Nursing Perspective: Informed Consent and Patient Empowerment

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Informed consent is an important and essential component of patient care. With the growing emphasis on multidisciplinary teams, nurses are increasingly responsible for obtaining informed consent for research studies and clinical interventions. This paper will focus on informed consent for research purposes. In the past, consent may have been viewed as a protective measure for the health care provider. Fortunately, the consent process now reflects the practice of truly informing the patient about the risks and benefits of the intervention at hand, as well as of alternative treatment. A focus on the basic components of consent can help to ensure that the patient is fully informed before providing consent.

The ability and the capacity to consent are essential prerequisites to the informed consent process. Much research and effort has been put forth in ensuring consentability of the patient prior to obtaining informed consent¹. A number of competency tools have been developed, although there is currently no gold standard for determining patient consentability.

Appelbaum advocated that valid informed patient consent should address the four domains of decisional capacity. Incorporating these four domains of decisional capacity into our practice can help to ensure that capacity is met². We have explored each of these four domains specific to our own nursing needs and how they may be assessed (see Table 1). Ensuring these domains are reviewed on an ongoing basis helps to maintain the integrity of consent.

Thoughtful appreciation of the informed consent process helps to equip patients with a better understanding of information presented to them. Patients who have a clear understanding of the information communicated to them, including benefits and risks of the intervention, risks of refusal, and an awareness of clinical equipoise, are better able to formulate sensible decisions. This paper examines patient empowerment through education as an influential contributor to the informed consent process.
Patient education can be actively pursued through a number of mechanisms. First, a brief summary of the disease or qualifying condition in question can often provide a segway to the study rationale. The study rationale often aims at providing more efficient care in terms of an equal or better treatment or diagnostic pathways. Patients should then be informed of usual treatment practices. Adequate time should be allotted to explain the traditional treatment regimens along with the associated risks and benefits. Patients then need to be assured that there is a gap in knowledge with respect to an ideal treatment regimen within their patient population. This clinical knowledge gap with respect to the therapeutic merits of each arm in a trial is defined as clinical equipoise\(^3\) and is essential in order for a study to proceed. Knowing that a study would not proceed without a gap in this information is important in helping patients feel comfortable about participating in the research process.

Once traditional treatment practices have been explained to the patient, details of the proposed research study may be discussed. Caution should be taken when explaining the risks and benefits of a study. It is important for patients to understand that participation in the study itself will not necessarily improve outcome, when compared with traditional treatment (often referred to as therapeutic misconception). Unintended influence with therapeutic misconception should be avoided.

Wendler and Grady suggest that patients who enroll in studies should have an appreciation of the research contribution that they will be making to society\(^4\). Knowing that study participation supports generalizable knowledge that may influence treatment in the future can provide patients with a sense of empowerment. In addition, there have been benefits demonstrated to study participation that have not been seen in regular treatment options\(^5\).

There are a number of methods to enhance patient comprehension of the consent process. Ample time to review the consent is essential to helping ensure an understanding of the information at hand. Providing patients with a quiet environment to review the consent can invite a discussion and formulation of any questions or concerns they may have.

There are various methods of presenting information to patients. Patients may be traditional learners opting for information to be presented to them in a structured manner. One may present this in an informal fashion in a one-to-one setting. Benefits of this presentation include a concise and rehearsed relay of information. However, some patients prefer a more interactive model of communication. Visual aids including diagrams, algorithms and flow charts may assist patients in the processing of information. Audiovisual aids can also be enabled to assist the learning process. Written materials can often complement the initial presentation. It has been noted that multiple methods of communications are often helpful in transferring knowledge to patients.

It is important for the personnel obtaining consent to encourage a non-judgmental atmosphere. This will ensure that the patient feels comfortable asking questions. Patients need to be assured that no question is too simple or insignificant. Study personnel can put patients’ minds at ease by asking the patient open-ended questions first to encourage discussion of the disease process and research study. Complimenting
patients’ questions by reassuring that they are often-asked or are valid questions is often encouraging to the patient.

