

# Clinical Meaning of the Family-Reported Outcome Measure (FROM-16): A Novel Dimension of Real World Data

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## Introduction

The major secondary burden of having a partner or family member with a health condition is often ignored, but now can be measured with the generic Family Reported Outcome Measure (FROM-16).

## Aim

The aim was clinical meaning assignment to FROM-16 scores by creating FROM-16 score-banding.

## Materials and methods

**Study design:** A cross-sectional online survey recruited family members (age ≥18 years) of patients with different health conditions through 58 UK-based patient support groups, three research support platforms (Healthwise Wales, Autism Research Centre-Cambridge University database, Join Dementia Research) and social service departments in Wales.



Family members completed the **FROM-16** and a **5-point Likert scale Global Question (GQ)** concerning overall impact of their relative's health condition on their quality of life.

**FROM-16:** The FROM-16 measures the impact of a patient's disease on the QoL of their family member or partner (Figure 1). The FROM-16 comprises 16 items with 3-point responses with a total score range of 0 - 32. Lower scores mean higher QoL [1].

Figure 1: Family Reported Outcome Measure (FROM-16)

**Family Reported Outcome Measure (FROM-16)<sup>®</sup>** Confidential

The following questions are about how your life is being affected by your family member's condition at the moment. Please mark one box for each of the 16 questions.

**Please answer the following questions:**

Your age: \_\_\_\_\_

Your gender: Male / Female

Your relationship to the patient: \_\_\_\_\_

Patient's diagnosis: \_\_\_\_\_

**Part 1: Emotional**

Because of my family member's condition...

	Not at all	A little	A lot
1. I feel worried	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I feel angry	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I feel sad	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I feel frustrated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. It is difficult to find someone to talk to about my thoughts	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Caring for my family member is difficult	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Part 2: Personal and Social Life**

Because of my family member's condition...

	Not at all	A little	A lot
7. It is hard to find time for myself	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. My every day travel is affected	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. My eating habits are affected	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. My family activities are affected	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I experience problems with going on holiday	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. My sex life is affected	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. My work or study is affected	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. My relationships with other family members are affected	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. My family expenses are increased	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. My sleep is affected	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please check that you have answered every question. Thank you.

For office use only Score for part 1 (out of 12): \_\_\_\_ Score for part 2 (out of 20): \_\_\_\_ Total score (out of 32): \_\_\_\_

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The GQ used was:

"How much is your life being affected by your family member's or partner's health condition at the moment?"

This measured the overall impact of a person's health condition on their family member/partner on a five-point Likert scale:

**0=no effect; 1= small effect; 2= moderate effect; 3=very large effect and 4= extremely large effect .**

The family member/partner was asked to tick one of the five options.

Multiple FROM-16 band sets were devised using an anchor-based approach whereby mean, median, and mode of the GQ scores were mapped to FROM-16 score. ROC-AUC analysis was employed to find FROM-16 cutoff scores between GQ bands 0-1; 1-2; 2-3; and 3-4.

The band set with the best agreement with GQ based on weighted Kappa (wk) was selected.

Table 1. Numbers of family members with each FROM-16 score and details of the corresponding GQ summary score (mean, median and mode).

FROM-16 score	GQ score							Family member totals	
	0	1	2	3	4	Mean	Median		Mode
0	34	18	2			0	0	0	54
1	27	41	1			1	1	1	69
2	28	65	7	2		1	1	1	102
3	12	90	13			1	1	1	115
4	15	84	32	2		1	1	1	133
5	10	101	37	3		1	1	1	151
6	3	99	65	5	1	1	1	1	172
7	5	73	60	5	1	1	1	1	144
8	1	79	65	17		2	2	1	162
9	5	60	98	17	1	2	2	2	181
10	2	49	93	23	1	2	2	2	168
11	3	49	83	25	5	2	2	2	165
12	1	38	98	37	5	2	2	2	179
13	1	24	93	44	7	2	2	2	169
14	1	19	109	49	9	2	2	2	186
15		16	103	61	7	2	2	2	187
16		13	88	82	14	2	2	2	197
17		5	70	71	20	3	3	3	166
18		4	64	79	14	3	3	3	161
19		3	55	85	17	3	3	3	160
20		4	46	107	26	3	3	3	183
21			35	83	44	3	3	3	162
22			34	63	30	3	3	3	127
23			17	83	56	3	3	3	156
24		1	16	73	38	3	3	3	128
25	1		6	49	44	3	3	3	100
26	1		9	33	61	3	4	4	104
27			1	40	61	4	4	4	102
28			2	27	60	4	4	4	89
29			2	21	54	4	4	4	77
30			1	18	41	4	4	4	60
31			1	11	45	4	4	4	57
32				5	42	4	4	4	47
<b>Family member totals</b>	<b>149</b>	<b>935</b>	<b>1406</b>	<b>1220</b>	<b>703</b>				<b>4413</b>

