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An evaluation of comprehensiveness, feasibility and acceptability of a fertility awareness educational tool

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Abstract The World Health Organization (WHO) and World Bank have identified infertility as a global public health issue. Since the 1980s, WHO has advocated for a focus on prevention, especially where the burden of prevalence is highest, specifically in women from low- and middle-income countries (LMIC). The aim of the two studies presented here is to demonstrate a process to enhance implementation efforts in fertility awareness programmes that could assist in preventing some forms of infertility, and increase understanding of factors that could result in fertility problems. The fertility status awareness tool (FertiSTAT) for the Middle East was adapted to provide an illustrative example of requirements for region- or country-specific adaptation. The mixed methods approach used included a survey of international medical experts concerning the comprehensiveness of risks included in the original FertiSTAT (Study I), and stakeholder meetings to assess the feasibility and acceptability of using an adapted FertiSTAT in the Middle East (Study II). The results indicate that the content of the original FertiSTAT was acceptable but not comprehensive in its coverage of potential risk factors; for example, it did not include genital tuberculosis, human immunodeficiency virus, consanguineous relationships and female genital mutilation/cutting. Furthermore, stakeholder meetings revealed that implementation in the Middle East would be enhanced by the use of more culturally sensitive wording. The data highlight the importance of implementation research with participants from LMIC, and the need for standardized protocols for adaptation of any fertility awareness programme or tool before practical application.

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KEYWORDS: infertility, fertility awareness, education, sociocultural, geographic and economic influences, feasibility and acceptability, FertiSTAT, global health, low- and middle-income countries

<https://doi.org/10.1016/j.rbms.2018.06.003>

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Introduction

Prevention focus

The World Health Organization (WHO) and World Bank have identified secondary infertility as a global public health issue (WHO/World Bank, 2011). WHO has advocated for a focus on the prevention of secondary infertility, especially in low- and middle-income countries (LMIC) where prevalence is highest (Mascarenhas et al., 2012; Van der Poel and World Health Organization, 2012). The prevention of fertility problems and promotion of 'fertility care' (Zegers-Hochschild et al., 2017) is addressed in some higher income countries and settings (National Women's Health Policy, Australia; Macaluso et al., 2010), but is under-researched and underserved in LMIC and lower-resource settings. The gap in fertility care should be addressed to ensure that policy meets reproductive needs across the lifespan, and to promote equity of access through knowledge about these issues in LMIC (Van der Poel and World Health Organization, 2012). Improvements in fertility care could also have broader health impacts through improvements in pre-pregnancy health. Addressing an unmet need for family planning and infertility services through the provision of universal access to sexual and reproductive health care are national targets within the sustainable development goals (United Nations General Assembly, 2015), supported through the WHO global reproductive health strategy (WHO, Reproductive Health and Research, 2004). WHO considers its intervention targets in reproductive health, including fertility care, as being 'of equal weight' to strengthen the attainment of sexual health as a whole (WHO, 2017). One important aspect of fertility care is improving awareness of the prevention of infertility by highlighting factors that can have a negative impact on fertility or cause fertility problems.

Fertility awareness tools

'Fertility awareness' has been proposed to include knowledge of reproduction, fecundity, fecundability, related risk factors and reproductive options (Zegers-Hochschild et al., 2017). Educational and information tools aimed at increasing public and self-awareness about reproductive health and fertility care have been developed recently in high-income countries. These tools use diverse methods to increase awareness including: (i) websites dedicated to fertility that tailor the information which visitors receive according to the risks they present on the site (e.g. 'yourfertility' website; Hammarberg et al., 2013); (ii) public health initiatives that use self-assessment tools as a hook to attract people to sites that provide relevant fertility education (e.g. 'test your fertility'; De Cock, 2011); and, more recently (iii) fertility assessment clinics where people can have their fertility evaluated through history-taking and biomedical tests (Hvidman et al., 2015; Petersen et al., 2015). This article reports two studies describing the process used to examine whether FertiSTAT, a fertility awareness tool developed in the UK, could be acceptable for dissemination and implementation within other sociocultural contexts.

FertiSTAT

FertiSTAT was developed as a self-administered tool for women to increase personal awareness of risk factors that negatively impact ability to achieve a pregnancy [available in printed and online versions; see Bunting and Boivin, 2010 and online supplementary material]. The tool uses 22 lifestyle and reproductive questions (i.e. risk indicators) to generate a risk profile and, based on this, personalized fertility guidance and suggested actions (e.g. to change behaviour, monitor symptoms until ready to attempt pregnancy, or seek medical advice now), weighted for importance via a colour-code system. The tool is appropriate whether women are trying to become pregnant or are using contraception. FertiSTAT was designed to assist women make informed decisions about risks (e.g. lifestyle) and to know when to seek timely medical advice if desired. The risk indicators were identified from empirical research as showing a reliable association with infertility, which has been medically defined as the inability to become pregnant after 12 months of unprotected intercourse or due to other medical or functional diagnoses of a reproductive disorder (Zegers-Hochschild et al., 2009, 2017). The FertiSTAT risk indicators are global and are assumed to operate similarly on fertility wherever people reside (e.g. similar effects of smoking on fertility across countries). Using a multifactorial weighted model, FertiSTAT was shown to discriminate to a high degree (i.e. 85.8%) between fertile women and those who had been medically diagnosed and confirmed infertile (Bunting and Boivin, 2010). FertiSTAT can assist in public health campaigns about fertility problems, and has been used in Belgium (e.g. 'test your fertility'; De Cock, 2011) and international media (Portugal, Japan, UK), but has not been evaluated or used in the Middle East to date.

FertiSTAT was selected over other available public awareness options based on its strengths, namely more comprehensive risk coverage, use of critical thresholds for each risk (e.g. number of cigarettes smoked, kilograms overweight), weighting of risks (e.g. absence of periods versus irregular periods), consideration of additive relationships between risks (age, years infertile), validation through case-controlled research studies (as described) and low cost (Bunting and Boivin, 2010). FertiSTAT is inexpensive because it comprises one sheet of paper and does not require maintenance compared with other options (e.g. apps and websites). This advantage is critical for successful dissemination in many countries and settings, especially LMIC. Despite all of the advantages listed, it was not known whether FertiSTAT would be appropriate for wider global use.

