17. How did you complete the questionnaire? Please select the one answer that best describes your situation. By myself, without any help from anyone else. a. b. By myself, except someone else circled the answers on the questionnaire form for me. With the help of someone else. c. đ. This questionnaire was completed by a family member, without help from the subject or patient. This questionnaire was completed by a nurse or other health professional, without e. help from the subject or patient. Please specify type of health professional: This questionnaire was completed by another person, without help from the subject f. or patient. Please specify relationship to subject or patient:

Feeny, Furlong and Torrance 1997.

#### Uses of HUI?

- to measure health-related quality of life for clinical trials
- to measure functional status for clinical studies
- to measure outcomes for costeffectiveness and cost-utility analyses
- to measure health status for use in routine clinical practice and quality assurance programs
- to describe and monitor the health of general populations
- to investigate determinants of health
- to substitute for complex direct preference measurements

#### **HUI Data Collection**

- use HUI questionnaires to collect data on health status; code and analyze results according to algorithms documented by the HUI Group
- questionnaires are available in a variety of formats and languages for different applications
- HUI2 and HUI3 systems are complementary
- measures are appropriate for broad range of subjects (6 years of age plus).

### List of Selected Services and Prices

- 1. Application and Interpretation Package
- basic information and reprints;
   permission to use the most appropriate
   questionnaires and coding algorithms for
   one study; up to 1 day of consulting on
   choice of measures, study design,
   analysis.

  \$ 4,000.00
- 2. Single-Centre HUI Training Session at McMaster (n < 8 trainees)
- 1 trainer and advance readings with up to 1 day of ongoing consultations (does not include scheduling or travel expenses of trainees)
   \$ 3,000.00
- 3. Multi-Centre HUI Training Session at McMaster (n < 20 trainees)
- 2 trainers and advance readings with up to 2 days of ongoing consultations (does not include scheduling or travel expenses of trainees) \$7,000.00
- 4. Other services
- advice about design, data collection, analysis
- preparing of coding algorithms
- review of reports/manuscripts
- clinical application consulting
- direct utility measurement
- interviewing props, scripts, manuals,
- workshops

Prices upon request.

#### Notes:

- a) All prices are quoted in Canadian dollars, payable by cheque or draft drawn on a Canadian or U.S.A. account.
- b) Prices are subject to change without notice.
- c) Prices are exclusive of applicable taxes.
- d) Prices do not include travel costs (time and expenses).

# HUI

## **Health Utilities Index**

ON ALITHY OF LIFE



Centre for Health Economics and Policy Analysis

Health Utilities Group McMaster University May 1997

#### What is HUI?

- a system for measuring health status, health-related quality of life, and producing utility scores
- generic, preference-scored, comprehensive, compact
- based on explicit conceptual framework of health status and health-related quality of life
- there are 3 versions of HUI:
   HUI Mark 1 (HUI1);
   HUI Mark 2 (HUI2); and
   HUI Mark 3 (HUI3)
- each version includes a health status classification system and formula for calculating utility scores
- HUI2 and HUI3 describe thousands of unique health states
- scoring formulas are well grounded in theory and based on preference data from community surveys
- conceptual and measurement properties described in numerous papers published in peer-reviewed scientific journals and books.

#### **Applications of HUI**

- over 300 investigators have used HUI in a wide variety of studies in over 20 countries
- more than 200,000 subjects have been assessed using HUI.

### Where Do I Obtain HUI Questionnaires and Documentation?

- the HUI Group at McMaster University develops and maintains data collection forms and procedure manuals
- the appropriate HUI questionnaire is determined by study design factors (e.g., language, mode of administration, relationship of respondent to subject)
- HUI questionnaires are designated to minimize the burden of data collection
- a well-documented package is currently available for 15-item self-administered questionnaires (the package includes directions for data analysis; questionnaires are available for 1 week / 2 weeks / 4 weeks / "usual health" recall periods, and in English and French-Canadian language)
- a well-documented package (as above) is currently available for 40-item interviewer- administered questionnaires, but to date in English language only
- other questionnaires and translations are also available, in various states of documentation
- requests for information about the HUI should be addressed to:

Pr. David Feeny or William Furlong
Health Utilities Index Group
Health Sciences Centre Room 3H3
Centre for Health Economics and Policy Analysis
McMaster University
1200 Main Street West
Hamilton, Ontario, Canada L8N 3Z5
Fax (905) 546-5211.

