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Dear HPN Consumer:

The Oley Foundation is fortunate to be collaborating with the European Home Artificial Nutrition Workgroup to participate in a widespread study of the effect of home parenteral nutrition on quality of life. This is important to Oley in that it will promote understanding of issues experienced by consumers. We are hopeful that what is learned from the study may even be applicable to consumers around the world to make HPN practices better for you as well as for those elsewhere. It may also make it possible to compare the effects of newer techniques, such as small intestinal transplantation, with life on HPN.

You are the ones who experience this therapy on a day to day basis, so you are in a unique position to help the medical field understand the impact that it has had on your life. Because of your expertise with home parenteral nutrition, we are asking you to fill out the enclosed questionnaires. One of these is the newly validated Quality of Life questionnaire which is designed for those on home parenteral nutrition. A second form is called the SF-36 which is a medical quality of life questionnaire which is not specifically aimed at HPN consumers, but is a more general format. This allows comparison with people with a variety of medical issues. In addition there is an Oley specific questionnaire which was developed primarily because of differences in parenteral nutrition reimbursement between the U.S. and Europe. There is also a brief medical questionnaire which will help us understand the impact of various disease states on HPN and vice versa. These questionnaires should not require more than an hour to complete. It is not necessary to complete all of them in one day, but we would appreciate it if you could finish them within 2-3 days. We would request that you, the consumer, complete them personally.

All of this leads to the question of confidentiality. All of the forms will be coded as soon as they arrive in the Oley Foundation office. Only Cathy, the Oley Administrative Assistant, will have access to your identification, and she will remove the name before any of the questionnaires are passed on for review. Records of the identity will be secured in a locked safe, so that if/when repeat questionnaires are sent out over a period of years, it will be possible to make direct comparisons of the effect of time and experience on your outcomes. If you wish to allow your personal physician or home care company to know about your completed questionnaires, it will be up to you to share them. Oley will not be sending the forms that still contain your name to anyone.

I feel that this is an exciting project and I am hopeful that we in the U.S. will have a strong response and that various European countries will as well. Remember, you are the **expert** in this area, so please help to educate us that are responsible for your well-being while you are on home parenteral nutrition.

Gratefully yours,

Darlene Kelly, MD, PhD
Oley Foundation Chair for Research

Note: *This research project has been approved by Albany Medical Centers Institutional Review Board (IRB) as an exempt study. This exempt status eliminates the need for participants to sign consent forms.*

The **Q**ley Foundation

Name: _____

Address: _____

City: _____ ST: _____ ZIP: _____

Telephone: (____) _____ - _____

Email: _____

ID #: _____

HPN - QOL[®] (version 1.0)

Questionnaire to assess the quality of life of adult patients receiving home
parenteral nutrition

Patient initials..... Date of birth (day, month, year).....

HPN centre Today's date (day, month, year)

Please answer as many questions as possible by circling the number that reflects your experiences. N/A = not applicable

During the past year (or since you started HPN)		Much worse	Worse	No change	Better	Much better
1	How has HPN made you feel?	1	2	3	4	5
2	How has HPN affected your ability to go on holiday?	1	2	3	4	5
3	How has HPN affected your ability to travel?	1	2	3	4	5
During the past week		Not at all	A little	Quite a bit	Very much	
4	Has HPN felt a burden to you?	1	2	3	4	
5	Have you had concerns about your weight?	1	2	3	4	
6	Has the presence of your catheter affected your body image?	1	2	3	4	
7	Have you felt physically less attractive?	1	2	3	4	
8	Have you felt supported by your hospital nutrition team?	1	2	3	4	
9	Have you had access to a portable pump? Y / N If so, has it improved your ability to get around?	1	2	3	4	N/A
10	Have you had trouble doing strenuous activities, like carrying a heavy shopping bag or suitcase?	1	2	3	4	
11	Have you had trouble taking a long walk?	1	2	3	4	
12	Have you had trouble taking a short walk outside the house?	1	2	3	4	
13	Have you needed to stay in bed or a chair during the day?	1	2	3	4	
14	Have you needed help with eating, dressing, washing yourself or using the toilet?	1	2	3	4	
15	Have you felt tired?	1	2	3	4	
16	Have you felt lacking in energy?	1	2	3	4	
17	Has HPN disturbed your sleep pattern?	1	2	3	4	
18	Have you worried about your current health?	1	2	3	4	
19	Have you worried about the future?	1	2	3	4	
20	Were you able to socialise?	1	2	3	4	
21	Were you able to exercise?	1	2	3	4	