Geographic variation in risk

It is known that the global distribution of disease and the corresponding patterns of health risks vary according to geography (WHO, 2009). Variations in risks for fertility problems and infertility have been explored in narrative reviews (Bosdou et al., 2016; Ericksen and Brunette, 1996; Leke et al., 1993; Sharma et al., 2009). These reviews suggest that variations in the prevalence of cultural practices (e.g. consanguineous marriages, female genital mutilation/cutting), communicable disease [e.g. human immunodeficiency

virus (HIV), genital tuberculosis] and healthcare practices (e.g. dilatation and curettage) that could impact fertility do exist, and should be reflected in educational efforts to improve fertility awareness. A first step in adapting fertility awareness tools such as FertiSTAT would be to determine whether the risks included in the tool are comprehensive, and are able to cover exposure to risks according to geographical setting, other disease burdens or exposures, and sociocultural factors.

Feasibility and cultural appropriateness

The usefulness of evidence-based educational tools is improved if tools are culturally appropriate (Healey et al., 2017). The effectiveness of addressing risk factors through tailored educational health messages has been demonstrated (Noar, 2006), including in reproductive health (Baird, 2009). Adapting evidence-based tools and interventions developed in one country for another raises several issues about feasibility (Bowen et al., 2009) and cultural appropriateness (Kreuter et al., 2003) that could be addressed through stakeholder meetings. Feasibility data help determine whether further evaluation of a health intervention (e.g. service, product) is warranted. Feasibility can cover diverse components: first, acceptability to providers and users (e.g. suitability, attractiveness); second, demand (e.g. individual or organizational intention to use); third, practicality (e.g. resources needed); and fourth, dissemination and implementation issues (e.g. constraints) (Bowen et al., 2009). Consultation with stakeholder groups and users prior to adaptation is useful to elicit relevant, culturally appropriate information (Kreuter et al., 2003). Stakeholders can help adapt tools to the surface characteristics of a target group (e.g. appearance and language) or to deeper sociocultural characteristics (e.g. values, beliefs) that might affect their implementation and effectiveness (Resnicow et al., 1999). The exchange between attendees in a stakeholder meeting could allow more diverse opinions to emerge than with individual surveys. A systematic review of studies comparing health and mental health services with and without culturally adapted interventions showed better outcomes among the latter for a range of services (e.g. improved uptake of HIV tests, decreases in alcohol-induced problem behaviour; Healey et al., 2017). These findings support an examination of the feasibility and sociocultural appropriateness of using awareness tools such as FertiSTAT outside of the setting of their initial development.

Aim

The aim of this work was to determine the perceived comprehensiveness, feasibility of use and acceptability of FertiSTAT among multiple stakeholders (providers and users) in settings outside of the development context (UK). A mixed method process of adaptation was undertaken. In Study I, the aim was to ascertain the comprehensiveness of the risk factors included in the original FertiSTAT. A survey of doctors practising in diverse LMIC worldwide was used to identify additional risk factors for inclusion when adapting FertiSTAT for wider use. In Study II, stakeholder meetings

were used to collect qualitative data about the feasibility and acceptability of using an adapted FertiSTAT that included the additional risk factors identified in Study I in the Middle Eastern region.

Study I. Survey of medical experts to assess the comprehensiveness of the FertiSTAT risk factors and to identify potentially relevant additional risk factors

Materials and methods

Participants and recruitment

A list of experts active in education and training in LMIC ($n = 106$) was generated with input from a former Director of Medical Education and the International Federation for Fertility Societies, and by searching contact information for fertility clinic websites in Africa and the Middle East ($n = 44$). These medical experts were invited to participate in the survey. Eligibility criteria included being a medical doctor, and actively assessing and treating individuals with potential fertility problems. Participants were not provided any financial incentive for involvement. The School of Psychology (Cardiff University) Ethics Committee provided review and approval for the project.

Materials

Study questions were embedded in an online survey generated with Qualtrics (Qualtrics, Provo, UT, USA). All survey questions were indicated optional. The questionnaire was developed specifically for the study and comprised three sections. First, the 22 lifestyle and reproductive risk factors in the original FertiSTAT were presented for information to make respondents aware of the risks already included. Second, a 'structured list' of additional risks not included in the original FertiSTAT was presented, which included medical conditions associated with fertility problems and additional risk factors identified from narrative literature reviews of risk factors in diverse regions that include LMIC and other lower-resource settings. For each item on the 'structured list', participants were asked to indicate whether the item should be considered for inclusion as a risk factor for female infertility in an adapted FertiSTAT (yes/no). An open text box provided space to provide reason(s) or justification(s) for inclusion of the particular risk factor. The third and final section was a second open text box that asked participants to specify any other risk factor that they felt was relevant to their country of practice (hereafter 'participant-generated list'). Again, participants were asked to indicate a reason(s) or justification(s) for inclusion of their proposed risk factor in an adapted FertiSTAT tool.

Background sociodemographic and medical practice questions were asked (e.g. country of practice, type of specialization, number of years practising, healthcare sector). Country of practice was classified into income countries (low, lower-middle and upper-middle income) according to the Development Assistance Committee (DAC) list of overseas development aid (ODA) recipients (Organisation for Economic Co-operation and Development, 2017).

Procedure

Participants were invited to the study via e-mail and instructed to click on a hyperlink that led them to information about the study, the consent form and the survey. At the end of the survey was a 'submit' button that participants clicked to submit their data.

Data analysis

Reasons given for inclusion of new risks were grouped according to type (medical, reproductive or lifestyle). When participants gave multiple reasons, descriptive statistics were used to report frequency data.

