Results of a Qualitative and Field Study Using the WHOQOL Instrument for Cancer Patients

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The main purpose of the study was to evaluate quality of life (QOL) among cancer patients using the WHOQOL-100 instrument and to see if any significant differences were seen in cancer stages, treatment status and prognosis. This study consisted of two parts; qualitative and quantitative. For the qualitative study, two focus groups were conducted by medical professionals to establish the applicability of the WHOQOL instrument in evaluating the QOL of cancer patients, but most participants were negative about using a generic instrument such as WHOQOL. For the quantitative study, 197 cancer patients (average age 55.86) from eight medical centers using the WHOQOL instrument, in addition to each patient's information sheet filled in by their own physicians, were analyzed. The average overall QOL score was 3.39. There was high reliability (Cronbach's alpha = 0.9685) and a high correlation between the psychological and the environmental domains (r =0.7021), the physical domain and the level of independence (r = 0.6031) and social relations and the environment (r = 0.6856) and between health conditions perceived by patients and QOL scores. In addition, differences by gender, treatments and cancer sites were also found to be significantly different at the 5% significance level. The results indicated that the WHOQOL core instrument was sensitive enough to evaluate the QOL of cancer patients.

Key words: quality of life – WHO – cancer patients – cancer

INTRODUCTION

QUALITY OF LIFE RESEARCH INSTRUMENTS IN JAPAN

Quality of life (QOL) research has become increasingly popular among Japanese clinicians since the late 1980s and the number of publications including QOL as a keyword reached more than 3000 in 1995 (1). Along with this, there has been an increase in the number of instruments newly developed for the assessment of quality of life in the Japanese. Despite the large number of publications, however, only a limited number of them have reported on the results of QOL research using a QOL instrument.

The instruments most frequently used in such publications can be classified into three groups: those translated into Japanese from an English instrument; those translated and modified from English ones; and those originally developed in Japanese. However, the publications using instruments translated from English frequently fail to give any description of procedures for cultural adaptability. Where instruments have been modified to Japanese culture, no description of the grounds for the modification is given. And with instruments developed in Japanese, it is rare to find a definition of QOL, a description of the development procedure or psychometric analysis of the results (2). Moreover, despite the fact that a consensus seems to have been reached among researchers in the USA and European countries in the late 1980s that only subjective evaluations of health should be regarded as health-related QOL (3-6), most original Japanese instruments concentrate on people's symptoms and their degree of activity in daily life.

In this sense, the WHOQOL-100 in Japanese is unique (7–9). The WHOQOL-100 is a comprehensive health-related QOL assessment scale whose protocol and content structure were deliberately developed based on a clear definition of QOL which reflected the state of health as defined by the World Health Organization (WHO). It consists of 100 questions abstracted from 300 questions used in pilot instruments based on a data analysis of field studies conducted in 15 collaborating centers around the world. As it was developed simultaneously throughout the world in more than 15 languages, this instrument has made it possible to compare QOL internationally.

The Japanese version was developed by the authors who participated in the pilot study as one of the collaborating centers after going through the procedure of a translation and backtranslation (8). It has five-point differential response scales which were selected from those often used in health status measures in Japan and ensured that the descriptors for each of the response scales would fall 25, 50 and 75% between the two anchor points, using 15 subjects. Each response to a question was accumulated as a point except some of the questions which reversed the direction of the degree. This instrument has also been proved psychometrically sound (10).

OOL RESEARCH ON CANCER PATIENTS IN JAPAN

The principal cause of death in Japan is cancer. It was reported that 263 000 people died from various cancers in 1995 and the mortality rate in that year was 211.6 per 100 000 population (11). The quality of medical treatment and technology in cancer care are relatively high in Japan, but the rights of patients and informed consent are not yet fully recognized. Whether or not to tell patients the name of their disease is still decided by the physician and, according to a survey conducted by the Ministry of Health and Welfare in 1992 (12), only 18.2% of the patients were so informed, while 42.5% found out themselves and 25.1% did not know their diagnosis at all. There is as yet no consensus in the medical field regarding the concept and definition of informed consent itself.

