Dental School Patients’ Understanding of Informed Consent

Raha Ghafurian

Abstract: The purpose of this qualitative exploratory study is to describe and analyze adult patients’ understanding of informed consent, using the University of Pennsylvania School of Dental Medicine’s consent form. Randomly sampled, anonymous patients at the school’s clinic were asked to read the form and highlight any statements they found to be confusing, while also rating the form as “easy,” “needing minor changes,” or “needing major changes.” This survey tested the hypothesis that the reading level of the form exceeds that of the average patient and thus, as education level increased, so would comprehensibility while the number of confusing statements would decrease. The results were analyzed for trends in gender and education level, and the statements proving most problematic to the largest number of patients were identified and analyzed. Contrary to the hypothesis, the most highly educated patients highlighted more statements, inspiring a new hypothesis that this occurred because of highly educated patients’ ability to distinguish between the literal meaning of the words and their implications. Revisions were made to the identified aspects of the form, and new surveys were completed, with the result that the modifications were successful and the new hypothesis was supported.

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The responsibility of a clinician in ensuring informed consent was defined by the High Court of Australia in Rogers v. Whitaker (1992) as “to provide the information that would reasonably be required by a person in the position of the patient.” The clinician is therefore professionally and ethically obligated to take all possible steps toward improving patient understanding of consent. This study aims at providing practitioners with information on how to do that.

In 1995, Lawson and Adamson completed a study of the readability of fifteen phrases commonly found in consent forms, providing subjects with each term in the context of a sentence and then asking them to supply a definition of the term. The researchers found that the average subject lacked a clear understanding of the terminology; often the subjects had a notion of what the word meant but not a true understanding, which the researchers suggest “can prove dangerous in consent forms.” That study found the factor that correlated most strongly with patients’ comprehension of the forms was education level and suggested that consent forms be written at a ninth grade level and alternate sources of information be available for those who are illiterate. Similarly, in a study by Silva and Sorrell, the reading levels of five informed consent forms were analyzed and determined to be “intended for upper division undergraduate or graduate students,” well above the suggested ninth grade level proposed by Lawson and Adamson. These studies warned, however, that just because subjects have the ability to read at a particular level does not necessarily mean they “choose” to and therefore readability is one of various other factors (clarity, type, and difficulty of information, how the information is presented and by whom, etc.) important for patient comprehension of informed consent forms. Thus, in order to account for all of the aforementioned variables, patients’ perception of their overall comprehension of the informed consent forms is analyzed in this study, and this information will be evaluated in the context of the education level of the subjects.

Although much work has been done studying readability of informed consent forms for patients participating as subjects in research trials, very little research is available regarding the informed consent forms signed by patients undergoing day-to-day
procedures performed at dental schools or in private practices. The Stanley et al. study is an exception: in it, the researchers investigated whether additional verbal and/or written information would increase clinical patients’ comprehension of informed consent and found no improvement in understanding or anxiety.1 My study took a different approach in that it focused on the informed consent form itself rather than auxiliary information. It is hoped that by identifying the aspects of the form that are most incomprehensible to patients and using that information to make constructive changes to the informed consent form, other institutions may also benefit from the knowledge gained.

The aim of this study was to answer the following questions:
1. How comprehensible are the University of Pennsylvania School of Dental Medicine (SDM) informed consent forms for the average patient?
2. Are there particular statements that cause the most confusion?
3. Is comprehensibility correlated with gender or educational level?

In addition, I sought to test the hypothesis that the reading level of the form exceeds that of the average patient and thus, as education level increased, so would comprehensibility while the number of confusing statements would decrease.

Materials and Methods

For this study, a convenience sample was taken in each phase, with twenty anonymous volunteer patients over eighteen years of age approached for interview (without inducements) as they waited outside the SDM Main Clinic for their dental appointments. As no names or identifiers were recorded, it was impossible to locate and/or contact the volunteers from the first phase for participation in the second phase; thus, two separate groups participated in each phase. Patients were selected on a volunteer basis following verbal explanation of the study and its implications by the researcher. For each phase, data collection occurred in three two-hour sessions between approximately 12:00 noon and 2:00 p.m. Every patient in the waiting room was individually approached by the researcher with verbal explanation of the study and its implications. Those patients willing to volunteer their time were included as participants. A proposal of this study was reviewed by the University of Pennsylvania Institutional Review Board and was determined to meet the eligibility criteria for Category 2 exemption for IRB review. No informed consent forms were used; rather, the IRB approved using the following script to obtain patient consent to participation:

“Hello. I am Raha Ghafurian, a dental student here at Penn. I am working on a project for a class and would like to ask your opinion about the consent form we use in the Main Clinic. This will take about ten minutes, and I will not include your name or any personal identifiers for this study. Are you willing to talk with me for a few minutes?”

