

# **Cultural Adaptation of Patient-Reported Outcomes in Systematic Reviews: How to Evaluate Equivalence**

**W-38**

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# Appreciation

- Catherine Acquadro
- MAPI Research Trust for sponsoring PRO Methods Group
- Mona Martin, HRA and Katrin Conway and Iliana Petkova, MAPI Research Trust for providing support and materials for today's workshop
- Translation and Cultural Adaptation Special Interest Group of International Society for QoL Research (Katrin Conway and Donald Patrick, Co-Chairs)

# After this session, you will be able to:

- Define methods for translation of patient-reported outcome measures (PROs) for use cross-culturally
- Specify the steps involved in translation
- Identify and evaluate issues of quality of translation in global clinical trials included in Cochrane reviews

# The Context

Growing Interest in PROs



Development of PRO instruments...  
in only one language (UK/US /CAN English)



Adaptation for use in global clinical trials



Translation &  
Cultural adaptation

# *Standard Translation Practices for Written Text...*

- Usually based on the work of a single translator
- Primary point of evaluation tends to be proofreading
- Back translation (when done) is not always evaluated
- Rarely tested on target reader population
- Focus on speech patterns and literary flow
- **PROVIDES INFORMATION**

# *Translation of Research Measures ...*

- Not intended for an individual reader
- Must be taken to represent the very same concept across an entire population of readers
- Each item must explicitly represent a single clear concept
- **RESEARCH TRANSLATIONS ARE INTENDED TO *OBTAIN* INFORMATION**

## *Example ...*

Not at all =0

Hardly =1

Somewhat =2

Moderately =3

A good Deal =4

A great Deal =5

A very Great Deal =6

Translation of Likert type scale response options requires **separate and unique word values** that distribute across a scale and maintain the integrity of the scale

*Translations may become awkward for cultures that do not have a wide variety of descriptors to use.....*

Not at all =0

Hardly =1

Somewhat =2

Moderately =3

A good Deal =4

A great Deal =5

A very Great Deal =6

But each data point must remain distinctly different in order to protect the range and integrity of the scale.

Otherwise the research data may be skewed.



*Translations may become awkward for cultures that do not use extremes in their language patterns....*



*But the integrity of the scale must remain if the measure is to be useful in multi-cultural research*

# Considering Word Values....

## Negative Values

- Restrict
- Interfere
- Impede

## Neutral Values

- Affect
- Notice
- Occur

## Positive Values

- Enhance
- Support
- Encourage

-5   -4   -3   -2   -1   0   +1   +2   +3   +4   +5

## *Another need for translation of research items ...*

Translations must explicitly and fully present all critical parts of the questionnaire item.

Anything left as inherent or assumed introduces variability [*variation in patient perception*] and will produce “noise” in the data.

## *Example Item...*

Because of your diabetes, how much of the time during the past week did you worry about your health?

- **CONCEPT** (*worry about health, feel depressed, have symptom*)
- **RECALL PERIOD** (*during the last week, in the last 24 hours*)
- **ATTRIBUTION** (*because of my diabetes, depression, etc.*)
- **LINK TO RESPONSE SCALE** (*How much, how often, how difficult*)

# *How do translations affect study data?*

- Accuracy of the data
- Magnitude of the results
- Skewed response data
- Loss of comparability
- Lost ability to aggregate multi-cultural datasets

# Three Routes to Cross-Cultural PRO Instruments

- **Translation only.** An instrument is developed in one language, usually English, within one country and the instrument is translated into one or several other languages.
- **Cultural adaptation.** An instrument is developed in a source language and the intercultural relevance and conceptual equivalence have been considered prior to development of the source language. **Translation to other languages is still needed.**
- **Simultaneous development.** An instrument is developed simultaneously in different countries and languages and the source language needs only to track the items contributed from all countries. New versions follow the process in (1) or (2) as, after development, it is almost always impossible to change the items in other languages.

# Definitions

**Cultural Adaptation**



**Two phases**



**I**

**Linguistic Validation  
(translation)**

**II**

**Psychometric Validation  
(reliability, validity,  
responsiveness to change)**

# Definitions: Equivalence

- 6 types of Equivalence\*
  1. Conceptual
  2. Semantic
  3. Operational
  4. Psychometric
  5. Item
  6. Criterion
  
- The Linguistic Validation covers the first three

*\*Stewart AL, Napoles-Springer A. Health-Related Quality of Life Assessments in Diverse Population Groups in the United States. Medical Care 2000; 38 (9) suppl II:102-124.*



# Definitions: Equivalence

- **Conceptual equivalence of constructs and items**

Achieved when the constructs (theoretical notion being measured) exist, are relevant and are acceptable in all cultures. The items should also represent the definition of the constructs. **Example: functional status, pain**

- **Semantic equivalence**

Obtained when items mean the same thing to people from different groups and in the target and source languages. **Example: unbearable pain on a 0-10 rating scale**

# Definitions: Equivalence

- **Operational equivalence**

Ensures that standardized methods of survey administration are appropriate for the target culture. **Example: self administration**

- **Psychometric or measurement equivalence**

Achieved when comparable psychometric properties are observed in the source and target measures. **Example: similar factor structure**

# Definitions: Equivalence

## ■ Item equivalence

Observed when a) items are not differentially more difficult (e.g. biased) in the target culture than in the original, b) item weights reflect comparative importance of items in all groups and c) the meaning of and distance between response choices is similar across cultures. **Example: response distribution**

## ■ Criterion equivalence

Is obtained when the interpretation of scores is the same across groups, and when compared with norms for each group. Translated versions should also demonstrate similar associations with any previously set independent criterion established during the validation of the original version. **Example: a score of 10 means same thing in each language**

# Types of Translation Difficulties

Problems arising from the translation process fall into four categories.

