THE VALIDATION OF THE MALAY TRANSLATED SLEEP APNEA QUALITY OF LIFE INDEX (SAQLI) IN PATIENTS WITH OBSTRUCTIVE SLEEP APNEA

BY

DR NOR IDAYU MOHD YUSOF

Dissertation Submitted In Partial Fulfillment of the Requirement for the Degree of Master of Medicine
(Otorhinolaryngology-Head and Neck Surgery)

UNIVERSITI SAINS MALAYSIA

MAY 2011

TABLE OF CONTENTS

CHAPTER 1

INTRODUCTION AND LITERATURE REVIEW

CHAPTER 2

OBJECTIVES OF STUDY

CHAPTER 3

METHODOLOGY

CHAPTER 4

RESULTS

CHAPTER 5

DISCUSSION

CHAPTER 6

CONCLUSIONS

CHAPTER 7

LIMITATIONS

CHAPTER 8

RECOMMENDATIONS

REFERENCES

APPENDICES

ABSTRACT

THE VALIDATION OF THE MALAY TRANSLATED SLEEP APNEA QUALITY OF LIFE INDEX (SAQLI) IN PATIENTS WITH OBSTRUCTIVE SLEEP APNEA

Introduction: The Sleep Apnea Quality of Life Index (SAQLI) is a disease specific instrument developed to record the key elements of obstructive sleep apnea syndrome disorder that are important to patients and act as an outcome as well as an evaluative measure in clinical trials.

Objectives : The objectives of this study were to translate SAQLI into the Malay language and to determine the feasibility, validity and reliability of the Malay version of SAQLI.

Study design and methodology : This was a cross sectional study conducted at Sleep and General ORL-HNS Clinic, Hospital Universiti Sains Malaysia, Kubang Kerian, Kelantan. Eighty two respondents were involved. The Malay translated SAQLI and a previously Malay translated and validated Short Form 36 (SF-36) were administered by interviewer. The translation used forward, backward and respondent testing and has been reviewed for face and content validity. The Malay translated SAQLI were administered again at two to four weeks interval. Analysis included the determination of the scaling assumptions, feasibility, reliability and validity.

Results : All subjects completed the questionnaire successfully. The Malay version of SAQLI has no floor or ceiling effects. The four domains of the Malay SAQLI have means ranging from 3.59 to 4.82 and standard deviation, sd ranging from 0.846 to 0.945. The Cronbach's alpha were very high >0.95 for all domains; domain daily functioning: 0.966, domain social interaction 0.981 and domain emotional functioning 0.971 suggested items redundancy. The standard of test-retest reliability was also fulfilled with intraclass correlation coefficients were excellent ranging from 0.796 to 0.984. The Pearson item-scale correlation between item and its hypothesized scale was 0.4 or above, thus item-scale convergent and discriminant validity were satisfied. Factor analysis showed items in the three domains all loaded on the hypothesized scales. Known group validity showed no significant correlations between SAQLI and AHI ($p>0.05$). Criterion validity was confirmed by significant correlations with SF-36 subscale scores.

Conclusion : The translation of the Malay version of SAQLI was acceptable. The feasibility is present and the scaling assumptions met. The internal consistency and intraclass correlation coefficients were excellent. The content validity has been established with evidence of acceptable construct and criterion validity. The Malay version of SAQLI should be used in the management and studies involving OSAS patients and a shorter version of SAQLI is recommended.

ABSTRAK

Pengenalan: “Calgary Sleep Apnea Quality of Life index (SAQLI)” adalah instrumen spesifik penyakit yang dicipta untuk merekodkan elemen utama dalam sindrom pernafasan tidur terhalang (OSAS) yang penting untuk pesakit dan bertindak sebagai hasil dan juga alat evaluasi dalam percubaan klinikal

Objektif: Objektif kajian ini ialah untuk menterjemah SAQLI ke Bahasa Melayu dan seterusnya menilai kebolehsanaan, kesahan dan kebolehpercayaan SAQLI versi Bahasa Melayu.

Cara kajian dilaksanakan: Kajian ini adalah kajian keratan rentas yang dijalankan di Klinik Tidur dan Klinik Am ORL-Kepala dan Leher, Hospital Universiti Sains Malaysia, Kubang Kerian, Kelantan. 82 orang responden terlibat. SAQLI versi Bahasa Melayu dan Short Form 36 (SF-36) yang telah diterjemah dan telah diuji kesahannya diberikan oleh penemuduga. Proses terjemahan melibatkan terjemahan ke hadapan, ke belakang dan ujian responden. Semakan kesahan muka dan kesahan kandungan dijalankan. SAQLI versi Bahasa Melayu diberi sekali lagi dalam tempoh dua ke empat minggu. Analisis meliputi penilaian anggapan skala, kebolehsanaan, kesahan dan kebolehpercayaannya.

Keputusan: Kesemua subjek telah melengkapkan borang soal-selidik dengan jayanya. SAQLI versi Bahasa Melayu tidak mempunyai kesan lantai dan siling. Empat domain SAQLI Bahasa Melayu mempunyai nilai purata di antara 3.59 ke 4.82 dan sisihan piawai dari 0.846 ke 0.945. Alpha Cronbach adalah sangat tinggi >0.95 untuk kesemua domain; domain kefungsian harian: 0.966, domain interaksi sosial 0.981 dan domain kefungsian emosi 0.971 mencadangkan item yang berlebihan. Piawai untuk kebolehpercayaan ujian semula juga dipenuhi dengan pekali korelasi intrakelas yang cemerlang dari 0.796 ke 0.984. Item-skala pekali korelasi Pearson antara item dan skala hipotesisnya adalah 0.4 dan ke atas, maka item-skala kesahan pemusatan dan pembezaan telah dipenuhi. Analisis faktor menunjukkan item dalam ketiga-tiga domain mencapai nilai bebanan faktor ke atas skala yang telah dihipotesiskan. Kesahan kumpulan yang dikenali menunjukkan tiada korelasi signifikan antara SAQLI dan AHI ($p>0.05$). Kesahan kriteria juga dibuktikan melalui korelasi signifikan dengan skor subskala SF-36.

Kesimpulan: Penterjemahan SAQLI boleh diterima. SAQLI versi Bahasa Melayu menunjukkan kebolehsanaan yang baik dan anggapan skala dipenuhi. Kekonsistenan dalaman dan korelasi intrakelas adalah cemerlang. Kesahan kandungan telah dibuktikan manakala kesahan gagasan dan kriteria juga menunjukkan bukti yang boleh diterima. Justeru, SAQLI versi Bahasa Melayu patut diguna dalam pengurusan dan kajian melibatkan pesakit OSAS dan versi pendek SAQLI adalah disyorkan.

ACKNOWLEDGEMENTS

Thanks to Allah, the Most Merciful and Most Graceful and with His blessings has allowed me to complete this study.

First and foremost, special praise and prayers to the Almighty God, for blessing me with my beloved husband, children and parents. Their invaluable love, support and understandings had inspired me to keep on going during the difficult times of my life. Without them all of this would not have been worthwhile.

I would like to express my utmost gratitude to the following persons who have contributed to the successful completion of this study.

- My supervisor, Dr Hazama Mohamad
- My co-supervisor, Dr Norkhafizah Saddki
- Dr Wan Norarifin and Dr Kamarul Imran for helping in statistical analysis
- Assoc Prof Baharudin Abdullah, the Head, Dept. of ORL-HNS
- All ORL and Sleep Clinic staffs
- All patients who had volunteered for this study
- Last but not least, all my teachers, past and present

APPENDICES

APPENDIX A : PROFORMA

NAME	
RN	
AGE	
SEX	
ETHNIC	
HEIGHT	
WEIGHT	
BMI	
AHI	

APPENDIX B: CALGARY SLEEP APNEA QUALITY OF LIFE INDEX (SAQLI)

This questionnaire has been designed to find out how you have been doing and feeling over the last 4 weeks. You will be questioned about the impact that sleep apnea and/or snoring may have had on your daily activities, your emotional functioning, and your social interactions, and about any symptoms they might have cause.

A. Daily functioning

I. Most important daily activity. With regard to performing your most important, usual daily activity (e.g., work, school, child care, housework, etc.) during the previous 4 week:

1. How much have you had to force yourself to do this activity? [yellow card]

2.How much of the time have you had to push yourself to remain alert while performing this activity? [yellow card]

3. How often have you adjusted your schedule to avoid this activity because you felt that you would be unable to remain alert while doing it? [yellow card]

4. How often do you use all of your energy to accomplish only this activity? [yellow card]

II. Secondary activities. With regard to activities other than your most important daily activity during the previous 4 week:

5. How much difficulty have you had finding the energy to exercise and/or do activities that you find relaxing (leisure activities)? [green card]

6. How much difficulty have you had finding the time for activities that you find relaxing? [green card]

7. How much difficulty have you had with your ability to do exercise and/or activities that you find relaxing? [green card]

8. How much difficulty have you had getting chores done around the place where you live? [green card]

III. General functioning. During the previous 4 week:

9. How much difficulty have you had with trying to remember things? [green card]

10. How much difficulty have you had with trying to concentrate? [green card]

11. How much of a problem have you had with having to fight to stay awake? [red card]

B. Social interactions

The following questions pertain to how your relationship with your partner, other household members, relatives, and/or close friends have been during the previous 4 weeks. If you have not interacted with a partner, etc. in the previous 4 week, please try to work out how your relationship might have been with these people.

