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Needs evaluation questionnaire for liver disease: a novel assessment of unmet needs in patients with chronic liver disease

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Abstract

Patients with chronic liver disease face debilitating complications in their daily living and constantly report several types of unmet needs, but there is a paucity of validated questionnaires to assess these needs. In this study, we present the development of the Needs Evaluation Questionnaire for Liver Diseases (NEQ-LD) for the assessment of unmet needs in patients with chronic liver disease. Two hundred eighty-six outpatients with chronic liver diseases from a single tertiary referral center completed the NEQ-LD and related validity measures. Item response theory analyses were performed and demonstrated the strong psychometric properties of the questionnaire. Differential item functioning analyses showed that the scale functions equally across groups differing for age, sex, and presence of cirrhosis, suggesting the large applicability of the NEQ-LD for the assessment of unmet needs and between-group comparisons.

Andrea Bonacchi and Francesca Chiesi share first authorship.

Abbreviations: 2PL: The two-parameter logistic IRT model; CFI: Comparative Fit Index; DIF: Differential Item Functioning; HADS: Hospital Anxiety and Depression Scale; HADS-A: Anxious symptoms subscale; HADS-D: Depressed mood subscale; IRT: Item Response Theory; MCS-12: Mental health subscale; NEQ: Need Evaluation Questionnaire; NEQ-LD: Needs Evaluation Questionnaire for Liver Disease PCS-12: Physical Health subscale; RMSEA: Root Mean Square Error of Approximation; SF-12: Short Form 12; SNAC: Supportive Needs Assessment tool for Cirrhosis; TLI: Tucker-Lewis index; WB-NRSs: Well-being Numerical Rating Scales.

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Criterion validity measures provided evidence that unmet needs were positively associated with measures of depression and anxiety and negatively associated with measures of subjective well-being and physical and mental health. Unmet needs were expressed by a high percentage of patients, especially in the areas of information and dialogue with clinicians. One third of the sample reported material needs. Most of the items describing unmet needs were reported more frequently by patients with cirrhosis. *Conclusion:* We developed a reliable, valid, and largely employable instrument that can promote patient-centered care and facilitate support services in Hepatology.

INTRODUCTION

Patients with chronic liver disease face potentially debilitating complications that can have a major impact on daily living, and often undergo treatments with significant side effects, putting them in need of several types of support.^[1] An “unmet need” is defined as the gap recognized between the level of service and support received from the health-care system and the one perceived to be necessary to achieve optimal physical and psychosocial well-being.^[2–5] Unmet needs represent a desire to receive support for specific problems and a request for greater assistance from both the staff involved in routine care and the healthcare institution at large. Previous research in patients with chronic illnesses and particularly in patients with cancer showed that needs are distributed in some main areas, including information, education, dialogue with clinicians,^[6,7] assistance/care,^[8,9] psychosocial or spiritual support,^[10–12] and sexual well-being.^[13]

A meta-analysis of 16 prospective studies concluded that psychological distress is associated with liver disease mortality.^[14] Thus, improving quality of life and decreasing psychological distress are highly relevant in the treatment of patients with liver diseases. Unmet needs are related to distress and to the quality of life of patients with chronic illness, and their assessment is associated with the efficacy of clinical and psychosocial interventions, and with satisfaction with care.^[2]

Unmet needs have been investigated in many studies, but most of these are qualitative, while the few quantitative studies did not use reliable and validated tools (e.g., scales and questionnaires) suitable for patients with chronic liver disease.^[15] The use of reliable and validated tools with strong psychometric properties is critical in large-scale studies and to improve reproducibility. Moreover, previous research has focused on patients with specific liver diseases, and whether the results may be generalized across different types of liver diseases remains to be assessed.^[1,15]

To fill this gap, a scale was recently developed to evaluate the needs of patients with cirrhosis—the Supportive Needs Assessment tool for Cirrhosis

(SNAC)^[16] where evidence for internal consistency, structural validity, and test-criterion validity in this group of individuals was provided. Nonetheless, a validated scale applicable to patients with chronic liver diseases to measure unmet needs, irrespective of the etiology and severity of illness, is not available.^[17] Therefore, a single questionnaire to assess unmet needs would be a valuable tool for clinics where patients with a large varieties of liver diseases are managed. Along this line, given the growing demand to understand various unmet needs, an optimal goal is to have instruments assessing disease-specific needs and consisting of general items together with tailored items targeted on the clinical field of interest.^[18]

Starting from this assumption, we aimed to develop a modification of the Need Evaluation Questionnaire (NEQ)^[19,20] specifically addressing needs and preferences pertaining to chronic liver diseases, which we defined as the Needs Evaluation Questionnaire for Liver Diseases (NEQ-LD). Specifically, we first aimed to test the item-scale and full-scale characteristics and performance of the NEQ-LD using the item response theory (IRT) as previously reported for the NEQ.^[21] Second, we evaluated the broad applicability of NEQ-LD in patients with different types of chronic liver diseases. Third, we compared the unmet needs of patients with and without cirrhosis using this instrument.

EXPERIMENTAL PROCEDURES

Participants

We recruited 349 consecutive outpatients with chronic liver diseases scheduled for a visit at the Liver Clinics of Azienda Ospedaliero-Universitaria Careggi, a tertiary referral center connected to the University of Florence, Italy, between October 2018 and July 2019. Inclusion criteria were: (1) an established diagnosis of chronic liver disease; (2) age > 18 years, (3) Italian as a first language, (4) lack of conditions that impaired the patient’s ability to complete the self-reported questionnaires and to release personal information in an interview by the staff, and (5) absence of cognitive

impairment. A diagnosis of cirrhosis was made according to clinical history, histology or imaging, including elastography. No patients were on the transplant list at the time of evaluation. Patients followed up for a short period of time for acute or self-limited conditions (e.g., drug-induced liver injury) were not enrolled.

