# Development and validation of a multidimensional instrument to assess the healthcare needs of sub-fertile couples in the Colombo district Sri Lanka

Gayani Gunawardhana \*, Sanjeeva Godakandage \*\*, Manuj Weerasinghe \*\*\*

\* Health Promotion Bureau, Ministry of Health, Sri Lanka
 \*\* Family Health Bureau, Ministry of Health, Sri Lanka
 \*\*\* Department of Community Medicine, Faculty of Medicine, University of Colombo, Sri Lanka

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#### Abstract-

**Introduction:** To achieve patient satisfaction, diverse unmet healthcare needs of sub-fertile couples should be identified and addressed at all levels. However, such an instrument to identify the healthcare needs of the sub-fertile couple is lacking.

**Method**: Items generation for the Healthcare Need Assessment-Subfertility (HNA-Sf) tool was done by conducting In-depth Interviews (IDI) (n=20) and Focus Group Discussions (FGD) (n=8) with sub-fertile individuals and healthcare workers. The best items were selected through the Delphi technique. The construct validity of the drafted tool was assessed with exploratory factor analysis (EFA) in a cross-sectional study, with 225 sub-fertile couples. The internal consistency of items was measured with Cronbach's alpha. Test-retest reliability was assessed with thirty participants.

**Results**: Fifty-eight items were generated through qualitative methods (FGD and IDI). Fifty-one items were selected via the Delphi technique with a panel of experts for EFA. The final drafted HNA-Sf tool after EFA compromised 37 items under five main domains named 'basic information needs', 'information needs on treatments', 'communication needs', 'psycho-social needs', and 'autonomy and respect needs'. The Cronbach's reliability for the HNA-Sf tool range from 0.856-0.912 in female partners and 0.855-0.904 in male partners. The Kappa coefficient of the selected 10 items varied between 0.773 to 0.908.

**Conclusion and recommendation**: Newly developed HNA-Sf is a valid and reliable tool to measure the healthcare needs of subfertile couples. The tool can be used to identify the healthcare needs of sub-fertile couples.

*Index Terms*- subfertility, healthcare needs, information needs, psychological needs, communication needs.

#### I. INTRODUCTION

This publication is licensed under Creative Commons Attribution CC BY. http://dx.doi.org/10.29322/IJSRP.13.05.2023.p13723 Subfertility is a disease of the reproductive system. Clinically it is defined as a 'failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse (1). Subfertility can affect all aspects of family life causing various psychological and emotional disturbances affecting both male and female partners leading to frustration, depression, hopelessness, guilt, and eventually conflicts (2,3). Therefore, subfertility is a major family issue that needs to be addressed with utmost care and confidentiality. Some sub-fertile couples do not commence or continue subfertility treatments due to various reasons, such as lack of information, myths, social issues, economic impact, and psychological problems (4)

Subfertility prevalence is higher in low and middle-income countries than in high-income countries (5). With available literature, the prevalence of subfertility is approximately 15% among Sri Lankan couples (6). To organize effective services and plan healthcare interventions, diverse unmet healthcare needs of sub-fertile couples should be identified and addressed. A healthcare need assessment of sub-fertile couples is needed for this purpose (7).

Healthcare needs are defined as "needs that can benefit from healthcare interventions such as health education, prevention of diseases, diagnosis, treatments, rehabilitation, etc." (7). In most research studies, emphasis is given to the assessment of healthcare needs to enable a plan for future health interventions.

Healthcare needs of sub-fertile couples can be categorized under the following areas: information and communication needs, emotional support, autonomy and respect, continuity of care, and financial support (8). Subfertility is an area with a lot of myths and misconceptions. Therefore, sufficient knowledge on fertility, risk factors, causes of subfertility, and treatment options are needed, and insufficient knowledge affects the treatment-seeking behavior and continuation of the treatments (9,10). Psychological or emotional distress can be a result of various reasons such as social pressure, female age, treatment not resulting in a pregnancy, poor support from healthcare workers, fear, etc. Fulfilling the psychological needs will, in turn, reduce emotional distress and perhaps lead to higher success in treatment (8,11,12,13). Several research pieces of evidence proved that sub-fertile couples required a wide range of psychological support and counseling interventions (14,15).

