General population reference values for the EQ-5D-5L index in Poland:
estimations using a Polish directly measured value set

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General population reference values for the EQ-5D-5L index in Poland: estimations using a Polish directly measured value set

Short title: EQ-5D-5L index Polish population norms

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**Introduction**

The EQ-5D is, apart from the Short Form-36 (SF-36), one of the most popular generic instruments for the measurement of health-related quality of life (HRQoL) [1-3]. The questionnaire is available in two versions: original, three-level (EQ-5D-3L) and the more recent five-level form (EQ-5D-5L). In comparison to EQ-5D-3L, EQ-5D-5L possesses some psychometric advantages, including a lower ceiling effect and higher sensitivity [4]. A Polish validation of EQ-5D-5L has recently been published [5].

The use of EQ-5D in Poland is supported by the availability of many country-specific tools. Local valuation studies enable the estimation of quality-adjusted life years (QALY), taking the health preferences of Polish society into consideration [6,7]. Population norms research allows the results from a specific patient to be related to the mean value of the reference group from the general population - matched for age and gender [8,9].

General population reference values for the EQ-5D-5L index in Poland, published in 2017 [9], were based on an old and imperfect approach to calculating health state utility values (HSU). In that study, the Polish interim EQ-5D-5L value set, based on a crosswalk method and questionnaire mapping, was used [10]. HSU for EQ-5D-5L were obtained, based upon Polish preferences for EQ-5D-3L [6], by using an official mapping algorithm developed by the EuroQol Group [11].

Recent years have seen the publication of a new EQ-5D-5L index estimation method in Poland [7]. In this research, the health preferences of a representative group within Polish society (n=1252) were studied with direct methods, including the time trade-off (TTO) and discrete choice experiment (DCE), with a final utility model based on both types of data (hybrid model). This published method of calculating the EQ-5D-5L index is currently the
preferred way, as recommended by the EuroQol Group and by AOTMiT (Polish HTA Agency) guidelines [8,12].

The current study aims to update the 2017 population norms for the EQ-5D-5L index in Poland using the recently published and currently recommended value set [7], based on a large national survey of Polish society health preferences and direct valuation methods.

**Methods**

**Polish EQ-5D-5L norms study**

The sampling details of the Polish normative study have been described in previous publications [8,9]. Population norms were estimated based on data from 3963 respondents (46.8% males, age range 18-87 years), which was representative of the adult population of Poland in terms of gender, age, geographic region of residence, education and socio-professional group (see Table 1 in [9]).

Several HRQoL questionnaires were distributed. The EQ-5D-5L answers allowed three different outcomes to be calculated: the subjective perception of health according to the EQ visual analog scale (EQ VAS), the level of health limitations within EQ-5D-5L dimensions and the EQ-5D-5L index values according to the Polish interim value set [9]. As estimations of the first two outcomes remain valid, in this manuscript we have restricted our focus to an update of EQ-5D-5L index norms.

**The Polish EQ-5D-5L values set**

In the current study, EQ-5D-5L index values were calculated based on the recently published Polish directly measured value set, which was developed with the standardized EuroQol Valuation Technology (EQ-VT 2.0) [7]. The final model was based on the time trade-off
(TTO) and discrete choice experiment (DCE) data, and took into account health preferences, as well as some specificity of Polish society (i.e. an unwillingness to trade in TTO by religious people). The described value set is characterized by the following: a wide range – from -0.590 (extreme limitations in all EQ-5D-5L dimensions) to 1.000 (no health limitations), a mean value of 0.476, 4.4% of all health states (from a total of 3125) perceived by Polish respondents as being worse than death (utility < 0), and a continuity of scale (second highest value 0.982).

Analysis

We estimated the following descriptive statistics for the EQ-5D-5L index: the mean and the standard error, the 25th, 50th (median) and 75th percentile. The results were presented for the whole sample and for both sexes separately, using predefined age groups: 18-24, 25-34, 35-44, 45-54, 55-64, 65-74 and 75+ years, as standardized in other research, in order to facilitate comparisons [8,9]. The statistical significance of differences between the indices based on the two analyzed value sets was assessed with a two-sided Wilcoxon's signed ranks test. The analysis was performed using StatsDirect 2.8.0 (StatsDirect Ltd, England) statistical software.

Ethics

The current manuscript is a secondary study (based on published studies) and did not directly involve humans or animals. Neither approval from an ethics committee nor written informed consent from patients was required.

Results

Table 1 shows EQ-5D-5L index population norms for Poland, calculated with the recently published directly measured (TTO and DCE-based) Polish EQ-5D-5L value set. Estimations
are presented according to various age and sex categories to facilitate the use of the norms in clinical practice (i.e. comparison of a patient with a reference group from the general population).

As expected, EQ-5D-5L index values decrease with age. Males are characterised by having higher mean health state utility values than females, in all age groups, except 55-64 years.

EQ-5D-5L index values estimated with the final value set were generally higher (57.4%) or equal (38.5%) to those estimated using the interim value set [9]. The mean difference of 0.034 was statistically significant (P <0.001). Similarly, the mean differences in the subsequent age groups (0.020, 0.022, 0.029, 0.037, 0.044, 0.047, 0.037) were also significant (p<0.001; Supplementary material, Figure S1).

