Perceptions of pregnant women with low educational attainment about informed consent after registering into randomized controlled trial in India

– A qualitative study

Dr. Ramya Shenoy *, Dr. Kundabala M **, Dr. Animesh Jain ***

* Associate Professor, Dept. of Public Health Dentistry, Manipal College of Dental Sciences, Mangalore, Manipal University
** Professor & Associate Dean, Dept. of Conservative Dentistry, Manipal College of Dental Sciences, Mangalore, Manipal University
*** Associate Professor, Dept. Community Medicine, Kasturba Medical College, Mangalore, Manipal University

Introduction

INFORMED CONSENT

• The process of communication between a patient and physician
• To give adequate information to patient before deciding to undergo a major treatment or enrolled into trial
• Must be documented in written format

Drawbacks of a consent form, many patients still do not understand
• Basic information about the risks & benefits
• Alternatives of their proposed treatment options

The potential reasons for the failure of informed consent
• Cognitive impairments
• Learning disabilities, hearing or vision impairments
• Confusion about the purpose of the consent process
• Stress or time pressure
• A feeling of intimidation

Aim of the study

Perceptions of pregnant women with low educational attainment about informed consent after registering into randomized controlled trial in India

Methodology

• A cross sectional study
• A consecutive sample of 120 subjects aged 18 or above, participating in randomized controlled trial was surveyed.
• Ethical clearance for the present study was obtained.
• The purpose of the study was explained
• The interview was carried out using interview schedule , which included, study objectives, potential benefits and risks, and participants’ rights and obligations.
• It was reassured to the participant that there were no right or wrong answers.
• Interview was started with brief introductory session.
• Data were collected from August/2013 to October/2013.
• The questionnaires were filled in right after they had agreed to participate and signed the consent.
• Descriptive statistics were provided to measure subjects understanding of the informed consent.
• Data was coded and analyzed using the SPSS version 17.0

Results

<table>
<thead>
<tr>
<th>Questions</th>
<th>Yes</th>
<th>No</th>
<th>Don't know</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are you satisfied with the information given?</td>
<td>98</td>
<td>21</td>
<td>13</td>
</tr>
<tr>
<td>Did you follow the meaning of “Research purpose”?</td>
<td>100</td>
<td>20</td>
<td>16</td>
</tr>
<tr>
<td>Do you understand that you can refuse to have this procedure?</td>
<td>105</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>Do you think any benefits after enrolling into trial?</td>
<td>94</td>
<td>26</td>
<td>21.7</td>
</tr>
<tr>
<td>Do you think any risks after enrolling into trial?</td>
<td>120</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Would you need more information before you decided? What information?</td>
<td>120</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>

• Validation of informed consent forms is necessary, especially for low literacy patients.
• Introductory session on informed consent for all the participant is must. This saves time.
• This results agrees with the findings of study carried out by Dawes et al.

Conclusion

• In general, the understanding about basic components of the informed consent in this population of low educational attainment was good, particularly, in regard to study objectives and participants rights.
• Knowledge on study benefits, risks and the term like trial was poor. These items should be the focus of strategies to enlighten the subjects regarding informed consent.
• Further studies to assess the quality of the informed consent process are warranted.

Demographics

• Out of 120 enrolled, 78% had High-school education or less, and only 2% had attended College.
• Mean age of the participants were 24±3.5 years.

Recommendations

• Informed consent process should be considered as one of the patient safety target.
• Shared decision along with informed consent may be required in case of trials and procedures involving high risk.

References

2. Dawes PJ, Davison P.