mittent (see table III). We need more information on symptom details.

Report bias must also be considered. Most women have headache at some time. We asked about "frequent headaches," but after a dural tap a woman's perception of the term might be influenced by events in the puerperium, particularly if she had experienced or been warned about the possibility of headache. Thus infrequent and mild headache might be overreported by this group. Response bias is also relevant. Although our estimated 78% response rate was high, non-respondents were likely to include more of the women who had dural taps without subsequent problems. All forms of bias demand further investigation before causal inferences can be drawn.

Mechanisms to account for prolonged headache have been considered for spinal anaesthesia. Vandam and Dripps investigated long term symptoms after 10 098 spinal anaesthetics and suggested that vascular changes may occur or that the headache, after being initiated by cerebrospinal fluid drainage, might be perpetuated by the stress of everyday life.[16] Abouleish suggested that the dural tear might not repair adequately, with a resulting fistula and possible continuous leakage of cerebrospinal fluid, complicated subsequently by psychological, vascular, and muscular factors.[17] The larger gauge needles used for epidural as compared with spinal anaesthesia might mean that inadequate or delayed repair is more likely.

Prolonged headache after accidental dural puncture was initially considered extremely unlikely.[1,8] More recent case reports suggest that they might occasionally occur.[12] Our study suggests that long term symptoms occur more often than this. The limited data on characteristics of the symptoms and the reliance on lengthy recall in our study demand an extremely cautious consideration of a possible causal relation but make it very clear that the topic requires further investigation.

Dr J Selwyn Crawford helped in initiating this research up to his death in August 1988. Thanks are due to the women who participated. The work was financed by a grant from the Department of Health. A copy of the questionnaire used in the survey may be obtained from CM.

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# Factors affecting quality of informed consent

Christine Lavelle-Jones, Derek J Byrne, Peter Rice, Alfred Cuschieri

**Abstract**

***Objective*—To examine the factors influencing quality of informed consent.**

***Design*—Prospective study comprising interviews with patients and patients' completing standard questionnaires.**

***Setting*—Academic surgical unit of large teaching hospital.**

***Patients*—265 patients undergoing intrathoracic, intraperitoneal, and vascular surgical procedures. Of these patients, 192 have been followed up for six months.**

***Main outcome measures*—Patients' recall of information at various points in the study; this score was compared by age, provision of written information, cognitive function, intelligence quotient (IQ), mood state and personality traits, and health locus of control.**

***Results*—The patients were best informed immediately after signing the consent form and from then on recall of information deteriorated. A total of 172/250 (69%) patients admitted to not reading the consent form before signing it. Old age adversely affected recall of information at all assessment points. Impaired cognitive function reduced information recall only during the stay in hospital. Patients with above average IQs handled information better than those with a lower IQ except immediately after the signing of consent forms. Patients with an internal locus of health control (that is, those who believed their health to be in their own control) were better informed than those with an external locus of health control. Operation information cards improved recall only on the day of discharge.**

***Conclusion*—Elderly patients and patients with below average IQ, impaired cognitive functions, and an external locus of control have poor information recall. Written information may be more useful if given before admission to hospital.**

**Departments of Surgery and Psychiatry, Ninewells Hospital and Medical School, University of Dundee, Dundee DD1 9SY**
Christine Lavelle-Jones, *research assistant, department of surgery*
Derek J Byrne, *senior surgical registrar*
Peter Rice, *consultant psychiatrist*
Alfred Cuschieri, *professor of surgery*

Correspondence to:
Professor Cuschieri.

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## Introduction

Informed consent is a legal requirement for all surgical procedures. Despite this a substantial number of patients are unaware of important details concerning their surgery.[1,2] A few studies have reported on the effect of written as opposed to oral information on the quality of informed consent,[2,3] but no investigation has assessed the relation of characteristics of individual patients to the appreciation and recall of specific information relating to treatment. Effective strategies to improve this may need to be different in various groups as understanding and recall of medical information may be influenced by age, intelligence quotient (IQ), cognitive function, and factors in the patient's mood or personality. We studied prospectively the effect of these variables on recall of medical informa-

tion by patients before and after elective surgical treatment and assessed the value of reinforcement of verbal communication by information cards.