Patients often find support systems beneficial in reviewing and reflecting on the choices with which they have been presented. Family, friends, and even a primary health care provider are often resources that the patient will turn to in times of decision making. Health care providers can be faxed or phoned to help facilitate and expedite this discussion. Patients may require additional time overnight to come to a decision with which they are comfortable.

Once consent has been agreed upon and the consent form signed, a copy should be presented to the patient, as well as the primary health care provider, if desired. It is important to develop and keep an open rapport with the patient. Educating the agreeing study participant should be an ongoing process and continue throughout the duration of the study. Reminders reiterating the purpose of the study, review of risks and benefits, and ensuring the patient's ongoing approval to continue are helpful in continuing open dialogue. It is imperative that the subject be kept current on any new concerns that may arise throughout the study period. Study participation should never be taken for granted and ongoing consent should be maintained. If agreed, support systems should be encouraged to accompany patients throughout the course of the study, including the enrollment and follow up period.

Ensuring that the client has an identifier study card in the event that they require unrelated therapy that may contradict study treatment is important. Study diaries can be helpful to the patient for keeping an ongoing record of events. The study participant should have on hand phone numbers for the health care providers, in order to discuss questions or concerns.

It is helpful to keep the patient aware of study duration and endpoints they have met. It is expected that a sense of partnership and accomplishment will develop between the study participant and the health care provider as the follow-ups are completed. The patient should feel appreciated with a sense of contribution to future patient care. An ongoing role of patient advocate should envelope the health care provider.

Serrano-Gil and Jacob have described how encouraging patients to help manage disease can positively influence their long-term treatment outcomes. They note that knowledge alone does not increase patient confidence and motivation for self-management. Adequate structure with ongoing support of patients should be in place in order to facilitate long-term success.

The strategies that we have outlined, if actively pursued, can provide the patient with a sense of autonomy and empowerment, while ensuring the process of informed consent has been achieved. Members of the research team should always be cognizant of the fact that “consent is a process – not a form”.

References

Table 1: Criteria Exhibiting Domains of Decisional Capacity

<table>
<thead>
<tr>
<th>Domain of Decisional Capacity</th>
<th>Principle</th>
<th>Subjective Patient Behavior</th>
<th>Objective Patient Behavior</th>
<th>Nursing Follow-up Ensuring Ongoing Capacity</th>
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<tbody>
<tr>
<td>Understanding relevant information</td>
<td>Patient education conforms with Good Clinical Practice (GCP) Guidelines</td>
<td>Listening to/learning about their disease and treatment</td>
<td>Asks questions to study staff to clarify information Knowing what treatment or procedure that they have agreed to (i.e. drug name, placebo)</td>
<td>Review purpose of study at follow-up visits</td>
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<tr>
<td>Appreciating risks &amp; benefits</td>
<td>Discussion of risks of benefits conforms with GCP guidelines</td>
<td>Body language acknowledging understanding of discussion re: risks and benefits (i.e. nodding of head, etc.)</td>
<td>Direct questions specific to risks or benefits or side effects Verbalizing potential side effects Verbalizing potential signs and symptoms of recurrence of disease</td>
<td>Assess for signs &amp; symptoms of disease at follow-up Assess for adverse events</td>
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<td>Understanding treatment options</td>
<td>Informed consent is an ongoing process</td>
<td>Understanding both study and non-study alternatives Body gestures indicating learning (leaning forward, arms uncrossed, etc.)</td>
<td>Verbalizes understanding of treatments Asks relevant questions Patient being compliant with study drug</td>
<td>Calculate and ensure treatment compliance Ensure ongoing patient understanding of treatment with review at follow-up visits</td>
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<td>Communicating a choice</td>
<td>Participation in a research study is voluntary</td>
<td>Exhibiting body behavior either for or against study choice (arms crossed, etc.)</td>
<td>Signed/refused consent Accepting copy of consent and study aids/drug to take home Accepting study drug</td>
<td>Ongoing review of voluntary nature of study Keeping follow-up appointments</td>
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