- **Cultural difficulties:** include the proper or improper usage of certain words, phrases based on the culture of a given society, as well as the specifics of the society itself such as the education system, health care system, societal or religious taboos, etc.
- **Conceptual / Semantic Difficulties:** are those that arise in conveying the meaning of a statement in a foreign language.
- **Idiomatic Difficulties:** correspond to the use of certain phrases, or the means of conveying ideas that are unique to a particular region, country, or society.
- **Grammatical difficulties:** include difficulties linked for instance to the grammar of a given language.

# Richard W. Brislin's Guidelines for Item Development

1. use short, simple sentences;
2. employ the active rather than the passive voice;
3. repeat nouns instead of using pronouns;
4. avoid metaphors and colloquialisms;
5. avoid the subjunctive;
6. add sentences to provide context for key ideas;
7. avoid adverbs and prepositions telling "where" or "when";
8. avoid possessive forms where possible;
9. use specific rather than general terms;
10. avoid words indicating vagueness regarding some event or thing;
11. use wording familiar to the translators;
12. avoid sentences with two different verbs if the verbs suggest two different actions.



# Example

**Name of questionnaire:** Diabetic Foot Ulcer (DFS) **Language of the original:** UK English

**Original item:** How much have your foot ulcer problems made you choose a different kind of holiday or short break that you would have preferred?

**Response scale:** 1 =Not at all; 2 =A little bit; 3 =Moderately; 4 = Quite a bit; 5 = A great deal

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**Nature of translation difficulty:** ambiguous original

**Issue 1:** unclear focus (2 different verbs)

**Issue 2:** use of 2 words (“holiday” and “short break”) with different semantic fields to describe one overall (undefined) concept

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**Solution 1:** Rewrite item according to Richard W. Brislin

**Solution 2:** Define the overall concept to facilitate choice of most appropriate term.

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**Reformulated item:** “How much has your foot ulcer determined your choice of holiday?”



→ Example confirms Richard W. Brislin's Guidelines

→ Definition of concepts is key to comprehension of original and development of translations

# Methodology: Steps

16 weeks





# Methodology: Players

Author



Coordinating Center



## Local team 1

Consultant

« Forward » translators

« Back » translator

Clinician

Patients

## Local team 2

Consultant

« Forward » translators

« Back » translator

Clinician

Patients

## Local team 3

Consultant

« Forward » translators

« Back » translator

Clinician

Patients

At least 10 participants per language  
version

# Forward Step

Source

Conceptual definition of each item

*Author*

1 "forward"  
translation

1 "forward"  
translation

*Professional  
Translators*

Version 1

*Consultant*

Report

*Consultant  
Coordinating Center*

# Examples

*Swedish → UK English → For use in the US*

*Disease area: Angina Pectoris*

**Original**

En kortare promenad (ungefär 2 km)  
A short walk (about 2 km)

**Final UK version**

Short walk (about a mile)

**Test on  
American population**

One mile is not a short walk !!

**Problem**

What is important? "1 mile" or "short walk"?

# Examples

*Swedish → UK English → For use in the US*

*Disease area: Angina Pectoris*

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En kortare promenad (ungefär 2 km)  
A short walk (about 2 km)

**Final UK version**

Short walk (about a mile)

**Test on  
American population**

One mile is not a short walk !!

**Problem**

What is important? "1 mile" or "short walk"?