## Patients and methods

### INTAKE AND RANDOMISATION

Patients were entered into the study from the waiting lists of the three surgical consultants within one academic surgical unit. Patients undergoing intrathoracic, intraperitoneal, and arterial procedures were included, but those whose intended operations would have resulted in an obvious visible external change were excluded—for example, mastectomy, repair of inguinal hernia, ligation of varicose veins, removal of subcutaneous and cutaneous lesions, etc. All patients received the same verbal communication throughout their stay in hospital but half were also provided with operation information cards (see below) on a random basis. The randomisation was performed after entry into the study.

### PROTOCOL

The same sequence of events was conducted for each patient (box). The various psychological and psychometric tests were conducted by a research worker (CL-J) independent of the surgical team. The house officer then clerked the patient. When this was completed the house officer explained various details of the surgical treatment to the patient, including the aim of the operation, operative surgical details, postoperative care (referring to pain control, drains, intravenous lines, nasogastric tubes, etc), and the patient's recovery after surgery. Common complications were discussed.

The house officer then asked the patient if any points could be clarified or questions answered. It was important for the purposes of the study that the oral information given by the house officer was the same as that on the written operation information card. These interviews were taped with the full knowledge of both patients and house officers to ensure that the oral information on which patients' recall would later be tested was in fact given by the house officer. The house officers' performance was scored out of six based on the operation information cards, thus ensuring that the patients who received only oral information received the necessary factual information contained in these cards. Patients who were randomised to receive an operation information card were given these at this point and were left to read them for 30 minutes. The house officer then returned and dealt with any other questions the patient may have had to ask. The standard consent form was then signed. This informs the patient of the name of the operation to be performed, the fact that an appropriate anaesthetic will be administered, that no particular surgeon will perform the surgery, and that any other procedure deemed absolutely necessary during the course of the operation will be performed.

An explanation of the operation would previously have been given to the patient in the outpatient department before admission to hospital. On the evening before surgery the consultant or senior registrar visited the patient and further explained the operation and dealt with any of the patient's questions.

The second assessment of the patient's knowledge was conducted by the research assistant within one hour of signing of the consent form. Contact with the patient was maintained throughout the stay in hospital, and the third assessment was carried out on the day of discharge. The median length of stay was five days with a range of 1-92 days.

On the days of admission and discharge a note was made of any drugs which may have altered comprehension and recall of information. Admission to the intensive care unit was recorded for the same reason.

Patients were seen at the outpatient clinic at 4 to 6 weeks after discharge from hospital, when the fourth assessment interview was conducted. Patients who failed to turn up for their appointment were sent a letter with a questionnaire to assess their recall of information. The final assessment was conducted six months later by a postal questionnaire.

**Protocol of study**

- Admission interview: first assessment of patient's knowledge
- Questionnaire testing: research worker
- Clerking and detailed explanation by house officer
- Random allocation of operation information cards
- Signing of consent form
- Second assessment of patient's knowledge: within 1 hour of signing consent form
- Third assessment of patient's knowledge: day of discharge from hospital
- Fourth assessment of patient's knowledge: 4-6 weeks after discharge
- Final assessment of patient's knowledge at 6 months after discharge.

### PSYCHOMETRIC TESTING

Psychometric testing was conducted using four well validated systems.

*The mini-mental state assessment* assesses orientation, registration, attention and calculation, recall, language, conscious level, reading, writing, and spatial appreciation. It provides a score indicating overall cognitive function. A score of below 20 is found only in those patients with a considerable degree of clinical cognitive impairment, and so for the study patients with a score of less than 20 were regarded as having poor cognitive function.

*The Schonell graded word reading test* examines the ability of patients to pronounce a series of words. It has been shown to have good correlation with more sophisticated types of measurement of IQ. The use of a verbally based test was felt to be particularly relevant for the purposes of this study. A score of over 100 represents an above average IQ and one of 100 or below represents a below average IQ.

*The Crown-Crisp experiential index* is a self administered questionnaire which provides ratings on several mood and personality traits. These were trait anxiety, state (phobic) anxiety, obsessionality, somatisation (hypochondriasis), depression, and histrionic (hysterical) personality traits. For the different traits recognised cut off values were used to separate normal from abnormal. These values correspond to the mean scores of a group of general hospital outpatients: for free floating anxiety 3 in men and 5 in women, for phobic anxiety 3 and 5 respectively, for obsessionality 7 in both sexes, for somatic concomitants of anxiety 4 and 6 respectively, for depression 3 and 4; for hysterical anxiety 3 in both sexes.

