

# Informed consent?

Or is it?

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**Abstract—** It was investigated to determine how effectively an individual would retain and recall information delivered to them approximately 6 months prior to cataract surgery. This information was delivered as part of the informed consent by the Doctor, and the legal consent was signed just prior to the cataract surgery starting. The questionnaire was given to one group of patients before the surgery, and the same questionnaire was given to another group after the surgery was complete.

**Keywords:** recall, cataract, informed, legal, consent

## INTRODUCTION

The process of informed consent [1] is widely accepted as basic standard of care for any significant medical procedure and is based upon the ethical and legal principle of autonomy. Central to the principle of autonomy is the role of the patient as the key decision-maker. The process of informed consent is one that involves explanation of the procedure and disclosure of potential risks and proposed benefits. It is based on the expectation that patients assimilate and weigh information against their own value structures and health expectations and then decide for or against undergoing the procedure.[2]

Although informed consent is a patient's basic right, it is often taken for granted that most patients are happy to do as their physician advises. Most patients thought the consent form was a legal document and they had to sign it, although most recognized that they could change their mind.[3]

## METHODS

Cataract surgery was chosen because of the large number of patients that could respond to this information in a shorter period of time to facilitate a possibly more accurate result, with consideration of  $p < 0.05$ . Six surgeons signed consent to allow their patients to participate. Patient participation was based on response, as all patients were given a questionnaire in an envelope at the hospital. Based on their completion of it and return to reception/nurse, this was considered their consent to participate in the study. With the envelope, they had the option to not participate and leave the survey blank which was also as per the Ethics Board. The study included two groups. March 1-15, 2012 Group One of 55 patients filled

out a questionnaire prior to their surgery, while on March 16-31, 2012, a second group of 27 filled out a questionnaire post surgery. The average age of group 1 was 73.14, while the average of age of group 2 was 69.88. The gender was similarly equal for both groups.

The ethnicity majority for the groups was 83.33% Caucasian for Group 1, 84.62% of Caucasian for Group 2. The remainder was First Nations/ Inuit 5.56%, Middle Eastern 3.7%, Asian 1.85%, African Canadian/West Indian 5.56 and 1.85% East Indian for Group 1. Group 2's remaining ethnicity is 3.85% Asian, 3.85 African Canadian/West Indian and 7.69% East Indian. Only a small percentage were unable to speak English (1.82%)

Anxiety was also measured using the Visual Analog Scale, although there did not seem to be significant differences between the two groups. (Group 1 1.48/5 and Group 2 1.32/5) [4]

### *Maintaining the Integrity of the Specifications*

It was felt that after the questionnaires were complete that it would have been more effective to have had one consistent nursing staff administer the pre and post-operatively administered questionnaires. As a result of inconsistent staff administering these questionnaires, there was inconsistency in their anxiety grading.

The questionnaire administered for both groups was approved by the Health Research Ethics Board at the University of Alberta and is as follows:

**Date:** \_\_\_\_\_

**Surgeon:** (mark surgeon with an X)

Dr. Buski \_\_\_ Dr. Chan \_\_\_ Dr. D. Climenhaga \_\_\_

Dr. H Climenhaga \_\_\_ Dr. Damji \_\_\_ Dr. Dorey \_\_\_

Dr. Edwards \_\_\_ Dr. Hennig \_\_\_

Dr. Hodges \_\_\_ Dr. Johnson \_\_\_ Dr. Kassiri \_\_\_

Dr. Kaye \_\_\_ Dr. Kutzner \_\_\_ Dr. Lehmann \_\_\_

Dr. Macdonald \_\_\_ Dr. Mah \_\_\_ Dr. McCabe \_\_\_

Dr. Rudnisky \_\_ Dr. Weis \_\_ Other: \_\_\_\_\_

**Patient Demographics:**

**Age Range:**

0-10 \_\_\_\_ 11-20 \_\_\_\_ 21-30 \_\_\_\_  
31-40 \_\_\_\_ 41-50 \_\_\_\_ 51-60 \_\_\_\_  
61-70 \_\_\_\_ 71-80 \_\_\_\_ 81-90 \_\_\_\_  
91-100 \_\_\_\_ >101 \_\_\_\_

**Gender:** Male \_\_\_\_ Female \_\_\_\_

**Race:**

White/ Caucasian \_\_\_\_  
Black - African Canadian/ West Indian \_\_\_\_  
Native American/ First Nations/ Inuit \_\_\_\_  
Hispanic/ Latino \_\_\_\_  
Asian Canadian: \_\_\_\_  
- Chinese/ Japanese/ Southeast Asian \_\_\_\_  
- East Indian \_\_\_\_  
- Middle Eastern \_\_\_\_  
Other: \_\_\_\_\_

**Language:**

First Language:

Second and Other Fluent Languages:

**Who is filling out this questionnaire?**

Patient \_\_\_\_  
Parent/ Guardian \_\_\_\_  
Substitute Decision Maker \_\_\_\_  
Health Care Provider \_\_\_\_

**Information on Cataracts**

Where do cataracts occur in the eye?