The following are the reasons to develop a new tool to assess the healthcare needs of sub-fertile couples. Firstly, none of the tools included all dimensions of healthcare needs. Most of these tools evaluate only one dimension of their needs, e.g., the emotional needs, counseling needs, or the economic burden (16). Secondly, most of the tools developed to assess the needs of clinic patients would miss the needs of couples who are not in treatment. Thirdly, most of the existing evidence is generated with qualitative assessments (17,18). The present tool assess the gravity of unmet healthcare needs with quantitative measurements. Fourthly, most of the tools are designed to assess the needs of sub-fertile couples who live in high-income countries.

The objective of this study was to develop a valid and reliable instrument to assess the healthcare needs of sub-fertile couples.

## II. METHODS

To develop the 'Healthcare Needs Assessment-Subfertility (HNA-Sf) tool' the researchers used a stringent process (19), which includes defining the concept, generation of the item pool, selection of the best items, confirmation of the structure of the tool, pre-testing, and testing for psychometric properties.

The concept of 'healthcare needs' as agreed upon by the panel of experts: Needs that can be provided by the healthcare system which can be beneficial to sub-fertile couples, such as health education including information provision, disease prevention, the fulfillment of the communication gap, addressing psycho-social needs, addressing the autonomy and respect needs and addressing the needs in diagnosis and treatments.

The item pool was generated with qualitative studies (Focus Group Discussions and In-depth Interviews) and the tools available in the literature to measure the same constructs. Generated item pool consisted of 58 items. The best items were selected through Delphi technique reviews by a panel of experts. The panel was requested to review the relevance of each item to the construct under study and the appropriateness and acceptability of the wording in the local context on a 10-point Likert Scale separately. Seven items were removed as they had a mean rating score of less than 3 for relevance. Other items were modified with the suggestions of the experts. Fifty-one best items were selected and were then subjected to assessment of their construct validity via Exploratory Factor Analysis (EFA) and reduced to 37 items. Exploratory factor analysis was carried out from data collected by a cross-sectional study in randomly selected five Public Health Midwives (PHM) areas in one Medical Officer of Health (MOH) area. The study population was male and female partners of sub-fertile couples registered in the updated eligible family register, which is a register of couples used by grass root level healthcare workers. Exploratory factor analysis was carried out for male and female partners separately. Reliability was assessed through test-retest reliability by selecting 10 items and reassessing these items with 30 participants 2 weeks following the first assessment. The whole country is divided into 352 MOH areas for health administration purposes and the PHM area is a

subdivision of a MOH area catered by a Public Health Midwife for domiciliary care in Sri Lanka (20).

The sample size for the EFA study was determined with the recommendations of the previous literature and five participants for each item were recruited (21). Therefore, for the EFA 255 participants were recruited. Informed written consent was obtained from each participant before data collection.

All the interviews and discussions for item generation (FGD and IDI) were audio recorded and transcribed by the principal investigator (PI). The PI read the interview responses in IDI and SGDs and looked for a pattern among the information given by the informants. After getting familiarized with the data, initial codes were developed. Codes developed were converted to items that assess the needs of sub-fertile couples without changing the original meaning of the code.

The EFA study data entry and the statistical analysis were conducted by the PI using the Statistical Package for Social Sciences (SPSS) version 21. Before EFA, data were initially screened for suitability for factor analysis. The reliability of the instrument was ensured by assessing the internal consistency. A Cronbach's alpha score of more than 0.7 was considered adequate. The selected 10 items from the HNA-Sf tool were administered to 30 participants, two weeks apart to assess the test-retest reliability.

# III. RESULTS

Two hundred and twenty-five sub-fertile couples responded to the newly developed tool with 51 items. The mean age of the female partner was 35.1 years (SD= 5.9) and the male partner was 37.9 years (SD=5.4). Most of the couples were Sinhala Buddhists. The basic socio-demographic characteristics of the couples were given in Table 1.

Exploratory Factor Analyses for male and female partners were conducted separately. Before conducting EFA data were screened for their suitability. For both male and female partners, Kaiser-Meyer-Olkim (KOM) test was well above 0.5 (female partners = 0.938 and male partners= 0.949) and highly significant. The correlation matrix revealed that there were some variables with low correlation below 0.3 in female partners (Question numbers:18,31,32,33,36,44) and male (Question partners numbers:7,18,8,32,36,37). Those items were removed. Eigenvalues above 1 were retained and for female partners, they ranged between 1.15-21.44, and for male partners, they ranged between 1.12-21.9. After removing the above six variables from the male and female partner's datasets separately, 45 variables were considered in Principal Component Analysis. The rotation of the variables was carried out using various oblique rotational methods. Finally, with varimax rotation, a good model fit with the data was obtained in both partners. Then the process of removing and adding variables to obtain a sound factor matrix was performed. Out of the 45 items, 37 items were loaded into five factors logically in both partners. Eight items in female partners (Q6, Q7, Q8, Q28, Q29, Q30, Q37, Q46) and male partners (Q6, 08, 029, 030, 031, 033, 044, 046) showed cross-loading and not load to a factor with more than 0.4 (22) coefficients were removed. In female partners, five factors explained 75.42% of the variability, and in male partners, five factors explained 75.3% of the variability in the data set. The variables were assigned to the