*The health locus of control scale* is a scale which measures the extent to which individuals believe they have control over events in their lives with particular reference to health matters. Individuals who think that they have a high level of control over their health are described as having an internal locus of control (score $\leq 38$). Those who believe they have little or no control over their health are described as having an external locus of control (score $> 38$).

**Operation information card**

**Cholecystectomy**

Below is some information about your operation

**PLEASE READ CAREFULLY**

(1) Your gall bladder is diseased.

(2) There are gall stones in your gall bladder.

(3) Your gall bladder and the gall stones will be removed during the operation. This is performed by the keyhole technique in most patients (95%) but some people have to have their tummy opened for technical reasons (5%).

(4) You will have a full general anaesthetic for the operation, which means you will be asleep for the surgery.

(5) You will be in hospital for 2-10 days after the operation, depending on how the operation was performed and whether any gall stones were found outside the gall bladder in the main liver tubes.

(6) Depending on how the operation was performed and the amount of physical activity associated with your employment, life style, etc, you will take from two weeks to three months to get back to your normal routine.

### OPERATION INFORMATION CARDS

Operation information cards related to specific diseases were designed to contain three items of information relating to the nature of the operation and three items on recovery, side effects, and after treatment. An example is shown in the box. The information related to the procedure consisted of simple statements on organ to be operated on (for example, the operation is carried out on the large bowel); the nature of the intended procedure on that organ (for example, the diseased part of the large bowel is removed and the bowel joined up again); and the reason for the surgery (for example, to relieve the symptoms and prevent the disease in the bowel progressing). The information related to treatment outlined specific details on recovery, side effects, and follow up (for example, some diarrhoea when your bowels move after the operation; your bowels should return to normal within a couple of weeks; you will be in hospital for about seven to 10 days after your surgery).

### ASSESSMENT OF PATIENT'S KNOWLEDGE

The same six items of information formed the basis on which the patient's knowledge concerning his or her treatment was assessed on a range of 0 to 6. Patients who scored 1-3 points were deemed poorly informed whereas those who scored 4-6 points were considered to be well informed. All the assessments except for the final one at six months were conducted on the basis of an interview between the patient and the research assistant (CL-J).

### STATISTICAL ANALYSIS

Statistical comparisons of the various groups concerning the amount of information recalled were carried out with the Mann-Whitney U test and $\chi^2$ test as appropriate.

## Results

To date 265 patients (100 men and 165 women) have been recruited, with 192 completing the study, having been followed up for six months. The median (range) age was 61 (21-87) years. Operation information cards were allocated to 130 patients, the other 135 patients receiving only oral information. The junior house officers scored highly on their oral communication skills. Two hundred and forty one interviews were awarded six points by the research team—that is, full marks—10 five points, and one each four and three points. (No data were available on the 13 other interviews.)

### SEQUENTIAL RECALL, STAFF PERFORMANCE, AND EFFECT OF AGE, IQ, AND COGNITIVE FUNCTION

For the entire cohort studied the information recall was best immediately after the consent form was signed. It remained significantly better than the recall on admission on the day of discharge ($p=0{\cdot}0001$; $\chi^2$ test) but had deteriorated to that on admission at four to six weeks after discharge and was significantly worse ($p=0{\cdot}001$; $\chi^2$ test) at six months (table I).

Patients stated that junior medical staff gave them most of the information they had acquired during their stay in hospital. The next best were the consultants followed by the nursing staff. The proportion of each category of staff regarded by the patients as sources of information varied with the time this question was asked during the patient's hospital stay but the order remained the same (table II).

At all stages of the study patients over 60 years of age had less recall than younger patients (table III). No significant relation between IQ and age was found but cognitive function was significantly inferior ($p=0{\cdot}001$; $\chi^2$ test) in patients over 60 years compared with younger patients. Fewer patients over 60 years read the consent form ($p=0{\cdot}02$; $\chi^2$ test). The 78 patients who actually read the consent form, however, were not significantly better informed than the 172 who failed to do so.

