

**NIDDK Liver Transplantation Database
MANUAL OF OPERATIONS (MOOP)**

FORM: QA (QUALITY OF LIFE: ADULTS)

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The quality of life form is meant to be filled out by the transplant patient or candidate and is self-explanatory. The form should be filled out at the following times.

1. Initial evaluation and at pre-transplant re-evaluations.
2. If more than 6 months have elapsed since the most recent evaluation, the form should be filled out again within 2 weeks of transplantation.
3. Yearly after the first transplant, up to 5 years.

The patient should be encouraged to fill out the form on his/her own. Help may be provided by the LTD coordinator if the patient is too ill, confused, or unable to understand the questions because of educational, cultural or language difficulties. In these situations the LTD coordinator can read the questions to the patient and record the answers.

If the patient is too sick to answer the questions (as may occur if he/she has fulminant hepatic failure), special arrangements will need to be made. As an interim solution, the LTD coordinator should identify the next of kin and fill out the first 16 questions based on the best information that can be provided by the next of kin. The name of the next of kin and relationship (spouse, child, sibling, parent, etc.) should be recorded. In addition, an attempt should be made to have the patient fill out the form when he/she has improved. Thus, the form might be filled out after the liver transplant in a patient who is first seen and is transplanted when in hepatic failure and coma. In this situation, the LTD coordinator should ask the patient to fill out the form based on his/her quality of life before the transplant and before the immediate problem that might have precipitated the hepatic failure and coma. In patients with fulminant hepatic failure from acute hepatitis, the information should reflect how they were feeling before they got the acute hepatitis and not how they felt during the few weeks while they slipped into hepatic failure.

Once the form is filled out, the LTD coordinator should check that the form was filled out correctly and completely, returning to the patient if questions are missed or obviously misunderstood and answered in an inconsistent manner. If the patient does not want to answer a question, he/she should put a mark through it on the questionnaire.

The answers to all questions on the form should be kept confidential and none revealed to the physicians or nurses responsible for the patient's care, or even to the principal investigator for the Liver Transplantation Database. This confidentiality should be maintained even for answers that might seem to have an impact on the patient's care such as a history of drinking alcohol or answers that indicate severe depression.

Eight QA forms were transcribed from the quality of life forms used by the Fujisawa FK506 study. These forms can be identified by the "Forms filled out" variable. Additional responses to 5 questions were incorporated in the LTD form to accurately transcribe data from the FK506 forms.

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Question 29

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