1. How upset have you been about being told that your snoring was bothersome or irritating? [green card]
2. How upset have you been about having to (or possibly having to) sleep in separate bedrooms from your partner? [green card
3. How upset have you been as a result of frequent conflicts or arguments? [green card]
4. How aware have you been of not wanting to talk to other people? [green card]
5. How much concern have you had about the need to make special sleeping arrangements if you were travelling and/or staying with someone? [green card]
6. How guilty have you felt about your relationship with family members and/or close personal friends? [green card]
7. How often have you looked for excuses for being tired? [yellow card]
8. How often have you experienced wanting to be left alone? [yellow card]
9. How often have you felt like not wanting to do things together with your partner, children, and/or friends? [yellow card]
10. How much of a problem have you felt there is with your relationship to the person who is closest to you? [red card]
11. How much of a problem have you had from not being involved in family activities? [red card]
12. How much of a problem have you had with inadequate and/or frequent sexual intimacy? [red card]
13. How much of a problem have you had with a lack of interest in being around other people? [red card]

C. Emotional functioning

With respect to how you have been feeling inside during the previous 4 week:

1. How often have you been feeling depressed, down, and/or hopeless? [yellow card]
2. How often have you been feeling anxious or fearful about what was wrong? [yellow card]
3. How often have you been feeling frustrated? [yellow card]
4. How often have you been feeling irritable and/or moody? [yellow card]
5. How often have you been feeling impatient? [yellow card]
6. How often have you been feeling that you are being unreasonable? [yellow card]
7. How often have you been getting easily upset? [yellow card]

8. How often have you experienced a tendency to become angry? [yellow card]
9. How often have you been feeling like you were unable to cope with everyday issues? [yellow card]
10. How concerned have you been about your weight? [green card]
11. How concerned have you been about heart problems (heart attack or heart failure) and/or premature death? [green card]

D. Symptoms

Below is a list of symptoms that some people with sleep apnea and/or who snore may experience. As each symptom is read please indicate whether it has been a problem or not (answer yes or no). Circle those symptoms that you have experienced during the previous 4 week. Once the list is finished please write down additional symptoms in the blank spaces you may have had that are not included in the list below. Next select the five most symptoms you have experienced. For each of the five symptoms please identify how much it has been. [red card]

1. Decreased energy
2. Excessive fatigue
3. Feeling that ordinary activities require an extra effort to perform or complete
4. Falling asleep at inappropriate times or places
5. Falling asleep if not stimulated or active
6. Difficulty with a dry or sore mouth/throat upon awakening
7. Waking up often (more than twice) during the night
8. Difficulty returning to sleep if you wake up in the night
9. Concern about the times you stop breathing at night
10. Waking up at night feeling like you were choking
11. Waking up in the morning with a headache
12. Waking up in the morning feeling unrefreshed and/or tired
13. Waking up more than once per night to urinate
14. A feeling that your sleep is restless
15. Difficulty staying awake while reading
16. Difficulty staying awake while trying to carry on a conversation
17. Difficulty staying awake while trying to watch something (concert, movie, TV)
18. Fighting the urge to fall asleep while driving
19. A reluctance or inability to drive for > I hour
20. Concern regarding close calls while driving due to your inability to remain alert
21. Concern regarding your or other's safety when you're operating a motor vehicle or machinery
22. ----------
23. ----------

E. Treatment-related symptoms

If you haven't had some type of therapy for sleep apnea and/or snoring leave this section blank. Below is a list of symptoms that some people who have been treated for sleep apnea and/or snoring may experienced. As each symptom is read please indicate whether it has been a problem or not (answer yes or no). Circle those symptoms that you have experienced during the previous 4 week. Once the list is finished please write down any symptoms in the blank spaces you may have had that are not included in the list below. Next select the five most important symptoms you have experienced. For each of the five symptoms please identify how much of a problem it has been. [red card]

1. Runny nose
2. Stuffed or congested or blocked nose
3. Excessive dryness of the nose or throat passages, especially upon awakening
4. Soreness in the nose or throat passages
5. Headaches
6. Eye irritation
7. Ear pain
8. Waking up frequently during the night
9. Difficulty returning to sleep if you awaken
10. Air leakage from the nasal mask
11. Discomfort from the nasal mask
12. Marks or rash on your face
13. Complaints from your partner about the noise of the CPAP machine
14. Having fluid/food pass into your nose when you swallow
15. A change in how your voice sounds
16. Pain in the throat when swallowing
17. Pain or aching in your jaw joint or jaw muscles
18. Feeling self conscious
19. Aching in your teeth that lasts at least an hour
20. Discomfort, aching, or tenderness of your gums
21. Hardship in being able to pay for the treatment
22. A sense of suffocation
23. Excessive salivation
24. Difficulty chewing in the morning
25. Difficulty chewing with your back teeth that persists most of the day
26. Movement of the teeth so that the upper and lower teeth no longer meet properly
27. ----------
28. ----------

F. Impact

Complete this section only if you have completed section E above

I. Please think of the questions in Sections A, B, C, and D. having been treated for your sleep apnea and/or snoring do you believe that overall there has been an improvement in your quality of life since you started treatment? If yes, how much of an impact on your quality of life has there been as reflected by the questions asked in Sections A, B, C and D. Place a mark on the line

Scale:

0_____10

(no impact) (extremely large impact)

II. Please think of the symptoms that developed as a result of being treated for sleep apnea and/or snoring that you highlighted in Section E. How much of an impact on your quality of life have these symptoms had?

Scale:

0_____10

(no impact0 (extremely large impact)

Response options

Yellow card	Green card	Red card
1.All the time 2.A large amount of the time 3.A moderate to large amount of the time 4.A moderate amount of the time 5.A small to moderate amount of the time 6.A small amount of the time 7.Not at all	1.A very large amount 2.A large amount 3.A moderate to large amount 4.A moderate amount 5.A small to moderate amount 6.A small amount 7.None	1.A very large problem 2.A large problem 3.A moderate to large problem 4.A moderate problem 5.A small to moderate problem 6.A small problem 7.No problem

APPENDIX C: THE MALAY VERSION OF SAQLI

(Pesakit)

Nama/ No kajian:

Tarikh:

A. FUNGSI HARIAN

Skala jawapan

1. Sangat besar **(R&G)**, setiap masa **(Y)**
2. Besar
3. Sederhana ke besar
4. Sederhana
5. Kecil ke sederhana
6. Kecil
7. Tidak **(R)**, Tiada **(G)**, Tidak langsung **(Y)**

Petunjuk soalan

(R) Merah **masalah**

(G) Hijau **jumlah**

(Y) Kuning **jumalah masa**

I Aktiviti Harian Paling Penting

1. Berapa banyakkah anda perlu MEMAKSA DIRI ANDA MELAKUKAN AKTIVITI INI? (Y)

   1 2 3 4 5 6 7

2. Berapa banyakkah masa anda diperlukan bagi MEMAKSA DIRI ANDA SENTIASA KEKAL BERJAGA SEWAKTU MELAKUKAN AKTIVITI INI? (Y)

   1 2 3 4 5 6 7

3. Berapa kerapkah anda telah MENGUBAH JADUAL UNTUK MENGELAK AKTIVITI INI KERANA ANDA MERASAKAN TIDAK MAMPU UNTUK KEKAL BERJAGA SEMASA MELAKUKANNYA? (Y)

   1 2 3 4 5 6 7

4. Berapa kerapkah anda MENGGUNAKAN SEMUA TENAGA ANDA UNTUK MENYELESAIKAN HANYA AKTIVITI INI? (Y)

   1 2 3 4 5 6 7

II. Aktiviti Sampingan

5. Berapa sukarkah anda dapati untuk MEMPUNYAI TENAGA BAGI TUJUAN BERSENAM DAN/ATAU MELAKUKAN AKTIVITI YANG RINGAN YANG MENENANGKAN (AKTIVITI WAKTU LAPANG)? (G)

   1 2 3 4 5 6 7

6. Berapa sukarkah anda dapati untuk MENCARI MASA BAGI TUJUAN MELAKUKAN AKTIVITI RINGAN YANG MENENANGKAN (AKTIVITI WAKTU LAPANG)? (G)

   1 2 3 4 5 6 7

7. Berapa sukarkah anda dapati DENGAN KEMAMPUAN YANG ANDA ADA UNTUK MELAKUKAN AKTIVITI SENAMAN DAN/ATAU AKTIVITI RINGAN YANG MENENANGKAN? (G)

   1 2 3 4 5 6 7

8. Berapa sukarkah anda dapati untuk MELAKSANAKAN TUGASAN HARIAN DI SEKITAR TEMPAT TINGGAL ANDA? (G)

   1 2 3 4 5 6 7

III. Fungsi Umum

9. Berapa sukarkah anda dapati untuk cuba MENGINGATI SESUATU PERKARA? (G)

   1 2 3 4 5 6 7

10. Berapa sukarkah anda dapati untuk cuba MENUMPUKAN PERHATIAN? (G)

    1 2 3 4 5 6 7

11. Berapa banyakkah masalah yang anda dapati untuk TERUS BERADA DALAM KEADAAN JAGA? (R)

    1 2 3 4 5 6 7

B. INTERAKSI SOSIAL

1. Berapa kecewakah anda apabila anda DIBERITAHU YANG DENGKURAN ANDA MENGGANGGU DAN TIDAK MENYENANGKAN? (G)

   1 2 3 4 5 6 7

2. Berapa kecewakah anda apabila terpaksa (atau berkemungkinan) untuk TIDUR DALAM BILIK TIDUR BERASINGAN DARIPADA PASANGAN ANDA? (G)

   1 2 3 4 5 6 7

3. Berapa kecewakah anda akibat KONFLIK DAN PERTENGKARAN YANG SELALU BERLAKU? (G)

   1 2 3 4 5 6 7

4. Berapa sedarkah anda berkenaan keadaan yang TIDAK MAHU BERCAKAP DENGAN ORANG LAIN? (G)

   1 2 3 4 5 6 7

5. Berapa banyakkah perhatian yang anda berikan kepada KEPERLUAN UNTUK MEMBUAT UBAHSUAI TEMPAT TIDUR ANDA JIKA ANDA MELANCONG ATAU TINGGAL BERSAMA ORANG LAIN? (G)