Patients who scored highly in the mini-mental state assessment were better informed immediately after signing the form and on the day of discharge than were patients who scored poorly (table IV). At other times cognitive function did not seem to be a significant factor in recall of information. Patients with an above

TABLE I—*Recall of information by patients at various assessment points before and after surgery. Values are numbers (percentages) of patients*

| Assessment point | Poorly informed (score 0-3) | Well informed (score 4-6) |
|---|---|---|
| Admission (n=256) | 153 (60) | 103 (40) |
| Immediately after consent (n=253) | 49 (19) | 204 (81) |
| Day of discharge (n=242) | 102 (42) | 140 (58) |
| Outpatient review at 4-6 weeks (n=223) | 133 (60) | 90 (40) |
| At 6 months after discharge (n=192) | 161 (84) | 31 (16) |

TABLE II—*Best sources of information according to patients admitted to hospital for surgery. Values are numbers (percentages) of patients*

| Source of information | Timing of question: Immediately after consent signed (n=253) | Timing of question: On day of discharge (n=242) |
|---|---|---|
| Junior doctors | 126 (50) | 77 (32) |
| Consultants | 51 (20) | 65 (27) |
| Nursing staff | 15 (6) | 27 (11) |
| Everybody | 8 (3) | 44 (18) |
| Other* | 53 (21) | 29 (12) |

*Includes videos, friends, spouses, and newspapers.

TABLE III—*Effect of age (in years) on recall of information at various times before and after surgery*

| Assessment point | Median (range) information score: Age >60 years | Age ≤60 years | p Value* |
|---|---|---|---|
| Admission | 3 (1-6) (n=131) | 4 (1-6) (n=125) | <0·00001 |
| Immediately after consent | 4 (2-6) (n=130) | 5 (2-6) (n=123) | <0·00001 |
| Day of discharge | 3 (1-6) (n=122) | 4 (2-6) (n=120) | <0·00001 |
| Outpatient review at 4-6 weeks | 3 (1-6) (n=117) | 4 (2-6) (n=106) | <0·00001 |
| At 6 months after discharge | 3 (1-4) (n=95) | 3 (1-6) (n=97) | 0·0011 |

*Mann-Whitney U test.

average IQ scored better on testing of information recall at all assessment points except immediately after signing the consent form compared with those with a below average IQ (table V).

EFFECT OF OPERATION INFORMATION CARDS

As no information card had been given to patients at the assessment on admission the lack of a significant difference at this point reflects equivalence of the groups (table VI). The patients who received written information were no better informed one hour after signing the consent form than the group who received only oral information, but those who received written information had higher information scores on the day of discharge (table VI). The operation information cards did not influence the recall of medical information at the assessment after discharge (table VI). The effect of age on the response to written information was examined. On the day of discharge younger patients ($\leq 60$ years) who had received an operation information card had significantly better recall ($p=0{\cdot}003$; $\chi^2$ test) than patients of a similar age who did not receive a card. By contrast in older patients ($>60$ years) there was no significant difference between the two groups. At the other assessment points age did not alter the response to written information.

Differences in IQ did not have much bearing on the effect of written information but there was a significantly better recall of information on the day of discharge in patients who received the operation information card and had an IQ $>100$ compared with those with a similar IQ randomised to receiving no card ($p=0{\cdot}02$; $\chi^2$ test).

The relation between cognitive function and the impact of written as opposed to only oral information was also assessed. The only significant difference ($p=0{\cdot}02$; $\chi^2$ test) observed was on the day of discharge, when patients who scored well in testing of cognitive function and had received an operation information card scored better in recall testing than those without written information who had scored equally well on cognitive function testing. Written information did not make any difference to patients with poor cognitive function.

TABLE IV—*Effect of cognitive function on recall of information at various times before and after surgery*

| Assessment point | Median (range) information score* | | p Value† |
|---|---|---|---|
| | ≤20 | >20 | |
| Admission | 3 (1-6) (n=63) | 3 (1-6) (n=193) | 0·28 |
| Immediately after consent | 4 (2-6) (n=62) | 4 (3-6) (n=191) | 0·04 |
| Day of discharge | 4 (1-6) (n=56) | 4 (2-6) (n=186) | 0·04 |
| Outpatient review at 4-6 weeks | 3 (2-6) (n=38) | 3 (1-6) (n=185) | 0·18 |
| At 6 months after discharge | 3 (2-4) (n=41) | 3 (1-6) (n=151) | 0·14 |

*Score on mini-mental state examination; ≤20 indicates improved cognitive function.
†Mann-Whitney U test.