All research was conducted in accordance with both the Declarations of Helsinki and Istanbul. All participants were made aware that their data would be deidentified, that no individual data would be eventually used to identify patients and that the decision to participate would not have affected the care received. Written informed consent was obtained from all participants. Ethical approval was obtained from the local Institutional Review Board (CEAVC n.10574_oss).

Design, measure, and procedure

A descriptive observational design was adopted in this cross-sectional survey.

Development of a NEQ-LD

The NEQ-LD was developed including 23 items from the NEQ^[19,20] and 4 items (i.e., “I need help in transfer from home to hospital,” “I need more dialogue between hepatologists and general practitioner,” “I need more help to maintain my normal daily activities as much as possible,” and “I need help in facing problems with my sex life”) adapted from the “Supplementary outpatient module” proposed by Bonacchi et al.^[22] A focus group discussion including 3 hepatologists and a clinical psychologist with experience in Hepatology was conducted to remove items from the NEQ deemed inappropriate for patients with liver diseases, and to develop items specific to the hepatologic context. None of the 27 items developed in oncology were deemed inappropriate or unusable in Hepatology by the experts, and 2 items were added (“I need to have more information on the transmission of my disease” and “I need to have more information on norms and behaviors that can improve my health [healthy balanced diet, appropriate exercise, etc.]”). These additional items are largely aligned with the literature towards health attitudes and behaviors specific to patients with liver diseases.^[23] Thus, we obtained a self-administered instrument with 29 dichotomous items (i.e., yes/no answer) about informative, assistance/care, relational, psychoemotional and spiritual support, and material needs. Higher scores indicate that there are more unmet needs (range: 0–29). Since the NEQ-LD is a newly developed instrument for patients with liver diseases, we added an open-ended question at the end to ask patients to list any further unmet needs that were not included in the questionnaire. With this additional question, we aimed to ascertain the requirement to add new items to better describe patients’ unmet needs.

The participants filled out a paper-and-pencil self-report battery that included the NEQ-LD and the following scales (for a detailed description, see Supplementary File 1, <http://links.lww.com/HC9/A23>).

Well-being numerical rating scales^[24]

The Well-being Numerical Rating Scales consists of 5 items that evaluate physical, psychological, relational, spiritual, and general well-being with higher scores indicating higher well-being. In the current study, we administered the item assessing general well-being (range: 1–10).

Short-form 12 items health survey^[25] (Italian version^[26])

The Short-Form 12 items Health Survey assesses Physical and Mental Health (PCS-12 and MCS-12, respectively) and higher scores represent greater levels of perceived health (range: 6–20 and 6–27 for PCS-12 and MCS-12, respectively).

Hospital anxiety and depression scale (HADS)^[27] (Italian version^[28])

The HADS screens for symptoms related to depressed mood (HADS-D) and anxious symptoms (HADS-A) with higher scores representing greater distress. The anxiety and depression scores are categorized as normal (0–7), mild (8–10), moderate (11–14), and severe (15–21).

This battery was presented by psychologists or residents during the follow-up ambulatory visit. Patients were assured that participation was voluntary, and that nonadherence would not have altered the care received. They did not receive any assistance in completing the battery. Participants completed the questionnaire in ~15–25 minutes and were debriefed upon participation.

Statistical analyses

Listwise deletion was used when a case had > 10% of missing answers.^[29] Otherwise, analyses were conducted applying pairwise deletion. SPSS version 27.0, FACTOR 10.8,^[30] and IRTPRO 4.0^[31] were used for descriptive, group comparisons and correlations, factor analyses, and IRT, respectively. IRT was employed to test the psychometric characteristics of the items and the whole questionnaire. Preliminarily, we computed the item percentages of positive answers to check the variability in item responses and assumptions for IRT (unidimensionality and local

dependence). Then, to test the psychometric properties of the NEQ-LD, the 2-parameter logistic IRT model was employed to assess the severity (b) and the discrimination (a) characteristics of the items. The *Test Information Function* was used to evaluate the precision (i.e., reliability) of the scale.

Inside the IRT framework, *differential item functioning* (DIF) analyses were conducted to test the measurement equivalence of the scale comparing sexes, ages (i.e., ≤ 60 vs. > 60 years), and patients diagnosed with cirrhosis versus patients with different liver diseases. Indeed, cirrhosis is associated with numerous systemic complications (e.g., portal hypertension, ascites), leading to a lower quality of life and greater mortality.^[32] From a psychometric point of view, if 2 randomly selected patients, male and female, younger and older, with and without cirrhosis hold the same unmet need, they should have the same probability of endorsing the item describing this need. If this is not the case, the observed difference is not an actual difference, but it depends on some artifacts in the measurement process. This essential measurement issue is adequately addressed by DIF analysis that is based on the comparison across groups of the trait-consistent endorsement of an item and it allows to detect NEQ-LD items that are interpreted differently by males and females, younger and older patients, or patients with or without cirrhosis. Additional information about IRT analyses can be found in Supplementary File 2 (<http://links.lww.com/HC9/A24>).

The Pearson r correlations were computed to test the validity of the NEQ-LD. A total score was computed adding the affirmative answers (range: 0–29). The degree to which the score correlated with external theoretically connected variables provided evidence of validity. In detail, low-to-medium effect size positive correlations ($0.20 < r < 0.40$) were expected for depression and anxiety, while low-to-medium effect size negative associations (correlations $-0.40 < r < -0.20$) were hypothesized for perceived health status and well-being. Finally, χ^2 tests were used to compare each need between patients with and without cirrhosis. Cramer's V values were used for effect size measures: values between 0.10 and 0.30 represent a moderate effect, from 0.30 to 0.50 a medium effect, and > 0.50 a large effect. To compare scale scores between patients with and without cirrhosis, we performed t tests, and Cohen d was used as a measure of effect size (values from 0.2 to 0.5 are indicators of a small effect, values from 0.5 to 0.8 represent a medium effect, and values > 0.8 a large effect).