If patient says yes, I will proceed with:

“Here is the consent form we use in the Main Clinic. Will you read it and use this yellow highlighter to mark the words or sections that you think are confusing or not clear to patients? Can you tell me why you think that these sections are confusing or not clear? As we finish, please fill out the attached form to identify your gender, education level, and overall opinion of the form.”

Patients were asked to read the Main Clinic’s informed consent form and highlight any parts of the form that they found to be confusing. Patients were advised that they could complete the survey forms anonymously and that their names would not be used in any analysis or publication of results.

After reading the informed consent forms, patients were also asked to fill out a few demographically oriented multiple-choice questions:
• What is your gender? Male, Female
• What is your highest level of education? Less than 8th grade, Some high school, Completed high school, Some college, Completed college, Graduate school
• What is your opinion about the form? Easy to read, Needs minor changes, Needs major changes

Once all of the patients were surveyed, those statements, words, or phrases that generated the most confusion were identified, and the language used was analyzed to determine possible explanations for the perceived incomprehensibility. The results were analyzed with regard to gender and education level of the patient to look for possible trends or contributing factors. Suggestions were then made on how to clarify the statements so that the same amount of information was present in the forms but modified to be more
comprehensible to the average SDM patient. Three administrators at SDM were contacted to approve the modifications made before the second phase of interviewing proceeded.

In the second phase of the study, twenty new patients—sampled in an identical fashion as the first pool—were surveyed. These patients were asked one additional question as per the request of the administration:

Do you think it would be helpful to have a:
Glossary of definitions, Point person to be able to ask questions of regarding the form

After all of the surveys were completed, the results were again analyzed in the same fashion as in the first phase, and comparisons were made between the two forms to determine if the modifications made were indeed beneficial.

### Results

In the first phase of the study, nine out of twenty patients (45 percent of total) highlighted statements as being confusing, with three statements found to be confusing to three patients each (15 percent of total); no statement was highlighted more than three times. The three most problematic statements were:

1. As a COMPREHENSIVE CARE patient, you have access to a 24-hour dental emergency service.
2. The entire payment must be made before such treatment is finished.
3. There may be a charge for failing to keep an appointment or cancellation with less than 24 hours notice.

Thirteen out of twenty patients called the form “easy”; seven suggested that it needed minor changes; and none believed that it needed major changes. Of the three patients who had completed some high school, all found the form easy, while of those who had completed high school or who had some college two out of three (66 percent) per group found it easy and one out of three (33 percent) thought it needed minor changes. For the patients who had completed college, only three out of eight (38 percent) thought it was easy, and five out of eight (62 percent) thought it needed minor changes. Finally, of the two patients who had attended graduate school, one found it easy, and the other found it needed minor changes (Table 1). Of the nine people who highlighted statements, one had some high school, two had some college, five (the majority) had completed college, and one had completed graduate school. Thus, the patients with the higher education levels were found to be more likely to both highlight statements and to suggest that the form needed minor changes. No associations between comprehensibility and gender were found.

These results led to the formation of a new hypothesis: that the most highly educated patients highlighted more statements because of their ability to distinguish between the literal meaning of the words and their implications. We therefore analyzed and modified the most confusing statements as follows:

1. As a COMPREHENSIVE CARE patient, you have access to a 24-hour dental emergency service.
   Problem: Educated patients understood that the literal meaning of comprehensive (large in scope) does not define it in this context. Patients needed clarity on what procedures are included in “comprehensive care.”
   Revision: As a COMPREHENSIVE CARE patient (patient who has been registered for continuing treatment for all dental needs not just emergency care), you have access to a 24-hour dental emergency service.

2. The entire payment must be made before such treatment is finished.
   Problem: Educated patients were aware of the ambiguity of the financial responsibilities to which they were being asked to consent (e.g., which procedures the statement refers to, what happens if a patient is unhappy with treatment). Thus, the confusion seems to be due to the vagueness of those responsibilities rather than comprehensibility of the words.
   Revision: The entire fee must be paid before your treatment is finished.

**Table 1. Survey data from phase 1: education level versus overall comprehensibility, by number selecting each category out of total respondents**

<table>
<thead>
<tr>
<th>Education Level</th>
<th>Easy</th>
<th>Minor Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Some high school</td>
<td>3/3</td>
<td>0/3</td>
</tr>
<tr>
<td>Completed high school</td>
<td>2/3</td>
<td>1/3</td>
</tr>
<tr>
<td>Some college</td>
<td>2/3</td>
<td>1/3</td>
</tr>
<tr>
<td>Completed college</td>
<td>3/8</td>
<td>5/8</td>
</tr>
<tr>
<td>Graduate school</td>
<td>1/2</td>
<td>1/2</td>
</tr>
</tbody>
</table>
3. There may be a charge for failing to keep an appointment or cancellation with less than 24 hours notice.

