

**Insights from outside BJOG**  
**November 2015**

**Clinical guidelines updates**

*To be added at proof stage.*

**New reports and guidelines**

*Health worker roles in providing safe abortion care and post-abortion contraception*

This guideline, published by the World Health Organisation (WHO), investigates and provides recommendations on the safety, feasibility and acceptability of involving a wider range of health workers in providing abortion and post-abortion care. The guideline states that despite safe and effective interventions for abortion almost 22 million unsafe abortions occur every year. Increasingly, task shifting and task sharing is becoming a widespread practice in countries with a shortage of specialist health care professionals and this guideline emphasises that possibilities exist in most countries for expanding health worker roles to provide this type of care. The range of health professionals considered in this guideline includes obstetrics and gynaecology professionals, doctors not specialised in obstetrics and gynaecology, associate clinicians, midwives and auxiliary nurse midwives, nurses and auxiliary nurses, complementary medicine doctors, pharmacists and pharmacy assistants and lay health workers. Recommendations relating to safe abortion care and the management of complications are provided including on: management of abortion and post-abortion care in the first trimester (including vacuum aspiration, medical management, management of incomplete abortion and self-management); management of abortion and post-abortion care beyond 12 weeks (including dilation and evacuation and medical abortion); recognising and managing non-life threatening complications (including post-abortion infection and post-abortion haemorrhage); counselling and information provision (including information on safe providers, legal issues and contraception options); post-abortion contraception provision (including insertion and removal of intrauterine devices (IUDs) and implants and tubal ligation). Future research needs are outlined including the safety, effectiveness and feasibility of expanding the role of the pharmacists and lay health workers in providing abortion and post-abortion care, the development of tools and checklists to aid the assessment both of abortion completeness and of eligibility for medical abortion, implementation research investigating the most effective interventions to expand health worker roles within different health systems. Guideline supplements summarise the evidence to decision frameworks, the evidence base for benefits and harms and the evidence base for acceptability and feasibility that all underpin the recommendations provided.

[http://apps.who.int/iris/bitstream/10665/181041/1/9789241549264\\_eng.pdf?ua=1&ua=1](http://apps.who.int/iris/bitstream/10665/181041/1/9789241549264_eng.pdf?ua=1&ua=1)

*Sexual health, human rights and the law*

This comprehensive report, produced by the Department of Reproductive Health and Research of the World Health Organization (WHO/RHR), discusses the relationship between sexual health, human rights and the law and using examples from countries around the world demonstrates how sexual and reproductive health can be supported through legal systems which uphold international human rights agreements and

standards. Eight main topics were identified that explore sexual health, how laws address sexual and reproductive health issues and also how human rights standards are addressed in national and international legal documents. The topics include: non-discrimination; penalization of sexuality/sexual activities; state regulation of marriage and family; gender identity/expression; violence; availability, accessibility, acceptability and quality of sexual health services; information, education and expression related to sexuality and sexual health; sex work. The report comprises chapters on health services for the promotion and protection of sexual health (including creating enabling legal and regulatory frameworks and eliminating barriers to services for sexual health, ensuring quality and respect of human rights in the provision of sexual health services and elimination of discrimination in access to health services); information and education for sexual health (including legal restrictions on sexuality information and education and human rights standards and legal protections); sexual and sexuality-related violence (including sexual assault and rape, forced marriage, trafficking for forced prostitution and female genital mutilation). Nine legal and policy implications are highlighted including: has the State adopted legislative and all other measures necessary to prevent, investigate and punish acts of violence, including all forms of sexual violence?; does the State recognize that forced sterilization or other coerced or forced procedures affecting sexual and reproductive health are a violation of human rights?; has the State taken appropriate and effective measures to eliminate FGM, through both legislation as well as education and public awareness campaigns?; do laws contain provisions that guarantee the protection of human rights for people engaged in sex work? Table 1 lists the core international human rights treaties relevant to the protection of human rights in relation to sexual and reproductive health.