# MARK III (OHS/GSS) HEALTH STATUS CLASSIFICATION SYSTEM: ATTRIBUTES AND FUNCTIONAL LEVEL DESCRIPTIONS

[NOTE: all descriptions refer to usual level of ability or disability]

	VISION		HEARING
1.	Able to see well enough to read ordinary newsprint and recognize a friend on the other side of the street, without glasses or contact lenses.	1.	Able to hear what is said in a group conversation with at least three other people, without a hearing aid.
2.	Able to see well enough to read ordinary newsprint and recognize a friend on the other side of the street, but with glasses.	2.	Able to hear what is said in a conversation with one other person in a quiet room without a hearing aid, but requires a hearing aid to hear what is said in a group conversation with at least three other people.
3.	Able to read ordinary newsprint with or without glasses but unable to recognize a friend on the other side of the street, even with glasses.	3.	Able to hear what is said in a conversation with one other person in a quiet room with a hearing aid, and able to hear what is said in a group conversation with at least three other people, with a hearing aid.
4.	Able to recognize a friend on the other side of the street with or without glasses but unable to read ordinary newsprint, even with glasses.	4.	Able to hear what is said in a conversation with one other person in a quiet room, without a hearing aid, but unable to hear what is said in a group conversation with at least three other people even with a hearing aid.
5.	Unable to read ordinary newsprint and unable to recognize a friend on the other side of the street, even with glasses.	5.	Able to hear what is said in a conversation with one other person in a quiet room with a hearing aid, but unable to hear what is said in a group conversation with at least three other people even with a hearing aid.
6.	Unable to see at all.	6.	Unable to hear at all.

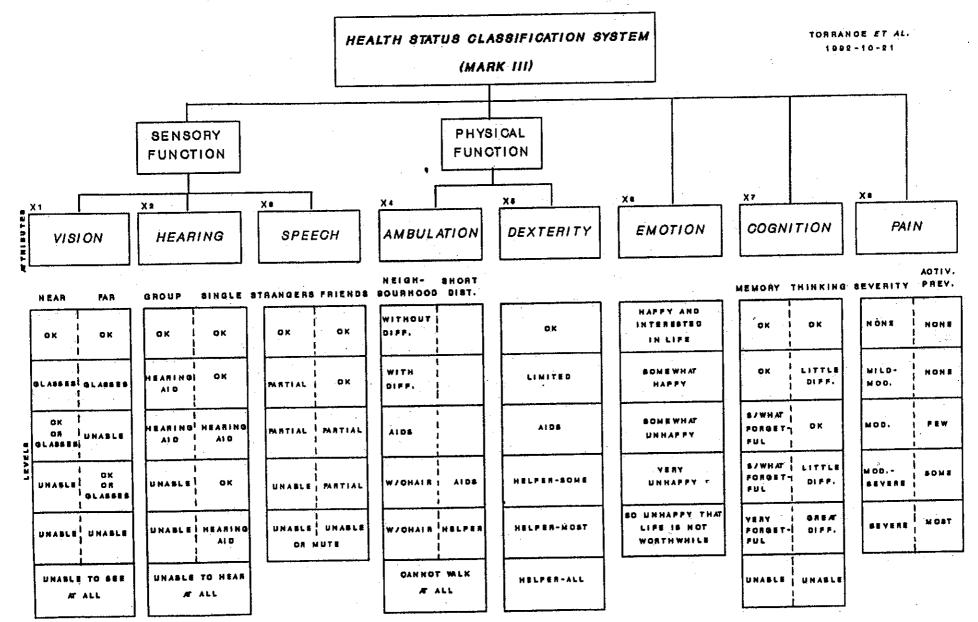
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	SPEECH		AMBULATION
1.	Able to be understood completely when speaking with strangers or friends.	1.	Able to walk around the neighbourhood without difficulty, and without walking equipment.
2.	Able to be understood partially when speaking with strangers but able to be understood completely when speaking with people who know me well.	2.	Able to walk around the neighbourhood with difficulty; but does not require walking equipment or the help of another person.
3.	Able to be understood partially when speaking with strangers or people who know me well.	3.	Able to walk around the neighbourhood with walking equipment, but without the help of anothe person.
4,	Unable to be understood when speaking with strangers but able to be understood partially by people who know me well.	4.	Able to walk only short distances with walking equipment, and requires a wheelchair to get arounthe neighbourhood.
5.	Unable to be understood when speaking to other people (or unable to speak at all).	5.	Unable to walk alone, even with walking equipment. Able to walk short distances with the help of another person, and requires a wheelchair to get around the neighbourhood.
<del> </del>		6.	Cannot walk at all.

