



The Polish version of the Quality of Life Assessment of Growth Hormone Deficiency in Adults (QoL-AGHDA) — four-stage translation and validation

Polska wersja kwestionariusza oceny jakości życia u dorosłych pacjentów z niedoborem hormonu wzrostu — 4-etapowy proces tłumaczenia i walidacji

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Abstract

Introduction: The Quality of Life Assessment of Growth Hormone Deficiency in Adults (QoL-AGHDA) was developed simultaneously in five languages (English, Swedish, German, Italian and Spanish) to measure quality of life (QoL) in adult patients with Growth Hormone (GH) deficiency. The aim of the project was to produce a validated Polish version of the QoL-AGHDA that was conceptually equivalent to the UK-English version.

Material and methods: Translation and validation procedure consisted of 4 stages. Stage 1: A bilingual translation panel [7 participants, fluent in both English and Polish (Polish as their first language) with university education] translated the questionnaire. Stage 2: A lay translation panel (6 participants of an average to lower than average educational level, speaking only the target language) reviewed the wording of the draft version produced by bilingual panel to improve clarity and immediacy. Stage 3: The translated questionnaire was then field-tested with 15 adults with GH deficiency. Stage 4: Finally, the amended version underwent psychometric evaluation to check its reliability and validity (it was administered to 85 GH-deficient adults on two occasions, two weeks apart).

Results: The Polish QoL-AGHDA version was successfully adapted and it is characterized by a high degree of reliability and validity. The test-retest reliability coefficient for the Polish QoL-AGHDA was 0.92. The Cronbach's Alpha coefficient for the Polish QoL-AGHDA was 0.91 (N = 70) at Time 1 and 0.94 (N = 79) at Time 2. Correlation between QoL-AGHDA and Nottingham Health Profile items confirmed high convergent and divergent validity.

Conclusions: The Polish QoL-AGHDA is a reliable and valid measure of QoL suitable for use in clinical studies and routine clinical practice. (*Pol J Endocrinol* 2008; 59 (5): 374-384)

Key words: QoL-AGHDA, quality of life, GH deficiency in adults, validation, Polish version

Streszczenie

Wstęp: Kwestionariusz QoL-AGHDA (*Quality of Life Assessment of Growth Hormone Deficiency in Adults*) został opracowany w 5 językach (angielskim, szwedzkim, niemieckim, włoskim i hiszpańskim) w celu oceny jakości życia (QoL, *quality of life*) u pacjentów dorosłych z niedoborem hormonu wzrostu (GH, *growth hormone*). Celem obecnej pracy było opracowanie walidowanej polskiej wersji QoL-AGHDA, równoważnej koncepcyjnie z wersją angielską.

Materiał i metody: Proces tłumaczenia i walidacji składał się z 4 etapów. Etap 1: Tłumaczenie kwestionariusza z języka angielskiego na język polski [uczestniczyło w nim 7 osób z wyższym wykształceniem, płynnie posługujących się językiem angielskim i polskim (przy czym język polski był ich językiem ojczystym)]. Etap 2: Etap „roboczy” — zweryfikowanie słownictwa zastosowanego na etapie 1 w celu poprawienia przejrzystości i stopnia zrozumienia przetłumaczonego kwestionariusza (uczestniczyło w nim 6 osób z podstawowym lub



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średnim wykształceniem, posługujących się wyłącznie językiem polskim). Etap 3: Ocena przetłumaczonego kwestionariusza przez pacjentów grupy docelowej w celu jego ewentualnego zweryfikowania (uczestniczyło w nim 15 dorosłych pacjentów z niedoborem GH). Etap 4: Psychometryczna ocena zweryfikowanej polskiej wersji kwestionariusza, mająca na celu sprawdzenie jego wiarygodności (niezawodności) i trafności tłumaczenia (uczestniczyło w nim 85 dorosłych pacjentów z niedoborem GH, których dwukrotnie, w odstępie dwutygodniowym, poproszono o wypełnienie kwestionariusza).

Wyniki: Polska wersja QoL-AGHDA została pomyślnie zaadaptowana i charakteryzuje się ona wysoką wiarygodnością (niezawodnością) i trafnością tłumaczenia. Współczynnik wiarygodności (niezawodności) obliczony za pomocą metody powtórnego testowania wyniósł 0,92. Współczynnik Cronbacha, w pierwszym i drugim badaniu na etapie 4 walidacji, wyniósł odpowiednio 0,91 (N = 70) i 0,94 (N = 79). Korelacja pomiędzy wartościami uzyskanymi w kwestionariuszach QoL-AGHDA i NHP (*Nottingham Health Profile*) potwierdziła wysoki stopień zbieżnej i rozbieżnej trafności polskiej wersji QoL-AGHDA.