Results

In total, 41 of 150 (27.3%) medical experts participated in the survey. The majority of participants were from Africa and the Middle East (63.4%, $n = 26$), and most participants (75.6%, $n = 31$) were from low, lower-middle and upper-middle income countries of ODA recipients. Of these, 51.6% ($n = 16$) practised in least-developed or low-income countries (Sudan, $n = 6$; Uganda, Nepal, Kenya, Nigeria, $n = 2$ each; Egypt, Paraguay, $n = 1$ each) and 48.4% ($n = 15$) practised in ODA upper-middle-income countries (South Africa, $n = 10$; Libya, Tunisia, Turkey, Uruguay, Panama, $n = 1$ each). Remaining participants (22% of all participants) practised in higher income countries not on the DAC list (Russia, Spain, $n = 2$ each; Belgium, UK, USA, Kazakhstan, Taiwan, $n = 1$ each). Of the 33 participants who responded to the training question, almost all (32/33) had specialist training in addition to training in obstetrics and gynaecology (e.g. reproductive medicine or reproductive endocrinology and infertility). On average, years of medical practice was 28.7 [standard deviation (SD) 9.4] and years of fertility practice was 19.3 (SD 10.75). Of the 34 participants who answered the question concerning their setting, 50% ($n = 17$) were in the private sector alone, five were in the public sector alone, nine were in both sectors, and three were in other settings (e.g. academic institutions). The average number of fertility patients (or couples) with fertility problems managed per week was 31.58 (SD 18.4, median = 30).

Table 1 shows the percentage agreement that risk factors and medical conditions on the 'structured list' should be included in an adapted FertiSTAT. The percentage agreement varied, with medical and reproductive conditions (e.g. cancer, HIV) generating higher endorsement for risks than 'practices' (e.g. consanguinity). Specifically, 75.9–97.0% of the total sample endorsed additional risk factors arising from infection or communicable diseases (e.g. HIV, genital tuberculosis or postpartum infection), 50.0–86.5% endorsed non-communicable diseases (e.g. diabetes, lupus), and 37.5–54.2% endorsed cultural practices (e.g. female genital mutilation/cutting). Overall, 25 participants suggested other risk factors relevant to their country of practice. Factors included: medical (e.g. medications, thyroid disease), reproductive (e.g. adhesions/fibroids), or lifestyle and environment (e.g. vitamin D deficiency, occupation/exposure). Lifestyle and environment were suggested less commonly.

Table 1 also includes frequency of justifications reported for inclusion of the risk factors. Few participants provided a

specific reason, but this depended on the type of risk. For example, more people endorsing a reproductive condition provided a justification than those endorsing a practice. A reason was reported for approximately half of the participant-generated risk factors, mainly for proposed lifestyle risks.

Study II. Assessing the feasibility and acceptability of implementing an adapted FertiSTAT in the Middle East among multiple stakeholders

Methods

Participants and recruitment

Two meetings were held in the Middle East. The first was held in Egypt in November 2016 at the 2016 annual conference of the Middle East Fertility Society (MEFS). The mission of MEFS is to improve fertility care for couples in the Arab world and Middle East through the transfer of medical knowledge and the promotion of scientific research. The MEFS Administration identified 30 medical experts practising in the Middle East and planning to attend the MEFS conference, and sent them an e-mail inviting them to participate in the study. Of the 30 invited, 28 (93.3%) agreed to participate and 21 were able to attend the stakeholder meeting (4 November 2016) facilitated by RRB and SvDP. Seven experts were unable to attend group meetings due to scheduling conflicts, and participated in individual interviews with the facilitators at a later time on the same day as the group session. The second stakeholder meeting was held in Sudan in December 2016 under the guidance and leadership of the National Reproductive Health Programme (NRHP) of the Sudanese Federal Ministry of Health. NRHP sent invitations to policy makers, representatives from womens' and youth groups, and local experts in individual and group qualitative research methodologies in Sudan. Of the 15 individuals invited, 11 were able to attend the meeting facilitated by RRB and JB. The invitations for all meetings included an agenda which stated that the comprehensiveness of an adapted FertiSTAT and the feasibility and acceptability of its use in the Middle East would be discussed. No incentives were offered to attendees, but lunch was provided at both meetings.

Materials and procedure

The FertiSTAT discussed during stakeholder meetings (adapted FertiSTAT) comprised the original 22 risk factors plus an additional five factors endorsed as relevant to LMIC from Study I. Of the 36 risk factors investigated in the survey (15 structured list, 21 patient-generated), five warranted further consideration for inclusion in FertiSTAT due to consensus among survey participants and consistency with extant empirical literature on their importance, exclusion from the original FertiSTAT, and evidence garnered from ongoing systematic reviews and meta-analysis showing association with fertility (ongoing research). These were: consanguinity, female genital mutilation/cutting, HIV, genital tuberculosis and bacterial vaginosis, and water-pipe smoking as an additional method of using tobacco. A section on non-communicable diseases (e.g. diabetes) was also included. Prior to the meetings, collaborators (EFS, former Director of MEFS) advised the meeting facilitators that the use of a self-administered tool in the Middle East might

Table 1 Percentage of respondents to the item who endorsed risk factors in structured list (1a), participant-generated risk factors (1b) and main reasons provided for risk factor inclusion in FertiSTAT.

