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JOURNAL ARTICLE
SUMMARY SERVICE

March 2016

Zika in Rio

There has been serious concern that Zika virus infection is teratogenic. Sporadic reports of microcephaly and other central nervous system (CNS) abnormalities have emerged from regions in South America where ZIKV has rapidly spread through the population. ZIKV has become endemic because of the immune naivety of the populace and the efficiency of its transmission via its vector (Aedes Aegypti mosquitoes). The infection is seldom pyrexial but has the following clinical features: maculopapular rash, pruritus, arthralgia and conjunctival injection. It is positively diagnosed by reverse-transcriptase polymerase-chain-reaction (RT-PCR) which was first used for ZIKV identification in Brazil in 2015.

In response to the observed increase in cases of CNS abnormalities, especially in areas of high ZIKV prevalence, a surveillance group in Rio de Janeiro started tracking mother-infant pairs when a maternal rash and other clinical symptoms were reported (Brazil et al *NEJM* 2016 doi: 10.1056/NEJMoa1602412). In the last six months 88 women were enrolled and 72 tested positive for ZIKV between 6 and 34 weeks gestation.

This cohort has been carefully monitored because of their ZIKV positive status, not because they constituted a high-risk group for other obstetrical reasons. Ultrasonic findings and examination at birth have revealed very high rates of abnormal outcomes. There have been 12 anomalous outcomes of the 42 pregnancies where ultrasound measurements were taken serially and these included stillbirths, microcephaly, cerebral calcifications, abnormal arterial flow studies, growth restriction and oligo- or anhydramnios.

Up to the date of Brazil's publication (February 2016), eight of the 72 have delivered – with 2 miscarriages and 2 stillbirths. The researchers note that their ultrasound findings have "showed serious and frequent problems in fetal and central nervous system development affecting 29% of the 42 women" in their cohort. This mal-development rate is far higher than expected from an otherwise low-risk group and the investigators believe their data "provide further support for a link between maternal ZIKV infection and fetal and placental abnormalities that is not unlike that of other viruses that are known to cause congenital infections characterized by intrauterine growth restriction and placental insufficiency."

In a separate case report, a patient who contracted ZIKV infection at 13 weeks' gestation was noted to have a growth-restricted fetus with microcephaly. The pregnancy was terminated at 29 weeks and ZIKV was found at autopsy by RT-PCR and the complete genome of ZIKV was recovered from the fetal brain (Mlakar et al *NEJM* 2016;374:951-8).

Editorial Comment
These observational reports do not claim to have established a scientifically credible link between ZIKV and congenital abnormalities but they raise the circumstantial evidence to near certainty. To attribute this level of suboptimal outcomes in an otherwise low-risk group, to chance or another cause is stretching coincidence beyond the limits of elasticity in JASS's opinion.

From these data it appears that infection at any gestation is dangerous – not only during embryogenesis – so pregnant women should take all possible precautions if they are in a high-risk area.

Induction in older women

Women having their first child after the age of 35 years constitute a group who are at raised risk of maternal and fetal complications. Older primigravidae may have had difficulty in conceiving or may have used Assisted Reproductive Technology thus raising levels of concern socially and obstetrically. They should have had trisomy screening and are generally considered to be of above average maternal risk because the following conditions are more frequently encountered than in the population at large: hypertensive disorders, gestational diabetes, placental abnormalities plus fetal risks such as preterm delivery, low birth weight and macrosomia.

In the UK, the 35+ age group has a caesarean section (CS) rate of 40% and induction rates well above the national mean. Both patients and obstetricians perceive these older-woman pregnancies to be at greater risk of poor outcomes and the threshold for inducing labour "near term" is very low. Ideally there should be delivery of a healthy fetus from an uncomplicated pregnancy at the gestational age of minimal risk; so the idea of induction during the week preceding the expected date of delivery is a favoured option. There are, however, concerns that induction on the grounds of maternal age alone could further raise the woman's chance of a CS.