RESULTS

Sample description

The questionnaire was proposed to 349 patients, and 286 (82%) accepted to participate in the study.

Minimal data were missing across all scales. Thus, only 8 cases were excluded using listwise deletion because $> 10\%$ of the answers were missing. For the remaining cases ($N = 278$) the missing values remained under 3% of the total sample, and pairwise deletion was used. Data on sociodemographic and clinical characteristics of the sample are reported in (Table 1).

Item descriptives

Percentages of affirmative answers ranged from 4.7% to 63.7%, indicating a large variability in item endorsement (Table 2). Most participants (percentages ranging from 40% to 60%) had informative needs about their diagnosis, treatments, and future conditions, but also about rules and behaviors that can improve their health (e.g., diet, physical activity). About one third of the sample reported material needs (e.g., better services from the hospital, more economic-insurance information) and needs of more comprehensible information and more reassurance by the clinicians, along with symptoms control. Percentages between 30% and 15% were observed for the relational needs (e.g., to feel more useful for the family, to speak with people who have had the same experience, to be more helped to maintain the normal daily activities, and to be more reassured by the relatives) and the need to know more about the transmission of the disease. About 15% of the sample expressed other material needs (e.g., economic help), psychoemotional needs (e.g., speaking with a psychologist, to feel less abandoned, and less commiserated), and assistance/care needs (e.g., help with transfers from home to hospital need, more respect for intimacy, more attention from nurses). Finally, the less perceived needs ($< 10\%$) were related to help dealing with problems in the sexual sphere, help for eating, dressing, and going to the bathroom, and to the need to speak with a spiritual assistant.

A total of 35 patients responded to the open-ended question. The answers included the need of a prompt recovery (29%), physical relief (20%), and peace of mind (6%) along with the need to be comforted and reassured by physicians (12%). Upon evaluating these needs in the context of the scale, the psychometric team agreed there were large overlaps with existing items (e.g., physical relief aligns with having symptoms better controlled). Other answers dealt with the need for clear information on the disease (12%), the therapeutic treatment regimen (6%), and the diet (12%). Finally, 1 patient (3%) expressed the need “to fall in love,” clearly outside the aims of the current scale. Taken together, these answers did not reveal additional needs that were not included in the developed questionnaire, that is, they did not suggest that new items have to be added to the NEQ-LD.

TABLE 1 Basic sociodemographic and clinical characteristics of the patients enrolled in this study

	n (%)
Sex	
Female	126 (54.7)
Male	152 (45.3)
Age (years)	
≤ 60	133 (47.8)
> 60	145 (52.2)
Marital status	
Single	58 (20.9)
Married	172 (63.3)
Divorced	22 (7.9)
Widowed	22 (7.9)
Educational level	
Primary	47 (17.2)
Secondary	84 (30.8)
High school	104 (38.1)
University	38 (13.9)
Occupation	
Retired	110 (40.1)
Worker	139 (50.7)
Other	25 (9.2)
Chronic liver Disease	
NAFLD	25 (9.6)
Hepatobiliary cancer (HCC/cholangiocarcinoma)	15 (5.7)
Primary biliary cholangitis	10 (3.8)
Primary sclerosing cholangitis	9 (3.4)
Chronic hepatitis B	32 (17.2)
Chronic hepatitis C	99 (53.2)
Alcoholic liver disease	31 (16.7)
Autoimmune hepatitis	24 (12.9)
Undefined chronic liver disease	16 (6.1)
Cirrhosis	
Yes	115 (43.0)
No	152 (57.0)
Previous HE^a	
Yes	31 (27.0)
No	84 (73.0)
Ascites^a	
Yes	39 (33.9)
No	76 (66.1)

^aIn patients with cirrhosis.

Factor analysis and local dependence

The first factor extracted explained 28.9% of variance, which satisfies the criterion for unidimensionality. Indeed, the one-factor model demonstrated good fit indices (χ^2_{377}

= 753.42, $p < 0.001$, CFI = 0.96, TLI = 0.96, RMSEA = 0.06). Factor loadings were adequate except for item 18 (Table 2). Finally, all χ^2 linkage disequilibrium statistics were < 10 attesting the absence of an excess of covariation among item responses that is not accounted for by a unidimensional IRT model. These results show that the prerequisites for IRT analysis were met.

Item psychometric characteristics

IRT has potential benefits in testing the psychometric properties of a scale because it is a statistical modeling procedure that assumes the characteristics of items and the characteristic of individuals are related to the probability of a positive response. IRT models attempt to explain the relationship between latent traits (unobservable characteristic or attribute) and their manifestations (observed responses) and establish a link between the properties of items on an instrument and individuals responding to these items, assuming that the latent construct and items are organized in an unobservable continuum.

For the NEQ-LD we tested the 2-parameter logistic model that includes 2-item parameters (results are reported in Table 2). The b parameter can be interpreted as the “satisfaction” of the need described by the item and, specifically, higher values identify met needs. The b values ranged from -0.43 to 6.25 and all the b values were above the mean trait level (corresponding to 0) except for 2 that were slightly below the mean. This means that needs perceived to a lesser extent are items 26 and 18, while items 2 and 29 represent compelling needs. The b parameters should be evenly spaced along the trait to provide a differentiation and variability when measuring the unmet needs. (Figure 1) graphically represents that NEQ-LD items met this requisite. The items were quite well distributed along the trait continuum, suggesting that the scale assesses unmet needs associated with different levels of importance.

The a parameter represents the discrimination ability of the item. The higher the a , the better the item’s ability to differentiate between people with different levels of unmet needs. The discrimination values (a) ranged from 0.50 to 3.35 and 20 items out of 29 showed a high or very high discriminative ability. The steepness of most of the curves for most items, depicted in (Figure 1), corresponds to this characteristic.

