

Translation and Validation of Medical Outcome of Study (MOS) of Short Form Health Survey SF-36 in Hindi

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ABSTRACT

Background: The Health Related Quality of Life (HRQL) is concerned with understanding how health influences an individual capacity to lead satisfying life. Patient-centric outcome surveys are frequently employed to evaluate and track HRQL. Medical outcome study of short form (sf-36) Health Survey is commonly utilized general tool to assess the HRQL, comprising thirty-six questions across eight dimensions. To gauge health within a community, a dependable and validated tool is essential. **Objectives:** To assess the quality of life related to health in individuals and to predict their overall health status, aiding in the diagnosis of their overall well-being. Facilitating the diagnosis of the patient's general well-being. Additionally, this evaluation proves valuable for future research endeavors. **Materials and Methods:** Conducting a study based on the population, the SF-36 Hindi questionnaire was given for a cohort comprising 543 healthy individuals with an average aged 18 years or older in Udaipur and its surrounding villages. Data collection was conducted by trained interviewers and all participants have been interviewed at their respective locations. The translated SF-36 Hindi was administered and was filled by the individuals itself. Statistical analyses were carried out for establishing the validity and reliability of the scale-level items. To examine the high order factor structures and the principal component analysis with varimax rotation was employed. **Results:** Total 543 individuals surveyed, 65.56% were male and 34.43% were female. Exploratory factor analysis was conducted for SF-36 based on the eight subscales, using the polychoric correlation and varimax rotation. Four items (MH26, MH30, SF20 and SF32) were loaded on different subscale which had low standardized estimates. KMO value was determined to be 0.816 and the barlett's test for sphericity examination resulted in a statistically significance ($p < 0.001$). Reliability test was performed for each domain and were found to be statistically significant. **Conclusion:** In conclusion, the research indicates that the utilization of SF36 in the Hindi language is deemed appropriate for estimation the quality of life in adults within Indian population.

Keywords: Health Related Quality of Life, SF-36, Health Survey, Hindi questionnaire, Translation, validation.

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INTRODUCTION

The Quality of Life (QoL) is commonly described as perceived quality of life an individual's daily existence, serving as an assessment of their overall well-being and satisfaction. It involves physical, social and emotional aspects of individual's life. The quality of life is a comprehensive belief which comprises all the aspects of life of the person. Disease and treatment of that disease may affect psychological, social and physical of patients well-being as well as biological status.¹ A high quality of life is generally

correlated with positive outcomes such as good physical and mental health meaningful relationships financial security access to education and opportunities, a safe and comfortable living environment and a sense of purpose and fulfillment conversely a low quality of life may be characterized by poor physical and mental health, social isolation, financial struggles, inadequate living condition and a lack of satisfaction or fulfillment in life. Health Related Quality of Life (HRQL) the HRQL pertains to holistic influence of an individual's health on their mental, emotional, physical and social well-being status, influencing their capacity to lead a satisfying life. It takes into consideration various factors such as an emotional well-being, physical activity, social activity, cognitive abilities and pain or discomfort; among others.² "The concepts of quality of life related to the health encompasses various dimensions, addressing both subjective and objective



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health aspects. It is impacted by various factors, encompassing age, gender, culture, socioeconomic status and the presence of chronic conditions. There are several dimensions of HRQL which includes.³

General health perceptions

This dimension includes individual's overall perception of patient's health, including their perceived level of health, energy and vitality.

Sensation of pain and discomfort

This dimension refers to an individual's experience of pain and discomfort and includes both acute and chronic pain as well as discomfort related to specific health conditions.

Physical functioning

This pertains to an individual's capacity to participate in everyday activities like walking, climbing stairs and fulfilling household responsibilities. And the SF-36, created as a concise alternative to the RAND Health Insurance Study (HIS) during the 1980s, stands as a widely employed health survey. It evaluates eight domains Health-Related Quality of Life (HRQL): role limitations due to Physical health issues (RP), Bodily Pain (BP), Physical Functioning (PF), General Health perceptions (GH), Vitality (VT), Social Functioning (SF), Role limitations due to Emotional problems (RE) and Mental Health (MH). These domains can be consolidated into two summary scores the Mental Component Summary (MCS) and the Physical Component Summary (PCS). Comprising 36 questions formatted with Likert responses, respondents express their agreement with statements on a scale ranging from 0-100, where the high scores indicate better health. The SF-36 is accessible in various languages, including Spanish,⁴ French,⁵ Russian,⁶ Swedish,⁷ Korean,⁸ German,⁹ Chinese,¹⁰ Finnish,¹¹ Danish,¹² Hungarian,¹³ English,¹⁴ Hebrew,¹⁵ Italian,¹⁶ Japanese,¹⁷ Polish,¹⁸ Norwegian,¹⁹ Dutch,²⁰ Afrikaans,²¹ among others, has been employed in various settings such as clinical trials, population health surveys and clinical practice. Translation and validation process of SF-36 in Hindi was carried by Richa Sinha *et al.* in 2012.²² This study was performed only on small sample size; author stated that work should be done on more sample size. Therefore, the current research aimed to study on more sample size (543) for the reliability and validation of medical outcome of study short form health survey SF-36 in Hindi. Since 2012 to 2022 there were no any study was carried out to translate and validate in Hindi of SF36 hence this is study was the need of current scenario.