TABLE V—*Effect of intelligence quotient on recall of information at various times before and after surgery*

| Assessment point | Median (range) information score* | | p Value† |
|---|---|---|---|
| | ≤100 | >100 | |
| Admission | 2 (1-6) (n=56) | 3 (1-6) (n=197) | 0·0001 |
| Immediately after consent | 4 (2-6) (n=55) | 4 (2-6) (n=197) | 0·30 |
| Day of discharge | 3 (1-6) (n=52) | 4 (1-6) (n=189) | 0·03 |
| Outpatient review at 4-6 weeks | 3 (1-5) (n=45) | 3 (2-6) (n=177) | 0·04 |
| At 6 months after discharge | 3 (1-5) (n=34) | 3 (2-6) (n=158) | 0·015 |

*Schonell graded word reading test; ≤100 represents below average IQ.
†Mann-Whitney U test.

TABLE VI—*Effect of operation information card on recall of information at various times before and after surgery*

| Assessment point | Median (range) information score | | p Value* |
|---|---|---|---|
| | Card given | No card given | |
| Admission | 3 (1-6) (n=127) | 3 (1-6) (n=129) | 0·75 |
| Immediately after consent | 4 (2-6) (n=126) | 4 (2-6) (n=127) | 0·68 |
| Day of discharge | 4 (2-6) (n=121) | 3 (1-6) (n=121) | 0·015 |
| Outpatient review at 4-6 weeks | 3 (2-6) (n=112) | 3 (1-6) (n=111) | 0·55 |
| At 6 months after discharge | 3 (2-5) (n=98) | 3 (1-6) (n=94) | 0·63 |

*Mann-Whitney U test.

EFFECT OF MOOD STATE AND PERSONALITY TRAITS

Histrionic personality traits and obsessionality did not affect recall at any point in the study. Patients with trait anxiety and state (phobic) anxiety had less recall on admission (table VII). Those with depression had inferior recall on admission, on the day of discharge, and six months later. Patients with high somatisation scores had poorer recall at all assessment points except at the postoperative check at six months.

Patients with an internal locus of control (who believe they have a large measure of control over their own health) had superior recall of information on discharge from hospital and at the reviews at six weeks and six months (table VIII).

EFFECT OF DRUGS AND SURGERY

The drugs that were considered to have a possible effect on comprehension and recall consisted mainly of codeine compound analgesics and hypnotics, although single patients were taking barbiturates, chlorpromazine, mianserin, triazolam, amitryptyline, and buprenorphine. On the day of admission 205 patients were taking no such drugs, 48 patients one such drug, and three patients two such drugs. On the day of discharge 113 patients were taking no such drugs, 111 patients one such drug, 17 patients two such drugs, and one patient three such drugs. At both admission and discharge there was no significant difference in the amount of information recalled between the group who had taken no drugs and those who had taken the drugs mentioned above.

As no minor operations were included in the study no analysis of the effect of major surgery on comprehension can be made. Thirty five patients were treated in the intensive care unit postoperatively, possibly indicating, among other things, a more major procedure, but this number was too small for analysis.

## Discussion

About half of inpatients awaiting investigation or treatment, or both, are unhappy with the amount of information received.[4] Only some patients (14% to 66%) are able to recall basic details of their surgery.[1,2,5,6] Previous studies have sampled patients' recollection of medical information on one occasion only.[1,2,5,6] In our study recall was tested at sequential intervals. The patients were best informed immediately after they signed the consent form, and from then on their recall deteriorated with time to reach the lowest level at the review at six months. The decay in information retention with time may be of interest in litigation when patients are expected to recall information they received concerning an operation many months previously.