	DEXTERITY		EMOTION
1.	Full use of two hands and ten fingers.	1.	Happy and interested in life.
2.	Limitations in the use of hands or fingers, but does not require special tools or help of another person.	2.	Somewhat happy.
3.	Limitations in the use of hands or fingers, is independent with use of special tools (does not require the help of another person).	3.	Somewhat unhappy.
4.	Limitations in the use of hands or fingers, requires the help of another person for some tasks (not independent even with use of special tools).	4.	Very unhappy.
5.	Limitations in use of hands or fingers, requires the help of another person for most tasks (not independent even with use of special tools).	5.	So unhappy that life is not worthwhile.
6.	Limitations in use of hands or fingers, requires the help of another person for all tasks (not independent even with use of special tools).		

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	COGNITION		PAIN
1.	Able to remember most things, think clearly and solve day to day problems.	1.	Free of pain and discomfort.
2.	Able to remember most things, but have a little difficulty when trying to think and solve day to day problems.	2.	Mild to moderate pain that prevents no activities.
3.	Somewhat forgetful, but able to think clearly and solve day to day problems.	3.	Moderate pain that prevents a few activities.
4.	Somewhat forgetful, and have a little difficulty when trying to think or solve day to day problems.	4.	Moderate to severe pain that prevents some activities.
5.	Very forgetful, and have great difficulty when trying to think or solve day to day problems.	5.	Severe pain that prevents most activities.
6.	Unable to remember anything at all, and unable to think or solve day to day problems.		



#### McMASTER UNIVERSITY

Centre for Health Economics and Policy Analysis and Department of Clinical Epidemiology and Biostatistics 1200 Main Street West, Hamilton, Ontario, CANADA 18N 3Z5



Centre des études économiques et politiques sur la santé et Département d'épidémiologie clinique et de biostatistique TEL: (905) 525-9140 Exc. 22122 FAX; (905) 546-5211

E-Mail:

feeny@mcmail.cis.mcmaster.ca

June 8, 1998

Dr. Takamoto Uemura
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School of Medicine
KEIO University
35 Shinanomachi, Shinjuku-ku
Tokyo 160-8582
Japan

Telephone: 81-3-3353-1211, ext. 2655

FAX: 81-3-3359-3686

E-Mail: takauem@mc.med.keio.ac.ip

Dear Dr. Uemura:

RE: Plans for the Development of Japanese Language Materials for the Health Utilities Index Mark 2 (HUI2) and Mark 3 (HUI3) Systems

I think we had very productive discussions on June 4 and 5, 1998 during your visit to McMaster University. In this letter I will summarize key points in our proposed agreement concerning your efforts to create HUI materials suitable for use in Japan. In particular we agreed that the following seven items would be published in Japanese and made available for use in Japan without restriction subject to the usual requirements for appropriate citation. Some of these items already exist and could be translated and published in Japan in the immediate future (Now). Other items are still under development and would be available for translation in the future (Later). It should be noted that under the proposed agreement, users in Japan would have access to HUI materials similar to (Items 1-5 and 7) or more favourable (Item 6) than users in Canada.

- 1. Health Status Classification Systems, HUI2 and HUI3 (Now). The HUI2 and HUI3 health-status classification systems as published in English in Feeny et al. 1995 would be translated into Japanese and culturally adapted for use in Japan and published.
- 2. Brief Descriptions of the HUI2 and HUI3 Multiplicative Multi-Attribute Utility Functions (HUI2, Now; HUI3, Later). The Canadian scoring functions for the HUI2 and HUI3 systems would be translated into Japanese and published so that users could convert health status information obtained using HUI into utility (health-related quality of life) scores.



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Centre des études économiques et politiques sur la santé et Département d'épidémiologie clinique et de biostatistique

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feeny@mcmail.cis.mcmaster.ca

November 28, 1997

Dr. Takamoto Uemura Department of Hygiene and Preventive Medicine Keio University 35 Shinanomachi, Shinjuku-ku Tokyo, Japan

Dear Dr. Uemura:

Thank you for your letter of October 29, 1997. My colleagues and I have reviewed the two back translations of the Japanese version of the HUI2/HUI3 "15Q" questionnaire, one labelled as the "Reference" (R) back translation and one that was unlabelled, which I will refer to as the "Non-Reference" (NR) back translation.

