Recall from informed consent counselling for cataract surgery

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The authors investigated the effect of giving written material on information recall from informed consent counselling for cataract surgery. Fifty English-speaking patients who underwent non-urgent cataract extraction at Flinders Medical Centre, South Australia, were prospectively enrolled. Systematic counselling for cataract surgery was provided, with a written copy of the content given to a randomly selected group of patients (n = 24). All subjects completed a questionnaire after counselling and again at two weeks after surgery to test their satisfaction with, and recall of, information provided. Patients were found to be satisfied with the amount of information they received and most were able to recall details about the cataract surgery procedure. However, many could not recall success rates or complication rates and only a minority could list any complication. The provision of written information did not significantly alter recall ($p>0.05$). Recall was significantly better immediately after counselling than two weeks after surgery ($p<0.05$). Younger patients also had significantly better recall ($p<0.05$). Patients were happy with the information they had been given but did not remember enough from the informed consent process to satisfy legal requirements.

INTRODUCTION

The nature and definition of informed consent varies according to legal and ethical sources and from one country to another.[1] However, world-wide, gaining informed consent is an important part of clinical practice. The right of patients to make decisions for themselves is a tenet of ethical medical practice and is required by law. Australian law expects doctors to inform patients of the benefits and risks of treatment in a manner that is relevant in scope and detail for the patient. The law also expects doctors ensure patients understand what they have been told.[2] As demanding as the law is, clinicians have serious doubts about how much patients understand of what they are told, no matter how carefully this has been done.[3]

Informed consent in cataract surgery has been studied previously.[4] Morgan and Schwab

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[1] RS Lord, "Informed Consent in Australia," (1995) 65 Aust N Z J Surg 224.
[2] ibid, *Rogers V Whitaker* (1992) 109 ALR 625.
[3] J Shankar, "Patients' Memory for Medical Information," (2003) 96 J R Soc Med 520.
[4] H Brown, M Ramchandani, JT Gillow, and MD Tsaloumas, "Are Patient Information Leaflets Contributing to Informed Consent for Cataract Surgery?," (2004) 30 J Med Ethics 218, K Kikuchi, and T Hara, "Patients'

considered the influence of age, education, previous cataract surgery, anxiety and gender, and concluded that retention was poorer in older patients and patients with a low standard of education.[5] Vallance *et al* found poor recall of specific details related to cataract surgery initially after consent was obtained with deterioration of recall one month later.[6] It has been established that older patients have more trouble recalling information presented for informed consent, but other factors may influence this age-related decline, including education level and environmental exposure.[7] The recall of information deteriorates from the time the information is provided.[8]

The current authors investigated how much information patients recall after pre-operative counselling for cataract surgery and again after surgery. Fifty patients who were considered to require cataract surgery were given information about the benefits and risks of the procedure. All were given the relevant information verbally and half were randomly assigned to receive the same information in printed form. A questionnaire was used to assess their ability to recall the information that they had been given. This was administered immediately after the provision of informed consent and again two weeks after cataract surgery. Factors influencing a patient's ability to recall the information were assessed statistically.

This simple method of evaluating the effectiveness of achieving informed consent was used because it follows procedures commonly used in clinical practice. It looks at a particular procedure, cataract surgery, which is one of the most frequently performed operations and it uses recall as the test strategy; the test commonly used in educational and legal institutions.

METHODS

Fifty adult patients who agreed to participate were all being booked for routine non-urgent cataract extraction with intraocular lens insertion under local anaesthesia. All were from an English-speaking background.

To ensure all patients received identical counselling we carefully developed an information sheet explaining the risks and benefits of cataract surgery (Appendix). This was written in as simple terms as possible, minimising jargon, and including all important content areas for cataract surgery informed consent.[9] The reading age of the information was independently assessed to be 8 years of age. This information sheet was read to patients as part of the clinical consultation with the doctor. The patient was given the opportunity to respond, and any questions asked were answered according to the current clinical standards and the information was reiterated where appropriate.

