

Insights from outside BJOG

June 2017

Clinical guidelines updates

To be added at proof stage.

New reports and guidelines

Consolidated guideline on sexual and reproductive health and rights of women living with HIV

This consolidated guideline, produced by the World Health Organization (WHO), states that it takes account of the major changes in HIV-related research and policy-making that has occurred in the ten years since the WHO published '*Sexual and reproductive health of women living with HIV/AIDS: guidelines on care, treatment and support for women living with HIV/AIDS and their children in resource-constrained settings*'. The guideline, aimed at national policy makers, health care professionals and programme managers, provides sexual and reproductive health-related guidance and good practice advice to enable supportive care to be provided to women living with HIV. The guideline is based on the results of a Global Values and Preferences Survey and reflects the opinions of women living with HIV. The framework illustrated in Figure 1 helpfully sets out the structure of the guideline and enables good practice statements and WHO recommendations which can be easily identified and understood within the context of the consolidated guideline as a whole. Table 1 provides a summary list of WHO recommendations for the sexual and reproductive health and rights of women living with HIV that includes recommendations regarding healthy sexuality across the life course, protection from violence and creating safety, community empowerment, sexual health counselling and support, family planning and infertility services, antenatal care and maternal health services, safe abortion services, sexually transmitted infection and cervical cancer services. Table 2 provides a summary list of WHO good practice statements for the sexual and reproductive health and rights of women living with HIV that includes: psychosocial support; social inclusion and acceptance; supportive laws and policies and access to justice; brief sexuality communication; prevention of perinatal transmission of HIV.

<http://apps.who.int/iris/bitstream/10665/254634/1/WHO-RHR-17.03-eng.pdf?ua=1>

Better beginnings: improving health for pregnancy

This themed review, prepared by the National Institute for Health Research (NIHR) in the UK, focusses on modifiable risk factors in women from preconception through to the post-partum and aims to help improve evidence-based maternal health-related service provision. The review outlines available evidence that can help women around the time of pregnancy and includes chapters on improving health before pregnancy, stopping smoking, healthy diet and nutrition supplements, healthy weight, breastfeeding, alcohol and drug use, violence against women, and addressing mental health problems and psychosocial stress. For each chapter links to individual research studies are provided and a 'read more' box includes links to websites and guidelines where further information is available. The 'Evidence Highlights' section outlines key messages including: when women access services before and between pregnancies, opportunities should be taken to improve health behaviours and manage long-term

health conditions; financial incentives to stop smoking in pregnancy may be helpful but more research is needed; using metformin in pregnancy for women with obesity is currently not recommended to improve pregnancy outcomes unless they have type 2 diabetes; sidecar cots in hospitals improve breastfeeding initiation but not duration; brief advocacy interventions by health professionals to empower women can improve mental health and may reduce abuse in pregnancy; providing one-to-one support for disadvantaged women during pregnancy and after birth, using a doula, led to a positive care experience and increased breastfeeding; the use of psychotropic medication before and during pregnancy requires specialist review.

<http://www.dc.nihr.ac.uk/themed-reviews/Better-beginnings-web-interactive.pdf>

Assisted Reproductive Technology Surveillance — United States, 2014

This surveillance summary from the US Morbidity and Mortality Weekly Report (MMWR), provides a detailed breakdown of state-specific information regarding assisted reproduction technology (ART) procedures performed in 2014 and includes a comparison of birth outcomes between ART outcomes and outcomes for all newborns in the US in 2014. This report is based on data collected by the web-based National ART Surveillance System (NASS) that includes data from 52 areas (the 50 states, the District of Columbia, and Puerto Rico). The report states that a total of 169,568 ART procedures were performed across 458 fertility clinics in the US in 2014 and that this resulted in 56,028 live-birth deliveries. Eight areas (Connecticut, the District of Columbia, Hawaii, Illinois, Maryland, Massachusetts, New Jersey, and New York) reported ART procedure rates that were more than one and a half times the national average. The report discusses embryo transfer and patient's age, singleton and multiple births, adverse perinatal outcomes, elective single-embryo transfer rates, and ART low birthweight infants and preterm births. Of the eight included tables, table one provides a detailed list of the number and outcomes of assisted reproductive technology procedures, by the female patient's reporting area of residence at time of treatment and table two lists the number of assisted reproductive technology embryo transfer procedures among patients who used fresh embryos from their own eggs, by female patient's age group and reporting area of residence at time of treatment.