**Contact with  
author**

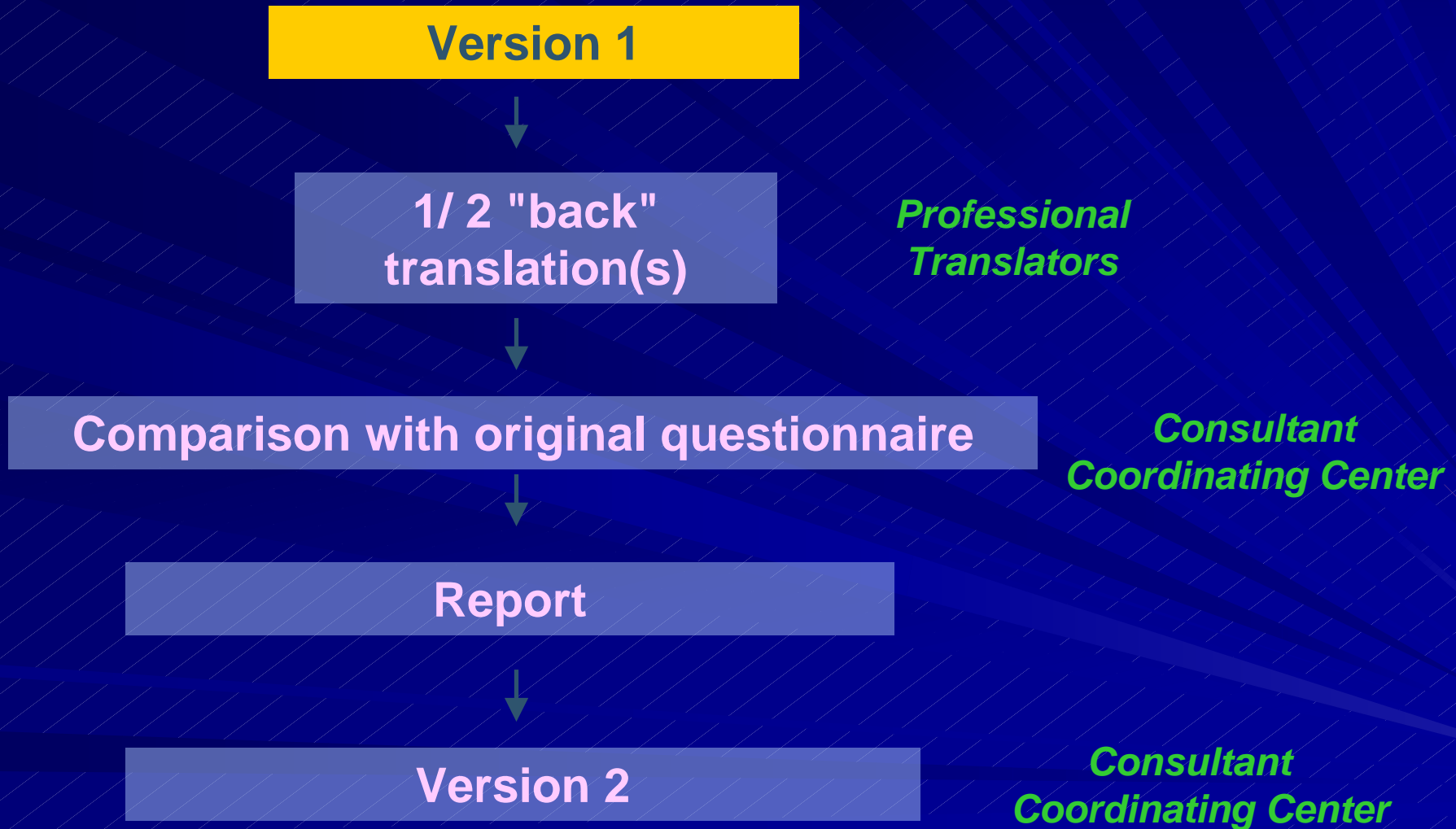


Concept = short walk

**Final American  
version**

Short walk (several blocks)

# Back Translation Step



# Examples

Danish → Finnish -- Existing UK version used to support

Questionnaire = Danish Prostate Symptom Score  
(DAN-PSS-1)

*Q2A: Do you consider your urinary stream as:  
Normal / Weak / Very weak / Dribbling*

**Problem** BT of response choices 2 & 3 =  
"slowly /very slowly" instead of "weakly/very weakly".

**Solution** "hitaasti" (slowly) and "hyvin hitaasti" (very slowly) were changed for "heikosti" (weakly) and "hyvin heikosti" (very weakly).

# Test on Clinician and Patients

Version 2

Review by a clinician/expert in the field

*Clinician*

Version 3

Patient interviews/Cognitive Debriefing

- Filling out of the questionnaire
- Analysis of the interpretation of each item

*Consultant*

Report

Version 4

*Consultant  
Coordinating Center*

# Examples

Original: **Canadian English**

Title: **'Parent/Guardian Asthma Questionnaire' (Asthma)**

- All translations of the word **'guardian'** were checked during cognitive debriefing to ensure that they were easily understood and commonly used by respondents.

*For example:*

- *'Questionnaire for parent/guardian about asthma' in Afrikaans*
- *'Questionnaire for parents or (persons) responsible for patients with asthma' in Chilean Spanish*
- *'Questionnaire about asthma for parent/guardian' in Chinese for Hong-Kong*
- *'Parent/guardian asthma questionnaire' in Danish*