After agreeing to participate in the study, patients were asked to complete the document entitled 'Informed Consent In Eye Surgery: Questionnaire' (the questionnaire). The content area of the questionnaire included important aspects of outcomes and potential complications as well as patient satisfaction with the informed consent process. The questionnaire was written with a combination of closed and open questions. Closed questions were asked wherever appropriate, to minimise errors in interpretation during the analysis (see Table 1).

Understanding of the Informed Consent for Cataract Surgery," (1996) 15 J Ophthalmic Nurs Technol 216, CG Kiss, S Richter-Mueksch, E Stifter, G Diendorfer-Radner, M Velikay-Parel, and W Radner, "Informed Consent and Decision Making by Cataract Patients," (2004) 122 Arch Ophthalmol 94, D Scanlan, F Siddiqui, G Perry, and CM Hutnik, "Informed Consent for Cataract Surgery: What Patients Do and Do Not Understand," (2003) 29 J Cataract Refract Surg 1904.

[5] LW Morgan, and IR Schwab, "Informed Consent in Senile Cataract Extraction," (1986) 104 Arch Ophthalmol 42.

[6] JH Vallance, M Ahmed, and B Dhillon, "Cataract Surgery and Consent; Recall, Anxiety, and Attitude toward Trainee Surgeons Preoperatively and Postoperatively," (2004) 30 J Cataract Refract Surg 1479.

[7] RP Kessels, "Patients' Memory for Medical Information," (2003) 96 J R Soc Med 219,
J Sugarman, DC McCrory, and RC Hubal, "Getting Meaningful Informed Consent from Older Adults: A Structured Literature Review of Empirical Research," (1998) 46 J Am Geriatr Soc 517, SA Small, Y Stern, M Tang, and R Mayeux, "Selective Decline in Memory Function among Healthy Elderly," (1999) 52 Neurology 1392.

[8] C Lavelle-Jones, DJ Byrne, P Rice, and A Cuschieri, "Factors Affecting Quality of Informed Consent," (1993) 306 BMJ 885.

[9] H Brown, M Ramchandani, JT Gillow, and MD Tsaloumas, "Are Patient Information Leaflets Contributing to Informed Consent for Cataract Surgery?," (2004) 30 J Med Ethics 218.

Table 1. The questionnaire and corresponding correct answers

Question	Response options for closed questions	Correct response
1. Have you had previous eye surgery? If yes, what was your operation for?	Yes/No Open	N/A
2. What is the condition for which you are going to have surgery?	Open	Cataract
3. How much information were you given about your operation?	Too much/Enough/Too little	N/A
4. Did you feel you understood the information you were given?	Yes/No	N/A
5. Did you feel you were given the opportunity to ask questions?	Yes/No	N/A
6. What are the alternative forms of treatment for your eye condition, if any?	Open	Defer surgery No medical alternative
7. How often is the operation successful?	Open	95.0 to 99.5 per cent inclusive
8. Do you think you will need glasses after the operation?	Yes/Possibly/No/Don't know	Yes or possibly
9. Will something be implanted in the eye?	Yes/No/Don't know	Yes
10(a). Is there a risk you may lose the sight in the eye? 10(b). If yes, how often does this happen?	Yes/No/Don't know Open	Yes 1 in 200
11. Please list all the complications of the surgery that you can recall.	Open	(i) Haemorrhage (ii) Infection (iii) Retinal detachment (iv) Damage to capsule (v) Optic nerve damage*

- Exact wording not required; maximum score of five.

Patients were randomly assigned to the group receiving a written copy of the information; patients with an even hospital record number were given the written copy. They were asked to read the material and to take it home and read it again. The questionnaire was repeated by telephone two weeks after surgery. The study complied with the principals of the Declaration of Helsinki, and was approved by the Flinders University Ethics Committee.