The house officers were perceived by the patients as being the most effective in imparting information relating to surgical treatment. This agrees with a previous report[7] and was most evident immediately after signing the consent form, a task supervised by the house officers during this study in accordance with the routine practice in this surgical unit. The low rating of the nursing staff in information dissemination, as perceived by the patients, was surprising. Immediately after the consent form was signed 21% of patients

TABLE VII—*Effect of mood state and personality traits* on recall of information at various times before and after surgery (significant results underlined)*

| Assessment point | Trait anxiety | | | Depression | | | Histrionic (hysterical) | | | Obsessionality | | | Phobic anxiety | | | Somatisation | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | >4 | ≤4 | p Value | ≥4 | <4 | p Value | ≥3 | <3 | p Value | ≥7 | <7 | p Value | >4 | ≤4 | p Value | ≥5 | <5 | p Value |
| Admission | 3 (1-6) (n=122) | 3 (1-6) (n=134) | 0·026 | 3 (1-6) (n=173) | 3 (1-6) (n=83) | 0·0002 | 3 (1-6) (n=99) | 3 (1-6) (n=157) | 0·24 | 3 (1-6) (n=143) | 3 (1-6) (n=113) | 0·50 | 3 (1-6) (n=118) | 3 (1-6) (n=138) | 0·05 | 3 (1-6) (n=201) | 4 (1-6) (n=55) | 0·00001 |
| Immediately after consent | 4 (2-6) (n=122) | 4 (2-6) (n=131) | 0·67 | 4 (2-6) (n=173) | 4 (3-6) (n=80) | 0·71 | 4 (2-6) (n=99) | 4 (2-6) (n=154) | 0·63 | 4 (2-6) (n=143) | 4 (2-6) (n=110) | 0·69 | 4 (2-6) (n=118) | 4 (2-6) (n=135) | 0·70 | 4 (2-6) (n=200) | 5 (2-6) (n=53) | 0·005 |
| Day of discharge | 4 (2-6) (n=119) | 4 (2-6) (n=123) | 0·74 | 4 (1-6) (n=165) | 4 (3-6) (n=77) | 0·0024 | 4 (1-6) (n=93) | 4 (1-6) (n=149) | 0·31 | 4 (1-6) (n=141) | 4 (1-6) (n=101) | 0·81 | 4 (1-6) (n=113) | 4 (1-6) (n=129) | 0·43 | 4 (1-6) (n=189) | 4 (2-6) (n=53) | 0·01 |
| Outpatient review at 4-6 weeks | 3 (2-6) (n=111) | 3 (1-6) (n=112) | 0·08 | 3 (1-6) (n=152) | 3 (2-6) (n=71) | 0·07 | 3 (2-6) (n=84) | 3 (1-6) (n=139) | 0·15 | 3 (2-6) (n=130) | 3 (1-6) (n=93) | 0·91 | 3 (2-6) (n=102) | 3 (1-6) (n=121) | 0·70 | 3 (1-6) (n=175) | 4 (2-6) (n=48) | 0·04 |
| At 6 months after discharge | 3 (1-5) (n=98) | 3 (1-6) (n=94) | 0·74 | 3 (1-5) (n=131) | 3 (2-6) (n=61) | 0·0008 | 3 (1-6) (n=75) | 3 (1-5) (n=117) | 0.14 | 3 (1-5) (n=114) | 3 (1-6) (n=78) | 0·66 | 3 (1-5) (n=84) | 3 (1-6) (n=108) | 0·85 | 3 (1-5) (n=149) | 3 (2-6) (n=43) | 0·24 |

*Crown-Crisp experiential index. Scores above cut off value (anxiety traits) or equal to and above cut off value (the others) indicate that the trait or state is present.

TABLE VIII—*Effect of health locus of control on recall of information at various times before and after surgery*

| Assessment point | Median (range) information score* | | p Value† |
|---|---|---|---|
| | ≥38 | <38 | |
| Admission | 3 (1-6) (n=160) | 3 (1-6) (n=96) | 0·11 |
| Immediately after consent | 4 (2-6) (n=159) | 4 (2-6) (n=94) | 0·65 |
| Day of discharge | 4 (1-6) (n=153) | 4 (1-6) (n=89) | 0·018 |
| Outpatient review at 4-6 weeks | 3 (2-6) (n=142) | 3 (1-6) (n=81) | 0·04 |
| At 6 months after discharge | 3 (1-4) (n=120) | 3 (1-6) (n=72) | 0·05 |

*Score of ≥38 indicates patients who believe they have little or no control over their health; score of <38 indicates high level of control.
†Mann-Whitney U test.

considered that most information they possessed on their surgical treatment had been obtained from sources other than the hospital. This worrying finding requires further evaluation.

Age was the only variable measured in the study which significantly affected recall at all assessment points. This effect has been documented previously.[1] There was no significant relation between age and IQ, and though cognitive function was significantly and inversely related to age, it was not consistently related to recall of information. Therefore age seems to be an independent factor.