Wnioski: Polska wersja QoL-AGHDA pozwala na wiarygodną (niezawodną) i trafną ocenę jakości życia i może być stosowana zarówno w badaniach klinicznych, jak i w codziennej praktyce lekarskiej. (*Endokrynol Pol* 2008; 59 (5): 374–384)

Słowa kluczowe: QoL-AGHDA, jakość życia, niedobór GH u dorosłych, walidacja, wersja polska

Introduction

Along with the increasing globalization and cross-cultural communication, as well as the escalating number of international clinical trials, the need for instruments to measure quality of life (QoL) available in different language versions becomes obvious. Although there is also considerable consensus on the requirements such versions must fulfil, the methodology remains markedly controversial. As for the former, the original questionnaire and all its language versions must be conceptually equivalent *i.e.* express the same concepts, and not literal meanings; each language version must be culturally relevant and acceptable to the target population and they must also be psychometrically comparable [1]. The most commonly recommended translation and validation process is the one reported as “Translation and cultural adaptation of patient reported outcomes measures — principles of good practice” and prepared by the ISPOR task force group [2]. The alternative method referred to as the dual-translation panel [3] and recommended by the Quality of Life Assessment of Growth Hormone Deficiency in Adults (QoL-AGHDA) developer, was applied in this work.

It is well documented that growth hormone (GH) deficiency in adult patients results in a higher risk of cardiovascular disease leading to increased mortality and in a decreased QoL [4]. Current evidence, gained from the use of QoL-AGHDA in some West European countries, confirmed the extent of QoL impairment in adult patients with GH deficiency in comparison with country-specific values of general population [5]. In turn, long-term GH replacement resulted in sustained improvements towards the normative country-specific values of QoL [6, 7].

The QoL-AGHDA [8] is a disease-specific instrument designed to measure QoL in adult patients with GH deficiency. It adopts the needs-based model of QoL outlined by Hunt and McKenna in 1992 [9]. This model postulates that life gains its quality from the ability of the individual to satisfy his/her needs. In other words,

fulfillment of human needs secures life satisfaction and consequently QoL depends on the personal capacity to satisfy these needs. It is assumed that the highest QoL is equal to the fulfillment of all needs while the lowest is when only a few needs are being met. In this concept, poor health interferes, in most cases adversely, with satisfying these needs, and thus has a negative impact on QoL. Nevertheless, this model assumes that as long as the primary needs are fulfilled — for example, by compensation mechanisms — QoL remains unaltered.

The aim of the project was to produce a Polish translation of the QoL-AGHDA that was conceptually equivalent to the UK-English version.

Translation panels (a bilingual and a lay panel) met to translate the questionnaire. This translated questionnaire was then field-tested with people with GH deficiency. Finally, the amended version underwent psychometric evaluation to check its reliability and validity.

Material and methods

Questionnaires

QoL-AGHDA

QoL-AGHDA (developed by Galen Research, Manchester UK) was constructed based on in-depth interviews with adult patients with GH deficiency (n = 35; 14 men; age range 20–59 years) attending the Christie Hospital in Manchester, UK.

Almost all patients were dissatisfied with their body image and complained of lack of energy (94% and 91%, respectively), 83% had problems with memory and concentration, 71% described themselves as being short-tempered and easily irritated, 66% suffered from lack of strength and stamina, 63% experienced reduced physical and mental drive and 57% had difficulties coping with stressful situations and avoided external stimulation [10].

The pool of items was prepared based on the interviews and finally the measure was constructed of 25 items that evoke yes/no answers, acknowledging or denying certain problems. The QoL-AGHDA score is

computed by summing a number of recognized problems *i.e.* each “yes” answer is assigned a score of 1, and therefore a high numerical QoL-AGHDA score denotes poor QoL. It is recommended that incomplete questionnaires should be excluded from the analysis [8].

Five language versions (English, Swedish, German, Italian and Spanish) were developed simultaneously using dual translation panels [3]. The language versions for the US, France [11], Belgium, the Netherlands, Denmark, Norway and Iceland were developed later. Recently, the Japanese version has been published; however, it needs to be emphasized that it was produced with a different methodology (back/forward translation) [12].

Nottingham Health Profile (NHP)

NHP was used as a comparator. NHP is a generic instrument, designed to measure subjective health status in the following domains: physical mobility, pain, sleep, emotional reactions, social isolation and energy. The measure consists of a number of statements that describe certain problems and a respondent is expected to recognize issues related to him/her. The NHP score is presented either as a profile (scores per individual domains as described above) or as a single index, based on weighting system for each domains.

KIMS (Pfizer International Metabolic Database)

Patient Life Situation Form (KIMS PLSF)

KIMS PLSF is a patient-reported outcome (PRO) questionnaire that is used to record information about respondent’s demographic, personal situation, education and job status, societal functioning, healthcare utilization, general well-being, physical activity during the leisure time and treatment satisfaction [14]. In the current study selected KIMS PLSF items, namely level of physical activity and satisfaction with it, measured by visual analogue scale (VAS), were included in the 4th stage of validation. KIMS PLSF is routinely used to collect PRO in hypopituitary adults with GH deficiency followed in KIMS [15].

