

Insights from outside BJOG

November 2016

New reports and guidelines

Missed Periods: Scotland's opportunities for better pregnancies, healthier parents and thriving babies the first time . . . and every time

This report, published by the NHS Greater Glasgow and Clyde (Public Health), brings together currently available evidence regarding the role and impact of preconception care concluding that preconception health, education and care should be made a priority in Scotland. The report states that more than 1 in 10 deliveries in Scotland require an extra level of care in the post-partum period and that of the 70,000 known conceptions that occurred in Scotland in 2015 fewer than 54,000 live births resulted. The report includes chapters covering: why the preconception period matters; when myths about preconception hide realities; what has gone wrong and what bodes well for Scotland; how Scotland can get preconception right. Appendix A presents evidence and lessons learned, including from three continents, in the form of a comprehensive resource list. Appendix B outlines a number of recommendations aimed at the health and voluntary sectors and other relevant organisations including: provide on-going screening, monitoring, counselling and assistance to women and men from childhood through to childbearing age; accord far more attention and far higher priority to parent education and support having a track record of preventing child maltreatment and other Adverse Childhood Experiences (ACEs) from happening in the first place; apply what has been learned from previous conceptions to the planning of, and preparation for, the next pregnancy; encourage and support the creation and widespread completion of Reproductive Life Plans. A 'stop light' preconception checklist has been developed that it is hoped will be discussed, understood and acted upon by all prospective mothers and supported by all prospective fathers.

<http://www.nhsggc.org.uk/media/237840/missed-periods-j-sher-may-2016.pdf>

Guideline for collection, analysis and presentation of safety data in clinical trials of vaccines in pregnant women

These guidelines, developed by the Brighton Collaboration Working Group, have been developed in response to identified difficulties in bringing together the results of published research studies where differing definitions of terms have been used thus making it impossible to compare the results and for conclusions to be elicited. These guidelines apply to all phases of clinical trials involving assessment of safety data of vaccines in pregnant women and relate to data collected from the mother, fetus or infant. Specific recommendations are provided on: clinical trial site background data collection; pre-vaccination screening; vaccine and immunisation data; follow-up monitoring data; data collection for AEFI (priority 1); data analysis; data presentation.

<http://www.ncbi.nlm.nih.gov/pubmed/27481360>

HIV prevention toolkit: A gender-responsive approach

This toolkit, developed by the U.S. Department of Health and Human Services, Office on Women's Health (OWH), provides practical support and recommendations regarding how to integrate gender into HIV/AIDS programmes. The toolkit has been designed for use by health professionals, programme manager and service providers

and provides an overview of HIV/AIDS among women and adolescent girls in the U.S. (including information on the prominence of heterosexual transmission, violence against women and HIV risk, and the types of interventions that work for women and adolescent girls), a detailed discussion of the social determinants of HIV/AIDS (including structural, social and individual level factors) and a chapter outlining the four domains of gender and how gender, sex and sexuality intersect. Section five discusses gender integration and gender analysis and provides guidance on conducting a gender analysis and preparing gender analysis frameworks including a checklist. Section six provides comprehensive and practical help in how to get started in integrating gender within programme design, implementation, monitoring and evaluation. An accompanying training guide, including a Facilitator's Manual and Participant's Manual is also provided along with suggested training slides developed to support a 3-day course.

<https://www.aids.gov/pdf/owh-gender-responsive-hiv-prevention-toolkit.pdf>

Additional training materials:

<https://blog.aids.gov/2016/06/tools-to-promote-gender-responsiveness-in-hiv-prevention-programs-for-women-and-girls.html>

Atlas of eHealth country profiles

The World Health Organisation (WHO) Global Observatory of eHealth (GOe) has recently completed the third global survey of eHealth bringing together eHealth data for 125 WHO member States for the year 2015. The survey focused on eHealth in support of universal health coverage and the atlas presents this data as a series of country profiles with selected eHealth indicators highlighted. The 8 indicators focus on: eHealth foundations (including specific national policies, strategies, funding sources, capacity building); legal frameworks for eHealth; telehealth; electronic health records (including health facilities with electronic health records or other electronic systems); use of e-learning in health sciences (by both students and health professionals); mHealth (for accessing, providing or collecting health information); social media (health organisational use or individual and community use); big data (national policies or strategies).

http://apps.who.int/iris/bitstream/10665/204523/1/9789241565219_eng.pdf

Innovations and patents

Patent applications

US2016228458 (A1) Preventing or mitigating chemotherapy induced alopecia using vitamin D. Narain, NJ., McCook, JP., Jimenez, JJ. 11 August 2016.

