Thrombophilia ad dies vitae

Cohn, D.M.

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Chapter 6

Quality of life after pulmonary embolism: validation of the Pulmonary Embolism Quality of Life questionnaire (PEmb-QoL)

Based on: Cohn DM, Klok FA, Middeldorp S, Scharloo M, Büller HR, van Kralingen KW, Kaptein AA, Huisman MV. J Thromb Haemost 2010; in press.

Abstract

Background

Even though quality of life (QoL) has become a key component of medical care, there is no instrument available that specifically measures QoL after pulmonary embolism (PE). Recently, the Pulmonary Embolism Quality of Life (PEmb-QoL) questionnaire has been developed to address this gap.

Objective

To evaluate the validity of the PEmb-QoL questionnaire.

Methods

We distributed the PEmb-QoL questionnaire and the Short Form-36 (SF-36) questionnaire twice among consecutive subjects with a history of objectively confirmed acute PE. Internal consistency reliability, test-retest reliability, convergent validity and criterion validity of the PEmb-QoL were assessed using standard-scale construction techniques.

Results

90 participants completed the questionnaires twice. Internal consistency was adequate (Cronbach's α 0.62-0.94), as well as test-retest reliability (intra-class correlation coefficients: 0.78-0.94). Furthermore, correlation between the PEmb-QoL questionnaire and the SF-36 questionnaire supported convergent validity.

Conclusion

The PEmb-QoL questionnaire is a reliable instrument to specifically assess QoL following PE, which is helpful in the identification of patients with decreased QoL following acute PE.

Introduction

Pulmonary Embolism (PE) is a common disorder characterized by the obstruction of the pulmonary arterial tree by floating thrombi predominantly originating from the leg or pelvic veins.[1] Although PE has traditionally been considered to be an acute disease, the long term natural course in patients surviving the acute thromboembolic event can be complicated by recurrent episodes of PE or deep vein thrombosis, bleeding complications caused by anticoagulant treatment, arterial cardiovascular events and in rare cases by chronic thromboembolic pulmonary hypertension (CTEPH).[1-4] CTEPH may present as fatigue, limited exercise tolerance or shortness of breath and affects approximately 4% of PE patients within 2 years following the initial event, as reported in one study.[3] Moreover, patients often have residual dyspnoea complaints years after the acute thromboembolic event.[5]

Quality of life (QoL) has become an important outcome aspect of medical care. QoL can be assessed by generic or disease-specific questionnaires. The latter are more sensitive than generic questionnaires to detect and quantify small changes that are relevant to patients. Several disease-specific QoL instruments have been developed for deep venous thrombosis (DVT), a condition closely related to PE and considered a manifestation of the same disease entity.[6-10] Furthermore, several specific questionnaires for symptoms of the respiratory tract have been created, such as the Cambridge Pulmonary Hypertension Outcome Review (CAMPHOR)[11]or the Chronic Respiratory Disease Questionnaire (CRQ).[12] However, since respiratory or other symptoms that affect QoL after PE have never been purposely studied, we have developed a new measure -the Pulmonary Embolism Quality of Life (PEmb-QoL) questionnaire-, based on symptoms as reported by 10 interviewed participants with severe complaints following PE. Details on the development of the PEmb-QoL questionnaire have been described previously.[13] The complete questionnaire is presented in the Appendix.

The PEmb-QoL was modelled on the quality of life after DVT (VEINES-QOL/Sym) questionnaire[6,7,9] Both questionnaires assess the frequency of symptoms, the time of day at which the complaints are at their worst, and ADL as well as work related problems. However, the PEmb-QoL questionnaire is distinct from the VEINES-QOL/Sym in the inclusion of pulmonary-specific symptoms, adding questions on limitations in daily physical activities, and extending the number of questions on emotional functioning. Moreover, in order not to lose valuable information, we decided to assess the different areas of limitations as separate dimensions, instead of combining items into two subscales (symptoms and QoL), as is the case in the VEINES-QOL questionnaire. In the present

paper, we report results from the validation study that was performed to assess the psychometric and clinical characteristics of the questionnaire.