I have a number of points. First, overall you and your colleagues have done an excellent job! Congratulations! Below we raise a number of issues that require clarification. In our experience the need for clarification is routine. We are pleased with the progress that has been made.

Second, it is often the case that problems that a reviewer identifies in the back translation are not in fact problematic in the translated version itself. Comments on the back translation are comments on both the translation and the back translation. As you point out, the quality of the "Reference" translation may be higher than that of the "Non-Reference" one.

Third, we had expected your group to notify us when you would begin the work of translating 15Q so that we would have provided you with the most up-to-date version. You have translated an older version of 15Q. Modest additional work will be required to update your translation. To assist you, I have enclosed a copy of "HUI23SU.15Q," (May, 1997). This is the latest version of 15Q for the usual health state.

In particular, the May 1997 version of 15Q differs from the earlier version on the following items.

- 1) the instructions to respondents have been expanded (eg., we added that all information provided is confidential, there are no right and wrong answers);
- 2) in the stem of Q5 we changed "when speaking the same language with strangers" to "when speaking your own language with people who do not know you";
- 3) in Q8 response options b, c, d, and e we added "or discomfort";
- 4) in Q14 response option e we changed ", usually requiring hospitalization or psychiatric institutional care" to "; to the point of needing professional help";
- 5) in Q15 response options b, c, d, and e we added "or discomfort";
- 6) we added Q16, the global health question;
- 7) we added Q17, the question about who completed the questionnaire.

Fourth, all copies of questionnaires should state explicitly that the questionnaire is "not for use without the permission of the HUI Service Centre" and that the Japanese translation was conducted with the permission of the holders of the copyright on 15Q questionnaires: Feeny, Furlong, and Torrance.

Fifth, below we have provided more detailed comments on specific portions of the back translations. We suggest that you revise the "best" Japanese translation to accommodate the changes required for updating (point 3 above) and the potential changes discussed below. We further suggest that you then have the revised Japanese version independently back translated by two persons and send us the results for another round of review. Once the basic usual health state 15Q has been finalized, it would perhaps then be appropriate to modify it to accommodate the other standard recall periods: one week, two weeks, and four weeks. At this point, I think it would be premature to engage in that work.

Comments on Questions in your Letter of October 29. You had a question about "ability" in the translation. Although given my lack of knowledge of Japanese I cannot be certain, it would appear that you have selected the correct concept. HUI2 and HUI3 are based on capacity (or ability), not on performance. Performance reflects capacity and ability as well as preference and opportunity. Our focus is on what you health status permits you to do or inhibits you from doing, not what you choose to do. The use of "I" in the responses seems fine.

Comments on Specific Questions. In Questions 1 and 2 the emphasis should be on the ability to see, not on how well you read (or recognize). The question is about vision, not literacy. This should be reflected in both the question and in the response options.

Similarly in Questions 3 and 4, the focus is on hearing, not recognition. In addition, in answer option 3d, it should mean that the respondent do not use a hearing aid. (The NR version seemed fine on this point but not the R version.)

Similarly in Questions 5 and 6 the focus is on speaking. In addition, we have modified these questions to specify that the subject is speaking their own language to someone who knows them well (or does not know them).

Question 7. In the R version "slightly" may not capture the meaning of "somewhat". In the NR version, "fairly" may not capture the meaning of "somewhat". (Emotion questions are often difficult to translate.) In addition, for 7a in the NR version, hobbies probably does not capture the meaning well. Further please note that the wording of Questions 7 and 14 should be similar or identical, although the response options differ substantially.

Question 8. The concepts of pain in this question are severity (mild, moderate, severe) and degree of activity limitation (none, few, some, or most activities). In the R version, 8b does not seem correct. The level of pain is more than a bit. Further in the R version answer d should refer to some activities and answer e to most activities. In the NR version 8c should be moderate, not mild.

Question 9. It might be useful to confirm the cultural concept of "neighbourhood". Frankly, it is difficult to define. We meant to imply that the subject is able to walk several hundred meters outdoors (but in a non-challenging environment). Further, the intent of the question is not just walking but physically moving about. The back translations appear to be compatible with these ideas. I invite your comments.

Question 10. The intent here is that people have the use of all ten digits and both hands. The use of both hands appears to be missing in the NR version (10a).

