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Validation of Kazakh and Russian Generic Drug Questionnaire

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Abstract

Background: The widespread use of generic drugs (GDs) represents a key strategy for reducing medication costs for patients and the healthcare sector. Promoting the rational use of GDs requires a clear understanding of physicians' knowledge and attitudes, assessed through reliable and culturally validated instruments. This study aimed to adapt and validate the Kazakh and Russian versions of a standardized questionnaire designed to evaluate physicians' knowledge and attitudes toward GDs. The validated tool is intended to support future research, educational programs, and policy efforts aimed at enhancing the rational prescription and utilization of GD in the Republic of Kazakhstan.

Methods: The questionnaire underwent a standardized forward–backward translation process in accordance with internationally accepted guidelines for cross-cultural adaptation of survey instruments. A pilot study was subsequently conducted among physicians in Shymkent, Republic of Kazakhstan, to evaluate its clarity and applicability in real-world conditions. To examine the psychometric properties of the Kazakh and Russian versions, Confirmatory Factor Analysis (CFA) was carried out using the Structural Equation Modeling (SEM) module in Jamovi software. In addition, descriptive statistics, standardized factor loadings, factor covariances, and model fit indices were calculated to assess the validity and internal structure of the instrument.

Results: Confirmatory Factor Analysis (CFA) supported the hypothesized two-factor model comprising the latent constructs "Information" and "Attitude" in both the Kazakh and Russian versions of the questionnaire. The majority of items demonstrated statistically significant standardized factor loadings, with several exceeding the recommended threshold of 0.70, indicating strong associations with their respective latent variables. The estimated correlation between the two factors was moderate in the Kazakh version (r = 0.599) and strong in the Russian version (r = 0.780), suggesting a meaningful conceptual relationship between physicians' knowledge and attitudes toward generic drugs.

Conclusion: The psychometric evaluation confirmed that the questionnaire has an adequate internal structure, with most items showing significant factor loadings and acceptable model fit. These findings support its use as a reliable tool for assessing physicians' awareness and attitudes toward generic medicines in Kazakhstan.

Keywords: Generic Drugs, Knowledge, Attitude, Physicians, Validation, Kazakh, Russian

Conflicts of Interest: None declared Funding: None

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↑What is "already known" in this topic:

GDs are widely acknowledged as cost-effective alternatives to brand-name medicines and are essential for enhancing global access to treatment. Multiple validated instruments have been developed and used internationally to assess physicians' knowledge and attitudes toward GDs. However, no culturally and linguistically validated tool has previously been available for use in the Republic of Kazakhstan in its official languages, Kazakh and Russian.

→What this article adds:

This article presents the first validated versions of a questionnaire assessing physicians' knowledge and attitudes toward GDs in both Kazakh and Russian. The instrument demonstrated acceptable internal consistency and construct validity based on confirmatory factor analysis, although some model fit indices suggest that further refinement may improve its performance. The validated tool provides a valuable starting point for future studies and policy initiatives aimed at enhancing rational prescribing of GDs in Kazakhstan.

Introduction

Ensuring equitable access to medicines is recognized as a global health priority, as articulated in the United Nations Sustainable Development Goal 3 (1). Achieving universal health coverage requires not only the availability of essential medicines but also their affordability (2). In this regard, generic drugs (GDs) play a vital role by expanding access to pharmacotherapy while helping to contain rising healthcare expenditures (3).

The promotion of GDs is one of the most effective strategies to reduce medication costs for both healthcare systems and patients (4). Beyond their economic impact, GDs contribute to broader social value by increasing market competition and lowering drug prices, thereby facilitating access to essential treatments. Enhanced affordability through GDs may also improve long-term treatment adherence in chronic conditions. Many countries have implemented generic substitution policies that have led to significant cost savings and improved access to medicines (5).

In 2023, the Association for Accessible Medicines (AAM) reported that generics and biosimilars led to \$445 billion in savings in the United States, with cumulative savings exceeding \$3.1 trillion over the past decade (6). In the U.S., nine out of ten prescriptions are for GDs, underscoring their central role in national healthcare systems (7).