   1 2 3 4 5 6 7

6. Berapa banyakkah rasa bersalah anda dalam PERHUBUNGAN DENGAN AHLI KELUARGA ATAU RAKAN KARIB ANDA? (G)

   1 2 3 4 5 6 7

7. Berapa kerapkah anda MENCARI ALASAN AKIBAT KEPENATAN? (Y)

   1 2 3 4 5 6 7

8. Berapa kerapkah anda rasakan MAHU DIBIARKAN BERSENDIRIAN? (Y)

   1 2 3 4 5 6 7

9. Berapa kerapkah anda rasakan seperti TIDAK MAHU MELAKUKAN APA-APA BERSAMA-SAMA DENGAN PASANGAN ANDA, AHLI KELUARGA DAN/ATAU RAKAN-RAKAN? (Y)

   1 2 3 4 5 6 7

10. Berapa banyakkah masalah yang anda rasakan ada dengan PERHUBUNGAN ANDA DENGAN ORANG YANG PALING RAPAT DENGAN ANDA? (R)

    1 2 3 4 5 6 7

11. Berapa banyakkah masalah yang anda ada akibat TIDAK TERLIBAT DALAM AKTIVITI KELUARGA? (R)

    1 2 3 4 5 6 7

12. Berapa banyakkah masalah yang anda hadapi dengan HUBUNGAN SEKSUAL YANG TIDAK MENCUKUPI/TIDAK KERAP? (R)

    1 2 3 4 5 6 7

13. Berapa banyakkah masalah yang anda hadapi akibat KURANGNAY MINAT UNTUK BERGAUL DENGAN ORANG LAIN? (R)

    1 2 3 4 5 6 7

C. FUNGSI EMOSI

1. Berapa kerapkah anda merasa TERTEKAN, MURUNG DAN/ATAU PUTUS ASA? (Y)

    1 2 3 4 5 6 7

2. Berapa kerapkah anda mengalami perasaan CEMAS ATAU TAKUT TENTANG APA YANG SILAP? (Y)

    1 2 3 4 5 6 7

3. Berapa kerapkah anda mengalami perasaan KECEWA? (Y)

    1 2 3 4 5 6 7

4. Berapa kerapkah anda mengalami perasaan MUDAH MARAH DAN/ATAU TERLALU MENGIKUT EMOSI? (Y)

    1 2 3 4 5 6 7

5. Berapa kerapkah anda mengalami perasaan TIDAK SABAR? (Y)

    1 2 3 4 5 6 7

6. Berapa kerapkah anda mengalami perasaan anda BERSIKAP SECARA TIDAK MUNASABAH? (Y)

   1 2 3 4 5 6 7

7. Berapa kerapkah anda mengalami perasaan MUDAH SEDIH? (Y)

   1 2 3 4 5 6 7

8. Berapa kerapkah anda dapati anda berkemungkinan menjadi MUDAH MARAH? (Y)

   1 2 3 4 5 6 7

9. Berapa kerapkah anda mengalami perasaan bahawa ANDA TIDAK BOLEH MENANGANI ISU HARIAN? (Y)

   1 2 3 4 5 6 7

10. Berapa bimbangkah anda mengenai BERAT BADAN ANDA? (G)

    1 2 3 4 5 6 7

11. Berapa bimbangkah anda mengenai MASALAH JANTUNG (SERANGAN JANTUNG ATAU KEGAGALAN JANTUNG) DAN/ATAU MATI PADA USIA LEBIH MUDA? (G)

    1 2 3 4 5 6 7

D. GEJALA

1. Kurang bertenaga
2. Penat berlebihan
3. Merasakan bahawa aktiviti biasa memerlukan usaha yang lebih untuk dilakukan atau disempurnakan
4. Tertidur di masa dan tempat yang tidak sesuai
5. Tertidur jika tidak diransang atau tidak aktif
6. Masalah dengan kering atau sakit mulut/tekak selepas bangun tidur
7. Selalu terjaga (lebih dari dua kali) sepanjang tidur malam
8. Kerumitan untuk kembali tidur setelah terjaga pada waktu malam
9. Risau akan keadaan berhenti bernafas pada waktu malam
10. Terjaga waktu malam akibat rasa tercekik
11. Bangun pagi dengan sakit kepala
12. Bangun pagi dalam keadaan tidak segar dan/atau rasa penat
13. Bangun lebih dari sekali pada waktu malam (secara purata) untuk membuang air kecil
14. Perasaan bahawa tidur anda resah
15. Sukar untuk kekal berjaga sewaktu membaca
16. Sukar untuk kekal berjaga sewaktu dalam perbualan
17. Sukar untuk kekal berjaga sewaktu sedang menonton sesuatu (seperti konsert, teater, filem di pawagam, rancangan televisyen)

18. Terpaksa berlawan dengan rasa untuk tertidur sewaktu memandu
19. Rasa tidak mahu atau tidak boleh memandu lebih daripada satu jam
20. Risau berkenaan tertidur sewaktu memandu disebabkan oleh ketidakupayaan baik secara separuh atau seluruhnya untuk kekal berjaga
21. Risau berkenaan keselamatan diri atau orang lain sewaktu anda mengendalikan kenderaan bermotor dan/atau jentera bermotor
22. ----------
23. ----------
24. ----------

Skala respon:

1- Masalah sangat besar
2- Masalah besar
3- Masalah sederhana ke besar
4- Masalah sederhana
5- Masalah kecil ke sederhana
6- Masalah kecil
7- Tiada masalah

Gejala-gejala yang dipilih

1._____

Skala respon: 1 2 3 4 5 6 7

2. _____

Skala respon: 1 2 3 4 5 6 7

3._____

Skala respon: 1 2 3 4 5 6 7

4._____

Skala respon: 1 2 3 4 5 6 7

5. _____

Skala respon: 1 2 3 4 5 6 7]

\

E. RAWATAN GEJALA YANG BERKAITAN

1. Hidung berair
2. Hidung tersumbat
3. Rasa kering yang melampau pada hidung atau saluran tekak terutama sewaktu bangun tidur
4. Rasa sakit dalam hidung atau saluran tekak
5. Sakit kepala
6. Ketidakselesaan mata
7. Sakit telinga
8. Kerap terjaga pada waktu malam
9. Sukar tidur semula jika terjaga
10. Angin keluar dari topeng hidung
11. Ketidakselesaan akibat daripada topeng hidung
12. Tanda atau radang pada muka
13. Komen dari pasangan akibat bunyi bising mesin CPAP
14. Terdapat makanan/cecair masuk ke hidung sewaktu menelan
15. Perubahan bunyi suara anda
16. Sakit dalam tekak sewaktu menelan yang berakhir sekurang-kurangnya satu jam
17. Sakit pada sendi rahang atau otot untuk mengunyah
18. Merasa malu
19. Sakit dalam gigi yang berlarutan sekurang-kurangnya sejam
20. Tidak selesa atau sakit pada gusi
21. Kesukaran untuk membayar kos rawatan
22. Rasa lemas
23. Pengeluaran air liur berlebihan
24. Kesukaran mengunyah pada waktu pagi
25. Kesukaran mengunyah dengan gigi belakang yang berpanjangan sepanjang hari
26. Peralihan kedudukan gigi yang menyebabkan gigi atas dan bawah tidak lagi bertemu pada kedudukan yang betul
27. _____
28. _____

Skala respon:

1- Masalah sangat besar
2- Masalah besar
3- Masalah sederhana ke besar
4- Masalah sederhana
5- Masalah kecil ke sederhana
6- Masalah kecil
7- Tiada masalah

Gejala-gejala yang dipilih

1._____

Skala respon: 1 2 3 4 5 6 7

2._____

Skala respon: 1 2 3 4 5 6 7

3._____

Skala respon: 1 2 3 4 5 6 7

4. _____

Skala respon: 1 2 3 4 5 6 7

5._____

Skala respon: 1 2 3 4 5 6 7

F. KESAN RAWATAN

Jika anda tidak menggunakan sebarang rawatan untuk masalah apnea tidur dalam masa empat minggu sebelum ini, sila tinggalkan kosong ruangan berikutnya tanpa diisi.

I. Fungsi Harian, Interaksi Sosial, Fungsi Emosi, Gejala

Sila ingati kembali soalan-soalan di bahagian **A,B,C DAN D.** Setelah mendapat rawatan untuk masalah pernafasan sewaktu tidur anda ini, adakah anda rasakan terdapat perubahan ke arah lebih baik dari segi kualiti hidup anda semenjak rawatan dimulakan?

Ya _____
Tidak _____

Jika ya, berapa banyakkah kesannya terhadap kehidupan anda? (Sila tandakan di atas garisan)

0 _____10
Tiada kesan Sangat besar kesannya

II. Gejala yang dirawat

Sila ingati kembali gejala yang dialami sebagai kesan rawatan untuk masalah pernafasan sewaktu tidur anda (**Bahagian E)**. Berapa banyakkah kesan gejala ini terhadap hidup anda? (Sila tandakan di atas garisan)

0 _____10

Tiada kesan Sangat besar kesannya

Terima kasih atas kerjasama anda melengkapkan soalselidik ini.

APPENDIX D: THE MALAY TRANSLATED SF-36

SOAL SELIDIK KUALITI HIDUP SF-36

Perhatian:

Ini adalah satu kajiselidik yang meminta anda memberi pandangan tentang kesihatan anda. Maklumat yang diperolehi akan dapat membantu menentukan perasaan anda dan menguji tahap kemampuan anda melakukan kerja-kerja seharian.

Sila tandakan (√) bagi tiap -tiap soalan yang tepat kepada diri anda pada ruang yang disediakan. Jika anda tidak pasti tentang jawapan bagi sesuatu soalan, cubalah pilih jawapan setakat yang anda mampu berdasarkan pendapat anda sendiri.

1. Secara umum, kesihatan anda bolehlah dianggap sebagai:

[Tandakan satu jawapan]

1) Cemerlang ☐
2) Sangat baik ☐
3) Baik ☐
4) Sederhana ☐
5) Teruk ☐

2. Berbanding dengan setahun yang lalu, bagaimana anda rasa kesihatan anda secara umum sekarang?

1) Jauh lebih baik dari setahun lalu ☐
2) Agak lebih baik dari setahun lalu ☐
3) Lebih kurang sama dengan setahun lalu ☐
4) Agak lebih teruk dari setahun lalu ☐
5) Jauh lebih teruk dari setahun lalu ☐

3. Senarai aktiviti berikut mungkin anda lakukan pada hari biasa. Adakah kesihatan anda sekarang menyekat anda melakukan aktiviti-aktiviti ini. Jika ya, setakat mana?

