

with abnormal chromatin packaging. However, there were no significant correlations between varicocele and apoptosis and mitochondrial damage (Table 1)

Limitations, reason for caution: The sperm were obtained from men who underwent fertility evaluations. This descriptive study was based on *in vitro* evaluations.

Wider implications of the findings: The presence of varicocele may produce spermatozoa with less protamination, which may impair sperm DNA integrity and fertility. Given the extant literature, varicocele repair and antioxidant intake should be considered to reduce DNA damage in sperm.

Study funding/competing interest(s): The authors report no conflicts of interest.

Trial registration number: Not applicable. The local ethics committee authorised the study.

Cross border reproductive care

P-047 Cross-border reproductive care among French patients eligible for ART funding in France

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Study question: The study aimed to explore social characteristics, medical histories and experiences of cross-border reproductive care (CBRC) among French patients who were eligible for full funding for ART treatment in France.

Summary answer: Of the French CBRC patients, 49% fulfilled criteria for full funding for ART treatment in France. The majority (85%) went abroad to obtain oocyte donation due to inadequate availability of medical care and to oocyte shortage in France.

What is known already: CBRC is often described as a phenomenon reflecting law evasion. However, the reality is much more complex and other motivations could explain CBRC, in particular better access to ART treatment. Access may, for example, be restricted by treatment cost and shortage of gamete donation. Very little information is available on CBRC motivated by restricted access to ART in the home country.

Study design, size, duration: Between 2010 and 2012, a self-administered questionnaire was completed by 140 French CBRC patients in four fertility centres in Belgium, Denmark, Greece and Spain. Of the 140 patients, 68 were selected because they were eligible for full funding of ART treatment in France.

Participants/materials, setting, methods: Participants were selected as fulfilling criteria for full funding of ART treatment in France: heterosexual couple, woman aged <43 years and treatment used abroad legally available in France. The self-administered questionnaire was anonymous and was returned directly to the research team

Main results and the role of chance: The French CBRC patients who participated were mainly from the Paris region (49%), did not have a child (74%), belonged to the middle and upper class (42% of women and 61% of men), were aged 38 years, had previously used ART in France (82%) and had been trying to have a child for 5 years. They crossed borders mainly to obtain oocyte donation (85%). The majority (75%) used CBRC because of difficulties in accessing ART in France, particularly the long waiting list for gamete donation. Surprisingly, 25% of patients wrongly believed that oocyte donation was not legal in France or that it was not legal when the woman was aged over 38 or 40 years.

Limitations, reason for caution: Larger, wider-ranging studies are needed as our series of 68 patients may not be typical of all French CBRC patients, especially because the study was carried out in only four ART centres and so cannot be considered as representative.

Wider implications of the findings: These findings provide new information on the complex and increasing phenomenon of CBRC in Europe. By focusing on patients who fulfilled criteria for full funding of ART treatment in their home country, this study highlighted an aspect of CBRC that has previously

been neglected. It should be better taken into account in further research in this field.

Study funding/competing interest(s): Funding was received from the Institute Emilie du Châtelet through the Ile-de-France regional authority, the French Biomedicine Agency and the Research Institute of Public Health (IReSP). Competing interest: none declared.

Trial registration number: Not applicable.

Developing countries and infertility

P-048 Is the world health organization assessing and monitoring global infertility prevalence: determining burden when addressing a poorly addressed global public health issue

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Study question: Has WHO been able to generate prevalence values or definitions for subfertility/infertility that are being used by clinicians, policy makers, governments and key stakeholders? Have the lack of diagnosis and management of sub-fertile/infertile individuals and couples significantly hindered obtaining global burden estimates?

Summary answer: Limited dedication to addressing the global majority of the infertile with management and treatment, coupled with limited ability to diagnosis subfertility within developing country health care services, results in inability for UN Member States, especially in developing countries, to use a WHO epidemiological indicator to generate an infertility prevalence value.

What is known already: Estimates of infertility prevalence derived by WHO since 1984 have varied widely with reports of global estimates of 80 million women (1984), 186 million couples in developing countries (2004), 33.4 million women infertile due to unsafe abortion/maternal sepsis (2011) and 39.6 million and 48.5 million women in 1990 and 2010, respectively (2012). Each prevalence assessment was reached using a different mechanism and developing different definitions of infertility in order to determine and report a global burden value.

Study design, size, duration: Retrospective and systematically analysis will compare definitions that have led to mechanisms, algorithms and qualifiers which have been used to generate and to report WHO infertility prevalence values since the 1980s. An analysis will be made on the processes used to generate WHO Recommended indicators for infertility prevalence and determination.