Eyelids \_\_\_\_

Sclera and Conjunctiva (white of the eye) \_\_\_\_

Cornea \_\_\_\_

Lens \_\_\_\_

Retina \_\_\_\_

I don't know \_\_\_\_

What are cataracts?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

I don't know \_\_\_\_

Do you feel you have an understanding of what cataracts are?

YES \_\_\_\_ NO \_\_\_\_

**Information on Cataract Surgery**

Is this laser surgery?

YES \_\_\_\_ NO \_\_\_\_

Will there be a blade involved?

YES \_\_\_\_ NO \_\_\_\_

Will anything be removed from the eye?

YES \_\_\_\_ NO \_\_\_\_

Will anything be placed inside the eye?

YES \_\_\_\_ NO \_\_\_\_

How long is the surgery? 0-10 minutes \_\_\_\_ 11-30 minutes \_\_\_\_  
31-60 minutes \_\_\_\_

Have you been told how pain will be controlled during the surgery? YES \_\_\_\_ NO \_\_\_\_

Will you get numbing drops? YES \_\_\_\_ NO \_\_\_\_

Will you get a general anesthetic? YES \_\_\_\_ NO \_\_\_\_

Do you feel you understand what cataract surgery is?

YES \_\_\_\_ NO \_\_\_\_

**Risks of Cataract Surgery**

Were any of the following discussed with you?

Retinal detachment \_\_\_\_ Decreased vision \_\_\_\_

Glaucoma \_\_\_\_ Need for glasses \_\_\_\_

Bleeding \_\_\_\_ Inflammation \_\_\_\_

Infection \_\_\_\_ Resident involvement \_\_\_\_

Double vision \_\_\_\_

Will you likely need glasses for distance after surgery?

YES \_\_\_\_ NO \_\_\_\_

Will you likely need glasses for near activities after surgery?

YES \_\_\_\_ NO \_\_\_\_

Do you feel the risks and benefits of cataract surgery were told to you? YES \_\_\_\_ NO \_\_\_\_

The Consent to participate was as follows:

**Consent form for patients.**

**Part 1:**

Title of Project: Cataract Surgery and Patient  
Comprehension: Assessing Physician Pre-operative  
Communication.

Principal Investigator: Dr. Ian MacDonald  
Phone Number(s): 780-735-5954

Co-Investigator: Dr. Christopher Hanson  
Phone Number(s): 780-668-2486

Research Coordinator: Georgie Jarvis  
Phone Number(s): 780-735-4986

**Part 2**

Do you understand that you have been asked to be in a  
research study? Yes \_\_\_\_ No \_\_\_\_  
Have you read and received a copy of the attached  
Information  
and agree to participate in this study? Yes \_\_\_\_  
No \_\_\_\_

Comments:

Signature of Research Subject

(Printed Name)

Date: \_\_\_\_\_

Do you understand the benefits and risks involved in taking  
part in this research study? Yes \_\_\_\_ No \_\_\_\_  
Have you had an opportunity to ask questions and discuss  
this study? Yes \_\_\_\_ No \_\_\_\_ ☐ ☐

Do you understand that you are free to withdraw from the  
study at any time until the questionnaire is handed in and  
this will not in any way affect your surgery or be known to  
your surgeon or operating room staff? Yes \_\_\_\_ No  
\_\_\_\_

Has the issue of confidentiality been explained to you?  
Yes \_\_\_\_ No \_\_\_\_

Do you understand who will have access to your records?  
Yes \_\_\_\_ No \_\_\_\_

Who explained this study to you?

☐ ☐  
  
☐

I believe that the person signing this form understands what  
is involved in the study and voluntarily agrees to participate.

Signature of Investigator or Designee  
\_\_\_\_ Date \_\_\_\_\_

**THE INFORMATION SHEET MUST BE ATTACHED  
TO THIS CONSENT FORM AND A COPY GIVEN TO  
THE RESEARCH SUBJECT**

## RESULTS

Interestingly, pre-op results versus post-op results were very similar and were therefore reported together as results in this study.