Reliability

Inside the IRT framework, reliability is evaluated as the precision of the test at different levels of the measured trait. Instead of providing a single value for reliability (e.g., Cronbach α), information across trait scores is computed. The more information the test provides at a particular level, the smaller the error associated with the measurement

TABLE 2 Percentage of affirmative answers, factor loadings, χ^2 fit statistic, item discrimination (*a*), and severity (*b*) estimates of items of the Needs Evaluation Questionnaire for Liver Diseases (NEQ-LD)

NEQ-LD Item	Yes (%)	λ	$S-\chi^2$	<i>df</i>	<i>P</i>	<i>a</i>	<i>b</i>
1. I need more information about my diagnosis	40.9	0.58	30.45	16	0.015	1.92	0.32
2. I need more information about my future conditions	63.7	0.55	10.88	13	0.621	2.02	-0.43
3. I need more information about the exams I am undergoing	39.2	0.62	21.36	16	0.165	2.14	0.37
4. I need more explanations on treatments	43.9	0.66	13.05	13	0.446	2.76	0.21
5. I need to be more involved in the therapeutic choices	36.7	0.63	17.27	15	0.302	2.31	0.44
6. I need clinicians and nurses to give me more comprehensible information	32.4	0.71	27.70	12	0.006	3.35	0.53
7. I need clinicians to be more sincere with me	28.4	0.63	23.92	16	0.091	2.34	0.71
8. I need to have a better dialogue with clinicians	42.1	0.64	13.04	15	0.601	2.31	0.27
9. I need my symptoms (pain, nausea, insomnia, etc.) to be better controlled	33.1	0.60	18.24	17	0.376	2.03	0.58
10. I need more help for eating, dressing, and going to the bathroom	5.8	0.33	10.10	9	0.344	1.73	2.23
11. I need more respect for my intimacy	14.7	0.55	13.00	13	0.450	2.63	1.21
12. I need more attention from nurses	15.1	0.53	21.21	14	0.096	2.39	1.24
13. I need to be more reassured by the clinicians	31.7	0.62	15.72	17	0.545	2.29	0.60
14. I need better services from the hospital (bathrooms, meals, cleaning)	34.2	0.49	20.61	18	0.298	1.42	0.64
15. I need to have more economic-insurance information (tickets, invalidity, etc.) in relation to my illness	33.8	0.59	24.57	17	0.105	1.89	0.57
16. I need economic help	14.4	0.42	19.16	15	0.206	1.46	1.62
17. I need to speak with a psychologist	14.4	0.31	14.49	19	0.755	0.99	2.11
18. I need to speak with spiritual assistant	4.7	0.08	4.01	8	0.856	0.50	6.25
19. I need to speak with people who have had my same experience	23.0	0.32	34.57	20	0.022	0.86	1.60
20. I need to be more reassured by my relatives	15.5	0.49	11.35	16	0.788	1.93	1.34
21. I need to feel more useful in my family	23.4	0.49	24.13	19	0.191	1.54	1.07
22. I need to feel less abandoned to myself	14.4	0.43	11.71	16	0.764	1.63	1.52
23. I need to be less commiserated by other people	13.3	0.42	19.38	15	0.197	1.64	1.59
24. I need help with transfers from home to hospital	13.7	0.30	24.07	17	0.117	0.97	2.21
25. I need more dialogue between the hospital clinicians and my doctor	40.3	0.55	21.96	17	0.185	1.71	0.36
26. I need help dealing with problems in the sexual sphere	8.3	0.27	18.68	11	0.070	1.15	2.51
27. I need more help to maintain my normal daily activities as much as possible	16.2	0.42	13.04	16	0.671	1.45	1.51
28. I need to know more about the transmission of my disease	24.1	0.61	12.12	14	0.597	2.30	0.87
29. I need to know more about rules and behaviors that can improve my health (healthy and balanced diet, appropriate physical activity, etc.)	55.8	0.49	13.88	14	0.460	1.41	-0.21

Note: Parameters were computed under the 2PL model (*a* = discrimination, *b* = severity).

α was fixed at 0.001 to adjust for multiple comparisons ($0.05/29 = 0.0017$).

Abbreviations: *df*, degrees of freedom; 2PL, 2-parameter model.

(i.e., the higher the reliability). The test information curve can be represented graphically (Figure 2) and it shows the local reliability of a test. Within a large range of trait (from -0.075 to 2.25), the amount of test information was equal to or >5 indicating that the NEQ-LD was highly informative. Indeed, if we convert the information in the associated reliability ($r = 1-1/\text{Information}$), reliability was ≥ 0.80 within this range. Since summed scores of the NEQ-LD (i.e., the number of unmet needs reported by the patient) can be translated in IRT trait scores, we can observe that the NEQ-LD is very reliable for a wide score range (precisely, from 2 to 25 unmet needs).

DIF analysis

From a psychometric point of view, if 2 randomly selected patients, male and female, younger and older, with and without cirrhosis hold the same unmet need, they should have the same probability of endorsing the item describing this need. If this is not the case, the observed difference is not an actual difference, but it depends on some artifacts in the measurement process. This essential measurement issue is adequately addressed by IRT procedures called DIF. DIF is based on the comparison across

