

Development of a EORTC Questionnaire for Patients with GI-related Neuroendocrine Tumours

This presentation presents a synopsis of the findings and the rationale for the proposed changes to the questionnaire.

Investigators

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Patient Numbers

- England = 61
- Northern Ireland = 25
- Sweden = 31
- Germany = 22
- Italy = 16
- The Netherlands = 25
- **TOTAL = 180**

Distribution of Tumours

Site of Primary

- Ileum = 57
- Pancreas = 66
- Other = 24
- Not known = 33
- Gastrinoma = 20
- Insulinoma = 8

Overview

- This presentation presents the proposed changes to G.I.NET 35. The changes arise from:
 - Results of phase 3 analysis,
 - Comments from collaborators and patients,
 - Distribution of responses for each question.
- The new questionnaire to be used in phase 4, G.I.NET 20, is then presented.

Changes to NET35

Proposed Changes		Not at All	A Little	Quite a bit	Very Much
	During the past week:				
Keep	31. Did you have hot flushes?	1	2	3	4
Keep	32. Have you noticed or been told by others that you looked flushed/red?	1	2	3	4
Delete	33. Did you have trouble with wheezing?	1	2	3	4
Change	34. Did you have abdominal pain?	1	2	3	4
Keep	35. Did you have a bloated feeling in your abdomen?	1	2	3	4
Change	36. Were you troubled by passing wind/gas/flatulence?	1	2	3	4
Change	37. Have you lost weight?	1	2	3	4
Merge	38. Have you had bone pains?	1	2	3	4
38 + 39	39. Have you had aches or pains in your muscles or joints?	1	2	3	4

Changes to NET35

Change	40. Did you have night sweats?	1	2	3	4
Delete	41. Did you have headaches?	1	2	3	4
Keep	42. Were you worried about the tumour recurring in other areas of the body?	1	2	3	4
Change	43. Were you concerned about disruption of family life?	1	2	3	4
Change	44. How distressing, do you feel, has your illness or treatment been to those close to you?	1	2	3	4
Delete	45. Did you worry about your children developing the disease?	1	2	3	4
Change	46. Have you been worried about dying?	1	2	3	4
Delete	47. Have you worried about events at the next appointment?	1	2	3	4
Keep	48. Did you have any limitations in your ability to travel?	1	2	3	4
Delete	49. Have you had trouble having social contact with friends?	1	2	3	4

Changes to NET35

Change	50. To what extent have you been troubled with side effects from your treatment?	1	2	3	4
Delete	51. Did you have any anxiety about receiving the best treatment?	1	2	3	4
Keep	52. Have you had a problem from repeated injections?	1	2	3	4
Delete	53. Did you worry about the effect of your disease or treatment on other organs or parts of your body?	1	2	3	4
Delete	54. Were you satisfied with the care you received from your doctors?	1	2	3	4
Change	55. Did you worry about the results of your examinations and tests?	1	2	3	4
Delete	56. Did you have problems with your investigations (tests)?	1	2	3	4
Change	57. Has the information given about your physical condition and treatment been adequate?	1	2	3	4
	During the past four weeks:				
Change	58. Did you experience any change in your sexual activity?	1	2	3	4

Changes to NET35

Specific Issues

Zollinger-Ellison syndrome/gastrinoma:

Keep	59. Have you had acid indigestion or heartburn?	1	2	3	4
Delete	60. Have you felt nauseated?	1	2	3	4
Delete	61. Have you vomited?	1	2	3	4
Keep	62. Have you had trouble eating?	1	2	3	4

Insulinoma

Delete	63. Did you have seizures?	1	2	3	4
Delete	64. Did you collapse?	1	2	3	4
Delete	65. Did you sweat at anytime of the day?	1	2	3	4

Summary

- Adapted questionnaire has 20 questions.
- Gastrinoma questions put into general questionnaire.
- Not enough Insulinoma data so questionnaire not to be used for these patients.
- Assessment time changed from 1 week to 4 weeks.



EORTC QLQ – G.I.NET20

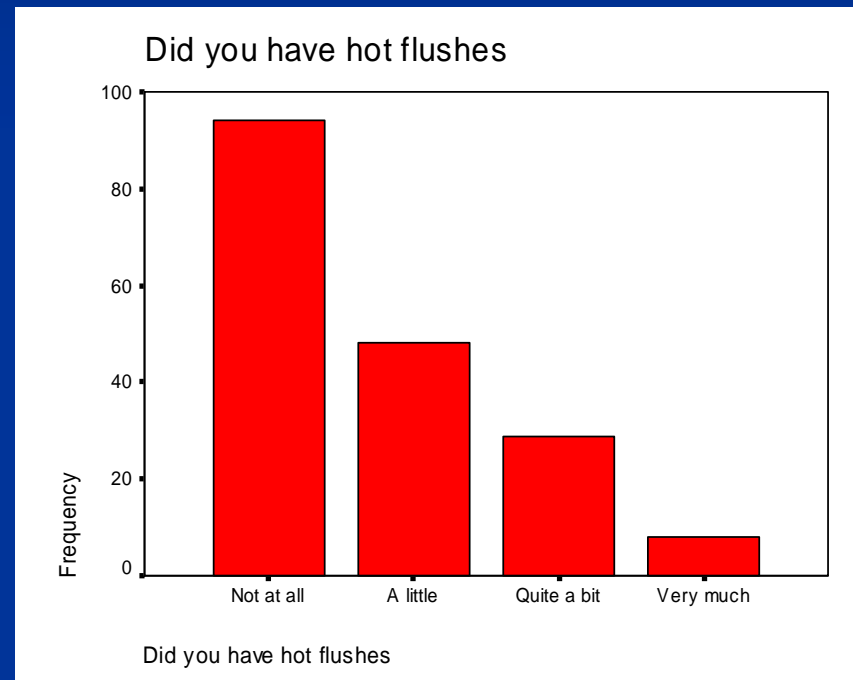
Patients sometimes report that they have the following symptoms or problems. Please indicate the extent to which you have experienced these symptoms or problems during the past 4 weeks. Please answer by circling the number that best applies to you.

During the past four weeks:

		Not at all	A little	Quite a bit	Very much
31.	Did you have hot flushes?	1	2	3	4
32.	Have you noticed or been told by others that you looked flushed/red?	1	2	3	4
33.	Did you have a problem with sweating?	1	2	3	4
34.	Have you had aches or pains in your muscles or bones?	1	2	3	4
35.	Did you have abdominal discomfort?	1	2	3	4
36.	Did you have a bloated feeling in your abdomen?	1	2	3	4
37.	Have you had a problem with passing wind/gas/flatulence?	1	2	3	4
38.	Have you had acid indigestion or heartburn?	1	2	3	4
39.	Have you had difficulties with eating?	1	2	3	4
40.	Have you had side-effects from your treatment?				
	<i>(If not applicable please circle N/A)</i>	N/A			
41.	Have you had a problem from repeated injections?				
	<i>(If not applicable please circle N/A)</i>	N/A			
42.	Were you worried about the tumour recurring in other areas of the body?	1	2	3	4
43.	Were you concerned about disruption of home life?	1	2	3	4
44.	Have you worried about your health in the future?	1	2	3	4
45.	How distressing has your illness or treatment been to those close to you?	1	2	3	4
46.	Have you had a problem with losing or gaining weight?	1	2	3	4
47.	Did you worry about the results of your tests?				
	<i>(If not applicable please circle N/A)</i>	N/A			
48.	Did you have any limitations in your ability to travel?	1	2	3	4
49.	Has the information given about your disease and treatment been adequate?	1	2	3	4
50.	Has the disease or treatment affected your sex life (for the worse)?				
	<i>(If not applicable please circle N/A)</i>	N/A			

Q31 Did you have hot flushes?

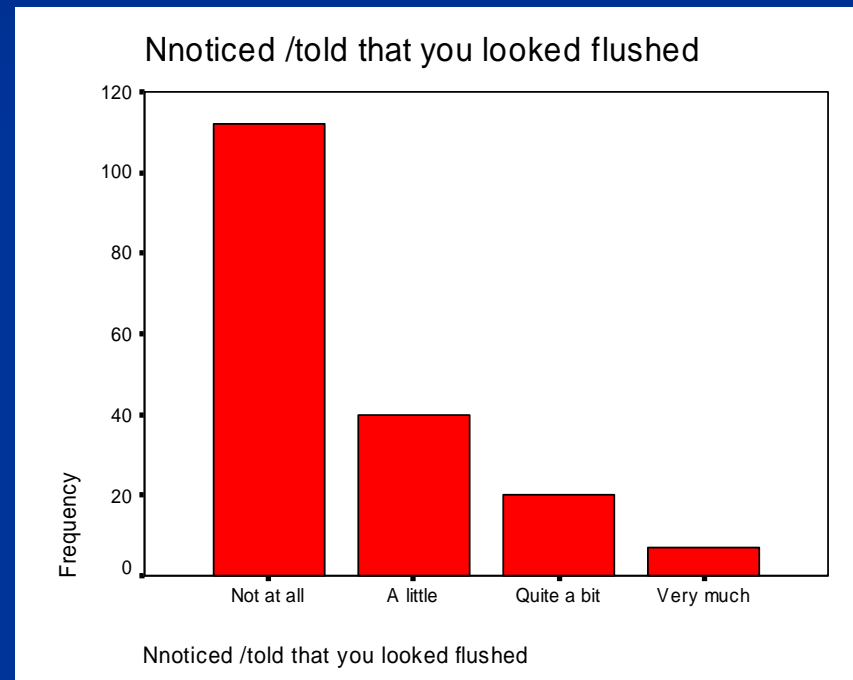
- No negative comments from staff or patients.
- Question to stay.