AIM AND OBJECTIVES

Aim

“Translation and validation of Medical Outcome Study (MOS) of short form health survey SF-36 in Hindi”.

Objectives

To observe the quality of life related health in individuals and evaluate the commonly health status of the population using SF-36 questionnaire for the ease in diagnosis of patient's general health and also useful in upcoming researches.

MATERIALS AND METHODS

Materials

- Predesigned data collection form for demographic detail, medical and medication history.
- Short Form-36.
- Informed consent form (Hindi).

Study Site: Udaipur, its suburb villages and vicinity.

Study Type: Observational prospective study Population: Adult male and female (age >18).

Statistical analysis used

SPSS version 25 was used for statistical analysis. Item-level validity was established through tests including item internal consistency, equality of item scale correlations and item discriminant validity. Satisfactory item internal consistency is defined as an item correlating at 0.40 or higher. Scale-level validity and reliability were assessed by ensuring substantial variability in SF-36 scale scores and acceptable internal consistency (Cronbach alpha coefficient of 0.70 or more). Exploratory factor analyses on the eight SF-36 scales, using principal component analysis with varimax rotation, explored higher-order factor structures in the Indian general population.

Sampling Methods

Purposive Sampling for Adaptation and Translation of SF-36 from English to Hindi involves the translation of questionnaire items by a skilled professional with expertise in health survey questionnaire translation. The translated content will be subjected to back-translation in the English by an unbiased individual, followed by a thorough analyze to identify and address any potential discrepancies. The final translated version was adjusted to align with the sociocultural context of India and pilot testing was conducted to incorporate necessary modifications.

Inclusion and exclusion criteria

Inclusion Criteria

Individuals having age ≥ 18 years, residents of India.

Subjects from all community, gender and race.

Literate patient those who can understand local language Hindi and are able to give response.

Individuals having no psychological and physiological disorder that could affect the answers.

Exclusion Criteria

Pregnant and lactating mothers.

Patients having history of depression and psychiatric disorders.

Sample Size

=1.96 at 5% level of significance.

$1-\beta = 0.8413$ at 20% power of study.

$r=0.12$ expected correlation coefficient.

$N=[(Z\alpha + 1-\beta) C] 2+3$

Where $c=1/2 \log (1+r/1-r)$

Number of sample size =543

Study Procedure

This study is based on a population sample and the SF-36 Hindi was administered to healthy individuals aged 18 years or older in Udaipur, including its suburbs and nearby villages. A group of trained interviewers were gather data, conducting interviews with all participants at their respective locations. Individuals were presented with an informed consent form, seeking their agreement to participate in the study. After that the data collection form was filled by our volunteers, including demographic detail, medication history and medical histories were taken. The translated SF-36 Hindi was self-administered by individuals to evaluate the SF-36's capability to differentiate between groups with variations in factors known to enhance the Quality of Life (QoL), various factors are considered, including age, gender, residential area and comorbidities, utilized as grouping variables.

Source of Data

Informed consent form was provided to the individuals for their consent to participate in this study. After taking consent,

translated SF-36 Hindi was administered and their demographic detail, medication history and medical history were taken for the comparison of known group performance to evaluate the capability of SF-36 in discerning differences among groups influenced by factors recognized to impact Quality of Life, this study considers age, gender, residential area and the comorbidities as the variables for grouping.

RESULTS

The pilot study was performed firstly in which the total number of individuals is 50 and was administered for face validation and acceptability and some words were changed for its adaptation in Hindi language. Out of which total 50 patients 35 were male and 15 were the female. Low missing data were found and only 2% data were found missing. The Reliability test were performed of each domain and found satisfactory result above 0.7 (Cronbach's Alpha). After that the need is generated that the study has to be performed on large population for the proving the validation and reliability of the scale in Indian population with adaptations in Indian scenario. The study was conducted in Udaipur's nearby villages and suburbs vicinity with the total number of 543 participants in which 64.27% were within the age range of 18-29,

Table 1: Age Group Distributes of the Population.

