

## **Insights from outside BJOG** **January 2018**

### **Clinical guidelines updates**

*To be added at proof stage*

### **New reports and guidelines**

#### *Materials to support cancer patients, caregivers, and health workers*

This toolkit for K4Health was developed by the American Cancer Society and the Johns Hopkins Center for Communication Programs and contains patient education materials that have been prepared in collaboration with the Ministries of Health in Uganda, Kenya and Ethiopia and additional cancer-related stakeholders within these countries. The toolkit content has been specifically designed to help patients and carers cope with cancer diagnosis and are based on two existing American Cancer Society booklets 'After diagnosis: a guide for patients and families' and 'Listen with your heart: talking with the person who has cancer'. Country-specific educational materials are provided for each of the three countries. For use in Ethiopia booklets on 'After diagnosis: a guide for patients', 'Listen with your heart: what we can do to take care of a loved one with cancer', 'Cancer information for patients', 'A guide to cancer for health professionals' are available in Amharic and English. For use in Kenya three booklets have been produced in Swahili and English: 'What you need to know about cancer: a guide for patients and caregivers'; 'How to communicate with cancer patients: tips for health care workers'; 'What you need to know about cancer: for use with patients and caregivers'. For use in Uganda booklets are available in Luganda and English on 'Coping with cancer: a booklet for cancer patients', 'Caring for cancer patients: a booklet for caregivers of cancer patients', 'Cancer information for patients and their families'. Documentation is available on the process used (the P Process) to develop the materials to aid the production of similar materials in other countries and an adaptation guide and library of images have been provided to support health professionals and programme managers in producing their own materials.

<https://www.k4health.org/toolkits/cancersupportmaterials>

#### *A guide to identifying and documenting best practices in family planning programmes*

This guide, developed by the World Health Organization (WHO) Regional Office for Africa, aims to highlight the importance of and help health professionals, public health officials and others working in family planning services to identify, document and share knowledge of what works, how it works and why. The guide includes useful templates to aid documentation of best practices to help ensure that all the information required to make informed decisions about replicating best practices are available. Chapter 3 focuses on scaling up best practices and includes a summary of the elements of the definition of scaling up and chapter 4 provides a number of suggestions regarding how to disseminate this guide widely. Table 1 provides a useful summary of best practice criteria and the annexes contain a detailed best practice template for writing up best practice and a checklist for identifying practices for potential scale up.

<http://apps.who.int/iris/bitstream/10665/254748/1/9789290233534-eng.pdf?ua=1>

*Providing long-acting reversible contraception (LARC) learning resource package (modular/facility-based)*

This learning resource package, produced by JHPiego, has been designed for use by trainers and programme staff to aid in the provision of training to health care professionals on the topic of long-acting reversible contraception (LARC). The package uses a modular design with 10 individual modules available covering: introduction to long-acting reversible contraceptives (LARCs); family planning counselling; medical eligibility and client assessment; quality of care; infection prevention for LARC methods; copper intrauterine device (Copper T 380A); hormonal intrauterine device (LNG-IUS); postpartum intrauterine device; post-abortion intrauterine device; contraceptive implants. For each module a facilitator and a learner document is provided containing detailed information about the module objectives and a session plan and sample schedule, assessment information and pre- and post-test questionnaires, an activity list, checklists, handouts, job aids and some facilitator tools.

[http://resources.jhpiego.org/resources/Modular\\_LARC\\_LRP](http://resources.jhpiego.org/resources/Modular_LARC_LRP)

*Seventeen ways to end female genital mutilation/cutting: lessons from the field*

This booklet is a companion to the 2016 Annual Report for the UNFPA-UNICEF Joint Programme on Female Genital Mutilation/Cutting (FGM/C) and specifically focuses on highlighting the challenges, achievements and methods that those involved in the Joint Programme use to help change the practice of FGM/C in different countries. As the title alludes to, the booklet contains 17 experience-based recommendations from different organisations and individuals working within communities to bring an end to FGM/C. Examples are provided from Sudan, Guinea, Uganda, Ethiopia, Eritrea, Egypt, Burkina Faso, Kenya, Nigeria, Somalia, Senegal, Gambia, and Guinea-Bissau. The seventeen ways to end female genital mutilation/cutting outlined here include: accentuate the positive; orchestrate local efforts; create webs of protection; support commitments; work from within; stay open to opportunities; implement sanctions progressively; end impunity; use media creatively; build bridges; enlist tribal elders; power up partnerships; work with the grass roots.