(Bulatkan satu jawapan sahaja bagi tiap-tiap akitiviti)

Aktiviti	Ya, banyak terhad	Ya, sedikit terhad	Tidak terhad langsung
a. Aktiviti-aktiviti berat seperti berlari, mengangkat barang-barang berat, mengambil bahagian dalam acara sukan berat	1	2	3
b. Aktiviti-aktiviti sederhana seperti mengalih meja, menyangkul, menggunakan pencuci hampagas, bowling atau bermain golf	1	2	3
c. Mengangkat atau membawa barang keperluan dan barang makanan dari kedai ke rumah	1	2	3
d. Menaiki beberapa anak tangga	1	2	3
e. Menaiki satu anak tangga	1	2	3
f. Menunduk, melutut atau membongkok	1	2	3
g. Berjalan melebihi jarak sebatu	1	2	3
h. Berjalan melebihi suku batu	1	2	3
i. Berjalan sepanjang satu padang bola	1	2	3
j. Mandi atau memakai pakaian	1	2	3

4. Sejak 4 minggu yang lalu adakah anda mengalami masalah berikut dalam kerja atau aktiviti harian lain yang disebabkan oleh kemampuan fizikal anda?

(Bulatkan satu jawapan bagi setiap pernyataan)

	Ya	Tidak
a. Mengambil masa lebih lama untuk menyiapkan sesuatu kerja atau lain-lain aktiviti	1	2
b. Kurang tercapai seperti yang diharapkan	1	2
c. Terhad mengikut jenis-jenis kerja atau aktiviti lain	1	2
d. Mengalami kesukaran dalam menjalankan kerja atau aktiviti lain (contohnya memerlukan usaha-usaha tambahan)	1	2

5. Sejak 4 minggu yang lepas, adakah anda mengalami masalah dalam kerja atau apa-apa aktiviti harian biasa akibat masalah emosi (seperti mengalami kemurungan atau gelisah)?

(Bulatkan satu jawapan bagi setiap pernyataan)

	Ya	Tidak
a. Mengambil masa yang lama untuk menyiapkan sesuatu kerja atau aktiviti	1	2
b. Mencapai kurang daripada apa yang diinginkan	1	2
c. Tidak dapat melaksanakan kerja atau aktiviti lain dengan teliti seperti biasa	1	2

6. Sejak 4 minggu yang lepas, sejauh manakah kesihatan fizikal atau masalah emosi mengganggu hubungan sosial anda dengan keluarga, kawan-kawan, jiran atau kumpulan?

1) Langsung tidak ☐
2) Sedikit ☐
3) Sederhana ☐
4) Agak banyak ☐
5) Terlalu banyak ☐

7. Sejauh manakah kesakitan badan yang anda alami sejak 4 minggu yang lepas?

1) Tiada ☐
2) Sangat ringan ☐
3) Ringan ☐
4) Sederhana ☐
5) Teruk ☐
6) Sangat teruk ☐

8. Sejak 4 minggu yang lepas, sejauh manakah kesakitan mengganggu kerja harian anda?

(termasuk kerja di dalam dan di luar rumah)

1. Langsung tidak ☐
2. Sedikit ☐
3. Sederhana ☐
4. Agak banyak ☐
5. Terlalu banyak ☐

9. Soalan-soalan berikut adalah berkenaan perasaan dan keadaan anda semasa 4 minggu yang lepas. (Bulatkan satu jawapan yang menggambarkan keadaan atau perasaan yang anda alami atau paling hampir dengan pengalaman anda kepada setiap soalan)

	Sepanjang masa	Kebanyakan masa	Agak kerap	Kadang-kadang	Sangat sedikit	Tidak pernah
a. Adakah anda merasa bertenaga dan ceria	1	2	3	4	5	6
b. Pernahkah anda merasa gelisah	1	2	3	4	5	6
c. Pernahkah anda merasa sedih dan seolah-olah tiada siapa boleh menggembirakan anda	1	2	3	4	5	6
d. Pernahkah anda merasa aman dan tenteram	1	2	3	4	5	6
e. Adakah anda mempunyai banyak tenaga	1	2	3	4	5	6
f. Pernahkah anda mengalami perasaan sedih atau pilu	1	2	3	4	5	6
g. Adakah anda merasa kehabisan tenaga	1	2	3	4	5	6
h. Pernahkah anda menjadi seorang yang periang	1	2	3	4	5	6
i. Adakah anda merasa letih	1	2	3	4	5	6

10. Sejak 4 minggu yang lepas, sejauh manakah kesihatan fizikal atau masalah emosi mengganggu kegiatan sosial anda (seperti menziarahi kawan-kawan, sanak saudara dan lain-lain)?

[Tandakan satu jawapan]

1. Sepanjang masa ☐
2. Kebanyakan masa ☐
3. Kadang-kadang ☐
4. Sedikit ☐
5. Tidak pernah ☐

11. Nyatakan samada pernyataan ini benar atau tidak bagi diri anda?

(Bulatkan satu nombor sahaja bagi setiap pernyataan)

	Sungguh benar	Selalunya benar	Tidak pasti	Selalunya tidak	Pasti tidak
a. Saya lebih senang mendapat penyakit berbanding orang lain	1	2	3	4	5
b. Saya sihat seperti mana orang lain yang saya kenali	1	2	3	4	5
c. Saya jangkakan kesihatan saya semakin terganggu	1	2	3	4	5
d. Kesihatan saya berada dalam keadaan yang sangat baik	1	2	3	4	5

APPENDIX E : AN EXAMPLE OF HOW TO SCORE THE SAQLI

The following is a hypothetical example of scores recorded from administering the SAQLI prior to and after an intervention. The patient had not previously been treated so there were no Treatment Related Symptoms recorded (Domain E) when the SAQLI was administered for first time. When the SAQLI was administered following the intervention in this example, only 4 Treatment Related Symptoms were identified.

SAQLI PRE INTERVENTION **SAQLI POST INTERVENTION**

	DOMAIN					DOMAIN					
Q's	**A**	**B**	**C**	**D**	**E**	**A**	**B**	**C**	**D**	**E**	**EC**
1	**4**	**2**	**3**	**2**		**5**	**3**	**3**	**5**	**2**	**5**
2	**3**	**1**	**4**	**2**		**3**	**5**	**4**	**5**	**3**	**4**
3	**3**	**4**	**4**	**3**		**4**	**4**	**3**	**4**	**2**	**5**
4	**2**	**3**	**2**	**1**		**5**	**3**	**2**	**4**	**4**	**3**
5	**4**	**2**	**1**	**3**		**4**	**2**	**3**	**7**		
6	**5**	**2**	**1**			**5**	**2**	**2**			
7	**2**	**4**	**3**			**2**	**4**	**4**			
8	**1**	**3**	**4**			**3**	**4**	**5**			
9	**4**	**2**	**1**			**4**	**4**	**2**			
10	**1**	**1**	**2**			**2**	**3**	**4**			
11	**4**	**6**	**1**			**5**	**6**	**4**			
12		**2**					**4**				
13		**4**					**5**				
TOTAL	**33**	**36**	**24**	**11**	**0**		**42**	**49**	**36**	**25**	**17**
MEAN SC	**3.00**	**2.76**	**2.18**	**2.20**	**0**		**3.82**	**3.77**	**3.27**	**6.25**	**3.40**

IMPACT SCORE I: /10 =7.4 IMPACT SCORE II: /10 =5.2 WEIGHTING FACTOR: IS II/IS I = 5.2/7.4=0.70

SAQLI (PRE INTERVENTION) SCORE: MS A+B+C+D/ 4 = 3.00+2.76+2.18+2.20 /4 = 2.54

SAQLI (POST INTERVENTION) SCORE: MS A+B+C+D – [MS E X weighting fact] /4 = 3.82 + 3.77 + 3.27 + 6.25 – [3.40*0.70]/ 4 = 3.68

APPENDIX F : SCORING OF SF-36

SCALES	FINAL ITEM	REVERSE SCORING[b]
PHYSICAL FUNCTIONING 3a, 3b, 3c, 3d, 3e, 3f, 3g, 3h, 3i, 3j	1 2 3	-
ROLE PHYSICAL 4a, 4b, 4c, 4d	1 2	-
BODILY PAIN[a] 7 8	1 2 3 4 5 6 6 if 7 = 1 5 if 7 from 2-6 4 if 7 from 1-6 3 if 7 from 1-6 2 if 7 from 1-6 1 if 7 from 1-6	- + + + + + +
GENERAL HEALTH 1	5 4.4 3.4 2.0 1.0	+ + + + +
11a, 11c 11b, 11d	1 2 3 4 5 5 4 3 2 1	- +
VITALITY 9a, 9e 9g, 9i	6 5 4 3 2 1 1 2 3 4 5 6	+ -
SOCIAL FUNCTIONING 6 10	5 4 3 2 1 1 2 3 4 5	+ -
ROLE EMOTIONAL 5a, 5b, 5c, 5d	1 2	-
MENTAL HEALTH 9b, 9c, 9f 9d, 9h	1 2 3 4 5 6 6 5 4 3 2 1	- +

[a]question 7 and 8 were all answered [b] + for reversed score - for no reversed score

$$\text{Transformed scale} = \frac{\text{Actual raw score} - \text{lowest possible raw score}}{\text{Possible raw score range}} * 100$$

Example: a physical functioning raw score of 21 would be transformed as follows:

$$\frac{21 - 10}{20} (100) = 35$$

Where lowest possible score = 10 and possible raw score range = 20

APPENDIX G: BORANG MAKLUMAT DAN KEIZINAN PESAKIT

MAKLUMAT KAJIAN

Tajuk Kajian: **Validasi Versi Bahasa Melayu Sleep Apnea Quality of Life Index (SAQLI) pada Pesakit Obstruksi Apnea Tidur.**

Nama Penyelidik: **Dr. Nor Idayu Mohd Yusof (39836)**

Pengenalan

Obstruksi apnea tidur (OSA) adalah masalah kesihatan global yang sering berlaku disebabkan oleh aliran udara yang terhenti akibat obstruksi pada saluran pernafasan atas semasa tidur. Kebanyakan pesakit OSA mempunyai kualiti hidup sihat yang terjejas. SAQLI adalah instrumentasi berkaitan kualiti hidup sihat yang spesifik untuk pesakit OSA. SAQLI versi Bahasa Melayu yang telah divalidasi akan membolehkan penilaian kualiti hidup untuk pesakit OSA tempatan.