# International Harmonization

Version 4



## IH Meeting:

- Comparison by group of languages
- Checking of concepts

*Professional Translators  
Coordinating Center*



Control by Consultant



Report

*Consultant  
Coordinating Center*



Version 5

# Examples

## Quality of Life Questionnaire for Functional Digestive Disorders (FDDQL)

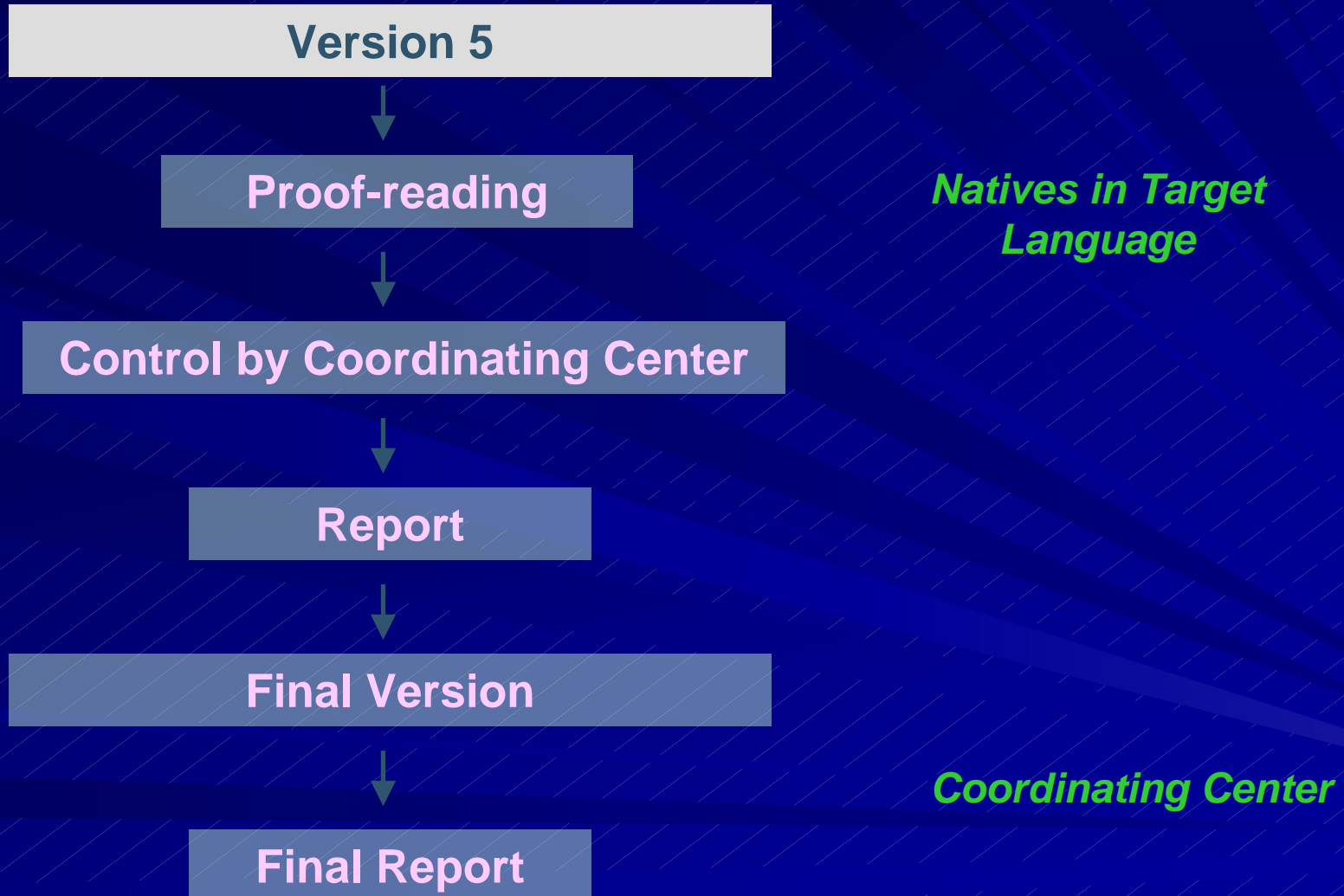
French → UK English, US English, Canadian English

**Original** Item 13: "La moindre aggravation de vos douleurs ou de votre transit intestinal vous a-t-elle angoissé(e) ?"

**Problem** Although very commonly used in France, the phrase "transit intestinal" (referring to the progression of food inside the intestines) was particularly difficult to render in all the languages.

**Solution** UK English = bowel function  
US English = intestinal activity  
Canadian English = bowel activities

# Proof-reading & Final Report



**Workshop Exercise:**  
**Translation of Incontinence Quality of Life  
Neurogenic Module**

- **Distribute Back Translation Report for the (Simplified Chinese for Singapore) Translation of the I-QOL NM**
- We shall go through each item on the Back Translation Report
- Please make an evaluation if the back translation of each item in Chinese is equivalent to the original American English item

# Workshop Exercise: Translation of Incontinence Quality of Life Neurogenic Module

<b>Original English</b> <i>(do not translate bolded location indicators)</i>	<b>Reconciled Forward Translation</b>	<b>Back translation into English</b> <i>Retain all formatting (underlining, caps, color text) in the translation to match the English</i>	<b>Evaluation</b>
<b>Title, I-QOL NM</b> <b>Incontinence Quality of Life (I-QOL) Neurogenic Module</b>	尿失禁患者的生活素质 (I-QOL) 神经科单元	<b>The quality of life of people who suffer from Urinary Incontinence (I-QOL) Neurology Unit</b>	