To investigate these concerns, Walker et al (*NEJM* 2016;374:813-22) induced half of a cohort of women over 35 years old and expectantly managed the other half (until an indication for delivery arose or spontaneous labour occurred). There was no difference in the CS rates between those induced and those managed expectantly (32% v 33%). There were no serious maternal or fetal untoward outcomes in the 600 pregnancies in the trial, leading the researchers to conclude that induction during the 39th week does not increase CS rates in 35+ year old women.

If an obstetrician gauges that a woman of advanced maternal age should be induced for "statistical" reasons, the mother-to-be can be reassured that her chances of delivery by CS will not be increased. The study was not powered to assess fetal morbidity or mortality but the UK stillbirth rate among older women at 39 weeks is similar to that of 25 to 29 year-old women at 41 weeks gestation (RCOG Scientific Impact Paper 34, 2013), so those making intervention decisions will have to weigh up the risks of intra-uterine demise against those of induction, now knowing the CS risk is no greater than more conservative management.

Grobman makes the point that no intervention should be adopted in a natural process unless benefit has been established (*NEJM* 2016;374:880-1). Induction on the basis of maternal age will remain a decision between the patient and her care-provider, but now with more facts at their disposal.

Steroids for late preterm deliveries

A study from the US has shown that maternal steroids given after 34 weeks but before 37 weeks result in fewer respiratory complications neonatally (Gyamfi-Bannerman et al *NEJM* 2016 doi: 10.1056/NEJMoa1516783). Considering that statistically 8% of all deliveries take place in the late preterm window this has potentially a large effect on clinical obstetric practice and consequences for Neonatal Intensive Care Units worldwide.

Aspirin against cancer

There is evidence that aspirin has a protective effect against cancer. More specifically it has been shown that people taking low-dose aspirin for prophylaxis against cardiovascular event recurrences have lower rates of colorectal cancer than the general population. This effect has been sufficiently robustly established for the influential US Preventative Services Task Force to recommend its use as a chemotherapeutic agent with anti-cancer properties in those with previous CVS disease.

It is tempting to extrapolate this effect to the public at large but there have to be assurances before recommendations could be made to encourage whole populations of healthy people to take any therapeutic agent. Firstly, it should be shown that the anti-cancer effect is not restricted to a specific group; in this case, sufferers from CVS disease. Secondly the magnitude of the effect and the drug's effect on other cancers needs exploration. Thirdly dosages, frequency, duration of use and side-effects need to be established.

Data are now appearing that partially answer these questions from a large observational study group that included the Nurses' Health Study and the Health Professionals Follow-up Study numbering over 130 000 United States citizens (Cao et al *JAMA* Oncol 2016. doi: 10.1001/jamaoncol.2015.6396). The investigators showed that taking 0.5 to 1.5 standard aspirin tablets per week on a regular basis did have a protective effect against gastro-intestinal cancers. Greater reductions were noted for colorectal malignancies with larger effects with increased dosages and longer duration of use. The order of effect was 15% for all gastro-intestinal cancers but there was no effect on breast, prostate or lung cancer rates. There was a 3% reduction for any malignancy after 5 years of use.

Interestingly they found colorectal incidences decreased in aspirin users who did, and did not undergo endoscopic screening, suggesting its positive effect can be enjoyed in conjunction with screening. So far so good, but there are no large randomised controlled trials measuring potential harmful effects such as bleeding or overall mortality benefits, so this information may only be considered "one step closer" to its use in the general population (Vilar et al *JAMA Oncol* 2016.doi:10.1001/jamaoncol.2015.6395).

Editorial disclosure:

In the interests of transparency, JASS's editor who is the author of this summary has no family history of cancer but has been taking low-dose aspirin daily for the last 20 years as prophylaxis against colo-rectal cancer and undergoes 5 yearly screening by colonoscopy.

Food, dementia and cancer

As populations age and dementia becomes more common, ways of decreasing the effect of neurological disorders are seen as more important. A Mediterranean diet with exercise has been recommended to reduce the risk of cognitive decline but some have questioned whether the "less meat, more fish" component could be counter-productive because of raising mercury levels in the brain which could be related to neurological malfunctions (Kröger & Laforce *JAMA* 2016;315:465-6).