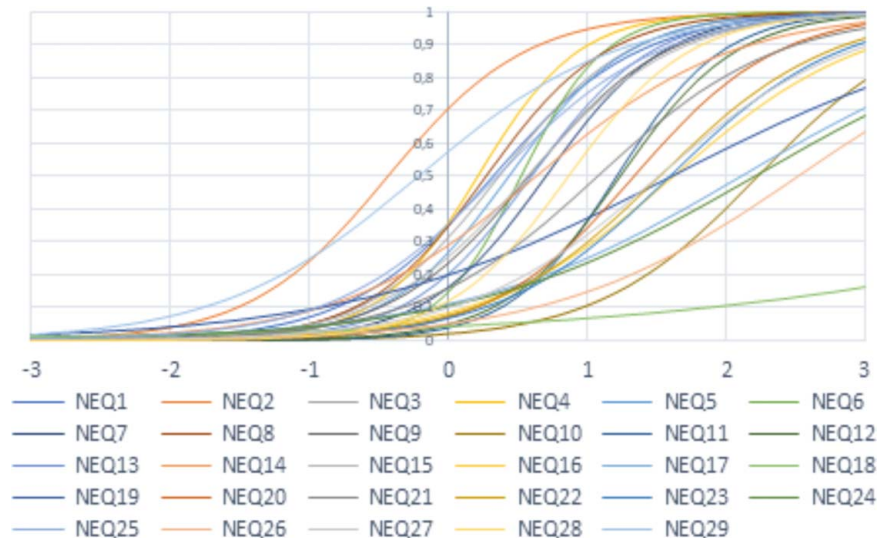


FIGURE 1 Item characteristic curves of each item of the Needs Evaluation Questionnaire for Liver Diseases (NEQ-LD). Latent trait (theta) is shown on the horizontal axis. The probability of item endorsement is shown on the vertical axis.

groups of the trait-consistent endorsement of an item that allows to detect biased items. These results are reported in (Table 3). No items were identified as having DIF except for item 19 (“I need to speak with people who have had my same experience”) when comparing younger (<60 years) and older patients, that is, b parameters were significantly different ($p < 0.001$) and the need was more affirmed by younger patients. Since only 1 out of 29 items showed DIF, this difference can be considered negligible, and we can conclude that the NEQ-LD functions equally across groups.

Validity

As expected, evidence of construct validity was found (Table 4). Using the NEQ-LD total score, medium negative correlations were observed between NEQ-LD and general well-being ($r = -0.33$) and between NEQ-LD and the perceived physical and mental health ($r = -0.39$ and -0.40 , respectively). In addition, moderate positive correlations were observed for depression ($r = 0.34$) and anxiety ($r = 0.28$).

Prevalence of unmet needs in patients with and without cirrhosis

Item endorsement percentages are reported in (Table 5). Additional information about descriptives, group-comparison tests, and effect size can be found in Supplementary File 3 (<http://links.lww.com/HC9/A25>). Significant differences associated with moderate effect size were found for 7 out of 29 items, and patients with cirrhosis reported almost always higher percentages of affirmative answers when compared with patients without cirrhosis (Table 5). Specifically, the larger differences were observed for item 24 ($p < 0.001$, $V = 0.24$) followed by items 10 and 13 ($p < 0.01$, $V = 0.16$ and $p < 0.01$, $V = 0.17$, respectively) concerning need for help with transfers from home to hospital, help for eating, dressing, and going to the bathroom, and being reassured by the clinicians. Smaller differences were observed for items 3 ($p < 0.05$, $V = 0.14$), 6 ($p < 0.05$, $V = 0.12$), 21 ($p < 0.05$, $V = 0.12$), and 23 ($p < 0.05$, $V = 0.12$) concerning clinical information, and need to feel more useful for and less commiserated by other people. (Figure 3) highlights the items of the NEQ-LD receiving a high proportion of affirmative answers, according to the presence or

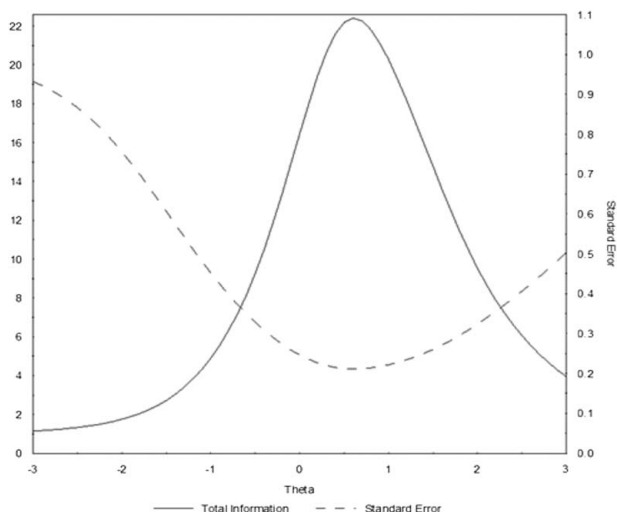


FIGURE 2 Test information function of the Needs Evaluation Questionnaire for Liver Diseases (NEQ-LD). Latent trait (theta) is shown on the horizontal axis. The amount of information (solid line) and the SE (dotted line) yielded by the test at any trait level are shown on the vertical axis.

TABLE 3 DIF analyses of the Needs Evaluation Questionnaire for Liver Diseases (NEQ-LD) across diseases, sexes, and ages