<https://www.cdc.gov/mmwr/volumes/66/ss/ss6606a1.htm>

In a state of crisis: meeting the sexual and reproductive health needs of women in humanitarian situations

This policy review, produced by the Guttmacher Institute, provides an overview of the roles and responsibilities of different international agencies in protecting, providing and meeting the sexual and reproductive health needs of women during conflicts and other humanitarian situations. The review states that in terms of the 129 million people around the world currently requiring humanitarian aid, around a quarter are reproductive-age women and adolescent girls. Despite improvements in recent years in providing sexual and reproductive health services during humanitarian emergencies, the review states that implementation of agreed policies and standards has not always occurred. Barriers to implementation are reported to be cultural, research-based and financial with many barriers not specifically related to sexual and reproductive health service provision. The review concludes by highlighting the World Humanitarian Summit held in May 2016 and a report, submitted ahead of the Summit by the United Nations Secretary General, in which five core responsibilities for action were outlined, two of which called for prioritisation of sexual and reproductive health services as a means to empower women and girls, and ensuring

provision of support to survivors of sexual and gender-based violence. The summit reportedly resulted in key commitments from non-governmental and governmental leaders regarding upholding humanitarian principles and working to ensure better preparedness and response to international humanitarian crises.

https://www.guttmacher.org/sites/default/files/article_files/gpr2002417_1.pdf

Innovations and patents

Patent applications

US9579055 (B1) Apparatus for non-invasive fetal biosignal acquisition. Rood AT, Shaw GS, Moore JM, Wajda D, Orbital Res Inc. 28 February 2017.

This patent application relates to the invention of non-invasive apparatus for diagnosing or monitoring electrophysiological signs in pregnant women and fetuses. Specifically, this involves the use of an adjustable electrode harness to obtain biopotential measurements such as ECG, EEG, EMG with the potential to distinguish fECG from maternal signals other than mECG.

https://worldwide.espacenet.com/publicationDetails/biblio?CC=US&NR=9579055B1&KC=B1&FT=D&ND=3&date=20170228&DB=EPODOC&locale=en_EP#

EP3135692 (A1) Antibodies to endoplasmin and their use. Ferrone S, Wang X, Conrads TP, Favoino E, Hood B. 1 March 2017.

This patent application discusses isolated monoclonal antibodies and antigen binding fragments of these antibodies, with specific reference to fully human antibodies that specifically bind endoplasmin (Grp94). It is proposed that such antibodies can be used to detect or treat tumours that express endoplasmin such as breast cancer or ovarian cancer.

This claims the benefit of U.S. Provisional Application No. 61/355,516, filed June 16, 2010, which is incorporated herein by reference in its entirety.

https://worldwide.espacenet.com/publicationDetails/biblio?CC=EP&NR=3135692A1&KC=A1&FT=D&ND=3&date=20170301&DB=EPODOC&locale=en_EP#

EP3133173 (A1) New fetal methylation marker. Lo YMD, Chiu RWK, Chim SSC, Ding C, Chan KC, Wong HN, Yuen KCR. 22 February 2017.

This patent application discusses the finding by the authors that the presence of genes such as RASSF1A, APC, CASP8, RARB, SCGB3A1, DAB2IP, PTPN6, THY1, TMEFF2, and PYCARD in a biological sample obtained from a pregnant woman that are methylated are derived from the fetus whereas the same genes in the sample from the pregnant woman are unmethylated. This discovery allows for the detection of the presence of fetal DNA in biological samples which can help in the diagnosis of certain pregnancy-related conditions.

This application claims priority to U.S. Provisional Patent Application Serial No. 60/797,506, filed May 3, 2006, the contents of which are hereby incorporated by reference in the entirety for all purposes.

https://worldwide.espacenet.com/publicationDetails/biblio?CC=EP&NR=3133173A1&KC=A1&FT=D&ND=3&date=20170222&DB=EPODOC&locale=en_EP#

AU2015287867 (A1) Systems and methods for measuring fetal cerebral oxygenation. 23 February 2017.

This patent application relates to the development of optoacoustic devices and methods comprising a console unit and a handheld probe which can be used to measure blood oxygen levels in a fetus during childbirth to determine whether a caesarean delivery is indicated.

This application claims the benefit of U.S. Provisional Application Nos. 62/021,946, filed July 8, 2014 and entitled "System and Methods for Measuring Fetal Cerebral Oxygenation," and 62/168,081, filed May 29, 2015 and entitled "System and Methods for Measuring Fetal Cerebral Oxygenation," which applications are incorporated herein by reference.

Legal matters

Philippines plugs reproductive health funding gaps

The Philippine Government has recently reversed a decision, taken in January 2016, that cut funding for state-provided contraceptive services. The reversal is said to indicate the President's commitment to reproductive health and the rights of Filipino women to have access to modern family planning options.