During the past week		Not at all	A little	Quite a bit	Very much	
22	Were you able to do shopping?	1	2	3	4	
23	Were you able to take part in hobbies or leisure activities?	1	2	3	4	
24	Were you able to cope with daily life?	1	2	3	4	
25	Were you able to feel independent?	1	2	3	4	
26	Have you felt bloated?	1	2	3	4	
27	Were you able to eat food?	1	2	3	4	
28	Were you able to drink fluids?	1	2	3	4	
29	Have you had pain after eating or drinking?	1	2	3	4	N/A
30	Have you had nausea/vomiting?	1	2	3	4	
31	Have you had aches or pains in your muscles or joints?	1	2	3	4	
32	Have you had other pain?	1	2	3	4	
33	Have you felt depressed?	1	2	3	4	
34	Have you felt tense?	1	2	3	4	

During the past YEAR (or since you started HPN)		Not at all	A little	Quite a bit	Very much	
35	Have you felt you wanted to go out to work?	1	2	3	4	
36	Were you able to go out to work?	1	2	3	4	
37	Has HPN caused financial worries?	1	2	3	4	
38	Do you have a stoma (ileostomy/colostomy/gastrostomy)? Please tick box	Yes []		No []		

If you have a stoma please go to questions 39-40

If you do not have a stoma please go to questions 41-43

During the past week

<u>For patients who have a stoma</u>		Not at all	A little	Quite a bit	Very much
39	Have you had problems caring for your stoma?	1	2	3	4
40	Have you had problems with your stoma site?	1	2	3	4

For patients who do not have a stoma

		Not at all	A little	Quite a bit	Very much
41	Have you had frequent bowel movements?	1	2	3	4
42	Have you had difficulty with moving your bowels?	1	2	3	4
43	Have you had painful bowel movements?	1	2	3	4

Please answer each of the following questions by circling the relevant number:

During the past week

44 How has your quality of life been?

0	1	2	3	4	5	6	7	8	9	10
Very bad										Very good

45 How has your quality of life been affected by your HPN?

-5	-4	-3	-2	-1	+1	+2	+3	+4	+5
Very much for the worse				0					Very much for the better

46 How has your quality of life been affected by your underlying illness?

-5	-4	-3	-2	-1	+1	+2	+3	+4	+5
Very much for the worse				0					Very much for the better

During the past FOUR WEEKS

		Not at all	A little	Quite a bit	Very much	
47	To what extent were you interested in sex?	1	2	3	4	
48	To what extent were you sexually active?	1	2	3	4	N/A

49 Are there any answers to the questionnaire that you would like to expand on? Please feel free to write in the space below:

.....

.....

.....THANKYOU

Permission to use this questionnaire from: Mrs Janet Baxter Ninewells Hospital & Medical School DUNDEE DD1 9SY Telephone: + 44 1382 496558	This work is supported by: The Scottish Home Parenteral Nutrition Managed Clinical Network
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Oley Medical Information