In the Republic of Kazakhstan, healthcare expenditures represented approximately 3.7% of GDP in 2022, highlighting the urgent need for cost-effective pharmaceutical strategies (8). Structured generic substitution policies could yield significant savings in the national healthcare budget. As of 2023, over 7,000 medicines were registered in Kazakhstan, with GDs comprising over 70% of this total (9). GDs are also extensively used within publicly funded programs targeting defined patient populations (10).

Pricing regulations in Kazakhstan mandate that GDs be priced approximately 30% lower than the average cost of originator medicines over the preceding three years (11). Prior to market entry, generics must undergo mandatory bioequivalence testing to confirm their comparability in quality, safety, and efficacy to their reference counterparts (12). Consequently, generic substitution is considered a key tool for controlling pharmaceutical expenditures (13) and advancing equitable access to treatment (14). Despite these structural supports, misconceptions and limited awareness among physicians and patients regarding the quality and effectiveness of GDs remain persistent barriers to their rational use (15).

A previous study assessed physicians' knowledge and attitudes toward GDs across six regions of Kazakhstan using a structured questionnaire. However, the process of adapting and validating this instrument in Kazakhstan's two official languages, Kazakh and Russian, had not been thoroughly documented (16).

This study addresses this gap by presenting the linguistic adaptation and psychometric validation of the Kazakh and Russian versions of a questionnaire designed to evaluate physicians' knowledge and attitudes toward GDs. The validated tool is expected to contribute to future research, education, and policy efforts aimed at promoting the rational use of GDs in the national healthcare system.

Methods

Validation Process

The development and adaptation of the questionnaire followed a structured validation protocol to ensure linguistic, cultural, and psychometric suitability for use in the Republic of Kazakhstan. The validation procedure comprised four key stages: preparation, translation, preliminary testing, and statistical evaluation.

Preparation

The original questionnaire, developed and validated by Chua et al. (17), was selected due to its established effectiveness in assessing physicians' knowledge and attitudes toward generic drugs (GDs). This instrument served as the foundation for the adaptation process.

Translation and Cultural Adaptation

The linguistic validation adhered to internationally accepted cross-cultural adaptation guidelines (18). Two independent translators, native speakers of Kazakh and Russian without medical backgrounds, produced initial forward translations from the original English version. After reconciliation, a unified draft (Version 1) was created.

Subsequently, a native English-speaking translator, blinded to the original questionnaire, conducted a back-translation. The back-translated version was compared with the original to evaluate semantic and conceptual equivalence. Discrepancies were resolved through expert discussion, leading to Version 2.

Version 2 was pretested among 20 native Kazakh speakers and 20 native Russian speakers. Respondents provided structured feedback on clarity, cultural appropriateness, and comprehension. Since 90% of participants reported no issues with understanding, no additional modifications were required, and Version 2 was accepted as the final version in both languages.

Pilot Testing

To examine feasibility of the adapted instruments under real-world conditions, the final Kazakh and Russian versions were administered to a total of 336 physicians (175 completed the Kazakh version; 161 completed the Russian version). Eligible participants were practicing physicians aged 24 years or older who regularly prescribed medications and consented to participate.

Questionnaire Structure

The questionnaire comprised three sections:

1. Demographics – Six items capturing gender, age group, years of practice, professional role, leadership status, and type of workplace.

- 2. Knowledge of GDs Six items assessing physicians' familiarity with generic drugs, adapted from the original questionnaire (17).
- 3. Attitudes Toward GDs Seven items evaluating physicians' perceptions using a 5-point Likert scale (from "strongly agree" to "strongly disagree").

This structure was based on the conceptual framework established by Chua et al. and was cross-validated using methodology similar to that employed by Tsaprantzi et al. (17), which included item refinement and expert review to ensure content and face validity.

Statistical Analysis

Descriptive statistics were computed using SPSS Statistics 23 to characterize the study population. Absolute frequencies (n) and percentages (%) were calculated for categorical variables, and means with standard deviations were reported for continuous variables.

To evaluate the psychometric properties of the Kazakh and Russian versions, Confirmatory Factor Analysis (CFA) was conducted using the Structural Equation Modeling (SEM) module in Jamovi. A two-factor model was hypothesized, representing the latent constructs "Information" and "Attitude."

Standardized factor loadings were interpreted with a minimum threshold of 0.50, although select items with theoretical relevance were retained despite lower values. Factor covariances were estimated to assess interconstruct relationships.