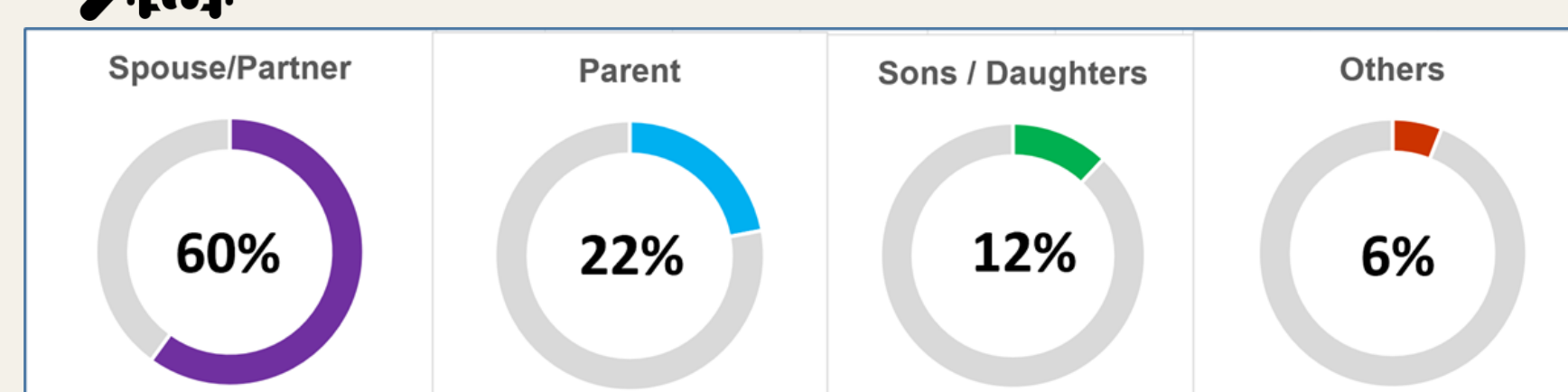
Family Reported Outcome Measure; GQ: Global question; GQ score: 0=No effect; 1=Small effect; 2=Moderate effect; 3=Very large effect; 4=Extremely large effect.

## Results

- 4,413 family members/partners of patients with >200 health conditions across 27 medical specialities completed the survey.
- Mean age of family members (male 35%; female 65%) = 57 years (range 18-95) and mean age of patients (male 45%; female 55%) = 61 years (range 2-100)
- Mean FROM-16 score = 15.02 (range 0-32, SD=8.08), mean GQ score = 2.32 (range 0-4, SD=1.08).
- Spearman correlation: FROM-16 and GQ scores ( $r_s = 0.79$ ,  $p = 0.001$ )



### Relationship to patient



### Distribution across the UK

- England: 1895 (43%)
- Northern Ireland: 48 (1%)
- Scotland: 185 (4%)
- Wales: 2285 (52%)

Figure 2. Relationship between the Family Reported Outcome Measure (FROM-16) and the mean, mode, and median of the Global Question(GQ) score.