Mean=1.75

Q32 Have you noticed or been told by others that you looked flushed/red?

- No negative comments.
- Question to stay.

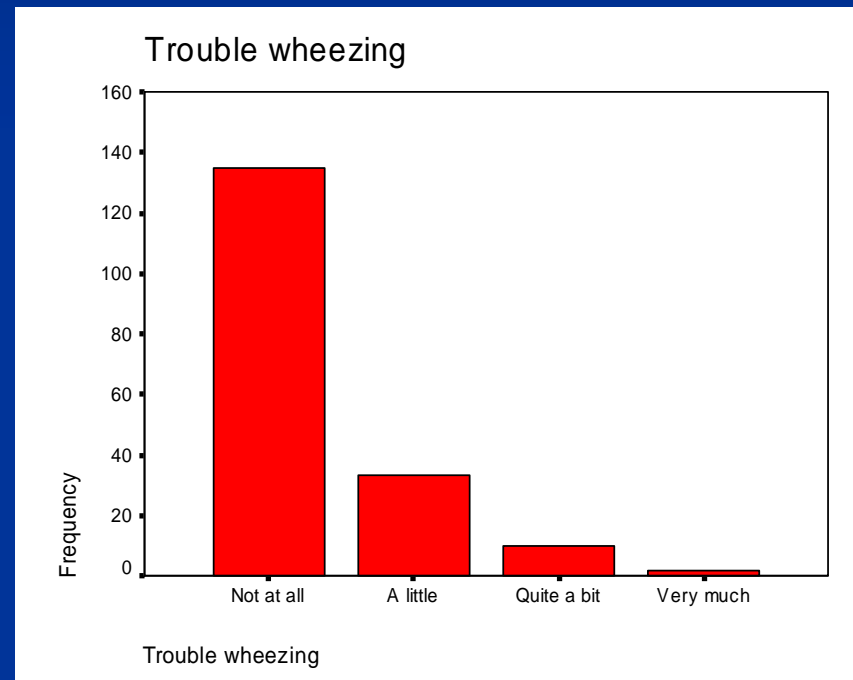


Mean=1.58

Q33 Did you have trouble with wheezing?

Comments:

- Patients-1 patient said difficult to answer.
- Difficult to translate into German.
- Question to be deleted.

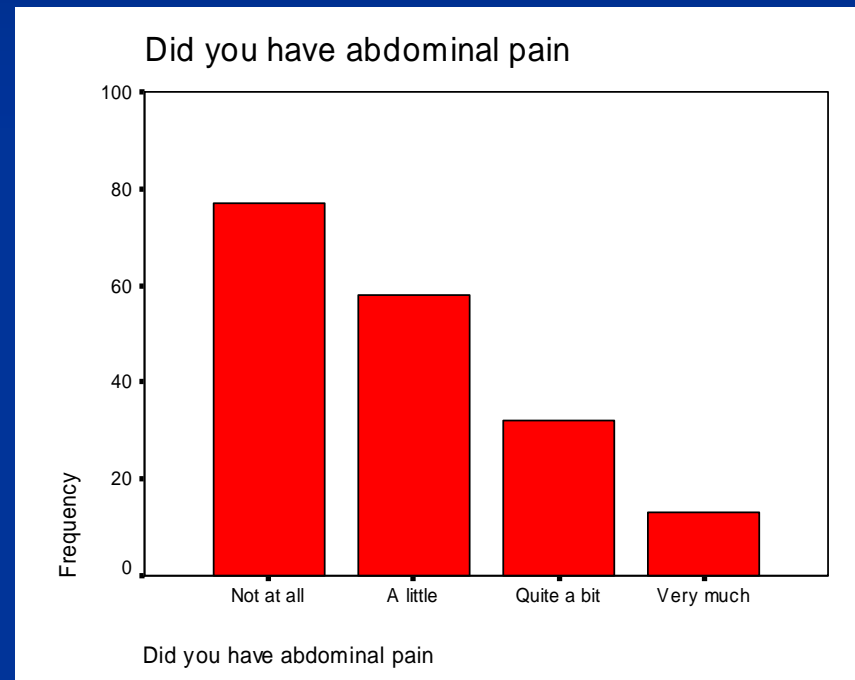


Mean=1.33

Q34 Did you have abdominal pain?

Comments:

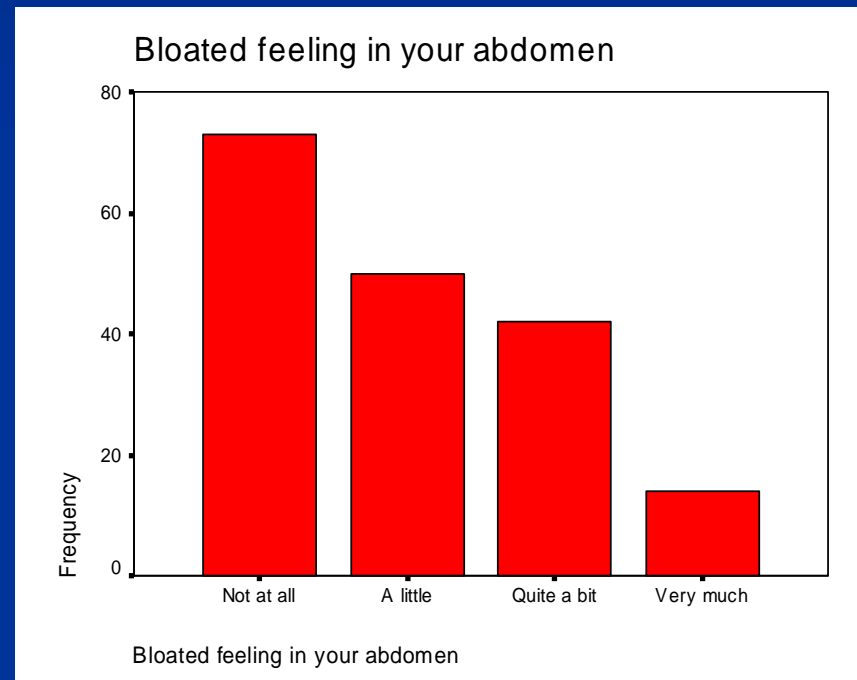
- 1 Patient said difficult to describe pain.
- Staff-said use word discomfort not pain.
- Change wording to *Did you have abdominal discomfort?*



Mean=1.9

Q35 Did you have a bloated feeling in your abdomen?

- No negative patient comments.
- Wording changed in German.
- Question to stay.

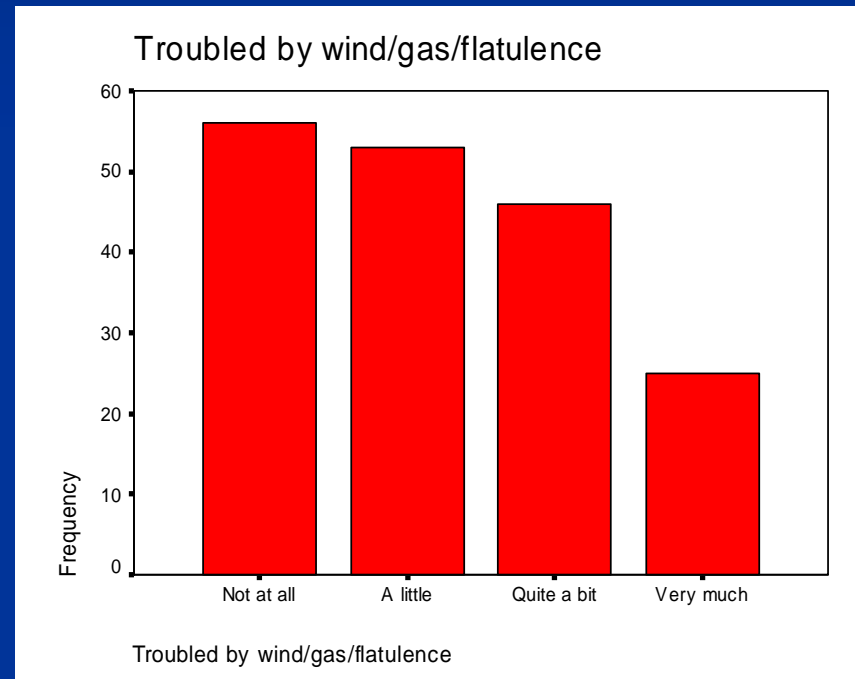


Mean=1.99

Q36 Were you troubled by passing wind/gas/flatulence?

Comments:

- Patients-no negative comments.
- Avoid word troubled.
- Change wording to *Have you had a problem with passing wind/gas/flatulence?*

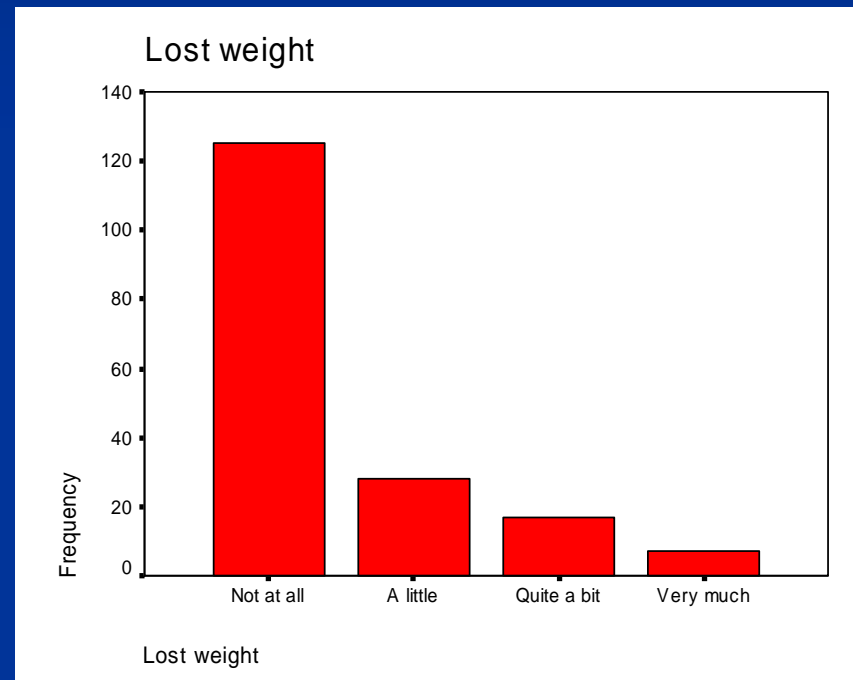


Mean 2.23

Q37 Have you lost weight?