factor with the highest loading. Though the removal of items was done in different stages with male and female partners finally the same set of items was retained. The final factor loading for each domain and the items that remain are presented in Table 2.

The internal consistency of items in the domain was measured with Cronbach's alpha. The Cronbach's alpha coefficients exceeded the criterion of 0.7 (Nunnally's criteria) in all domains (Table 3). Ten selected items from the newly developed HNA-Sf tool were re-administered to thirty participants two weeks apart by the principal investigator. The Kappa coefficient of items varied between 0.773 to 0.908 (Table 4). Therefore, the Healthcare Needs Assessment tool items showed substantial and almost perfect agreement on the above two different occasions over two weeks (23).

Abbreviations- IDI: In-depth Interviews; FGD: Focus Group Discussions; EFA: Exploratory Factor Analysis; PHM: Public Health Midwife; MOH: Medical Officer of Health; SPSS:

Characteristics	Female Number (n=255)	Male Number (n=255)
	& Percentage	& Percentage
	(%)	(%)
Age	Mean age 35.1	Mean age 37.9
-	(SD=5.9)	(SD=5.4)
Ethnicity		
Sinhala	233 (91.3)	231 (90.5)
Tamil	6 (2.4)	8 (3.2)
Muslim	15 (5.9)	15 (5.9)
Burgher	1 (0.4)	1 (0.4)
Religion		
Buddhist	208 (81.6)	206 (80.8)
Christian/ Catholic	28 (11.0)	28 (10.9)
Islam	15 (5.9)	15 (5.9)
Hindu	4 (1.5)	6 (2.4)
Highest Educational		
Level		
No formal education	3 (1.2)	4 (1.6)
Grade 1-5	5 (1.9)	9 (3.5)
Grade 6- Grade 11	65 (25.4)	56 (21.9)
GCE O/L <sup>1</sup> passed	72 (28.4)	72 (28.2)
Up to GCE $A/L^2$	61 (23.9)	43 (16.8)
GCE $A/L^2$ passed	35 (13.8)	51 (20.1)
Tertiary education	14 (5.4)	20 (7.9)
Subfertility		~ /
Primary	121 (47.5)	121(47.5)
Secondary	134 (52.5)	134 (52.5)

Statistical Package for the Social Sciences.

Competing interests-

The authors declare that they have no conflict of interest.

Ethics approval-

Ethics clearance was granted by the Ethics Review Committee of the Faculty of Medicine, University of Kelaniya, Sri Lanka (Ref No: P/282/12/2017). The research was carried out following the guidelines of the ethics committee listed in the ethics statement.

Table 1. Distribution of the study participants by sociodemographic and subfertility-related characteristics, in the cross-sectional study, performed to assess the Exploratory Factor Analysis of the drafted 'Healthcare Need Assessment-Subfertility' tool.

<sup>1</sup> General Certificate in Education (Ordinary Level) <sup>2</sup> General Certificate in Education (Advanced Level)

Table 2: Final factor loading of the items assigned to each domain of drafted 'Healthcare Need Assessment-Subfertility' tool after varimax rotation, in exploratory factor analysis in male and female partners.

Quest	Items	Factor Loading	
ion*		Female	Male
(No.)			
	Basic information need on subfertility		
Q1	To know about how the baby is conceived	.727	.746
Q2	To know about the 'fertile period' of the menstrual cycle.	.774	.709
Q3	To know about the causes of male subfertility.	.803	.764
Q4	To know about the causes of female subfertility.	.797	.767
Q9	Information needs on treatmentTo know about methods to avoidunhealthybehaviorscausing	.583	.506
Q10	subfertility To know when it is necessary to meet a doctor for the first time for the management of subfartility	.551	.590
Q11	the management of subfertility. To know about the places, where we should go first, to start treatment	.511	.500
Q12	To get to know about the details of the treatment process and condition while being treated for subfertility	.660	.669
Q13	To get to know about the availability of treatment options in the government sector free of charge.	.594	.687
Q14	To know about the treatment procedures/ facilities for subfertility management in the private sector.	.716	.725
Q15	To know about the adverse effects arising from the treatments	.687	.765
Q16	for subfertility. To get to know about what issue would be addressed by the treatment that I and my partner are undergoing	.645	.654
Q17	undergoing To know about the reasons for treatment failures up to now.	.669	.699