Another concern from a medicolegal viewpoint is that 69% of patients admitted to not reading the consent form before signing it. This agrees with the results of a previous study, which reported that 60% of patients had not read the consent form "carefully."[5] Age was one factor responsible for this but some blame must fall on the medical staff for not emphasising the importance of reading the consent form. There are patients, however, who are averse to detailed knowledge of their disease and its treatment. In these patients undue insistence by medical staff that the consent form should be read may generate anxiety and distress. In fact the patients who read the consent form (and presumably were generally more concerned about their treatment) recalled no more information than patients who did not.

Patients with impaired cognitive function showed impaired ability to retain and recall information while in hospital, but this did not persist after discharge. This may be due to the effects of physical illness on cognitive function, which subsequently improves in parallel with clinical progress. Patients with borderline cognitive function show better memory function in their own homes than in unfamiliar surroundings such as hospital wards.

As expected, patients with above average IQs handled information better than those with a lower mental ability at all assessment points except immediately after the signing of consent forms. Patients with below average IQs did not benefit from written information.

Patients who received an operation information card were significantly better informed only on the day of discharge but seemed to have no advantage immediately after the consent form was signed. Possible reasons for this include failure to read the operation information card or excessive concern about their operation such that retention of the information is impaired.

The optimal time for patients to receive operation information cards is before admission, either when the patient is put on the waiting list or one week before treatment. In a previous report 86% of patients who were issued with an information sheet two weeks before admission were found to be well informed of the basic details of their surgery compared with 55% with no written information.[2] The information sheets used in this study,[2] though simple, were longer than the operation information card used in our investigation. The formulation of written information should assume that a considerable number of patients will have an IQ below average or impaired cognitive function. An information leaflet that is too complicated or one that uses technical or scientific language will not achieve the desired effect.[8]

Histrionic personality traits and obsessionality did not affect recall at any stage of the study, whereas patients with high somatisation scores had poor recall of information at all assessment points except at the follow up at six months. Patients with trait anxiety and depression were poorly informed on admission but the clerking process and the verbal communication on the nature of the intended surgery by house officers reassured these patients so that immediately after the consent form was signed they were as well informed as the rest of the study group.

The assessment of health locus of control showed that patients who thought that they had control over their health were better informed than those who thought external forces shaped their destiny. The observation that the latter group of patients seemed uninterested in the details of their surgery is a factor that may influence recovery from surgery. Thus, as well as targeting these patients for extra effort in communication, special measures may be needed to optimise their recovery.

The use of drugs did not affect recall on admission, after signing the consent forms, and on the day of discharge. We could not examine the effect of the magnitude of surgery on the patients' recall of information because no minor operations were included in the study.

We have identified certain groups of patients that are likely to receive, process, and recall information relating to their surgery poorly. They include elderly people, patients with a low IQ, those with impaired cognitive functions, and those with an external health locus of control. Written information is helpful but probably should be given to patients before admission to hospital. Handouts and leaflets for patients must be carefully worded to maximise comprehension and recall.

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# Prolonged infection with hepatitis B virus and association between low blood cholesterol concentration and liver cancer

Zhengming Chen, Anthony Keech, Rory Collins, Brenda Slavin, Junshi Chen, T Colin Campbell, Richard Peto

## Abstract

***Objective*—To determine whether prolonged infection with hepatitis B virus is associated with a lower blood cholesterol concentration.**

***Design*—Cross sectional study.**

***Setting*—81 villages in rural China with a high prevalence of chronic infection with hepatitis B virus.**

***Subjects*—1556 apparently healthy men aged 35-64 years, randomly selected.**

***Main outcome measures*—Hepatitis B virus carrier state; plasma concentrations of cholesterol, apolipoprotein B, and apolipoprotein A I.**

***Results*—238 (15%) of the men were positive for hepatitis B surface antigen, indicating that they were chronic carriers. Plasma concentration of cholesterol was 4·2% (0·11 mmol/l) lower among carriers (that is, positive for hepatitis B surface antigen) than among non-carriers (95% confidence inverval 0·6% to 8·0% (0·01 to 0·21 mmol/l), $p < 0·05$), and apolipoprotein B concentration was 7·0% (0·036 g/l) lower (2·8% to 11·2% (0·014 to 0·058 g/l), $p < 0·001$). In contrast, no association was observed between plasma concentrations of cholesterol or apolipoprotein and hepatitis B that had been eradicated (that is, patient positive for hepatitis B core antibody but negative for hepatitis B surface antigen).**