# Workshop Exercise: Translation of Incontinence Quality of Life Neurogenic Module

<b>Original English</b> <i>(do not translate bolded location indicators)</i>	<b>Reconciled Forward Translation</b>	<b>Back translation into English</b> <i>Retain all formatting (underlining, caps, color text) in the translation to match the English</i>	<b>Evaluation</b>
Title, I-QOL NM <b>Incontinence Quality of Life (I-QOL) Neurogenic Module</b>	尿失禁患者的生活素质 (I-QOL) 神经科单元  <b>Suggested revision by in-country:</b> 尿失禁患者的生活素质 (I-QOL) 有关神经的单元	<b>The quality of life of people who suffer from Urinary Incontinence (I-QOL) Neurology Unit</b>  <b>Back translation of suggested revision:</b> <b>The quality of life of people who suffer from Urinary Incontinence (I-QOL) Neurogenic Unit</b>	<b>HRA Question:</b> In a neurogenic bladder, the nerves that are supposed to carry these messages to the brain and from the brain to the muscle of the bladder telling them either to tighten or release do not work properly. Does the Chinese translation “neurology” give the above meaning? If not, please provide a revise forward and back translation as appropriate. Thanks <b>In-country response:</b> The revised version gives a clearer picture regarding to neurogenic functions when literally translated will be “related nerve unit” <b>HRA Decision: Accept Revised translation to closer match the original English version.</b>

# Workshop Exercise: Translation of Incontinence Quality of Life Neurogenic Module

Original English <i>(do not translate bolded location indicators)</i>	Reconciled Forward Translation	Back translation into English <i>Retain all formatting (underlining, caps, color text) in the translation to match the English</i>	Evaluation
<b>Q1, I-QOL NM</b> I have to limit caffeine drinks or alcohol because of my urinary problems or incontinence.	因为尿失禁问题，我必须节制饮用含咖啡因或酒精的饮料。	Due to urinary incontinence problem, I need to control the intake of beverage with caffeine or alcohol.	

# Workshop Exercise: Translation of Incontinence Quality of Life Neurogenic Module

Original English <i>(do not translate bolded location indicators)</i>	Reconciled Forward Translation	Back translation into English <i>Retain all formatting (underlining, caps, color text) in the translation to match the English</i>	Evaluation
<p>Q1, I-QOL NM I have to limit caffeine drinks or alcohol because of my urinary problems or incontinence.</p>	<p>因为尿失禁问题，我必须节制饮用含咖啡因或酒精的饮料。</p> <p><b>Suggested revision by in-country:</b> 因为泌尿问题或尿失禁，我必须节制饮用含咖啡因或酒精的饮料。</p>	<p>Due to urinary incontinence problem, I need to control the intake of beverage with caffeine or alcohol.</p> <p><b>Back translation of suggested revision:</b> Due to urinary problems or incontinence, I need to control the intake of beverage with caffeine or alcohol.</p>	<p><b>HRA:</b> “I need to control the intake of beverage with caffeine or alcohol” is acceptable for “I have to limit caffeine drinks or alcohol”</p> <p><b>HRA Question:</b> The original English version is “urinary problems or incontinence” not “urinary incontinence problem” Please provide a revised forward and back translation as appropriate.</p> <p>Thanks</p> <p><b>In-country response:</b> That is a mistake, a revised forward provided 或</p> <p><b>HRA Decision: Accept Revised translation for the word “or”.</b></p>



# Workshop Exercise: Translation of Incontinence Quality of Life Neurogenic Module

<b>Original English</b> <i>(do not translate bolded location indicators)</i>	<b>Reconciled Forward Translation</b>	<b>Back translation into English</b> <i>Retain all formatting (underlining, caps, color text) in the translation to match the English</i>	<b>Evaluation</b>
<b>Q2, I-QOL NM</b> I worry about the long-term effects of catheterizations on urinary tract infections and other health problems.	我担心插入导管导尿会造成长期性的尿道感染和其他的健康问题。	I worry that the insertion of catheter to pass urine would lead to long-term urinary infection and other health problems.	

# Workshop Exercise: Translation of Incontinence Quality of Life Neurogenic Module

<b>Original English</b> <i>(do not translate bolded location indicators)</i>	<b>Reconciled Forward Translation</b>	<b>Back translation into English</b> <i>Retain all formatting (underlining, caps, color text) in the translation to match the English</i>	<b>Evaluation</b>
<b>Q2, I-QOL NM</b> I worry about the long-term effects of catheterizations on urinary tract infections and other health problems.	我担心插入导管导尿会造成长期性的尿道感染和其他的健康问题。	I worry that the insertion of catheter to pass urine would lead to long-term urinary infection and other health problems.  <b>Revised back translation:</b> I worry that the insertion of catheter to pass urine would lead to long-term urinary tract infection and other health problems.	<b>HRA:</b> “insertion of catheter to pass urine” is acceptable for “catheterizations” <b>HRA Question:</b> The original English version is “urinary tract infections” not “urinary infection” Please provide a revised forward and back translation as appropriate. Thanks <b>In-country response:</b> The Chinese version does mention “urinary tract” but it is missing in the back translation. See the revised back translation. <b>HRA Decision: Accept Reconciled Forward Version &amp; Revised Back Translation to closer match original English.</b>