NEQ-LD Item	Cirrhosis						Sex				Age			
	No		Yes		Male		Female		< 60 years		≥ 60 years			
	χ^2	<i>P</i>	χ^2	<i>P</i>	χ^2	<i>P</i>	χ^2	<i>P</i>	χ^2	<i>P</i>	χ^2	<i>P</i>		
1	1.2	0.284	0.2	0.619	0.9	0.340	0.0	0.998	0.5	0.492	0.1	0.798		
2	0.0	0.902	0.7	0.401	0.0	0.896	0.0	0.828	1.4	0.241	0.2	0.631		
3	0.9	0.347	0.3	0.566	0.0	0.863	0.1	0.786	0.0	0.859	0.9	0.346		
4	1.4	0.239	0.1	0.821	0.5	0.496	0.0	0.974	0.3	0.555	0.5	0.486		
5	0.7	0.414	0.8	0.363	0.7	0.407	0.1	0.804	0.0	0.923	0.0	0.935		
6	1.0	0.317	0.0	0.871	0.0	0.899	0.1	0.712	1.8	0.178	1.7	0.188		
7	1.0	0.317	0.2	0.628	1.3	0.264	0.4	0.530	1.3	0.250	1.0	0.309		
8	0.0	0.847	0.9	0.337	1.8	0.182	0.2	0.619	0.0	0.975	0.1	0.729		
9	2.5	0.114	0.0	0.853	0.7	0.399	0.7	0.407	1.3	0.260	0.3	0.560		
10	0.0	0.988	5.3	0.022	0.3	0.608	1.7	0.198	2.2	0.143	3.2	0.072		
11	0.2	0.670	0.2	0.635	0.0	0.979	0.2	0.696	0.7	0.398	1.2	0.280		
12	0.6	0.421	0.0	0.928	0.1	0.766	0.0	0.832	1.2	0.271	0.3	0.605		
13	2.2	0.135	0.5	0.479	0.6	0.429	0.4	0.505	2.4	0.125	0.8	0.370		
14	0.3	0.573	2.8	0.097	0.0	0.896	0.3	0.602	0.8	0.382	0.0	0.992		
15	1.6	0.213	0.0	0.991	0.1	0.809	0.1	0.819	0.9	0.356	4.6	0.032		
16	2.0	0.157	0.9	0.344	0.7	0.405	0.1	0.710	0.3	0.573	8.3	0.004		
17	0.6	0.435	0.7	0.395	0.5	0.469	0.0	0.866	0.2	0.622	8.6	0.003		
18	0.6	0.458	0.9	0.336	0.2	0.640	4.2	0.041	0.1	0.775	0.0	0.904		
19	0.5	0.475	3.8	0.052	0.0	0.901	0.4	0.546	0.1	0.730	11.8	<0.001		
20	4.5	0.034	0.8	0.383	0.2	0.648	1.5	0.226	1.2	0.271	0.1	0.784		
21	0.9	0.353	0.6	0.438	0.1	0.815	1.1	0.290	2.4	0.124	0.1	0.766		
22	0.1	0.741	0.3	0.559	0.0	0.899	0.0	0.963	2.1	0.151	2.7	0.099		
23	3.1	0.077	0.6	0.437	0.3	0.601	2.0	0.157	2.5	0.117	4.7	0.030		
24	0.3	0.573	9.8	0.002	0.6	0.428	1.4	0.239	0.0	0.923	7.8	0.005		
25	0.2	0.633	1.2	0.271	0.0	0.953	0.0	0.932	0.0	0.998	1.5	0.223		
26	1.7	0.198	0.0	0.951	3.9	0.048	0.9	0.348	0.4	0.503	2.0	0.154		
27	0.1	0.726	1.2	0.273	0.0	0.856	0.2	0.625	0.0	0.872	1.6	0.208		
28	0.1	0.754	0.2	0.658	0.4	0.512	0.2	0.696	0.3	0.602	0.4	0.549		
29	0.0	0.894	0.0	0.922	0.4	0.526	0.2	0.670	0.5	0.479	0.2	0.683		

Note: DIF was calculate under the 2PL logistic model. α was fixed at 0.001 to adjust for multiple comparisons ($0.05/29 = 0.0017$).

Abbreviations: a, discrimination; b, location; DIF, differential item functioning; 2PL, 2-parameter model.

absence of cirrhosis. An independent sample t-test showed that patients without cirrhosis scored significantly lower on the NEQ-LD (6.96 ± 6.61) when compared with the patients with cirrhosis [8.76 ± 6.15 , $t = -2.27$ ($df = 265$), $p < 0.05$; Cohen $d = -0.28$]. Additional group comparison between patients with and without cirrhosis in other psychological tests are shown in Supplementary File 3 (<http://links.lww.com/HC9/A25>).

DISCUSSION

Despite their importance, unmet needs in patients with liver diseases have been only marginally investigated,

and the assessment of unmet needs has not entered clinical practice.^[1,15] In a review examining the needs for support and information in patients with cirrhosis and in their families,^[15] all the healthcare professionals reported that patients had a poor understanding of their disease, and required more information on the treatments and on methods to receive greater practical and psychological support. Hence, there is a clear demand for the development of reliable and validated tools to assess specific needs relevant to patients with liver diseases.

In this study, we developed a scale to evaluate the unmet needs of patients with liver diseases. We hypothesized that an optimal instrument to assess disease-specific needs should include items of general

TABLE 4 Means (and SDs) and bivariate correlates between the Needs Evaluation Questionnaire for Liver Diseases (NEQ-LD), well-being, subjective perception of health, depression, and anxiety

	Range	Mean	SD	1	2	3	4	5
1. NEQ-LD	0–29	7.77	6.46	—	—	—	—	—
2. WB-NRSs	1–10	7.05	1.77	–0.33 ^a	—	—	—	—
3. PCS-12	6–20	14.51	3.31	–0.40 ^a	0.50 ^a	—	—	—
4. MCS-12	9–28	18.96	4.33	–0.36 ^a	0.72 ^a	0.53 ^a	—	—
5. HADS_D	0–18	6.64	3.86	0.34 ^a	–0.65 ^a	–0.51 ^a	–0.71 ^a	—
6. HADS_A	0–19	6.56	3.72	0.28 ^a	–0.42 ^a	–0.35 ^a	–0.63 ^a	0.56 ^a

Abbreviations: HADS indicates Hospital Anxiety (A) and Depression (D) Scale; MCS-12, Mental Health Score; PCS-12, Physical Health Score; WB-NRS, Well-being Numerical Rating Scale—General well-being.

^aCorrelation is significant at $p < 0.01$ (2-tailed).

importance along with tailored items targeted on the clinical field of interest. Starting from this assumption, we developed the NEQ-LD for Hepatology through a modification of the NEQ,^[19,20] a self-administered tool largely used in clinical practice and in research, to identify unmet need in patients with cancer.^[22,33] Such a tool can be helpful to support patients in care planning, reduce anxiety, and improve the quality of care.

