr>
<tr>
<td>Subtenon's</td>
<td>3</td>
<td>1 hypertension</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 panic/claustrophobia</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 confused/hyperventilating</td>
</tr>
<tr>
<td>Subconjunctival</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Topical alone</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Intracameral</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Combinations</td>
<td>1</td>
<td>Hypotension (<em>sedated pre-op</em>) after RBA+PBA</td>
</tr>
<tr>
<td>Not stated</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>23</td>
<td>3</td>
</tr>
</tbody>
</table>
4.5.12. Report form question 12 ("orbital" adverse events)

12. Were there any Orbital adverse events?

[ ] NO ORBITAL ADVERSE EVENTS
[ ] Perforation or penetration of globe
[ ] Retrobulbar or periocular haemorrhage:
  How severe was it?
    [ ] Minor (no mass effect)
    [ ] Marked (causing proptosis)
[ ] Expulsive haemorrhage
[ ] Inadequate analgesia, making the operation difficult or complicated
[ ] Inadequate akinesia, making the operation difficult or complicated
[ ] Other orbital/ocular adverse event, to which the LA may have contributed (Please give brief details) ..................................................

A total of 76 "orbital" adverse events were reported in the initial week, an incidence of 2.7% (pie chart 12.1). Clinical aspects are summarised in table 12.2. These adverse events are discussed further in sections 4.6.1.3, 4.6.2.6.2.

Pie Graph 12.1. "Orbital" adverse events in the initial week.

- No orbital adverse events 2550 (90.2%)
- Orbital adverse events 76 (2.7%)
- No response 201 (7.1%)
Table 12.2. Clinical detail of 76 reported "Orbital" adverse events in the initial week.

<table>
<thead>
<tr>
<th>LA technique</th>
<th>'Minor Orbital' adverse events</th>
<th>'Major Orbital' adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Inadequate analgesia, causing surgical difficulty</td>
<td>Inadequate akinesia, causing surgical difficulty</td>
</tr>
<tr>
<td>Peribulbar</td>
<td>12&lt;sup&gt;(a)&lt;/sup&gt;</td>
<td>12&lt;sup&gt;(a,b)&lt;/sup&gt;</td>
</tr>
<tr>
<td>Retrobulbar</td>
<td>1&lt;sup&gt;(a)&lt;/sup&gt;</td>
<td>4&lt;sup&gt;(a,b)&lt;/sup&gt;</td>
</tr>
<tr>
<td>Subtenon's</td>
<td>1</td>
<td>4&lt;sup&gt;(b,e)&lt;/sup&gt;</td>
</tr>
<tr>
<td>Sub-conj.</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Topical alone</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Intra-cameral</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Combinations</td>
<td>3&lt;sup&gt;(a)&lt;/sup&gt;</td>
<td>1&lt;sup&gt;(a)&lt;/sup&gt;</td>
</tr>
<tr>
<td>Not stated</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>18&lt;sup&gt;(a)&lt;/sup&gt;</td>
<td>21&lt;sup&gt;(a,b)&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

71 'Minor Orbital' adverse events<sup>(a,b,f)</sup> 5 'Major Orbital' adverse events<sup>(c)</sup>

---

a: Inadequate analgesia and akinesia co-existed with 2 PBA, 1 RBA and 1 combination (PBA+RBA)
b. 'Minor' retrobulbar haemorrhage (without proptosis) co-existed with inadequate akinesia with 1 PBA, 1 RBA and 1 STA.
c. In one case of retrobulbar haemorrhage, the operation took place on the same day and was complicated by expulsive haemorrhage.
d. There were 2 further reports of choroidal haemorrhage with PBA during this week.
e. Subtenon's anaesthesia and periorcular haemorrhage: one patient had 'subconjunctival haemorrhage ++'; the other had periorcular haemorrhage and inadequate akinesia.
f. Seven further 'miscellaneous' minor orbital adverse events were reported, but do not appear in the table.
4.6. Adverse Event Report Forms

4.6.1. Overall picture of adverse event reporting.
The overall incidence of reported adverse events in the initial week was 0.9% for “systemic” adverse events (section 4.5.11) and 2.7% for “orbital” adverse events (section 4.5.12). For the second phase of the survey, adverse events were reported at a lower rate. This under-reporting was particularly true for the more minor adverse events, but the rate of reporting for the more “severe” systemic adverse events did fall within the wide range of uncertainty as predicted by first-week returns. Serious adverse events were reported in association with all LA techniques.

4.6.1.1. Response rate for the two phases of the Survey
The instructions for the Survey stated that any adverse events that could be attributed to LA should be reported, using a pink Adverse Event Form attached to a yellow Report Form. In the initial week, when all LA’s were to be reported, there were 26 Systemic adverse events, and 76 Orbital adverse events, from a total of 2827 correctly completed forms (sections 4.5.11-12). In three months, a total of 261 Adverse Events were reported. This comprised 85 Systemic and 169 Orbital adverse events, and 7 cases in which adverse events of both categories occurred. Weekly reporting of Adverse Events is summarised in bar chart AE 0.1. There thus appears to be a degree of under-reporting of adverse events in the second phase of the Survey.
This under-reporting in the second phase can be expected, given the design of the Survey. In the initial week, respondents were asked to complete a report Form for every LA, regardless of whether or not an adverse event occurred. In the second phase, only LA-associated adverse events were to be reported. Thus, the respondent would have to recognise an adverse event to be LA-associated, remember that the Survey was still taking place, find the appropriate forms and make a report. Every effort was made to facilitate this process, including the production of poster to remind respondents of the Survey, and a plastic dispenser, containing all forms and instructions, which was mailed direct to every theatre in which intraocular surgery was performed. (see Methods, section 3.3.10).

A degree of under-reporting is perhaps inevitable, particularly for the less serious adverse events. However, there seemed to be much less under-reporting for the "severe" adverse events. These are defined and discussed in detail below. There were 3 "severe" adverse events in the initial week, and a further 19 in the subsequent 12 weeks of the Survey. The number reported in the second phase
does fall within the range of uncertainty of prediction, based on first-week returns.

4.6.1.2. “Severe” Systemic adverse events

The most serious ‘Systemic’ adverse events were classified as ‘Severe’ if they fulfilled at least one of the following criteria: (i) the person reporting the event described it as ‘life-threatening,’ (ii) the patient had an epileptic fit (excludes those already on anti-epileptic drugs), (iii) the patient was transferred from theatre to an Intensive Therapy Unit (ITU), (iv) death in the operating theatre, (v) on follow-up of a Systemic Adverse Event, subsequent death was attributed to the Adverse Event itself. These criteria, and the number of reports fulfilling them, are summarised in Box AE 0.2.

Box AE0.2. Summary of criteria for definition as ‘Severe Systemic Adverse Events’.

| (i)  | Described by respondent as ‘life-threatening’ | (18 reports) |
| (ii) | Epileptic fit | (3 reports) |
| (iii) | Transferred from theatre to an Intensive Therapy Unit | (3 reports) |
| (iv) | Death in theatres | (no reports) |
| (v)  | Subsequent death attributed to the Adverse Event | (1 report) |

A total of 22 ‘Severe Systemic Adverse Events’ were reported in three months, as summarised in Table AE0.3. Other reported adverse events, not fulfilling the criteria for classification as ‘Severe’, included bradycardia, tachycardia, other dysrhythmias, deoxygenation, unresponsiveness to speech, panic, confusion, and vomiting. These events are discussed in more detail in the following sections.
Table AE 0.3.
Brief description of each ‘Severe’ systemic adverse event reported.
ASA Grade= American Society of Anesthesiologists’ classification of physical status; IDDM = insulin-dependent diabetes mellitus; NIDDM = non-insulin-dependent diabetes mellitus; IHD = ischaemic heart disease; 
P = pulse rate per minute; BP = blood pressure in millimetres of mercury; 
IV = intravenous; ITU = intensive therapy unit; n/a = not available.

### Case SS1
Male, born 1920’s, ASA grade II
Peribulbar: 8 ml Lignocaine, Bupivacaine, Hyaluronidase
5 minutes later:
Confusion, contralateral amaurosis, bradycardia, respiratory depression, epileptic fit.
Given oxygen, glycopyrrolate, diazepam; operation postponed
Classified as “Severe” because: Epileptic fit
Follow up: No lasting effects. Uneventful surgery under GA.

### Case SS2.
Male, born 1930’s, ASA Grade II, Hypertensive
Peribulbar: 8 ml Lignocaine, Bupivacaine, Hyaluronidase
30 minutes later:
Bradycardia (P=36), hypotension, nausea and retching
Given atropine, operation completed
Classified as “Severe” because: ‘Life-threatening’
Follow up: No lasting effects

### Case SS3.
Female, born 1910’s, ASA grade II
Peribulbar: 5 ml Lignocaine, Bupivacaine, Hyaluronidase
1-2 minutes later:
Bradycardia (P=33), hypotension, unresponsive to speech for 1 minute
Given oxygen, atropine. Operation commenced when patient stabilised
Classified as “Severe” because: ‘Life-threatening’
Follow up: No lasting effects

### Case SS4.
Female, born 1910’s, ASA Grade III, Hypertension & IHD
Peribulbar: 10 ml Prilocaine, Hyaluronidase
20 minutes later:
Deoxygenation, unresponsive to speech
Given oxygen, cyclizine
Classified as “Severe” because: ‘Life-threatening’
Follow up: n/a
### Case SS5.
Male, born 1920's, ASA Grade III, NIDDM & IHD  
Peribulbar: 10ml Lignocaine, Bupivacaine, Hyaluronidase.  
IV midazolam  
Event occurred in theatre, before LA was given  
Bradycardia, atrial fibrillation  
Given oxygen, atropine  
Classified as "Severe" because: 'Life-threatening'  
Follow up: n/a

### Case SS6.
Male, born 1900's, ASA Grade II  
Peribulbar: 6 ml Lignocaine, Hyaluronidase  
15 minutes later:  
Agitation, poorly responsive to speech. P=80, BP=200/110  
Given oxygen, atropine; operation not started  
Classified as "Severe" because: 'Life-threatening', Transfer to ITU  
Follow up: No lasting effects. Subsequent surgery (LA) uneventful

### Case SS7.
Female, born 1900's, ASA Grade II, Hypothyroidism  
Peribulbar: 8 ml Prilocaine, Hyaluronidase  
IV midazolam and fentanyl  
Initial (uneventful) injection to wrong side.  
Event occurred 1 minute after second peribulbar  
Oxygenation 85%, patient unresponsive for 20 seconds.  
Given flumazenil, operation proceeded  
Classified as "Severe" because: 'Life-threatening'  
Follow up: No lasting effects

### Case SS8.
Male, born 1910's, ASA grade II, NIDDM & Leukaemia  
Peribulbar: 10 ml Lignocaine, Bupivacaine, Adrenaline, Hyaluronidase  
10 minutes later:  
Anaphylaxis (attributed to platelet infusion)  
Anaphylaxis treated, operation not started  
Classified as "Severe" because: 'Life-threatening', Transfer to ITU  
Follow up: Patient died of pulmonary embolism (not related to LA)
### Case SS9
Male, born 1910’s, ASA Grade I
Peribulbar: 6 ml Bupivacaine
20 minutes later:
Bradycardia (P<30)
Management not stated; operation completed
Classified as “Severe” because: ‘Life-threatening’
Follow up: No lasting effects

### Case SS10
Male, born 1920’s, ASA Grade II, IDDM, IHD & epilepsy
Peribulbar: 8 ml Lignocaine, Bupivacaine, Hyaluronidase
3 minutes later:
Hypoglycaemia, deoxygenation, unresponsive to speech
Given oxygen, ephedrine, dextrose; operation not started.
Classified as “Severe” because: ‘Life-threatening’
Follow up: n/a

### Case SS11
Male, born 1920’s, ASA Grade III, hypertension
Peribulbar: 7 ml Lignocaine, Bupivacaine, Hyaluronidase
Noted before LA given:
Hypertension, tachycardia (blamed on stress of having LA surgery)
Hypertension treated
Classified as “Severe” because: Subsequent death blamed on this event
Follow up: MI next day; died 4 days later

### Case SS12
Female, born 1920’s, ASA grade I
Peribulbar: 8 ml Prilocaine, Hyaluronidase
10 minutes later:
Grand mal fit
Given oxygen, thiopentone; operation postponed
Classified as “Severe” because: Epileptic fit
Follow up: No lasting effects. Uneventful surgery under GA.

### Case SS13
Male, born 1920’s, ASA grade II, Hypertension
Peribulbar: 10 ml Lignocaine, Bupivacaine, Hyaluronidase
7 minutes later:
Confusion, apnoea, P=30, BP= 98/30
Given oxygen, glycopyrrolate, ephedrine, operation postponed
Classified as “Severe” because: ‘Life-threatening’
Follow up: No lasting effects. Uneventful surgery under GA
Case SS14.
Female, born 1930's, ASA grade I
Peribulbar: 5 ml Prilocaine, Hyaluronidase
10-12 minutes later:
Hypertension, tachycardia, epileptic fit.
Given oxygen, manual respiration with bag
Classified as "Severe" because: Epileptic fit
Follow up: Residual scotoma in this eye (presumed intraneural injection)

Case SS15.
Male, born 1950's, ASA Grade I
Peribulbar: 4ml Bupivacaine, Hyaluronidase
20 minutes later:
Bradycardia (P=38). Panic, hyperventilation
Atropine given, operation abandoned
Classified as "Severe" because: 'Life-threatening'
Follow up: No lasting effects.
Uneventful re-operation with sedation, 3 days later
### Case SS16
Female, born 1920's, ASA grade II, Osteoarthritis
Retrobulbar: 9ml Lignocaine, Adrenaline, Hyaluronidase,
Oral Temazepam
5 minutes later: bradycardia (P=24), unresponsive to speech
Given atropine
Classified as “Severe” because: ‘Life-threatening’
Follow up: No lasting effects

### Case SS17
Male, born 1930's, ASA Grade I
Retrobulbar: 7ml Bupivacaine, Hyaluronidase
5 minutes later:
Confused and unresponsive,
Slow breathing, poor oxygenation.  P=75; BP=115/63
Given oxygen, converted to GA.
Operation proceeded
Classified as “Severe” because: ‘Life-threatening’
Follow up: No lasting effects

### Case SS18
Female, born 1910's, ASA Grade II, IHD
Topical Amethocaine 1%
25 minutes later (2 minutes after g. carbachol 3%):
Hypotension, bradycardia and myocardial ischaemia
Given oxygen, atropine
Classified as “Severe” because: ‘Life-threatening’. Transfer to ITU
Follow up: n/a

### Case SS19
Male, born 1920's, ASA grade IV, NIDDM, IHD, sideroblastic anaemia
Topical Amethocaine, topped up with Intracameral 1ml Lignocaine
IV fentanyl/ midazolam
Following top-up and IV sedation:
Brief apnoea. Unresponsive to speech
Ventilated with facemask and bag. Operation completed.
Classified as “Severe” because: ‘Life-threatening’
Follow up: No lasting effects.

### Case SS20
Female, born 1910's, ASA grade II
Retro + Peribulbar:
10 ml Lignocaine, Bupivacaine, Adrenaline, Hyaluronidase
3 minutes later:
Shallow breathing, deoxygenation, unresponsive to speech, transient VII nerve palsy
Given oxygen, operation not started
Classified as “Severe” because: ‘Life-threatening’
Follow up: No lasting effects. Uneventful surgery under GA.
**Case SS21**
Female, born 1910's, ASA Grade II, hypertension, IHD
LA technique not stated:
10 ml Lignocaine, Bupivacaine, Adrenaline, Hyaluronidase
30 minutes later:
Angina, sinus tachycardia with ectopics
Given oxygen, glyceryl trinitrate; operation proceeded
Classified as "Severe" because: 'Life-threatening'
Follow up: n/a

**Case SS22**
Female, born 1910's, ASA grade II, IDDM
LA technique not stated:
8 ml Lignocaine, Bupivacaine, Adrenaline, Hyaluronidase
15 minutes later:
Sinus tachycardia
Given esmolol, operation proceeded
Classified as "Severe" because: 'Life-threatening'
Follow up: n/a

### 4.6.1.3. "Severe orbital adverse events"

These were defined as one or more of the following sight-threatening adverse events: (i) globe penetration or perforation, (ii) Periocular haemorrhage causing proptosis, (iii) expulsive haemorrhage (Box AE0.4).

