

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

Guidelines for Users

May 2016

1. Background Information

Introduction

The choice of outcome measure(s) for complex diseases such as Growth Hormone Deficiency (GHD) presents a dilemma, often resulting in the need for numerous instruments in an attempt to assess the different impairments, activity limitations, and resulting participation restriction experienced.

Galen Research developed the Quality of Life Assessment of Growth Hormone Deficiency in Adults (QoL-AGHDA) in recognition of the lack of adequate outcome measures to assess the impact of GHD and its treatment on quality of life (QoL). The instrument was designed to be specific to adult GHD patients and to be valid, reliable and responsive to improvement or deterioration in QoL.

The development of the QoL-AGHDA employed a needs-based model in which QoL is defined as the extent to which individuals are able to meet their needs. By concentrating on needs, items are more likely to be relevant to all patients, regardless of age, gender or status, reducing the occurrence of items that are irrelevant to some respondents. Furthermore, as needs are universal, even though the method of meeting these needs may differ between cultures, adapting the measures for use in other languages and cultures is less problematic.

In developing this instrument, the importance of the patient as the source of QoL information was paramount, in order to produce a relevant QoL instrument specific to GHD. Using informal and unstructured interview techniques allow the respondents to talk about the aspects of their life that they felt were important to them. The interviews indicated that GHD has a detrimental effect on many areas of life. Transcripts from these interviews form the source items for the QoL-AGHDA.

The QoL-AGHDA has a number of features which make it particularly suitable for inclusion in clinical trials and studies and for routine clinical practice. As the content of the questionnaire was derived from interviews with patients, it reflects the concerns of relevance to them. As such, it is not surprising that patients find it highly acceptable. It is

also easy to understand, answer and score. In addition, as all the items in the measure are relevant to every potential respondent, the problem of missing data is minimised.

Description of the QoL-AGHDA

The QoL-AGHDA is a 25-item measure, designed to assess the QoL of adults with GHD. Each item is in the form of a simple statement to which patients indicate whether or not it is true for them at that moment. This two-point response system was selected as it presents the minimum burden on respondents and is the simplest in relation to ease of scoring and equivalence of translation.

There are currently sixteen language versions of the QoL-AGHDA available for use; UK (English), US (English), Germany (German), France (French), Belgium (Flemish), Belgium (French), Brazil (Portuguese), Czech Rep. (Czech), Denmark (Danish), Greek (Greece), Hebrew (Israel), Hungary (Hungarian), Italy (Italian), Netherlands (Dutch), Poland (Polish), Serbia (Serbian), Spain (Spanish), Slovakia (Slovakian), Slovenia (Slovenian) and Sweden (Swedish).

Theoretical basis for the QoL-AGHDA

The theoretical basis for the QoL-AGHDA is the needs-based model of QoL.¹ This model postulates that life gains its quality from the ability and capacity of the individual to satisfy his or her human needs. Thus, QoL is at its highest when these needs are fulfilled and at its lowest when few needs are satisfied. GHD interferes with the individual's ability to meet their needs and, consequently, QoL is reduced. Similarly, successful treatment increases ability to satisfy needs, leading to an improvement in QoL. While needs are largely universal, different illnesses interfere with the fulfilment of different needs. Consequently, it is possible to develop disease-specific measures that are able to determine the impact of an illness and its treatment from the patient's perspective.

¹ Hunt SM, McKenna SP. The QLDS: A scale for the measurement of quality of life in depression. *Health Policy* 1992; 22: 307-319.

Development of the QoL-AGHDA

The QoL-AGHDA was initially developed for use in the UK. The items were derived from qualitative interviews with adults with GHD in the UK. Semi-structured patient interviews were conducted to establish face and content validity of the instrument. Respondents had little trouble completing the questionnaire and found the content to be highly appropriate to their situation. A two-administration postal survey was conducted. Application of the Rasch model showed that, overall, items from both measures showed excellent stability over time and minimal differential functioning by age or gender. Item fit statistics and results from assessments of local item dependency were used to produce the final 25-item QoL-AGHDA.

Psychometric properties of the QoL-AGHDA

Reliability was assessed by the test-retest method, with the questionnaire administered to the same set of respondents on two occasions, two weeks apart. High test-retest correlation coefficients were observed. For patients whose condition (in terms of reported severity or flare of symptoms) had not changed between administrations, all values exceeded the minimum 0.85 required for instruments intended for use in clinical trials. Internal consistency was assessed by Cronbach's alpha coefficients and these were high at both time points, indicating that the items were adequately inter-related.

Table 1: Test-retest reliability and internal consistency of the QoL-AGHDA

Country	Test-retest reliability*	Internal consistency**
UK	0.93	0.93

* Spearman rank correlation coefficient

** Cronbach's alpha coefficient

Convergent and divergent validity was demonstrated by correlating the QoL-AGHDA with the General Well-Being Index (GWBI). Moderately high associations were found with the GWBI (0.74).

The QoL-AGHDA was consistently able to distinguish groups that differed according to self-related general health.