Problem: Educated patients recognized that this description of the SDM patient disappointment policy is ambiguous. Once again, the problem here appeared to be the vagueness of the information not the wording or format.

Revision: There may be a charge for failing to keep an appointment or cancellation with less than 24 hours notice, and you may also be dismissed from treatment at the dental school if you fail to give your student dentist 24 hours of notice of cancellation a second time.

Once these modifications were made, the results of the survey changed dramatically. The total number of patients who made suggestions decreased from 45 percent to 20 percent (with decreases in both genders), the total number of patients who found the form easy rose from 65 percent to 90 percent, and the number of patients who felt that the form needed minor changes decreased from 35 percent to 10 percent (Figure 1). Thus, the overall comprehensibility of the revised form was found to have increased. Again, no gender association was found with the results. In terms of patient education level (Figure 2), the biggest change was found in the “completed college” group in which previously 62 percent of patients found that the unrevised form needed minor changes while 38 percent found the form to be easy. With the new form, 100 percent of the “completed college” group rated the form as easy. Finally, there was only one statement that was highlighted more than once as being confusing, and it was highlighted by only 2/20 (10 percent) of patients. Thus, overall the revisions made were found to be very successful,

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**Figure 1. Overall comprehensibility: original versus modified form**

*Note: The number of patients finding the form easy increased from 65 percent to 100 percent with the modified form. Those finding it needed minor changes dropped from 35 percent to 10 percent.*

**Figure 2. Education level versus comprehensibility: original versus modified form**

*Note: The biggest change was in the “completed college” group, in which the percentage of patients finding the form easy increased from 38 percent with the original form to 100 percent with the modified form.*
with improvements made in every category. Finally, in terms of the additional question added on the survey form in the second phase, 45 percent of patients thought a point person would be helpful, 15 percent thought that a glossary of terms would be helpful, and 40 percent thought neither addition was needed (Figure 3).

One major limitation of this study is the fact that previous research suggests that patients should be actively involved in the attainment and evaluation of their understanding of informed consent. For example, multiple-choice questions should be asked evaluating recall ability, and health care personnel should be available to discuss the protocol and answer any questions the patient may have. Such active involvement was not examined in the current study. Likewise, although patients were asked if a point person would be a helpful addition, no such resource was actually available to participants. Another limitation of the study is that there was no test of what knowledge the patients actually gained, which may be evaluated by recall tests. This study simply assessed patients' perceived ability to understand the informed consent form and did not incorporate any means of objectively evaluating their comprehension. A third limitation is that this study focused only on the informed consent procedure at the Main Clinic of the SDM. Other clinics in the school, as well as in other dental schools and private practices, use different forms. Therefore, although other institutions may benefit from suggestions made regarding shared themes or terminology, the analysis and conclusions of the study are most applicable to the Main Clinic at this school and its patient population.

Additionally, patients may be embarrassed to admit that they are having difficulty comprehending the document, and therefore results may be biased or may overestimate patients’ understanding of the document. On the other hand, patients may feel under time pressure to complete the interview and therefore may rush through it, highlighting statements that they may have understood had they given themselves adequate time to think, thus underestimating their comprehension. It is possible that these forces could balance one another and that the variation created could even out.

Finally, there are limitations within the ideal of informed consent itself. As Stanley et al. emphasize, true informed consent can never be attained in all practicality, as “it requires a detailed understanding of physiology, pathology, and anatomy.” Likewise, as pointed out by Silva and Sorrell, informed consent is a contradictory entity in that, to be informed, patients “need complex information; and they need information about risks—all of which have been shown to decrease comprehension . . . adequate disclosure and sufficient comprehension may be inversely related.” Thus, informed consent is an ideal, and clinicians should strive to ensure that their patients are as close as practically possible to being truly informed.

Conclusions

This study had three main objectives: determining the overall comprehensibility of the informed consent forms used at the University of Pennsylvania School of Dental Medicine, identifying which statements were most problematic for patients, and identifying any association between comprehensibility and gender or educational level. The study was initiated under the hypothesis that the reading level of the informed consent form exceeds that of the average patient and thus, as educational level increased, so too would patient understanding of the form. After the first round of surveying and the surprising results that as educational level rose so too did the number of highlighted confusing statements, a new hypothesis was generated: educated patients found more statements to be confusing than less educated patients because of their ability to distinguish between the literal meaning of the statements and their implications when referring to financial matters and undefined terms. More highly educated patients were able to identify areas of the informed consent form that were vague or lacking proper definition.
(e.g., referring to patients as “comprehensive care” patients without defining what types of procedures were included under such an umbrella term), while less educated patients were more likely to see the word “comprehensive” and accept it—knowing its general definition—without analyzing its use in such a context. Thus, the more highly educated patients highlighted such terminology because they understood they were signing consent for indefinite procedures and fees, while less educated patients were less aware of the ambiguity. With modifications to the form and a new round of surveying, the second hypothesis was supported by the success of the revisions (improvement of comprehensibility overall and, in particular, among more highly educated patients). Thus, the revised informed consent form should be considered for implementation at the clinic and the administration should consider the designation of a point person to whom patients could ask questions regarding the form.