Model fit was assessed using conventional indices, including χ^2 /df, Comparative Fit Index (CFI), Tucker-Lewis Index (TLI), Root Mean Square Error of Approximation (RMSEA), and Standardized Root Mean Square Residual (SRMR). Although exploratory factor analysis (EFA) was performed in prior studies, this study focused on CFA as the principal method to test the instrument's construct validity in its adapted versions.

Results

All stages of linguistic adaptation confirmed that there were no significant differences between language-adapted forms of the questionnaire. While the expert commission made minor modifications to question wording to enhance clarity, no substantive differences were found that would affect the conceptual equivalence of the questionnaire.

A total of 336 physicians participated in the study (175 completed the Kazakh version, 161 completed the Russian version). Participants were randomly selected from various healthcare institutions in Shymkent in January 2023.

The median time to complete the questionnaire was 13 minutes (range: 11–19 minutes). Respondents reported no barriers in understanding or answering the questions. Additionally, the Likert scale format did not cause any difficulties, and participants found the question wording simple and clear. Tables 1 and 2 provide an overview of the socio-demographic characteristics of the respondents.

Kazakh version (tab.1): The majority of respondents, 141 (80.6%) were female, with 62 (35.4%) aged over 50

Table 1. Respondents' demographic characteristics (Kazakh version) (n=175)

Variable(s)		No.	%
Gender	Male	34	19.4
	Female	141	80.6
Age (years)	24-30	12	6.9
	31–40	54	30.9
	41-50	47	26.9
	> 50	62	35.4
Years in practice	1-5	21	12.0
-	6-10	22	12.6
	>10	132	75.4
Position	Non-specialist	-	-
	Specialist	175	100.0
Responsibility position	Senior	31	17.7
	Non-senior	144	82.3
Place of work	Public health sector	131	74.9
	Private health sector	44	25.1

Table 2. Respondents' demographic characteristics (Russian version) (n=161)

Variable(s)		No.	%
Gender	Male	39	24.2
	Female	122	75.8
Age (years)	24-30	67	41.6
	31–40	56	34.8
	41-50	22	13.7
	> 50	16	9.9
Years in practice	1-5	72	44.7
*	6-10	31	19.3
	>10	58	36.0
Position	Non-specialist	131	81.4
	Specialist	30	18.4
Responsibility position	Senior	42	26.1
	Non – senior	119	73.9
Place of work	Public health sector	84	52.2
	Private health sector	77	47.8

years. Most had >10 years of medical practice experience (n=132, 75.4%), and 131 (74.9%) were employed in the public healthcare system. All respondents were specialists.

Russian version (tab.2): Most respondents, 122 (75.8%) were female, with 41.6% aged between 24–30 years. The majority had 1–5 years of practice experience (n=72, 44.7%), and 84 (52.2%) worked in the public health sector. Unlike the Kazakh version group, (131) 81.4% of respondents were non-specialists.

Table 3 displays the results of the confirmatory factor analysis (CFA) performed on the Kazakh version of the questionnaire using data from 175 participants. The analysis supported a two-factor model consisting of the latent constructs Information and Attitude.

Within the Information factor, items Q2 (0.761), Q3 (0.792), and Q1 (0.494) demonstrated strong and statistically significant factor loadings (p < .001), indicating a good representation of the latent construct. Items Q4 (0.267), Q5 (0.225), and Q6 (0.316) also showed significant loadings, albeit of lower magnitude.

For the Attitude factor, most items showed moderate to strong statistically significant loadings: q1 (0.553), q2 (0.553), q4 (0.498), q5 (0.464), q6 (0.512), and q3 (0.385), all with p-values less than .001. In contrast, item q7 (0.158) did not achieve statistical significance (P = 0.114), suggesting a limited contribution to the construct.

All statistically significant items had 95% confidence intervals that did not include zero, further supporting the reliability and validity of the measurement model.

Table 4 reports the factor covariance estimates from the confirmatory factor analysis (CFA) of the Kazakh version of the questionnaire (n = 175). The covariance between

the two latent constructs, Information and Attitude, was statistically significant, with an estimate of 0.599 (SE = 0.0673, 95% CI: 0.467 to 0.731, Z = 8.90, P < 0.001), indicating a moderate to strong positive association between the two factors.