Incidentally pregnant women have been cautioned about excessive mercury intake through eating fish too often but there have been no studies supporting such advice.

In an extraordinary trial that involved measuring mercury levels in autopsied brains of recently deceased 90 year olds, raised mercury levels were not related to a greater risk of Alzheimer's disease

(AD) but previously recorded seafood intake was related to a lowered risk of AD (Morris et al *JAMA* 2016;315:489-97). This is reassuring news for those eating 1 to 3 seafood meals per week and following a Mediterranean style diet.

Higher consumption of processed meats such as bacon, sausages, cured meats, polony or to a lesser extent unprocessed red meat is associated with an increased risk of cancer – particularly colorectal malignancies (Friedrich *JAMA* 2015;314:2496). Being overweight or obese also raises cancer risks whereas exercise and long-term aspirin tip the scales in the other direction. Cigarette smoking is the most potent carcinogenic process known so lifestyle choices remain crucial health determinants.

Ovarian function & cancer treatment

When young women are treated for breast cancer, they receive chemotherapy and endocrine therapy as part of their management. These therapies interfere with ovarian function resulting in an induced premature menopause and/or infertility. To circumvent these repercussions, embryo or oocytes cryo-preservation is recommended in those who desire reproductive capacity but another approach is being investigated – that of ovarian suppression prior to chemotherapy.

The theory is that giving luteinising hormone-releasing hormone analogues to women before they start chemotherapy might suppress ovarian function and thus avoid an early menopause and maintain reproductive capacity. Lambertini et al (*JAMA* 2015;314:2632-40) investigated this possibility by dividing 300 women with breast cancer into 2 groups, one receiving ovarian suppression while the other group did not. Those given LHRH analogues had a higher probability of recovering their ovarian function than those not given LHRH analogues. The suppression, which was with triptorelin, did not affect disease-free survival and offers an additional strategy for women faced with potential ovarian malfunction as part of anti-cancer treatment protocols.

Those interested in a systematic review and meta-analysis of this topic are referred to:
Munhoz et al *JAMA Oncol* 2016;2:65-73.

Mental health in the spotlight

Mental health has been much in evidence in the journals with the UK promising an extra £1 billion per year allocation to improved services and the US Preventative Services Task Force (USPSTF) recommending Primary Care screening for depression (O'Dowd *BMJ* 2016;352:i933 and O'Connor et al *JAMA* 2016;315:388-406).

Women are more prone to depression than men with Major Depressive Disorder (MDD) being the leading cause of disease-related disability in women worldwide. During pregnancy and postpartum, one in ten women suffer from a MDD which is amenable to treatment and has good outcomes if it is timeously diagnosed, hence the recommendation of the USPSTF.

Every obstetrical and gynaecological consultation should include a direct enquiry into the mental well-being of the patient – and a responsive ear to the reply.

Politics & family planning

The United States of America has a confusing record in terms of women's rights. Laws and attitudes vary so radically from enlightened to misogynistic, that it is difficult to gain a consistent picture of what the country wants for the health of its women.

The dichotomy is apparent in the statements of political front-runners for the presidency where at least one aggressive campaign against women is being waged by the Republicans. Donald Trump has repeatedly belittled women and believes those who have a termination of pregnancy (TOP) should be punished (later retracted) and contraception limited.

Each year in the US 700 000 TOPs are performed and an American woman has a one in three chance of having a TOP in her lifetime (www.cdc.gov/reproductivehealth/data_stats/index.htm). Fully 40% of all unintended pregnancies end in a TOP. It seems an odd approach to advocate contracting rather than expanding family planning services and it is the reluctance by conservatives to provide wider contraceptive availability that is concerning.

The *New England Journal of Medicine* has highlighted how women's reproductive rights are under threat from politicians with conservative views, especially targeting the Planned Parenthood organisation (Richards *NEJM* 2016;374:801-3).