Age group distributes of the population		
Age	No. of population	Percentage
18-29	349	64.27%
30-39	83	15.28%
40-49	55	10.12%
50-59	35	6.44%
60-69	19	3.49%
>_70	2	0.36%

Table 2: Gender Distributes of the Population.

Males	66%
Females	34%

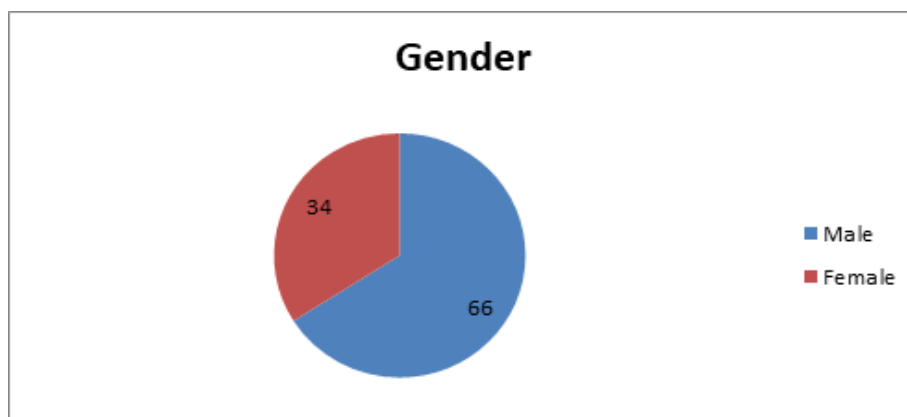


Figure 1: Gender Distribution of the Population.

Table 3: Marital Status of the participant.

Marital status	No. of population	Percentage
Married	299	55.06%
Unmarried	237	43.64%
Divorcee	1	0.18%
Widowed	6	1.104%

Table 4: The average demographics of the individuals who participated in the study.

Demographic details	List of Communalities	List of Communalities
Average age	30.32 Years	12.080
Average height	5.4 Feet's	2.353
Average weight	63.23 Kg	10.587
Average temperature	97.39 C	7.359
Average systolic BP	119.75 mmHg	8.108
Average diastolic BP	80.82 mmHg	6.108

15.28% were in age range of 30-39 and 10.12%, 6.44%, 3.49%, 0.36% were within the age range of 40-49, 50-59, 60-69 and >70 (Table 1) with the mean age of 30 years. In this study 65.56% were males and 34.43% were females (Table 2).

The total population in which 55% of the population was married, 43% was unmarried, 0.18% was divorcee and 1.104% was found widowed. Detailed marital status is depicted in Table 3.

Different demographic details are depicted in Table 4 with their mean and standard deviations.

And For the validation process, we carried out various tests, like reliability analysis by cronbach's alpha, and for validity, we ran factor analysis. For validity, exploratory factor analysis was carried out. EFA is used to estimate the number of factors and their suitability. EFA included two parameters to estimate the number of factors: (1) Communalities, and (2) factor loadings. For communalities, items that have value less than 0.5 and for factor loadings, items that have value less than 0.4 were excluded. In initial factor analysis, communalities of four items (MH26, MH30, SF20, and SF32) were 0.170, 0.153, 0.034, and 0.108, respectively, while their factor loadings were -0.367, -0.367, -0.114, and 0.158, respectively. These four items did not fit in both conditions, hence they were excluded. After excluding MH26, MH30, SF20, and SF32 again, factor analysis was carried out, and their new communalities and factor loadings are depicted in Tables 5 and 6.

Table 6 also depicts the Kaiser-Meyer-Olkin (KMO) Measure of Sampling Adequacy (0.804) and Bartlett's Test of Sphericity (Sig: 0.000). Both KMO and Bartlett's tests were found appropriate.

Kaiser-Meyer-Olkin Measure of Sampling Adequacy 0.804

Table 5: List of Communalities.

	Communalities	
	Initial	Extraction
GH_1	.693	.667
GH_2	.508	.446
GH_33	.642	.536
GH_34	.678	.777
GH_35	.481	.389
GH_36	.449	.387
PF_3	.436	.433
PF_4	.446	.441
PF_5	.436	.426
PF_6	.523	.546
PF_7	.500	.524
PF_8	.381	.378
PF_9	.500	.515
PF_10	.567	.583
PF_11	.579	.563
PF_12	.385	.315
RP_13	.473	.563
RP_14	.428	.509
RP_15	.517	.634
RP_16	.466	.530
RE_17	.221	.280
RE_18	.270	.448
RE_19	.271	.425
VT_23	.646	.731
VT_27	.642	.729
VT_29	.197	.207
VT_31	.445	.525
MH_24	.244	.327
MH_25	.319	.477
MH_28	.238	.315
BP_21	.329	.543
BP_22	.323	.473

Extraction Method: Principal Axis Factoring.