1a. Structured list	Risk factors	Endorsed <i>n/N</i> (%)	Principal reasons given to justify endorsement (<i>n/N</i> of responses)				
			Unsure <i>n/N</i> (%)	Specific reason (<i>n/N</i> , %)	No reason given <i>n/N</i> (%)		
Practices	FGM/C	13/24 (54.2)	2/13 (15.4)	Reduces ovarian reserve (1/13, 7.7)	10/13 (76.9)		
	Consanguinity	13/26 (50.0)	1/13 (7.7)	Recurrent miscarriage (2/13, 15.4)	10/13 (76.9)		
	Water-pipe smoking	9/24 (37.5)	3/9 (33.3)	Reduces ovarian reserve (1/9, 11.1)	5/9 (55.6)		
	Reproductive factors	Bacterial vaginosis	12/27 (44.4)	0/12 (0)	Recurrent miscarriage (1/12, 8.3); tubal damage (1/12, 8.3)	10/12 (83.3)	
		HIV	22/29 (75.9)	4/22 (18.2)	Reduces ovarian reserve (3/22, 13.6); endometrial damage (6/22, 27.3)	9/22 (40.9)	
		GTB	32/33 (97.0)	2/32 (6.3)	Reduces ovarian reserve (1/32, 3.1); Asherman syndrome (adhesions) (5/32, 15.6); tubal damage (7/32, 21.9); endometrial damage (3/32, 9.4)	14/32 (43.8)	
	Medical conditions ^a	Postabortion infection	34/36 (94.4)	2/34 (5.9)	Asherman syndrome (adhesions) (7/34, 20.6); tubal damage (10/34, 29.4); endometrial damage (2/34, 5.9)	13/34 (38.2)	
		Postpartum infection	28/30 (93.3)	2/28 (7.1)	Asherman syndrome (adhesions) (7/28, 25); tubal damage (7/28, 25); endometrial damage (2/28, 7.1)	10/28 (35.7)	
		Repeated D&C	26/30 (86.7)	1/26 (3.8)	Asherman syndrome (adhesions) (9/26, 34.6); cervical damage (1/26, 3.8)	15/26 (57.7)	
		Cervical electrocautery	14/25 (56.0)	0/14 (0)	Endometrial damage (1/14, 7.1); cervical damage (2/14, 14.3)	11/14 (78.6)	
Diabetes		26/35 (74.3)					
Kidney disease		22/32 (68.8)					
SLE (lupus)		25/34 (73.5)					
Sickle cell anaemia	16/32 (50.0)						
	Cancer	32/37 (86.5)					
1b. Participant-generated list			Unsure <i>n/N</i> (%)	Specific reason (<i>n/N</i> , %)	No reason given <i>n/N</i> (%)		
Medical	Medications (pharmaceutical, psychotropic or traditional)		3/25 (12.0)	0/3 (0)	Toxins (3/3, 100)	0/3 (0)	
	Male factor (e.g. cancer treatment)		6/25 (24.0)	0/6 (0)	Reduced male fertility (6/6, 100)	0/6 (0)	
	Thyroid disease/treatment		7/25 (28.0)	0/7 (0)	(0/7, 0)	7/7 (100)	
	Anaemia		1/25 (4.0)	0/1 (0)	(0/1, 0)	1/1 (100)	
	Autoimmune diseases		1/25 (4.0)	0/1 (0)	(0/1, 0)	1/1 (100)	
	Cushing syndrome		1/25 (4.0)	0/1 (0)	(0/1, 0)	1/1 (100)	
	Chronic liver disease		1/25 (4.0)	0/1 (0)	(0/1, 0)	1/1 (100)	
	Inflammatory bowel disease		1/25 (4.0)	0/1 (0)	(0/1, 0)	1/1 (100)	
	Reproductive	Adhesions/fibroids		2/25 (8.0)	0/2 (0)	Tubal damage (2/2, 100)	0/2 (0)
		Vaginitis		1/25 (4.0)	0/1 (0)	(0/1, 0)	1/1 (100)
Dyspareunia			1/25 (4.0)	0/1 (0)	Reduced coitus (1/1, 100)	0/1 (0)	
Pelvic tuberculosis			1/25 (4.0)	0/1 (0)	(0/1, 0)	1/1 (100)	
Pregnancy-related infection			1/25 (4.0)	0/1 (0)	(0/1, 0)	1/1 (100)	
Hyperprolactinaemia			1/25 (4.0)	0/1 (0)	(0/1, 0)	1/1 (100)	
Lifestyle	Low vitamin D		1/25 (4.0)	0/1 (0)	Poor oocyte quality (1/1, 100)	0/1 (0)	
	Occupation/exposure		3/25 (12.0)	0/3 (0)	Male factor (3/3, 100)	0/3 (0)	
	IUD		2/25 (4.0)	0/2 (0)	Risk of PID (1/2, 50)	1/2 (50)	
	Extreme exercise		1/25 (4.0)	0/1 (0)	Reduction in pulsatile GnRH release (1/1, 100)	0/1 (0)	
	Undernutrition/anorexia		1/25 (4.0)	0/1 (0)	(0/1, 0)	0/1 (0)	

1b. Participant-generated list		Unsure n/N (%)	Specific reason (n/N, %)	No reason given n/N (%)	
Lifestyle	Vaginal lubricants	1/25 (4.0)	0/1 (0)	May be spermicidal (1/1, 100)	0/1 (0)
	Anal sex	1/25 (4.0)	0/1 (0)	Increases risk of prostatitis (1/1, 100)	0/1 (0)

n, number responding 'yes' to inclusion in adapted FertiSTAT; *N*, total number responding to question (yes or no); NR, not reported; unsure, participant indicated not knowing how risk factor affects fertility; FGM/C, female genital mutilation/cutting; GTB, genital tuberculosis; D&C, dilatation and curettage for any reason; SLE, systemic lupus erythematosus; IUD, intrauterine device; PID, pelvic inflammatory disease; GnRH, gonadotrophin-releasing hormone.

Sample size varies by question.

^a Participants were not asked to provide reasons for these medical conditions.

not be feasible given education and literacy levels among typical clients and patients. Therefore, the authors developed two versions of the adapted FertiSTAT for discussion with stakeholders: a flipchart version appropriate for community health workers (trained individuals from the community who are not necessarily medically trained) to use with clients; and a checklist version appropriate for healthcare providers (physicians and nurses) to use with their patients. The flipchart is one of the methods used by WHO and other non-government organizations (NGOs), such as the Population Council, at the level of primary care in regions of lower literacy when communicating reproductive health issues (e.g. contraception) (WHO, 2005). The flipchart version was two-sided with one page facing the client and the other facing the provider. The page facing the client depicts information using pictures and simple graphics; the other page faces the service provider and displays corresponding key questions, detailed information and discussion points for the provider to educate the client on the FertiSTAT item. The checklist version showed, on a single page, the list of FertiSTAT risk indicators that providers could check off as affecting the consulting patient. Checklists are used increasingly to efficiently condense a large quantity of information, describe essential evidence-based criteria, and enhance the objectivity and reproducibility of communications between practitioners and patients, including settings where there is low literacy (Hales et al., 2008). As noted, the adapted versions (flipchart, checklist) included 28 items: the 22 original FertiSTAT risk indicators, five additional risk factors identified in Study I, and an item including all the medical conditions. It should be noted that two of the 22 items concerned risk factors for men (mumps during puberty, undescended testicle).