Procedure for Translation

Dual-panel translation methodology [16] allows for obtaining language versions that are conceptually equivalent to the original, and ensures that items are understood in the same way in different countries and represents similar level of severity across countries. It is not always possible to find a „natural” translation for an item in a new language or, where it is possible to find a “natural” translation, it sometimes does not mean the same as the original. Where this is the case, it is necessary to find a phrase that describes an equivalent concept. Linguistic equivalence is of secondary importance in this methodology. In addition, it is vital that

Table I. Bilingual panel (1st stage) demographics

Tabela I. Dane demograficzne dotyczące etapu 1 walidacji

Gender	Profession
Female	Teacher MSc (Econ)
Female	Market analyst MSc (Econ)
Female	Medical department MSc (Econ)
Male	Physician, product manager
Male	Physician, medical adviser
Female	Database director, Ph.D. (Pfizer representative)
Female	Professor of medicine

the new items are expressed in common (everyday) language, so that they will appeal to future respondents.

Dual-panel translation and validation methodology consists of 4 stages, namely:

1. A bilingual translation panel — to provide the initial translation into the target language;
2. A lay translation panel — where items are assessed for comprehension and “naturalness” of language;
3. Field-testing for face and content validity — performed in a small group of target audience (patients);
4. Assessment of psychometric and scaling properties.

Stage 1: Bilingual translation panel

The purpose of this panel was to translate the instructions, items and response categories to the target language (Polish).

The bilingual panel comprised individuals who were fluent in both English and Polish, with Polish as their first language. All participants were university educated and half of them had a clinical background (Table I). The panel coordinator was a Professor of Medicine who represented the local investigator (M.K.-L.). Her role was to encourage the panel members to reach consensus on the appropriate translations for the instructions, items and response options. The leader was also required to ensure that no panel member was too dominant. Participants worked as a team and all had the opportunity to express their opinion. The meeting was also attended by a representative of the QoL-AGHDA developer [8], whose role was to guide the process and, as needed, explain the conceptual meaning of the items to panel members.

The panel was clear about the purpose of the workshop and given a brief description of GH deficiency in adults, the effects of the disease on QoL, and the meaning of QoL-AGHDA test in the evaluation of QoL in GH-deficient patients.

The panel members received the English version of the instrument a week before the translation panel

Table II. Lay panel (2nd stage) demographics

Tabela II. Dane demograficzne dotyczące etapu 2 walidacji

Gender	Age	Profession
Male	36	Animal assistant/cleaner
Male	32	Watchmaker's assistant
Male	60	Retired
Female	49	Cleaner
Female	46	Cleaner
Female	52	Unemployed

meeting; they were asked to read it through with a view to translating, with the following requirements in mind:

- capturing the same QoL concepts as in the English items;
- producing a comprehensible formulation of the concept;
- producing an acceptable formulation of the concept.

They were informed that the translated questionnaire would be presented to Lay Panel members and that alternative translations might be produced where agreement could not be reached.

The items were presented to the group one-by-one and their meaning explained. Alternative translations suggested by individual group members were considered by the whole group. Each item was discussed until agreement was reached. Where consensus could not be reached, alternative versions of the item were taken forward for consideration by the lay panel.

The panel took two hours and twenty minutes.

Stage 2: Lay translation panel

The second translation panel consisted of 6 individuals (3 males and 3 females) of an average to lower than average educational level, who were considered to be more typical of the target population (Table II). None of the individuals included in the lay panel were bilingual. Five participants spoke only Polish and one had limited knowledge of English. All were physically active and from the Łódź province; none were GH deficient.

The purpose of this second panel was to ensure that the final wording of the items was appropriate to typical patients. The original source language version was not available to the interviewees. They were presented with the version translated by the bilingual panel and asked to comment on them in terms of comprehension and acceptability. In particular, they were asked to decide whether their phrasing and language was acceptable or whether these should be changed to make the items more "natural", while maintaining the original meaning. They were also asked to choose between any

Table III. Demographics of the field-test sample (3rd stage)

Tabela III. Dane demograficzne dotyczące etapu 3 walidacji

Gender (n)	
Male	6 (40%)
Female	9 (60%)
Total	15 (100%)
Age (years)	
Mean (SD)	37 (16)
Median (IQR)	30 (22–55)
Range	19–62

alternative translations that the bilingual panel had produced.

It was the role of the group leader (who had also been the leader of the bilingual panel; M.K.-L.) to ensure that the original meaning was maintained in the final translation.

Stage 3: Field-testing for face and content validity

The purpose of the field-test interviews was to test the applicability, comprehension, relevance and comprehensiveness of the new instruments with relevant respondents (patients with GH deficiency).

Patients were recruited from the Department of Endocrinology and Metabolic Diseases, Medical University of Łódź, Poland. Only one patient was on GH replacement therapy.

