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# Health-Related Quality of Life in Assyrian/Syrian and Swedish-Born Patients with Type 2 Diabetes

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### Authors' contributions

This work was carried out in collaboration between all authors. Author MT performed the experiments and gathered the data. Authors MT, SEJ, PW analyzed the data. Authors MT, NSS, SEJ, LA and PW contributed reagents/materials/analysis tools. Authors MT, PW wrote the first manuscript and consecutive drafts of the manuscript. Authors MT, NSS, SEJ, LA, PW contributed to the analyses and editing of the manuscript, and approved the final manuscript.

Research Article

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### ABSTRACT

**Aims:** To investigate whether there is an association between ethnicity and healthrelated quality of life in patients with type 2 diabetes and to analyze if the association remains after adjusting for possible confounders.

**Methodology:** A 12-item Short-form Health Survey - SF-12 was used. The associations between health-related quality of life and ethnicity, sex, age, marital status, educational status, BMI and age of onset of diabetes, were evaluated using linear regression analyses ( $\beta$ -coefficient and 95% CI).

Study Design: Cross-sectional.

**Place and Duration of Study:** This study is based on health-survey conducted among patients with type 2 diabetes on four Primary Health Care Centers in town of Södertälje (Sweden) during 2006-2008.

**Results:** Assyrians/Syrians reported significantly lower scores on six out of eight dimensions and two component summaries (physical and mental) of quality of life than Swedes (with exception of role limitation due to physical problems and vitality). After

adjustment for sex, age, marital status, education, BMI and age of onset of diabetes Assyrians/Syrians scored statistically significant lower bodily pain dimension ( $\beta$ coefficient = -16.0, 95 % CI = -24.7 - -7.2) and poorer mental health ( $\beta$ -coefficient = -12.1, 95% CI = -18.5 - -5.7) than Swedes. **Conclusions:** The present study shows that Assyrian/Syrian patients reported significantly lower health-related quality of life than Swedish-born patients. Measurement of health-related quality of life in patients with type 2 diabetes should be included into investigation and could be useful in guiding and evaluation of treatment intervention. The knowledge on self-reported quality of life could prevent early diabetes complications.

Keywords: SF-12; diabetes type 2; immigrants; Swedes.

#### **1. INTRODUCTION**

Although, physical and mental well-being are important issues, health-related quality of life (HRQL) is not broadly investigated in diabetes patients. It has been shown that diabetes affected the HRQL significantly [1,2]. The patients with diabetes had a worse quality of life than people without chronic disease but better HRQL than individuals with other chronic diseases [3-5]. A study measured HRQL by SF-36 in older Hispanic population in U.S concluded that those with diabetes type 2 had significantly worse physical health than those individuals without diabetes disease [6]. As several review studies suggest better health status and ability to control their disease improved quality of life in diabetes patients [3]. According to a review of quality of life in patients with diabetes type 2 in the Nordic countries foreign-born patients were among those who were at higher risk for poor quality of life [7]. Author of this review suggest prospective research investigating transcultural and ethnic aspects and impact of lifestyle interventions. A Swedish study done in elderly patients with diabetes showed that the study population had poorer quality of life and physical health particular than the general population [8].

Our previous study based on the same sample but not question including in SF-12 rather one question on self-reported health including into a health questionnaire with 52 items concluded that Assyrian/Syrian patients with type 2 diabetes had approximately five times greater risk of having poor self-rated health than Swedish-born patients [9]. This ethnic difference was not explained by socioeconomic factors. The aims of the present study are to examine health-related quality of life based on SF-12 health survey in Assyrian/Syrian and Swedish-born patients and whether the association between ethnicity and health-related quality of life remained after adjusting for possible confounders such as sex, age, marital status, educational level, body mass index and age of onset of diabetes.