Tujuan Kajian

Tujuan umum.

Untuk validasi SAQLI yang telah dialihbahasa ke Bahasa Melayu pada pesakit obstruksi apnea tidur..

Tujuan spesifik.

1. Untuk melakukan alihbahasa dan alihbahasa semula SAQLI versi English ke Bahasa Melayu.
2. Untuk menentukan validiti SAQLI yang telah dialihbahasa ke Bahasa Melayu yang ianya termasuk;
    a. Validiti berdepan (face validity)
    b. Validiti kandungan (content validity)
    c. Validiti konstruk (construct validity)
3. Untuk memeriksa kebolehgantungan dan kestabilan SAQLI yang telah dialihbahasa ke Bahasa Melayudengan menentukan;
    a. Konsistensi dalaman (internal consistency)
    b. Kebolehgantungan ujian dan ujian semula (test-retest realibility)

Kelayakan Penyertaan

Ciri-ciri pesakit yang layak.

1. Pesakit yang didiagnosa OSA yang mendapatkan rawatan di Sleep Clinik dan klinik umum ORL Hospital Universiti Sains Malaysia, sepanjang tempoh kajian.
2. Berusia 18 tahun dan ke atas.
3. Boleh membaca dan menulis dengan baik Bahasa Melayu.

Ciri-ciri mereka yang tidak layak.

1. Bukan warganegara Malaysia.
2. Buta huruf.
3. Pesakit yang mempunyai masalah gangguan kognitif semasa temuduga.
4. Pesakit yamg mempunyai masalah pertuturan dan pendengaran.

Prosedur–prosedur Kajian

Kebenaran bertulis untuk menyertai kajian ini akan diambil setelah pesakit diterangkan secara menyeluruh dan faham mengenai tujuan, kepentingan dan faedah-faedah kajian.

Soal selidik SAQLI akan diberikan kepada subjek dengan bantuan penemuduga. Ujian semula akan diadakan dalam jangkamasa 2-4 minggu dari temuduga pertama.

Risiko

Tiada sebarang risiko terhadap anda.

Melaporkan Pengalaman Kesihatan

Sila hubungi Dr Nor Idayu Mohd Yusof (nombor telefon 0194135424) atau jururawat terlatih (097664360). Anda boleh menghubungi pada waktu siang atau malam.

Penyertaan Dalam Kajian

Kesudian anda terlibat dalam kajian ini adalah secara sukarela. Anda boleh menolak penyertaan dalam kajian ini atau anda boleh menamatkan penyertaan anda dalam kajian ini pada bila-bila masa, tanpa sebarang hukuman atau kehilangan sebarang manfaat yang sepatutnya diperolehi oleh anda.

Manfaat

Anda akan dirujuk kepada Pakar untuk rawatan lanjut jika terdapat ketidaknormalan atau masalah perubatan yang dikesan semasa kajian ini.

Soalan

Sekiranya anda mempunyai sebarang soalan mengenai prosedur kajian ini atau hak-hak anda, sila hubungi;

Dr. Nor Idayu Mohd Yusof (39836).
Jabatan Otorinolaringologi HUSM.
Pusat Pengajian Sains Perubatan
USM Kampus Kesihatan.
Tel: 0194135424

Sekiranya anda mempunyai sebarang soalan berkaitan kelulusan Etika kajian ini, sila hubungi;

Puan Mazlita Zainal Abidin
Setiausaha Jawatankuasa Etika Penyelidikan (Manusia) USM
Pelantar Penyelidikan Sains Klinikal, USM Kampus Kesihatan.
No. Tel: 09-7663756 / 09-7663760

Kerahsiaan

Segala butiran maklumat pesakit adalah sulit sepertimana dalam fail pesakit.

Tandatangan

Untuk menyertai kajian ini, anda mesti menandatangani serta menarikhkan halaman tandatangan.

LAMPIRAN 1

Borang Keizinan Pesakit
(Halaman Tandatangan)

Tajuk Kajian: **Validasi Versi Bahasa Melayu Sleep Apnea Quality of Life Index (SAQLI) pada Pesakit Obstruksi Apnea Tidur.**

Nama Penyelidik: **Dr Nor Idayu Mohd Yusof (39836)**

Untuk menyertai kajian ini, anda atau wakil sah anda mesti menandatangani mukasurat ini. Dengan menandatangani mukasurat ini, saya mengesahkan yang berikut:

- Saya telah membaca semua maklumat dalam Borang Maklumat dan Keizinan Pesakit ini **termasuk apa-apa maklumat berkaitan risiko yang ada dalam kajian** dan saya telah pun diberi masa yang mencukupi untuk mempertimbangkan maklumat tersebut.
- Semua soalan-soalan saya telah dijawab dengan memuaskan.
- Saya, secara sukarela, bersetuju menyertai kajian penyelidikan ini, mematuhi segala prosedur kajian dan memberi maklumat yang diperlukan kepada doktor, para jururawat dan juga kakitangan lain yang berkaitan apabila diminta.
- Saya boleh menamatkan penyertaan saya dalam kajian ini pada bila-bila masa.
- Saya telah pun menerima satu salinan Borang Maklumat dan Keizinan Pesakit untuk simpanan peribadi saya.

Nama Pesakit (Dicetak atau Ditaip)	**Nama Singkatan & No. Pesakit**
No. Kad Pengenalan Pesakit (Baru)	**No. K/P** (Lama)
Tandatangan Pesakit atau Wakil Sah	**Tarikh** (dd/MM/yy) (Masa jika perlu)
Nama & Tandatangan Individu yang Mengendalikan Perbincangan Keizinan (Dicetak atau Ditaip)	**Tarikh** (dd/MM/yy)
Nama Saksi dan Tandatangan	**Tarikh** (dd/MM/yy)

Nota: i) Semua subjek/pesakit yang mengambil bahagian dalam projek penyelidikan ini tidak dilindungi insuran.

APPENDIX H: PATINENT INFORMATION AND CONSENT FORM

RESEARCH INFORMATION

Research Title: **The Validation of the Malay Version of the Sleep Apnea Quality of Life Index (SAQLI) in Patients with Obstructive Sleep Apnea**

Researcher's Name: **Dr Nor Idayu Mohd Yusof (39836)**

Introduction

Obstructive sleep apnea(OSA) is a common global health disorder results from cessation of the airflow due to upper airway obstruction during sleep. Most patients with OSA have impaired health related quality of life. SAQLI is a specific health related quality of life (HRQOL) instruments for patients with OSA. Validated Malay version of SAQLI will enable the assessment of QOL in local patients with obstructive sleep apnea.

Purpose of the Study

GENERAL OBJECTIVE.
To validate the Malay translated SAQLI in patients with obstructive sleep apnea.

SPECIFIC OBJECTIVES.

1. To perform back to back translation of the English version of SAQLI into Malay language.
2. To determine the validity of the Malay translated SAQLI which includes;
    a) face validity
    b) content validity
    c) construct validity
3. To examine the reliability and stability of the Malay translated SAQLI by determining;
    a) internal consistency
    b) test-retest reliability

Qualification to Participate

Inclusion/exclusion criteria

Inclusion criteria

a) Patients diagnosed as OSA who attended Sleep Clinic and general clinic of ORL, HUSM during the study period.
b) Age 18 years old and above
c) Who were able to read and write fluently in Malay language

Exclusion criteria

a) Non-Malaysian
b) Illiterate

c) Patients with serious condition who showed clear cognitive disturbance during interview.
d) Patients with speech and hearing difficulty

Study Procedures

Consent to participate in the study will be taken after subject has been thoroughly explained and understood regarding the purposes, importance and benefits of the study.

SAQLI questionnaire will be administered to the subject with interviewer guidance. A retest will be held within 2-4 weeks of the first interview.

Risks

This study brings no risk nor harmful to you.

Reporting Health Experiences.

Do call Dr. Nor Idayu Mohd Yusof (contact number: 0194135424) or the staff nurse (09-7664360). You can call at anytime; day or night.

Participation in the Study

Your willingness as a participant in this study is entirely voluntary. You may refuse to take part in the study or you may stop participating in the study at anytime, without a penalty or loss of benefits to which you are otherwise entitled.

Possible Benefits

If there is an abnormality or other medical problem detected during this study, you will be referred to the specialist for further management.

Questions

If you have any question about this study or your rights, please contact;

Dr Nor Idayu Mohd Yusof (39836)
Department of Otolaryngology
USM Health Campus.
Tel: 0194135424

If you have any questions Regarding the Ethical Approval, please contact;

Puan Mazlita Zainal Abidin
Secretary of Research Ethics Committee (Human) USM
Clinical Science Research Platform
USM Health Campus
No. Tel: 09-7663756 / 09-7663760 (P)

Confidentiality

Your medical information will be kept confidential by the study doctor and staff and will not be made publicly available unless disclosure is required by law

Signatures

To enroll into the study, you must sign and date the signature page.