In one example of political meddling, Texas changed its financial involvement with Planned Parenthood affiliates because of their liberal, full contraceptive programmes, thus making its services less available. This resulted in certain products, such as long-acting injectable hormonal contraceptives being restricted and poorer women being denied the contraception of their choice and the consequence was a rise in unintended pregnancies (Stevenson et al *NEJM* 2016;374:853-60).

There is also the issue of maternity leave where the US lags behind other developed countries in its antiquated legislation (Rubin *JAMA* 2016;315:643-5).

But there are positive signs, not least of which is the Democratic presidential candidacy of Hillary Clinton who will hopefully build on the gains being made on the family planning front. Examples of progress are in the improved unintended pregnancy rates.

Overall the US has a below-average record for unintended pregnancies with "half" being the likely number quoted which is much higher than other developed countries. The latest data (for 2011) show a downward trend with the new figure of 45% representing a commendable improvement. The fall in unintended pregnancies has been greatest in the better educated sectors of the population. The groups showing least change remain the poor and those cohabiting, so that it seems that some policies interfere with the real world situations where enlightenment and access are most needed (Finer & Zolna *NEJM* 2016;374:343-52).

Another major gain has been the acceptance of Long-Acting Reversible Contraception (LARCs) for adolescent women as a means of controlling high teenage pregnancy rates. Research has shown a marked reduction in unintended pregnancies in teenagers but it brings with it the use – or lack thereof – of condoms to prevent sexually transmitted infections (STIs). A study involving condom use in American school-goers showed that LARC users did not make use of condoms as frequently as oral contraceptive pill-takers (Steiner et al *JAMA Pediatr* 2016.doi:10.1001/jamapediatrics.2016.0007). They also had 2 or more sexual partners more often, implying a greater need for barrier protection from STIs which has resulted in a call for "a better message" to be conveyed to young people (Potter & Soren *JAMA Pediatr* 2016 doi:10.1001/jamapediatrics.2016.0141).

However, adherence to the "belt and suspenders" approach is known to be below 10% in adolescents so the messages are not being heeded in their present format. Is it not time for the ingenuity of smart phone technology and social media networking to derive rewards for responsible sexual behaviours?

Another leap forward this year has been in the deregulation of hormonal contraceptives to older women. Some states are allowing women over the age of 18 years to obtain oral contraceptive pills and hormonal patches from their pharmacists without having to visit a medical practitioner. (Yang et al *JAMA* 2016. doi:10.1001/jama.2016.2327).

Pharmacists have to carry out basic health checks before prescribing the contraception while LARCs are not available as freely. Despite the clear health and financial advantages, many states still oppose this wider access on political and religious grounds.

The American Congress of Obstetricians and Gynecologists is clearly indicating its support for modern means of TOP (www.acog.org/About-ACOG/News-Room/Statements/2016/ACOG-Statement-on-Medication-Abortion) so leadership is being shown with scientific advances articulated and one hopes championed by politicians of repute.

World perspective on contraception

India will soon surpass China as the world's most populace nation. Unlike China it does not have a co-ordinated Family Planning policy and in the next 35 years India is expected to gain 500 million new citizens so its government is reviewing its contraception provision policy (Barry & Dugger *New York Times* 20th February, 2016). The present mass sterilisation programmes – which carry out 4 million tubal litigations per year – are woefully out of date.

There remains a perception that Indian women distrust the drug companies which sell reversible contraception methods so there are attitudinal barriers, but the proposed changes auger well for the future. Public policy looks set to change and there is the hope that the supply of Long-Acting Reversible Contraceptive products will emancipate millions of Indian women from the yoke of uncontrolled reproduction.

Editorial Comment

Free access to contraception should be the norm throughout the world but progress towards such a goal is slow. There are minimal health risks to oral contraceptives (OCs) yet many countries require prescriptions for their use – notably the US, Canada, most European countries including the UK, despite their comprehensive back-up health services.