At both meetings, participants were given a presentation regarding the development and use of the original FertiSTAT. The adapted version (flipchart, checklist) was then presented and discussed in relation to comprehensiveness of risk indicators, applicability, feasibility and cultural/regional acceptability. Discussion included specifics of implementation, such as target audience, setting and practicality of use (e.g. format). Due to the sensitivity of the topics, recording devices were not utilized; however, detailed notes (including direct quotes) were taken by SvdP and RRB for the first set of meetings, and by a Sudanese research assistant for the meeting in the Sudan.

Data analysis

RRB and SvdP conducted thematic analysis (Braun and Clarke, 2006) and derived codes from all meeting notes

(inductive coding) about perceived feasibility and acceptability of the adapted FertiSTAT. Codes with the same meaning (e.g. 'population of interest' and 'target population') were combined. Coders discussed and reached agreement on whether each code communicated a unique meaning or fit with other existing codes. Each coder organized codes into main themes, and these were discussed between coders to ensure the cohesiveness of each theme and consistency with the overall meanings in the dataset. Subthemes within the main themes were also identified to facilitate understanding and presentation of the results. Participant quotes were used to illustrate meanings. The use of parentheses within quotations in the results section below indicates text added for clarity, while omitted text is represented using '(...)'. All illustrative quotations are from medical experts, unless profession is specified. The meeting in which the quote originated has been indicated using M1 (Meeting 1) and M2 (Meeting 2).

Results

The attendees of the first meeting at the MEFS conference were 28 medical experts practising in 10 countries in the Middle East. All were ODA recipients except Saudi Arabia. Countries were low or lower-middle income (Sudan, Egypt, Syria) or upper-middle income (Algeria, Iraq, Jordan, Lebanon, Libya, Turkey). The attendees of the second meeting were 11 stakeholders from Sudan, comprising representatives from: the Ministry of Health (NRHP), medical societies (Sudanese Society of OBGYN and Sudanese Reproductive Health and Embryology Society), reproductive health expert from the United Nations Population Fund (UNFPA), national NGOs [e.g. Regional Institute of Gender, Diversity, Peace and Rights, Sudan (RIGDPR), HIV Unit of JASMAR Human Security Organization), a previous patient, epidemiologists, medical doctors from local universities (University of Khartoum, Ahfad University, National Ribat University), and medical experts practising in the public and private sectors. As shown in Table 2, thematic analysis resulted in five main themes, described below.

Need for fertility awareness in the Middle East

Fertility awareness was considered to be necessary and timely: "there is a niche for such tools especially because our societies are geared towards childbearing" (M1) due to perceived lack of "information about risk factors", "misconception about what is a risk" (M1) and lack of knowledge about when to seek medical advice causing people to seek

Table 2 Themes emerging from thematic analysis of data gathered at both meetings (see text for elaboration on themes).

Theme	Summary of theme
Need for fertility awareness in the Middle East	Fertility awareness was endorsed based on societal emphasis on childbearing and perceived widespread misconceptions about fertility and lack of fertility knowledge
Content acceptability and suggested tool changes	The content of the adapted FertiSTAT that was acceptable The wording of certain items found to be unacceptable or only acceptable if modified to be better understood and more culturally sensitive
Target audience for adapted FertiSTAT	Suggestions for the appropriate age and marital status of the target audience on which to use the adapted FertiSTAT included: couples preparing for marriage, newlyweds and young unmarried individuals (men and women) Suggestions about subgroups (e.g. refugees) as separate target audiences were made
Setting for implementation	Regional level settings: disagreement about the possibility of a regional tool Country/community level settings: urban and rural settings may have different needs Possible settings for dissemination and implementation include: schools, primary healthcare facilities, infertility clinics (tertiary level), community and media
Need for further research (setting specific) and a working group	Next steps require setting up a working group to finalize the content of the material and oversee necessary regional research Areas for future research: assess implementation in proposed settings and target populations; identify which format would be suitable for which setting; field testing the wording used to appropriately communicate complex, sensitive or stigmatizing topics to determine acceptability and alternatives; evaluate research to ensure highest possible quality of research (empirically sound); ethical problems (e.g. screening) will lead to huge demand and services need to be available

treatment “too early or too late” (M1). Greater knowledge on these topics would help “reduce the burden” (M1) on healthcare systems and individuals, and potentially reduce the prevalence of known preventable causes of infertility “if they know when to get help” (M1). Participants also spoke more generally about the topic. The social stigma of infertility was highlighted for men: “(...) they (men) deny having the problem because it is shameful, makes him less of a man” (M2); “male infertility is a stigma” (patient, M2). Another issue supporting increasing fertility awareness was misunderstanding of information that people obtained from the internet: “the main problem is the internet, where individuals look up on say PCOS (polycystic ovary syndrome) and immediately find infertility as the end” (M2).

Content acceptability and specific tool changes

There was consensus that, “with some adjustment to the language” (M1), an adapted FertiSTAT could potentially be culturally acceptable and used in the Middle East. The absence of PCOS from the adapted FertiSTAT was noted because it was common in the practice of some doctors: “(...) 30% of my patients have PCOS” (M2).

However, there was conflicting opinion about wording. Some suggested that certain risk factors should be removed, altered or only communicated to specific audiences due to their sensitive nature:

“Sex with multiple partners is unacceptable in a community of husbands and wives (...) the word ‘partner’ particularly should not be used” (M2).

