

The fertility quality of life (FertiQoL) tool: development and general psychometric properties[†]

Jacky Boivin^{1,*}, Janet Takefman², and Andrea Braverman³

¹Cardiff Fertility Studies Research Group, School of Psychology, Cardiff University, Tower Building, Park Place, Cardiff Wales CF10 3AT, UK

²McGill University Health Centre, Reproductive Centre, Department of Obstetrics and Gynecology, McGill University, Montreal, Canada

³Department of Obstetrics and Gynecology, University of Medicine and Dentistry of New Jersey, Newark, NJ, USA

*Correspondence address. E-mail: boivin@cardiff.ac.uk

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BACKGROUND: To develop the first international instrument to measure fertility quality of life (FertiQoL) in men and women experiencing fertility problems, to evaluate the preliminary psychometric properties of this new tool and to translate FertiQoL into multiple languages.

METHOD: We conducted a survey, both online and in fertility clinics in USA, Australia/New Zealand, Canada and UK. A total of 1414 people with fertility problems participated. The main outcome measure was the FertiQoL tool.

RESULTS: FertiQoL consists of 36 items that assess core (24 items) and treatment-related quality of life (QoL) (10 items) and overall life and physical health (2 items). Cronbach reliability statistics for the Core and Treatment FertiQoL (and subscales) were satisfactory and in the range of 0.72 and 0.92. Sensitivity analyses showed that FertiQoL detected expected relations between QoL and gender, parity and support-seeking. FertiQoL was translated into 20 languages by the same translation team with each translation verified by local bilingual fertility experts.

CONCLUSIONS: FertiQoL is a reliable measure of the impact of fertility problems and its treatment on QoL. Future research should establish its use in cross-cultural research and clinical work.

Key words: infertility / quality of life / psychology / treatment / assisted reproductive technologies

Introduction

'Quality of life' (QoL) was defined by the World Health Organization (WHO) as an '... individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns...' (WHOQOL, 1995). The WHOQOL measures QoL broadly according to 29 facets (e.g. self-esteem, mobility and safety). QoL measurement is important to identify aspects of fertility problems associated with poor QoL and advance research in health service-evaluation, patient satisfaction and policy-making through the use of a standard measurement tool (Saxena *et al.*, 2001).

Psychosocial studies convincingly demonstrate a high incidence of negative reactions to infertility and its treatment (Verhaak *et al.*, 2007) that impact on overall life satisfaction and well-being (Greil, 1997), success of treatment (Boivin and Schmidt, 2005), willingness to continue with treatment (Smeenk *et al.*, 2004), treatment evaluation (Dancet *et al.*, 2010) and the long-term satisfaction people can

hope to achieve if treatment is unsuccessful and they remain childless (Daniluk, 2001). Therefore, the need to measure and take into account QoL in infertility is imperative and tackling this measurement hurdle could lead to improved patient outcomes.

The 14 existing self-report measures of infertility-specific distress, treatment reactions and QoL shown in Supplementary data, Table SI do not fulfill the need for a fertility specific QoL assessment tool (the table includes details of development sample, content and reference). The fertility problem inventory (FPI: Newton *et al.*, 1999) is the most frequently used distress measure. However, the items were developed without consultation with people experiencing fertility problems and the validation sample comprised primarily Caucasian patients from a homogeneous socioeconomic category using assisted reproductive techniques. Further, the FPI assesses level of strain rather than the broader construct of QoL and does not separate effects due to infertility treatment from those due to childlessness, which is important given the emotional challenges of each. These issues apply to most measures listed in Supplementary data, Table SI. The

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most frequently used QoL measure was developed for women suffering from polycystic ovarian syndrome (Cronin *et al.*, 1998). Several studies have examined its psychometric properties (Jones *et al.*, 2008) and used it to investigate moderators of QoL (e.g. obesity) and cross-cultural effects. Results confirm its reliability and the importance of cultural background as a moderator of QoL (Schmid *et al.*, 2004; Adamson, 2009). However, this and other quality of life measures for infertility were designed for specific sub-populations (e.g. endometriosis, male factor) and therefore cannot be used as generic measure for all people with fertility problems.