Comments:

- Patients-2 say have gained weight or weight fluctuates.
- Staff-important question.
- Change wording to *Have you had a problem with losing or gaining weight?*

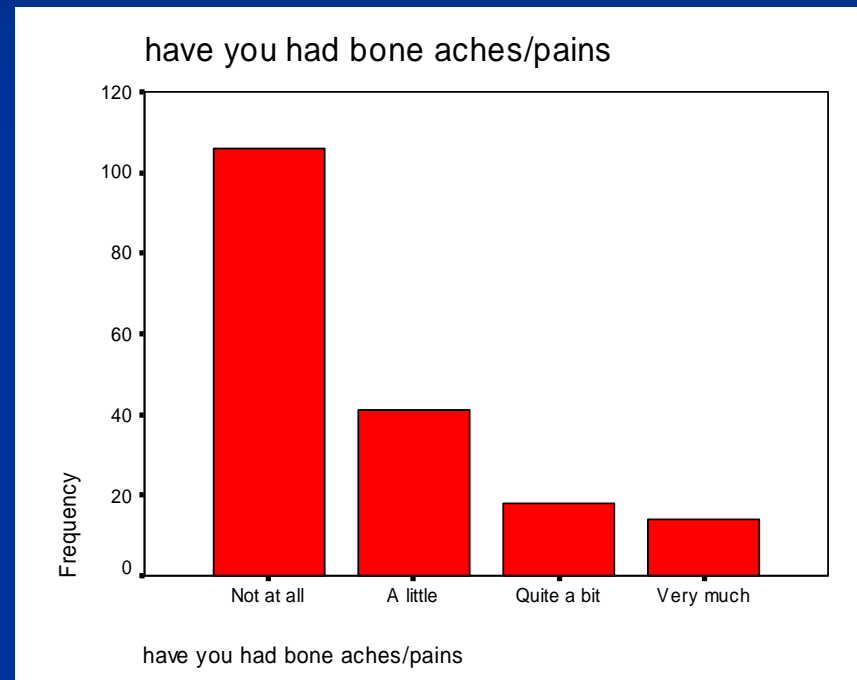


Mean=1.46

Q38 Have you had bone aches or pain?

Comments:

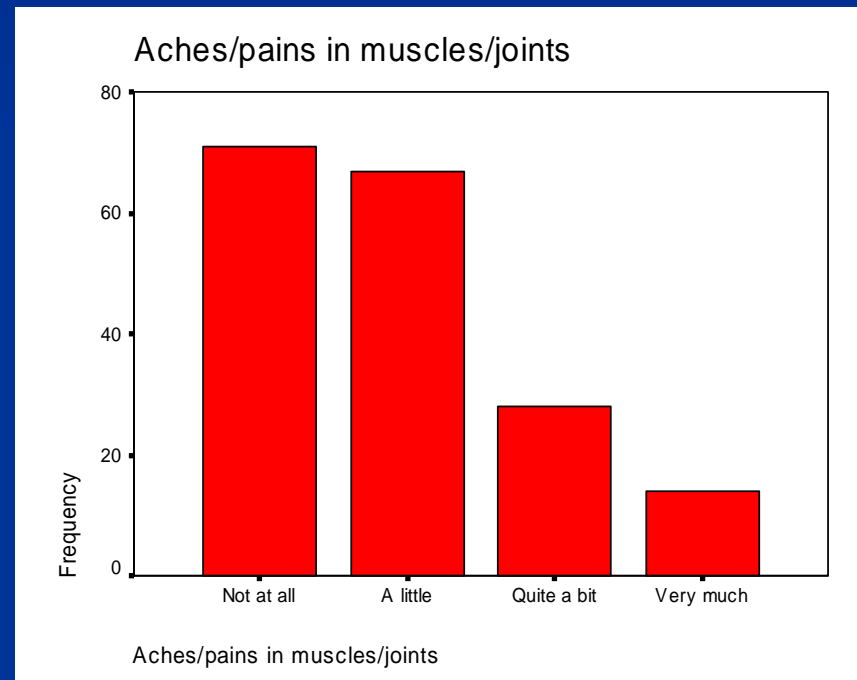
- Patients-1 said confusing.
- Amalgamate with Q39.
- Change wording to *Have you had aches and pains in your muscles or bones?*



Mean=1.67

Q39 Have you had aches or pains in your muscles or joints?

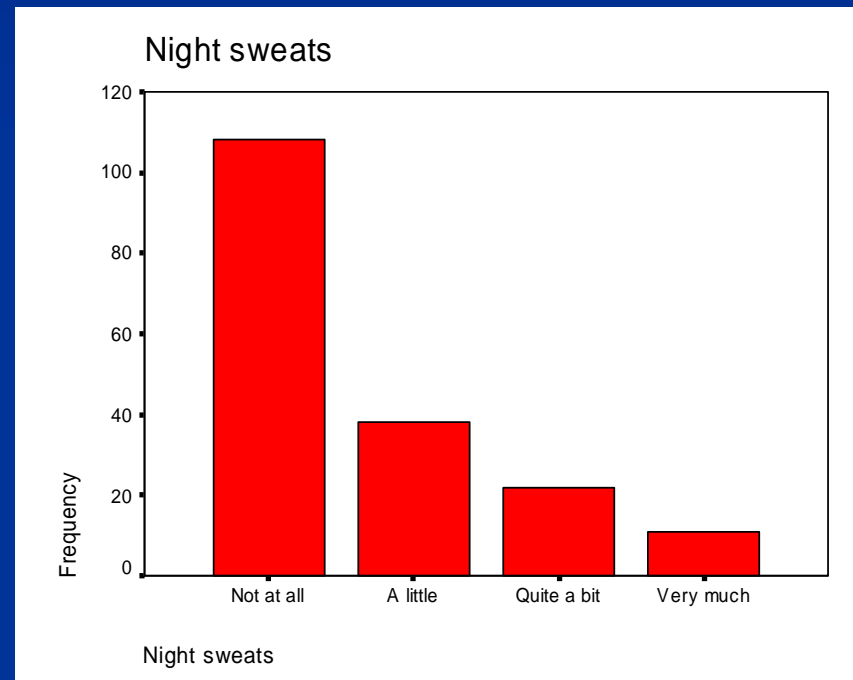
- No negative comments from patients or staff.
- Amalgamate with Q38



Mean=1.93

Q40 Did you have night sweats?

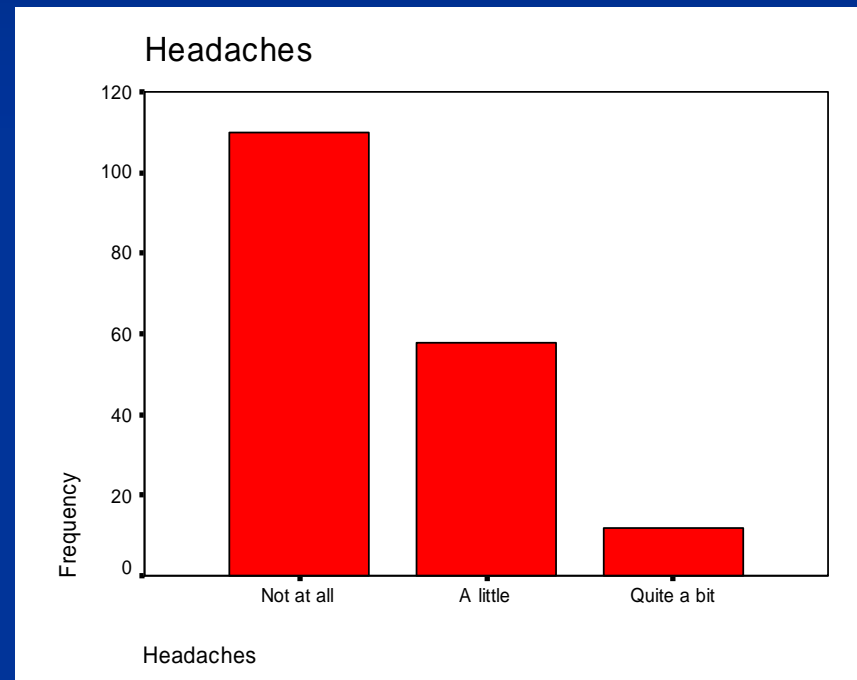
- No negative comments from patients.
- Amalgamate with Q65.
- Change wording to *Did you have a problem with sweating?*



Mean=1.65

Q41 Did you have headaches?

- No negative patient or staff comments.
- Delete this question.