**Box AE0.4. Definition of "Severe orbital adverse events"**

<table>
<thead>
<tr>
<th>(i)</th>
<th>Penetration or perforation of globe</th>
<th>(8 reports)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(ii)</td>
<td>Periocular haemorrhage causing proptosis</td>
<td>(26 reports)</td>
</tr>
<tr>
<td>(iii)</td>
<td>Expulsive haemorrhage</td>
<td>(4 reports)</td>
</tr>
</tbody>
</table>

Expulsive haemorrhage (acute intraoperative suprachoroidal haemorrhage), while frequently associated with a poor outcome, is not generally agreed to be a complication of LA itself (Beatty et al 1998; Bukelman et al 1987; Ingraham et al 1989). For the first week of the Survey, the Report Form contained a specific request for each of these three Orbital events to be reported. Thereafter, reporting of adverse events relied on the respondent recognising an adverse event to be related to the LA itself. We therefore did not expect many reports of expulsive haemorrhage after the first week.

Severe Orbital adverse events are summarised below in table AE0.5
### Table AE0.5.

**‘Severe Orbital’ adverse events during the whole of the Survey.**

<table>
<thead>
<tr>
<th>LA technique</th>
<th>Estimated Number of LA’s given in 3 months (95% CI)</th>
<th>Perforation/penetration</th>
<th>Retrobulbar (pericocular) haemorrhage (severe, causing proptosis)</th>
<th>Expulsive haemorrhage&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peribulbar</td>
<td>42,700 (33,000-55,100)</td>
<td>6</td>
<td>18</td>
<td>2</td>
</tr>
<tr>
<td>Retrobulbar</td>
<td>11,000 (8,400-14,400)</td>
<td>1</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>Subtenon’s</td>
<td>4,380 (3,280-5,840)</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Subconjunctival</td>
<td>2,860 (2,100-3,880)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Topical alone</td>
<td>1,870 (1,340-2,600)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Intracameral</td>
<td>46 (11-188)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Combosinations</td>
<td>1,450 (1,020-2,060)</td>
<td>1 (RBA+PBA)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Not stated</td>
<td>780 (510-1,190)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>65,100 (48,500-81,700)</td>
<td>8</td>
<td>26</td>
<td>4&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>a</sup>: Data on expulsive haemorrhage was specifically requested for patients who had LA in the first week, resulting in two of the four reports. As LA is not generally agreed to be a risk factor for expulsive haemorrhage, we did not expect many reports thereafter.

<sup>b</sup>: Total number of combined retro+ peribulbar anaesthetics in the 3 months was calculated to be 830 (95% CI: 550-1250).

#### 4.6.1.4. Submission rate for Adverse Event Forms

Some adverse events were reported on a yellow Report form, but there was no attached pink Adverse Event form. This was particularly true of the more minor adverse events, in the initial week. For 204 of the reported adverse events, an Adverse Event form was attached (pie chart AE0.6). As discussed above in...
section 4.6.1.1, there appeared to be a high level of under-reporting of adverse events in the second phase of the Survey.

Pie Graph AE0.5.
Proportion of reported Adverse Events for which a completed Adverse Event report form was also returned.

<table>
<thead>
<tr>
<th>Adverse Event form completed</th>
<th>204 (78%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>57 (22%)</td>
</tr>
</tbody>
</table>
4.6.2. Responses to the individual questions on the Adverse Event Report form

The questions on the pink Adverse Event Report Form are reproduced below, along with a summary of responses.

4.6.2.1. Adverse Event question 1 (patient details)

<table>
<thead>
<tr>
<th>q. AE 1. Patient/event details: (This is required so we can match this form with the yellow form you have also completed for this patient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of operation: ........../........../1996</td>
</tr>
<tr>
<td>Year of birth</td>
</tr>
<tr>
<td>[ ] 1890’s</td>
</tr>
<tr>
<td>[ ] 1940’s</td>
</tr>
<tr>
<td>Sex: [ ] Male [ ] Female</td>
</tr>
<tr>
<td>Type of adverse event [ ] Systemic [ ] Orbital [ ] Both</td>
</tr>
</tbody>
</table>

The first three parts are duplicate the local anaesthetic Report Form, in order to match up any pairs of forms that were not physically attached together before mailing. Responses to these first questions are discussed in the above section.

In three months, a total of 92 Systemic and 176 Orbital adverse events were reported, including 7 cases in which adverse events of both categories occurred (pie graph AE1.1). The question of under-reporting is addressed in section 4.6.1.1, above.
Pie Graph AE1.1. Types of adverse events reported in 3 months

Systemic: 85 (32.6%)
Orbital: 169 (64.7%)
Both: 7 (2.7%)
4.6.2.2. Adverse Event question 2 (was the event “life-threatening”?)

q. AE 2. Do you consider that this adverse event was “Life-threatening”?

[ ] No  [ ] Yes

Of a total 92 “systemic” adverse events reported, 18 were considered to be “life threatening” by the respondent (pie graph AE2.1). Three of these cases were reported in the initial week.

None of the “orbital” adverse events were considered life-threatening. Sixteen of the 85 reported “systemic” adverse events, and 2 of 7 “combined systemic & orbital” adverse events, were considered “life-threatening”.

This question was one of those used to determine whether a systemic adverse event was “severe” (see Box AE0.2, section 4.6.1.2). The 18 “life-threatening” events are summarised in table AE 0.3, in section 4.6.1.2.

**Pie Graph AE2.1. Proportion of reported "systemic" adverse events that were considered to be "life-threatening".**
### 4.6.2.3. Adverse Event question 3 (what happened?)

**q. AE 3. If a systemic adverse event occurred: What happened?**

<table>
<thead>
<tr>
<th>Adverse Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood pressure too high</td>
</tr>
<tr>
<td>Blood pressure too low</td>
</tr>
<tr>
<td>Pulse too fast</td>
</tr>
<tr>
<td>Pulse too slow</td>
</tr>
<tr>
<td>Angina</td>
</tr>
<tr>
<td>Abnormal heart rhythm (Please describe)</td>
</tr>
<tr>
<td>Cardio-respiratory arrest</td>
</tr>
<tr>
<td>Breathing rate too slow, or apnoea</td>
</tr>
<tr>
<td>Breathing rate too fast</td>
</tr>
<tr>
<td>Oxygenation too low</td>
</tr>
<tr>
<td>Unresponsive to speech</td>
</tr>
<tr>
<td>Anxiety/panic attack</td>
</tr>
<tr>
<td>Confusion/agitation</td>
</tr>
<tr>
<td>Epileptic fit</td>
</tr>
<tr>
<td>Other systemic adverse event (please describe)</td>
</tr>
</tbody>
</table>

A variety of Systemic adverse events were reported, the raw data appearing as tables AE3.1-2. For many patients, more than one box was ticked for question AE3, which is why the columns in table AE3.1 sum to over 100%. More accurate descriptions of some adverse events were obtained from the follow-up forms, which asked for a free-text description of “what happened?”

The 22 “severe” systemic adverse events from the three-month survey are summarised above in table AE0.3, section 4.6.1.2. Other reported adverse events, not fulfilling the criteria for classification as “severe”, included bradycardia, tachycardia, other dysrhythmias, deoxygenation, unresponsiveness to speech, panic, confusion, and vomiting.

In the initial week, 23 “systemic” adverse events were reported, giving a reported incidence of 23/2827, or 0.9%. Three of these events were “severe”. These 23 cases are summarised in table AE3.3. The frequency of reported “systemic” adverse events for the three-month Survey period is summarised in table AE3.4. This shows that all LA techniques were associated with systemic adverse events. “Severe” systemic adverse events were reported in association with injection techniques and also the “newer” topical and intracameral techniques. However, the descriptions of these latter events (section 4.6.1.2, table AE0.3, cases SS18-19) indicate that these two “severe systemic” cases
could more easily be explained as side-effects of a topical miotic and intravenous sedation, rather than LA per se.

Table AE3.1
Description of all reported systemic adverse events: raw data.

<table>
<thead>
<tr>
<th>All reported Systemic adverse events (n = 92)</th>
<th>“Life-threatening” Systemic adverse events (see q.AE2 and table AE0.3) (n = 18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood pressure too high</td>
<td>18 19.5%</td>
</tr>
<tr>
<td>Blood pressure too low</td>
<td>12 13%</td>
</tr>
<tr>
<td>Pulse too fast</td>
<td>16 17%</td>
</tr>
<tr>
<td>Pulse too slow</td>
<td>24 26%</td>
</tr>
<tr>
<td>Angina</td>
<td>4 4%</td>
</tr>
<tr>
<td>Abnormal heart rhythm</td>
<td>8 9%</td>
</tr>
<tr>
<td>Cardio-respiratory arrest</td>
<td>0 0%</td>
</tr>
<tr>
<td>Breathing rate too slow, or apnoea</td>
<td>5 5%</td>
</tr>
<tr>
<td>Breathing rate too fast</td>
<td>7 8%</td>
</tr>
<tr>
<td>Oxygenation too low</td>
<td>15 16%</td>
</tr>
<tr>
<td>Unresponsive to speech</td>
<td>11 12%</td>
</tr>
<tr>
<td>Anxiety/panic attack</td>
<td>25 27%</td>
</tr>
<tr>
<td>Confusion/Agitation</td>
<td>12 13%</td>
</tr>
<tr>
<td>Epileptic Fit</td>
<td>3 3%</td>
</tr>
<tr>
<td>Other systemic adverse event*</td>
<td>43 47%</td>
</tr>
<tr>
<td>No Response</td>
<td>1 1%</td>
</tr>
<tr>
<td>Total</td>
<td>204</td>
</tr>
</tbody>
</table>

*Other reported Systemic Adverse events: see table AE3.2
<table>
<thead>
<tr>
<th>&quot;Other&quot; adverse event</th>
<th>Number of reports (all 92 systemic adverse events)</th>
<th>Number of reports (22 &quot;severe&quot; adverse events)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Claustrophobia</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>&quot;Totally un-cooperative&quot;</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Aware of heartbeat / palpitations</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Tremor</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Faint / vasovagal episode</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Urinary incontinence</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>&quot;Funny turn&quot;</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Focal sensory loss</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Reminded of torture</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Nausea &amp; vomiting</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Shallow breathing</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Anaphylaxis</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Hypoglycaemia</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Needle phobia</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Orthopnoea</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Muscle cramps</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Periocular erythema</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Sweaty &amp; feeling faint</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Myocardial ischaemia</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Supra-ventricular tachycardia</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Ventricular ectopics</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Sinus bradycardia</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Sinus tachycardia</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Sinus tachycardia &amp; ectopics</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Sinus arrhythmia</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Pulsus bigemini</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>
Table AE3.3.
Systemic adverse events reported in the initial week of the survey.
Patients given oral pre-medication or intravenous sedation are indicated in italics. Criteria for definition of an adverse event as ‘Severe’ are summarised in Box AE0.2.

<table>
<thead>
<tr>
<th>Technique, incidence of reported adverse events</th>
<th>Description</th>
</tr>
</thead>
</table>
| Peribulbar: 17/1854 | 3 hypertension (1 with ventricular ectopics; *had pre-med*)  
3 bradycardias (1 with pulsus bigemini, 1 with panic, *1 sedated pre-op*)  
2 tachycardias (1 supraventricular, *1 sedated pre-op*)  
1 palpitations  
1 vasovagal faint  
1 unspecified cardiovascular system problem (*had pre-med*)  
1 ‘totally uncooperative’  
2 panic only (*both sedated pre-op*)  
2 deoxygenation (1 with claustrophobia, *1 sedated pre-op*)  
1 urinary incontinence  
2 “severe” reactions (see table AE0.3):  
bradycardia & atrial fibrillation (case SS5)  
ddeoxygenation, unresponsive (case SS7) |
| Retrobulbar: 2/479 | 1 panic/tremor  
1 panic/confusion  
1 “severe” reaction (see table AE0.3)  
ddeoxygenation, unresponsive (case SS17) |
| Subtenon’s: 3/190 | 1 hypertension  
1 panic/claustrophobia  
1 confused/hyperventilating |
| Subconjunctival: 0/124 |  |
| Topical alone: 0/81 |  |
| Intracameral: 0/2 |  |
| Combinations: 1/64 | Hypotension (*sedated pre-op*) after RBA+PBA |
| Not stated: 0/34 |  |
| Total: 23/2827 |  |
Table AE3.4.
Frequency and incidence of reported Systemic adverse events during the whole of the Survey. Criteria for definition of an adverse event as ‘Severe’ are summarised in Box AE0.3.

<table>
<thead>
<tr>
<th>LA technique</th>
<th>Estimated Number of LA’s given in 3 months</th>
<th>‘Severe’ systemic adverse events</th>
<th>Total systemic adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of reports</td>
<td>Reported incidence (95% CI)</td>
<td>No. of reports</td>
</tr>
<tr>
<td>Peribulbar</td>
<td>42,700</td>
<td>15 3.5 per 10,000 (2.0-6.2)</td>
<td>64 15.0 per 10,000 (10.5-21.4)</td>
</tr>
<tr>
<td>Retrobulbar</td>
<td>11,000</td>
<td>2 1.8 per 10,000 (0.4-7.4)</td>
<td>8 7.3 per 10,000 (3.5-15.2)</td>
</tr>
<tr>
<td>Subtenon’s</td>
<td>4,380</td>
<td>0 13.7 per 10,000 (5.9-32.1)</td>
<td>6 7.0 per 10,000 (1.7-29.0)</td>
</tr>
<tr>
<td>Subconjunctival</td>
<td>2,860</td>
<td>0 5.4 per 10,000 (0.7-39.1)</td>
<td>2 7.0 per 10,000 (1.7-29.0)</td>
</tr>
<tr>
<td>Topical alone</td>
<td>1,870</td>
<td>1 21.7 per 10,000 (19-2400)</td>
<td>4 21.4 per 10,000 (7.6-60.4)</td>
</tr>
<tr>
<td>Intracameral</td>
<td>46</td>
<td>1 12.1 per 10,000 (6.0-109)</td>
<td>1 217 per 10,000 (19-2400)</td>
</tr>
<tr>
<td>Retro + Peribulbar</td>
<td>830</td>
<td>1 3.4 per 10,000 (2.1-5.5)</td>
<td>92 14.1 per 10,000 (10.2-19.6)</td>
</tr>
<tr>
<td>LA not stated</td>
<td>2</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>65,100</td>
<td>22</td>
<td>92</td>
</tr>
</tbody>
</table>
4.6.2.4. Adverse Event question 4 (when the event occurred)

q. AE 4. How long after the LA was given did the adverse event occur?
After about .............. minutes

“Systemic” adverse events were reported to occur up to 65 minutes after the block, with the earliest adverse event (a bradycardia) occurring 2 minutes before the LA was given. Mean time to adverse event was 12.3 minutes. Data for all 92 reported systemic adverse events are summarised in bar chart AE4.1

For “severe” systemic adverse events, the mean time to the event was 12.7 minutes (range: 0-30 minutes, see bar chart AE4.2, and fuller description of these events in table AE0.3 in section 4.6.1.2).

Bar graph AE4.1. Time from LA to “systemic” adverse event (all 92 reports).
13 cases have been omitted from the chart because the time was not recorded.
Bar graph AE 4.2. Time from LA to "severe systemic" adverse event. For one of the 22 reports, the time was not stated.
4.6.2.5. Adverse Event question 5 (who managed the event)

q. AE 5. Who helped to manage this adverse event? Tick as many boxes as apply.

- [ ] anaesthetist, who was already in theatre
- [ ] anaesthetist, called from elsewhere
- [ ] junior ophthalmologist
- [ ] consultant ophthalmologist
- [ ] physician
- [ ] other doctor (please specify)
- [ ] cardiac arrest team

Most of the 92 reported cases of Systemic adverse event were managed by an anaesthetist (table AE 5.1). In no case did a cardiac arrest team assist with management. Responses were similar for the 22 “severe” cases (table AE5.1).