Matrix a. seven factors were extracted, requiring 19 iterations.

The Reliability analysis using Cronbach's alpha was found significant value ($p > 0.6$) and depicted in Table 7.

DISCUSSION

Our study findings indicate that the translated version of the SF-36 questionnaire demonstrates satisfactory reliability and factor validity when applied to the Hindi-speaking population

Table 6: List of Communalities.

Items	Factors list						
	1	2	3	4	5	6	7
GH_1	–	.795	–	–	–	–	–
GH_2	–	.650	–	–	–	–	–
GH_33	–	.717	–	–	–	–	–
GH_34	–	.851	–	–	–	–	–
GH_35	–	.595	–	–	–	–	–
GH_36	–	.592	–	–	–	–	–
PF_3	.642	–	–	–	–	–	–
PF_4	.650	–	–	–	–	–	–
PF_5	.648	–	–	–	–	–	–
PF_6	.710	–	–	–	–	–	–
PF_7	.718	–	–	–	–	–	–
PF_8	.606	–	–	–	–	–	–
PF_9	.710	–	–	–	–	–	–
PF_10	.758	–	–	–	–	–	–
PF_11	.730	–	–	–	–	–	–
PF_12	.505	–	–	–	–	–	–
RP_13	–	–	.674	–	–	–	–
RP_14	–	–	.648	–	–	–	–
RP_15	–	–	.717	–	–	–	–
RP_16	–	–	.676	–	–	–	–
RE_17	–	–	–	–	–	–	–
RE_18	–	–	–	–	–	.473	–
RE_19	–	–	–	–	–	.470	–
VT_23	–	–	–	.807	–	–	–
VT_27	–	–	–	.802	–	–	–
VT_29	–	–	–	.423	–	–	–
VT_31	–	–	–	.669	–	–	–
MH_24	–	–	–	–	.463	–	–
MH_25	–	–	–	–	.556	–	–
MH_28	–	–	–	–	.426	–	–
BP_21	–	–	–	–	–	–	.579
BP_22	–	–	–	–	–	–	.533

in Udaipur, Rajasthan, India. This conclusion is supported by the results of the polychoric correlation analysis, which revealed statistically significant reliability across all domains of the questionnaire. One of the notable strengths of our research lies in the meticulous design of the preliminary version of the translated questionnaire. Through a comprehensive review and cross-cultural adaptation process, we ensured that the questionnaire was culturally relevant and linguistically appropriate for the target population. Noteworthy adaptations include replacing activities like vacuum cleaning, bowling and playing golf with sweeping, mopping and cooking and units

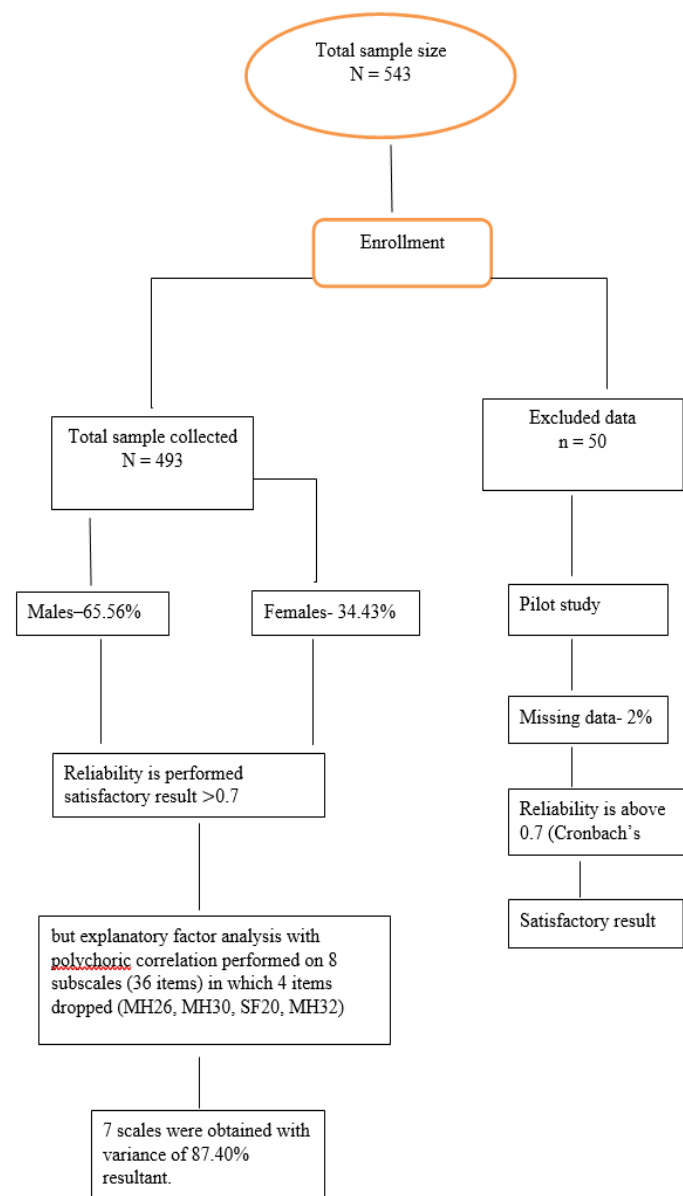
like miles were converted to kilometers and expressions like "walking several blocks" were modified to "walking one or several streets" to align with the Indian context and conducting back translation for validation purposes. The preliminary version of the forward-translated questionnaire underwent pilot testing on a total population of 50 and SF-36 translated questionnaire was administered for face validation and acceptability and some words were changed for its adaptation in Hindi language. Out of 50 individuals 35 were males and 15 were females. Low missing data were found and only 2% data was found missing. The Reliability test was performed for each domain and was