<https://www.hrw.org/news/2017/01/13/philippines-plugs-reproductive-health-funding-gaps>

Malawi amends Constitution to remove child marriage loophole

The Malawian Parliament recently abolished a legal loophole in the Constitution that allowed children between the ages of fifteen and eighteen to marry as long as they had parental consent. The loophole arose as the minimum age of marriage as set out by the Constitution differed from that set out in the Marriage, Divorce and Family Relations Act which stipulates that the minimum age of marriage is eighteen.

<https://www.hrw.org/news/2017/02/23/malawi-amends-constitution-remove-child-marriage-loophole>

Clinical trials

Clinicians keen to keep up-to-date regarding clinical studies that are currently recruiting may find the following informative.

Title PrEP implementation for mothers in antenatal care (PrIMA)

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| Registration | https://www.clinicaltrials.gov/ct2/show/NCT03070600 | | |
| Description | This phase 4 study aims to explore the effectiveness and feasibility of a targeted pre-exposure prophylaxis (PrEP) model for the prevention of HIV in pregnant women attending antenatal care clinics in Western Kenya. | | |
| Outcome measures | Primary: maternal HIV incidence. | Secondary: appropriate PrEP use; PrEP adherence; PrEP duration; partners HIV self-test; infant birthweight; infant growth; PrEP exposure. | |
| Study site | Washington, US and Nairobi, Kenya. | Anticipated study | April 2021. |

end date

Title IVM versus IVF: differences in patients' emotional adjustment and quality of life (EMAQOLIVMIVF)

Registration <https://www.clinicaltrials.gov/ct2/show/NCT03066349>

Description This case-control study aims to compare a conventional ovarian stimulation protocol versus an in-vitro maturation (IVM) protocol followed by in vitro fertilisation (IVF) in terms of the psychological impact of treatment on women. In addition, the investigators will examine the differences in quality of life between the two groups of women.

Outcome measures **Primary:** FertiQol score. **Secondary:** Hospital Anxiety and Depression Scale.

Study site Brussels, Belgium. **Anticipated study end date** 31 March 2019.

Title Functional study of the hypothalamus in magnetic resonance imaging (MRI) in polycystic ovary syndrome (PCOS) (MRI-PCOS)

Registration <https://clinicaltrials.gov/ct2/show/NCT03043924>

Description This comparative study aims to investigate whether activation of the hypothalamic-pituitary-gonadal axis in women with Polycystic Ovary Syndrome (PCOS) is associated with transient microstructural and metabolic changes in the female hypothalamus. The investigators state that the study will use high resolution magnetic resonance imaging (MRI) to assess water diffusion and measure proton magnetic resonance spectra.

Outcome measures **Primary:** change in the Apparent Diffusion Coefficient (ADC). **Secondary:** change in the metabolite concentrations; correlation coefficient (Spearman or Pearson) between the ADC and serum hormonal levels (FSH, luteinizing hormone, oestradiol, AMH); correlation coefficient (Spearman or Pearson) between the metabolite concentrations and serum hormonal levels (FSH, luteinizing hormone, oestradiol, AMH).

Study site Lille, France. **Anticipated study end date** March 2019.

Title Pelvic floor exercise before surgery in women with pelvic organ prolapse (CONTRAPOP)

Registration <https://www.clinicaltrials.gov/ct2/show/NCT03064750>

Description This randomised study aims to determine whether pelvic floor exercise and lifestyle advice before surgery for either vaginal prolapse or urinary incontinence improves outcomes in women post-surgery.

Outcome **Primary:** pelvic floor strength (muscle strength assessed by palpation (Modified Oxford Scale)). **Secondary:** pelvic floor strength (muscle strength assessed by Perineometry -

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| measures | Peritron®); pelvic floor strength (muscle strength assessed by electromyography); pelvic floor strength (muscle strength assessed by transperineal pelvic floor ultrasound); pelvic organ prolapse (measured with the Pelvic Organ Prolapse Quantification (POP-Q) System); pelvic organ prolapse (measured with the Pelvic floor distress inventory (PFDI)); urinary incontinence (measured with the Pelvic floor distress inventory (PFDI)). |
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| Study site | Trondheim, Norway. | Anticipated study end date | 1 October 2017. |
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Title Application of greenlaser in dysfunctional uterine bleeding of perimenopausal women

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| Registration | http://www.chictr.org.cn/showprojen.aspx?proj=18250 |
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| Description | This randomised controlled trial aims to investigate the safety and effectiveness of photoselective vaporisation of the uterine endometrium with green laser for the treatment of dysfunctional uterine bleeding in peri-menopausal women. |
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| Outcome measures | Primary: hemostasis effect. | Secondary: side effects. |
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|-------------------|-----------------|-----------------------------------|-------------------|
| Study site | Shaanxi, China. | Anticipated study end date | 31 December 2018. |
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