In total fifteen interviews (*i.e.* one interview with one patient) were conducted between May and July 2006. The interviews were conducted by the local investigator (M.K.-L.) in the Department of Endocrinology and Metabolic Diseases, Medical University of Łódź.

The majority (60%) of the field-test sample was female. The mean age of the sample was 37.3 years. The sample ranged in age from 19 to 62 years (Table III).

In the interviews (which were one-to-one and semi-structured) respondents were asked to complete the questionnaire in the presence of an interviewer, who made a note of any obvious difficulties or hesitation over particular items. Interviewees were then asked to comment on the questionnaire items, instructions and response format. Specifically, respondents were asked whether they thought the items were relevant, applicable and comprehensible and if they thought any important aspects of their experience of GH deficiency had been omitted.

Once their spontaneous views had been elicited, interviewees were asked specific questions about items that had been highlighted a priori as requiring discussion. These were alternative wordings for the same or similar concepts, or items that were seen as being potentially problematic for some or all respondents.

Stage 4: Assessing psychometric and scaling properties

Procedure for Psychometric Evaluation

The data needed to establish the psychometric properties of the new Polish version of the QoL-AGHDA were collected from patients with GH deficiency. The QoL-AGHDA was administered on two occasions (Time 1 and Time 2), with two weeks between administrations. Participants also completed the NHP and the KIMS PLSF at Time 1. The latter questionnaire included questions about demography; gender, age, marital status, employment and self assessment (as a VAS) for the level of and satisfaction with physical activity during the leisure time.

One hundred and seventy four (174) patients with GH deficiency were recruited from 5 different endocrine centers (either clinics or outpatient departments) in Poland: Department of Endocrinology and Metabolic Diseases (Polish Mother's Memorial Hospital), Medical University of Łódź; Department of Endocrinology, Medical University of Łódź; Department of Endocrinology, Metabolic Diseases and Internal Diseases, Pomeranian Medical University (Szczecin); Department of Endocrinology, Metabolism and Internal Diseases, Poznań University of Medical Sciences; Department of Endocrinology and Diabetology, Collegium Medicum in Bydgoszcz (Nicolaus Copernicus University in Toruń).

Eighty six (86) patients accomplished the 4th stage, as 88 patients did not answer to the questionnaire either on the first or on the second occasion. Finally, the sample consisted of 85 people (due to some missing data in case of one patient) who experienced GH deficiency. A slight majority (51.8%) of the sample were male. The mean age of the sample was 49.4 years and ranged from 18 to 75 years (Table IV).

The 4th stage of the validation process encompassed:

1. The test-retest reliability of a measure is an estimate of its reproducibility over time when no change in condition has taken place. It was assessed by correlating scores on the QoL-AGHDA collected on the two different occasions. A high correlation indicates that the instrument produces low random measurement error. A minimum value of 0.85 is required [17]. Spearman rank correlation coefficients were employed to assess the reliability of the Polish QoL-AGHDA.
2. Internal consistency was assessed using Cronbach's alpha coefficients. Alpha measures the extent to which the items in a scale are inter-related. A low alpha (below 0.7) indicates insufficient inter-relations of items [18]. Low Corrected-Item Total Coefficients (CITCs) (below 0.2) can be indicative of an item not contributing adequately to the overall scale with high CITCs (above 0.8) indicating that an item is redundant, adding little extra to the scale.

Table IV. Demographics of the sample accomplishing psychometric evaluation (4th stage)

Tabela IV. Dane demograficzne dotyczące etapu 4 walidacji

Gender (N = 85)	
Male	44 (51.8%)
Female	41 (48.2%)
Missing	0 (0.0%)
Age (years)	
Mean (SD)	49.4 (11.16)
Median (IQR)	53 (32–63)
Range	57
Min-Max	18–75
Marital status	
(Living as) married	40 (47.1%)
Not married	44 (51.8%)
Missing	1 (1.2%)

3. Convergent and divergent validity can be evaluated by assessing the level of association between scores on a scale and scores from comparator scales that measure related and unrelated constructs, respectively. For the present investigation, the NHP was used as the comparator instrument. QoL-AGHDA scores were correlated with NHP subscale scores using Spearman rank correlation coefficients.

Statistical analysis

Non-parametric statistical tests (Spearman Rank and Mann-Whitney tests) were used throughout the analyses due to the ordinal nature of the measures employed. All statistical analyses were conducted using the SPSS 15 program (originally, Statistical Package for the Social Sciences).

Test-retest reliability

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Construct validity

Convergent and divergent validity can be evaluated by assessing the level of association between scores on a scale and scores from comparator scales that measure related and unrelated constructs, respectively. For the present investigation, the NHP was used as the comparator instrument. QoL-AGHDA scores were correlated with NHP subscale scores using Spearman rank correlation coefficients.