Table 7: Reliability Statistics.

Domains	Cronbach's alpha	No. of items
PF	0.891	10
RP	0.829	4
GH	0.858	6
BP	0.620	2
RE	0.638	3
VT	0.750	4
MH	0.634	3

found statistically significant. The subsequent study, involving a sample size of 543 participants, further reinforced the reliability and validity of the SF-36 questionnaire. Our chosen sample size aligns with recommendations for reliability and validity studies in the literature.^{23,24} Validity assessment, conducted through polychoric correlation and varimax rotation were for the establishment of eight scales. All the 36 items were loaded on the different subscales in which four items (MH26, MH30, SF20 and SF32) were dropped due to low values of communalities and factor analysis. The remaining 32 items after exclusion of four dropped items were analyzed again for exploratory factor analysis which gave significant results. The reasons for the deletion of items were the cultural differences were seen in the other studies.²⁵⁻²⁹ In our study the explanatory factor analysis was considered over confirmatory factor analysis because there are no generalized Hindi backups available. Explanatory factor analysis was preferred over confirmatory factor analysis due to the absence of generalized Hindi backups for the SF-36 questionnaire. This decision was made to ensure a thorough exploration of the questionnaire's underlying factor structure in the Indian context. The internal consistency, as measured by Cronbach's alpha, ranged from .634 to .858, indicating statistically significant reliability. Similar study was conducted by Richa Sinha *et al.* in 2012²² with a sample size of 184 wherein she stated that this study needs to be carried out in larger sample size. Therefore, the current research aimed to study on more sample size (543) for the reliability and the validity of medical outcome research of SF health survey SF-36 in Hindi. Shayan ahmed nazar *et al.*²⁵ Performed a study in Afghanistan in which 7+2 items were dropped off because of their low significance and in our study 4 items were dropped in Indian population. Notably, our study contributes to the existing literature by addressing the specific needs of the Hindi-speaking population in India. Despite the strengths of our study, several limitations should be acknowledged. We excluded pregnant and lactating women from our sample, as their physical activity and mental health may differ from the general population. Additionally, individuals under 18 years of age were also excluded, limiting the generalizability of our findings to this demographic. Future research could focus on further validating the SF-36 questionnaire in diverse Indian populations and exploring its applicability in clinical and research

Consort Chart



settings. Additionally, addressing the limitations of our study by including a more diverse sample, including pregnant and lactating women and individuals less than 18 years of age, would enhance the generalizability of the findings.

CONCLUSION

In conclusion, this research demonstrates that the SF-36 in Hindi language is deemed suitable for evaluation the Quality of Life (QOL) in adults within Indian population.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

SF: Short Form; **MOS:** Medical Outcome Study; **QoL:** Quality of Life; **HRQL:** Health related quality of life; **HIS:** Health Insurance Study; **RP:** Role Limitations Due to Physical Health Issues; **BP:** Bodily Pain; **PF:** Physical Functioning; **GH:** General Health Perceptions; **VT:** Vitality; **SF:** Social functioning; **RE:** Role limitations due to emotional problems; **MH:** Mental health; **MCS:** Mental Component Summary; **PCS:** Physical component summary.

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