“Items regarding things like multiple partners need to be delivered in a sensitive manner (...) use ‘extramarital affairs’ or ‘previous relationships’ (...) but you have to ask” (M2).

However, others felt that the adapted FertiSTAT tool could be used as designed in their country or clinic setting. The terminology was “comprehensible” with some modification of “medical terminology like endometriosis and PID (pelvic inflammatory disease) (that) should be replaced with more understandable terminology, which would require deliberation at length and with several experts” (M1). Some also felt that wording/phrasing might need to be “country specific (...) or specific to particular community settings (within countries)” (M1).

A reproductive health expert from a Sudanese NGO (RIGDPR, M2) mentioned the importance of the provider in asking about risk factors: “you have to be careful when asking these women (...) your body language, choice of words” (M2).

Target audience

Diverse target audiences were suggested for the adapted FertiSTAT tool. A reproductive health expert from a Sudanese NGO (RIGDPR, M2) suggested that the materials should “target couples who are about to get married” (M2), and a representative from UNFPA in Sudan noted that “school children (and) university students are the main targets” (M2). Recommendations appeared to depend on views of current social norms: “You can’t talk about these things (sex) with people who are not married yet (M1); “Times are changing (...) in some places” (M1). However, in both meetings, integration into existing programmes for young people was recommended. For example, premarital counselling which is “mandatory about certain medical disorders such as HIV and hepatitis B and C to receive a marriage certificate in Egypt” (M2), and “free youth workshops held by the Ministry of Youth, targeting couples who are about to get married and educating them about things like family planning, HIV testing” (RIGDPR, NGO, M2).

Other specific targets were “unique subcultures within each country that may have different needs and level of understanding (...) (or) acceptability” (M1). One example was the refugee population “who despite their circumstances are very keen on having children and the need for fertility awareness is acute” (M1). Broader dissemination was also suggested: “these tools should be tested at community level targeting the general population” (M1).

Setting for implementation

The fourth main theme concerned the macro/micro level setting for implementation of fertility awareness tools. There were suggestions that there should be “a Middle East version” (M1) that was tailored to the needs of that specific region. However, others disagreed: there “cannot be a regional tool” and we “cannot (even) have a country tool” and “a regional tool may not be possible but a national tool would be beneficial” (M1). This view was based on the diversity of people within the region or a country, and the exposure to different risks; for example, female genital mutilation/cutting is highly prevalent in Sudan and Egypt, but is almost non-existent in Lebanon and Oman. Further, different settings could have different needs; for example, there may be a “need to develop a rural and an urban version (format) for each country” (M1). A reproductive health expert from a Sudanese NGO (RIGDPR) made a similar suggestion, emphasizing the difference in literacy levels across the country (M2).

At the country/community level, several suggestions for use and dissemination were made, including schools, primary healthcare facilities, infertility clinics (tertiary level), media and community (as described above). There was agreement that the primary healthcare level setting would help reach the widest audience. Several medical experts (M1 and M2) expressed an opinion that the school setting (regardless of age of pupils) would not be appropriate due to the sensitive issues raised (e.g. sexual activity and illegal drug use), but not all agreed. Some felt that adolescents were already exposed to these issues (M1 and M2). Others, including an epidemiologist (M2) and representatives from Sudanese NGOs (M2), expressed the view that “integrating the material in the curriculum of schools and universities would be best” (M2). This was further reinforced by ongoing activities; for example, in Sudan, the “Ministry of Health and Ministry of Education with the support of UNICEF are in the process of rolling out (in schools) an adolescent health module on fertility, targeting ages 10–19 years” (NRHP representative, M2). It was stated that “interventions have to start early (...) first place should be at the school, train the teachers, give the information to the educators” (M2). There was consensus that further research was necessary to ascertain acceptability and utility in schools, and if and how to target different adolescent and young adult age groups (M1 and M2).

In addition, a checklist was suggested for use by nurses or the patients themselves in fertility clinics (tertiary care) prior to the consultation with the fertility specialist (M1 and M2). Although the fertility clinic may seem late for prevention, often couples who attend these clinics are not infertile and do not require fertility interventions, but do require reproductive health education including fertility awareness knowledge. Participants expressed the view that

“all my clients are infertile and this (adapted FertiSTAT) would be useless (at this stage)” (M1), while others reinforced the well-known statistic that “we get many (patients) who are NOT infertile, but they think they are, so it (adapted FertiSTAT) would be very helpful” (M1) in making patients aware of risks identifying those who might require medical attention.

The use of media such as television, radio, internet and social media (e.g. Facebook, WhatsApp) was discussed as potential viable dissemination platforms in both meetings. In Sudan, the material could be disseminated in group format rather than one-on-one: “village meetings, community gatherings, rather than individual(ly)” or via print media “in clinics, outpatient departments, magazines” (M2). A representative from a local university (M2) suggested using the flipchart version and taking advantage of existing health promotion programmes like the “rural extension program at Ahfad University” to improve fertility awareness. Every year, Ahfad University sends students to rural villages to deliver health education messages; fertility could be one of these topics. Midwives and healthcare visitors were also suggested as potential local healthcare providers who could be trained to disseminate this information, as they are the “main care providers in rural areas where 80% of deliveries are at home” (M2). Finally, the demographic characteristics of participants (e.g. education, socio-economic status) were perceived to possibly necessitate the use of “different tools/formats for different settings” (M1). For example, the provider flipchart would be useful for settings where individuals have lower education levels, the checklist would be helpful within a fertility care clinic or health centre, and a self-administered questionnaire would be suitable only for settings where potential users are “well educated” (M1).