Table AE5.1. Who helped manage “systemic” adverse events

<table>
<thead>
<tr>
<th></th>
<th>All 92 reported cases</th>
<th>22 “Severe systemic” cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaesthetist, who was already in theatre</td>
<td>61 (66%)</td>
<td>17 (77%)</td>
</tr>
<tr>
<td>Anaesthetist, called from elsewhere</td>
<td>15 (16%)</td>
<td>6 (27%)</td>
</tr>
<tr>
<td>Junior ophthalmologist</td>
<td>9 (10%)</td>
<td>3 (14%)</td>
</tr>
<tr>
<td>Consultant ophthalmologist</td>
<td>11 (12%)</td>
<td>3 (14%)</td>
</tr>
<tr>
<td>Physician</td>
<td>5 (5%)</td>
<td>2 (9%)</td>
</tr>
<tr>
<td>Other doctor (unspecified)</td>
<td>2 (2%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Cardiac arrest team</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>No response</td>
<td>9 (10%)</td>
<td>1 (5%)</td>
</tr>
</tbody>
</table>
4.6.2.6. Adverse Event question 6 (management of the event)

q. AE 6. What action was taken to manage this adverse event? 
(Tick as many boxes as apply)

(a): Action by Anaesthetist, Physician or equivalent
[] Monitoring and reassurance only
[] Air/oxygen supply improved
[] Drugs given (Please name drugs): ..................................................
[] Patient sedated
[] Converted to General Anaesthetic
[] Cardiopulmonary resuscitation
[] No action by anaesthetist or physician

(b): Action by Surgeon
[] Operation not started
[] Operation technique changed
[] Operation finished early
[] Operation took place as planned

4.6.2.6.1. “Systemic” adverse events

In around one half of the “systemic” adverse events, drugs were administered in order to manage the adverse event (table AE6.1). Seven cases were converted to general anaesthetic, in the three months of the survey. This gives a reported incidence of around 1 in 10,000 for emergency conversion from LA to GA, though this may be an under-estimate due to under-reporting (see section 4.6.1.1). There were no reports of cardiopulmonary resuscitation.

Table AE6.2 summarises the surgeon’s actions in response to Systemic adverse events. In around a third of cases, the operation was either not started (if the adverse event occurred before surgery began), or was finished early.
Table AE6.1. Action taken by anaesthetist or physician (Systemic adverse events).

<table>
<thead>
<tr>
<th>Action Taken</th>
<th>All 92 reported cases</th>
<th>22 “Severe systemic” cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitoring and reassurance only</td>
<td>23</td>
<td>25%</td>
</tr>
<tr>
<td>Air/oxygen supply improved</td>
<td>32</td>
<td>35%</td>
</tr>
<tr>
<td>Drugs given*</td>
<td>45</td>
<td>49%</td>
</tr>
<tr>
<td>Patient sedated</td>
<td>13</td>
<td>14%</td>
</tr>
<tr>
<td>Converted to General Anaesthetic</td>
<td>7</td>
<td>8%</td>
</tr>
<tr>
<td>Cardiopulmonary resuscitation</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>No action by anaesthetist or physician</td>
<td>6</td>
<td>7%</td>
</tr>
<tr>
<td>No response</td>
<td>10</td>
<td>11%</td>
</tr>
</tbody>
</table>

*Drugs given to manage the 22 “severe” systemic adverse events are summarised in table AE0.3.

Table AE6.2 Surgeons' responses to Systemic adverse events.

<table>
<thead>
<tr>
<th>Response</th>
<th>All 92 reported cases</th>
<th>22 “Severe systemic” cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation not started</td>
<td>21</td>
<td>23%</td>
</tr>
<tr>
<td>Operation technique changed</td>
<td>1</td>
<td>1%</td>
</tr>
<tr>
<td>Operation finished early</td>
<td>6</td>
<td>7%</td>
</tr>
<tr>
<td>Operation took place as planned</td>
<td>42</td>
<td>46%</td>
</tr>
<tr>
<td>No response</td>
<td>23</td>
<td>25%</td>
</tr>
</tbody>
</table>

4.6.2.6.2. Orbital Haemorrhage

Results are presented for those cases in which a “severe” orbital haemorrhage occurred. This was defined in q12 of the Report Form as a ‘retrobulbar or periocular haemorrhage, causing proptosis’. Actions by anaesthetists and surgeons are summarised in table AE6.3.

In around a quarter of cases of “severe” orbital haemorrhage, acetazolamide was given to lower the intraocular pressure. The operation took place as planned in 3
of 26 cases (one phacoemulsification, one “manual” extracapsular cataract extraction, one trabeculectomy); acetazolamide was not used for these three cases. Follow-up questionnaires were not returned for these three cases, so the final outcome is not known. In one further case of “severe” orbital haemorrhage, acetazolamide was given prior to extracapsular cataract extraction that day. Surgery was complicated by an expulsive haemorrhage. The follow-up questionnaire (section 3.4.6) revealed that the eye had become phthisical, and was removed because of chronic pain.

In most (81%) cases of “severe” orbital haemorrhage, surgery was postponed. Follow-up data was obtained for 12 of the 26 cases of ‘severe’ orbital haemorrhage, and 19 “non-severe” cases. There were no further reports of long-term problems associated with orbital haemorrhage.

Management of orbital haemorrhage has been discussed in the literature (section 2.3.2.13). Cionni and Osher stress the importance of lowering the intraocular pressure and careful monitoring of the patient before considering whether to proceed with surgery on the same day. Their series of sixty such cases passed without incident. In one of the cases described above, surgery proceeded on the same day, and an expulsive haemorrhage occurred. It is not certain whether the case was managed according to Cionni’s protocol. Because expulsive haemorrhage is a rare event (0.1% in the initial week of this survey, 0.2% in other studies (Sekine et al 1996; Speaker et al 1991)), Cionni’s series of 60 cases cannot prove that their protocol is safe. Likewise, this one case reported to the Survey does not prove that orbital haemorrhage increases the risk of expulsive haemorrhage.

Table AE6.3. “Severe” orbital haemorrhage (causing proptosis): Action by anaesthetists and surgeons, for 26 reported cases.

<table>
<thead>
<tr>
<th>Drugs given</th>
<th>8 (all acetazolamide)</th>
<th>27%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation not started</td>
<td>21</td>
<td>81%</td>
</tr>
<tr>
<td>Operation technique changed</td>
<td>1</td>
<td>4%</td>
</tr>
<tr>
<td>Operation finished early</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Operation took place as planned</td>
<td>3</td>
<td>12%</td>
</tr>
<tr>
<td>No response to q.6</td>
<td>1</td>
<td>4%</td>
</tr>
</tbody>
</table>
4.6.2.7. Adverse Event question 7 (patient's general condition on leaving theatre)

q. AE 7. Would you say that the patient’s general condition was significantly worse on departure from the theatre complex?

[ ] No  [ ] Yes, general condition had worsened  [ ] Patient died

There were no reports of death in the operating theatre. As expected, none of the “orbital” adverse events were associated with a worsening of general condition.

Results for the “systemic” adverse events are presented as pie-charts AE7.1 (all 92 reported events) and pie chart AE7.2 (“Severe” systemic adverse events).

In all, twelve patients were reported to have a “worse” general condition on leaving theatres. This included 8 of the 22 “severe systemic” adverse events. The other 4 were: (i) atrial fibrillation with heart failure, (ii) confused and unresponsive with tachycardia and nausea, (iii) anxiety attack, treated by sedation in an ASA grade III patient, (iv) sinus bradycardia.

**Pie Graph AE7.1. Patients' general condition on leaving theatres.**
*Pooled responses for all 92 "systemic" adverse events.*

<table>
<thead>
<tr>
<th>Condition</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Same</td>
<td>70</td>
<td>76%</td>
</tr>
<tr>
<td>Worse</td>
<td>12</td>
<td>13%</td>
</tr>
<tr>
<td>Died</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>No response</td>
<td>10</td>
<td>11%</td>
</tr>
</tbody>
</table>
4.6.2.8. Adverse Event question 8 (post-operative ward accommodation)

q. AE 8. Was postoperative ward accommodation changed as a result of this adverse event?

- [ ] No, patient went back to ward/daycare unit as planned
- [ ] Yes, a planned Daycase was kept in overnight on the Eye ward
- [ ] Yes, transferred to Medical ward or similar
- [ ] Yes, transferred to Intensive Therapy Unit
- [ ] Was not transferred due to other factors (e.g. bed unavailable), but should have been transferred to accommodation as ticked above

In most cases, the patient was returned to the ward or day-care unit after a "systemic" adverse event (pie charts AE8.1 and AE8.2). Transfer to an Intensive Therapy Unit (ITU) was one of the criteria for defining an adverse event as "severe" (see box AE0.2, section 4.6.1.2). The one patient who was transferred to a medical ward had atrial fibrillation and heart failure.
Pie Graph AE8.1. Postoperative ward accommodation after "Systemic" adverse events. Pooled data for all 92 reports.

- No change: 65 (71%)
- Daycase kept in: 12 (13%)
- Medical ward: 1 (1%)
- ITU: 3 (3%)
- Bed unavailable: 0
- No response: 11 (12%)

Pie Graph AE 8.2. Postoperative ward accommodation. Data for 22 "Severe systemic" adverse events.

- No change: 12 (55%)
- Daycase kept in: 6 (27%)
- Medical ward: 0
- ITU: 3 (13%)
- Bed unavailable: 0
- No response: 1 (5%)
4.6.2.9. Adverse Event question 9 (pre-existing medical conditions)

q. AE 9. Does the patient have any of the following chronic medical conditions?

- [ ] Insulin dependent diabetes
- [ ] Non-insulin dependent diabetes
- [ ] Hypertension (treated or untreated)
- [ ] Ischaemic heart disease
- [ ] Chronic obstructive airways disease
- [ ] Other severe chronic medical condition (please specify) ..................................
- [ ] None of the above __________________________________________________

Questions 9 and 10 were asked in order to get a better description of the patients who had adverse events. Ideally, these questions would have been included in the yellow Report Forms for the initial week, in order to get information as to the health profile of the patients who did not have adverse events. This information would have been useful as a “control”, to compare the health profiles of patients who had adverse events against those who did not. However, asking for this information on every patient in the initial week was felt to be too burdensome, and likely to adversely affect participation.

Responses are summarised in table AE9.1. This table shows the prevalence of chronic disease among patients who had “systemic” and “orbital” adverse events. Results should be interpreted with caution, in view of the differing proportion of non-respondents in the three groups, the lack of a “control” group in which there were no adverse events, and the high prevalence of pre-existing medical disease. Among patients who had adverse events, only 26% had no chronic medical conditions, and the prevalence was the same among “orbital and “systemic” adverse events. These findings are in agreement with a 1996 UK paper on pre-operative cataract patients, which indicated a 77% prevalence of pre-existing medical disease.(McKibbin 1996)
Table AE 9.1. Prevalence of chronic medical disease in patients who had adverse events.

<table>
<thead>
<tr>
<th></th>
<th>All 169 &quot;Orbital&quot; adverse events</th>
<th>All 92 &quot;Systemic&quot; adverse events</th>
<th>Subset: 22 &quot;Severe Systemic&quot; adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin dependent diabetes</td>
<td>9 5%</td>
<td>2 2%</td>
<td>1 5%</td>
</tr>
<tr>
<td>Non-insulin dependent diabetes</td>
<td>4 2%</td>
<td>10 11%</td>
<td>4 18%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>45 27%</td>
<td>24 26%</td>
<td>5 23%</td>
</tr>
<tr>
<td>Ischaemic heart disease</td>
<td>22 13%</td>
<td>24 26%</td>
<td>6 27%</td>
</tr>
<tr>
<td>Chronic obstructive airways disease</td>
<td>12 7%</td>
<td>13 14%</td>
<td>0 0%</td>
</tr>
<tr>
<td>Other severe chronic medical condition</td>
<td>16 10%</td>
<td>18 20%</td>
<td>5 23%</td>
</tr>
<tr>
<td>None of the above</td>
<td>44 26%</td>
<td>24 26%</td>
<td>7 32%</td>
</tr>
<tr>
<td>No response</td>
<td>51 30%</td>
<td>11 12%</td>
<td>2 9%</td>
</tr>
</tbody>
</table>
q. AE 10. Preoperative ASA grade.
(American Society of Anesthesiologists’ classification of physical status)

[ ] Grade I   A normally healthy individual
[ ] Grade II  A patient with systemic disease, which is not incapacitating
[ ] Grade III A patient with severe systemic disease, which is incapacitating
[ ] Grade IV  A patient with incapacitating systemic disease, which is a constant threat to life

This question was included for the same reasons as q.AE9. The ASA grading system, which is summarised in question AE10 above, is widely used in the UK as a classification of pre-operative physical status. Responses are shown in table AE10.1.

Because ASA grade correlates to some extent with the presence of chronic disease, some similarities can be expected between tables AE9.1 and AE10.1. Both tables indeed show that there was a similar distribution of chronic disease and ASA grading, among those who had “systemic” or “orbital” adverse events. For reasons explained above (under q. AE9), no such data were collected for the patients who had no adverse events.

These data were used to further describe the patients in whom adverse events occurred (see table AE0.3). A subset of the data was used to compare the patient profiles of those who had “severe systemic” adverse events, against a “comparison group” who had “minor” orbital adverse events (see section 4.8).

Table AE10.1.
Pre-operative ASA grading for patients who had adverse events.

<table>
<thead>
<tr>
<th></th>
<th>All 169 “Orbital” adverse events</th>
<th>All 92 “Systemic” adverse events</th>
<th>Subset: 22 “Severe Systemic” adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASA grade I</td>
<td>29 (17%)</td>
<td>17 (18%)</td>
<td>5 (23%)</td>
</tr>
<tr>
<td>ASA grade II</td>
<td>69 (41%)</td>
<td>47 (51%)</td>
<td>13 (59%)</td>
</tr>
<tr>
<td>ASA grade III</td>
<td>18 (11%)</td>
<td>17 (18%)</td>
<td>3 (14%)</td>
</tr>
<tr>
<td>ASA grade IV</td>
<td>0 (0%)</td>
<td>2 (2%)</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>No response</td>
<td>53 (31%)</td>
<td>9 (10%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Total</td>
<td>169 (100%)</td>
<td>92 (100%)</td>
<td>22 (100%)</td>
</tr>
</tbody>
</table>
4.6.2.11. Adverse Event question 11 (who did the pre-operative assessment)

Table AE 11.1 shows the raw data. In most cases, the pre-operative assessment of general health was performed by more than one category of personnel. In 25 cases (9.6% of all reports), the assessment was performed by a nurse only, and in 6 cases (2.3%), it was performed by a consultant ophthalmologist only. There was no evidence to suggest that nurse-only assessment was confined to patients who had non-injection anaesthetics. Of a total of 261 reported adverse events, 14% had retrobulbar anaesthesia and 69% had peribulbar. Of 25 adverse events that had been assessed by a nurse only, 20% had retrobulbar anaesthesia, and 68% peribulbar.
Table AE 11.1. Who assessed the patient’s general health as part of the work-up prior to surgery? (Raw data).