Patient demographics were assessed by inspection and matching of the two groups determined by ANOVA and Chi-square testing. Responses to the questionnaire were reported by inspection and tested for the significance of difference between groups by Chi-square testing. Changes over time were tested by Wilcoxon sign rank test. We also attempted to identify factors that may affect patients' understanding of the information they were given. These included age of the patient, gender, previous eye surgery, whether the patient had been given a written copy of the risks and benefits of surgery, and the time difference between pre-operative and post-operative responses. The effects of these factors were tested with Chi-square testing or logistic regression. Statistical analyses were performed using the software program Statistical Package for Social Sciences (SPSS) v12.0.1 (SPSS Inc). Figures were drawn using KaleidaGraph v3.51 (Synergy Software).

RESULTS

Of the 50 patients in the study group, 19 were males and 31 females. Mean age at the time of pre-operative completion of the questionnaire was 69.9 (SD 11.6) years. Twenty-four were assigned to receive a written copy of the instructions and 26 were assigned to not receive a copy. The two groups were similar for gender (received written copy, 16 females and 8 males; no written copy, 15 females and 11 males χ^2=-0.43, p>0.05) and age (received written copy, 72.6 (SD 11.6) years, no written copy 67.7 (SD 11.4) years ANOVA F=1.93, p>0.05).

The questionnaire was completed an average of 10.1 (SD 16.1) minutes after the pre-operative signing of the surgery consent form. All patients received cataract surgery under local anaesthesia by phacoemulsification with intraocular lens implantation. There were no surgical or post-operative complications. The questionnaire was completed post-operatively an average of 79.0 (SD 53.2) days after the pre-operative completion.

Table 2 lists the correct response rate on each question for both groups and at both time-points. All questions were tested for significant differences between groups and between visits. There were 3 questions for which recall significantly deteriorated from the pre-operative visit to the post-operative visit. There were no questions on which the group who took written information home performed significantly differently to the group who did not take written information home (χ^2, p>0.05). However, on two questions (7 & 10b) deterioration of recall from the pre-operative visit to the post-operative visit was only significantly worse for the group that did not take home the written information. Even though the groups were not significantly different when directly compared at either the pre-operative or post-operative testing, it could be argued that there was a trend towards a difference which may be significant with a much larger sample (sample size calculation based on question 7 with a type 1 error of 0.05 and a power of 80%, a sample size of 304 in each group would be required). While this may be true, the level of recall on these questions remains extremely poor for both groups.

Table 2. Frequency of responses pre-operatively and post-operatively

Question 1. Have you had previous eye surgery?

	Pre-op responses		Post-op responses	
	Yes	**No**		
Total (n=50)	64.0%	36.0%	–	–

Question 2. What is the condition for which you are going to have surgery?

	Pre-op responses		Post-op responses	
	Correct	**Incorrect**	**Correct**	**Incorrect**
Total (n=50)	92.0%	8.0%	94.0%	6.0%
Written copy (n=24)	100.0%	0.0%	95.8%	4.2%
No written copy (n=26)	84.6%	15.4%	92.3%	7.7%

Question 3. How much information were you given about your operation?

	Pre-op responses			Post-op responses		
	Too much	**Enough**	**Too little**	**Too much**	**Enough**	**Too little**
Total (n=50)	0.0%	100.0%	0.0%	0.0%	94.0%	6.0%
Written copy (n=24)	–	–	–	–	95.8%	4.2%
No written copy (n=26)	–	–	–	–	92.3%	7.7%

Question 4. Did you feel you understood the information you were given?

	Pre-op responses		Post-op responses	
	Yes	**No**	**Yes**	**No**
Total (n=50)	100.0%	0.0%	100.0%	0.0%

Question 5. Did you feel you were given the opportunity to ask questions?

	Pre-op responses		Post-op responses	
	Yes	**No**	**Yes**	**No**
Total (n=50)	96%	4%	90%	10%
Written copy (n=24)	95.8%	4.2%	87.5%	12.5%
No written copy (n=26)	96.2%	3.8%	92.3%	7.7%

Question 6. What are the alternative forms of treatment for your eye condition, if any?