#### 2. MATERIALS AND METHODS

#### 2.1 Participants and Data Sources

During 2006-2008 a health-survey was conducted among patients with type 2 diabetes on four Primary Health Care Centers in town of Södertälje. A total of 354 participated in the survey (Assyrians/Syrians (n=173) and Swedes (n = 181)). The health-survey consisted of total 52 questions on physical health, mental health, socio-demographic characteristics, medical values, anthropometric measurements and quality of life (SF-12) etc. Potential survey participants were selected consecutively from the registers of patients with type 2

diabetes at the centers. Neither the health care center registers nor official Swedish statistics include information on ethnicity; rather, persons are identified by country of birth, parents' country of birth, and citizenship. For this reason, identification of prospective participants (both Swedes and Assyrians/Syrians) was undertaken using participants' surnames and the health care center personnel's personal knowledge of patients. A sex- and age matched list of possible participants was then developed by the first author. Next, prospective participants were contacted by phone and invited to a face-to-face interview to fill out a questionnaire and have blood pressure and anthropometric measurements taken. The interviews were conducted either by first author or by one of six participating General Practitioners (GPs) at the primary health care centers.

Information on ethnicity and socio-demographic characteristics was gathered in the face-toface interviews. Anthropometric measurements, including height (cm), weight (kg), and waist circumference (cm), were made after the interview by the first author or participating GPs.

Most Assyrians/Syrians in Sweden live in a municipality near Stockholm – Södertälje, in which first and second generation immigrants (not all Assyrians/Syrians) constitute 42.7% of the total population [10]. All Assyrian/Syrian participants came from countries in the Middle East or had parents who came from the Middle East. A total of 33.5% came or had parents who came from Turkey; 30.6% from Iraq, 20.2% from Syria, and the rest from Lebanon or other countries.

#### 2.2 Dependent Variable – Health-Related Quality of Life (HRQL)

Health-related quality of life was measured by the SF-12 Health Survey. The SF-12 is a short-form of 149-item Health survey, Medical Outcomes Study (MOS) and is well validated, translated into many languages and widely used in research [11]. SF-12 is a general health status instrument with 12 items measuring eight health-related concepts: general health perception (GH), physical functioning (PF), bodily pain (BP), role limitations due to physical problems (RP), vitality (V), social functioning (SF), role limitations due to emotional problems (RE), perceived mental health (MH), two summary scores, the physical component summary (PCS-12) and the mental component summary (MCS-12) [11]. The items had been summed up the given scores of 0-100 range and were estimated continuously with higher score as indicator of better HRQL [12]. Effect size was used instead of cut-off-values for analyzing of differences between two ethnic groups. The HRQL might be explored by generic or disease-specific questionnaires [13]. We chose to study multidimensional assessments of quality of life by generic rather disease-specific measures with are more sensitive for assessing effects of interventions [14]. We chose this version of MOS questionnaire as we anticipated possible problems with low response rate with the longer versions, such as SF-36.

### 2.3 Independent Variables

Age was categorized into three groups: 32–59, 60–69 and ≥70 years, resulting in a similar proportion of patients in each of the groups. *Ethnicity* was defined as Swedish-born and Assyrian/Syrian-born immigrants including both first and second-generation immigrants from Turkey, Iraq, Syria and Lebanon. The identification of the studied immigrant population is based on two ways of self-identification among this group which was explained by the participants themselves having historic and cultural explanations. Therefore we choose to consider them as one ethnic group with two identification definitions, as Assyrians/Syrians.

*Marital status* was classified as married/cohabiting, living alone or living with children/siblings. *Educational level* was divided into three groups according to the duration of school education: (1) low (<9 years) including those without education at all, (2) intermediate (9–11 years) and (3) high (>11 years). *Body mass index* (BMI) was calculated as weight divided by height squared and defined as normal (<25), overweight (25.0-29.9) and obese ( $\geq$ 30). *Age of onset of diabetes* was categorized into 5 groups with ten years in each group: (1) 30-39; (2) 40-49; (3) 50-59; (4) 60-69 and (5)  $\geq$  70 years.

#### 2.4 Statistical Analysis

Excel-program and the statistical software Stata version 9 [15] was used to estimate the prevalence of the outcome variable, mean values and standard deviation (SD). Tests of the level of significance of explanatory variables between the two ethnic groups were performed by Mann-Whitney test. Effect size presented differences between the two groups and was calculated according Kazis et el. [16] and Cohen [17] as small (0.20-0.39), as moderate (0.40-0.79) and as large ( $\geq$ 0.80). However, the limit for moderate effect is now often set at 0.50. Multiple linear regressions were applied to estimate the  $\beta$ -coefficient and 95 % CIs (Confidence intervals) for the association between each dimension of SF-12 and the explanatory variables separately. Ten models are taken into consideration adjusted for all explanatory variables, including socio-demographic characteristics such as age, sex, marital status and educational level and objective health status measure as BMI and age of onset of diabetes.