Patient Information and Consent Form
(Signature Page)

Research Title: **The Validation of the Malay Version of the Sleep Apnea Quality of Life Index (SAQLI) in Patients with Obstructive Sleep Apnea**

Researcher's Name: **Dr Nor Idayu Mohd Yusof (39836)**

To become a part this study, you must sign this page. By signing this page, I am confirming the following:

- I have read all of the information in this Patient Information and Consent Form **including any information regarding the risk in this study** and I have had time to think about it.
- All of my questions have been answered to my satisfaction.
- I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.
- I may freely choose to stop being a part of this study at anytime.
- I have received a copy of this Patient Information and Consent Form to keep for myself.

Patient Name (Print or type)	**Patient Initials** and **Number**
Patient I.C No. (New)	**Patient I.C** No. (Old)
Signature of Patient or Legal Representative	**Date** (dd/MM/yy)
Name of Individual Conducting Consent Discussion (Print or Type)	
Signature of Individual Conducting Consent Discussion	**Date** (dd/MM/yy)
Name & Signature of Witness	**Date** (dd/MM/yy)

INTRODUCTION AND LITERATURE REVIEW

1.1 Background of Study

Health disorders have a major impact on quality of life. In recent years, the emphasis on measuring health has been broadened to include more than just the traditional indices such as morbidity and mortality (Saxena and Orley, 1997). There has been a gradual shift away from relying on only clinical and laboratory indicators of illness and a move toward measures that incorporate the patients' point of view (Wood-Dauphinee, 1999). Physiologic measures provide information to clinicians but are of limited interest to patients; they often correlate poorly with functional capacity and well being, the areas in which patients are most interested and familiar (Guyatt *et al.*, 1993). Measuring health related quality of life (HRQOL) thus now becomes important for measuring the impact of chronic disease.

Quality of life is a vague concept defined and measured in many different ways. Subjective well-being, the fulfilment of social roles and functional status are increasingly important domains or issues of medical concern in societies in which a majority of the sick suffer from chronic disease. Symptom relief, slowing down disease progression and improvements in functional ability therefore become major goals in therapeutic strategies. These goals can be met successfully if the patient's estimation of his or her well-being is taken into account. Therefore, any assessment of therapy has to

take into account the quality of life in addition to traditional biomedical parameters (Siegrist and Junge, 1989).

Clinicians and policymakers are also recognizing the importance of measuring health related quality of life to inform patient management and policy decisions (Guyatt *et al*., 1993). Improvements in therapy and patient-physician relationships are considered among the major benefits of assessing the quality of life in clinical practice.

Obstructive sleep apnea syndrome (OSAS) is a common disorder in many ethnic populations. It is now recognized as a major public health problem due to its high prevalence, increased morbidity and mortality, high medical costs and increased public safety risk (Kryger *et al*., 1996). The impact of OSAS is potentially profound and wide-ranging with a number of studies noting adverse effects on physical, emotional, and intellectual capacities, as well as functional quality of life (Kales *et al*., 1985; Pillar and Lavie, 1998; Finn *et al*., 1998; Engleman and Douglas, 2004). Taking into account the different cultural and personal expectations regarding health and coping ability that each patient possesses, HRQOL can differ markedly among patients with the same severity of disease, thus offering a nuanced portrait of a patient's illness (Testa and Simonson, 1996).

.

Given the high prevalence of OSAS in diverse populations and the adverse cardiovascular, cognitive, and psychological sequelae associated with it, it is not surprising that there has been considerable interest in assessing HRQOL in patients

with this disorder. The inclusion of quality of life as an outcome measure is now expected in most clinical trials (Flemons and Tsai, 1997). Valid, reliable and responsive instruments should thus be developed to assess this impairment.

1.2 Definition of OSA and OSAS

Obstructive sleep apnea (OSA) is defined as cessation of airflow but with continued respiratory effort, patient must have at least five obstructed breathing events per hour (or 30 events per 6 hours of sleep) confirmed by polysomnography (AASM, 2005).

Obstructive sleep apnea syndrome (OSAS) is characterized by repetitive episodes of complete or partial upper airway obstruction that occur during sleep. The former results in cessation of breathing (apnea); the latter results in hypoventilation (hypopnea). Apnea termination requires arousal and the resulting frequent awakenings lead to daytime symptoms such as daytime sleepiness, and impaired concentration. Obstructive sleep apnea hypopnea syndrome (OSAHS) is a newer term with similar meaning (Thorpy, 2005, Kryger, 2003).

1.3 Prevalence of OSAS

OSAS (apnea/ hypopnea index (AHI) >5/h and excessive daytime sleepiness) affects about 2% of females and 4% of males (Young *et al*., 2002a). A more recent report estimated that OSAS affects approximately 5% of adults; however, the prevalence of OSAS may be increasing because of recent obesity trends (Banno *et al*., 2005).

Most epidemiological studies have investigated Caucasians, and there are few studies to assess the population of other races. The prevalence of OSAS in Asians is estimated as 4.5% in males and 3.2% in females (Kim *et al*., 2004). OSAS prevalence study done in Singapore estimated 20.8% of a healthy adult population has OSAS and the prevalence among the major ethnics was found to be 30%, 19.7% and 12% in Malays, Chinese and Indian respectively (Puvanendran and Goh, 1999).

There is scanty local data from Malaysia. In 2007, Kamil et al reported that prevalence of habitual snoring, apnea and excessive daytime sleepiness were 47.3%, 15.2% and 14.8% respectively. They also found that 8.8% of male and 5.1% of female respondents were clinically suspected to have OSAS (Kamil *et al*., 2007).

1.4 Risk factors Associated with OSAS

Gender and aging as are risk factors for OSAS. The other common risk factors for OSAS include obesity, enlarged tonsils and adenoids, and craniofacial abnormalities (e.g., retrognathia and micrognathia) (Young *et al*., 1993, Peppard *et al*., 2000).

1.4.1 Aging

Several studies have shown a higher prevalence of OSAS in older people. Although it can occur at any age, OSAS typically presents between the ages of 40 and 60 and increases with age (Young *et al*., 1993; Ancoli, 1989). It has been reported that OSAS is present in about 6% of people between the ages of 50-70 years (Zamarron *et al*.,

1999). The Sleep Heart Health Study showed that 25% of males and 11% of females in the age group 40 to 98 years had an AHI of higher than 15 events per hour (Young *et al*., 2002b). Age related anatomical changes in pharynx which lead to increased upper airway collapsibility may partly explain the increased prevalence of OSAS in older people (Malhortra *et al*., 2000).

1.4.2 Gender Differences

Epidemiological studies have shown that OSAS occurs more predominantly in males. Men are twice likely to develop OSAS with an estimated prevalence of 4% vs 2% in women (Young *et al*., 2000a). Males with OSAS are more likely to have symptoms of snoring, observed apnea or sleepiness; females with OSAS have more symptoms of depression or morning headache (Redline et al., 1994).

1.4.3 Obesity

The vast majority of OSAS cases are obese and obesity is probably the most important risk factor for OSAS (Young *et al*., 2002a). There is a relationship between body weight and AHI: a 10% weight gain has been shown to predict an approximately 32% increase in the AHI, and a 10% weight loss predicted a 26% decrease in the AHI, and a 10% increase in weight predicted a sixfold increase in the odds of developing moderate to severe sleep-breathing disorder (Peppard *et al*., 2000). Obesity can cause airway narrowing as a result of excess of fat tissue around the neck. Neck circumference corrected for height has also been reported to be useful as a predictor of OSAS (Davies *et al*., 1992).

1.4.4 Familial Factors

Familial factors may play a role in the pathogenesis of OSAS. There is a report which supports a genetic predisposition to OSAS: a significant portion of SDB is associated with ApoE epsilon4 in the general population (Kadotani *et al*., 2001). Abnormal craniofacial anatomy is common in familial groups with OSAS. A case control of first degree relatives of patients with OSAS, showed that relatives of patients with OSAS were more likely to have episodes of snoring and daytime sleepiness and had higher AHI. In addition, they also had narrower upper airways with maxillae and mandibles that were more posterior than normal and longer soft palates with wider uvulae (Mathur and Douglas, 1995). These findings suggest that genetic factors that determine upper airway structure and craniofacial anatomy may contribute to the aggregation of OSAS in some families (Guilleminault *et al*, 1995).

1.5 Clinical Presentation of OSAS

Patients with OSAS have a wide spectrum of symptoms that range from snoring to a more complex psychological, physiological and cognitive effects. The symptoms are typically divided into daytime and nocturnal symptoms as presented in Table 1.1 (Kryger, 2004). While the nocturnal symptoms of OSAS are more characteristic and tend to be more specific for the disease, the common daytime symptoms are less specific as they can result from abnormal sleep of any cause.

OSAS is commonly associated with loud snoring, apneic events such as choking and gasping during sleep (George *et al*., 2003). Indeed, the only two symptoms that make

OSAS patients attend the clinic are loud snoring and excessive daytime somnolence (EDS) (Dobbin and Strollo, 2002). In addition, choking and breathing pauses seen by partner during sleep is the third common reason for referral to a sleep clinic (Schlosshan and Elliott, 2004).

Table 1.1 Subjective symptoms of obstructive sleep apnea syndrome

Daytime	Nighttime
Sleepiness	Snoring
Fatigue	Observed apneas and gasping
Impaired memory	Frequent awakenings
Symptoms of gastroesophageal reflux	Choking
Morning headache	Sweating
Depressive symptoms	Palpitations
Impotence or decreased libido	Nocturia

Adapted from Kryger, 2004.

Physical examination of the patient with suspected OSAS is of great value and can reveal characteristic findings suggestive of upper airway obstruction as shown in Table 1.2 (Kryger, 2002).

Table 1.2 Common clinical features in patients with obstructive sleep apnea syndrome

Obesity
Increased neck collar size
Retrognathia
Micrognathia
Enlarged tonsils and adenoids
Nasal obstruction (mouth breathing)
Peripheral edema

Adapted from Kryger,2002.

1.6 Diagnosis of OSAS

The diagnostic criteria of OSAS must fulfill both subjective symptoms and five or more obstructive breathing events documented by overnight monitoring (Figure 1.1) (AASM,1999).