# Workshop Exercise: Translation of Incontinence Quality of Life Neurogenic Module

<b>Original English</b> <i>(do not translate bolded location indicators)</i>	<b>Reconciled Forward Translation</b>	<b>Back translation into English</b> <i>Retain all formatting (underlining, caps, color text) in the translation to match the English</i>	<b>Evaluation</b>
<b>Q3, I-QOL NM</b> Accessibility and privacy in public toilets are important to me.	对我来说，能够方便使用及到达和拥有隐私的公厕是很重要的。	Public toilets that are convenient to use and reach and give privacy are very important to me.	<b>Back Translator's Comment:</b> The Chinese version sounded odd. Deletion of 3 words (as indicated) might be necessary depending on the original version. “对我来说，能够方便使用(及到达)和拥有隐私的公厕是很重要的。”

# Workshop Exercise: Translation of Incontinence Quality of Life Neurogenic Module

Original English <i>(do not translate bolded location indicators)</i>	Reconciled Forward Translation	Back translation into English <i>Retain all formatting (underlining, caps, color text) in the translation to match the English</i>	Evaluation
<p><b>Q3, I-QOL NM</b> Accessibility and privacy in public toilets are important to me.</p>	<p>对我来说，能够方便使用及到达和拥有隐私的公厕是<b>很</b>重要的。</p> <p><b>Suggested revision by in-country:</b> 对我来说，能够方便使用和拥有隐私的公厕是重要的。</p>	<p>Public toilets that are convenient to use and reach and give privacy are very important to me.</p> <p><b>Back translation of suggested revision:</b> A public toilet that is convenient to use and <b>provides</b> privacy is important to me.</p>	<p><b>Back Translator's Comment:</b> The Chinese version sounded odd. Deletion of 3 words (as indicated) might be necessary depending on the original version. “对我来说，能够方便使用(及到达)和拥有隐私的公厕是很重要的。”</p> <p><b>HRA Questions:</b></p> <ol style="list-style-type: none"> <li>1. Could we rephrase the Chinese sentence to “The accessibility and privacy in public toilets are important to me”? to be closer to the original English version.</li> <li>2. Please read the Back Translator's comment and revise as appropriate.</li> </ol> <p>Thanks.</p> <p><b>In-country response:</b> To translate “accessibility” to Chinese will require some lengthy explanation because there is no direct translation for that, hence the Back Translator's comment on deleting the words. I suggest we adopt the Back Translator's suggestion, which is a compromise between making the Chinese sentence sounds right and depicting the meaning of “accessibility”. And “very” is deleted from the Chinese translation to match the original English.</p> <p><b>HRA Decision:</b> Accept Revised translation to closer match original English version.</p>

# Workshop Exercise: Translation of Incontinence Quality of Life Neurogenic Module

<b>Original English</b> <i>(do not translate bolded location indicators)</i>	<b>Reconciled Forward Translation</b>	<b>Back translation into English</b> <i>Retain all formatting (underlining, caps, color text) in the translation to match the English</i>	<b>Evaluation</b>
<b>Q4, I-QOL NM</b> It bothers me to have to catheterize on a regular schedule.	得定时导尿对我来说是种困扰。	The need to catheterize on regular basis is a torment to me.	

# Workshop Exercise: Translation of Incontinence Quality of Life Neurogenic Module

Original English <i>(do not translate bolded location indicators)</i>	Reconciled Forward Translation	Back translation into English <i>Retain all formatting (underlining, caps, color text) in the translation to match the English</i>	Evaluation
<p><b>Q4, I-QOL NM</b> It <b>bothers</b> me to have to catheterize on a regular schedule.</p>	<p>得定时导尿对我来说是种<b>困扰</b>。</p>	<p>The need to catheterize on regular basis is a <b>torment</b> to me.</p> <p><b>Revised back translation:</b> The need to catheterize on regular basis is a <b>bother</b> to me.</p>	<p><b>HRA:</b> “regular basis” is acceptable for “regular schedule” <b>HRA Question:</b> “torment” is not the same as “bothers” “bothers” is “annoying”, “troublesome”, or “petty discomfort” Please revise accordingly. Thanks. <b>In-country response:</b> “Torment” is not the right translation of the Chinese version; the Chinese expression literally means “bother”. <b>HRA Decision: Accept.</b></p>

# Workshop Exercise: Translation of Incontinence Quality of Life Neurogenic Module

<b>Original English</b> <i>(do not translate bolded location indicators)</i>	<b>Reconciled Forward Translation</b>	<b>Back translation into English</b> <i>Retain all formatting (underlining, caps, color text) in the translation to match the English</i>	<b>Evaluation</b>
<b>Q5, I-QOL NM</b> It bothers me to have to use incontinence pads or diapers.	得使用失禁垫或成人尿片对我来说是种困扰。	The need to use incontinence pad or adult's diaper is a torment to me.	