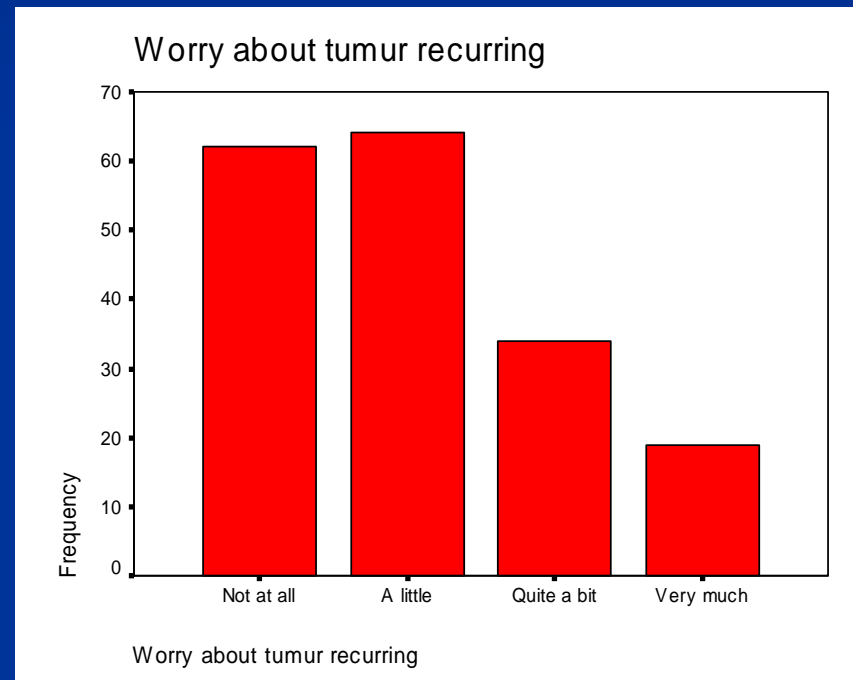


Mean 1.45

Q42 Were you worried about the tumour recurring in other areas of the body?

Comments:

- 2 patients found this difficult to answer.
- No adverse comments from staff.
- Question to stay.

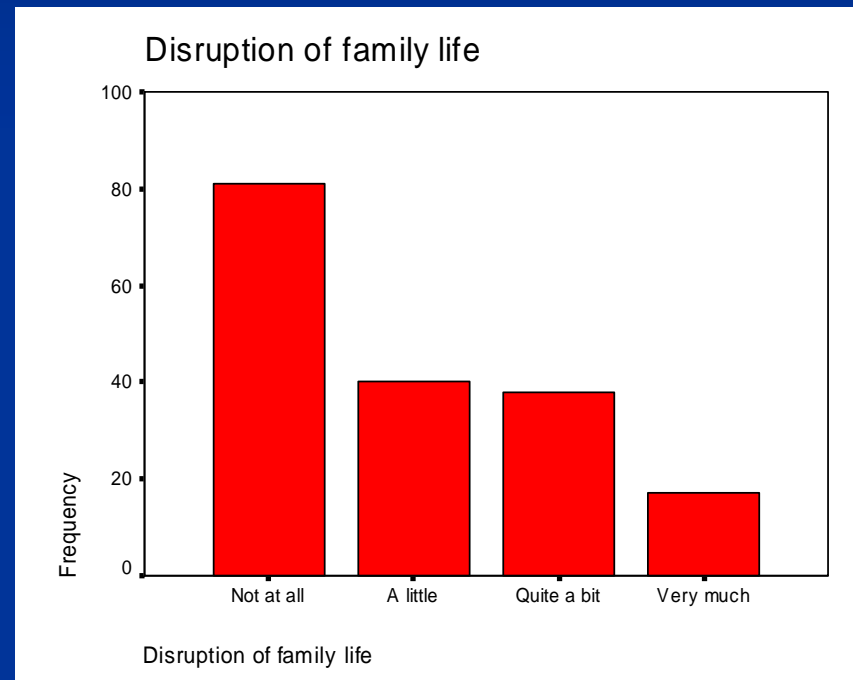


Mean=2.05

Q43 Were you concerned about disruption of family life?

Comments:

- Question not applicable for 2 patients.
- Staff said reword to include home routine.
- Question reworded to *Were you concerned about disruption of home life?*

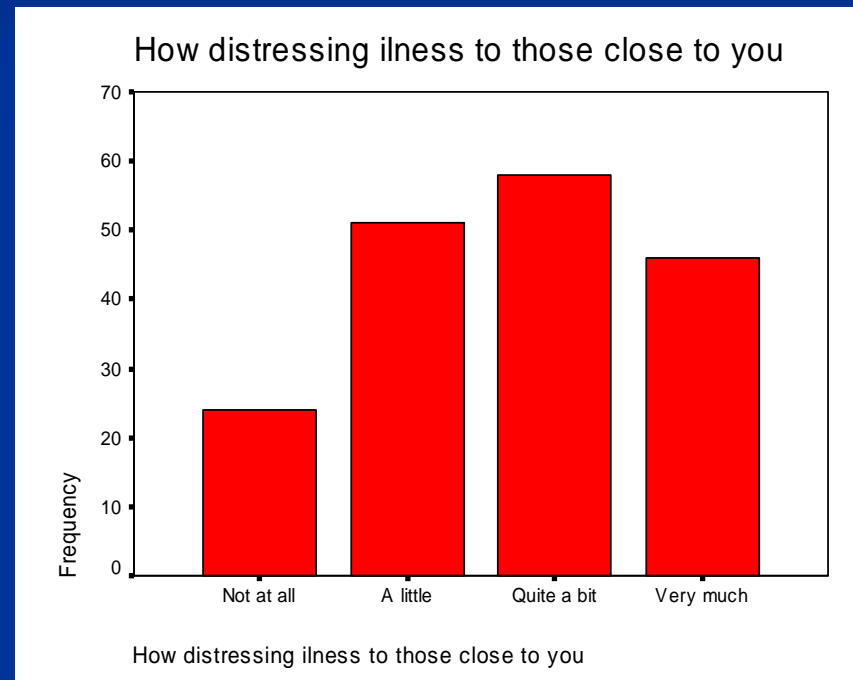


Mean=1.95

Q44 How distressing, do you feel, your illness or treatment has been to those close to you?

Comments:

- Patients –3 difficult to answer,1 upset by question.
- Staff said to make question clearer.
- Change wording to *How distressing has your illness or treatment been to those close to you?*

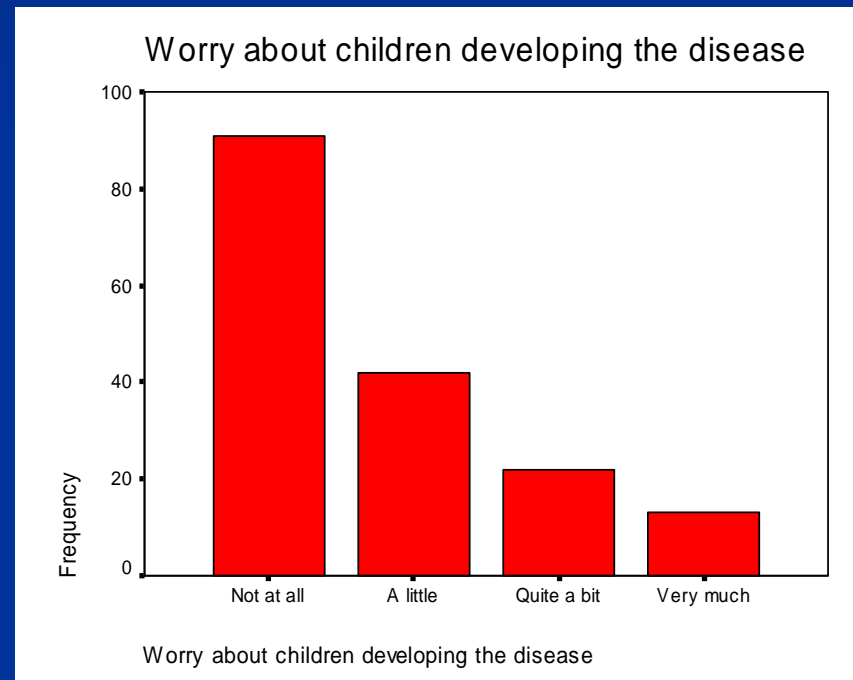


Mean=2.7

Q45 Did you worry about your children developing the disease?

Comments:

- 9 patients said question was upsetting, irrelevant or confusing.
- Staff said to delete it because of patients comments.
- Question to be deleted.

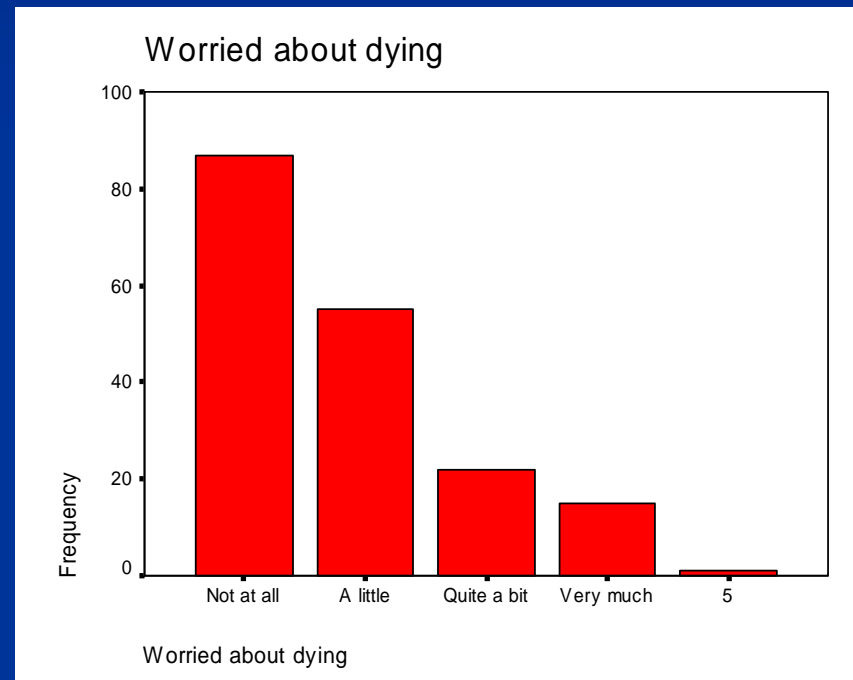


Mean=1.75

Q46 Have you worried about dying?