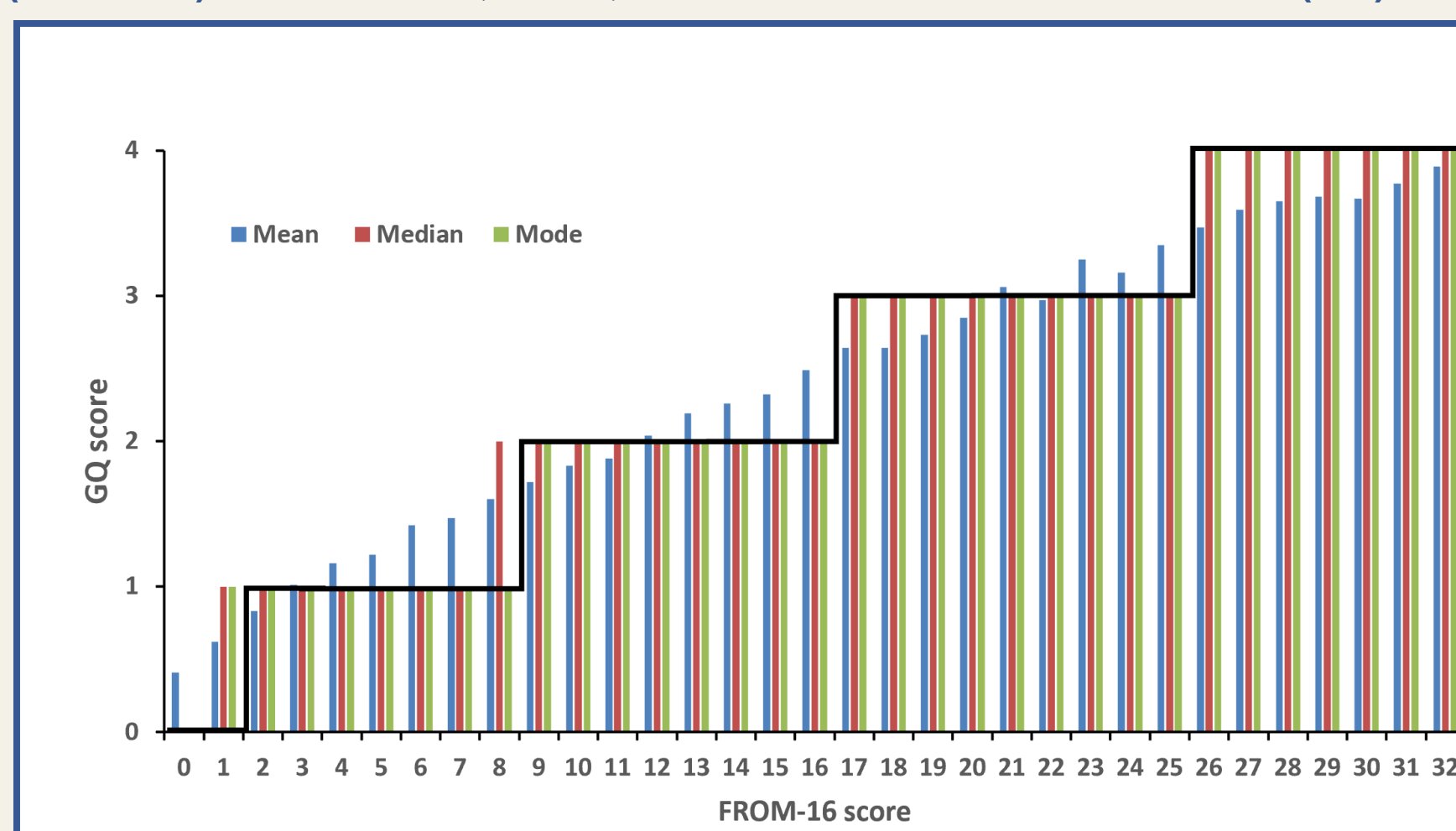


Figure 3. The receiver operating characteristic (ROC) curve and Area Under Curve (AUC) analysis, FROM-16 cut-off scores between GQ bands 0-1, 1-2, 2-3, 3-4