# Workshop Exercise: Translation of Incontinence Quality of Life Neurogenic Module

Original English <i>(do not translate bolded location indicators)</i>	Reconciled Forward Translation	Back translation into English <i>Retain all formatting (underlining, caps, color text) in the translation to match the English</i>	Evaluation
<p><del>Q5, I-QOL-NM</del> It <b>bothers</b> me to have to use incontinence pads or diapers.</p>	<p>得使用失禁垫或成人尿片对我来说是种<b>困扰</b>。</p>	<p>The need to use incontinence pad or adult's diaper is a <b>torment</b> to me.</p> <p><b>Revised back translation:</b> The need to use incontinence pad or adult's diaper is a <b>bother</b> to me.</p>	<p><b>HRA:</b> “incontinence pad or adult’s diaper” is acceptable for “incontinence pads or diapers” <b>HRA Question:</b> “torment” is not the same as “bothers” “bothers” is “annoying”, “troublesome”, or “petty discomfort” Please revise accordingly. Thanks. <b>In-country response:</b> “Torment” is not the right translation of the Chinese version; the Chinese expression literally means “bother”. <b>HRA Decision: Accept.</b></p>



# Incontinence Quality of Life Neurogenic Module

## Incontinence Quality of Life (I-QOL) Neurogenic Module

PLEASE CHOOSE THE RESPONSE THAT APPLIES BEST TO YOU RIGHT NOW  
AND CIRCLE THE NUMBER OF YOUR ANSWER.

IF YOU ARE UNSURE ABOUT HOW TO ANSWER A QUESTION, PLEASE GIVE THE  
BEST ANSWER YOU CAN. THERE ARE NO RIGHT OR WRONG ANSWERS. YOUR  
ANSWERS WILL BE KEPT STRICTLY CONFIDENTIAL.

*(Please circle the number of your answer)*

1. I have to limit caffeine drinks or alcohol because of my urinary problems or incontinence.

1 EXTREMELY  
2 QUITE A BIT  
3 MODERATELY  
4 A LITTLE  
5 NOT AT ALL

2. I worry about the long-term effects of catheterizations on my urinary tract infections and other health problems.

1 EXTREMELY  
2 QUITE A BIT  
3 MODERATELY  
4 A LITTLE  
5 NOT AT ALL

3. Accessibility and privacy in public toilets are important to me.

1 EXTREMELY  
2 QUITE A BIT  
3 MODERATELY  
4 A LITTLE  
5 NOT AT ALL

4. It bothers me to have to catheterize on a regular schedule.

1 EXTREMELY  
2 QUITE A BIT  
3 MODERATELY  
4 A LITTLE  
5 NOT AT ALL

5. It bothers me to have to use incontinence pads or diapers.

1 EXTREMELY  
2 QUITE A BIT  
3 MODERATELY  
4 A LITTLE  
5 NOT AT ALL

Language (Country) version

1

## 尿失禁-生活素质 (I-QOL) 有关神经的单元

请选择最符合您目前情况的答案，并把该答案的号码圈出。

如果您无法确定该如何回答某个题目，请选择您认为最恰当的答案。  
答案没有对或错。您的答案将受严格的保密。

*(请圈出您的答案号码)*

1. 因为泌尿问题或尿失禁，我必须节制饮用含咖啡因或酒精的饮料。

1 极度  
2 非常  
3 适度  
4 有一点  
5 完全不会

2. 我担心插入导管导尿对我的尿道感染和其他的健康问题造成的长期性影响。

1 极度  
2 非常  
3 适度  
4 有一点  
5 完全不会

3. 对我来说，容易找寻、方便使用和拥有隐私的公厕是重要的。

1 极度  
2 非常  
3 适度  
4 有一点  
5 完全不会

4. 得定时插入导管导尿对我来说是种困扰。

1 极度  
2 非常  
3 适度  
4 有一点  
5 完全不会

5. 得使用失禁垫或成人尿片对我来说是种困扰。

1 极度  
2 非常  
3 适度  
4 有一点  
5 完全不会

Simplified Chinese (Singapore) version

1

# Summary: Translation and Cultural Adaptation

- Producing high quality translation is labor intensive and time consuming
- The availability of standardized guidelines and centralized review procedures can improve the quality of the translations and the efficiency with which those translations are produced
- The people involved in the translation process are critical in determining a questionnaire's performance in a new country or culture
- To ensure credibility of their methods, investigators need to specifically describe the process used and justify their recruitment criteria

# Evaluating Translations in Global Clinical Trials

- Meta-analyses require pooling of data
- Systematic reviewers must decide how to categorize PROs and when to pool results
- To pool data across two PROs that are conceptually related (two language versions), be alert to
  - possible differences in correlations between pre and post measures in different language versions
  - possible differences in ability to detect changes in each language version

# Principles of Pooling PRO Data

- Similar for all outcomes used in Cochrane reviews
- Problem is in potential for heterogeneity of results in pooling different language versions of PROs
- Many sources of heterogeneity—patients, interventions, methods, and PROs may differ