Q19	To know about the trustworthy		
	people/ institutions treating	.482	.529
	subfertility		
Q20	To know about the help, can get		
	for the psychological problems	.594	.523
	arising due to subfertility		
	Communication needs		
Q21	To get the opportunity to question		
L.	the health staff regarding solving		
	the problems that arise due to	.618	.538
	subfertility.		
Q22	To feel that my issue is properly		
$\mathbf{V}^{22}$	understood by the health staff	.679	.569
Q23	To explain my condition simply		
$\chi^{23}$	and understandably by the health	.706	.655
	staff to me and my partner.	.700	.055
Q24	When breaking 'bad news' be		
Q24	more mindful of my feelings and	.757	.690
	emotions by the health staff.	.151	.070
Q25	To minimize the use of English		
$Q^{23}$	technical words by health staff		
	when explaining the situation and	.718	.638
	the treatments.		
Q26	The availability of a sincere		
Q20	person to discuss my problem	.642	.666
	freely in a difficult situation	.042	.000
Q27	To discuss my problems regarding		
$Q^{2}$	subfertility with the Public Health	.762	.695
	Midwife in the field	.702	.095
	Psycho-social needs		
034			
Q34	To receive emotional support	624	635
Q34	To receive emotional support from my partner in stressful	.624	.635
-	To receive emotional support from my partner in stressful situations caused by subfertility.	.624	.635
Q34 Q35	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support	.624	.635
-	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support from relatives and friends in	.624 .666	.635 .744
-	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support from relatives and friends in stressful situations caused by		
Q35	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support from relatives and friends in stressful situations caused by subfertility.		
-	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support from relatives and friends in stressful situations caused by subfertility. To receive emotional support	.666	.744
Q35	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support from relatives and friends in stressful situations caused by subfertility. To receive emotional support from relatives/friends during the		
Q35 Q38	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support from relatives and friends in stressful situations caused by subfertility. To receive emotional support from relatives/friends during the treatment failure.	.666	.744
Q35	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support from relatives and friends in stressful situations caused by subfertility. To receive emotional support from relatives/friends during the treatment failure. To receive emotional support	.666	.744 .781
Q35 Q38	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support from relatives and friends in stressful situations caused by subfertility. To receive emotional support from relatives/friends during the treatment failure. To receive emotional support through counseling during	.666	.744
Q35 Q38 Q39	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support from relatives and friends in stressful situations caused by subfertility. To receive emotional support from relatives/friends during the treatment failure. To receive emotional support through counseling during treatment failure situations.	.666	.744 .781
Q35 Q38	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support from relatives and friends in stressful situations caused by subfertility. To receive emotional support from relatives/friends during the treatment failure. To receive emotional support through counseling during treatment failure situations. To receive attention from the	.666 .634 .705	.744 .781
Q35 Q38 Q39	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support from relatives and friends in stressful situations caused by subfertility. To receive emotional support from relatives/friends during the treatment failure. To receive emotional support through counseling during treatment failure situations. To receive attention from the healthcare staff, for psychological	.666	.744 .781
Q35 Q38 Q39	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support from relatives and friends in stressful situations caused by subfertility. To receive emotional support from relatives/friends during the treatment failure. To receive emotional support through counseling during treatment failure situations. To receive attention from the healthcare staff, for psychological depression due to treatment	.666 .634 .705	.744 .781 .704
Q35 Q38 Q39 Q40	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support from relatives and friends in stressful situations caused by subfertility. To receive emotional support from relatives/friends during the treatment failure. To receive emotional support through counseling during treatment failure situations. To receive attention from the healthcare staff, for psychological depression due to treatment failures.	.666 .634 .705	.744 .781 .704
Q35 Q38 Q39	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support from relatives and friends in stressful situations caused by subfertility. To receive emotional support from relatives/friends during the treatment failure. To receive emotional support through counseling during treatment failure situations. To receive attention from the healthcare staff, for psychological depression due to treatment failures. The willingness of the partner to	.666 .634 .705	.744 .781 .704
Q35 Q38 Q39 Q40	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support from relatives and friends in stressful situations caused by subfertility. To receive emotional support from relatives/friends during the treatment failure. To receive emotional support through counseling during treatment failure situations. To receive attention from the healthcare staff, for psychological depression due to treatment failures. The willingness of the partner to actively participate in the	.666 .634 .705 .657	.744 .781 .704 .666