In summary, the need for a quality of life measure for infertility measure has not been fully met. Given the importance of addressing this need, the European Society of Human Reproduction and Embryology (ESHRE) and the American Society of Reproductive Medicine (ASRM) joined forces with Merck-Serono S.A. Geneva-Switzerland (an affiliate of Merck KGaA Darmstadt, Germany) to create the fertility quality of life (FertiQoL) measure (2002–2009). The overall aim of the FertiQoL project was to develop an international instrument to measure QoL in men and women experiencing fertility problems. Secondary aims were to evaluate the psychometric properties of the tool and to translate FertiQoL in multiple languages. The development phase was carried out according to the protocol used for the development of the WHOQOL measure (WHO, 1998) and is briefly described in the present article. However, the main focus of this report is on the psychometric evaluation.

Methods

Participants

Men and women experiencing fertility difficulties with and without medical experience were sampled from one fertility clinic in Australia, Canada, New Zealand, UK and two clinics from the USA. Patient advocacy websites in these countries (i.e. ACCESS, American Fertility Association, Resolve, Infertility Awareness Association of Canada, International Consumer Support for Infertility, Infertility Network UK) hosted the online survey. The clinic sample consisted of 291 women and 75 men, and the online sample consisted of 1014 women and 34 men. The Ethics Committee of the School of Psychology, Cardiff University approved the online study and the Internal Review Board of each clinic approved the clinic studies.

Materials

The *Background Information Form* covered socio-demographic status (e.g. age, education), medical history (e.g. current illness) and fertility-related characteristics (e.g. duration of infertility).

FertiQoL prototype: The FertiQoL items were designed to translate abstract concepts (e.g. commitment, sense of belonging) into quantitative items that could collectively indicate the impact of fertility problems on QoL. Full details of item generation for the prototype are described in the Supplemental file and briefly presented here. As shown in Table I, item-generation involved four stages: generating potential items; eliminating redundant, irrelevant and outlier items; validation among people with fertility problems, and cross-cultural survey of acceptability and feasibility. A comprehensive literature review and consultation with psychosocial infertility experts generated an initial pool of 302 items on consequences of fertility problems on QoL in the following 14 areas (e.g. marriage/partnership, social network, emotions, cognitions,

coping, treatment, physical health etc.). The authors classified the 302 items into three levels of increasing concept specificity: dimensions (e.g. interpersonal), domains (e.g. partner relationship) and facets (e.g. intimacy) to form groups of items tapping into related aspects of QoL. Classification and subsequent focus groups reduced this pool to 102 items, which were submitted to the acceptability and feasibility study (see Table I). The prototype evaluated in the present study included these 102 Core items and 27 optional treatment items identified through the feasibility and acceptability phase.

Translation

FertiQoL was produced in English and translated into 20 languages: Arabic, Chinese, Croatian, Danish, Dutch, English, Finnish, French, German, Greek, Hindi, Italian, Portuguese, Romanian, Russian, Serbian, Spanish, Swedish, Turkish and Vietnamese (see www.fertiqol.org to download FertiQoL; Korean and Hungarian versions in progress). Cardiff University professional translators carried out the first translation, and two local fertility experts reviewed it to ensure that it was appropriate to local customs and fertility word usage. Cross-cultural data will be presented in a separate paper.

Procedure

The items in the prototype FertiQoL survey were randomly presented and rated on a scale of 0–4, where higher scores indicated more favorable QoL. The online survey (prototype FertiQoL and Background Information Form) was designed using SurveyTracker software for Training Technologies, inc and the paper version for clinic distribution was designed using InDesign. Webmasters were provided with a hyperlink to the survey. In clinics, FertiQoL coordinators at each site distributed the study pack to consecutive patients who returned completed surveys anonymously in a marked collection box in the patient waiting room.