Comments:

- 9 patients said question was upsetting or intrusive.
- Staff said change to question about future health.
- Wording changed to *Have you worried about your health of the future?*



Mean=1.83

Q47 Have you worried about events at the next appointment?

Comments:

- Staff said question unclear.
- Question to be deleted.

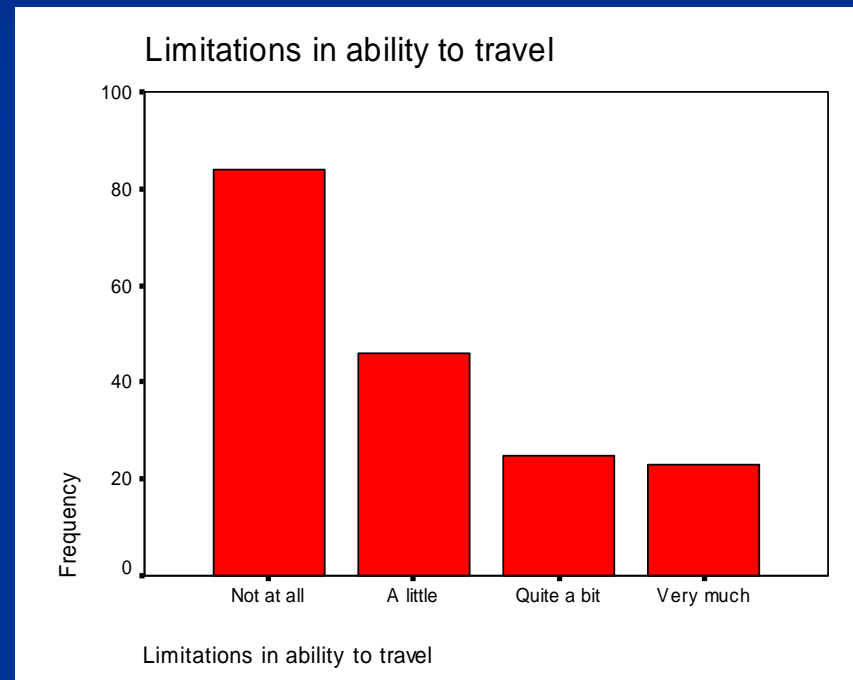


Mean=1.88

Q48 Did you have any limitations in your ability to travel?

Comments:

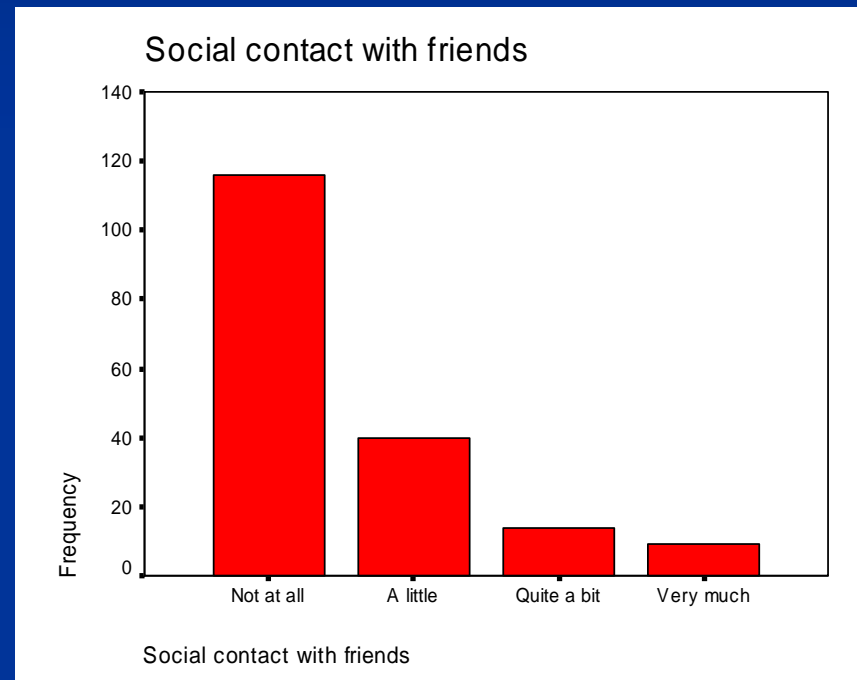
- 3 patients said question confusing.
- Question to stay.



Mean=1.88

Q49 Have you had trouble having social contact with friends?

- Staff commented that it correlates with C30 questionnaire.
- Question to be deleted.

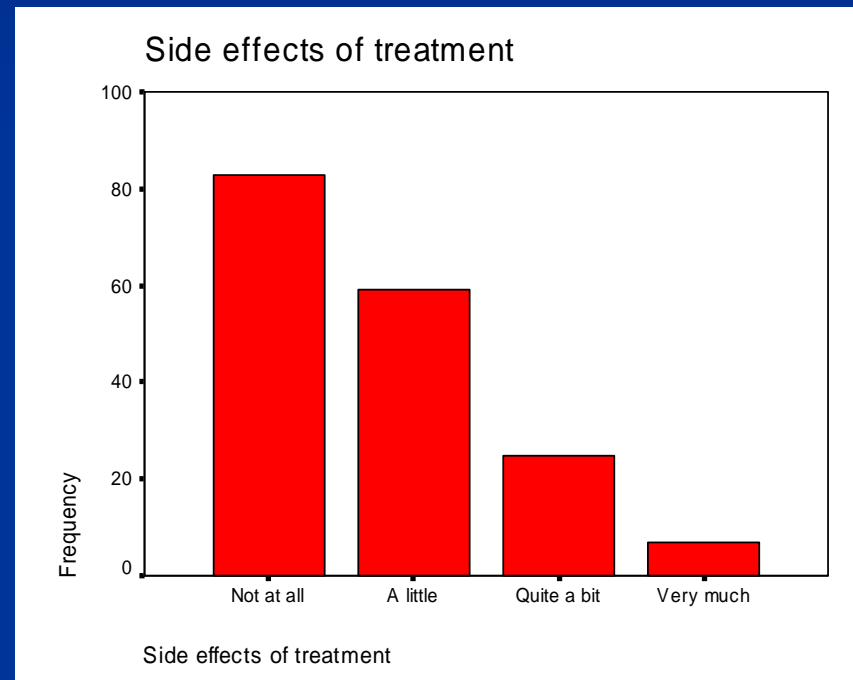


Mean=1.55

Q50 To what extent have you been troubled with side-effects from your treatment?

Comments:

- 4 patients found question confusing or irrelevant.
- Avoid word troubled.
- Use not applicable box within scale.
- Wording changed to *Have you had side-effects from your treatment?*

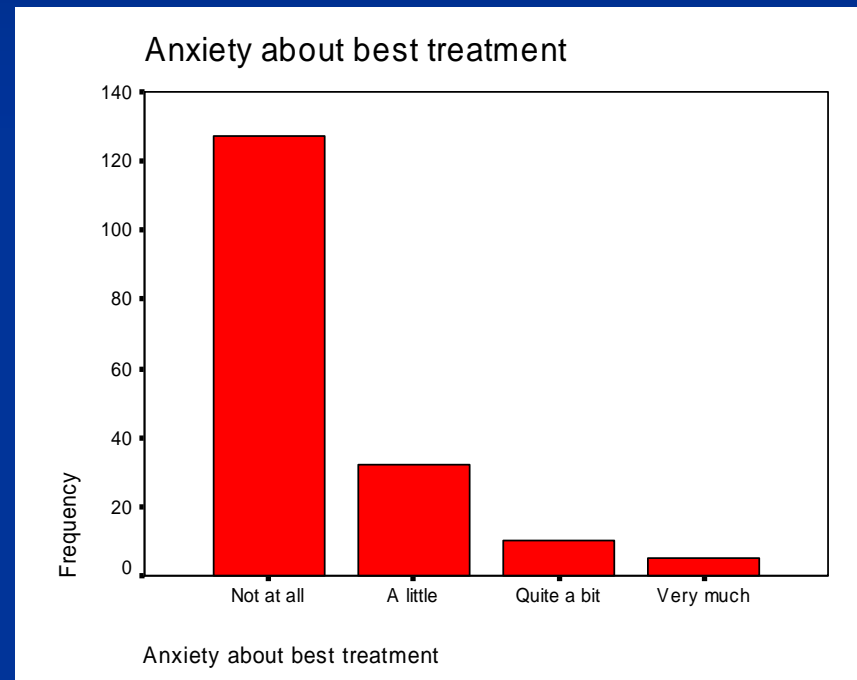


Mean=1.76

Q51 Did you have any anxiety about not receiving the best treatment?

Comments:

- 2 patients said difficult to answer.
- Staff commented it could make patients worry.
- Question to be deleted.