We first tested the characteristics of each item and of the whole NEQ-LD to investigate the performance of each item and of the overall scale. As previously done for the original NEQ,^[21] we investigated the psychometric properties of the NEQ-LD employing the IRT, which provides a detailed item analysis and scale reliability, to test the suitability of the questionnaire in measuring unmet needs in patients with chronic liver diseases. The spread of severity parameters indicated that the described needs were perceived to a different extent by patients. Specifically, needs less often reported included “I need help dealing with problems in the sexual sphere” and “I need to speak with a spiritual assistant,” while compelling needs were “I need more information about my future conditions” and “I need to know more about rules and behaviors that can improve my health (e.g., healthy and balanced diet, appropriate physical activity).” Most of the items have a large discrimination power that reflects the degree to which an item functions in measuring the assessed topic. Typically, items with low discrimination indices are often ambiguously worded or inconsistent with the questionnaire. Hence, all the items of the NEQ-LD are psychometrically sound and the scale was highly reliable. In addition, validity measures supported the adequacy of the whole scale in measuring unmet needs. In line with the literature,^[14,15,33] negative relationships were observed with well-being and individual’s subjective perception of physical and mental health, while anxiety and depression were positively correlated with the NEQ-LD total score. Overall, these results support the utility of the NEQ in detecting unmet needs in patients with liver disease.

The second aim of this study was to establish whether the scale was metrically invariant across sex,

age, and different chronic liver diseases because the instrument should be psychometrically sound and equally suitable to patients with different characteristics. Thus, we investigated the measurement equivalence of the scale comparing males and females, younger and older patients, and patients diagnosed with or without cirrhosis. The assessment of DIF suggested that the NEQ-LD items equally perform across groups and, except for 1 item when compared by age, all items did not show a different functioning across groups. Thus, regardless of the patient’s characteristics, these data suggest that all respondents attribute the same meaning to the items and have the same understanding of their wording (i.e., the obtained measures are not biased due to artifacts in the assessment process).

Finally, we aimed to provide a first description of the unmet needs in Hepatology using this tool, comparing patients with and without cirrhosis. The request for additional information on prognosis was perceived as unmet need in more than half of the patients which is not surprising in patients with a chronic and often severe disease.^[20] This is in line with previous studies reporting that patients with cirrhosis required to have better information about their disease and different aspects of care^[34,35] and about how to manage their symptoms.^[36] These observations are consistent with those provided by the use of NEQ in patients with cancer, where information needs were the most relevant in all stages of the disease.^[37] More intriguingly and at difference with previous reports,^[15] 55% of patients felt that the amount of information on diet and lifestyle was not sufficient. This is an aspect that goes well along with a disease that affects the gastrointestinal system, and particularly the liver, the function of which is associated with nutrient metabolism and possible toxicity. Several items were reported as unmet needs by > 30% of patients. Among these, the need for better communication regarding the diagnosis of the disease and the diagnostic workup. This underscores the importance of spending time discussing with the patient a plan for the management of the disease. Along these lines, more extensive dialogue with clinicians was felt as a need by 42% of patients. An

TABLE 5 Affirmative answer for each item of the Needs Evaluation Questionnaire for Liver Diseases (NEQ-LD) by cirrhosis (liver disease patients with and without cirrhosis)

NEQ-LD Item	No (%)	Yes (%)	Cirrhosis		Cramer's V
			χ^2 (df=1)	p	
1. I need more information about my diagnosis	38.8	44.3	0.83	0.363	0.06
2. I need more information about my future conditions	61.2	67.0	0.94	0.331	0.06
3. I need more information about the exams I am undergoing	32.9	47.0	5.44	0.020	0.14
4. I need more explanations on treatments	39.5	50.4	3.19	0.074	0.11
5. I need to be more involved in the therapeutic choices	34.9	38.3	0.33	0.568	0.04
6. I need clinicians and nurses to give me more comprehensible information	27.0	38.2	3.86	0.049	0.12
7. I need clinicians to be more sincere with me	23.7	33.9	3.39	0.066	0.11
8. I need to have a better dialogue with clinicians	40.1	44.3	0.48	0.489	0.04
9. I need my symptoms (pain, nausea, insomnia, etc.) to be better controlled	28.9	37.4	2.13	0.145	0.09
10. I need more help for eating, dressing, and going to the bathroom	2.6	10.4	7.08	0.008	0.16
11. I need more respect for my intimacy	12.5	18.3	1.71	0.192	0.08
12. I need more attention from nurses	13.2	16.5	0.59	0.441	0.05
13. I need to be more reassured by the clinicians	24.4	40.0	7.49	0.006	0.17
14. I need better services from the hospital (bathrooms, meals, cleaning)	34.2	31.3	0.25	0.617	0.03
15. I need to have more economic-insurance information (tickets, invalidity, etc.) in relation to my illness	30.3	37.4	1.50	0.221	0.08
16. I need economic help	10.5	18.3	3.28	0.070	0.11
17. I need to speak with a psychologist	15.1	13.9	0.08	0.780	0.02
18. I need to speak with spiritual assistant	5.9	3.5	0.84	0.358	0.06
19. I need to speak with people who have had my same experience	25.7	19.1	1.58	0.208	0.08
20. I need to be more reassured by my relatives	15.1	16.5	0.10	0.757	0.02
21. I need to feel more useful in my family	19.1	29.6	3.99	0.046	0.12
22. I need to feel less abandoned to myself	12.5	18.3	1.71	0.192	0.08
23. I need to be less commiserated by other people	9.9	18.3	3.95	0.047	0.12
24. I need help with transfers from home to hospital	6.6	23.5	15.63	<0.000	0.24
25. I need more dialogue between the hospital clinicians and my doctor	39.5	40.9	0.05	0.818	0.01
26. I need help dealing with problems in the sexual sphere	7.2	8.7	0.19	0.661	0.03
27. I need more help to maintain my normal daily activities as much as possible	12.5	20.9	3.39	0.065	0.11
28. I need to know more about the transmission of my disease	20.4	28.7	2.48	0.116	0.09
29. I need to know more about rules and behaviors that can improve my health (healthy and balanced diet, appropriate physical activity, etc.)	52.0	60.9	2.10	0.147	0.09

Note: Values between 0.10 and 0.30 represents a moderate effect, from 0.30 to 0.50 a medium effect, and >0.50 a large effect.

important aspect confirmed by the present study is related to more practical needs, especially those related to the availability of services and to economic issues. As previously reported by Valery et al.,^[16] these were particularly relevant in patients with cirrhosis, who needed more assistance in the activities of daily living and for transportation to the hospital.