Statistical analysis

Data were screened and duplicate internet protocol (IP) addresses were eliminated unless of different gender and response pattern. Descriptive statistics and correlations were used to identify the best items for each *a priori* domain of QoL (e.g. emotional, mind/body, relational and social). This *a priori* work was done to ensure that conceptually similar groups of items were entered into the factor analysis. Factor analyses (orthogonal rotation) were computed (clinic, online) to ascertain relations among these items. Items with factor loadings less than 0.30 and eigenvalues less than one were eliminated. The FertiQoL total and subscale scores were computed and transformed to scaled scores and summary statistics (e.g. reliability coefficient, mean and standard deviation) produced. Scaled scores were computed to achieve a range of 0–100, making comparisons between scales easier. For scaling, items were reverse-scored (where necessary); all items then summed and multiplied by 25/k, where k was the number of items in the desired subscale or total scale. Higher scores mean better QoL. For the sake of brevity, only final analyses are shown here. These analyses generated the final FertiQoL, which composed 24 core items, plus 10 optional treatment items). See www.fertiqol.org for final FertiQoL in all languages and for scoring instructions.

Results

Sample characteristics

Table II shows background characteristics and these show that the Clinic group were older, and included more men, single women, same-sex couples and people with a university-education, but fewer American and UK residents and people living in rural/

Table 1 FertiQoL item generation, selection and reduction.

Task and aims	Participants	Materials	Outcome
Literature review and expert consultation to generate potential items	Psychosocial experts in reproductive health ($n = 17$) FertiQoL Steering Committee ($n = 10$) Groups included: researchers, psychologists, social workers, counselors, patients, gynecologists, nurses, clinicians in 11 countries: Australia, Canada, Denmark, France, Germany, Italy, New Zealand, Sweden, Switzerland, UK, USA	Psychosocial studies Existing fertility-related tools Treatment evaluation tools QoL measures WHO development manual	302 items in 14 domains (e.g. partnership, self-esteem and career)
Classification and reduction of item pool to eliminate redundant or irrelevant items or rare QoL effects	FertiQoL Technical Working Group (Boivin, Takefman, Braverman) and expert panel	WHO selection criteria: items should be revealing of QoL, cover key domains, use simple language, ask about single issues, free of ambiguity, etc	Item pool reduced to 116 items WHO response scales matched to items
Focus groups with patients to validate the items generated by the experts and uncover any effects overlooked by the experts	17 focus groups ($n = 136$ participants): Canada, Germany, Mexico, USA, Italy ^a Purposive sampling for age (< or >35 years), gender, duration of infertility (< or >2 years) and parity (< or >1 child) Psychosocial experts facilitated open, unstructured discussion groups followed by structured feedback exercise on FertiQoL item pool; duration 1.5–2 h	Structured interview guide (facilitators), workbooks (participants) and 116 item-pool FertiQoL	Item decrease from 116 to 102 (22 items eliminated and 8 added) based on > or <50% endorsement Added 18 treatment items; Wording corrected; eliminated and/or combined redundant items; improved face validity; ensured items pertained to QoL and response scale appropriate
Survey to assess acceptability and feasibility of FertiQoL item style in different languages	$n = 525$ men and women in 10 countries: Argentina ($n = 48$), Brazil ($n = 96$), Canada ($n = 59$), France ($n = 63$), Germany ($n = 37$), Greece ($n = 32$), Italy ($n = 47$), Mexico ($n = 46$), New Zealand ($n = 11$), Spain ($n = 43$), UK ($n = 79$) and the USA ($n = 43$)	102 Core FertiQoL + 27 optional treatment items Additional items inquired about clarity, coverage and problems with item pool Material translated by experts	Final Core FertiQoL pool for psychometric phase was 102 items + 27 optional Treatment items FertiQoL well accepted, perceived to be important and timely Items easy to understand and relevant FertiQoL completing 15–20 min Main problems: items that did not apply to all people (e.g. single or untreated) and timeframe for 'Instructions' required

WHO, World Health Organization; TWG, technical working group (Boivin, Takefman, Braverman). FertiQoL TWG involved in all aspects of project development.