The variances of the latent factors Information and Attitude were fixed to 1.000 as reference parameters (denoted by superscript ^a), which is a common practice in CFA to identify the model and allow for estimation of covariances and loadings.

These results support the theoretical relationship between the constructs and further confirm the internal structure of the instrument.

Model fit (Kazakh version, n = 175) was assessed using the chi-square test for exact model fit. The test yielded a statistically significant result: $\chi^2(64) = 257$, P < 0.001.

Although the fit indices do not reach conventional thresholds for good model fit (e.g., CFI and TLI \geq 0.90; RMSEA and SRMR \leq 0.08), they provide useful insights into the current structure. The results (Table 5 and Table 6) suggest that the model may benefit from further refinement, such as reviewing item loadings or factor relationships, to enhance its alignment with the observed data.

The model includes two latent constructs: Information (Inf) and Attitude (Att) (Figure 1). Observed variables Q1–Q6 load onto the Information factor, while items q1–q7 load onto the Attitude factor. A covariance is specified between the two latent factors. Unidirectional arrows represent standardized factor loadings; bidirectional arrows indicate factor covariances and residual variances.

Table 6 summarizes the confirmatory factor analysis (CFA) results for the Russian version of the questionnaire

Table 3. Confirmatory Factor Analysis ((Kazakh version) (n=175))

				95% Confidenc	e Interval		
Factor	Indicator	Estimate	SE	Lower	Upper	Z	P
Information	Q1	0.494	0.0757	0.3456	0.643	6.52	<.001
	Q2	0.761	0.0615	0.6403	0.881	12.37	<.001
	Q3	0.792	0.0635	0.6680	0.917	12.48	<.001
	Q4	0.267	0.0774	0.1149	0.418	3.44	<.001
	Q5	0.225	0.0829	0.0626	0.388	2.72	0.007
	Q6	0.316	0.0733	0.1726	0.460	4.31	<.001
Attitude	ql	0.553	0.0612	0.4326	0.673	9.03	<.001
	q2	0.553	0.0528	0.4498	0.657	10.48	<.001
	q3	0.385	0.0842	0.2200	0.550	4.57	<.001
	q4	0.498	0.0523	0.3957	0.601	9.53	<.001
	q5	0.464	0.0751	0.3164	0.611	6.17	<.001
	q6	0.512	0.0670	0.3811	0.644	7.65	<.001
	q7	0.158	0.0997	-0.0377	0.353	1.58	0.114

Table 4. Factor Estimates ((Kazakh version) (n=175))

Factor Covarianc	es						
				95% Confid	ence Interval		
		Estimate	SE	Lower	Upper	Z	P
Information	Information	1.000a					
	Attitude	0.599	0.0673	0.467	0.731	8.90	<.001
Attitude	Attitude	1.000^{a}					

^a fixed parameter

Table 5. Fit Measures ((Kazakh version) (n=175))

				RMSEA 9	90% CI
CFI	TLI	SRMR	RMSEA	Lower	Upper
0.706	0.642	0.108	0.131	0.115	0.148

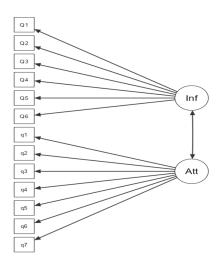


Figure 1. Structural diagram of the confirmatory factor analysis model for the Kazakh version of the questionnaire (n = 175).

(n = 161). Two latent constructs were tested: Information and Attitude.

For the Information factor, all six items demonstrated statistically significant loadings (P < 0.001). Items Q2 (0.629), Q3 (0.656), and Q6 (0.499) showed moderate to strong loadings, indicating a meaningful representation of the latent construct. Other items—Q1 (0.377), Q4 (0.450), and Q5 (0.394)—had lower but still significant factor loadings.

For the Attitude factor, most items exhibited moderate to strong statistically significant loadings: q1 (0.699), q2 (0.469), q3 (0.421), q4 (0.488), q5 (0.503), and q6 (0.570), all with p-values < .001. Item q7 had a low loading (0.192) and did not reach conventional statistical significance (P = 0.058), suggesting it may be a weaker indicator of the underlying construct in the Russian version.

All statistically significant items had 95% confidence intervals that did not cross zero, supporting the reliability of the factor structure.

