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Qualitative research in the ESHRE guideline on psychosocial care in infertility and medically assisted reproduction

The guideline development group of the ESHRE guideline on psychosocial care in infertility and medically assisted reproduction; S. Gameiro¹, J. Boivin¹, E. Dancet^{2,3}, M. Emery⁴, P. Thorn⁵, U. Van den Broeck², C. Venetis⁶, C.M. Verhaak⁷, T. Wischmann⁸, and N. Vermeulen⁹

Sir,

It was with interest that we read the invited commentary by Hammarberg and colleagues (Hammarberg *et al.*, 2016) on how to use and evaluate qualitative research. However, we were surprised to see them expressing disappointment 'to find that evidence from research using qualitative methods was not included in the formulation of the guidelines', referring to the ESHRE Guideline on routine psychosocial care in infertility and medically assisted reproduction (Gameiro, *et al.*, 2015). This reply intends to clarify the position of the Guideline Development Group (GDG) regarding the use of qualitative research in general and in the delineation of best practice recommendations.

First, we would like to make it clear that the GDG did not *a priori* decided to exclude qualitative studies. The decision not to rely on individual qualitative studies for formulating the recommendations was made as a consequence of following the rigorous 12-step methodology for writing guidelines outlined in The ESHRE Manual (Nelen, et al., 2009), and supported by the ESHRE methodological expert (N.V.). In the following paragraphs we will further clarify the employed method.

We started with considering all research relevant to answer each of the research questions underlying the recommendations. This means that quantitative and qualitative studies were equally considered. All the evidence gathered to answer each research question was evaluated based on the principles of evidence-based practice (Sackett, et al., 2000), which rely both on the design of the studies and on evaluation of the studies with design-specific criteria. These principles define qualitative research, but also case-control studies and case reports, as lower quality evidence when compared to randomised controlled trials (RCTs) and meta-analysis. One criterion for such ranking is the fit between research question and study design. Describing all the ranking criteria is beyond the scope of this Letter but the interested reader is directed to the publications of the centre of evidence-based medicine (OCEBM Levels of Evidence Working Group, 2011). This means all studies were evaluated, regardless of being quantitative or qualitative. We used the Criteria for Evaluating Qualitative Studies developed by the Qualitative Research and Health Working Group to evaluate qualitative studies (Bromley, et al., 2002). After all studies were evaluated, we followed the *a priori* decision to only consider level 2 or higher quality evidence for formulating the recommendations and this resulted in excluding studies.

Second, it is important to clarify that qualitative evidence was indeed considered when summarized in systematic reviews or collected within cohort study designs. Such evidence proved particularly relevant when addressing patient preferences of care.

Third, it is explicitly stated in the Guideline when qualitative evidence offered a different perspective to the recommendation, the discrepancy was noted and relevant studies cited (for an example see page 43 of the Guideline) In most cases, however, we found no qualitative studies that contradicted the recommendations.

Finally, we would like to make clear that qualitative research methods are not the best methods by which to generate practice recommendations. As Hammarberg stated, qualitative methods ‘are used to answer questions about experience, meaning and perspective, most often from the standpoint of the participant’. Qualitative research is based on a small number of participants, is not particularly concerned with the generalization of findings, and does not attempt to achieve replicable outcomes. It naturally follows that qualitative research methods are not the best to inform practice recommendations, which describe actions that are true or work best for the majority of (a specific group of) patients, that health professionals can implement and whose effect can be measured. Even qualitative researchers acknowledge the limitations of qualitative methods to answer clinical and policy questions (*Greenhalgh, et al., 2016*).

This does not mean that the GDG does not appreciate qualitative studies. For example, a qualitative study may be adequate to understand why a specific practice recommendation is not having the expected impact. Indeed, all GDG members are familiar and experienced with qualitative research methods. We are aware of the value of qualitative methods to capture real-life experiences of health, illness and medical interventions and have no hesitation in using them in the context of our own research, when these prove to be the most adequate methods to address the research questions at stake (Dancet, et al., 2012, Emery, et al., 2004, Schick, et al., 2016). We acknowledge the value of qualitative research methods to advance knowledge about multiple health issues not suitable to be researched with quantitative methods (Greenhalgh, et al., 2016).

In summary, we hope we have reassured our colleagues that we did not disregard qualitative evidence in the guideline but merely weighted the appropriateness of the different types of evidence available to support the recommendations. All relevant qualitative studies were included, evaluated and used when it provided a perspective that was not evident from just using the quantitative data.

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Conflict of Interest:

S.G., E.D., M.E., U.V.d.B., and N.V. report no conflicts of interest. J.B. reports grants from Merck&Co, consulting fees from Merck Serono S.A. and Speaker's fees from Merck Serono S.A. P.T. reports consulting fees from the German government and being the Chair of the German Society for Fertility Counselling. C.V. reports consulting fees from Merck Serono S.A. C.M.V. reports being adviser in projects for Merck Serono S.A. and Ferring S.A. on patient educational material. T.W. reports speaker's fees from Repromed, DGPM, Breitbach, DAAG, fiore, LPTW, MSD, salary/position funding at TAB-beim-Bundestag, BZgA, and being the Vice-chair of the German Society for Fertility Counselling.