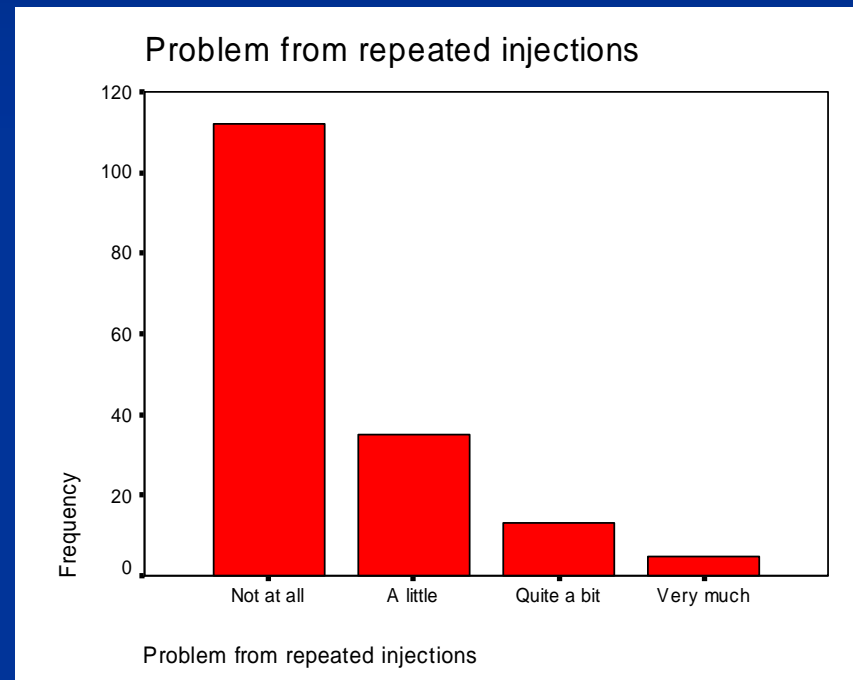


Mean=1.4

Q52 Have you had a problem from repeated injections?

Comments:

- 7 patients said question not relevant.
- Staff agreed to add not applicable box within scale.
- Question to stay.

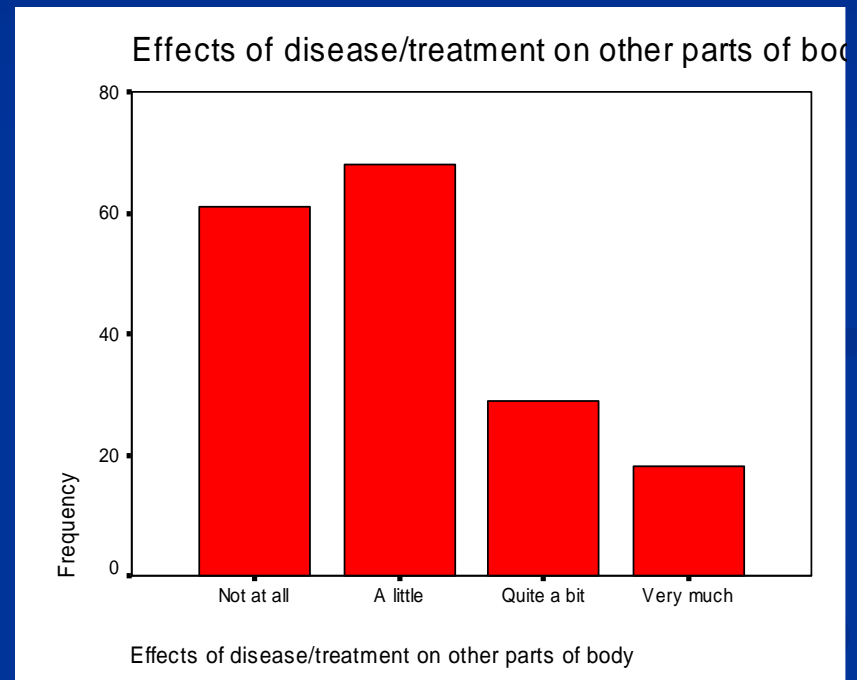


Mean=1.48

Q53 Did you worry about the effect of your disease or treatment on other organs or parts of your body?

Comments:

- 5 patients found question upsetting.
- Question to be deleted because of patients comments.

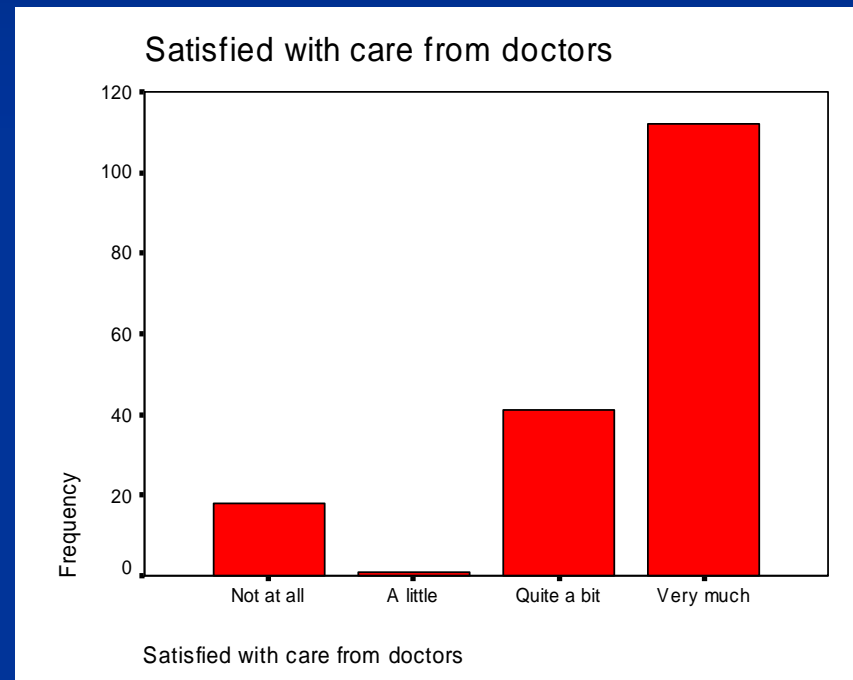


Mean=2.0

Q54 Were you satisfied with the care you received from your doctors?

Comments:

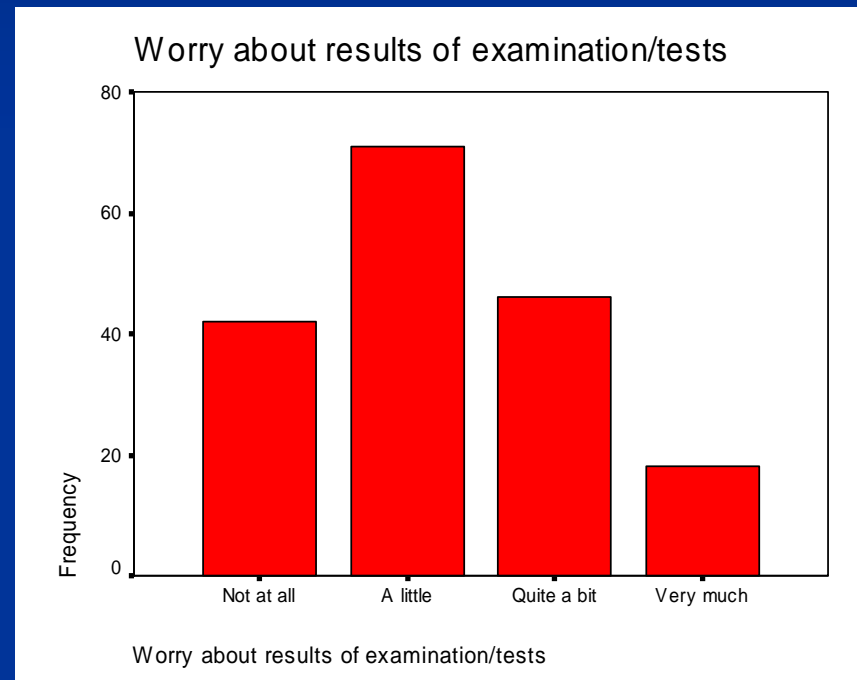
- 7 patients found question confusing-gp or hospital?
- Staff said patients may give biased answers.
- Question to be deleted.



Mean=3.44

Q55 Did you worry about the results of your examinations and tests?

- Staff said to make question clearer because of translation difficulties.
- Use not applicable box within scale.
- Wording changed to *Did you worry about the results of your tests?*

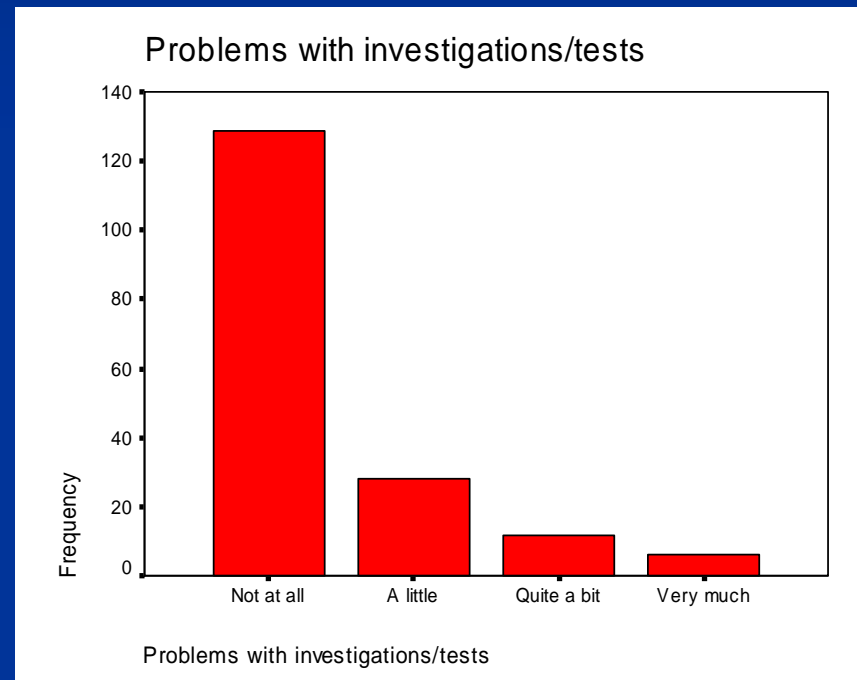


Mean=2.22

Q56 Did you have problems with your investigations (tests)?