^aFocus groups in Singapore cancelled due to the Severe Acute Respiratory Syndrome (SARS) virus.

suburban areas compared with the Online sample. The Clinic sample was more likely to have at least one child, a shorter duration of infertility but less likely to have other health problems.

Item analyses

Descriptive and inferential statistics were used to screen for problematic items. Items were deleted for several reasons [i.e. highly skewed

Table II Demographic characteristics of the online and clinic samples^a.

Variable	Online (n = 1048)	Clinic (n = 366)	Test statistic (χ^2 or t)
Demographic			
Age in years mean (SD)	32.9 (4.9)	35.2 (4.0)	7.9 ^b
Women % (n)	96.8 (1014)	79.5 (291)	113.4 ^b
Relationship status % (n)			49.4 ^b
Single	0.2 (3)	4.0 (13)	
In stable relationship			
Same-sex	1.7 (18)	6.2 (20)	
Heterosexual	98.0 (1027)	89.8 (289)	
Years in partnership mean (SD) ^d	6.85 (3.9)	7.0 (3.9)	0.6
University education (% yes, n)	57.1 (598)	66.2 (139)	9.5 ^c
Residence % (n)			40.4 ^b
Urban	28.3 (296)	27.1 (95)	
Suburban	55.8 (584)	69.5 (244)	
Rural	15.9 (166)	3.4 (12)	
Country % (n)			243.4 ^b
Australia/NZ	14.5 (152)	25.1 (92)	
Canada	10.3 (108)	42.0 (154)	
UK	8.7 (91)	2.7 (10)	
USA	64.1 (672)	30.2 (111)	
Other	2.4 (25)	—	
Reproductive characteristics			
Parenthood % (n)	18.9 (197)	30.1 (108)	19.8 ^b
Years infertile mean (SD)	3.4 (2.9)	2.9 (2.0)	2.4 ^c
Know why infertile, % (n)	75.4 (790)	70.3 (225)	3.3
Perceived diagnosis % (n)			82.4 ^b
Unexplained	10.9 (86)	14.0 (38)	
Female factor	44.5 (351)	18.0 (49)	
Male factor	19.9 (157)	21.7 (59)	
Mixed	11.9 (94)	14.7 (40)	
Same-sex	1.6 (13)	3.3 (9)	
Age-related	4.1 (32)	8.8 (24)	
Other	7.1 (56)	19.5 (53)	
Other health problems % (n)	30.8 (309)	24.0 (260)	5.8 ^c
Years treated mean (SD)	2.03 (2.4)	2.43 (1.8)	1.6

A total of 491 people did not provide data years of treatment due to no treatment experience or missing data.

^aSample size varies per variable.

^b $P < 0.001$.

^c $P < 0.05$.

^dFor people in partnerships.

distribution, high inter-correlations (of >0.80 among item set), poor scale coherence, interpretive issues]. Other items were deleted because they measured broad constructs (e.g. self-esteem) that could be better captured by measures designed for that purpose and that, if retained, would confound associations with those measures in future research. The final FertiQoL item set submitted for exploratory factor analysis was comprised of 24 items from the core set of items and 10 items from the optional treatment module. The 24 core items were conceptualized as reflecting QoL in the emotional, mind-body (i.e. cognitive and physical), relational and social domains. The 10 optional treatment items were conceptualized as

indexing treatment environment and treatment tolerability. An additional two items measuring satisfaction with QoL and physical health were retained for the FertiQoL measure to indicate general physical and QoL satisfaction, but were not included in the factor analysis.