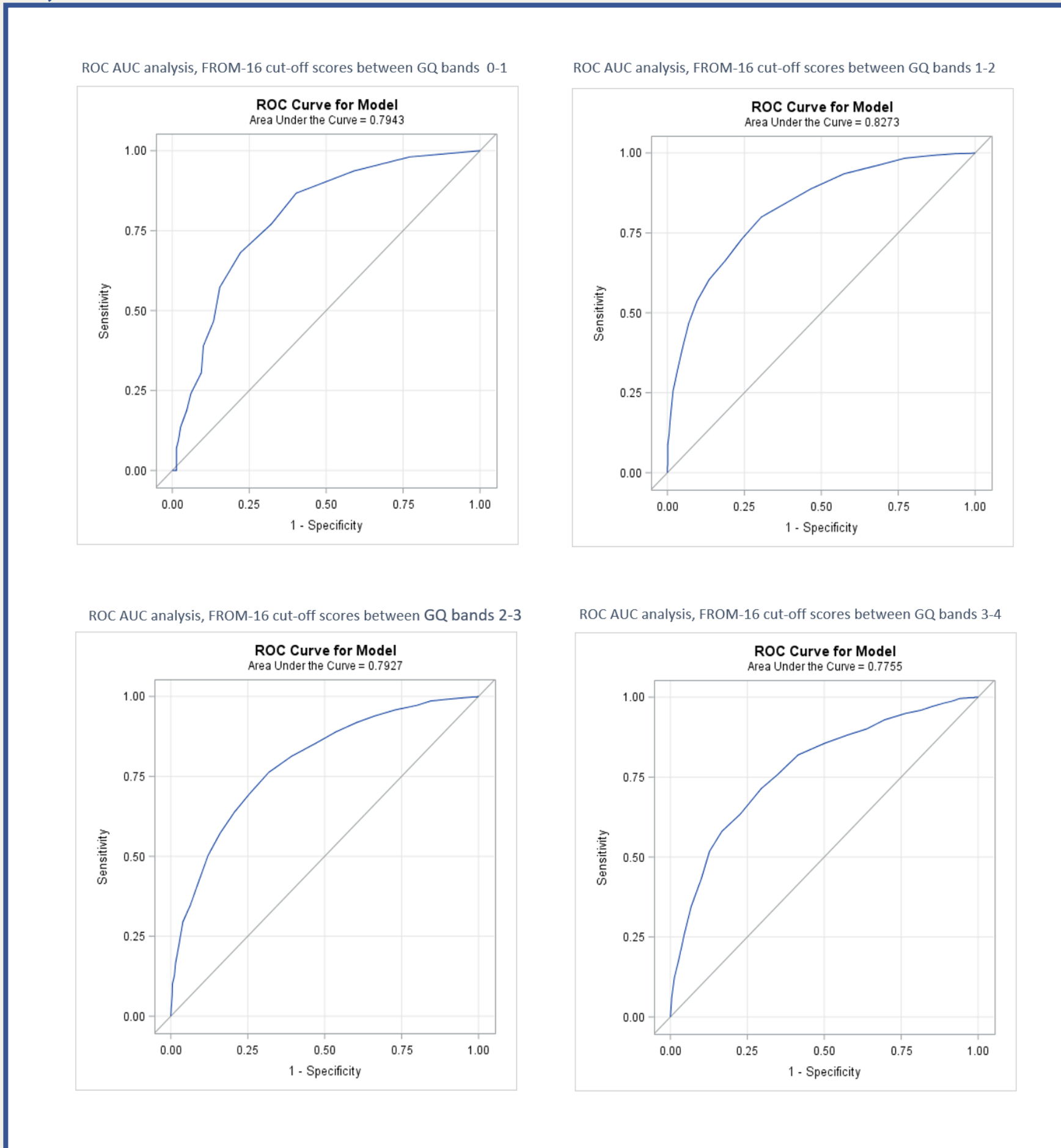


Table 2: Weighted Kappa Coefficients of agreement for separate possible sets of bands of the FROM-16 scores

Banding Set	Assignment of FROM-16 scores into bands					Weighted Kappa (wk) coefficient of agreement
	Band 0	Band 1	Band 2	Band 3	Band 4	
Set A	0	1-7	8-16	17-25	26-32	0.588
Set B	0	1-8	9-16	17-25	26-32	0.594
Set C	0-1	2-7	8-16	17-25	26-32	0.590
<b>Set D</b>	<b>0-1</b>	<b>2-8</b>	<b>9-16</b>	<b>17-25</b>	<b>26-32</b>	<b>0.596</b>
Set E	0-2	3-7	8-16	17-25	26-32	0.588
Set F	0-2	3-8	9-16	17-25	26-32	0.595
ROC AUC*	0-4	5-9	10-16	17-23	24-32	0.574