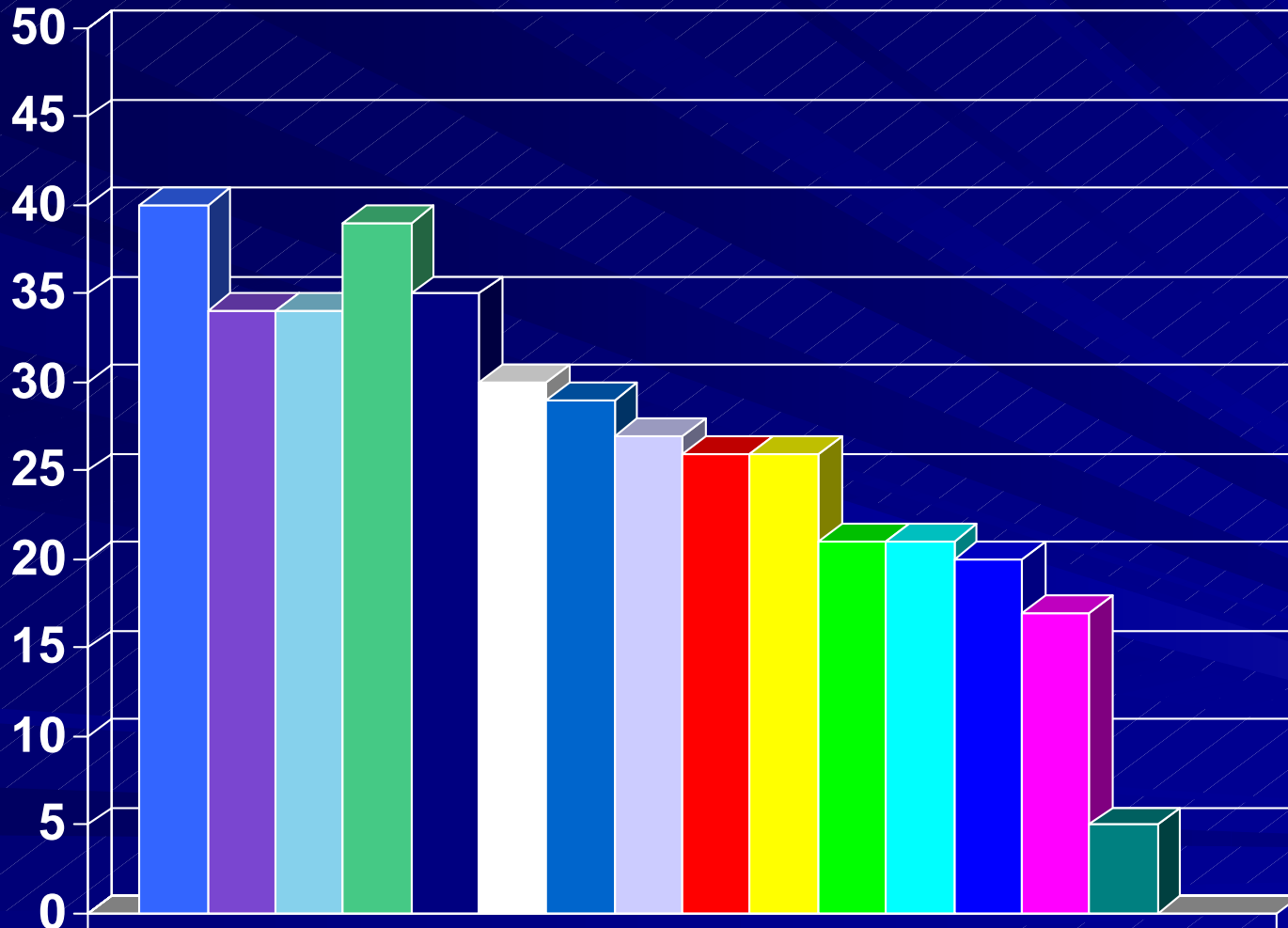


# Example: Participant countries in international clinical trials

Country	No. Pts	Country	No. Pts
U.S.A	258	Russia	28
France	141	Croatia	24
Argentina	98	Italy	23
U.K.	85	Peru	23
Poland	71	Hungary	22
Germany	61	Israel	14
Belgium	46	Netherlands	11
Spain	42	Canada	3



# Example: Pain and/or Analgesic progression



USA	258
France	141
Poland	71
Peru	23
UK	85
Argentina	98
Croatia	24
Netherlands	11
Italy	23
Germany	61
Russia	28
Israel	14
Belgium	46
Spain	42
Hungary	22

# Does language versions predict the heterogeneity of results?

- Again, language version only 1 of many potential explanations
- Review and grade the quality of the translations
- If quality predicts smaller effects and compelling explanation, exclude some language versions
- Sensitivity analyses driven by quality grading

# Evaluating Language Versions

- Obtain information on methods used to translate and culturally adapt
- Grade quality of translation (does it follow recommended steps)
- See if quality rating predicts results
- Include those studies that have acceptable quality
- All this sounds easy but difficult to do



# Evaluating Language Versions

- Most clinical trials do not provide information on how PRO instruments were translated or culturally adapted
- Information may be difficult to retrieve
- Example from clinical trial of deep brain stimulation for Parkinsons

# Summary for Meta-Analyses

- Evaluate individual language versions of a PRO instrument
- Each language version may be a different instrument
- Grade translation process
- Study heterogeneity of findings FROM MULTIPLE SOURCES
- Pool those of higher quality if translation predicts heterogeneity

**Thank you for your participation**

Please join the PRO Methods Group if you  
are interested