Exploratory factor analyses and internal consistency

Kaiser-Meyer-Olkin measures of sampling adequacy were >0.80 demonstrating sufficient inter-correlation among items to perform

Table III Factor loadings for online and clinic (in parenthesis) samples on FertiQoL items.

	Core FertiQoL				Optional Treatment FertiQoL module	
	Emotional	Relational	Mind/body	Social	Treatment environment	Treatment tolerability
Angry	0.752 (0.800)					
Grief/loss	0.763 (0.792)					
Sad/depressed	0.730 (0.772)					
Fluctuate hope/despair	0.643 (0.759)					
Jealousy and resentment	0.737 (0.634)					
Unable to cope	0.640 (0.594)					
Affectionate		0.749 (0.732)				
Difficult to talk		0.629 (0.696)				
Negative impact on relationship		0.707 (0.633)				
Content relationship		0.768 (0.616)				
Strengthen relationship		0.713 (0.603)				
Satisfied sexual relationship		0.575 (0.600)				
Fatigue			0.731 (0.745)			
Pain/discomfort			0.566 (0.663)			
Feel worn out ^b			0.620 (0.627)			
Disrupt activities			0.704 (0.625)			
Concentration	(0.634) ^a		0.554 (0.413)			
Life on hold ^b	(0.577) ^a		0.572 (0.355)			
Family understand				0.669 (0.669)		
Friend support				0.751 (0.649)		
Society expect				0.495 (0.446)		
Isolated	(0.558) ^a			0.509 (0.531)		
Handle/pregnant others ^b	0.538 ^a (0.589) ^a			0.306 (0.350)		
Shame, embarrassment ^b	0.527 ^a (0.580) ^a			0.319 (0.440)		
Interactions with staff					0.813 (0.784)	
Quality treatment information					0.802 (0.784)	
Quality surgery and medical treatment					0.780 (0.763)	
Fertility staff understand us					0.728 (0.750)	
Quality emotional services					0.632 (0.664)	
Medical services desired available					0.576 (0.585)	
Bothered effect daily activities and work						0.799 (0.790)
Bothered physical effects						0.792 (0.732)
Complicated medication and procedures						0.645 (0.715)
Treatment effects on mood						0.645 (0.681)
Online eigenvalue (% variance)	7.62 (31.8)	2.61 (10.9)	1.44 (6.0)	1.16 (4.8)	3.48 (34.9)	1.92 (19.3)
Clinic eigenvalue (% variance)	8.93 (37.8)	2.37 (9.9)	1.23 (5.1)	1.08 (4.5)	3.80 (38.0)	1.68 (16.8)

Bold indicates first item of each domain.

Some items reversed to avoid negative loadings. See www.fertiqol.org for final FertiQoL item wording, response scale wording and downloads in 20 languages. Only factor loadings >0.30 are shown. Factor loadings for Clinic sample in parenthesis.

^aIndicates a cross-loadings.

^bWording for these items changed as a result of psychometric evaluation and participant feedback.

Table IV Means and standard deviations for FertiQoL subscales and total scaled scores for the validation sample (online, clinic combined).

Scale	<i>n</i>	QoL domain	Number of items	Cronbach alpha	Mean (SD) Scaled score 0–100
Core subscales					
Emotional	1349	Impact on emotions (e.g. causes sadness, resentment, grief)	6	0.90	45.10 (23.2)
Mind-body	1338	Impact on physical health (e.g. fatigue, pain), cognition (e.g. poor concentration) and behavior (e.g. disrupted daily activities)	6	0.84	54.86 (21.2)
Relational	1330	Impact on partnership (e.g. sexuality, communication and commitment)	6	0.80	68.70 (19.2)
Social	1343	Impact on social aspects (e.g. social inclusion, expectations and support)	6	0.75	51.10 (20.6)
Core FertiQoL	1226	Average quality of life in all core domains	24	0.92	54.60 (16.8)
Treatment subscales					
Environment	1072	Impacts related to treatment environment (e.g. access, quality, interactions with staff)	6	0.84	61.53 (19.6)
Treatment tolerability	1093	Impacts due to consequences of treatment (e.g. physical and mode effects, daily disruptions)	4	0.72	58.81 (20.6)
Treatment FertiQoL	1043	Average quality of life for all treatment domains	10	0.81	60.43 (16.2)
Total FertiQoL	930	Average quality of life for all core and treatment domains	34	0.92	55.43 (14.8)