#### 2.5 Ethical Considerations

The study was approved by the Regional Ethical Committee of the Karolinska Institutet (reference No. 2006/4:8, 2006-09-27). All participants received information about the study in written and verbal form.

### 3. RESULTS AND DISCUSSION

Descriptive characteristics for a total of 354 individuals (Assyrian/Syrian-born (n = 173) and Swedish-born (n = 181)) are presented in Table 1. There were statistical differences between two groups in age (P-value = 0.03), educational status (P-value = <0.05) and body mass index (P-value= 0.02). Assyrians/Syrians were younger, had lower educational status and 57.6 % of them had body mass index more than 30 (obese), while 42.5 % of Swedish-born patients were classified as obese. Age of onset of diabetes did not differ between both ethnic groups. Fifty five percent of Assyrian/Syrian patients used translator as help for responses.

Mean values, standard deviation and effect size on each of ten dimensions of SF-12 by ethnicity are shown in Table 2. Assyrian/Syrian patients scored statistically significant lower than Swedish-born patients on eight of ten dimensions; with exception in scores of role limitations due to physical problems and vitality which were similar between the two studied groups. Nevertheless, statistically significant differences scores were noted in both physical component summary (PCS-12) and the mental component summary (MCS-12), as resulted in that Assyrians/Syrians reported poorer HRQL than Swedish-born patients. The effect size reached the level of moderate differences only as regard mental health, with all other significant differences reaching small differences.

Socio-demographic	Assyrians/	Swedes	Test of
Variables	Syrians	n (%)	difference
	n (%)		P- value
Total	173 (48.9)	181 (51.1)	
Gender			
Female	84 (48.5)	80 (44.2)	0.41
Male	89 (51.5)	101 (55.8)	
Age (years)			
32-59	80 (46.5)	59 (32.6)	0.03*
60-69	47 (27.9)	59 (32.6)	
≥70	45 (26.2)	63 (34.8)	
Educational status			
Low < 9 years (incl. 0 years)	128 (74.0)	89 (49.1)	0.00**
Intermediate 9-11 years	8 (4.6)	38 (20.9)	
High > 11 years	36 (21.4)	54 (30.0)	
Body mass index	32.8 ± 20.2***	29.8 ± 5.7***	0.06
BMI (kg/m <sup>2</sup> )			
Normal (<25)	20 (11.8)	27 (15.0)	0.02*
Overweight (25.0 – 29.9)	52 (30.6)	76 (42.5)	
Obese (≥ 30)	98 (57.6)	76 (42.5)	
Age of onset of diabetes	53.6 ± 10.6	55.3 ± 11.1	0.16
(years)			
30-39	21 (12.1)	17 (9.4)	0.22
40-49	39 (22.5)	31 (17.1)	
50-69	86 (56.1)	106 (58.6)	
≥ 70	16 (9.3)	27 (14.9)	

# Table 1. Socio-demographic characteristics of Assyrians/Syrians and Swedes with test of statistical differences by *P*-value, n=354

Bold-faced numbers are statistically significant \*P-value <0.05, \*\* P-value <0.001

# Table 2. SF-12 dimension scores with mean and standard deviations (SD) and *P*-values by ethnicity, n=354

Scales*	Assyrians/Syrians	Swedes	P-value	Effect size
GH	33.1 (25.3)	41.1 (24.5)	0.00**	0.32
PF	54.2 (36.2)	64.8 (37.0)	0.00**	0.30
RP	50.3 (49.0)	58.6 (47.5)	0.10	0.20
RE	57.5 (49.1)	72.8 (42.6)	0.00**	0.31
BP	50.4 (41.0)	67.7 (33.7)	<0.05**	0.42
V	52.7 (36.2)	51.2 (30.7)	0.70	0.04
МН	60.5 (29.6)	74.3 (24.1)	<0.05**	0.50
SF	69.4 (38.0)	81.5 (28.2)	0.00**	0.32
PCS-12	39.0 (12.4)	42.0 (12.0)	0.01**	0.24
MCS-12	45.5 (13.6)	51.5 (11.3)	<0.05**	0.44