	Pre-op responses		Post-op responses	
	Correct	**Incorrect**	**Correct**	**Incorrect**
Total (n=50)	88.0%	12.0%	86.0%	14.0%
Written copy (n=24)	91.7%	8.3%	83.3%	16.7%
No written copy (n=26)	84.6%	15.4%	88.5%	11.5%

Question 7. How often is the operation successful?

	Pre-op responses		Post-op responses	
	Correct	**Incorrect**	**Correct**	**Incorrect**
Total (n=50)*	56.0%	44.0%	36.0%	64.0%
Written copy (n=24)	50.0%	50.0%	41.7%	58.3%
No written copy (n=26)*	61.5%	38.5%	30.8%	69.2%

Question 8. Do you think you will need glasses after the operation?

	Pre-op responses				Post-op responses			
	Yes	**Possibly**	**No**	**Don't know**	**Yes**	**Possibly**	**No**	**Don't know**
Total (n=50)	64.0%	20.0%	4.0%	12.0%	74.0%	16.0%	0.0%	10.0%
Written copy (n=24)	66.7%	16.7%	0.0%	16.7%	70.8%	12.5%	–	16.7%
No written copy (n=26)	61.5%	23.1%	7.7%	7.7%	76.9%	19.2%	–	3.8%

Question 9. Will something be implanted in the eye?

	Pre-op responses			Post-op responses		
	Yes	**No**	**Don't know**	**Yes**	**No**	**Don't know**
Total (n=50)	90.0%	2.0%	8.0%	90.0%	0.0%	10.0%
Written copy (n=24)	91.7%	8.3%	0.0%	83.3%	–	16.7%
No written copy (n=26)	88.5%	3.8%	7.7%	96.2%	–	3.8%

Question 10(a). Is there a risk you may lose the sight in the eye?

	Pre-op responses			Post-op responses		
	Yes	**No**	**Don't know**	**Yes**	**No**	**Don't know**
Total (n=50)	76.0%	16.0%	8.0%	68.0%	22.0%	10.0%
Written copy (n=24)	70.8%	12.5%	16.7%	62.5%	25.0%	12.5%
No written copy (n=26)	80.8%	19.2%	0.0%	73.1%	19.2%	7.7%

Question 10(b) If yes, how often does this happen?

	Pre-op responses		Post-op responses	
	Correct	**Incorrect**	**Correct**	**Incorrect**
Total (n=50)*	44.7% (n=38)	55.3%	20.6% (n=34)	79.4%
Written copy (n=24)	52.9% (n=17)	47.1%	33.0% (n=15)	66.0%
No written copy (n=26)*	38.1% (n=21)	61.9%	10.5% (n=19)	89.5%