Q35 Q38 Q39 Q40 Q41	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support from relatives and friends in stressful situations caused by subfertility. To receive emotional support from relatives/friends during the treatment failure. To receive emotional support through counseling during treatment failure situations. To receive attention from the healthcare staff, for psychological depression due to treatment failures. The willingness of the partner to actively participate in the treatment of subfertility.	.666 .634 .705 .657 .534	.744 .781 .704 .666 .619
Q35 Q38 Q39 Q40	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support from relatives and friends in stressful situations caused by subfertility. To receive emotional support from relatives/friends during the treatment failure. To receive emotional support through counseling during treatment failure situations. To receive attention from the healthcare staff, for psychological depression due to treatment failures. The willingness of the partner to actively participate in the treatment of subfertility. To avoid unnecessary interference	.666 .634 .705 .657	.744 .781 .704 .666
Q35 Q38 Q39 Q40 Q41 Q42	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support from relatives and friends in stressful situations caused by subfertility. To receive emotional support from relatives/friends during the treatment failure. To receive emotional support through counseling during treatment failure situations. To receive attention from the healthcare staff, for psychological depression due to treatment failures. The willingness of the partner to actively participate in the treatment of subfertility. To avoid unnecessary interference by others on my subfertility issue.	.666 .634 .705 .657 .534	.744 .781 .704 .666 .619
Q35 Q38 Q39 Q40 Q41	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support from relatives and friends in stressful situations caused by subfertility. To receive emotional support from relatives/friends during the treatment failure. To receive emotional support through counseling during treatment failure situations. To receive attention from the healthcare staff, for psychological depression due to treatment failures. The willingness of the partner to actively participate in the treatment of subfertility. To avoid unnecessary interference by others on my subfertility issue. Availability of counseling	.666 .634 .705 .657 .534 .748	.744 .781 .704 .666 .619 .678
Q35 Q38 Q39 Q40 Q41 Q42	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support from relatives and friends in stressful situations caused by subfertility. To receive emotional support from relatives/friends during the treatment failure. To receive emotional support through counseling during treatment failure situations. To receive attention from the healthcare staff, for psychological depression due to treatment failures. The willingness of the partner to actively participate in the treatment of subfertility. To avoid unnecessary interference by others on my subfertility issue. Availability of counseling services for marital problems	.666 .634 .705 .657 .534	.744 .781 .704 .666 .619
Q35 Q38 Q39 Q40 Q41 Q41 Q42 Q43	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support from relatives and friends in stressful situations caused by subfertility. To receive emotional support from relatives/friends during the treatment failure. To receive emotional support through counseling during treatment failure situations. To receive attention from the healthcare staff, for psychological depression due to treatment failures. The willingness of the partner to actively participate in the treatment of subfertility. To avoid unnecessary interference by others on my subfertility issue. Availability of counseling services for marital problems caused by subfertility	.666 .634 .705 .657 .534 .748	.744 .781 .704 .666 .619 .678
Q35 Q38 Q39 Q40 Q41 Q42	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support from relatives and friends in stressful situations caused by subfertility. To receive emotional support from relatives/friends during the treatment failure. To receive emotional support through counseling during treatment failure situations. To receive attention from the healthcare staff, for psychological depression due to treatment failures. The willingness of the partner to actively participate in the treatment of subfertility. To avoid unnecessary interference by others on my subfertility issue. Availability of counseling services for marital problems caused by subfertility	.666 .634 .705 .657 .534 .748 .675	.744 .781 .704 .666 .619 .678 .671
Q35 Q38 Q39 Q40 Q41 Q42 Q43	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support from relatives and friends in stressful situations caused by subfertility. To receive emotional support from relatives/friends during the treatment failure. To receive emotional support through counseling during treatment failure situations. To receive attention from the healthcare staff, for psychological depression due to treatment failures. The willingness of the partner to actively participate in the treatment of subfertility. To avoid unnecessary interference by others on my subfertility issue. Availability of counseling services for marital problems caused by subfertility The availability of a program to focus on positive thinking for sub-	.666 .634 .705 .657 .534 .748	.744 .781 .704 .666 .619 .678
Q35 Q38 Q39 Q40 Q41 Q42 Q43	To receive emotional support from my partner in stressful situations caused by subfertility. To receive emotional support from relatives and friends in stressful situations caused by subfertility. To receive emotional support from relatives/friends during the treatment failure. To receive emotional support through counseling during treatment failure situations. To receive attention from the healthcare staff, for psychological depression due to treatment failures. The willingness of the partner to actively participate in the treatment of subfertility. To avoid unnecessary interference by others on my subfertility issue. Availability of counseling services for marital problems caused by subfertility	.666 .634 .705 .657 .534 .748 .675	.744 .781 .704 .666 .619 .678 .671