Known groups validity can be assessed by testing the ability of the measure to distinguish between groups of people that differ according to a factor which is known or suspected to influence quality of life scores. The factors used for the present investigation were 2 visual analogue scales: 'activity level' (scores above or below median VAS score) and 'satisfaction with activity' (scores above or below median VAS score) and item 28 of the NHP: 'I'm in constant pain' (yes/no). Non-pa-

rametric tests for independent samples (Mann-Whitney U Test) were employed to test for differences in QoL-AGHDA scores between groups.

Results

Stage 1: Bilingual translation panel (Table V)

The panel discussed whether to use direct translation from English, or to use alternative wording for most of the items, including Polish idioms (or almost idioms — frequently used phrases). In case of items 4, 8, 9, 11, 12, 15, 21, 24, 25, the interviewees used idioms or frequently used phrases.

The first part of the Instructions to the questionnaire (*"LISTED BELOW ARE SOME STATEMENTS that people may make about themselves"*) was translated with a Polish phrase that could be presented as "This questionnaire contains some statements which may apply to you". After discussion, it was decided *not* to replace the word "statement" with "question".

The next part of the Instruction (*"Read the list carefully..."*) was almost directly translated. Instead of "a tick", "a small cross" was used; this kind of mark is

Table V. Discussion of particular items of QoL-AGHDA by bilingual and lay translation panels

Tabela V. Dyskusowanie słownictwa kwestionariusza QoL-AGHDA podczas etapu 1 i 2 walidacji

Item content	Stage 1 – Bilingual translation panel	Stage 2 – Lay translation panel
Item 1 "I have to struggle to finish jobs"	The statement was translated with alternative words which could be presented as "I finish what I have started with difficulties"	One individual initially misunderstood "I have to struggle to do whole jobs, i.e. to start and to finish jobs", but after a short discussion with other individuals, who found this item clear, she accepted the original form
Item 2 "I feel a strong need to sleep during the day"	The statement was indirectly translated as "During the day I like (I am forced to like) very much to sleep"	Although people thought the item clear, they all suggested replacing the infinitive "to sleep" with an idiom, meaning something like "I feel drowsy/languid"
Item 3 "I often feel lonely even when I am with other people"	Almost direct translation was used, except the tense of the verb was clarified	This item was clear but — after much discussion — the panel replaced "...even being with people" with "...even if I am with people"; which was a more direct translation
Item 4 "I have to read things several times before they sink in"	A Polish idiom was used in the second part; "...before contents of the text will reach me"	Four people suggested replacing the idiomatic translation ("...before contents of the text will reach me") with ("before I understand it"); again, a more direct translation
Item 5 "It is difficult for me to make friends"	No change	No change
Item 6 "It takes a lot of effort for me to do simple tasks"	This item was compared to item 1 and the difference discussed. An almost direct translation from the English was made, but the infinitive "to do" was omitted (this is grammatically acceptable in Polish)	This item was compared with item 1 and the difference discussed. The bilingual panel omitted the infinitive "to do" (grammatically correct in Polish), but most of the lay panel suggested replacing it, not as an infinitive, but as a gerund "doing"
Item 7 "I have difficulty controlling my emotions"	"Feelings" was used instead of "emotions"	All individuals found the item clear, but suggested replacing the word "feelings" with "emotions"

cont. →

Table V cont. Discussion of particular items of QoL-AGHDA by bilingual and lay translation panels

Tabela V cd. Dyskutowanie słownictwa kwestionariusza QoL-AGHDA podczas etapu 1 i 2 walidacji