<table>
<thead>
<tr>
<th></th>
<th>All 169 &quot;Orbital&quot; adverse events</th>
<th>All 92 &quot;Systemic&quot; adverse events</th>
<th>Subset: 22 &quot;Severe Systemic&quot; adverse events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ophthalmologist</td>
<td>23 14%</td>
<td>19 21%</td>
<td>4 18%</td>
</tr>
<tr>
<td>(consultant)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anaesthetist</td>
<td>32 19%</td>
<td>22 24%</td>
<td>5 23%</td>
</tr>
<tr>
<td>(consultant)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ophthalmologist</td>
<td>70 41%</td>
<td>39 42%</td>
<td>12 55%</td>
</tr>
<tr>
<td>(non-consultant)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anaesthetist</td>
<td>14 8%</td>
<td>6 7%</td>
<td>0 0%</td>
</tr>
<tr>
<td>(non-consultant)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nurse</td>
<td>52 31%</td>
<td>43 47%</td>
<td>9 41%</td>
</tr>
<tr>
<td>Physician</td>
<td>2 1%</td>
<td>3 3%</td>
<td>1 5%</td>
</tr>
<tr>
<td>Other*</td>
<td>2 1%</td>
<td>3 3%</td>
<td>1 5%</td>
</tr>
<tr>
<td>No-one</td>
<td>0 0%</td>
<td>0 0%</td>
<td>0 0%</td>
</tr>
<tr>
<td>No response</td>
<td>50 30%</td>
<td>8 9%</td>
<td>0 0%</td>
</tr>
<tr>
<td>Total</td>
<td>169</td>
<td>92</td>
<td>22</td>
</tr>
</tbody>
</table>

4.6.2.12. Adverse Event question 12 (regular medication)

q. AE 12. Please name the medications the patient was taking regularly prior to the operation (no need to give dosages)

This question was asked in order to get more information on the patients who had adverse events. It was also important in categorising Systemic adverse events as "severe". One of the criteria for a "severe" adverse event was an epileptic fit, in a patient who was not already taking anti-epileptic drugs (see Box AAE0.2, section 4.6.1.2 for other criteria). Of three patients reported to have epileptic fits, none were taking anti-epileptics.

Detail of patient's medical treatment was also required in order to audit compliance with the Colleges' guidelines for pre-operative assessment of patients with chronic disease. This is discussed in the following section.
4.6.2.13. Adverse Event question 13 (pre-operative work-up)

<table>
<thead>
<tr>
<th>q. AE 13. Which aspects of the preoperative workup are recorded in the notes?</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] general medical history</td>
</tr>
<tr>
<td>[ ] blood pressure</td>
</tr>
<tr>
<td>[ ] examination (with a stethoscope)</td>
</tr>
<tr>
<td>[ ] electrocardiogram (ECG)</td>
</tr>
<tr>
<td>[ ] chest x-ray</td>
</tr>
<tr>
<td>[ ] urinalysis</td>
</tr>
<tr>
<td>[ ] blood count</td>
</tr>
<tr>
<td>[ ] blood urea/electrolytes</td>
</tr>
<tr>
<td>[ ] blood sugar</td>
</tr>
</tbody>
</table>

Raw data are presented in table AE13.1. As discussed above, these data are only available for patients who had adverse events, and not for a “control” group who had uneventful surgery. If adverse events occurred at random, this group would be a true representation of the LA population as a whole. Because some adverse events may have been anticipated, it is likely that, on average, the patients in table AE13.1 had a more thorough pre-operative work-up than the patients who had uneventful LA.

204 respondents completed the Adverse Event form, at least in part, and their responses were used in compiling table AE 13.2. Because of an error, there was no check-box for “none of the above” (i.e no pre-operative examination). Ten respondents ticked no boxes in q. AE13, though they did respond to most of the other questions on the Adverse Event form. This may mean that these 10 patients had no formal pre-op examination, or simply that the respondent did not wish to complete this section. The author’s personal experience indicates that, indeed, some centres were not performing any routine pre-operative tests at the time of the Survey.

The question of pre-operative testing has been the subject of controversy in recent years (Walters and McKibbin 1997). A recent study, in which almost 20,000 patients were randomised to have a history and examination alone, or to have a standard battery of medical tests in addition, concluded that “routine
medical testing before cataract surgery does not measurably increase the safety of the surgery” (Schein et al 2000).

### Table AE13.1. Pre-operative assessment for patients who had adverse events. Raw data for all 204 respondents

| Medical history | 187 | 92% |
| Blood pressure (BP) | 174 | 85% |
| Stethoscope examination | 72 | 35% |
| Electrocardiogram | 90 | 44% |
| Chest x-ray | 16 | 8% |
| Urinalysis | 67 | 33% |
| Blood count | 57 | 28% |
| Urea/electrolytes | 53 | 26% |
| Blood sugar | 41 | 20% |
| None of above / No response* | 10 | 5% |

*Ten respondents had answered most of the questions on the Adverse Event form, but did not tick any of the boxes for AE13. This may mean that the patient had no formal pre-op examination, or that the respondent did not wish to complete this section. The omission of a “none of the above” check-box from the Adverse Event forms was an error.

### 4.6.2.13.1. Audit of compliance with the 1993 Guidelines

“*A full history and examination, including measurement of blood pressure and urinalysis, should be performed in all cases...”*

Compliance with this standard is summarised in table AE13.2. The published standard implies that a stethoscope should be used for the examination, but is not explicit. For this reason, table AE13.2 also includes the proportion that had history/blood pressure/urinalysis without stethoscope examination.

Compliance with this standard (history, examination, blood pressure, urinalysis) was only 13% (see table AE13.2). This does not mean that all of the other 87% of pre-op assessments were contrary to the spirit of the guidelines. For example, blood tests may be considered an appropriate alternative to urinalysis, and a history taken by a consultant anaesthetist may be more useful than a medical examination performed by some ophthalmologists. If blood sugar were considered to be an adequate substitute for urinalysis, then a further 8 (4%) would have complied fully with this standard. Likewise, an anaesthetist’s assessment instead of stethoscope examination would have allowed a further 12
Table AE 13.2
Audit of guideline: History and basic examination for all patients.

<table>
<thead>
<tr>
<th>Published standard</th>
<th>Observed</th>
</tr>
</thead>
<tbody>
<tr>
<td>History + Examination + Blood pressure + Urinalysis</td>
<td>100% History + Examination + Blood pressure + Urinalysis</td>
</tr>
<tr>
<td>History + Blood pressure + Urinalysis</td>
<td>31% (63/204)</td>
</tr>
<tr>
<td>History + Blood pressure</td>
<td>83% (169/204)</td>
</tr>
</tbody>
</table>

"Electrocardiography (ECG) – for patients over 60 and those with symptoms or signs of cardiovascular disease, including ischaemic heart disease of hypertension"

Compliance with the ECG Guidelines was around 50%, for all groups assessed (table AE13.3).

Table AE 13.3.
Audit of guideline: Electrocardiography.

<table>
<thead>
<tr>
<th>Published standard</th>
<th>Observed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year of birth before 1930’s (q. R1)</td>
<td>100% ECG</td>
</tr>
<tr>
<td>Ischaemic heart disease (q. AE 9)</td>
<td>100% ECG</td>
</tr>
<tr>
<td>Hypertension (q. AE 9)</td>
<td>100% ECG</td>
</tr>
<tr>
<td>ECG</td>
<td>47% (72/152)</td>
</tr>
<tr>
<td>ECG</td>
<td>54% (25/46)</td>
</tr>
<tr>
<td>ECG</td>
<td>51% (35/69)</td>
</tr>
</tbody>
</table>

"Chest X-ray- for patients with a history or signs of chronic lung disease or any suggestion of malignancy or pulmonary stenosis”

Adherence to this guideline was assessed for patients with chronic obstructive airways disease (COAD, table AE13.4). Compliance was 12% for COAD patients. In all, 16 patients (8%) had a chest x-ray. Chest X-ray can be considered a more invasive test than blood-tests, as it involves exposing the
patient to ionising radiation. The survey methodology does not permit any
assessment of the appropriateness or otherwise of chest x-ray in individual cases.

Table AE 13.4. Audit of guideline: Chest X-ray.

<table>
<thead>
<tr>
<th>Chronic obstructive airways disease (q. AE 9)</th>
<th>Published standard</th>
<th>Observed</th>
</tr>
</thead>
<tbody>
<tr>
<td>100% Chest X ray</td>
<td>12% (3/25)</td>
<td></td>
</tr>
</tbody>
</table>

"Urea, creatinine and electrolytes should be performed in patients over 60,
those with renal disease, and those taking cardiac, renal or steroid drugs"

For patients aged over 60, compliance with this guideline was 30% (table AE13.5).

Table AE 13.5. Audit of guideline: Blood Urea and Electrolytes (U&E).

<table>
<thead>
<tr>
<th>Year of birth before 1930's (q. R1)</th>
<th>Published standard</th>
<th>Observed</th>
</tr>
</thead>
<tbody>
<tr>
<td>100% U&amp;E</td>
<td>30% (46/152)</td>
<td></td>
</tr>
</tbody>
</table>

"All diabetics and patients on steroids need blood sugar estimation"

Table AE13.6 shows that blood sugar was estimated in around 60% of diabetic patients. A further 4 patients (16%) had pre-operative urinalysis but no blood sugar estimation. It is possible that some of the remaining patients kept their own records of blood sugar levels, which were not recorded in the case-notes.

Table AE 13.6. Audit of guideline: Blood sugar.

<table>
<thead>
<tr>
<th>Insulin dependent diabetes (q. AE9)</th>
<th>Published standard</th>
<th>Observed</th>
</tr>
</thead>
<tbody>
<tr>
<td>100% blood sugar</td>
<td>55% (6/11)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Non-insulin dependent diabetes (q. AE9)</th>
<th>Published standard</th>
<th>Observed</th>
</tr>
</thead>
<tbody>
<tr>
<td>100% blood sugar</td>
<td>64% (9/14)</td>
<td></td>
</tr>
</tbody>
</table>

"Haemoglobin in all women, men over 60 and those with signs of anaemia"

Compliance was 26% for women, and 44% for men over 60 (table AE13.7). Again, in some cases in which haemoglobin was not estimated, the patient was assessed pre-operatively by a consultant anaesthetist (a further 24 cases, or 14%).
Table AE 13.7. Audit of guideline: Haemoglobin.

<table>
<thead>
<tr>
<th></th>
<th>Published standard</th>
<th>Observed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female (q. R1)</td>
<td>100% haemoglobin</td>
<td>26% (29/113)</td>
</tr>
<tr>
<td>Male, Year of birth before 1930's (q. R1)</td>
<td>100% haemoglobin</td>
<td>44% (24/55)</td>
</tr>
</tbody>
</table>

Overall compliance with the 1993 Guidelines for pre-operative assessment and monitoring

Overall compliance was assessed by combining the responses to questions AE13 (Pre-operative assessment), AE 17 (intravenous canula), and AE 18-20 (monitoring) and R8 (availability of anaesthetist). Results are presented under q. AE20.

4.6.2.13.2. Was there a different pattern of pre-operative assessment for the different LA techniques?

Because of the relatively small number of Adverse Event forms received, it was not possible to make a formal comparison of the degree of per-operative assessment of different LA techniques. However, no major differences were apparent (table AE13.8).

Table AE 13.8. Compliance with guidelines for pre-operative assessment, for the different LA techniques. Small numbers of returns preclude statistical comparison.

<table>
<thead>
<tr>
<th></th>
<th>History + Examination + Blood pressure + Urianalysis</th>
<th>History + blood pressure</th>
<th>Urea &amp; electrolytes (age 60+)</th>
<th>Haemoglobin (age 60+)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peribulbar</td>
<td>9% 13/140</td>
<td>83% 116/140</td>
<td>31% 33/108</td>
<td>33% 36/108</td>
</tr>
<tr>
<td>Retrobulbar</td>
<td>25% 8/31</td>
<td>94% 29/31</td>
<td>38% 8/21</td>
<td>38% 8/21</td>
</tr>
<tr>
<td>Sub-Tenon's</td>
<td>0% 0/6</td>
<td>50% 3/6</td>
<td>25% 1/4</td>
<td>25% 1/4</td>
</tr>
<tr>
<td>Sub-conjunctival</td>
<td>0% 0/2</td>
<td>50% 1/2</td>
<td>- 0/0</td>
<td>- 0/0</td>
</tr>
<tr>
<td>Topical</td>
<td>40% 2/5</td>
<td>80% 4/5</td>
<td>33% 1/3</td>
<td>33% 1/3</td>
</tr>
</tbody>
</table>
4.6.2.14. Adverse Event question 14 (pre-medication and sedative agents)

q. AE 14. Please enter all Pre-medication or Sedative agents administered as part of the PLANNED anaesthesia procedure.

If none was given, tick the box marked "none".
You need not include eye-drops, nor changes to diabetes regimens.

[ ] None given

Name ........................................ Dose ..................................... Route .................
Name ........................................ Dose ..................................... Route .................
Name ........................................ Dose ..................................... Route .................

Data from the initial week showed that around 2.9% of cases used pre-medication, 4.8% used intravenous sedation, and 0.1% used both (pie chart R6.1). Thus, around 8% of all LA’s were accompanied by sedation.

Of the 204 completed Adverse Event forms, 23 (11%) of the patients had some sort of sedation (table AE14.1). This is somewhat higher than the overall figure of 8% for the initial week. However, chi-squared testing indicated that this difference was not statistically significant ($p = 0.38$). Examination of the detailed reports (from the follow-up forms) suggests that at least some of the adverse events could be attributed to sedation. For example, apnoea in cases SS7 and SS19 (table AE0.3, section 4.6.1.2) could possibly be attributed to the intravenous sedative used.

Table AE14.1. Use of pre-medication and intravenous (i.v.) sedation

<table>
<thead>
<tr>
<th></th>
<th>Patients who had adverse events (3 months)</th>
<th>All of first week returns</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-medication</td>
<td>7</td>
<td>81</td>
</tr>
<tr>
<td>i.v. sedation</td>
<td>15</td>
<td>135</td>
</tr>
<tr>
<td>Both</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Neither</td>
<td>171</td>
<td>2487</td>
</tr>
<tr>
<td>No response</td>
<td>10</td>
<td>120</td>
</tr>
<tr>
<td>Total</td>
<td>204</td>
<td>2827</td>
</tr>
</tbody>
</table>

Sedative agents were not described for most of the 23 cases. Intravenous agents used were midazolam (2 reports), fentanyl (2), propofol (1) and droperidol (1). Pre-medication agents were diazepam (1) and temazepam (1).
4.6.2.15. Adverse Event question 15 (type of needle or cannula used)

q. AE 15. Type of needle or cannula used to give the local anaesthetic.

[ ] Designed for ocular LA use (e.g. retrobulbar needle)
[ ] Designed for another use (e.g. intravenous needle or lachrymal cannula)

This question was included in order to get more information about LA techniques. More detail was requested in the follow-up forms, sent to respondents who reported orbital haemorrhage.

Table AE15.1 shows the responses of respondents who completed most other parts of the Adverse Event form. It indicates that 64% of reported “orbital” adverse events occurred in association with needles/cannulae designed for ocular LA, as opposed to 39% of the “systemic” adverse events. It has been stated that certain adverse events are more likely to occur with certain types of needle: for example, there is controversy as to whether an ‘intravenous’ or a ‘retrobulbar’ needle is more likely to enter the optic nerve, or penetrate the globe (see section 2.3.2.3 for discussion). Because there was such a broad range of types of reported adverse events, further analysis of the raw data would be unhelpful.

Table AE 15.1. Type of needle/cannula used to give LA. Analysis according to type of adverse event.

<table>
<thead>
<tr>
<th>Type of adverse event</th>
<th>Needle or cannula designed for ocular LA</th>
<th>Needle or cannula designed for another use</th>
<th>No response</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orbital</td>
<td>77 64%</td>
<td>36 30%</td>
<td>7 6%</td>
<td>120</td>
</tr>
<tr>
<td>Systemic</td>
<td>31 39%</td>
<td>35 45%</td>
<td>12 15%</td>
<td>78</td>
</tr>
</tbody>
</table>

Table AE15.2 shows the type of needle or cannula used to give the LA, for each of the LA techniques. Ideally, this information would have been requested, in more detail, for all LA’s given in the initial week. However, this was not done in order to keep the Report forms simple and concise. Hence, there is no information as to whether the distribution of needle/cannula type for patients who had adverse events is representative of the LA population as a whole.

It can be seen that the majority of adverse events that occurred with retrobulbar anaesthesia were associated with specially-designed needles. Further detail was
gained from the Follow-up forms that were sent to respondents who reported orbital haemorrhage (see Appendix 9 for forms, data presented in table AE15.3). These also indicated that, for patients who had retrobulbar anaesthesia, the majority of reported Orbital adverse events were occurred in conjunction with a ‘retrobulbar’ needle. Because the Survey did not record the type of needle used in uneventful cases, no conclusions can be inferred as to the safety or otherwise of these needles. The same applies for needles used in peribulbar anaesthesia (tables AE15.2, AE15.3).