1. Year you started nutritional support: _____ HPN _____ HEN _____ Both

2. Diagnosis requiring HPN:

Short bowel syndrome due to

- | | | | |
|-------------------------|--------------------------|---------------------------|--------------------------|
| Crohn's disease | <input type="checkbox"/> | Gastroschesis | <input type="checkbox"/> |
| Ischemic bowel disorder | <input type="checkbox"/> | Volvulus | <input type="checkbox"/> |
| Radiation enteritis | <input type="checkbox"/> | Necrotizing enterocolitis | <input type="checkbox"/> |
| Cancer | <input type="checkbox"/> | Atresia | <input type="checkbox"/> |
| Hirschsprungs | <input type="checkbox"/> | Other | <input type="checkbox"/> |
| Trauma | <input type="checkbox"/> | | |

(Check both Radiation enteritis and cancer if applicable)

Motility disorder/obstruction due to

- | | |
|--------------------------------|--------------------------|
| Gastroparesis | <input type="checkbox"/> |
| Pseudo obstruction | <input type="checkbox"/> |
| Small bowel/ colon obstruction | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |

Swallowing disorder due to

- | | |
|--------|--------------------------|
| Cancer | <input type="checkbox"/> |
| Stroke | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |

3. Insurance coverage

- | | |
|-------------------|--------------------------|
| Medicare | <input type="checkbox"/> |
| Private Insurance | <input type="checkbox"/> |
| Medicaid | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |

4. To help us understand the volume you infuse, please answer the following:

- | | | | |
|---------------------------------|------------------|--------------------|----------------------------|
| Amount of HPN: | _____ liters/day | _____ liters/week. | _____ hours infusing daily |
| Amount of I.V. hydration: | _____ liters/day | _____ liters/week | _____ hours infusing daily |
| Amount of tube feeding formula: | _____ liters/day | _____ liters/week. | _____ hours infusing daily |
| Amount of enteral hydration: | _____ liters/day | _____ liters/week | _____ hours infusing daily |

5. Have you had HPN related complications in the past 2 years?

No (Go to question 6)

Yes <input type="checkbox"/>	How many?	Inpatient	Outpatient
Catheter related infection	_____	_____	_____
Catheter clotted	_____	_____	_____
Catheter broken	_____	_____	_____
Catheter fallen out	_____	_____	_____
Bone disease; Fracture	_____	_____	_____
Liver Disease; Jaundice	_____	_____	_____
Fluid/Electrolyte imbalance	_____	_____	_____

6. Are you dependent on someone for your care?

- No
- Yes If yes: Family Visiting Nurse

7. Rank the following items in the order that they distress you the most

(#1 = the most troublesome, #9 = the least). A blank box = non applicable

- . HPN therapy _____
- . Underlying diagnosis _____
- . Pain _____
- . Ostomy _____
- . Draining fistula _____
- . Financial coverage issues _____
- . Social restrictions _____
- . Dietary restrictions _____
- . Inability to eat _____

THANK YOU!

Revised 9/09

Oley Foundation Supplemental Consumer Questions

	Describe your level of activity:					
		Very active	Active	Somewhat active	Not active at all	
1	Prior to your illness	1	2	3	4	
2	After your illness, but before HPN	1	2	3	4	
3	Since you started HPN	1	2	3	4	
	Describe your mental health:	Very good	Good	Poor	Very poor	
		1	2	3	4	
4	Prior to your illness	1	2	3	4	
5	After your illness, but before HPN	1	2	3	4	
6	Since you started HPN	1	2	3	4	

	During the past year					
		Not at all	A little	Quite a bit	Very much	
7	Has your HPN led to increased stress within your family?	1	2	3	4	
8	Have you had feelings of guilt due to the burden of HPN on your family members?	1	2	3	4	
9	Have you had feelings of resentment toward family members not on HPN?	1	2	3	4	
10	Do you feel that family members resent you because of your medical condition & needs?	1	2	3	4	
11	If someone else is your primary caregiver, do you worry about his/her health?	1	2	3	4	
12	Do you worry about the financial well being of the family because of health care costs?	1	2	3	4	