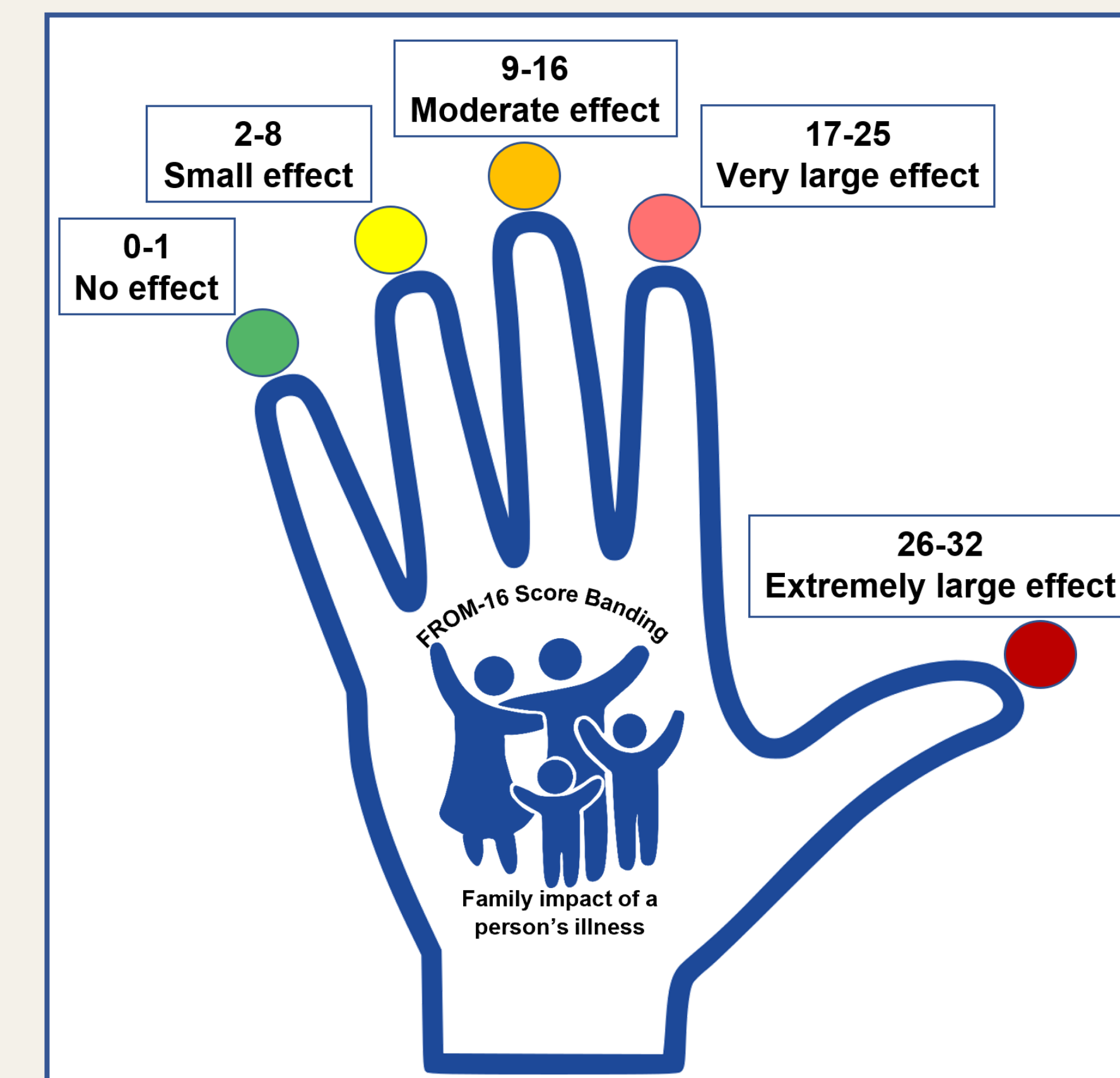
\*Youden Index cut-off values

Table 3. Proposed FROM-16 score banding with the distribution of GQ scores for the bands 0,1, 2-8, 9-16, 17-25, 26-32; wk coefficient of agreement = 0.596

Set D	FROM-16 score band	GQ score					Family member Totals n(%)
		0	1	2	3	4	
Band 0	0-1	61	59	3			123 (3%)
Band 1	2-8	74	591	279	34	1	979 (22%)
Band 2	9-16	12	268	765	338	49	1432(32%)
Band 3	17-25	1	17	343	693	289	1343(30%)
Band 4	26-32	1		16	155	364	536(12%)
Family member Totals n(%)		149 (3%)	935 (21%)	1406 (32%)	1220 (28%)	703 (16%)	4413

Family Reported Outcome Measure; GQ: Global question; GQ score: 0=No effect; 1=Small effect; 2=Moderate effect; 3=Very large effect; 4=Extremely large effect.

Figure 3. Proposed FROM-16 score banding. The effect mentioned is the level of adverse effect on the quality of life of a patient's partner or family member.



## Conclusions

- FROM-16 score banding provides new information to clinicians about how to clinically interpret scores and score changes, allowing better informed clinical decisions for patients and families
- FROM-16's score banding, and short administration time, demonstrate its potential to support clinical practice and health service research
- The now meaningful information from the use of FROM-16 can be used to measure and understand more globally the wider burden of disease, providing a novel dimension to the use of "direct clinical data".

## Acknowledgements

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## References

- Golics, C. J., Basra, M. K. A., Finlay, A. Y., & Salek, S. (2014). The development and validation of the Family Reported Outcome Measure (FROM16) to assess the impact of disease on the partner or family member. *Qual Life Res.*, 23(1), 317-326.

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