Methods

Participants

The Dutch version of the PEmb-QoL was distributed among consecutive participants of a large follow-up study in patients with a history of acute PE referred to the Leiden University Medical Centre. Inclusion criteria were objectively confirmed PE diagnosed between January first 2001 and July first 2007. All surviving patients were invited for a control visit in our outpatient clinic. We asked a random, consecutive subsample of 93 participants to complete the PEmb-QoL and Short-Form 36 (SF-36) questionnaires shortly before this visit. After first review, incomplete questionnaires were completed at the study visit. For assessment of test-retest reliability, participants were instructed to complete both questionnaires for a second time (within a two week period) at home shortly after the visit and return these by mail. Incomplete returned questionnaires were completed by the patients following contact by telephone. We excluded participants with language barriers who could not complete the questionnaires in Dutch. The study protocol was approved by the Medical Review Ethics Committee of the Leiden University Medical Centre and all patients provided written informed consent.

Measures

PEmb-QoL questionnaire

We applied the disease specific PEmb-QoL questionnaire which we developed to assess QoL in patients with PE.[13] The original version of this questionnaire was developed in Dutch. For the creation of the English version (see Appendix), the Dutch version was independently translated by two native English speakers and subsequently back-translated by a third native English speaker. The PEmb-QoL questionnaire contains 6 dimensions: frequency of complaints, ADL (activities of daily living) limitations, work related problems, social limitations, intensity of complaints and emotional complaints. Higher scores indicate worse outcome.

SF-36 questionnaire

The SF-36 is a generic QoL measure containing 8 scales (physical functioning, social functioning, physical role functioning, emotional role functioning, mental health, vitality,

bodily pain, and general health), scoring 0 to 100, with higher values indicating better health.[14] Two summary scores are created by combining scales into a physical health summary score and mental health summary score.

Outcome measures

We expected that the PEmb-QoL dimensions frequency of complaints, ADL limitations, work related problems, social limitations and intensity of complaints would have higher correlations with the physical health summary score of the SF-36, whereas emotional complaints would have a higher correlation with the mental health summary score. The outcome measures of this analysis were internal consistency reliability (which assesses whether several items that propose to measure the same general construct produce similar scores), test- retest reliability, convergent validity, criterion validity (as assessed by comparing the PEmb-QoL dimensions with the dimensions of the SF-36 disease generic questionnaire), and the association of patient demographics, comorbid conditions and PE characteristics with higher or lower QoL in our patient population.

Statistical Analyses

The responses were entered and analysed in SPSS version 16.0.2. Means and standard deviations were calculated for normally distributed variables. Non-normally distributed variables were expressed in medians with ranges. We performed a factor analysis on the items of the PEmb-QoL with varimax rotation to examine the underlying constructs. Internal consistency reliability was calculated with Cronbach's α.[16] Following the recommendations of DeVellis, internal consistency reliability was considered adequate if Cronbach's α was higher than 0.7.[17] Demographic associations of the PEmb-QoL dimensions were tested using independent sample T-tests in case of two categories and analysis of variance with post-hoc Scheffé tests[18] in case of more than two categories. Test re-test reliability was expressed as intra-class correlation coefficients. We calculated inter-dimension correlations and criterion validity with bivariate Spearman correlation coefficients.

Results

Patients

The questionnaires were distributed amongst 93 participants, of whom 90 completed the questionnaire after a median period of 38 months (range 10 – 91 months) following the PE.

Three participants (3.2%) were excluded due to inability to complete this questionnaire in Dutch because of language barriers. The number of missing items was very low; however the exact number could not be calculated as all missing items were completed by the respondents following contact by phone with the researchers. Demographic and clinical characteristics are presented in Table 1.

Table 1. Demographics of 93 included patients

demographics of the study population	
Male sex (n, %)	44 (47)
Age (years ±SD)	56±14
Recurrent PE (n, %)	19 (20)
Concurrent illness	
malignancy (n, %)	12 (13%)
pulmonary disease (e.g. COPD) (n, %)	14 (15%)
cardiac disease (n, %)	6 (7%)
Time to registration event* (range)	3 years and 2 months (10 months – 7 years and 7 months)

PE=pulmonary embolism, n=number. * time span between registration acute PE and study inclusion.