Table 7 presents the factor covariance estimates from the confirmatory factor analysis (CFA) of the Russian version of the questionnaire (n = 161). A statistically significant covariance was observed between the latent constructs Information and Attitude, with an estimate of 0.780 (SE = 0.0619, 95% CI: 0.659 to 0.901, Z = 12.6, P < 0.001). This indicates a strong positive relationship between the two constructs.

The variances of both latent variables were fixed to 1.000 (indicated by superscript ^a) for model identification purposes—a standard approach in structural equation modeling.

These results support the conceptual connection between the constructs and suggest coherence within the measurement model.

Model fit (Russian version, n = 161) was assessed using the chi-square test for exact model fit. The test yielded a statistically significant result: $\chi^2(64) = 198$, P < 0.001, suggesting that the model does not achieve exact fit with the observed data. However, given the high sensitivity of the chi-square test to sample size, it is commonly interpreted alongside additional fit indices for a more compre-

Table 6. Confirmatory Factor Analysis ((Russian version) (n=161))

			95% Confidence Interval					
Factor	Indicator	Estimate	SE	Lower	Upper	Z	P	
Information	Q1	0.377	0.0858	0.20900	0.546	4.39	<.001	
	Q2	0.629	0.0732	0.48536	0.772	8.59	<.001	
	Q3	0.656	0.0721	0.51453	0.797	9.09	<.001	
	Q4	0.450	0.0863	0.28101	0.619	5.22	<.001	
	Q5	0.394	0.0848	0.22745	0.560	4.64	<.001	
	Q6	0.499	0.0825	0.33728	0.661	6.05	<.001	
Attitude	q1	0.699	0.0681	0.56512	0.832	10.26	<.001	
	q2	0.469	0.0614	0.34852	0.589	7.64	<.001	
	q3	0.421	0.0859	0.25221	0.589	4.90	<.001	
	q4	0.488	0.0569	0.37654	0.600	8.57	<.001	
	q5	0.503	0.0625	0.38015	0.625	8.05	<.001	
	q6	0.570	0.0722	0.42878	0.712	7.90	<.001	
	a7	0.192	0.1012	-0.00638	0.390	1.90	0.058	

Table 7. Factor Estimates ((Russian version) (n=161))

Factor Covariances

		95% Confidence Interval						
		Estimate	SE	Lower	Upper	Z	P	
Information	Information	1.000a						
	Attitude	0.780	0.0619	0.659	0.901	12.6	<.001	
Attitude	Attitude	1.000^{a}						

a fixed parameter

Table 8. Fit Measures ((Russian version)(n=161))

				RMSEA 90% CI		
CFI	TLI	SRMR	RMSEA	Lower	Upper	
0.760	0.707	0.0866	0.114	0.0963	0.132	

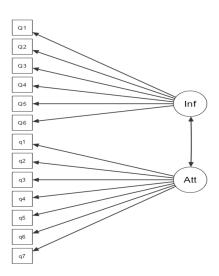


Figure 2. Structural diagram of the confirmatory factor analysis model for the Russian version of the questionnaire (n = 161).

hensive evaluation.

Table 8 displays further model fit statistics. While these values fall below conventional thresholds for good model fit (e.g., CFI and TLI \geq 0.90; RMSEA and SRMR \leq 0.08), they nonetheless provide useful information on model performance. The results suggest that the model captures meaningful structure but may benefit from further refinement to improve its fit to the data.

Figure 2 illustrates the hypothesized measurement model tested in the confirmatory factor analysis. The model includes two latent variables: Information (Inf) and Attitude (Att). Items Q1–Q6 load onto the Information factor, and items q1–q7 load onto the Attitude factor. The bidirectional arrow between the two latent factors represents their covariance. The unidirectional arrows from the latent variables to the observed items indicate standardized factor loadings.

Discussion

The statistical validation methods applied in this study were broadly aligned with those used by Tsaprantzi et al., who conducted a psychometric evaluation of a similar questionnaire in Greece. Both studies utilized Confirmatory Factor Analysis (CFA) to assess construct validity. While Tsaprantzi et al. used AMOS 20 (17), this study employed Jamovi software with the SEM module. In both cases, a two-factor model was tested, comprising the latent constructs "Information" and "Attitude".