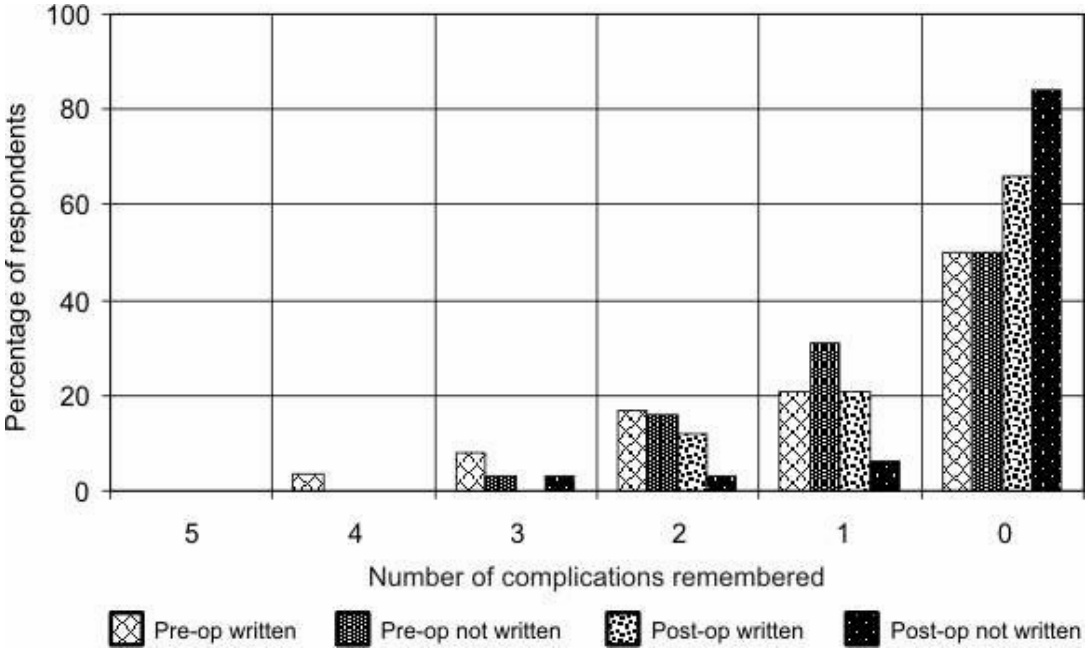
Question 11. Please list all the complications of the surgery you can recall

	Pre-op responses						Post-op responses					
	5	**4**	**3**	**2**	**1**	**0**	**5**	**4**	**3**	**2**	**1**	**0**
Total (n=50)*	0.0%	2.0%	6.0%	16.0%	26.0%	50.0%	0.0%	0.0%	2.0%	8.0%	14.0%	76.0%
Written copy (n=24)*	–	4.2%	8.3%	16.7%	20.8%	50.0%	–	–	0.0%	12.5%	20.8%	66.7%
No written copy (n=26)*	–	-	3.8%	15.4%	30.8%	50.0%	–	–	3.8%	3.8%	7.7%	84.6%

* Pre-op responses significantly poorer than post-op responses (Wilcoxon signed rank test, $p<0.05$)

Recall of individual complications was uniformly poor with at least half of all patients unable to name any. The differences between the group who received a copy of written information and the group that did not were not significantly different (χ^2 $P>0.05$). The decrease in recall that occurred post-surgery was significantly different for both groups (Wilcoxon sign rank test, $p<0.05$).

Figure 1. Recall of individual complications



Across the whole cohort, younger patients were better able to recall their treatment alternatives, the success rate of surgery, the presence of a possibility of losing the sight, and

potential complications ($p<0.05$). The patient's gender did not influence the results, nor did previous eye surgery, previous cataract surgery, or time lapsed between pre-operative and post-operative assessment ($p>0.05$).

DISCUSSION

These results of the questionnaire indicate that not all information given to patients as part of the informed consent process can be recalled; information regarding the rate and possible complications of surgery is poorly retained. This was despite being given appropriate information, carefully written in everyday common language with an independently verified reading age of 8 years. Moreover, all patients pre-operatively confirmed that they were happy with the information they had received. Post-operatively some reported that they should have received more information but they wanted to know more about the process rather than benefits and risks. These findings are similar to previous studies.[10]

The provision of informed consent for this group of patients is all that can reasonably be done, and is what is done in most clinical settings. Indeed, clinical staff believed all patients had an adequate understanding of the risks and benefits of cataract surgery. This highlights the difficulty clinicians have in evaluating whether a patient understands what they are told. The poor recall is both disappointing and disturbing.

Eight percent did not know the name of the operation they were about to have – and 6% still did not know even after they had been through the procedure. Pre-operatively, only 76% appreciated that there was any risk of losing vision as a consequence of cataract surgery, and 16% believed there was no risk of this happening. Of those who acknowledged the risk of visual loss, 45% knew the order of the risk.