\* GH-general health perception; PF-physical functioning; RP-role limitations due to physical problems; RE-role limitations due to emotional problems; BP-bodily pain; V-vitality; MH-perceived mental health; SF-social functioning; PCS-12-physical component summary; MCS-12-mental component summary. \*\* Bold-faced numbers are statistically significant P-value <0.05. Table 3 shows sex differences in mean values on all SF-12 dimensions between Assyrians/Syrians and Swedes. Swedish-born women scored significantly higher for general health and for mental health than Assyrian/Syrian women. On the other hand, the physical summary component health was similar between Swedish-born women and Assyrian/Syrian women. While Swedish-born men scored higher for both physical and mental component summary measures in relation to Assyrian/Syrian men. As regards magnitude of effect size, among men this reached moderate level for bodily pain and mental health, whereas all other scale reached small level except for vitality scoring less than that. Among women, effect size reached small level for all scales but vitality and role limitations due to physical problems less than that.

The results of adjustment for only significant confounding factors such as ethnicity, sex and BMI ( $\geq$  30) are shown in Table 4. Other explanatory variables age, marital status, education and age of onset of diabetes were not statistically significant (not shown in table). There was strong association between ethnicity and six of eight outcomes and two component summaries (physical and mental) of HRQL. Our results showed significantly lower outcome for Assyrians/Syrians than Swedes. The only exception was the score for role limitations due to physical problems and for vitality. The  $\beta$ -coefficients for bodily pain ( $\beta$ -coefficient = -16.0), social functioning ( $\beta$ -coefficient = -13.0) and for mental health ( $\beta$ -coefficient = -12.1) remained statistically lower in Assyrians/Syrians than in Swedes even after adjustment for sex, age, marital status, education, BMI and age of onset of diabetes. Furthermore, Swedes scored higher for all mental health dimensions ( $\beta$ -coefficient = 5.3) and all physical dimensions (β-coefficient = 3.2) than Assyrians/Syrians. Regardless ethnicity, men scored significantly higher than women for nine of ten dimensions of HRQL with the exception for social functioning. Almost the same pattern is shown for obese participants where βcoefficient for this group remained significantly lower than for participants with normal BMI (<25) for five of ten dimensions related to physical health: role limitations due to physical problems ( $\beta$ -coefficient = -19.2), physical functioning ( $\beta$ -coefficient = -12.7), bodily pain ( $\beta$ coefficient = -12.2), general health ( $\beta$ -coefficient = -9.6) and physical component summary (-5.8). Differences in  $\beta$ -coefficients in mental component summary were not statistically significant between patients with obese BMI and normal BMI.

The main result of this study is that Assyrian/Syrian patients with type 2 diabetes reported significantly lower health-related quality of life than Swedish-born patients. Furthermore, such factors as to be women and to be obese were significantly and independently related to worse quality of life.

Scales*		Men				Women		
	Assyrians/Syrians	Swedes	P-value	Effect size	Assyrians/Syrians	Swedes	<i>P</i> -value	Effect
GH	37.0 (26.0)	44.1 (24.3)	0.07	0.30	29.2 (24.5)	37.3 (24.3)	0.04	0.33
PF	60.1 (38.0)	73.0 (33.5)	0.01	0.34	48.0 (33.4)	54.2 (38.2)	0.25	0.20
RP	58.4 (48.4)	68.0 (45.6)	0.17	0.20	41.5 (48.2)	47.0 (47.6)	0.45	0.11
RE	63.0 (48.6)	78.3 (39.2)	0.03	0.31	52.0 (49.4)	65.5 (46.0)	0.08	0.30
BP	54.3 (42.0)	75.0 (32.0)	<0.05	0.50	46.4 (39.4)	59.0 (34.0)	0.04	0.32
V	61.0 (36.4)	56.2 (30.0)	0.21	0.13	44.3 (34.2)	45.0 (31.0)	0.83	0.02
МН	64.0 (31.0)	78.3 (24.3)	<0.05	0.50	57.1 (28.0)	69.0 (23.0)	0.01	0.43
SF	73.6 (36.8)	84.4 (28.0)	0.04	0.30	65.0 (39.0)	78.0 (28.4)	0.04	0.33
PCS-12	41.0 (12.4)	44.5 (10.7)	0.04	0.30	36.3 (12.0)	38.5 (13.0)	0.25	0.20
MCS-12	47.1 (13.7)	53.0 (11.0)	0.01	0.43	44.0 (13.4)	50.0 (12.0)	0.00	0.45

Table 3. SF-12 dimension scores by ethnicity and sex with mean and SD, P-value and effect size, n=354

\* GH-general health perception; PF-physical functioning; RP-role limitations due to physical problems; RE-role limitations due to emotional problems; BPbodily pain; V-vitality; MH-perceived mental health; SF-social functioning; PCS-12-physical component summary; MCS-12-mental component summary.