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Q47	To select a doctor according to my will.	.907	.634
Q48	Maintenance of privacy at the consultation with the doctor.	.494	.790
Q49	Maintenance of privacy at the examination, investigations, and treatments.	.724	.674
Q50	To consider my decision for the treatment process.	.912	.652
Q51	Receiving and treating me warmly and friendly manner by the healthcare staff at the clinics	.912	.800
	*Question numbers mentioned were the questionnaire used for data colle	0	

Table 3: Cronbach's alpha coefficient of each domain of the 'Healthcare Need Assessment-Subfertility' tool by gender in the cross-sectional Study.

Domain (factors)	Cronbach's alpha co-efficient- female	Cronbach's alpha co-efficient- male
Basic information on subfertility	0.894	0.889
Information needs on treatment	0.912	0.904
Communication needs	0.856	0.860
Psychosocial needs	0.861	0.855
Autonomy & respect needs	0.902	0.874

 Table 4: The Kappa Coefficient of each selected 10 items in the

 developed 'Healthcare Need Assessment-Subfertility' Tool.

#### IV. DISCUSSION

The newly developed 'Healthcare Need Assessment- Subfertility' (HNA-Sf) tool is a valid and reliable tool to measure the healthcare needs of sub-fertile couples. It comprised 37 items in five main domains named basic information needs, information needs on treatments, communication needs, psycho-social needs, and autonomy and respect needs. To the best of the author's knowledge, this is the first validated instrument to assess the healthcare needs of sub-fertile couples.

The tool development process was planned meticulously to minimize potential biases and ensure the quality of the outcomes. First, with a comprehensive literature search and with expert opinion, a construct for healthcare needs was developed that includes all the domains representing healthcare needs. A systematic stepwise procedure was used to identify items. Obtaining expert opinion for the selection of items, forward and backward translation of the draft tool, pretesting of it, and assessing psychometric properties, contributed to the improvement of the quality of the tool (24).

Item generation was completed through different methods that included a thorough literature search, Focus Group Discussions (FGD), and In-depth Interviews (IDI) with relevant stakeholders. A similar approach has been followed by a study done by Gail et al, 2012 in the development of the 'Supportive Care Need Survey-Short form 34 (SCNS-SF 34) tools to assess the supportive care needs of cancer patients. As the Principal Investigator (PI) conducted all the qualitative interviews, inter-observer bias was eliminated, although intra-observer or researcher bias may have remained. To minimize this bias and to ensure the uniformity of all interviews, an interviewer guide was used by the Principal Investigator (PI) during interviews.

Exploratory Factor Analysis (EFA) was performed on the newly developed HNA-Sf tool for the male and female partners separately to explore the underline factor structure with a crosssectional study. It created a similar five-factor (domain) model in Health Need Assessment Subfertility (HNA-Sf) tool for both male and female partners. Therefore, the same tool (i.e., the HNA-Sf tool) was used to assess the healthcare needs of both partners. This is comparable with global literature, where the same tool had been used to assess the different aspects of the needs of both male and female partners. Examples include Cardiff Fertility Knowledge Scale (16) and the Patient-centered Care Questionnaire (8).

In the absence of a gold standard to assess the criterion validity, which is the best form of validation, the HNA-Sf tool was validated through the below-mentioned methods. The expert panel evaluated the relevance of each item to the construct to assess the healthcare needs of sub-fertile couples and the cultural appropriateness of the wording in the developed HNA-Sf tool with a score that confirmed the content validity (24). Exploratory Factor Analysis was carried out for the data collected through a cross-sectional study to explore the underlying factor structure of the newly developed HNA-Sf tool. Exploratory Factor Analysis established the construct validity of the tool, and it was used for

the selection of the best items for the tool and to test the psychometric properties of the tool (24, 25).