Need for further research (setting specific) and a working group

More research was thought to be necessary for adapting the original FertiSTAT prior to implementation within the Middle East. The MEFS experts thought that the creation of a working group that could “finalize the content of the material” (M1) and oversee necessary regional research was the logical next step for implementation. In addition, research was needed for wording of guidance to ensure the appropriate assignment of blue, yellow, orange or red flags for new risk factors (M1 and M2). Prospective testing in multifactorial models would be required to detect how these additional risk indicators would alter prediction values compared with the original FertiSTAT prediction capacity (Bunting and Boivin, 2010). These research gaps were perceived to be essential to ensure appropriate guidance or referral (i.e. audience, format, wording) and to maintain the integrity of FertiSTAT as a validated tool. It was noted that the “integration of fertility awareness tools and research regarding testing different formats” would require the involvement of “professional societies” and “public health experts who would be more able to advise on where within existing healthcare services the tools can be integrated and what level of content (difficulty)” (M1). There was concern over research quality, and one participant stated that “the research (would) need to be well-coordinated and implemented (...) one bad application or extreme negative outcome could potentially destroy the whole project (and

working group)” (M1). The research would need to be empirically sound, requiring “systematic reviews and proof of principle for the model for adaptation” (M1) including research design for pilot testing of tools and adaptation process. Finally, there was concern about ethics; an epidemiologist stated “this project can be very complex, the aim of the educational program is prevention through screening programs; however, when that (the screening) starts (and may identify risks to or fertility problems), there will be a huge demand (for access to fertility care) that may cause an ethical problem, you have to provide services or a referral pathway to cope with the demand generated by the screening” (M2).

General discussion

Principal findings

The main finding of the studies was that using fertility awareness tools in contexts outside their development requires adaptation of risk factors, language of communication and methods of dissemination.

Comprehensiveness of risk factors

An important issue for awareness tools is that the risks they include should be comprehensive and relevant to the region, country or community settings within which the tool will be used. The survey revealed that medical experts primarily from Africa and the Middle East (63%) considered the original FertiSTAT to lack some risks relevant in their country of practice. These perceptions were in line with published accounts of importance of investigating region-specific risk factors in the Middle East (Bosdou et al., 2016; Serour, 2002) and other regions (Leke et al., 1993) for prevention and treatment of infertility. The omission of relevant risk factors in the present adaptation begs the question of whether it would ever be possible to achieve a fertility awareness tool that has a complete list of risk factors that could be used in different regions of the world. Consensus on key risk factors for other health awareness tools has been achieved (e.g. prepregnancy health; Frayne et al., 2016). We believe that consensus could be achieved for the field of fertility awareness, and would evolve gradually as the evidence on risk factors is systematically reviewed and evaluated. This consensus could also preclude the need for generating multiple versions of FertiSTAT to fit within countries and within settings. The process of adaptation used in the present studies (survey and stakeholder meetings) could facilitate accessing the relevant information for consensus.

There was variation in the level of endorsement for risks. Variation could reflect the reality that less endorsed risks associated with cultural practices (e.g. female genital mutilation/cutting, water-pipe smoking) were actually less risky for fertility than the communicable (e.g. HIV, genital tuberculosis) or non-communicable (e.g. diabetes, lupus) risks that are more highly endorsed. Alternatively, it could be that evidence about less endorsed risks such as cultural practices and their impact on fertility is not robust, not yet adequately assessed or not yet communicated to or accepted by medical experts. Future research needs to update knowledge about poorly known or understood risks,

and communicate that in training. The reasons/justifications provided for the ‘reproductive’ risk factors were in line with those provided in existing literature on causal mechanisms that would underpin training, showing its importance in what doctors know. Training should be updated about other risks as evidence of their level of influence (whether significant or not) is accumulated. However, it should be noted that it was not possible to fully evaluate understanding of mechanisms of action or other factors that could explain variation in endorsement because the majority of participants did not provide a reason/justification for endorsing a risk. As FertiSTAT has been empirically validated, any newly endorsed and proposed risk factor needs to be subjected to systematic review and meta-analysis (when feasible) before inclusion in an adapted FertiSTAT is empirically warranted.

Some assumptions made in developing the original FertiSTAT were questioned in the present studies. In the original FertiSTAT, medical conditions (e.g. diabetes) were excluded on the grounds that the general practitioner or disease specialist would have informed affected patients about potential risks to their fertility, making the need to raise awareness of such risks unnecessary in a fertility awareness tool (Bunting and Boivin, 2010). However, the results of Study I suggest that this assumption may not apply widely. Not all participating medical experts knew the fertility effects of the medical conditions examined; for example, 14% did not agree that cancer could be a risk for reduced fertility. This finding is consistent with an international systematic review that postdates the original FertiSTAT, showing that approximately one-third of cancer survivors surveyed did not recall being told about the effects of cancer or its treatment on their fertility or reproductive potential (Tschudin et al., 2010). Of course, it could be that doctors and oncologists know about risks but do not provide information due to low accessibility of treatment or options to resolve infertility. This possibility also needs to be considered. However, providing evidence-based education and information that enables patients to make informed choices, even when these are few, is consistent with ethical medical practice. In turn, evidence gathered from patients who benefit from this knowledge will help to impact national policies that ensure greater access to health prevention and care, which are critical components for all health problems. Together these findings suggest that assumptions underlying inclusion or exclusion of risk factors in fertility awareness tools should be examined, especially when introducing a tool in a new country within settings where there is limited access to universal health care, or where there is inadequate adherence to, or lack of, best practice guidelines in reproductive care or other health areas impacting fertility.

Feasibility and acceptability

The concept of using a tool to increase fertility awareness was accepted and perceived to be feasible. However, some challenges exist. The use of a self-administered version of FertiSTAT was not considered to be appropriate for the typical client or user in the Middle East, and provider-administered flipcharts or checklists were preferred due to lower education and literacy. Content and wording were challenged, and perceived to require being made appropriate for the country

and specific population (married, unmarried). In this case, “appropriate” is in reference to social conventions about permissibility of discussing taboo topics with different members of a community, reinforcing social norms as powerful drivers of medical healthcare-seeking, especially in LMIC (Finlayson and Downe, 2013; Thaddeus and Maine, 1994). It should be noted that hesitation about taboo topics could also be due to the significant penalties or shame of engaging in illegal activities in Muslim countries (e.g. alcohol use; Islam and alcohol, 2012). Together, violation of social or legal norms could be very problematic for individuals and also for medical doctors who learn about them. These issues identified for the Middle East could also be relevant for other countries wanting to adapt FertiSTAT or other fertility awareness tools.

