ABSTRACT

Purpose. To evaluate understanding of the fundamental concepts of informed consent by the public and patients.

Methods. Questionnaires were distributed to any persons (aged more than 16 years) attending the Palmerston North Hospital (excluding in-patients). The first 1000 completed questionnaires were analysed using the Chi squared test.

Results. The fundamental concepts of informed consent were not appreciated by most respondents; only 18%, 13%, and 5% of them agreed with its implications in terms of self-autonomy, confidentiality, and battery, respectively. 64% of respondents preferred to take sole responsibility to decide which procedure to undergo, 31% preferred to be guided by the surgeon, and 5% by a brief explanation only. 21% of the respondents considered the surgeon liable in the event of an unmentioned rare complication, 43% considered the surgeon not liable, and 34% were undecided.

Conclusion. Understanding of medico-legal implications of informed consent (e.g. self-autonomy, confidentiality, and battery) by the public and patients is poor. Their expectations regarding self-autonomy seem unrealistic. It is time for surgeons, legal experts, and the public to confer and make informed consent a practical, user-friendly tool rather than the legal obstacle that it is today.

Key words: confidentiality; consent forms; informed consent; liability, legal

INTRODUCTION

Informed consent is voluntary authorisation by a patient or research subject, with full comprehension of the risks involved for diagnostic or investigative procedures and for medical and surgical treatment. It acts as a contract between the surgeon and patient, with medico-legal implications.¹ It is formulated after precedents of (1) medical experimentation carried out in the name of science, with no regard to basic human rights;²,³ (2) patients’ requests being ignored.
and insufficient information being given prior to the procedure.²,⁴

Its core value is the right of self-determination, which derives into: informed consent, truth, and confidentiality, which further derive into 2 main medico-legal implications: battery and negligence.⁵ Informed consent is obtained prior to a surgical procedure to safeguard the surgeon from being accused of battery and medical negligence.

Although informed consent is an integral part of medical practice, its role remains controversial.⁶–⁹ Previous studies have looked into what patients want to know about procedures,¹⁰,¹¹ how much information they want to receive,¹²,¹³ the ways of communicating it and helping them to perceive risk,¹⁴ how knowledgeable they are,¹⁵ and how much they retain following informed consent.¹⁶,¹⁷ It is difficult for patients to understand associated risks and complications,¹⁸,¹⁹ and to retain information.²⁰,²¹ The ever increasing number of medical litigations arising from medical practice also aggravate the problem of informed consent. Whenever a case is cited, further dimensions are added and complicate practice.²²–²⁵ We therefore examined public and patient understanding of the fundamental concepts of informed consent.

**MATERIALS AND METHODS**

This study was carried out at the Palmerston North Hospital in New Zealand. The regional ethics committee was consulted and determined that approval was not required. A pilot self-administered questionnaire was distributed to 20 orthopaedic outpatients. Patient feedback was obtained to clarify objectives. The modified questionnaire was distributed to another 20 outpatients and further analysed. The final questionnaire was distributed to 1200 persons in all out-patient clinics excluding the psychiatric clinic. The receptionist in each clinic was instructed to give the questionnaire to every person aged >16 years presenting at the front desk (excluding staff and in-patients). The first 1000 completed questionnaires were analysed using the Chi squared test.

**RESULTS**

1049 questionnaires were returned; 49 of them were discarded, as >4 of the 13 questions or the last 3 questions were unanswered. The 1000 completed questionnaires were from subjects aged 16 to 96 (mean, 51; standard deviation [SD], 17) years, who were categorised into 4 groups spanning 20 years each. Patient demographics are summarised in Table 1. A further 52 questionnaires were received after the study. No attempt was made to track down the missing questionnaires.

In response to a question relating to complications following surgery, 77% of respondents would talk to their surgeon; only 7% would write a complaint and 7% would seek legal advice. This suggests that most respondents had high acceptability of complications (Table 2).

In response to a question relating to the understanding of informed consent, 67% of respondents considered it as permission for various procedures, 47% considered it a means of giving

### Table 1

<table>
<thead>
<tr>
<th>Demographics</th>
<th>No. (%)</th>
</tr>
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<tbody>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>619 (62)</td>
</tr>
<tr>
<td>Female</td>
<td>380 (38)</td>
</tr>
<tr>
<td>Not responded</td>
<td>1 (0.1)</td>
</tr>
<tr>
<td>Purpose of visit</td>
<td></td>
</tr>
<tr>
<td>Attending out-patient clinic</td>
<td>607 (61)</td>
</tr>
<tr>
<td>Accompanying patient</td>
<td>261 (26)</td>
</tr>
<tr>
<td>Visiting patient</td>
<td>26 (3)</td>
</tr>
<tr>
<td>Other</td>
<td>95 (10)</td>
</tr>
<tr>
<td>Not responded</td>
<td>11 (1)</td>
</tr>
<tr>
<td>Occupation</td>
<td></td>
</tr>
<tr>
<td>Not in paid employment</td>
<td>223 (22)</td>
</tr>
<tr>
<td>Salaried worker</td>
<td>393 (39)</td>
</tr>
<tr>
<td>Self-employed</td>
<td>100 (10)</td>
</tr>
<tr>
<td>Retired</td>
<td>281 (28)</td>
</tr>
<tr>
<td>Not responded</td>
<td>3 (0.3)</td>
</tr>
<tr>
<td>Highest achieved education</td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>47 (5)</td>
</tr>
<tr>
<td>Secondary</td>
<td>700 (70)</td>
</tr>
<tr>
<td>University</td>
<td>131 (13)</td>
</tr>
<tr>
<td>Postgraduate or similar</td>
<td>115 (12)</td>
</tr>
<tr>
<td>Not responded</td>
<td>7 (1)</td>
</tr>
</tbody>
</table>