In the present study, several standardized factor loadings exceeded 0.7 (e.g., Q2, Q3), similar to the results reported by Tsaprantzi et al. Notably, some items with lower loadings were retained due to theoretical significance, which is consistent with the original study. The correlation between the two latent factors was moderate to strong in both versions (Kazakh: 0.599; Russian: 0.780), aligning with the strong association found in the Greek version (17).

However, model fit indices in this study (e.g., CFI = 0.706, RMSEA = 0.131 for the Kazakh version) were lower than those reported by Tsaprantzi et al. (CFI = 0.96, RMSEA = 0.044), suggesting that the measurement model may require further refinement in the Kazakh and Russian contexts. Despite this, the internal structure of the questionnaire showed acceptable psychometric properties, and the methodology was adapted appropriately for the target population.

Strengths

This study has several important strengths. First, it is the first attempt to adapt and validate a questionnaire assessing physicians' knowledge and attitudes toward generic drugs in both Kazakh and Russian languages, the official languages of Kazakhstan. The rigorous translation and validation process strictly followed internationally accepted guidelines, including forward and backward translation, expert evaluation, and pilot testing.

Second, a relatively large sample size was involved in the pilot stage (336 respondents), which strengthens the generalizability of the findings and ensures a more comprehensive analysis of psychometric properties.

Third, exploratory and confirmatory factor analyses were both conducted, providing robust evidence of the construct validity of the questionnaire.

Finally, the use of the questionnaire in both state and private sector settings increases the external validity and reflects the real-world environment of healthcare provision in Kazakhstan.

Limitations

As the data were collected solely in the city of Shymkent, the findings may have limited geographical generalizability. Physicians in other regions of Kazakhstan may have different levels of awareness and attitudes toward generic drugs due to local prescribing practices, access to education, and institutional policies.

Another limitation lies in the fact that the Russianspeaking group had a higher proportion of non-specialists and younger physicians compared to the Kazakh-speaking group. This demographic imbalance could potentially influence the psychometric characteristics of the questionnaire and should be considered in subsequent studies.

Moreover, while the sample size was sufficient for validation purposes, it may not be fully representative of the entire physician population in Kazakhstan, especially with regard to specialties, healthcare institutions, and experience levels.

Conclusion

The psychometric evaluation of the Kazakh and Russian versions of the questionnaire confirmed acceptable internal consistency and supported the hypothesized two-factor structure ("Information" and "Attitude") based on CFA results. Although several model fit indices (e.g., CFI, RMSEA) fell below ideal thresholds, the factor structure remained conceptually coherent and statistically stable.

Methodological parallels with the study by Tsaprantzi et al. were observed, particularly in the retention of theoreti-

cally important items and identification of inter-factor relationships. However, the lower fit indices emphasize the need for further refinement and cultural calibration of the tool in the Kazakhstani context.

Overall, the questionnaire represents a promising instrument for assessing physicians' knowledge and attitudes toward generic medicines. With targeted improvements, it could be effectively utilized as a reliable instrument for advancing research, supporting educational initiatives, and informing policy-making in the area of rational drug use.

Recommendations

Future research should apply the validated questionnaire to a larger and more diverse sample of physicians across multiple regions of Kazakhstan. This would allow for further refinement of the instrument and evaluation of its psychometric performance across varied clinical, linguistic, and institutional contexts.

Regular re-validation of the tool is also recommended to ensure that it maintains reliability and construct validity over time, particularly as the healthcare system and physicians' perceptions of generic drugs continue to evolve.

The validated questionnaire can serve as a practical instrument for national and regional studies aimed at monitoring trends, evaluating the impact of educational initiatives, and informing health policies to promote the rational use of generic medicines.

Authors' Contributions

Zhandulla Nakipov: Study design

Ulugbek Musaev: Statistical processing of data

Indira Smagylova: Descriptive analysis

Karlygash Raissova: Questionnaire Developer

Zhanar Bukeyeva: Writing an article

Gaukhar Dauletova: Writing an article

Assiya Turgambayeva: Implementation of the plan

Zakira Kerimbayeva: Implementation of the plan

Dinara Kaliyeva: Designing the method and statistical analysis

Nabil Joseph Awadalla: Designing the method and statistical analysis.

Ethical Considerations

Decision LBC NJSC AMU No. 4. Session No. 10 date 11/25/2022.

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Conflict of Interests

The authors declare that they have no competing interests.

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