Participants/materials, setting, methods: WHO reports, guidance, manuals and articles that are WHO derived or written on behalf of WHO, by expert advisors and collaborating agencies will be assessed. Responses provided within context to the unmet need will be compared over time in linkage with these documents presenting estimated global burden and prevalence values.

Main results and the role of chance: Limited dedication to addressing and limited ability to diagnosis, manage and treat the global majority of the infertile within developing country health care services, results in inability for these UN Member States to use a WHO epidemiological infertility prevalence indicator. Despite the gains in other MNCRH indicators, trends in infertility prevalence rates remain stubbornly unmoved. Can the global community confidently support that "prevention" is not the only answer? Global commitment to support research, monitoring and evaluation of the infertile is slightly increasing, however mainly through limited linkages with other global public health initiatives rather than through recognition of the unmet need of the infertile themselves. This is despite extremely large and significant identification of its global burden on health, and therefore impact on health systems.

Limitations, reason for caution: Rates of maternal mortality, child mortality and other maternal, newborn, child and reproductive health (MNCRH) indicators are decreasing in global estimates. "Prevention" of infertility had taken center stage

beginning in the late 1980s, with an expectation that as rates of MNCRH indicators decreased, the burden of infertility would naturally fall.

Wider implications of the findings: If efforts were made to reach a consensus-driven, agreed upon definition and algorithm for infertility prevalence, (in collaboration with WHO, WHO partners in infertility, and its UN Member States) coupled with a consensus-driven standardized functional protocol for evaluating sub/infertility in men and women which WHO could recommend to all UN Members States, these could significantly contribute to global understanding of this "disease of the reproductive system" and result in more equitable access and treatment worldwide.

Study funding/competing interest(s): HRP Special Programme in Human Reproduction

Trial registration number: Not applicable

P-049 HMG-only protocol for IVF, a practical and more affordable option for developing countries

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Study question: Can HMG-only protocols be a practical, successful and more affordable alternative to the GnRH long stimulation protocol for patients undergoing IVF in developing countries?

Summary answer: HMG-only protocol is a practical, successful and more affordable alternative to the GnRH long down-regulation protocol for patients undergoing IVF in developing countries. It is also associated with a lower incidence of ovarian hyperstimulation syndrome.

What is known already: The long GnRH agonist down-regulation protocol followed by FSH/HMG stimulation is now a standard protocol to achieve controlled ovarian hyperstimulation prior to IVF or ICSI. However, this protocol is expensive and requires a longer stimulation time. Natural cycle IVF and clomiphene citrate stimulation protocols are associated with lower pregnancy rates compared to down-regulation protocols.

Study design, size, duration: Retrospective analysis of data from all 3233 IVF and ICSI cycles performed in our unit from 1st January 2007 to 31st December 2011 was conducted. Of those, 2928 cycles were stimulated using an HMG-only protocol and 305 cycles were stimulated by a standard GnRH agonist long protocol.

Participants/materials, setting, methods: The study was conducted in our Assisted Reproduction Unit. Monitoring was effected by serial ultrasound scanning of the follicles. There were no statistically significant differences between both groups regarding the age of the couple, the duration of pregnancy or the indication of IVF or ICSI.

Main results and the role of chance: There were no significant differences in the number of ampoules used, the number of oocytes, metaphase II oocytes, premature or postmature oocytes retrieved, number of grade I and grade II embryos obtained or the number of embryos replaced, between both groups of patients. The overall clinical pregnancy rate was 28.30%. In the HMG-only group, the clinical pregnancy rate was 28.11% compared to 30.16% in the GnRH group (30.16%) ($P = 0.478$) ($OR = 1.105$; 95% $CI = 0.854-1.430$). The mean cost of the HMG-only cycle was US\$ 1101.82 compared to US\$ 1758.18 for the GnRH cycle. Eleven patients developed ovarian hyperstimulation (OHSS) in the GnRH agonist group (3.9%) compared to thirty seven in the HMG-only group (1.26%) ($P < 0.0001$) ($OR = 0.277$; 95% $CI = 0.140-0.550$).

Limitations, reason for caution: Although the HMG-only protocol is more affordable than the GnRH agonist long stimulation protocol, it may still be too expensive for many patients in developing countries. The findings of this study should also be confirmed in a prospective randomized trial.

Wider implications of the findings: The HMG-only protocol is a simple and less expensive protocol for IVF and ICSI and offers a practical and successful alternative for infertility specialists in developing countries compared to the classical GnRH agonist long stimulation protocol. It is also associated with a significantly lower incidence of OHSS.

Study funding/competing interest(s): The study was self-funded and there are no conflicts of interest for any of the authors.

Trial registration number: The study was registered and approved by the Institutional Research Board of the Alexandria Fertility Center.