Factor analysis (with varimax rotation) supported the underlying dimensions producing 6 factors which accounted for 72% of the total variance. The rotated component matrix is presented in Table 2. Table 3 lists the internal reliabilities of the dimensions, as expressed by Cronbach's α, as well as inter-dimension correlations between the PEmb-QoL dimensions. Internal reliability was high (≥0.87) for the dimensions frequency of complaints, ADL limitations, work related problems, and emotional complaints but lower for the dimension intensity of complaints (α = 0.62). We assessed whether deletion of any of the items in the various dimensions could increase the internal reliability of any of the dimensions (and hence whether the PEmb-QoL questionnaire could be abridged). However, deletion of any of the items from the various dimensions did not lead to substantial improvements of the dimensions' internal consistency reliability. The highest correlations between dimensions were found between intensity of complaints and all other dimensions ($0.60 \leq r \leq 0.79$). Except for work related problems and frequency of complaints (r=0.42), all dimensions were moderately correlated ($0.56 \leq r \leq 0.82$).

Table 2. Rotated component matrix of the PEmb-QoL questionnaire

Pemb-QoL items	Frequency of complaints	ADL limitations	Work related problems	Social limitations	Intensity of complaints	Emotional complaints
1a	**0.771**	0.230	0.202	-0.095	0.223	0.023
1b	**0.806**	0.172	0.029	0.062	0.115	0.047
1c	**0.608**	0.232	-0.014	-0.044	0.040	0.298
1d	**0.757**	0.154	-0.078	0.062	0.151	0.255
1e	**0.628**	0.195	-0.063	-0.359	0.321	0.083
1f	**0.766**	0.075	0.163	-0.061	-0.042	0.242
1g	**0.772**	0.144	0.101	-0.044	-0.019	0.298
1h	0.267	0.424	0.045	0.000	**0.617**	0.190
2	N.A.					
3	N.A.					
4a	0.200	0.158	-0.049	**-0.779**	-0.029	-0.020
4b	0.239	**0.674**	0.322	0.275	0.166	0.129
4c	0.522	**0.568**	0.273	0.182	0.051	0.129
4d	0.118	**0.601**	0.321	0.098	0.433	0.098
4e	0.186	**0.785**	0.251	0.099	0.142	0.085
4f	0.109	**0.860**	0.121	0.011	0.073	0.188
4g	0.138	**0.757**	0.215	0.073	0.391	0.059
4h	0.122	**0.832**	0.084	0.086	-0.009	0.156
4i	0.104	**0.778**	0.231	0.166	0.083	0.162
4j	0.250	**0.833**	0.184	-0.116	0.164	0.101
4k	0.243	**0.845**	0.054	-0.033	-0.006	0.197
4l	0.224	**0.845**	0.020	-0.002	-0.052	0.228
4m	0.291	**0.696**	-0.057	0.070	-0.155	0.157
5a	0.182	0.463	**0.603**	0.133	0.099	0.250
5b	0.105	0.514	**0.651**	0.056	0.132	0.282
5c	0.113	0.559	**0.672**	-0.045	0.147	0.194
5d	0.171	0.565	**0.633**	-0.058	0.171	0.194
6	0.349	**0.600**	0.192	-0.005	0.038	0.311
7	**0.792**	0.314	0.061	-0.167	0.232	0.109
8	0.314	**0.554**	0.178	-0.032	**0.507**	0.291
9a	0.458	0.144	0.108	0.324	-0.044	**0.503**
9b	0.170	0.105	0.164	0.007	0.161	**0.811**
9c	0.042	0.147	-0.003	0.062	0.089	**0.266**
9d	0.284	0.210	0.111	0.066	0.184	**0.834**
9e	0.339	0.231	0.125	0.061	0.141	**0.791**
9f	0.097	0.218	0.138	0.113	0.156	**0.811**
9g	0.433	0.333	0.368	0.009	0.093	**0.439**
9h	0.059	0.374	0.245	0.250	0.043	**0.460**
9i	**0.500**	**0.389**	**0.347**	0.252	-0.076	0.283
9j	0.352	0.353	-0.055	0.158	-0.072	**0.592**

Highest factor loadings are stated in **bold.**

Table 3. Internal Consistency Reliability and Correlations between PEmb-QoL dimensions