In the words of Lawson and Adamson, “If consent forms are written in language that subjects do not fully understand, then there is no guarantee that they know all the information they need to know to make a well-educated decision.” It is the responsibility of clinicians to ensure that informed consent is truly informed. This study aimed to reduce potential barriers hindering realization of this goal.

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**REFERENCES**

APPENDIX

Patient Understanding and Informed Consent

UNIVERSITY OF PENNSYLVANIA
SCHOOL OF DENTAL MEDICINE

Patient Name: ____________________________
Chart No.: ________________________________
Birth Date: ________________________________

General Information: The University of Pennsylvania School of Dental Medicine (also referred to as the “SDM”) is a teaching institution, and patients accepted into the teaching program will have their treatment supervised by members of the SDM faculty. Treatments will meet or exceed the standards of care in the profession of dentistry and will be provided in a considerate, respectful, and confidential manner. However, such treatment may require more time than if done by a private dentist, as most appointments will require approximately one to three hours. Also, patients are expected to be available once and sometimes twice a week.

Emergency Dental Care: Emergency dental treatment is intended to provide relief of severe pain and infection for individuals in acute need. As a COMPREHENSIVE CARE patient (patient who has been registered for continuing treatment for all dental needs not just emergency care), you have access to a 24-hour dental emergency service. There is a charge associated with this service.

Consent to Dental Procedures: As a patient you will have access to current and complete information about your condition and will, unless otherwise specified, receive continuity of treatment, be provided an estimate of the cost, and receive dental care according to a properly sequenced plan of treatment. Before receiving treatment you should ask the student dentist or student dental hygienist about the procedure(s) that he/she recommends you undergo and ask any questions you may have before you decide whether or not to give your consent for the procedure(s) to be done. All dental procedures may involve risks for unsuccessful results and/or complications, and no guarantee is made as to result or cure. You have the right, at all times, to be informed of any such risks, as well as the nature of the procedure, the expected benefit, the availability of alternative methods of treatment, and the risks of no treatment. Dental radiographs will be made as necessary and appropriate for examinations, diagnosis, consultation, and treatment. You have the right to consent to or refuse any proposed procedure at any time prior to its performance.

Financial Responsibility: You will be charged for treatment according to the fee schedule in effect at the time of service. A fee estimate will be provided prior to beginning treatment, and you must be prepared to pay for services as they are accomplished. However, for procedures such as a denture, bridge, or crown, a portion of the fee is required before starting treatment. The entire fee must be paid before your treatment is finished. You agree to be responsible for all charges for dental services and materials not paid by your dental plan. By signing this agreement you authorize payment of dental benefits otherwise payable to you, directly to the SDM, and to the extent permitted under applicable law, you authorize release of any information relating to the claim. If your account is referred to collections, you will be responsible for all additional collection costs.

Dental Medical Records: The dental medical record, radiographs (x-rays), photographs, videos, models, and diagnostic aids relating to your treatment are the property of the SDM. The SDM may use and disclose this personal health information as allowed by law, including but not limited to, for the purpose of providing health care, processing payments, and running our operations. Information about HIV status, mental health, and substance abuse is subject to privacy protection under state and federal law. The SDM may use and disclose this personal health information as allowed by law, including but not limited to, for the purpose of providing health care, processing payments, and running our operations. Information about HIV status, mental health, and substance abuse is subject to privacy protection under state and federal law, and the SDM will generally not disclose such information unless you sign an authorization to do so, the disclosure is allowed by court order, or in limited and regulated other circumstances.

Keeping Your Appointment: Failure to keep your appointments for whatever reason could result in the discontinuation of treatment. There may be a charge for failing to keep an appointment or cancellation with less than 24 hours notice, and you may also be dismissed from treatment at the dental school if you fail to give your student dentist 24 hours of notice of cancellation a second time.

Discontinuation of Treatment: The SDM reserves the right to discontinue dental treatment whenever it is considered advisable and in the best interest of you and/or the SDM teaching program. Should treatment be terminated, any remaining credit balance for services not yet provided will be refunded to you. If you have any complaints which cannot be resolved at the student or faculty level, you may contact the Office of the Patient Advocate at (215) 573-4742 to request an appointment.

Your signature on this form certifies that you have read and understand the information provided on the form, that you have received a copy, and that you accept dental care and treatment under the described terms and conditions.

Date: ____________________________
Signature: __________________________

Signature of Insured: __________________________

If signed by other than the patient, indicate relationship: parent or legal guardian: __________________________

Witness Signature: __________________________