### Table 2

<table>
<thead>
<tr>
<th>Response</th>
<th>No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Talk to your surgeon</td>
<td>771 (77)</td>
</tr>
<tr>
<td>Talk to your family doctor or other health professional</td>
<td>528 (53)</td>
</tr>
<tr>
<td>Talk to family and friends</td>
<td>256 (26)</td>
</tr>
<tr>
<td>Write a complaint</td>
<td>65 (7)</td>
</tr>
<tr>
<td>Seek legal advice</td>
<td>65 (7)</td>
</tr>
</tbody>
</table>
information regarding the operation, and 31% considered it as a legal requirement for doctors carrying out the operation. The fundamental concepts of informed consent were not appreciated by most respondents; only 18%, 13%, and 5% of the respondents agreed with its implications in terms of self-autonomy, confidentiality, and battery, respectively (Table 3).

In response to a question relating to the preferred decision-making process on surgery, 64% preferred to take sole responsibility for deciding which procedure to undergo, 31% preferred to be guided by the surgeon, and 5% preferred a brief explanation only (Table 4). 88% of respondents wanted to know the worst-case scenario (however remote the possibility), 5% did not, and 8% were undecided. 91% were aware of the risk of serious complications, whereas 9% were not.

In response to a hypothetical situation relating to the surgeon liability, 21% considered the surgeon liable, 43% felt not liable, and 34% were undecided (Table 5).

Respondents’ understanding of medical negligence and battery was not significantly correlated to gender (p=0.4), age (p=0.2), occupation (p=0.7), or education (p=0.3). Educated women in younger age-groups preferred to take responsibility of making their own decision on surgery (p<0.001). Women in younger age-groups considered the surgeon liable for any unmentioned complication (p≤0.001). There was no association between the degree of education and perception of the surgeon’s liability (p=0.2). Respondents who were unaware of major risks of complication were more likely to consider the surgeon liable (p=0.001).

**DISCUSSION**

Understanding of medico-legal implications of informed consent (e.g. self-autonomy, confidentiality, and battery) by the public and patients is poor. When patients do not understand what informed consent is about, how valid are any claims they make? For an informed consent to be valid, patients need to understand what it is supposed to achieve. Whose responsibility is it to ensure this? Should patients attend a ‘legal tutorial’ prior to undergoing a surgical procedure?

It was surprising that 64% of the respondents preferred to decide which procedure to undergo...
on their own. Do patients really wish to make such
decisions on their own? Can they realistically achieve
this and how much knowledge would they require?
For a total hip replacement, for example, they
might have to select the type of prosthesis, whether
cemented or uncemented, the type of head, etc. This
seldom occurs in day-to-day practice, as the surgeon
outlines the expected procedure giving its strengths
and weaknesses and then gets the patients’ input. In
such cases, do patients still think that they can decide
on their own? It is their initial perceptions that guide
the subsequent actions.

The response regarding the surgeon’s liability is
disturbing, as it is difficult for patients to remember
what information they have received. It is difficult
to pose a question indicating that the patient has
forgotten what he/she was already told. Patients need
not be able to recall all the facts but should be aware
of the facts at the time of making decisions. As to
whether informed consent is obtained or not remains
dilemma; after all it is the patient’s perception that
matters. If they feel that the doctor has not mentioned
a particularly rare complication, 21% of respondents
considered the doctor liable. If the doctor did mention
it and the patients still underwent surgery, thereby they
accepted the higher risk of common complications.
How does one rationalise the practical importance of
enumerating every single complication? For a risk to
be significant the patient should attach significance to
it. Unfortunately legal proceedings do not elaborate
what exactly this significance means.23,26 88% of
respondents wanted to know the worst-case scenario.
If patients were informed of this routinely, would
consenting for a procedure not indicate acceptance
of this remote possibility (a less serious complication
that may not have been mentioned) or any in-between
eventuality?

Informed consent implies that the patients have
and indeed need all details pertaining to a particular
procedure to make an informed decision. If this
(comprehensive information) is not provided, then
patients cannot truly make a decision on their own, but
must be guided to a decision that does not constitute ‘true’ informed consent. Is a guided decision not an
acceptable proposition?

The time has come to revisit informed consent.
Medicine and its ethics have advanced a great deal
over the past 50 years.27 What was done 50 years
ago would be unthinkable today. There are marked
differences between medical research and the day-
to-day practice of surgery.28 Research is performed
to answer a particular question. It is targeted at a
group of individuals and most importantly there is
no assurance that an individual will benefit from
partaking in the research. For a procedure to be
offered, the benefit to the individual should outweigh
the possible detriment. It is time for the surgeons, legal
experts, and the public to confer and make informed
consent a practical, user-friendly tool rather than the
legal obstacle that it is today.

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