This patent application proposes the use of vitamin D compounds, including Vitamin D3 or calcitriol, in a daily dose of about 10-40 µg to prevent or treat chemotherapy-induced alopecia. The patent particularly discusses alopecia related to taxane-based chemotherapies for the treatment of ovarian, cervical, endometrial, fallopian tube or primary peritoneal cancer.

This application is a continuation application of PCT Patent Application No. PCT/US2014/040084, filed May 29, 2014 (Attorney Docket No.: 119992-09220), which, in turn, claims priority to U.S. Provisional Application Ser. No. 61/828,448, filed May 29, 2013 (Attorney Docket No.: 119992-09201), entitled "Preventing or

Mitigating Chemotherapy Induced Alopecia Using Vitamin D”, the entire contents of which are hereby expressly incorporated herein by reference.

https://worldwide.espacenet.com/publicationDetails/biblio?DB=EPODOC&II=4&ND=3&adjacent=true&locale=en_EP&FT=D&date=20160811&CC=US&NR=2016228458A1&KC=A1

EP3052125 (A2) Composition and method for therapeutic agent delivery during pregnancy. Bidwell, III GL. & George, EM. 10 August 2016.

This patent application discusses compositions containing an elastin-like polypeptide (ELP) coupled to a therapeutic agent and methods for using the composition to control the amount of the therapeutic agent that crosses the placenta in pregnant women requiring treatments for diseases and disorders during pregnancy.

This application claims priority from U.S. Provisional Application Serial No. 61,885,300, filed October 1, 2013, the entire disclosure of which is incorporated herein by this reference,

https://worldwide.espacenet.com/publicationDetails/biblio?CC=EP&NR=3052125A2&KC=A2&FT=D&ND=3&date=20160810&DB=EPODOC&locale=en_EP

WO2016126879 (A1) Falloposcope and method for ovarian cancer detection. Black, J., Barton, J., Utzinger, U., Tate, T., Keenan, M. 11 August 2016.

This patent application discusses the invention of a falloposcope, with an optical imaging system and a diameter of less than 1 millimetre, which when inserted through a lumen of the vagina, cervix, uterus and fallopian tube can be used for screening for fallopian tube and/or ovarian cancer.

The present application claims priority to United States Provisional Patent Application number 62/111,440 filed 3 February 2015, the contents of which are incorporated herein by reference.

https://worldwide.espacenet.com/publicationDetails/biblio?DB=EPODOC&II=6&ND=3&adjacent=true&locale=en_EP&FT=D&date=20160811&CC=WO&NR=2016126879A1&KC=A1

WO2016123044 (A1) Methods and materials for treating endometriosis. Daftary, GS. 4 August 2016.

This patent application outlines the use of histone acetyl transferase inhibitors from a group consisting of garcinol, anacardic acid, CPTH-2, curcumin, and MB-3 in women with endometriosis to reduce scarring or reduce the progression of scarring from endometriosis. The authors also discuss the use of the same histone acetyl transferase inhibitors as a method for slowing the development of endometriosis.

This application claims the benefit of U. S. Provisional Serial No. 62/108,438 filed January 27, 2015. This disclosure of the prior application is considered part of (and is incorporated by reference in) the disclosure of this application.

https://worldwide.espacenet.com/publicationDetails/biblio?CC=WO&NR=2016123044A1&KC=A1&FT=D&ND=3&date=20160804&DB=EPODOC&locale=en_EP

Legal matters

Lesbian couples sue over fertility treatment rules

In the U.S. state of New Jersey, three same-sex couples have brought a lawsuit against the State claiming that the 2001 State insurance mandate, which regulates funding for

fertility treatment, discriminates against non-heterosexual women. The mandate does require health insurers to fund fertility treatment but only for couples who can provide evidence of infertility after two years of unprotected sexual intercourse. This case is believed to be one of the first to contest the legal definition of infertility.

http://www.bionews.org.uk/page.asp?obj_id=688588&PPID=688853&sid=204

U.N. experts call for Dominican Republic to repeal restrictive abortion laws

The United Nations has recently issued a statement to President Medina of the Dominican Republic urging him to uphold the laws encompassed in the amended penal code which was introduced in 2014. Since the introduction of the amendment the Constitutional Tribunal of the Supreme Court in the Dominican Republic has declared it unconstitutional and the Senate is currently debating a new penal code which is far more restrictive than that introduced in 2014. The United Nations has called for all restrictive legal provisions for abortion to be lifted particularly for women where there is a risk to health, women who have been victims of rape or incest or where there is a fetal impairment.