[http://apps.who.int/iris/bitstream/10665/175556/1/9789241564984\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/175556/1/9789241564984_eng.pdf?ua=1)

*Reaching young married women and first-time parents for healthy timing and spacing of pregnancies in Burkina Faso*

This technical brief, published by Pathfinder International, highlights key findings and lessons learned from a programme developed to support increased contraceptive use and healthy timing and spacing of pregnancies amongst young married women and first-time parents in Burkina Faso. The brief states that Burkina Faso has a high total fertility rate and low contraceptive prevalence rates and that at the time of programme initiation there was a lack of evidence regarding how best to reach this population. The programme, which was implemented in collaboration with the Burkina Faso Ministry of Health and local partners, had two main goals: firstly to increase access to and use of contraceptives and other sexual and reproductive health services amongst young married women and first time parents and secondly to increase support amongst communities, households and individuals for delaying pregnancy until at least the age of 18 years and to space subsequent pregnancies. The brief states that the programme drew on the experiences of other projects targeting increased contraceptive use previously implemented around the world including the PRACHAR project in Bihar, India and the GREAT project in Northern Uganda. The project involved home visits by specially trained community health workers and also regular small group sessions, and at a community-level male partners and community leaders were provided with information on contraception and healthy timing and spacing of pregnancy. Overall, 650 young married women were supported by the programme over the course of a year and the regular group sessions reached 4,269 people. The technical brief concludes that the programme identified a need for sexual and

reproductive health services amongst young married women and first-time parents in Burkina Faso and that elements from other programmes can be successfully adapted for use in other settings. The report stresses the need for those involved to engage and fully understand the context in which they are working and to design the programme around the rural or urban setting in which the programme is located and address the dynamics of the relationships of the population being targeted including those in the community with most influence.

<http://www.pathfinder.org/publications-tools/pdfs/Reaching-Young-Married-Women-and-First-Time-Parents-for-Healthy-Timing-and-Spacing-of-Pregnancies-in-Burkina-Faso.pdf?x=54&y=24>

*RACGP - Female genital cosmetic surgery - A resource for general practitioners and other health professionals*

This toolkit, developed by the Royal Australian College of General Practitioners, aims to provide advice and practical recommendations for general practitioners on how to manage women who request non-medically indicated female genital cosmetic surgery (FGCS). The authors highlight that there is a lack of evidence-based research in this area and that FGCS raises many issues amongst health professionals and general practitioners including drawing comparisons with female genital mutilation/cutting. The toolkit outlines the range of female genital cosmetic surgical procedures including labiaplasty (the most commonly carried out procedure), perineoplasty, vaginoplasty, hymenoplasty and vulval lipoplasty and discusses the risks and complications of these procedures. The toolkit states that requests for female genital cosmetic surgery are rising in Australia and chapter 2 discusses the factors influencing increased demand such as perceptions of 'normal' versus 'desirable', the role of digital communication and digital images and fashion trends. Chapter 3 provides a set of National Health and Medical Research Council (NHMRC) practice-point level recommendations, which include: listening to the patient and investigating the reason for the request; taking a medical, gynaecological and psychosexual history; addressing all symptoms and concerns; explaining the FGCS procedure and what it entails; referring the patient. Chapter 4 outlines how Australia and territories legislation for female genital mutilation/cutting applies to FGCS and chapter 5 discusses FGCS requests from adolescents. Six summary recommendations are provided: informed general practitioners can reduce unnecessary anxiety regarding vulval/genital anatomy; patient examination should be performed by the general practitioner or referred to a doctor experienced in women's health; it is important to consider mental health and relationship abuse issues and refer accordingly; educate patients about genital diversity; refer patients initially for a gynaecological assessment; if younger than 18 patients should be referred to a specialist adolescent gynaecologist. The appendices provide a range of useful information on the Australia Media code of conduct on body image, how and what to ask when taking psychosexual patient history, guidelines for gynaecological examinations and procedures, fact sheets on female cosmetic surgery and the law, a link to the good medical practice code of conduct, and statements from key international medical and obstetric and gynaecological organisations.