All items reversed or scored so that higher scores indicate more favorable QoL. Core FertiQoL refers to see www.fertiqol.org for final FertiQoL items, response scale wording and downloads in 20 languages. Bold refers to total scores.

factor analyses. Table III shows factor loadings for the Online and (in parenthesis) Clinic samples for the Core FertiQoL and Optional Treatment Module domains. The first factor explaining item variance in the Core FertiQoL was the Emotional subscale explaining 31.8% (Online) and 37.8% (Clinic) of the item variability. Other factors (mind/body, relational and social) explained 10% or less of the item variance but all eigenvalues were above one. Loadings showed that items conceptualized to tap into the same concepts all had high factor loadings (>0.30) on their designated factor. Cross-loadings were observed for items of the mind/body (i.e. concentration, life on hold) and social domains (i.e. isolation, shame) onto the emotional domains. For the Optional Treatment Module, the first factor was Treatment Environment, explaining 34.0% (Online) and 38.0% (Clinic) of item variance. There were no cross-loadings for the Treatment Quality and Treatment Tolerability subscales. Table IV shows summary information for all FertiQoL scales. Core FertiQoL and Treatment FertiQoL were normally distributed and individual subscales were normally distributed (data not shown), with only the relational subscale showing mild positive skew toward more favorable QoL in this domain.

Sensitivity analyses for sub-scales and total scores

Potential moderators of QoL (gender, parenthood status and recruitment source) were examined in relation to FertiQoL scores. Women had a significantly lower Core FertiQoL ($M = 53.3$, $SD = 16.2$) than did men ($M = 72.1$, $SD = 14.7$) ($t(1224) = 10.3$, $P < 0.001$). Core FertiQoL was significantly lower for participants without children ($M = 53.3$, $SD = 16.3$) than participants with children ($M = 59.5$, $SD = 17.7$) ($t(1217) = 5.27$, $P < 0.001$). Participants recruited from

the online patient advocacy and support sites had significantly lower scores ($M = 50.7$, $SD = 15.1$) than did participants recruited from clinics ($M = 67.8$, $SD = 15.6$) ($t(1224) = 16.6$, $P < 0.001$).

The relationship between treatment subscales and six treatment persistence items (e.g. likelihood of trying further treatment, couple agreeing to persist, thinking of ending treatment) was also examined. Greater intention to persist with treatment was significantly associated with better Treatment FertiQoL ($r(1026) = 0.172$, $P < 0.001$), especially in the Clinic sample ($r(206) = 0.289$, $P < 0.001$).

Discussion

It is currently accepted that to effectively measure the impact of disease, one needs a disease-specific instrument (WHOQOL, 1995). FertiQoL is a reliable and sensitive measurement tool for QoL in individuals with fertility problems. More than 2000 people with fertility problems contributed to the creation of FertiQoL, and it was developed using an integrated mixed-method approach that included literature reviews, international expert consultations, patient focus groups, a cross-cultural feasibility and acceptability survey, and a psychometric survey evaluation. FertiQoL comprises of a Core module evaluating the impact of fertility problems on emotional, mind-body, relational and social domains and an optional Treatment module evaluating treatment environment and tolerability. Subscales and total scales show mainly high reliability and sensitivity of FertiQoL to well-established moderators of QoL. FertiQoL is available in 20 languages with more translations in progress. This project was fully realized as a result of collaboration among ESHRE, ASRM and Merck S.A. Geneva-Switzerland (an affiliate of Merck KGaA Darmstadt, Germany). It is expected that FertiQoL will significantly

contribute to future research and clinical endeavors aimed at investigating and ultimately improving QoL in people with fertility problems.