Questions 11 and 12. In the R version, 11a, one needs to be able to remember most things, not almost everything. The meaning may not be correct here. In Questions 11 and 12, the focus is on the severity of the cognitive problems (remembering or thinking) rather than frequency. Again the meaning may not be correct. In NR 12a, the standard for normal cognition may be too demanding.

Question 13. In the NR version, the self care orientation (as opposed to other aspects of daily living) does not come through. It does come through in the R version. In 13b the person needs neither the help of others or special equipment. 13b in the R version mentions the absence of the need for help from other persons; in the NR version the specification is more vague. In the English version we omitted both statement; they were taken as understood. If these statements are included in the Japanese version for 13b, it should explicitly cover both the lack of need of help from devices and other persons. In 13c and 13d it should be "or" not "and".

Question 14. Please note that we have changed 14e (see new version of 15Q). Does "upset" mean "fretful" (NR version)? Does "tense" mean "fretful" (R version)? Again, emotion questions are difficult to translate. Further, the stem questions in 7 and 14 should be identical or very similar.

Question 15. In the NR version, in 15b, it should be "or", not "and" for the options for pain relief. In 15b in the R version, some pain may not mean occasional pain. In the R version, 15c, "some" relief should be just relief. 15d in the R version captures the meaning better than 15d in the NR version; the impairment of activities is not occasional - - it is frequent.

Questions 16 and 17 (May 1997 15Q in English) will need to be translated.

In spite of the length of the list of items for clarification or revision, we are very pleased with the progress to date. I look forward to our continued collaborations. Please note that currently there is a postal strike in Canada. Therefore please check with your postal authorities before mailing items to us and if the strike has not yet been settled, please use alternative services. In the interest of timeliness, I will transmit this letter via e-mail. A copy along with the enclosures will be mailed (in the United States).

Sincerely yours,

David Feeny, Ph.D.

Professor of Economics and

Clinical Epidemiology and Biostatistics

cc: Dr. Johanna L. Bosch

William Furlong

Dr. George W. Torrance

### Answer to your comments on our back-translation of October 29th.

As you mentioned, we left "NOURYOKU" which represents capacity and ability. Whether or not using "I" were small problem because "I" seems to appear on the process of back translation due to translator's taste. Original Japanese Q dose not have "I" (WATASHI).

### Answer to your comments on our back-translation

In Q1 and 2, we changed Japanese in order to reflect the concept of "see" directly.

### Answer to your comments on our back-translation

In Q3 and Q4, Yes, we understood correctly. We use a verb represents "hear", and know that the respondent do not use a hearing aid.

### Answer to your comments on our back-translation

Q5 and Q6 have to be translated again. But it was very interesting that I forward translated this questionnaire just like as new version (their own language), OH!!! I am a fortune teller!

### Answer to your comments on our back-translation

Q7, We altered word "YAYA" into "NANTONAKU" in order to represents somewhat. We noted Q14 also. Japanese version 7a seems to capture original meaning well.

### Answer to your comments on our back-translation

Q8, We altered Japanese in order to express more sever situation generally from 8b to 8c. Please refer back translation.

### Answer to your comments on our back-translation

Q9, My comments is that, "working around neighborhood" seems work around less than several hundred meters, in Japan. But we use suitable word represents physically moving about.

In original question, you used verb "walk" definitely, so we couldn't express more correctly than this. As my understanding, we capture same intents and the distance may show relative changes according to country size and exercise.

### Answer to your comments on our back-translation

Q10, May be your comments due to misbacktranslation, but we have done small changes to secure the meaning of "all ten digits and both hands".

#### Answer to your comments on our back-translation

Q11a, our Japanese represents "most things". We altered 11b and 11c in order to represent severity rather than frequency. As for 12a, we altered expression a little less demanding.

#### Answer to your comments on our back-translation

Q13, we altered 13b more represents "independently". Also "or" were insisted in 13c and 13d.

#### Answer to your comments on our back-translation

I understood that emotional question is very difficult and it seems like not to have correct answer. But, in this case, we capture correct meaning of "fretful". As you advice, we discuss a little more about 7 and 14 too.

#### Answer to your comments on our back-translation

Q15, yes we translated correctly in 15b concerning to "or" and "occasional". 15c seems to be OK, as well as 15d. Generally, NR version tends to be translated too much.

Next procedure, we will send you new back translation from HUI23SU,15Q.

Again, thank you very much for your sincere instruction and kindness.