Several measures were adopted to minimize sampling errors in EFA. Sampling adequacy was checked using the Kaiser Meyer Olkin (KMO) measurement. The KMO for female partners was 0.938 and for male partners, it was 0.949. Those are well above the acceptance level of 0.5 (26). Bartlett's Test of Sphericity in both male and female participants was significant, which showed that the population correlation matrix is significantly different from the identified matrix (p<0.01.). These confirmed the sampling adequacy and factorability of the data set. The following measures were taken to minimize information bias in validation studies. Only two data collectors were used to collect data to minimize inter-observer variation. Before data collection, two-day training sessions for data collectors were arranged to ensure uniform administering of the tool, and the PI made random checks on the data collection procedure.

The reliability assessment ensures the stability of the instrument. The internal consistency of each domain of the male and female sub-fertile partners was assessed with Cronbach's alpha and for each domain, it was well above 0.7 indicating good internal consistency.

The good temporal stability of the instrument was assessed with test-retest reliability. Values of Kappa lower than 0.4 are considered poor. A Kappa coefficient between 0.6-0.8 is considered a substantial agreement and above 0.8 are considered

Items	Kappa Coefficient
To know about how the baby is conceived	0.826
To know about the places, where we should	0.773
go first, to start treatment	
To get to know about the availability of	0.788
treatment options in the government sector	
free of charge.	
To know about the adverse effects arising	0.909
from the treatments for subfertility.	
To get to know about what issue would be	0.870
addressed by the treatment that I and my	
partner are undergoing	
To receive emotional support from my partner	0.780
in stressful situations caused by subfertility	
To minimize the use of English technical	0.823
words by health staff when explaining the	
situation and the treatments	
The willingness of the partner to actively	0.832
participate in the treatment of subfertility	
To discuss my problems regarding subfertility	0.873
with the Public Health Midwife in the field	
Maintenance of my/my partner's privacy at	0.831
the examination, investigations, and	
treatments	

an almost perfect agreement (23). The kappa coefficient of items varied between 0.773 to 0.908 indicating a substantial to almost

perfect agreement indicating good temporal stability of the HNA-Sf tool.

# V. CONCLUSION

The newly developed HNA-Sf tool for assessing multidimensional aspects of the healthcare needs of sub-fertile couples reported adequate validity and reliability. Therefore, this tool can be used to measure the healthcare needs of sub-fertile couples and improve the provision of facilities for the management of subfertility. The tool would be useful for the process of service evaluation and policymaking.

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# References

- Gnoth C, Godehardt E, Frank-Herrmann P, Friol K, Jürgen Tigges, Freundl G: Definition and prevalence of subfertility and infertility. *Human Reproduction* 2005, 5:20 Pages 1144– 1147, <u>https://doi.org/10.1093/humrep/deh870</u>
- 2. Bakhtiari A, Basirat Z, Nasiri-Amiri F: Sexual dysfunction in women undergoing fertility treatment in Iran: prevalence and associated risk factors. *Journal of reproduction & infertility* 2016, Jan 17(1):26.
- **3.** Tabong PT, Adongo PB: Infertility and childlessness: a qualitative study of the experiences of infertile couples in Northern Ghana. *BMC pregnancy and childbirth* 2013, Dec;13(1):1-0.
- 4. Klitzman R: Impediments to communication and relationships between infertility care providers and patients. *BMC women's health* 2018, 18(1):1-2.
- 5. Ombelet W: Global access to infertility care in developing countries: a case of human rights, equity and social justice. Facts, views & vision. bGyn. 2011, 3(4):257.
- 6. Lansakkara L: Psychological aspects of infertility, among currently married females in reproductive age and the service needs of fertility impaired couples in the district of Colombo. *Thesis in, Post Graduate Institute of Medicine 2006*
- Wright J, Williams R, Wilkinson JR: Development and importance of health needs assessment. BMJ. 1998 Apr 25;316(7140):1310-3. doi: 10.1136/bmj.316.7140.1310. PMID: 9554906; PMCID: PMC1113037.
- 8. Van Empel IW, Nelen WL, Tepe ET, van Laarhoven EA, Verhaak CM, Kremer JA: Weaknesses, strengths and needs in fertility care according to patients. *Human Reproduction* 2010, Jan 1;25(1):142-9.
- **9.** Bennett LR, Wiweko B, Bell L, Shafira N, Pangestu M, Adayana IP, Hinting A, Armstrong G: Reproductive knowledge and patient education needs among Indonesian women infertility patients attending three fertility clinics. *Patient education and counseling* 2015, Mar 1;98(3):364-9.
- 10. Dancet EA, Van Empel IW, Rober P, Nelen WL, Kremer JA, D'Hooghe TM: Patient-centred infertility care: a qualitative study to listen to the patient's voice. *Human Reproduction* 2011, Apr 1;26(4):827-33.
- 11. Vayena E, Rowe PJ, Griffin PD: Current practices and controversies in assisted reproduction: report of a meeting on