Certain methodological limitations need to be taken into account. First, despite the multi-disciplinary contributions from experts worldwide, focus groups and a feasibility and acceptability study in 10 countries, the final psychometric evaluation only occurred in five English-speaking countries. Second, targeted efforts to recruit a diverse group of people were not entirely successful in recruiting particular subgroups (i.e. secondary infertile, men). Indeed, more psychometric research on men is required to fully establish reliability and validity. Third, the major proportion of the final sample was recruited online, and differences between the Online and Clinic sample were observed. Although, data generated online have been shown to be as valid as data collected through traditional methods (Bunting and Boivin, 2007; Lieberman, 2008), one would need to determine whether the differences observed warrant a more in-depth analysis—for example, a different set of norms for clinic samples. We eliminated records coming from the same IP address but it may be possible that the same person replied more than once to the survey. Finally, the subscales of the Core FertiQoL were not entirely orthogonal with cross-loadings on the social and mind/body domains. While these associations are expected, we have now modified the final wording of four FertiQoL items to reduce these cross-loadings. Further evaluation of these changes and FertiQoL as a whole on a new sample is required for final validation. These main limitations should be addressed in future psychometric research evaluating FertiQoL. However, the strengths of our mixed-method approach, and consultation and evaluation from infertile people ensure that FertiQoL captures the key life domains affected by fertility problems. It is hoped that FertiQoL will become a gold standard for the measurement of QoL for individuals experiencing fertility problems (whether in treatment or not).

FertiQoL will be useful to clinicians and researchers alike. FertiQoL can be used to identify people at risk of impaired QoL so that psychosocial resources can be offered and subscale scores could identify the specific domains where intervention might be most beneficial. Recent research has shown a close correspondence between Core FertiQoL and standardized measures of anxiety and depression in a Dutch sample (Aarts et al., 2011). The availability of FertiQoL in 20 languages will facilitate essential cross-cultural research, particularly in developing nations (Ombelet et al., 2008; van Balen and Bos, 2010). However, whether cross-cultural differences exist, whether different populations have different mean scores and whether separate cultural norms are needed are all important questions that need to be addressed in future research.

A unique aspect of FertiQoL compared with other QoL measures is the optional 10-item treatment module. This module measures QoL in respect of treatment quality (interactions with staff, quality of information), and treatment tolerability (effects on mood, disruptions daily life). These subscales can be used to assess effectiveness of new treatments/medications, to monitor quality of services and to optimize patient treatment experiences. Research has shown that quality of treatment and its tolerability are predictors of treatment satisfaction (Dancet et al., 2010) and willingness to persist with treatment (Olivius et al., 2004), the latter also shown in the present study. Further a recent large, multi-centered study showed a strong association between a high level of patient-centered care and favorable FertiQoL scores (Aarts et al., 2010). However, the sensitivity of

Treatment FertiQoL for these purposes needs to be investigated in clinical trials of new interventions.

In conclusion, the overall aim of the FertiQoL project was to develop an international instrument to measure QoL in men and women experiencing fertility problems, with the collaboration of individuals experiencing fertility problems and international experts in the field. This objective was accomplished and future use of FertiQoL will be essential to establish FertiQoL as an essential measurement tool for practice, research, health service-evaluation and policy-making.

Supplementary data

Supplementary data are available at <http://humrep.oxfordjournals.org/>.

Authors' roles

All authors participated in the development of FertiQoL and its multiple studies. J.B. and J.T. wrote the manuscript, and A.B. reviewed it.

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References

- Aarts JWM, van Empel IW, Boivin J, Kremer JAM, Verhaak CM. Quality of life measure as an extra tool for delivering patient-centred care. In: *Annual Meeting of the European Society for Human Reproduction & Embryology*, Rome, 2010.
- Aarts JWM, van Empel IWH, Boivin J, Nelen WK, Kremer JAM, Verhaak CM. Relationship between quality of life and distress in infertility: a validation study of the Dutch FertiQoL. *Human Reprod*, 2011;**26**:1112–1118.