2. Value of the QoL-AGHDA for Clinical Trials and Clinical Studies

The QoL-AGHDA provides a valuable tool for assessing the impact of GHD and its treatment on QoL in international clinical trials and other research studies. As the instrument does not focus directly on symptoms or functioning, it allows the overall impact of treatment and adverse effects to be assessed, irrespective of the nature of the intervention.

The QoL-AGHDA has a number of features that make it particularly suitable for inclusion in clinical trials. The content of the questionnaire was derived from interviews with people with GHD and, thus, the items reflect issues of concern to the patients themselves and are phrased in an appealing way. Following item generation, the development and testing of the instrument continued in the UK. Consequently, it was possible to remove items that were problematic at each stage of the testing procedure, maximising the relevance and applicability of the final measure.

Respondents find the QoL-AGHDA highly acceptable, simple to understand and easy to answer. As all items are relevant to every potential respondent, the problem of missing data is minimised. The measure is also easy to administer and score - important considerations for a clinical trial. The instrument has been shown to have excellent test-retest reliability, internal consistency and construct validity. As such, researchers and clinicians can have confidence in the scores obtained on the measure. Furthermore, the low levels of measurement error observed over time together with its ability to show differences between severity groups, provide strong indications that the QoL-AGHDA will be responsive to changes in QoL associated with effective treatment. The instrument will be invaluable in showing the benefits of treatment from the patient's perspective.

3. Guidelines for the Administration of the QoL-AGHDA

The developmental methodology for the QoL-AGHDA was designed to produce an instrument of the highest acceptability and psychometric quality. Nevertheless, such properties are of little value if the measure is not administered in an appropriate way.

The following section describes the ideal way to administer the QoL-AGHDA, or indeed any patient-completed instrument. While it is recognised that practical considerations may make it necessary to deviate from the ideal, it is important to remember that the more administration is standardised, the more confidence that can be placed in the results obtained.

Planning considerations

The following list outlines some of the practical issues that need to be considered when setting up the environment in which the patients are to complete the QoL-AGHDA.

- Patients should always complete the QoL-AGHDA in the same room, prior to clinical consultation.
- If possible, the same member of staff should administer the measure on each occasion and be able to deal with questions and difficulties.
- This member of staff should be familiar with the instrument and be aware of its importance to the trial.
- The QoL-AGHDA should be completed in a quiet place in which respondents will not be interrupted by people passing through.
- Members of the family should not be present while the questionnaire is completed. The patient should be alone when he or she fills in the QoL-AGHDA and on no account should he or she be helped to fill it in or encouraged to give a particular answer.
- Make sure that the patient has a pen or pencil that works, something to rest the questionnaire on and that he or she has no difficulties with reading. If there are reading difficulties, the QoL-AGHDA should not be administered at all.
- The QoL-AGHDA generally takes between five and fifteen minutes to complete but no pressure should be put on slower respondents to rush their completion.

Introducing the QoL-AGHDA to the patient

In administering the QoL-AGHDA to the patient, he or she should be instructed as follows:

“I would like you to fill in this questionnaire, it will only take a few minutes. It asks about your Growth Hormone Deficiency and how it affects your life at the moment. You simply answer ‘true’ if you think that the statement applies to you and ‘not true’ if it does not apply.

For some of the questions you may not be sure what to answer - in that case answer according to how you feel at the moment.

It is important that you answer as honestly as you can and that you answer every question, even if you say ‘no’ to a lot of them.

Please read the instructions carefully before you begin”

On completion of the QoL-AGHDA

A careful check should be made before the patient leaves that every item on the questionnaire has been answered. Missing data cause problems for data analysis.

Possible problems with administering the QoL-AGHDA

The main problems likely to be encountered with the administration of the QoL-AGHDA are:

- The respondent does not want to answer ‘True’ or ‘Not True’ but rather ‘sometimes’.

Remind the respondent that he/she should answer for how he/she feels at the moment. If the respondent insists on answering ‘sometimes’, these responses should be coded as ‘True’.

- The respondent feels that some items are identical.

This is not the case, all items are different and no attempt is made to trick or test the respondent. The respondent should be given this information and (if necessary) allowed to look back through the form after completing it.

- The respondent fails to answer all the items or misses out a complete page.

The completed form must be checked very carefully before the patient leaves the room to ensure that every item has been completed.

4. Guidelines for Scoring and Analysing the QoL-AGHDA

Deriving Total QoL-AGHDA Scores

Each statement on the QoL-AGHDA is given a score of “1” or “0”. A score of “1” is given where the item is affirmed, indicating adverse QoL. All item scores are summed to give a total score or index. Scores can range from 0 (good QoL) to 25 (very poor QoL).

Missing data

For cases with between one and six missing responses, the total score is calculated as follows:

$$T = \frac{x}{25 - m} \times 25$$

Where:

T is the final total score

x is the item summation score

m is the number of missing items.

Cases with more than six missing responses cannot be allocated a total score.