A survey of OC availability in 147 countries showed (Grindlay et al Contraception 2013;88:91-6):

Informally available without prescription	-	*38%*
Legally available without prescription (no screening)	-	*24%*
Legally available without prescription (screening)	-	*8%*
Prescription only	-	*30%*

JASS believes that informal availability without prescription of all contraceptives would be the greatest advancement of health of the 21st century.

Snippets

Vitamin D in pregnancy & multiple sclerosis

The prevalence rates of multiple sclerosis (MS) increase as distance from the equator increases, suggesting sunlight or vitamin D association with the disorder. This biological link is strengthened by the finding that populations with a lack of sun exposure, but having diets rich in vitamin D, also have low MS rates.

Greenberg (*JAMA* 2016:doi.10.1000/jamaneurol.2016.0018) has put forward two possible connections between vitamin D deficiency and MS. The first links vitamin D and activation of the immune system and effects on autoimmunity through T-cell regulation while the second links vitamin D deficiency with lipid metabolism during myelogenesis.

Associating myelin integrity and MS could have origins in fetal developments so Munger et al (*JAMA Neurol* 2016.doi:10.1001/jamaneurol.2015.4800) looked at vitamin D levels during pregnancy and MS development in later life, up to the age of 27 years, in a cohort of mothers in Finland whose blood samples had been preserved all these years (the Finnish Maternity Cohort). The researchers found that maternal vitamin D deficiency in early pregnancy was associated with a doubling of the risk of MS in their offspring (RR 1.90:95%CI 1.20-3.01).

Editorial Comment
This is a remarkable example of diligent bio-banking research correlating blood samples taken decades ago with present day clinical findings. The outcome adds evidence to the link of maternal vitamin D insufficiency and MS suggesting "that correction of vitamin D deficiency during pregnancy may reduce the risk of MS in the offspring".

This is persuasive evidence for vitamin D supplementation for all at-risk women in early pregnancy.

Vitamin D & wheezing children

There have been observational trials suggesting an association between extra vitamin D supplementation in pregnancy and wheezing in children. Wheezing or asthma is increasing in young people but 2 randomised trials this year have refuted any relationship with vitamin D deficiency or high-dose administration in pregnancy (Chawes et al *JAMA* 2016;315:353-61 & Litonjua et al *JAMA* 2016;315:362-70).

Doses of thousands of units of vitamin D given throughout gestation did not result in a significant reduction in cases of wheezing or asthma so recommendations for supplementation beyond the present 400 IU/day are not warranted (von Mutius & Martinez *JAMA* 2016;315:347-8).

Osteoarthritic knees & vitamin D

Painful knees in old age are often caused by osteoarthritis where the thickness of the tibial cartilage is reduced. Some observational studies have suggested that vitamin D supplementation is beneficial in reversing this process and relieving knee pain but controlled trials have been lacking.

Jin et al (*JAMA* 2016;315:1005-13) from Australia carried out a trial in vitamin D deficient 60 year-old volunteers with knee pain, giving them large doses of vitamin D for 2 years or placebo. The active substance made no difference to cartilage thickness or pain scores so their findings cannot support vitamin D's use for this indication.

Hormones for menopausal symptoms

Often in medicine there is enthusiastic adoption of new drugs or practices followed by the finding of adverse effects, and over-reaction when the intervention is underutilised before sanity prevails and the medication or procedure finds its rightful place clinically.

Hormone therapy around the time of the menopause transition is an example of such an intervention that is now finding its correct place for the treatment of worrisome menopausal symptoms. Using hormones for long-term medication of chronic disorders is still under investigation but targeted treatment with hormones for menopausal symptoms is good medicine.

Two of the original Women's Health Initiative trial investigators (Manson & Kannitz *NEJM* 2016;374:803-6) now make a plea for judicious use of hormone therapy and state that for those "who have moderate-to-severe vasomotor symptoms, a consensus has emerged that the benefits of hormone therapy are likely to outweigh the risks". They ask for this message to be transmitted to the profession as they feel the topic is poorly understood by trainees entering the clinical arena. Women are receiving mixed messages and mixed treatments, often ending up with their using unregulated substances that are potentially harmful.