P-050 Health related quality of life in women and their partners accessing infertility care at an urban, public tertiary referral centre in South Africa

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Study question: What is the health-related quality of life (HRQoL) among infertile couples living in South Africa and is it influenced by sociodemographic variables? Do generic and disease specific instruments correlate in this group of patients?

Summary answer: HRQoL was significantly affected in women, as reflected by low scores in the emotional and psychological domains of the instruments used. This was not observed in men. Education, secondary infertility and time attempting fertility were predictors of HRQoL. Similarities and differences were observed in comparison of the domains of instruments.

What is known already: Many studies report on single domain outcomes and illustrate the negative impact infertility has on economic, family, religious and psychological well being of the women affected. They suffer from lack of self esteem, marital instability, stigmatisation and abuse. There are few studies that examine the effect of infertility on males and the results are conflicting. There are no HRQoL studies from Africa.

Study design, size, duration: This was a cross sectional, descriptive study involving 170 women and 52 partners. Data was collected between March and August 2011.

Participants/materials, setting, methods: Women attending their initial consultation at the infertility clinic of a public tertiary referral centre were recruited. Male partners were invited to participate subject to their presence and willingness. Generic (WHOQol-brev) and disease-specific (FertiQoL) instruments were administered. Domain scores were calculated for each questionnaire.

Main results and the role of chance: We had a 100% response rate because the questionnaires were administered. Gendered suffering in women was illustrated by the low mean scores in the emotional and psychological domains of the WHOQol-brev and the FertiQoL respectively. This was not observed in men. Mean domain scores were the same for men and women in all other domains of the WHOQol-brev. Women scored lower than men in all domains of the FertiQoL. Higher education, secondary infertility and a longer duration of infertility had a positive effect on certain domains. There was a significant difference between the mean scores in the emotional and mind/body domains of disease specific compared with the psychological and physical domains of the generic instrument. The results of the social domains were comparable.

Limitations, reason for caution: This sample represents women and their partners seeking medical intervention for infertility - a self selected group. Results cannot be extrapolated to women and men not seeking care, living in rural settings or accessing private infertility care. We did not evaluate other life events which may have influenced QoL.

Wider implications of the findings: The results illustrate that the generic QoL instrument does identify the domains in which women are affected but underestimates the impact of the effect. We can therefore use this instrument to compare the impact of infertility to other diseases. Disease specific instruments must be used when comparing the effect of infertility between different populations/cohorts.

This data is the first of its kind in South Africa and can be used as a comparison for future studies.

Study funding/competing interest(s): There are no competing interests to declare.

Trial registration number: There was no trial registration number.

P-051 Gender preference and demand for preconception sex selection: a survey among middle-class pregnant women in Ghana

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Study question: Is there a gender preference and desire for preconception sex selection among middle-class pregnant women living in Ghana, West Africa?

Summary answer: For the middle-class Ghanaian population surveyed, the majority of pregnant women displayed no preference for the gender of their offspring or to access sex selection technology, even if it was offered for free; where a gender was preferred, the desire for girls was higher than the desire for boys.

What is known already: The demand for sex selection for non-medical or social reasons remains a highly controversial area of reproductive medicine, with son preference remaining common in countries throughout Asia and the Middle East, whilst studies from Europe, North America and the Caribbean indicate less bias. Although previous studies have sampled attitudes of Africans living elsewhere, no data has been published on opinions of West Africans living in their ancestral countries.

Study design, size, duration: A cross sectional study using a self-report questionnaire consisting of 20 questions distributed to 143 pregnant women from 1st June – 1st November 2012. All responses were kept anonymous and participation was voluntary. Information was collected on demographics (marital status, education, age, religion and ethnicity) and views on preconception sex selection.

Participants/materials, setting, methods: 143 pregnant women participated in the study, whilst attending an antenatal clinic in a private hospital in Accra, Ghana. Self-report questionnaires were individually distributed and collected during one visit.

Main results and the role of chance: There was a 100% response rate to the questionnaires. Most women were in established relationships (97.2%), educated to University level (93.0%), of African descent (88.1%), Christian (81.1%), aged 26-30 years (39.2%) and had planned their pregnancies (70.4%). 47.9% did not know the sex of their fetus, and 60.1% of this group had no gender preference. For the future, most wanted an equal number of boys and girls (37.1%), whilst 18.8% desired more girls than boys and 7.7% desired more boys than girls. 22.4% stated that they would consider using sex selection technology if it was available. Regarding sex selection for social reasons, 40.6% stated this should be permitted, whilst 25.9% stated that this should be prohibited and 33.6% were undecided.