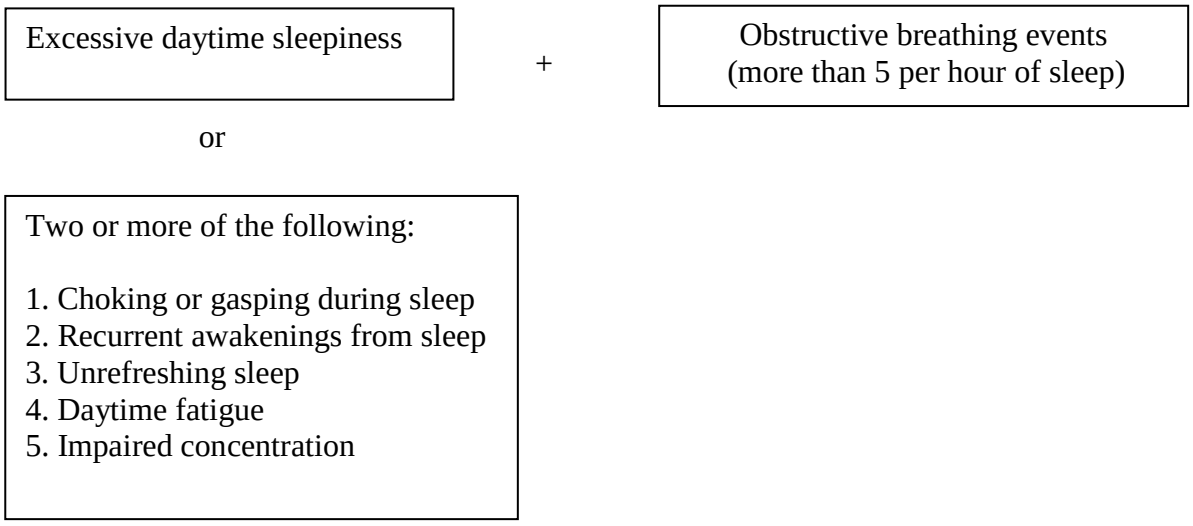

Fig. 1.1 Diagnostic criteria for obstructive sleep apnea syndrome.

Adapted from AASM, 1999.

1.6.1 Polysomnography

The Standards of Practice Committee of the American Sleep Disorders Association has identified polysomnography (PSG) as the diagnostic tool for sleep apnea. An overnight PSG with recording of respiratory variables such as apnea– hypopnea index (AHI) and levels of oxygen saturation are the gold standard measures used for the diagnosis of sleep apnea (Riley *et al*., 1995). PSG involves in simultaneous and continuous measurement of multiple physiological parameters during sleep. This study is typically obtained at night in a sleep laboratory for the purpose of identifying, as best as possible given the novel environment, the patient's typical sleep and its associated pathologies. There are full (16 channels) and partial (8 channels). Full PSG includes measurements of electroencephalogram (EEG), electrocardiogram (ECG), electrooculogram (EOG), postural muscle tone, electromyogram (typically using submental EMG), chest and abdominal movement, peripheral limb movements (upper and/or lower limb EMG), sleeping position, oxygen saturation (SaO2), nasal and oral airflow, respiratory effort and snore detector (Douglas et al.,1992).

Results of PSG are most often reported using the Apnea-Hypopnea Index (AHI), which can be used to diagnose obstructive sleep apnea. The AHI cut-offs of 5, 10, or even 15 (respiratory disturbances per hour) have commonly been used as a clinical diagnostic measure of sleep apnea (AASM, 1999).

1.6.2 Assessments of the Severity of OSAS

Assessments of OSAS severity were also getting worldwide attention. Many objective and subjective sleep and psychological tests have been used to identify and assess the severity of OSAS. These measures include apnea-hypopnea index (AHI), biomarkers and EDS metrics (Baha *et al*., 2008).

The AHI is the average number of apnea and hypopnea per hour of sleep. This index has been widely used to define the diagnosis of OSAS. It is also frequently used as the primary metric to define disease severity in many clinical patients (Baha *et al*., 2008). Many researchers also include the probability and degree of sleepiness along with AHI as criteria in assessing the severity of OSAS as shown in Table 1.3.

Table 1.3 Severity Criteria of OSAS

	Sleepiness	Sleep-related obstructive breathing events (/h)
Mild	Unwanted sleepiness or involuntary sleep episodes during activity requiring little attention (e.g., watching TV, reading)	5-15
Moderate	Unwanted sleepiness or involuntary sleep episodes during activity requiring some attention (e.g., meetings, concerts)	15-30

Table 1.3 cont

Severe	Unwanted sleepiness or involuntary sleep episodes during activity requiring active attention (e.g., eating during conversation, operating a motor vehicle)	>30

The severity criteria consists of two components: severity of sleepiness and obstructive breathing events during sleep. The rating of severity is determined based on the most severe component. For example, if a patient has 5–15 sleep-related obstructive breathing events per hour and severe sleepiness which met the sleepiness criteria above, the patient should be considered to have severe obstructive sleep apnea syndrome. Adapted from AASM, 1999.

1.7 Morbidity Related to OSAS

OSAS adversely affects several organ systems as summarize in Table 1.4 (Schlossan and Elliott, 2004). It has been associated with cardiovascular, neurological, behavioral, cognitive, social consequences, and even sudden death (Flemons and Whitelaw, 2002). It has also been shown to be associated with increased prevalence of myocardial infarction, cerebrovascular accidents and hypertension in numerous epidemiological studies (Sher, 1999; Leung and Bradley, 2001; Shahar *et al*., 2001). Similarly, behavioral and cognitive consequences of OSA have been noted and include excessive daytime sleepiness, increased motor vehicle accidents (MVA), and changes in short-term memory and cognitive function (Antonelli *et al*., 2004). Social consequences of OSAS include snoring and disruption of marital harmony. Therefore many of these patients seek treatment of the disease generally not for the treatment of physiologic metrics but instead for their clinical consequences (Flemons and Reimer, 2003).

Table 1.4 Obstructive sleep apnea syndrome: associated conditions and clinical manifestations in non-sleep medical fields

Field	Associated disorders and conditions, presentation
Cardiology	Hypertension, left ventricular hypertrophy, angina pectoris, myocardial infarction, arrhythmia, heart failure, pulmonary hypertension, cor pulmonale, peripheral edema, sudden death
Respirology	Respiratory failure, nocturnal shortness of breath, postpolio syndrome
Endocrinology	Diabetes mellitus, insulin resistance, metabolic syndrome, hypothyroidism, acromegaly
Neurology	Stroke, epilepsy, impaired memory, cognitive dysfunction
Gastroenterology	Gastroesophageal reflux disease (GERD)
Hematology	Polythemia
Psychiatry	Depression, anxiety disorder, Schizophrenia
Urology	Nocturia, impotence, erectile dysfunction, reduced libido
Gynecology and obstetrics	Pregnancy, menopause, polycystic ovary syndrome (PCOS)
Otorhinolaryngology	Enlarged tonsils, adenoids, nasal obstruction
Ophthalmology	Glaucoma, non-arteritic ischemic optic neuropathy
Anesthesiology	Difficulty of intubation, prolonged apneic episodes after operation
Dentistry and Orthodontics	Retrognathia, micrograthia

Adapted from Schlosshan and Elliott, 2004.

1.8 OSAS and Quality of Life

The quality of sleep is intrinsically linked to quality of life. Impaired quality of life has been identified by the American Academy of Sleep Medicine Task Force on Sleep-Related Breathing Disorders in Adults as one of the associated features of obstructive sleep apnoea and sleep hypoventilation syndrome (AASM, 1999).

The impact of sleep disordered breathing on the quality of life of patients and their partners is a major factor in seeking and complying with treatment. Repeated arousals from apneas and hypopneas give rise to troublesome symptoms such as excessive daytime sleepiness, irritability, decreased concentration, poor memory, and decreased energy. Other symptoms, such as snoring, gasping, apneic periods, and restlessness, disturb the sleep of the bed partner. Sequelae of these symptoms may include decreased productivity, job losses, safety risks, motor vehicle accidents, disrupted marital and social relationships, loss of the enjoyment of leisure activities, and depression. Associated health problems such as obesity, hypertension, and heart failure may further compromise quality of life (Flemons and Tsai, 1997; Flemons and Reimer, 1999).

Patients' experience of their illnesses as assessed by health related quality of life (HRQOL) indices is increasingly recognized as an important component of the disease process, with respect to initial presentation, diagnosis, and treatment success (Hunt *et al*., 1985). Given the prevalence of OSA and its detrimental effects on both physical and mental function, it is not surprising that the health-related quality of life (HRQOL) among persons with OSA is receiving increased attention in the research literature. For many years, the treatment outcomes of sleep apnea were assessed by conventional

clinical parameters such as the apnea hypopnea index (AHI), the Epworth Sleepiness Scale (ESS) and snoring. The measurement of physiological and laboratory parameters are important for determining the effect of treatment on specific symptoms or physiology, but cannot be used as a surrogate outcome for quality of life in sleep apnea, given the poor correlation between the impairment of quality of life and the severity of sleep apnea (Flemons, 2000, Davis *et al*., 1993). An important goal of health care is to enhance the quality of life; therefore, health-related quality of life (HRQOL) is a clinically significant outcome measure. The rapidly growing list of available HRQOL instruments encourages the measurement of HRQOL alongside more traditional, biologic health outcomes. Physiologic indices may improve with treatment, but HRQOL may not, and vice versa.

1.9 Definition of Quality of Life (QOL)

The term “quality of life” first surfaced in 1920, but it was not until the 1960s that it came to public notice in North America (Wood-Dauphinee, 1999). However the conceptual entity ‘quality of life’ remains ill-defined and no widely accepted definition of QOL was available.

In the mid-1980s, Kaplan noted that quality of life as it relates to health, was concerned with the impact of disease and treatment on disability and daily functioning (Kaplan, 1985), and Greer talked about physical, emotional and social well being after the diagnosis and treatment (Greer, 1984). Bullinger *et al* found that HRQOL focused on

the impact of perceived health on an individual's ability to live a fulfilling life (Bullinger *et al*., 1993).