A practical consequence of this work is that the scale can be used to identify patients with particularly high levels of unmet needs, opening the way to intervention to provide targeted and effective answers. Moreover, invariance implies that the same scoring and interpretation

rules can be used in subgroups of patients with different demographic and clinical characteristics. At the same time, the NEQ-LD can be used in research projects to collect information that allow those involved in healthcare policies to allocate the resources available where the need is greater and more urgent. Finally, the NEQ-LD can be used in evaluating the appropriateness and effectiveness of the care system after the implementation of targeted intervention protocols and services aiming at the reduction of the unmet needs of patients.

Along with the aforementioned strengths, the current research has some limitations that must be

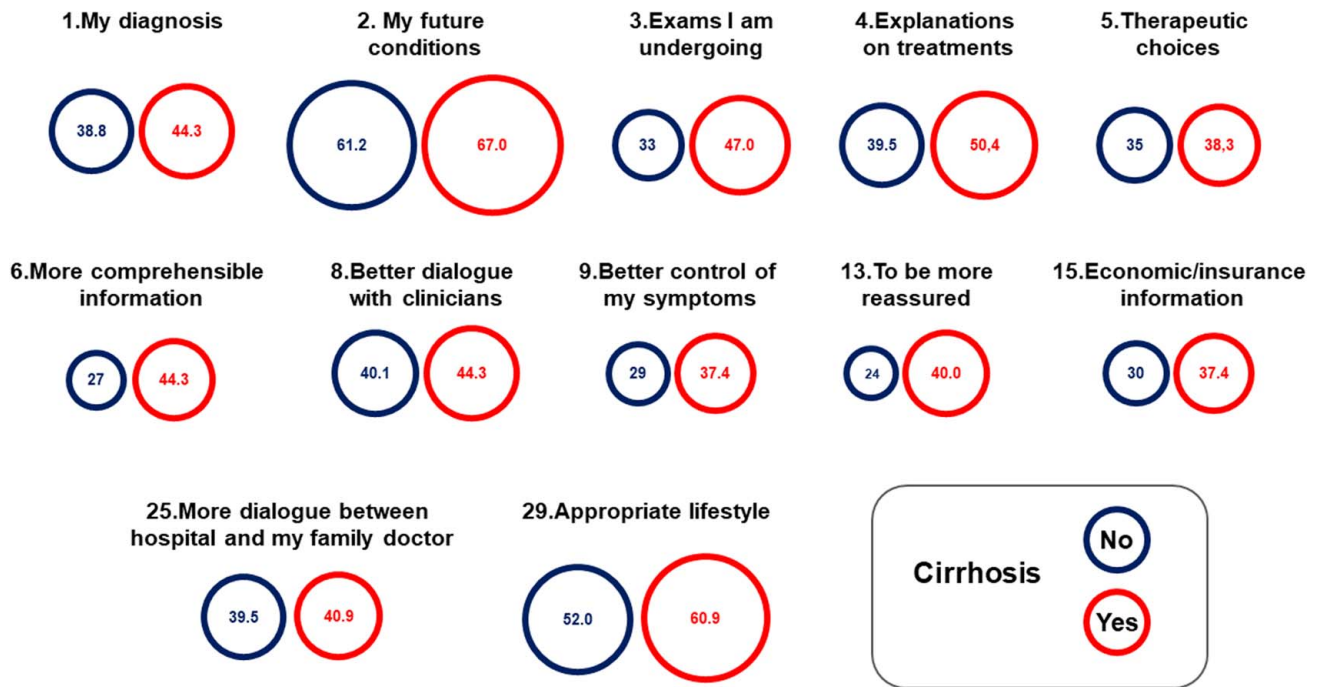


FIGURE 3 Percentages of affirmative answers in items of the Needs Evaluation Questionnaire for Liver Diseases (NEQ-LD) according to the presence or absence of cirrhosis. The size of each circle is proportional to the percentage of affirmative answers, indicated inside. Only items with affirmative answers >35% in at least 1 of the 2 groups are depicted, together with the relative number in the NEQ-LD.

acknowledged. First, item 18 (I need to speak with a spiritual assistant) had poor psychometric properties (i.e., low factor loading, poor discriminative ability, very low endorsement). These results suggest this item does not assess unmet needs as well as other items in the questionnaire, given that the residual SD is larger than the factor weight. Hence, needs may be different in samples comprising both secular and spiritual and/or religious patients. Future studies should evaluate whether this item performs better in a sample enriched in religious and/or spiritual patients. Nonetheless, it has been recognized in other fields (e.g., oncology) that the spiritual needs of patients are rarely met^[38] and that the presence of spiritual pain may be an important component of a patient's distress acting as a mediator of anxiety and depression.^[39,40] Therefore, we decided to maintain this item because this issue was rarely addressed in patients with chronic liver disease.^[15] Second, we employed relatively small samples to test DIF. Future studies should confirm and extend the current results, for example testing invariance differences among other subsamples of patients (e.g., type of hepatitis) or extremely different groups (e.g., very young vs. very old patients). Third, because the study was only conducted in Italian patients, the results may not be necessarily extendable to other populations. After the development of different versions, DIF analysis should be performed across language and settings to provide evidence of the invariance properties of the scale. Finally, because patients with any grade of cognitive impairment were not included, the scale may

not be applicable to patients with any level of hepatic encephalopathy.

In conclusion, the results reported herein provide evidence supporting the use of the NEQ-LD for a reliable and valid assessment of unmet needs in patients with chronic liver diseases. These findings emphasize the potential utility of this tool in clinical practice to promote patient-centered care and to facilitate support services.

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CONFLICT OF INTEREST

Nothing to report.

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