<http://www.racgp.org.au/download/Documents/Guidelines/Female-genital-cosmetic-surgery-toolkit.pdf>

**Innovations and patents**

### **Patent applications**

*EP2895185 (A1) Stimulation of ovarian follicle development and oocyte maturation. Hsueh, A.J.W., Cheng, Y., Deguchi, M., Kawamura, K. 22 July 2015.*

This patent application outlines compositions and methods for contacting follicles either in an ex vivo culture or in vivo with an agent that can disrupt signalling in the Hippo pathway or an agent that can act downstream of disrupted Hippo signalling to promote the growth of ovarian follicles to a pre-ovulatory stage. In terms of disrupting signalling, the agent is said to be one that polymerizes, or stabilizes polymerized, actin including cyclic peptide jasplakinolide (JASP) or sphingosine 1 -phosphate (S1 P) receptor modulator. CCN growth factor proteins are proposed for acting downstream of disrupted Hippo signalling.

[http://worldwide.espacenet.com/publicationDetails/biblio?CC=EP&NR=2895185A1&KC=A1&FT=D&ND=3&date=20150722&DB=EPODOC&locale=en\\_EP](http://worldwide.espacenet.com/publicationDetails/biblio?CC=EP&NR=2895185A1&KC=A1&FT=D&ND=3&date=20150722&DB=EPODOC&locale=en_EP)

*WO2015109116 (A1) Metabolic screening for gestational diabetes. Koos, B.J. 23 July 2015.*

This patent application outlines a method for screening for susceptibility to diabetes, particularly gestational diabetes. Specifically, it is stated that this involves determining levels of one or more metabolic markers present in a sample of urine obtained from a pregnant woman (typically between 6-14 weeks gestation) and comparing this to a previously determined level in a control sample.

This application claims the benefit of United States provisional patent application number 61/927,657, filed January 15, 2014, the entire contents of which are incorporated herein by reference.

[http://worldwide.espacenet.com/publicationDetails/biblio?DB=EPODOC&II=18&ND=3&adjacent=true&locale=en\\_EP&FT=D&date=20150723&CC=WO&NR=2015109116A1&KC=A1](http://worldwide.espacenet.com/publicationDetails/biblio?DB=EPODOC&II=18&ND=3&adjacent=true&locale=en_EP&FT=D&date=20150723&CC=WO&NR=2015109116A1&KC=A1)

*US2015209378 (A1) Effective treatment of ovarian cancer using triciribine and related compounds. Cheng, J.Q. 30 July 2015.*

This patent application proposes a therapeutic composition for the treatment of ovarian cancer (and other conditions caused by abnormal cell proliferation) that can result in reduced toxicity in certain patients. Specifically, this invention relates to determining (by obtaining a biological sample from a tumour) patients with ovarian cancers which overexpress Akt kinase (which the authors have identified as tumours that are sensitive to the cytotoxic effects of TCN and related compounds) and administering triciribine, triciribine phosphate or a related compound to the patient in various dosing regimens to reduce toxicity.

This application is a continuation of U.S. application Ser. No. 13/936,864, which is allowed, which is a continuation of U.S. application Ser. No. 12/206,504, which was filed Sep. 8, 2008, and is abandoned, and claims the benefit of U.S. provisional patent application No. 60/935,942, which was filed Sep. 7, 2007, the disclosures of each of which is incorporated herein by reference in their entireties.