The whole sorry saga could have been prevented if the original data had been made timeously available to the scientific community by the investigators (Baber *O&G Mag* 2016;18:21-3).

Supporting pregnant teenagers

Intuitively one suspects that giving a pregnant teenager support during her pregnancy and for the 2 years thereafter, would be a good idea. One could also reasonably anticipate that if a woman in that situation had a dedicated partnership with a Family Nurse, with whom she had 40 structured home visits, there would be clearly measurable benefits.

A study was conducted in the UK in which over 800 teenagers received such care, compared with 800 teenagers who had the usual NHS care and outcomes were measured in terms of smoking during pregnancy, baby's birth weight, another pregnancy within 2 years and hospital attendance for the baby in his or her first 2 years (Robling et al *Lancet* 2016;387:146-55). Despite diligent attention, the nurse-assisted women had no better outcomes than those who had routine care in any of the major criteria. Smoking rates (56%) in each arm and a second pregnancy before the child's second birthday years (66%) were unaffected by frequent prolonged visits, at a cost of an extra £4 500 per participant.

Editorial Comment

Family Nurse Partnerships in the United States have shown advantages but the British study failed to demonstrate benefits to a disadvantaged group of women. Giving diligent one-to-one support did not break the cycle of repetitive pregnancies and the investigators concluded "the programme cannot be considered cost effective".

It does not appear that providing trained health-care support to this vulnerable group on an individual basis makes a difference. How depressing.

Athol Kent

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March 2016

Dear Colleague

This month's JASS has more summaries and comment on politics and family planning than ever before. I am no fan of politics but I am a fan of family planning – so when the two collide I feel compelled to take note and take sides.

Politicians often offend my sensibilities and the American Presidential race is almost devoid of reasoned arguments about important topics like women's health and world affairs. But one of the most significant steps in combatting unpalatable ideas, is understanding those you oppose. I promise I will not continue in this sortie into the political quagmire in future issues (well I sort of promise, unless provoked)!

Zika virus is undoubtedly highly teratogenic and its threat to pregnant women is real. A world response will hopefully be forth-coming so efforts to combat its effect are co-ordinated. A vaccine is a priority and mosquito control by genetic modification is a fascinating prospect.

Vitamin D is also in the spotlight again and the potential link with multiple sclerosis from the Finnish Maternity Cohort is proof of the advantages forward-thinking research that was initiated decades ago.

JASS provides objective summaries of the literature but there have been a steady increase in requests for editorial opinion. This is cautiously provided and clearly indicated in italics so you may readily distinguish research from its interpretation.

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Kind regards

Athol Kent

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JASS questions for March 2016

True/False

1. There is clear-cut evidence that women exposed to the Zika virus are at increased risk of teratogenic central nervous system anomalies ___________
2. Inducing older women on the grounds of age increases their risk of having a caesarean delivery ___________
3. Taking low-dose aspirin over many years has been shown to reduce a person's risk of developing colorectal cancer ___________
4. Eating fish more than once a week leads to increased levels of mercury in the brain which is detrimental in terms of dementia risk ___________
5. Women who receive chemotherapy for breast cancer have an increased chance of regaining ovarian function if they are treated with luteinising hormone-releasing hormone analogues prior to the chemotherapy ___________
6. In the United States the unintended pregnancy rate is above 50% and is continuing to rise according to the latest data ___________
7. India's family planning policy relies heavily on sterilisation as its major form of contraception ___________
8. There appears to be a link between the risk of multiple sclerosis and low vitamin D levels in pregnancy ___________
9. Vitamin D given to older adults who are vitamin D deficient and have arthritic knee pain reduces the pain they experience ___________
10. Giving pregnant teenagers in the UK consistent support during their pregnancy and for 2 years thereafter, reduces their chances of another pregnancy during those 2 years ___________

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