Nevertheless, QOL research on cancer patients accounted for 40% of the total number of QOL publications in 1993 (1). Translated QOL instruments for cancer patients, such as that of the European Organization for Research and Treatment of Cancer (EORTC) (13) and the Functional Living Index—Cancer (FLIC) (14), have been as commonly used in Japan as originally developed instruments. Since 1990 when the Ministry of Health and Welfare organized QOL research groups for different diseases, the Kurihara group has produced a QOL instrument for patients under chemotherapy (15,16), concentrating on ADL and physical condition in five phases taken from FLIC. This has become the standard QOL instrument in Japan.

CANCER-SPECIFIC MODULE OF WHOQOL

With the development of the core instrument, a cancer-specific module has been planned as one of the specific modules of the WHOQOL instrument development project (4). The detailed protocol of the module was developed at meetings in Paris and Nagasaki (17–19). However, it has not yet been decided whether a WHOQOL cancer-specific module needs to be developed or whether the WHOQOL core instrument should be used with some modification. Moreover, there is still some doubt as to whether a generic instrument like WHOQOL is appropriate to evaluate QOL in cancer patients as cancer-specific instruments exist. The WHOQOL module will concentrate on treatment and prognosis specificity and be based on a person's perception of his or her own position in life.

Immediately after the Nagasaki meeting, some of the researchers in Japan who had shown an interest in comparative study agreed to start conducting a survey of cancer patients in their affiliated medical institutions and organized the WHOQOL cancer module development research group of Japan.

SUBJECTS AND METHODS

QUALITATIVE STUDY

For the qualitative study, two focus groups were organized in Tokyo by one of the authors.

SUBJECTS

The first focus group consisted of seven medical professionals, oncologists and nurses and the second group consisted of five patients who had been treated at National Cancer Hospitals within the last 5 years. In addition, two patients in terminal care at St Marianna Hospital were interviewed at their bedsides.

METHOD

First, the participants were asked to read through the WHO-QOL-100 and assess whether they considered it a suitable instrument to measure the QOL of cancer patients and to check 24 facets to see if any aspects should be added or excluded for the QOL of cancer patients to be measured by a moderator. Then, they were asked to describe the attitudes most typically taken by patients when they are first given the diagnosis and the difference that getting cancer had made to their lives.

All the interviews were recorded on audio tape.

QUANTITATIVE STUDY (FIELD STUDY)

SUBJECTS

For the quantitative study, subjects were selected after being given a full explanation of the purpose of the study by the researchers and after having agreed to participate in the study. They were recruited from among both outpatients and inpatients at eight medical institutions in Japan: Cancer Research Institute, Kanagawa Cancer Center Research Institute, Nishi-Kobe Medical Center, Saga Medical School, Saiseikai Central Hospital, St Marianna University, National Cancer Center Hospital and Nagasaki University.

In order to assess the variables that influence the QOL of patients, the subjects were classified into six patient groups (Appendix A) by disease condition (early vs advanced), treatment

status (on vs off) and prognosis (good vs bad). At least 30 participants were expected to participate in each patient group.

For this purpose, a comparative study has been planned to evaluate the QOL of eight different groups of cancer patients classified in terms of cancer stage (early vs advanced), current treatment (under vs without) and prognosis (good vs bad). However, it was agreed based on the results of qualitative study that two of the eight patient groups should be excluded, namely patients in both early and advanced stages under active treatment and those in remission, since it was pointed out it would not be realistic to include them.

METHOD

After being told that the questions should be answered as comprehensively as possible, each subject was asked to fill in the WHOQOL-100 questionnaire in Japanese and the researchers were also asked to fill in each patient's treatment history in a constructed questionnaire (Appendix B).

DATA ANALYSIS

The following are the statistical procedures used to find some common characteristics among subjects by using SPSS version 6.1: (1) the mean QOL score in each domain; (2) correlation between domains; and (3) correlation between scores in each domain and demographic characteristics (factors on the patient's information sheet, which was filled in at the same time as the QOL questionnaire). Also, we were interested in factors which had an effect on QOL scores and so we conducted an analysis of variance with the paired comparisons.

RESULTS

In considering the QOL of cancer patients, it seems logical to describe first the results of the qualitative study, then the quantitative study.

QUALITATIVE STUDY

Focus group of medical professionals

The medical professionals' comments concerning the WHO-QOL-100 questinnaire were somewhat negative owing to its generic nature and its excessive length.