[http://worldwide.espacenet.com/publicationDetails/biblio?CC=US&NR=2015209378A1&KC=A1&FT=D&ND=3&date=20150730&DB=EPODOC&locale=en\\_EP](http://worldwide.espacenet.com/publicationDetails/biblio?CC=US&NR=2015209378A1&KC=A1&FT=D&ND=3&date=20150730&DB=EPODOC&locale=en_EP)

*US2015202467 (A1) Apparatus and methods for transurethral treatment of stress urinary incontinence. Diederrich, C.J., Burdette, E., Wootton, J.H. 23 July 2015.*

This patent application relates to the invention of systems and methods using ultrasound energy for the treatment of stress urinary incontinence. Specifically, this method involves the use of a delivery catheter placed within the female urethra to apply thermal therapy or high acoustic energy to the surrounding tissues. This application is a 35 U.S.C. §111(a) continuation of PCT international application number PCT/US2013/048350 filed on Jun. 27, 2013, incorporated herein by reference in its entirety, which claims priority to, and the benefit of, U.S. provisional patent application Ser. No. 61/665,299 filed on Jun. 27, 2012, incorporated herein by reference in its entirety. Priority is claimed to each of the foregoing applications. [http://worldwide.espacenet.com/publicationDetails/biblio?CC=US&NR=2015202467A1&KC=A1&FT=D&ND=3&date=20150723&DB=EPODOC&locale=en\\_EP](http://worldwide.espacenet.com/publicationDetails/biblio?CC=US&NR=2015202467A1&KC=A1&FT=D&ND=3&date=20150723&DB=EPODOC&locale=en_EP)

### **Legal matters**

*U.N. Committee calls on Croatia to expand reproductive health services and end discrimination against women*

The United Nations Committee on the Elimination of Discrimination against Women (CEDAW) has urged the Croatian government to ensure that women's rights during childbirth are upheld, in particular informed consent requirements, and that the government improve access to reproductive health services, including legal abortion services. The Committee also recommended that the refusal of health professionals to provide care on the grounds of conscience should not affect the ability of a woman to obtain care.

<http://www.reproductiverights.org/press-room/un-committee-calls-on-croatia-to-expand-reproductive-health-services-and-end-discrimination-against-women>

*Japan allows egg donation from strangers*

Following approval from the ethics committee of the Japanese Institution for Standardising Assisted Reproductive Technology, two women have become the first women in Japan to receive eggs from donors who are strangers. The committee stipulates that any children born as a result of such egg donation must be told about this before they begin elementary school and when they reach the age of fifteen they are permitted to find out the identity of the donor if they wish to do so. In contrast, children born as a result of a sperm donor in Japan are currently not allowed to ascertain the identity of the donor.

[http://www.bionews.org.uk/page\\_552828.asp](http://www.bionews.org.uk/page_552828.asp)

### **Clinical trials**

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

#### **Title Intrapartum rapid GBS testing in patients presenting with threatened preterm labor**

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| <b>Registration</b> | <a href="https://clinicaltrials.gov/ct2/show/NCT02511444">https://clinicaltrials.gov/ct2/show/NCT02511444</a>   |
| <b>Description</b>  | This study aims to determine the test characteristics of a rapid intrapartum real-time polymerase chain reaction (RT-PCR) compared to the standard intrapartum Group B Streptococcus (GBS) culture in women presenting with threatened preterm labour or with obstetric indications for preterm delivery with unknown |

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|                         | GBS status.   |   |                |
| <b>Outcome measures</b> | <b>Primary:</b> sensitivity of intrapartum GBS real time PCR compared to intrapartum GBS culture; positive predictive value of GBS Real time PCR performed intrapartum; negative predictive value of GBS real time PCR performed intrapartum; specificity of intrapartum GBS real time PCR compared to intrapartum GBS. | <b>Secondary:</b> neonatal GBS septicemia; composite neonatal morbidity; number of neonatal intensive care unit days; neonatal mortality rate; necrotizing enterocolitis; gestational age at delivery; vaginal delivery; postpartum hemorrhage; maternal intrapartum chorioamnionitis; maternal postpartum endometritis; neonatal respiratory distress. |                |
| <b>Study site</b>       | California, U.S.  | <b>Anticipated study end date</b>   | December 2016. |