<http://www.unfpa.org/sites/default/files/pub-pdf/17ways-web.pdf>

## **Innovations and patents**

### **Patent applications**

*WO2017176985 (A1) Isolation and analysis of fetal DNA from extravillous trophoblast cells retrieved from the endocervical canal. Drewlo S. & Armant RD. 12 October 2017.*

This patent application outlines methods to isolate DNA from fetal extravillous trophoblast cells from a pregnant woman and methods to analyse the fetal DNA obtained.

This application claims priority to U.S. Provisional Patent Application Serial No.62/318,982, filed April 6, 2016, the entire content of which is incorporated herein by reference.

[https://worldwide.espacenet.com/publicationDetails/biblio?CC=WO&NR=2017176985A1&KC=A1&FT=D&ND=3&date=20171012&DB=EPODOC&locale=en\\_EP#](https://worldwide.espacenet.com/publicationDetails/biblio?CC=WO&NR=2017176985A1&KC=A1&FT=D&ND=3&date=20171012&DB=EPODOC&locale=en_EP#)

*WO2017173250 (A1) Methods and compositions for SIRT1 expression as a marker for endometriosis and subfertility. Young SL., Lessey BA., Jeong JW. 5 October 2017.*

This patent application relates to a sensitive test for endometriosis and/or subfertility/infertility. Specifically, a sample of endometrium is obtained during the second half of a woman's menstrual cycle which is analysed to determine levels of expression of the SIRT1 gene and also levels of BCL6 gene expression. The patent also outlines methods for the treatment of women with endometriosis and subfertility/infertility and for assessing likelihood of successful implantation in vitro fertilisation procedures.

This application claims the benefit, under 35 U.S.C. § 119(e), of U.S. Provisional Application Serial No. 62/316,163, filed March 31, 2016 and U.S. Provisional Application Serial No. 62/471,915, filed March 15, 2017, the entire contents of each of which are incorporated by reference herein.

[https://worldwide.espacenet.com/publicationDetails/biblio?CC=WO&NR=2017173250A1&KC=A1&FT=D&ND=3&date=20171005&DB=EPODOC&locale=en\\_EP#](https://worldwide.espacenet.com/publicationDetails/biblio?CC=WO&NR=2017173250A1&KC=A1&FT=D&ND=3&date=20171005&DB=EPODOC&locale=en_EP#)

*AU2017228558 (A1) Noninvasive prenatal molecular karyotyping from maternal plasma. Lo YMD., Chan KC., Jiang P., Yu CYJ., Chiu WR. 5 October 2017.*

This patent application proposes methods, systems, and apparatus for the detection of microamplifications or microdeletions in the genome of a fetus. Specifically, a non-invasive biological sample is obtained from a pregnant woman including cell-free DNA from the fetus and from the woman.

The present application claims priority to U.S. Provisional Patent Application No.61/751,213, entitled "Noninvasive Prenatal Molecular Karyotyping from Maternal Plasma" and filed January 10, 2013, as well as to U.S. Patent Application No. 13/837,776, entitled "Noninvasive Prenatal Molecular Karyotyping from Maternal Plasma" and filed March 15, 2013. Each priority application is herein incorporated by reference in its entirety for all purposes.

[https://worldwide.espacenet.com/publicationDetails/biblio?CC=AU&NR=2017228558A1&KC=A1&FT=D&ND=3&date=20171005&DB=EPODOC&locale=en\\_EP#](https://worldwide.espacenet.com/publicationDetails/biblio?CC=AU&NR=2017228558A1&KC=A1&FT=D&ND=3&date=20171005&DB=EPODOC&locale=en_EP#)

*WO2017179012 (A1) Nutraceutical or pharmaceutical composition for use in the treatment of polycystic ovary syndrome or of diseases or disorders related thereto. Fioretti B. & Leonardi L. 19 October 2017.*

This patent application discusses a pharmaceutical or nutraceutical composition consisting of at least one inositol and resveratrol with at least one hydroxide of a bivalent or trivalent metal which can be used for prevention or treatment of metabolic disorders related to polycystic ovary syndrome or the symptoms associated with polycystic ovary syndrome.

[https://worldwide.espacenet.com/publicationDetails/biblio?CC=WO&NR=2017179012A1&KC=A1&FT=D&ND=3&date=20171019&DB=EPODOC&locale=en\\_EP#](https://worldwide.espacenet.com/publicationDetails/biblio?CC=WO&NR=2017179012A1&KC=A1&FT=D&ND=3&date=20171019&DB=EPODOC&locale=en_EP#)

## **Legal matters**

*Inter-American Commission on Human Rights calls for better access to reproductive health services*

The Inter-American Commission on Human Rights (IACHR) has recently issued a statement reportedly highlighting the effect that laws that criminalise abortion under all circumstances have on the upholding of human rights with particular emphasis on

women's rights. The IACHR stated that all States must allow access to the specific health services required by women and girls as a result of their gender which should be provided free from violence and discrimination.