Limitations, reason for caution: This study was limited in that the survey took place in a private clinic accessed by middle-class women. The results may be representative of this subsection of the Ghanaian population, but may not represent all levels of society. Only women were surveyed, rather than their partners.

Wider implications of the findings: The non-preference for offspring gender or access to sex selection technology is similar to the findings from European, North American and Caribbean studies. Interestingly, where a gender was preferred, the desire for girls was higher than for that for boys, which is a novel finding and contrary to the son preference expressed elsewhere in the world. Further studies are needed to reveal if the opinions expressed are representative of middle-class women across West Africa.

Study funding/competing interest(s): This study was undertaken voluntarily with no competing interests.

Trial registration number: None required.

What is known already: The use of gonadotropins to stimulate multi-folliculogenesis alters endometrial expression of genes and proteins. These alterations may compromise embryo competency, when compared to natural cycles. It was only recently, with the wide acceptance of single embryo transfer as a practice, that the possibility of an undetected chemical pregnancy occurring concurrently with a clinical pregnancy could be excluded. Therefore, the effect of endometrium embryo interaction on biochemical pregnancy rates can now be studied in isolation.

Study design, size, duration: Retrospective case control study, approved by the McGill ethic committee which recruited patients from August 2008 through December 2012. Data was compared using chi-squared contingency and goodness of fit tests. Biochemical pregnancy reference values were obtained from the medical literature. IVF and controls were matched for age.

Participants/materials, setting, methods: Subjects ≤ 42 -years old, undergoing a single embryo transfer (SET), as part of a fresh or thawed IVF cycle. Each subject is represented once. Rates of biochemical pregnancy for fertile control subjects were obtained by pooling results from the medical literature (N = 439). (M Zinaman 1996, NJ Elish 1996, AJ Wilcox 1988).

Main results and the role of chance: The IVF group consisted of 1636 fresh and 188 frozen SET. The pregnancy rate per transfer for fresh and frozen IVF cycles were 39% and 40% respectively. The probability of different pregnancy outcomes (no pregnancy, clinical pregnancy, biochemical pregnancy and ectopic pregnancy) did not differ when comparing fresh and frozen IVFs, $p = 0.793$. The biochemical pregnancy rate for fresh and frozen IVF cycles was 14% for both. The biochemical pregnancy rate (14%) in the IVF group was lower than the range in the fertile control population (18%), $p = 0.01$. The age ranges of the IVF and fertile controls were 21 to 42 years. Among IVF subjects advancing age was associated with a lower likelihood of clinical pregnancy ($p = 0.0001$), while the likelihood of a biochemical pregnancy remained similar.

Limitations, reason for caution: Cryopreservation of embryos may induce injury however, only best quality embryos are frozen. Concurrently, a fresh SET sometimes used lower quality embryos which likely induced similar pregnancy outcomes between the two groups. Due to the nature of the biochemical pregnancy control group an in-house population is almost impossible to collect.

Wider implications of the findings: It could be theorized that IVF may result in an increase of biochemical pregnancies. However, early pregnancy wastage was lower when compared to a fertile age matched population. This may be due to selection of embryo transferred compared to single embryo genesis in nature. This finding was statistically significant however, mildly clinically significant. Literature review revealed that this is the first study to investigate this comparison. Further data would be needed to confirm this result.

Study funding/competing interest(s): None

Trial registration number: Retrospective study therefore, not indicated.

P-053 How successful is the medical management of early pregnancy failure (EPF) in clinical practice? Retrospective analysis of a combined protocol of mifepristone and misoprostol

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Study question: How effective is the combination of 600mg oral mifepristone followed by a maximum of 4 doses of mifepristone 400mcg vaginally in the management of early pregnancy failure (EPF) and what is the average time to expulsion of tissue?

Summary answer: This retrospective study showed that the actual clinical success rate for this combination protocol is markedly below that reported by studies in the literature, with differences possibly attributed to physician subjectivity in judging the success of treatment and patient preferences for continuing with or discontinuing the medical management.

What is known already: Various protocols and schemes for the medical management of EPF are used worldwide making it difficult to compare their success rates due to diverse dosing, timing, and routes of medication administration as well as to the lack of a standardized definition of successful treatment. Results of randomized and non-randomized studies place the failure rate of medical management of EPF at 10–50%.

Early pregnancy

P-052 Biochemical pregnancy rate may be lower in subjects undergoing in-vitro fertilization with single embryo transfer as compared to the fertile population, =42 years old

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Study question: Does in-vitro fertilization (IVF) affect the biochemical pregnancy rate?

Summary answer: The likelihood of an early pregnancy loss may be lower in IVF cycles when compared to published rates of biochemical pregnancy in fertile women ≤ 42 years old.