Table AE15.2. Type of needle/canula used to give LA. Analysis according to LA technique used.

<table>
<thead>
<tr>
<th></th>
<th>Needle or canula designed for ocular LA</th>
<th>Needle or canula designed for another use</th>
<th>No response</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peribulbar</td>
<td>62 44%</td>
<td>68 48%</td>
<td>11 8%</td>
<td>141</td>
</tr>
<tr>
<td>Retrobulbar</td>
<td>27 90%</td>
<td>2 7%</td>
<td>1 3%</td>
<td>30</td>
</tr>
<tr>
<td>Sub-Tenon's</td>
<td>4 66%</td>
<td>0 0%</td>
<td>2 33%</td>
<td>6</td>
</tr>
<tr>
<td>Subconjunctival</td>
<td>0 0%</td>
<td>1 50%</td>
<td>1 50%</td>
<td>2</td>
</tr>
</tbody>
</table>

Table AE15.3.
Type of needle used for patients who had orbital haemorrhage. Further data from ‘Retrobulbar’ Haemorrhage Follow-up Forms.

<table>
<thead>
<tr>
<th>Peribulbar LA</th>
<th>Needle designed for ocular LA</th>
<th>Needle designed for another use</th>
</tr>
</thead>
<tbody>
<tr>
<td>“minor” bleed</td>
<td>2 ‘Peribulbar’ needle</td>
<td>8 25G intravenous</td>
</tr>
<tr>
<td></td>
<td>4 ‘Retrobulbar’ needle</td>
<td>2 23G intravenous</td>
</tr>
<tr>
<td>“major” bleed</td>
<td>0 ‘Peribulbar’ needle</td>
<td>4 25G intravenous</td>
</tr>
<tr>
<td>(causing proptosis)</td>
<td>3 ‘Retrobulbar’ needle</td>
<td>1 23G intravenous</td>
</tr>
<tr>
<td></td>
<td>1 (?G) intravenous</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Retrobulbar LA</th>
<th>Needle designed for ocular LA</th>
<th>Needle designed for another use</th>
</tr>
</thead>
<tbody>
<tr>
<td>“minor” bleed</td>
<td>2 ‘Retrobulbar’ needle</td>
<td>0</td>
</tr>
<tr>
<td>“major” bleed</td>
<td>2 ‘Retrobulbar’ needle</td>
<td>1 23G intravenous</td>
</tr>
</tbody>
</table>
4.6.2.16. Adverse Event question 16 (name & volume of LA agents given)

q. AE 16. Please state what was used for the Local Anaesthetic.
Please enter the total amounts given to the eye/orbit only, and leave out any facial nerve block.

[ ] Lignocaine ("Xylocaine") strength ....................% volume .............ml
[ ] Bupivacaine ("Marcain") strength ....................% volume .............ml
[ ] Adrenaline strength ..................... volume .............ml
[ ] Hyaluronidase ("Hyalase") ..................... units
[ ] Other agent: Name ...................... strength .................... volume .............

Tables AE16.1 and AE16.2 summarise the LA agents used by those who reported adverse events. Lignocaine was the most commonly used agent (used in 73% of all reported blocks). The most common combinations were lignocaine + bupivacaine + hyaluronidase (31% overall), and lignocaine + bupivacaine + adrenaline + hyaluronidase (14% overall). Agents used for the four main LA techniques are summarised in tables AE16.3 – AE16.6.

Table AE16.1.
Agents used for local anaesthesia. Raw data for 204 respondents who completed Adverse Event Form (all LA techniques)

<table>
<thead>
<tr>
<th>Agent</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lignocaine</td>
<td>149</td>
<td>73%</td>
</tr>
<tr>
<td>Bupivacaine</td>
<td>114</td>
<td>56%</td>
</tr>
<tr>
<td>Prilocaine</td>
<td>38</td>
<td>19%</td>
</tr>
<tr>
<td>Adrenaline</td>
<td>55</td>
<td>27%</td>
</tr>
<tr>
<td>Felypressin</td>
<td>12</td>
<td>6%</td>
</tr>
<tr>
<td>Hyaluronidase</td>
<td>144</td>
<td>71%</td>
</tr>
<tr>
<td>No response/ none of above</td>
<td>9</td>
<td>4%</td>
</tr>
</tbody>
</table>
Table AE16.2. Use of different LA mixtures.  
Pooled data from 204 respondents who completed the Adverse Event Form (All LA techniques).

<table>
<thead>
<tr>
<th>LA mixture</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lignocaine / Bupivacaine / Adrenaline / Hyaluronidase</td>
<td>28</td>
<td>14%</td>
</tr>
<tr>
<td>Lignocaine / Bupivacaine / Adrenaline</td>
<td>2</td>
<td>1%</td>
</tr>
<tr>
<td>Lignocaine / Bupivacaine / Hyaluronidase</td>
<td>61</td>
<td>31%</td>
</tr>
<tr>
<td>Lignocaine / Adrenaline / Hyaluronidase</td>
<td>17</td>
<td>9%</td>
</tr>
<tr>
<td>Lignocaine / Adrenaline</td>
<td>6</td>
<td>3%</td>
</tr>
<tr>
<td>Lignocaine / Bupivacaine</td>
<td>16</td>
<td>8%</td>
</tr>
<tr>
<td>Lignocaine / Hyaluronidase</td>
<td>10</td>
<td>5%</td>
</tr>
<tr>
<td>Lignocaine</td>
<td>8</td>
<td>4%</td>
</tr>
<tr>
<td>Bupivacaine / Adrenaline / Hyaluronidase</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Bupivacaine / Adrenaline</td>
<td>1</td>
<td>0.5%</td>
</tr>
<tr>
<td>Bupivacaine / Hyaluronidase</td>
<td>3</td>
<td>2%</td>
</tr>
<tr>
<td>Bupivacaine</td>
<td>2</td>
<td>0.5%</td>
</tr>
<tr>
<td>Prilocaine / Felypressin / Hyaluronidase</td>
<td>7</td>
<td>4%</td>
</tr>
<tr>
<td>Prilocaine / Felypressin / Lignocaine</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Prilocaine / Felypressin / Bupivacaine</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Prilocaine / Felypressin</td>
<td>5</td>
<td>3%</td>
</tr>
<tr>
<td>Prilocaine</td>
<td>10</td>
<td>5%</td>
</tr>
<tr>
<td>Prilocaine / Lignocaine</td>
<td>1</td>
<td>0.5%</td>
</tr>
<tr>
<td>Prilocaine / Bupivacaine</td>
<td>1</td>
<td>0.5%</td>
</tr>
<tr>
<td>Prilocaine / Hyaluronidase</td>
<td>14</td>
<td>7%</td>
</tr>
<tr>
<td>No response</td>
<td>10</td>
<td>5%</td>
</tr>
</tbody>
</table>

Table AE16.3.  
Peribulbar anaesthesia: frequency of use of the different LA Agents (141 reported adverse events).

<table>
<thead>
<tr>
<th>LA Agent</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lignocaine</td>
<td>98</td>
<td>70%</td>
</tr>
<tr>
<td>Bupivacaine</td>
<td>80</td>
<td>57%</td>
</tr>
<tr>
<td>Prilocaine</td>
<td>32</td>
<td>23%</td>
</tr>
<tr>
<td>Adrenaline</td>
<td>36</td>
<td>26%</td>
</tr>
<tr>
<td>Felypressin</td>
<td>8</td>
<td>6%</td>
</tr>
<tr>
<td>Hyaluronidase</td>
<td>101</td>
<td>72%</td>
</tr>
<tr>
<td>No response/ none of above</td>
<td>4</td>
<td>3%</td>
</tr>
</tbody>
</table>

Table AE16.4.  
Retrobulbar anaesthesia: frequency of use of the different LA Agents. (30 reported adverse events).

<table>
<thead>
<tr>
<th>LA Agent</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lignocaine</td>
<td>23</td>
<td>77%</td>
</tr>
<tr>
<td>Bupivacaine</td>
<td>14</td>
<td>47%</td>
</tr>
<tr>
<td>Prilocaine</td>
<td>6</td>
<td>20%</td>
</tr>
<tr>
<td>Adrenaline</td>
<td>7</td>
<td>23%</td>
</tr>
<tr>
<td>Felypressin</td>
<td>4</td>
<td>13%</td>
</tr>
<tr>
<td>Hyaluronidase</td>
<td>23</td>
<td>77%</td>
</tr>
<tr>
<td>No response/ none of above</td>
<td>0</td>
<td>0%</td>
</tr>
</tbody>
</table>
Table AE16.5.
Sub-Tenon’s anaesthesia: frequency of use of the different LA Agents. (6 reported adverse events).

<table>
<thead>
<tr>
<th>LA Agent</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lignocaine</td>
<td>5</td>
</tr>
<tr>
<td>Bupivacaine</td>
<td>5</td>
</tr>
<tr>
<td>Prilocaine</td>
<td>0</td>
</tr>
<tr>
<td>Adrenaline</td>
<td>0</td>
</tr>
<tr>
<td>Felypressin</td>
<td>0</td>
</tr>
<tr>
<td>Hyaluronidase</td>
<td>3</td>
</tr>
<tr>
<td>No response/ none of above</td>
<td>1</td>
</tr>
</tbody>
</table>

Table AE16.6.
Sub-conjunctival anaesthesia: frequency of use of the different LA Agents. (2 reported adverse events).

<table>
<thead>
<tr>
<th>LA Agent</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lignocaine</td>
<td>2</td>
</tr>
<tr>
<td>Bupivacaine</td>
<td>0</td>
</tr>
<tr>
<td>Prilocaine</td>
<td>0</td>
</tr>
<tr>
<td>Adrenaline</td>
<td>2</td>
</tr>
<tr>
<td>Felypressin</td>
<td>0</td>
</tr>
<tr>
<td>Hyaluronidase</td>
<td>0</td>
</tr>
<tr>
<td>No response/ none of above</td>
<td>0</td>
</tr>
</tbody>
</table>

The volume of LA injected is summarised in bar graphs AE16.7 and AE16.8.
The mean volume given for peribulbar anaesthesia was 8.0 ml (standard deviation 2.5, range 1-16 ml), and for retrobulbar anaesthesia it was 5.3 ml (standard deviation 2.2, range 2-10ml). There were insufficient reports of the other techniques for statistical analysis. For sub-Tenon’s anaesthesia, reported volumes given were 3, 4, 6, 10, and 13ml (mean, 7.2 ml). Sub-conjunctival anaesthesia volumes were 0.5 and 3ml.

The volume of LA given varied between 1ml and 16 ml for injection methods.
The literature contains innumerable variations on the basic retrobulbar and peribulbar techniques, and it is easy to find descriptions of small-volume peribulbar (Agrawal and Athanikar 1994; Athanikar and Agrawal 1991; Hamilton et al 1988) and retrobulbar(Atkinson 1936; Hamilton et al 1988; Simonson 1992) techniques, and descriptions of large-volume techniques(Davis and Mandel 1986; Hamilton et al 1988; Meyer et al 1992). Most descriptions of the sub-Tenon technique use a lower volume of injectate, typically between 1.5 and 5 ml (Fukasaku and Marron 1994a; Greenbaum 1992; Greenbaum 1997;
Stevens 1992), though volumes up to 11ml (Li et al 2000) have been described. Subconjunctival anaesthesia is by necessity a small-volume technique, unless the injectate is also placed in another anatomical space.

Bar Graph AE16.7. Volume of LA injected: Peribulbar anaesthesia

4.6.2.17. Adverse Event question 17 (timing of siting an intravenous cannula)

q. AE 17. Was an intravenous cannula sited?

[ ] No  [ ] Yes, before the LA was given
[ ] Yes, after the LA was given
[ ] Yes, in order to manage a complication

This question was asked in order to audit the 1993 Guidelines on LA safety (Anon. 1993). It is a supplementary question to q.4 on the local anaesthetic report form (section 4.5.4). This showed that, in the initial week, 60.3% of all reported LA patients had an intravenous (i.v.) cannula sited.
The Guidelines state that "intravenous access should always be obtained, so that
drugs including those for resuscitation, sedation or the rapid lowering of
intraocular pressure can be given without delay" (Anon. 1993). There is no
explicit requirement to site a cannula before giving the LA. Of patients who
were reported to have a complication, 62% had an i.v. cannula sited before the
LA was given, and a further 6% had the i.v. cannula sited after the LA. Among
these complicated cases, a further 14 (7%) had an i.v. cannula sited in order to
manage a complication.

The literature indicates that life-threatening complications, such as brain-stem
depression, can occur shortly after the LA is given (see section 2.3.2.6 for
discussion). In the present Survey, several "severe systemic" adverse events
were reported to occur within 3 minutes of the LA (see table AE0.3, section
4.6.1.2). Thus, it would appear prudent to site an i.v. cannula prior to giving an
LA injection.

Pie Graph AE17.1. Use of intravenous canula
(204 reported adverse events)

<table>
<thead>
<tr>
<th>Description</th>
<th>Count</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>No i.v. canula</td>
<td>49</td>
<td>24%</td>
</tr>
<tr>
<td>Canula, before LA</td>
<td>126</td>
<td>62%</td>
</tr>
<tr>
<td>Canula, after LA</td>
<td>12</td>
<td>6%</td>
</tr>
<tr>
<td>For a complication</td>
<td>14</td>
<td>7%</td>
</tr>
<tr>
<td>No response</td>
<td>3</td>
<td>1%</td>
</tr>
</tbody>
</table>
4.6.2.18-20. Adverse Event questions 18-20 (timing of monitoring)

q. AE 18. Was pulse oximetry monitored during the operation?
[ ] No [ ] Yes, starting before the LA was given
[ ] Yes, starting after the LA was given
[ ] Yes, in order to manage a complication

q. AE 19. Was blood pressure monitored during the operation?
[ ] No [ ] Yes, starting before the LA was given
[ ] Yes, starting after the LA was given
[ ] Yes, in order to manage a complication

q. AE 20. Was electrocardiography monitored during the operation?
[ ] No [ ] Yes, starting before the LA was given
[ ] Yes, starting after the LA was given
[ ] Yes, in order to manage a complication

The reasoning behind questions AE 17-20 was the same: to assess safety and monitoring for LA cases, and to audit compliance with the 1993 Guidelines (Anon. 1993). Systemic adverse events can have rapid onset, soon after the LA is given. Therefore, it is wise to start monitoring before the LA is given. The Guidelines are not explicit as to when monitoring should commence, but state that "careful monitoring is essential... Monitoring should, in addition to verbal contact, include pulse oximetry, ECG and blood pressure measurement."

Raw data from the 204 respondents who completed Adverse Event Forms appear as pie graphs AE18, AE19, and AE20. These charts show a similar picture to that gained for all patients in the initial week, in which 93% had pulse oximetry, 41% blood pressure, and 55% ECG monitoring (see section R5). Of those cases in which monitoring was done, monitoring only commenced after the LA was given in over one quarter of cases. Analysis by LA technique was discussed in section 4.5.5.
Pie Graph AE 18.1. Monitoring with pulse oximetry. (Pooled responses from 204 respondents).

- No: 5 (2%)
- Yes, before LA: 138 (67%)
- Yes, after LA: 45 (22%)
- For a complication: 6 (3%)
- No response: 10 (5%)

Pie Graph AE19.1. Monitoring of blood pressure. (Pooled results for 204 adverse events).

- No: 91 (45%)
- Yes, before LA: 60 (30%)
- Yes, after LA: 28 (14%)
- For a complication: 13 (6%)
- No response: 12 (6%)

174
4.6.2.20.1. Overall compliance with the 1993 guidelines for pre-operative testing, per-operative monitoring and intravenous access

The 1993 Guidelines set out nine criteria for safe LA, ranging from pre-operative assessment to per-operative monitoring, intravenous access and the availability of an anaesthetist (See legend for Table AE20.2). Only a small percentage (3%) of cases fulfilled all nine criteria (table AE20.2). This does not mean that all of the other 97% of cases were necessarily “unsafe”. For example, in many of the cases for which urinalysis was not performed, blood tests were done. Some anaesthetists who cover LA lists prefer not to site an i.v. cannula for every case, but would be present and able quickly establish i.v. access in an emergency.