(a) Patients' concern. In the early stages, the patients' concern is directed only towards themselves. They then gradually open up to relationships with others and, in the final stage, when they start to function as members of society again, they start thinking about how to deal with matters in society. Hence the level of importance of the WHOQOL facet shifts according to which stage of disease the patient is suffering. Therefore, some aspects, e.g. the facets of physical safety and security, the physical environment and transport, could be excluded in order to shorten the questionnaire.

The main concern of inpatients who are suffering from pain, fatigue and lack of sleep is how to survive and they focus only on themselves. It is only after the physical aspects are coped with that they consider social relationships. They start paying attention to

the people with whom they come into contact frequently, such as nurses and doctors, and family members. As their colleagues may see them only occasionally, as visitors, they are no longer as important as before the patient was taken ill. Then after the patients reach the stage where they have got some perspective on their illness and their lives, they start worrying about how to return to society.

(b) Length of the questionnaire. The questionnaire should be shortened. Patients under chemotherapy usually feel too tired to answer anything lengthy. This relates to the issue of which stages of treatment should be chosen during which to give the questionnaire to patients. Chemotherapy procedures usually consist of 3–4 week sessions repeated three or four times. Thus, for almost 3 months, patients under treatment cannot function normally owing to the side effects and it can easily be imagined that patients will not have enough energy to answer a long questionnaire. If the questionnaire was shortened to limit the number of questions, this would leave only the physical aspects of QOL related to side effects. In this event, there are many other instruments that it would be preferable to use instead of the WHOQOL.

(c) Heterogeneity of cancer. All the WHOQOL facets seem important if considering patients as normal people with a disease, but as cancer has a variety of symptoms depending on the site at which the cancer appears, it is difficult to review the facets unless a specific target population is clarified. For example, for patients with lung cancer, as clothes can cover the scars from operations, the facet of body image may not be considered as important as for patients with buyo cheek cancer. Similarly, for patients with osteopathic cancer, the facet of mobility will be regarded highly because a wheelchair is a very important means of transportation.

Gender is another important factor to consider. For example, the main concern of female patients with obstetric and gynecological problems is whether or not they are still capable of conceiving after surgery. Hence, the facet of sexual activity can be considered important.

In addition, priorities differ with age. Actually, age can be a factor in selecting types of treatment; there is a tendency for patients over 70 to avoid aggressive treatments, even though mental age does not necessarily correlate with chronological age. However, the National Institute of Cancer Central Hospital will perform any operation desired by the patient, regardless of age.

Inpatients' lives are very circumscribed compared with those of outpatients, even though they may have similar symptoms. Practically speaking, inpatients tend not to confess how they really feel while they are in hospital, since they are worried about damaging their relationships with nurses and doctors by telling them honestly about their dissatisfaction. Hence it is better to administer the questionnaire after the patient has been discharged from the hospital and become an outpatient.

Patients in terminal care tend to be preoccupied with their own concerns. As WHOQOL covers most aspects of QOL, it is not sensitive enough to examine the QOL of this particular population. It would be better to develop a different questionnaire not

based on the WHOQOL core questionnaire if patients in terminal care are going to be the target population.

(d) Potential use of the questionnaire. The WHOQOL questionnaire can be used in the following cases. It is acknowledged that there are significant differences in the level of suffering of lung cancer patients between the USA, Europe and Asian countries. However, no data have been collected on the relative levels of satisfaction of patients in the three regions. The WHOQOL would be useful in comparing the effects of different treatments in different cultures. QOL assessments have often been used to compare the efficacy of treatments, particularly the efficacy of surgery vs chemotherapy. With surgery, even though there is a likelihood that the cancer will recur, at least the patient can go back to work within 2 weeks of the operation. With chemotherapy, on the other hand, the patient can be safeguarded from recurrence of the cancer, but can do nothing for almost 3 months except endure the side effects. To find out which treatment is better for a patient, a questionnaire such as the WHOQOL that covers broad aspects of life can be quite useful.

In addition, the WHOQOL can be an opportunity for the people surrounding the patient, such as their medical staff, family members and friends, to consider how to raise the patient's QOL.