<https://www.reproductiverights.org/press-room/inter-american-commission-on-human-rights-calls-for-better-access-to-reproductive-health->

#### *Call for Australia to allow mitochondrial donation techniques*

A campaign to change the law in Australia to allow mitochondrial donation has recently been launched. The technique which prevents the transmission of inherited mitochondrial diseases from the mother by conceiving a child using in vitro fertilisation with the genetic material from both parents and also a mitochondrial donor is currently illegal in Australia as it violates both the Research Involving Human Embryos Act 2002 and also the Prohibition of Human Cloning for Reproduction Act 2002.

[http://www.bionews.org.uk/page\\_889170.asp](http://www.bionews.org.uk/page_889170.asp)

### **Clinical trials**

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

#### **Title Intravaginal electrical nerve stimulation in women with non-contracting pelvic floor**

<b>Registration</b>	<a href="https://clinicaltrials.gov/ct2/show/NCT03319095">https://clinicaltrials.gov/ct2/show/NCT03319095</a>		
<b>Description</b>	This randomised controlled trial aims to investigate the effectiveness of intravaginal electrical stimulation on the ability of women, with a non-contracting pelvic floor, to achieve voluntary contraction of their pelvic floor muscles.		
<b>Outcome measures</b>	<b>Primary:</b> bidigital vaginal palpation.	<b>Secondary:</b> International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF).	
<b>Study site</b>	São Paulo, Brazil.	<b>Anticipated study end date</b>	February 2019.

#### **Title Ultrasound and photoacoustic imaging for cervical cancer**

<b>Registration</b>	<a href="https://clinicaltrials.gov/ct2/show/NCT03318107">https://clinicaltrials.gov/ct2/show/NCT03318107</a>		
<b>Description</b>	This phase 1 pilot study aims to assess the ability of a transvaginal probe using photoacoustic and ultrasound imaging to detect early tumour angiogenesis changes or residual tumours after systemic treatment in women with cervical cancer.		
<b>Outcome measures</b>	<b>Primary:</b> number of participants who complete the imaging protocol.	<b>Secondary:</b> reduction rate of tumour angiogenesis, charge pattern of blood oxygen saturation.	
<b>Study site</b>	Missouri, U.S.	<b>Anticipated study end date</b>	March 2019.

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end date

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**Title Auto-PAP therapy for improved fetal growth**

**Registration** <https://clinicaltrials.gov/ct2/show/NCT03318003>

**Description** This randomised study aims to investigate any relationship between night-time breathing disturbances during pregnancy and fetal growth patterns. In particular, to determine whether a breathing therapy called auto-PAP can minimise the slowing of fetal growth in the third trimester.

**Outcome measures** **Primary:** fetal weight trajectory. **Secondary:** placental hypoxia.

**Study site** Michigan, U.S. **Anticipated study end date** October 2019.

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**Title Psychological traits, sexuality and quality of life in patients with polycystic ovary syndrome**

**Registration** <https://clinicaltrials.gov/ct2/show/NCT03306459>

**Description** This observational study aims to investigate the association between polycystic ovary syndrome (PCOS) and psychological disturbances in women and will also seek to determine whether biochemical/phenotypical features of PCOS play a role in the type and severity of any reported psychological disorders.

**Outcome measures** **Primary:** quality of life. **Secondary:** sexuality, psychological distress, anger and aggressiveness.

**Study site** Barcelona, Spain. **Anticipated study end date** December 2020.

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**Title Effectiveness of estradiol valerate pretreatment in antagonist protocol for poor ovarian response patient**

**Registration** <https://clinicaltrials.gov/ct2/show/NCT03300518>

**Description** This randomised study aims to investigate the effectiveness of add-on oestrogen pre-treatment in a GnRH antagonist protocol on oocyte retrieval when compared to GnRH antagonist protocol alone in women with poor ovarian response.

**Outcome measures** **Primary:** the number of oocytes retrieved by the IVG 36 hours after hCG administration. **Secondary:** optimal number of embryo, ongoing pregnancy rate, clinical pregnancy rate.

**Study site** Hunan, China. **Anticipated study end date** December 2018.

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