Some of the stakeholders questioned the value of fertility awareness in the absence of, or very limited potential of, affordable services to improve fertility “to cope with the demand generated by the screening”. FertiSTAT was developed to increase informed decision-making about risk factors and assist in timely medical help-seeking when signs of disease were present (Bunting and Boivin, 2010). The signs, symptoms and preventable causes of fertility problems are not widely known in many countries, especially in LMIC (Bunting et al., 2013). Knowledge is valuable in itself for people to understand the factors that affect their health. Indeed, education is one of the components of health interventions most consistently associated with better health (including reproductive health; Baird et al., 2009). Without disease awareness, prevention is difficult to achieve; for example, people cannot reduce exposure to risk factors (e.g. lifestyle, environmental), make informed decisions about cultural practices affecting fertility (e.g. consanguinity, female genital mutilation/cutting), or seek timely (often inexpensive) care to reduce the effects in the early stages of progressive disorders (e.g. endometriosis), or for symptoms of fertility-related disorders that are ignored or normalized at primary care (e.g. heavy bleeding, pelvic pain). Thus, people could benefit even if (more costly) treatments were not affordable to them. Nevertheless, it is true that many countries now have fertility clinics (see worldwide list; Dyer et al., 2016), but not all care available is affordable. Ongoing initiatives to develop and implement methods that can lower the cost of interventions will help reduce costs. Furthermore, WHO recognizes the importance of fertility care in reproductive health programmes (WHO, 2017), and has initiated a number of activities to address fertility care within healthcare systems and services (van der Poel, 2016). In time, this recognition should help improve accessibility of treatment.

Limitations

There were limitations that should be acknowledged. The low survey response rate and the invitation to selected highly experienced medical experts working within the private sector could introduce bias. The risk profile and overall health of patients seen by such doctors could differ from those of general practitioners or gynaecologists working in public clinics. However, given that fertility care health services are mainly based within the private sector in

LMIC surveyed to date (IFFS Surveillance, 2016; Sullivan et al., 2013), survey responses do reflect those patients most likely to be treated. More research is needed on the risk profile of untreated (and publicly treated) groups. There was greater representation in the survey from regions that have more fertility clinics (e.g. South Africa). More clinics could reflect better access to care and greater willingness to address this stigmatized topic, potentially biasing results towards a more favourable view of fertility awareness initiatives. Respondents did not answer all questions on the survey, and the cause of non-response for specific items is not known. Non-response could be due to lack of knowledge or unwillingness to identify specific causes for reduced fertility, especially if these might attribute blame to a specific gender for a couple's problem. Despite these limitations, the survey and stakeholder meetings did comprise a diverse group of participants from countries that differed sufficiently from the UK (i.e. in cultural majority, geography, healthcare system) to inform the examination of whether the original FertiSTAT could be considered for wider use. The conclusion is that it is not, but it could be adapted to achieve that goal.

Future research

As noted, research is required to review and synthesize the data available on the risk factors that were not included in the original FertiSTAT and to develop appropriate guidance. Future research should aim to develop a fertility awareness tool for men, as the issue of male fertility was raised in both stakeholder meetings. The original FertiSTAT was developed and validated in women. It includes only two reliable predictors of reduced male fertility (i.e. mumps during puberty, undescended testicle). Since FertiSTAT was published, more rigorous studies of risks and fertilization in men have been performed (e.g. male obesity; Campbell et al., 2015) and it may be possible to generate a valid male FertiSTAT. Testing feasibility and acceptability would also be necessary because perceptions of male fertility and men's quality of life differ across countries (Sexty et al., 2016), including in the Middle East (Inhorn, 2012). After such steps have been taken, the process of globalizing FertiSTAT and similar tools requires more implementation research to validate their predictive value across countries, and to demonstrate their value in such settings.

Conclusion

The processes used in the present studies concur with cross-cultural adaptation guidelines that recommend consultations with health experts from the target population before implementation (Beaton et al., 2000; Guillemin et al., 1993). Globalizing health awareness should aim to ensure recognition of diversity in the opinions of experts and advisors, with the aim of accommodating the needs of the end-user. The principal lesson learnt through these studies was that fertility awareness tools such as FertiSTAT cannot be superimposed on target populations that might differ from the populations where such tools were originally developed. Although risk factors could have a common underlying mechanism globally, it would be a mistake to assume that this universality necessarily implies similarity in the fertility

risk factor profile to which people are individually exposed globally, or the method by which awareness of risk could be enhanced. FertiSTAT would benefit from inclusion of additional risk indicators in line with its introduction in new countries. This paper has presented a process of adaptation that could be used as other countries and regions become interested in FertiSTAT and other fertility awareness tools. It is critical to address these risk factors in order to sustain healthy fertile lives.

Acknowledgements

The authors wish to thank Professor Ian Cooke who helped generate the list of participants for the survey; the MEFS organizing committee and Prof Johnny Awwad who assisted in the identification of key participants and the organization of the expert meeting during the 2016 Middle East Fertility Society Conference in Egypt; Dr. Dalya El Tayeb, representative of the National Reproductive Health Programme of the Sudanese Federal Ministry of Health, who helped organize the Sudan stakeholder meeting; and Dr. Kawther Mohamed, research assistant, who helped with the Sudan stakeholder meeting. This research was supported by the Economic and Social Research Council, Global Challenges Research Fund (Impact Acceleration Grant No. ES/M500422/1) and the World Health Organization/ Human Reproduction Research Programme (WHO/HRP; UNDP/UNFPA/ UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction).

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.rbms.2018.06.003>.

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Received 8 August 2017; refereed 26 April 2018; accepted 25 June 2018.