What are Cataracts? (n=80,97.56%)

|                           |             |
|---------------------------|-------------|
| <i>Lens</i>               | 51 (63.75%) |
| <i>Cornea</i>             | 6 (7.50%)   |
| <i>Sclera/Conjunctiva</i> | 2 (2.50%)   |
| <i>Retina</i>             | 2 (2.50%)   |
| <i>I Don't Know</i>       | 20 (25.00%) |

What are cataracts? (n=70, 85.37%)

|              |             |
|--------------|-------------|
| Specific     | 27 (38.57%) |
| Vague        | 7 (10.00%)  |
| Possible     | 5 (7.14%)   |
| Wrong        | 13 (18.57%) |
| I Don't Know | 18 (25.71%) |

Specific: opacity of lens, film on lens, cloudy lens  
Vague: blurred vision, blocks eyesight, opaque tissue  
Possible: build up of medication, lens damage, build up of membrane on lens

|                                  |             |             |           |             |
|----------------------------------|-------------|-------------|-----------|-------------|
| Will drops be used?              | 75 (91.46%) | 72 (96.00%) | 0 (0.00%) | 3 (4.00%)   |
| Will a needle be used?           | 57 (69.51%) | 28 (49.12%) | 0 (0.00%) | 29 (50.88%) |
| Will it be a general anesthetic? | 59 (71.95%) | 10 (16.95%) | 0 (0.00%) | 49 (83.05%) |
| Pain Control used?               | 64 (78.05%) | 48 (75.00%) | 0 (0.00%) | 16 (25.00%) |

Wrong: tissue on eye, growth on eye, floater

|                     | Respondents | Yes         | Maybe     | No          |
|---------------------|-------------|-------------|-----------|-------------|
| Laser used?         | 61 (74.39%) | 19 (31.15%) | 0 (0.00%) | 42 (68.85%) |
| Blade used?         | 53 (64.63%) | 30 (56.69%) | 0 (0.00%) | 5 (8.06%)   |
| Anything taken out? | 62 (75.61%) | 57 (91.94%) | 0 (0.00%) | 5 (8.06%)   |
| Anything put in?    | 67 (81.71%) | 61 (91.04%) | 0 (0.00%) | 6 (8.96%)   |

|                  | Respondents | Yes        | Maybe     | No          |
|------------------|-------------|------------|-----------|-------------|
| Is it risk free? | 75 (91.46%) | 8 (10.67%) | 0 (0.00%) | 67 (89.33%) |

|                                     |             |             |             |             |
|-------------------------------------|-------------|-------------|-------------|-------------|
| Will you need glasses for distance? | 75 (91.46%) | 27 (36.00%) | 26 (34.67%) | 22 (29.33%) |
| Will you need glasses for reading?  | 73 (89.02%) | 44 (60.27%) | 20 (27.40%) | 9 (12.33%)  |
| Were risks discussed?               | 70 (85.37%) | 52 (74.29%) | 0 (0.00%)   | 18 (25.71%) |

Surgical Time Respondents Mean (min) Std Dev (min)

|             |                              |      |
|-------------|------------------------------|------|
| 66 (80.49%) | 19.621 (range 10-60 minutes) | 10.6 |
|-------------|------------------------------|------|

## DISCUSSION:

What is the key to consent?  
Does the patient need to understand everything?  
How much is enough?  
What about patient retention?  
This study mainly looked at patient's information retention and recall under stressful circumstances

The results:

Of 76 (92.68%) respondents, 59 (77.63%) felt that they understood cataracts. Seventeen (22.37%) felt that they did not.  
Regarding understanding surgery, of 70 (85.37%) respondents, 57 (81.43%) felt that they did, 13 (18.57%) felt they did not. Seventy-two (87.80%) responded to understanding the risks, 60 (83.33%) believed that they understood the risks, 12 (16.67%) believed they did not.

The patients themselves as a majority feel that they understand and are content with their knowledge.

### CONCLUSION:

Patient's ability to recall information provided during the informed consent process is not as optimal, or at least not what I expected we would find for results in our ophthalmology department/operating room. Clinicians have serious doubts about how much patients understand of what they are told, no matter how carefully this has been done [5].

Ways that we can improve these results in further research would be to have consistent handouts from all surgeon's, videos, surgical consent personnel, and for some, translators. Also the delivery of information 6 months in advance does have a factor in the recall. The recall of information deteriorates from the time it is provided [6].

Since this is a pilot study, we will look to increase surgeon numbers and patient respondents. Follow up studies looking at patient retention vs. patient initial understanding, may improve patient responses.

### REFERENCES

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