(e) Informing patients of their diagnosis. At the National Institute of Cancer Central Hospital, it is a principle that doctors inform patients of their cancer, which is rare in Japan. In most hospitals, the decision as to whether to inform patients depends on the doctor's personal beliefs. Some doctors try to conceal the fact that their patients have cancer right up to death. It is often observed, however, that once a patient realizes that the doctor has concealed the diagnosis, patients who have been informed are able to accept dying more peacefully than those who have not and remain suspicious about the diagnosis (12). Most patients, however, realize which illness they have, as information about cancer is very easily obtained in Japan.

One explanation as to why informed consent has not become established as a basic principle of medical practice in Japan is that doctors hesitate to inform patients of their disease because mental support systems for patients often do not exist in clinical settings. It has been pointed out that the relationship between medical staff and patients is now undergoing a change and it will be some time yet before patients start articulating their demands while they are being treated.

Focus group and interviews with cancer patients

Cancer patients in the focus group were asked two things: to review the WHOQOL-100 questions and to give their opinions on several issues in order to apply the WHOQOL-100 questionnaire to cancer patients in Japanese clinical settings. In addition, the question of the current situation of informed consent was also addressed.

First, the WHOQOL-100 was criticized for its length and the vagueness of the questions. Second, the participants recom-

mended that the questionnaire be administered to patients who already had some perspective on their cancer and their lives. Such patients should already have been cured or, even if not fully recovered, at least their condition should have stabilized.

Third, since the WHOQOL questionnaire covers a broad range of aspects of life, it was not thought to be applicable to patients whose concerns were very limited, such as those under chemotherapy or in terminal care, because only a few aspects of the WHOQOL are important to them and their concerns are likely to be focused more on themselves rather than on matters more strongly related to society. Every participant pointed out that nobody would want to fill out such a long questionnaire while in chemotherapy. In addition, it was thought that the emotional condition of patients taking painkillers was so unstable that their answers to the questionnaire would be different from those on normal days. Regarding informing patients of diagnosis, they all agreed that informed consent was a patient's right.

Field Study

Data were collected from 197 patients, consisting of 92 males (46.5%) and 105 females (53.5%), at eight different sites. The average age of the participants was 55.83 ± 13.63 . The number of participants at each center is recorded in Table 1. Other demographic characteristics, such as age group, educational background, marital status and treatment history are summarized in Table 2. The data are taken from the questions in each patient's information sheet which was filled in by a physician based on the patient's medical history. The QOL scores in each domain and patient groups are shown in Table 3. The average QOL score of each domain ranged from 3.34 (level of independence) to 3.46 (physical domain) and the overall average QOL score was 3.39 (cf. 3.75 for healthy people using WHOQOL-300).

High reliability was found among the 100 questions (Cronbach's alpha was 0.9685). High correlations were found between the psychological domain and the environmental domain (r = 0.7021), the physical domain and the level of independence (r = 0.6031) and social relations and the environment (r = 0.6856), as shown in Table 4.

Table 1. Number of participants at each center

Center	Males	Females	Total
Cancer Research Institution	5	13	18
Kanagawa Cancer Center	11	6	17
Nagasaki University	13	12	25
National Cancer Center Hospital	1	37	38
Nishi-Kobe Medical Center	9	7	16
Saga Medical School	13	6	19
Saiseikai Central Hospital	34	18	52
St Marianna University	6	6	12
Total	92	105	197

Table 2. Socio-demographic information on participants

Parameter		Male	Female	Total	Average QOL score
Age group	<30	9	2	11	3.47 ± 0.46
	30-39	4	7	11	3.21 ± 0.56
	4049	9	19	28	3.36 ± 0.42
	50-59	14	36	50	3.39 ± 0.52
	60-69	29	28	57	3.50 ± 0.45
	>70	17	7	24	3.53 ± 0.45
Education	Elementary	0	1	l	2.93
	Junior/Senior high	46	67	113	3.40 ± 0.51
	College/University	33	32	65	3.53 ± 0.40
	Graduate School	3	2	5	3.52 ± 0.32
Marital status	Single	12	18	30	3.34 ± 0.463
	Married	61	71	137	3.45 ± 0.49
	Separated/divorced	1	8	9	3.33 ± 0.36
	Widow(er)	6	7	13	3.63 ± 0.29
Surgery experience	Yes	34	21	69	3.48 ± 0.43
	No	39	31	49	3.43 ± 0.50
	Unknown			72	
Chemotherapy experience	Yes	39	23	62	3.56 ± 0.51
	No	33	26	59	3.38 ± 0.42
	Unknown			76	
Radiation therapy experience	Yes	12	12	24	3.46 ± 0.48
	No	62	39	101	3.45 ± 0.43
	Unknown			72	