Table AE 20.2
Overall compliance with the 1993 Guidelines, for each LA technique. The guidelines state that all patients should have (i) medical history, (ii) general examination, (iii) pre-operative blood pressure, (iv) urinalysis, (v) intravenous access, (vi) pulse oximetry, (vii) blood pressure monitoring, (viii) electrocardiographic monitoring, (ix) an
4.6.2.21. Adverse Event question 21 (request for follow-up)

*This final section is optional.*
*All data will be treated in the strictest confidence.*

q. AE 21. We may wish to contact you in a few months time, in order to request follow-up details on this patient. If you are happy for us to do this, please enter the following information:

- **Patient identification number:** ............................................................
- **Name of Ophthalmologist to be contacted:** ......................................
- **Contact address for Ophthalmologist:** .............................................
  .................................................................................................

It was necessary to get follow-up information on patients who had adverse events in order to assess any long-term effects. This was of particular interest for those patients who had “severe systemic” adverse events (defined in section 4.6.1.2). Ideally, the Survey would have followed up every patient who had an LA, but this was simply not practicable. To encourage full and frank reporting of adverse events, it was important to assure complete anonymity for those who wanted it. As a compromise, this voluntary follow-up section was included in the Adverse Event form.

Of the 204 adequately completed Adverse Event forms, 130 respondents (63%) entered a contact address for follow-up (pie chart AE21.1).
Follow-up forms were mailed to those who reported "systemic" adverse events or orbital haemorrhage. The forms are reproduced as Appendices 9 and 10. Responses will not be presented exhaustively, but are included in the relevant sections of the foregoing discussion.

4.7. What is the incidence of Adverse Events?
There was a low incidence of reported adverse events. In the initial week, when all LA's were to be reported regardless of whether or not an adverse event took place, the incidence of "orbital" adverse events was 2.7%, and incidence of "systemic" adverse events was 0.9%. In subsequent weeks, only adverse events were to be reported, so a degree of under-reporting was virtually inevitable. This under-reporting bias was particularly apparent for the more minor adverse events, and has already been discussed in section 4.6.1.1.

A total of 76 'Orbital' adverse events were reported in the first week, and are summarised in Table R12.2 (section 4.5.12). This gives an overall reported incidence of 76/2827 or 2.7% for 'Orbital' adverse events.
There were 92 reports of ‘Systemic’ adverse events during the three-month Survey, 26 of which took place in the initial week. These events are summarised in Tables AE0.3, AE3.1-3.3 (sections 4.6.1.2 and 4.6.2.3). Reported incidence of Systemic Adverse Events in the first week was 26/2827, or 0.9%.

‘Orbital’ adverse events are summarised in Tables R12.2, (section 4.5.12), and table AE0.5 (section 4.6.1.3). As would be expected from the Survey design, most reports of ‘minor’ adverse events were from the first week.

The reported incidence of globe perforation with retrobulbar anaesthesia was 1:11,000, or 0.9 per 10,000 (95% Confidence Intervals: 0.1-6.6 per 10,000). With peribulbar injections the incidence was 6:42,700, or 1.4 per 10,000 (95% CI: 0.6-3.3 per 10,000) and with combined retro+peribulbar it was 1:830 or 12.0 per 10,000 (95% CI: 1.6-89.4 per 10,000). (section 4.6.1.3)

‘Retrobulbar’ (periocular) haemorrhage was defined as ‘severe’ if there was associated proptosis. Calculated incidence of reported ‘severe’ retrobulbar haemorrhage (RBH) after retrobulbar injection was 8:11,000 or 7.3 per 10,000 (95% CI: 3.5 to 15.2 per 10,000), and after peribulbar injection the incidence was 18:42,700 or 4.2 per 10,000 (95% CI: 2.5-7.2 per 10,000). Less severe RBH was reported to occur about ten times as frequently (data from the first week, Table 12.2, section 4.5.12).

‘Severe Systemic Adverse Events’ were reported 3 times in the first week, and 19 times in the remainder of the three-month period. This second figure does fall within the range of uncertainty of prediction, based on the first-week returns. Incidence of reported ‘Severe Systemic Adverse Events’ in the three-month period was 22/65,100, or 3.4 per 10,000 (95% CI: 2.1-5.5 per 10,000).

It is likely that the actual incidence of adverse events was higher than estimated in this paper. In calculating the number of LA’s actually given during the
Survey, we made a correction for the 72.8% participation rate in the initial week. In calculating the incidence of Adverse Events, we assumed that all such events had been reported (i.e. 100% participation for adverse events). Table AE3.3 (section 4.6.2.3) summarises the 23 less severe Systemic Adverse Events were reported in the first week: if incidence and reporting had continued at the same rate, we would have expected a further 362 reports for the remainder of the Survey: the actual figure was 47, about one-eighth of that predicted. It is likely that there was also some under-reporting of the more serious adverse events.

Causes of low-response bias could include: lack of awareness of the Survey, failure to recognise that the event had taken place or was eligible, not considering an adverse event to be severe enough for inclusion, forgetting that the Survey was still running, unwillingness to spend time completing an Adverse Event Form, concern that the report may engender further time-consuming correspondence, embarrassment if safety Guidelines had not been followed, overwork, apathy, suspicion of an underlying motive for the Survey, and fear of being 'policed' by the Royal Colleges. We tried to minimise non-response bias from these causes by offering complete anonymity to respondents, and providing simple forms with a reminder poster which carried the eligibility criteria. During the first week of the Survey, when all LA’s were to be reported, there were 3 reports of Severe Systemic Adverse Events, as defined in Box AE0.4. Multiplying this by the workload factor of 16.76 (see Validation, section 3.4.3), this would predict around 50 reports in the three months, or 70 if we assume that the overall participation rate of 72.8% also applied. The actual number of Severe Systemic Adverse Events reported in the three-month period was 22, which does fall within the wide range of uncertainty of prediction based on the first-week’s returns. Thus it appears that there is probably less under-reporting for the more severe adverse events. From the incidents reported, we calculate that the number of life-threatening adverse events occurring annually in the United Kingdom is at least 100. Depending on the degree of under-reporting, the true figure may be in the order of a few hundred.
The novel design of the Survey makes it difficult to compare incidence of adverse events with other studies. Large case-series are often produced in centres with a special interest in LA safety, and as such their results may be better than average. As discussed above, we expect that the Survey suffered from a degree of under-reporting of serious adverse events. There is also the problem that severity of adverse events is not well defined in all studies. In this Survey, the 22 cases which fulfilled our strict criteria as of Severe Systemic Adverse Events gave a calculated incidence of 0.034% (95% confidence intervals: 0.021-0.055%), though the true figure is likely to be higher due to presumed bias from under-reporting. A study of 6000 consecutive retrobulbar blocks (Nicoll et al 1987) found ‘life-threatening’ complications in 0.13% of patients when given ‘appropriate premedication’ and a 2% lignocaine/0.5% bupivacaine/hyaluronidase mixture. Most of these patients exhibited the classical features of ‘brain stem anaesthesia’: respiratory depression, hypotension and bradycardia. Another non-randomised series of 3123 retrobulbar blocks (Wittpenn et al 1986) found the incidence of respiratory arrest to be 0.79% when using 4% lignocaine, and 0.09% when using 2% lignocaine, in patients who were also given oral or intravenous sedation. Hamilton’s personal series describes using a 2% lignocaine/0.75% bupivacaine/hyaluronidase/adrenaline mixture; less than 5% of patients were sedated. Brain stem anaesthesia was recorded in 0.15% of 5235 retrobulbar blocks and 0% of 5974 peribulbar blocks. (Hamilton et al 1988) Davis and Mandel’s multi-centre, prospective study of 16,224 consecutive peribulbar blocks, many of which were supplemented by sedation, identified one epileptic fit (0.006%) and no cases of cardiac or respiratory depression. (Davis and Mandel 1994) A series of 3000 subtenon’s blocks with 2% lignocaine found no systemic or orbital complications. (Fukasaku and Marron 1994b) In the present Survey, the incidence of adverse events was of similar order to these published figures, but the limitations of the Survey design preclude any critical comparison.
4.8. Is LA safe, and are some techniques safer than others?

An observational study of this type cannot answer the question of which LA technique is safest: this would require a prospective randomised trial so large that it could probably never be performed. However, it is interesting to compare the incidence of ‘Severe’ adverse events with the different LA techniques used in the Survey (Table AE3.4, section 4.6.2.3). Serious adverse events were seen with all LA techniques, though not all of these fulfilled the strict criteria for classification as ‘Severe’. The Survey did not show any LA technique to be obviously more or less safe than any other. However, it does give some evidence that the ‘newer’ techniques of topical, intracameral, sub-Tenon’s and sub-conjunctival anaesthesia are associated with fewer serious complications. As expected, there were no reports of severe orbital haemorrhage or globe perforation with these techniques. While there were reports of “severe” systemic adverse events (table AE0.3, section 4.6.1.2), the events associated with the ‘newer’ LA techniques could more easily be explained as side-effects of miotics, sedatives, or even the stress of having surgery.

Despite the large size of the Survey, there were not enough reports of serious adverse events to allow a comparison of safety of the different LA techniques. For the Survey to have sufficient power to allow such a comparison, we would have needed a data collection period of at least a year. There were several reasons why we felt that this would not be appropriate, the main ones being that a longer period of data collection could adversely affect participation (see bar chart AE0.1, section 4.6.1.1), and that there is a wide range of LA injection techniques, some of which may be described as ‘retrobulbar’ by one clinician and ‘peribulbar’ by another. As discussed above, the observational design of the Survey does not permit direct comparisons to be made.

An analysis was performed, to look at the features of the group who had “severe systemic” adverse events. The majority of these cases had peribulbar anaesthesia (table AE0.3, section 4.6.2.1), as did the majority of all LA cases (table R3.1, section 4.5.3). Because of the design of the Survey, there was no
data on the ASA grade, exact LA mixture or timing of intravenous access in the 'control' group who had uncomplicated LA. We therefore chose as our comparison group those patients who had 'Minor Orbital Adverse Events' (comprising 67 patients with inadequate anaesthesia or analgesia, or 'minor' periocular haemorrhage). As most (15) of the reported Severe Systemic Adverse Events occurred after peribulbar anaesthesia, we made a separate analysis for this LA technique (see table 4.8.1, below). Mann-Whitney, Chi-squared and Fisher's Exact test were used as appropriate. No significant differences were found between the two adverse event groups, with the single exception of lignocaine use. Lignocaine was used more commonly in the Minor Orbital Adverse Events group ($p = 0.02$; Chi-squared test).

**Table 4.8.1. Features of the patients who had 'Severe Systemic Adverse Events' associated with local anaesthesia.** The comparison group comprises patients who had 'Minor Orbital' Adverse Events. Most adverse events were reported to occur in patients who were given peribulbar anaesthesia (the most common LA technique). We have therefore made comparisons are made for the groups as a whole, and also for the subgroups of patients who had peribulbar anaesthesia. Criteria for definition of an adverse event as 'Severe' are summarised in Box AEO.4.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>All LA techniques</th>
<th>Peribulbar LA only</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>'Severe Systemic Adverse Events' group (all 22 patients)</td>
<td>'Minor' Orbital Adverse Events group (all 67 patients)</td>
</tr>
<tr>
<td>Gender (Male:Female)</td>
<td>12:10</td>
<td>27:38 (2 not stated)</td>
</tr>
<tr>
<td>Age: Born 1900's</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Born 1910's</td>
<td>8</td>
<td>21</td>
</tr>
<tr>
<td>Born 1920's</td>
<td>8</td>
<td>22</td>
</tr>
<tr>
<td>Born 1930's</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td>Born 1940's</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>Born 1950's</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Born 1960's</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>
Tests of significance used: Mann-Whitney, Chi-squared, and Fisher's exact test, as appropriate. ns = not significant; p values given for significant differences. *Lignocaine was used significantly less frequently in the group who had 'Severe Systemic Adverse Events' when compared with the group who had the 'Minor Orbital Adverse Events' of inadequate block or minor periocular haemorrhage.

In Table 4.8.1, an attempt was made to find any common features in the group of patients who had Severe Systemic Adverse Events, by comparing them with a group who had minor complications within the orbit. The proportion of patients with intravenous access or a dedicated anaesthetist was similar in both groups, implying that the Severe events had not been predicted in individual cases. Patient age, ASA grade, and use of sedation was similar in the two groups. The only significant difference was in the use of lignocaine: when the components of the LA mixture were compared separately, lignocaine was used significantly less in the group who had Severe Systemic Adverse Events. Numbers were too small...
to make a useful multivariate analysis for the overall LA mixture. The lower prevalence of lignocaine use in the Severe Systemic Adverse Events group may reflect a higher incidence of Minor Orbital events with lignocaine, a higher incidence of Systemic events with the other LA agents, or a random effect. Because this was not a prospective randomised study, Table 4.8.1 should not be considered as a direct comparison of safety. Thus, it cannot be used to argue for the safety or otherwise of any particular LA agent or of sedation.

There were no reports of death in the operating theatre for the three-month Survey, though one patient suffered hypertension and tachycardia prior to his LA injection, and his death due to a myocardial infarction the following day was attributed to the stress of having LA (patient SS11 in table AE0.3, section 4.6.1.2). The initial questionnaire to consultant ophthalmologists identified 10 cases of patient death attributed to LA, which is equivalent to one LA-associated death per twenty 25-year consultant careers (section 4.5.15). A questionnaire to UK ophthalmologists, published in 1994, identified 12 cases of LA-associated death,(Haider 1994) all but one of which occurred ‘on the operating table’ (Haider SA, pers. comm.). In view of the severity of some of the adverse events reported during our Survey, it is possible that timely intervention by anaesthetists prevented a number of deaths during the three-month period.

Serious ‘Systemic’ adverse events were reported in association with all LA techniques. Many of the events summarised in Table AE0.3 could be explained by the ‘classical’ routes of intraneural injection or systemic absorption of LA agents. Other events could be attributed to stress reaction, oculocardiac reflex, systemic effects of topical mydriatics, ocular hypotensive agents or sedatives, or causes unrelated to the LA or surgery. However these events were caused, the fact that they were seen with all LA techniques implies that theatre staff should be prepared for serious adverse events in all patients who have intraocular surgery.
4.9. Should the 1993 Safety Guidelines be revised?

Guidelines should be evidence-based. Criteria for drawing up guidelines have been developed, including explicit grading of the quality of the evidence used (Grilli et al 2000; Miller and Petrie 2000). When the 1993 Guidelines were drawn up, there was a dearth of good-quality data in the literature regarding LA safety. The present study adds to the pool of available evidence, as it documents the incidence and type of adverse events associated with LA in the “real world”. The two papers published as a result of this study (Eke and Thompson 1999a; Eke and Thompson 1999b) conclude that at least 100 “life-threatening” adverse events occur annually in the UK, in association with LA for intraocular surgery. As discussed in the preceding section and in section 2, it appears that the “newer” non-injection techniques are associated with significantly fewer “severe” complications.

The 2001 edition of the joint Royal Colleges’ safety guidelines has recently been published (Anon 2001). These guidelines have made good use of the increasing evidence base in the literature, including the peer-reviewed publications that have arisen from the present Survey (Eke and Thompson 1999a; Eke and Thompson 1999b). The specialty of local anaesthesia for intraocular surgery is developing rapidly, as exemplified by the recent change is use of the various LA techniques (see section 2.3 and 4.5.3). The success of the British Ophthalmic Anaesthesia Society, founded in 1998, reflects the interest in this field. The present Survey has contributed to the knowledge base, but there are still many uncertainties regarding safety of LA for intraocular surgery. Given these uncertainties, and the rapid expansion of published literature, the Colleges have sensibly planned to review the Guidelines in 2003.
Acknowledgements

I am extremely grateful to Professor John R Thompson of the University of Leicester, who was my supervisor for the project and co-author of the papers. Prof Thompson assisted with the design of the Survey, and data interpretation, and has been an excellent co-author.