Recollection of the likelihood of complications decreased post-operatively. Patients had particularly poor recollection of specific complications, with half the patients unable to remember any specific complication. After surgery the level of recollection decreased further. Similar decreases in recall over time were found by Scanlan *et al*.[11]

The patients who received a written copy of the information setting out the benefits and risks of cataract surgery were no more able to recall information than those who had only had the information read to them. This result was consistent across all questions.

Most previous studies of the benefit of providing written information either show no benefit or limited benefits of such material.[12] Either way, recall of informed consent information is poor with approximately 50% of questions correctly answered across studies. Only Scanlan *et al* report a significant benefit to providing written information to supplement informed consent for cataract surgery.[13] They found at 1 week post-surgery those given literature had 64% recall whereas those without had only 44% recall.[14] Given our findings and others, we suspect that

[10] D Scanlan, F Siddiqui, G Perry, and CM Hutnik, "Informed Consent for Cataract Surgery: What Patients Do and Do Not Understand," (2003) 29 J Cataract Refract Surg 1904, JH Vallance, M Ahmed, and B Dhillon, "Cataract Surgery and Consent; Recall, Anxiety, and Attitude toward Trainee Surgeons Preoperatively and Postoperatively," (2004) 30 J Cataract Refract Surg 1479.

[11] ibid

[12] TF Brown, E Massoud, and M Bance, "Informed Consent in Otologic Surgery: Prospective Study of Risk Recall by Patients and Impact of Written Summaries of Risk," (2003) 32 J Otolaryngol 368, Y Chan, JC Irish, SJ Wood, LE Rotstein, DH Brown, PJ Gullane, and GA Lockwood, "Patient Education and Informed Consent in Head and Neck Surgery," (2002) 128 Arch Otolaryngol Head Neck Surg 1269, P Graham, "Type of Consent Does Not Influence Patient Recall of Serious Potential Radiation Toxicity of Adjuvant Breast Radiotherapy," (2003) 47 Australas Radiol 416, IJ Langdon, R Hardin, and ID Learmonth, "Informed Consent for Total Hip Arthroplasty: Does a Written Information Sheet Improve Recall by Patients?," (2002) 84 Ann R Coll Surg Engl 404, AS Makdessian, DA Ellis, and JC Irish, "Informed Consent in Facial Plastic Surgery: Effectiveness of a Simple Educational Intervention," (2004) 6 Arch Facial Plast Surg 26, P Turner, and C Williams, "Informed Consent: Patients Listen and Read, but What Information Do They Retain?," (2002) 115 N Z Med J 218.

[13] D Scanlan, F Siddiqui, G Perry, and CM Hutnik, "Informed Consent for Cataract Surgery: What Patients Do and Do Not Understand," (2003) 29 J Cataract Refract Surg 1904.

[14] Ibid.

Scanlan *et al*'s results over-estimate the impact of written information upon recall and this is probably due to small numbers (2 groups of 14 patients) and no report of age matching of the two groups.

The present results support previous findings that younger patients could better recall information provided for informed consent.[15] The patient's gender did not influence the results, nor did previous eye surgery, previous cataract surgery, or time lapsed between pre-operative and post-operative assessment. This is in line with previous studies.[16]

Kiss *et al* hypothesised that poor recall of names and rates complications of cataract surgery may reflect cognitive dissonance meaning the patient does not want to associate the decision to proceed with surgery with the possibility of a poor outcome.[17] This concept is supported by research showing that people prefer to give greater weight to information supporting their decision compared to issues against the decision.[18] This may affect information recall if this "less important" information is less well remembered.

The poor recall demonstrated in this study is cause for concern. The legal requirement is that doctors not only provide patients with information relevant to their treatments and procedures, but that patients understand the information they are given. If surgery were to be restricted to those patients who can confirm by recall that they understand what they have been told, many patients who could benefit from sight-restoring surgery would be denied the opportunity. Elderly patients, in particular, would be disadvantaged.