PEmb-QoL dimensions	PEmb-QoL questions	Number of items	Cronbach's α	Mean score (SD)	Frequency of complaints	ADL limitations	Work related problems	Social limitations	Intensity of complaints
Frequency of complaints	Question 1*	8	0.90	1.9 (0.9)		-	-	-	-
ADL limitations	Question 4*	13	0.94	1.4 (0.5)	0.61***		-	-	-
Work related problems	Question 5*	4	0.87	1.3 (0.4)	0.42***	0.68***		-	-
Social limitations	Question 6	1	N.A.	1.5 (0.9)	0.66***	0.72***	0.59***		-
Intensity of complaints	Questions 7/8	2	0.62	2.2 (1.1)	0.79***	0.74***	0.60***	0.74***	
Emotional complaints	Question 9*	10	0.91	2.0 (1.1)	0.69***	0.66***	0.59***	0.70***	0.71***

ADL = Activities of Daily Living; *items reversely scored (higher scores indicate more complaints); N.A.= not applicable; ***p < 0.001

The results of the test re-test analysis are presented in Table 4. Intra-class correlation coefficients for test-retest analysis varied between 0.78 for work related problems and 0.94 for frequency of complaints.

Table 4. Test-retest reliability

PEmb-QoL dimensions	intra-class correlation coefficients
Frequency of complaints	0.94***
ADL limitations	0.87***
Work related problems	0.78***
Social limitations	0.83***
Intensity of complaints	0.85***
Emotional complaints	0.81***

***p<0.001

The results of the criterion validity are reported in Table 5. As expected, the PEmb-QoL dimensions frequency of complaints, ADL limitations, work related problems, social limitations and intensity of complaints had higher associations with the physical health summary score of the SF-36 questionnaire, whereas emotional complaints were most strongly associated with the mental health summary score. Frequency of complaints was most strongly correlated with vitality (r=-0.56), social functioning (r=-0.55) and physical functioning (r=-0.46). The strongest correlations for ADL limitations were physical functioning (r=-0.78), social functioning (r=-0.61) and vitality (r=-0.66). Work-related problems most strongly correlated with physical role functioning (r=-0.58) and physical

functioning (r=-0.53). The dimension social limitations was correlated with several SF-36 dimensions. We observed strong correlations with physical functioning (r=-0.54), social functioning (r=-0.55) and vitality (r=-0.53). Intensity of complaints was strongly correlated with the same SF-36 dimensions as frequency of complaints (but with higher correlations coefficients). The strongest correlations for emotional complaints were mental health (r=-0.57), vitality (r=-0.69) and social functioning (r=-0.60).

Table 5. Criterion validity: Pearson correlations between PEmb-QoL dimensions and SF-36 subscales

	SF-36									
PEmb-QoL	**Physical functioning**	**Social functioning**	**Physical role functioning**	**Emotional role functioning**	**Mental health**	**Vitality**	**Bodily pain**	**General health**	**Physical health summary**	**Mental health summary**
Frequency of complaints	-0.46**	-0.55**	-0.33**	-0.28**	-0.45**	-0.56**	-0.42**	-0.55**	-0.44**	-0.42**
ADL limitations	-0.78**	-0.61**	-0.53**	-0.39**	-0.45**	-0.66**	-0.49**	-0.63**	-0.66**	-0.39**
Work related problems	-0.53**	-0.50**	-0.58**	-0.43**	-0.40**	-0.54**	-0.29**	-0.53**	-0.51**	-0.39**
Social limitations	-0.54**	-0.55**	-0.45**	-0.31**	-0.38**	-0.53**	-0.35**	-0.51**	-0.50**	-0.35**
Intensity of complaints	-0.62**	-0.66**	-0.44**	-0.32**	-0.55**	-0.67**	-0.49**	-0.60**	-0.55**	-0.48**
Emotional complaints	-0.45**	-0.60**	-0.38**	-0.43**	-0.57**	-0.69**	-0.41**	-0.59**	-0.40**	-0.57**