Item content	Stage 1 – Bilingual translation panel	Stage 2 – Lay translation panel
Item 8 "I often lose track of what I want to say"	An idiom was used, "I often lose track when I am talking"	No change
Item 9 "I lack confidence"	The Polish version is "I do not believe in myself", which is almost an idiom	No change
Item 10 "I have to push myself to do things"	This item was compared to item 6 before being translated as "I frequently push myself to do (for doing) anything"	The panel compared this with items 1 & 6 and replaced "doing anything" with "to do something"
Item 11 "I often feel very tense"	An almost direct translation from the English, with a noun, "anxiety" replacing "very tense"	No change
Item 12 "I feel as if I let people down"	"I feel as if..." was replaced with "I have impression that...". The second part of the statement is more or less a direct translation and a near idiom in Polish	No change
Item 13 "I find it hard to mix with people"	The statement was translated by using alternative words; "I do not feel well with people whom I do not know well enough"	No change
Item 14 "I feel worn out even when I've not done anything"	"Tired" was used instead of "worn out"	No change
Item 15 "There are times when I feel very low"	An idiom was used which could be translated as "I am sometimes mentally down in the dumps" or "I am sometimes in a mental hole"	The lay panel added the adjective "deep" to the existing idiom ("I am sometimes <i>deeply</i> mentally down in the dumps" or "I am sometimes in a <i>deep</i> mental hole")
Item 16 "I avoid responsibilities if possible"	The Polish version could be presented as "If it is possible I do not like to be responsible for anything"	The original translation "I do not like to be responsible for anything" was replaced by "I avoid responsibilities"
Item 17 "I avoid mixing with people I don't know well"	The difference between this item and item 13 was discussed. This is an almost direct translation, but the phrase "I avoid the company of people..." was used instead of "I avoid mixing with people..."	After comparing this item with item 13, this item was accepted
Item 18 "I feel as if I am a burden to people"	This was translated almost directly, with "I am" used instead of "as if I am", and "to others" replacing "to people"	One individual suggested replacing "I feel..." by "It seems to me, that ...," and the latter version was accepted by the others
Item 19 "I often forget what people have said to me"	"I have been told" was used instead of "other people said to me"	The panel found this clear. One person proposed replacing the original translation "I often forget what I have been told" with "I often forget what other people said to me". However, after a short discussion, the former version was preferred
Item 20 "I find it difficult to plan ahead"	This item was discussed at some length. The Polish version could be presented as "I have difficulties with planning these (things) which I will be doing"	One individual understood this as "I find it difficult to plan exclusively for a very, very near future". After a short discussion, all individuals interpreted it correctly and accepted it without any changes
Item 21 "I am easily irritated by other people"	The Polish version produced translates as "Other people make me nervous easily"	Most of the panel found "Other people make me angry (nervous) easily" too complex and wordy and proposed a simple version "People make me angry (nervous)", which is frequently used in Polish
Item 22 "I often feel too tired to do the things I ought to do"	Almost a direct translation was used	One individual referred to the mornings, when she does not feel strong enough to do anything. The rest of the panel found this clear and accepted it without any changes
Item 23 "I have to force myself to do all the things that need doing"	This item was compared with items 1, 6 & 10. A direct translation was made	No change
Item 24 "I often have to force myself to stay awake"	The statement was translated with a Polish idiom, "I often have to fight against myself not to fall asleep during the day"	Initially, one member suggested replacing the frequently used phrase "I often have to fight against..." with "I often have to force / push myself". After discussion, the former was accepted as clear and optimal
Item 25 "My memory lets me down"	This idiom is almost a direct translation	No change

more frequently used in Polish. The second part of the Instruction (“Please answer every item. If you are not sure whether to answer YES or NO, tick whichever answer you think is most true in general”) took more discussion. It was translated using alternative words which could be translated as “Please mark one answer in case of each sentence. In case of any doubts, please mark this answer which applies to you more frequently”.

2. Stage 2: Lay translation panel (Table V)

Discussion on whether to use Polish idioms (or almost idioms — frequently used phrases) or to use direct translation from English concerned some items. In the case of items 2 and 21, the interviewees preferred using Polish idioms (or frequently used phrases) to using direct translation from English. Conversely, in case of item 4 they replaced a Polish idiom with a direct translation from English.

In case of some items using idioms the participants made no changes (items 8, 9, 11, 12, 15, 24, 25).

Discussion on whether to use direct translation from English or whether to use other alternative words (phrases) concerned some items. In the cases of items # 3, 6, 7, 10, 16, the interviewees preferred the direct translation from English to other words used in the original version made by the Professional Panel; thus, they have made changes accordingly. Conversely, in the case of item # 18, they suggested replacing a direct translation with other words.

No changes were made to the following items: 1, 5, 8, 9, 11, 12, 13, 14, 17, 19, 20, 22, 23, 24, and 25.

There were no individual items that caused particular problems. A brief summary of the discussion follows:

In the first part of the Instructions to the questionnaire the interviewees discussed the possibility of replacing the word “statement” (in the sentence “LISTED BELOW ARE SOME STATEMENTS...”) by “question”, however, they decided to leave the former word, which they thought optimal.

In the second part of the Instructions, although it was stressed that every item should be answered, the interviewees proposed adding the word “always” (“Please, always answer every item”). This double grammatical confirmation is more acceptable in Polish than in English.

The phrase “If you are not sure...” (still in the box), which was translated by the Professional Panel as “In case of any doubts...” was considered unnecessary.

Stage 3: Field-testing for face and content validity

1. General comments

The respondents completed the interview within the time between 2 and 10 minutes. The mean time to complete the questionnaire was 5.13 minutes.

All interviewees were clear about the purpose of the interview. All but one of the respondents read the instructions before starting to complete the measure. None of the respondents looked back at the instructions at a later stage and none of the interviewees failed to understand instructions once he/she had read them.

After completing the questionnaire, all the respondents stated that the items were relevant, easy to understand and acceptable. None of the questions were deemed inappropriate. None of the patients stated that any important aspects of his/her experience had been omitted and no other suggestions or comments about the questionnaire were made.

Almost all those interviewed found the questionnaire clear and easy to complete. Six patients found all the items clear and made no comments at all. Of these, one respondent noticed that characters were printed as UK English rather than Polish (for example ‘e’ and ‘z’ instead of ‘ę’ and ‘ż’). However, this does not affect the wording of items.