	Overall				
		Yes	No	Need more information	
13	Do you feel you control your quality of life?	1	2	3	
14	Do you feel your HPN controls your quality of life?	1	2	3	
15	Do you attend support group meetings or are you connected to a support organization (i.e. Oley Foundation, CCFA, etc.)?	1	2	3	
16	If depressed or anxious, are you taking medication for this?	1	2	3	
17	If depressed, are you seeing a professional for this?	1	2	3	
18	Do you believe that an intestinal transplant would improve the quality of your life?	1	2	3	
19	Would you consider an intestinal transplant even if your health on HPN is stable?	1	2	3	

Revised 9/09

SF36 Health Survey

INSTRUCTIONS: This set of questions asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Answer every question by marking the answer as indicated. If you are unsure about how to answer a question please give the best answer you can.

1. In general, would you say your health is: (Please tick **one** box.)

- Excellent
 Very Good
 Good
 Fair
 Poor

2. Compared to one year ago, how would you rate your health in general now? (Please tick **one** box.)

- Much better than one year ago
 Somewhat better now than one year ago
 About the same as one year ago
 Somewhat worse now than one year ago
 Much worse now than one year ago

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? **(Please circle one number on each line.)**

<u>Activities</u>	Yes, Limited A Lot	Yes, Limited A Little	Not Limited At All
3(a) Vigorous activities , such as running, lifting heavy objects, participating in strenuous sports	1	2	3
3(b) Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3
3(c) Lifting or carrying groceries	1	2	3
3(d) Climbing several flights of stairs	1	2	3
3(e) Climbing one flight of stairs	1	2	3
3(f) Bending, kneeling, or stooping	1	2	3
3(g) Walking more than a mile	1	2	3
3(h) Walking several blocks	1	2	3
3(i) Walking one block	1	2	3
3(j) Bathing or dressing yourself	1	2	3

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?
(Please circle one number on each line.)

	Yes	No
4(a) Cut down on the amount of time you spent on work or other activities	1	2
4(b) Accomplished less than you would like	1	2
4(c) Were limited in the kind of work or other activities	1	2
4(d) Had difficulty performing the work or other activities (for example, it took extra effort)	1	2

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (e.g. feeling depressed or anxious)?
(Please circle one number on each line.)

	Yes	No
5(a) Cut down on the amount of time you spent on work or other activities	1	2
5(b) Accomplished less than you would like	1	2
5(c) Didn't do work or other activities as carefully as usual	1	2

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours, or groups? (Please tick **one** box.)

Not at all

Slightly

Moderately

Quite a bit

Extremely

7. How much physical pain have you had during the past 4 weeks? (Please tick **one** box.)

None

Very mild

Mild

Moderate

Severe

Very Severe

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)? (Please tick **one** box.)

Not at all

A little bit

Moderately

Quite a bit

Extremely

9. These questions are about how you feel and how things have been with you during the past 4 weeks. Please give the one answer that is closest to the way you have been feeling for each item.

(Please circle one number on each line.)

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
9(a) Did you feel full of life?	1	2	3	4	5	6
9(b) Have you been a very nervous person?	1	2	3	4	5	6
9(c) Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
9(d) Have you felt calm and peaceful?	1	2	3	4	5	6
9(e) Did you have a lot of energy?	1	2	3	4	5	6
9(f) Have you felt downhearted and blue?	1	2	3	4	5	6
9(g) Did you feel worn out?	1	2	3	4	5	6
9(h) Have you been a happy person?	1	2	3	4	5	6
9(i) Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.) (Please tick **one** box.)

All of the time

Most of the time

Some of the time

A little of the time

None of the time

11. How TRUE or FALSE is each of the following statements for you?

(Please circle one number on each line.)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
11(a) I seem to get sick a little easier than other people	1	2	3	4	5
11(b) I am as healthy as anybody I know	1	2	3	4	5
11(c) I expect my health to get worse	1	2	3	4	5
11(d) My health is excellent	1	2	3	4	5

Thank You!