# Table 4. Results of regression analyses with β-coefficient and 95% confidence interval (CI) for SF-12 dimensions adjusted for significant confounders ethnicity, sex and BMI ≥ 30, n=354

Variables*	Assyrians/Syrians (ref. Swedes)	Men (ref. women)	<b>BMI ( ≥ 30)</b> (ref. < 25.0)
GH	<b>-6.2</b> ** (-12.1– -0.4)	<b>7.1</b> ** (1.7–12.5)	<b>-9.6</b> ** (-17.7– -1.4)
PF	<b>-9.9</b> ** (-18.2– -1.7)	<b>15.1</b> *** (7.5–22.7)	<b>-12.7</b> ** (-24.2 – -1.2)
RP	-7.6 (-18.9– 3.7)	<b>18.6</b> ** (8.1–23.0)	<b>-19.2</b> ** (-35.0 –3.5)
RE	<b>-11.6</b> ** (-22.7– -0.5)	<b>11.2</b> ** (1.0–21.4)	-10.8 (-26.4 – 5.0)
BP	<b>-16.0</b> *** (-24.7– -7.2)	<b>13.0</b> ** (5.0–21.0)	<b>-12.2</b> ** (-24.4 –0.0)
V	1.6 (-6.2–9.4)	<b>13.7</b> *** (6.5–21.0)	-6.3 (-17.3 –4.7)
MH	<b>-12.1</b> *** (-18.5– -5.7)	<b>8.9</b> ** (3.0– 14.8)	-1.2 (-10.1 –7.8)
SF	<b>-13.0</b> *** (-21.0– -5.2)	6.0 (-1.2– 13.3)	-0.6 (-11.6 –10.3)
PCS-12	<b>-3.2</b> ** (-6.1– -0.3)	<b>5.4</b> *** (2.7–8.1)	<b>-5.8</b> ** (-10.0 –1.8)
MCS-12	<b>-5.3</b> ** (-8.4– -2.3)	<b>2.8</b> ** (-0.0– 5.6)	-1.6 (-6.0 –2.7)

\*GH-general health perception; PF-physical functioning; RP-role limitations due to physical problems; RE-role limitations due to emotional problems; BPbodily pain; V-vitality; MH-perceived mental health; SF-social functioning; PCS-12-physical component summary; MCS-12-mental component summary. \*\* Bold-faced numbers are statistically significant with \*\* P-value = 0.05 and \*\*\* P-value = 0.00. Our results are supported by the results of several previous studies where participants from certain ethnic groups report poor HRQL [7,18,19]. Even to be women [20-22] and to be obese have been shown to have negative effect on HRQL [23-25]. Earlier studies have found women to have lower quality of life than men as regards patients with diabetes, two of them are a reviews on quality of life among patients in primary care in the Nordic countries [7] [14]. A study in patients with type 2 diabetes in Greece showed that female gender and years with diabetes were two of most important predictors of impaired quality of life [26]. However, it is difficult to compare results from different quality of life questionnaires. The SF-12 contains a limited amount of guestions compared to guestionnaires as the SF-36 and the SWED-QUAL, most often used in the Nordic countries [7], thus more often showing great differences. This is why the summary scores are more often used in comparisons between different studies. In contrast to this study the variable age of onset of diabetes included into statistical analyses in the current study was not a significant confounder. Ethnic differences in perceived health-related quality of life were highly poorer in Assyrian/Syrian patients than in Swedes even after adjustment for age of onset of diabetes. In above mentioned review on guality of life among patients in the Nordic countries is discussed that diabetes type 2 effects general health in the same way all over the world when it is compared with non-diabetic patients [14]. However, the impact of diabetes disease on health in the same country is highly associated to the ethnic background [27]. To find the explanation of transcultural differences requires specific studies. The fact that Assyrian/Syrian patients in the current study reported poorer health than Swedes might be associated with the stress-related situation in a new country and not directly to migration in itself. The new socio-economic challenges might result in difficulties with self-care of diabetes disease and other factors with negative impact on health. However, these issues need to be investigated.