***Conclusions*—Chronic hepatitis B virus infection, which usually starts in early childhood in China, seems to lead not only to a greatly increased risk of death from liver disease but also to a somewhat lower cholesterol concentration in adulthood. This common cause produces an inverse association between cholesterol concentration and risk of death from liver cancer or from other chronic liver diseases.**

**Imperial Cancer Research Fund and Medical Research Council Clinical Trial Service Unit, Nuffield Department of Clinical Medicine, University of Oxford, Radcliffe Infirmary, Oxford OX2 6HE**
Zhengming Chen, *research officer*
Anthony Keech, *research officer*
Rory Collins, *British heart foundation senior research fellow*
Richard Peto, *Imperial Cancer Research Fund professor in epidemiology and medical statistics*

**Department of Endocrinology and Chemical Pathology, United Medical and Dental School of Guy's and St Thomas's Hospitals, London**
Brenda Slavin, *senior lecturer*

**Institute of Nutrition and Food Hygiene, Chinese Academy of Preventive Medicine, Beijing, People's Republic of China**
Junshi Chen, *professor in nutrition*

**Division of Nutritional Sciences, Cornell University, Ithaca, New York 14853, United States**
Colin Campbell, *professor in nutritional biochemistry*

Correspondence to:
Dr Zhengming Chen.

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## Introduction

Several prospective epidemiological studies, set up mainly to examine the association of baseline blood concentration of cholesterol with subsequent rates of coronary heart disease, have also examined its association with subsequent rates of cancer.[1-14] Most[1-12] but not all[13 14] have found an inverse relation between cholesterol concentration and the subsequent risk of cancer. This seems to be due, at least in part, to a lowering effect of preclinical cancer on cholesterol concentration,[2-5 11] but other factors may also contribute to the inverse association.[15 16]

In China there are particularly high death rates from diseases of the liver. A prospective observational study in a Chinese population[12] (in which the mean cholesterol concentration is unusually low by Western standards) found a significant inverse association between blood concentration of cholesterol and subsequent mortality from non-malignant liver disease or from liver cancer, although not from other types of cancer. More recently a significant excess risk of death from liver cancer and chronic liver disease has been reported among North Americans with a low blood cholesterol concentration.[16] In China most deaths from liver disease are due to chronic infection with the hepatitis B virus.[17 18] We investigated the association between low blood cholesterol concentration and liver disease[12 16] by studying blood lipid concentrations among middle aged men in rural China, of whom about 15% were known to be carriers of the hepatitis B virus.[19]

## Subjects and methods

### BLOOD SAMPLES

A large geographical correlation survey in rural China was conducted between September and December 1983.[19] Sixty five counties throughout China were selected for the survey on the basis of wide variations in the 1973-5 death rates from seven major types of cancer (including liver cancer).[20] Two rural villages in different communes within each county were randomly selected, and a random sample stratified for age, consisting of about 25 apparently healthy men and 25 women (aged 35-64 years) from each village, was studied.

A sample of fasting venous blood (10 ml) was collected from each subject into a vacutainer. On the day of collection all blood samples were centrifuged in the local field survey centres to separate plasma from red blood cells, and 4 ml of plasma containing 20 mg sodium ascorbate was stored at −20°C. After several weeks the frozen samples were transferred to the study centre in Beijing, where they were aliquoted and stored at −30°C for subsequent analysis for, among other things, hepatitis B surface antigen and hepatitis B core antibody. Aliquots from 1882 men from 46 of the 65 counties (81 of the 130 communes) were transported by air on dry ice to Oxford in 1989 for analysis of *Helicobacter pylori* antibody[21] and subsequently stored at −80°C. Hence, before thawing out for the present analyses the samples had undergone two cycles of freezing and thawing.

### ASSAY OF HEPATITIS B VIRUS AND LIPID IN PLASMA

The presence of hepatitis B surface antigen was determined by a standard radioimmunoassay,[22] and hepatitis B core antibody was determined by enzyme linked immunosorbent assay (ELISA)[23] for 1564 of the 1882 men whose samples were stored in Oxford. For