I have referred the letters of those days when you and Johanna worked for Dutch version HUI.

It's our honor and pleasure to find that you are very much same with our project too!

1/ samuel o

Takamoto Uemura, M.D. Ph.D.

#### January 15, 1999

Dr. David Feeny
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3118 Dentistry / Pharmacy Centre
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Canada

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403 492 1217

E-mail: dfeeny@pharmacy.ualberta.ca

Dear Dr. Feeny, Dr. Furlong

### RE: Review of Second Back Translation of HUI23SU15Q; Revise, Jan 15th, 1999

Thank you very much for your revise to our 2<sup>nd</sup> back translation. I immediately had a meeting in this morning with one of back translator who are bilingual and on whom I most rely. (He lives quite near to me.)

I will report our translation procedures and corrections which I just performed according to your comments as below.

Please read it and give us permission to proceed survey. And as you wrote, I hope you understand the difficulties to convey 100% of Japanese meaning to the back translation. Among all comments, some are very useful and practically I agreed to correct or add, but some are only the problems between J-version and back translation. I mean Japanese version surely convey original meaning rather than back translation.

### Documentation of the Process of Translation.

1st forward translation were done by

1, Takamoto Uemura MD. PhD

2,Shunya Ikeda MD. PhD. MPH

3.Hisashi Moriguchi MD. MPH

4,DHC Ltd. (professional translator)

Sessions for checking validity and acceptability of Japanese version 1st session attendants

1, Azusa Imai (23 yeard old, female) pharmacologist

2, Chin Leelin (25 years old, female) pharmacologist

3, Koji Shirasaya (28 years old, male) PhD.

Director

Takamoto Uemura MD.PhD.

Shunya Ikeda MD. PhD.

2<sup>nd</sup> sesseion attendants

1, Chizu Yamashita (40 years old, female)

2, Ken Aoki (31 years old, male)

3, Mituko Akiyama (41 yeas old, female)

Director

Takamoto Uemura MD.PhD.

1st back translatio by

1, Ken Shibusawa (bi-lingual, grown at USA, graduated from MBA in UCLA)

2,DHC Ltd. (professional translator. Different person other than forward translator)

3, James Profkey (bi-lingual)

Arranged to unify by Ken Shibusawa

Observer

Takamoto Uemura MD.PhD.

. Revise on 1st back translation

1, Dvid Feeny PhD. McMaster University

Correction according to 1<sup>st</sup> revise (on Japanese version)

1, Takamoto Uemura MD. PhD.

2,Shunya Ikeda MD.PhD.

3, Hisashi Moriguchi MD. MPH.

Sessions for checking validity and acceptability of Japanese version

3<sup>rd</sup> session attendants

1, Yoshiko Uemura (36 years old, female)

2, Ken Shibusawa (37 years old, male)

Director

Takamoto Uemura MD.PhD.

2<sup>nd</sup> back translation by 2 independent translator

Arrangement by

1, Ken Shibusawa (bi-lingual)

Revise on 2<sup>nd</sup> back translation

1,David Feeny PhD. 2,William Furlong M.Sc.

Correction according to the revise on 2<sup>nd</sup> back translation 1,Takamoto Uemura MD. PhD. Consultant; Ken Shibusawa

### Correction on Japanese version

General Directions. "Usual" should modify "ability" rather than "condition". In the final sentence of the second paragraph, the meaning should be "apparent" repetition rather than repetition (which there is not). In the first sentence of the third paragraph, it would seem useful to invite respondents to think carefully about their response to each question. Comments; Japanese version well convey "ability". We added adequate word in the third paragraph. "AKIRAKANI CHOHUKUSHITEMO"

Question #1. The concept here is vision, not literacy in the form of the ability to read. We chose "newsprint" to convey fairly small print that might present a challenge to those with a mild visual impairment. Thus, in the stem and in each response it should be "ability to see to read" rather than "ability to read".

Comments; I can really clarify your concept, so we correct the verb in order to convey "see to read".

"MOJIWO HANNBETUSURU"

"YOMERU" were changed to "MIERU"

Question #2. The concept here is ability to see well enough to recognize a friend rather than "when seeing".

Comments; We changed the verb in order to more convey "see to distinguish" or

"recognize"

"MIWAKERU"

Question #3. Option (c) should refer to "even with a hearing aid" rather than "without hearing aid".

Comments; Japanese version well convey it.