WHO has defined QOL as an "individuals" perception of their position in life in the context of culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, level of independence, social relationships, and their relationship to salient features of their environment."

While experts continue to disagree on a single definition, there seems to be an emerging consensus that generic HRQOL takes into account levels of physical, mental, social and role functioning and includes abilities, relationships, perceptions, life satisfaction and well being (Bowling, 1995, Berzon *et al*., 1993; Stewart, 1992).

1.10 Quality of Life Instruments

Today most would agree that HRQOL instruments can supplement information from traditional measures of clinical endpoints and provide a clearer picture of the outcomes of care by taking patients' points of view into account. Different instrument have been developed to measure QOL in various categories.

Questionnaires are the basis of most quality of life measurements (Siegrist and Junge, 1989). Questionnaires are one of the most commonly used tools for data collection in clinical research because of their ease and simplicity of use. Questionnaires are not expensive and may be used to measure a large number of health outcomes including medical diseases of interest, functional status and quality of life (Saw and Ng, 2001). There is variety of questionnaire types that can be used, each of which has its advantages and disadvantages. Each questionnaire should be designed to minimize respondent and interviewer errors in the understanding of the questions and recording of the answers, as well as maintain the interest and cooperation of the respondent (Meadows, 2003).

There is also a wide range of methods for administering questionnaire for collecting patient-based information such as open in-depth interviews, structured personal interviews, telephone interviews and paper and pencil tests. These different methods certainly have an impact on measurement requirements such as validity, reliability and sensitivity to change (Siegrist and Junge, 1989). The strength and weaknesses of the different modes of HRQOL administration are summarized in Table 1.5 (Guyatt *et al*., 1993).

Table 1.5 Modes of administration of HRQOL measures

Mode of administration	Strengths	Weaknesses
Interviewer	-Maximizes response rate -Few if any missing items -Minimizes errors of misunderstanding	-Requires many resources, training of interviewers -More costly -May reduce willingness to acknowledge problems -Limits format of instrument
Telephone	-Cover a widely dispersed population -Low cost -Few if any missing items -Minimizes errors of misunderstanding -Less resource intensive than interviewer – administered mode	-Problems of sampling bias and generalizability of the findings -Unsuitable for samples which comprise people who are hard of hearing, older people.
Self administered	-Minimal resources required -Less expensive -Wider coverage in study population	-Greater likelihood of low response rate, missing items, misunderstanding
Surrogate responders	-Reduces stress for target group very elderly or sick	-Perceptions of surrogate may differ from target group

Adapted from Guyatt et al, 1993.

1.10.1 Types of HRQOL Measures.

Two basic approaches to quality of life measurement are available: generic instruments that provide a summary of HRQOL and specific instruments that focus on problems associated with single disease states, patient groups or areas of function (Guyatt *et al*., 1993).

1.10.1.1 Generic Instruments

The development of generic measures began in early 1970s and continues until today. Generic instruments include single indicators (such as global assessments) and instruments designed for use among a variety of people with different types of illness. They also include health profiles and preference- based (utility) measures (Wood-Dauphinee, 1999).

i. Health Profile

Health profiles are instruments that attempt to measure all important aspects of HRQOL. An example is The Sickness Impact Profile. Major advantages of health profiles include dealing with a variety of areas and use in any population, regardless of the underlying condition. It allows for broad comparisons of the relative impact of various health care programs. Generic profiles may however, be unresponsive to change in specific conditions (Guyatt *et al*., 1993).

ii. Utility Measures

Utility measures of quality of life are derived from economic theory. The key elements of utility measures are that they incorporate preference measurements and relate health states to death. Thus, they can be used in cost-utility analyses that combine duration and quality of life. The usefulness of utility measures in economic analysis is important when health care providers are asked to justify devoted to treatment (Guyatt *et al*., 1993).

1.10.1.2 Specific Quality of Life Instruments

Disease-specific measures have also proliferated. The specific instrument have been developed and validated to focus on aspects of health status that are specific to the area of primary interest such as the effects of treatment on obstructive sleep apnea.. It has potential for increased responsiveness and has the advantage of relating closely to areas routinely analyzed by clinicians (Flemons, 2004).

Because generic and specific instruments each have both strengths and weaknesses, the concurrent use of both types is often optimal in clinical studies (Patrick, 1989). Table 1.6 summarizes the strengths and weaknesses of both instruments.

Table 1.6 Characteristics of Measures of Health-Related Quality of Life

Approach	Strengths	Weaknesses
Generic instruments i.Health Profile	-Single instrument -Detects differentials effects on different aspects of health status -Comparisons across interventions, conditions possible	-May not focus adequately on area of interest -May not be responsive
ii.Utility Measurement	-Single number representing net impacts on quantity and quality of life -Cost-utility analysis possible -Incorporate death	-Difficulty determining utility values -Does not allow examination of effect on different aspects of quality of life -May not be responsive
Specific instruments	-Clinically sensible -May be more responsive	-Does not allow cross condition comparison -May be limited in terms of population and interventions

Adapted from Patrick, 1989.

1.10.2 QOL Instruments in OSAS

Researchers have used dozens of different instruments to measure HRQOL in patients with OSAS. Generic and sleep disorder-specific instruments consistently demonstrate impairment in multiple domains of HRQOL in OSAS (Atkeson and Basner, 2008). Although generic questionnaires are designed to measure all important aspects of

quality of life, they are theoretically less likely to detect changes in quality of life than a disease specific questionnaire in patient with OSAS. Table 1.7 shows list of instruments used in assessing HRQOL in patients with OSAS (Moyer *et al*., 2001).

Table 1.7 Instruments Used in Obstructive Sleep Apnea HRQOL Assessments

Generic Instruments	SF-36 Nottingham Health Profile Sickness Impact Profile Functional Limitations Profile EuroQol EQ-5D Munich Life Quality Dimension List
Specific Instruments	Calgary Sleep Apnea Quality of Life Instrument (SAQLI) Functional Outcomes of Sleep Questionnaire (FOSQ) OSA Patient Oriented Severity Index Franco's Pediatric OSA instrument Cohen's Pediatric OSA Surgery QOL questionnaire

Adapted from Moyer et al, 2001.

1.11 Testing the QOL Instruments

The International Quality of Life Assessment (IQOLA) project group determined that no one qualitative or quantitative step is sufficient to ensure validation. Thus, it developed a three-stage process designed to produce cross-culturally comparable translations of a questionnaire. In brief, the process included: (1) rigorous translation

and evaluation procedures to ensure conceptual equivalence and respondent acceptance, (2) formal psychometric tests of the assumptions underlying item scoring and construction of multiitem scales, and (3) examination of the validity of the scales and the accumulation of normative data and other interpretation guidelines (Bullinger *et al*., 1993).

1.11.1 Psychometry and Translation

There are a number of requirements that should be met for instruments intended to collect information from patients. These requirements refer to the psychometric properties of the instrument leading to its validation. The two standard requirements for instruments which measure abstract and subjective phenomenon are reliability and validity. For instruments designed for discriminative (defining cross-sectional differences between people) or predictive (predicting a concurrent or future gold standard) purposes, demonstration of reliability and validity is sufficient to ensure usefulness. However for evaluative instruments (those designed to measure longitudinal change over time), the instrument must detect clinically important changes over time, even those changes are small. This property has been referred as responsiveness (Guyatt *et al*., 1988).

Translation process has an issue of cross cultural adaptability, a problem that relates to the development, translation, or utilization of questionnaires in languages other than English. However we concur with Jones' commentary that 'the purpose of translation is not to produce a literal conversion of the questionnaire but to convey the spirit of the questionnaire items into different languages and cultures' (Jones, 1998).

WHO has developed considerable experience in translating health status measure into diverse languages. Based on this, a standard translation methodology has been developed using an iterative process of forward and backward translations complemented by a review process by monolingual and bilingual groups to ensure conceptual, semantic and technical equivalence (Saxena and Orley, 1997). Therefore a careful translation and back translation of quality of life questionnaires can produce non-English language versions that appear to behave in a very similar manner to their originals.

1.11.2 Reliability

The 'accuracy' of the data obtained from a questionnaire has two components: reliability and validity. Reliability is the stability of the data gathered. It is defined as the degree to which a measure gives 'consistent' or 'reproducible' values when applied in different situations, such as on different occasions on the same individual (test-retest reliability), or when a number of similar question-items are intended the same entity (inter-item consistency) (Saw and Ng, 2001). The most common indicators of reliability are test-retest reliability and internal consistency.

1.11.2.1 Test-Retest Reliability

The reliability of the questionnaire may be assessed by administering the questionnaire at two different points of time and seeing the degree of variation that occurs and this is

called test-retest reliability (Saw and Ng, 2001). This is a measure of how stable the respondents' responses are between time 1 and time 2, when we can assume that there should be no natural change in the response (Meadows, 2003). One problem related to estimating test-retest reliability is that people change between the first and second administration of a test, thus the interval should be carefully planned (Streiner and Norman, 1989; McDermott and Sarvela, 1998). To determine the test-retest reliability two methods are available: 1) counting the percentage of people whose retest scores fall within a 95% confidence interval of the first administration to determine the limit of agreement and 2) using intraclass correlation coefficient (Brazier *et al*., 1992; Ware *et al*., 1993).

The intraclass correlation coefficient is often the preferred statistical index for the exact agreement between two sets of response, which should not be less than 0.70 (Saw and Ng, 2001). A high intraclass correlation coefficient means that not much of the variability is due to variability in measurement on different occasions or, what amounts to the same thing, that the agreement between them is high (Prieto *et al*., 1997).

1.11.2.2 Internal Consistency

Internal consistency is another form of reliability. It is a measure of how well a group of questions 'tap' a particular concept. For example, we would expect a scale designed to measure physical ability to comprise items that tap the various aspects of the concept, e.g. the ability to climb stairs, walk a block, run 100 metres etc. If this were the case, the scale would then have a high internal consistency (Meadows, 2003).