*p<0.05; **p<0.01

Analysis of the associations between PEmb-QoL scores and various demographic parameters did not reveal substantial differences in QoL. Men reported slightly lower frequency of complaints (mean score 1.6 vs. 2.1; mean difference -0.48 [95CI -0.86; -0.11]). In addition, patients younger than 50 years (at the time of a first pulmonary embolism) reported higher scores for frequency of complaints (mean score 2.2 vs. 1.7; mean difference 0.59 [95%CI 0.14; 1.03]), as compared to respondents over 50 years of age. Furthermore patients with a concurring cardiac condition (such as heart failure or a prior myocardial infarction) reported more ADL limitations (mean score 2.0 vs. 1.3; mean difference 0.62 [95%CI 0.03-1.21]) and slightly more work related problems (mean score 1.7 vs. 1.2; mean difference 0.52 [95%CI 0.09-0.94]) as compared to respondents without cardiac or pulmonary comorbidity, or a concurring malignancy.

Discussion

The results from this validation study indicate that this newly developed disease-specific health-related QoL instrument PEmb-QoL is a valid and reliable instrument to assess QoL following PE. Internal reliability for all dimensions (except intensity of complaints) was adequate and comparable to the reliability of the VEINES-QOL/Sym scales.[6] Test-retest reliability was also adequate. The inter-correlations between the PEmb-QoL dimensions demonstrated logical relationships. Intensity of complaints correlated with a worse outcome in all other dimensions. This was expected as this dimension might actually affect a person's well-being in general. Also, its association with frequency of complaints is high, suggesting these dimensions could be taken together to form one summary score for symptom severity, comparable to the VEINES-QoL/Sym summary score.

We observed a tendency towards small floor and ceiling effects in some of the PEmb-QoL dimensions. This was assumed to be attributable to the time between the events and completion of the questionnaires. Therefore, we expect that other patient samples including those with a more recent event will show less floor or ceiling effects. Furthermore, we observed that work related problems most strongly correlated with physical role functioning and physical functioning. We hypothesized that this observation is explained by the fact that both dimensions focus on the extent of limitations performing work or physical exercise. Emotional complaints were more strongly associated with mental health and vitality as compared to emotional role functioning. This is also conceivable, as the wording of the items of this PEmb-QoL dimension closely matches the items of the SF-36 dimensions mental health and vitality. Also, the correlation between social limitations and social functioning was (almost) as high as the correlation with physical functioning and vitality. This is a plausible observation as well, since social activities are also influenced by the capability to perform exercises such as climbing stairs or walking a certain distance.

Limitations of our study comprise the exclusion of 3 participants due to language barriers and the lack of detailed comparison to healthy subjects. This comparison is difficult since the PEmb-QoL was designed for patients with acute PE and is by definition not applicable to subjects without this disease. Furthermore, the PEmb-QoL dimensions were created based on the contents of the items and not on the results of factor analysis. *Post hoc* varimax rotation analysis demonstrated that although most items fitted well in the proposed dimensions, few items had more than one high loading (for instance item 8 and 9i) or had higher loadings in other than those they were designated to. On the other hand,

item 9c had low loadings on all dimensions. As this is the first report of factor analysis of the PEmb-QoL questionnaire, future studies should assess whether some items might fit better in other dimensions, possibly allowing removal or regrouping of some items.
In summary, the PEmb-QoL is a valuable instrument for determining the disease-specific QoL in patients with previous acute PE. The clinical applicability of the PEmb-QoL remains to be studied in clinical outcome studies.

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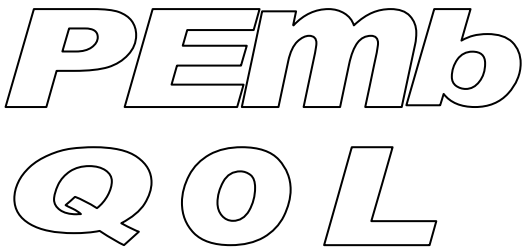
Appendix: the PEmb-QoL Questionnaire



Questionnaire

After having a

PULMONARY EMBOLISM

INSTRUCTIONS HOW TO ANSWER:
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.

These questions are about your **lungs.** The information you give should describe how you feel. You can also indicate how capable you are of carrying out your normal activities.