Table 3. Average QOL score by patient group

Domain	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6	Total
Physical	3.25	3.38	3.55	2.83	3.49	3.12	3.46
Psychological	3.31	3.40	3.48	2.60	3.26	3.45	3.38
Independence	3.15	3.10	3.52	3.18	3.39	2.93	3.36
Social relationship	3.19	3.28	3.41	2.15	3.28	3.27	3.36
Environmental	3.37	3.48	3.49	2.90	3.38	3.29	3.44
Spirituality/religion	3.50	3.43	3.45	2.75	3.42	3.50	3.44
Overall	3.28	3.34	3.48	2.76	3.36	3.25	3.39

Table 4. Correlation coefficients between domains

Domain	Physical	Psychological	Independence	Social relationship	Environment	Spirituality/religion
Physical	1.0000	0.5743	0.6726	0.4533	0.5392	0.3257
	(197)	(197)	(197)	(197)	(197)	(197)
Psychological	0.5743	1.0000	0.6031	0.5847	0.7021	0.5644
	(197)	(197)	(197)	(197)	(197)	(196)
Independence	0.6726	0.6031	1.0000	0.3069	0.4783	0.3152
	(197)	(197)	(197)	(197)	(197)	(196)
Social relationship	0.4533	0.5847	0.3069	1.0000	0.6856	0.4749
	(197)	(197)	(197)	(197)	(197)	(196)
Environment	0.5331	0.7021	0.4783	0.6856	1.0000	0.4832
	(197)	(197)	(197)	(197)	(197)	(196)
Spirituality/religion	0.3257	0.5644	0.3152	0.4749	0.4832	1.0000
	(196)	(196)	(196)	(196)	(196)	(196)

Table 5. Average QOL by chemotherapy experience

Domain	Chemotherapy experience		
	Yes $(n = 62)$	No (n = 59)	
Physical	3.36 ± 0.59	3.48 ± 0.77	
Psychological	3.32 ± 0.42	3.50 ± 0.53	
Independence	3.12 ± 0.64	3.43 ± 0.75	
Social relationship	3.30 ± 0.46	3.41 ± 0.52	
Environment	3.55 ± 0.52	3.38 ± 0.42	
Spirituality/religion	3.25 ± 0.78	3.49 ± 0.87	
Overall	3.30 ± 0.36	3.48 ± 0.51	

Table 6. Health condition and mean QOL scores for level of independence

Health condition answered by patients	Cases	Mean QOL score
Very bad	16	2.53 ± 0.80
Bad	61	2.94 ± 0.58
Neither bad nor good	65	3.50 ± 0.62
Good	37	3.84 ± 0.48
Very good	7	4.36 ± 0.18
Total	186	

No significant differences in mean scores in each domain were observed among the patients' groups. Regarding informed consent, only 20 patients were not informed of their diagnosis and there were no significant differences between the informed and non-informed groups.

The following are some additional findings from the average QOL scores according to different factors.

- (1) Female scores (3.45 ± 0.53) were significantly lower than male scores (3.31 ± 0.49) in the psychological domain (p = 0.050).
- (2) Patients from the National Cancer Center Hospital (3.67 \pm 0.54) had significantly higher scores for level of independence than those from Nagasaki University (2.92 \pm 0.80) at the 5% significance level.
- (3) Patients with bone and cartilage cancers (2.49 ± 0.73) were scored significantly lower than those with female genital organ cancers (3.57 ± 0.60) for level of independence at the 5% significance level.
- (4) Patients with lymphoid, hematopoietic and related tissue cancers (3.218 \pm 0.54) had lower scores than those with cancers of the digestive organs (3.48 \pm 0.54) in the psychological domain and similarly in their environment at the 5% significance level.
- (5) As shown in Table 5, patients under chemotherapy had significantly lower QOL scores in the psychological domain (3.32 \pm 0.42) than those not undergoing it (3.50 \pm 0.53) (*p*-value = 0.039). Similar results were seen for level of independence (p = 0.016) and environment (p = 0.041).
- (6) A strong correlation was seen between health conditions judged by patients themselves and their mean QOL scores. For example, as shown in Table 6, patients who answered

'very bad' (2.53 ± 0.80) or 'bad' (2.93 ± 0.61) scored significantly lower than those who answered 'good' (3.84 ± 0.48) or 'very good' (4.36 ± 0.17) for level of independence at the 5% significance level. Similar results were seen in the physical, psychological, social relationship, environment and spiritual domains.