The Survey would not have been a success were it not for the willing cooperation of ophthalmologists, anaesthetists and operating theatre staff in NHS hospitals throughout the United Kingdom. I would specifically like to acknowledge the assistance of Prof Tom Healey, Mr James McGill, Mr Tony Moore, Prof Ralph Rosenthal, Dr Tony Rubin, Ms Helen Seward, Mr John Sparrow, Mr Andrew Tullo, Dr Chris Wainwright, and all members of the Quality of Practice Committee of the Royal College of Anaesthetists, and the Clinical Audit Subcommittee of the Royal College of Ophthalmologists. Margaret Hallendorff and the staff of the Audit Unit at the Royal College of Ophthalmologists provided much practical support, as have the staff of the Department of Ophthalmology at the University of Leicester.

This project was funded by a grant to Core Audit Funds at the Royal College of Ophthalmologists, provided by the Department of Health.
Appendix 1:

Questionnaire sent to consultant ophthalmologists

See Methods section 3.3.7 and Results section 4.1.
Initial Survey of Local Anaesthetic Practice
for
All UK Consultant Ophthalmologists

This survey is completely anonymous.
All questions on this form refer to NHS practice only.

1. In total, how many “intraocular” operations are performed by your surgical firm in an average week? This means cataract, trabeculectomy, retinal reattachment, corneal grafting and related surgery, but not lasers, squints or lid work.

   About ................ operations per week

2. Of these operations, what is the usual frequency of the different types of anaesthesia?
   (Percentages should add up to 100%)

   % General  % Local alone  % Local + sedation

3. Type(s) of hospital where your firm performs intraocular surgery

   [ ] Teaching Hospital (General)  [ ] Teaching Hospital (Eye Specialist)
   [ ] District Hospital (General)  [ ] District Hospital (Eye Specialist)
   [ ] Cottage Hospital  [ ] Other: please specify ....................................................

The following questions refer to your firm’s LOCAL ANAESTHETIC practice.

4. How are patients routinely monitored?

   [ ] Blood pressure  [ ] Electrocardiography  [ ] Pulse oximetry  [ ] None of these

5. Is an intravenous cannula routinely sited?

   [ ] Yes  [ ] No

6. For what proportion of your LOCAL anaesthetic intraocular operations is there an anaesthetist in the theatre? (Present in case there is a problem with a local anaesthetic, not necessarily to give the LA itself.)

   % of these LA operations

7. Does your firm ever do intraocular surgery when there is no anaesthetist in the hospital?

   [ ] Yes  [ ] No

8. Does your firm ever do intraocular surgery when there is no anaesthetist and no cardiac arrest team in the hospital?
9. If you answered "Yes" to questions 7 or 8, in what type of hospital does this happen?

[ ] Teaching Hospital (General)  [ ] Teaching Hospital (Eye Specialist)
[ ] District Hospital (General)  [ ] District Hospital (Eye Specialist)
[ ] Cottage Hospital  [ ] Other: please specify ......................................................

The following questions refer to your personal opinions and preferences.

10. All other factors being equal, do you prefer your patients to have cataract surgery under Local or General anaesthesia?

[ ] General  [ ] Local alone  [ ] Local with sedation

11. In your opinion, who should give the local anaesthetic for intraocular surgery?

[ ] Ophthalmologists  [ ] Anaesthetists  [ ] Either

12a. Please describe your most favoured method of giving LA for cataract surgery:

[ ] retrobulbar  [ ] peribulbar  [ ] subtenon  [ ] subconjunctival
[ ] topical  [ ] other local (please specify) ..................................................

12b. Is a facial nerve block given?

[ ] Yes  [ ] No

13. What is your personal opinion regarding the need for an anaesthetist to cover intraocular surgery under local anaesthetic? (tick the opinion nearest your own)

[ ] Anaesthetist should be present, with no other responsibility than the current list
[ ] Anaesthetist should be available in the theatre complex in case of problems, but could also be attending to another list
[ ] Anaesthetist need not be in theatres, but should be available in an emergency
[ ] No need for anaesthetist involvement at all, provided there is a cardiac arrest team
[ ] No need for anaesthetist, even if there is no cardiac arrest team

Some final questions on your personal experience

14. How long have you been a consultant ophthalmologist? ............... Years

15. Since you became a consultant, have any of your patients ever died as a result of local anaesthesia for intraocular surgery?

[ ] No  [ ] Yes, ...............(number) of my patients have died

Thank you for taking the time to fill out this questionnaire. Please return it to the College in the enclosed prepaid envelope.

If you have any problems or questions, please contact the principal investigator for this project:
Mr Tom Eke FRCOphth, Audit Fellow, The Royal College of Ophthalmologists, 17 Cornwall Terrace, London NW1 4QW
Tel: 0116 2586171 (Office) or 0171 935 0702 (Audit Help Desk)
Appendix 2:

Questionnaire sent to consultant anaesthetists

See Methods section 3.3.8 and Results section 4.2.
Please complete this anonymous questionnaire, and return it in the enclosed envelope.

This questionnaire refers to the provision of anaesthetists for INTRAOCULAR surgery (i.e. cataract and similar operations), operating under LOCAL anaesthetic (LA). All questions on this form refer to NHS practice only.

1. Type(s) of hospital where your anaesthetists work

- [ ] Teaching Hospital (General)
- [ ] Teaching Hospital (Eye Specialist)
- [ ] District Hospital (General)
- [ ] District Hospital (Eye Specialist)
- [ ] Cottage Hospital
- [ ] Other: please specify ..............................................

2. For what proportion of your unit’s LOCAL anaesthetic INTRAOCULAR operations is there an anaesthetist in the theatre? (Present in the operating theatre or an adjacent theatre, in case there is a problem with a local anaesthetic, but not necessarily to give the LA itself.)

About ....................% of these LA operations

2a. If this figure is not 100%, why is this? Tick as many boxes as apply

- [ ] Staffing problems
- [ ] Policy of Anaesthetic Dept.
- [ ] Policy of Ophthalmologists
- [ ] Policy of Hospital Managers
- [ ] Other reason: please specify ..............................................

3. Does your hospital have a policy regarding provision of anaesthetists to cover intraocular surgery done using LA?

- [ ] Yes If “Yes”, please state policy or append a copy, if possible
- [ ] No
- [ ] Don’t Know
4. Does your department have a policy or programme for training anaesthetists to cover LA eye lists?

- [] Yes  If “Yes”, please state policy or append a copy, if possible
- [] No
- [] Don’t Know

5. In your unit, is there an anaesthetist(s) with a special interest or responsibility for LA eye lists?

- [] Yes
- [] No
- [] Don’t Know

6. In your personal opinion, who should give the local anaesthetic for intraocular surgery?

- [] Ophthalmologists
- [] Anaesthetists
- [] Either

7. What is your personal opinion regarding the need for an anaesthetist to cover intraocular surgery under local anaesthetic? (tick the opinion nearest your own)

- [] Anaesthetist should be present, with no other responsibility than the current list
- [] Anaesthetist should be available in the theatre complex in case of problems, but could also be attending to another list
- [] Anaesthetist need not be in theatres, but should be available in an emergency
- [] No need for anaesthetist involvement at all, provided there is a cardiac arrest team
- [] No need for anaesthetist, even if there is no cardiac arrest team

8. All other factors being equal, do you prefer patients to have cataract surgery under Local or General anaesthesia?

- [] General
- [] Local alone
- [] Local with sedation

Thank you for taking the time to fill out this questionnaire. Please return it to the Royal College of Ophthalmologists in the enclosed prepaid envelope.

If you have any problems or questions, please contact the principal investigator for this project:
Mr Tom Eke FRCOphth, Audit Fellow, The Royal College of Ophthalmologists, 17 Cornwall Terrace, London NW1 4QW
Tel: 0116 2586171 (Office) or 0171 935 0702 (Audit Help Desk)
Appendix 3:

Questionnaire sent to nurse in charge of eye theatres

See Methods section 3.3.9 and Results section 4.3.
LIST OF NAMES OF ALL OPERATING THEATRES WHERE EYE SURGERY IS DONE

Please give a contact address for EVERY individual operating theatre in your unit where Eye surgery takes place. Don't forget to include each separate theatre in Eye theatres, General theatres, etc. (For example: Eye Theatre 1, Eye Theatre 2, General Theatre 7.) If surgeons from your unit go to another hospital to operate (e.g. a Cottage Hospital), please also give the address for the theatres there.

Please return the completed form to Mr Eke, using the enclosed self-addressed envelope. Thank you.

<table>
<thead>
<tr>
<th>Theatre name</th>
<th>Hospital Name</th>
<th>Hospital Address</th>
<th>Contact Person (e.g. Sister)</th>
<th>Approximate number of Eye lists done per week in this theatre</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If you need more space, please continue on the back of this form.

Mr. Tom Eke, Audit Fellow, Royal College of Ophthalmologists, 17 Cornwall Terrace, London NW1 4QW
Appendix 4:

Contents of the Survey Pack

See Methods section 3.3.10.

The poster, instruction card, Local Anaesthetic Report Form and Adverse Event Report Forms are reproduced as Appendices 5-8.
National Survey of Local Anaesthesia for Ocular Surgery

1996

All district nurses in the UK have been invited to participate in this survey to
provide valuable information on local anaesthesia for eye surgery.

The forms are designed to be easily completed by any member of the
team involved in the care of the patient.

When to Complete the Forms
September 1st - November 30th 1996.

Definitive information to be included in the submission.

The Survey Pack contains all the forms and envelopes you will need for the Survey.
Appendix 5:

Poster from the survey pack

See Methods section 3.3.10.
Actual poster was A3 size, printed in colour (see Appendix 4).
All eye theatres in the UK have been invited to participate in this survey to investigate safety aspects of local anaesthetics administered for eye surgery.

The forms are designed to be easily completed by any member of theatre staff at the time of surgery.

When to Complete the Forms

**September 1st - 7th:** Please complete a **yellow** 'Local Anaesthetic/Surgery Report Form' for every case in which a local anaesthetic is given for intraocular surgery. If there is an adverse event please also fill in a **pink** 'Adverse Event Form'.

**September 8th - November 30th:** Complete the forms **only** if an adverse event occurs. Please complete a **yellow** 'Local Anaesthetic/Surgery Report Form' and a **pink** 'Adverse Event Form'.

**Criteria for inclusion in the Survey:**

1. Planned intraocular surgery for:
   - Cataract
   - Retinal Detachment
   - Glaucoma
   - Corneal Grafting
   - Other Intraocular Operations
   - Complications of these Operations

2. NHS patients

3. Operations during the Survey period (see 'When to Complete the Forms' above)

   **NB.** Patients who are given a local anaesthetic but **do not** have their operations that day (eg because of a complication of the LA) should also be included.

**Definition of an Adverse Event:**

Something which made you monitor the patient more closely, or take action.

An adverse event could be systemic (eg respiratory depression), or confined to the orbit (eg retrobulbar haemorrhage).

The Survey Pack contains all the forms and envelopes you will need for the Survey.

*Thank you for your help*
Appendix 6:

Instruction card from the front of the Survey pack

See Methods section 3.3.10, and illustration of the Pack on Appendix 4
In the actual Pack, this card was laminated.
All eye theatres in the UK have been invited to participate in this survey to investigate safety aspects of local anaesthetics administered for eye surgery.

The forms are designed to be easily completed by any member of theatre staff at the time of surgery.

---

**When to Complete the Forms**

**September 1st - 7th:** Please complete a **yellow** 'Local Anaesthetic/Surgery Report Form' for **every** case in which a local anaesthetic is given for intraocular surgery. If there is an adverse event please also fill in a **pink** 'Adverse Event Form'.

**September 8th - November 30th:** Complete the forms **only** if an adverse event occurs. Please complete a **yellow** 'Local Anaesthetic/Surgery Report Form' and a **pink** 'Adverse Event Form.'

---

**Criteria for inclusion in the Survey:**

1. Planned intraocular surgery for:
   - Cataract
   - Retinal Detachment
   - Glaucoma
   - Corneal Grafting
   - Other Intraocular Operations
   - Complications of these Operations

2. NHS patients

3. Operations during the Survey period (see 'When to Complete the Forms' above)

   Nb. Patients who are given a local anaesthetic but do not have their operations that day (eg because of a complication of the LA) should also be included.

---

**Definition of an Adverse Event:**

Something which made you monitor the patient more closely, or take action.

An adverse event could be systemic (eg respiratory depression), or confined to the orbit (eg retrobulbar haemorrhage).

---

This pack contains all the forms and envelopes you will need for the Survey.
Appendix 7:

Local anaesthetic report form

See Methods section 3.3.11, and results section 4.5.
Local Anaesthetic/Surgery Report Form

**When to complete this form**

**September 1st - 7th:** Please complete this form for every case in which a local anaesthetic is given for intraocular surgery. If there is an adverse event please also fill in a pink form.

**September 8th - November 30th:** Complete this form only if an adverse event occurs. Please also fill in a pink form.

The forms are designed to be easily completed by any member of theatre staff at the time of surgery. Detailed inclusion criteria and instructions can be found on the card in the Survey Pack. Please note that the Survey is both anonymous and confidential.

<table>
<thead>
<tr>
<th>Patient Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Date of operation:</strong></td>
</tr>
<tr>
<td><strong>Year of birth:</strong></td>
</tr>
<tr>
<td>1 1890's</td>
</tr>
<tr>
<td>4 1920's</td>
</tr>
<tr>
<td>7 1950's</td>
</tr>
<tr>
<td><strong>Sex:</strong></td>
</tr>
<tr>
<td>1 Male</td>
</tr>
<tr>
<td><strong>Planned admission type:</strong></td>
</tr>
<tr>
<td>1 Inpatient</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Planned Operation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(If a “combined” procedure, tick more than one box)</strong></td>
</tr>
<tr>
<td>1 Cataract (extra- or endocapsular)</td>
</tr>
<tr>
<td>2 Phacoemulsification</td>
</tr>
<tr>
<td>3 Cataract (other - specify)</td>
</tr>
<tr>
<td>4 Trabeculectomy</td>
</tr>
<tr>
<td>5 Retinal Reattachment</td>
</tr>
<tr>
<td>6 Corneal Graft</td>
</tr>
<tr>
<td>7 Other operation (specify)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Type of Local Anaesthetic</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>(Tick as many boxes as apply)</strong></td>
</tr>
<tr>
<td>1 Retrobulbar</td>
</tr>
<tr>
<td>2 Subtenon</td>
</tr>
<tr>
<td>3 Peribulbar</td>
</tr>
<tr>
<td>4 Subconjunctival</td>
</tr>
<tr>
<td>5 Facial block</td>
</tr>
<tr>
<td>6 Topical</td>
</tr>
<tr>
<td>7 Other Local (specify)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. Was an intravenous canula sited?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. Were any of these features monitored?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Blood Pressure</td>
</tr>
<tr>
<td>☐ Pulse Oximetry</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6. Was any premedication or intravenous sedative given as part of the PLANNED procedure?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7a. Local anaesthetic given by</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Ophthalmologist (consultant)</td>
</tr>
<tr>
<td>☐ Ophthalmologist (other)</td>
</tr>
<tr>
<td>☐ Anaesthetist (consultant)</td>
</tr>
<tr>
<td>☐ Anaesthetist (other)</td>
</tr>
<tr>
<td>☐ Other person (specify)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7b. This person has been giving LA’s for ocular surgery for:</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Two months or less</td>
</tr>
<tr>
<td>☐ More than one year</td>
</tr>
</tbody>
</table>
8. Was an anaesthetist available to cover this procedure?
1. Dedicated anaesthetist for this list
2. Anaesthetist available in theatre suite, but attending to another list
3. Anaesthetist only available in dire emergency (e.g., as part of cardiac arrest team)
4. No anaesthetist in the hospital

9. Type of hospital where the procedure took place:
1. Teaching Hospital (General)
2. Teaching Hospital (Eye Specialist)
3. District Hospital (General)
4. District Hospital (Eye Specialist)
5. Cottage Hospital
6. Other (specify)

10. In the last fortnight, has the patient been treated with regular Warfarin, Aspirin, or other anticoagulant or antiplatelet agent?
1. No
2. Warfarin
3. Aspirin
4. Other agent (specify)

Warfarin patients only: Was dosage reduced or stopped because of impending surgery?
1. No
2. Yes
3. Yes, changed to heparin

Warfarin patients only: Was the INR checked within 24 hours of surgery?
1. No
2. Yes

INR is the International Normalised Ratio (Prothrombin time vs control)
3. Yes: If “Yes”, please state INR:

We define adverse events as something which made you monitor the patient more closely or take action.