Three patients did not answer the items in sequence. When reading the questionnaire for the first time, they left some questions unanswered and returned to them later. No respondents referred to their earlier answers.

2. Response options

Two patients said that they would like a response option other than YES or NO, concerning item 2: *I feel a strong need to sleep during the day*. One said that **Item 2: I feel a strong need to sleep during the day** doesn’t relate to his everyday experience but happens ‘sometimes’. They later referred to items 4: *I have to read things several times before they sink in*, 7: *I have difficulty controlling my emotions*, 15: *There are times when I feel very low* and 25: *My memory lets me down*. This comment often occurs during field testing and usually means that the respondent hasn’t followed the instruction to answer ‘At the Moment’.

3. Item specific comments

One patient did not understand **item 1 “I have to struggle to finish jobs”** on first reading and asked the interviewer to explain it. He understood the explanation and did not suggest any changes.

There were no suggestions concerning alternative wording. One patient suggested removing the word “easily” from **Item 21, I am easily irritated by other people** but this would affect the meaning of the item.

One patient commented that the items should be more detailed, especially **Item 25, My memory lets me down**. This echoed a comment made during UK field tests.

4. Summary

All suggestions or questions recorded during the interviews related exclusively to the content of particular

Table VI. Correlations between QoL-AGHDA and NHP scales

Tabela VI. Korelacje pomiędzy wartościami uzyskanymi w kwestionariuszach QoL-AGHDA i NHP

QoL-AGHDA	NHP						
	Energy scale	Pain scale	Emotional reactions	Sleep scale	Social isolation	Physical mobility	NHP total
Pearson Correlation	.682**	.396**	.826**	.405**	.565**	.456**	.806**
Sig. (2-tailed)	.000	.001	.000	.000	.000	.000	.000
N	78	77	78	78	79	80	73

items, which mirrors the original English version. No respondents commented on the wording suggested by the lay panel, which will be used (during stage 4) without changes.

Stage 4: Assessing Psychometric and scaling properties

1. Test-retest reliability

The test-retest reliability coefficient for the Polish QoL-AGHDA was 0.92 (N = 84). This indicates very low levels of random measurement error and confirms the reliability of the questionnaire

2. Internal consistency

The Cronbach's Alpha coefficient for the Polish QoL-AGHDA was 0.91 (N = 70) at Time 1 and 0.94 (N = 79) at Time 2, indicating that the instrument has adequate inter-relatedness of items. All corrected-item total correlation (CITC) coefficients were between 0.2–0.8 at both time points.

3. Construct validity

Convergent and divergent validity

Table VI shows the correlation coefficients between the QoL-AGHDA and the NHP scales at Time 1. The QoL-AGHDA correlated well with the NHP as expected. The highest correlations were observed between the QoL-AGHDA and the NHP emotional reactions scale. This was expected as emotional components are an important feature in QoL. The QoL-AGHDA also correlated well with the NHP total score which was unsurprising as the NHP total score is an overall measure of health related QoL which overlaps with overall QoL.

Discriminative validity

Construct validity was tested by assessing how well the QoL-AGHDA was able to distinguish between groups based upon their physical activity during the leisure time measured by two VAS (scores above or below the median) and their responses to item 28 of the NHP

(‘I’m in constant pain’). The first of the VAS measured participants’ self-assessed level of physical activity (scores rated between ‘totally inactive’ to ‘extremely active’). QoL-AGHDA scores were significantly higher for the group reporting lower levels of activity. The second of the VAS measured a satisfaction with physical activity (‘totally dissatisfied’ to ‘completely satisfied’). Significantly higher QoL-AGHDA scores were found for the group reporting lower levels of satisfaction. For item 28 of the NHP QoL-AGHDA scores were significantly higher in the group who reported constant pain.

The final Polish version of the QoL-AGHDA is presented below (in appendix).

Discussion

The translation and validation of the Polish version of the QoL-AGHDA was accomplished via the 4-stage process.

The bilingual panel found that all the items and response options were translatable, though a few were noted for special attention by the lay panel with respect to acceptability. No cultural barriers were noted in any of the items. The panels were able to translate the QoL-AGHDA with acceptable alternative wordings for all response options and items that were queried.

The field-test interviewees were able to understand and respond to all the questionnaire items.

The final translation was then tested psychometrically with people who experience GH deficiency. At this step, the feasibility was moderate, because only 48.9% (85/174) of patients recruited accomplished the study. However, such a result was expected due to the fact that the QoL-AGHDA was administered on two occasions; accordingly, much larger group than required was recruited initially, and therefore, the number of the final sample was within the required frame, which was perfect for statistical analyses.

The analyses of the final translation indicate that the adaptation of the QoL-AGHDA into Polish has been

successful. High test-retest correlations indicated a high degree of reliability with no evidence of excessive random measurement error. The internal consistency of the measure was confirmed, with evidence that all items were adequately inter-related.