Question #4. The stem of the question should specify a conversation with only one other person. Option (c) should refer to "even with a hearing aid" rather than "without hearing aid". Comments; Japanese version well convey it.

Question #5. "The contents of the conversation" should be replaced by the words spoken. The focus her is on speech and the quality of the articulation, not comprehension in the cognitive

sense. What we are interested in is their ability to pronounce clearly.

Comments; I really well found the concept and agree to the arrangement. We arranged Q and option in order to convey how well one can pronounce word to let others understood, not well in conversation.

"KOTOBAWO KAWASHI"

"HANASHI" were changed to "KOTOBA"

Question #6. An "acquaintance" may not convey accurately "someone who knows you well". In addition, here, as in Question 5, the focus is on pronunciation, not comprehension. Comments; We arranged Japanese Q to express "someone who knows you well". I imagine when one has a problem of motor speech, it would be very important whether "someone know one "well" or not.

"acquaintance=SHIRIAI" were changed to "ANATANOKOTOWO YOKUSHITTEIRUHITO"

Question #7. In option (a), "delighted" may be too strong to convey "interested in life" accurately. Comments; Japanese version well convey it.

In option (e) we are concerned that "lost the meaning of life" may not convey "lost the desire to live" or "life is not worthwhile" accurately. Comments; You might misread live to life.

Japanese version well convey it.

Question 8. We think that it appears to have been difficult to translate the adjectives mild, moderate, and severe. Option (b) needs to refer to mild to moderate pain and the word for "moderate" needs to be used again in option (c). In option (c) the disruption is a "few activities" rather than the degree of activity restriction in general. In option (d), "too much pain" might be too strong; the concept is moderate to severe pain. In option (d), it is that some activities are disrupted, rather than "greatly restricted".

Comments; The first Japanese version has a direct translation of the adjectives. But in some session to check its acceptability, attendants found that mild, moderate, severe pain are hard to imagine. I replace adj and add some explaining words to show the degree of pain such as "endurable".

We did two alterations

- 1, We put the direct translation of adj.
- 2,The degree of how much activities are prevent in options (c)(d) were slightly lightened.

Question #9 (e). Is it clear that "another" means "another person"?

Question #10 (e). Is it clear that "another" means "another person"? In options (d), (e), and (f), the assistance is relative to the number of tasks rather than amount of time.

Comments; Japanese version well convey it.

Question #11. In option (a) it should be "most things" instead of most of the time. Comments; Japanese version well convey it.

Question #12. Option (a) should include the ability to think clearly. Comments; We added clearly to option (a) in Japanese version. "HAKKIRITO"

Question #13. It should be clear that "take care of yourself" refers to a somewhat limited set of activities involved in self care rather than a broader concept. In option (a) "regularly" needs to imply "normally and without difficulty". In option (b) it is not clear that the meaning conveys without the help of tools or another person. In option (c) the meaning needs to convey without the help of another person. In option (d), "another" needs to be understood as "another person".

Comments; Concerning to option (a) Japanese version well convey it. To option (b)(c), we agreed to your comments and added words "JIBUNDE" in order to clearly convey your

comments. To (d), Japanese version well convey it.

Question #15. The phrasing for 15 (a) should be the same as for 8 (a). Comments; Japanese version is so. "Prevent" seems too strong for disrupt. Comments; We put Japanese word to mean more disrupt=JYAMANI.

In option (b) the meaning includes "occasional" pain rather than just a low level of pain.

Comments; Japanese version well convey it.

In option (e), the pain cannot be alleviated by any medication, not just oral medicines. Comments; We changed option (e) to emphasis "cannot be alleviated by any medication" "DONNA TIRYOU DEMO".

Question #16. In (d), "okay" may be too "good" (too little impairment) for "Fair". Comments; Option (d) okay represented "MAZUMAZU" which means "not good not bad" I believe "Fair" means something like that but if you suggest a little more worse degree word, "AMARIYOKUNAI" = not so good.

In option (e), indeed "not very good" may not convey the degree of severity properly. Stronger wording is indicated.

Comments; Yes we put stronger word.

"AMARIYOKUNAI" were changed to "HUKENKOU"

Question #17. In (e) you might add "physician" to the list to clarify. Comments; We did it.

I hope you find these alteration could be fine. I would be happy to explain more. We look forward to working with you to make a Japanese version and its survey. I strongly wish to use this translation to the survey sooner.

I will transmit this via e-mail.

Sincerely yours,