**Discussion**

Based on the EQ-5D-5L responses from a representative sample of Polish citizens and the recently published and officially recommended value set, we estimated population norms for the EQ-5D-5L index in Poland, according to age group and gender. The normative data obtained should be used as reference values in research and in individual patient monitoring.

The results of our study provide a solution to the problem faced by Polish HRQoL researchers over the last two years. Estimating the patient's EQ-5D-5L index based on the new value set [7] and comparing it against the old population norm [9] would lead to flawed conclusions. In most cases, it would underestimate the impact of the disease on HRQoL.

The population norm based on the new value set is systematically higher than the norm based on the mapping. This is in line with the general characteristics of both value sets, as described in [7]. The directly measured TTO- and DCE-based value set has several advantages: a wider
range of values (-0.59 to 1.0), a smaller gap between the best state of health (11111; utility = 1.0) and the first state with health limitations (11112; utility = 0.982), and a lower concentration of values for moderate health states.

The choice of a new value set is justified by scientific reasons (the advantage of direct measurement over indirect methods and mapping) and complies with the EuroQol Group's current recommendations [7]. The use of new Polish population norms for the EQ-5D-5L index allows for the simultaneous consideration of the distribution of EQ-5D-5L health states (the descriptive part of the questionnaire) among the general Polish population and the preferences of Polish society towards EQ-5D-5L-defined health states.

In clinical practice, the application of new population norms makes it possible to easily compare an individual patient's health state with the population mean by gender and age. From the public health perspective, it provides an opportunity to easily estimate the burden of disease for a given condition. These results may be used in outcome measurement in clinical care, economic analyses, and health technology assessment reports for new drugs and medical devices.

**Conclusions**

In conclusion, the currently described Polish population norms for the EQ-5D-5L index, developed through the use of the directly-measured value set, should replace the population norms for the EQ-5D-5L index that were published in 2017.
References:


Table 1. EQ-5D-5L index population norms for Poland, by age group and gender (index values based on directly measured time trade-off and discrete choice experiment-based Polish EQ-5D-5L value set).

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>18 - 24</th>
<th>25 - 34</th>
<th>35 - 44</th>
<th>45 - 54</th>
<th>55 - 64</th>
<th>65 - 74</th>
<th>75 and more</th>
<th>Total respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3963</td>
</tr>
<tr>
<td>Total</td>
<td>456</td>
<td>617</td>
<td>654</td>
<td>612</td>
<td>797</td>
<td>525</td>
<td>302</td>
<td></td>
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<tr>
<td>Mean</td>
<td>0.983</td>
<td>0.975</td>
<td>0.967</td>
<td>0.935</td>
<td>0.900</td>
<td>0.860</td>
<td>0.760</td>
<td>0.922</td>
</tr>
<tr>
<td>Standard error</td>
<td>0.002</td>
<td>0.003</td>
<td>0.002</td>
<td>0.005</td>
<td>0.005</td>
<td>0.008</td>
<td>0.013</td>
<td>0.002</td>
</tr>
<tr>
<td>Q1</td>
<td>0.980</td>
<td>0.970</td>
<td>0.952</td>
<td>0.932</td>
<td>0.895</td>
<td>0.844</td>
<td>0.600</td>
<td>0.922</td>
</tr>
<tr>
<td>Median</td>
<td>1.000</td>
<td>1.000</td>
<td>0.982</td>
<td>0.970</td>
<td>0.952</td>
<td>0.925</td>
<td>0.843</td>
<td>0.970</td>
</tr>
<tr>
<td>Q3</td>
<td>1.000</td>
<td>1.000</td>
<td>1.000</td>
<td>1.000</td>
<td>1.000</td>
<td>0.970</td>
<td>0.932</td>
<td>1.000</td>
</tr>
<tr>
<td>Men</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1853</td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>238</td>
<td>311</td>
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<td>295</td>
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<tr>
<td>Mean</td>
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<td>0.969</td>
<td>0.947</td>
<td>0.890</td>
<td>0.880</td>
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<tr>
<td>Standard error</td>
<td>0.002</td>
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<td>0.004</td>
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<td>0.008</td>
<td>0.011</td>
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<tr>
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<td>0.970</td>
<td>0.952</td>
<td>0.945</td>
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<tr>
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<td>1.000</td>
<td>0.970</td>
<td>0.952</td>
<td>0.945</td>
<td>0.844</td>
<td>0.975</td>
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<tr>
<td>Q3</td>
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</tr>
<tr>
<td>Women</td>
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<td>218</td>
<td>306</td>
<td>352</td>
<td>317</td>
<td>418</td>
<td>297</td>
<td>202</td>
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<td>-----</td>
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<td>-----</td>
<td>-----</td>
</tr>
<tr>
<td>Mean</td>
<td></td>
<td>0.981</td>
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<td>0.966</td>
<td>0.924</td>
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<td></td>
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<td>0.004</td>
<td>0.003</td>
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<td>0.006</td>
<td>0.012</td>
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<tr>
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<td>0.970</td>
<td>0.952</td>
<td>0.918</td>
<td>0.843</td>
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<tr>
<td>Q3</td>
<td></td>
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<td>1.000</td>
<td>1.000</td>
<td>1.000</td>
<td>0.982</td>
<td>0.952</td>
<td>0.925</td>
</tr>
</tbody>
</table>

DCE - discrete choice experiment

TTO – time trade-off

Q1 – first quartile

Q3 – third quartile