<http://www.reproductiverights.org/press-room/un-experts-call-for-dominican-republic-to-repeal-restrictive-abortion-laws>

Clinical trials

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

Title Effect of intrauterine injection of HCG on pregnancy outcome in repeated implantation failure patients

Registration	https://clinicaltrials.gov/ct2/show/NCT02870855		
Description	This randomised trial aims to investigate whether intrauterine injection of human chorionic gonadotropin (hCG) before blastocyst transfer improves the implantation rate in women with repeated implantation failure.		
Outcome measures	Primary: clinical pregnancy rate.	Secondary: spontaneous abortion rate; ectopic pregnancy rate.	
Study site	China.	Anticipated study end date	June 2018.

Title Bladder directed vs. pelvic floor therapy in IC/BPS

Registration	https://clinicaltrials.gov/ct2/show/NCT02870738		
Description	This randomised trial aims to assess the effectiveness of bladder directed therapy (bladder instillations) compared to pelvic floor physical therapy in women with interstitial cystitis/bladder pain syndrome (IC/BPS). The investigators wish to determine the role of the pelvic floor in contributing to pelvic pain and		

	voiding dysfunction in women with IC/BPS.		
Outcome measures	Primary: markedly/moderately improved on global response assessments.	Secondary: change in symptoms.	
Study site	Michigan, U.S.	Anticipated study end date	August 2020.

Title Impact of physical activity for chronic pelvic pain (IPA-CPP)

Registration	https://clinicaltrials.gov/ct2/show/NCT02867774		
Description	This pilot study aims to assess the effectiveness of an 8-week physical activity programme, specifically designed for patients with chronic pain, on the function and quality of life of women with chronic pelvic pain. Women will be asked to complete a web-based assessment tool at the start of the programme, upon completion of the 8-week programme and then again 4 weeks after the conclusion of the programme.		
Outcome measures	Primary: pain.	Secondary: physical function; fatigue; sexual function; sleep; anxiety; depression; catastrophization; overall symptom improvement.	
Study site	Michigan, U.S.	Anticipated study end date	July 2017.

Title Evaluation of adipokines in obese and non-obese Egyptian women with polycystic ovary syndrome

Registration	https://clinicaltrials.gov/ct2/show/NCT02869750		
Description	This observational study aims to investigate the clinical effects of adipokines (ghrelin, resistin, adiponectin) in both obese and non-obese women with polycystic ovary syndrome. Serum levels of follicle stimulating hormone, luteinizing hormone, testosterone, glucose, insulin, adiponectin, resistin and resistin will be measured and the differences compared between the groups.		
Outcome measures	Primary: serum ghrelin level; serum resistin level; serum adiponectin level.	Secondary: glucose/insulin ratio; serum testosterone level.	
Study site	Egypt.	Anticipated study end date	March 2017.

Title Labor and delivery implant insertion: a randomized controlled trial (LADII)

Registration	https://clinicaltrials.gov/ct2/show/NCT02866643		
Description	This phase 3 trial aims to assess the safety of immediate post-partum insertion of a contraceptive implant (etonogestrel) on breastfeeding, particularly on lactogenesis. The investigators will compare immediate post-delivery insertion in the delivery room (0-2 hours following delivery) with post-partum insertion, in the ward, of a contraceptive implant before medical discharge (24-48 hours following delivery).		

Outcome measures	Primary: time to lactogenesis Stage II (questionnaire).	Secondary: breastfeeding continuation and exclusivity (questionnaire); contraceptive continuation (questionnaire); patient satisfaction with choice of implant as form of postpartum contraception (questionnaire); pregnancy rates (questionnaire); postpartum care visits (questionnaire).
Study site	California, U.S.	Anticipated study end date June 2018.

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