This publication is licensed under Creative Commons Attribution CC BY. http://dx.doi.org/10.29322/IJSRP.13.05.2023.p13723 medical, ethical and social aspects of assisted reproduction, held at WHO Headquarters in Geneva, Switzerland. World Health Organization; 2002.

- 12. Brandes M, van der Steen JO, Bokdam SB, Hamilton CJ, de Bruin JP, Nelen WL, Kremer JA: When and why do subfertile couples discontinue their fertility care? A longitudinal cohort study in a secondary care subfertility population. *Hum Reprod* 2009, Dec;24(12):3127-35.
- 13. Yakout SM, Talaat M, Fayad EM: Emotional problems of Infertile Egyptian women. *Journal of Nursing Education and Practice* 2017, 7(1).
- 14. Jafarzadeh-Kenarsari F, Ghahiri A, Zargham-Boroujeni A, Habibi M: Exploration of the counseling needs of infertile couples: A qualitative study. *Iranian Journal of Nursing and Midwifery Research* 2015, Sep;20(5):552.
- 15. Bakhtiari A, Basirat Z, Nasiri-Amiri F: Sexual dysfunction in women undergoing fertility treatment in Iran: prevalence and associated risk factors. *Journal of reproduction & infertility* 2016 Jan;17(1):26.
- 16. Bunting L, Tsibulsky I, Boivin J: Fertility knowledge and beliefs about fertility treatment: findings from the International Fertility Decision-making Study. *Human reproduction* 2013, Feb 1;28(2):385-97.
- 17. Hasanpoor-Azghdy SB, Simbar M, Vedadhir A: The emotional-psychological consequences of infertility among infertile women seeking treatment: Results of a qualitative study. *Iranian journal of reproductive medicine* 2014, Feb;12(2):131.
- Peterson BD, Pirritano M, Christensen U, Boivin J, Block J, Schmidt L: The longitudinal impact of partner coping in couples following 5 years of unsuccessful fertility treatments. *Human reproduction* 2009, Jul 1;24(7):1656-64.
- 19. Redding CA, Maddock JE, Rossi JS: Measurement of Theoretical Constructs for Health Behavior. *Californian Journal of Health Promotion* 2006, Mar 1;4(1):83-101.
- 20. Family Health Bureau: Annual report 2019, Volume 19, ISSN 2345-9484, page 12.
- 21. Comrey AL, Lee HB: A first course in factor analysis (2nd edition). *New York: Routledge* 1992. Available from: <u>https://www.taylorfrancis.com/books/</u> 9781315827506
- 22. Izquierdo I, Olea J, Abad FJ: Exploratory factor analysis in validation studies: uses and recommendations. *Psicothema* 2014, 26(3):395-400
- 23. Landis JR, Koch GG: The measurement of observer agreement for categorical data. *Biometrics* 1977 Mar 1:159-74.
- 24. Streiner DL, Norman GR, Cairney J: Health measurement scales: a practical guide to their development and use. *Oxford University Press, USA* 2015
- 25. Wijesinghe SD, Fernando DN: Maternal Perceptions of Quality of Antenatal Care Services in Sri Lanka: Development and Validation of a Multi-dimensional Instrument. *International Journal of Interdisciplinary and Multidisciplinary Studies* 2014;1(10):171-9.
- 26. Cerny BA, Kaiser HF. A study of a measure of sampling adequacy for factor-analytic correlation matrices. *Multivariate behavioral research* 1977, Jan 1;12(1):43-7

## 182

## AUTHORS

**First Author** – Gayani Gunawardhana - Health Promotion Bureau, Ministry of Health, Sri Lanka. gayanikau@gmail.com Second Author – Sanjeeva Godakandage – Family Health Bureau, Ministry of Health, Sri Lanka. sspgodakandage@yahoo.com Third Author – Manuj Weerasinghe- Department of Community Medicine, Faculty of Medicine, University of Colombo, Sri Lanka. manujchri@gmail.com Correspondence Author – Gayani Gunawardhana gayanikau@gmail.com