- Adamson GD. Global cultural and socioeconomic factors that influence access to assisted reproductive technologies. *Womens' Health* 2009; **5**:351–358.
- Boivin J, Schmidt L. Infertility-related stress in men and women predicts treatment outcome one year later. *Fertil Steril* 2005; **83**:1745–1752.
- Bunting L, Boivin J. Decision-making about seeking medical advice in an internet sample of women trying to get pregnant. *Hum Reprod* 2007; **22**:1662–1668.
- Cronin L, Guyatt L, Griffiths E, Wong E, Azziz R, Futterweit W, Cook D, Dunaif A. Development of a health-related quality-of-life questionnaire (PCOSQ) for women with polycystic ovary syndrome (PCOS). *J Clin Endocrinol Metabol* 1998; **83**:1976–1987.
- Dancet EAF, Nelen WLDM, Sermeus W, De Leeuw L, Kremer JAM, D'Hooghe TM. The patients' perspective on fertility care: a systematic review. *Hum Reprod Update* 2010; **16**:467–487.
- Daniluk JC. Reconstructing their lives: a longitudinal, qualitative analysis of the transition to biological childlessness for infertile couples. *J Couns Dev* 2001; **79**:439–449.
- Greil AL. Infertility and psychological distress: a critical review of the literature. *Soc Sci Med* 1997; **45**:1679–1704.
- Jones GL, Hall JM, Balen AH, Ledger WL. Health-related quality of life measurement in women with polycystic ovary syndrome: a systematic review. *Hum Reprod Update* 2008; **14**:15–25.
- Lieberman DZ. Evaluation of the stability and validity of participant samples recruited over the internet. *CyberPsychol Behav* 2008; **11**:743–745.
- Newton CR, Sherrard W, Glavac I. The fertility problem inventory: measuring perceived infertility-related stress. *Fertil Steril* 1999; **72**:54–62.
- Olivius C, Friden B, Borg G. Why do couples discontinue *in vitro* fertilization treatment? A cohort study. *Fertil Steril* 2004; **81**:258–261.
- Ombelet W, Cooke I, Dyer S, Serour G, Devroey P. Infertility and the provision of infertility medical services in developing countries. *Hum Reprod Update* 2008; **14**:605–621.
- Saxena S, Carlson D, Billington R. The WHO quality of life assessment instrument (WHOQOL-Bref): the importance of its items for cross-cultural research. *Qual Life Res* 2001; **10**:711–721.
- Schmid J, Kirchengast S, Vytiska-Binstorfer E, Huber J. Infertility caused by PCOS: health-related quality of life among Austrian and Moslem immigrant women in Austria. *Hum Reprod* 2004; **19**:2251–2257.
- Smeenk JM, Verhaak CM, Stolwijk AM, Kremer JAM, Braat DDM. Reasons for dropout in an *in vitro* fertilization/intracytoplasmic sperm injection program. *Fertil Steril* 2004; **81**:262–268.
- van Balen F, Bos HMV. The social and cultural consequences of being childless in poor-resource areas. Facts, views and vision in obstetrics and gynaecology, *Monograph* 2010; **2**:1–16.
- Verhaak CM, Smeenk JM, Evers AWM, Kremer JAM, Kraaijmaat FW, Braat DDM. Women's emotional adjustment to IVF: a systematic review of 25 years of research. *Hum Reprod Update* 2007; **13**:27–36.
- World Health Organization. *World Health Organisation Quality of Life (WHO-QOL)*. User manual. Geneva: World Health Organization, 1998.
- World Health Organization Quality of Life assessment (WHOQOL): Position paper from the World Health Organisation. *Soc Sci Med* 1995; **41**:1403–1409.