Diabetes type 2 can be undiagnosed in many years in population both in Western [28] and developing countries [29]. Despite that fact, it is noteworthy that majority of patients with Assyrian/Syrian ethnic background were diagnosed with diabetes type 2 after emigration from their countries of birth to Sweden. As the patients reported for us, they did not know if they had diabetes or not before immigration to Sweden. They explained that with such factors as lack of doctors and poor health care system in the country of origin and stress before and under migration. Additionally it might be explained by the lack of knowledge and/or low educational level (e.g. 20.0% of Assyrian/Syrian participants in this study were illiterate: 25.0% of women and 14.6% of men). These factors are in accordance with results from a Turkish study which showed that socio-demographic characteristics of patients such as advanced age, lower educational and income levels affect quality of life in 1601 diabetes mellitus, hypertension and obesity patients from south-eastern city in Turkey [30]. So that might mean that the age of onset of diabetes in Assyrian/Syrian patients was earlier than the age they reported in the present study.

In opposite to our results a large national representative survey of U.S. population (n=36,697) investigated the impact of cardio-metabolic risk factors (diabetes, hypertension and BMI) on health-related quality of life (HRQL) showed a decreasingly strong association to physical function. In this large survey either ethnicity or male sex had statistically significant impact on HRQL [31]. Self-perception of own quality of life can be influenced by country of birth [32], gender [22] or culture [33, 34].

Previous studies in the same study population showed that Assyrian/Syrian patients with type 2 diabetes had better values of blood lipids and less prevalence of hypertension than Swedes. Despite these important health factors, they reported much worse general health [35]. Poorer mental health in Assyrian/Syrians might be explained by migration factors. Such

factors as the reason for migration to Sweden, length of immigration or/and the information on number of first and second generation of immigrants were not including into analyses in this study. However the fact that 55% of Assyrian/Syrian participants in this health-survey used translator in Assyrian, Suryoyo, Arabic or Kurdish languages for response of the questionnaire can influences social functioning and therefore quality of life. Moreover, the fact that Assyrian/Syrian ethnic group is older may play a role in self-reported quality of life, we chose to use age as continuous variable and it has been shown to be statistically significant in only one outcome - role limitations due to physical problems. Dividing into group may give another pattern of impact of age on self-reporting of quality of life.

This study has both limitations and strengths. The major strength of this study is its novelty to examine health-related quality of life in the population group from Middle East based on self-identification and not on country of birth or geographic areas. As first limitation is its cross-sectional nature. It is not possible to draw extensive causal conclusions and the results of this study cannot be generalized to the representative sample of Assyrian/Syrian ethnic group in Sweden due to small sample size. On the other hand we can consider the study sample as reasonable representative for Assyrian/Syrians with diabetes type 2 in Sweden because of the fact that this large high-cohesion group has been established particularly in Södertälje The second limitation was that our attempt to match the two ethnic groups considering age was not successful because of the fact that Assyrian/Syrian patients with type 2 diabetes were younger than Swedes with the same disease. The third limitation was to use the SF-12 which contains a limited amount of questions, why it is difficult to compare our results with studies using questionnaires with more questions. However, we chose this instrument to avoid a lower participation rate.

## 4. CONCLUSIONS AND CLINICAL IMPLICATIONS

The present study shows that Assyrian/Syrian patients reported significantly lower healthrelated quality of life than Swedish-born patients. Despite the limitations, the findings of this study can be useful in clinical practice for planning primary health care services for Assyrian/Syrian patients with type 2 diabetes. In addition, measurement of quality of life in patients with type 2 diabetes could be useful in guiding and evaluating of treatment intervention. Furthermore, the knowledge on self-reported quality of life could prevent early diabetes complications and promote longer and healthier life with diabetes. Prospective studies including migration factors might help us to explain why the subjective health-related quality of life in Assyrian/Syrian patients is worse than in native Swedish-born patients. This knowledge is highly important in improvement of health outcomes and status in immigrant groups in Sweden.

### CONSENT

All authors declare that all participants received information about the study in written and verbal form and provided verbal informed consent prior to the onset of participation, and again before information was gathered from medical records, and for publication of this original article.

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# CONFLICT OF INTEREST

The authors have not declared any conflicts of interest.

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