

SUPPLEMENTAL FILE B

Detailed description of FertiQoL item generation, selection and reduction

Creation of FertiQoL item pool

A mixed method approach was used to generate the FertiQoL item pool for the evaluation phase including (a) expert consultation, (b) focus groups with patients, and (c) survey with people experiencing fertility problems who were/were not undergoing treatment. This process is summarized in Table 1 of the article.

a) Expert consultation

The initial item pool for the FertiQoL measure was generated from three sources to identify the life domains affected by fertility problems and childlessness: (1) reviews of psychosocial studies in infertility, (2) existing fertility-related assessment tools (see SUPPLEMENTAL Table A), treatment evaluation tools, (3) the World Health Organization development manual (WHO, 1998) and related quality of life papers, and (4) input from psychosocial experts in reproductive health (n=17) and the FertiQoL Steering Committee (n=10) (i.e., and from various professions (researchers, psychologists, social workers, counsellors, patient user groups, gynecologists, nurses, fertility doctors) based in 11 countries (Australia, Canada, Denmark, France, Germany, Italy, New Zealand, Sweden, Switzerland, United Kingdom, United States).

This process generated 302 items related to consequences of fertility problems on quality of life covering the following topics (number in parenthesis is number of items generated per topic): marriage/partnership (40), social network (38), emotions (30), cognitions (30), coping (29), treatment (20), self-esteem (18), career and finances (18), psychological consequences (17), optimism/pessimism (17), reactions to alternative options to parenthood (16), physical health (10), importance of children (13) and impact on lifestyle (6). The FertiQoL technical working group classified the 302 items into three levels: domains (e.g., interpersonal), dimensions (e.g., partner relationship) and facets

(e.g., intimacy) to form groups of items tapping into aspects of quality of life. Each of the three levels of classification (domains, dimensions, facets) was seen to be increasingly more specific with regard to the particular aspect of quality of life being assessed. In total, 63 item-categories were generated.

This structured list was sent to the expert panel who were asked to use the World Health Organization (WHO) criteria to decide on wording and inclusion in the FertiQoL item pool presented to the focus groups (WHO, User manual, Appendix 2, p .60, 1998). These criteria were that responses to items: would be revealing of quality of life, cover key domains affected by fertility problems, used simple language (e.g., avoiding double-negatives), items asked about single issue/facet and were free of ambiguity, could be phrased as short questions, omitted any reference to historical timeframe, and were worded to be applicable to infertile people in a range of situations. This process eliminated redundant, irrelevant and infrequent effects of infertility on quality of life and the item pool was reduced to 116 items. Response scales were then matched to item content using the WHO response scales (WHO, User manual, Appendix 1, 1998): intensity (not at all – extremely); capacity (not at all – completely); frequency (never – always) and evaluation (very satisfied - very dissatisfied or very good - very poor). The reason for using multiple response scales is because not all items could be made to conform to the same scale and because diversity minimises response sets (e.g., acquiescence) (Robinson et al. 1991).

b) Focus groups

Focus groups were organized to validate the items generated by the experts against a patient's perspective. These groups were also used to uncover any important effects overlooked by the experts. Participants in the focus groups were recruited to ensure diversity according to socio-demographic characteristics found to be relevant to reactions to infertility: age (i.e., < or > 35 years, gender, duration of infertility (< or > two years of infertility) and parenthood status (see for reviews Greil et al. 1997). Four focus groups of 8 people each were conducted in Canada, Germany and Mexico, two groups of 8 people in the United States and three groups of 8 people in Italy (17 focus groups, 136

participants). Focus groups were also planned for Singapore but these were cancelled due to the Severe Acute Respiratory Syndrome (SARS) epidemic in that region.

Psychosocial experts from each country facilitated the focus groups based on materials and guidance provided by the FertiQoL technical working group. Materials were translated and back-translated to English by translators at Merck-Serono S. A. Geneva-Switzerland (an affiliate of Merck KGaA Darmstadt, Germany). This guidance comprised a participant workbook that contained items culled from those generated by fertility experts as well as a leader topic guide. The topic guide for facilitators described: (a) aim of FertiQoL; (b) its sponsors; (c) expected users (d) objectives of focus groups, and (e) instructions to facilitators to guide participants through the FertiQoL questions and elicit feedback about these. The focus groups lasted between 1.5 and two hours. This information was also conveyed to participants at the start of each focus group in a separate information sheet. Because direct face-to-face personal questioning could be awkward for as personal a topic as infertility, participants were asked to indicate reactions in terms of “what you have experienced or heard others have experienced”. Participants were first asked to describe areas of their (or others’) life positively or negatively affected by fertility problems to generate consequences independent from concepts generated by experts. Further people were asked to discuss the importance of the consequences to quality of life. Only after this open-period of discussion was the structured content introduced in the focus group. The structured content was organized around the themes and items generated by the experts (e.g., emotions, partnership, social network) were discussed. For example, participants were asked to describe any physical consequences of their fertility problems and their effect on quality of life. Facilitators used a standard feedback form to report data from their focus groups to the FertiQoL technical working Group.