The Polish QoL-AGHDA was able to distinguish between people based on their self-reported level of physical activity and their satisfaction with it. The Polish QoL-AGHDA was also able to distinguish between people based on the NHP item 'I'm in constant pain'.

It has been documented in statistical analyses that a validated Polish version of the QoL-AGHDA is conceptually equivalent to the UK-English version.

The study has not evident limitations.

On the basis of these results, it is concluded that the Polish QoL-AGHDA is a reliable and valid measure of QoL suitable for inclusion in clinical studies and routine clinical practice.

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Quality of Life Assessment of Growth Hormone Deficiency in Adults (QoL-AGHDA) Wersja polska

(tłumaczenie i walidacja: Małgorzata Karbownik-Lewińska, Andrzej Lewiński, Stephen McKenna, Agnieszka Kokoszko, Sławomir Mucha, Jan Komorowski, Barbara Krzyżanowska-Świniarska, Maria Gryczyńska, Jerzy Sowiński, Roman Junik, David Meads, Maria Kołtowska-Hägström, 2008 rok)

Ten kwestionariusz zawiera pewne stwierdzenia, które mogą Pana/Pani dotyczyć. Proszę uważnie przeczytać poniższe zdania i zaznaczyć krzyżykiem odpowiedź: TAK — jeśli dane stwierdzenie Pana/Pani dotyczy lub NIE — jeśli nie dotyczy

Proszę zawsze zaznaczyć jedną odpowiedź przy **każdym** zdaniu.
Proszę zaznaczyć tę odpowiedź, która częściej Pana/Pani dotyczy.

	TAK	NIE
Z trudnością kończę to, co zacząłem/zaczęłam	<input type="checkbox"/>	<input type="checkbox"/>
W ciągu dnia czuję się bardzo ospały/a	<input type="checkbox"/>	<input type="checkbox"/>
Często czuję się samotnie, nawet gdy jestem wśród ludzi	<input type="checkbox"/>	<input type="checkbox"/>
Muszę przeczytać tekst kilkakrotnie, zanim go zrozumiem	<input type="checkbox"/>	<input type="checkbox"/>
	TAK	NIE
Mam kłopoty z nawiązywaniem znajomości	<input type="checkbox"/>	<input type="checkbox"/>
Wkładam wiele wysiłku w wykonanie prostych czynności	<input type="checkbox"/>	<input type="checkbox"/>
Z trudem panuję nad swoimi emocjami	<input type="checkbox"/>	<input type="checkbox"/>
Kiedy mówię, często tracę wątek	<input type="checkbox"/>	<input type="checkbox"/>
	TAK	NIE
Brak mi wiary w siebie	<input type="checkbox"/>	<input type="checkbox"/>
Często zmuszam się, żeby coś zrobić	<input type="checkbox"/>	<input type="checkbox"/>
Często odczuwam niepokój		
	TAK	NIE
Mam wrażenie, że sprawiam ludziom zawód	<input type="checkbox"/>	<input type="checkbox"/>
Źle się czuję w towarzystwie osób, których nie znam zbyt dobrze	<input type="checkbox"/>	<input type="checkbox"/>
Nawet kiedy nic nie zrobiłem/am, czuję się bardzo zmęczony/a	<input type="checkbox"/>	<input type="checkbox"/>
	TAK	NIE
Czasami jestem w głębokim psychicznym dołku	<input type="checkbox"/>	<input type="checkbox"/>
Jeśli to możliwe, unikam odpowiedzialności	<input type="checkbox"/>	<input type="checkbox"/>
Unikam towarzystwa osób, których dobrze nie znam	<input type="checkbox"/>	<input type="checkbox"/>
	TAK	NIE
Wydaje mi się, że jestem ciężarem dla innych	<input type="checkbox"/>	<input type="checkbox"/>
Często zapominam, co mi powiedziano	<input type="checkbox"/>	<input type="checkbox"/>
Mam kłopoty z zaplanowaniem tego, co będę robił/a	<input type="checkbox"/>	<input type="checkbox"/>
Ludzie łatwo mnie denerwują	<input type="checkbox"/>	<input type="checkbox"/>
	TAK	NIE
Często czuję się zbyt zmęczony/a, żeby zrobić to co muszę	<input type="checkbox"/>	<input type="checkbox"/>
Zmuszam się do robienia tego, co do mnie należy	<input type="checkbox"/>	<input type="checkbox"/>
Często muszę walczyć ze sobą, żeby nie zasnąć w ciągu dnia	<input type="checkbox"/>	<input type="checkbox"/>
Pamięć mnie zawodzi	<input type="checkbox"/>	<input type="checkbox"/>

Proszę wrócić do pierwszego pytania i upewnić się, że przy **każdym** zdaniu została zaznaczona odpowiedź TAK lub NIE.
Dziękuję za wypełnienie kwestionariusza.