### Title Effect of luteal progesterone support on pregnancy rates with combined clomid/gonadotropin & IUI

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| <b>Registration</b>     | <a href="https://clinicaltrials.gov/ct2/show/NCT02510534">https://clinicaltrials.gov/ct2/show/NCT02510534</a>   |                                   |            |
| <b>Description</b>      | This phase 1, prospective, randomised trial aims to determine the effectiveness of the addition of luteal progesterone support on clinical pregnancy rates in young women who have undergone ovulation induction with combined clomiphene citrate and gonadotropin protocol with intrauterine insemination. Women will be randomised to receive either Menopur 150 international units x 1 dose (control) or Menopur 150 international units x 1 dose and Endometrin 100mg twice a day x 14 days (treatment arm). |                                   |            |
| <b>Outcome measures</b> | <b>Primary:</b> effect on pregnancy rate measured by detectable embryonic cardiac activity.   | <b>Secondary:</b> not specified.  |            |
| <b>Study site</b>       | Florida, U.S.   | <b>Anticipated study end date</b> | July 2016. |

### Title Pertussis immunization during pregnancy: effect in term and preterm infants (MAMA)

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| <b>Registration</b>     | <a href="https://clinicaltrials.gov/ct2/show/NCT02511327">https://clinicaltrials.gov/ct2/show/NCT02511327</a>  |  |            |
| <b>Description</b>      | This observational study aims to investigate whether administration of a pertussis vaccination during pregnancy offers protection to preterm infants through higher titers of maternal antibodies. Four cohorts of women-infant pairs will be recruited either before or directly after delivery. Preterm and term infants will be compared and they will also be compared with vaccinated and unvaccinated women. |  |            |
| <b>Outcome measures</b> | <b>Primary:</b> titers of maternal pertussis specific antibodies.  | <b>Secondary:</b> titers of pertussis specific antibodies in infants after 3 doses of a pertussis vaccine; titers of pertussis specific antibodies in infants before and after a fourth dose of a pertussis vaccine; Th1 immune responses in preterm and term born infants before and after a primary series of infant pertussis vaccines; Th2 immune responses in preterm and term born infants before and after a primary series of infant pertussis vaccines; titers of pertussis specific IgA antibodies in breast milk. |            |
| <b>Study site</b>       | Antwerp, Belgium.  | <b>Anticipated study end date</b>  | June 2018. |

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end date

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**Title Emotional processing and oxytocin mechanisms in premenstrual dysphoric disorder: a pilot study**

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**Registration** <https://clinicaltrials.gov/ct2/show/NCT02508103>

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**Description** This pilot study aims to explore the differences in brain response to emotional information in women with severe premenstrual mood symptoms and who were either abused in early life or were not. In addition the investigators wish to explore the effect of using a nasal spray containing oxytocin on brain response and also whether the spray improves premenstrual moods symptoms.

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**Outcome measures** **Primary:** change in premenstrual symptom severity; neural response to cognitive-emotional processing tasks during functional magnetic resonance imaging (fMRI). **Secondary:** not specified.

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**Study site** North Carolina, U.S. **Anticipated study end date** June 2016.

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**Title A comparison of epidural analgesia: continuous infusion versus programmed intermittent boluses**

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**Registration** <https://clinicaltrials.gov/ct2/show/NCT02510287>

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**Description** This randomised study aims to compare the effectiveness of the continuous infusion strategy with programmed epidural intermittent bolus for the management of pain in pregnant women requiring an epidural during labour.

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**Outcome measures** **Primary:** pain level in labouring women measured by the Numeric Analog Scale. **Secondary:** not specified.

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**Study site** Bogota, Colombia. **Anticipated study end date** July 2016.

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