More strenuous attempts at achieving informed consent are possible. Video recordings of information and interactive computer-based systems have been used in some places. Whether this approach is acceptable to elderly patients and whether it results in better recall is unconfirmed.[19] It may be that the resistance to learning in patients like these is affected by biological factors, such as age,[20] and also psychological and cultural factors as yet undefined. For example, many patients for one reason or another are prepared to trust their medical attendants to make medical decisions for them. Such patients have no motivation to digest, understand or recall what is said to them by their doctors. Whatever the reasons for the poor recall of information in this typical group of cataract patients, it is clear that the legal requirements are difficult to achieve, at least in this group of patients. What is required by law and what is achievable in clinical practice seem out of step.

CONCLUSION

Patient's ability to recall information provided during the informed consent process is poor. Recall deteriorates with time after surgery and is not improved by the provision of written material.

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[15] RP Kessels, "Patients' Memory for Medical Information," (2003) 96 J R Soc Med 219, LW Morgan, and IR Schwab, "Informed Consent in Senile Cataract Extraction," (1986) 104 Arch Ophthalmol 42.

[16] Ibid.

[17] CG Kiss, S Richter-Mueksch, E Stifter, G Diendorfer-Radner, M Velikay-Parel, and W Radner, "Informed Consent and Decision Making by Cataract Patients," (2004) 122 Arch Ophthalmol 94.

[18] E Jonas, S Schulz-Hardt, D Frey, and N Thelen, "Confirmation Bias in Sequential Information Search after Preliminary Decisions: An Expansion of Dissonance Theoretical Research on Selective Exposure to Information," (2001) 80 J Pers Soc Psychol 557.

[19] FA Campbell, BD Goldman, ML Boccia, and M Skinner, "The Effect of Format Modifications and Reading Comprehension on Recall of Informed Consent Information by Low-Income Parents: A Comparison of Print, Video, and Computer-Based Presentations," (2004) 53 Patient Educ Couns 205.

[20] RP Kessels, "Patients' Memory for Medical Information," (2003) 96 J R Soc Med 219, C Lavelle-Jones, DJ Byrne, P Rice, and A Cuschieri, "Factors Affecting Quality of Informed Consent," (1993) 306 BMJ 885, LW Morgan, and IR Schwab, "Informed Consent in Senile Cataract Extraction," (1986) 104 Arch Ophthalmol 42, J Sugarman, DC McCrory, and RC Hubal, "Getting Meaningful Informed Consent from Older Adults: A Structured Literature Review of Empirical Research," (1998) 46 J Am Geriatr Soc 517.

APPENDIX: CATARACT SURGERY INFORMATION

The following cataract surgery information was read aloud to the patient in the outpatient clinic:

You have a cataract which is an opacity of the lens in your eye and this accounts for your poor vision.

Since your poor vision is restricting your lifestyle it needs to be improved.

The treatment for cataracts that affect vision is to remove them and replace your lens with an artificial lens. There is a standard procedure which is done all around the world for this purpose.

The chances of you getting good vision after surgery are high. More than nineteen out of twenty patients achieve vision as good as they had twenty or thirty years ago. You may need spectacles to achieve this vision, either for distance vision or for reading, or both.

All operations have their risks. The chances of your vision being made worse in the operated eye is about 1 in 200. Haemorrhage, infection, retinal detachment or damage to the capsular support system of lens at the time of surgery may occur and result in this loss of vision.

The surgery is done under local anaesthesia which is safer than having a general anaesthetic but it too has its risks. Haemorrhage or damage to the optic nerve can occur but this is very rare.

If you do not have surgery then your vision may stay the same but it is likely to get progressively worse. It is very unlikely to improve without treatment.

The timing of the surgery is not too important. If you decide to defer the surgery then nothing is lost. It is no more difficult to do the surgery in a year or two than it is now. It may take four or five weeks after surgery before you get your spectacles and achieve your best vision.