Feedback from the focus group showed that participants appreciated the opportunity to provide their views and thought the FertiQoL project worthwhile. Based on their feedback we (a) eliminated items endorsed by < 50% of groups and incorporated new

facets endorsed > 50% groups. Based on general feedback we corrected wording issues (e.g., acceptable to both gender, improved clarity and specificity of wording); eliminated and/or combined redundant items; improved face validity to make clearer distinctions within and between facets; ensured all items pertained to quality of life and ensured response scale in line with items. The total number of items decreased from 116 to 102 (22 items eliminated and 8 added). The final structure included four domains (i.e., overall, personal, interpersonal, healthcare), eight dimensions (underlined below) and the 23 facets linked to them (i.e., [affect = infertility syndrome, positive feelings, hopefulness, coping effectiveness], [psychological=body image, self-perceptions, fertility fixation], [physical =health practices, somatic changes]; [spiritual=morals and beliefs, life meaning]; [partner relationship=intimacy, commitment, communication, discord, sexuality]; [social=expectations, belonging, support]; [occupation=interference]; [medical=accessibility and quality, burden of treatment]; [psychoeducational=interactions with medical team]. Together these resulted in 102 items (e.g., Do you feel sexually attractive? rated on the five-point intensity scale of not at all to extremely). The fertility experts panel further examined the items and structure (at the Annual Meeting of the American Society of Reproductive Medicine, 2003) and made minor revisions that included: fine-tuning the wording of some items (i.e., physical dimension), grouping items according to response scale (e.g., capacity, intensity), reducing the number of response scales, randomising questions within response categories. The experts also decided that it would be best to extract treatment questions to create a separate and optional treatment module because not all people who would complete FertiQoL would have treatment experience. These amendments were made and the first FertiQoL prototype created.

c) Acceptability and feasibility survey

In this phase the acceptability and feasibility of FertiQoL as an assessment tool for quality of life was investigated. Participants were recruited to ensure diversity for gender, age and education (none, primary, secondary, tertiary) but all were recruited from fertility clinics by the FertiQoL coordinator in that country. Country coordinators were responsible for ensuring that ethical approval was obtained as per country regulation.

Supplemental Table 2 in Boivin, J, Takefman, J, Braverman, A. (2011) The fertility quality of life (FertiQoL) tool: development and general psychometric properties. Human Reproduction, 26(8), 2084–2091

The core FertiQoL module and the optional FertiQoL treatment module were translated from English into the target language using forward and backward process by skilled translators with a final check of the wording performed by the fertility expert coordinator from each country. Additional items at the end of the questionnaire asked participants to indicate (a) which questions, if any were unclear and why, (b) whether there were other important areas of their life related to infertility that were not included in this questionnaire and (c) to provide any other additional comments. Materials were translated and back-translated to English by translators at Merck-Serono S. A. Geneva-Switzerland (an affiliate of Merck KGaA Darmstadt, Germany).

In total 525 people participated in participated in the acceptability phase of FertiQoL from 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), United Kingdom (n=79) and the United States (n=43). The sample was 56.5% (n=297) female, 45.5% (n=239) were aged 35 years or less and 60.7% educated to at least secondary level (n=319). The results showed that FertiQoL was well accepted in all countries with positive comments indicating that items were easy to understand, relevant and indicative of the effect infertility and its treatment had had on their quality of life. Moreover, individuals felt satisfied that such a measure was being developed and felt the time to complete, 15-20 minutes, was reasonable (men required longer time to complete). The problems reported were in relation to items that did not apply to all people, that is, single women queried partnership items, untreated people queried items about interactions with the ‘fertility medical team’ and people with secondary infertility felt items concerning life without children were not applicable. These issues were addressed but overall few modifications to FertiQoL were necessary with only 20 items altered. The other main comment related to the “Instructions” to FertiQoL and the fact that these had not provided the timeframe for thinking about items. Respondents are now instructed to complete FertiQoL in relation to ‘current thoughts and feelings’. Overall, couples attending fertility clinics provided support for the FertiQoL project.

FertiQoL was amended in light of these comments and the version for the prototype

psychometric phase was created. The item pool tested in the acceptability phase was retained despite redundancy because multiple items of each dimension/facet were required to identify the best set of items in the psychometric evaluation phase. The core FertiQoL tested in the psychometric phase contained 102 items as well as the optional treatment FertiQoL module, which contained 27 items. Ten countries submitted acceptability reports.

References

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