1. During the past 4 weeks, how often have you had any of the following symptoms from your lungs?					
(Circle 1 answer on each line)	**Every day**	**Several times a week**	**About once a week**	**Less than once a week**	**Never**
Pain behind or between the shoulder blades?	1	2	3	4	5
Pain on or in the chest?	1	2	3	4	5
Pain in the back?	1	2	3	4	5
Sensation of pressure?	1	2	3	4	5
Feeling that there is "still something there"?	1	2	3	4	5
"Burning sensation" in the lungs?	1	2	3	4	5
"Nagging feeling" in the lungs?	1	2	3	4	5
Difficulty in breathing or breathlessness?	1	2	3	4	5

2. At what time of day are your **lung symptoms** most intense? (circle *one answer*)

1. On waking
2. At mid-day
3. At the end of the day
4. During the night
5. At any time of the day
6. Never

3. Compared to one year ago, how would you rate the **condition** of your **lungs** in general now? *(circle one answer)*

1. Much better now than one year ago
2. Somewhat better now than one year ago
3. About the same now as one year ago
4. Somewhat worse now than one year ago
5. Much worse now than one year ago
6. I did not have any problems with my lungs

4. **The following items are about activities** that you might do in a typical day. Do your **lung symptoms** now limit you in these activities? If so, how much?				
(Circle one answer on each line)	**I do not work**	**YES, Limited A Lot**	**YES, Limited A Little**	**NO, Not Limited At All**
a. **Daily activities at work**	0	1	2	3
b. **Daily activities at home** (e.g. housework, ironing, doing odd jobs/repairs around the house, gardening, etc…)		1	2	3
c. **Social or activities** (such as travelling, going to the cinema, parties, shopping)		1	2	3
d. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports		1	2	3
e. **Moderate activities**, such as moving a table, hovering, swimming or cycling		1	2	3
f. Lifting or carrying groceries		1	2	3
g. Climbing **several** flights of stairs		1	2	3
h. Climbing **one** flight of stairs		1	2	3
i. Bending, kneeling, or squatting		1	2	3
j. Walking **more than half a mile**		1	2	3
k. Walking **a couple of hundred yards**		1	2	3
l. Walking **about one hundred yards**		1	2	3
m. Washing or dressing yourself		1	2	3

5.	During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of your **lung symptoms**?		
	(Circle one answer on each line)	**YES**	**NO**
a.	Cut down the **amount of time** you spent on work or other activities	1	2
b.	**Accomplished less** than you would like	1	2
c.	Were limited in the **kind** of work or other activities	1	2
d.	Had **difficulty** performing the work or other activities (e.g. it took extra effort)	1	2

6. During the past four weeks, to what extent have your **lung symptoms** interfered with your normal social activities with family, friends, neighbours or groups? (Circle one answer)

1. Not at all
2. Slightly
3. Moderately
4. Quite a bit
5. Extremely

7. How much pain around your shoulder blades / pain in your chest have you experienced during the past four weeks? (Circle one answer)

1. None
2. Very slight
3. Slight
4. Quite a bit
5. Serious
6. Very serious

8. How much breathlessness have you experienced in the past four weeks? (Circle one answer)

1. None
2. Very slight
3. Slight
4. Quite a bit
5. Serious
6. Very serious

9. These questions are about how you feel and how things have been with you during the past four weeks as a result of your **lung symptoms**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past four weeks -						
(Circle one answer 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**
were you worried about having another pulmonary embolism?	1	2	3	4	5	6
did you feel irritable?	1	2	3	4	5	6
would you have been worried if you had to stop taking anticoagulant medication?	1	2	3	4	5	6
did you become emotional more readily?	1	2	3	4	5	6
did it bother you that you became emotional more quickly?	1	2	3	4	5	6
were you depressed or in low spirits?	1	2	3	4	5	6
did you feel that you were a burden to your family and friends?	1	2	3	4	5	6
were you afraid to exert yourself?	1	2	3	4	5	6
did you feel limited in taking a trip?	1	2	3	4	5	6
were you afraid of being alone?	1	2	3	4	5	6

Legend to the Appendix:
Higher scores indicate worse outcome. Scores for all dimensions are calculated by the sum of the scores for each item of the dimension divided by the number of the items. Questions 1, 4, 5 and 9 are reversed scored. Questions 2 and 3 provide descriptive information.