11a. Were there any Systemic adverse events?
1. No Systemic Adverse Events
2. Cardiovascular system problem
3. Respiratory or oxygenation problem
4. Neurological or psychiatric problem
5. Patient unresponsive
6. Cardiorespiratory arrest
7. Other (describe)

11b. If an adverse event occurred, what was done about it?
1. Patient was monitored more closely
2. Action was taken

12. Were there any Orbital adverse events?
1. No Orbital Adverse Events
2. Perforation or penetration of globe
3. Retrobulbar or periocular hemorrhage: How severe was it?
4. Minor (no mass effect)
5. Major (causing proptosis)
6. Expulsive hemorrhage
7. Inadequate analgesia, making the operation difficult or complicated
8. Inadequate akinesia, making the operation difficult or complicated
9. Other orbital/ocular adverse event, to which the LA may have contributed. Please give brief details:

If there is an adverse event, please also complete a pink Adverse Event Report Form and attach it to the relevant yellow form.

Thank you for completing this form. Please complete one of these yellow forms for every intraocular LA procedure you do during the week of 1st - 7th September 1996 and attach a completed pink form for those which have adverse events. For the remainder of the Survey (8th September - 30th November 1996) forms should only be completed if an adverse event occurs. Thus, every patient who has an adverse event should have both a yellow and a pink form completed. Full criteria for the Survey can be found on the front of the Survey Pack, which contains all necessary forms together with envelopes for their return to the Royal College of Ophthalmologists.

If you have any problems or questions, please contact the principal investigator for this project:
Mr Tom Eke FRCOphth, Audit Fellow, The Royal College of Ophthalmologists, 17 Cornwall Terrace, London NW1 4QW
Telephone: (0116) 258 6171 (Office) or (0171) 935 0702 (Audit Help Desk)
Appendix 8:

Adverse event report form

See Methods section 3.3.12, and results section 4.6.
Adverse Event Report Form

When to complete this form

You need only complete this form if there is an Adverse Event in a patient who has had a Local Anaesthetic. You are reminded that this survey is both anonymous and confidential.

Adverse events occurring during the study period should be reported. Definitions and criteria for inclusion in the survey are written on the card in the Survey Pack. You should already have filled in a Local Anaesthetic/Surgery Report Form for this patient; please attach it to this form before filling.

Patient/Event Details (This is required so that you can match this form with the yellow form you have also completed for this patient)

of operation: ........................................... 1996

of birth: .............................................

1890's 1900's 1910's

1920's 1930's 1940's 1950's

1960's Other .............................................

Male 2 Female

of adverse event:

1 Systemic 2 Orbital 3 Both

you consider that this adverse event is “life-threatening”?  

1 No 2 Yes

3. If a Systemic adverse event occurred:

What happened?

Blood pressure: 1 too high 2 too low

Pulse: 3 too fast 4 too slow

5 Angina

6 Abnormal heart rhythm (describe)

7 Cardiorespiratory arrest

8 Breathing rate too slow, or apnoea

9 Breathing rate too fast

10 Oxygenation too low

11 Anxiety/panic attack

12 Confusion/agitation

13 Unresponsive to speech

14 Epileptic fit

15 Other systemic adverse event (describe)
Please answer all the following questions, regardless of the type of adverse event.

4. How long after the LA was given did the adverse event occur?
   After about ............... minutes

5. Who helped to manage this adverse event?
   (Tick as many boxes as apply)
   - Anaesthetist, who was already in theatre
   - Anaesthetist, called from elsewhere
   - Physician
   - Cardiac arrest team
   - Junior ophthalmologist
   - Consultant ophthalmologist
   - Other doctor (specify) .....................

6. What action was taken to manage this adverse event?
   (Tick as many boxes as apply)
   (a): Action by Anaesthetist, Physician or equivalent:
   - Monitoring and reassurance only
   - Patient sedated
   - Air/oxygen supply improved
   - Converted to General Anaesthetic
   - Drugs given (name) .........................

   - Cardiopulmonary resuscitation
   - No action taken by anaesthetist or physician

   (b): Action by Surgeon
   - Operation not started
   - Operation took place as planned
   - Operation technique changed
   - Operation finished early

7. Would you say the patient's general condition was significantly worse on departure from the theatre complex?
   - No
   - Yes, general condition had worsened
   - Patient died

8. Was postoperative ward accommodation changed as a result of this adverse event?
   - No, patient went back to ward/daycare unit as planned
   - Yes, a planned Daycase was kept in overnight on the ward
   - Yes, transferred to a Medical ward or similar
   - Yes, transferred to Intensive Therapy Unit
   - Was not transferred due to other factors (e.g., bed unavailable), but should have been transferred to accommodation as ticked above

9. Does the patient have any of the following chronic medical conditions?
   - Insulin dependent diabetes
   - Non-insulin dependent diabetes
   - Hypertension (treated or untreated)
   - Ischaemic heart disease
   - Chronic obstructive airways disease
   - Other severe chronic medical disease (specify) ..................
   - None of the above

10. Preoperative ASA grade
    (American Society of Anesthesiologists classification of physical status)
    - Grade I A normally healthy individual
    - Grade II A patient with systemic disease which is not incapacitating
    - Grade III A patient with severe systemic disease, which is incapacitating
    - Grade IV A patient with incapacitating systemic disease, which is a constant threat to life
1. Who assessed the patient's general health as part of the work-up prior to surgery? (Tick as many boxes as apply)
- Ophthalmologist (consultant)
- Anaesthetist (consultant)
- Ophthalmologist (non-consultant)
- Anaesthetist (non-consultant)
- Nurse
- Physician
- Other (specify)
- No-one

2. Please name the medications the patient was taking regularly prior to the operation (no need to give dosages)

3. Which aspects of the preoperative work-up are recorded in the notes?
- General medical history
- Blood pressure
- Examination (with a stethoscope)
- Electrocardiogram (ECG)
- Chest X-ray
- Urinalysis
- Blood count
- Blood urea/electrolytes
- Blood sugar

14. Please enter all Premedication or Sedative agents administered as part of the planned anaesthesia procedure. (If none was given, tick the box marked “none”. You need not include eyedrops, nor changes to diabetes regimens)
- None given

15. Type of canula used to give the local anaesthetic:
- Designed for ocular LA (eg retrobulbar needle)
- Designed for another use (eg intravenous or lachrymal canula)

16. Please state what was used for the Local Anaesthetic. (Enter the total amounts given to the eye/orbit only; omit any facial nerve block)
- Lignocaine (“Xylocaine”)
  - Strength % Volume ml
- Bupivacaine (“Marcain”)
  - Strength % Volume ml
- Adrenaline
  - Strength Volume ml
- Hyaluronidase (“Hyalase”) units
- Other agent (name)
  - Strength Volume ml
<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
</table>
| 17. Was an intravenous cannula sited?                                   | 1. No  
|                                                                         | 2. Yes, before the LA was given  
|                                                                         | 3. Yes, after the LA was given  
|                                                                         | 4. Yes, in order to manage a complication                              |
| 18. Was Pulse Oximetry monitored during the operation?                  | 1. No  
|                                                                         | 2. Yes, starting before the LA was given  
|                                                                         | 3. Yes, starting after the LA was given  
|                                                                         | 4. Yes, in order to manage a complication                              |
| 19. Was Blood Pressure monitored during the operation?                  | 1. No  
|                                                                         | 2. Yes, starting before the LA was given  
|                                                                         | 3. Yes, starting after the LA was given  
|                                                                         | 4. Yes, in order to manage a complication                              |
| 20. Was Electrocardiography monitored during the operation?             | 1. No  
|                                                                         | 2. Yes, starting before the LA was given  
|                                                                         | 3. Yes, starting after the LA was given  
|                                                                         | 4. Yes, in order to manage a complication                              |

This final section is optional. All data will be treated in the strictest confidence.

We may wish to contact you in a few months time, in order to request follow-up details on this patient. If you are happy for us to do this, please enter the following information:

Patient identification number: 
Name of Ophthalmologist to be contacted: 
Contact address for Ophthalmologist: 

Thank you for completing this form. All patients who have adverse events during the Survey period (1st September - 30th November 1996) should have a yellow and a pink form completed. Full criteria for the Survey can be found on the card in the Survey Pack, which contains all necessary forms together with envelopes for their return to the Royal College of Ophthalmologists.

If you have any problems or questions, please contact the principal investigator for this project:
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Appendix 9:

Orbital haemorrhage follow-up form

See Methods section 3.4.6, and results section 4.5, 4.6
'Retrobulbar' Haemorrhage Review Form

This form is for follow-up of patients who had a Retrobulbar or Periocular Haemorrhage, associated with Local Anaesthesia for ocular surgery. All data will be treated in strictest confidence.

| Patient identification number: | 170513D |
| Date of Adverse Event: | 31/10/1996 |
| Severity of Haemorrhage: | MINOR (No mass effect) |

1. What was done to manage this Retrobulbar Haemorrhage?
   - [ ] pressure on orbit
   - [ ] medications (e.g. Diamox®) Please name: ..........................................................
   - [ ] surgical decompression:
     - [ ] lateral canthotomy
     - [ ] other Please specify: ........................................................................
   - [ ] Operation technique changed Please describe: ...........................................
   - [ ] Operation took place as planned

2. What type of needle was used to give the local anaesthetic?
   Please specify type (e.g. retrobulbar needle, intravenous needle, etc) and size

Only complete section 3 if the operation went ahead on the same day

3. Were there any operative problems? eg vitreous bulge, choroidal haemorrhage
   - [ ] No
   - [ ] Yes, the following operative problems occurred:
     Please specify:

   If you answered q.3, now go straight to q.5.

Only complete section 4 if the operation was delayed until a later date

4a. When was the surgery done? DD/MM/YY: ...........................................

4b. What type of anaesthetic was used?
   - [ ] General anaesthetic
   - [ ] Local anaesthetic:
     - [ ] retrobulbar
     - [ ] peribulbar
     - [ ] subconjunctival
     - [ ] topical
     - [ ] subtenon
     - [ ] other local (please specify)...........................................
4c. Aspirin patients only: was aspirin stopped prior to the second operation?
[ ] No  [ ] Yes

4d. Warfarin patients only: Was dosage reduced or stopped prior to the second operation, because of impending surgery?
[ ] No  [ ] Yes  [ ] Yes, changed to heparin

4e. Warfarin patients only: Was the INR checked within 24 hours of surgery?
INR is the International Normalised Ratio (Prothrombin time vs. control).
[ ] No  [ ] Yes: If Yes, please state INR

5. Do you think that this Retrobulbar Haemorrhage had any permanent effect on visual function? (e.g. optic atrophy or diplopia)
[ ] No  [ ] Yes (give details):

Thank you for completing this form. Please return it, using the pre-paid envelope, to:
Mr Tom Eke, Audit Fellow, The Royal College of Ophthalmologists, 17 Cornwall Terrace, London NW1 4QW.
Tel: 0116 2586171 (Office) or 0171 935 0702 (Audit Help Desk).
Appendix 10:

'Systemic' adverse event follow-up form

See Methods section 3.4.6, and results section 4.6.
Confidential Review Form for Adverse Events

This form is for follow-up of patients who had a 'Systemic' Adverse Event (i.e. a problem other than in the eye or orbit) associated with Local Anaesthesia for ocular surgery. All data will be treated in strictest confidence.

| Patient identification number: | B074535 |
| Date of Adverse Event:         | 4/11/1996 |

1. Please describe, in words, what actually happened when the above Adverse Event occurred. As appropriate, please include details of: duration of Adverse Event, pulse rate, blood pressure etc.

2. Did the patient die, or suffer any lasting effects of this Systemic Adverse Event? (e.g. hemiplegia)
   - [ ] No
   - [ ] Yes, patient died as a result of this Adverse Event
   - [ ] Yes, patient had other problems (please give details):

3. As a result of this Systemic Adverse Event, was the patient kept in hospital for longer than planned? If the patient was kept in for a purely ocular reason (e.g. IOP rise), tick 'No'.
   - [ ] No
   - [ ] Yes, a day-case was kept in overnight
   - [ ] Yes, the patient was kept in for an extra .......... nights

4. Was the final result of surgery affected by this Adverse Event?
   e.g: no IOL, operation still not done, visual field defect, etc.
   - [ ] No
   - [ ] Yes (give details):

5. If the patient has had further ocular surgery since the Adverse Event, please give details:
   (Include the type of operation, anaesthetic, any adverse events, and outcome.)

Thank you for completing this form. Please return it, using the pre-paid envelope, to:
Mr Tom Fke Audit Fellow The Royal College of Ophthalmologists 17 Cornwall Terrace London NW1 4OW
Appendix 11:

List of presentations and publications related to the Survey

Peer reviewed publications:
Eke T, Thompson JR.
The National Survey of Local Anaesthesia for Ocular Surgery
(i): Survey methodology & current practice.

Eke T, Thompson JR.
The National Survey of Local Anaesthesia for Ocular Surgery
(ii): Safety profiles of local anaesthesia techniques.
*Eye* 1999; 13(2): 196-204.

Submitted for publication:
Eke T, Thompson JR.
Hemorrhagic complications of local anesthetic injections: The effect of warfarin
(Coumadin®) and aspirin.

Scientific correspondence:
Eke T, Thompson JR.
National survey of local anesthesia for ocular surgery in the United Kingdom.

Eke T, Thompson JR.
The National Survey of Local Anaesthesia for Ocular Surgery
*Eye*, 1999; 13: 810-811

Eke T, Thompson JR.
The National Survey of Local Anaesthesia for Ocular Surgery.
Other publications:
Eke T, Thompson JR.
The National Survey of Local Anaesthesia for Ocular Surgery: early report.
London: Royal College of Ophthalmologists, 1997

Presentations at scientific meetings:
Eke T, Thompson JR.
Do anaesthetists cause more globe perforations than ophthalmologists?
Evidence from the National Survey of Local Anaesthesia for Ocular Surgery.
British Ophthalmic Anaesthesia Society, Inaugural Conference.
Middlesbrough, June 1999

Eke T, Thompson JR
The National Survey of Local Anaesthesia for Ocular Surgery
British Ophthalmic Anaesthesia Society, Inaugural Conference
Middlesbrough, June 1999

Eke T, Thompson JR.
Safety of retrobulbar and peribulbar injections in patients taking anticoagulants.
Association for Research in Vision and Ophthalmology (ARVO)
Ft Lauderdale, USA: May 1998.

Eke T, Thompson JR
The National Survey of Local Anaesthesia for Ocular Surgery
Royal College of Ophthalmologists audit conference: ‘Audit at the Cutting Edge’
London, May 1998

Eke T, Thompson JR
Safety of retrobulbar and peribulbar injections in patients taking anticoagulants
Royal College of Ophthalmologists Annual Congress
Glasgow, April 1998
Eke T, Thompson JR
The National Survey of Local Anaesthesia for Ocular Surgery: Safety Aspects
Royal College of Ophthalmologists Annual Congress
Glasgow, April 1998

Eke T, Thompson JR
Safety aspects of local anaesthesia and warfarin use in ocular surgery
European Society of Regional Anaesthesia (ESRA) Annual Scientific Meeting
Chester, April 1998

Eke T, Thompson JR
Lessons from the National Survey of Local Anaesthesia for Ocular Surgery
Royal College of Ophthalmologists seminar: ‘Encouraging Local Audit’
London, January 1998

Eke T, Thompson JR
Safety aspects of periocular injections in patients taking anticoagulants
Midland Ophthalmological Society: Annual General Meeting
Birmingham, September 1997

Eke T, Thompson JR
The National Survey of Local Anaesthesia for Ocular Surgery: initial results
Royal College of Ophthalmologists Annual Congress
Birmingham, April 1997
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Safety aspects of local anaesthesia for intraocular surgery

Thesis submitted for the degree of Doctor of Medicine at the University of Leicester

by

Thomas Eke
University of Leicester

September 2001