Comments:

- 3 patients found it confusing.
- Staff said question is confusing.
- Question to be deleted.

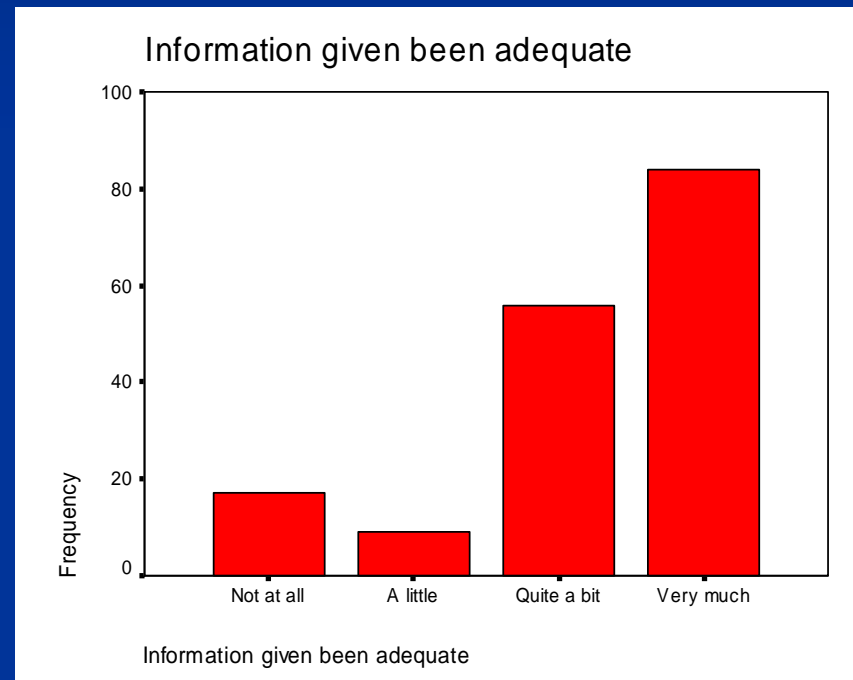


Mean=1.4

Q57 Has the information given about your physical condition and treatment been adequate?

Comments:

- 4 patients found question confusing.
- Staff said change wording from physical condition to disease.
- Wording changed to *Has the information given about your disease and treatment been adequate?*

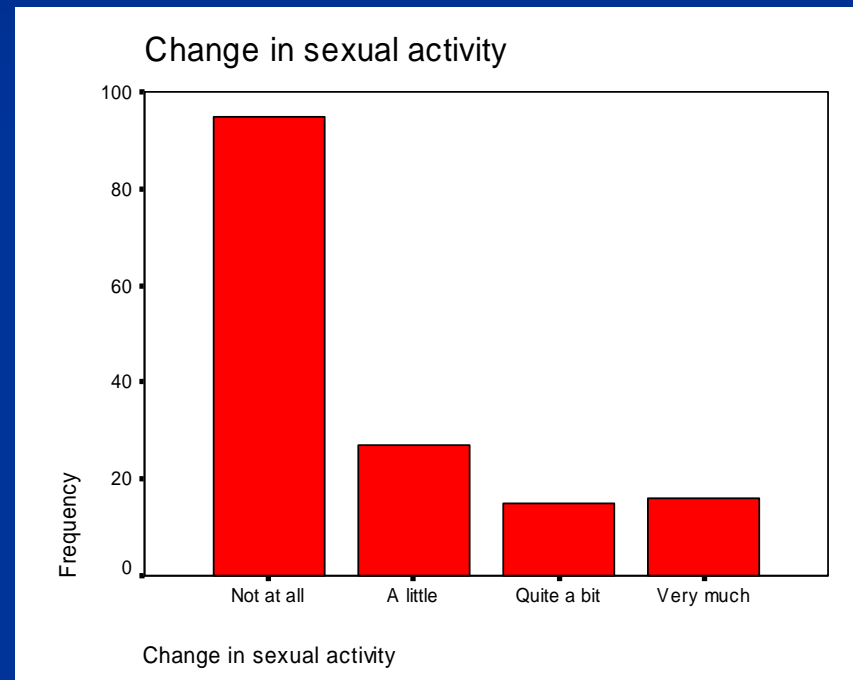


Mean=3.24

Q58 Did you experience any change in your sexual activity?

Comments:

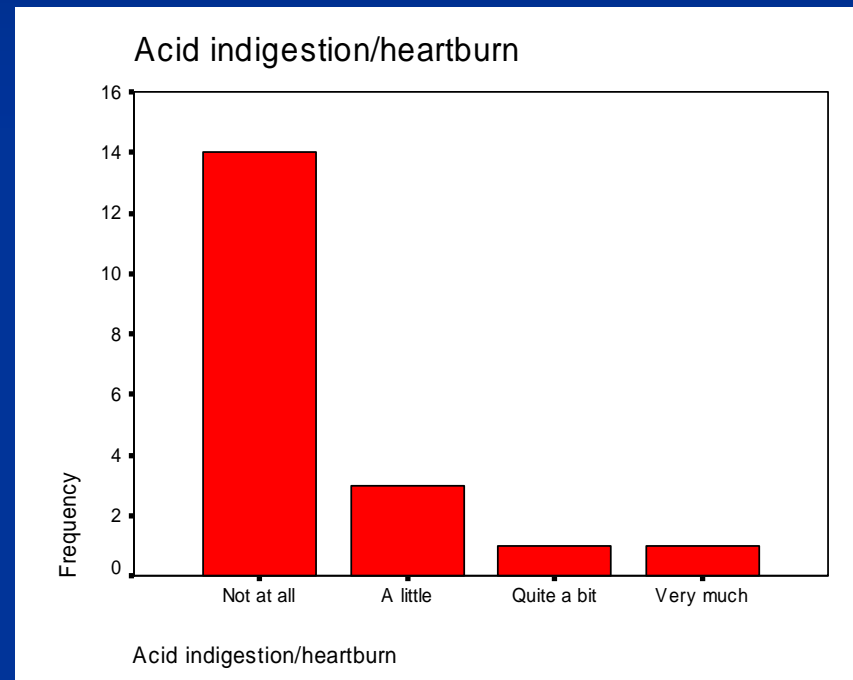
- 12 patients said not question was not relevant, annoying or upset.
- Staff said use LMC sexuality question and remove word bothered.
- Use not applicable box within scale.
- Wording changed to *Has the disease or treatment affected your sex life for the worse?*



Mean=1.65

Q59 to 62 Gastrinoma questions.
Q59 Have you had acid indigestion or heartburn?

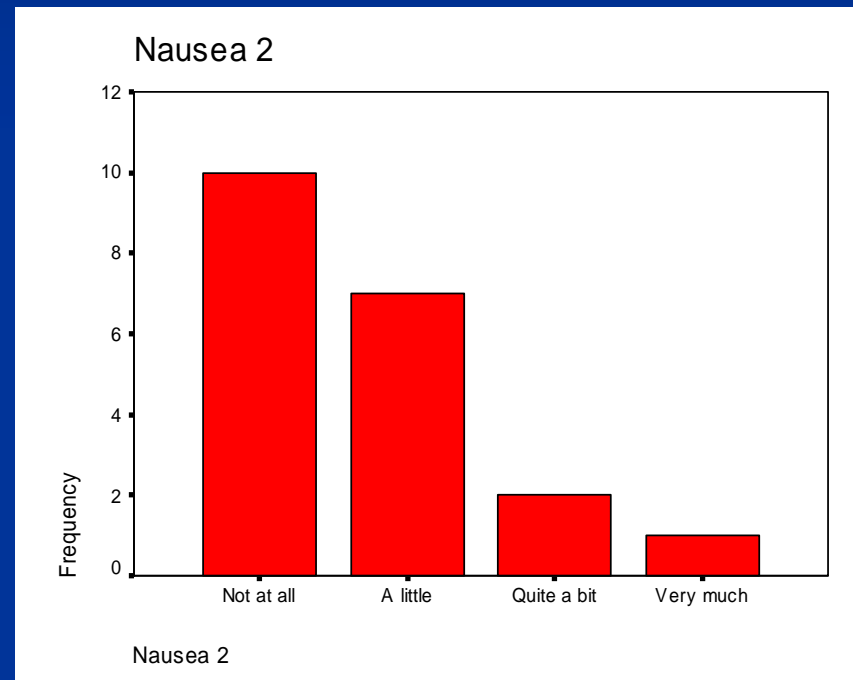
- No patient comments.
- Staff said is a general symptom so move to general questionnaire.
- Question to stay but moved to general questionnaire.



Mean=1.42

Q60 Have you felt nauseated?