DISCUSSION

In recent years, the number of QOL studies among cancer patients has increased, but as we pointed out, only a limited number of studies met certain criteria of research (1). Therefore, we conducted QOL research among cancer patients using the WHOQOL instrument that we had participated in during its development.

Based on the results of the qualitative study, we obtained findings similar to those which had often been pointed out: (1) difficulty of evaluation of QOL among cancer patients, (2) difficulty of selection of cancer-specific questions, (3) importance of using the shortest questionnaire for cancer patients given their state of health and (4) difficulty of patients in accepting cancer diagnosis. Further, it was found that some of the facets pointed out by the focus groups as irrelevant to the QOL of cancer patients, such as environmental factors, may in fact be relevant to QOL, based on the results of the quantitative study.

In the quantitative study, several findings which we had not anticipated were obtained. For example, no differences were observed among patient groups classified by the physicians but strong correlations were seen between QOL score and health condition as judged by the patients. Some early-stage cancer patients with a good prognosis actually marked themselves bad in health terms. This may suggest that health condition as judged by the patients themselves at the time when the questionnaire was administered is a more reliable predictor of their QOL. However, it is definitely necessary to carry out further studies to be able to assess what are good predictors of QOL.

Some of the results suggest that mean QOL scores in cancer patients differ depending on the site, treatment and socio-demographic factors. For example, chemotherapy treatment which was potentially toxic was found to be distressing enough to lower QOL scores.

Regarding the adequacy of using the WHOQOL-100, it was found to be too long for physicians to use on a daily basis, a fact pointed out in both the field and qualitative studies. In addition, the instrument will not be accepted by physicians unless it is more responsive to changes in the health status of patients.

As a result, it seems that the WHOQOL-100 instrument is applicable to cancer patients because it is responsive to differences among them. This is a great advantage because patients with different cancer sites and undergoing different treatments can be comprehensively compared.

In the next field study, therefore, it is planned to evaluate the QOL of cancer patients longitudinally, using the WHOQOL-Bref. This consists of 26 items, and has just been produced based on the validation study of the WHOQOL-100 (20).

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APPENDIX A: PATIENT GROUPS

Group	Disease stage	Active treatment at present	In remission at present
1	Early	Yes	No
2	Advanced	Yes	No
3	Early	No	Yes
4	Early	No	No
5	Advanced	No	Yes
6	Advanced	No	No

APPENDIX B: PATIENT INFORMATION SHEET Date: / /19 Investigator's name: Case no.: Patient's name (initial): Birth date: / /19 Gender: M/F Diagnosis: ICD-10 code: Clinical condition: First date of referral: Primary site (Main site: / /19 / /19 Metastasis/Recurrence (Main site:) Current Treatment (for the last three months): If yes: Surgical operation (Yes/No) Title of operation: Radiation therapy (Yes/No) If yes: Site: Gy/week, Total Amount of radiation: Gy/day, Gy Chemotherapy (Yes/No) If yes: mg/day, for Name of drug days, total mg Name of drug mg/day, for days, total mg Name of drug mg/day, for days, total mg Name of drug mg/day, for days, total mg Other treatment (Yes/No) If yes: Pain killer (Name:) Laxative drug (Name:)) Nutritious substance (Name: Neuroleptic or major tranquilizer (Name:) Symptoms (Circle one which is appropriate): 1 Weariness. 2 Tiredness. 3 Unpleasantness. 4 Sleeplessness. 5 Loss of appetite. 6 Nausea. 7 Diarrhea. 8 Abdominal pain. 9 Other pain. 10 High temperature. 11 Hair loss. 12 Numbness. 13 Aphtae. 14 Walking problems. 15 Language problems. 16 Visual problems. 17 Hearing problems. 18 Others.

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