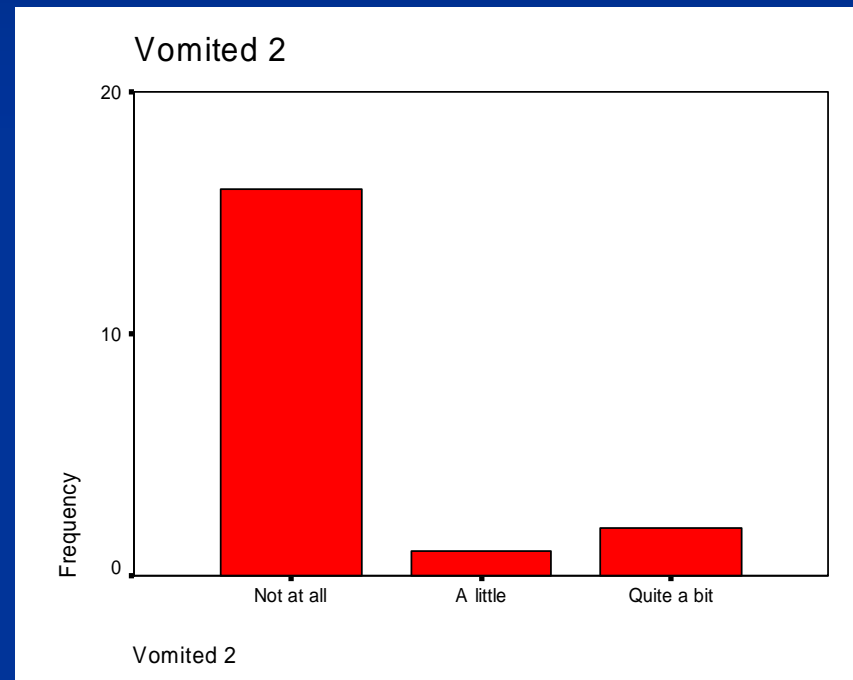
- Staff commented this question is in C30.
- Question to be deleted.



Mean=1.7

Q61 Have you vomited?

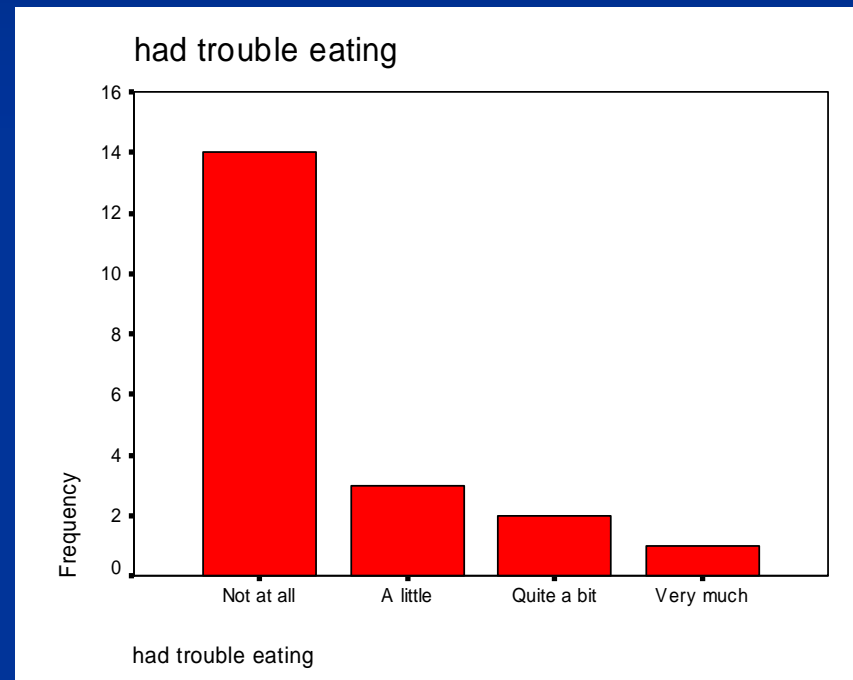
- Staff commented question is in C30.
- Question to be deleted.



Mean=1.26

Q62 Have you had trouble eating?

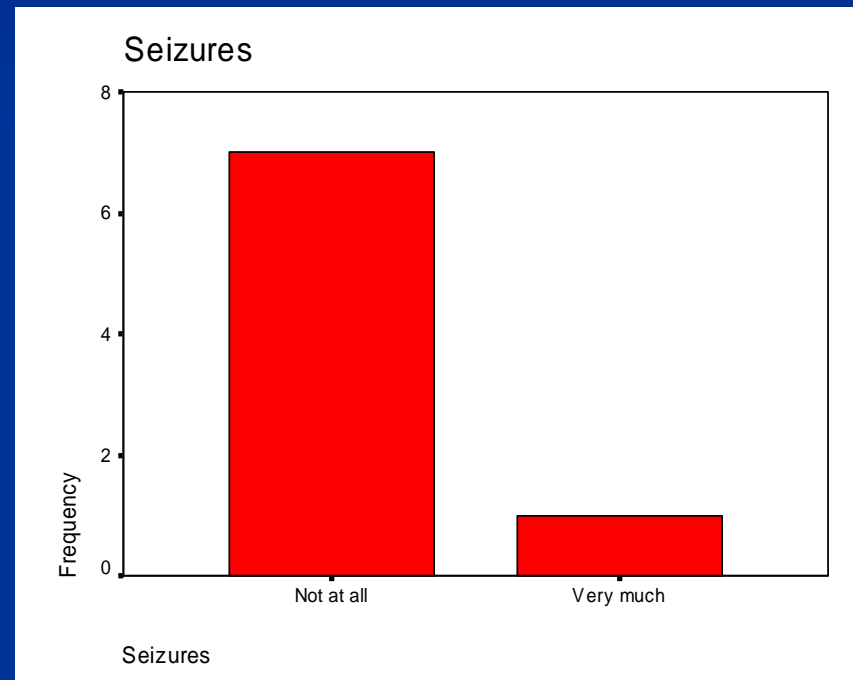
- No negative patient comments.
- Avoid word troubled.
- Wording changed to *Have you had difficulties eating?*



Mean=1.5

Q63 to 65 Insulinoma questions. Q63 Did you have seizures?

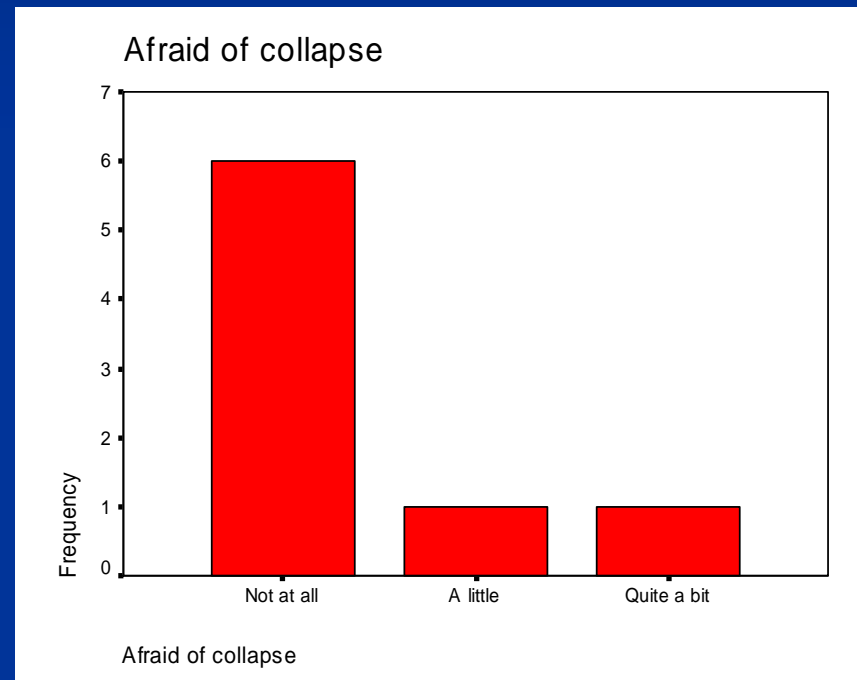
- Not enough patients seen so staff agree that questions Q63 to 65 deleted.
- Questionnaire not to be used for patients with Insulinoma.



Mean=1.38

Q64 Were you afraid you were going to collapse?

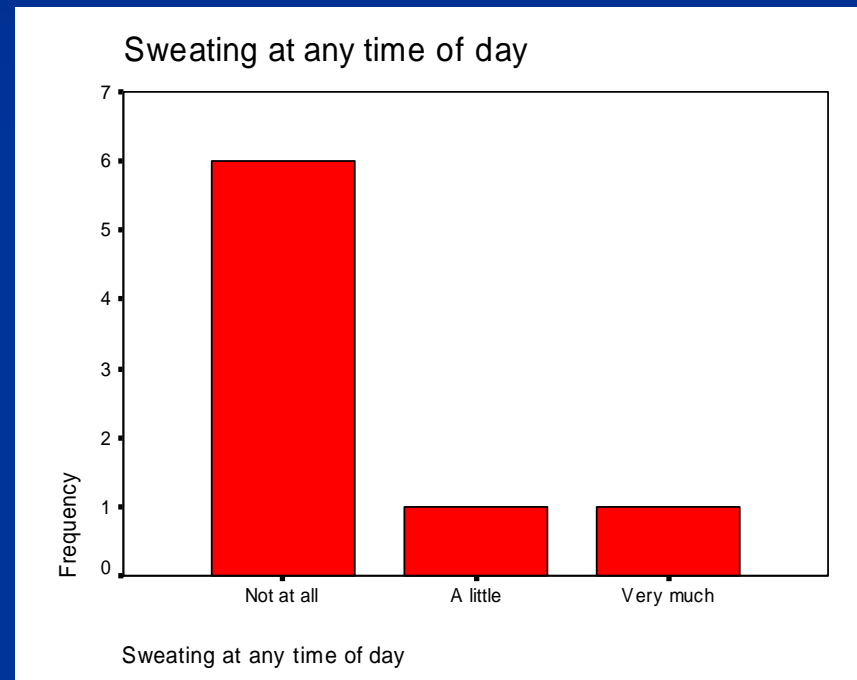
- Question deleted.



Mean=1.38

Q65 Did you sweat at anytime during the day?

- This question has been amalgamated with Q40.
- Question deleted.



Mean=1.5